IMPLEMENTATION OF A WEB-BASED LABORATORY INFORMATION SYSTEM (LIS) IN A HIV CARE AND TREATMENT PROGRAM: KENYATTA NATIONAL HOSPITAL COMPREHENSIVE CARE CENTRE (KNH CCC) CASE

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Abstract
Laboratory services are critical in initiating and monitoring of Antiretroviral Treatment (ART) in HIV patients. However, timely availability of laboratory test results to the clinician remains is a challenge in most health care facilities due to misplaced or misfiled patients test results. The objective of this paper is to describe a web-based laboratory information system implemented to alleviate these problems at KNH CCC. As part of the University of Nairobi Institute of Tropical and Infectious Diseases (UNITID) fellowship training program from 2010 to 2012, functional and operational requirements for the laboratory information system were drawn from a rigorous needs assessment exercise involving all stakeholders through iterative discussions and workflow analysis of the laboratory activities. The system was developed using J2EEE platform and hosted in Ubuntu server edition version 10.0.4. LIS integrates with the laboratory's clinical analysers and uses language parsing technique to acquire test results electronically. Intensive training of users was conducted before the system was deployed for use in KNH CCC laboratory. Parallel-run deployment method was adopted where the old and the new systems were used alongside each other for a period of one month. A web-based laboratory information system with specimen bar code labelling functionality has been deployed in KNH CCC. The clinician is able to access the results real time and the reception staffs are able to tell the % of analysis work done per patient. Since its implementation in March 2012, over 10,000 laboratory test orders have been captured. Electronic laboratory information system has a large potential to improve quality of care by improving acquisition and transmission of laboratory test results. Key lessons learnt for new system acceptability is that iterative discussions with all stakeholders followed by training sessions to all laboratory personnel are critical.

Key words: Laboratory services, test results, timely, quality, needs assessment, training

1.0   Introduction
Laboratory services is an essential component of HIV/AIDS prevention and treatment among other diseases especially considering the fact that commencement of Antiretroviral Treatment(ART) in HIV patients is informed by laboratory tests such as CD4 counts, viral load among other tests. Laboratory information at the point of care is essential for determining prevalence and incidence rates of infection and disease, for monitoring treatment efficacy and for identifying infected individuals who can be offered prevention and treatment.[1] Therefore, the content the laboratory delivers makes it critical to patient safety, quality of care, and speed to diagnosis. According to Blaya *et al.* (2007), laboratory information constitutes as much as 65% of the content of the electronic Health Record (EHR) and impacts 70% of clinical decision making.It is critical, therefore to capture laboratory information at the point of care. Kenyatta National Hospital Comprehensive Care Centre (CCC) which provides care and support to PLHIVs has in house laboratory services but have had challenges associated with manual handling of results such as loss and misplacement of patients' laboratory results leading to delays in diagnosis and treatment.

1.1   Laboratory Information Systems
Comprehensive and effective data management in health care facilities continues to be a bottleneck due to the legacy systems which only allow manual processes of data capture, storage and transmission (Hao *et al.*2006). An essential complement to the provision of laboratory testing is a laboratory information system to track each step in the testing process, from the administration of tests to the receipt of test results, thus catalyzing timely decision-making and action around diagnosis, treatment and care (Maria and Anna, 2006). Moreover, system integration is known to reduce the time to transfer data as well as eliminate the manual transcription errors (Patricia *et al*. 2009),thus ensuring a decrease in turn-around-times (TAT) of laboratory results (Blaya *et al*. (2007) and Westbrook *et al. (*2006)). Healthcare associations and government agencies worldwide also support the use of

bar coding as a tool to reduce medical errors. [7] Most developed countries have incorporated laboratory information systems in their laboratory services. However, in Kenya, laboratory information systems are not common in most heath care facilities despite their critical role in care delivery.

