DESIGN AND IMPLEMENTATION OF A BASIC LABORATORY INFORMATION SYSTEM FOR RESOURCE-LIMITED SETTINGS

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Ruban Monu

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DESIGN AND IMPLEMENTATION OF A BASIC LABORATORY INFORMATION SYSTEM FOR RESOURCE-LIMITED SETTINGS

Approved by:

Professor Santosh Vempala, Advisor School of Computer Science Georgia Institute of Technology

Mark DeZalia International Laboratory Branch Centers for Disease Control and Prevention

Professor Michael L. Best School of International Affairs and School of Interactive Computing *Georgia Institute of Technology*

Date Approved: 17 May 2010

To my parents, sister and Jesus Christ.

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SUMMARY

We describe the C4G Basic Laboratory Information System (BLIS), a joint initiative of Computing for Good (C4G) at Georgia Institute of Technology, the Centers for Disease Control and Prevention (CDC) and Ministries of Health in several countries in Africa. A majority of U.S. Presidents Emergency Plan for AIDS Relief (PEPFAR)-supported laboratories in Africa have been using paper logs and manual entries for tracking laboratory specimens and results. These methods make it difficult to efficiently manage and analyze data within the laboratory and, furthermore, for these data to inform decisions at higher levels. Moreover, a significant proportion of errors have been observed to be clerical in nature. BLIS aims at providing a robust, customizable, and easy-to-use system that tracks laboratory specimens, results, lab workflow and reports. It is meant to be an effective and sustainable enhancement to manual logs and paper-based approaches. The system is designed to work in low-resource laboratories with limited IT equipment and across sites with good, intermittent or no internet availability. With varied practices, workflow and terminology being utilized across laboratories in PEPFAR countries, the system has been developed to enable each laboratory or country to customize and configure the system in a way that suits them best. We describe various aspects of C4G BLIS including flexible database schema design, configurable reports, customizable registration forms, multi-lingual support, and system development model for rapid incorporation of user feedback.

CHAPTER I

INTRODUCTION

1.1 Introduction and Scope

Electronic laboratory information systems (LIS) have become key components of clinical and public health laboratory infrastructure in developed countries. In resourcelimited laboratories of the developing world, such systems are at the earliest stages of development and test samples and results related data are largely managed by non-standardized paper-based systems and manual entry methods. Due to this, the burden of record-keeping hampers laboratory staff from focusing on performing tests. Additionally, the time taken to report infection-related trends to concerned agencies is often high enough to severely restrict the effectiveness of any resulting public health response efforts.

Laboratories in many such regions are becoming obvious candidates for implementing information and communication technology (ICT) for better public health outcomes. Consequently, existing laboratory data management needs to be upgraded to a level that is sufficient to improve laboratory data quality, reduce the manual data entry work done by laboratory technicians, and aid in timely and routine reporting of disease trends. In such circumstances, an LIS that works well in resource-limited settings, reduces the dependence on paper-based systems and adapts well to varied workflow practices is a critical requirement. Factors such as customizability, ease of use and early and constant involvement of the target laboratory staff are also key to ensuring that any new system is sustainable and addresses the needs of the laboratory staff and technicians. A sustainable system also requires addition of certain features at the technical level like flexible database schema, scope for multiple identifiers and user-driven locale settings. These factors will be discussed in detail in Section 3.4.

In 2003, the United States Government launched the President's Emergency Plan for AIDS Relief (PEPFAR) [1], an inter-agency initiative to provide \$15 billion over five years to fund prevention, care and treatment services in countries that were hardest hit by the HIV/AIDS epidemic. In the first five years of the program, the focus was on establishing and scaling up prevention, care and treatment programs. A number of public health laboratories were established in order to provide services to the intended population across the highest-prone regions of the developing world. In 2008, PEPFAR was reauthorized with a budget of up to \$48 billion over five years to combat HIV/AIDS, tuberculosis, and malaria. The focus of PEPFAR shifted from rapid scale-up to the quality, reliability and sustainability of the country programs.

