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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ACRONYMS

ABO antibodies blood group
AIDS acquired immune deficiency syndrome
ALT alanine aminotransferase
APTT activated partial thromboplastin time
ART antiretroviral therapy
ARV antiretroviral (drug)
ASOT antistreptolysin O titer
AST aspartate aminotransferase
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
DHO district health officer
DMO district medical officer
EID early infant diagnosis
ELISA enzyme-linked immunosorbent assay
EMLS Essential Medical Laboratory Services
ESR erythrocyte sedimentation rate
FBC full blood count
FSH follicle-stimulating hormone
GF Global Fund
GGT gamma-glutamyl transpeptidase
Hb hemoglobin
HIV human immunodeficiency virus
HTSS Health Technical Support Services
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>JSI</td>
<td>John Snow, Inc.</td>
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<tr>
<td>LDH</td>
<td>lactate dehydrogenase</td>
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<td>LFT</td>
<td>liver function tests</td>
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<td>MOH</td>
<td>Ministry of Health</td>
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<td>PCR</td>
<td>polymerase chain reaction</td>
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<td>PT</td>
<td>prothrombin time</td>
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<tr>
<td>QA</td>
<td>quality assurance</td>
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<tr>
<td>QC</td>
<td>quality control</td>
</tr>
<tr>
<td>Rh</td>
<td>Rhesus factor</td>
</tr>
<tr>
<td>RMS</td>
<td>Regional Medical Stores</td>
</tr>
<tr>
<td>SDP</td>
<td>service delivery point</td>
</tr>
<tr>
<td>SGOT</td>
<td>serum glutamic-oxaloacetic transaminase</td>
</tr>
<tr>
<td>SGPT</td>
<td>serum glutamic pyruvic transaminase</td>
</tr>
<tr>
<td>SOP</td>
<td>standard operating procedure</td>
</tr>
<tr>
<td>STI</td>
<td>sexually transmitted infection</td>
</tr>
<tr>
<td>TB</td>
<td>tuberculosis</td>
</tr>
<tr>
<td>TPHA</td>
<td>treponema pallidum haemagglutination test</td>
</tr>
<tr>
<td>TSH</td>
<td>thyroid-stimulating hormone</td>
</tr>
<tr>
<td>TWG</td>
<td>technical working group</td>
</tr>
<tr>
<td>USAID</td>
<td>U.S. Agency for International Development</td>
</tr>
<tr>
<td>WBC</td>
<td>white blood cell</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>ZN</td>
<td>Ziehl-Neelsen</td>
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EXECUTIVE SUMMARY

As the organizational structure of laboratories in limited-resource settings has evolved in response to the human immunodeficiency virus (HIV), tuberculosis, and other infectious diseases; and as more peripheral laboratories have become involved in providing routine testing, the need for laboratory standardization has become more pronounced. Standardization is an approach to manage laboratory services that enables the rational allocation of limited resources to benefit the population as a whole. The process involves setting test menus, techniques, and laboratory equipment for every level in the system. 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; they may be clinical. For example, when 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 results in economies of scale, which allows national laboratory programs leverage in negotiating service and maintenance contracts. In addition, having a smaller range of equipment and techniques facilitates the training of staff. Finally, fewer products flowing through the supply chain enhances the agility, manageability, and efficiency 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; if machines break down, or if there is a sudden change in consumption, commodities can be redistributed to other facilities, thereby reducing the risk of expiries and stockouts.

A number of steps are involved in the process for defining and implementing national laboratory standards. The standardization process should begin with an assessment to establish the current context of the laboratory system; including the tests, techniques, and equipment currently in use at each level of the system. There should then be a workshop or series of meetings to introduce standardization; build consensus; and define test menus, techniques, equipment, and product lists, by level, in the system. Setting test menus should be done in consultation with a wide-range of participants, including laboratory personnel, clinicians, program managers, medical staff, procurement officers, supply chain managers, and implementing partners. This 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, takes into consideration the timeframe and resources required to fully implement the standards. A series of activities are required to implement the standards; these can be broadly categorized as policy, supply chain, and health 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. These include selecting the appropriate products, designing and
implementing a logistics system, conducting national quantification, and procuring the necessary commodities. Without a continuous and reliable flow of commodities, laboratories may return to procuring locally; and standardization will not be properly implemented and the benefits realized. Finally, health systems interventions include the development of standard operating procedures (SOPs) to provide guidance on how to run the standard tests using the chosen techniques and equipment, updated curricula to reflect the new standards and trainings for staff on the new equipment, and standardized techniques. A case study on Malawi’s experience with standardization is included in appendix 1; it provides a practical example of how the standardization process and each of the steps has been undertaken in-country.
Laboratory services act as a cornerstone for public health programs by supporting diagnosis, monitoring, screening, and surveillance to control and manage diseases. Under-diagnosis and misdiagnosis of infectious diseases, such as tuberculosis (TB) and malaria, due to 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, resulting in a poor prognosis, especially for HIV 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 vertical disease programs. Previously, national reference laboratories provided all the testing services for public health programs. However, as the demand for these 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. While this transfer carries measurable benefits in terms of scaling up and expanding testing services for a public health response, it has also meant that these peripheral laboratories now conduct sophisticated routine testing. During this expansion, the absence of a standardized approach to laboratory testing to peripheral laboratories has resulted in a proliferation of tests, techniques, and equipment, including the required commodities, across laboratories.

In the present time, to simplify their management and rationalize the allocation of limited resources, the peripheral laboratories, which have functioned in the past as stand-alone entities, are viewed more and more as part of the national networks. Part of the evolution has involved the centralizing of the supply chain so that all laboratory commodities are sourced from a central warehouse, marking a shift from the previous scenario when each of these facilities procured their individually selected equipment and sourced the required commodities from local vendors. This shift 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.

Standardization, as a policy intervention, represents a public health approach to managing laboratory services. It promotes the most efficient and cost-effective use of limited resources to serve the majority of the population. Within the context of the public health approach, standardized operational guidelines can help to ensure therapeutically effective and economically efficient health service delivery. When implemented effectively, standard treatment and testing guidelines offer advantages to patients (easier understanding of disease progression and treatment benefits), providers (gives an opportunity to
develop and monitor quality of care standards), supply chain managers (makes demand more predictable), and health policymakers (promotes efficient use of financial and human resources). 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, allowing resources to be maximized while preserving quality services.
WHAT IS STANDARDIZATION?

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

Practically, for each of the required testing areas (e.g., hematology, chemistry, etc.), a standard list of tests that are required at each level of the system (e.g., full blood count should be available at central- and district-level hospitals) should be selected as a first step in the process. After the tests are selected, the most appropriate technique will be chosen for each test, at each level of the system (e.g., flowcytometry to conduct CD4 counts at the district level). Finally, equipment will be selected that is most suitable for each automated technique and context (e.g., FACScount CD4 machine for the district level). See appendix 1 for a practical example of the selection process for tests, techniques, and equipment that were used during the standardization workshop in Malawi.

