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***Abstract*— In Honduras, the use of digital information systems in healthcare is limited due to factors such as low investment, poor infrastructure, and restricted access to technology, particularly in rural areas. Primary care centers face additional challenges, including insufficient staff training, financial limitations, and uneven access to resources, which delay the modernization of healthcare services. Given these challenges, the primary healthcare center of El Níspero in Santa Bárbara, Honduras, still relies on paper records to manage patient and laboratory data, which can lead to errors, delays, and inefficiencies. Recognizing that implementing a Laboratory Information System (LIS) is essential for improving the accuracy, efficiency, and traceability of laboratory processes, a LIS designed to meet the specific needs of the center was proposed. Its functionality was evaluated using a tool that defines the requirements for operating a basic laboratory in a resource-limited environment. Additionally, a survey was conducted among the staff involved in lab processes to understand their perceptions, satisfaction levels, and any resistance to change. The requirements mapping showed that 48% of functionality was achieved and 88% of adaptability between the physical formats and the proposed LIS was accomplished. The survey results indicated a positive attitude among the staff towards shifting from manual procedures to using a LIS, with high levels of acceptance and satisfaction. In summary, this study demonstrates that the implementation of the LIS-GNU system has the potential to significantly improve laboratory operations in resource-limited settings.**

Keywords—clinical data management, digital health, GNU Health, laboratory information system.

I. Introduction

The Ministry of Health of Honduras has launched a roadmap for digital transformation, outlining a clear path toward the modernization of the healthcare system, with key strategies such as the Electronic Health Record and telemedicine [1], [2]. In this context, the implementation of a Laboratory Information System (LIS) is crucial, as it would enable the efficient integration of laboratory processes with the Electronic Health Records (EHR), improving the accuracy and availability of clinical results and optimizing medical decision-making. Furthermore, a LIS would strengthen epidemiological surveillance and operational efficiency in laboratories, aligning with the goals of digital health transformation and improving both medical care and disease prevention.

An estimated 70% of medical decisions rely on laboratory results, including blood, urine, and other fluid analyses [3]. In this context, LIS are essential components for the functionality and operability of clinical laboratories [4]. In general, a LIS is designed to improve access to high-quality diagnostic testing and to deliver accurate, timely information that supports patient care, public health planning, and informed policy decision-making [5]. However, in resource-limited settings, implementing an LIS presents not only a significant challenge but also a valuable opportunity to improve healthcare quality.

The implementation of an LIS varies widely across different regions, such as Asia, Africa, and Latin America. For example, in Spain, 55% of healthcare centers have a system for laboratory order and result reporting [6]. In Latin America, LIS adoption is gradually increasing with the aim of improving health service efficiency and effectiveness. However, the region faces considerable challenges, including limited technological infrastructure, a shortage of personnel trained in information technology, insufficient investment in healthcare technology, difficulties with system interoperability, and inconsistencies in local and international regulations.

Selecting and adapting a LIS for a low-resource setting requires consideration of multiple factors, including cost, ease of use, adaptability to local needs, and availability of technical support. The literature addresses both open-source and commercial LIS options. Examples of open-source systems include OPENELIS, BLIS, and BIKALIMS [3], [7], [8], [9], while commercial systems include Labka, Agilab, and Orchard Harvest [10], [11]. The main differences between open-source and commercial LIS revolve around cost, adaptability, flexibility, and security. Another viable open-source option is the Occhiolino LIS, integrated into GNU Health. [12].

A detailed analysis was conducted on the context of Honduras regarding the adoption of EHR and Health Information Systems (HIS). For this, a representative sample of 24 hospitals was selected, including both public and private institutions. The findings of the study showed that only 25% of the hospitals surveyed have implemented EHR, and approximately 25% have LIS [13]. Recent studies indicate that simply adopting EHR systems may not be enough to fully obtain their benefits. Instead, the key factor for realizing the advantages

of EHRs is their meaningful use or meaningful integration into healthcare practices [14].

