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LESSONS LEARNED IN MANAGING LABORATORY SUPPLIES



DELIVER's experience with all health systems has proven that a sound logistics system is the foundation of a successful program. The same holds true with laboratory systems.

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INTRODUCTION

Improving supportive services has been recognized as strategically critical to the success of service delivery in HIV/AIDS, tuberculosis (TB), and malaria control programs. Specifically, laboratory services have been identified as one of the cornerstones upon which those health programs are built. As a result, the success of the programs is dictated, at least in part, by quality laboratory services that are capable of keeping pace with the increasing needs and demands of the programs. With this understanding, efforts to respond to those diseases have been expanded to include the strengthening of laboratory services for diagnosis, and monitoring and evaluation of treatment efficacy. Successful delivery of those services is contingent on improving laboratory services and on ensuring continuous availability of essential laboratory commodities.

Providing the commodities to support those programs begins with strengthening the laboratory systems that manage the commodities so the programs can avoid stock imbalances and program-devastating stockouts. Laboratory systems, however, pose a unique challenge to ensuring a continuous supply because of the sheer number of commodities that require managing. For example, as illustrated in figure 1, a comprehensive HIV/AIDS program can require hundreds of commodities for complete and quality service delivery.

In many settings, laboratory services have been incapacitated by years of neglect. Yet, given recent and future plans for service expansion, it is critical for countries to make significant investments in strengthening laboratory services, specifically the logistics systems that manage laboratory commodities.

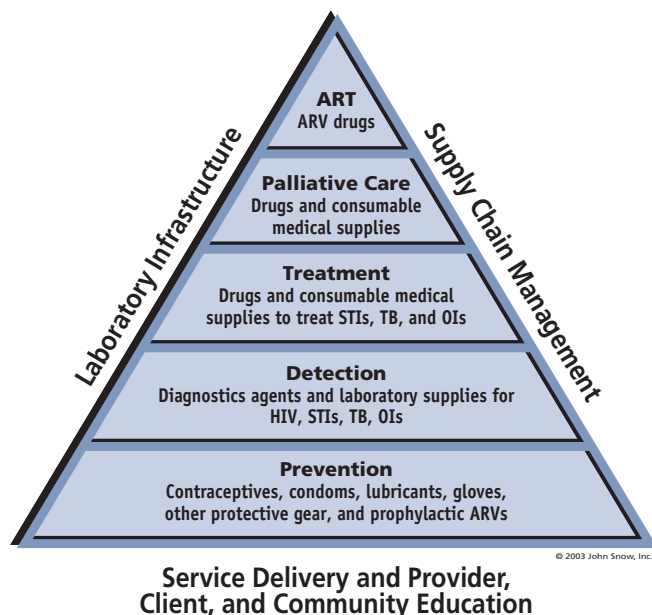
Because many countries and programs are just now recognizing the need to strengthen laboratory services, not much work has been done in this area. However, to date, DELIVER has been a pioneer in this effort and has learned many valuable lessons through practical, in-country experiences. The following sections describe the five key lessons that DELIVER has learned.



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Figure 1. A Comprehensive HIV/AIDS Program



THE FIRST STEP IN STRENGTHENING LABORATORY SERVICES IS TO CONDUCT AN ASSESSMENT OF THE CURRENT SYSTEM

Without a baseline assessment of the current laboratory system, programs will have difficulty identifying critical issues and opportunities for improvement. Also, the success of any strengthening initiative cannot be assessed without a baseline measurement for comparison. Therefore, an initial assessment of the laboratory system provides a vital base upon which strengthening efforts are built.

Depending on the objectives of the baseline assessment, a sample of laboratories operating at the different levels of the system (i.e., central, regional, provincial, zonal, district, etc.) should be visited to collect information on the following:

- Policies guiding the services
- Forecasting and procurement
- Financing
- Organizational structure (i.e., equipment maintenance, laboratory network, laboratory staff capacity, etc.)
- Laboratory testing services

- Laboratory supplies logistics
- Laboratory infrastructure.

