Abstract—The use of laboratory testing is crucial in the clinical decision-making process. Laboratory errors encompass any deviation that occurs throughout the entire testing process. A Laboratory Information System (LIS) is a software that handles the reception, processing, and storage of information generated throughout the laboratory workflow. A Hospital Information System (HIS) is a system designed to handle healthcare data. Although HIS has been implemented in various hospitals across Sri Lanka, Lady Ridgeway Hospital for Children (LRH) holds the distinction of being the first hospital to successfully integrate a LIS module into their HIS. This integration allowed healthcare providers at LRH to directly order laboratory tests within the HIS and enabled the laboratory to transmit test results directly to the clinicians through the HIS.

The primary goal of this short report is to assess the benefits received from the use of LIS in mitigating errors in the pre-analytical, analytical, and post-analytical phases of laboratory testing. With the collaboration of both health informatics and laboratory experts, and carefully balancing advantages with drawbacks, the LIS can reduce cost and improve healthcare delivery.

Keywords—Laboratory information system, laboratory testing, health informatics

I. INTRODUCTION

The use of laboratory testing is crucial in the clinical decision-making process. Laboratory errors encompass any deviation that occurs throughout the entire testing process, spanning from test order to the reporting and interpretation of results. Pre-analytical, analytical, and post-analytical phases of the entire testing process are used to categorize laboratory errors. While the pre-analytical phase includes activities from test ordering to specimen delivery, the analytical phase involves the actual testing of the specimen. The reporting and interpretation of the laboratory result is part of the post-analytical phase (Watson & Schoonmaker, 2010). The majority of laboratory errors occur in phases other than the analytical phase (Plebani, 2009). Health informatics interventions can play a significant role in mitigating laboratory errors and reducing turnaround time. These interventions include electronic ordering of laboratory tests, specimen tube barcode labeling, and automated reporting of laboratory test results.

A Laboratory Information System (LIS) is a software that efficiently handles the reception, processing, and storage of information generated throughout the laboratory workflow (McCudden et al., 2020). Its primary function is to automate and streamline the management of all data related to the testing process. A Hospital Information System (HIS) is a system specifically designed to handle healthcare data (Benning & Knaup, 2020). It encompasses various software, hardware, and processes that enable the collection, storage, management, and transmission of a patient's electronic medical record (EMR). Therefore, integration of HIS and LIS significantly improves healthcare delivery by streamlining information flow.

Over the past years, HIS has been increasingly implemented in hospitals in Sri Lanka. Lady Ridgeway Hospital for Children (LRH) is a leading healthcare facility in Sri Lanka specializing in pediatric care. It handles a significant volume of laboratory tests to support the medical treatment of the pediatric population. While HIS has been implemented in various hospitals across Sri Lanka, LRH holds the distinction of being the first hospital to successfully integrate a LIS module into their HIS as a lab module. This integration allows healthcare providers at LRH to directly order laboratory tests from outpatient departments, wards, or clinics within the HIS. Additionally, the two-way functionality of the system enabled the laboratory to transmit test results directly back to the ordering healthcare providers through the HIS, eliminating the need for manual result entry and faster delivery of patient reports.

This short report focuses on assessing the challenges faced during LIS implementation and its impact on healthcare delivery at LRH.
II. PRE-IMPLEMENTATION ASSESSMENT

Automation and the advancement of health informatics have drastically changed medical laboratories. There was a significant advancement in its laboratory capabilities at LRH by purchasing high-capacity automated analyzers for clinical chemistry. Despite having high-quality laboratory equipment, there were still numerous manual procedures in place. Patient registration was slow due to the receiving counter relying on handwritten patient data. This limited the number of patients that could be processed daily, despite the analyzer’s high throughput capabilities. Furthermore, all ordered tests were entered manually into each analyzer. The process of manually marking tubes or aliquots with barcodes, as well as transferring samples from tubes to aliquots, increased the risk of identification errors, due to factors such as staff fatigue. Following the completion of tests, patient reports were generated by printing results from each analyzer onto separate sheets of paper. These individual sheets were then attached to create the final report for the patient. These were visually unappealing and difficult to read due to the varying fonts and formats used on different sheets of paper. The results were initially subjected to technical validation by the medical laboratory technologist (MLT), followed by subsequent clinical validation carried out by the medical team in the chemical pathology department under the supervision of the chemical pathologist, who had limited access to previous results which hindered the ability to compare data, potentially impacting the interpretation of the results. The workflow before the implementation of LIS can be observed in Fig. 3.