Typically, there is a stark contrast between standardized and non-standardized systems; therefore, the concept of standardization may be best understood by reviewing the following two scenarios.

**Scenario #1: Non-standardized laboratory system**

In a non-standard setting, there is the potential 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 may also use different techniques and equipment to run tests; between facilities at the same level of health system, the same tests may be offered but different techniques or equipment are used to conduct those tests. All these different tests, techniques, and equipment require a different set of correlated products. The variations between the tests, techniques, and equipment for each laboratory, and even for laboratories at the same level of a non-standardized system, typically result in a large total number and variety of products that are used across the supply chain. For example, in Kenya, before the standardization exercise, 3,000 products were required to run all the tests provided at laboratories in the national network.

When the laboratory is responsible for selecting tests, techniques, and equipment, naturally, the equipment chosen will suit the unique needs of that laboratory, e.g., the tests ordered by the clinicians will be performed on equipment appropriate for the volume of testing. This can result in many different types of machines being used throughout the country for the same test. While this is reasonable when viewing a laboratory as a stand-alone facility, it becomes difficult when the supplies for that equipment come from a central point and the peripheral laboratories are part of a national network. The central warehouse now 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 non-standardized 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 the individual laboratories sourcing commodities to the centralized

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1 Note: All trademarked equipment brands referenced in this text are illustrative and in no way endorse a particular brand or product.
model, this poses a particularly significant challenge because of the large number of products that must be managed, ordered, distributed, and stored from a central place to meet a variety of demands from a non-standardized system.

**Scenario #2: Standardized laboratory system**

A standardized system is one in which each laboratory at the same level of the system 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 certain level of laboratory testing services; if patients transfer between facilities, their results can be compared. Laboratory staff can easily transfer between facilities because they are familiar with the techniques and equipment used at all facilities; generalized refresher training courses can be provided for all staff. And, commodities can be managed through a central logistics system, rationalizing resources and benefiting from economies of scale.

The following sections will further expand on the benefits of a standardized system (scenario 2) and how to practically 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 the 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 high-quality commodities to provide testing services. However, the benefits of standardization reach far beyond just reducing the complexity of the supply chain to include benefits for the overall management of laboratory services across the country and to 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, 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 and, 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 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. This will maximize the use of health services offered at close-to-client settings, avoid unnecessary referrals, and 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 the scale-up environment, it is very important that programs can estimate the required resources and plan adequately so that services are not interrupted.

I. Equipment Maintenance

In many countries, machine breakdown is a common challenge in 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 procuring a large number of the same machines. Having multiple machines of the same kind and centralizing the procurement functions allows the program to negotiate better service and maintenance contracts with manufacturers and/or distributors. 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 functional 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 because the same testing techniques and equipment are used at each level of the system, training programs are uniformed and simplified, and staff can more easily transfer between facilities.

3. Quality Assurance

Standardization also supports the development of a robust quality assurance program, because it allows for results to be compared across facilities, increasing the reliability and consistency of test results.

SUPPLY CHAIN BENEFITS OF STANDARDIZATION

Standardization benefits the supply chain by streamlining the number of laboratory products that must be managed in the supply chain. For example, in Kenya, the national laboratory inventory was reduced from an estimated 3,000 items to less than 300 following the standardization exercise. Each test conducted using a different technique or equipment typically requires a unique set of products. As figure 1 shows, the range of commodities required increases exponentially with each additional testing technique used. Standardization typically reduces the variety and range of products required, not the total volume; therefore, it results in a larger volume for fewer commodities.

Figure 1. Testing Techniques and Estimated Number of Commodities
The reduction in the number of supplies that must flow through the laboratory supply pipeline reduces congestion and complexity in the supply chain and yields a number of benefits. 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 from standardization.

1. **Streamlines the selection of products following the standardization of tests, techniques, and equipment**
   After the standardization process is complete, products selection is the process of deciding exactly which products are required for the tests, techniques, and equipment selected. With fewer products to buy, the central warehouse can become more familiar with the products and can ensure that the specifications meet the needs of the laboratories. Regularly updating the central warehouse catalogue is more manageable in a standardized system, thereby improving communication between the laboratory staff and warehouse staff.

2. **Supports the development of a national logistics system and the central management of commodities**
   Practically, 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 products necessary throughout the system. In addition, ordering and reporting forms for laboratory commodities can be designed to have the list of standard products preprinted to improve communication between the laboratory staff and the central warehouse and 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 these products**
   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 products required to carry out each of these tests. This allows the central warehouse and the program to focus their attention on ensuring that this smaller, priority list of products is available when and where required.

   ![](image)
   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 ensuring an ongoing supply would be available. Better stock manageability and a commitment to ensuring ongoing supply of these products resulted in a reduction of the stockout rate at the central level from 70 percent to 2 percent.
4. Enables redistribution of products in the supply chain

Standardization also allows redistribution of products throughout the laboratory network. In a standardized system, facilities at the same level will typically be conducting the same tests using the same techniques/equipment and will, therefore, require the same products. If one facility is undersupplied while another is oversupplied, stock can be transferred between the facilities because the same products are used for the same test techniques. The agility achieved by being able to move products in the supply chain 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 also avoids stock wastage due to equipment breakdowns—if a facility has a sudden decline in the usage of reagents due to machine failure, they 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.

In one country, the transfer of reagents for a high-level chemistry analyzer from one of the MOH laboratories to a partner laboratory, due to equipment breakdown, saved the ministry nearly $30,000, since 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.

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

In non-standardized systems, conducting a national forecast for laboratory commodities can be extremely challenging. In most countries, logistics data, and 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 requires the conversion of the forecasted number of tests (or a number of patients to number of tests) into products based on assumptions about the techniques and equipment used to conduct each type of test. 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 non-standardized system, one facility may be conducting different tests using different techniques and equipment than 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, to produce an accurate forecast in a non-standardized system, assumptions about the commodities required for each technique and equipment used throughout the country must be made for each individual facility. This makes a national quantification exceptionally time and resource intensive. At times, as in the Kenya example described in the text box above, national

In Kenya a quantification for laboratory commodities had to be preceded by standardization. For most testing areas, 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 meant that it was not possible to complete the national quantification for all of the hematology machines and, ultimately, the procurement of hematology reagents and consumables had to occur at a local level.

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\(^2\) Note: All trademarked equipment brands referenced in this text are illustrative and in no way endorse a particular brand or product.
quantification is not possible without standardization and, 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 and the reduction of the cost of some supplies because a larger quantity of a smaller number of products is required. In the case of Kenya, instead of buying smaller quantities of 3,000 products, for example, larger quantities of 300 supplies were procured at a lower price.

