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APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

Laboratory Information Systems Project Management:

A Guidebook for International Implementations

November 2018

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EXECUTIVE SUMMARY

Laboratory Information Systems (LIS) play a key role in laboratories meeting quality standards, decreasing transcription errors, reducing turnaround time from specimen receipt to reporting of results, and improving patient outcomes. In the last decade, technological advances in laboratory instrumentation has led to higher specimen volumes and a greater demand and reliance on laboratory data to support clinical and public health needs. These advances demonstrated that paper-based record keeping and results reporting were inefficient and could not support the laboratory's business needs. As a result, there has been a tremendous growth in the demand for adoption of LIS at all levels. This increased use of LIS has allowed end users to more clearly articulate detailed system requirements, in turn leading vendors to develop more attractive, viable LIS options.

In order to use this Guidebook effectively, the following areas must be agreed upon by institution and country leadership prior to LIS selection:

1. Defining success
2. Defining sustainability
3. Defining standards
4. Adopting a standard set of procedures throughout
5. Defining sustainability for the country/lab

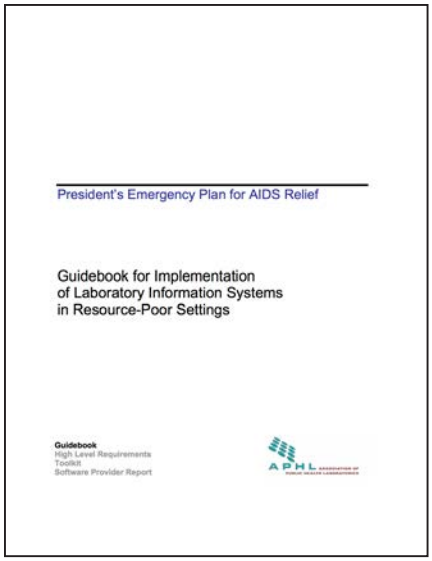
The Guide has something for everyone. Novices who are considering LIS in their laboratory for the first time will find a starting place and a complete implementation narrative to follow, while more experienced implementers who have questions on certain topics or are looking for a strategic approach to a problem will find the support they need.

Much of the material draws from a four-day training on LIS conducted at the African Center for Integrated Laboratory Training in South Africa, Uganda and Ukraine for data managers and laboratorians.

Introduction

This publication is the result of a major revision of the *Guidebook for the Implementation of Laboratory Information Systems in Resource Poor Settings* (2005). LIS impact patient health and public health by enabling efficient management of instruments and data so that accurate information is provided quickly. LIS delivers test results for patient care, monitors quality of testing systems, and provides real-time disease surveillance test results. LIS increases the capabilities and capacities of diagnostic and public health laboratories. The world's medical care and public health systems could not provide the improved patient care and prevention of disease outbreaks we now have without LIS. The guide can help initiate and implement a Laboratory Information System (LIS) in laboratories at many levels—from a nationwide rollout based on a strategic plan to an individual laboratory site with the necessary infrastructure and human resources to support the ongoing cost of a LIS. This guide follows the sequence of an LIS implementation. Users can begin with the section that corresponds to their place in the LIS implementation cycle.

Whatever the driver, the *LIS Guidebook* design takes into account the varied needs and abilities of governments, their public health and clinical laboratories, as well as other Non-Governmental Organizations/Implementing Partners responsible for LIS selection and implementation. The overall organization and layout of each LIS Guide section reflects feedback and guidance from various in-country LIS implementation teams and information system subject matter experts.



Original 2005 Guidebook

This guide provides a comprehensive overview of both technical and programmatic LIS components, a systematic process to evaluate and select appropriate LIS solutions, and a set of clearly-defined implementation steps. Whether a laboratory's management chooses to implement an LIS in facility or whether a government decides to roll out an LIS nationwide, the steps outlined will be valuable to both scenarios.

Taken as a whole or in part, the purpose of this guide is to reveal the intricacy of a typical LIS implementation and to ensure that decision makers and project teams have the information and tools necessary to think strategically when considering all the pieces of the LIS ecosystem, not just the LIS itself.

This guide is organized in a linear format that follows a typical LIS implementation chronologically through its life cycle. This structure allows users to reference a single section, or to begin with the section that best corresponds to their place in the LIS implementation cycle.

To make the contents as user-friendly and accessible as possible, each section is equipped with a road map. At a glance, readers can see where they are in the LIS ecosystem and the audience that most benefits from a given set of information.

Figure 1a: Overview of the LI(M)S Ecosystem
Several components come together to create a healthy and sustainable LIS/LIMS, which has a direct impact on a country's public health

Laboratory Information Systems (LIS) Overview

1. The Basics
   - History of LIS/LIMS
   - Workflows
   - Components
2. Why Laboratories Need a Dedicated LIS
   - Determining Need
   - Types of LIS
   - Role of LIS in Quality Improvement
   - Types of LIS Systems
3. Core Functions of an LIS
   - Cross Cutting
   - Pre-Analytical
   - Analytical
   - Post-Analytical
4. Data
5. Use of Data by Role
   - Roles
   - Data Source Types (OLTP and OLAP)
   - Data Life Cycle
   - Data Collection and Use
   - Application Architecture
6. Data Management

THE BASICS

A laboratory information system (LIS) is a computer-based information management system created specifically for laboratories. An LIS is used to support workflows in the laboratory—as well as the repository to store laboratory data—while supporting the laboratory mission. The goal is to deliver correct and complete information to laboratory staff, managers and customers as efficiently as possible by following four main processes.

1. Track laboratory information during the testing process (from sample log-in to reporting)
2. Collect, store, archive and analyze laboratory data
3. Report test results for patient care
4. Report data to administration, Ministry of Health (MOH) and other agencies

LIS vs. LIMS

LIS and *LIMS* are terms that are sometimes used interchangeably. *LIS* is traditionally used to refer to systems that support clinical settings and patient-specific specimens while *LIMS* are systems designed to support public health, national reference laboratories, research laboratories or other non-clinical settings and are sample centric, with focus on data analysis and workflow and features to meet regulatory requirements. This Guide applies to both LIS and LIMS, however for ease of use, the term LIS is used throughout.

With evolving technologies and ever-changing needs, LIS are also incorporating features they may not have had traditionally. Currently, both LIS and LIMS systems support data tracking, instrument interfacing and workflow efficacy. While all laboratories are subject to government regulation, clinical laboratories must also satisfy patient privacy guidelines. A good LIS will track who accesses patient sample data, which can provide verification of privacy compliance. Many LIMS, however, will now do the same.

While this Guidebook has a range of audiences, our target readers are decision-makers and employees of clinical laboratories. APHL has been engaged with both clinical and public health laboratories globally and worked with both LIS and LIMS. To that end, APHL has chosen LIS as the preferred term and area of focus for this publication.

Prior to 1970, health organizations developed their own LI(M)S in order to make data management and reporting more efficient. These LI(M)S take considerable time and resources to implement. With the advent of technology, some laboratories were able to procure custom-built systems in the 1970s. In the following decade, laboratory instrument makers began to develop commercial

LI(M)S solutions designed to increase the efficacy of their particular merchandise. Still, these software-instrument solutions were narrow in focus, industry-specific and required extensive customization. This resulted in both large implementation expense and time frame.

As technology and processors became more advanced—yet lower in cost—in the 1990s and 2000s, informatics developers created broad, flexible LI(M)S that required less customization that their predecessors. Additionally, developers created open source systems. Today, laboratories have a variety of choices to track, analyze, and report laboratory data.

Table 1a: History of LIS/LIMS

The evolution of laboratory information (management) systems from 1970 to present

	1970-1980	1980-1990	1990-2000	2000+
Data Recording	Pen & Paper	Pen & Paper	PC	Bar Coding
Data Analysis	Slide Rule & Calculator	Calculator & First LIS software	LIS/LIMS software	LIS/LIMS Software (PC- or Web-based)
Data Storage	Paper-based logs	Books	Electronic Database	Electronic Database
Report Generation	Type Writer	Type Writer & Word Processor	Stand-alone Computers	Electronic
Report Sharing	Postal Mail	Postal Mail	Fax & E-mail	Electronic

Laboratories have certain responsibilities to ensure successful LIS implementation and maintenance.

Responsibilities	Q/A Questions
Awareness	Who knows about the LIS? Who needs to know about the LIS? What management positions need to approve and support the LIS? What is the level of staff morale?
Adoption	Who is the management behind LIS? Does everyone receive training? What is the staff morale? How does LIS adoption affect staff morale?
Behavior Change	Do care providers use LIS data to make decisions about patient care? Has LIS use and improved TAT lead to improved care?

Laboratory Business Processes and Functions

In 2003, APHL and the Public Health Informatics Institute (PHII) developed the LIMS Functional Requirements Document that lists 16 core business processes of a laboratory. An LIS supports these 16 business processes. In 2013, as part of the process of developing the Informatics Self-Assessment Tool, APHL and the experts involved added 3 business functions related to data exchange and interoperability, core Information Technology (IT) services and policies and procedures.

1. Laboratory Test Processing
2. Test Scheduling
3. Proactive Specimen/Sample Collection (Prescheduled Tests)
4. Specimen and Sample Tracking/Chain of Custody
5. Media, Reagent, Stains, Controls, etc. Manufacturing
6. Inventory Control Including Kits & Forms Management
7. General Laboratory Reporting
8. Statistical Analysis and Surveillance
9. Billing for Laboratory Services
10. Contract and Grant Management
11. Training, Education and Resource Management
12. Lab Certifications/Licensing
13. Customer Concerns/Suggestions
14. Quality Control (QC) and Quality Assurance (QA) Management
15. Laboratory Safety and Accident Investigation
16. Laboratory Mutual Assistance/Disaster Recovery
17. Core IT Services: Hardware and Software
18. Budgeting and Funding
19. Policies and Procedures

WHY LABORATORIES NEED A DEDICATED LIS

Laboratory information systems work because they automate the process of collecting, tracking, analyzing, reporting, and storing specimen data. Laboratories with a solid LIS can strengthen country public health through data sharing between and among laboratories, clinicians and public health networks. To that end, high quality data produced and shared efficiently by laboratories with an LIS have far-reaching positive consequences. As compared to other healthcare services, laboratory processes are unique and rely on systems with a laboratory-operations focus. Further, public health and hospital laboratories require even more specialized processes to fulfill their unique mission. And most LIS can be integrated with a hospital information system (HIS).

Types of LIS

There are two common types of LIS: (1) a module within a hospital information system (HIS) and (2) a stand-alone LIS. An LIS within HIS serves mostly as a means to capture results and a few key elements of data. The second system—a dedicated LIS—shares most of the components listed above and can support all the business processes within a laboratory.

Table 1b: Two Common LIS Types
Difference between LIS as a module in HIS and a dedicated LIS

	HIS LIS Model	Dedicated LIS
Focus	• Diagnostic focus • Supports physicians' diagnostic workflow with little surveillance or epidemiological testing support	• Laboratory Focus • Supports laboratory processes including modules for diagnostic and epidemiological workflows.
Center	• Patient centric • Requires specific identification of patient related to specimen. Expects users to report one result per patient per care incident.	• Specimen centric • Handles varying levels of patient identification. Able to report results grouped by incident, patient or submitter, depending on need.

Figure 1a: LIS as Part of HIS

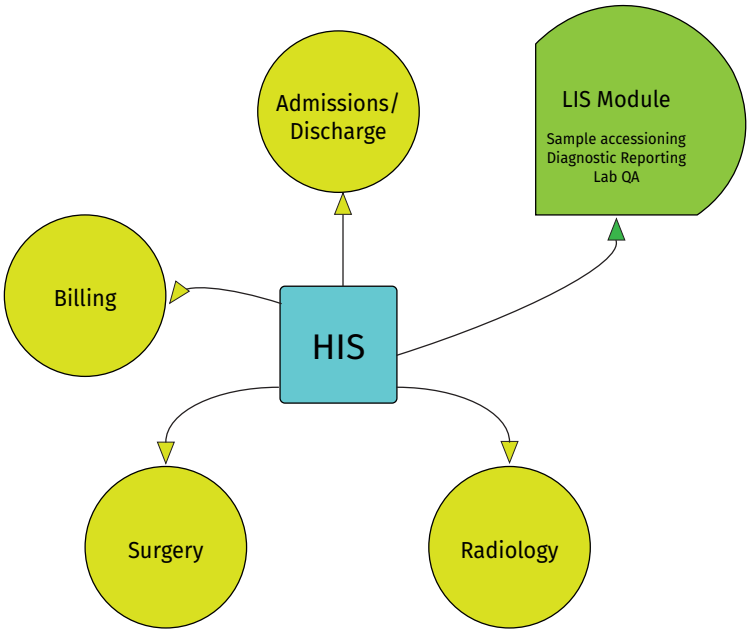
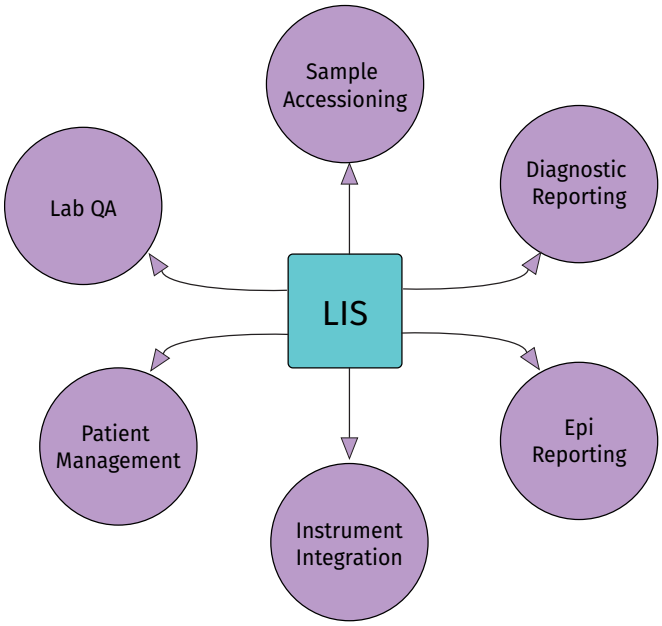


Figure 1b: Dedicated LIS



Determining Need

There are a variety of factors to consider when evaluating the need for a LIS, including

- Volume of testing
- Test menu
- Complexity of testing
- Relationship/linkage with referral laboratory and overall Laboratory Network
- Number of users
- Types and number of equipment to interface

LIS Concerns, Processes and Responsibilities

Each laboratory differs in size, patient volume, and resources. The administrators and working groups who wish to implement LIS need to take into account:

- regulatory compliance;
- accreditation requirements;
- patient confidentiality protections;
- equipment interfacing and compatibility;
- IT staffing;
- anticipation of future needs;
- budget; and
- workflow.

Additionally, pilot location(s) and accurately detailed requests for proposals (RFPs) contribute to successful LIS implementation.

To determine whether an LIS is doing what it is supposed to do and benefiting the lab, there must be pre- and post-implementation indicators developed with standardized tools to capture associated data. Assessments using standardized tools must be collected. If there are no data, there is no way to measure success or failure. Periodic LIS evaluations/assessments must be conducted to monitor the LIS. Additionally, laboratories must monitor vendor performance, ensure continuous availability of supplies, ensure continuous support for software and hardware, plan and budget for further expansion, and implement expansion.

To ensure sustainability, ministries of health must budget for on-going costs (e.g., supplies, stationery, and license fees, where applicable) and for vendor contracts (hardware and software, or cloud hosing where applicable and acceptable), train on-site super users and establish dedicated LIS and Help Desk officers.

Public Health Laboratory Core Functions

1. Disease Prevention, Control and Surveillance
2. Integrated Data Management
3. Reference and Specialized Testing
4. Environmental Health and Protection
5. Food Safety
6. Laboratory Improvement and Regulation
7. Policy Development
8. Public Health Preparedness and Response
9. Public Health Related Research
10. Training and Education
11. Partnerships and Communication

LIS Benefits and Continuous Quality Improvement

An LIS provides laboratories with a tool to aggregate, analyze and manage laboratory data. Labs can compile information from the LIS and provide timely reports for surveillance, program management, and health policy formulation. As a result, the total laboratory testing process and data management improve, providing better QC/QA.

Areas of focus for the LIS

- Adjusting the workflow in the laboratory
- Developing management tools such as duty rosters
- Improving laboratory record keeping and management
- Ensuring appropriate training of staff
- Equipment maintenance procedures

LIS Highlights

- Improved laboratory data management
- Improved laboratory efficiency
- Improved quality
- Adoption of international lab standards
- Prompt and efficient delivery of accurate and complete information to lab staff and managers
- Workflows support
- Information tracking during the testing process
- Collection, storage, archiving and analysis of data
- Reporting of test results for patient care
- Reporting of data to MOH and other agencies
- Repository to store lab data and system used to support workflows in the laboratory
- Improved and appropriately managed data security

Table 1c: Types of LIS Software

Laboratories choose between commercial off the shelf, custom and open source software based on their needs and budgets

	Commercial Off the Shelf (COTS)	Custom	Open Source
License	License fee per seat, per concurrent user, or site wide	No fees	No fees (typically)
Implementation	May be per year or perpetual	Can be very costly	Fee for services and other costs
Support	Varies, but usually managed through a service level agreement (SLA) by the vendor	Requires ongoing internal support	Support often provided through combination of online community and internally

CORE FUNCTIONS OF AN LIS

An LIS supports the three main phases of a specimen life cycle: pre-analytical, analytical and post-analytical.

Pre-Analytical

This systematic collection of data greatly improves data security, facilitates better data validation and prevents damaged or lost data. It does not simply automate a problematic manual process; the LIS redesigns the process and then automates it. As a result, the pre-analytical phase:

- reduces log in time
- ensures correct identification of specimens
- creates a database of patients
- creates and maintains a unique specimen ID
- helps identify mislabeled specimens
- barcodes samples.

Analytical

In the analytic phase, the LIS:

- Enables correct specimen and test identification through use of pre-analytical data available in the LIS
- Assists in workload management by automated capture of results from instruments
- Reduces transcription errors from instrument data
- Validates results
- Assists in quality control (QC) management

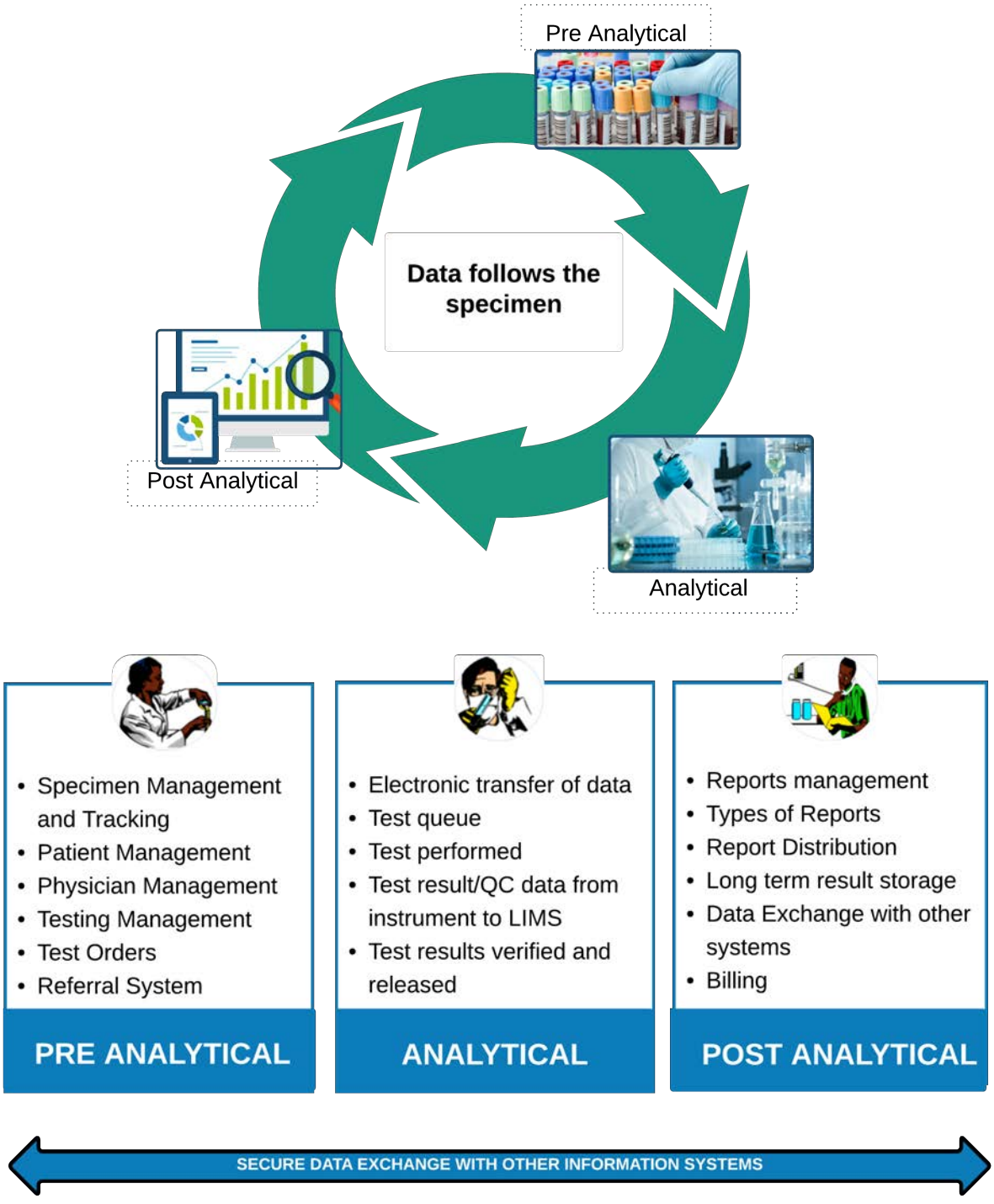
Within the analytic phase, the LIS can have an impact on process monitoring, workflow, instrument interfacing, and quality assurance support.

Process Monitoring
LIS can make sample location and sample status constantly available for each specimen throughout the laboratory process. It also provides the ability to monitor workflow metrics, such as turnaround time.

Cross Cutting Functions

- Specimen inventory management
- Management reports
- Reagent inventory management
- Training, education and resource management
- Laboratory policies and standard operating procedures
- Laboratory mutual assistance and disaster recovery
- Quality assurance (QA)
- External quality assurance/ Proficiency testing (EQA/PT)

Figure 1c: LIS Core Functions
LIS addresses the needs of all three analytical phases.



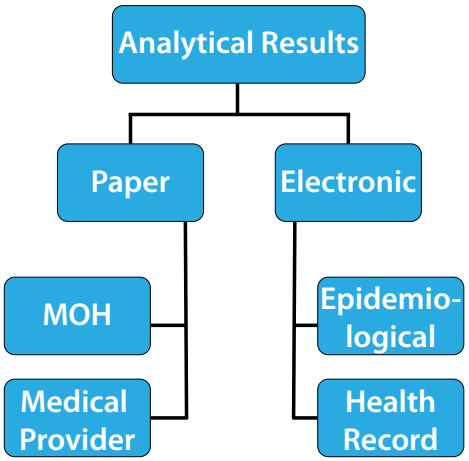
Rules/Alerts for Improved Workflows
An LIS establishes rules to ensure that users follow proper procedures. Within the system, alerts notify users when actions are required through alerts.

Instrument Interfacing
One directional interfacing, like direct data import from instruments, can reduce data transcription errors and speed up analytic processes. More advanced implementations may use a bi-directional interface where the LIS can send data to the instrument to set up a run and results and QC data are automatically returned to the LIS.

Automate Quality Assurance (QA) Support
LIS automatically tracks and generates reports for common QA functions such as:

- Specimen Rejections
- Specimen Transfers
- Deficiency/Corrective Action Log Sheet
- Communication Log
- Occurrence Management Log
- Analyzer use and maintenance needs
- Instrument and Run QC

Figure 1d: Distribution of data from the LIS

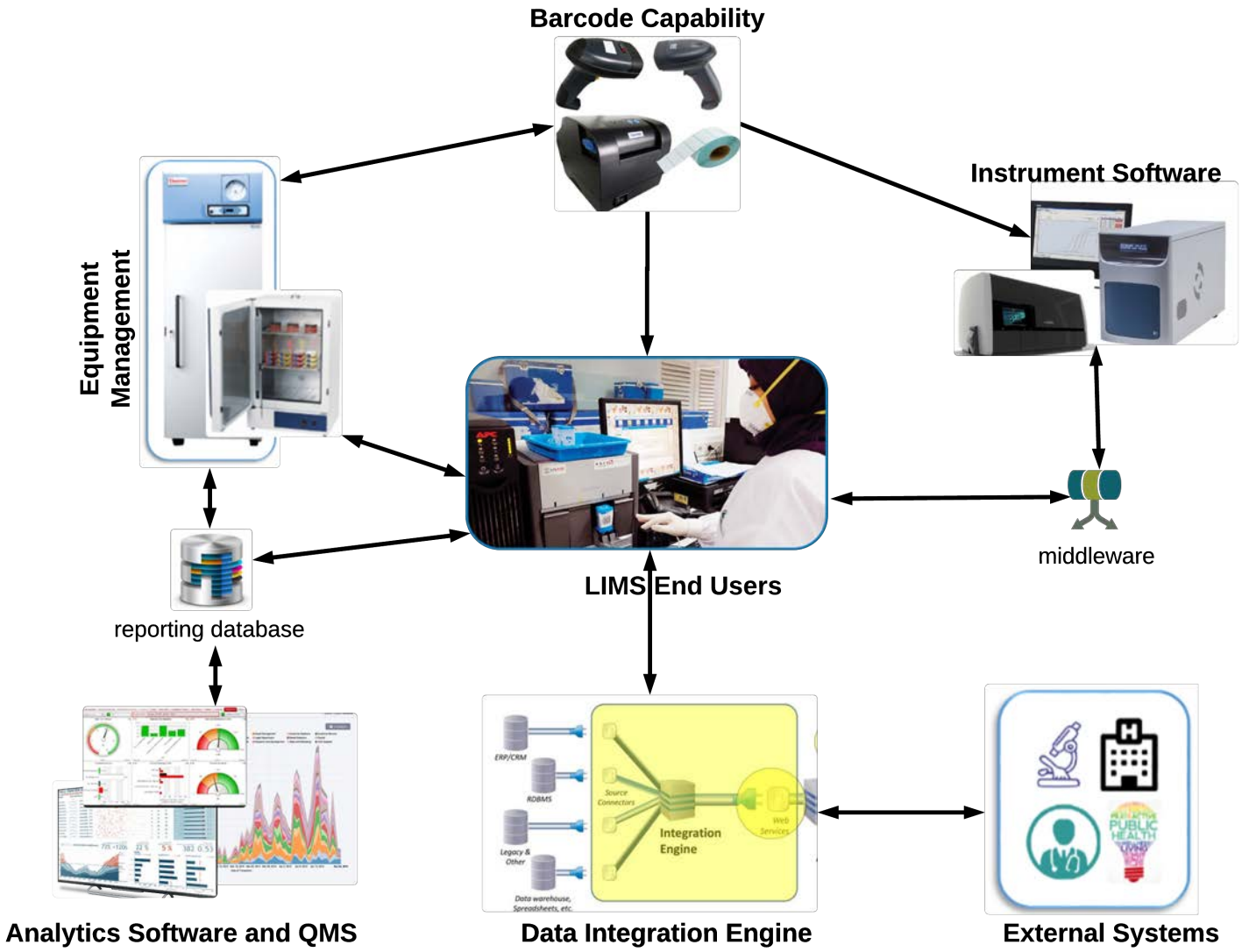


Post Analytical

In the post analytic phase, the focus is on submitting laboratory data to various recipients based on the purpose of testing. Laboratory results can be submitted to patients, health care providers and public health officials at sub national and/or national levels.

Laboratory data can be presented as individual results with either specific or de-identified accompanying data aggregated by facility or geographic location. Additional information can be submitted as needed including diagnostic cut-offs, surveillance limits to enable decision making.

Figure 1e: LIS Components
LIS software integrates laboratory instruments



UNDERSTANDING AND MANAGING DATA

Data are the backbone of all laboratories. Accurate and consistent data are especially critical for laboratories to function and to have a voice in public health, surveillance and outbreak response.

Data Life Cycle

There are six stages to a data life cycle within an LIS:

- Collection
- Input
- Processing and quality assurance
- Analysis
- Reporting
- Use of data for decision making

Collecting and Using Data

A laboratory is only as good as the quality and accuracy of its work. There must be a minimum required set of data elements essential for identifying patient demographics, specimens and test results before implementing an LIS. Since the pre-analytical phase is the primary source of laboratory errors, placement of information on the Test Request Form should duplicate placement of the field sequence on the LIS screen.

All aspects of data collection—including processing methods—affect data quality. Usage needs, although difficult to ascertain, also influence quality levels.

Data Definitions

Attribute
Property or characteristic of an object also known as variable or field.

Collection of Attributes
Describes an object instance or record.

Forms of Data
Data may be collected and used in different forms: facts, information, and knowledge.

Facts
Details such as raw results and statistics

Information
Data that is compiled, analyzed and may be presented in tables and reports

Knowledge
Information that is interpreted and evaluated to explain a situation and/or to make decisions

Data Reuse
Taking a data asset and using more than once for the same purpose

Data Combination
Joining data from multiple sources to arrive at a more comprehensive solution

Three Main Types of Data Use

Reporting	Ad-hoc Queries	Data Analysis
Includes analytical reports and key performance indicators	Include asking questions about events and/or triggers both in real-time • "What is happening now?" • "What has happened in the past?"	Includes making predictions about events, triggers and/or Epi patterns/trends • "What will happen?" • "How/why did it happen?"

Data quality greatly affects its ongoing value. Laboratories, being often the initial source data, are therefore vital to the many future uses of that information.

Examples of Valuable Data Use

Measles Vaccination	Influenza Outbreak	Patient demographics
Quality of data that is input into the LIS will allow for detection of increase in measles positivity rate resulting in immunization in unprotected populations	Rapid movement of diagnosis result and patient demographics key to outbreak responses	Laboratories are the source for test results and associated QA/QC but the clinic/hospital/care provider is the source data for information about the patient. Therefore, quality of patient data available in the LIS is determined by the quality of data provided by the care provider, assuming there are no errors at the point of data entry by laboratory staff.

Many data, however, are collected and not used (typically demographic information). While the collection of unused data is expensive, it too is integral to the overall LIS life cycle.

Storing Data (OLTP & OLAP)

Data may be stored via two systems: online transactional processing (OLTP) and online analytical processing (OLAP).

Online transactional processing (OLTP) systems
OLTP provides mostly operational support, this type of storage is tuned for fast insert, update and selection. Most LIS are OLTP systems.

Online analytical processing (OLAP) systems
Providing mostly reporting support, this type of storage uses data that originate from operational systems, which is then refactored for reporting and analysis. Most epidemiology and surveillance systems are OLAP systems.

Application Architecture

Application architecture is the framework or outline of an organization's systems relative to their requirements including description of the interaction between applications and databases. Typical application architecture involves a presentation layer, a logic layer and a data layer. This architecture can be used in the development of either a simple LIS where the web user interface communicates directly with the database or a robust LIS architecture where an application layer sits between the web interface and the database and manages validation and business logic. For more information about system architecture, see *Chapter 4: LIS as a Project in a Laboratory*, *Section 3: LIS Functional and Technical Requirements*, in this publication.

For successful data management:

- Formally standardize data management, quality control and security processes
- Understand your data needs thoroughly before collecting data
- All stakeholders consulted for data needs
- Quality related performance measures must be in place
- Revisit data use planning on a regular basis. As stakeholders learn to use the system, they will also learn how to use the data more effectively

USE OF DATA BY ROLE

To have a well-functioning LIS, laboratories must take the time to formally establish plans for the definition, production and usage of data. It is important to integrate quality assurance and standardization into existing operational processes and monitor for consistent quality and appropriate compliance, security and risk management. Below is a list of how various laboratory staff ideally use data.

