President's Emergency Plan for AIDS Relief

# Guidebook for Implementation of Laboratory Information Systems in Resource-Poor Settings

**Guidebook**
High Level Requirements
Toolkit
Software Provider Report

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## Section 1. About the LIS Documents

This Guidebook is one of four documents in a set of informational materials provided by the Association of Public Health Laboratories (APHL) in support of the activities of the President's Emergency Plan for AIDS Relief (Emergency Plan) for the purpose of improving the efficiency of laboratory testing for the treatment and prevention of HIV infections and AIDS. The U.S. President's Emergency Plan for AIDS Relief through the Office of the Global AIDS Coordinator (OGAC) has provided funding for this project. This document is a cooperative effort of APHL and the Centers for Disease Control and Prevention.

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Comments, questions, and other correspondence regarding these documents may be sent to APHL in care of Patina Zarcone, Director, Strategic Initiatives and Research, at pzarcone@aphl.org. Information and assistance regarding the use of these documents by country HIV/AIDS programs or national laboratory programs may be sent to APHL in care of Ralph Timperi, Acting Director, Global Health Programs, at rtimperi@aphl.org.

### Revision History

No changes are to be made to this document unless approved.

| Date | Revision | Description |
|---|---|---|
| 07-2005 | 1.0 | Initial draft release |
| 10-24-2005 | 2.0 | Initial public release<br>- Updated look and feel<br>- Updated content to fit with other documents in LIS Implementation set |

## Section 2. Introduction

The government of the United States, under the President's Emergency Plan for AIDS Relief (Emergency Plan), has pledged $15 billion for the five-year period of 2003–2008 to combat HIV/AIDS. The initiative's goals are to treat at least two million HIV-infected persons with anti-retroviral therapy; care for 10 million persons infected with or affected by HIV, including orphans and vulnerable children; and prevent seven million HIV infections. The Centers for Disease Control and Prevention (CDC) is a partner in these unified initiatives, which are orchestrated by the Office of the Global AIDS Coordinator (OGAC), and under the Global AIDS Program (CDC GAP) helps resource-constrained countries prevent HIV infection; improve treatment, care, and support for people living with HIV; and build capacity and infrastructure to address the HIV/AIDS pandemic.

CDC GAP has program activities in 25 countries: the 15 Emergency Plan focus countries of Botswana, Cote d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Vietnam and Zambia; and among the many other Emergency Plan countries ten additional countries, which are Angola, Brazil, Cambodia, China, D.R. Congo, India, Malawi, Senegal, Thailand and Zimbabwe.

Improving country infrastructure for laboratory services is an essential component of HIV/AIDS prevention and treatment, and a major objective of CDC/GAP. Sustainable and flexible Laboratory Information Systems (LIS) are needed for the continuum of patient care, monitoring and evaluation, and planning to effectively reduce the global burden of HIV/AIDS and enable effective management of the complex challenges ahead. In order for prevention and treatment efforts to be effective, we must have reliable data for planning, resource allocation, and program operations. At the point of care for patients, we must be able to capture laboratory information that is essential for determining prevalence and incidence rates of infection and disease, for monitoring treatment efficacy and for identifying infected individuals who can be offered prevention and treatment services in addition to the core LIS functions of laboratory management and quality assurance.

An electronic (computerized) LIS, whether a basic standalone computer or a robust web-based networked system, is a necessity for management of the high volume of laboratory data generated in the effort to stem the HIV/AIDS pandemic. Paper-based systems are a barrier to assuring the quality of laboratory services and to succeeding in the effort to prevent HIV/AIDS. With appropriate planning and proper selection of hardware and software, computerized processing of information is feasible and desirable for every environment.

To assist HIV/AIDS programs in acquiring appropriate LIS systems, we have developed a standard process to use for identifying reliable LIS solutions for different country programs. This document is one component of a nested set of resources developed by the APHL to support the development of LIS in resource-limited settings. Users of this document are encouraged to become familiar with the content of each of these references. We recommend that the users start with the Guidebook to familiarize themselves with the overall approach being described in this set of references. Specifically, the set of references includes:

1. **Guidebook for Implementation of Laboratory Information Systems** (Guidebook) describes strategic and implementation planning for LIS, the overall LIS development cycle, and effective management of LIS projects. This document provides laboratory managers/project managers and laboratory supervisors a tool to aid effective planning and oversight of an LIS Project.
2. **High Level Requirements (HLR)** document identifies information system standards for objectively evaluating LIS applications and is useful for selecting systems and providers. The HLR describes in detail the functionalities of an LIS, i.e., what the system should be able to do and the currently accepted best practices for meeting industry standards.
3. **LIS Toolkit** is a detailed manual for technical staff and is a companion document to the HLR. It is valuable to the individuals who will be involved in LIS evaluation and in the selection of LIS providers and applications.

4. **LIS Software Provider Report** is a continually updated list of commercially and publicly available laboratory software applications and providers that have been identified and meet the HLR or meet basic requirements for Interim (RM) LIS solutions. Providers and their applications are placed in one or more of four groups to aid users in efficiently finding appropriate providers:
    - Fully capable network solutions
    - Limited functionality solutions that meet core HLR
    - Basic application solutions that have limited functionality and do not meet all core HLR
    - Freeware (e.g., Epi Info) or software not designed specifically for LIS (e.g., MS Access) that can be programmed to meet LIS functionality (and does not meet all core HLR).

APHL continues to search for appropriate applications for Emergency Plan LIS needs. As LIS applications are identified, they are added to the provider list. APHL updates this list every several months to add and remove names of providers or software applications. This list provides an efficient means to locate providers that have applications that should not require significant modifications to meet the users' needs. Users of this document may know of other appropriate providers. If so, contact information for other providers may be sent to APHL in care of Patina Zarcone, Director, Strategic Initiatives and Research, at pzarcone@aphl.org ).

## Section 3. Summary

All too often, the development or purchase and deployment of software are plagued by cost overruns, delays, and delivery of poorly performing LIS, problems that are typically similar across organizations, large and small. Two common problems associated with successful implementation of an LIS are lack of adequate initial requirements and sufficient LIS expertise. The HLR developed by APHL provides users a means of developing adequate and appropriate initial requirements.

Although the information provided in this set of LIS guidance materials does not eliminate the need for outside LIS expertise, this documentation enables users to be informed customers who can identify gaps and the types of technical assistance needed, and thereby obtain appropriate and cost-effective expert assistance.

To achieve the desired quality outcome, senior management must lead the commitment to a systematic process that is managed by a team with well-defined roles. Communication with other projects that are implementing LIS and the sharing of lessons learned are key elements of effective project management.

A successful project requires management's involvement at all stages of the process.

The establishment of new positions, especially that of LIS Project Manager, is critical, as the major tasks of LIS implementation cannot be delegated as additional responsibilities of current employees. LIS implementation is disruptive to laboratory operations, and preparations must be made to address the associated stresses while maintaining support for the project. Affected employees carry additional duties until the LIS is working well. Because LIS implementation requires many months, it is important to keep everyone informed of progress and working toward a successful outcome.

This Guidebook is a concise description of the LIS implementation process. It is intended for management and all levels of users. Individuals that have specific responsibilities for project objectives must be familiar also with the comprehensive tools that are referenced, e.g., High Level Requirements Document and LIS Toolkit. Questions and comments on the Guidebook may be addressed to Ralph Timperi (rtimperi@aphl.org).

## Section 4. LIS Planning and Implementation

The goal of this Guidebook is to provide a set of clearly defined steps to implement laboratory information systems (LIS) in laboratories of varying size, capacity and function. The focus of the document is on laboratories supporting HIV/AIDS testing, surveillance, prevention, and care and treatment in resource-constrained settings. However, the process can be used to address the information management needs of most types of public health and infectious disease laboratories.

LIS may range in complexity from networked computers and servers with connectivity to automated testing equipment handling a large volume of specimens to a standalone computer serving a small laboratory that uses manual equipment. An LIS may also be a paper-only system where everything is done manually, or a hybrid of manual and computer components.

At the highest level, these are the steps toward a successful implementation:

1. Strategic and financial planning
2. Defining your LIS needs and selecting a solution that can meet those needs within your budget
3. Developing or adapting an LIS for your site, training its users, and implementing the LIS
4. Supporting, maintaining, and updating the LIS.

Design and implementation of LIS requires a team of experts who understand concepts of laboratory operations, software design, systems analysis, and logistics planning —including finances.

Similar to developing complex management information systems in areas such as surveillance or monitoring and evaluation, a detailed project plan (a description of tasks and “who, what, where, and when” information) improves the efficiency and effectiveness of the process. In addition, the importance of following a standard process that uses proven methods cannot be overemphasized and is essential to accomplish the critical elements of LIS implementation, from planning to maintenance.