In one country, as a result of standardization, the equipment range was narrowed. Together, the Ministry of Health (MOH) and cooperating partners negotiated maintenance contracts with the suppliers and linked this 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 procuring more of each individual reagent rather than smaller quantities of many different reagents.
Test menus, techniques, and equipment comprise the building blocks of laboratory standardization. These building blocks will be used to review or create laboratory standard operating procedures that will 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 of these elements. Following is a brief explanation of each, the relevant considerations, and 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 system, 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 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 laboratory staff, establish the laboratory tests list by level that will enable clinicians to deliver services efficiently. These 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 due to 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, to ensure that they 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 2 for an example of test menus by level.

Policymakers, laboratory staff, 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; and laboratory staff must endeavor to make these tests available, using the established standards. Ongoing dialogue between policymakers, clinicians, and laboratory staff 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.
TECHNIQUES

Techniques can be generally defined as a specific method used to carry out a test 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, there are at least four different techniques for malaria testing, including Field stain, Geimsa stain, flow cytometry, and rapid diagnostic tests. 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 technical ideal, 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 3 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 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 like water baths, timers, and centrifuges, do not usually pose a big problem as they do not require extensive training for proper use, specialized reagents, consumables to operate, or significant service and maintenance. The more complex analyzers are typically the main focus of the standardization exercise; they pose a number of special considerations. This is because they are expected to produce very accurate results 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 as 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.
Standardization is a multi-step process that should be deliberate, purposeful, and participatory. 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. If needed, it is important to build capacity within MOH so that they take leadership of the process from the beginning.

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

As shown in figure 2, a number of steps are needed to prepare for and implement laboratory standardization. Each step in this process will be discussed in greater detail in this section.

**Figure 2. The Standardization Process**
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 provide funding, as well as implementing partners and their role in the providing laboratory services
- environmental factors, such as the procurement policies and the influence of the current suppliers with a view to how it may impact the standardization process
- tests menus, techniques, and equipment currently in use at different levels of the system
- gaps in testing services identified by laboratory staff, clinicians, and public health programs.

This assessment will involve either visiting sites and mapping the variety of test menus, techniques, and equipment in use or distributing a survey to laboratories to solicit this information. See appendix 4 for an example of a tool that can be used to collect this data.

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 these key issues will be used to facilitate decision making 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 these barriers can be determined early in the process. Clear policies supporting standardization and, in particular, the procurement of brand-specific equipment needs 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 agree on the outcomes, the implementation of standardization is likely to have many barriers.

There are two options for building consensus on the standards. Either a workshop can be convened, where 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 buy-in from all stakeholders is essential to achieving standardization. Participants should include a wide range of stakeholders:

- laboratory staff from all levels of the system
• clinicians from all levels of the system
• nursing staff from all levels of the system
• program managers
• implementing partners, such as nongovernmental organizations (NGOs) and faith-based organizations
• procurement officers
• supply chain managers.

It may not be necessary for all stakeholders to be present for the entire process of establishing test menus, techniques, and equipment. The expertise and participation of policymakers, laboratory staff, and clinicians is required when determining test menus; this 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 standardizing techniques and equipment, the number of participants can be reduced to only 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 the stakeholders with interest and expertise in certain areas participate during key points where their input is required. Generally, it is critical to have 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, certain sections of the workshop that require technical laboratory skills—for example, during the selection of techniques—a smaller group of participants is required. An example of standardization workshop goals and objectives and schedule are provided in appendices 5 and 6, respectively. The aforementioned considerations about participation should be included when developing the workshop materials and content.

a) Introduction to 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 establish a commitment to it. This first session must include all stakeholders, including laboratory personnel, clinicians, program managers, medical staff, procurement officers, supply chain managers, and implementing partners. This is also an opportunity to identify barriers to standardization and to determine solutions to these barriers.

b) Reviewing 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 on the current context and to identify any gaps in testing services, or 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 to then define the new standards.
c) Setting Test Menus by Level

After the current situation is discussed, the next step will be 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 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, program staff, and partners. When placing the participants into groups, assign them to the group that is selecting test menus for a level of the system 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, equipment, and supplies to treat cardiac events, then the district-level laboratory needs also 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 monitoring patients that 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 only provided in referral laboratories, due to the utilization, equipment cost, and scarcity of skills required to operate sophisticated laboratory instruments; but, the collection of samples does occur at the lower levels. Sample collection also requires the availability of commodities and trained staff.

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 outlining current testing services can be provided and to which the groups can make edits. An example worksheet is provided in the appendix 7.

After the test menus for each level have been set by the individual groups, consensus between all participants must be achieved, as support from all stakeholders is essential. Sufficient time must be allocated for each group to present their decisions to the larger group and for the other participants to offer their inputs and reach consensus. This 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 on the final test menu, by level. See table 1 for an illustrative test menu, by level, for the hematology testing area.
Table 1. Example Test Menus for Hematology

<table>
<thead>
<tr>
<th>Laboratory Tests</th>
<th>Central Hospitals</th>
<th>District Hospitals</th>
<th>Health Centers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Send Out</td>
<td>On Site</td>
<td>Send Out</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>√</td>
<td></td>
<td>√</td>
</tr>
<tr>
<td>Total WBC</td>
<td>√</td>
<td></td>
<td>√</td>
</tr>
<tr>
<td>Differential count</td>
<td></td>
<td></td>
<td>√</td>
</tr>
<tr>
<td>Full blood count</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sickle Cell - screening</td>
<td></td>
<td></td>
<td>√</td>
</tr>
<tr>
<td>Sickle Cell - confirmatory</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prothrombin time</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activated partial thromboplastin time</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibrinogen test</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reticulocyte count</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Erythrocyte sedimentation rate</td>
<td></td>
<td></td>
<td>√</td>
</tr>
<tr>
<td>Lupus erythromatous</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD4 Count</td>
<td></td>
<td></td>
<td>√</td>
</tr>
<tr>
<td>CD4 %</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**d) Defining 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 mostly include laboratory staff with 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 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 from training institutes, NGOs, and mission laboratories.