Laboratory managers focus on workload management (e.g., who is doing what tests and when testing is taking place). An LIS helps them to visualize key activities, audit turnaround times, anticipate critical events, determine potential bottlenecks, track supplies and inventory, and identify trends and patterns.

Data managers focus on data collection, data management, data reporting and analysis. They also supervise staff responsible for data entry. They are the ones who work with the data the most. They can benefit from LIS capabilities that share resource management data with institutional mainframes.

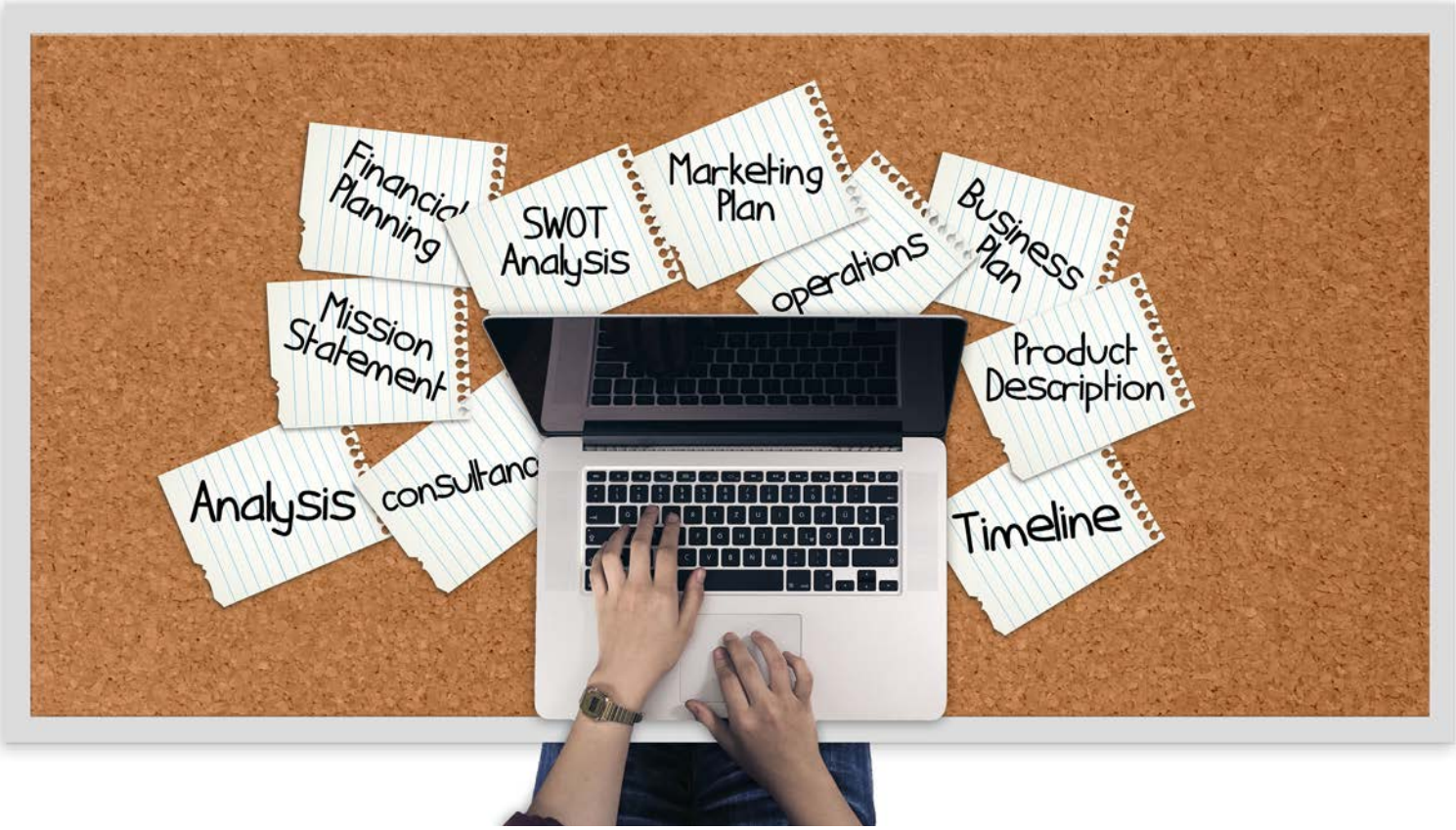
LIS administrators work with laboratory and field personnel to optimize LIS functions for the laboratory, field and QA/QC operations of the laboratory. They define and articulate rules required for data accuracy and consistency, as well as identify and resolve data quality issues.

Laboratory technicians log-in samples, work with analyzers, and store data on computers. An LIS provides a computer system to analyze, store, and print results, assisting with technicians' workloads and automating complex computations that would have previously relied on manual methods.

Accountants in larger healthcare organizations or hospitals track financial data related to laboratory sample analysis. Because an LIS will track all patient data related to specimen samples, accountants may easily export lab costs directly to client invoices.

Starting a National LIS Program

1. Vision, Mission and Defining Success
2. Buy-In
   - Program/Project Charter
   - Business Case
3. Program Management/Team Structure
   - Project Sponsor
   - LIS Technical Working Group
   - LIS Project Management Team
   - LIS Task Force/Subcommittee
   - Implementing Partner
4. Strategic Planning
5. Implementation of a National LIS
   - Implementation Approach
   - Paper-Based Information System
   - LIS Pilot and Selection of Sites
   - Expansion
   - Criteria for Pilot Site Selection
6. SLIPTA Checklist and Accreditation
7. Monitoring and Evaluation
   - Indicators
   - Assessment
8. Use of Data to Support Public Health Surveillance
9. Challenges and Lessons Learned
10. Sustainability: Enhancements and Expansion
    - Financial
    - Development of an IT Human Resources Plan
    - Development of a Hardware Maintenance Plan
    - Creating Value



VISION, MISSION AND DEFINING SUCCESS

An important part of any initiative is to establish its purpose, its strategic objectives and its implementation processes. Plans to implement a Laboratory Information System (LIS) should flow from a national laboratory strategic plan (reference) and fit in the overall national public health or MOH vision. Similarly, strategic initiatives for LIS with related items of budget, responsibility, metrics and time line should be described in the National Laboratory Strategic Plan (NLSP). If these initiatives do not already exist, the laboratory technical working group (TWG) should be established and should be responsible for developing them.

As part of the visioning exercise, it is important to define the expected outcomes, preferably measurable ones, for this program. This will aid in business case development during this stage and also serves as a basis of a monitoring and evaluation plan to measure the success of the implementation(s).

Facilitated workshops or laboratory TWGs should discuss, define and decide on potential elements of success resulting from the proposed LIS implementation. Success may be defined at multiple levels to cover a variety of aspects like awareness and education on LIS, adoption, behavior changes, as well as aspects focused on the laboratory operations and indicators of performance and improved quality. The following chart may serve as a starting point for discussions.

Discussion Points for Defining Success

Topic	Questions	Points
Awareness and education on LIS	Do all laboratory personnel understand the importance of data and information management and the impact of the LIS on strengthening the laboratory? Do health care providers at the facility and referring healthcare institutions (doctors, hospitals, etc.) know about the LIS and quality improvement initiatives in the laboratory?	This will improve the engagement level and therefore increase the success rate for implementation. Engaging these stakeholders to help them understand the improved operations, quality and turnaround time (TAT) for laboratory results will lead to better patient care as they will more actively engage the laboratory for testing services.
Adoption	Is this the only system authorized by the laboratory management for laboratory informatics activities or do they allow more than one system to be followed? How many users are using the system in comparison with users that went through training and are in the system as users? How many manual workarounds are being done?	Tracking of these on a monthly basis will help in developing trend graphs for analysis and necessary corrective action. For example, additional training, modifications to the system to accommodate the workflow, etc. This information will be gathered from the healthcare institutions and from data analysis. Another success criterion from an adoption perspective is to track the expansion of the usage of system/solution from the initial disease grouping to additional ones.
Behavior changes	Are more patients coming to the laboratory for tests given shorter wait-times to receive test results? Has the faster turnaround time (TAT) and improved accuracy led to better patient care and treatment?	More test orders from physicians.
Laboratory operations	What has been the effect of the program at the lab level? For example, in areas like laboratory capacity, quality metrics, employee morale, employee skill sets, customer satisfaction, ability to meet international laboratory standards, etc.	The use of laboratory and data management indicators such as turnaround times and number of transcription errors are common and useful indicators for measuring the success of the LIS. Assessments also play a critical role in the monitoring and evaluation of the LIS implementation. Developing assessment tools and standards based on the defined success criteria for the laboratory with routine monitoring visits provides valuable data on the success of the implementation.

BUY-IN

Buy-in is a critical aspect of LIS projects as it precipitates strong support, participation and effective implementation. Buy-in occurs on many levels. The program/project charter provides documented support from the project sponsor and senior leadership. The LIS project business case conveys the project justification, expected benefits, chosen approach and costs. Thus, the business case provides a means to further communicate with the stakeholders to make sure they understand and support the project as described. Furthermore, there are numerous potential stakeholders for the LIS project, which are directly or indirectly impacted by the implementation and operational phases. These include stakeholders in the departments and programs within the government Ministry, which will utilize the laboratory data, such as the epidemiologists and leadership in the Ministry of Health's departments of communicable disease prevention and control and the national laboratory program. LIS implementation more directly impacts others at the facility level, including health facility leadership, doctors and clinical care staff, facility IT personnel, and the laboratory management and staff at the facility. Patients are critical stakeholders as well and are directly impacted by both longer wait times in the early implementation stages when laboratory staff gain familiarity with the LIS as well as the ultimate reduced turnaround time once the LIS is fully adopted. All have a role in the development of the LIS and benefit from its operation. Strong communication throughout the project lifespan is necessary to obtain and maintain buy-in and participation at all levels to ensure the successful National LIS Program and implementation.

Program/Project Charter

The LIS program/project charter captures the intent of the initiative and documents the necessary information required by decision makers to approve the project for support and funding. The project charter should include the needs, scope, justification and resource commitment, as well as the project sponsor's decision to proceed or not to proceed with the project. The intended audience of the LIS project charter is the project sponsor and senior leadership. The scope of the charter document could be at the program level and/or at a specific rollout level. This artifact also serves as a reference document during the execution phase of the project.

Business Case

Purpose

The business case captures the reasoning and justification for initiating or implementing the LIS project. Developing a business case helps stakeholders be on the same page in terms of the expected outcomes from the initiative as well as an estimate of the investment. This exercise also facilitates discussion into sustainability aspects of the program beyond the initial implementation. The business case is the responsibility of MOH, the project sponsor and stakeholders. Subject matter experts (SMEs) from cross-functional areas, including laboratory management and laboratory personnel, are active participants.

Development and Structure

Business cases range from formal, comprehensive and structured, to informal and limited in detail. The typical business case involves capturing both qualitative and quantitative impacts and/or outcomes resulting from an initiative. From a return-on-investment perspective, the focus of the LIS business case should be more on positive public health outcomes driven rather than direct financial returns from the implementation. The structure of a business case could include:

- project background,
- expected benefits and cost of doing nothing,
- consideration of options with evaluation and justification of each option,
- project costs, and
- gap analysis between options identified as well as staying with paper-based alone.

The public health outcomes identified as part of the business case focus should align with the success criteria developed earlier. The process of compiling this information has two steps.

1. Compile information on both quantitative and qualitative aspects with respect to current-state, across categories, which serves as the baseline. Note the following:
   - improved data quality,
   - decreased turnaround time in results reporting,
   - betterment in patient care and treatment,
   - development of local/in-country human resource capacity,
   - resulting socio-economic impact, and
   - managing and improving workflow and laboratory practices.
2. Compile implementation costs or estimates. The incremental positive outcomes provide data for the justification.

PROGRAM MANAGEMENT/ TEAM STRUCTURE AND ORGANIZATION

Successful LIS development and implementation hinges on well-organized participants who fit into formal team structures. These structures will result in effective communication and inclusion of relevant stakeholders helping the LIS project and programs evolve.

Organization

Structure and governance mechanisms are critical for the success of the rollout. A typical governance structure comprises four main participant (groups).

1. The sponsor (usually within the Ministry of Health) provides direction, funding and approval of projects.

2. LIS technical working group (TWG) includes membership representing users from all levels of the laboratory system, MOH IT and management and partners who support and/or use laboratory services. The TWG is responsible for setting policies and procedures, monitoring and evaluating the LIS operations and assessing future plans and setting direction.

3. Project management teams (as needed) manage the specific initiatives from budget, tasks, resources, issues and risks and are responsible for implementation, validation and go live of the LIS.. A key person is the project manager who should be hired during the early planning phase and continue on after the system goes live at least until the system is stable and an IT support capacity is in place.

4. Laboratory technical assistance advisor for the program consults and offers guidance. A Human Resources plan should include the project staffing for the first phase and the strategic plan, specific objectives and time line for an IT infrastructure sufficient to support the overall LIS goal.

The implementation partner may be a part of one or more of these groups.

A well-designed and executed project management plan allows for and encourages the team and stakeholders to learn more about the problem domain as the project progresses and provides a

structure for updating the scope, constraints and schedule throughout the course of the project.

Figure 2a includes a typical LIS team structure and organization model as reference for implementation. This model is also used to frame the discussion of this section and as reference in this document. Once the organizational structure is finalized, the next step is to solicit and recruit participating members.

Purpose

These processes offer a mechanism for consensus building across stakeholders on various critical aspects of rollout and implementation and provide a conduit for recommendations to decision makers and funding entities.

Groups involved

- Implementation partner facilitates the development of Governance processes
- Technical Working Group will be involved in the development
- MOH will review and approve the recommended structure
- Lab management and laboratory personnel of pilot sites are informed of the developed processes

Steps

1. Define the team structure/organization for the project

2. Outline the decision-making and conflict-resolution processes.

   - All proposals flow to technical working group (TWG) for reviews.
   - TWG then either rejects or recommends the proposal for sponsor review and approvals.
   - Sponsor body, up on review, will either reject or approve the recommendations.

   A variation of this basic model is to delegate more decision-making power to TWG with vetoing authority resting with sponsors. Delegation could be tiered. For example, any financial decision under certain dollar amount (or equivalent currency) threshold can be reviewed and approved by the TWG. Anything above that threshold is still reviewed and approved by the sponsors.

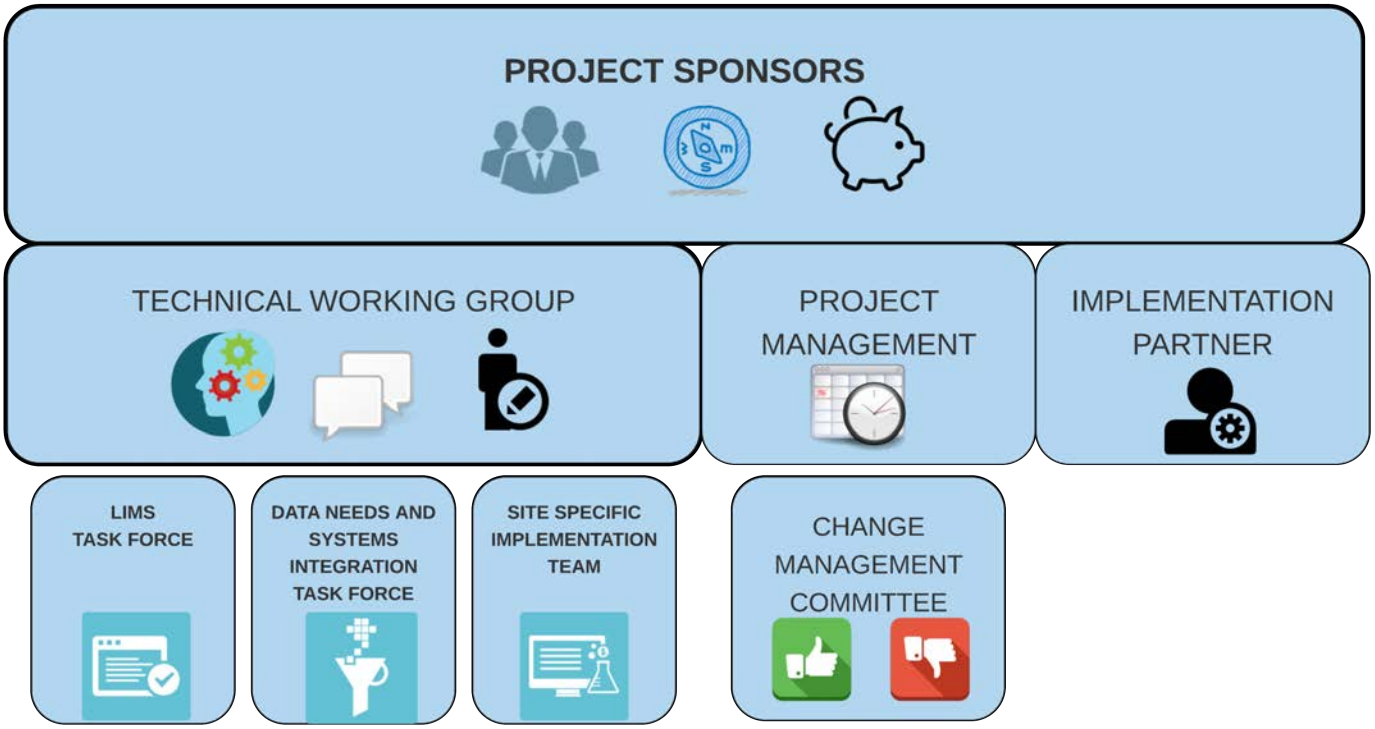
   This model will provide the agility and flexibility for the teams without slowing the project progress.

3. Typically, the Project Management Team is kept out of the decision-making process and focuses on facilitating the process.

Timing

Establishing a governance structure needs to happen as part of the Visioning/Planning process once the TWG is formed. This process will be followed once established.

Figure 2a: LIS Team Structure
The three tiers of the governance structure allow for thorough LIS implementation planning.



Project Sponsor

The project sponsor initiates the project, provides strategic direction, high-level goals, funding and project approval. The sponsor is often the government leadership and donor. For example, the Ministry of Health leadership and US Centers for Disease Control and Prevention have acted as sponsors for LIS projects. The project sponsor supports the project implementation in several additional ways.

- Engages appropriate participants (decision makers)
- Directs and approves project budget
- Deals with conflict resolution and final decision making
- Communicates with TWG and implementation partner through LIS project managers
- Approves final action plan
- Approves scope of pilot

LIS Technical Working Group

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 process from thought to completion.

As previously mentioned, an initial step of the process is the formation of a high-level management team known as the LIS TWG. 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.

The LIS TWG Participants

- Laboratory leadership and policy makers
- Laboratorians representing different levels and programs, especially the national laboratory
- Information technologists
- Partners
- Users of laboratory services or data, such as monitoring and evaluation and disease surveillance and control programs

Pilot sites

The LIS TWG is accountable to the project management team and is key in guiding implementation, critical in getting buy-in, providing the right guidance and starting off the project in the right direction. The LIS TWG should establish a Terms of Reference for the different groups that outlines each group's scope, their purpose and structure. The work of the LIS implementation does not always need to be completed by frequent LIS TWG meetings. Instead, the different task forces may perform more focused work at a pilot site or technical specialty and report back to the LIS TWG.

LIS Project Management Team

A project management team should be established early in the process. In addition to the Ministry of Health, the team should include participants who will take on the responsibility of keeping the project on track. The project management team must implement the LIS while coordinating budgets, tasks, human and financial resources and managing for risks. The team must communicate effectively with all stakeholders and is accountable to the sponsor. The project management team members should have representative expertise in laboratory and/or information systems. Based on an assessment of project tasks that require supplemental or additional capabilities to assure success, an external consultant's involvement should be considered to provide support to the project management team. It is crucial not to underestimate the time commitment required of these individuals to ensure the success of the project.

The project leader can be from the laboratory or information system team if he or she has the necessary skills, abilities and availability. The project leader needs many qualities to achieve success. The leader should have:

- expertise in the area the system is being installed,
- leadership skills,
- interpersonal skills,
- ability to relate to people at different organizational levels with diverse views of the project (e.g., administrators, pathologists, IS personnel, and phlebotomists),
- consideration and respect from other stakeholders,
- the authority to encourage people to work together to complete mutually set goals, and
- knowledge of the time commitment involved and support from their leadership to serve in this capacity.

In-country Project Management Team

- Accountable to Project Sponsors
- Provides MOH guidance and direction on Project Mission Statement
- Co-Chairs of the TWG
- Identifies in-country resources
- Provides hired consultants on the team with needed documentation and direction
- Provides direct input into Project Scope and Time line
- Shares Information/ Decisions from Project Sponsors with rest of the team

LIS Task Force/Subcommittee

A task force/subcommittee is formed (as needed) for a specific task. Members are subject matter experts or identified for specific aspect of the LIS Project. The task force is led or chaired by an LIS TWG member and the Task Force is accountable to the LIS TWG.

Examples of LIS Task Force/Subcommittee

1) LIS Site Task Force

- From Pilot and non-pilot labs
- Core team in defining requirements and identifying gaps etc.
- Coordinate site installation and trainings
- Assist LIS vendor in localizing LIS software and reports for the site

2) Health Indicators/Data Needs Task Force

- Perform an assessment of data that is currently collected, how it is collected (paper/electronic/spreadsheet) and how data is sent to LIS (mail/fax/electronic)
- Indicators of Health
- Laboratory capacity (reagents, workforce, etc.)
- Programmatic uses (TB, AIDS & Malaria control programs)
- Data usage for clinical decision making
- Develop requirements for surveillance and disease reporting
- PEPFAR Indicators

3) Other

- Collaboration opportunities in-country:
    - Critical to collaborate with working groups such as PEPFAR Care & Treatment, Prevention, Strategic Information (SI) Teams
    - With similar groups at the national level as laboratory is a cross cutting program area.
- Collaboration opportunities on-continent:

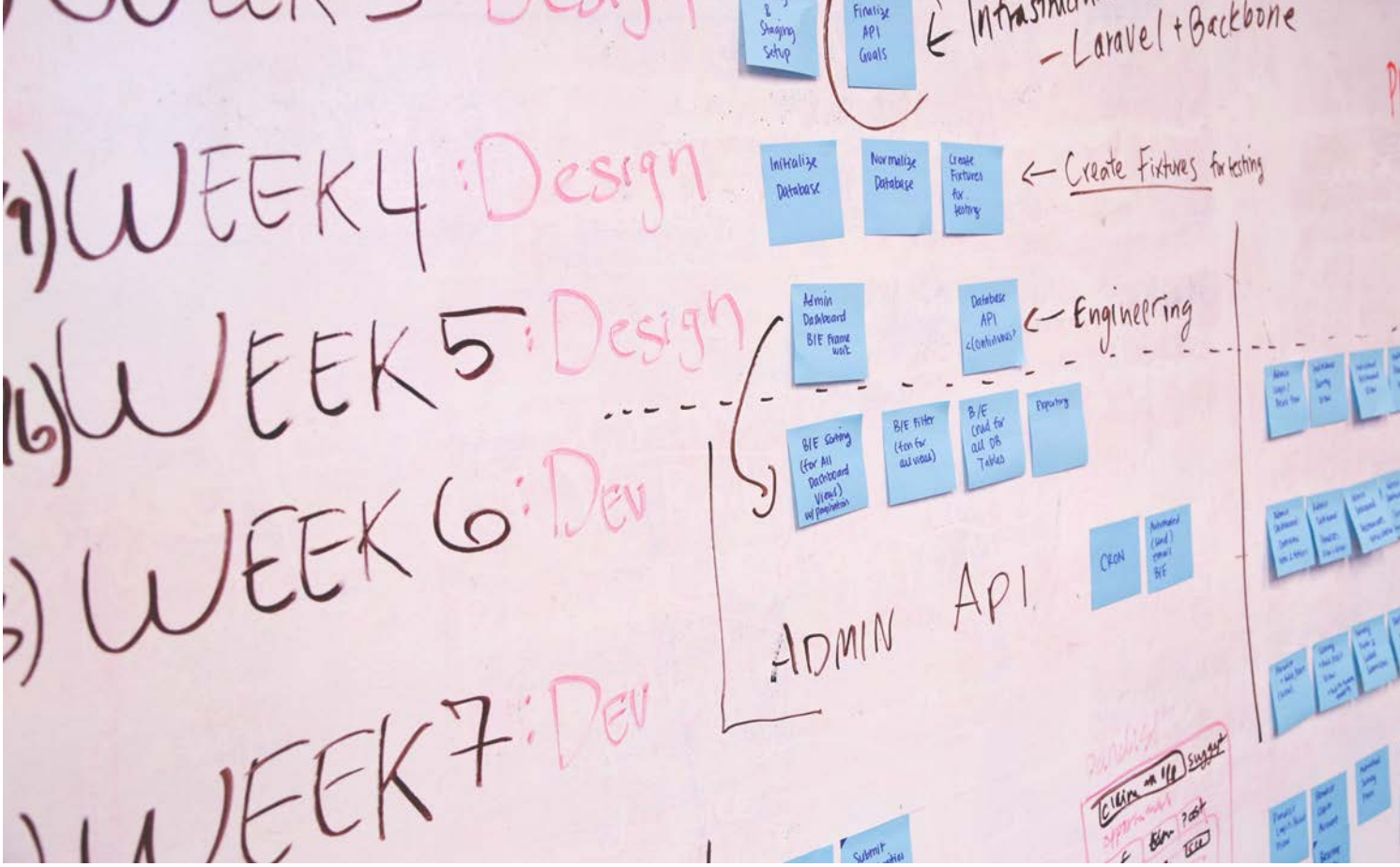
  Collaborate with LIS TWG's or laboratory tech working groups/user groups in neighboring countries to better understand dependencies

Implementing Partner

The implementing partner provides LIS technical expertise and implementation experience to the LIS project to assist the LIS Project Sponsor and Project Management team and ensure a successful LIS program and project. The implementing partner may assist in a range of activities including:

- developing the scope of the LIS project;
- site assessments and requirements gathering;
- development of request for proposals (RFP) to evaluate LIS vendors' applications;
- strategic planning;
- LIS training and education;
- hardware installation;
- IT human resource and sustainability planning; and
- LIS software development.

The implementing partner is a member of the LIS TWG and responsible to the project management team. APHL, for example, fulfills this role in a number of country programs.



STRATEGIC PLANNING

Purpose

The strategy and approach to implement a national LIS program should be developed during the strategic planning phase whether this is a module in a National Laboratory Strategic Plan or a more focused LIS Strategic Plan.

Thinking through the approach and coming up with the short-term and long-term perspective before venturing into the implementation will enhance the success of the program while minimizing any associated risks that arise.

The LIS Strategic Plan should:

- span 3-5 years,
- show clear commitment to sustainable LIS model,
- outline mission of MOH and its vision for LIS,
- outline clear goals and objectives for LIS, and
- be widely distributed and easily understandable by all stakeholders.

The LIS Strategic Plan must also clearly link back to the overall National Laboratory Strategic Plan and Laboratory Policies and provide a framework for the LIS Operational or Action Plan.

Development Process of LIS Strategic Plan

The development process for the LIS Strategic Plan should follow core development principles and an established formula (process) for development.

Inclusiveness: All stakeholders are involved.

Participation: All relevant groups participate.

Consultation: Relevant individuals, government departments, national and international organizations are meaningfully consulted or informed during the process.

The process to develop strategic plans in the laboratory setting is well established. This process can be applied to the development of a LIS Strategic Plan and includes four main steps.

1. Define mission and vision.

2. Create a strengths, weaknesses, opportunities and threats (SWOT) Analysis and use it to define the short- and long-term goals and strategic objectives. The goals and objectives should be specific, measurable, achievable, realistic and timely (SMART).

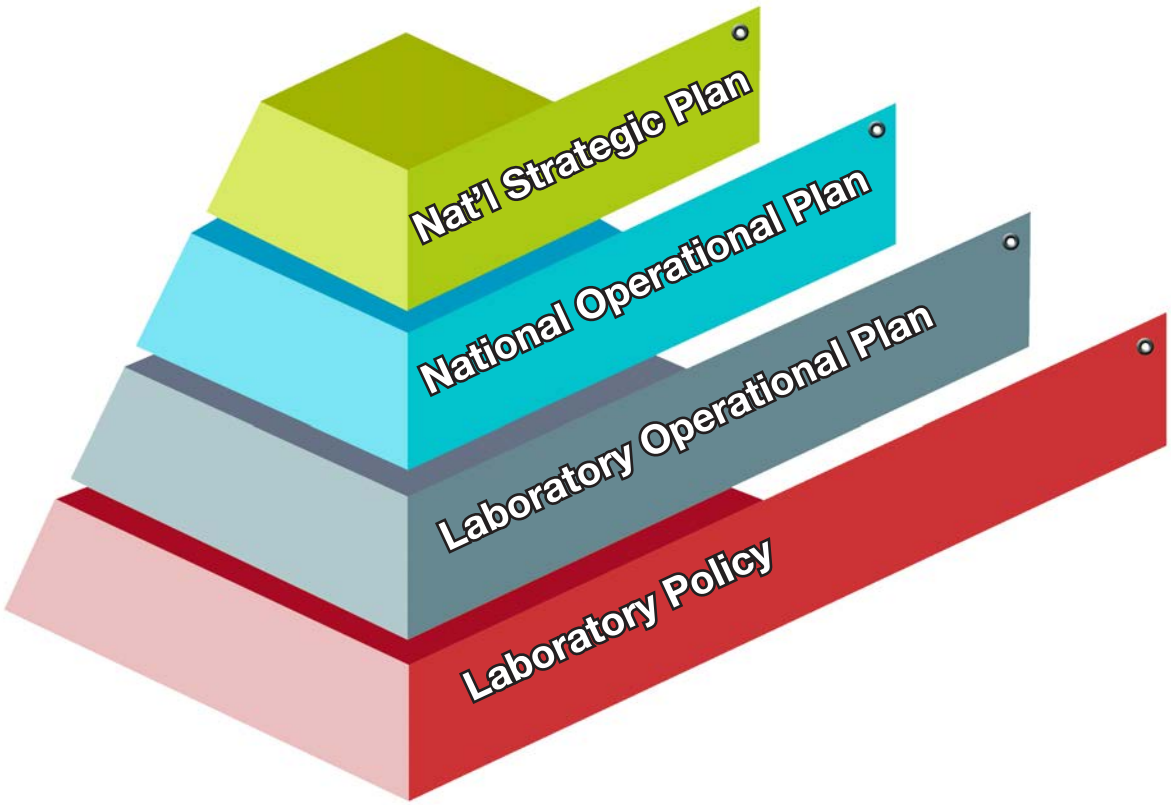
3. Use strategic plan information to create operational/action plan. Use strategic goals and objectives to identify discrete activities or projects required to accomplish the work of the strategic plan (e.g., infrastructure strengthening; RFP development; standardization of laboratory forms). Identify fiscal and human resources and assign ownership of specific objectives. Define the time line and time frame, while continuously assessing feasibility and monitoring the plan's progress

4. In the SWOT analysis, identify issues or problems that need to be changed, identify resources, responsible parties to be used in helping to reach goals and timelines and budget.

Possible Pitfalls of Not Following this Development Process

- Unrealistic objectives
- Scope creep or changes in a project's scope after it begins
- Lack of long-term funding
- Lack of buy-in/consensus from project members
- No "responsible parties"
- Lack of continual communication

Figure 2b: Hierarchy of the National Laboratory Policy, Strategic Plan and Operational (Action) Plans



Summary and Examples of LIS Strategic Plan

The LIS strategic Plan development process including the associated review of policy guidelines, environmental scan and a SWOT analysis, leads to a three- to five-year strategic plan that sets the mission, vision, objectives and goals. It also produces an LIS action plan (typically one year) that provides tasks and actions with responsibilities, timelines and budgets. It is critical to involve the right people and produce plans all stakeholders will implement/understand. Refer to Appendix C.