DELIVER has developed a generic assessment tool titled the *Assessment Tool for Laboratory Services (ATLAS) 2006* that can be adapted to each country’s context. This tool addresses the areas mentioned in the above list.

In Uganda, DELIVER, in collaboration with the Ministry of Health (MOH) and the Centers for Disease Control and Prevention (CDC), conducted an assessment of all laboratories in the country in an effort to meet the objectives of different stakeholders involved in strengthening laboratory services. An example of one objective was to upgrade the infrastructure of laboratories. Without an assessment of the current state of laboratories, stakeholders would be unable to identify which laboratories needed to be involved in the infrastructure building process and the extent of their involvement. In the future, the success of the infrastructure building process will be measured against the baseline that is provided by the assessment.

Furthermore, in-country experience in Kenya has demonstrated the same lesson. In Kenya, the assessment was done for selected laboratories in collaboration with the MOH, the National Public Health Laboratory Services (NPHLS), and the African Medical and Research Foundation (AMREF). The main focus was to improve the logistics system and the procurement process, and to upgrade the infrastructure for these selected laboratories. The selected laboratories were assessed with the intention of eventually applying the same improvement model countrywide. Again, without the assessment, it would have been difficult to identify strategic and purposeful interventions for this pilot program and to convert the successes of the pilot program to an improvement model that could be rolled out across all laboratories in Kenya.

Finally, in Ghana, DELIVER and the Ministry of Health/Ghana Health Services conducted an assessment with the objective of improving the countrywide logistics system for laboratory commodities. The assessment would also ensure that

Ghana would be ready to successfully expand antiretroviral therapy services. In this assessment, selected laboratories at all levels of the system and from different regions were sampled to gain a picture of the functioning of the different laboratory service components. This assessment proved to be critical to the identification of potential gaps in the system and to the seizure of opportunities for improvement.

Thus far, DELIVER assessments have succeeded in providing stakeholders with information on the current state of laboratory services, thus enabling stakeholders to identify and to set priorities for areas of improvement. By their very nature, those assessments also serve as critical baselines for measuring the success of the strengthening process. In each of the assessments, the findings paved the way for recommendations for improvement and set the stage for effective and strategic interventions.

In conclusion, conducting a system assessment before undertaking any program strengthening efforts has proven to be a critical first step and an important driver of program success.

WITHOUT COMMITMENT FROM ALL STAKEHOLDERS AND THE ESTABLISHMENT OF A COORDINATING BODY, LABORATORY STRENGTHENING EFFORTS CANNOT BE SUCCESSFUL

In most laboratory system settings, multiple stakeholders are involved in their supply and operation (e.g., governments and donors), which poses a unique challenge to program management. If a commitment across stakeholders is not secured, then the sustainability of laboratory services will be severely jeopardized. Furthermore, even with a commitment across stakeholders, successful functioning of the laboratory system is difficult to achieve without a central coordinating body that is empowered to make decisions and that is tasked with overseeing laboratory system operations. In most programs, even those programs in which commitment has been secured, the lack of a central coordinating body has crippled laboratory system functions.

In Kenya, a country in which stakeholder commitment had already been reasonably secured, DELIVER participated in an effort to establish a coordination committee responsible for advising the NPHLS and the National AIDS Control Program on all matters relating to laboratory services. The committee focused on the coordination of donors and stakeholders for the purposes of financing and procuring laboratory supplies, the development of operational policies and guidelines on laboratory testing procedures, and the determination of the logistics system components for laboratory reagents and supplies. Additionally, DELIVER led the formation of a logistics subcommittee that was tasked with overseeing the functioning of the laboratory logistics system.

