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Laboratory Information Management System: A Case Of Family Aids Care And Educational Services (Faces)

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Executive Summary: *The role of information management system is crucial in organizations since its elements can substantially be found in any organization, small or big. Family Aids Care and Educations Services-FACES being a care provision organization to patients living with HIV/ AIDS is no exception. FACES was incepted in 2004 and was operational in one facility with a staff base of about a dozen people. But this has since increased many folds due to patients increasingly seeking its services. FACES has rapidly expanded its services to the entire Nyanza province in the last few years, with an increased staff base of over 700 people. Currently, the organization is serving over 100,000 patients. This huge number of patients translates to more work, especially in the laboratory department where samples are drawn and tested to aid clinical decision. Such tests include CD4 counts, PCR, and Cretinine. FACES laboratory department faces major handicap in collection and dissemination of tests and test results. This study is intended not only to improve service delivery at the lab but also make it easier for the department to generate their periodic reports with ease. The key objective of this project was to design, develop and test a working prototype of a laboratory information system. This was achieved by initially obtaining primary data and information from the potential systems consumers through oral interviews and observation, which was analyzed and the problem statement evaluated to realize the viability of a new system. The above methods are preferred since they provide more insights to the information workflow and users' requirement since the success of any system is in its usability. The data gathered at the lab formed the basis of key functionalities of the proposed system, though additional materials gathered from other secondary sources during literature review were also introduced so as to improve the overall quality of the system and to ensure it adhered to the best development practices. Waterfall methodology was preferred, using the collected information to build the new prototype, which was expected to satisfy users' requirements as well as the objectives set earlier*

I. INTRODUCTION

Medical Health Information Systems (MHIS) have evolved over time in recent years due to various advancements in technology. A number of hospital institutions have embraced the idea of managing their patients' health records electronically. This has improved efficiency and effectiveness in storing while reducing the cost of patient information management and retrieval of such information when required for prompt decision making (Munash University, 7 July 2012)

A number of laboratory software have been developed, proprietary or open source, to help streamline the workflow and automate processes within the medical laboratories. In most cases, such software are often bundled with inpatient, outpatient, pharmacy, lab and even financial management modules. (Munash University, 7 July 2012)

Medical labs within Comprehensive Care Centres (CCC) on the other hand have not benefited much from similar developments. CCCs are centres that provide health care support to special patients with special needs and attention, more specifically the persons living with HIV/AIDS (PLWHAs). The CCCs contrast with ordinary healthcare providing institutions in the workflow and most fundamentally the nature of its clientele. Therefore it is essential to consider laboratory information management systems for CCCs to facilitate quality service provision and timely decision making based on the measureable indicators provided. This will ultimately impact positively on the quality of care and other services and enhance overall patients' healthcare as a result (Author, 2012). *2*Family Aids Care and Education Services (FACES) is a comprehensive care and treatment clinic offering high quality care and education services to individuals and families infected and affected by HIV/AIDS (Faces-Kenya, 2010).

The program enrols new patients whose HIV status has been confirmed into care. It also continues to offer quality care to the existing patients within its catchment areas while offering referral options to patients who opt to receive care elsewhere. (Faces-Kenya, 2010)

In order to efficiently serve the patients, the program has various departments handling various aspects of patients during a visit. Laboratory being one such department plays a very key role in medically determining various tests results that are vital in making sound medical decision on patient health progress.

A REVIEW OF INTERNET TECHNOLOGY ADOPTION LITERATURE

Sometimes known as a laboratory information system (LIS) or laboratory management system (LMS), a laboratory information management system (LIMS) is a software-based laboratory and information management system that offers a set of key features that support a modern laboratory's operations. Those key features include — but are not limited to — workflow and data tracking support, flexible architecture, and smart data exchange interfaces, which fully "support its use in regulated environments. The features and uses of a LIMS have evolved over the years from simple sample tracking to an enterprise resource planning tool that manages multiple aspects of laboratory informatics. Due to the rapid pace at which laboratories and their data management needs shift, the definition of LIMS has become somewhat controversial. As the needs of the modern laboratory vary widely from lab to lab, what is needed from a laboratory information management system also shifts. The result is the definition of a LIMS is dependent upon the user. Dr. Alan McLelland of the Institute of Biochemistry, Royal Infirmary, Glasgow highlighted this problem in the late 1990s by explaining how a LIMS is perceived by an analyst, a laboratory manager, an information systems manager, and an accountant, "all of them correct, but each of them limited by the users' own perceptions. (Wikipedia, 2012)

The LIMS is an evolving concept, with new features and functionality being added often. As laboratory demands change and technological progress continues, the functions of a LIMS will likely also change. Despite these changes, a LIMS tends to have a base set of functionality that defines it. That functionality can roughly be divided into five laboratory processing phases, with numerous software functions falling under each:

- The reception and log in of a sample and its associated client data.
- The assignment, scheduling, and tracking of the sample and the associated analytical workload.
- The processing and quality control associated with the sample and the utilized equipment and inventory.
- The storage of data associated with the sample analysis.
- The inspection, approval, and compilation of the sample data for reporting and/or further analysis.