This paper describes the design and implementation of a web-based laboratory information system with specimen bar code labelling feature to automate laboratory services in Kenyatta National Hospital Comprehensive Care Centre thereby facilitating electronic patient data capture and transmission of the test results to the clinician in timely and efficient manner. This system was designed based on needs assessment and workflow diagrams**.**

2.0   Materials and Methods
2.1   Needs Assessment
The first step in developing the laboratory information system was to gather users' requirements by conducting a needs assessment of the major stakeholders: the facility manager, clinicians, laboratory personnel and data entry staff. After working with the technical team, a functional requirements document which details all the major modules of the system was created. In addition system requirements covering the hardware and software components necessary for successful deployment and usage of LIS were also specified and documented. While most requirements were identified during this initial period, others emerged during the implementation process.

2.2   System Design
The laboratory information system was designed to be web-based operating in a client/server environment. The web based laboratory information system has two levels of integration: the first one to three analyzers in the laboratory - Cyflow analyzer for CD4 count tests, Universal 320R analyzer for haemogram tests and Lisa300 Plus for chemistry tests; the second one to IQCare EMR system facilitating electronic acquisition and transmission of test results to the patient's electronic file. The system integration design layout is shown in Figure 1. The computers linked to the analyzers were configured in the local area network (LAN) where language parsing techniques were exploited to capture test results into LIS database. The output of the system processes is an aggregate of the test results from respective analyzers which goes to the doctor for diagnosis. The system was also designed to flag out of range test results thereby calling for immediate action by the lab personnel and to track the state of pending test results by indicating the percentage of the work done.
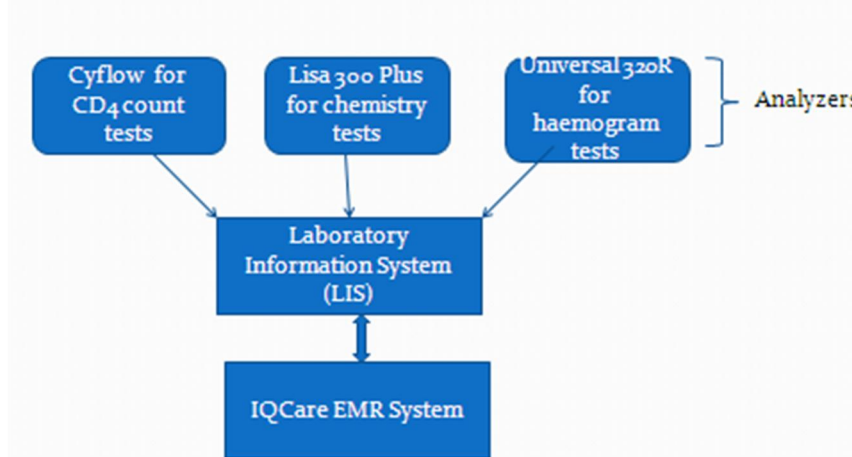

Figure 1: System integration design layout

To protect patient's confidentiality, the system incorporated extensive encryption and system access controls based on user roles in the system. There are six user roles, each of which has particular type of authority as shown in Table 1.

Table 1: User roles and their authority

Role	Authority
System administrator	Create/activate/suspend manager, technologist, clerk, records and student user accounts.
Laboratory Manager	Add/edit/update/delete/browse/print test order in the system. Validates test results before release.
Laboratory Technologist	Add/update/browse test order in the system.
Laboratory Clerk	Add/browse test order in the system.
Records clerk	Browse test order in the system
Student	Browse test order in the system

Using WHO guidelines[8] on handling patient laboratory results in conjunction with discussions with National Reference Laboratory personnel, access profiles for the different types of users were defined. The ultimate goal of the system was to enforce confidentiality which was lacking in the manual system.

2.3   Integrating Specimen Barcode Labelling

The system adopted linear type of bar code labeling technique to identify patients' specimens uniquely at the point of registering the patients' order in the system. A barcode generator was programmed within the system which used ID Automation bar code proprietary font for converting the numbers to barcodes. A hybrid type of integration of the barcode system into LIS was adopted where parallel labeling system type was adopted to print batch labels for the main specimens while seamless labeling type was applied to aliquot specimens. The unique identifiers on the main labels are composed of the barcodes and its equivalent 8 digit long number while the aliquot labels are composed of the specimen identifier with a unique extension. Aliquot labels are printed on demand. A bar code reader scans the specimen identifier into the system thereby eliminating transcription errors.