Prior to forming the coordinating committee, the lack of consensus among stakeholders, as well as nonstandard laboratory procedures, had resulted in the duplication of efforts in many areas. For example, the Global Fund was involved in supplying laboratory commodities to the Kenya laboratory system. Before the coordination of all stakeholders was implemented, the same laboratory commodities were being supplied by the NPHLS, thus resulting in an oversupply of commodities at some laboratories and an undersupply at other laboratories. Once a coordinating body was established, commodity supply was communicated among all stakeholders and alternate supply quantities were taken into account in NPHLS planning, which eliminated the duplicate supply of commodities. Finally, the coordination of all stakeholders created a forum in which standardization efforts could be communicated. As a result of the creation of this forum, a system in which different tests, techniques, and commodities were being used was converted into a standard system, and technical standard operating procedures (SOPs) were developed for testing services systemwide.

As DELIVER's in-country experience has shown, securing the commitment of stakeholders is only the first step in creating a functional and sustainable laboratory system. Establishing a coordinating body that represents all stakeholders, a body that is empowered to make decisions regarding

laboratory system operations (e.g., standardization of protocols, scope of quantification, procurement specifications, design of logistics system, etc.), is the crucial second step in creating a successful laboratory program. With each step in place, strengthening laboratory services to ensure the continuous availability of laboratory supplies can be successfully executed.

NONSTANDARDIZED LABORATORY SYSTEMS ARE UNMANAGEABLE BECAUSE OF THE NUMBER OF COMMODITIES REQUIRING MANAGEMENT

Nonstandardized laboratory systems provide an insurmountable obstacle to the management of laboratory supplies. By their very nature, laboratory systems require numerous commodities to ensure quality performance. Standardized laboratory systems require the management of potentially hundreds of commodities. In a nonstandardized system, the management of potentially hundreds of commodities can easily reach into the thousands. This number is because, in a nonstandardized system, different tests can be conducted using different techniques, each of which can have unique commodity requirements. Those tests can result in an exponential increase in the number of commodities requiring management.

In both Kenya and Uganda, DELIVER was tasked with quantifying laboratory supplies. However, quantification was not possible without first undergoing a standardization process for the laboratory system. Before the standardization process, the laboratory required the management of many hundreds of laboratory commodities. In each country, the stakeholders that were involved acted in partnership with DELIVER to standardize test menus and testing techniques. This partnership led to a consensual agreement of required reagents and consumables needed for each test and to the subsequent reduction by roughly 60–75 percent in the commodities requiring management.

Furthermore, in Kenya, the standardization process was used to guide the development of new laboratory policies and the updating of existing



policies and SOPs for every level of the system, allowing for standardized instrumentation to be procured. Finally, in Kenya, selection of the tests to support a comprehensive HIV/AIDS program was conducted using the list of recommended tests that were identified in the standardization process.

DELIVER has proven from its in-country experience that standardizing testing protocols, instrumentation, and procedures—and, therefore, standardizing the commodities managed in the laboratory system—is an essential step to ensuring efficient and effective management of laboratory supplies. Standardization drives product selection, quantification, and quality assurance. Once standardized test menus and testing techniques are developed, the product selection process is simplified, and laboratories at the same level of the system can use the same techniques to conduct selected tests. Those techniques will ultimately result in consistent, higher-quality testing across the public health system.

The Standardization Must Be Done in a Consultative Process Representing All Levels of the Laboratory System

National laboratory program managers who are engaged in standardizing laboratory services can make decisions for testing procedures and for selecting laboratory supplies. However, infrastructure capacity and laboratory personnel skills to imple-

ment those decisions can be considered only in a consultative process in which stakeholders representing the laboratory system are present. Otherwise, appropriate quantities and types of reagents and equipment would not be selected, which would create a risk of stockouts and wastages.

In both Kenya and Uganda, DELIVER—in collaboration with the countries' Ministries of Health and other development partners (e.g., AMREF, CDC)—facilitated the standardization process by convening a consensus-building workshop. DELIVER and the partners recognize that the standardization of the laboratory system affects all levels within the system. Therefore, the consensus-building workshop consisted of representatives from each level of the public health system involved in laboratory services, including the central level (NPHLS for Kenya and Central Public Health Services in Uganda), plus the laboratory staff members and key stakeholders who are involved in supporting laboratory services.