The selected techniques must address the testing needs agreed-to by the initial larger group. Techniques should be determined for each type of test based on the capacity of the staff and 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 a Sample Hematology Tests

<table>
<thead>
<tr>
<th>Test Menus</th>
<th>Techniques</th>
<th>CENTRAL HOSPITAL</th>
<th>DISTRICT HOSPITAL</th>
<th>HEALTH CENTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>HaemoCue</td>
<td>HemoCue</td>
<td>HaemoCue</td>
<td></td>
</tr>
<tr>
<td>CD4 count</td>
<td>flow cytometry</td>
<td>flow cytometry</td>
<td>flow cytometry</td>
<td></td>
</tr>
<tr>
<td>CD4 %</td>
<td>flow cytometry</td>
<td>flow cytometry</td>
<td>flow cytometry</td>
<td></td>
</tr>
</tbody>
</table>

**e) Selecting 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 as many factors must be considered and 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 that were involved with defining test menus and techniques should be involved in selecting equipment. 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 (WHO) is provided in appendix 8. 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, select the relevant criteria according to the context, and prioritize these 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 requires additional research to find out what equipment neighboring countries use and evaluating it based on the country-specific criteria.
Table 3. Example of Variety of CD4 Count Equipment\(^3\) in One Country Pre-Standardization

<table>
<thead>
<tr>
<th>District Hospital</th>
<th>Western District</th>
<th>East District</th>
<th>Northern District</th>
<th>Southern District</th>
<th>Central District</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>District Hospital</strong></td>
<td>Cyflow SL3</td>
<td>FACS Calibur</td>
<td>Sysmex KX21</td>
<td>Cyflow counter</td>
<td>FACS count</td>
</tr>
<tr>
<td><strong>Health Center</strong></td>
<td>Guava</td>
<td>Refer samples to district-level laboratory</td>
<td>Coulter-manual</td>
<td>FACS Count</td>
<td>POOCH</td>
</tr>
</tbody>
</table>

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 are not properly trained in using the equipment, or there has been insufficient supplies of reagents due to 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 FACS Calibur 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 referred to the district.

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

<table>
<thead>
<tr>
<th>District Hospital</th>
<th>Western District</th>
<th>East District</th>
<th>Northern District</th>
<th>Southern District</th>
<th>Central District</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>District Hospital</strong></td>
<td>FACS Calibur Sysmex KX21(^4)</td>
<td>FACS Calibur Sysmex KX21</td>
<td>FACS Calibur Sysmex KX21</td>
<td>FACS Calibur Sysmex KX21</td>
<td>FACS Calibur Sysmex KX21</td>
</tr>
<tr>
<td><strong>Health Center</strong></td>
<td>Refer samples to district-level laboratory</td>
<td>Refer samples to district-level laboratory</td>
<td>Refer samples to district-level laboratory</td>
<td>Refer samples to district-level laboratory</td>
<td>Refer samples to district-level laboratory</td>
</tr>
</tbody>
</table>

\(f\) **Creating 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 the standards are disseminated and understood by all laboratory personnel and health staff throughout the country. Since standardization is a policy intervention, it will require formulation, high-level endorsement, and promotion before implementation takes place.

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\(^3\) Note: All trademarked equipment brands referenced in this text are illustrative and in no way endorse a particular brand or product.

\(^4\) Note: All trademarked equipment brands referenced in this text are illustrative and in no way endorse a particular brand or product.
In most instances, a standardization technical working group (TWG), consisting of key laboratory staff that were involved with the workshop, should be established to formulate a relevant policy document, follow endorsement and promotion, and coordinate the implementation of the standards. This TWG will only be required 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, health 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, as the context differs in each country, additional activities may also be required.

**Policy Activities**

Ministerial and/or other high-level support for the implementation of 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 their 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, program and laboratory staff, and implementing partners. The role of this committee will be to meet every two or three years to thoroughly review the list and 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 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 sub-set 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 commodities required to fulfill the standards are available. Without a continuous and reliable flow of commodities, laboratories will quickly return to old habits of procuring locally; standardization will not be properly implemented nor the benefits realized. Below is a list of one-time and on-going supply chain system strengthening activities:

1. **Product Selection:** Developing a product list is not technically part of the standardization exercise, as this list will not be included in the official policy, but is an important step in implementing the
standards. Once tests, techniques, and equipment have been chosen, it is necessary to choose the products required to conduct these tests using the chosen techniques and equipment. As 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.

A smaller sub-set of the standardization workshop participants should be tasked with listing all the products, reagents, and consumables that are necessary to conduct the tests, 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 9 can help guide participants through the process of selecting correlated products for each test, technique, and equipment; it will ensure that they have listed all categories of commodities (e.g., reagents, consumables).

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

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 and 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 categorized and classified (e.g., slow versus fast moving) in order to determine how these products should be managed within the system. To read more on designing logistics systems for laboratory commodities following standardization to ensure an adequate and constant supply of laboratory commodities, refer to the 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 on quantification of health commodities, refer to 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. As procurement staff 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.
Health 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 the types of health system activities that will be required in order to build capacity in the system and personnel to implement the standards. Depending on the country context, additional or fewer activities may be required.

1. **Developing/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, as these will serve as the operational documentation that guides laboratory staff on the standards.

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

3. **Facilitating Refresher Trainings for Laboratory Staff:** To reinforce the standards and ensure that all staff are competent to adhere to them, refresher courses on the standard techniques and on how to operate equipment should be provided for all laboratory staff. These trainings should occur in both the in-service and pre-service training settings.
CONCLUSION

Standardization is the process of selecting a standard list of tests, techniques, and equipment at each level of the system that ultimately results in streamlining the required commodities. Standardization aligns requirements in human resources, infrastructure, and funding needed at each level of the health system. In this way, standardization is a policy intervention that enables 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 clinically beneficial and cost-effective outcomes.

Standardization is a long-term process that requires time, resources, as well as the leadership and commitment of the MOH, and participation by donors and other partners. There are several key steps in the standardization process. As a first step in the process, a baseline assessment serves to both define the tests, techniques, and equipment currently being used in the system and to provide important information about the structures, stakeholders, and policies that will influence the process. The assessment findings are typically presented during a consensus building workshop where they are used to create a standard list of tests, techniques, and equipment, by level, and come up with a correlated list of required products. It is important to engage a wide range of stakeholders in this process, including laboratory staff, clinicians, and policymakers, particularly during the selection of tests, so that the tests selected can meet the service delivery requirements while taking into consideration capacity issues.

Once the standards are selected, an implementation plan, which takes into consideration the resources and steps required, should be developed. There are three distinct categories of next steps following the standardization workshop, including policy, supply chain, and health systems activities. Policy activities include the documentation of the outcome of the standardization workshop national policy documents and 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 the implementation of a number of supply chain strengthening activities, including product selection, the design and implementation of a logistics systems to manage laboratory commodities, and the national quantification and procurement of commodities. Finally, to ensure that staff will be able to implement the new standards, a number of health systems interventions are required, including the development of clinical SOPs and curricula to be used in training staff in the new standards.