In Honduras, several systems like LiSalud, Hexalis, Laboratorio Pskloud, and ControlLab have been introduced, providing viable solutions. However, GNU Health includes an integrated LIS, which offers greater compatibility and adaptability within its overall platform. There is a close relationship between LIS and EHR, as in recent years there has been an effort to integrate laboratory information management modules into a single electronic health record structure. This integration aims to reduce costs and ensure the smooth flow of information [15].

In April 2023, a collaborative project began between the Níspero Health Center and the Central American Technological University (UNITEC), with the primary objective of assessing the working conditions and operational processes of the center, which constituted the first phase of the project. In January 2024, both institutions formalized an agreement to continue the implementation process based on the analysis conducted. Between January and April 2024, the second phase of the project was carried out, focusing on the creation and adaptation of a personalized medical record for the center, based on six specific formats. The third phase, involves the integration of a LIS within GNU Health, specifically designed to meet the center's needs, given its essential role in the medical care process. Currently, this center in Santa Bárbara, Honduras, relies on paper formats for clinical laboratory records, which significantly slows down the medical care process. Most of the tests conducted here fall into hematology, clinical chemistry, and immunology, supplemented by specific exams in line with the regional health program. Daily, between 40 and 60 tests are performed, totaling around 1,500 tests per month, representing a considerable volume for a primary healthcare center.

The main goal of this study is to adapt the GNU LIS to the existing processes and formats at El Níspero, aligning them with the Ministry of Health (SESAL) standards. Additionally, this study intends to analyze the system's functionality using a standardized evaluation tool, along with a general assessment of its adaptability.

II. Methodoloy

This research uses a mixed-methods approach, combining quantitative and qualitative techniques to integrate data effectively. It is descriptive, focusing on documenting the adaptation, functionalities, and operational requirements of the LIS. This documentation establishes a solid foundation for the current system and future improvements. Fundamental to the approach are specific tools and procedures selected to analyze system adaptation and ensure alignment with the clinical laboratory's operational needs at El Níspero.

- *Formats Mapping:* for the mapping process, the clinical laboratory order sheet and the list of exams requested by the SESAL were collected. This data was then recorded and organized in an Excel spreadsheet to evaluate whether the LIS includes the specified exams or not.
- *GNU-Health:* GNU Health is an open-source, health information system specifically designed to manage hospital operations and facilitate the digitization of medical records. It is adapted to meet the needs of healthcare facilities in low and middle income countries, where access to advanced technology may be limited. The system provides a wide range of functionalities, including patient management, clinical records, and medical billing, which streamline healthcare delivery and improve service efficiency. GNU Health uses FHIR (Fast Healthcare Interoperability Resources), a modern HL7 standard designed for flexible and easy electronic healthcare data exchange based on web technologies. Currently, the GNU Health FHIR server supports 12 resources, including Diagnostic Report, which covers completed lab tests but not the detailed test data. One of its integrated components is the Laboratory Information System (LIS), known as Occhiolino. This LIS module is fully compatible with the GNU Health platform, offering essential features for managing laboratory operations such as test orders, sample tracking, result reporting, and data analysis [16]. HL7
- *Laboratory Information System Functionality Assessment* Toolkit (LIS-FAT): is a specialized instrument developed to offer a structured and standardized framework for evaluating the functionality and performance of LIS. By providing a comprehensive evaluation of system functionality, the LIS-FAT serves as a valuable tool for optimizing laboratory workflows, improving diagnostic accuracy, and enhancing overall healthcare service delivery.