HIS in use at LRH is an open-source system released under GNU Affero General Public License version 3. This presented a promising opportunity as it meant that the LIS module could be implemented within the HIS framework with further customization by the health informatics team. However, the team encountered challenges related to interfacing the analyzers with the LIS module. The analyzers used in the laboratory required specific software interfaces to communicate and transmit test data to the LIS. Integrating these interfaces with the existing LIS module required coordination with the local agents of the analyzer. In addition to the software challenges, the LIS implementation required additional hardware resources. The hospital needed computers for data entry and result reporting, barcode readers for efficient specimen identification, printers for generating test labels and reports, and tablets for mobile access to the LIS system. To accommodate these hardware requirements, the health informatics team under the supervision of the consultant in health informatics conducted an inventory of the existing hardware infrastructure and assessed the need for upgrades and new acquisitions.

III. IMPLEMENTATION OF LIS

The implementation of the LIS at LRH involved the collaborative efforts of experts in the fields of health informatics and chemical pathology. The Hospital Health Information Management System (HHIMS), developed by the Information and Communication Technology Agency (ICTA) in collaboration with the Ministry of Health of Sri Lanka to support various hospital functions was an open-source software that facilitated the implementation of HIS with an LIS module. Traditional software development is time-consuming and expensive, but leveraging existing open-source software offered a significant advantage by reducing both time and cost requirements. Previously, many hospitals in Sri Lanka faced challenges integrating the LIS with the HIS due to the lack of an interface between the laboratory analyzers and the HIS. This lack of connectivity prevented data exchange between the two systems. To address this interfacing issue, the health informatics department worked closely with the local agents of the fully automated analyzer providers. They collaborated on customizing the necessary software interfaces, with the introduction of middleware, a software solution that acts as a bridge between the analyzers and the HIS, so that integration became possible. What made this development even more significant was that the middleware solution was at no cost, making it accessible to hospitals with limited resources. This emphasizes the significance of locally adapted health informatics solutions for cost-cutting, particularly in low-resource settings. Similarly, a government hospital in Malawi during the development of the LIS used custom hardware specifically mobile workstations, used in test ordering by clinicians to minimize cost (Monga et al., 2019). The health informatics team procured the required computers, barcode readers, printers, and tablets.

Furthermore, it was ensured that the hospital staff received adequate training on the new hardware and software interfaces. This training included familiarizing staff with using barcode readers for accurate specimen identification, operating printers for generating labels and reports, and utilizing tablets for mobile access to the LIS system. On the other end, medical MLTs and health assistant staff were trained to read barcodes, cross-check the information with the LIS, and validate the generated reports.

IV. WORKFLOW AFTER IMPLEMENTATION OF LIS

To begin the testing procedure, the physician uses a unique patient identifier in the form of a barcode, which provides access to the patient's information in the HIS. This unique identifier was assigned upon the patient's arrival at the hospital, following a one-time patient registration process that generates a barcode label which served as a paper-based continuity of care document kept by the patient. When the patient's barcode was scanned, their summary, including past test orders and their status, along with available test results, was displayed at the HIS interface.