A typical LIS implementation may take 12–18 months. For special situations, this document also addresses situations where an LIS may need to be implemented more quickly: for example, where there is a rapid expansion of testing needs or the political situation prohibits a more systematic and thoughtful approach. A description of a rapid methodology (RM) to develop an interim solution, with limited functionality, is provided and may be an appropriate first step in settings where LIS experience is limited. However, this RM solution is not intended to be a substitute for the standard process described in the Guidebook.

Two examples of LIS implementation projects are provided as case studies that describe typical situations that may be faced by readers of this document. These case studies are meant to illustrate the requirements of LIS of varying size and complexity, steps that should be taken to select the appropriate solution, and some of the issues that may affect the successful completion of the project.

The users of this document are encouraged to make modifications to suit their specific environments, but not change the essential aspects of the recommended process.

This document can be adapted for use in different settings to guide the LIS project management process. A well-planned and managed project requires the user to:

- Define the steps that will be followed in the pilot implementation of an LIS
- Develop the details for each step of the process to meet specific circumstances and regulations in their situation
- Based on their defined plan, obtain advice and consultation as needed to supplement local expertise and experience
- Establish a timeline with milestones and commitments from project participants to achieve live operation of a pilot LIS deployment.

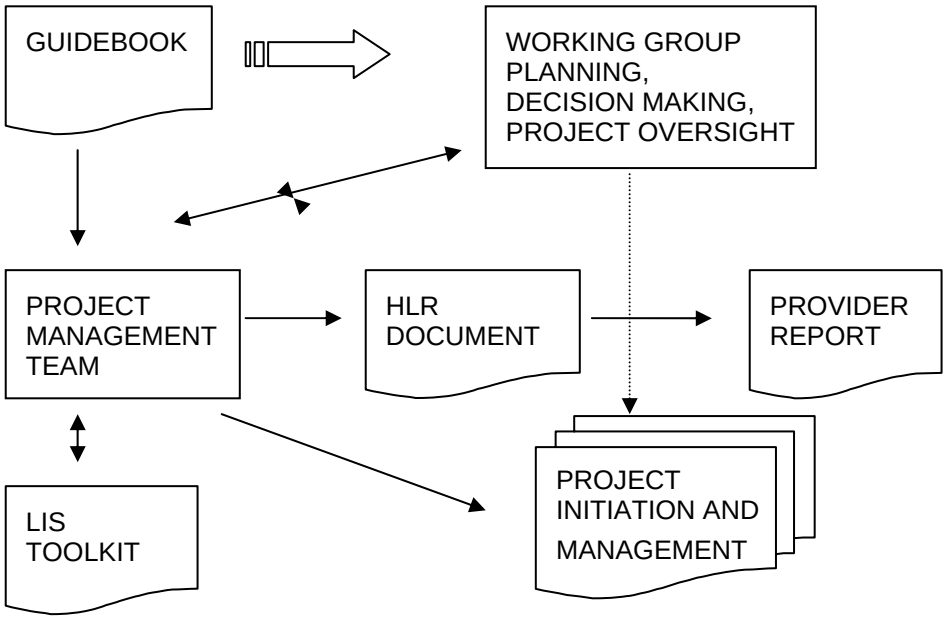


*Figure 1. Relationship of Documents and Project Management*

## Steps Required to Implement an LIS Project

This document focuses on the planning, development and implementation of LIS projects. In taking on such complex projects, it is often useful to start small and then expand as the experience and the capacity of the team and staff grows. For example, this document may be used initially to guide the development of a "pilot" project or a limited scope project, and subsequently to develop a multi-year, countrywide LIS utilizing the experience gathered from a pilot project. A pilot project should serve as a learning experience as well as the foundation for a strategic planning process for subsequent scale-up or expansion.

Figure 2 is a schematic diagram of an eight-step process for a pilot LIS. Each of these major steps is described briefly in the following narrative section. References are provided for more detailed information found in the companion documents as well as other reference materials. The individual components that are contained within the eight steps can be grouped differently and the overall process can be grouped to fit local conditions, but each of the components is necessary to assure the successful development of LIS that will meet the needs of the users.

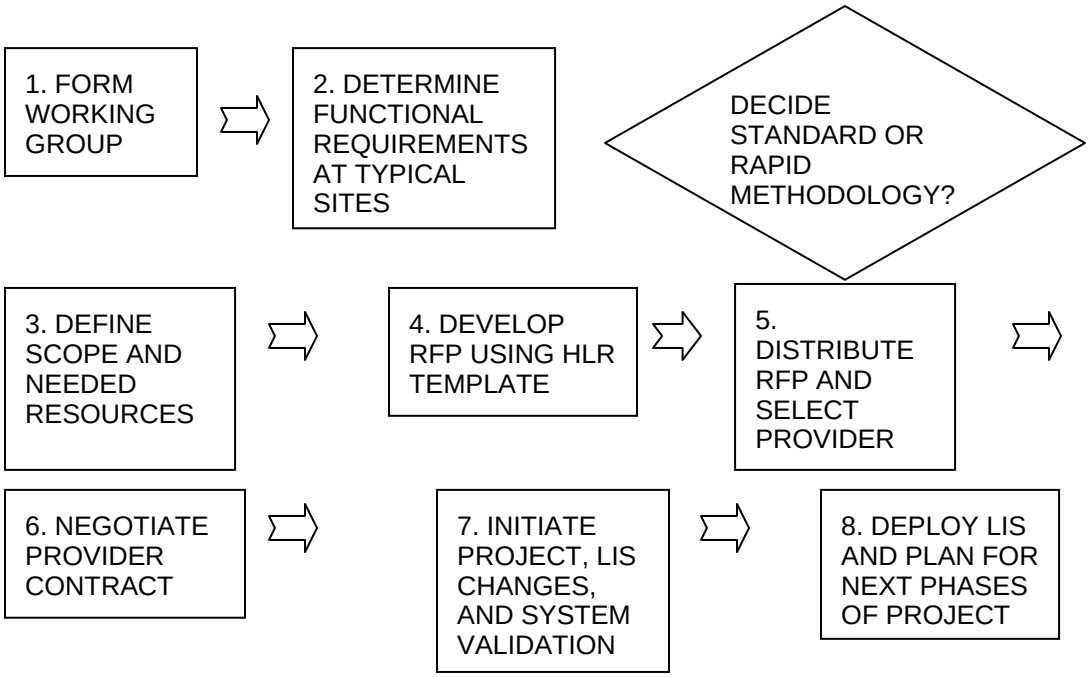


*Figure 2. Implementing a Countrywide LIS: Eight Critical Steps*

### Step 1. Organize an LIS Working Group

Effective communication with and participation by stakeholders is the key to successful development and implementation of an LIS. There are many potential users of laboratory data and these key stakeholders need to be made aware of the value of a quality LIS by participating in the development process.

A high-level management team, known as the LIS Working Group, must be formed as the first step of the process. Its job is to provide oversight of the process, promote communication among stakeholders, and make strategic planning and policy decisions. The composition of this group should reflect the country's organizational, financial, and policy-making framework.

In addition, a Project Management team should be established early in the process to include those individuals who will take on the responsibility of ensuring that the project is kept on track. Consultant involvement should be based on the Working Group's assessment of project tasks that require supplemental or additional capabilities to assure success. **It is crucial not to underestimate the time commitment required of these individuals to ensure the success of the project.**

| LIS Working Group Members | LIS Project Management Team |
|---|---|
| ✓ Chief of Party or designee | ✓ LIS Project Manager |
| ✓ MOH Representative | ✓ Senior Laboratory Staff of the pilot laboratories |
| ✓ National Laboratory Director | ✓ Representative(s) of Laboratory Staff at bench level for testing services that will be included in the pilot application |
| ✓ Information Technology Project Manager | |
| ✓ Financial Manager | ✓ IT Contractor Representatives (once the application is selected and contract is approved) |
| ✓ Technical Advisor | ✓ Technical and /or Management Consultant |

### Step 2. Use the HLR to Identify Country-specific Functional Requirements

Select one or more laboratories that are typical and represent the testing services that could be included in the first phase of the LIS. For example, you may decide to include only HIV testing (rapid, EIA and confirmatory) or you may want to include HIV testing, chemistry, and hematology testing services in the first phase of the implementation.

During the assessment of country-specific functional requirements, the LIS Working Group and the Project Management Team must make two major strategic decisions about the LIS.

- What is the *vision* for the long-term goal of an LIS: should its design be web-based, a network or a standalone system, and how many laboratory services will be included?
- What is the *scope* for the first phase of the LIS: how much functionality will be incorporated and which laboratory testing will be included?

In addition to defining the scope of the first (pilot) phase of the project, the LIS Working Group may decide that local conditions justify an accelerated implementation plan. Implementation of an LIS in less time than is typical for these projects (12-18 months) may require compromises in functionality and flexibility. However, a rapid implementation plan may be the appropriate choice to meet pressing laboratory management needs and also to provide an opportunity for developing local knowledge and experience in LIS in a setting where LIS has not been used previously or there is minimal experience.