The methodology employed in this study follows a structured, sequential approach, commonly referred to as a step-by-step methodology. This approach is characterized by a defined order of execution, with built-in flexibility for integrating feedback between phases. The process is divided into six distinct phases:

1. *Requirements Analysis:* The initial phase centers on defining and documenting the core requirements for the LIS. A field survey is conducted at El Níspero clinical laboratory to analyze current processes, including the types of tests performed, their result formats, and the lab's operational needs. Requirements are assessed using two primary methodologies:
   - *Adaptability Evaluation:* In this step, items from existing formats are transcribed into an Excel sheet, categorized by their relevance to the LIS module, and used to assess the adaptability of current manual formats to the GNU Health LIS.
   - *Functionality Evaluation:* The LIS-FAT toolkit is used to assess if the GNU Health LIS meets required functions, classifying them as either satisfied or not satisfied based on set criteria.
2. *Model Design:* based on the gathered requirements, this stage designs the LIS architecture adapted to El Níspero laboratory, prioritizing key feature integration, scalability, usability, and compatibility with existing infrastructure.
3. *Adaptation:* In this phase, the initial LIS design is customized to fit the specific needs and operations of El Níspero laboratory. Adjustments to functionality and user interface are made to ensure efficient, intuitive use. The

process may include iterative refinements based on feedback from users and technical staff.

4. *Comprehensive Testing:* this phase validates the system's functionalities against the defined requirements. It includes testing modular features like sample tracking, result generation, and reporting. Personnel such as the microbiologist, doctor, and administrator receive training to ensure effective use of the LIS. Trained staff then perform simulated test runs to confirm the system accurately processes samples and generates results, verifying that all components function correctly before deployment.
5. *Verification:* This critical phase ensures the system meets all requirements. The microbiologist, doctor, and administrator, with the project team, evaluate its performance. Feedback leads to adjustments, and major issues may require returning to the adaptation phase for further refinement.
6. *Implementation:* the final phase involves the activation and deployment of the LIS into the real production environment of El Níspero laboratory. This step marks the transition from the development phase to full operational use. During this phase, the system undergoes final validation, and any remaining issues are solved to insure smooth integration into the daily workflow.

The validation methodology is designed to evaluate the LIS across three key dimensions, confirming it aligns with established standards and meets the specific needs of the clinical environment. Each component contributes to verifying the system's functionality, user satisfaction, and adherence to industry standards. The validation process includes, user Acceptance Testing, where pre-implementation tests and pilot sessions are conducted in a controlled environment to ensure the LIS meets the specific requirements of the Healthcare Center and to identify potential issues before full deployment. Additionally, user feedback is collected through surveys distributed via Google Forms to assess satisfaction and resistance to change during real-world use. Finally, the GNU LIS is evaluated using the Toolkit to confirm compliance with the standards established by the Association for Pathology Informatics (API) [17], ensuring the system operates efficiently and meets the defined operational and clinical requirements.

III. Results

The Center is equipped with the essential technological infrastructure, including the necessary medical and electronic devices required for clinical laboratory processes. The available equipment includes a small oven, a clinical chemistry analyzer, a hematology analyzer, and a microscope. Additionally, the laboratory has two backup batteries, a computer, and a printer to support daily laboratory operations. These components were crucial for conducting a general analysis of the basic operational requirements.

Based on this, the results are categorized into three key areas, each providing a different view of the proposed LIS's performance and potential for improvement. System functionality focuses on the ability of the LIS to meet predefined technical and operational requirements System adaptability evaluates the flexibility of the LIS to integrate with existing workflows, formats, and operational needs, including the incorporation of new tests and instruments. Lastly, the survey of satisfaction and resistance to change captures feedback from laboratory personnel, to assess the perceived benefits, user satisfaction, and potential barriers such as technical limitations.

A. Functionality

The pre-analytical stage includes all processes that occur prior to sample analysis, such as the collection of patient clinical information, the request for laboratory tests, patient preparation, sample collection, labeling, and other related activities. Proper management during this stage is critical to ensuring the accuracy of the subsequent tests.