APHL HQ staff at the 2016 ASLM meeting held in Cape Town, South Africa. APHL had several posters on the laboratory informatics projects supported in various countries (Reshma Kakkar, Sherrie Staley, Ava Onaiaja)

IMPLEMENTATION OF LIS AS A NATIONAL PROGRAM

The process for the LIS program implementation is described in four parts: national laboratory strategic plan, national laboratory operational plan, laboratory operational plan and laboratory policy. The program implementation steps should be viewed as a whole, since the outcomes from each step influence the others and, together, play a significant role in determining the program's overall level of success. The process should include feedback loops to improve the program effectiveness. It is often useful to start small and then expand as the experience and the capacity of the team and staff grow. For example, this document may initially guide the development of a "pilot" project or a limited scope project and subsequently develop a multi-year, countrywide LIS utilizing the experience gathered from a pilot project. The pilot project serves as a learning experience, as well as the foundation for a strategic planning process for subsequent scale-up or expansion.

Implementation Approach

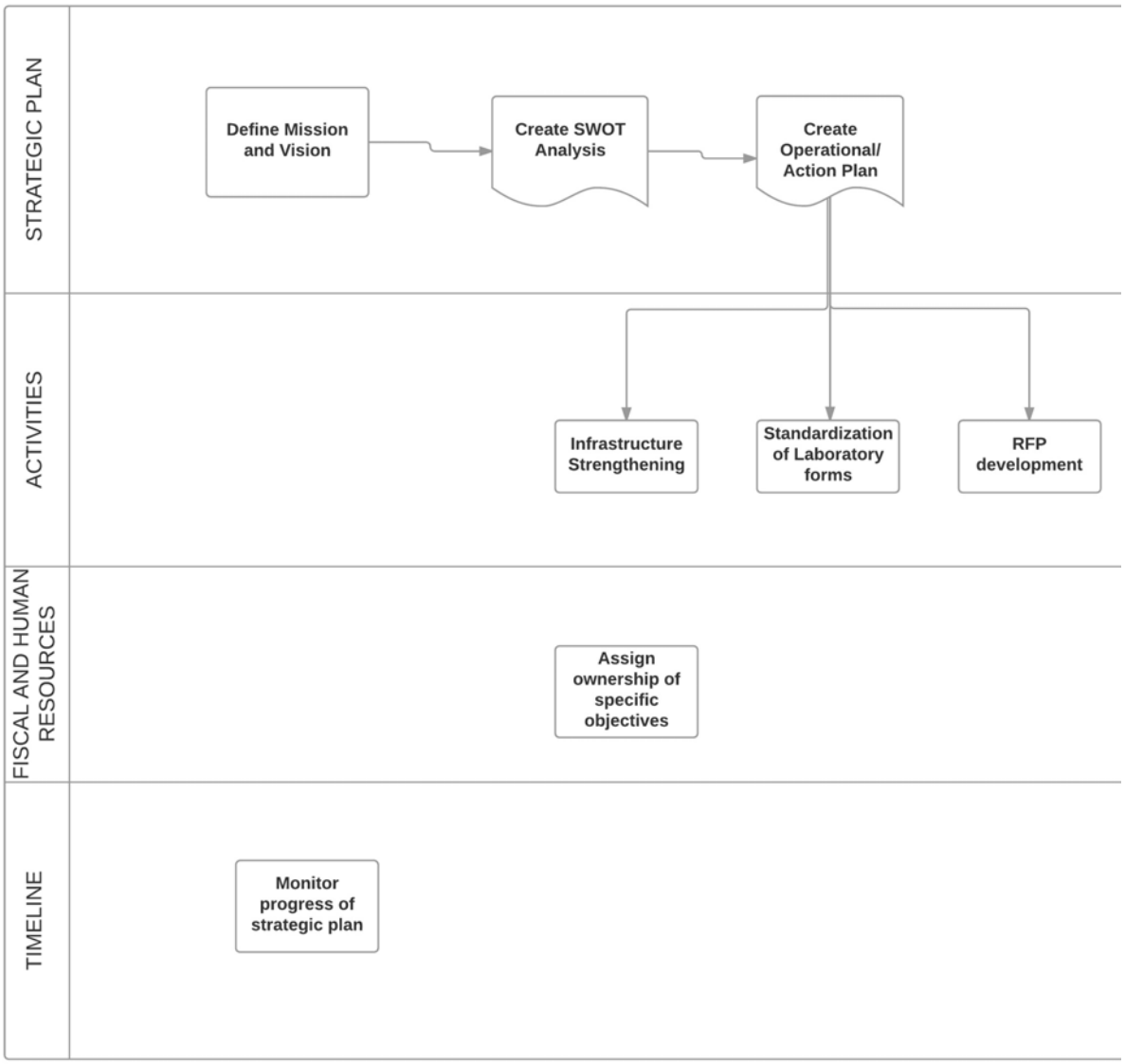
The objective of a typical LIS National Program is to improve information management, data collection and reporting and provide enhanced quality laboratory testing services. Two core implementation principles help ensure its success.

1. Commitment: MOH should approve and own the plan, while other agencies should support the plan.

2. Continual process: The plan should be governed by a process of continuous improvement and be flexible in approach with yearly check points on feasibility.

To support a National LIS Program there are two basic implementation approaches:

Figure 2c: Implementation of LIS as a National Program



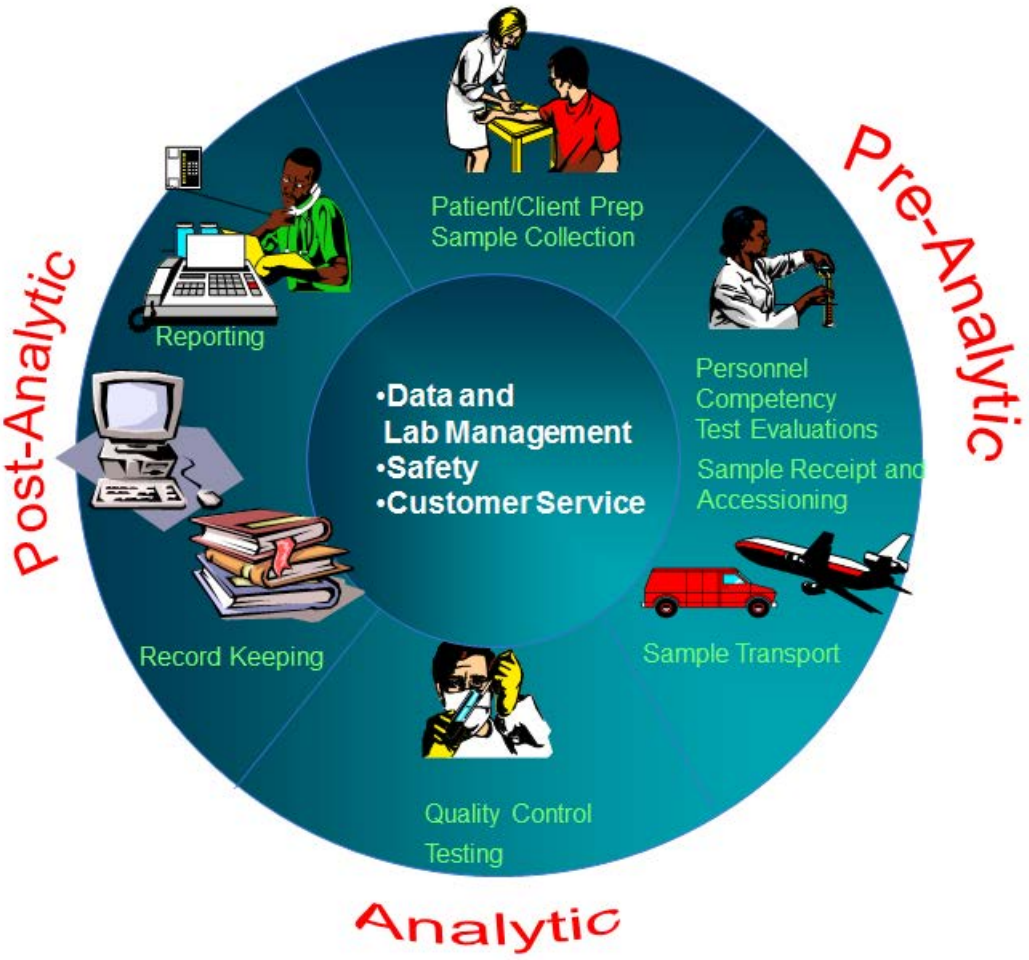
1. Strengthen paper-based LIS at low-level laboratories or throughout the laboratory network.

2. Install electronic LIS at the central, regional, provincial, reference and/or district hospital laboratories to collect, aggregate, analyze and manage laboratory data.

The specifics and scope of each installation may vary significantly with consideration for the priorities and resources available. For example, it may be necessary to consider strategic vs. tactical priorities. The selected solution should be scalable to all types of tests performed within the national laboratory system while the initial scope of the initial implementation or pilot phase could be for a particular laboratory section or type of testing capability such as chemistry or immunology.

The following illustration depicts a spectrum of LIS options relative to laboratory level and function beyond those just noted.

Figure 2d: LIS Sustainability Components



Paper-Based Information System

Standardization of the paper-based information system (paper IS)—including standard request forms, registers and data reporting forms—is a critical component to strengthen the LIS. In limited-resource countries, the paper IS will usually represent the most common system found in laboratories and the largest source of data. The paper IS must be developed to serve the needs of laboratories at all levels. Even if the range of laboratories require different forms, they must use the same set of standards for definition of data elements and content.

There are two objectives that necessitate the strengthening of the paper-based system.

1. To improve information management, data collection and reporting throughout the laboratory network.

2. To standardize the paper IS before initiating a LIS pilot or rollout. In this case, implementation of paper IS solidifies the requirements for the automated system and leads to an effective selection and implementation process. Also, this fine-tunes the paper IS for a later rollout of electronic LIS in lower-tier laboratories.

Approach to Development

The standardization and strengthening of the paper IS should be treated as a mini-project by itself. APHL has developed a framework for a standard paper-based system that can be used as a model or reference to assist in this effort. Below are seven steps to follow.

1. Plan the introduction and release.
2. Scope it to only one or two laboratory test sections.
3. Leverage the methodology and training materials developed by APHL from prior implementations in other countries.
4. Plan and conduct training to accommodate the change.
5. Ensure pre-printed stationery and other necessary items are available at the laboratory.
6. Be onsite for the initial week or two to provide the necessary support.
7. Capture any necessary tweaks or changes to the steps planned for roll-out to use in future rollouts.

There may be multiple variations of logbooks and registers across the in-country laboratories. APHL's paper-based system can be used as a baseline to simplify and standardize the tools used in labs, to introduce the customized paper-based system to pilot labs, to use the lessons learned to enhance paper-based systems for wider use and to refine the requirements for the automated solution. This also facilitates an easy transition from the paper-based system to an automated system as it becomes available and introduced.

The project management team will need to provide the necessary support from planning and execution of this step, while the process will be completed by the LIS TWG and/or task forces assigned to strengthen the paper IS. An implementation partner may also bring subject matter experts and experience with the process. Active participation from pilot labs is critical for a successful outcome.

Timing

The initiation of standardized paper systems should be carried out after the design of a paper-based system is approved but before publishing the RFP for an automated LIS.

LIS Pilot and Selection of Sites

Purpose

The LIS pilot is important to test the system and implementation approach, develop resources and expertise, and evaluate and serve as a model with lessons learned for future deployments. Pilot site selection is one of the initial steps to be completed once the Technical Working Group and Project Management teams are formed and the RFP process is completed. The number of pilot sites should be small to minimize complexity. Two to three sites is a good number for Pilot implementation.

Future expansion and rollouts depend on the success of pilot site implementation. Establishing the criteria for pilot site selection early on in the process is even more important than selecting the

pilot sites themselves. LIS TWG and project management teams can then select sites at a later time, provided they meet these criteria. It is also important to recognize that the goal of a pilot can be more than pre-staging for the roll out of the LIS to additional sites.

The pilot can serve as a proof of concept exploration and to build project momentum. These are inherently competing objectives and, therefore, planning groups must strike a conscious balance when planning the pilot to ensure appropriately placed emphasis.

Groups Involved with Pilot Site Selection

- The LIS technical working group (LIS TWG) is responsible for establishing the criteria for pilot site selection and for short-listing the sites.
- The sponsor should review and approve the list.
- Laboratory management of proposed pilot sites should be involved in the final decision and sign-off on the project charter.
- If applicable, information systems group supporting these labs on-site should be involved in the final decision and sign-off on the project charter.

Steps Involved with Pilot Site Selection

Before choosing a pilot site, selection participants must accomplish two main two main steps:

1. Development of a mini-charter for the pilot by the project management team to list pilot goals so they are clearly understood by all stakeholders

2. Development of criteria for selection of pilot sites (see chart for more detail).

To minimize complexity, the country's Ministry of Health should approve only two or three sites for pilot implementation.

It is often helpful to plan to do more than one pilot. This allows focus on different aspects of the project risk profile with each. For instance, an early proof-of-concept pilot with a more established laboratory can help ensure that the system can fulfill the organization's complex needs. A second pilot with a remote laboratory can allow the team to reflect and refine the rollout process based upon what they experienced in that scenario.

If the objective is to understand the challenges to implement in a remote site with unstable infrastructure, then make a conscious decision whether to include the foreseen challenges in the initial pilot or defer them to the second pilot. Including the challenges in the initial pilot will increase the complexity, as it adds more "unknown" parameters.

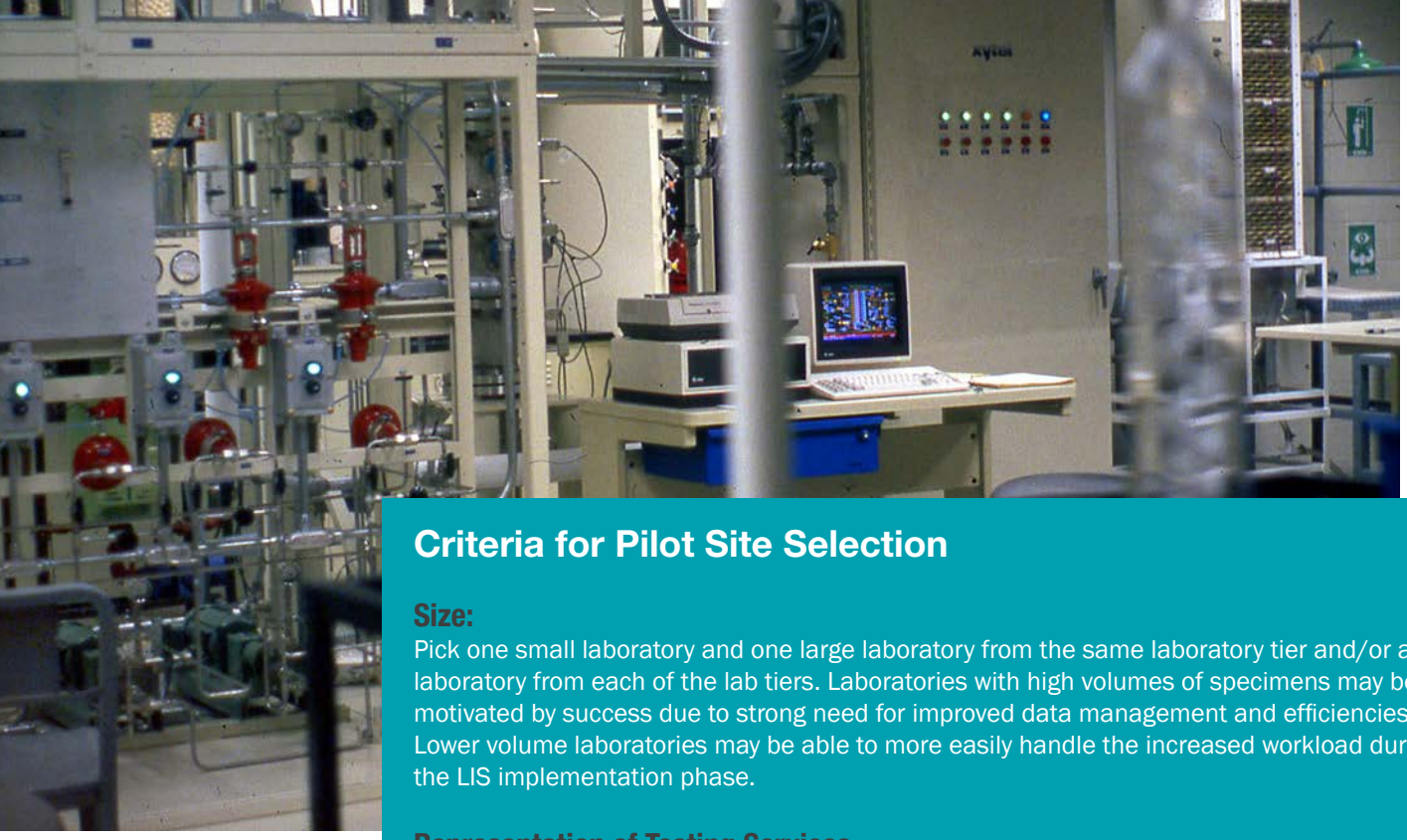
Timing of Site Selection

Pilot site selection is one of the initial steps to be completed once the LIS TWG and project management teams are formed and the RFP process is completed.

Unknown Parameters

Level of interest from laboratories to participate, both from lab management and lab personnel point-of-view. Buy-in to the concept, understanding the benefits from modernization and commitment to participate from pilot labs is critical for success.

For more on the implementation of the LIS at the pilot site, please refer to the section on LIS in the Laboratory.



Criteria for Pilot Site Selection

Size:

Pick one small laboratory and one large laboratory from the same laboratory tier and/or a laboratory from each of the lab tiers. Laboratories with high volumes of specimens may be motivated by success due to strong need for improved data management and efficiencies. Lower volume laboratories may be able to more easily handle the increased workload during the LIS implementation phase.

Representation of Testing Services

Select one or more laboratories that are typical and represent the testing services that could be included in the first phase of the LIS such as the number of programs supported, tests and related services (i.e., HIV, TB, malaria control, etc.). The selected laboratories should generate data that is needed for public health surveillance and can be captured and reported by the LIS, thus meeting the laboratory's informational needs. Alternatively the focus could be on use of the LIS for operations optimization and automation thus satisfying the laboratory's functional needs. These attributes will provide data for decision-making and valuable information for scaling up or rolling out the system to additional sites or specific laboratory programs. During the initial implementation phase, it may be decided to include only HIV testing (rapid, EIA and confirmatory) or it may be decided to include HIV testing, chemistry and hematology testing services in the first phase of the implementation.

Logistics

Physical location of the laboratory from an accessibility perspective can be important. Access to reliable infrastructures like electricity and telecommunications and space for the LIS computer and hardware components can figure heavily into the decision process.

Supportive Laboratory Management and Personnel

This takes into account the level of interest in participation from the points-of-view of both laboratory management and personnel. Support for the concept, an understanding of the benefits from modernization and a commitment to participate from pilot labs are critical for success. Consider laboratories that have shown effectiveness and eagerness in other laboratory quality improvement initiatives at their facility, as well as laboratory management that have effectively participated in or supported national or regional laboratory strengthening programs.

Technical infrastructure Already in Place

If there is a good representation of laboratory instrumentation from laboratories across the country, or from a "go-forward standards" perspective, then it will be a good candidate for the pilot. In addition, if the laboratory already has some computer systems in place, then focus can be placed on a LIS implementation.

Expansion

Expansion in this context is about going beyond initial pilot implementation. At a high-level, there are two categories of expansion:

1. rollout of the solution beyond pilot sites, and

2. enhancing the solution with more features and capabilities.

Thinking through the financial aspects and budget for any expansion is critical.

Rollout Beyond Pilot Sites

Even though the purpose of a pilot site is to fulfill the vision of improved patient care and optimize laboratory environments, disseminating the solution at the local and country level will be significant. Also, by looking beyond the pilot implementation, the team will have a better negotiation advantage with vendors. This follows the step-wise approach for the program that began with the pilot implementation and incorporates the lessons learned in each future rollout.

Consistent implementation will facilitate simpler infrastructure, streamlined processes and optimal platform for human capacity build-up.

Expansion Participants

- Sponsors to provide guidance and to ensure financial viability
- The LIS technical working group to lead the initiative
- Task forces facilitating migration towards the consistent implementation while being sensitive to local context and accommodating them as appropriate.
- An LIS vendor providing the support for planning and implementation

Expansion Steps

1. Group the number of sites for each rollout into batches and keep the batch size to less than six for better manageability. The criteria in selecting the sites should be based on the pilot site selection criteria.

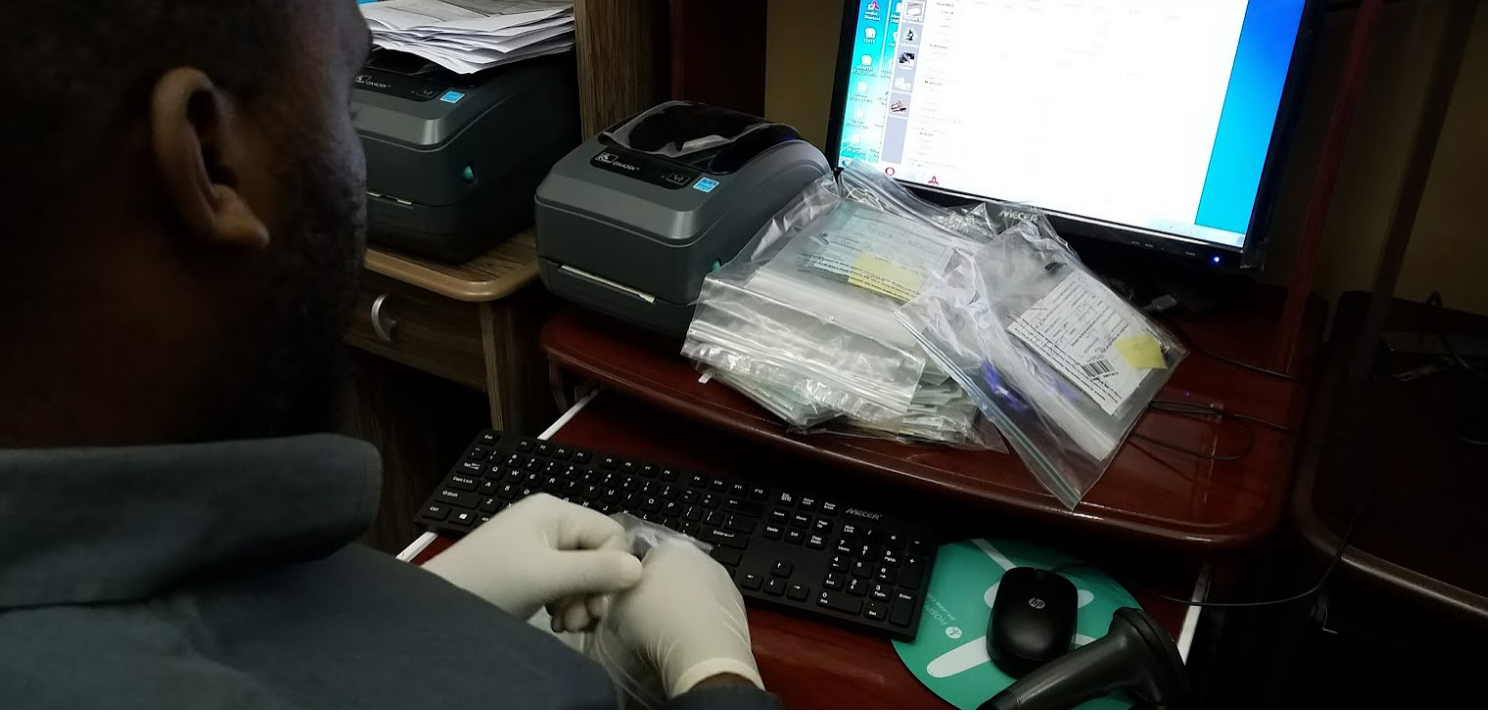
2. The project should be modeled on pilot implementation with appropriate modifications based on the experiences gained during the pilot rollout.

3. Sustainability aspects are considered and updated as more sites adopt the solution.

Timing of Expansion

Any planning for post-pilot expansion should be done as part of visioning phase in developing the overall rollout framework. Include the framework during vendor negotiations, design and implementation to ensure scalability.

Consider starting the next phase of rollout once the initial pilot rollout is complete and the project reaches a stable state. This will leverage the positive momentum and infrastructure from the pilot phase.



MONITORING AND EVALUATION

Measuring the success of the LIS project is critical to show the return on investment to the sponsors. Development of a strong monitoring and evaluation plan early in the project lifespan will help measure the success of the LIS project and may also be utilized to manage the expectations of the laboratory, stakeholders and sponsors. Laboratories must monitor the progress of the implementation, identify gaps and areas for further improvement, and to provide data for evaluation and consideration on the future of the LIS project.

This section explains the development and use of indicators and assessments to measure success pre- and post-implementation in the laboratory environment, describes quality improvements achievable via LIS implementation and presents methods of developing assessment tools to monitor and measure success.

Indicators

The use of indicators is an important aspect of a monitoring and evaluation plan. The laboratory domain and information systems utilize standard indicators to monitor quality.

- Transcription errors
- Turnaround time (TAT)
- Translation errors

Automated aspects of the LIS—such as barcode readers, labels and the interface of the LIS software with analytical instrumentation—can reduce errors and turnaround times. However, the LIS project may increase the time for completing certain aspects of testing, especially early in the implementation and adoption period. An LIS provides the opportunity to improve efficiencies in the laboratory (visible in the turnaround time indicator) and in compiling statistical reports significantly faster than if performed manually. The table below provides an example of the three indicators presented in this section and the data they provided on the LIS implementation at four sites.

Indicator Monitoring Example at Four Laboratories Pre- and Post-LIS implementation

	Transcription Errors/ Month		Av. TAT of Archived Report Retrieval		Time to Compile Monthly Statistics	
Lab	**Pre**	**Post**	**Pre**	**Post**	**Pre**	**Post**
A	820	0	6 min	<1 min	96 hrs	<5 min
B	51	0	9 min	<1 min	2 hrs	<5 min
C	175	0	3 min	<1 min	24 hrs	<5 min
D	151	0	3min	<1 min	32 hrs	<5 min

The laboratory quality management system and quality improvement also provide other potential laboratory quality indicators.

- Specimens registered prior to testing
- Levey Jennings charts plotted daily for all quantitative tests
- Ability to link Lab data to Electronic Medical Records (EMR) or other Health Management Information Systems (HMIS)
- Staff trained in basic computer and software skills
- Audit trail available
- Ability to track TAT
- Electronic backup of data

Assessment

There are a variety of options to measure success.

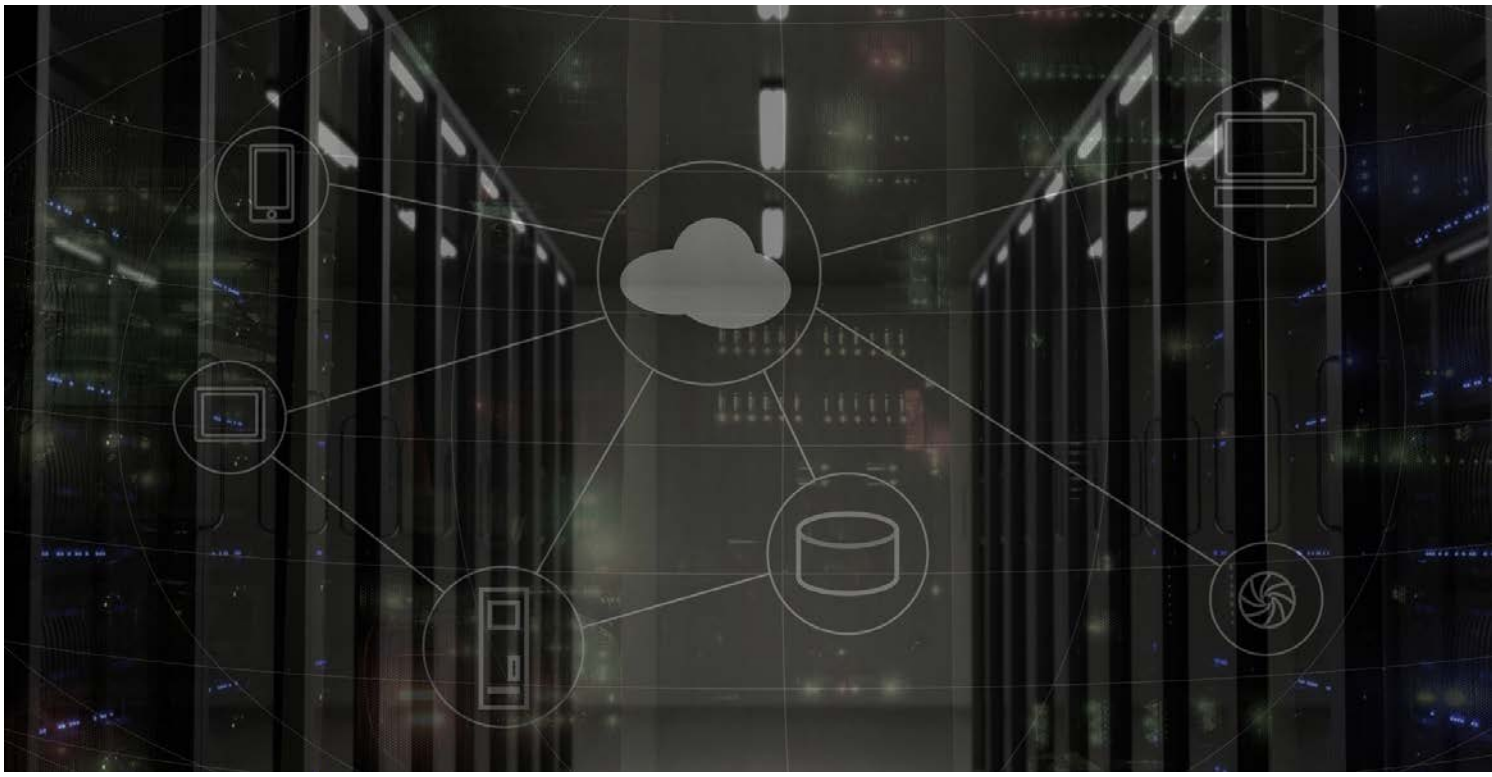
1. Develop a country-specific assessment tool.

2. Use SLIPTA checklist, the guidelines in ISO 15189:2012 Section 5.9: Information Management (see Appendix E).

Laboratory assessments should occur approximately six months and one year post-implementation—it takes time to establish the assessment system within the individual laboratory. A simple scoring system that allows for assessment of the LIS in the laboratory against previously developed success criteria should be employed to monitor and compare performance over time. A section for non-conformity reporting and written recommendations should also be included.

Sample Assessment Summary Results 6 months and 12 months post implementation (%)

Time period following implementation	Lab A	Lab B	Lab C	Lab D
6 Months	70	68	70	68
12 Months	61	88	88	88
% Improvement	-9 (various challenges)	20	18	20



USE OF DATA TO SUPPORT PUBLIC HEALTH SURVEILLANCE

Public health and clinical laboratories support testing for patients, surveillance and outbreak response. These data are valuable to the national laboratory program for monitoring diseases and outbreaks, distribution of workload across laboratories, quality assurance and are of significance to epidemiology teams and prevention and control programs.