Initial scope of C4G BLIS has been on such PEPFAR-supported service-delivery laboratories and to address their data collection, storage, and analysis needs. These laboratories typically receive patients, collect specimens, perform tests and return the results back to the patients, generally on the same day. BLIS focuses on addressing two major areas of public health systems in developing regions that have a significant scope for improvement.

Firstly, there is a need to efficiently manage and maintain all data about patients, specimens and test results that is generated within the laboratory facility. Our emphasis is on reducing the margin of errors made during transcription in the laboratories and provide a single point of entry for all patient and specimen data. An effective LIS will also reduce the burden on the laboratory technician on having to log all the details, where it takes much of their time, instead of them working on the specimens gathered.

Secondly, accurate and reliable clinical laboratory test results are a critical component of a public health approach to disease management in resource-limited settings and C4G BLIS is intended to assist in efforts to improve the dissemination of aggregate laboratory data to public health officials to aid in laboratory resource allocation and disease response.

1.2 Related Work

There have been a few ICT projects for developing countries, aimed at improving public health care, in general, and laboratory information management specifically. These projects have had similar objectives of improving collection and maintenance of laboratory and patient data while being suitable for use at low-resource laboratories.

OpenELIS [3] [4] is an open-source LIS with a focus on HIV care and treatment. OpenMRS [5] is a community-developed, open-source, enterprise medical record system. SmartCare [24] is an electronic health record system. Bika LIMS [6] is a web-based tool that has been developed as an LIS solution. NetAcquire LIS [7], MEDITECH [8] and StarLIMS [9] are some of the commercial LIS systems that exist. Baobab Health [23] has developed a touchscreen-based open source patient management information system.

There have been some advanced LIS systems implemented at higher-level reference laboratories in PEPFAR countries. Unfortunately, no system is currently being used in the middle and lower-level service delivery laboratories.

1.3 Organization of the thesis

The rest of the thesis is organized as follows. Chapter 2 provides a background on the role and characteristics of hospital laboratories across Africa along with their organizational hierarchy. Given the low-resource settings in most of these laboratories, this chapter focuses on the challenges and benefits associated with the introduction of an electronic laboratory information system. Chapter 3 describes the feedback-based development process that has been followed for C4G BLIS and design principles arrived at based on the feedback. It is followed by a description of system functions and technical innovations incorporated to ensure the system is flexible and customizable by the end user. The chapter ends with a discussion on future scalability. Chapter 4 presents preliminary results based on initial surveys and end-user evaluation, along with qualitative observations. Chapter 5 concludes the thesis with an outline of how we see the C4G BLIS initiative moving forward and the critical role played by the CDC and implementing partners in working towards a sustainable solution for management of laboratory data.

CHAPTER II

BACKGROUND

This chapter gives a background of hospital laboratories in Africa, an organizational description of hierarchy and roles, along with the challenges and benefits associated with the introduction of electronic LIS systems in public health laboratories in Africa.

2.1 The Critical Role of Hospital Laboratories in Africa

During the first five years of PEPFAR program, the focus was on expanding access to HIV prevention, care and treatment in low-resource settings [1]. The key to implementing this was through setting up or upgrading hospital laboratories closest to the target population. During this phase, the program supported provision of treatment to more than 2 million people, care to more than 10 million people, including more than 4 million orphans and vulnerable children, and prevention of mother-to-child treatment services during nearly 16 million pregnancies [1]. However, efforts to bring treatment and care to the unreached populations need to continue as Africa is still home to 60% of the world's HIV/AIDS burden, 90% of its malaria cases and nearly a quarter of the world's tuberculosis sufferers, as of 2009 [14].