At this stage, get expert advice from a person experienced in LIS design and implementation.

These decisions will frame the parameters of the LIS project; changes will mean significantly increased project cost and time.

If the initial decision is to implement an interim RM solution, freeware or locally developed systems using freeware may be suitable for LIS needs at single locations, though these systems tend to be less robust. The initial choice of an interim system does not dictate that a freeware solution is the only option. Freeware options often lack the functionality to provide connectivity among multiple sites, or the robustness to be changed readily to accommodate local needs or changes in services. For example, Epi Info or MS Access are tools that can be used to develop simple LIS for individual locations providing limited functionality, including equipment interfacing and electronic information exchange, but may not be the best choice for an interim solution.

The choice of platform or base system should be made by the LIS Working Group, with the input and advice of technical and laboratory management experts who understand the requirements and the available resource for LIS. This decision will affect how the RFP is developed and which providers will be considered for LIS development.

### Step 3. Decide Scope, Choose Methodology, Select Pilot Sites, and Define Needed Resources

Defining the scope of the pilot project is essential to the financial and strategic planning process. The Working Group should decide whether the first stage will be accomplished under a rapid or standard timeline, and choose pilot sites that reflect the diversity of the laboratory system; these decisions assure that planning for subsequent steps is well informed by the experience gained during this phase.

If the National Laboratory is part of the pilot project, only a single laboratory within the national system should be selected. This minimizes the risk of failure or catastrophic delay of a pilot project due to increased complexity and/or not including other types of laboratories (such as a peripheral laboratory) in the pilot. Once the pilot sites have been identified, a basic laboratory evaluation should be done to obtain the baseline information to determine the readiness of the sites for the pilot project (see Appendix C for Laboratory Evaluation Checklist). Site assessment may reveal issues that need be addressed prior to or during the LIS project, such as improvements in the specimen acquisition procedure or test reporting system.

Two to four sites are usually an ideal, manageable number of locations for a pilot project.

Once the LIS Working Group has reviewed and selected the final group of sites, the HLR document should be edited to meet any specific or special LIS needs based on information gathered during the pilot sites' evaluation. The completed assessment of LIS functional needs, selection of pilot sites and determination of the scope of the fist phase will provide information for a preliminary cost estimate for the project. Costs of LIS implementation may include:

- LIS application purchase or license (if using a commercial product)
- Development of detailed functional specifications and required changes to an application to meet local functional requirements
- Time of current laboratory staff who will be needed for development/modification, validation and deployment of an LIS (This can be significant! Laboratories that have high testing demands can be stressed during LIS development.)
- Hiring of additional staff and consultants who may be needed for project management, training, system support and maintenance
- Hardware, cabling, Internet costs and development environment (network environment in which application is tested)
- Training of LIS users and deployment of the application.

The Working Group is responsible for preventing "scope creep" during the pilot phase. In every LIS project there are pressures to do more initially; from laboratories who need to improve quality; from sectors of the health system that need more complete and timely data; and from application providers who propose features and functionality that increase costs. These changes can cause long delays in completing the project and loss of commitment from stakeholders. The best plan for success in the short and long run is to maintain a focused, systematic approach and resist the natural desire to fix many problems at once. As the pilot project progresses, participants learn to be smarter and wiser in their decision making and management of the project. As this evolution occurs, the development team will arrive at a level at which the speed and effectiveness of LIS development and implementation increases dramatically. Start smaller and grow effectively.

### Step 4. Develop a Request for Proposals (RFP) using the HLR Document Templates

The RFP defines the scope of work in enough detail to enable providers to determine if their application is suitable for your needs and to estimate their costs in providing the application. The RFP should be prepared according to the requirements of the funding agency using the HLR and the LIS Toolkit documents as guides for specifications. Typically, the HLR document is attached as an appendix to the RFP. Refer to the Toolkit for detailed information regarding RFP preparation, including a sample. The following brief checklist describes the major considerations to be reviewed with the LIS Working Group.

*LIS Working Group Checklist*

| **LIS WORKING GROUP CHECKLIST FOR RFP** | | | |
|---|---|---|---|
| **Project Name:** LIS Pilot Project | **Project Code:** | | |
| **Checklist Items** | **Yes** | **No** | **Comments** |
| Have all of the relevant background materials been reviewed, such as the contract requirements, application requirements documentation, and LIS Guidelines? | | | |
| Has the project management team worked with the affected stakeholders to define the project scope? | | | |
| Is the RFP defined in terms of functional requirements, resources required, end products that result, including quality standards (in accordance with the definitions in the HLR)? | | | |
| Does the RFP address:<br>• Business functions?<br>• Organizational areas affected?<br>• Systems to be replaced?<br>• Functionality to be included in the pilot system? | | | |
| Is the RFP quantified to the extent possible (e.g., by identifying the expected size of the pilot and final system in function points)? | | | |
| Does the RFP clearly identify the boundaries of the project (i.e., does it document important exclusions from scope as well as the scope of work to be included)? | | | |
| If there are any aspects of the RFP where the scope is not bounded, is there a defined strategy to contain any scope issues? | | | |
| Is there consensus on the scope of the project, as defined? | | | |
| Will the scope statement, as defined, provide a meaningful point of reference (baseline) for ongoing scope management (e.g., will it be clear to all parties when proposed changes are in or out of scope)? | | | |

Checklists such as this one should also be used for in-house development projects, including adaptation of freeware products. In-house or freeware products require as much rigor and resource as commercial product and should be evaluated under the same set of guidelines.

### Step 5. Advertise and Send RFP, Review Proposals, and Select Provider

The RFP should be advertised as required by the funding agency/authority. Preferably, the RFP will be sent to a limited number of providers known to have applications that meet high-level requirements or meet functional requirements of the LIS project as defined for the pilot phase. It is reasonable to pre-select a small number of providers based on the identified functional needs of the LIS and the known features of available applications. Review of LIS proposals should be done rigorously and complemented by direct discussions with providers. The Project Management Team reviews proposals, evaluates submitted solutions, and recommends product and provider to the LIS Working Group for award of the contract. If an in-house solution is an option, the in-house development team should be required to respond to the RFP and evaluated under the same set of rules as commercial vendors.

> Limiting the number of RFPs to pre-qualified providers is the only feasible way to assure timely progress and a sound choice in LIS development.

### Step 6. Negotiate Provider Contract

Once the recommended provider is chosen, the Project Management Team should finalize the negotiation with the provider/vendor. This includes a meeting with selected provider to confirm contract details and commitments and to negotiate final contract price. The manager with authority to make contractual obligations must attend this meeting. If this meeting concludes with agreement with the recommended provider, the LIS Project Manager arranges a series of meetings to prepare for the launch of the project. This may include:

- Informational meetings with stakeholders to describe the LIS Project and the project management process
- Presentations and discussions with all staff at the project's pilot site(s)
- Preliminary meeting with provider to review project commencement
- Provider presentation for project commencement to include pilot site staff, management, and all interested stakeholders

### Step 7. Application Changes and Enhancements Developed and Validated

Project Manager (PM) leads and coordinates activities with provider and laboratory staff to develop detailed specifications and determine required changes and enhancements to base application. The PM is a member of the LIS Working Group (WG), and through this forum cost estimates are developed for system modifications. LIS Working Group approves recommendations for changes and enhancements and a final budget. PM is responsible for maintaining the project on time and within budget. The PM, working with the application provider, develops a project management chart with tasks, responsibilities, and timeline. Progress on project milestones must be measured and reported weekly. Regular and special meetings are scheduled by the PM to meet operational and information needs of all stakeholders.

Based on presentations from PM, senior laboratory staff and consultants, WG identifies training needs, maintenance and support needs, and hardware needs, and recommends budgets to the appropriate authority for approval. PM coordinates these activities with the entities that implement these activities, such as MOH employees, purchasing authorities, donors, and consultants to assure that all requirements are accomplished on time and that the stakeholders are informed of milestone accomplishments as well as problems that must be solved.

Once application enhancements have begun and preliminary testing of the application is underway, the PM reviews the tasks and timeline for the system deployment plan with all affected parties; confirms feasibility of tasks, timeline and availability of funding; and coordinates discussion of any recommended or required changes.

Also at this time, the Working Group begins a discussion of the next steps for LIS development including the following questions:

- What sites will be added in the next year(s) of the project?
- What is the estimated funding commitment that is available?
- What functionality should the system have at the various levels of the health system?
- What are the maintenance and support costs for the planned system and how will funding be sustained?
- What are the project outcomes and how will success be measured, especially in regard to improvement in patient care?

### Step 8. Deploy and Assess Pilot LIS; Define Next Phase of LIS Development

The goal of the deployment is to launch a validated system at the pilot sites. Specific objectives include:

- Installation of the system hardware and infrastructure
- Pretest of the system infrastructure
- Installation of the application and conversion of specified data
- Training of users and IT staff
- Documentation of successful training of participants and dates of their training.