The clinician could request new tests using this information. This system additionally maintained track of the tests that the hospital offered, preventing the ordering of unavailable tests. This replaced the traditional paper request forms. After receiving the test order, the HIS created a unique number for the sample, which was printed on a label together with other test order information in both barcode and human-readable formats. The specimen was tracked throughout the whole testing procedure using the unique number, which was manually attached to the specimen tube. Additionally, the system kept track of the time the specimen label was printed, which was used as a timestamp for sample collection thereby fastening the process of specimen reception. Furthermore, the electronic format ensured that all necessary information was accurately recorded, reducing the
risk of errors, and improving the quality of communication between the laboratory and clinicians. The samples were correctly matched with patient information due to the use of barcode labels which reduced the need for manual identification. Upon the specimen's arrival at the laboratory, the laboratory receptionist followed a two-step process. First, they scanned the barcode on the specimen container and simultaneously visually inspected both the container and the test order documentation. Based on this assessment, the receptionist decided whether the specimen should be accepted or rejected. In case of specimen rejection, a notification was sent to the nursing officers through the system, for the recollection of the specimen. If the specimen is deemed acceptable, the laboratory receptionist forwarded the specimen to the MLTs for analysis. One of the key benefits of LIS is the automated order transfer from the system to the laboratory analyzers. This eliminated the need for manual entry of test orders on the analyzers, allowing MLTs to mainly focus on the analytical phase. Once the sample is analyzed the two-way interface between LIS and the analyzers eliminated the need for result re-entry which reduces transcription errors. The results were automatically transmitted to the LIS, where they were made available to the MLTs for technical validation. Subsequently, the medical team clinically validated the results by obtaining information from the clinicians. If necessary, retesting was done using the same sample and if the sample was insufficient, a new specimen was requested through the LIS. The validation interface contained patient demographics and the current test results. Results were highlighted if outside the reference range based on age, sex, and the analyzer if relevant. Previous results of the patient could be accessed through the interface with a simple click of a button. Critical values determined based on the expert opinions of the chemical pathologist and relevant specialists were entered into the LIS and any result falling outside this established range was flagged for further attention. Once the result was verified, it was promptly notified to the clinician through the system. Therefore, LIS could easily monitor the turnaround time, which was the time taken from sample collection to the generation of the final report. The LIS significantly reduced the need for issuing copies of lost reports, reducing cost and saving time for both the laboratory and the clinical team. The workload of the health assistant staff was reduced as there was no need to dispatch results manually. The post-analytical phase was significantly hastened with the implementation of the LIS and the reduction in manual processes. Access to the LIS was limited to authorized staff only, with a unique identification number and password. Furthermore, the LIS maintained a log of all activities performed within the system. Using data from the LIS allows for important operations like establishing reference ranges and conducting scientific studies. The availability of a data repository enabled clinical and laboratory professionals to study trends and run statistical analyses. Fig. 4 highlights the workflow after the implementation of LIS.

V. IMPACT OF LIS ON HEALTHCARE DELIVERY

A. Positive Impacts

- **Reduction in turnaround times for test results** The hospital experienced delays in issuing test results before LIS implementation due to manual data entry. The LIS reduced turnaround times for test results by electronically generating test orders and updating results to the system as soon as they were available.

- **Automation of routine laboratory procedures** The LIS automated routine laboratory processes including tracking samples and reporting results. Due to this, there was less need for manual intervention, reducing human error. The workload of assistant health staff was reduced as manual dispatch of results was not required.

- **Improved report accuracy** Manual data entry errors and transcription errors were decreased with the use of LIS.

- **Integration of LIS with the electronic medical record (EMR)** The hospital's existing EMR system was integrated with the LIS which allowed clinical and laboratory data to be accessed by healthcare professionals from a single platform. The ability to compare laboratory results against previous test results allowed clinicians to provide patient care with a more holistic approach.

- **Real-time data availability for healthcare providers** Real-time data from the LIS made it possible to access patient test results once available, which facilitated clinical decision-making.

- **Improved statistical reports** The laboratory was able to produce statistical reports more quickly and accurately due to the availability of real-time data. This helped in monitoring the efficiency of laboratory operations and resource allocation. Data could also be used for establishing reference ranges and conducting scientific studies.

B. Negative Impacts

- **Increased cost** Implementation and maintenance of the LIS can be costly. The initial investment in hardware, software, and staff training placed a significant financial burden on the hospital's budget.