There are several pieces of core functionality associated with these laboratory processing phases that tend to appear in a LIMS.

Lab IMSs differ in functionality and platform on which they run. Some run on device webpages, some may be standalone while others may exhibit client-server architecture.

More complex LIMS are device specific and are often closed ended making it hard to interface with other applications. (Wikipedia, 2012)

Though there are proprietary off the shelf LIMS available out there, some of them rarely simple enough to satisfy the needs of smaller laboratory in remote setups. Some of the LIMS reviewed include: (Author, 2012)

2.1.1 Sample Master by Accelerated Technology Laboratories

The Sample Master LIMS product provides a total laboratory data management solution that brings the ease and familiarity of Windows-based, point-and-click operability to the laboratory. Sample Master has an intuitive user interface, hot lookups, pull-down menus and allows users to modify screen captions. It features uncluttered screens and dozens of modifiable canned reports. Users can easily incorporate new screens, report forms, queries, pull-down menus, macros and modules. The product details are as follows:

Platforms: Windows, Web Based

Support: 24/7, Regular Business Hours, Online/Self Service

The major merits of Sample master include Intuitive and friendly user interface; Modifiable canned reports, Flexibility and extendibility. On the other hand, this LIMS, though Windows based, it run on a web platform, which is suitable for client server implementation. But this system doesn't sufficiently address the simplicity that would endear it to a remotely located rural laboratory.

2.1.2 OpenMRS Laboratory Module

After the clinician has ordered laboratory investigation for patient, this module handles interactions with system for collecting samples (blood, urine etc.) from patients for laboratory investigation, preparing samples, conducting investigation and recording results.

The personnel involved in this module are mainly Lab attendants/Nurse and Lab approvers. Lab Investigation orders can be received from Screener module and/or OPD module. This module is an extension of the core OpenMRS code base and runs on OpenMRS API.

The module is web based and runs on Tomcat web manager with a MySQL back-end.

This is a simple and easy to use module which is majorly used for capturing the lab test result per patient. Through standard reporting interface, the user may be able to produce some simple reports that may be linked to the regular patient encounter details captured on various encounter forms.

2.1.3 Professional Lab Information Systems - *Prolis*

PROLIS is a Windows® and Web hybrid Client Server system built using .NET technologies and MS SQL Server 2005. This relatively complex software proven strengths include:

- Automating the management of the laboratory business with integrated Quality Control and Regulatory Compliance.
- It provides a barcode aided interface (bi-directional or uni-directional) with any laboratory equipment.
- Also provides its Outreach module to have the laboratory offer a 24/7 access to the patient results and new patient accession, to her clients (physicians and clinics).
- It offers a 100% automated report delivery mechanism module, to Fax or Email Lab Report automatically to notify providers of their patient's critical results along with regular ones.
- *Prolis* offers a bi-directional HL7 interface for EMR and Reference Lab.
- It offers the laboratory the capability to retrieve the data in the Insurance specific format to satisfy the Contract requirements.
- *Prolis* offers an integrated Laboratory Billing Solution and accounting functions and more.

Prolis is a unique design of concept dictionaries that extends the system's functionality to meet various testing scenarios thus making it ideal for variety of laboratories i.e Physician Office Laboratory (POL), Reference Laboratory - aiding patient care, Hospital Laboratory.

This system has been specifically structured to handle various types of business with a customizable hold of Quality Control module throughout the process. PROLIS is equipped with not only today's growing demands of various Interfaces, ranging from connecting to a digital camera attached to the microscope to a bidirectional communication with an automatic analyzer, interfacing with the reference laboratory's system to interfacing with the system of regulatory agencies, it addresses the interfacing with various EMR systems at the laboratory's client's sites.

In conclusion the systems that have so far been reviewed have some common features ranging from web based capabilities to the complexities of handling reagents inventory and also managing the Laboratory revenue collection. The only outstanding weakness that remains to be addressed is the aspect of simplicity. Most laboratories found in the developing countries like Kenya only have the most basic test equipment and the workflow remains so simple.