At this time a summary should be prepared showing the actual costs of the new system project compared with original budgeted costs.

The final step of deployment is acceptance testing, which is often done by an independent IT expert to validate the operating characteristics of the LIS.

# Appendix A. Information Used to Define This Project

## Levels of Laboratories

The laboratory environment in most resource-constrained countries stretches across a continuum from the most basic screening facility to high complexity diagnostic laboratories. In order to implement LIS based on the high-level requirements in these varied environments, three main levels have been used to describe the laboratories (as described by the World Health Organization).

**Peripheral Level** – Perform simple tests such as microscopy, simple diagnostic methods using rapid kits. Quality control records may or may not be kept in electronic format. The HLR addresses how to capture data consistently at these sites, and use a PC platform to maintain a database that supports test performance, QC and test reporting. In the scenario where laboratories at this level do not have a PC, all records are on paper forms. The HLR addresses how to capture data from these sites into the electronic database of LIS

**Provincial/District Level** – Laboratories that perform some high complexity and definitive diagnostic testing, and receive specimens referred by Peripheral Level laboratories and/or from in-patients. These laboratories often, or should, have a LIS that manages specimens, patient data, test reporting and internal quality control and assurance.

**Central Referral Level** – Perform definitive diagnostic test methods as well as screening and other basic test methods and test specimens referred by the other level laboratories. In some scenarios these laboratories are National Reference Laboratories (NRL), which set quality control standards, and assure quality of laboratory testing. These laboratories often, or should, have a LIS that manages specimens, test and patient data, and support quality control/assurance. In addition, these laboratories have or should have the capability to receive and transmit laboratory data electronically.

| Level | Types of Testing | LIS | Connectivity | Full Time Laboratorian |
|---|---|---|---|---|
| Peripheral | Screening | No | No | Sometimes |
| Provincial/District | Some diagnostic testing | Rarely | Sometimes | Yes |
| Central Referral | Full diagnostic testing | Sometimes | Yes | Yes |

### Current Data Collection in Laboratories

Between the peripheral and the central levels, there is considerable variability in the services provided and the sophistication of the LIS used, or needed. In some cases, the complexity of the services and resources in provincial laboratories can be similar to that at central referral laboratories.

Typically, patient information is collected on paper forms at facilities when patients are registered at a health clinic, testing laboratory or other facility. Specimens may be collected at a health facility and transported to a laboratory (in the same building or distant site) or the patient may be sent to the laboratory where a specimen will be collected. The laboratory, in addition to a paper form with patient information and test requested, typically maintains a log book that records in chronological order patients, specimens, and results. At the provincial level laboratories, this information may be entered into an LIS. A paper process often requires redundant data entry, is labor intensive, and can result in a high number of errors. Moreover, it is a challenge to summarize patient results over time from log books and paper records. An LIS can reduce errors using a variety of procedures and tools. However, it may be difficult to realize efficiencies and cost effectiveness with a LIS in low test volume environments. This circumstance must be accommodated in the HLR.

## Opportunities

For the purpose at hand, development of the LIS process envisions an integrated Information Technology (IT) infrastructure that would support the improvement of services delivered to patients, remove redundant data entry, improve the efficiency of laboratories, and improve the quality of laboratory services by enabling assurance of accurate test results that are made available to appropriate persons when needed. In this context “integrated” means a system whose components can exchange clinical and management data among themselves and with external systems without requiring operator intervention. This same infrastructure would allow the local and national health authorities to monitor laboratory workload as well as the quality and timeliness of the services delivered. Additionally this same infrastructure could be used by the U.S. Government through its various departments to evaluate the efficacy of its efforts to halt the spread of AIDS.

The LIS requirements can guide development of a country plan for LIS. The functions that an LIS can provide include the ability to manage accounts, test requests/orders, specimen tracking/storage, test status, results, reports and a laboratory knowledge database. The system can also provide quality control/assurance and data mining capabilities that support a quality management system for the overall laboratory network.

## Representation of a Sample LIS

Figure 3 (next page) presents a schematic representation of one option of a system as it might be deployed in a country. The model architecture depicted here has been designed to take in to account the varying levels of sophistication and complexity that various entities in the country can support. The needs of the laboratories in the affected countries vary depending upon whether the laboratory is at the peripheral, district/provincial or central level as noted in the figure. We anticipate that different solutions ranging from those designed to just collect and transmit data at the peripheral and district level to full fledged Laboratory Information Systems at the Central Referral and National Reference level will be needed to fulfill the requirements of each country. To be truly effective, however, these systems will all have to be integrated at the national level.

The functional (i.e. what functions the system will be able to perform) and system (what hardware and software components are needed to deliver those functions) needs of each country can be segmented into two categories.

The first category corresponds to peripheral and district facilities that have few resources and focus primarily on screening and other low complexity testing and only need to collect patient and test result data.

The second category corresponds to higher resource facilities such as central and national labs that perform more complex testing and need to manage testing, specimens, workflows etc. in addition to collecting and tracking patient and test result data. Additionally, we can anticipate that at least some peripheral sites will not have access to computers and will continue to collect all data on paper forms and transport it to sites that have computer access.

These categories can be used to define a phased deployment approach where the minimal system functionality, corresponding to the first category, is deployed in an initial phase. The first phase functionality would satisfy the data collection needs of all the sites. Later phases would deploy functionality corresponding to the second category that would satisfy the process management needs of the more complex laboratories.

These phases are further described in the main body of this document and in the Toolkit.

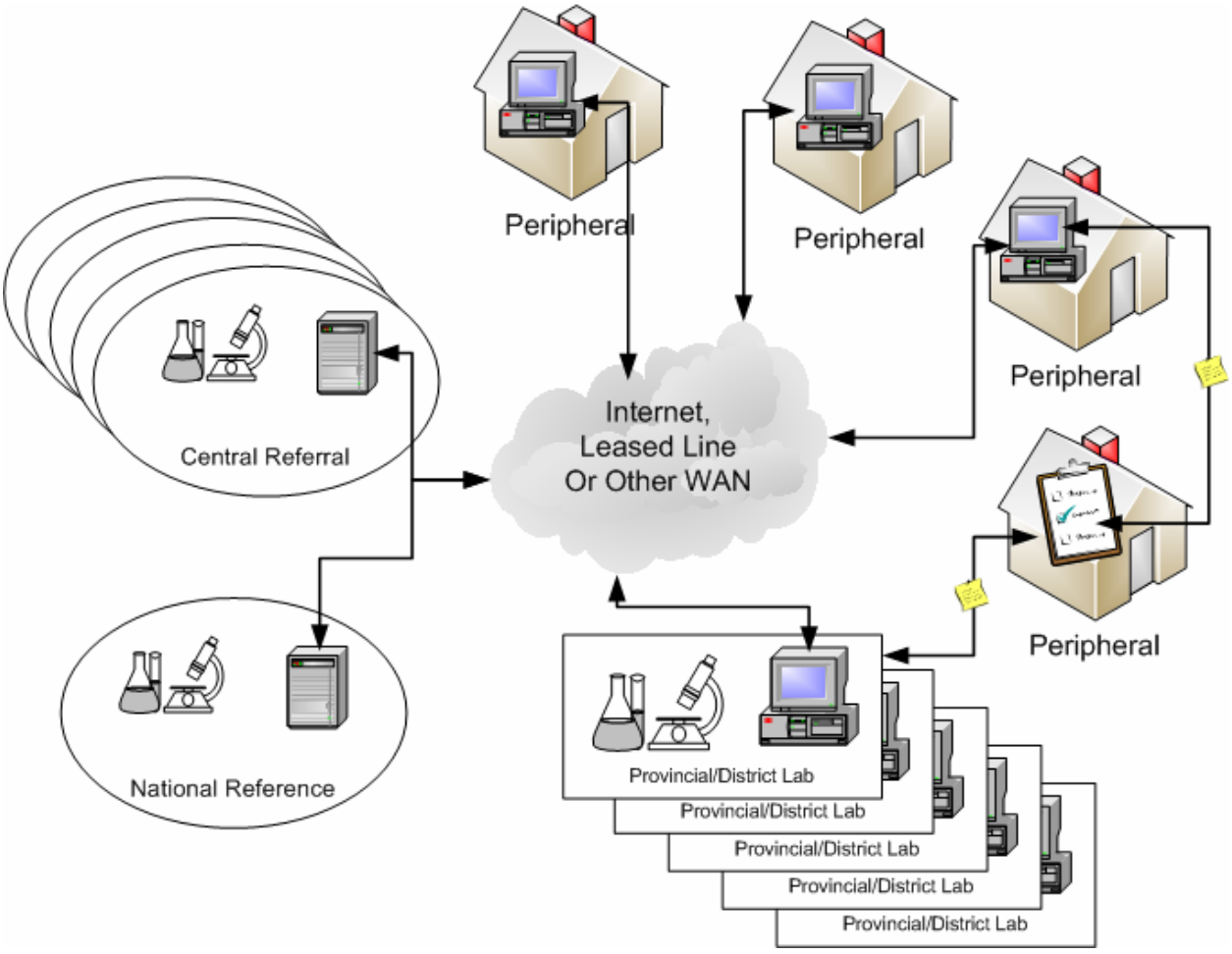


*Figure 3 – Country Laboratory Test Management and Surveillance Infrastructure.*

## Goals

The following are the objectives for the now-completed phase of the project:

1. Capture the high level requirements for the Laboratory Information Systems of the various types of laboratories in the Emergency Plan–supported countries.
2. Validate these requirements against the experience of the in-country HHS and local healthcare officials involved with Emergency Plan efforts.
3. Identify a number of Commercial-Off-The-Shelf (COTS) and home grown, free or low cost applications designed to support lab activities that meet these requirements.
4. Provide the tools needed to select appropriate developers/providers of LIS.
5. Provide the tools needed to select and modify as needed a specific LIS solution(s) to meet country requirements.