The full implementation process takes time and resources; an ongoing commitment by stakeholders to the enforcement and updating of the standards is critical. The steps in the standardization process are detailed in the case study of the Malawi standardization experience in appendix 1.
APPENDIX 1

MALAWI STANDARDIZATION CASE STUDY

Background
In February 2009, the Malawi Ministry of Health (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, where 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 managers. 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; 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 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 5 shows the test menu selected for the hematology testing area, by level, in the system.

<table>
<thead>
<tr>
<th>CENTRAL HOSPITAL</th>
<th>DISTRICT HOSPITAL (incl. Community Hospital)</th>
<th>HEALTH CENTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full blood count</td>
<td>Full blood count</td>
<td>Hemoglobin</td>
</tr>
<tr>
<td>Differential count</td>
<td>Differential count</td>
<td>White blood cell count</td>
</tr>
<tr>
<td>Sickle cell screening</td>
<td>Sickle cell screening</td>
<td></td>
</tr>
<tr>
<td>Sickle cell confirmatory test</td>
<td>Sickle cell confirmatory test</td>
<td></td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>Hemoglobin</td>
<td></td>
</tr>
<tr>
<td>Prothrombin time</td>
<td>Prothrombin time</td>
<td></td>
</tr>
<tr>
<td>Activated partial thromboplastin time</td>
<td>Activated partial thromboplastin time</td>
<td></td>
</tr>
<tr>
<td>Fibrinogen test</td>
<td>Erythrocyte sedimentation rate</td>
<td></td>
</tr>
<tr>
<td>Erythrocyte sedimentation rate</td>
<td>Reticulocyte count</td>
<td></td>
</tr>
<tr>
<td>Reticulocyte count</td>
<td>CD4 count</td>
<td></td>
</tr>
<tr>
<td>Lupus erythematosus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD4 count</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD4 %</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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 5) is shown in table 6.

Table 6. List of Techniques for Hematology in Malawi

<table>
<thead>
<tr>
<th>Test Menus</th>
<th>Techniques</th>
<th>CENTRAL HOSPITAL</th>
<th>DISTRICT HOSPITAL</th>
<th>HEALTH CENTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full blood count</td>
<td>Hematology analyzer</td>
<td>Hematology analyzer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White blood cell count</td>
<td>Sodium metabisulphate</td>
<td>Sodium metabisulphite</td>
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<tr>
<td></td>
<td>Sodium dithionate</td>
<td>Solubility</td>
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<tr>
<td>Sickle cell screening</td>
<td>Electrophoresis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sickle cell confirmatory test</td>
<td>HemoCue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>HemoCue</td>
<td>HemoCue</td>
<td>HemoCue</td>
<td></td>
</tr>
<tr>
<td>PT</td>
<td>Hematology analyzer</td>
<td>Tube method</td>
<td></td>
<td></td>
</tr>
<tr>
<td>APTT</td>
<td>Hematology analyzer</td>
<td>Tube method</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibrinogen test</td>
<td>Hematology analyzer</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>ESR</td>
<td>Westergreen</td>
<td>Westergreen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reticulocyte count</td>
<td>Brilliant cresol blue</td>
<td>Brilliant cresol blue</td>
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</tr>
<tr>
<td></td>
<td>New Methylene blue</td>
<td>New Methylene blue</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hematology analyzer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lupus erythromatous</td>
<td>Latex agglutination</td>
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<td></td>
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<tr>
<td>CD4 Count</td>
<td>Flowcytometry</td>
<td>Flowcytometry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD4 %</td>
<td>Flowcytometry</td>
<td>Flowcytometry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 7.
Table 7. List of Standard Equipment

<table>
<thead>
<tr>
<th>Type of Analyzers</th>
<th>Central</th>
<th>District</th>
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</thead>
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<tr>
<td><strong>Biochemistry</strong></td>
<td>Humastar 180 / Humalyte ISE</td>
<td>Humalyzer 3000</td>
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<tr>
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<td>Keylab</td>
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<tr>
<td><strong>Hematology</strong></td>
<td>Sysmex XT 1800</td>
<td>Sysmex KX21</td>
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<tr>
<td></td>
<td>Sysmex KX21</td>
<td></td>
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<tr>
<td><strong>CD4</strong></td>
<td>EPICS</td>
<td>Partec Cyflow SL3</td>
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<tr>
<td></td>
<td>Partec Cyflow SL3</td>
<td>FACS count</td>
</tr>
</tbody>
</table>

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) catalogue 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 catalogue 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.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Date</th>
<th>Responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft standardized list of tests, techniques, equipment, consumables,</td>
<td>June</td>
<td>Standardization TWG (all central-level managers)</td>
</tr>
<tr>
<td>and reagents, by level, to be edited by all participants and coordinated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>by a smaller technical group of central laboratory managers.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final list to be sent to the Deputy Director for Health Technical Support</td>
<td>June</td>
<td>Standardization TWG (all central-level managers)</td>
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<tr>
<td>Services (HTSS) Diagnostics Department for approval and formal</td>
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<tr>
<td>documentation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liaise with procurement unit to assist in implementation of</td>
<td>June</td>
<td>USAID</td>
</tr>
<tr>
<td>standardization.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dissemination of new standards to laboratory staff and refresher</td>
<td>December</td>
<td>USAID</td>
</tr>
<tr>
<td>trainings to staff at all level to ensure they have the skills to provide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>the tests.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activity</td>
<td>Date</td>
<td>Responsible</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>--------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Orientation of stakeholders including clinicians, nursing staff, and</td>
<td>July</td>
<td>USAID</td>
</tr>
<tr>
<td>development partners of the new standards for laboratory services.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incorporation of the standard techniques and analyzers into training</td>
<td>December</td>
<td>USAID</td>
</tr>
<tr>
<td>programs.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Formation of a standardization committee</td>
<td>June</td>
<td>MOH</td>
</tr>
<tr>
<td>Annual reviews of the standardized list.</td>
<td>Annually</td>
<td>Standardization committee</td>
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</table>
APPENDIX 2