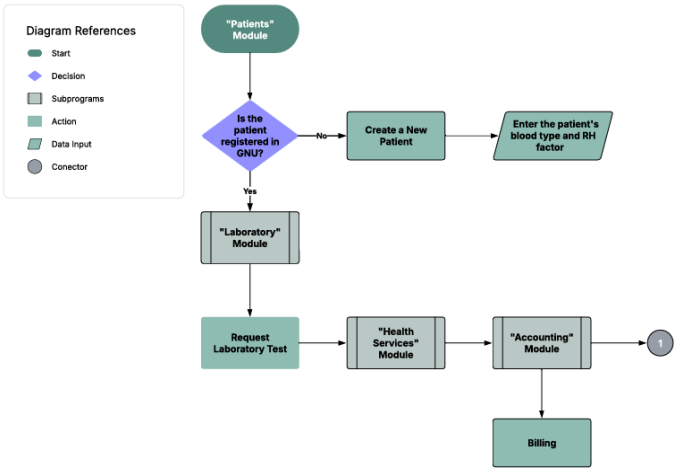

Fig. 1. Pre-analytical Stage is carried out by the administrative staff, includes the workflow from verifying whether the patient is registered in the GNU system to generating the final laboratory order for the next phases.

The analytical stage refers to the actual testing or examination of the sample in the laboratory. This includes the processes and techniques used to perform the test, analyze the results, and ensure accuracy.

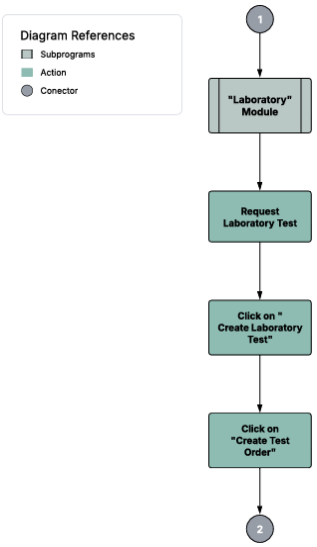

Fig. 2. The analytical stage is carried out by the microbiologist and includes the workflow from the confirmation of laboratory tests to the entry of results obtained from the analytical equipment.

The post-analytical stage includes activities after the sample has been analyzed, such as interpreting results, reporting findings, and assuring that the information is delivered to the appropriate healthcare professionals for decision-making.

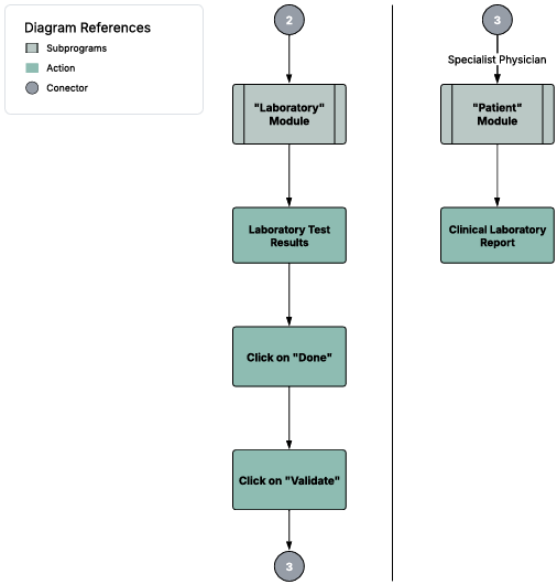

Fig. 3. Post-analytical stage, is carried out by the microbiologist and the specialist physician, each with specific roles in the LIS. It illustrates the process of result validation, after which the results are automatically attached to the patient's profile, until the specialist physician proceeds with their review.

The data presented in Table I highlights the key categories derived from the functionality evaluation tool, organized across the pre-analytical, analytical, and post-analytical stages, along with a cross-functional approach. This matrix compares the predefined requirements with those met by the proposed LIS.