Clinical

The clinical system requires laboratory data to manage and care for the patient. The clinical case may be suspect or initial results may be provided by a clinical laboratory using routine diagnostics or rapid tests. The public health laboratory will conduct a confirmatory test and these results need to be reported back to the clinical site. If it is a reportable disease, these must be reported to the appropriate department/entity for prevention and control.

Outbreak/Notifiable Disease

Lab testing in response to outbreaks is conducted in response to notification. Protocols are existing or established to determine case definition and testing requirements and a list of laboratories approved to conduct testing for specific pathogens. Outbreak numbers are established to link tests conducted by approved laboratories for each outbreak. It is important the test results are communicated back to back to the clinical system and associated patient. At the same time, outbreak reports and access to these data need to be provided to appropriate entities responsible for prevention and control.

Surveillance

Surveillance systems are established for previously identified diseases which provide passive or active monitoring. These surveillance systems support local and national surveillance programs at the departments of prevention and control and may also be linked to broader regional programs. Electronic systems exist for collection and reporting of these laboratory data such as Flunet, WHONet and Measles.net. Linking central public health lab data to these systems would enhance reporting and surveillance systems.

To facilitate the outbreak response and clinical needs of a national laboratory program, a central laboratory data repository can be invaluable. This repository that collects, stores and analyzes data from multiple laboratory facilities to support national health programs and research. The purpose of the central database may be to:

- provide information to manage a national laboratory program;
- support the transmission of laboratory data for disease reporting, surveillance and outbreak response;
- link patient level data at multiple sites to support patient care; and
- provide de-identified data for research.

National Lab Program Central Database

There are disease reporting information systems available for reporting clinical diagnosis of diseases. They may be developed based on national disease reporting guidelines and regulations or provide an architecture with ability to develop and customize. An example is DHIS2, which provides aggregate clinical data for disease reporting in many countries. Individual diseases may also have their own systems for reporting laboratory data (e.g., WHONET, Flunet and MeaslesNet). These systems may also have the ability to collect patient level laboratory data or individual level clinical data for outbreak response.

However, there may be a need to separately compile the laboratory data from LIMS electronic and/or paper systems at multiple facilities and provide timely data for the national laboratory, disease reporting, surveillance and outbreak response. This integrated laboratory central database could support the tiered lab system and link to the disease reporting and surveillance systems for epidemic prone diseases such as HIV, flu (routine & emerging), measles, EVD, yellow fever, cholera and shigella. The national laboratory program could utilize this data to monitor the laboratory system outbreak response, quality control and supply chains.

Having a central database to collect these data, connect to other systems and allow access to these data helps establish the networks in a tiered laboratory system and links to epidemiology, surveillance and response programs.

Challenges and Lessons Learned

The following challenges and lessons learned are based on several decades of experience implementing and managing LIS, distributed across subject matter experts and across continents. The list is detailed, but not exhaustive, and is intended to give users enough information to be prepared.

Challenges	Reasons for Successful LIS Implementations	Lessons Learned

• Shortage of skilled staff
  ○ Numbers
  ○ Understanding of principles
• Infrastructure: electricity, temperature
• Equipment repair
• Supply chain: local, cross-border
• Information handling (lack of LIS)
• Sustainability
• Unstandardized HMIS systems that should be integrated to LIS
• Analytical equipment that cannot be interfaced with LIS
• High staff turnover especially for LIMS Administrators
• Lack of buy-in from laboratory management
	• Well defined requirements
	• Sufficient resources/funding
	• Comprehensive process for vendor/application selection
	• Maintaining defined scope of project
	• Strong communication internally, as with sponsors
	• Commitment and leadership
	• Strong project planning and project management
	• Managing expectations of users or sponsors
	• Human resources
	• Governance (strong)
		• Define requirements clearly
		• Select appropriate software vendor/application
		• Utilize domain expertise
		• Support and direction from senior management
		• All customizations should add value
		• Well defined accountability, roles and responsibilities
		• Include all stakeholders
		• Involve appropriate users in process
		• Plan data load, testing/validation, training and support
		• Ensure necessary communication

SUSTAINABILITY: ENHANCEMENTS AND EXPANSION

Every aspect of LIS maintenance must be sustainable and scaleable, which means it should be able to continue over a period of time, be maintained at a certain level and have the capacity to endure and adapt based on ever-changing data needs. Several factors affect sustainability.

- Good communication
- Sharing of resources and expertise
- Awareness of ongoing costs and ability for continued funding
- Willingness to learn from the past, i.e., implement lessons learned
- Flexibility
- Collaboration and involvement of all stakeholders
- Sharing good performance/performance indicators (e.g., downtime)

The LIS National Program must be maintained to ensure continued operation of the LIS sites; doing so will improve access to laboratory data for decision-making and disease reporting and will support public health initiatives. The LIS health facility and laboratory must also support sustainability at the site level. There are several areas of focus to support sustainability of the LIS National Program.

- Financial
- IT Human Resource Plan for LIS Deployment, Maintenance and Support
- Hardware Maintenance and Support
- Creating Value with the LIS Solution

Financial

The implementation of a LIS program requires significant resources to support the National Program and sites. Sustainability of the LIS thus requires an evaluation of the costs of the National Program; scope of the project and the support needed at the site level to identify needed financial resources. This takes place initially as part of the visioning exercise discussions, but should be updated regularly during the annual budget process and as key decisions are required in the implementation phase. For example, whether to expand beyond pilot sites or enhance the solution with custom modifications, project-based funding is necessary. Without a properly aligned budget, the solution cannot be enhanced and be kept current with user needs and opportunities.

Methodology

- Make this part of visioning exercise discussions. Try and have a definitive answer regardless of decision to have a budget or not to have a budget for this purpose. That clarity will drive lots of decisions and negotiations down the line after visioning.
- It may be difficult to determine exact amounts at the early stage of implementation, so focus on developing a framework approach. In other words, identify potential funding sources over the course and duration of the program.
- Use the annual budget planning to finalize numbers for subsequent periods.
- The rollout of LIS releases and upgrades by the vendor could be part of the operational budget as it potentially doesn't require any special capital outlays and is covered under annual maintenance fees.

LIS Cost Estimates

Budget Category	Details
Project Management	• Assessment, planning and design • Implementation partner • Requirements and RFP bidding process
LIS Software and vendor services	• Licenses • Customization, configuration and localization • Technical support and maintenance • Training
Installation Costs	• Development of detailed functional specifications and changes needed to meet requirements • Training • Hardware (Computers, barcode printers, normal printers, surge protection) • Computer network and Internet • Software (Server OS, Database SQL, Antivirus, Computer OS, Office software)
Human Resources	• Project coordination • Staff for training • Staff for system support • Staff for project management support • Staff for maintenance • New positions • Technical assistance • Current laboratory staff needed for requirements gathering, validation and intensive training (additional paid hours) • Backfilling
Operational Costs	• Utilities (electricity, telecommunications, back-up generator, etc.) • Replenishing of supplies (printer toners, bar code labels, stationery, etc.)

Key considerations to secure funding

- Understand funding requirements, constraints and limitations
- Facility level support (fee for service possibility)
- Support from National Program
- Present success and value of the LIMS to sponsors
- Include in planning phase
- Ensure that cost estimates are realistic and accurate
- Include cross-functional review
- Determine long term sustainability cost
- Plan for IT Human Resource

As the LIS National Program matures and the installations at the site level are more established, accurate costs of the LIS program and the needed resources to sustain the program can be determined. Access to financial resources and capabilities to support and maintain the LIS vary widely from site to site based on country and on facility. After the value and benefits of the LIS at the facility level become clear and the costs are determined, the laboratory site and facility should try to assume operational and maintenance costs. This may be more appropriate at larger facilities or hospitals that can charge a fee for service. Certain sites connected to health control programs may be fully reliant on National Program support; therefore, it may make sense to categorize facilities and map their budget resources while developing the sustainability plan. The sustainability plan must also identify the human resources and required budget for the IT maintenance and support from the LIS National Program, as well as at the site or facility level.

The LIS IT Human Resource Plan Framework

1. Identify the available IT human resources to support LIS deployment, maintenance and data usage
   - LIS Vendors
   - Facility-level IT personnel (e.g., hospital IT staff at the LIS site)
   - LIS supervisors in the laboratory
   - Possible government or MOH-level IT department
   - University IT programs
   - Hardware suppliers with associated IT software and hardware support
   - Private companies with IT software and hardware training programs
2. Clearly define roles and responsibilities of IT human resources deployment, maintenance and support.
   - LIS software
   - Computer network and hardware
3. Develop educational resources to support learning and user guides to provide clear documentation.
4. Include training program to build capacity of key local IT human resources.
5. Budget to support the needs of the IT human resource plan, as well as incentives and retention programs.

Development of an IT Human Resource Plan for LIS Deployment, Maintenance and Support and Building Capacity

Human resource planning is critical for a project's success. The LIS National Program should include a developed and updated IT human resource plan to build the local IT human resource capacity, which reduces costs, response times for troubleshooting, and improves sustainability. The HR Plan must comprehensively cover all staffing needs; it must have a budget to support the needs, incentive and retention programs and training and in-country capacity building and processes to increase data utilization, among other things.

Deployment of the LIS is often performed by the LIS vendor; however, aspects of this deployment may be performed by the local IT human resources as the LIS National Program matures. Additionally, local IT staff must support and maintain the LIS software, network and hardware with limited, if any, downtime.

While IT support availability will vary by setting, developing countries must also contend with infrastructure weaknesses (e.g., electricity, IT) that may cause interruptions, computer viruses and damage to the system.

IT HR Plan involves the following groups:

- The project management team that owns the task
- The LIS TWG, working with the project management team, should perform the analysis and formulate an approach.
- Subject matter experts (SMEs) from cross functional areas, including laboratory management and laboratory personnel, could be active participants.
- The sponsor and TWG are responsible for ensuring the approach is thorough and the mechanisms/framework are in place from a fiscal budget and allocation perspective.
- The implementation partner serves in a consulting role.

IT HR Plan involves the following steps:

1. A comprehensive plan from a project and post-project perspective

    a. Project/Roll-out :

        i. Develop an inventory of skill sets and map them to the roles needed during the project

        ii. Conduct a conscious assessment in terms of availability and skills from internal resources perspective

        iii. Consider hiring external resources (i.e. consultants) for the short-term while developing the local talent in the long-term

        iv. Explore Pre-service opportunities with local academic institutions

    b. Post-Project

        i. Assess the needs to support operations, post implementation.

        ii. Conduct a conscious assessment in terms of availability and skills from internal resources perspective

iii. If any new positions are identified then proceed with recruitment so the person can join the project team at its onset and will be able to have the necessary hands-on experience

2. A fiscal budget

   a. Understand the level of effort and allocate budget to accommodate any additional work staff are required/expected to perform during the project. This should be of a finite duration and typically for a shorter period. For example, double data entry by laboratory personnel during parallel testing.

   b. Conduct a fiscal budget planning and allocation session to ensure sustainability over the long term.

3. Pursue a centralized/shared services approach as the core model and deviate to a dedicated resources model as an exception.

4. Consider "train-the-trainer" approaches to develop in-country capacity. This will also reduce the costs for subsequent rollouts.

5. Use the "typical roles" provided in the Appendix as a baseline to seed the discussion and map out the gaps.

6. The HR Plan, especially the post-project component, should be one of the key inputs into system's architecture requirements and/or preferences.

Timing:

The baseline HR Plan needs to be developed as one of the initial deliverables of planning phase. This may go through subsequent revisions as the project progresses. Any change to the baseline and or assumptions should go through the review and vetting process prior to adoption.

Development of a Hardware Maintenance Plan: Replace Outdated and/or Malfunctioning Hardware, Troubleshooting

See Appendix G for examples of hardware maintenance tracking.

Creating Value

Creating value for the LIS involves continuous improvements to the original solution with more features and capabilities than the baseline version deployed during the pilot phase. Enhancements happen primarily to accommodate deferred functionality from previous phases and priorities, solve any issues discovered post-rollout and leverage upgrades done by the vendor as part of enhancing their product. These enhancements may include the regular version upgrades offered by the vendor.

Creating value involves the following groups:

- Sponsors to provide guidance and to ensure financial viability
- The TWG to lead the initiative
- Task forces to identify and prioritize the incremental enhancements
- The LIS vendor providing the support for planning and implementation

Creating value involves the following steps:

1. Prioritizing the features/requirements from the deferred list

2. Grouping the requirements based on value/impact, level-of-effort to implement including testing/training etc., as well as time-to-market (elapsed time) to make the particular enhancement

3. The list should be maintained in a central repository (e.g., single spreadsheet maintained by a designated member of change control board)

Timing:

Compiling a list of deferred features should occur from the initial scope phase, with requirements prioritization and gap analysis-related activities conducted during the previous phases. When funding is available, it should be used for customized enhancements as well as for upgrades/releases by the vendor (assuming they are not covered under annual maintenance fees).

LIS as a Project in a Laboratory

1. Assessments
   - Site assessments
   - Workflow analysis
2. Scope
3. LIS Functional and Technical Requirements
4. Standardization
5. Interfacing with Laboratory Instruments
6. Minimum/Required Data Elements
7. System Specifications
   - Infrastructure specifications
   - Software specifications
8. Quality Standards
9. Implementation
   - LIS Software Alignment: Gap Analysis and Prioritization
   - LIS Software Alignment: Develop Customization
   - LIS Software Alignment: Change Control Process
   - LIS Software Alignment: Data Migration
   - Installation: Infrastructure
   - Installation: LIS Hardware and System Software
   - Installation: LIS Software
   - Testing: Factory Acceptance Testing
   - Testing: Integration Testing
   - Testing: Stress and Performance Testing
   - Testing: User Acceptance Testing
   - Testing: System Reliability Demonstration (in Parallel)
   - Training: Computer training
   - Training: LIS User
   - Training: LIS Advanced/Super User
   - Training: Systems Administrator
   - Training: Pre-Service
   - Going Live: Operational Readiness
   - Going Live: Supported Supervision
10. Sustainability
    - Operations
    - End-User support
    - User Administration
    - Master Data Management
    - Backup and Recovery
    - Printing support
    - Emergency Shutdown
    - Support: Help Desk
    - Support: Issue/Incident Log
    - Change management
    - Support: Level 1
    - Support: Level 2
    - Support: Level 3
    - Maintenance and Change Management Plan
    - LIS Software and Operating System FAQ
    - Budget

ASSESSMENTS

Once the pilot sites have been identified, laboratory evaluation should be done to obtain the baseline information to determine the readiness of the sites for their respective pilot projects. This encompasses aspects related to Infrastructure strengthening (i.e., facilities, communication, technical, utilities) and process improvement (i.e., specimen acquisition procedure, test reporting system, etc.) including readiness regarding paper-based system implementation.

Site Assessments

Site assessments will help with gap analysis. Project participants can identify and prioritize items that must be addressed prior to or during the LIS project. These items can then become part of project planning. This process will also further refine the requirements being developed.

Site assessments involves the following groups

- The project management team will facilitate this process.
- The implementation partner will typically bring in a SME to conduct site assessments and submit gap analyses reports.
- Site-specific task group will be part of the assessment team
- The working group will be involved in the process and review the assessment reports and prioritize the gaps.
- The sponsor will need to approve any recommendations made by the team.

Site assessment involves the following steps:

1. Use the assessment template provided in the Appendix as a starting point and customize it for the specific LIS project

2. Inform laboratory leadership about site visits and secure their approval

3. Make it a one team visit with all SMEs, rather than multiple silo visits by SMEs, to minimize disruption at laboratories and optimize the trip's effectiveness and efficiencies.

Timing:

Once the pilot sites are selected, planning should begin. This should be prior to completing the Design and Define steps discussed in next section.

Chapter Navigation

Due to the many sections in this chapter, use the navigation tools in the margins to keep track of where you are in the chapter. Main sections follow the teal hexagonal navigation bar; the navigation numbers correspond with the numbers of the main sections in the mini table of contents on page 64 (see left).

Due to the length of the Implementation and Sustainability sections, they have their own subsection navigation. Subsections follow the rust-colored circular navigation bar. Those navigation numbers correspond with the numbers of subsection bullets that comprise each section. For example, "Implementation" has 19 subsections; therefore, the navigation bar for that section will follow 19 circles.

Workflow Analysis

A work flow analysis helps to identify gaps with respect to recommended model from a process, people and tools perspective. It improves the pre-analytic phase by creating a patient database/ repository; improving identification of patients, barcodes and session numbers for better ID of patients; and reducing log-in time.

Focus areas during the analytic phase

- Improved accuracy in identification of specimen and test all specimens were labeled with barcodes
- Improved workload management
- Reduced transcription resulting in increased accuracy and less time spent on discrepancy resolution
- Identification of delayed or missing tests
- Validation of results and better identification of unusual results that could be directed to super user or senior manager

The post-analytic workflow analysis looks into areas facilitating reporting results faster. The reduced turn-around-time (TAT) results in positive impact on patient care.

Workflow analysis involves the following groups

- The project management team will facilitates this process.
- The implementation partner will typically bring in a SME to conduct the work flow analysis and submit the identified gaps.
- A site-specific task group will be part of the assessment team.
- Working group will be involved in the process, review the assessment report and prioritize the gaps.
- The sponsor will need to approve any recommendations made.

Workflow analysis involves the following steps

1. Use the recommended process flows provided in Appendix F and paper-based system tools as a baseline.

2. Perform gap analysis during the site visits with respect to the baseline.

3. Pay attention to these focus areas.

    - Processes and Standards
        - Unique identifiers
        - Data Standardization
    - Tools and Techniques
        - Paper-based registers, logs, etc.
        - Cataloging and indexing mechanisms
    - Organizational / Physical space (central reception area vs. spread out, if applicable)

Timing:

- Preferably as part of site assessments
- Prior to completing the Design and Define steps discussed in next section.

SCOPE

A project's scope clearly documents what the project/initiative aims to accomplish; it explicitly determines which items fall outside of the initiative's focus. Using this approach throughout the project's life cycle will set the stage for efficient, focused requirements that result in a detailed design. A clearly-defined scope allows laboratories to accomplish its program goals while bound by a finite set of resources and an agreed-upon time frame.

Home improvement is a good example of how having a project scope can help. The project may start out with the installing a new roof, but then a new deck is requested. When the homeowners want to also replace all of the kitchen cabinets, redo the kitchen floors and knock down a wall, the homeowners soon realize that none of these other tasks has anything to do with finishing the roof on time and keeping the rain from leaking into the house. If the homeowner and contractor had specified at the beginning that the only thing he would be doing would be replacing the roof, the project would have been completed on time and on budget.

Defining scope involves the following groups:

- The project management team should facilitate this process.
- The working group provides a recommendation.
- The sponsors will approve and also serve as escalation points in case of any conflicts.

Defining scope involves the following steps:

1. Collaborate with the funding authority/agency to define the broad goals /objectives of the program.

2. Engage sponsors and working group to refine, define and finalize.

Timing:

This should be drafted as part of developing the charter and finalized after assessments.

Figure 3a: Scope Parameters
A clearly defined project scope should meet certain parameters to keep the project running smoothly.

Scope Examples

In-scope

1. Capture the high level requirements for the Laboratory Information (Management) Systems for the various types of laboratories in the country.
2. Validate these requirements against the experience of the in-country HHS and local healthcare officials involved with emergency plan efforts.
3. Determine pilot sites and conduct site assessments to determine readiness for a LIS.
4. Identify a number of commercial-off-the-shelf (COTS) and home grown, free or low cost applications designed to support laboratory activities that meet these requirements.
5. Provide the tools needed to select appropriate developers/providers of LIS.
6. Provide the tools needed to select and modify as needed a specific LIS solution(s) to meet country requirements.

Out-of-scope

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.

LIS FUNCTIONAL AND TECHNICAL REQUIREMENTS

The accompanying High Level Requirements (HLR) document describes comprehensive functional and system requirements. Figure 3a depicts them in a logical view. Use the HLR document and modify it to fit a specific environment. Each implementation is unique; the key is to understand and document the requirements for the LIS.

The minimal system has been defined specifically to meet the data collection and reporting requirements associated with the Emergency Plan–funded programs. Each country will likely need to choose and deploy a single system for collecting patient, order and result data from the variety of sites where this data is generated. The objective of deploying these systems is to provide each country with the basic ability to quickly and easily collect and aggregate HIV incidence and prevalence data across the entire country and to be able to review and analyze this data in a timely manner. Implicit to that objective is providing clinicians accurate laboratory results in a timely manner to allow for better decision making about a patient's health and treatment options.

At a minimum, the system needs to accept patient data, create a test request, accept the test results and export this data via an electronic or physical medium.

Requirements development involves the following groups

- Task forces will be responsible for compiling requirements
- The working group will partner with the task forces to prioritize requirements
- The implementation partner will provide necessary consulting and subject matter expertise
- The sponsors will review and approve the scope and priorities recommended by the working group

Method of collecting requirements

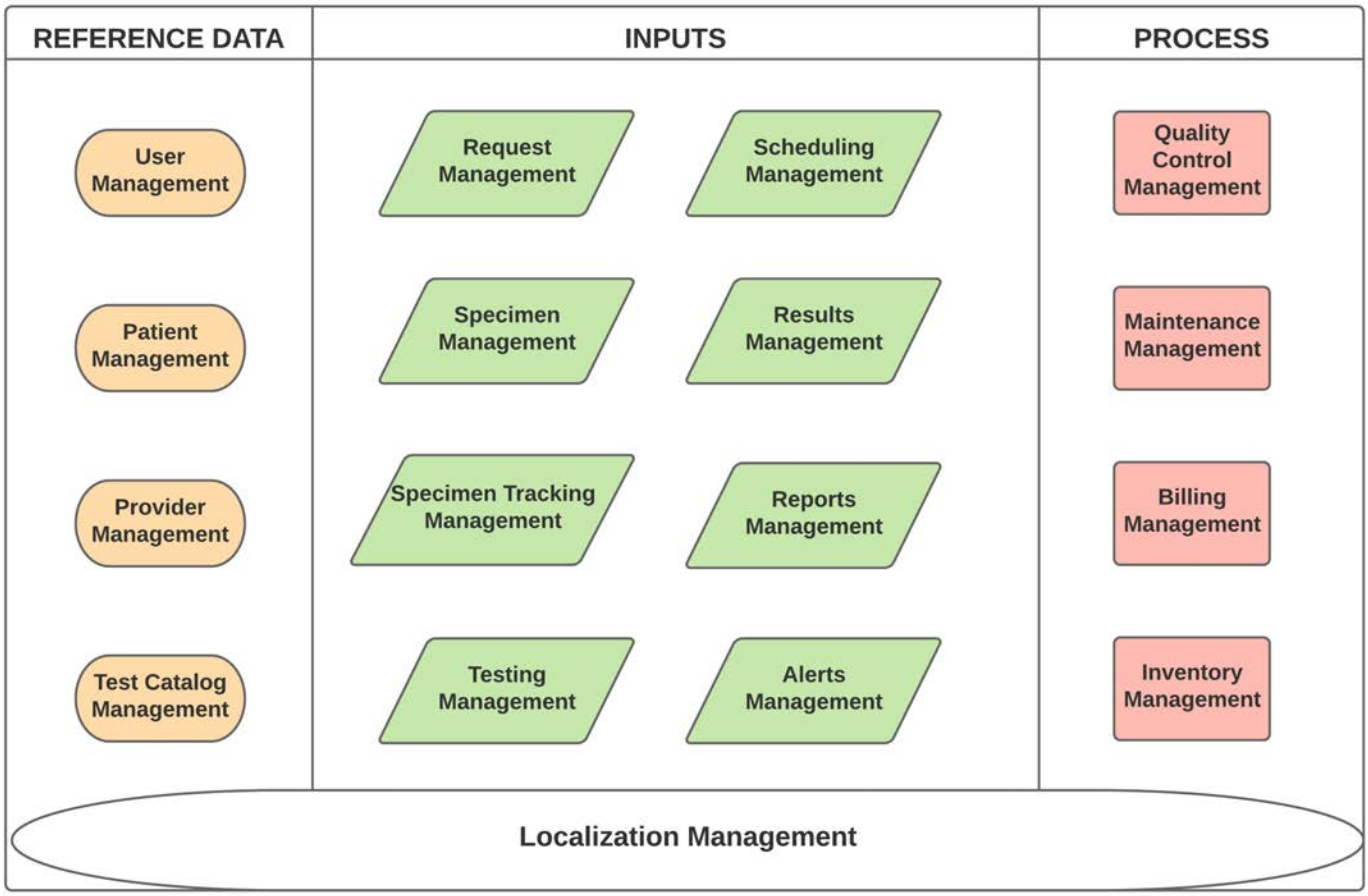
1. Use the accompanying HLR as the baseline.
2. Use the results from site assessments to narrow down details, process flows and screen navigation.
3. Ensure "reporting requirements" are considered and met in the finalized set of requirements.

Timing of collecting Requirements

- This is a key step and should be started once the project teams are formed.
- The initial draft should be used to perform gap analysis during the site assessments.
- After site assessments are complete, the requirements should be finalized and be made available to become part of RFP.

Figure 3a: LIS High Level Requirements

The systems context diagram illustrates the minimum requirements that a laboratory should expect from a LI(M)S product and can be used when shopping for potential LI(M)S software.



System Requirements			
Backup/Restore Architecture	Anti-virus Architecture	Audit Trail Architecture	Monitoring and alerts Architecture
Connectivity/Network	High availability Architecture	Security Architecture	Integration/Interface Architecture
Hosting Architecture	Hardware and Operating System	Software Architecture	Database Management System

System High Level Requirements

These requirements ensure that information is compiled and prioritized and will become the essential part of a Request for Proposal (RFP), providing context for vendors to respond. Requirements are also essential in order to develop correct specifications--functional (what) and technical (how).

1. User management
   - □ Provide roles-based access
   - □ Require a unique user ID and password for system access
   - □ Allow authorized users to create user profiles
   - □ Allow authorized users to search for user profiles
   - □ Allow authorized users to modify user profiles
   - □ Allow authorized users to delete user profiles.
2. Patient management
   - □ Provide a unique patient ID
   - □ Create a patient profile
   - □ Modify a patient profile
   - □ Delete a patient profile
   - □ Search for a patient profile
   - □ Check for duplicates.
3. Specimen management
   - □ Register a specimen
   - □ Enter specimen identifiers from labels
   - □ Associate a specimen to a patient
   - □ Modify a specimen
   - □ Delete a specimen.
4. Order management
   - □ Support tests related to HIV and opportunistic infections
   - □ Create an order for a specific patient
   - □ Associate a specimen to the order
   - □ Modify an order
   - □ Search for an order
   - □ Delete an order
   - □ Check for duplicate orders.
5. Link to patient registry, if it exists
6. Ad hoc query capability
7. Archiving of records
8. Linking/interfacing ability to other standard databases (e.g., a hospital or health information system)

STANDARDIZATION

Standardization implies doing things in a common, pre-defined way. For example, one process is used for data exchange formats, another for test report formats, etc. Applying standardizations to the way data is handled—through the use of both processes and/or tools—provides documented agreements on how to represent, format, define and report data.

Interoperability and Data Exchange

Data integration allows diverse systems to communicate through the use of common data standards. Data integration not only makes laboratory reporting easier; it makes the LIS more valuable to all stakeholders, including partners outside the health facility (e.g., MOH agencies). LIS standardization facilitates data comparison and reconciliation which leads to interoperability, or the ability of information systems or devices to exchange and interpret data.

LIS Standardization Impact

- Test database/catalog
- Specimen types
- Electronic messaging
- Test order/ result form
- Content

Tools to Enable Standardization

- Test submission form
- Patient test report
- Specimen rejection form
- Specimen transfer form
- Deficiency or corrective action form
- Communication log or Occurrence management log

Benefits of Using Standards

- Allows for rapid response
- Improved patient management/outcomes
- Faster TAT for referral specimens
- Minimize duplication of effort; streamlined workflow
- Improved case reporting
- Challenges of using standards
- There are many standards and many jurisdictions
- Needs to be a shared effort with site and program IT staff/vendors
- While several standards may be freely available, there are costs associated with implementation
- Infrastructure needs to put in place as part of the implementation of standards
- Use of standards also means electronic reporting of laboratory data. This needs to be an acceptable means to receive results
- There must be agreement and subsequent guidance and regulations to support the use of standards, including the version that will be followed.

Commonly Used Standards for Laboratory Data

Logical Observation Identifiers Names and Codes (LOINC)
A universal standard for identifying laboratory observations, developed by Regenstrief Institute and declared as the preferred code for laboratory test names by HL7

Systemized Nomenclature of Medicine (SNOMED)
This standard applies to medical terms, including diseases, anatomy, procedures, substances, etc.

International Classification of Diseases-10 (ICD-10)
Codes used for reporting for medical diagnoses and inpatient procedures

Health Level 7 (HL7)
An information interchange/ messaging standard

INTERFACING WITH LABORATORY INSTRUMENTS

An LIS can directly capture laboratory instrument data output by automating the flow of data from the instrument. Since many LIS vendors have expertise in laboratory instrument interfacing, it is useful to include an inventory of laboratory instrument specifications along with the RFP. As part of the RFP, laboratories should request information on interfacing capabilities from LIS vendors.

Since data standardization will have a direct impact on the data exchange, it will simplify the implementation.

Purpose

Having ability to exchange data between laboratory instruments and LIS and automate this process will decrease workload on laboratory staff and eliminates human errors from manual data entry.

Groups Involved in Laboratory Instruments Interfacing

- LIS task force should be leading this.
- LIS TWG should review and recommend standardization requests to sponsors.
- The implementation partner will provide consultation and requested assistance.
- Laboratory analyzer vendor will be responsible for providing access to the instrument interface as well as interface manuals.

Steps Involved in Laboratory Instrument Interfacing

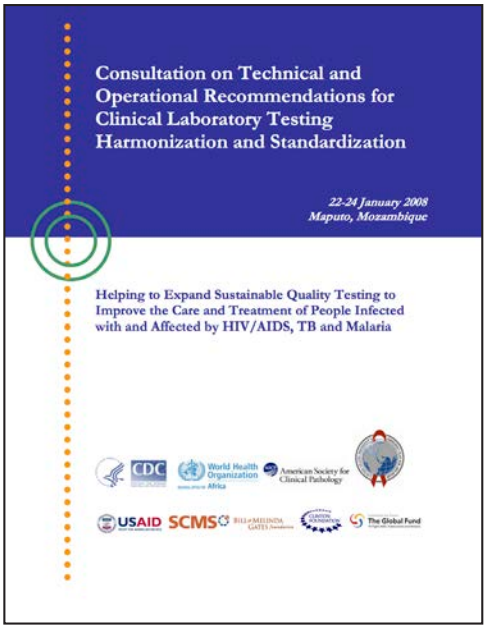
1. Compile an inventory of laboratory instruments from site assessments. Inventory should include the current format of the output (i.e., basic text file vs. proprietary format), if there is a RS232 port, etc.

2. Refer to the Maputo Report to gain an understanding of types of testing and potential instruments used in a laboratory setting. (*Report is available online, see right for cover image.*)

3. Recommend a national standardization (if applicable) across laboratories.

4. Prioritize a list of laboratory instruments that would benefit from automation (e.g., instruments with high volume of tests).

5. Negotiate with vendors about pricing if interfacing multiple similar instruments at different laboratories since code would be written only once and used multiple times. Ability and experience with interfacing should be included in vendor selection criteria.



Timing of Laboratory Instrument Interfacing

Compiling the inventory should be part of site assessments, and be completed prior to RFP publication. It should be its own section and/or exhibit to any RFP documents.

MINIMUM/REQUIRED DATA ELEMENTS

For each grouping or capability mentioned in the requirements, a set of minimum or required data elements for the pre-analytical, analytical and post-analytical phases should be identified. These identified fields should be appear as mandatory data entry fields with specific override capabilities or with a default value to handle exceptions. The same concept holds true for data exchange/ interfaces with other systems from an inbound and outbound data flow perspective. Without entering the minimum data required, a user will not be able to proceed through that phase or move on to the next phase.