2.4   Integration into Laboratory workflow

The laboratory information system needed to be integrated within the workflow of the busy CCC laboratory. A thorough workflow analysis of all the laboratory activities, each staff responsibilities and tests performed was carried out. The system was designed to follow the existing workflow of intake, processing and reporting. However the workflow was adjusted slightly to incorporate data entry, scanning of barcode labels on specimen tube(s), generation of barcode labels on demand for aliquot specimens and printing of test results from the system. Workflow adjustment was achieved through interactive discussions with the system users, site observations and use of Use Case diagrams which was later followed by intensive training sessions for all laboratory personnel. These changes in workflow however did not result in increased time demands. Instead, the revised system resulted in greater efficiency for most laboratory personnel, since the laboratory test results are acquired electronically as opposed to writing by hand.

2.5   System Testing

The system was developed and tested in modules and put up in a staging environment for testing by the quality control team. To coordinate and document the testing activities, Red mine online project management and issue tracking software was used where discovered bugs during testing and issues related to the system testing were posted. It tracked all issues raised, by whom and to who and the level of urgency. This hastened the debugging period as it was accessible online. The documentations of the system were uploaded in the same tool for the attention of the members of the quality assurance team.

2.6   Information Technology Assessment

The technical team conducted a though assessment to determine the state of the local area network (LAN) infrastructure, availability and usability of computers dedicated for laboratory services, internet access and physical security. The assessment identified key deficits which informed the project budgeting in terms of hardware and software requirements for improving the LAN. Level of IT skills of the laboratory personnel and other prospective system users' assessment was also conducted. Training needs were identified to address the skills gap for effective use of the new system once deployed.

2.7   Training
Adequate training was conducted before authorized users were allowed to use the system in production environment. This was provided at two levels: user training which was designed for laboratory personnel that would be using the system on day-to-day basis and; technical training which was designed for IT staff intended to provide support in terms of LIS administration and maintenance. The training sessions were performed on the LIS staging environment. System issues raised during the training phase were tracked and addressed. Further issues were captured through the post training evaluation feedback form.

2.8   System Deployment
The laboratory information system was developed and deployed on a Linux Apache MySQL PHP (LAMP) platform and was installed in a server running on Ubuntu operating system with the clients operating on Windows XP. It supports concurrent browser-based users. It was put into piloting phase immediately after installation for a period of one month. The system had to be continually expanded and adapted to the needs encountered during the pilot phase. During the rollout phase of initiating the system into production environment, a parallel-run implementation method was adopted where the old and the new systems were used alongside each other. A rollout guideline document shown in appendix 7 was developed and availed to all users for reference to ensure conformity in using the system. This was in addition to the training received previously. Troubleshooting problems throughout the deployment phase was inevitable. Most of the problems were administrative or hardware related such as replacing a switch which could not handle the traffic hence causing disconnection every morning.

3.0   Results
A web based laboratory information system with barcode labelling feature was deployed successfully and put into full production in KNH CCC from 1st March, 2012. Based on the comments of the users, the new system is simple, user friendly and aligns with the previous workflow. Consequently, the users did not have to do major adjustments in the way they did work previously.Prior to deployment of the new system, training sessions were held where 8 laboratory personnel, 4 data clerks and 1 ICT person were trained. This was followed later by a technical training session to support administration of the system where 3 ICT staff and the system administrator were trained.

3.1   System Usage
The system has been successfully integrated into the hospital's operations. Since its implementation, over 1000 test orders and results had been captured by the system within the first month. Feedback from system users has been positive. This feedback has been captured by the continued usage of the system and also in form of conversations by the M&E team with clinical and laboratory personnel. A strong indicator of the system's utility is the request to expand the system to the other 14 laboratories of KNH. To enhance the system and to maintain user "buy-in", a lot of care was taken to respond to critical comments and suggestions by users.