2.1.4 ProtLIMS

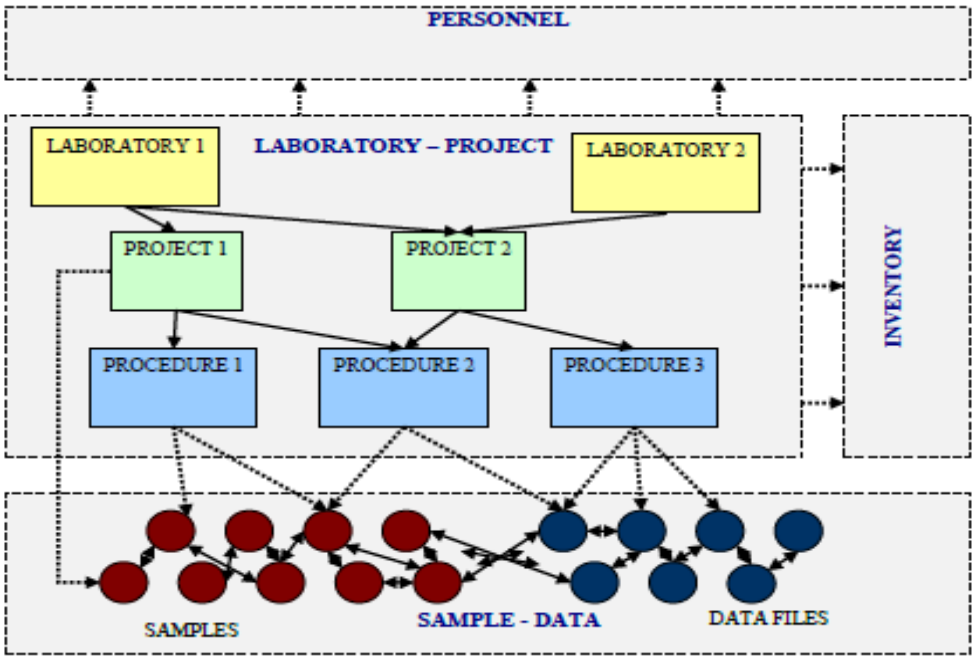
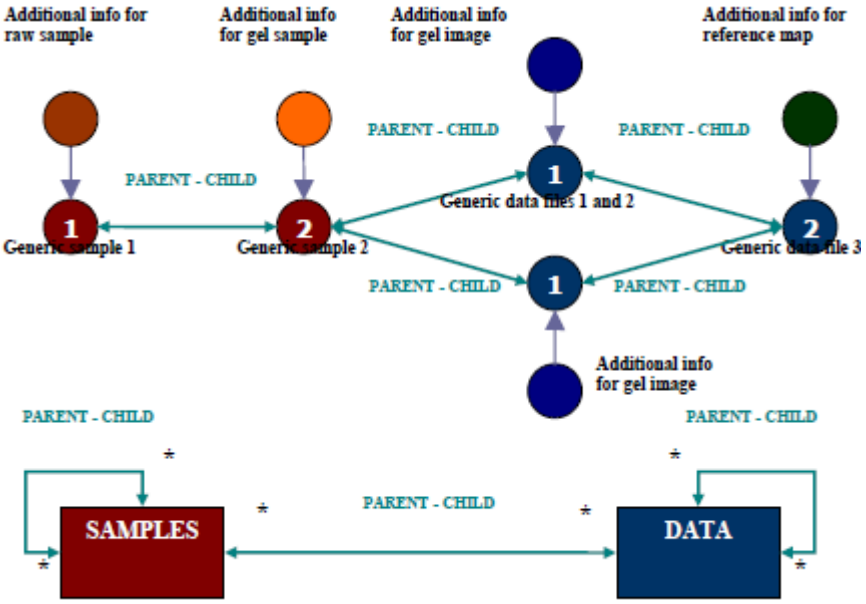


Figure 2.1 **- ProtLIMS structure overview**

ProtLIMS system can be logically separated into several packages. Sample-data package contains information researcher are especially interested in: samples, data files and associations between them.

Sample object represents any biological sample from raw tissue to 2d gel. Generic set of properties (including unique ID) is defined for all samples. At the same time each sample can have additional properties such as

attributes and references to complicated data structures. The set of additional properties depends on sample type. Samples can be derived from each other.
Data file is usually associated with a file in LIMS storage. Data file can be image, text, binary file, etc. Each data file has set of generic properties (including unique ID) plus additional properties depending on its data type. Data file can be derived from other data files and samples.



EACH SAMPLE OR DATA FILE CAN HAVE MULTIPLE PARENTS AND MULTIPLE CHILDREN

Associations between samples and datafiles have inheritance nature.
Each workflow brings new sample and data types into system. As long as each sample is generalized form generic sample and each data file is generalized from generic data file inheritance between samples and datafiles can be obtained. Diversity of new sample types is achieved by additional properties.
Project level purpose is to organize samples and data in logical units according to research workflow, and to add information about sample and data history. As we conduct sample procedures, we get additional information about used protocols, equipment, etc. Project level also stores information about personnel permissions on laboratory projects.
The following describes permission management in ProtLIMS. Owning, sharing and publishing concepts are clarified below.
When user creates project:

- User becomes project owner and gets FULL permission on created project
- User's laboratory gets FULL permission on created project
- User can automatically give all user's laboratory personnel FULL permission on project or choose not to

Any user with FULL permission on project can:

- Share project with personnel of certain laboratory (give CHANGE permission to laboratory and CHANGE permission to all laboratory personnel)
- Share project with certain people in certain laboratory (give CHANGE permission to laboratory and FULL or CHANGE permission to selected people in this laboratory)
- Publish project to certain laboratory (give READ permission to laboratory and READ permission to all laboratory personnel)
- Publish project to certain person (give READ permission to specified person)
- Publish project to everybody (give READ permission to any valid system user)

User with FULL or CHANGE permission belongs to the project personnel. This means that user can work on project adding new procedures, registering and associating new samples, entering project details etc.
The main difference between FULL and CHANGE permissions is that person with FULL permission can give permissions away to other people and laboratories. Person with CHANGE permission does not have right to do so.