In resource-limited settings, the public health and health care needs are often met at the same point [2]. Often, these public health laboratories are single room or two-room setups with various lab sections like Chemistry, Hematology, Microbiology, etc. Lack of adequate number of personnel results in sharing of roles and responsibilities amongst all of the in-house staff. Effectively, all laboratory staff and technicians including the lab administrator, perform tasks ranging from specimen collection, patient registration at the reception area, laboratory testing itself, and results entry and verification. These service-level laboratories are instrumental in taking the fight against the spread of HIV/AIDS, malaria, tuberculosis and other such diseases to the people who are hardest hit by them. Going forward, additional and timely funding for global health work will only follow improvements in the current data collection inefficiencies, and accounting in the work that is being presently funded. A functional and sustainable LIS is a necessity in order to bring about these improvements.

2.1.1 Organizational Hierarchy and Flow of Healthcare Data

Around 2000 PEPFAR-supported laboratories exist across various countries in Africa. These public health laboratories can be classified [25] into-

- Peripheral/Service Delivery level These are point of care laboratories characterized by small-size of facility (typically one or two rooms), low-resource setting and limited number of lab personnel. They perform tests such as microscopy, and simple diagnostic methods using rapid kits. Quality control records are mostly kept in paper format.
- 2. Provincial/District level These laboratories perform some higher complexity testing, and receive specimens referred by peripheral level laboratories and/or from in-patients. Some of them have an LIS and are attached to medium-sized hospitals. They perform testing for both in-patients in adjoining wards and out-patients.
- 3. National/Central Referral level They perform definitive diagnostic test methods as well as screening, and test specimens referred by the other level laboratories. These laboratories often have an LIS and support quality control/assurance. Some of them also have the capability to receive and transmit laboratory data electronically.



Figure 1: Reporting and Procurement Flowchart (Ministry of Health, Uganda)

Figure 1 shows the flow of information between different agencies and laboratories that are part of the countrywide health care setup in Uganda. Precise reporting of infection trends and statistics is critical in identifying the need for additional equipment, drugs and reagents at the concerned health centers. In Uganda, HMIS 55b reports contain cumulative monthly information about infection rates and test counts done for HIV and other such tests. Due to the use of logbooks and registers, the time taken by lab technicians to prepare such reports sometime goes up to 4-5 days which is a significant delay especially in the event of an impending disease outbreak. This again highlights the importance of expediting report generation time, which can be attained through the use of an ICT solution.

2.2 Initiation of Laboratory Information Systems for Africa 2.2.1 Challenges

Despite a pressing need for an effective LIS for data collection and dissemination, a number of challenges remain in the deployment of an ICT solution to this problem in Africa –

- Power supply Absence of constant supply of electricity poses a huge deterrent to the introduction of any computer-based solution.
- Lack of requisite equipment Quite often, regular power cuts hamper the use of automatic testing equipment and technicians must revert to less sophisticated and less precise testing methods.
- Low internet penetration In areas where constant power supply is present, internet availability is rare. Lack of connectedness among various laboratories gives the impression that involving an ICT solution will most probably be unfeasible.
- Computer proficiency Laboratory staff often do not have prior experience using computers on a regular basis. In some of the user evaluations conducted for BLIS, participants had to be instructed on basic use of keyboard and mouse for interacting with the computer.
- Equipment maintenance Funding programs provide computers and/or automatic testing equipment to laboratories as aid. However, more often than not, the procurement of such items is highly non-standardized and maintenance policies are significantly overlooked. This results in equipment lying in the laboratories waiting for months to be repaired or upgraded.



Figure 2: Sample logbook I

- Local expertise Capacity-building programs for system engineering and similar skills are not present close to field locations, and if present, they are not always aware of projects being funded from outside the country. This poses a challenge to the sustainability of such projects.
- Ad-hoc use of log books Log book formats are often non-standardized and prone to erroneous data entry. Figures 2 and 3 show examples of the kind of logbooks used in these laboratories. In the event of column widths not being enough for entire test results data, technicians have to improvise by using adjoining columns and/or using registers as auxiliary logbooks. Figure 4 shows an example of such registers.

2.2.2 Benefits

Having mentioned the associated challenges, an effective LIS solution which can address these challenges has benefits that can greatly improve quality of lab data for making informed clinical decisions.