In each case, assembling this diverse group enabled any and all questions to be answered in one forum. For example, program managers were able to provide clarification on higher-level policy considerations, while representatives from individual laboratories were able to inform people about the feasibility of implementation at the lowest levels. By participating in this consultative process, the groups were able to successfully define the following essential elements:

- Test menus by level
- Testing techniques by level
- Commodity requirements (including quantities) by level
- Instrumentation by level.

Practical, in-country experience has proven that engaging representatives from all levels of the laboratory system is a critical determinant of success for the overall standardization effort. Therefore, conducting the standardization process through the facilitation of a consensus-building workshop allows for the development of appropriate and feasible SOPs.

The Standardization Process Must Be Followed by an Implementation Plan

Implementing recommendations from the standardization process presents a few challenges. The greatest challenge to date has been the handling of equipment that is outside the standardized system; the equipment would logically be removed from the system. However, most laboratories are reluctant to discard any instrument—whether it is working or not, especially high-value equipment.

The decision to remove nonstandardized equipment has financial implications. The public health laboratory system will have to secure funding and replace instruments that do not match the published standards. This will pose a challenge for the donor community by limiting their procurement options.

The other challenge countries face when they standardize their laboratory system is the potential inconsistency between the standards and the training of the current laboratory staff. The change may require additional training for personnel. Traditionally, personnel experience and the availability of equipment and supplies have guided testing techniques rather than standards. Consequently, during the consensus-building workshop, these issues need to be addressed and solutions need to be incorporated in the implementation strategy.

In Kenya, the MOH is currently experiencing those challenges. Although the National Public Health Laboratory Services, in collaboration with stakeholders, is working to develop an implementation plan, the handling of equipment that does not match the standards is still an outstanding issue. On the other hand, SOPs for testing services have been developed based on the recommended testing protocols from the standardization workshop. A training needs assessment will be conducted by the MOH, DELIVER, and stakeholders, followed by a national roll-out training to support the newly designed standardized logistics system.

DELIVER's experience continues to prove that a standardized implementation plan is as critical as the standardization process itself. Standardization is never complete until the challenges of implemen-

tation are addressed, such as training gaps and inconsistencies in the definitions of supplies and equipment. The standardization process, including implementation, is an emerging issue in the supply chain management of laboratory commodities; it will require continued creativity and innovation.

IN THE ABSENCE OF USAGE DATA, SERVICE STATISTICS DATA SHOULD BE USED FOR QUANTIFICATION AND PROCUREMENT PURPOSES

Laboratory services have traditionally been a neglected component of the health system. Consequently, few logistics data are available for laboratory commodities. The lack of logistics data presents a special challenge to the quantification and to the subsequent procurement of laboratory commodities. Past usage data have been found to be the most representative indicator of future usage data for quantification and procurement purposes. Most laboratory systems, however, do not have data on commodity usage. Therefore, procurement of supplies is being done without logistics data, and the wrong commodities are being procured in the wrong quantities and for the wrong facilities.

In both Kenya and Uganda, logistics data—specifically usage data—were not available. DELIVER was forced to use service statistics to estimate future requirements. First, test techniques used throughout the system were determined. Next, the quantities of each commodity required for use with these testing techniques were determined. Finally, test numbers at each level were multiplied by the quantities of commodities needed for each test; this calculation was used to develop the final quantification and procurement estimates. Using service statistics, decision makers were able to make informed decisions that were based on available data to ensure that the commodities were being supplied in the right amounts to the right places throughout the laboratory system.

For more information on quantifying lab supplies see the *Guide for Quantifying Laboratory Supplies* on the DELIVER website at deliver.jsi.com.