READ permission gives user right to browse project results. It includes information about samples, datafiles and full project report. This option can be useful for sharing results with project customer in facility-like laboratories.

FULL, CHANGE and READ permissions form hierarchy. Person with higher permission has lower permission as well.
The following is a protLIMS general architecture.

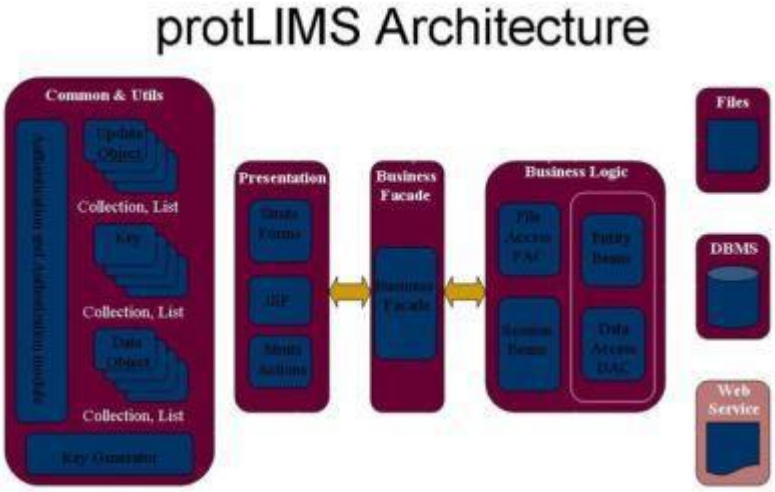


Fig 2.3 protLIMS general architecture.

2.2 CONCEPTUAL FRAMEWORK
The system assumed a very simple framework which involved the following sections:

- **Input:** This includes the raw patient demographic information captured at the initial point of contact with the patient. Such information also involves basic patient encounter information and most importantly the specific test request details.
- **Processing:** The system clusters and processes the input data into meaningful information that may later be used for decision making. This includes processing and analyzing patient specific test
- **Output:** The captured data once processed is used to generate accurate reports which are not only used by the lab, but also other departments and the program at large to make timely decisions.

This can be summarized in a simple MIS diagrammatically as follows:

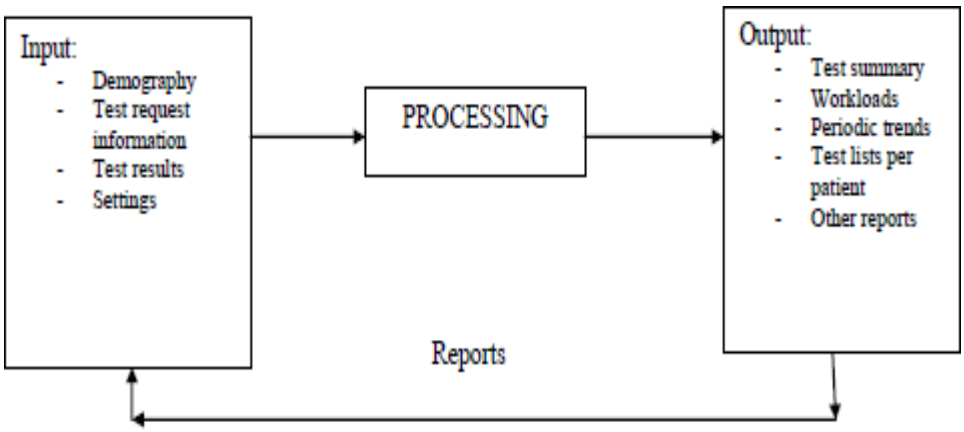


Fig 2.4: System Overall framework

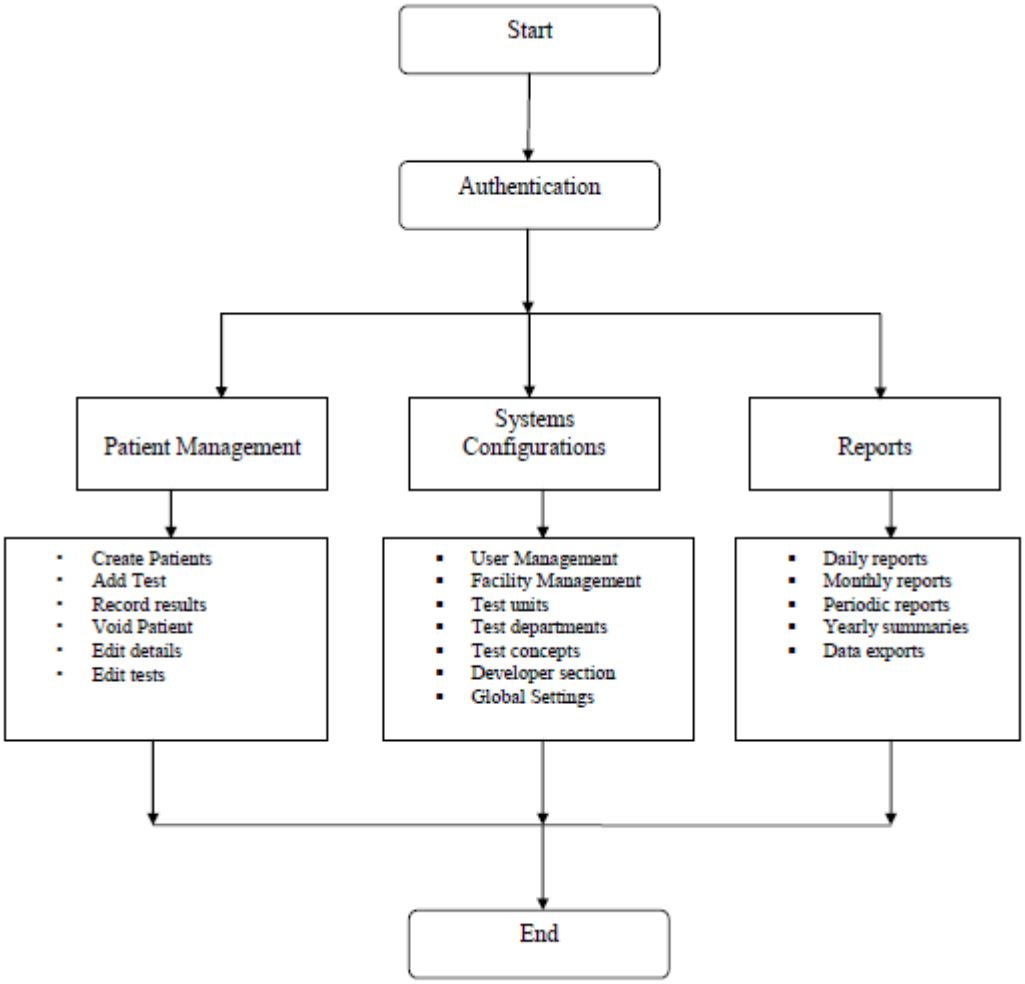


Fig 2.5: Lab IMS Conceptual Framework

II. DESIGN

A methodology is composed of one of the software development models used in conjunction with one or more techniques. The techniques of prototyping, clean room, and object-oriented are ways to implement the waterfall, incremental, and spiral models. These techniques may be mixed and matched on a single project. Also, portions of a technique may be used without using all aspects of that technique. Therefore a project using the spiral model may combine prototyping with object- oriented analysis and design and also use clean room testing techniques.

For the purpose of this study Waterfall model was preferred using the. The waterfall model is an approach to development that emphasizes completing a phase of the development before proceeding to the next phase. In conjunction with certain phase completions, a baseline is established that "freezes" the products of the development at that point. If a need is identified to change these products, a formal change process is followed to make the change. The graphic representation of these phases in software development resembles the downward flow of a waterfall.

Each box in the figure overleaf, represents a phase. Output from each phase includes documentation. The phases below show detailed design phase including software as part of their output. Transition from phase to phase is accomplished by holding reviews. These, provide the insight into the developer's progress. At critical points on the waterfall model, baselines are established, the last of which is the product baseline. This final baseline is accompanied by audits.

The water fall model ensures that each development phase is thoroughly reviewed and completely certified before moving to the next phase. It also provides flexibility of going back to the previous phases should there be need. The following are the key stages that will be involved