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Figure 3: Sample logbook II

- Reduction of record-keeping burden A software solution that maintains consistency and persistence of entered data can go a long way in reducing the burden of record keeping on laboratory staff.
- Fewer errors Clerical errors at the pre-analytic and post-analytic stage form the bulk of errors in laboratories as shown in figure 5. An electronic LIS that performs precise validation of reference ranges and allowable values at the point of data entry can reduce the number of such errors.
- Reduced waiting time and more reliable results for patients When bulk of data maintenance is done by the LIS, laboratory technicians can focus on their main task of performing and interpreting tests. This leads to lesser reduced times for patients and to more accurate test results.
- Ability to trace patient and specimen history The manner in which log books are ordered by date of entry, a simple lookup for a patient name or sample ID on log book can take minutes if the date of registration is not known. On the other hand, an electronic LIS enables fast and precise lookup/retrieval of



Figure 4: Additional register used for lack of space in logbooks

existing data records in the system.

- Ease of reporting Generating cumulative statistics is straightforward on an electronic LIS, whereas generating a simple count of tests done over a time period can take hours as logbook entries need to be read sequentially for manual counting.
- Ability to view aggregate trends Once data is consistently being maintained in a laboratory information system, it opens up possibilities to perform various kinds of analysis on the corpus of test results and to infer trends and patterns. This can in turn facilitate informed decision making allocation of laboratory commodities and resources.
- Country-wide integration We are at a stage where ICT solutions are being introduced throughout the developing world. At such an early stage, it is imperative to build systems that in the longer term, integrate with other countrywide systems that would eventually be used, for e.g. patient medical records system, national ID databases, etc. A LIS solution should ideally form an integral part



Figure 5: Stage-wise Proportion of Laboratory Errors



Figure 6: Public Health Data Architecture

of a countrywide Health Management Information System (HMIS). Figure 6 depicts the various components of public health data architecture [27] that our target countries may eventually develop. We see C4G BLIS as a candidate that effectively fills in the need for a sustainable laboratory system for routine test data that is generated in service-delivery labs.

CHAPTER III

DESIGN OF C4G BLIS

3.1 Overview

Any proposed ICT solution that aims at augmenting or substituting manual approaches needs to ensure that the solution caters exactly to the needs of the target users and requires low training time. Therefore, approaching the problem with an intensive feedback based design methodology is essential.

During the course of our preliminary surveys and user evaluations, it was observed that laboratory staff were able to quickly relate to and appreciate functions of the system that closely aligned with their existing modes of operation. For example, after the initial round of feedback collection, it was recognized that certain kinds of reports in the existing C4G BLIS prototype were neither relevant nor potentially useful for the laboratory staff. In a subsequent round of feedback collection, the need to have custom fields and localized terminology was recognized and incorporated. When evaluating the next version of the system, technicians knew exactly what they needed to enter in the registration forms with little or no instructions. Making the registration fields highly relevant helped to instill confidence in the system among the target users, as they were able to easily map the task of data entry in logbooks to data entry on BLIS.

3.1.1 Development Process

From the outset, the focus has been on starting with a minimal system, engaging end users, and developing and refining C4G BLIS based on interactive feedback. The phases of development followed so far can be classified as–

- Requirements gathering phase This involved reaching out to potential users in laboratories and gathering information by including a questionnaire and a survey. This phase proved to be useful in getting a sense of the laboratory environment, basic needs to be fulfilled by BLIS and the extent to which the existing paper-based methods could be augmented by the introduction of an electronic LIS.
- 2. Review phase This consisted of several iterations of user evaluation on selected review phase labs. User evaluations typically contained 4-6 tasks for the technicians to perform on the system. This phase helped us to improve and simplify the user interface along with obtaining list of further features to be added to BLIS.
- 3. Pilot phase This phase began with identifying pilot laboratories and performing focused user evaluations and system refinement for them. While shortlisting laboratories for pilot phase, factors such as facility size, number of personnel and site location were taken into account to ensure that BLIS is tested on a wide variety of laboratory environments. This would help in gauging the degree of customizability and system stability in response to variable workload and workflows.