Purpose

It ensures the system meets the objectives and expectations at the macro and micro level. A system is expected to report on certain criteria and if the data is not collected then it defeats the whole purpose of the exercise. This will ensure:

- data quality and completeness,
- clinicians and end users have an expectation of reliability from the LIS, and
- reporting on required criteria is complete.

Groups Involved with Minimum Data Elements

- Respective Task forces are responsible to identify these fields for each phase of the analytical processes
- The implementation partner will provide consultation/guidance as needed

Steps Involved with Minimum Data Elements

1. Consider the different users/stakeholders of data/information in your requirements gathering
2. Back-track from reporting requirements to ensure the base data is captured at the appropriate transaction level: 1) the patient or single-test level to care providers and 2) aggregate level data up the chain to central or national level
3. Review with the implementation partner SME
4. Consider reviewing best practices from international labs and capturing data that may be relevant to QA

Timing of minimum data elements

This should be part of requirements gathering for each of the three phases of the analytical process.

SYSTEM SPECIFICATIONS

Infrastructure Specifications

Specifications for infrastructure components are based on the assessment and solution requirements. Scope includes the core information technology components, as well as strengthening the ancillary infrastructure to ensure reliability and endurance of the LIS solution. The table below outlines some key points to consider.

Specification	Key Points
Blueprint for equipment deployment	• Physical layout of the end-user equipment (computer desktops for users in the lab) • Hosting facility and capacity (data center) for backend components (computer servers, network switches, etc.) • Include physical layout of laboratory instruments so the computers are placed in a suitable location.
Electricity/power	• Capacity planning for the electricity power required to support the solution • Design of and redundant power supplies/sources. Service level agreements with respect to 'auto-switch' when primary source fails as well as how long, in clear unit of measures like hours or minutes, the secondary source can supply the required or reduced capacity • Provision capability to separate supply to backend (servers) and frontend (desktop) components
Air conditioning, including capacity planning	Air conditioning is a must for the data center where servers, networking switches and the database will be hosted. It is a recommendation for other locations, such as where computer workstations for users and printers are installed.
Hardware to host the LIS applications	• Design artifacts like logical architecture and physical architecture specifying the required hardware components and the inter-connectivity between these components. • Computer server specifications for hosting the LIS application. • Determine if the database server is recommended to be on a dedicated server or can co-exist on the application server. Perform a cost-benefit analysis. • Consideration for hardware clustering to accommodate high-availability (HA) requirements • Computers serving as servers should have lights-out management (LOM) capacity to support remote administration and maintenance

Specification	Key Points
Computer Storage	• Request capacity plan for the storage attached to the back-end servers and scalability for future growth • Request that the design is based on appropriate redundant array of independent disks (RAID) level to minimize data loss and avoid disruption due to hard disk drive failures • Request the specifications for the hard disks (speed of discs, type of discs (SATA vs. SAS vs. SSD), etc.) • Specify the requirements for backup and recovery processes • Focus on outcomes. Let the vendors come back with proposals on achieving outcomes
Computer Network	• Capacity plan based on the usage patterns including peak-time projections • Appropriate design choices and considerations for local area networks (LAN) and wide area networks (WAN) • Interfacing requirements with Lab instruments. • Viability of wireless networks (WiFi) for LANs • Accommodate the security, privacy and encryption requirements • Infrastructure for Internet connectivity
Monitoring and Alerts *This is about monitoring hardware and diagnosing issues with the system*	• Proactive monitoring and diagnosis expectations should be part of specifications • Automated alerts via preferred communication mechanism (email, fax, SMS, etc.) to users/administrators responsible for the system • Alerts should be classified into informational, warning and fatal categories indicating the severity of the incident
End-user Computing Equipment	• Form factor, size and shape of computer central processing unit (CPU) case, guidance or preference to accommodate the physical space available at end-user work-space. • Monitor size • Other peripherals. For example, include a barcode scanner at each location where there is a need to scan a barcode for specimen id to retrieve the record from LIS. • Ergonomics based setup • Ensure enough power-outlets or capacity (in case an power strip is being considered) available for the devices • If a WiFi is part of the design, then ensure the workstations have the necessary network adapters or cards

Purpose

The project infrastructure and future project phases rely on the detailed specifications. These specifications will also aid in developing a concise yet comprehensive RFPs.

Groups Involved with Infrastructure Specifications

- The LIS task force is responsible in developing the logical and physical architecture of the solution in collaboration with the SME provided by the implementation partner
- The implementation partner will provide a SME
- The working group will review and recommend the solution for approval by the sponsors
- Sponsors will have the final say
- The project management team will facilitate the tasks per the project plan

Steps Involved with Infrastructure Specifications

Infrastructure strengthening (electricity, air conditioning, computer network, physical facilities, etc.) specifications are developed based on site visits and other assessment related activities. Hardware and system software specifications are based on the LIS solution architecture (i.e., stand-alone vs. LAN based system vs. WAN based system).

Infrastructure Specifications Timing

Compiling specifications should coincide with the site assessments; a draft should be ready shortly after completing all site assessments. Preliminary specifications can include mapping out locations of laboratory instruments, any existing computers, any existing wiring in place and other requirements.

Hardware and system software specifications are developed in conjunction with the LIS software vendor selection. However, developing and having preliminary specifications is a best practice.

Software Specifications

The specifications and requirements for the LIS software are already defined and should be derived from the accompanying HLR document. Functional and business requirements have been discussed earlier in the Requirements section.

In this section the specifications are more system level, which focuses on the technical architecture, rather than application level, which focuses on end-user functionality and features. Using the home improvement analogy, system level specs are the foundation and building materials used, while application level tackles the house layout in room location, positioning, etc. The table below outlines some key points to consider.

Specification	Key Points
Solutions/Systems Architecture Options (stand-alone vs. LAN-based vs. WAN-based)	• More centralized architecture offers better efficiencies however it relies on continuous network connectivity. • A stand-alone deployment requires no network connectivity, a LAN deployment requires network connectivity within the facility or campus and WAN deployment requires network connectivity between a laboratory facility and a remote location where the servers are hosted. • If the vendor solution is client- or server-based architecture, then a WAN deployment is not advised since there could be response time issues due to network latency. The amount of data that will need to go back and forth will consume a good portion of the network bandwidth.
Utilities	Utilities that facilitate start-up, immediate shutdown, shut-down and other maintenance procedures from the systems administrator position will maintain system and data integrity during these processes while remaining a user-friendly system.
Configuration	The system should be free of hard-coded values as configuration parameters and should be designed based on a data-driven configuration. This will provide flexibility and shorter TAT if a change is expected.
Hard Coding (adding information to software code that constrains flexibility for future modifications)	Request to explicitly document all hard coded aspects of the system as part of RFP response.
Version Updates and Patches	As newer versions and patches are released by the operating system vendors (server side and client side), the vendor should certify that they are compatible with the LIS and provide the steps for migration along with the release notes.
Future Upgrades	Future upgrades, including releases made by the LIS vendor, must be backward compatible and include all capabilities built into the current system. As a guideline, the newer release should offer “same or better” capability for each of the listed requirements.

Purpose

The more detailed the specifications are, the less ambiguity there will be for future phases of the project. These specs will aid in developing a concise yet comprehensive RFP.

Groups Involved with Software Specifications

- The LIS task force will be responsible in developing the logical and physical architecture of the solution in collaboration with SMEs provided by the implementation partner.
- The implementation partner will provide SMEs.
- The LIS TWG will review and recommend the solution for approval by the sponsors.
- Sponsors will have the final say.
- The project management team will facilitate the tasks per the project plan.

Steps Involved with Software Specifications

1. The vision and charter along with site assessment report will help in defining the system architecture for the LIS (stand-alone system vs. LAN-based vs. WAN-based).

2. Use the accompanying HLR as the baseline to develop specifications within context.

3. Consider local capacity (skills and resource availability) while specifying any preferences around system software platforms (i.e., Unix vs. Windows platforms and/or J2EE vs. Microsoft.net platforms, etc.), as well as the database platform. If the analysis suggests any constraints, then include them in the RFP, otherwise leave open to allow flexibility in future decision-making.

Timing

This task should be started as early as possible once the task groups are formed, and should culminate when the RFP is developed and published for vendor responses. After vendor selection, these specifications will turn into inputs for the test plan and eventually into a system-related documentation suite.

LIS Training at the Ethiopia Public Health Institute, Addis Ababa, Ethiopia organized by APHL

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QUALITY STANDARDS

Quality standards serve as a baseline for solution acceptance criteria. These include specifications and acceptance procedures developed as part of the project, in addition to references to applicable industry best practices and standards.

Purpose

Defining these quality standards early in the process will facilitate a quality-focused mind set leading to a best-in-class implementation and an optimal solution.

Groups Involved with Quality Standards

- Task forces should compile the quality criteria for the respective areas.
- The LIS TWG should review and approve the quality criteria.
- The implementation partner advises on the quality aspects of the solution.
- The project management group incorporates the quality standards into the development of the RFP.
- A project management team member should be responsible for QA/QC.

Steps Involved with Quality Standards

1. Document the outcomes/capabilities expected rather than specifying “How-to” during requirements gathering and compilation.

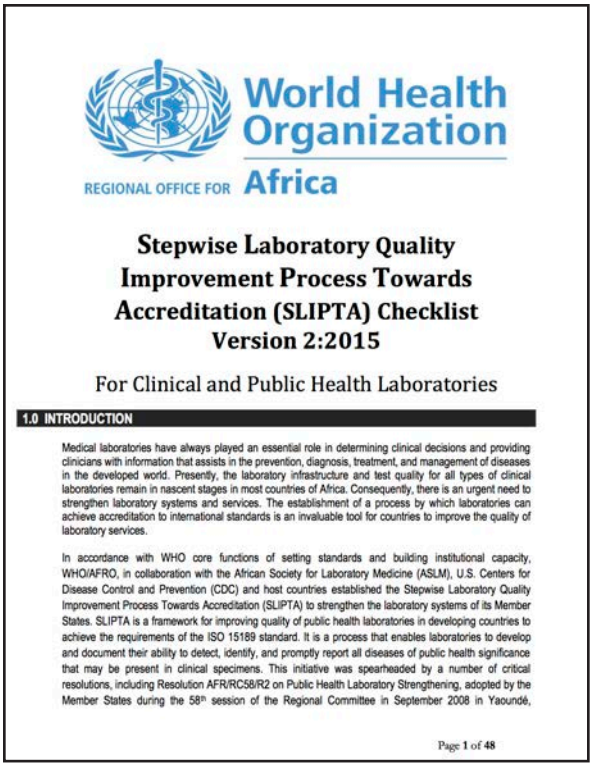
2. Develop detailed specifications for the infrastructure components like computer networks, electricity power outlets, alternative electricity sources (e.g., uninterruptible power supply [UPS], generator), air conditioning, etc. Specifications should mention both the operating conditions and the environmental factors.

3. Use industry standard equipment and insist on certified equipment where possible.

4. Compile a list of different types of tests to be conducted as part of acceptance and proof-of-performance; develop associated detailed test scripts and execution plans.

5. As part of the RFP, request documentation on internal QA/QC processes followed by the bidder or vendor.

6. Compose preventive maintenance procedures and expectations to sustain operations


World Health Organization
REGIONAL OFFICE FOR Africa

Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist Version 2:2015

For Clinical and Public Health Laboratories

1.0 INTRODUCTION

Medical laboratories have always played an essential role in determining clinical decisions and providing clinicians with information that assists in the prevention, diagnosis, treatment, and management of diseases in the developed world. Presently, the laboratory infrastructure and test quality for all types of clinical laboratories remain in nascent stages in most countries of Africa. Consequently, there is an urgent need to strengthen laboratory systems and services. The establishment of a process by which laboratories can achieve accreditation to international standards is an invaluable tool for countries to improve the quality of laboratory services.

In accordance with WHO core functions of setting standards and building institutional capacity, WHO/AFRO, in collaboration with the African Society for Laboratory Medicine (ASLM), U.S. Centers for Disease Control and Prevention (CDC) and host countries established the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) to strengthen the laboratory systems of its Member States. SLIPTA is a framework for improving quality of public health laboratories in developing countries to achieve the requirements of the ISO 15189 standard. It is a process that enables laboratories to develop and document their ability to detect, identify, and promptly report all diseases of public health significance that may be present in clinical specimens. This initiative was spearheaded by a number of critical resolutions, including Resolution AFR/RC58/R2 on Public Health Laboratory Strengthening, adopted by the Member States during the 58th session of the Regional Committee in September 2008 in Yaoundé,

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Timing

This phase takes place at the onset of requirements gathering.

SLIPTA Checklist and Accreditation

In collaboration with the African Society for Laboratory Medicine (ASLM), U.S. Centers for Disease Control and Prevention (CDC) and host countries, WHO/AFRO established the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) to improve the laboratory systems of its Member States. Several critical resolutions led to this initiative, including the Maputo Declaration to strengthen laboratory systems and Resolution AFR/RC58/R2 on Public Health Laboratory Strengthening, adopted by the Member States during the 58th session of the Regional Committee in September 2008 in Yaoundé, Cameroon.

Clinical, public health, and reference laboratories participating in the SLIPTA are reviewed bi-annually. These laboratories work to meet requirements set by international standards. This accreditation process offers a pathway for continuous improvement, a mechanism for identifying resource and training needs, a measure of progress and a link to the WHO/AFRO National Health Laboratory Service Networks.

In 2015, the World Health Organization (WHO) published Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist Version 2:2015 for Clinical and Public Health Laboratories. The SLIPTA checklist--which serves as part of the SLIPTA audit documentation--specifies quality and competency requirements meant to raise laboratory service quality up to established national standards. The checklist is based on ISO standard 15189:2012 (E), as well as CLSI guideline QMS01-A4 publication entitled Quality Management System: A Model for Laboratory Services, Fourth Edition. The audit checklist score corresponds to the number of stars awarded to a laboratory.

Section 9 from the SLIPTA Checklist can be used to determine how far along a laboratory is in its goal of accreditation, specifically in the information management category. Conducting an exercise using this section can help develop a non-conformity report that can then be used by laboratory management to address gaps. A sample of Section 9 is available in the *Appendix E* of this *Guidebook*.

IMPLEMENTATION

Planning

The review and/or revision plans for pilot implementation.

Purpose

Implementation is a major milestone that occurs far into the plan. It is worthwhile to pause and review plans and assumptions, then adjust as needed. These reviews adjustments should include the major components of the plan like scope, human resources, budget, schedule and stakeholder management.

Groups Involved with Implementation

- The project management team should lead this exercise.
- The task forces and the LIS TWG actively participate.
- Hardware and application software vendor representatives should be involved while developing the schedule for implementation.

Steps Involved with Implementation

A facilitated working session with all parties to this step is an effective, efficient way to accomplish this. The team should review the scope and discuss if anything needs to be adjusted based on the previous phases, review tasks ahead and map human resources capacity to see if any changes are needed. The outcome of the working session is a detailed project schedule with milestones and associated roles & responsibilities for the remainder of the implementation.

Timing

Implementation occurs once the contract is awarded to the application software vendor.

For information on paper-based systems, see *"Implementation of LIS as a National Program" in the "LIS Overview" Section* in this *Guidebook*.

Chapter Navigation

The "Implementation" section of this chapter has 19 subsections. There is a navigation tool in the margins throughout this section to help you keep track of where you are in the implementation process.

LIS Software Alignment: Gap Analysis and Prioritization

Gap analysis and prioritization compare the requirements and workflow to the selected LIS; this process identifies customization requirements. Once the requirements are compiled, the next step is to prioritize them and choose the baseline functionality the vendor needs to provide in the selected system.

An alternative is to adopt the processes the system offers "as is." This approach may result in too much reliance on the vendor for initial implementation and may result in a "lock-in" for future upgrades. Also, the implementation may miss on the best practices and standards that will evolve over time by the broader laboratory community.

Purpose

One of the key selection criteria for the software should be the alignment to functional requirements. The closer the software capabilities are to the requirements, the need for customization decreases. However, no "off-the-shelf" LIS will be able to provide the exact functionality required for any implementation. Therefore, the need to perform gap analysis and prioritize customization requests is an important step. The gap analysis is performed against the requirements compiled as part of the "define and design" steps listed earlier.

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 short- and long-term success 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.

Groups Involved with Gap Analysis and Prioritization

- The task forces, working group and project management teams are involved.
- The vendor is involved in level-of-effort estimations, feasibility assessments and final negotiations for the customization.

Steps Involved with Gap Analysis and Prioritization

1. Respective Task Forces should compare the requirements (including the to-be workflows for automation) to the selected system's capabilities and document the gaps of the system. Each gap should be prioritized into one of three categories: High, Medium and Low. This categorization will help optimize cost and time dimensions which are finite in nature.

2. Ask the vendor to install a demo version of the software so the team can review the software with respect to gaps. Needless to say, the prerequisite for this step is having the required infrastructure (computing equipment) to install the demo version.

Timing

This occurs after a vendor is selected and contract is awarded. It would also be beneficial if this is done after piloting the paper-based system for few weeks.

LIS Software Alignment: Develop Customization

Modifications to the application software (LIS) per agreed upon customization requests

Purpose

These are the customizations deemed to be critical for LIS implementation.

Groups Involved with Customization

- The vendor team primarily owns this step.
- The working group and respective task forces may be involved in clarifying requirements, if needed and enacting periodic checks to evaluate the progress of customizations.
- The project management team will be involved in planning aspects from budget, timelines and quality.
- The implementation partner will provide any requested consultation assistance

Steps Involved with Customization

The vendor is responsible for developing documentation on the customizations and having these approved prior to the actual development (e.g., software requirements specifications) that describes each customization in detail. Depending on the number of customizations and the level of effort involved, the capabilities may be made available in multiple software releases to minimize complexity.

LIS Software Alignment: Change Control Process

A process to identify, review and decide on changes to the baseline customization requirements

Purpose

An issue is discovered while a particular workflow is running, a system is going through one of the acceptance tests, or while a system is being used, resulting in a change request. Since the development of customizations have been agreed upon across all stakeholders and communicated to the vendor, any further changes to baseline requirements require a process to discuss and decide on the priority of any change requests.

Groups Involved with Change Control

- An internal Change Management Committee is established under the LIS TWG and project management team with representation from all groups. This will be the group that prioritizes the gaps and requirements for customization.
- Sponsor- and TWG-level review and approvals are required for certain types of changes that have budget implications.
- The vendor representative will be involved in subsequent discussions and decision making.

Steps Involved with Change Control

1. Incorporate a change control process from the beginning so everyone is aware of the correct process.

2. Be sure to enforce the rule that no change request will be entertained, discussed or accommodated by the vendor unless it is approved by the Change Management Committee. Usage of a standard change request form is recommended. A sample template is provided in Appendix H.

3. Members of task forces complete the forms as they discover potential gaps based on field experiences from paper-based system rollout or some form of testing of the selected solution.

4. The project management team collects the forms. Figure 3b illustrates a typical Change Control Process which can be used as a baseline for your specific implementation.

Using a house construction analogy, once the blueprint is finalized, any changes deemed as required are discussed with the builder. The homeowner will make a final determination based on cost and time line estimates from the builder to proceed with the change, defer it for later or totally discard the change.

Timing

The process and mechanisms should be put-in-place once the “define and design” phase is complete. The Change Management Committee should meet on a predefined frequency to review all change requests. During the paper-based system rollout and during the testing phases of the implementation, the Committee should meet more frequently; preferably, at least once every two weeks.

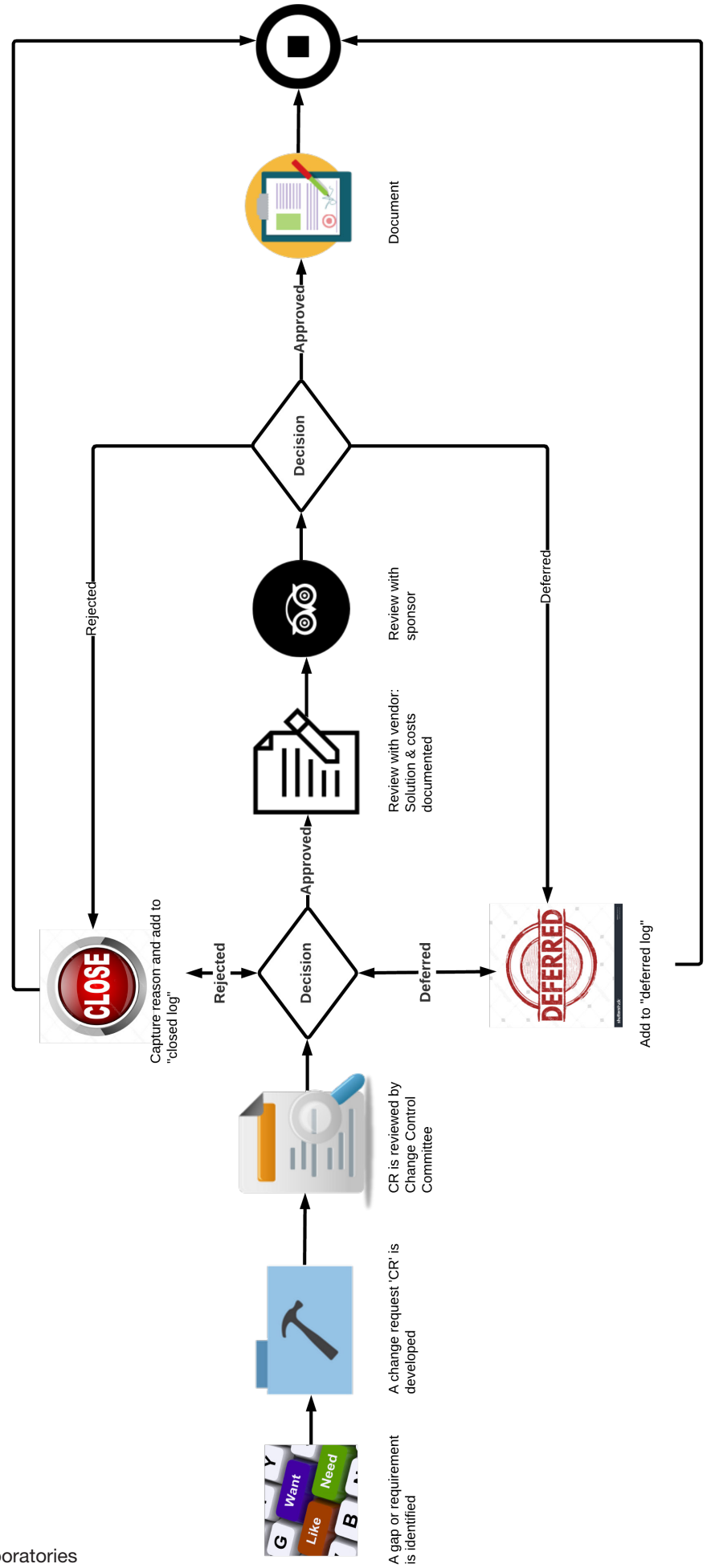


Figure 3b: Change Control Process

LIS Software Alignment: Data Migration

A process to import data from the old system. The system will either start with this data or they can be used for as a historical perspective.

Purpose

Data file conversion is needed when migrating between platforms on the same system or bringing data from one system into another. To determine whether all data need to be entered into the LIS consider how data will be used in the current system, as well as regulatory agency requirements.

Groups Involved with Data Migration

- Task forces are involved in defining the data migration requirements.
- The LIS vendor is responsible to develop the process and tools to perform the data migration.
- The project management team should ensure that this activity is part of the schedule and an agreed upon deliverable from the vendor.

Steps Involved with Data Migration

1. Data may be taken from manual files and entered into the system or data can be converted by an automated or manual method. Ensure all required data is included in the migration requirements, along with any necessary transformation/translating logic.

2. Make a conscious decision to bring or not to bring other data that is not deemed as required going forward.

3. Test the conversion when converting files between platforms on the same system or bringing data from one system to another. Do not convert 10,000 files at one time—do a test sample, validate the data, check that the patient name matches all data there and all data elements came across in the expected fields, then convert small batches of the data.

Timing

- Testing plans for data migration should be designed as part of the earlier activities
- Perform sample dry runs of migration process prior to completing the acceptance tests
- Final data migration is done once at each participating pilot site prior to production cutover. This data will be the seed data for the system as it goes live for the pilot site.

Installation: Infrastructure

Installation of technical infrastructure like computer networks, electricity power outlets

Purpose

This step is critical as everything else depends on it. Below are the benefits of proper infrastructure installation.

- LAN access is available to all laboratory instrumentation and users.
- Appropriate hardware necessary to set up a LAN within each laboratory is available.
- Each laboratory has access to the Internet at the laboratory location.
  N.B.: Internet connectivity may not be needed for the solution to function; however, it will be crucial for remote assistance and troubleshooting by the vendor.
- Stable, uninterrupted electricity/power needs are addressed to operate the system.

Groups Involved with Infrastructure

- TWG should be leading this effort. They are responsible for procurement of all needed equipment per design, engage with a local vendor/contractor to perform the installation including necessary cabling.
- Implementation partner can assist in quality control aspect of the installation by providing a SME in network administration.
- Lab management should:
  - provide access to lab areas for installation,
  - supervise the installation, and
  - provide alternate (temporary) work space to lab personnel, if required.

Steps Involved with Infrastructure

Computer - Local Area Network

1. Identify number of LAN ports and locations within the laboratory and install cable from a central location to those ports.

   a. Work with laboratory management to determine locations of laboratory instrumentation and location of standalone PCs.

   b. Ensure number and location of ports are sufficient for existing and future instrumentation.

   c. Always include additional capacity for future expansion.

      i. Consider including one additional port for each drop location and make them inactive with the ability make them active as needed in future.

      ii. Additional capacity can also be provided using portable routers at a later time.

      iii. Perform a cost-benefit analysis between the options, if possible.

2. Identify and install routers, switches, access points, hubs and gateways necessary

to complete a local area network in each laboratory and locate this hardware in a central laboratory location.

3. If wireless (WiFi) is part of the infrastructure architecture ensure coverage and signal strength at all required physical spaces including redundancy and high availability aspects.

4. Identify and install Internet access to each laboratory preferably at a location where such access can be made available to the LAN.

5. Ensure that all cable, LAN hardware and Internet access are installed prior to the installation of any LIS software application.

Electricity/Power

1. Identify and install the number of power outlets needed across the facility based on the layout of hardware.

2. Ensure capacity is within acceptable and legal limits.

3. Uninterrupted power supply (UPS) is installed and tested. The UPS should supply power, at the minimum to the central servers in the system architecture, so the system can be shut-down in an orderly manner.

4. Voltage stabilizers, if needed, are provisioned and ready to plug-in equipment.

5. If it's part of scope, alternate power sources, like generators, are installed and tested. UPS can keep it going only for a short duration; if the lab needs constant connectivity, then generators will be required.

Air Conditioning

Install Air conditioning equipment with sufficient capacity, in the facility hosting the centralized server hardware.

Timing

This is the first step in installation and should be planned to start right after the application software is selected and physical architecture/design is agreed upon by all parties.

Installation: LIS Hardware and System Software

Installation of computer equipment related to the LIS software. This includes servers, end-user workstations, printers, barcode label printers, barcode scanners, etc. Positioning of the end-user computing equipment should be in-line with the ergonomic considerations captured during the design phase. The hardware installation includes system software (operating system with latest patches, anti-virus software, backup and restore software, etc.) installs, implementation of the computer networks, implementation of the security modules, and provision connectivity of the equipment.

If a productivity suite of applications like word processing and spreadsheets are part of the scope, then they should be installed on the user workstations at this time.

Purpose

This is the second step in the installation process laying the foundation for application software installation. This hardware will host the LIMS application software.

Groups Involved with Hardware and System

- Technical Working Group should be leading this effort. They are responsible for procurement of all needed equipment per design.
- Hardware vendor is responsible for the installation and ensuring compatibility with the LIMS specifications.
- Implementation partner can assist in quality control aspect of the installation.
- Lab management should provide access to lab areas for installation, supervise the installation, and provide alternate (temporary) work space to lab personnel if required.
- A designee from each lab is responsible for keeping up with inventory, contacting vendor for maintenance/troubleshooting, minimizing time lost due to malfunctioning computers, etc., for their respective lab. Preferably, this person should be the super user of the system at the lab.

Steps Involved with Hardware and System

1. If the installation vendor is different from the hardware supplier, ensure proper inventory control mechanisms are in place like receipts, storage and issuance. Tracking of defective items and returns are part of this process.
2. Install/configure computer networking domain and firewall policy.
3. Hardware should be shipped with the system software pre-installed. If not, install the system software.
4. Add computers to the network domain.
5. Install antivirus software and other system utilities on all computers including the end-user workstations.
6. Install printers and ensure they are accessible from computers.
7. Connect barcode scanners and ensure basic scanning capability is functional.
8. Test UPS capability simulating a power outage.

9. Test Internet connectivity.

Timing

This is a prerequisite to the LIS application software install. The installation should occur once the technical infrastructure is in place or in conjunction with it. The sooner this step is done will provide that much lead time for end-users to get familiarized with computing platforms, especially if productivity software is installed on it.

Installation: LIS Software

Installation and configuration of LIS software

Purpose

This is the crux of the project. Once the system is installed and configured, it will be available for day-to-day use.

Groups Involved with Software

- LIMS Task Force should lead this effort.
- LIMS vendor is responsible for the installation, configuration and implementation.
- APHL/implementing partner will assist in quality control aspect of the installation.
- Lab management should provide access to lab areas for installation, supervise the installation, and provide alternate (temporary) work space to lab personnel if required.

Steps Involved with Software (Performed by Vendor)

1. Install any required utility software like Databases, application servers, etc.
2. Install common software components on the servers.
3. Configure the LIS software per design and specifications.
4. Install "client" software on end-user machines.
5. Create "user accounts" and set security privileges.
6. Install and configure interfaces with lab instruments.
7. Integrate printing (including barcode print) and scanning capabilities from within LIS system.
8. Setup backup and recovery configuration on the central server and database, at the minimum, to mitigate the risk of losing data should a malfunction occur.
9. Enable user-friendly mechanisms for start-up and orderly shut-down of the system
10. Provide a written document stating that all of the above (plus anything else identified during project) has been completed and tested by the vendor and is ready for integration testing.

Timing

Prerequisites for this step are:

- installation of infrastructure, and
- installation and configuration of hardware and system software.

This phase coincides with the successful completion of "Factory Acceptance Testing," explained in next section.

Testing: Factory Acceptance Testing

Factory acceptance testing is a vendor demonstration on their side that features capabilities/customizations that are part of the release, are functional and meet the readiness criteria for deployment. A successful outcome means satisfying the acceptance criteria.

N.B.: The vendor demonstration is hosted at the vendor facility; therefore, the demonstration may not reflect the operating environment of the lab. This test should cover, however, the breadth and depth of the system to the maximum extent possible.

Purpose

To ensure the system is ready for deployment. Deployment is resource intensive and it makes sense to check the system live in Vendor's environment prior to accepting the release of software for deployment.

Groups Involved with Factory Acceptance Testing

- LIMS Task Force should lead this effort.
- LIMS vendor is responsible for providing a fully functional test instance of the solution.
- APHL/implementing partner will assist in quality control aspect.
- Lab management should participate in the test as deemed necessary.

Steps Involved with Factory Acceptance Testing

Since the test environment is hosted at vendor site, participation in these tests should use mechanisms that leverage Internet technologies (e.g., logging into vendor provided workstation via Remote desktop connection and/or VPN, web conferencing, etc.) when travel to vendor site is not practical and eats into the project budget.