The following lists what this project/document is **not** intended to do:

1. Identify requirements that are not directly relevant to the GAP LIS such as hospital management.
2. Identify detailed operating procedures of laboratories.

3. List all possible vendors that provide software systems that might meet the requirements of some appropriate solutions, in whole or in part.
4. Recommend specific vendors for specific GAP country LIS solutions.
5. Provide in-depth functional and operational characteristics of a LIS.
6. Describe design aspects of the LIS including object models or database schemas.

## Approach

The following approach is recommended to meet the CDC's goals for this requirements definition phase:

1. Capture our current understanding of the high level functional, system and operational requirements for GAP-specific LIS.
2. Create an online survey to solicit information specific to GAP LIS.
3. Provide this document to CDC GAP and country experts for feedback.
4. Host a conference of CDC and country healthcare professionals to review captured requirements and solicit feedback.
5. Finalize the requirements and publish the document for final review by CDC and country experts.
6. Provide a list of recommended LIS vendors that are qualified to provide systems the can satisfy these requirements.
7. Provide a toolkit that CDC and country experts can use to:
    a. Self identify/evaluate LIS that can meet their needs.
    b. Solicit bids and select vendors to provide LIS for a country-wide integrated system.
8. Provide a non-technical Guidebook to accompany the selection methodology.

# Appendix B. Examples of LIS Development

## LIS Case Study 1: Pilot Project to Implement LIS for Rapid HIV Testing and Confirmatory Testing

### Setting

CDC/Country Program (CDC/CP) is supporting the Country policy to implement a two-test algorithm for HIV screening. In order to manage the data from testing significantly more people, an LIS implementation project is undertaken with the limited goal of providing a computer system specifically for tracking HIV testing.

### Current Situation

Rapid HIV testing will be introduced into 42 clinics over a three-month period. Specimens that have discordant results in the two-test algorithm will be sent to the national laboratory for further testing by EIA. Persons who test positive (two different Rapid Test positives) will have a venous blood sample drawn and the serum specimen submitted to the national laboratory.

### Project Experience

CDC/CP holds a preliminary meeting with program staff who has reviewed the OGAC documents for LIS Implementation. At this meeting, the following initial tasks are identified and assigned to individuals for completion in two weeks.

- Chief of Party will invite stakeholders to participate on an LIS Working Group
- Chief of HIV Treatment Section will provide a list of clinic locations and a single point of contact in MOH to coordinate LIS implementation
- CDC/CP Administrative Director will review the list of potential LIS providers, discuss options with CDC/GAP and be prepared to present a summary of options to the LIS Working Group
- An allocation of $150,000 is earmarked for the LIS project
- A five-person team is formed with two representatives from MOH/HIV Section to do a rapid assessment of the environment at the clinics in regard to their capacity to implement an LIS (see APHL RELY template).

At the first meeting of the LIS Working Group, the CDC/CP Administrative Director and the Chief of MOH/HIV Section are designated as Co-Chairs of the LIS WG. The national laboratory director is designated as the Project Manager for the LIS Implementation.

Following a discussion of options (presented by the CDC/CP Administrative Director), a review of funding resources, and description of the plan for rollout of Rapid HIV Testing, the following decisions are made by the LIS Working Group:

- $150,000 allocation will be available for the project with expenditures subject to approval by the CDC/CP Administrative Director
- The Project Manager will coordinate readiness assessment and initial functional requirements assessment with assistance from CDC/GAP
- The goal is for the Project Manager to present a report in four weeks to the LIS WG describing the current situation in the clinics and a proposal for LIS. The LIS WG will determine the scope and budget for the project based on the PM report.

After completing the four-week assessments, the PM makes a report including the following information:

- None of the clinic sites has a computer. All sites have electricity although the power supply is not reliable at many sites.
- Most laboratory personnel are unfamiliar with the use of computers and few have working knowledge of basic applications such as word processing and spreadsheets.
- An estimated average of 50 persons will be screened each day (Monday–Thursday at each clinic site)
- MOH operates a courier service that travels to each clinic once per week.

The LIS WG authorizes the PM to proceed with development of an RFP for implementation of an LIS with the following scope of work:

- CDC/CP requests proposals from qualified providers to develop or modify an existing laboratory information system to manage patient and specimen information for 50,000 patients per year with two Rapid HIV tests done per person and a confirmatory or additional HIV serologic test done on 10,000 persons.
- The system must be capable of scanning paper test request forms, generating bar code labels, and exporting test reports in an electronic format to a central database.
- The transport of the information must be capable both electronically and in a transportable media such as CD-ROM.
- The provider must offer a two-day training course in basic computer operation at five sites in the country prior to deployment of the LIS, and a provide CD-ROM training course in use of the computer.
- The provider must deliver a one-day training course on use of the LIS at five sites in the country, and have on-site assistance available for the first four weeks following LIS deployment.
- The project must be completed 6 months from the acceptance of a contract.

The LIS WG decides to send the RFP to three providers listed on the OGAC-suggested provider list. After review of proposals, the LIS WG accepts the recommendation of the Project Management Team to award a contract to an LIS provider who has an application used in over 10 clinical laboratories in Africa; however, the decision is made to accept the alternate proposal of the provider to develop a new module specifically for CDC/CP that will manage test results for HIV testing and provide the required functions stipulated in the RFP. This option will not require payment of an annual licensing fee.

Although long-term use will be limited to the specific designed functions, the advantages to this option are rapid development of a simple module by an experienced provider, simple operation with less chance of failure, and ease of use for laboratory staff inexperienced in computer use. LIS WG decides that this initial investment will be cost-effective and make the system more ready to scale up to more complex systems if that is desired, while providing timely support for expanding rapid testing as soon as possible.

The system will provide weekly test report summaries to MOH, provide the laboratory with a searchable database and QC data to manage patient and test information, and provide the national laboratory with data for evaluating test kit performance.

Following a three-week assessment of the laboratory processes and sites, the provider develops a prototype system within three months and uses this early system as a tool in the training courses provided in the country four months after the start of the project. When training is conducted, PCs are delivered to each clinic site so that laboratory personnel have the ability to continue improving their skills using the CD-ROM training program provided by the contractor.

At the time of deployment, the provider goes on site at each clinic site and has the laboratory personnel enter patient and specimen data; export data to a CD-ROM for transport to the national laboratory; print

bar codes for specimens and hand label specimen tubes with patient and specimen number; run the QC report module. Because the central database is asynchronous with the local databases, all changes are managed through a corrections module developed by the provider. These changes are transported to the national laboratory and merged with the central database through a process to assure completeness and accuracy of all data in the central database.

## LIS Case Study 2: The Experienced Vendor with a Good Track Record, Recommended through Reliable Persons Known to LIS Project Lead

### Setting

CDC/Country Program (CDC/CP) in a country where the national laboratory system is under the direction of the Ministry of Health. The public health laboratory network consists of provincial hospital laboratories with associated health clinics, and VCT and PMTCT sites. HIV/AIDS and TB programs are operated independently by divisions of MOH. Laboratory directors report to a National Laboratory Director at the MOH central laboratory, and receive funding directly from MOH.

### Current Situation

Personal computers are available only in three of 15 provincial hospital laboratories and all laboratory divisions of the national reference laboratory (HIV/AIDS, TB, STD, Parasitology, Measles, Diarrheal Diseases, and Respiratory Diseases. There is no laboratory information system operating at any site, and Microsoft Excel is used to create worksheets, inventories and other laboratory records where available. All other laboratory information is in paper form. Telephone modem dial-up Internet access and e-mail is available to computers at the national reference laboratory.

### Project Experience

CDC/CP has set a target of a 200% increase in the number of HIV-infected persons on ART in the next 12 months. Based on the significant number of persons who will need to be screened by rapid HIV antibody tests, and the concomitant increase in the number of HIV antibody confirmatory tests, HIV viral load assays, CD4 assays and related laboratory analyses, the Director, CDC/CP has determined that information management will require an automated laboratory information system to be installed as quickly as possible. An initial earmark of $150,000 has been allocated in the current year budget for this purpose with the expectation to continue this level of funding for 3 years.