Figure 7 describes the various stages of C4G BLIS development process beginning from the initial interactions with the CDC Global AIDS Program - International Laboratory Branch (ILB) to the pilot phase currently in progress. Figure 8 shows the various countries that participated in the initial requirements gathering and review phases. As the scope and requirements of the project became clearer, the role of CDC headquarters and CDC country offices in bringing the respective Ministries of Health, facility administrators, and laboratory managers on board was important to ensure early and constant access to the end users in participating laboratories. As the project



Figure 7: C4G BLIS development process timeline



Figure 8: Participant countries for requirements gathering and review phase

approached pilot phase, Global Health Systems Solutions (GHSS) and African Field Epidemiology Network (AFENET) were selected as our local implementing partners. Focused user evaluations and orientation for laboratory staff was conducted by them in order to prepare for deployment of BLIS in the pilot laboratories. During the pilot phase, GHSS and AFENET serve as local technical support in assisting the laboratories with installation of the system, working closely with CDC in-country staff, respective laboratory directors and communicating additional feedback to the C4G group.

3.2 Design Principles

This section elucidates the design principles behind C4G BLIS along with system architecture and functions.

3.2.1 Simplicity and Ease of Use

When designing a software system for users with little or no prior experience in using computers, it is essential to have simplicity at the core of the user interface design [26]. Also, some of the assumptions behind interface design for regular users have to be discarded. With this in mind, the following are some of the considerations made for ensuring simplicity of BLIS user interface–

- Selective disclosure of user interface Only the required parts of the screen should be displayed at any given point in time. This can be done by on demand loading of required page elements [11], for example, when the user selects a menu option.
- Simple color scheme Use of limited number of colors on the screen is ideal. If the user is overwhelmed or confused by too many colors vying for his attention, he is unlikely to develop an effective mental model of the interface [10]. This is especially pertinent to users having limited experience with IT tools.
- Relevant hints User should always have a quick reference to help information when needed. Short and precise hints about the relevant task can be presented to the user in the form of tips boxes on the screen without the need to navigate to another page.
- Progress awareness User should be aware that the system is working even though the screen does not change for a brief period. The screen should show small animated page elements called progress spinners that indicate that a new page is loading or form submission is in progress.

The above guidelines for simplicity help in keeping the tasks streamlined and enable the user to visualize the status of an ongoing process on the system.



Figure 9: Laboratory Workflow in Resource-limited Settings

3.2.2 Adaptability to Existing Workflow

Low-resource laboratories generally follow flexible workflow. The reasons behind this are often lack of adequate personnel, variability in number of patient visits, and shared use of lab space, equipment and/or reagents for multiple tests.

- Sequencing and grouping of specimen tests and data entry tasks varies based on daily workload. For instance, if number of patients on the given day is high, sample registration, tests and results entry is done in batches.
- In spite of the inherent inefficiencies of paper-based methods, flexibility in entering data can be relatively easy to attain while working with logbooks than on an electronic information system.
- There might be periods where power supply is not available in the laboratories. In such situations, it becomes important to ensure that the data in BLIS is eventually consistent with paper records being used in the absence of power supply.

Figure 9 shows typical workflow steps involved during routine testing in servicedelivery laboratories. While completely obliterating the need for paper forms and registers would be an ideal scenario for reducing the burden on lab technicians, it is not always possible in low-resource settings where constant power supply is not a safe assumption. Consequently, the trade-off entails an ideal system being one which aims at reducing the inefficiencies of paper-based approaches, and simultaneously allows for data availability in the absence of power supply through a printout of daily or periodic logs.

3.2.3 End-user Customizability

End-user customizability is essential for keeping the LIS relevant and usable in spite of the variability in the way different laboratories operate—

- It allows the users to customize the system behavior and requirements according to their needs.
- 2. It helps in providing a sense of ownership of the system to the participating laboratories.
- 3. It is useful in projects where the initial requirements are not exhaustive and specifications build with time. As subsequent requirements come up, some of those an be incorporated by customizing parts of the system that need to be enhanced to fulfill these new requirements.
- 4. An increased degree of customization reduces the time required to frequently engineer small modifications in software. This can make a great difference especially in situations where the source of technical or engineering expertise is not close to the actual field locations.