Timing

This should be done for each release of application software, as a passing gate prior to proceeding with deployment at lab level. The test must be repeated until it meets the acceptance criteria for a given release. Also, when dealing with multiple releases, a portion of the test should focus on "regression test" to make sure the new build didn't break any existing functionality.

Testing: Integration Testing

Testing is conducted at the lab to validate the installation and configuration. Scope includes LIMS functionality, interfaces with lab instruments, testing of printing and barcode scanning, etc., from within LIMS.

Purpose

To ensure installation, configuration and integration meets the acceptance criteria to enter into User Acceptance Testing. This is a comprehensive test to ensure all components are functioning both individually and as a collective solution.

Groups Involved with Integration Testing

- LIS Task Force should lead this effort.
- LIS vendor providing the necessary support onsite or via remote web based sessions.
- Hardware & system software vendor provides the necessary support with onsite presence.
- Instrumentation vendors offer their support processes.
- APHL/implementing partner will assist in quality control aspect.
- Lab management should participate in the test as deemed necessary.
- Lab management should provide access to lab areas to conduct the test and provide alternate (temporary) work space to lab personnel, if required.

Steps Involved with Integration Testing

1. Follow the test plan, scenarios and scripts developed as part of quality standards.

2. Mark each scenario as pass or fail.

3. Log all defects/issues in a register. Using vendor's help desk or service desk to log tickets is an option. Do not to lose information about defects, issues, etc. discovered during the test.

Timing

This test is done once installation at the Lab is complete and prior to proceeding with User Acceptance Test.

Testing: Stress and Performance Testing

This test focuses on the system's ability to process and respond to peak usage. Peak usage is where maximum number of users access the system during a normal/typical day or during a special situation where there will be more than usual number of users (e.g., high volume of lab tests, etc.). Any bottlenecks are identified at this time and adjusted to acceptable levels of performance.

Purpose

This test will ensure that the solution and the technical architecture has the capacity to handle peak loads.

Groups Involved with Stress and Performance Testing

- The LIMS task force leads this effort.
- Project Management Team will facilitate the planning and execution of this test.
- Both hardware and software vendors will be help conduct the test, troubleshoot identified issues, propose and review resolution with the task force and, upon approval, implement the resolution.
- Lab personnel should participate in conducting the test.

Steps Involved with Stress and Performance Testing

1. Use the quality standards developed with respect to performance and load testing and refine it as needed. If not developed during Quality standards, use the requirements related to performance criteria and develop a baseline.
    - Number of concurrent/simultaneous users that can be logged-on to the system
    - Acceptable response time from the system to an user interaction with the system The response times may vary based on the feature being tested. In other words, accessing a report may have little longer response time compared to data entry or query, because the processing time required to compile the report may be more than a single record in a data entry scenario.
    - Acceptable response time between real-time interfaces with the lab instruments
2. Pursue simulated load (use computer program to mimic peak load), as it is not practical to expect a maximum number of users to be available to perform the test. The tools required to perform this test should be provided by the LIS vendor as be part of the negotiation process, with no additional cost. The vendor should have the capability to test its solution in its development environment. Ask the vendor to use the same as part of this implementation.
3. Once an acceptable state is achieved, make it a "gold standard" and lock the configuration. The vendor should provide a document detailing all parameters in the physical architecture.
4. If a similar deployment is being considered across all pilot labs, then use this "gold standard" as baseline to configure those prior to running tests at subsequent sites.

Timing

This testing occurs once the system is installed and completes integration test.

Testing: User Acceptance Testing

Test conducted at the lab by the lab personnel to confirm the functionality

Purpose

This round of comprehensive testing ensures that installation, configuration and integration meet the acceptance criteria of end users. It also ensures that all components are functioning both individually and collectively.

Groups Involved with User Acceptance Testing

- Lab personnel are in the lead chairs.
- LIS Task Force provides the needed support.
- LIS vendor provides the necessary support onsite or via remote web based sessions.
- Hardware and system software vendor provides the necessary support with onsite presence.
- Instrumentation vendors offer their support processes.
- APHL/implementing partner will assist in quality control aspect.
- Lab management should participate in the test, as deemed necessary.
- Lab management should provide access to lab areas to conduct the test and provide alternate (temporary) work space to lab personnel, if required.

Steps Involved with User Acceptance Testing

1. Follow the Test plan, scenarios and scripts developed as part of quality standards.

2. Mark each scenario as pass or fail.

3. Log all defects/issues in a register. Using vendor's help desk or service desk to log tickets is an option. Do not to lose information about defects, issues, etc., discovered during the test.

Timing

This test is done once installation and integration test are performed and system is cleared for User Acceptance Test.

Testing: System Reliability Demonstration (in Parallel)

In short, this is the endurance test. Lab personnel will use the system for an extended period (vs. for a shorter duration during earlier tests) and in parallel with the current system to compare results and identify and resolve any anomalies and discrepancies. If a paper-based system is implemented as recommended, then that will be the primary system during this period.

Purpose

This demonstration verifies three main concerns.

- Installation and configuration is reliable over a prolonged period of time.
- Functionality is in-line with expectations by comparing it with a primary system.
- Addresses any concerns raised during use of primary system.

Groups Involved with Demonstration

- Lab personnel are in the lead chairs.
- LIS Task Force provides the needed support.
- LIS vendor provides the necessary support onsite or via remote web based sessions.
- Hardware and system software vendor provides the necessary support with onsite or remote presence.
- Instrumentation vendors offer their support processes.
- Implementation partner may assist in quality control aspect.
- Lab management should participate in the test, as deemed necessary.
- Lab management should provide access to lab areas to conduct the test and provide alternate (temporary) work space to lab personnel, if required.

Steps Involved with Demonstration

1. Follow the Test plan, scenarios and scripts developed as part of quality standards.

2. Mark each scenario as pass or fail.

3. Log all defects/issues in a register. Using vendor's help desk or service desk to log tickets is a preferred method. Do not to lose information about defects, issues, etc., discovered during the test.

Timing

This test is done once User Acceptance Test is completed and after end-users are trained on the new system.

Training: Computer Training

This foundational training related to usage of computers comprises:

- starting, log-in/log-off and shutting down a user workstation,
- overview of installed software programs on a desktop and how to use them,
- accessing hard drive and organizing and managing the folders, etc.,
- ability to print,
- verifying network connectivity,
- security aspects, and
- advanced training that may include training in productivity software (e.g., word processing, spreadsheets, presentation aids etc.)

Purpose

Computer training provides users with required familiarity regarding computer usage and care. This is useful for new users and serves as a refresher for users who are familiar with computers.

Groups Involved with Computer Training

- Project management team should facilitate the training.
- Hardware vendor typically is responsible for the training.
- End users from pilot labs should be the primary participant in this program.
- Lab management should be involved in the process to schedule staff so that there is minimal impact to operations during training.

Steps Involved with Computer Training

1. Schedule multiple training sessions to minimize operational impact at labs and accommodate normal lab operations.

2. Provide hands-on training (vs. slide deck) for learning and retention.

3. Determine whether it's optimal to conduct training at a central facility across all pilot labs or conduct training at each location.

Timing

Computer training occurs once the computers are installed at the lab facility.

Training: LIS User

This application software training for the end-users focuses on system's capabilities and usage in day-to-day lab activities. It involves in-depth walk-through of the system module-by-module in a systematic and comprehensive manner.

Purpose

Participants use this training to gain better understanding of the newly introduced capability and able to use the system as part of day-to-day lab operations and activities.

Groups Involved in LIS User Training

- Project management team facilitates the training process.
- Site specific task force is involved in coordinating the training at their respective location.
- Software vendor is responsible for the training.
- End users from pilot labs should be the primary participants in this program.
- Lab management should adjust the schedule to minimize impact on operations during training.

Steps Involved in LIS User Training

1. Tailor training to match the go-forward workflow at the pilot lab.
2. Video record the training for future playback and reference material, if possible.
3. Schedule multiple training sessions to minimize operational impact at laboratories.
4. Conduct hands-on training (vs. slide deck) for learning and retention.
5. Conduct this training at each laboratory.

Timing

LIS user training occurs once the new system is installed at a pilot lab and ready for use. The timing of training should be close to system's availability.

Training: LIS Advanced/Super User

This advanced, in-depth application software training for super users focuses on system's capabilities, as well as know-how related to manual processes with respect to managing and maintaining the system. Following are some typical areas that should be part of this training.

- Adding/modifying users to the system
- Site specific Master data management
- Processes run at a specified frequency (i.e., daily/weekly/monthly, etc.)
- Orderly start-up and shut-down of the system on a daily basis as well as during emergencies like power failure
- Backup and recovery procedures
- Printer support like replacing toners and cartridges
- Level-1 support/On-site responder's training

Purpose

Having this knowledge local/onsite will help in minimizing the down time for the system.

Groups Involved with Super User Training

- Project management team facilitates the training process.
- Site specific Task force is involved in coordinating the training at their respective location.
- Software vendor is responsible for the training.
- Super users from pilot labs should be the primary participants in this program.
- Lab management should be involved in designating the super users for the laboratories plus approving the schedule to ensure minimal impact to operations during training.

Steps Involved with Super User Training

1. Identify at least two people for each site for this role.
2. Conduct this training at each laboratory.
3. Include applicable SOPs as part of this training.
4. Provide job aids to the super users for easy and quick reference.

Timing

This training should occur once the new system is installed at a pilot lab and ready for use. The timing of training should be close to system's availability.

Training: Systems Administrator

This advanced in-depth systems view of the training for technical SMEs focuses on technical know-how with respect to managing and maintaining the system. Below are some typical areas that should be part of this training.

- Logical and physical architecture review of the overall solution, including hardware, software, networking, printers, etc.
- Level-1 and Level-2 support and troubleshooting procedures prior to contacting the vendor support

Purpose

Having this knowledge local/onsite will help in minimizing the down time for the system.

Groups Involved with Systems Administrator Training

- Project management team facilitates the training process.
- Site specific Task force is involved in coordinating the training at their respective location.
- Hardware vendor & software vendor are responsible for the training.
- System administrators, supporting the pilot labs, are the primary participants in this program. If hardware vendor is providing this support locally, then LIMS vendor should provide this training to them.
- Lab management should be involved in this process and adjust the schedule for minimal impact to operations during training.

Steps Involved with Systems Administrator Training

1. Training should be a joint-effort between the hardware and software vendors.
2. Conduct this training at each laboratory.
3. Include applicable SOPs as part of this training.
4. Provide job aids to the administrators for easy and quick reference.

Timing

This training occurs once the new system is installed at a pilot lab and ready for use. The timing of training should be close to system's availability.

Training: Pre-Service

Integrating the training with pre-service program if one is in effect. If pre-service was considered and made part of the rollout during visioning exercise, it is imperative to include that program in the training plans and execution.

Purpose

Pre-service training develops in-country capacity and leverages opportunities where a pre-service program can provide first responder/on-site support.

Groups Involved with Pre-Service Training

- TWG is involved in engaging with the academic institutions.
- Project management team facilitates the training processes.
- Lab management will review and approve the pre-service agreements, if they are providing first responder/onsite support.

Steps Involved with Pre-Service Training

1. Partner with local academic institutions.
2. Offer one or two seats in respective training sessions.
3. Ensure security and access privileges to live system are not compromised.
4. Gain commitment from academic institution; they can provide any first responder onsite support and let the SOPs reflect that.

Timing

Pre-service training occurs as part of planning and execution of overall training.

Going Live: Operational Readiness

All prerequisites are completed for each site to ensure each pilot site is ready to cut-over to new system

Purpose

Operational readiness provides a smooth transition from the current system to the new system.

Groups Involved with Operational Readiness

- Site-specific task force leads this effort.
- Project management team provides the necessary planning and execution support.
- Hardware vendor & software vendor completes a final verification of the overall solution and certifies the system as operational ready.
- TWG and other task forces are involved in planning the cut-over activities.
- Lab involvement includes end-user sign-off and management sign-off to switch over.

Steps Involved with Operational Readiness

This is an important activity. After months of hard work, get the staff excited about the cutover. Evaluate whether the LIS is ready to go live by using the guidelines below.

1. Installation and testing are complete.
2. Hardware, networks, interface devices, operating system software and application software have been installed and tested.
3. The database is completely tested during various tests, test data is removed, data migration completed, master data is validated
4. Performance/Load testing is completed;
5. Backup and recovery is tested and documented.
6. Standard operating procedures are validated and documented (e.g., system operations, report handling and distribution, and support & maintenance).
7. Training is complete for users, operational staff, support staff and customers.
8. Notify everyone of the intention to go live.
9. Verify the timetable, exact sequence of events, and potential effects of these events on the user.
10. Freeze the system from any further changes, however small/minor they seem.
11. Publish the timetable and get sign-offs from upper management and all involved departments.
12. Develop and publish a detailed activation plan. This plan includes every step from the time you start to bring the system live—steps to turn off the old system, the point at which to change over, the time to stop entering results in the old system and the time to start

the system.

13. Maintain the ability to go back to current operations and/or manual procedures from contingency planning perspective.

14. Set up a help desk for reliable support that will be available consistently during work hours. The use of “trouble tickets” will document the problem and the time it was fixed. This center can either supplement the vendor help desk or the vendor help desk can fulfill this function.

15. Make sure the decision makers are available from start to system stable; in the event of a crisis situation, they can make the decision to revert to paper-based methods.

Timing

This step is a prerequisite to go live and occurs in preparation to go live.

Going Live: Supported Supervision

Supported supervision takes place during a brief period after cutting-over to production (live system) where onsite support and hand-holding is offered to mitigate any issues, incidents and user orientation.

Purpose

Supported supervision minimizes impacts of any unforeseen incidents caused by system malfunction. It is available to ease the end-user apprehensiveness as they are using the system for the first time in live mode. This phase helps laboratories to learn, adapt and adjust the process for future use.

Groups Involved with Supported Supervision

- Site-specific task force leads the effort for their respective pilot site.
- Project management team performs the planning and provides the necessary support during execution.
- TWG, sponsors and lab management are informed and available for decision making in case of an incident/crisis.
- SMEs, from both hardware and software vendors, are available onsite as agreed-upon during the planning of this activity. They may need to be in multiple places depending on number of sites that are going live and the type of solution architecture (i.e., LAN vs. WAN based solution).
- Vendor
- Trained system administrators
- Trained super users

Steps Involved with Supported Supervision

1. This is factored in the vendor contract so that there is no additional cost involved.
2. Use the help desk discussed in the previous section to provide the human resources necessary to support the end user. These individuals could be a mix of vendors and staff.
3. Document all incidents for tracking and future reference.
4. Review pre–Go live documentations and signoffs.
5. Observe how users utilize the LIS, clarify misconceptions and suggest how users could improve their work flow using the LIS.
6. Strengthen local super user skills in supporting their laboratory
7. Monitor support given by the vendor during this period. Are issues raised being resolved in time?
8. Monitor equipment and/or external system integration.

Timing

Supported supervision occurs once the system is cut-over to live mode. Usually this phase lasts for 2 – 3 weeks.

SUSTAINABILITY

The system is live and must have mechanisms in place to run smoothly with no or minimum disruptions to operations. Thinking, approach and execution of the sustainability plan must be comprehensive. The Ministry of Health must maintain the program to sustain post implementation and post USG support.

In simple terms now we have the “lights on,” we need to have mechanisms in place to “keep the lights on.” This section touches on few key areas on this topic.

Purpose

Every system needs some care and feed to operate smoothly. So much thought, effort and resource consumption led to this milestone. Without proper sustainability plan the system could malfunction—for reasons that are preventable—causing disruptions to operations leading to end-user disappointment resulting in resistance to adoption.

Also, funding is usually for a defined and limited period of time with no guarantee of continued funding following the end of this cycle.

Groups Involved with Sustainability

- Sponsor and TWG are responsible to ensure the approach is thought-through and mechanisms/framework are in place from a fiscal budget and allocation perspective.
- LIS task force provides the recommendations and standard operating procedures (SOPs) related to operations.
- Change management and control committee specify and ensure change management SOPs.
- LIS vendor provides ongoing maintenance, upgrade support, user training and anything else team deems necessary.
- Hardware and system software vendor provides ongoing maintenance, upgrade support

and anything else team deems necessary.

- Instrumentation vendors provide ongoing maintenance, upgrade support and anything else team deems necessary.
- Infrastructure vendors provide ongoing maintenance, upgrade support and anything else team deems necessary.
- Lab management ensures adherence to relevant SOPs, budget planning and monitoring, human resources and capacity planning and tracking, providing information for year-to-year budget planning.
- Super users in laboratory participate in developing and implementing SOPs and fulfill first responder role to system emergency needs.
- End-users in lab follow applicable SOPs.

Steps Involved with Sustainability

Below is a recommended approach for sustainability planning.

1. Develop high-level approach and framework during the Vision and Planning phases of the initiative.

2. Gain consensus/concurrence from all stakeholders (primarily sponsor, MOH, TWG, laboratory management) for the developed framework.

3. Standard Operating Procedures (SOPs): Develop detailed SOPs as part of the quality standards and requirements compilation.

4. Training: Use every opportunity to test, train and iterate on SOPs during user training, UAT and SRDT. User refresher training should be part of annual planning.

5. Budget planning should be part of strategic (multi-year) planning and tactical (annual) allocation

6. Sustainability at a high level can be broken down into two sub-categories: operations and maintenance and change management plan. The rest of this section discusses these two in detail.

Timing

Sustainability cannot be an afterthought. The topic should be part of discussion right from the vision phase of the project and is iterated to the next level of detail throughout each phase of the project. Without this commitment, it is not wise to proceed with the initiative.

Some level of sustainability planning is required for each phase of deployment (i.e., for pilot or subsequent rollouts). This will result in amendments and enhancements to the overall sustainability planning.

Chapter Navigation

The “Sustainability” section of this chapter has 12 subsections. There is a navigation tool in the margins throughout this section to help you keep track of where you are in the list of sustainability considerations.

Operations: User Administration

This task involves creating and maintaining users to provide access to the system and granting the appropriate role for performing relevant lab functions/operations.

Purpose

The system should reflect the personnel changes in the lab. This capability should be taken seriously, as ensuring right access with right privileges for each user to the system is fundamental.

Groups Involved

- Lab management is responsible to adhere to SOPs related to personnel changes.
- Super user designated for the lab is responsible to perform the changes in the system.
- End-user impacted by these changes should verify and confirm the access and authorization.

Process

Follow the SOP related to user administration. A general guideline should be all changes related to user administration should occur only after proper request and approval process.

Timing

This should occur whenever there is a personnel change.

Operations: Master Data Management

Master data, also known as reference data, once created usually is static and will be referenced in other areas of information gathering. This task involves creating and maintaining master data to ensure consistency and control in the ongoing maintenance and application use of this information.

An example of this is “Test Catalog Management” in the High Level Requirements (HLR).

Purpose

Lack of process will result in multiple (potentially inconsistent) versions of the same master data causing inaccuracies and manual reconciliation procedures increasing complexity of the implementation.

Groups Involved

- Lab management is responsible to adhere to SOPs related to Master data.
- Change management and control committee to review and approve Master Data affecting all Labs.
- Advanced/Super user (Librarian) is responsible to perform the changes in the system.

Process

Follow the SOP related to master data management. A general guideline should be all changes related to Master Data should occur only after proper request and approval process.

Timing

This occurs whenever there is a need to add a new master code or change an existing one.

Backup and Recovery Procedures

Data stored in the system is copied to an alternate storage media on a frequent basis and kept on-site and in a remote location for redundancy purposes. Recommended frequency for backup is at the least once a day.

Purpose

In the event of accidental loss of data from the primary system, these copies are used to restore data to a last known point, which is referred to here as recovery procedures. With a daily backup in case of an incident, the most data a site would loose would be a day's worth of data.

Groups Involved

- Systems administrator or Super user (librarian) can be responsible to perform the backup processes.
- LIS vendor and/or hardware vendor will be responsible for providing the necessary automation and simple user interface to initiate and successful completion of backup process.
- Systems administrator could be responsible to perform the recovery processes, if needed.
- LIS vendor and/or hardware vendor will be responsible for providing the necessary support during recovery process.

Steps Involved

1. Develop and follow SOP for backup process.
2. Develop and follow SOP for recovery process.
3. As a general guideline, both SOPs should be tested thoroughly prior to going live, as well as conduct periodic tests post production.
4. Backups should be performed when system is in offline mode (not available to users) to ensure all data is being backed up. Otherwise, there is a risk of capturing incomplete data, which may lead to inconsistent data in case of recovery. It is therefore recommended to perform backups nightly once the system is shutdown for the day.
5. Backups may take some time depending on the amount of data so it's imperative to allow enough time to complete the process and provision it in the daily processes.
6. In the event of recovery, the time depends on amount of data to be restored and will be approximately double the backup time. This includes the procedures to ensure the recovery is complete and the system is restored to a stable state.

Timing

- Backup procedure is conducted per the agreed upon frequency—usually, at least once every day.
- Recovery process is tested periodically.
- Recovery process is performed in the event of data loss.

Printing Support

Ensure print capability performs as per expectations— printers are accessible from the system, routine printer maintenance is performed and adequate printing related supplies and consumables are on-the-shelf. Ideally, there should be more than one printer for a high volume laboratory or for laboratories that print results by test type rather than combine all tests requested for a patient.

Purpose

A variety of operational process may be tied to printing of hard copies. A printer malfunction can result in business disruption. Here are some examples:

Barcode label printing is tied to a printer either on site or at a central location, if the labels are pre printed.

Printing of results is dependent on printers.

Groups Involved

- Systems administrator or Super user (librarian) can be responsible for printer support.
- Management is responsible for providing budgetary/fiscal support, which means having funds to have a backup printer (or buy new one if backup does not work), funds for consumables such as paper, barcode labels, ink cartridges/toner, etc.
- In case of barcode printer, vendor will provide level-2 and level-3 support.
- Network administrator may also be involved for complex issues related to a regular printer or barcode printer.

Steps Involved

1. Develop and follow the SOP for inventory management related to print supplies and consumables.
2. Train all end-users to load paper and clear paper jams.
3. Train super users to change toners, ink cartridges etc.
4. Use a voltage stabilizer for each printer.
5. Consider connecting the central/common printers to UPS, if possible, and all barcode printers for sure.
6. Plan to have more than one printer available per location for redundancy purposes.
7. Train super users to change system or end-user computer configuration to redirect printing to a different printer in case of a printer malfunction.

Timing

- Follow recommended maintenance by the printer manufacturer.
- Follow inventory management SOP to ensure adequate printing supplies/consumables are available onsite at the lab.

Emergency Shutdown

Emergency shutdown ensures the system is shut-down in an orderly fashion in the event of power outage.

Purpose

Abrupt shutdown results in data loss and/or corruption resulting in system malfunction.

Groups Involved

- Systems administrator or Super user (librarian) can be responsible for emergency shut-down.
- Systems administrator or Super user (librarian) can be responsible for system startup once situation is rectified.
- LIS vendor and/or hardware vendor will be responsible for providing the necessary automation and simple user interface to initiate an emergency shut-down. System should report successful shut-down.
- LIS vendor and/or hardware vendor will be responsible for providing the necessary automation and simple user interface to initiate a system startup process. System should report successful startup and readiness to start using.

Steps Involved

1. Develop and follow the SOP for emergency shutdown.

2. Develop and follow the SOP for system start-up.

Timing

A case of power outage where the system runs on UPS and SOP calls for an emergency shut down.

Support: Help Desk

As a support structure for end users requiring help, the Help Desk is a part of the system sustainability. Without the ability to do immediate trouble shooting or document missing functions, the system would not sustain.

Purpose

Using a Help Desk will avoid business disruptions, increase system adoption rate and enhance user experience.

Groups Involved

- Systems administrator or super user (librarian)
- Hardware/System software vendor
- Infrastructure vendor
- LIS Vendor

Steps Involved

1. Develop and follow the SOP for support desk requests.

2. Have predefined and contractually binding service level agreements (SLAs) with vendors.

As described in "Section 5.4.2. Incident Processing and Tracking" in the 2005 Guide, the selected vendor shall define a technical support process to enable the lab to submit support requests in the event of problems or issues with the LIS. Incidents should be able to be submitted either by phone, email or using a web form. The support system should have the ability to track support incidents that are submitted via either of these methods.

Once the customer submits a technical inquiry to the support organization, an "incident" is generated. An incident is the processing of a technical inquiry or the attempt to solve a technical problem, regardless of the number of required phone calls or e-mails. Opened incidents remain open until a solution is achieved or the incidents closed upon mutual agreement with the customer.

The lab shall determine the urgency of the support inquiry in coordination with the support organization. The support engineer may use his or her reasonable discretion to change the processing order of inquiries in case of identical urgency and priority, or for reasons of efficiency, provided that the postponed customer does not suffer any significant disadvantages.

Timing

Create the Help Desk, as needed, once the system is operational.

Below are factors that affect the decision to hire IT staff to maintain the LIS.

- Early original planning
- In-house LIS staffing
- A super user to provide coverage role
- Centralized hospital or MOH IT Support
- In-country vendor
    - Use of MOU and MOA between parties
    - Define service level requirements up-front
    - Annual service contract
    - Help Desk

Support: Issue/Incident Log

This repository (log/register) captures all issues and incidents requiring support/help desk assistance.

Purpose

The log helps in variety of ways.

- Ensures SLAs are met by the vendor
- Identifies patterns on recurring issues/incidents so problem can be tackled at the root-cause level
- Helps to enhance end-user training approach and knowledge base

Groups Involved

- End users requesting help
- Systems administrator or super user (librarian) who maintains this log/register
- Hardware/System software vendor
- Infrastructure vendor
- LIMS Vendor

Steps Involved

1. This should be part of SOP for support desk requests.

2. Use this process during user training, user agreement testing and system requirements demonstration testing.

Timing

The issue/incident log should be created as needed once system is operational/live.

Support: Level-1

As the name indicates, this is the first level of support; support personnel are accessible and response time is in minutes rather than in hours.

Purpose

A first responder support structure, consisting of onsite staff, ensures help is available quickly. Most of the support requests could be resolved by walking users through the business process flow or helping them to navigate the system or some simple configuration. Having this type of knowledge on-site will enhance the response time. Also, these people are trained to identify more complex issues and escalate the issue/incident to the appropriate next level.

Groups Involved

- End users requesting help
- Systems administrator or super user (librarian) provides the Level-1 support
- On-site staff who are trained to provide this type of support
- If not resolved, then escalate to the next level:
  - hardware/system software vendor,
  - infrastructure vendor, or
  - LIS vendor.

Steps Involved

1. This should be part of SOP for support desk requests.

2. A support request is logged in the issue/incident log. The issue log is maintained by the on-site level-support personnel.

3. Use this process during user training, user acceptance testing (UAT) and system requirements demonstration testing (SRDT).

4. Training and job-aids for Level-1 support should be part of the program rollout.

Timing

Rollout Level-1 support, as needed, once system is operational/live.

Support: Level-2

Using the second level of support means that the issue is little more involved and requires assistance from the vendor.

Purpose

Level-2 support provides access to technical expertise in resolving an issue/incident.

Groups Involved

- End users requesting help
- Systems administrator or super user (librarian)
- Hardware/System software vendor who is local (but not necessarily on-site at lab) provides the Level-2 support
- If not resolved, then level-2 will escalate to the next level:
  - infrastructure vendor, or
  - LIS vendor.

Steps Involved

1. This should be part of SOP for support desk requests.
2. A support request is logged in the issue/incident log.
3. Use this process during user training, UAT and SRDT.

Timing

Level-2 support should become available, as needed, once system is operational/live.

Support: Level-3

As the name indicates, this is the third level of support, meaning the issue is complex and requires assistance from multiple vendors.

Purpose

Level-3 support provides access to technical expertise and application software in resolving an issue/incident.

Groups Involved

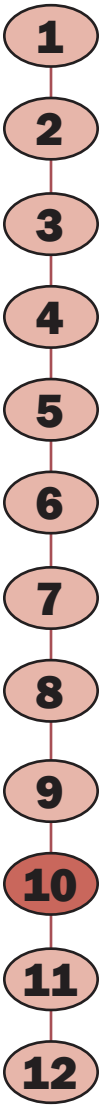
- End users requesting help
- Systems administrator or super user (librarian)
- Hardware/System software vendor who is local (not necessarily on-site at the laboratory)
- One of the following will be the primary owner for Level-3:
  - Infrastructure vendor
  - LIMS Vendor

Steps Involved

1. This should be part of SOP for support desk requests
2. A support request is logged in the issue/incident log
3. Use this process during user training, UAT and SRDT

Timing

Level-3 support should be put into place, as needed, once system is operational/live.



Maintenance and Change Management Plan

Due to the complicated nature of this section, the editors have chosen to illustrate the details of the Maintenance and Change Management Plan as a table rather than the text format otherwise used in this section to describe the purpose, groups involved, steps and timing of this activity.

Questions	LIS Application Software			Operating Platform	
	Bug Fixes	Customizations & Enhancements	Upgrades	Operating System (OS)	Hardware
What is it?	Resolving root cause for incidents and issues that are identified as deficiencies in the system	Software changes made on request to enhance system functionality and/or to suit custom workflows. The end product/release should include all the bug fixes done so far.	Software changes made by vendor as part of their product roadmap The end product/release should include all the bug fixes done so far, as well as customizations and enhancements done specifically for this implementation.	System software level changes This should have no negative impacts on the functionality of the LIS application.	Hardware level changes Replacing a malfunctioning printer or hard disk or adding more memory to server, etc.
Why do we need it?	Frequent recurrence of an issue /incident causing disruptions and negative user perception Show stopper deficiency impacting the workflow, and/or data integrity	Enhanced user productivity and experience. Examples: • A new report or a new screen, etc. • Interface to a special lab instrument • patient report format updated to comply with new ISO criterion.	To keep current with the vendor's product and be compliant with vendor's product life cycle and support commitments	OS vendors release patches and service packs enhancing the fundamental software from functionality and security vulnerabilities perspective	To restore system to its normal operating state resulting from malfunctioning or end-of-life equipment

Questions	LIS Application Software			Operating Platform	
	Bug Fixes	Customizations & Enhancements	Upgrades	Operating System (OS)	Hardware
Who is involved?	• Change management committee • Vendor • UAT task force	• Change management committee to review and approve the enhancement request and release schedule and rollout plan from vendor • LIS vendor • UAT task force	• Change management committee to review upgrade release notes and approve the release schedule and rollout plan from vendor • LIS vendor • UAT task force	• Change management committee to review and approve the release schedule and rollout plan • hardware and system software vendor • LIS vendor to certify LIS application for the upgrade • UAT task force	• Change management committee • Hardware and system Software Vendor • UAT task force
How do we do it?	Follow the production release SOP	Group several enhancement requests into a release and manage it like a mini-project Follow the production release SOP	Follow the production release SOP	Follow the production release SOP	Follow the production release SOP
When do we do it?	As needed, if it is a show stopper	Per the release schedule	Per the release schedule	As needed	As needed

Budget

Budget speaks to financial resource planning and allocation to maintain the system (i.e., "to keep the lights on") only. Hence, this excludes budget related to expansion from both enhancements to the current system, rollouts to new labs perspective and costs associated with initial rollout, including all hardware and software procurements.

Typical Budgeted Items

- Hardware and system software maintenance and support fees
- LIS application software maintenance and support fees
- Utility software (e.g., antivirus, backup, productivity suite, etc.) maintenance and licenses
- Training and travel costs for new users and refresher training
- Training and travel costs for new super users and refresher training
- Consumables like office supplies, printing paper, printer cartridges and toners, barcode labels, backup media, etc.
- Replacement of malfunctioning and out-of-warranty generators, UPS, voltage stabilizers.
- Repair/maintenance or replacement of air conditioners depending on the life and state of the equipment
- Replacement of end-of-life and out-of-warranty computing equipment like network switches/routers, computers and human interface devices like monitors, keyboards, mice, etc.
- Utility (electricity, Internet access, etc.) bills related to this infrastructure
- Preprinted stationery for Paper-based system

Purpose

Without an explicit plan and allocation of budget, maintenance of the system will be ad hoc and the system would fail resulting in business disruption, failure in adoption, etc., defeating the whole purpose and objective of the initiative. For example, using handwritten lab numbers because there are no barcode labels.

