REPUBLIC OF LIBERIA

NATIONAL LABORATORY SYSTEM

LABORATORY INFORMATION MANAGEMENT SYSTEM (LIMS) IMPROVEMENT PLAN

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1. Introduction

The information produced by diagnostic laboratories has a great impact on healthcare systems in the form of diagnosis and treatment of diseases. This data has many other secondary uses in research and formulation of policy. To this effect, it is in the best interest of laboratory personnel that the data they avail is accurate and released to clients expeditiously. Recent advances in data management have seen the increased use of Laboratory Information Management System (LIMS) in the laboratory setting. LIMS allows the laboratory to coordinate the flow of data right from the receipt of samples to the release of results seamlessly.

The decision to acquire a LIMS system is a consultative process that must be carefully evaluated by laboratory management and stakeholders. The process should include establishing criteria and specifications that support the strategic goals of the laboratory and therefore what the acquisition seeks to achieve must be very clear. The purchase will not only affect activities within the laboratory but also compliance with regulatory requirements and the needs of customers or clients.

Although LIMS has been piloted in selected facilities in Liberia including the National Public Health Reference Laboratory (NPHRL), most information management in the laboratories is the traditional paper-based system. One of the objectives for the National Laboratory Strategic Plan (NLSP) (2019 – 2024) is to establish an effective, integrated LIMS for the management, analysis, and reporting of laboratory specimens, processes, and data[1]. To realize this objective, the Ministry of Health (MoH) and the National Public Health Institute of Liberia (NPHIL) are making concerted efforts to improve and expand the current electronic system in addition to strengthening the widely used traditional paper-based system.

2. The Main Challenges with the LIMS Piloted at NPHRL

The LIMS that was piloted at NPHRL for 6 months in 2018 is currently nonfunctional due to several issues mainly pertaining to sustainability. The challenges included:

- A service contract for the LIMS was not available. Therefore, in the event of equipment breakdown there was no authorization to service equipment.

- A license was not provided for the equipment. This compromised the ability to upgrade the system whenever there were changes in reagents.
- A training manual for users was compiled but training was not done due to lack of funds to support training.
- Stability of electricity was an issue such that accessing the server became challenging.
- Limitation of access points, leading to low or limited network coverage.
- Although roles and responsibilities for data entry and verification were defined at the laboratory level, overall responsibility for maintenance, service and sustainability of operations and equipment were not defined.
- At the sample reception area, the barcode machine ran out of paper and restocking was not done.
- In Serology, the configuration of measles test results using the stipulated indicators became a challenge especially when the reagents being used for the test were changed from Sigma to Europe Immune.

3. The Improvement Plan

Against this background, several steps will have to be considered to improve the reimplementation of LIMS.

3.1 Selection of LIMS

It is vital that the reasons for choosing to use LIMS are clear. In addition, the scope of work must be defined. Laboratory managers must determine the data types and formats required for their workflow so that the IT team can configure the system properly to match the workflow sequence.

Several factors are considered when a laboratory decides to acquire LIMS. Some of these include:

- Flexibility in making changes to the system as the laboratory's demands change.
- A friendly user interface.
- Supplier expertise and post-installation technical support.

- Minimum allocated budget.[2]
- Integration of patient and specimen information.
- Overall support for patient management, care and treatment.

Ensure that NPHRL acquires the best selection that meets their needs by involving laboratory personnel in the initial stages of selection. The laboratory manager should clearly define the laboratory objectives with respect to LIMS; this will inform personnel on how the system will look like during the post-implementation period. The functions in the Total Testing Process (TTP) that need to be configured to the LIMS must also be identified. Laboratory personnel will prove to be very resourceful in this key exercise, since they understand the testing system extremely well. They will ensure that the selected LIMS can address their needs.

3.2 Roles and Responsibilities

Responsibilities for LIMS are both administrative and technical. Roles must be very clear and defined for accountability purposes. These responsibilities must be captured in the relevant Standard Operating Procedure (SOP).

3.2.1 Stakeholders

The Ministry of health (MoH) and the National Public Health Institute of Liberia (NPHIL), will be the main stakeholders in this venture. The MoH/NPHIL has an oversight responsibility to ensure that implementation is done such that the system is qualified as efficient to ensure client issues are well addressed. Funding bodies will want to know that monies are used as budgeted and that all targeted parameters are addressed properly and on time.