EXAMPLE OF TEST MENU BY LEVEL

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<tr>
<td><strong>Hematology</strong></td>
<td><strong>Hematology</strong></td>
<td><strong>Hematology</strong></td>
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<td>Full blood count</td>
<td>Full blood count</td>
<td>Hemoglobin</td>
</tr>
<tr>
<td>Differential count</td>
<td>Differential count</td>
<td>White blood cell count</td>
</tr>
<tr>
<td>Sickle cell screening</td>
<td>Sickle cell screening</td>
<td></td>
</tr>
<tr>
<td>Sickle cell confirmatory test</td>
<td>Sickle cell differential test</td>
<td></td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>Hemoglobin</td>
<td></td>
</tr>
<tr>
<td>Prothrombin time</td>
<td>Prothrombin time</td>
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<tr>
<td>Activated partial thromboplastin time</td>
<td>Activated partial thromboplastin time</td>
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<tr>
<td>Fibrinogen test</td>
<td>Erythrocyte sedimentation rate</td>
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<td>Erythrocyte sedimentation rate</td>
<td>Reticulocyte count</td>
<td></td>
</tr>
<tr>
<td>Reticulocyte count</td>
<td>CD4 %</td>
<td></td>
</tr>
<tr>
<td>Lupus erythematous</td>
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<tr>
<td>CD4 count</td>
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<td>CD4 %</td>
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<table>
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<td>Rh grouping</td>
<td>Rh grouping</td>
<td>Rh grouping</td>
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<tbody>
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<td>TB microscopy - Z-N</td>
<td>TB microscopy - Z-N</td>
</tr>
<tr>
<td>TB microscopy - fluorescence</td>
<td>TB microscopy - fluorescence</td>
<td>Gram stain</td>
</tr>
<tr>
<td>Culture and sensitivity</td>
<td>Culture and sensitivity</td>
<td>Wet prep</td>
</tr>
<tr>
<td>Blood</td>
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<tr>
<td>Pus swabs</td>
<td>Pus swabs</td>
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<tr>
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<td>Stool</td>
<td></td>
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<tr>
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<td>Urine</td>
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</tr>
<tr>
<td>Sputum</td>
<td>Sputum</td>
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<tr>
<td>CENTRAL HOSPITAL</td>
<td>DISTRICT HOSPITAL</td>
<td>HEALTH CENTER</td>
</tr>
<tr>
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</tr>
<tr>
<td>Aspirates CSF</td>
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<td>Stool microscopy</td>
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<tr>
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**Serology**

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34
<table>
<thead>
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<th>CENTRAL HOSPITAL</th>
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<td>Uric acid</td>
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<td>Tumor markers</td>
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# APPENDIX 3

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# APPENDIX 4
## PRE-STANDARDIZATION QUESTIONNAIRE

### 1. Tests Performed at Health Center Laboratory

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<td>☐ Hemoglobin estimation</td>
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2. Additional Tests Performed at District Hospital Laboratory

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<td>□ Differential blood counts</td>
<td>□ (other): ________________</td>
<td>□ ABX Micros</td>
</tr>
<tr>
<td>□ Platelet count</td>
<td>□ Hematology analyzer</td>
<td>□ : ABX Pentra 60</td>
</tr>
<tr>
<td>□ Reticulocyte count</td>
<td>□ (other): ________________</td>
<td>□ Coulter ACT Diff 5</td>
</tr>
<tr>
<td>□ Blood indices</td>
<td>□ Hematology analyzer</td>
<td>□ Coulter ACT Diff 8</td>
</tr>
<tr>
<td>□ (other): ________________</td>
<td>□ (other): ________________</td>
<td>□ MS4</td>
</tr>
<tr>
<td>□ (other): ________________</td>
<td>□ (other): ________________</td>
<td>□ MS9</td>
</tr>
<tr>
<td>□ (other): ________________</td>
<td>□ (other): ________________</td>
<td>□ other______________</td>
</tr>
<tr>
<td>□ CD4/CD8 count</td>
<td>□ Flow cytometry</td>
<td>□ FACScount</td>
</tr>
<tr>
<td>□ Non-cytofluorimetric</td>
<td>□ FACS Calibur</td>
<td>□ FACS Calibur</td>
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<tr>
<td>□ Manual</td>
<td>□ Partec Cyflow counter</td>
<td>□ Partec Cyflow counter</td>
</tr>
<tr>
<td>□ (other): ________________</td>
<td>□ Partec SL3</td>
<td>□ Partec SL3</td>
</tr>
<tr>
<td>□ (other): ________________</td>
<td>□ EPIC</td>
<td>□ EPIC</td>
</tr>
<tr>
<td>□ (other): ________________</td>
<td>□ Point of Care</td>
<td>□ Point of Care</td>
</tr>
<tr>
<td>□ (other): ________________</td>
<td>□ Guava</td>
<td>□ Guava</td>
</tr>
<tr>
<td>□ (other): ________________</td>
<td>□ other______________</td>
<td>□ other______________</td>
</tr>
<tr>
<td></td>
<td>HIV RNA</td>
<td>Roche</td>
</tr>
<tr>
<td>----------------</td>
<td>------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td></td>
<td>Real-time PCR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Heat-dissociated p24 antigen</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cavidi RT</td>
<td>Carvidi RT</td>
</tr>
<tr>
<td></td>
<td>(other): ________________</td>
<td>other</td>
</tr>
</tbody>
</table>

|                | Sodium metabisulphite        |        |
|                | Electrophoresis              |        |
|                | Other____________________    |        |

|                | Manual microscopy (field)    |        |
|                | Concentration                |        |
|                | (other): ________________    |        |

|                | Manual microscopy-           |        |
|                | Romanosky________________   |        |

|                | Direct saline                |        |
|                | iodine concentration         |        |
|                | (other): ________________    |        |

|                | Rapid screening kits         |        |
|                | ELISA                        |        |
|                | Western Blot                 |        |
|                | ________________             |        |

|                | Electrophoresis              |        |
|                | (other): ________________    |        |

|                | Electrophoresis              |        |
|                | (other): ________________    |        |

|                | ELISA                        |        |
|                | Latex agglutination          |        |
|                | (other): ________________    |        |

|                | RPR/VDRL carbon antigen      |        |
|                | TPHA                         |        |
|                | ________________             |        |

|                | Chemistry auto-analyzer      |        |
|                | manual photometer            |        |
|                | (other): ________________    |        |

|                | Cobas mira                  |        |
|                | Cobas integra                |        |
|                | Humamaster 180              |        |
|                | Keylab                      |        |
|                | CX5                         |        |
|                | CX9                         |        |
|                | Humalysyer 2000             |        |
|                | Humalysyer 3000             |        |

|                | SGOT (serum)                |        |
|                | SGPT (serum)                |        |
|                | Alkaline phosphatase (serum)|        |
|                | Renal function tests        |        |
|                | Blood glucose               |        |
|                | Serum electrolytes          |        |