Groups Involved

- Sponsors (MOH) are responsible to ensure the approach is thought-through and mechanisms/framework are in place from a fiscal budget and allocation perspective.
- Lab management is responsible to track spending against the allocation and provide that data for future planning.
- TWG is responsible in providing recommendations to MOH, as well as negotiating with the vendors.

Steps Involved

1. Include "operational budget impact" as a discussion point in all decisions made during the project.

2. Develop "operational impact" worksheet with respect to "total cost of ownership."

3. Annually, the budget for maintenance will be developed on a per site basis. The site budgets then can be added up to determine overall budget based on number of sites to be deployed in that year and number of sites ongoing from previous years. This process overlaps with two other planning activities:

    - laboratory planning exercise
    - MOH planning exercise

4. If finances are centrally managed, there should be consideration given to provide each site with an allowance (a sum of money) for them to manage locally and be responsible for purchasing supplies.

Timing

Budgeting should take place annually as part of strategic planning at MOH level and tactical planning at the lab level.

Project Management Plan

1. Project Management Overview
2. Project Schedule
3. Cost Management
   - Personnel and Services
   - Capital Costs
   - Cost of Ownership
4. Procurement Request for Proposal (RFP)
   - RFP Development
   - RFP Evaluation Criteria
   - RFP Publication/Distribution
   - Vendor/Bidder Conference
   - Vendor Selection
   - Award Vendor Contract
5. Human Resources Plan
6. Communication Plan
7. Risk Management

PROJECT MANAGEMENT OVERVIEW

The project management plan aims to accomplish 5 main goals.

- Document a formal, approved process to be followed as the project is executed.
- Documents the actions necessary to coordinate the various planning activities and
- Establish the decision-making structure for the rest of the project
- Establish how the project will be monitored, controlled and closed
- Establish the process by which the team is going to go about identifying key stakeholders and ensuring that they are appropriately kept apprised of the information they need to feel engaged in the process and provide appropriate feedback and decision support.

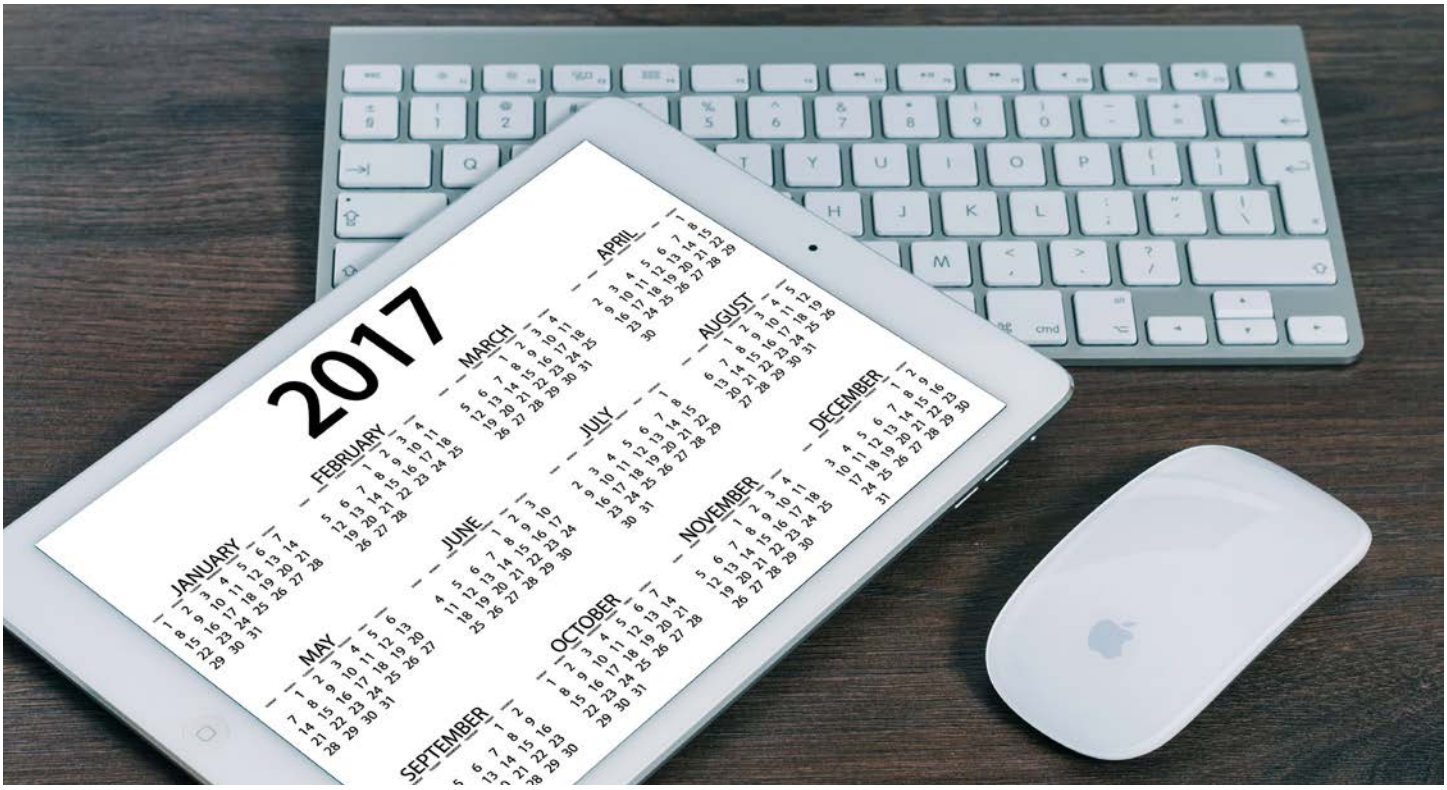
Below are other plans that feed into the project management plan.

- Scope Management
- Requirements management
- Schedule management
- Cost management
- Quality management
- Process Improvement
- Human Resources Plan
- Communications management
- Risk management

Project scope is addressed in the chapter "LIS as a Project in a Laboratory," in the section "Scope."

Requirements management is addressed throughout "LIS as a Project in a Laboratory."

Governance is addressed in "Program Management/Team Structure and Organization," in "LIS Overview."



PROJECT SCHEDULE

The project schedule is a hierarchical task list with time estimates, milestones and resources assigned to the task. Tasks are laid out indicating dependencies (i.e., if one task depends on another being either started or completed before being initiated).

It is this logically organized schedule that will serve as guiding post for the team in terms of tasks/activities, dependencies, human resource allocation, etc. It is imperative for the team to be able to follow as they plan and implement, to know if they are meeting deadlines and deliverables and to be able to report to all stakeholders on the accurate progress of the activity, as well show issues, constraints, etc.

Groups Involved

- The project manager ultimately is responsible for the following:
  - developing and maintenance of a project schedule,
  - working with the team and task leaders and providing the skills and knowledge to complete tasks, and
  - keeping senior management and the stakeholders informed of tasks that may be delayed or might otherwise affect the schedule or the quality of the project outcome.
- TWG and task forces are involved in schedule development and subsequent revisions.

Steps Involved

1. Select a tool of choice to capture the project schedule. Microsoft Project is an example.

2. To minimize licensing costs as well as minimize learning another tool that is not used by everyone on a regular basis, the plan is developed and maintained by the Project Manager and may be another member in the project management team but distributed /published as PDF so everyone can access it.

3. To develop a good plan one should start with task lists (Appendix C). Develop your im-

plementation specific plan from these. Along with the activities, milestones should be identified and agreed upon by all stakeholders.

4. Confirm resources. When tasks are assigned, make sure that available resources are adequate to the task.

5. The person assigned to a task is responsible for completion of the task on schedule, reporting progress against the task, and if a problem occurs, informing the project leader so the problem can be addressed before it adversely affects the total project.

6. A good project plan will help, but be ready to adjust the plan by adding resources or shifting tasks to prevent delays.

7. Consider these simple steps to develop and manage the project schedule.
    - Describe tasks in terms of the expected outcome (what the task will accomplish) and deliverables (how to show that the task is complete).
    - Assign tasks to a responsible person (task leader) to ensure task completion.
8. Estimate and document time and effort required.
    - Assign completion dates to tasks.
    - Require the task leader to report regularly on the amount of effort expended toward task completion and the percentage completed.
    - Expect the project manager to take corrective action if a task looks like it may not be completed on schedule (more time or effort expended than would be expected based on the percentage completed).
9. Involve vendors for the implementation phase to have one agreed upon plan between all parties.

10. Understand other projects and priorities pertaining to each pilot laboratory from information systems/technology (IT) supporting that laboratory, as well as from lab operations perspective and develop the schedule accordingly. This will help in avoiding schedule conflicts, deal with resource allocation, etc.

Timing

This is one of the key artifacts to be developed once the TWG and project management teams are formed. Once this baseline is established, it is reviewed and adjusted on a periodic basis as well as when transitioning to the next phase of the project. So for example, when the project moves into Implement phase, the schedule needs to be reviewed and fine-tuned with input from the selected vendors.

Project plans are dynamic. When a project is started, especially with a new product and new system provider, learning takes time. As you learn, the project plan may need to be altered; add a task, change a plan, modify a task, move a task, or reschedule it. Alteration to the project schedule would need to be done by the project manager after review and approval by TWG and task forces.

COST MANAGEMENT

This section provides an in-depth look at cost management the various aspects of LIS operations. Here, cost management is broken down into three main areas.

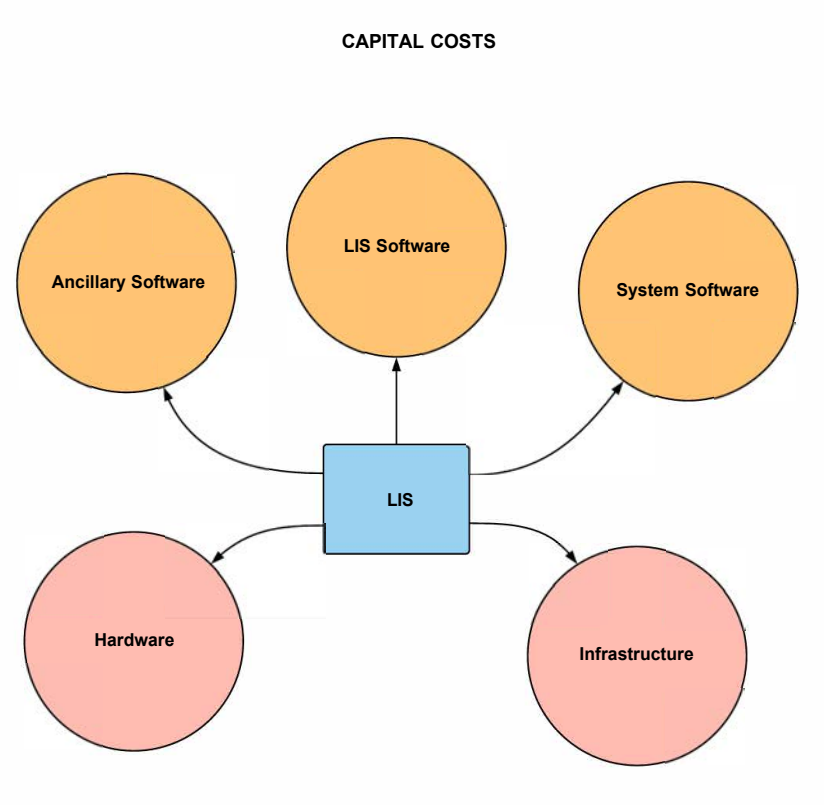
1. Personnel and Services
2. Capital Costs
3. Ownership

While the suggested cost breakdowns are ideal, real-life budgets and funding sources change regularly and implementation costs are often difficult to accurately predict. It is key to prioritize functional needs and have a structured plan to scale back implementation, if needed. A laboratory may need to scale back LIS operations if it cannot support them.

Cost Management: Personnel and Services

The main costs contributing to personnel and services are: planning, design and configuration, implementation and operations. Of these four, operations eventually becomes the largest cost.

Personnel and Services Costs	
Phase	**Details**
Planning	Many organizations launch a "discovery" project to establish initial LIS project planning and budgets. It is often helpful to bring in external help for initial planning steps. But even with external help, internal resources need to be dedicated to the planning process.
Design	Functional specifications development is a skill most laboratories do not have. Prototyping and initial configurations are completed by vendor resources before implementation and include the time of current laboratory staff who will be needed for specification development.
Vendor Implementation Services	• Vendor costs for services can be controlled if specific requirements defined up front. • Local staff work with vendor implementers to save you money and time overall. • Explore third-party implementation services for ancillary needs such as report writing or messaging. • Contract should include all specifications and breakdown of cost by all vendors. • Consultants can help organize the effort but the final decision needs to be local.



Cost Management: Capital Costs

These are costs that usually need to be undertaken initially prior to implementation. These can be high due to the type of procurement required as described in the diagram below. This is usually a one-time cost after which the items need to be maintained or replaced, as needed.

Capital Costs

Cost	Details

Hardware	• Workstations and server(s)
	  ○ Database, application, reporting
	  ○ Data storage and backup equipment
	• Networking hardware and services
	• Printers, barcode readers etc.

Physical Requirements	• Desks/workstations
	• Minor renovations for optimal workflow
	• Server environments
	  ○ Temperature
	  ○ Security
	• Power
	• Networking connectivity
	• Internal
	• External
	• Physical redundancy

Capital Costs	
Cost	**Details**

Software Licensing	• Application
	• Ancillary software
	  ○ Integration engines
	  ○ Reporting tools
	• System software
	  ○ Operating system
	  ○ Database

Ancillary Software	• Operating system, application platform and database • Reporting tools • Data visualization tools • QC analysis packages • Anti-virus software • Instrument integration software • Messaging engines
Ancillary Software Licensing	• Sometimes bundled with LIS software • Beware of limited OEM licensing restrictions • Not always less expensive buying through LIS vendor, always compare pricing • Don't forget maintenance agreement costs

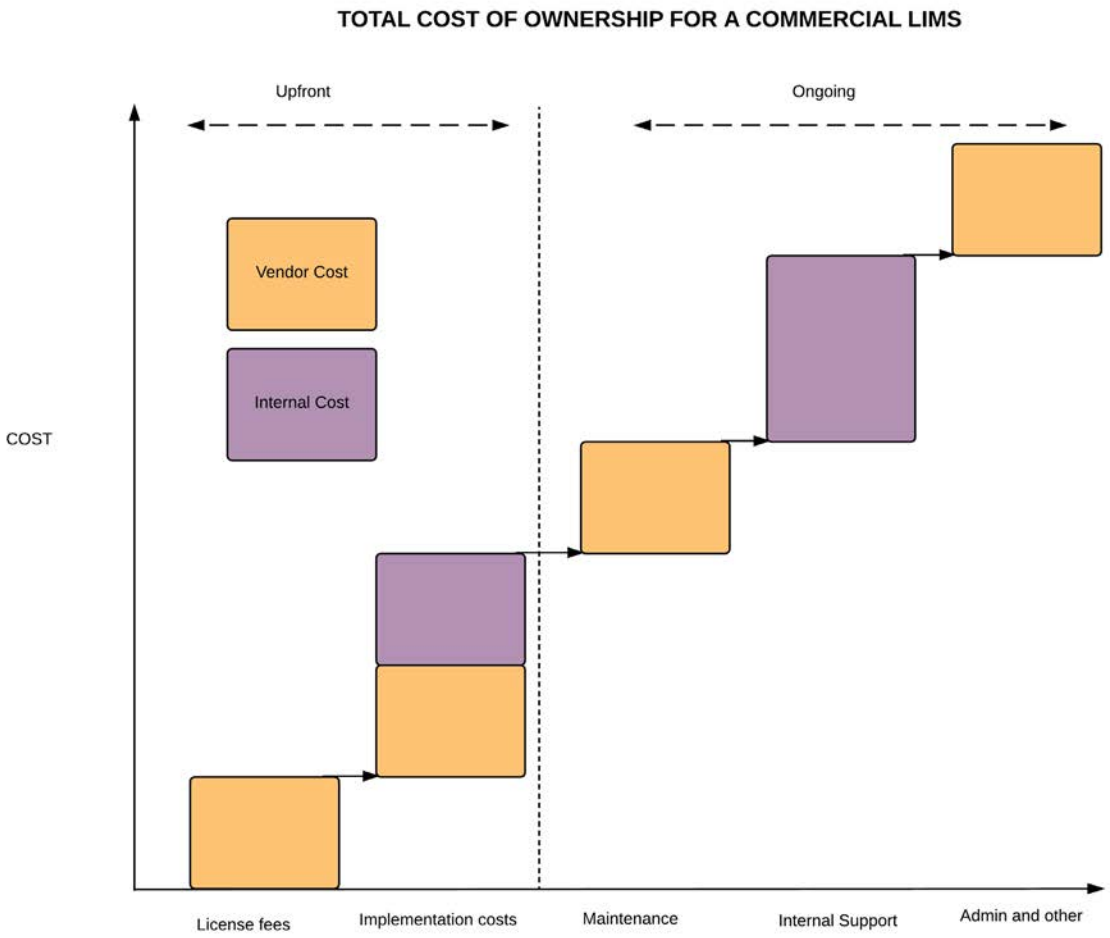
Licensing Models	• Metered licensing
	  ○ Per processor
	  ○ Per named user
	  ○ Per concurrent user
	• Site licensing
	• Bundled (OEM) licensing
	  ○ Database or ancillary tools
	  ○ Usually restricted to use within OEM system

Open Source Licensing	• Licensing is often free, but not always
	• There are still costs:
	  ○ OS/Database licenses
	  ○ Support
	  ○ Implementation
	• Laboratory must have a long-term support strategy (vendor, community, in-house)
	• Ideally, you can support yourself with adequate programming resources

Cost Management: Cost of Ownership

Maintenance, supplies, utilities, capital replacement, and operational support are ongoing costs related to continued use of the LIS. It is important to factor in all of these: a gap in any can impact the ability of the laboratory to effectively use the LIS. On the following page, a table breaks down the costs associated with ownership.

Figure 37: Example Cost of Ownership for Commercial Off the Shelf (COTS) LIS



Cost of Ownership	
Cost	**Details**
Operational Expenses	• Dedicate personnel to daily system maintenance • Ongoing vendor support for larger configuration or customization efforts to adjust to changes in business processes • Messaging support often requires occasional help from outside resources • Annual maintenance agreements

Maintenance	• Hardware support contracts
	  ○ Desktop/Server hardware
	  ○ Networking hardware
	• Software support contracts
	  ○ LIS
	  ○ Ancillary software
	• Building local capacity (e.g., help desk saves on cost)

Operational Support	• Backups • Antivirus/operating system updates • Archival/data disposal • Hardware maintenance • Networking hardware support • Help desk
Utilities	• Networking • Power • Air-conditioning
Supplies	• Backup tapes – or external hard drives • Printer paper and toner • Barcode label stock • Barcode printer ink • New user manuals
Capital Replacement	• Computer CPU's (~5 yrs) • Servers (~8 yrs) • Hard-disk drives (~3 yrs) • Printers (~5 yrs • Networking routers (~7 yrs) • UPS batteries (~2 years)

Cost of Ownership	
Cost	**Details**
Pro Forma Cost Analysis	• Provides objective financial information • Helps with planning and resource allocation to implement and sustain LIS • Enables decision makers to assess cost versus benefits of LIS strategies • Good starting point for discussion
Cost Components Included	• Assessment of laboratory operations and functional LIS needs • Hardware: computers, cabling, servers, etc. • Software development and installation: LIS development and other OTS applications such as report writer, installation of system including user training, basic computer training • Backfilling, new positions and technical assistance support • Service agreements for maintenance

Quality Management

The quality management plan includes the use of standards and compliance. With an LIS implementation, this would involve the collection of baseline data to be able to demonstrate improvements in quality once the LIS is implemented. The details of the baseline data to be collected (e.g., aspects of accuracy, completeness and timeliness) need to be included in the quality management plan.

Groups Involved

The TWG and Task Force must guide the details of the quality management plan and identify focus areas.

Steps Involved

1. Identify the standards to be followed and the compliance that the implementation must be measured against.

2. Identify elements to measure accuracy, completeness and timeliness

3. Develop a tool to capture baseline data for the elements identified

Timing

This needs to be developed once the TWG and task forces are formed as all aspects of the LIS project are affected by the Quality Management Plan. Quality metric and quality checklists are key to effective implementation.

PROCUREMENT: REQUEST FOR PROPOSAL (RFP)

An RFP is a tender process with a comprehensive package listing out detailed requirements and seeking proposals from potential vendors. It is a formal documentation highlighting gaps, needs and expectations of the stakeholders and covers the aspects of software and hardware specifications, requirements, etc., compiled from the previous activities. Simply put, an RFP is used to ask system providers what their system does and how they will handle your requirements. Usually, the RFP does not ask for a system specification. In other words, it is important to focus and be specific on "what" is needed and not on "how" aspects of solution. Asking questions allows the system provider to offer suggestions and demonstrate methods of operation that have not been thought of during earlier stages of the process. The RFP process will facilitate elicitation of the potential possibilities from vendors, cutting down on research and due-diligence needed by the project team on every option/alternative out there. The evaluating team has only to compare answers to the RFP and judge which ones they like best.

Even if there is limited funding for an LIS, putting together an RFP helps the country team visualize what they are looking for and develop standard criteria they can use to evaluate the LIS objectively, which is vital regardless of budget.

The RFP document should also provide guidelines and requisites for submitting the responses, since it is a formal document to engage with potential vendors. This will provide a mechanism to publish a common set of comprehensive requirements to the vendor community and solicit their responses. This process will allow for a standardized comparison across vendors and minimize subjectivity.

Groups Involved

- Technical Working Group
- Task forces
- Project Team
- Sponsor

Procurement: RFP Development

The development of the RFP is the first step taken of the entire RFP process. RFP development is initiated once the assessment phase is completed and comprehensive requirements are documented and agreed to by all stakeholders. A formal task with an approved process will facilitate development of a comprehensive RFP document with inputs, perspectives and approvals from all stakeholders.

System providers should not be asked to rush their responses unless there is good cause. One to two months is a reasonable amount of time to expect a detailed response.

Groups Involved

- Project management team will facilitate the process (see composition of project management team above).
- TWG in collaboration with the respective Task forces will develop the requirements and specifications.
- The Ministry of Health (MOH) and sponsors will review the RFP with MOH approving the RFP prior to publication.

Steps Involved

1. Develop and compile requirements and specifications from the previous steps.

2. Consider an interactive approach with at least one review cycle involving all stakeholders in between.

3. Freeze the version of RFP, from any further changes, upon completion of review cycle and approval process.

4. Separate RFP for *Application Software Provider* and H*ardware and System Software Provider*.

5. Use the RFP template provided in the guidebook as a baseline.

6. Use the checklist provided in the appendix to assess readiness of the RFP package.

Timing

- Start compiling the framework once the scope and pilot site selection is completed.
- Assimilate and compile information from ‘’Assessment ‘’activities.
- Initiate review cycle upon completion of Assessment check phase.

Procurement: RFP Evaluation Criteria

The RFP evaluation is a systematic and harmonized process to evaluate vendor responses to RFPs. Evaluation criteria will provide a means to review vendor proposals in a comprehensive perspective while presenting a common framework to rate each proposal making it easier to compare.

Groups Involved

- Project Management Team will facilitate the development of the evaluation criteria.
- TWG provides input during development and reviews the evaluation criteria.
- Sponsors and Ministry of Health will review and approve the evaluation criteria.
- Consult with implementation partner for assistance, as they may have in-depth experience in this area.

Steps Involved

1. Assign weights and scores to various system features to help with an unbiased selection process. These can then be totaled to come up with the final system provider ranking.

2. Use the sample RFP Evaluation Criteria and Matrix provided in the guidebook as a baseline.

3. Ensure evaluators are briefed and trained on how to use the criteria.

4. Pricing should be excluded from evaluation criteria and should be requested in a sealed/confidential manner so that it can be made available to the TWG and sponsors.

5. Conduct a bidders' conference for the short list vendors.

6. Ensure MOH representatives are present during the bidders' conference.

7. Evaluation tools:

    - request on-site demonstration by vendor
    - site visits to locations already using their product
    - phone surveys to get more details from current users about experience and challenges
    - follow-up site visits – to help as a tie breaker or to get more details on a single selected vendor that is potential finalist
    - home office visit – meet with management before signing contract
    - cost benefit analysis – if more than one system is in the final running
    - ranking/recommendation – document reasons/justification for system selection

Timing

Usually, the criteria are developed in conjunction with or right after an RFP is developed.

Procurement: RFP Publication/Distribution

The developed RFP is published for vendor's responses. This is a formal process to engage the bidders who may be able to respond to the RFP.

Group Involved

Project management team leads the process

Steps Involved

1. The RFP should be advertised as required by the funding agency/authority. This will influence whether it will be advertised locally/nationally or internationally.

2. 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. Doing a preliminary screening and capturing enough information to determine the appropriate vendors to even receive the RFP, is recommended. It includes system provider screening, preparation, sales presentations and preliminary proposals. It is reasonable to preselect a small number of providers based on the identified functional needs of the LIS and the known features of available applications. This will help limit the number of RFP's sent out and decrease workload resulting from reviewing all.

3. 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 and criteria as commercial vendors.

4. Follow the process very strictly/stringently to avoid any perception of favoritism, as otherwise it could result in an invalid process resulting in lengthy reconciliation steps.

5. The process should have mechanisms in place, and are published along with the original RFP, to amend an RFP should there be a need at sole discretion of the implementation team.

Timing

Distribution happens once the RFP is ready and approved by the sponsors.

Procurement: Vendor/Bidder Conference

The bidders' conference is a summit where all the shortlisted vendors are invited to come in person and present their solution in-country. The conference ensures vendor product demonstrations are in alignment with their respective responses and provides an opportunity to interact with vendor representatives. This format also allows completion of the process in a short time. For example, the following questions could be raised, if not already part of RFP or for further clarification, if they were asked:

- How much can the system be changed in-house i.e. making simple changes?
- How easy it is to pull and analyze data from the system?
- Once the system is live, how much will it cost to run?

Groups Involved

- Project management team will lead this effort.
- Members from task forces and working group are formed into a selection team.

Steps Involved

1. Prepare in-country selection team.
2. RFP proposals are evaluated based on criteria.
3. Use evaluation criteria developed to evaluate vendor/system.
4. Shortlist 5-6 LIS options.
5. Host Bidder conference and invite shortlisted bidders.
6. Implementation partner can be the neutral third party advising the vendors on the in-country specifics and coach them in highlighting the areas of their solution that would be good fit.
7. Vendors will give a demo of their product/solution.
8. Based on evaluation (quantitative score) negotiate and award the contract.

Timing

- After RFP publication and upon completion of the proposed review time frame
- Vendor responses should have been received and evaluated by this time

Procurement: Vendor Selection

This is a process of identifying the right vendor and system following the bidder conference and set of selection criteria. After a thorough evaluation and bidder conference observation/interaction, the team is in a position to recommend based on the selection criteria the top-ranked provider for negotiation. Document the reasons/justification for system selection and summarize the work to-date for presentation to relevant government officials and decision-makers.

The vendor selection process is required to identify the right vendor and finalize on a suitable product so contract negotiations can take place.

Groups Involved

- Project management team reviews proposals, evaluates submitted solutions and recommends product and provider to the TWG.
- TWG awards of the contract.

Steps Involved

1. Use the evaluation criteria developed earlier.
2. Perform reference checks.
3. Use additional interactions/notes obtained from the bidding conference demos.
4. Short list the top two choices with pros and cons documented clearly.
5. Present the short list to MOH for decision.

Timing

Selection is made after the bidder/vendor conference.

Procurement: Award Vendor Contract

A good contract is the culmination of a sequence of well-planned evaluation and selection tasks. It is the formalization of the understanding between two parties and must describe, in user terms, exactly what the system provider is proposing to install. Lower-ranked system providers should not be ruled out until an agreement is signed. Unless a contract is awarded, there is no formal agreement with the selected vendor. Hence, the implementation cannot move forward.

Groups Involved

- Project management team will lead the negotiations.
- TWG recommends the final contract.
- Sponsors and Ministry of Health will approve the terms of the contract .
- Contract is signed by both parties.

Steps Involved

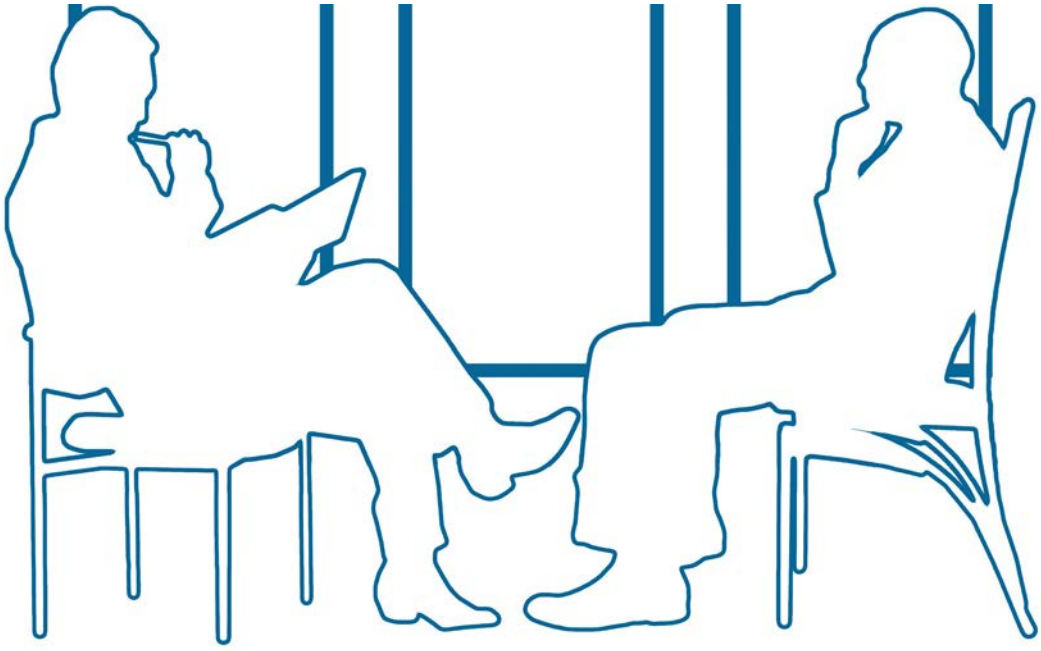
1. Meeting with selected provider to confirm contract details and commitments and to negotiate final contract price. The manager with authority to make contractual obligations, from the vendor side, must attend this meeting.

2. Contract negotiations almost always take longer than anticipated. The only way to make this task go quickly is to accept the standard contract with few changes. Significant changes must be reviewed and agreed to by executives and lawyers from both sides. This process takes time.

3. Upon agreement with the recommended provider, the project manager arranges a series of meetings to prepare for the launch of the Implementation phase.

Timing

The contract is awarded upon final selection of solution and completion of negotiation



HUMAN RESOURCES PLAN

A Human Resources (HR) Plan focuses on human resource needs for the initiative both from project and post-project perspective. It needs to be comprehensive covering all staffing needs, budget to support the needs, incentive and retention programs, training and in-country capacity building, etc.

HR planning is critical for a project's successful outcome. A comprehensive plan, balancing the tactical needs of the project and long-term in-country capacity building, will address issues/concerns in a proactive manner.