TABLE I. SUMMARY OF THE FUNCTIONAL REQUIREMENTS MATRIX

	Requirement Categories	Functional requirements per phase				LIS GNU Health			
		PR	AN	PO	CC	PR	AN	PO	CC
1	Sample collection/acquisition	3	2	0	1	1	1	0	0
2	Order entry	5	0	0	1	5	0	0	1
3	Test results	0	8	7	1	0	3	4	0
4	Verification and auto -verification	0	3	0	0	0	2	0	0
5	Worklists	0	2	0	0	0	2	0	0
6	Interoperability and data conversion	0	4	0	2	0	4	0	0
7	Instruments and handheld devices	0	4	0	0	0	0	0	0
8	Labels and Barcodes	1	0	1	1	1	0	0	1
9	Notifications and alerts	4	5	2	2	1	2	0	0
10	Regulations and Standards	0	0	0	1	0	0	0	0
11	Reports	0	1	0	2	0	1	0	0
12	Inventory	0	3	0	1	0	1	0	1
13	System downtime	0	1	0	1	0	1	0	0
14	Database/Technical	0	4	0	2	0	2	0	2
	Total, by stages	**13**	**37**	**10**	**15**	**8**	**19**	**4**	**5**

The validation of functional requirements was carried out through direct verification of the system, supplemented by a comprehensive review of the relevant LIS-GNU documentation. The results, categorized by stage, revealed variability in results: 61.54% in the pre-analytical stage (8 requirements met), 51.35% in the analytical stage (19 requirements met), 40% in the post-analytical stage (4 requirements met), and 33.33% in the cross-functional stage (5 requirements met). Based on these percentages for each stage, an overall weighted functionality rate of 48% was determined, reflecting 36 out of 75 specified requirements in the evaluation tool. This rate represents the fundamental functionality of the proposed LIS for potential future implementation at El Níspero. Additionally, a further mapping exercise was performed to assess the compatibility and adaptability between the physical formats and the LIS-GNU system.

B. Adaptability

The evaluation of adaptability focuses on the LIS's capacity to align with existing workflows, incorporate new tests and instruments. Within the laboratory module, a total of 29 tests were generated, supplemented by two specific formats: one for blood chemistry analysis and another for immunology. The majority of these tests were created in the LIS using pre-existing templates from the center, which included essential elements such as reference ranges, units of measurement, and predetermined pricing. This approach resulted in a high adaptability score of 94% for the LIS.

Additionally, a detailed mapping (shown in Table II) was conducted to validate the correspondence between the fields in the physical formats and those incorporated into the reports generated by the LIS. This process not only ensured that the digital reports accurately represented the information from the physical documents but also facilitated smoother transitions for laboratory personnel accustomed to manual processes.

TABLE II. REPORT MAPPING

Category		Items	Compliance
1	Header	Name	Yes
		Age	Yes
		Gender	Yes
		File	No
		Date	Yes
		Place of origin	No
		Physician	Yes
2	Body	Analyte	Yes
		Name	Yes
		Reference Value	Yes
		Observations	Yes
		Alerts	Yes
3	Footer	Microbiologist's signature	Yes

Additionally, a mapping (table III) of the order sheets used at El Níspero was carried out, with a specific focus on adapting them to the invoice generation process.

TABLE III. ORDER SHEET MAPPING

Items	Compliance
Patient's Name	Yes
Age	No
File number	No
Exam Name	Yes
Established Price	Yes
Signature and seal	Yes

This mapping process involved examining the existing order sheet formats, identifying essential data fields, and ensuring their precise integration into the digital system. The invoice generation through the GNU system provides a cumulative total, thereby facilitating better control of sales. A compliance rate of 66.7% was achieved. Although two items did not fully meet the requirements, they can be adapted through specific programming to fully achieve the desired percentage.

C. *Survey*

Following the adaptation of the LIS to meet the specific needs of the center, a survey was conducted among laboratory staff, including administrative personnel, doctor, microbiologists, and IT technicians. The survey, consisting of seven questions, aimed to assess their perceptions of the newly implemented GNU Health LIS, focusing on satisfaction levels and resistance to change. The results revealed a highly favorable reception, with all participants expressing positive views about the transition from manual processes to the LIS. They acknowledged the system's advantages in improving daily laboratory operations, particularly in terms of increased efficiency, improved management of patient data through a centralized platform, a reduction in data entry errors, and improved reporting capabilities.

Despite the overall satisfaction, several areas for improvement were identified. These included technical challenges such as compatibility issues, inadequate technological infrastructure, insufficient maintenance and support, and a lack of training. These insights emphasize the importance of addressing these challenges to optimize the system's adaptation and assure its continued efficient use in the laboratory.