<p>|                | Cobas mira                  |        |
|                | Cobas integra                |        |
|                | Humamaster 180              |        |
|                | Keylab                      |        |
|                | CX5                         |        |
|                | CX9                         |        |
|                | Humalysyer 2000             |        |
|                | Humalysyer 3000             |        |</p>
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Method</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total protein</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Examination of CSF for yeast</td>
<td>Negative staining-India ink</td>
<td>(other): ________________</td>
</tr>
<tr>
<td>Examination of CSF, pus, deposit, etc., micro-organisms</td>
<td>Gram stain</td>
<td>(other): ________________</td>
</tr>
<tr>
<td>Culture</td>
<td>Aerobic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Anaerobic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CO₂</td>
<td></td>
</tr>
<tr>
<td>Drug sensitivity</td>
<td>Disc diffusion</td>
<td>(other): ________________</td>
</tr>
<tr>
<td>Microscopy for plague</td>
<td>Wayson staining</td>
<td></td>
</tr>
<tr>
<td>Processing biopsy</td>
<td>Haematoxylin and eosin</td>
<td>(other): ________________</td>
</tr>
<tr>
<td></td>
<td>Other ________________</td>
<td></td>
</tr>
<tr>
<td>Semen analysis</td>
<td>Microscopy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>________________</td>
<td></td>
</tr>
<tr>
<td>Cytology</td>
<td>Microscopy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pup smear</td>
<td></td>
</tr>
<tr>
<td></td>
<td>________________</td>
<td></td>
</tr>
<tr>
<td>Sputum for TB</td>
<td>ZN stain</td>
<td>(other): ________________</td>
</tr>
<tr>
<td></td>
<td>(other): ________________</td>
<td></td>
</tr>
<tr>
<td>Urine sediment microscopy</td>
<td>Direct microscopy</td>
<td></td>
</tr>
<tr>
<td>Urine chemistry</td>
<td>Dipstix</td>
<td>(other): ________________</td>
</tr>
<tr>
<td></td>
<td>(other): ________________</td>
<td></td>
</tr>
<tr>
<td>Genito-urinary track specimens</td>
<td>Wet prep</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gram</td>
<td></td>
</tr>
<tr>
<td></td>
<td>KOH</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(other): ________________</td>
<td></td>
</tr>
<tr>
<td>Blood group</td>
<td>Tube method</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tile method</td>
<td></td>
</tr>
<tr>
<td>type and cross matching</td>
<td>Tube method</td>
<td></td>
</tr>
<tr>
<td>Skin snip for microfilaria</td>
<td>Saline direct</td>
<td>(other): ________________</td>
</tr>
<tr>
<td></td>
<td>(other): ________________</td>
<td></td>
</tr>
<tr>
<td>Examination for fungi</td>
<td>KOH</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(other): ________________</td>
<td></td>
</tr>
<tr>
<td>Procedure</td>
<td>Method</td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>-----------------</td>
<td></td>
</tr>
<tr>
<td>Confirmatory test for syphilis</td>
<td>TPHA</td>
<td></td>
</tr>
<tr>
<td>Routine screening of food handlers</td>
<td>Standard public health methods</td>
<td></td>
</tr>
<tr>
<td>Bacteriological examination of water, foods, and beverages</td>
<td>(other): ________________</td>
<td></td>
</tr>
<tr>
<td>(other): ________________</td>
<td>(other): ________________</td>
<td></td>
</tr>
<tr>
<td>(other): ________________</td>
<td>(other): ________________</td>
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</tr>
</tbody>
</table>
APPENDIX 5

EXAMPLE GOALS AND OBJECTIVES
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 6

**EXAMPLE OF STANDARDIZATION WORKSHOP SCHEDULE**

<table>
<thead>
<tr>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>8:30–9:30</strong></td>
<td><strong>8:00–9:00</strong></td>
<td><strong>8:00–10:00</strong></td>
<td><strong>8:00–10:00</strong></td>
<td><strong>8:00–10:00</strong></td>
</tr>
<tr>
<td>Introduction to standardization &amp; Maputo declaration</td>
<td>Ice breaker/Review Monday activities</td>
<td>Group activity 2: Presentation and consensus on techniques</td>
<td>Group activity 3: Presentation and consensus on equipment selection</td>
<td>Group activity 4: Product list development</td>
</tr>
<tr>
<td><strong>9:30–10.00</strong></td>
<td><strong>9:00–10:00</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Introduction to logistics</td>
<td>Group review of testing menus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>10:00–10:15</strong></td>
<td><strong>10:00–10:30</strong></td>
<td><strong>10:00–10:30</strong></td>
<td><strong>10:00–10:30</strong></td>
<td><strong>10:00–10:30</strong></td>
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<tr>
<td>Break</td>
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<td>Break</td>
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<tr>
<td><strong>10:15–10:45</strong></td>
<td><strong>10:30–12:00</strong></td>
<td><strong>10:30–12:00</strong></td>
<td><strong>10:30–12:00</strong></td>
<td><strong>10:30–12:00</strong></td>
</tr>
<tr>
<td>Advantages of standardization</td>
<td>Supply chain considerations</td>
<td>Group activity 3: Determining equipment criteria</td>
<td>Group activity 3: Presentation and consensus on equipment selection</td>
<td>Planning for implementation</td>
</tr>
<tr>
<td><strong>11:15–12:00</strong></td>
<td><strong>11:00–12:00</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Panel session vision for lab services in Malawi</td>
<td>Introduction to defining techniques</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>12:00-1:00</strong></td>
<td><strong>12:00–1:00</strong></td>
<td><strong>12:00–1:00</strong></td>
<td><strong>12:00–1:00</strong></td>
<td><strong>12:00–1:00</strong></td>
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<tr>
<td>Lunch</td>
<td>Lunch</td>
<td>Lunch</td>
<td>Lunch</td>
<td>Lunch</td>
</tr>
<tr>
<td><strong>1:00–3:15</strong></td>
<td><strong>1:00–3:00</strong></td>
<td><strong>1:00–2:00</strong></td>
<td><strong>1:00–3:00</strong></td>
<td><strong>1:00–3:00</strong></td>
</tr>
<tr>
<td>Group activity 1: Setting test menus</td>
<td>Group activity 2: Defining techniques</td>
<td>Group activity 3: Equipment evaluation</td>
<td>Group activity 4: Product list development</td>
<td>Final presentation of results to stakeholders</td>
</tr>
<tr>
<td><strong>3:00–3:15</strong></td>
<td><strong>3:00–3:15</strong></td>
<td><strong>3:00–3:15</strong></td>
<td><strong>3:00–3:15</strong></td>
<td><strong>3:00–3:15</strong></td>
</tr>
<tr>
<td>Break</td>
<td>Break</td>
<td>Break</td>
<td>Break</td>
<td>Break</td>
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<tr>
<td><strong>3:15–5:00</strong></td>
<td><strong>3:15–5:00</strong></td>
<td><strong>3:15–5:00</strong></td>
<td><strong>3:15–5:00</strong></td>
<td><strong>3:15–5:00</strong></td>
</tr>
<tr>
<td>Group activity 1: Presentations and consensus on test menus</td>
<td>Group activity 2: Defining techniques</td>
<td>Group activity 3: Equipment evaluation</td>
<td>Group activity 4: Product list development</td>
<td>Wrap up and closing</td>
</tr>
<tr>
<td><strong>49</strong></td>
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# APPENDIX 7