3.2.2 The LIMS Technical Working Group (TWG)

The TWG will provide oversight in the implementation of LIMS nationwide. They have the responsibility to:

- Identify the potential users of LIMS
- Define roles and responsibilities especially for those who:
    - Access patient data and information.
    - Enter patient data and examination results.
    - Change patient data or examination results.

    - Authorize the release of examination results and reports.
- Identify the major laboratory functions to be facilitated through LIMS.
- Define the LIMS budget.
- Identify equipment that will be integrated with LIMS.
- Determined software that will be suitable to be synchronized with the LIMS.
- Select the facilities where LIMS equipment will be installed.
- Define how LIMS will be maintained.
- Define elements of success.

The TWG shall comprise of hospital administrators (where applicable), laboratory managers/policy makers, LIMS administrators, data managers, laboratory technologists, and other pertinent persons. The chairperson of the group and the frequency of meetings will be decided during the inaugural meeting.

3.2.3 The Task Force

A task force will also be set up to support the implementation of LIMS. The mandate of this task force will include but not necessarily be restricted to the following:

- Coordination of LIMS implementation activities
- Focused work at selected sites
- Provision of updates to relevant stakeholders
- Highlighting challenges that need to be addressed.

This group will be composed of the implementing partner, project manager, LIMS administrators, LIMS technical staff, laboratory managers, laboratory technical staff and data and IT managers.

3.3 Implementation Strategy

To support the implementation of LIMS, a comprehensive plan with clear vision and mission statements must be drawn. This can either be a stand-alone document or an insert in the NLSP. The implementation plan should span the full length of the NLSP and should seamlessly fit into the other planned laboratory objectives.

Also, it may be prudent to implement the project in phases. This will allow for any teething problems to be addressed and changes made (if required) at reasonable costs as

opposed to full-scale implementation. Lessons learned can also be applied in subsequent phases.

The general implementation plan would take the approach that is listed in subsequent sections.

3.3.1 Clearance and Budget Commitment from MoH/NPHIL

The clearance will give the implementing team goodwill to access the various MoH/NPHIL facilities and to make decisions in favor of adequate and streamlined installations. The availability of an adequate budget will keep the project rolling on target.

3.3.2 Review/Revision of Policy Guidelines

Previous vision and mission statements in addition to objectives supporting the implementation of LIMS need to be reviewed for adequacy and revisions made if deemed necessary. The selection of objectives should take into consideration the results of the situational report.

3.3.3 Selection of pilot sites

Selection of pilot sites will usually be unique to a location. However, there are certain factors that need to be considered when selecting these sites. These include:

- Availability of appropriate infrastructure as per supplier requirements for installation of the system
- Volume and complexity of testing
- Test menu
- The overall laboratory network and various linkages
- Number of users
- Types and number of equipment to interface. Note that diversity in equipment models may require that the variation in equipment software be treated individually which may be more time-consuming than interfacing same model equipment. However, the availability of an LIMS interface manual should help in the resolution of any complexities.[3]

3.3.4 Installation of LIMS, testing and verification

Installations may not always go smoothly, therefore, a test run should be done to help root out any complications that may arise. This will keep rectification costs low. Furthermore, once installations are complete and verifications done, the steps listed below must be accomplished:

- Full documentation of the functional/verified system and availability of these standard procedures to users of the system. Users must attest to having read and understood the procedures.
- Training of personnel. This must be prioritized; laboratory staff will need to be very open minded about changing certain practices to follow the more efficient flow in a LIMS.
- Establishing levels of access/protection against unauthorized login.
- Safeguarding the system against tampering or loss. Note that laboratory data is mostly considered confidential and therefore data security must be ensured during implementation.
- Ensure full documentation of maintenance procedures.
- Ensure compliance with national or international requirements regarding data protection.
- Provide documented contingency plans to maintain services in the event of failure or downtime in information systems that affects the laboratory's ability to provide service.[3]

4. The Server

4.1 Choosing a Server

Choosing the most appropriate hosting environment for your data is a critical step that must be well thought out. The choice on whether to use on-site servers or cloud servers is dependent on many factors such as government policies on cloud hosting. Note that many African government policies prohibit the storage of government-related data on cloud servers.