3.2.4 Collaborative Improvements

A top-down approach to software development does not necessarily work as it leaves scope for mismatch between target users' requirements and system's capabilities.



Figure 10: C4G BLIS Architecture

The probability of mismatch is magnified when applied to ICT projects where user requirements and specifications build with time and successive iterations of software development [22]. Hence, we believe that for BLIS, it is important to ensure early and constant involvement of the target laboratory staff and technicians, identifying their short- and long-term needs, and ensuring that the system can match these needs.

With this goal in mind, emphasis has been on obtaining constant user feedback for every iteration of changes and enhancements to the system. This is in line with Agile development model where requirements and solutions evolve through collaboration between self-organizing cross-functional teams and target users [12].

3.3 System Design

3.3.1 System Architecture

C4G BLIS follows the classic three-tier architecture[13] in which the presentation, the application processing, and the data management are logically separate processes as seen in Figure 10. The data management layer consists of MySQL. Application is hosted on Apache web server with PHP as the scripting language. User interface pages are generated in HTML and use JavaScript for client-side validation and layout management. Additionally, AJAX is used for on-demand fetching of page elements. All of these software technologies used are open-source and provide non-restrictive licensing. Considering the fact that a majority of the target laboratories do not have reliable internet connectivity, BLIS currently operates as a standalone application. Despite this, the choice for using web-based technology over a conventional desktop application was due to the following factors-

- Future migration to a well-connected system hosted on a remote web server would be easier due to already existing web-based architecture.
- Web-based standards are platform independent and majority of the source code does not require modifications to run on multiple operating systems.
- Desktop applications are tightly coupled with the underlying platform and hence would require multiple versions to ensure that the system works on different platforms.
- As web browsers develop further and become more advanced, they are increasingly gaining the ability to perform functions such as local caching of data which a typical desktop application would perform.
- Within larger laboratory facilities, a web-based system can be easily shared on a local area network (LAN) by using one computer as the host machine. Preliminary tests performed on BLIS have shown that the system can be deployed on an ad-hoc wireless network with minimal setup time.

3.3.2 Functions

We now present the various functionality-related aspects of C4G BLIS.

 Patient and Specimen Registration – This module allows for registration of patients and specimens. As a first step, the patient record can be selected from matching previous visits, or new patient information is entered if no previous visit is found. Next step is registration of one or more specimens for this patient. The system collects only minimal patient data for purposes of specimen identification and unlike Medical Record Systems, the focus is on specimens and test results.

- 2. Results Entry BLIS provides multiple modes of results entry. Results for a single specimen can be entered, or if working in batches, all specimen results in a given batch can be entered into the system. The lab technician can also cross verify existing test results or generate a worksheet of pending tests to be printed out and assigned to lab staff.
- 3. Search Existing patient and specimen records can be retrieved based in search parameters and identifiers defined by the lab administrators. This allows for instant lookup of patient profile, test history, specimen information, results, remarks and other relevant fields that have been configured into the system.
- 4. Reports Reporting features are grouped into two types daily reports, and aggregate reports. Daily reports allow technicians to generate patient report after tests have been performed and export them into a Word document or print it out before handing it back to the hospital representative or patient. Aggregate reports allow a cumulative view of recorded data and statistics to inform laboratory management decisions. Figures 11, 12 and 13 show screenshots of some aggregate reports generated by BLIS, based on random data records.
- 5. Lab Configuration Management This module manages all configuration settings for any given laboratory. The lab administrator is provided with the following customizable options–
 - (a) User accounts Adding, modifying or deleting technician accounts and passwords.