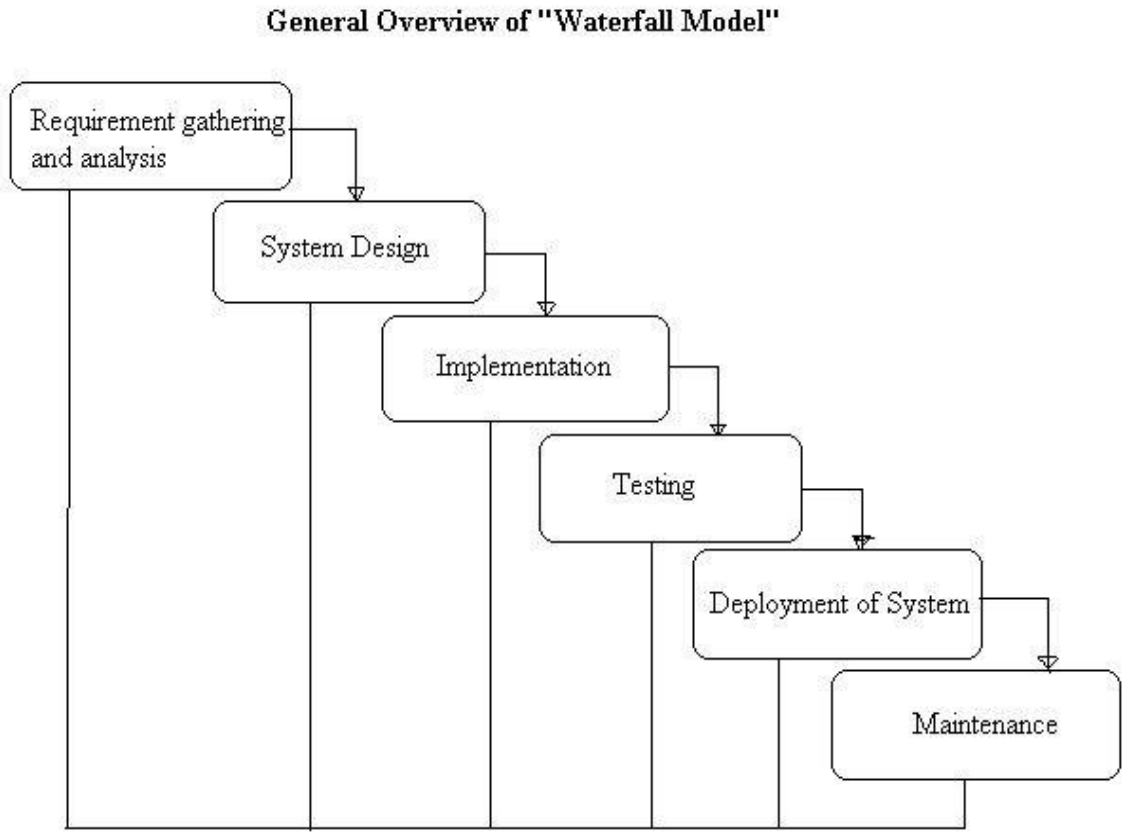


Fig 3.1: Waterfall model

WATERFALL MODEL PHASES

Requirement Analysis: Analysis gathers the requirements for the system. This is where detailed study of the user needs and specification will be carried out.
Design: This will focus much on high level design, i.e. kind of system is needed and how users will interact with it. It included interface design and data design.
Implementation: In this phase the designs will translated into code. Object oriented programming is preferred. The program will then be put into real world operations.
Testing: In this phase the system will get tested. Testing will be carried out in each units/modules. Then eventually, the separate modules will be consolidated to form a complete system. The system will be tested to ensure that interfaces between modules work (integration testing), the system works on the intended platform and with the expected volume of data (volume testing) and that the system will perform as expected by the end users (acceptance/beta testing).
System Deployment: This will be the final commissioning of the system. It will involve actual installation of the system on to user's machines and training of the users on how to use the system.
Maintenance: This either be based on need and additional user requirements or to mitigate bugs or any other changes that may be desired from time to time. Change could also happen because of some unexpected input values into the system

3.2. Data Collection Technique

Given the work setup of the organization, the most plausible fact gathering method that will be used in Oral interviews and Observation. The process will involve watching the work flow at the laboratory and discussing with the lab officers to understand their requirements.

3.2.1 Interviews

A set of specific questions were asked to the laboratory officers across the sampled facilities. This was focused on assessing the user requirements for an alternative system. See Appendices for sample questions asked during the interviews.

3.2.2 Observation

While still at the lab department, some of the time was taken to observe the lab attendants as they go about their normal work routines. This was very vital in getting the insight into the daily workflow at the department. The proposed system should conform to current workflow to ease implementation and changeover.

3.3 System Architecture

The proposed takes a very simple and straight forward design architecture that is easy to comprehend. It also provides clear technical description of various components that are core to the new system.

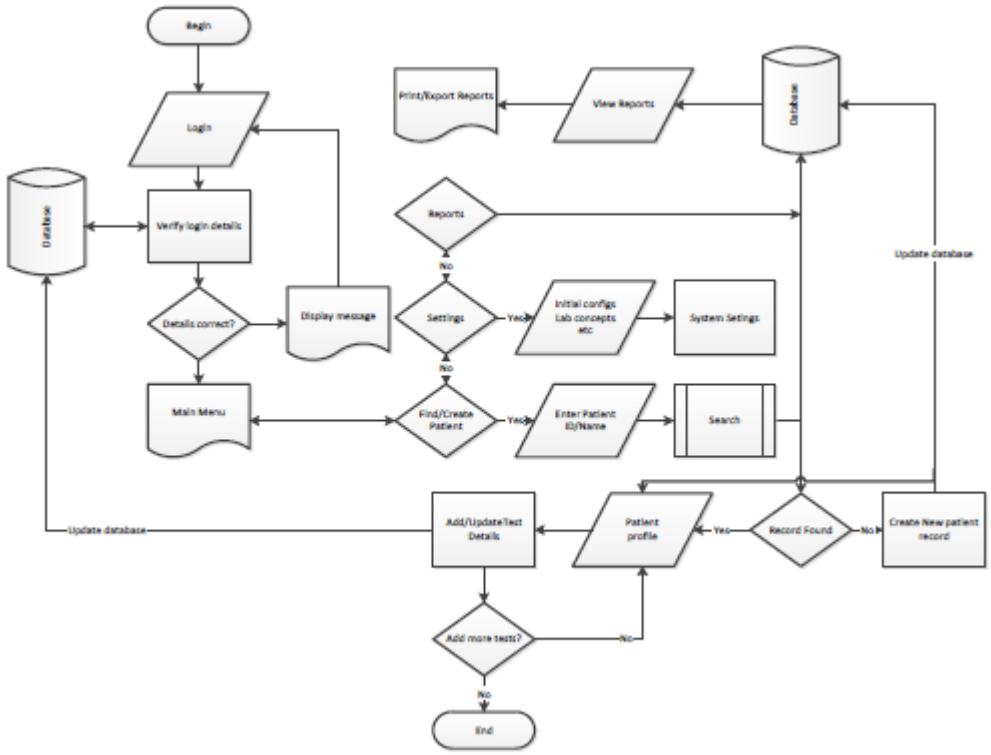


Fig. 3.3: Conceptual Model

IV. SYSTEM DOCUMENTATION

The following sections include useful information about using the Laboratory IMS.
Minimum Hardware and Software Requirements are as follows:

- Windows NT/XP/Vista/Win7/Win8 - 32/64 bit OS or higher version
- 512MB Memory or higher for best performance
- 40GB HDD Space
- CPU 2.10GHz or higher

The following is an easy to read user manual that will help any new employee to use this system to perform the following;

- Logging onto the system on startup,
- Working with various controls.
- Initial systems setups
- Configuring various tests and test groups
- Creating patient and updating existing patients,
- Recording tests and test result
- Deleting patients records*
- User configurations,
- Generating and printing reports.

4.1 System Installation
Before running the system, the user will need to have the system installed on his/her, machine. The installation process begins by running the executable file on the setup disk. The installation should be done by accepting all the default options whenever prompted. Installation is estimated to take less than five minute

4.2 Operating the System
Users will access the system by opening the system icon on the desktop or under the program files.
Once the program is completely loaded, the user will be prompted to log in.
Note: Only registered users will gain access to the system. The user must login by submitting Username and Password. The login credentials will be matched with the pre-recorded details and access shall only be granted where the information match.

4.2.1 Login
This is the first window that the user will be presented with. Login screen offers security feature and ensures that only authenticated users gain access into the system. There are two roles that may be assigned to a user. Admin users have all the privileges while Power user roles have some limitations. Users with administrative roles may choose to login or to add new users into the system. The following shows the user login screen.

Figure 4.2 System Login

After successful login, the system will open the main menu from where the user will be able to choose various functions.

4.2.2 Initial Configurations
For the very first run, the user will be presented with an initial system settings, which are set only once for each system instance. After a successful saving the presets, logoff is recommended to enable the new settings to take effect. The settings include:
- The name of the implementing facility.
- The Master Facility List (MFL) code for the facility
- Supporting organization (If any)
The following screenshot shows the presets screen with default details.

Fig. 4.3. System initial settings

4.2.3 Main Menu

After successful login and presets, the user is presented with specific menu items from where he will be able to perform specific operations. The menu comprise of seven option as shown in the figure below

Find/Create: Used for searching for existing (pre-recorded) patients or creating new patients details into the system

- **Settings**: Opens up a configuration windows where the user can set behavior of various components of the system. It is also used to set various laboratory tests, their test units and the specific ranges.
- **Report**: This takes the user to a simple reporting option screen from where the user pay specify the type of reports to display.
- **Log off:** Logs out the current user and takes the system to login mode.
- **Quit Application**: This exits the system to the desktop.
- **Shut down computer**: Can optionally be used by the user to shut down the computer right within the application environment.

4.2.4 Patient Dashboard

Patient dashboard provides a summarized view of the patient details alongside the chronology of all tests previously performed. It provides utilities for editing user basic information, adding new test or test results, editing current test, printing and exporting test results etc.