Groups Involved

- Project management team owns the task.
- TWG and project management team collectively should perform the analysis and come up with a recommendation.
- Subject matter experts (SMEs) from cross functional areas, including laboratory management and laboratory personnel, could be active participants.
- Sponsor and TWG are responsible to ensure the approach is thought-through and mechanisms/framework are in place from a fiscal budget and allocation perspective.
- Implementation partner serves in a consulting role.

Steps Involved

1. Have a comprehensive plan from a project roll out and post-project perspective.

    a. Project/Roll-out :

        i. Develop an inventory of skill sets and map them to the roles needed during the project.

        ii. Conduct a conscious assessment in terms of availability and skills from internal resources perspective.

iii. Consider hiring external resources (i.e., consultants) for the short-term while developing the local talent in the long-term.

iv. Explore pre-service opportunities with local academic institutions.

b. Post-Project

i. Assess the needs to support operations, post implementation.

ii. Conduct a conscious assessment in terms of availability and skills from internal resources perspective.

iii. If any new positions are identified, then recommended to proceed with the recruitment upfront so the person can join the project team from the get-go and will be able to have the necessary hands-on experience.

2. Fiscal Budget

a. Understand the level of effort and allocate budget to accommodate any additional work staff is required/expected to perform during the project. This should be a finite duration and typically for a shorter period. For example, double data entry by laboratory personnel during parallel testing.

b. Conduct a fiscal budget planning and allocation to ensure sustainability over the longer time horizon.

3. Pursue centralization/shared services approach as the core model and deviate to dedicated resources model as an exception.

4. Consider train-the-trainer approach to develop in-country capacity. This will also reduce the costs for subsequent rollouts.

5. Use the “typical roles” provided in the appendix as a baseline to seed the discussion and map out the gaps.

6. HR Plan, especially post-project component, should be one of the key inputs into system’s architecture requirements and/or preferences.

7. Plan for the transition of the project team into the Operations and Maintenance (O&M) phases of the project. Key project team members can transition into the roles of LIS administrator and SMEs can transition into an ongoing LIS committee role, for instance. It is important to make sure that team members are clear about their current responsibilities and their potential ongoing responsibilities and are comfortable with their role, whether it be to enhance the LIS or to maintain it.

Timing

The baseline HR Plan needs to be developed as one of the initial deliverables of planning phase. This may go through subsequent revisions as the project progresses. Any change to the baseline and or assumptions should go through the review and vetting process prior to adoption.

COMMUNICATION PLAN

A key objective of the project management plan is to establish the communication structure with all stakeholders, ensuring they all share a common understanding of the project purpose and status as things progress. The communication plan establishes the expectations around communication needs, modes and methods, frequency and reporting procedures for the project.

Once all key stakeholders are identified, they are grouped into three main categories.

- *Project Context*: Workflow users (often different types), data users (again often different types), management, sponsors, funding partners, implementation team, etc.
- *Project Responsibility*: Overall project decision makers, specific decision makers regarding key functions, implementers, SMEs etc.
- *Communication Needs*: Implementation, testing, validation, training, detailed project status, high level project status, etc.

This objective is rarely accomplished by the production or distribution of a set of documents. It usually requires many communications channels being created and maintained.

Groups Involved

- Project manager is responsible to develop a communication plan.
- All stakeholders (sponsors, TWG, implementation partner, task force, lab management, etc.) will provide input and sign-off of on the plan.

Steps Involved

1. Formal project documentation is reviewed and appropriately vetted by key stakeholders.
2. Stage gate meetings to discuss key project decisions and document the outcomes.
3. Use status update processes to bring the information to each group of stakeholders through an appropriate vehicle and with the correct level of context so they can review and support the project progress.
4. Provide training sessions.
5. Provide validation processes.
6. Make presentations.
7. Use “Project Dashboards” for regular, effective communications. The readers can get used to a common set of idioms and quickly consume the output from the project team through that mechanism.
8. All meetings whether in-person or virtual (conference calls) should publish formal meeting notes and all issues, decisions should be captured into a central log maintained by the project management team.

Timing

This is one of the key deliverables from the planning phase. Review the communications plan at regular intervals as well as prior to moving into a new phase. Revise as necessary to ensure it facilitates positive communication across all stakeholders.

RISK MANAGEMENT

Risk is inherent in every project and is neither intrinsically good nor bad. Risks to a project should not be feared but factored in as an important attribute of the project. All projects must understand and document risks. For a risk to be used effectively, it must be clearly stated, including both condition and consequence, and it must be easily understood. A condition-consequence risk statement helps to clearly articulate risk.

Example:

- Condition: Flammable liquids are stored in the warehouse.
- Consequence: The warehouse might catch on fire.

Tips for Risk Management

1. Effectively analyze risks and use risk data to make decisions.
    - Assess risk probability
    - Assess risk impact
    - Calculate risk exposure
2. Take specific action to minimize risk exposure.
    - Can be focused on probability or impact, although probability is most common
    - Only done for highest priority risks based upon exposure
      Example: Cross training staff to address the likelihood of turnover creating issues
3. Set contingency triggers.
   Example: Letting the physical evidence of fire prompt someone to call the fire department
4. Choose the appropriate type of triggers.
    - Point in time
      Example: If a key team member quits, what is the latest date to train a replacement?
    - Threshold
      Example: If the sample entry errors reaches 5%, then implement a new training plan.

Appendices

1. Appendix A: LIS Project Cost Spreadsheet (Samples)
2. Appendix B: SWOT Analysis
3. Appendix C: Examples of Strategic Plan Framework
4. Appendix D: Non Conformity Report Template
5. Appendix E: SLIPTA Checklist: Section 9
6. Appendix F: Sample Laboratory Assessment Tool
7. Appendix G: Sample Hardware Maintenance Tracking
8. Appendix H: Sample Change Request Form
9. Appendix J: Country LIS Evaluation
10. Appendix K: Sample Turnaround Time (TAT) Monitoring Tool

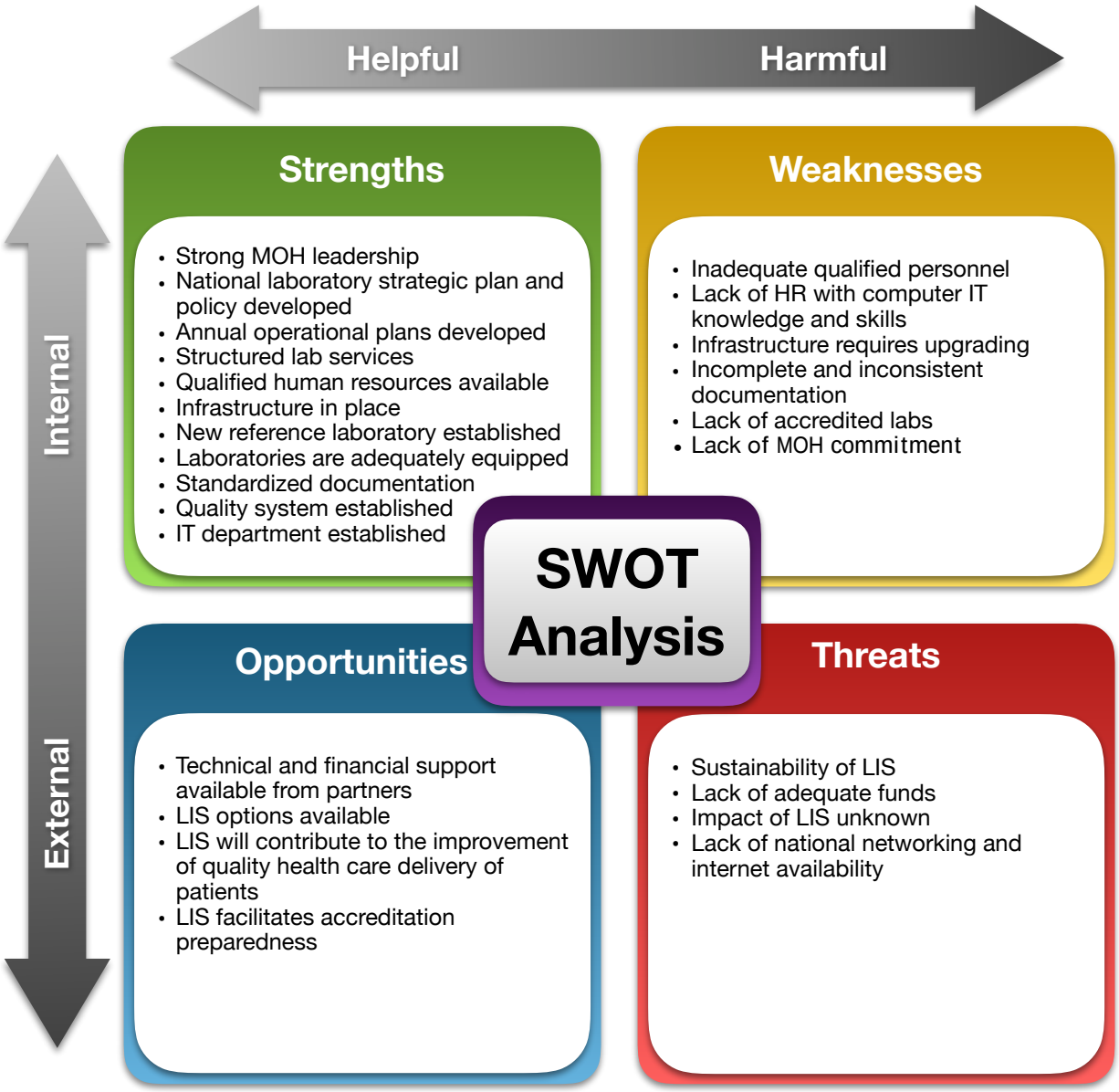
LIS Proforma Project Cost Summary (Capital)

		Q1	Q2	Q3	Q4	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Capital Costs	**Notes**	**$**	**$**	**$**	**$**	**$Q1-Q4**	**$**	**$**	**$**	**$**	**0**
COMPUTERS											
Work Stations	(amnt @ $ each)										
Servers	(amnt @ $ each)										0.00
Printers	(amnt @ $ each)										0.00
Computers Total $(000)		**0.00**	**0.00**	**0.00**	**0.00**	**Q1-Q4**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**
OTHER HARDWARE											
Networking Equipment	list equipment										
Barcode Printers	(amnt @ $ each)										0.00
Barcode Readers	(amnt @ $ each)										0.00
Tape Backup											0.00
Other Hardware Total $(000)		**0.00**	**0.00**	**0.00**	**0.00**	**Q1-Q4**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**
PHYSICAL COSTS											
Desks	(amnt @ $ each)										0.00
Renovations	Describe changes										0.00
Server Environments	Describe location										0.00
Power Install	Server power, etc.										0.00
Networking	Connection upgrade										0.00
Physical Total $(000)		**0.00**	**0.00**	**0.00**	**0.00**	**Q1-Q4**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**
SOFTWARE COSTS											
LIS License											0.00
Operating System											0.00
Database											0.00
Software Total $(000)		**0.00**	**0.00**	**0.00**	**0.00**	**Q1-Q4**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**
HARDWARE REPLACEMENT											
Server	After ___ years										0.00
Printers	After ___ years										0.00
Workstations	After ___ years										0.00
Barcode Hardware	Replace, "breakage"										0.00
Repacement Total $(000)		**0.00**	**0.00**	**0.00**	**0.00**	**Q1-Q4**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**
IMPLEMENTATION SERVICES											
Planning Costs	Travel, meetings										0.00
Vendor Implementation Services											
Training											
Needs Analysis Consultants	LPHA										0.00
Other Services	Local installers										0.00
Services Total $(000)		**0.00**	**0.00**	**0.00**	**0.00**	**Q1-Q4**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**
TOTAL CAPITAL COSTS:		**0.00**	**0.00**	**0.00**	**0.00**	**Q1-Q4**	**Yr. 2**	**Yr. 3**	**Yr. 4**	**Yr. 5**	**0.00**
CUMMULATIVE CAPITAL COSTS:		**0.00**	**0.00**	**0.00**	**0.00**	**Yr. 1**	**Yrs. 1-2**	**Yrs. 1-3**	**Yrs. 1-4**	**Yrs. 1-5**	**0.00**

LIS Proforma Project Cost Summary (Operational)

		Q1	Q2	Q3	Q4	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Operational Expenses	**Notes**	**$**	**$**	**$**	**$**	**$Q1-Q4**	**$**	**$**	**$**	**$**	**0**
HR COSTS											
LIS Administrator											
Help Desk											
Programmers	2 programmers										
Other Additional Staff Costs	OT for training, etc.										
Operational Support	Backups, antivirus										0.00
Vendor LIS Technical Staff	Help upgrading, etc.										0.00
HR Costs Total $(000)		**0.00**	**0.00**	**0.00**	**0.00**	**Q1-Q4**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**
UTILITIES											
Networking	list equipment										
Power											0.00
Utilities Total $(000)		**0.00**	**0.00**	**0.00**	**0.00**	**Q1-Q4**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**
MAINTENANCE											
Software	Maintenance agreement										0.00
Hardware	Only for 3 yrs.										0.00
Maintenance Total $(000)		**0.00**	**0.00**	**0.00**	**0.00**	**Q1-Q4**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**
TOTAL OPERATIONAL COSTS:		**$ Q1**	**$ Q2**	**$ Q3**	**$ Q4**	**Q1-Q4**	**Yr. 2**	**Yr. 3**	**Yr. 4**	**Yr. 5**	
CUMMULATIVE OPERATIONAL COSTS:						**Yr. 1**	**Yrs. 1-2**	**Yrs. 1-3**	**Yrs. 1-4**	**Yrs. 1-5**	

APPENDIX B: SWOT ANALYSIS



APPENDIX C: EXAMPLES OF LIS STRATEGIC FRAMEWORK

LIS Strategic Plan Framework

Goal: Strengthen Laboratory Information Services within National Health System laboratories						
Objective: All 300 laboratories nationwide shall implement eLIS by 2019						
	Resource	**2015**	**2016**	**2017**	**2018**	**2019**
Establish TWG and develop LIS SP	NHLS	X				
Request proposals and select LIS system	NHLS	X				
Implement and maintain LIS at 50 sites	NHLS	X	X	X	X	X
Implement and maintain LIS at 100 sites	NHLS		X	X	X	X
Implement and maintain LIS at 150 sites	NHLS			X	X	X
M&E LIS	NHLS		X	X	X	X

Example LIS Action Plan Sub Objective 1: Establish TWG and develop LIS Strategic Plan

Activity	Responsible	Cost	Target	Indicator	Q1	Q2	Q3	Q4
Identify 10 TWG members	CEO		Number of members	10 members	X			
Hold initial TWG meeting and develop TOR	TWG chairperson	20,000	1 meeting	TOR developed		X		
Conduct regular monthly meetings	TWG	20,000 per meeting	8 meetings held	Number of meetings held			X	X
Develop SP	TWG	20,000 per meeting	SP document	SP approved		X		

APPENDIX D: NON CONFORMITY REPORT TEMPLATE

LIS NON CONFORMITY REPORT: _____ Date: _____ Reported by: _____

No.	Non Conformities	Recommendations/ Comments	Checklist Question	ISO 15189 Reference	Major or Minor

APPENDIX E: SLIPTA SECTION 9

The SLIPTA Checklist is retrievable online at http://apps.who.int/iris/handle/10665/204423.

For each item, please circle as relevant Not Applicable (NA), Yes (Y), Partial (P) or No (N). All elements of the item must be satisfactorily present to indicate "yes". Provide explanation or further comments for each "partial" or "no" response.

SECTION 9: INFORMATION MANAGEMENT

Requirement	NA	Y	N	Comments	Score
9.1 <u>Test Result Reporting System</u> Are test results legible, technically verified by an authorized person, and confirmed against patient identity?	**Y**	**P**	**N**		2
ISO15189:2012 Clause5.8.1 **Note**: *Results must be written in ink and written clearly with no mistakes in transcription. The persons performing the test must indicate verification of the results. There must be a signature or identification of the person authorizing the release of the report.*					
9.2 <u>Testing Personnel</u> Are testing personnel identified on the result report or other records (manual or electronic)?	**Y**	**P**	**N**		2
ISO15189:2012 Clause 4.13 ; 5.5.1.1; 5.8.1 ***Note:*** *The person who performed the procedure must be identified on the report (hard copy or electronic) purposes of traceability.*					
9.3 <u>Report Content</u> Does the laboratory report contain at least the following:	**Y**	**P**	**N**		3

	Tick for each item as Yes (Y), Partial (P), No (N) or Not Applicable (NA)				
	Y	**P**	**N**	**NA**	
a) Test requested					
b) Identification of the laboratory					
c) Identification of all examinations performed by a referral laboratory					
c) Patient identification and location					
d) Name of the requester					
e) Date of primary sample collection (and time, relevant to patient care)					
f) type of primary sample					
g) Is the result reported in SI units where applicable?					
h) Biological reference intervals where applicable					
i) Is there space for interpretation or comments on results, when applicable?					
j) Identification of the person(s) reviewing and authorizing the report					
k) Date and time of the report					
l) Page number to total number of pages (e.g. "Page 1 of 5", "Page 2 of 5", etc.)					
m) When issuing revised reports, is it clearly identified as a revision and includes reference to the date and patient's identity in the original report and the user made aware of the revision?					
n) Does the revised record show the time and date of the change and the name of the person responsible for the change?					
o) Does the original report entry remain in the record					

when revisions are made?						
ISO15189:2012 Clause 5.8.2; 5.8.3; 5.9.3 ***Note:*** *When the reporting system cannot capture amendments, changes or alterations, a record of such shall be kept.*						
9.4 Analytic System/Method Tracing When more than one instrument is in use for the same test, are test results traceable to the equipment used for testing?	**Y**	**P**	**N**	**NA**		2
ISO15189:2012 Clause 4.13(g) ***Note:*** *There must be traceability of specimen results to a specific analytical system or method. Proficiency testing specimens would also fall under specimen results.*						
9.5 Archived Data Labelling and Storage Are archived results (paper or data-storage media) properly labelled and stored in a secure location accessible only to authorized personnel?	**Y**	**P**	**N**			2
ISO15189:2012 Clause 4.13; 5.10.3 ***Note:*** *All patient data, paper, tapes, disks must be retained as per the lab's retention policy and should be stored in a safe and ac[illegible] controlled environment.*						
9.6 Authorities and Responsibilities Has the laboratory defined and implemented authorities and responsibilities for the management and use of the laboratory information system– paper based and electronic, including maintenance and modifications that may affect patient care?	**Y**	**P**	**N**			2
Is the following in place and implemented?	**Tick for each item as Yes (Y), Partial (P), No (N) or Not Applicable (NA)**					
	Y	**P**	**N**	**N[illegible]**		
a) Controlled access to patient data and information						
b) Controlled access to enter patient data and examination results						
c) Controlled access to changing patient data or examination results						
d) Controlled access to the release of examination results and reports						
e) Verify that results that have been tra[illegible]d electronically or reproduced external to the labo[illegible]ory (computers, fax machines, email and websites a[illegible]d personal web devices) are correct.						
ISO15189:2012 Clause 5.9; 5.10.2; 5.10.3 ***Note:****"information systems" includes the managem[illegible]t op[illegible]d information contained in both computer and non-computerized systems. Some of the requirements may be more applicable to computer systems than t[illegible]on-comp[illegible]d systems. Computerized systems can include those integral to the functioning of laboratory equipment and standalone systems using generic soft[illegible]re, su[illegible]as wo[illegible]ocessing, spreadsheet and database applications that generate, collate, report and archive patient information and reports.*						
9.7 Information Manage[illegible] System Does the laboratory ha[illegible] evidence of how t[illegible] LIMS was selected?	**NA**	**Y**	**P**	**N**		2
ISO15189:2012 Clause 5.3.[illegible] ***Note:*** *The laboratory must ha[illegible]umented pro[illegible]dure and records for the selection, purchasing and management of equipment.*						
9.8 Test Result Are test results validated, int[illegible]preted and released by appropriately-authorized personnel?	**NA**	**Y**	**P**	**N**		2
ISO15189:2012 Clause 5.1; 5.8; 5.10.3; 5.9.1 ***Note:*** *There must be a signature or identification of the person authorizing the release of the report.*						
9.9 Verification of Electronic Laboratory Information System	**NA**	**Y**	**P**	**N**		2
	Tick for each item as Yes (Y), Partial (P) or No (N)					
	NA	**Y**	**P**	**N**		
a) Has the system been verified before implementation						

The SLIPTA Checklist is retrievable online at http://apps.who.int/iris/handle/10665/204423.

that include the verification reports to check functioning and inter-phasing by the laboratory?						
b) Records of the validation by the supplier available and approved for use?						
c) Ongoing system checks available for correct transmissions, calculations and storage of results and records.						
ISO15189:2012 Clause 4.13; 5.10.3 ***Note:*** *The lab must perform verification of system after upgrades and to ensure previously stored patient results have not been affected.*						
9.10 Is the Laboratory Information System properly maintained to ensure continued functioning:	**NA**	**Y**	**P**	**N**		2
	Tick for each item as Yes (Y), Partial (P), No (N) or Not Applicable (NA)					
	NA	**Y**	**P**	**N**		
a) Documented regular service by authorized and trained personnel						
b) Documented system failures with documented appropriate root cause analysis, corrective actions and preventative actions						
c) System operated in an environment recommended by the supplier for optimal functioning						
ISO15189:2012 Clause 5.10.3 ***Note:*** *If the LIS is maintained offsite, records of maintenance must be readily available .The la[illegible]hould incl[illegible] the LIS as part of their internal audit.*						
Section 9: Information Management Subtotal						21

The SLIPTA Checklist is retrievable online at http://apps.who.int/iris/handle/10665/204423.

APPENDIX F: SAMPLE LABORATORY ASSESSMENT TOOL

LIMS ASSESSMENT REPORT

[Facility Name]

[Address]

[Phone Number]

Contact Persons

Name	Designation	Phone	Email
	Hospital Superintendent		
	Laboratory Manager		
	IT		

Table of Contents

1 Background

1.1 Scope of Work

To assess the readiness of John Doe laboratory for the implementation of a LIMS.

1.2 Methodology

This report was compiled following an assessment carried out at the facility on Jan 1, 2017.

The assessment consisted of the following activities:

- a comprehensive tour of the laboratory
- interviews of the laboratory and hospital management
- interviews of the laboratory staff members
- interviews of the hospital IT administrators
- a tour of core IT infrastructure

2 Findings

2.1 Facility and Staffing

Day of the week	Shift	Staff on shift
Monday to Friday	8AM to 5PM	
Monday to Friday	5PM to 8AM	
Saturday and Sunday	8AM to 7PM	
Saturday and Sunday	7PM to 8AM	

2.1.1 Staff Count By Designation

Designation	Count
Supervisors - Technical	
Laboratory Technologists / Technicians (these perform tests)	
Laboratory Assistants / Data clerks (these do not perform tests)	
Other	

2.1.2 Staff Count By Qualification

Qualification	Count
University Degree	
Higher National Diploma	
Diploma	
Certificate	

2.2 Testing Capacity

The laboratory is logically subdivided into 5 sections. These are hematology, bio-chemistry, bacteriology, parasitology and serology/blood transfusion.

Approximately xyz tests are performed on a monthly basis.

2.2.1 Hematology Tests

Test Name/Method	Monthly Estimates
HB	
PCV, MCV, MCH, MCHC, RBC Total, WBC Total, Platelets, Differential CT (*Neu, Eos, Bas, Lym, Mon*)	
ESR	
Blood Parasites	
Sickle cell test, Clotting Time, Bleeding time	
Smear comments	
Prothrombin time, PTT	

The following analyzers are used for running hematology tests:

-
-

2.2.2 Biochemistry Tests

Test Name/Method	Monthly Estimates
Fasting blood sugar	
Random blood sugar	
Glucose tolerance test	
Urea (Creatinine, sodium, potassium, chloride)	
Calcium	
Bilirubin (total, direct, indirect)	
ALAT, ASAT, Alkaline phosphate	
Cholesterol	
Protein total	
Albumin	
Uric acid	
Triglyceride	
Gamma GT	

The following analyzers are used for running biochemistry tests:

-
-

2.2.3 Serology, Virology and Immunology Tests

Test Name/Method	Monthly Estimates
CD4/CD3	
VDRL	
Hepatitis B Antigen	
Hepatitis C Antigen	
Pregnancy Test	
Salm Typhil O, Salm Typhil H	
T3, T4, TSH	
PSA	
HIV Screen	

2.2.4 Bacteriology Tests

Test Name/Method	Monthly Estimates
Culture (Macroscopic, Gram Stain, FM, Indian Ink, Wet mount, Biochemistry testing, Media, Isolate Identification, Bacterial count, AFB)	
Resistance/sensitivity (Penicillin, Ampicillin, Cloxacillin, Chloramphenical, Tetracycline, Erythromycin, Gentamycin, Nitrofurantion, Amoxicillin-clavulanic acid, cefuroxime, ciprofloxacin)	

2.2.5 Parasitology Tests

Test Name/Method	Monthly Estimates
Malaria	
Stool	
HVS	
Urine	

2.2.6 Referred Tests

Test Name/Method	Referred To	Monthly Estimates
Viral Load		
EID		

Drug susceptibility testing		

2.3 Specimen Life Cycle

2.3.1 Sample Reception

2.3.2 Sample Referral

2.3.3 Test Results Reporting

2.3.4 Sample Storage

2.3.5 Inventory tracking

2.4 Infrastructure

2.4.1 Physical Infrastructure

2.4.2 Technical Infrastructure

- **Power supply**:
- **Computer network**:
- **Internet connection**:
- **Computers and printers**:
- **IT Personnel**:
- **Information Systems**:
  -
  -

3 Conclusion

3.1 Recommendations

-

Next steps

Sample Hardware Maintenance Tracking

EQUIPMENT MANAGEMENT							
EM1.	**Equipment Name**			EM7.	Is routine preventive maintenance performed and recorded for this equipment?	select one	Yes ☐ No ☐
	Manufacturer			EM8.	Date of last maintenance for this equipment	date	
	Model			EM9.	Date of last validation conducted on this equipment	date	
EM2.	Please List all tests done on this equipment in your laboratory			EM10.	In the 3 months for how many days was the equipment not functional?	write number of days	
				EM11.	Is there another equipment available onsite that can be used for conducting testing in the event this instrument is not functioning	select one	Yes ☐ No ☐
EM3.	Please list all tests that can be performed on this equipment but are not currently carried out by your lab?			EM12.	Are reagents/supplies available for this equipment for the next 3 months	select one	Yes ☐ No ☐
				EM13.	Does the lab have a reorder level for suppliers of this equipment?	select one	Yes ☐ No ☐
EM4.	Date equipment was commissioned for use (month/year)	Date		EM14.	Number of lab personnel trained on this equipment	Numeric	
EM5.	Is the equipment currently functioning	select one	Yes ☐ No ☐	EM15.	Date of last training on this equipment (based on records/evidence presented)	Date	
EM6.	Is there a service maintenance contract in place for this equipment	select one	Yes ☐ No ☐				

Description of Item: i.e. Label Printer	Manufacturer.[1] i.e. Zebra	Serial Number (catalogue #, model #, etc.)	Quantity	Condition[2]	Location[3]	Procured by	Comment
HP PROLIANT DL380/SERVERS	SERVER	CZ232207RB	1	Functional	XXX District H	YYYY	
DESKTOP COMPUTER	Dell	QXCPVI	1	Functional	XXX District H	YYYY	
DESKTOP COMPUTER	Dell	IRXCPVI	1	Functional	XXX District H	YYYY	
DESKTOP COMPUTER	Dell	25XCPVI	1	Functional	XXX District H	YYYY	
DESKTOP COMPUTER	Dell	53XCPVI	1	Functional	XXX District H	YYYY	
DESKTOP COMPUTER	Dell	5LXCPVI	1	Functional	XXX District H	YYYY	
DESKTOP COMPUTER	Dell	5MXCPVI	1	Functional	XXX District H	YYYY	
DESKTOP COMPUTER	Dell	5RXCPVI	1	Functional	XXX District H	YYYY	
UPS BACKUPS 650VA,230V ASEAN	APC	S3B1302X14608,694,731,740, 852,889,192	7	Functional	XXX District H	YYYY	
TRIPLITE SMX300XLRT2U SMART UPS RT 3000VA	Triplite	2217KWOPS 73390044	1	Functional	XXX District H	YYYY	
MECER -200VA AUTOMATIC VOLTAGE REGULATOR	Mecer	741303300709	1	Functional	XXX District H	YYYY	
HP Laserjet 401DN	HP	VNH6723232	1	Functional	XXX District H	YYYY	
Symbol LS SCANNER KIT WITH STAND	SYMBOL	syalnkc	1	Functional	XXX District H	YYYY	
cisco switch	CISCO	SFOC1722W469	1	Functional	XXX District H	YYYY	
ZEBRA PRINTER	Zebra	54JI24301478/1441	2	Functional	XXX District H	YYYY	

APPENDIX H: SAMPLE CHANGE REQUEST FORM

Laboratory Information System
CHANGE REQUEST

Contact Information:

Date Created:	**Your Name:**
Laboratory Name:	**Phone Number:**
Email Address:	**Other Contact:**

Request:

Select Type of request: **Enhancement to System** ☐ **Language Translation Change** ☐ **Unknown** ☐	**Select Priority:** **High priority** ☐ **Medium priority** ☐ **Low priority** ☐ **Unknown** ☐

Description:

Application Name:	**Version:**
Description (please include as much information as possible (supporting documentation, screen captures and any specifications, if applicable):	

Cost Implications: (Section to be used by vendor only)

Estimated Cost for System Change:
Indicate Scope of Work: **List of Affected Components (hardware, software, documents):**

Final Decision on Request: (Section to be used by LIS working group only)

LIS Working Group Meeting Date:	
Decision: **1) Approved** **2) Not approved** **3) Consider at a Later Meeting Date: Indicate estimated date: _____** **4) More information needed: Name person to follow up: _____** **Comments:** **Signatures of working group co-chairs: _____ _____**	

APPENDIX J: COUNTRY LIS EVALUATION

Country LIS Implementation Evaluation/Performance Checklist

Sample: LIS Implementation Evaluation/Performance Checklist Sections

- Section 1: Infrastructure (22)
- Section 2: Hardware (12)
- Section 3: Software (10)
- Section 4: Documentation and Records (24)
- Section 5: Results reporting (12)
- Section 6: System Operations and Applications (24)
- Section 7:Training and Competency (12)

Scoring system for each question: 2 points = Yes; 1 point = Partial; 0 points = No

Evaluation Criteria

- LIS implementation meets ISO 15189 requirements
- SLIPTA checklist used to audit LIS as part of laboratory operations
- Pre- and post-implementation indicator data developed
- Evaluation tools to assess overall LIS successful implementation developed
- Periodic LIS evaluations/assessments conducted

APPENDIX K: SAMPLE TURNAROUND TIME (TAT) MONITORING TOOL

Sample Turnaround Time (TAT) Monitoring Tool

	Lab A		Lab B		Lab C	
Indicator	**Baseline: paper based**	**After 6 months: LIS & paper based**	**Baseline: paper based**	**After 6 months: LIS & paper based**	**Baseline: paper based**	**After 6 months: LIS & paper based**
Patient/specimen registration time	4 min	1 min	3 min	1 min	2 min 7 sec	45 sec
Result entry time	5 min	1 min 3 sec	4 min	1 min	3 min 4 sec	1 min
Result search time	17min	45 sec	15 min	30 sec	12 min 3 sec	25 sec
Time taken to get monthly totals for report	2 hours	1 min	1 hr 45 min	1 min	34 min 7 sec	52 sec
Number of patients captured in a day	130	170	160	200	90	130
Rate of errors per week	18	5	20	2	16	2

Notes

Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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