3.2   System Features
The following key features are implemented in the current version of the laboratory information system:
i)   Patient/sample test order registration.
ii)   Specimen barcode labeling.
iii)   Electronic data acquisition from the CD4 clinical analyzer machine.
iv)   Central database and backup system.
v)   Validation of patients test results before release.
vi)   Audit trail to track and log all critical interactions with the user including capturing the identity of the user, the user's action and the timestamp of the action.
vii)   Link to allow users to specify test reference ranges.
viii)   System alert where test results above or below specified ranges are flagged.
ix)   Reports generation.
Figures 2, 3&4 below shows various screen captures of the system in operation in CCC laboratory. Figure 5 shows aggregated patient's test results from the three analyzers.
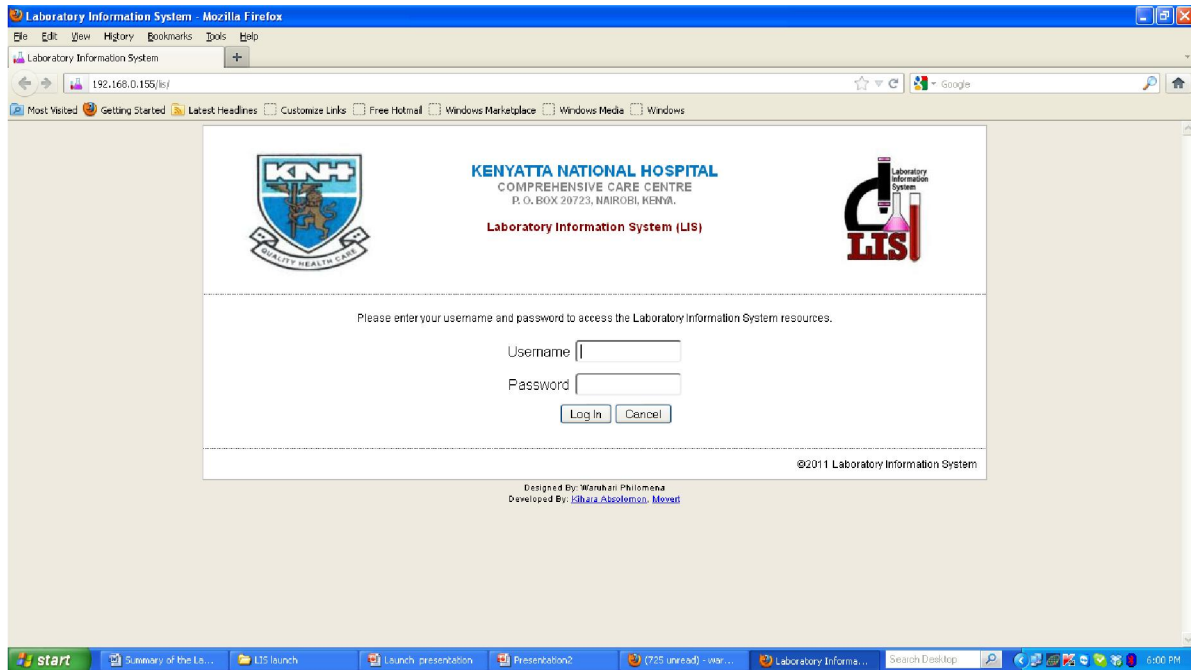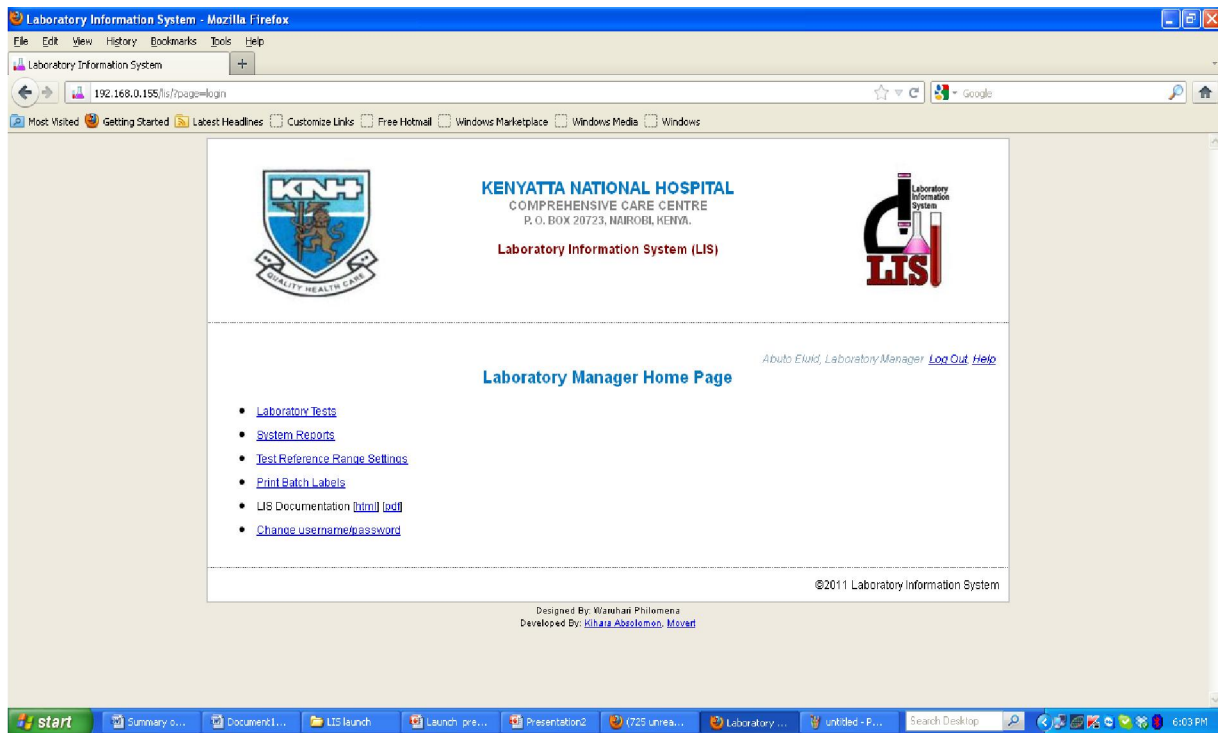
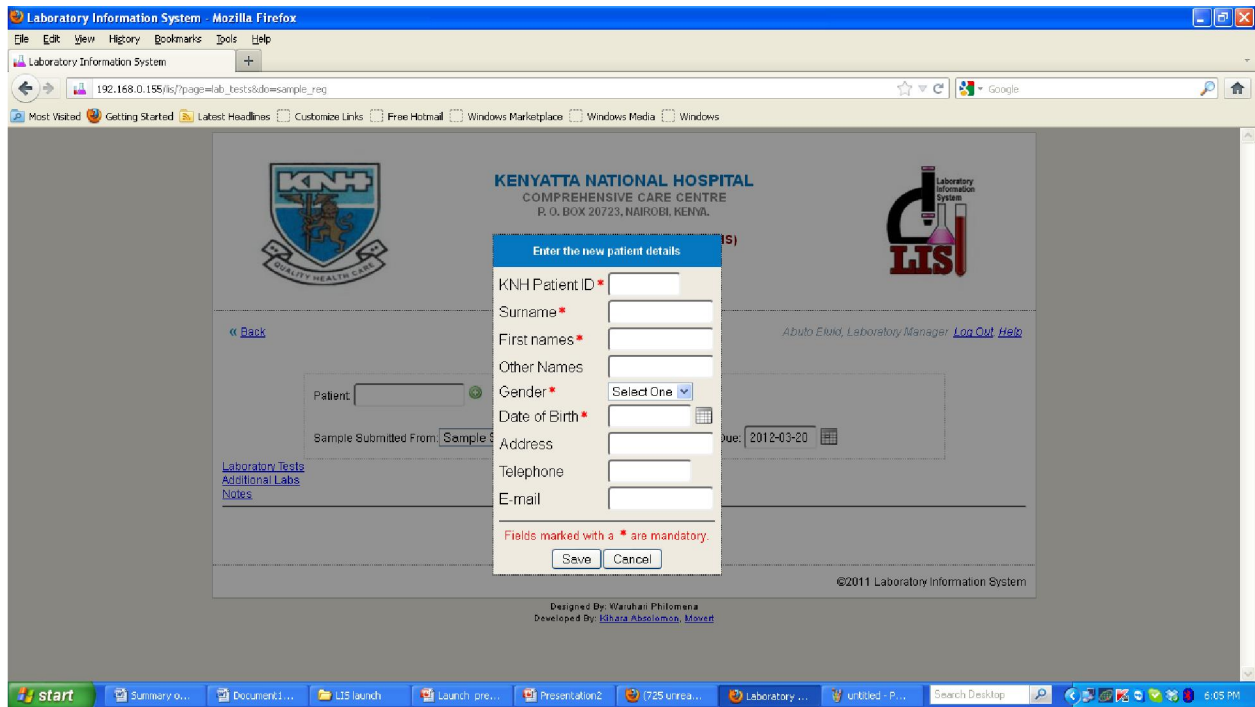*Figure 2. System login page*