### Strategy

CDC/CP has a staff person with considerable experience in IT operations for program evaluation. He also has a good working relationship with a senior laboratory manager in the United States who has experience with the implementation of LIS in a clinical laboratory. Through these contacts with experts, an application provider is identified who has installed an LIS in several U.S. laboratories that perform testing including HIV serology. Because of the importance of having LIS available quickly, and the excellent recommendations from users of the U.S. system, a time and materials contract is awarded to the U.S. provider to develop an implementation plan and budget for the installation of his application, with appropriate modifications to meet the needs of the CDC/CP. In order to control costs and assure a timely finish to the project, CDC/CP decides to limit the project to a pilot that will implement an LIS for HIV serology, HIV viral load and CD4 testing only. In addition, CDC/CP has decided that the pilot will be done at the HIV national reference laboratory and one provincial hospital laboratory to include the capability of electronic transfer of data between the two pilot sites.

## The Project

Because of the uncertainties of the project, the provider has proposed a budget of $35,000 for the initial assessment (3 weeks), $10,000 for one-time licensing fees for operating the application on up to 20 computers, $25,000 per year for ongoing maintenance and support costs, and an amount to be determined for program modifications following the initial assessment. Program modifications will be done on a time and materials basis. First year cost is $70,000 plus the cost of time and materials for the modifications. The project begins at the time of initial contact with the IT provider. Six weeks after contact a final contract is negotiated and signed by approving authorities. One month after signing of the contract the initial assessment begins, and a final report is provided to CDC/CP 6 weeks after start of the assessment. Total time elapsed to this point is 4 months.

IT Provider has now been paid $35,000 and proposes to make modifications to the application that are estimated to cost $120,000. However, IT Provider will agree to a fixed price contract; CDC/CP decides to limit the application to HIV serology and CD4 testing to reduce the cost of the contract, which is now $80,000, not including travel costs that will be charged separately and if CDC/CP requires Provider to be onsite. Total commitment at this point is $115,000. Four weeks were required to discuss and negotiate the final proposal and project time is now at 5 months. The IT Provider estimates that it will take seven weeks to complete the modifications to the application.

The IT Provider returns to the U.S. with detailed information about testing operations at the two pilot sites. Semi-weekly telephone conferences are scheduled to review programming progress (Friday) and any other project issues such as budget, change requests, and projected completion date. Because the original application was written for use in a typical small clinical laboratory in the U.S., the standard operating procedures and practices were very different from the operations in the CDC/CP. Basic information such as the identification of specimens and patients, names of tests and test kits were different. These differences required significant changes to be made to the reference tables in the application data base. In addition, the IT Provider determined that the lack of experience with PC use required the user data screens to be modified and supplemented with help information accessible through on screen links. Dropdown menus required considerable reworking to reflect terminology used in the laboratories.

After four weeks of work, the IT Provider had mock-up screens for the laboratory users to review. The initial screens were found to be unsatisfactory by the users who felt that the process flow on the computer did not follow their work flow, and did not allow for bypassing steps when appropriate or editing information efficiently. It was noted that demographic information was often missing and that the program required users to tab sequentially through each field even when the information was not available. In addition, editing information required the same sequential process to reach the field of interest. Changes were made to improve these functions and the work was completed nine weeks from the start date. The Project Time is now at 7 months, 1 week.

The IT Provider scheduled travel to CDC/CP three weeks after completion of the modifications in order to install the application. During conference calls, it was noted that only 5 of the 20 PCs to be available for the pilot project were currently on hand, and the remaining 15 were on back order with an expected delivery date of 3 weeks. It was also learned that the MOH had decided on a two-test algorithm using rapid tests to be done at provincial hospitals and concordant results considered final. Specimens with discordant test results would be sent to the national laboratory for final testing by EIA. This change in the testing process required a change order to the application at a cost of $5,000. Upon arrival by the IT Provider at CDC/CP the time of the project is 8 months and cost to date is $120,000.

Installation is scheduled to take four weeks, including training and debugging of the program, at the conclusion of which the IT Provider will be due $5,000 (licensing fee for 10 of the 20 planned computers), $6,250 first quarter maintenance and support fee and $15,000 travel and per diem for 2 IT staff for the four-week installation, training, and debugging phase. Program time is now 9 months and total cost is $146,250. Projected cost for the first year is $165,000 plus travel and per diem expenses for any on-site maintenance and support.

The IT Provider expects to be able to support the maintenance needs of CDC/CP remotely unless there is a major system failure. Online support and telephone consultation will be available from noon to 6 p.m., Monday-Friday. Telephone consultation will incur telephone charges. Support at other times and days, including U.S. holidays, will be billed at $100 per hour.

## Project Reviews

The most important differences in the management of these projects, noting critical elements carried out in the first example but not the second.

- Determining high-level functional requirements and scope of the project before awarding a contract with a provider
- Sticking to the scope and not allowing changes to the project unless absolutely necessary
- Having the provider directly involved in training to increase their understanding of operational needs.

# Appendix C. Laboratory Assessment Tool

## Checklist for Public Health Laboratory Assessment

### I. General Information

| |
|---|
| Name of the laboratory |
| Address of the laboratory |
| Level of the laboratory and administrative reporting |
| Name and contact information of head of Laboratory |
| Names, titles and contact information of other key staff (use reverse side of form or additional pages) |

*Building facilities and utility services*

| | | | |
|---|---|---|---|
| How is the state of the building | excellent/good | worn/maintained well | poor |
| When was the building built? | | | |
| Is the laboratory in a free-standing building or part of larger structure? | | | |
| Does the laboratory perform tests for: | | | |
| Bacteriology<br>Virology<br>Mycobacteriology<br>Parasitology<br>Mycology | Yes No<br>Yes No<br>Yes No<br>Yes No<br>Yes No | | |
| Is the laboratory connected to hospital service? | Yes No | | |
| How many rooms with bench space are there in the laboratory? | | | |
| What % of the working day do you have the following services available? | | | |
| Electricity<br>Running water<br>Gas (including bottled) | <50%<br><50%<br><50% | 50-95%<br>50-95%<br>50-95% | 95-100%<br>95-100%<br>95-100% |
| Is there a back-up power source in case of power failure (e.g. emergency generator)? | Yes No | | |
| If Yes, what systems are protected? | | | |
| Refrigerators/freezers | Yes No | | |

| | |
|---|---|
| Ventilation/AC<br>Computers<br>Other | Yes No<br>Yes No<br>Yes No<br>Not applicable |
| What ventilation is provided? | |
| Windows<br><br>Electrically-powered ventilation (exhaust, not fans) system or air-conditioning | Yes No |

| | | |
|---|---|---|
| What types of communications systems are available? | tick all applicable | Number |
| Post/courier | Yes No | |
| Telephone | Yes No | |
| Fax | Yes No | |
| E-mail (no. computers) | Yes No | |
| Internet (no. computers) | Yes No | |

*Specimen collection, labeling, and handling*

| | |
|---|---|
| Proportion of samples collected on site | <20% 20-50% 50-80% >80% |
| Does the laboratory use standardized request forms to order laboratory tests? | Yes No |
| Do request forms contain ALL of the following patient information: specimen source, date and time of collection, type of test requested? | Yes No |
| Do request forms provide details or a link which enable the lab to contact the patient? | Yes No |
| Are specimens that are received labeled with the patient's name and unique identifiers? | Yes No |
| Does the laboratory provide a unique accession number for all specimens? | Yes No |
| Does the laboratory have a logbook/electronic record of all specimens sent for diagnostic testing? | Yes No |
| Are specimens discarded after testing, or are they stored? | Discarded<br>Stored |

| | | | | | | |
|---|---|---|---|---|---|---|
| Are standard criteria used for discarding specimens with prolonged transit times (time of collection to time of processing in lab)? | | | | | Yes | No |
| Does the laboratory during evening/night shifts accept specimens? | | | | | Yes | No |
| If Yes, how are the following samples handled? | | | | | | |
| **Specimen** | **Plated immediately** | | **If no, held at (tick one)** | | | |
| CSF | Yes | No | 4°C | Ambient temp. | | 35°C |
| Blood culture | Yes | No | 4°C | Ambient temp. | | 35°C |
| Urine | Yes | No | 4°C | Ambient temp. | | 35°C |
| Does the laboratory refer samples to another laboratory for additional testing? | | | | | Yes | No |
| If Yes, reason for referral (tick all) | | | | | | |
| Confirmation | | | | | Yes | No |
| Identification of Unknown | | | | | Yes | No |
| Test not performed on site | | | | | Yes | No |
| If Yes, then by what method? | | | | | | |
| By regular post service | | | | | Yes | No |
| By special messenger | | | | | Yes | No |
| Courier service | | | | | Yes | No |
| Other (describe): | | | | | | |
| If Yes, number of samples sent per month | | | | | | |