- **Data Security** Concerns about data security and patient privacy arise when integrating patient data into an electronic system. There is always a risk of potential breaches and unauthorized access to sensitive patient information.

- **Maintenance and Upgrades** Regular maintenance and grades are required for the continuous smooth functioning of a LIS. In low-resource settings, maintaining the system and ensuring timely upgrades may pose logistical challenges.

- **Technical Issues** Like any computer-based system, LIS may experience downtime or encounter technical problems, which could disrupt laboratory operations and result reporting.

In low-income countries like Sri Lanka, the positive impacts of implementing LIS can significantly improve healthcare delivery by optimizing limited resources.
However, these technologies also come with challenges of increased costs associated with the implementation and maintenance of LIS which may strain already limited financial resources in low-income settings, potentially leading to delays in addressing technical issues and keeping technology up-to-date. Long-term sustainability may require support from government, donors, and other stakeholders. In Sub-Saharan African hospitals, limitations in infrastructure and equipment hindered the implementation of quality management systems reflecting the barriers in resource-limited settings to embrace technological advancements (Barbé et al., 2017).

VI. STAFF FEEDBACK

Staff satisfaction was evaluated through the use of a Google Form survey, which was distributed among a diverse group of health staff, including consultants, registrars, medical officers, house officers, nurses, medical laboratory technicians, and health assistants (Fig.I). This approach ensured that feedback was gathered from a wide range of individuals representing various roles within the healthcare or laboratory setting. Following the collection of survey responses, the data was analyzed using Microsoft Excel 2019.

Firstly, the survey revealed that all respondents, a notable 98.2%, demonstrated a high degree of readiness to adapt to the new system. A study conducted in a South African hospital revealed challenges in implementing HIS due to clinicians’ preference for the traditional paper-based system (Ohuabunwa et al., 2016). Similarly, in a study done in an Iranian hospital, the principal barrier to the implementation of HIS was identified as negative staff attitudes (Ahmadian et al., 2014). Staff resistance to change can be an obstacle during the implementation of a new system, which was not observed in our case. One of the key findings was that 63.6% of respondents acknowledged a reduction in paperwork since the LIS implementation. Additionally, 65.7% of respondents stated they could easily access the results, showing that the LIS had significantly improved the ability to retrieve laboratory data. In addition, 58.2% of respondents stated that the LIS implementation had resulted in faster result reporting. A remarkable 81.6% of respondents claimed that the LIS system has improved their general productivity, leading to improved outcomes and reduced workload for laboratory personnel. Finally, 51% of respondents said the training was sufficient, indicating room for improvement. In a laboratory setting, proper training is essential to ensure that all staff members can use the LIS efficiently. Computer literacy was identified as a mediating factor influencing the satisfaction of health professionals during the implementation of electronic medical records in developing countries (Tilahun & Fritz, 2015), highlighting the importance of computer training for healthcare professionals in these settings.

This short report highlights the benefits of implementing health informatics interventions to address issues in the laboratory testing process in low-resource settings. The implementation of LIS brings both opportunities and challenges to healthcare delivery. Faster turnaround times, improved data accuracy, electronic storage of data, decreased sample identification errors, and decreased translational errors are some of the advantages. The large amount of data available to chemical pathologists during verification increases the quality of results. Our survey showed a high level of staff readiness to change, with 98.2% stating they were eager to adopt the new system and 81.6% stating the LIS had increased their productivity, showing a positive impact on day-to-day operations. Although the majority (51%) found the training sufficient, there is space for improvement. Addressing potential negative impacts like high initial expenditure, data security concerns, and adequate staff training is required to ensure effective LIS implementation. Only with the collaboration of the chemical pathology and the health informatics experts can an optimal LIS for specific laboratory requirements be developed. The LIS can be a useful tool to reduce errors in the pre-analytical, analytical, and post-analytical phases by carefully balancing advantages with drawbacks thereby improving healthcare delivery.
REFERENCES