Figure 3: System user home page

Figure 4: Patient registration page

Figure 5: Patient's tests result form

The system has made it easier to generate monthly and daily/weekly reports for specified period of time as decision support tool for the management. Table 2 below shows the reports generated by LIS so far. Work is in

progress to enable the system to generate more reports such as patient history report, pending results report among others.

Table 2: Reports generated by LIS

Report	Informed	Purpose	Type of Access
Type and number of laboratory tests ordered daily	Facility and laboratory managers	Report and identify trends in laboratory performance.	Daily/weekly report prepared by the manager
Type and number of laboratory tests ordered monthly	Facility and laboratory managers	Report and identify trends in laboratory performance.	Monthly report prepared by the manager
Consolidated patient test results	The requester e.g the clinician	To commence patient treatment and care based on evidence.	Print button in the browse ordered test by the manager.

4.0   Discussions
The design and implementation of the laboratory information for KNH CCC was greatly inspired by the desire to improve patients' health out come by providing prompt and quality treatment and care.

4.1   Challenges and Obstacles
(i)   Analyzer interfacing was not fully achieved on two analyzers due to technical limitations. The haemogram analyzer needed a RS232C cable adapter to send test results to a computer. It was not possible to get assistance from the suppliers within the project period. The analyzer also experienced frequent breakdowns. The Chemistry analyzer firmware only supported DOS environment and hence could not be configured in the network for parsing of test results to LIS database. Time constraint is also another factor as it was no possible to follow the suppliers of the equipment.

(ii)   The actual date of birth is a mandatory field in the system while registering the patients but in some test request forms it was never captured. This forced the laboratory clerk registering the patient to default to an agreed date and month by the data entry staff for such cases.

(iii)   It was the aim of the system to enforce patient follow-up by capturing the patient telephone contact during registration. This had to be relaxed after realizing some patients do not have mobile phones or landline contact.

(iv)   The actual time available to accomplish the proposed objectives of the project was very limited.

4.2   Lessons Learned
Several lessons were learned from the experience of developing the electronic laboratory information system in KNH CCC:
(i)   All stakeholders must contribute to the design and implementation throughout the life of the project to ensure the system addresses the actual user needs. Initial requirements may not fully reflect user needs due to inexperience with the system hence the need for iterative requirements gathering.

(ii)   A clear vision, objectives and principles can ensure that a successful system does not get overloaded with non-core requirements.

(iii)   New systems should easily integrate into the existing workflow with minimum disruption and sufficient advantages to gain "buy-in".

(iv)   Adequate training in the system's use and benefits is paramount to system acceptance and utility.

5.0   Conclusion

Electronic laboratory information systems have the potential to improve patient care and public health monitoring. Some of the challenges experienced in health facilities, such as misfiling, transcription errors, double allocation of patient numbers are obstacles that a well-designed information system can overcome. However, creating well-designed information system is a difficult task necessitating appropriate resources, expertise and time to be successful. The web-based laboratory information system for KNH CCC met its objective of ensuring efficient and timely availability of accurate test results to the clinician, as a critical component of the overall process of patient care.

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