Although quantification is ideally done using logistics data, logistics data are not available in almost all laboratory systems. This lack of availability is a reality found through multiple laboratory system assessments. As a result of the lack of logistics data, service statistics, specifically number of tests performed, must be used as the best proxy for commodity usage for the purposes of quantification and procurement.

When quantifying in the absence of logistics data, the quantification must be done using test numbers for each test technique by level of the system. It is also necessary to include the projection of test numbers if supplies were continuously available, which is a scenario that has not been seen in many laboratory systems in many countries. Additionally, it is important to include commodities used for quality assurance and quality control. Finally, it is important to ensure that commodities needed to run each test are quantified and procured concurrently to guarantee that the right commodities—in the right quantities—are being procured at the right time for the right facilities.

THE LOGISTICS SYSTEM PROVIDES THE BASE FOR LABORATORY SERVICES

When laboratory services are operating without a logistics system, decisions are made in the absence of data, which then lead to inadequate stock levels (e.g., overstock situations, understock situations) at all levels of the system. Therefore, both physical and financial resources are not being allocated in an effective or efficient manner.

In Kenya, DELIVER worked with program stakeholders to design a logistics system for laboratory commodities. The logistics system consisted of two critical components: an inventory control system and a logistics management information system (LMIS) that included a reporting structure. The design also took into account three unique characteristics of the laboratory system and its commodities: large numbers of commodities require management, certain laboratory commodities have a short shelf life, and many commodities require cold chain storage.

When choosing the inventory control system for laboratory commodity management, the design team took into account the large numbers of commodities requiring management and their typically short shelf lives. As a result, the standard version of maximum-minimum inventory control system was chosen to reduce the number of commodities to regularly order. Also, a frequent resupply cycle was chosen to effectively shorten the pipeline to accommodate laboratory commodities with short shelf lives. The system was further streamlined to eliminate redundant warehousing and multiple levels of storage; this resulted in a two-level system—the central level storage and the service delivery points.

The LMIS propels the function of the logistics system. For Kenya, because of the large number of commodities requiring management, the design was also created to ensure that daily recording of usage data be limited to select tracer commodities that comparably had high value, limited supply, and high accountability. Finally, appropriate storage space and capacity for cold chain dependent reagents with short shelf lives required that the products be sent directly to the laboratories.

DELIVER's experience with all health systems has proven that a sound logistics system is the foundation of a successful program. The same holds true with laboratory systems. The design of the system that manages laboratory supplies must take into account the particularities of laboratory commodities and must include the two essential components of this system: an inventory control system

and an LMIS that includes a reporting structure. The laboratory logistics system can ensure that required commodities, in the right quantities, are in the right facilities at the right time and are ready for use if both essential components of the system are in place.

For more information on logistic systems for laboratory supplies, please refer to *Guidelines for Managing the Laboratory Supply Chain* on the DELIVER website at deliver.jsi.com.

CONCLUSION

Laboratory logistics management has traditionally been neglected and now finds itself as a critical driver of success at the forefront of strategic initiatives that are designed to strengthen essential public health programs. Efforts to improve laboratory services and to establish best practices are still in the beginning stages and will continue to evolve. Those efforts will require constant growth and innovation. However, DELIVER has established itself as a leader in this effort and has engaged in practical, in-country experience leading to significant strategic lessons in managing and strengthening laboratory services. The following lessons will serve as a solid foundation from which the public health community can move forward.

- The first step in strengthening laboratory services is to conduct an assessment of the current system.
- Without commitment from all stakeholders and the establishment of a coordinating body, laboratory strengthening efforts cannot be successful.
- Nonstandardized laboratory systems are unmanageable because of the numbers of commodities to be managed.
- In the absence of usage data, service statistics data should be used for quantification and procurement purposes.
- The logistics system provides the base for laboratory services.

Finally, as with any logistics management system, experience has proven that the logistics management of laboratory commodities cannot be successful without an integrative approach that involves communication and coordination of all stakeholders and that includes consensus across all stakeholders on common goals and activities.

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