*Reporting procedures*

| | | |
|---|---|---|
| Are records kept of the number and type of tests performed and results? | Yes | No |
| Does the laboratory use standardized forms to report lab results? | Yes | No |
| Does the laboratory have a list of diseases that are supposed to be reported to the Ministry of Health? | Yes | No |
| Does the lab staff know what diseases should be reported, whether or not there is a requirement for reporting? | Yes | No |
| Does the lab provide regular reports of patients with notifiable diseases to any of the following Ministry of Health offices/institutions? (tick all that apply) | | |
| District Health Office | Yes | No |
| State Health Office | Yes | No |
| Central Laboratory | Yes | No |
| National Communicable Disease Program | Yes | No |
| If reports are submitted, how frequently? | | |
| Weekly | Yes | No |
| Monthly | Yes | No |
| Quarterly | Yes | No |
| Other | Yes | No |
| If reports are submitted, by what means are they sent? | | |
| Line list | Yes | No |
| Telephone | Yes | No |
| FAX | Yes | No |
| Other (describe): | | |
| Do they keep register of persons with notifiable diseases? | Yes | No |
| If Yes, is the register computerized? | Yes | No |

| | | |
|---|---|---|
| If computerized, are back-up copies (hard copies or disc) of data made and archived? | Yes | No |
| *Quality control procedures and programs* | | |
| Is information gathered about laboratory turnaround times for specimens (time from receipt of specimen to issue of the report)? | Yes | No |
| Does the laboratory use any system for internal quality control? | Yes | No |
| Are internal controls included in each test run? | Yes | No |
| If Yes, is the performance of these internal controls recorded and monitored over time? | Yes | No |
| Does the laboratory participate in any external quality assurance or proficiency schemes? | Yes | No |
| If Yes, what programs? | | |
| Does the laboratory keep records of deliveries of reagents and materials? | Yes | No |
| Does the laboratory have a system for regularly monitoring of quantities of reagents and materials so that there is warning if stocks become low? | Yes | No |
| Does the laboratory have problems obtaining and maintaining most supplies of essential reagents and materials? | Yes | No |
| If Yes, what is the most important reason for not maintaining an adequate stock of reagents and supplies? | | |
| Information about how to obtain materials | Yes | No |
| Long delay ordering and delivery of materials | Yes | No |
| Lack of funds | Yes | No |
| Inconsistent demand for test from physicians | Yes | No |
| Is the functioning of ALL electrical or mechanical equipment routinely monitored and recorded (e.g. microscope calibration, temperature checks of refrigerators or incubators, calibration of pipettes or handling devices, autoclave function, etc.)? | Yes | No |

| | |
|---|---|
| Are calibration, maintenance and service records kept? | Yes No |
| *Safety* | |
| Does the laboratory staff receive training in laboratory safety? | Yes No |
| Is a safety manual easily accessible to the laboratory staff? | Yes No |
| What methods are used for solid waste disposal? | |
| Autoclaving | Yes No |
| Incineration | Yes No |
| Burial with no pre-treatment | Yes No |
| Is there a safety SOP | Yes No |
| What protective clothing/equipment is available for laboratory staff? (tick all) | |
| Gloves - latex | Yes No |
| Gloves - other | Yes No |
| Lab coats | Yes No |
| Safety glasses/visors | Yes No |
| Other (briefly describe): | |
| Are gloves worn for all manipulations of specimens, organisms, and reagents? | Yes No |
| If no, are they worn: | |
| Only for designated procedures? | Yes No |
| By the decision of the technician performing a test? | Yes No |

| If the laboratory performs tests for any sexually transmitted diseases, e.g. syphilis, gonorrhea, chancroid, please enter the information in the following table. | | | |
|---|---|---|---|
| Disease | Specimen type | Assay performed | Number/Month |
| | | | |
| | | | |
| | | | |

## II. Laboratory Inspection

Inspect the laboratory and complete the following form. Be courteous by first asking permission to open refrigerators, freezers, media storage closets and incubators to examine items contained therein. Some of the information collected during a walk-through will be used to verify information provided on the questionnaire. Make additional Notes as required, e.g. general cleanliness and organization of the laboratory, staff activity level, workload (specimens and inoculated plates present), and special facilities. Obtain copies of standard forms where indicated.

*Accessioning and reporting*

| Review accessioning logbook(s) if available. Roughly calculate the number of specimens submitted over a one-month period. Record number: *samples/month* | | |
|---|---|---|
| Review forms submitted with specimens. What proportion of specimens received are labeled with the patient's name and unique identifiers? | <50% > 50% | |
| Are copies of report forms available? | Yes No | |
| If Yes, obtain copies of standardized reports forms that are used. | | |
| *Manuals* | | |
| **Type of manual** | **Available** | **Date of last revision** |
| Test Procedures | Yes No | < 1 year 2-5 years<br>> 5 years No date |
| Safety | Yes No | < 1 year 2-5 years<br>> 5 years No date |
| Quality control | Yes No | < 1 year 2-5 years<br>> 5 years No date |

| | | |
|---|---|---|
| *Equipment and reagents* | | |
| Briefly look to see if reported number and type of equipment items is consistent with those reported on the questionnaire. Are findings generally consistent with responses above? | Yes No | |
| Inspect equipment to see if performance indicators (e.g., temperatures) are regularly recorded. | | |
| **Equipment item** | **Sheet present** | **Temps. Recorded (per cent complete)** |
| Refrigerators | Yes No | 0% 1-50% >50% |
| Freezers | Yes No | 0% 1-50% >50% |
| Incubators | Yes No | 0% 1-50% >50% |
| Inspect prepared reagents, dehydrated media, antibiotic susceptibility disks and prepared media to see if dates are recorded for the date prepared or opened and to see if expiration dates have passed. | | |
| Proportion of reagents labeled appropriately? | | None < 50% >50% |
| Expiration dates found? | | None < 50% >50% |
| For reagents with dates - percent outdated? | | None < 50% >50% |
| Inspect bacteriological media, both prepared and dehydrated, and reagents for signs of deterioration, e.g. drying, discoloration, hemolysis | | |
| Deterioration noted in bacteriological media | | None < 50% >50% |
| *Safety* | | |
| If biosafety hood is present, is it operational? | | Yes No No hood |
| Is a certification/inspection sticker present? | | Yes No Not applicable |
| If Yes, date of certification? | | Yes No Not applicable |
| Inspect laboratory for presence of biosafety equipment (gloves, sharps containers, safety glasses) | | |
| Gloves present? | | Yes No |

| | |
|---|---|
| Sharps containers? | Yes No |
| What proportion of staff are wearing gloves while performing procedures? | <1-50%<br>>50%<br>None<br>Unknown |
| Inspect equipment used for the disposal of biological wastes, e.g. autoclaves, incinerator. Is the hazardous waste disposal system operational? | Yes No |

## III. Quality Assurance

*Quality Assurance Policy and Practice*

Describe the QA/QC Program. Collect copies of any procedures and organizational charts related to QA/QC.

*Organization and staff*

Has the director assigned QA responsibilities? Yes No

Describe the staffing and organization of QA functions.

*Laboratory Self-Assessment (To be completed by institution)*

**I. Laboratory equipment**

| **Type and number of items available in your laboratory** | **Present** | | **Number** |
|---|---|---|---|
| Refrigerator | Yes | No | |
| Freezer at –20°C | Yes | No | |
| Freezer at –70°C | Yes | No | |
| Microscope with oil-immersion objective | Yes | No | |
| Analytical balance | Yes | No | |
| Candle jars | Yes | No | |
| Other Anaerobe jar | Yes | No | |
| Magnifying lens | Yes | No | |
| Loop/needle handles | Yes | No | |
| 0.01and 0.001ml calibrated loops | Yes | No | |
| Bunsen burner | Yes | No | |
| If no Bunsen burner, Electric heater or alcohol lamp to sterilize loops and needles | Yes | No | |
| Staining facilities-sink and slide rack | Yes | No | |
| Adequate glassware for media preparation (flasks, graduated cylinders, etc.) | Yes | No | |
| pH meter | Yes | No | |
| Manual pipettes (e.g. Eppendorf) | Yes | No | |
| Water distillation system | Yes | No | |
| Low-speed centrifuge ( hand or electrically powered) | Yes | No | |
| Autoclave - manually controlled | Yes | No | |
| Autoclave - electrically controlled | Yes | No | |
| Hot air oven | Yes | No | |
| Inverted microscope | Yes | No | |
| Fluorescent microscope | Yes | No | |
| Electron microscope | Yes | No | |
| ELISA plate reader | Yes | No | |
| ELISA washer | Yes | No | |

| | | |
|---|---|---|
| Electrically-powered waterbath | Yes No | |
| Warm air incubator | Yes No | |
| CO2 incubator | Yes No | |
| CO2 tanks | Yes No | |
| Liquid nitrogen storage | Yes No | |
| Safety cabinet- level 1 (operator protection. Open-fronted, unrecirculated airflow away from operator) | Yes No | |
| Safety cabinet- level 2 (protects operator and material from contamination. Open fronted, filtered supply and exhaust air) | Yes No | |
| Safety cabinet- level 3 (protects operator, material and environment from contamination-enclosed, negative pressure, HEPA filtered air supply and exhaust) | Yes No | |
| Is all equipment functioning?<br>(Ask this question after each equipment item,<br>if response is NO, record below) | Yes No | |
| If no, what items of equipment are not functioning? | | |