IV. DISCUSSION

A common issue in clinical labs is patient misidentification due to digital errors and incomplete data. Popescu's study [18] shows that HIS reduce such errors. GNU LIS addresses this by linking to the national registry (RNP), ensuring accurate data entry and supporting Popescu's findings from another angle.

GNU LIS is part of the GNU platform as an EHR, offering efficiency, better patient care, and data management. Sinard's U.S. study found 70% of providers prefer an EHR with an LIS, as LIS alone is insufficient; GNU LIS meets this premise [13]. Thomas's study highlights that integrated EHR-LIS solutions are more cost-effective than separate systems like Orchard Harvest, which has high costs. GNU LIS offers a lower-cost, complex, customizable solution [9].

Evaluation using the assessment tool showed GNU LIS has 48% compliance across 14 categories and 75 requirements, outperforming OpenELIS (33%) and BLIS (29.3%) by nearly 15%. Most lab errors occur pre-analytically, where GNU LIS performs well with 61.54% compliance, reducing incidents. However, gaps exist in instruments, handheld devices, and regulations.

GNU LIS achieved 93.5% adaptability to the center's formats but struggles with tests needing gender-specific reference ranges (uric acid, creatinine), limiting out-of-range alerts. Interoperability with auto-analyzers is lacking, requiring manual data entry prone to errors. A suggested fix is scanning hematology autoanalyzer results as PDFs attached to tests, reducing physical records.

The LIS supports three stages: pre-analytical (admin and doctor), analytical (microbiologist), and post-analytical (microbiologist and doctor). Three user roles with restricted access ensure security and efficiency, with training essential for updates.

The admission profile manages patient data, requests, and billing. The microbiologist profile allows test processing and result viewing, limited to the lab domain. Doctors access validated reports linked to patient histories.

User surveys show strong acceptance of the LIS transition, vital for safer, efficient health practices, though infrastructure remains a barrier. Minimum requirements include three networked computers and stable internet, as GNU Health uses cloud servers and basic backups.

In conclusion, GNU LIS is a valuable, cost-effective tool that improves clinical lab management and outperforms other systems.

V. CONCLUSION

The GNU LIS model was designed in accordance with SESAL standards and the center's processes, covering the three analytical stages of the laboratory: pre-analytical, analytical, and post-analytical. Each stage's functions were properly integrated to ensure efficient operation. The application of the LIS-FAT tool validated the feasibility of the proposed model, confirming that it provides adequate adaptability and traceability. The functionality analysis of GNU LIS, conducted using the LIS-FAT evaluation tool, verified compliance with the requirements, achieving a functionality percentage of 48%, indicating that the system can support the basic daily operations of the laboratory, though there is significant potential for further improvements. It is recommended to explore and implement updates, additional modules, or new strategies to expand operational requirements coverage and increase system efficiency. The process mapping was essential in meeting center's specific needs, achieving an overall adaptability of 88%, with adaptability percentages of 93.5% for tests, 84.6% for results reports, and 66.7% for invoices. Integrating LIS with an Electronical Health Record, as in the case of GNU Health, facilitates more efficient workflow management, reduces dependency on paper documentation, and strengthens coordination between the physician and other involved staff members. The optimized model of GNU Health LIS ensures

that all center's processes are fully compatible with the system, enhancing laboratory management and compliance with regulations, and demonstrating the flexibility and capability of GNU-LIS to adapt to more specific demands. The pilot implementation of the LIS at the Níspero Health Center is a key element for the digital transformation process of the Ministry of Health, as it allows for validating the system's viability in a real-world environment before its broader deployment. These trials provide an opportunity to identify potential deficiencies and areas for improvement, ensuring that the LIS is fully functional and aligned with the specific needs of the national healthcare system. The success of these pilot tests will be crucial for expanding digitalization to other health centers, improving service quality, diagnostic accuracy, and clinical decision-making, and making a significant contribution to the improvement of public health in Honduras.

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