## SETTING TEST MENUS WORKSHEET

<table>
<thead>
<tr>
<th>Laboratory Tests</th>
<th>Urban Health Centers</th>
<th>District Hospitals</th>
<th>Central Level</th>
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<tbody>
<tr>
<td></td>
<td>Send Out</td>
<td>On Site</td>
<td>Send Out</td>
</tr>
<tr>
<td><strong>Hematology</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Total WBC and differential</td>
<td></td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td><strong>Blood Bank</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood transfusion screening</td>
<td></td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td><strong>Microbiology</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TB microscopy</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>HIV screening</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Urine microscopy</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Stool microscopy</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Antenatal syphilis screening</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td><strong>Parasitology</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malaria microscopy</td>
<td>✔</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td><strong>Biochemistry</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urine chemistry</td>
<td>✔</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Blood glucose</td>
<td>✔</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td><strong>CSF Analysis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microscopy (cell count)</td>
<td>✔</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Indian Ink</td>
<td>✔</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Gram stains</td>
<td>✔</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>ZN stains</td>
<td>✔</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Protein</td>
<td>✔</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Glucose</td>
<td>✔</td>
<td></td>
<td>✔</td>
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</table>
APPENDIX 8

OPERATIONAL CONSIDERATIONS FOR EQUIPMENT SELECTION

Adapted from the Maputo Workshop on Standardization, hosted by WHO

<table>
<thead>
<tr>
<th>OPERATIONAL CONSIDERATIONS FOR EQUIPMENT SELECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CRITICAL</strong></td>
</tr>
<tr>
<td>Equipment assessed, in-country, CDC, WHO etc., and report available</td>
</tr>
<tr>
<td>Equipment uses existing regular power supply</td>
</tr>
<tr>
<td>Operator manual available in appropriate language</td>
</tr>
<tr>
<td>Technical manual available in appropriate language</td>
</tr>
<tr>
<td>Training offered on installation</td>
</tr>
<tr>
<td>Supplier installs and commissions equipment</td>
</tr>
<tr>
<td>Equipment in current production</td>
</tr>
<tr>
<td>Services engineers available</td>
</tr>
<tr>
<td>Throughput is appropriate for workload</td>
</tr>
<tr>
<td><strong>IMPORTANT AND DESIRABLE</strong></td>
</tr>
<tr>
<td>Machine will run as single platform</td>
</tr>
<tr>
<td>Equipment can run stat (ad hoc) samples</td>
</tr>
<tr>
<td>Machine has stable calibration settings</td>
</tr>
<tr>
<td>Machine can store test results</td>
</tr>
<tr>
<td>Machine can store QC results</td>
</tr>
<tr>
<td>Few operator-initiated maintenance activities</td>
</tr>
<tr>
<td>Minimal sample preparation before running on the machine</td>
</tr>
<tr>
<td>Machine is self-calibrating</td>
</tr>
<tr>
<td>Machine can interface with computer</td>
</tr>
<tr>
<td>Equipment used in the region</td>
</tr>
<tr>
<td>Reagents ready to use (no reagent preparation required)</td>
</tr>
<tr>
<td><strong>Program Needs</strong></td>
</tr>
<tr>
<td>------------------</td>
</tr>
<tr>
<td>Load and walk away system</td>
</tr>
<tr>
<td>Equipment can run sample batches</td>
</tr>
<tr>
<td>Machine can be upgraded</td>
</tr>
<tr>
<td>Equipment can self-diagnose</td>
</tr>
<tr>
<td>Machine has in-built printer</td>
</tr>
<tr>
<td>Same equipment in existence and use in-country</td>
</tr>
<tr>
<td>Technology has been used elsewhere</td>
</tr>
<tr>
<td>Equipment meets any program plans to increase testing</td>
</tr>
<tr>
<td>Maximum sample age (how long can the sample be stored before use)</td>
</tr>
<tr>
<td>Training on use of equipment less than 1 week</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Supply Chain</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent with shortest shelf life in kit is &gt;6 months</td>
<td>I</td>
</tr>
<tr>
<td>Reagents and supplies of equipment can be stored in existing space</td>
<td>I</td>
</tr>
<tr>
<td>Existing cold chain distribution can accommodate equipment reagents</td>
<td>I</td>
</tr>
<tr>
<td>Existing cold storage can accommodate reagents</td>
<td>I</td>
</tr>
<tr>
<td>Open system</td>
<td>I</td>
</tr>
<tr>
<td>Does not require additional accessories</td>
<td>I</td>
</tr>
<tr>
<td>Bulk reagents not used on machine (20-liter containers)</td>
<td>D</td>
</tr>
<tr>
<td>Equipment has no unique consumables, e.g., sample cups, cuvettes</td>
<td>D</td>
</tr>
<tr>
<td>Supplier lead time for supply of equipment (months)</td>
<td></td>
</tr>
<tr>
<td>Supplier lead time for supply of reagents and consumables (months)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Service &amp; Maintenance</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Machine can be switched off when not in use</td>
<td>I</td>
</tr>
<tr>
<td>Local agent available for product support</td>
<td>I</td>
</tr>
<tr>
<td>Equipment has spares kit, e.g., replaceable tubes, valves, filters, etc.</td>
<td>I</td>
</tr>
<tr>
<td>Equipment comes with 5–10 yrs. spares guarantee from manufacturer</td>
<td>I</td>
</tr>
<tr>
<td>Supplier has regional presence</td>
<td>D</td>
</tr>
<tr>
<td>Equipment fits in existing space</td>
<td>I</td>
</tr>
<tr>
<td>Existing generator can support equipment</td>
<td>I</td>
</tr>
<tr>
<td>Complements existing equipment</td>
<td>I</td>
</tr>
<tr>
<td>Works well in existing temperature range</td>
<td>I</td>
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<table>
<thead>
<tr>
<th><strong>Infrastructure Requirements</strong></th>
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<tbody>
<tr>
<td>Purchase price</td>
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<tr>
<td>Cost of start-up kit</td>
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<tr>
<td>Cost of accessories</td>
<td></td>
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<tr>
<td>Cost of consumables to run 1,000 tests</td>
<td></td>
</tr>
<tr>
<td>Cost of quality control materials specific to equipment required for 1,000 tests run</td>
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<tr>
<td>Cost of service contract</td>
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APPENDIX 9

EXAMPLE OF TEMPLATE FOR DEVELOPING PRODUCT LIST

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<tr>
<th>Test Menus</th>
<th>Techniques</th>
<th>Equipment</th>
<th>Durables</th>
<th>Reagents</th>
<th>Specimen Type</th>
<th>Consumables</th>
<th>CMS</th>
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