The following figure shows a **screenshot of the patient dashboard.**

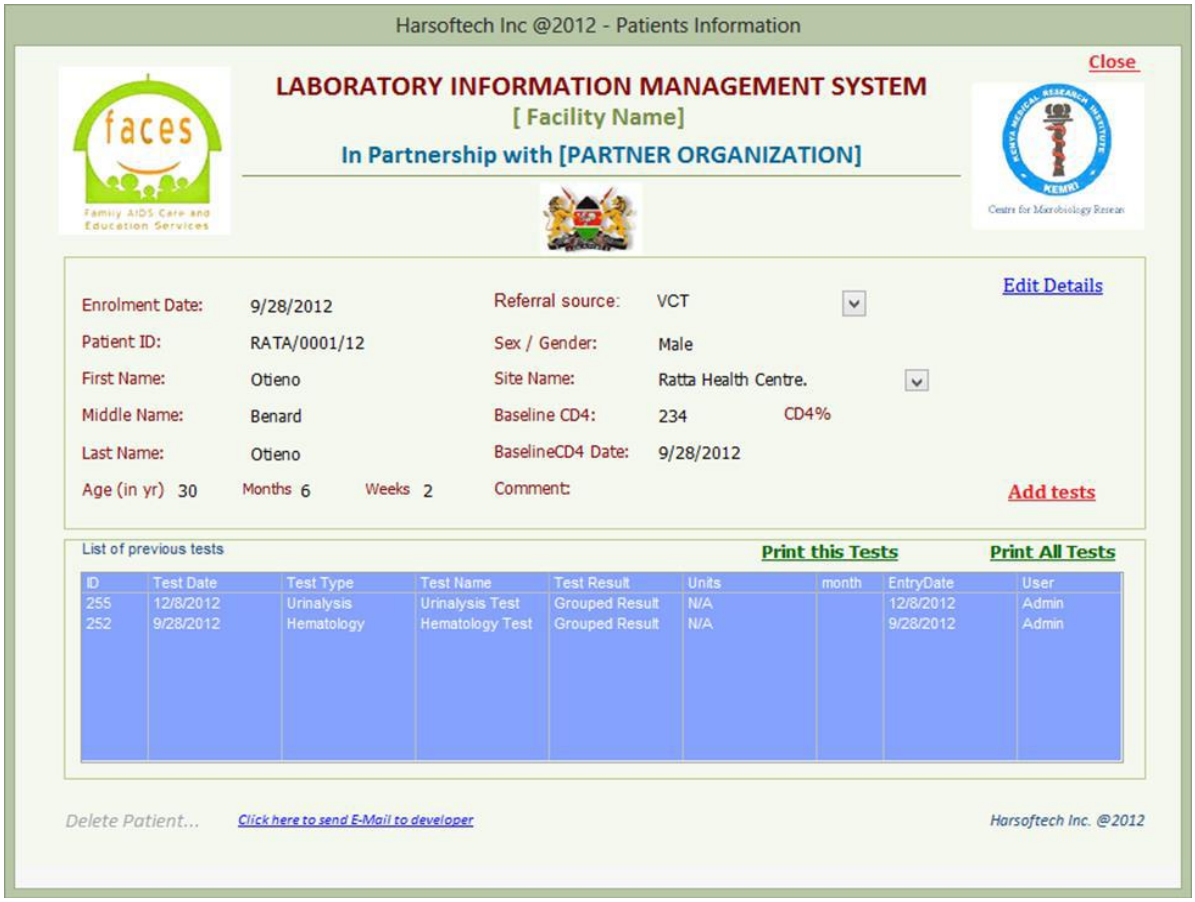


Fig 4.5 Patient Dashboard

4.2.4 Reports

The systems provides predefined report that have been customized to suit the general reporting needs of a typical laboratory department.

Among the predefined reports include the following:

i. Report by patient

These are reports based on patient information e.g.

- Patient referral source
- Patient records by facility

ii. Reports by Tests

This involves reports based on the test indicators. They include

- Patient current tests
- All tests
- Daily tests
- Monthly test
- User defined interval test

It is important to note that all the reports are exportable to excel for further manipulations.

The following shows a sample report generated from the system showing patients test history.

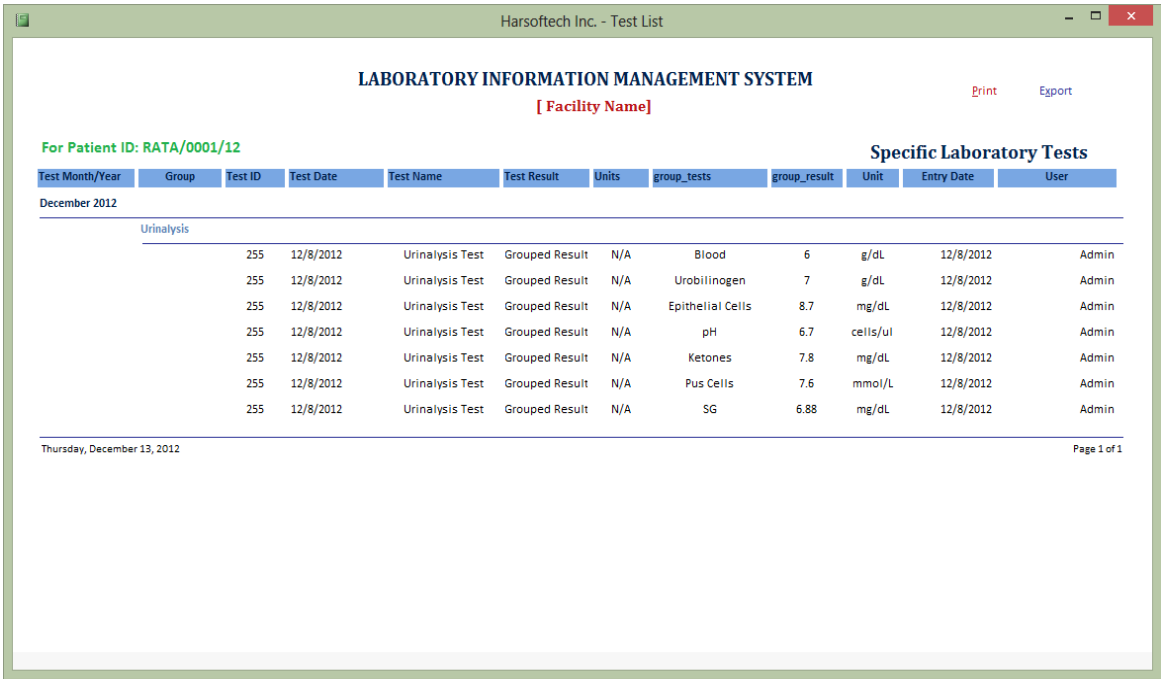


Fig 4.6 Sample Test report

V. CONCLUSION