Currently, cloud hosting in African countries is fraught with the inadequacy of legislative and regulatory frameworks containing appropriate guidelines making the rapid adoption of cloud computing non-conducive. To foster trust among stakeholders, a coherent regulatory framework guaranteeing transparency, data protection and respect for data integrity must be established.[4]

Against this background, choices must be made wisely. The advantages and disadvantages of each type of server are as follows (**Tables 1 and 2**):

Table 1. Advantages and Disadvantages of an On-site Server

Advantages	**Disadvantages**
Operatives have full control of the server with respect to such issues as memory space, speed	Manual modifications of hardware
One-off expense	Devices must be offline for upgrading
Limits performance issues and threats from malicious users hence better security	It can be stolen or relocated to an unknown environment
Easy to customize or configure	Can be damaged by fire, water, and other earthly disasters
It can be backed up remotely or manually	It has limited storage capacity for data
	Affected by abrupt power failure
	Requires relevant technical knowhow

Table 2. Advantages and Disadvantages of a Cloud Server

Advantages	**Disadvantages**
Improved data agility	Poor performance may result from multiple users crowding in the parent server
Easy and safe data backup	Latency issues due to poor internet speeds
Easy to scale up and integrate	a one-off transfer of large volumes of data to or from the cloud can be very costly, as can the storage of data in the cloud over very long periods

Safe from fire, water and other earthly disasters	Frequent movement of data between company and cloud can incur huge costs, in terms of bandwidth consumption especially when transfer times are lengthy
It cannot be stolen or relocated to a unknown destination	Lack of appropriate technical know-how may deter efficient operations
There is always room to add more storage to accommodate more data	The user has to trust the security measures put in by the hosting company
	Hackers may intrude and cause loss of data/breach of confidentiality

4.2 Server Access Sustainability

The purchase of a solar panel to support the server whenever the electricity supply is unstable will ensure the effectiveness and operationalization the server as needed.

5. Monitoring and Evaluation

5.1 Definition of Successful Implementation

Although success is subjective and may be unique in any given setting depending on the prevailing constraints, there are certain universal factors that might define it, including:

- Increase in laboratory productivity
- Improved data accuracy; automation will decrease transcription errors and improve data quality.
- Increase in the laboratory's overall effectiveness
- Increase in the level of quality control

In addition to these, appropriate quality indicators will need to be identified to further qualify the perceived success.

5.2 Quality Indicators

Some of the quality indicators that need to be monitored include turnaround time, transcription errors, translation errors, quality control, access restriction, charting of appropriate graphs and an alerting System.

Indicators used to monitor the laboratory quality management system and quality improvement also provide other potential quality indicators such as specimens registered prior to testing, Levey Jennings charts plotted daily for all quantitative tests, availability of audit trail and electronic backup of data.

6. Sustainability

Understanding your requirements is a key parameter in LIMS selection; running costs can be racked up very fast if modifications must be done often to address deficiencies. However, note that the more complex the operating system, the more expensive it becomes to run the project. An account must be taken of the circumstances specific to Liberia in terms of human, technical and financial resources that are available to sustain LIMS in the long-term.

It is therefore essential to:

- Ensure MoH/NPHIL initiate budgetary allocations annually to support LIMS operations.
- Implement training of technical personnel to ensure that the system is manned with the necessary expertise.
- Ensure availability of reliable power and backup system.
- Use a reliable vendor for ongoing maintenance, upgrade support, user training and any other support deemed necessary.
- Document a procedure for change management to ensure changes to the system are managed according to policy guidelines.
- Stakeholders remain engaged through regular meetings.

7. References

1. MoH. The Liberia National Laboratory Strategic Plan (2019 – 2024).
2. Christine Paszko and Carol Pugsley. Considerations in selecting a laboratory information management system (LIMS) September 2000.
3. APHL. Laboratory Information Systems Project Management: A Guidebook for International Implementations May 2019.
4. ITU. Cloud computing in Africa Situation and perspectives April 2012.