**II. Laboratory staff and supervision**

| **Number of staff in each category** | **Number** | **% of staff available in lab** |
|---|---|---|
| Supervisors — Medical/Scientific (do tests? ___) | | |
| Supervisors — Technical (do tests? ___) | | |
| Technologist/Technical (do tests? ___) | | |
| Laboratory assistants (not doing tests) | | |
| Clerical | | |
| What is the highest level of training achieved by technical staff performing diagnostic tests? (state number of staff for each option) | | |
| In-laboratory training only | | |
| Diploma course or specific training course | | |
| Degree level | | |
| Other (briefly describe): | | |
| Has training been conducted for your laboratory staff in the past year? | Yes No | |
| If Yes, indicate the type of training and the number of staff trained | | |

| | | | |
|---|---|---|---|
| Formal training at national lab | Yes | No | |
| Formal training on-site | Yes | No | |
| International training | Yes | No | |
| **Laboratory staff supervision** | | | |
| Who usually decides which tests to perform when the samples first arrive in the laboratory? | | | |
| The requesting clinician | Yes | No | |
| The technician | Yes | No | |
| Supervisor/director | Yes | No | |
| Laboratory protocol | Yes | No | |
| Who makes decisions about further testing if indicated? | | | |
| The technician | Yes | No | |
| Supervisor/director | Yes | No | |
| Are ALL tests reviewed before results sent for reporting? | Yes | No | |
| If Yes, who reviews the results of tests (or test runs)? | | | |
| Only the technician performing the test | Yes | No | |
| Another member of the technical staff | Yes | No | |
| Supervisor/physician | Yes | No | |
| Are ALL tests reviewed before results sent for reporting? | Yes | No | |
| If Yes, who reviews the final report before it is sent to the requesting clinician or other appropriate recipient? | | | |
| Only the technician performing the test | Yes | No | |
| Another member of the technical staff | Yes | No | |
| Supervisor/physician | Yes | No | |

**III. Reagents**

| | |
|---|---|
| What proportion of your reagents do you obtain from: | |
| A commercial supplier | % |
| From another laboratory | % |
| Prepared in-house | % |
| What type of water is used for preparation of media and reagents? | |
| Deionized | Yes No |

| | |
|---|---|
| Distilled | Yes No |
| Distilled and deionized | Yes No |
| Tap water | Yes No |

**IV. Tests performed at the laboratory**

List all the tests performed and the number of specimens tested each month by each method.

**V. Laboratory management**

| | |
|---|---|
| What are the normal hours/days of service of the laboratory? | |
| Number of days per week | <5 5 6 7 |
| Hours per day | <6 6-10 11-23 24 |
| If no 24-hour service, is out-of-hours or emergency service available? | Yes No |
| If there is 24-hour service, number of staff at the following times: | |
| 5 PM to 12 AM | |
| 12 AM to 7 AM | |
| How does the laboratory inform clients about the services it offers? | |
| Verbally only (informal) | Yes No |
| Printed list/Brochure | Yes No |
| Does the technical staff have access to typed or written protocols (Standard Operating Procedures) for performing each test? | Yes No |

## Appendix D. Rapid Methodology for LIS Implementation

Strict adherence to the standard process described in this Guidebook increases the probability for a successful LIS implementation. However, we recognize that some deviation from the process may be unavoidable in order to meet specific requirements based on political, financial, or technical needs.

Circumstances may require a decision to use a Rapid Methodology (RM) in order to implement an LIS application in a much shorter time than the typical project length of 12–18 months.

In order to accomplish a successful LIS implementation more quickly, we have condensed the critical steps into a rapid methodology (RM) that is appropriate for projects with significantly limited scope. An illustration and description of the steps follow. In projects using RM, it is even more critical to guard against changes in scope once the project has begun, and the participants must realize and accept limitations in scope.

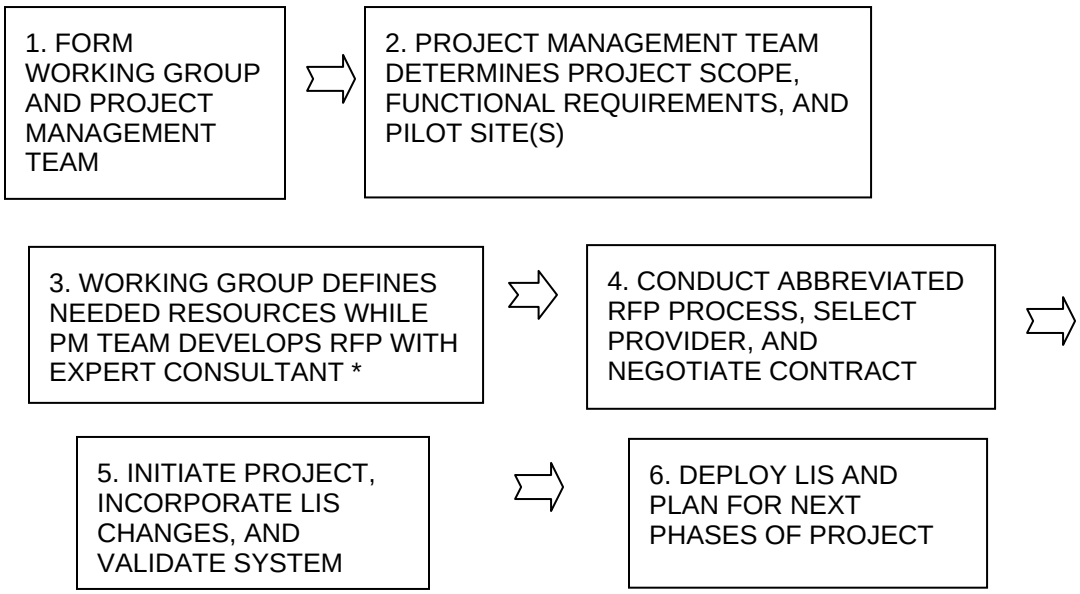


*Figure A3-1. Using RM for Implementing a Pilot Laboratory Information System: Eight Critical Factors in Six Steps*

In order to be successful, rapid methodology requires the following:

- Working Group must delegate a considerable amount of authority to the project management team.
- Project Manager must have the right set of technical and managerial skills to manage complex projects.
- Project Team must have access to capable and reliable information technology experts from the very beginning of the project. The expert consultant should have a proven track record in LIS development and implementation.
- There must be a clear and explicit understanding of trade off between the speed of deployment and the scope of the project.

**Step 1.** ***Form working group and project management team.*** The Project Leader (PL), who may be the National Laboratory Director or other senior public health official, must have the authority to determine the project strategy and implementation. This individual should consult with appropriate partners and identify an expert consultant to assist with planning and organization. The PL will establish a Working

Group, act as its chair, and identify/hire a Project Manager. The Project Manager, with assistance from the consultant and PL, is responsible for forming the Project Management Team.

**Step 2.** ***PM Team determines project scope, functional requirements and pilot sites.*** The Project Management Team, which will include the expert consultant, has the authority to make decisions and report to the Working Group on its progress for post-audit. The PM team will define a limited scope project that is feasible to accomplish in the time stated in the requirement. They will determine the functional requirements for the application and identify and gain commitment from a pilot site(s).

**Step 3.** ***Working Group defines needed resources and PM Team develops RFP.*** The Working Group is responsible for determining, based on information from the PM Team, the project resource needs, and providing adequate resources needed to accomplish tasks in a timely manner. The PM Team, using expert consultation, develops an RFP.

**Step 4.** ***Conduct abbreviated RFP process, provider selection and contract negotiation.*** The Project Manager requests three to five providers to submit their responses to RFP within three weeks. Telephone, fax and/or e-mail can be used for submission of the response. The PM must brief the WG chair of the selection process and, once a provider is selected, have the authority to negotiate the contract on the PM team's behalf.

**Step 5.** ***Initiate project, modify selected application as required and validate system.*** Regular meetings (preferably weekly or more) must be held between the PM and the Working Group. It is essential to the success of RM that regular and frequent communication takes place and opportunities are provided for key stakeholders to provide input.

**Step 6.** ***Deploy LIS and plan for next phase.*** The capability of the PM and expert consultant partnership is the most important element for success in this model of LIS implementation. As the project plan unfolds, the PM must form additional partnerships to mobilize resources for the additional elements of a successful implementation.