Figure 11: Example Turnaround Time Report

- (b) Registration fields configuration Due to variation in the name and type of identifiers and other fields used for tracking patients and specimens, BLIS allows the lab administrator to choose which fields to use in the registration forms. For instance, some facilities use Patient ID field for identifying a patient whereas some others use Daily Patient Numbers which are auto-increment sequences that get reset every day or week or month. Additionally, the administrator can create a new custom field which is not present in the list of default fields provided in the system. Choice of relevant date format is also provided. Section 3.4.1 describes the generation of custom fields in further detail.
- (c) Worksheet configuration In order to tailor the worksheets to the format being used at the facility, custom worksheets can be created by specifying which fields to include, addition of a user defined field, and column width for each of these fields. Additionally, header-text, title and footer-text can also be specified as shown in Figure 14.

Prevalence Rate | Hide Graph | « Back To Reports

Facility: Regional Hospital Lab* - Ghana | From:11-04-2010 | To: 11-05-2010



Figure 12: Example Prevalence Rate Report

- (d) Daily reports configuration With options similar to the ones in worksheet configuration, this feature enables generation of daily reports and logs in the required format.
- (e) Target turnaround time values Turnaround time (TAT) is defined as the duration between time of specimen registration and time the results are reported back. TAT can act as an indicator of overall performance of the laboratory and lab administrators can specify target or goal TAT values for different tests and gauge the degree of conformance to these goal values.
- (f) Infection report settings Aggregate reports showing cumulative statistics need to be sent periodically to the Ministry of Health or other relevant agencies. Lab administrators can specify age ranges, grouping by gender, reference value ranges for generating appropriate section wise counts. Figure 13 shows a preview of such a report.
- 6. Test Catalog This module allows for addition or modification of test and specimen types that are handled at the given facility. It manages metadata about all catalog entries, such as–
 - (a) Test Name

Print Export as Word Document Close This Page

Infection Report

Testlab1 - GT Reporting Period: 2009-10-06 to 2010-04-06

Facility Name:

Test performed	Lab Result	Sex	Age Group					Total	Total Tests
			0 - 10	10 - 20	20 - 50	50 - 100	M/F Total		
CD4	0-3000	M F	2 0	1 0	12 0	0 0	15 0	15	15
CD4%	0-90	M F	2 0	1 0	12 0	0 0	15 0	15	15
ALT/SGPT	0-1000 1001-2000	M F M F	5 0 0 0	6 0 0 0	11 0 0 0	0 0 0 0	22 0 0 0	22 0	22
URINE COLOUR	Straw Pale Yellow Deep Yellow Amber	M F M F M F M	1 0 2 0 1 0 1 0	1 0 0 0 0 0 1 0	4 0 3 0 3 0 2 0	0 0 0 0 0 0 0 0	6 0 5 0 4 0 4 0	6 5 4 4	19
URINE TURBIDITY	Clear Cloudy	M F M F	1 0 4 0	1 0 1 0	5 0 7 0	0 0 0 0	7 0 12 0	7 12	19
	P	M	3	1	6	0	10	10	S7

Figure 13: Example Infection Report

- (b) Compatible specimen types
- (c) Type of allowable result values (alphanumeric options, numeric ranges, etc.)
- (d) Reference ranges for all test indicators
- 7. Language and Terminology modification Some of the participating countries are situated in areas where English is not prevalent. For example, some of the laboratories in Cameroon have French as the dominant language. This resulted in the need to include multi-lingual support in BLIS. The system accomplishes this by utilizing local expertise in performing translation. Figure 15 shows screenshot of the language translation page where the user is prompted to enter corresponding terms in French for the BLIS. Section 3.4.2 describes the way

Add Custom Worksheet | Cancel

Name	CHEM worksheet	
Header	Bamenda Regional Lab - Cameroon	
Title	Chemistry Worksheet	
Footer	-End-	
Margins (%)	Top 2 Bottom 2 Left 2 Right 2	
Patient ID	C Yes • No	
Patient Number	⊙ Yes O No	
Additional ID	C Yes 🖲 No	
Custom Fields	Name Column Width Technician Comments 10 Add Another»	
Lab Section	Chemistry	
Alkaline Phos	nhatase	
Measures	Column Width (%)	
ALKP	10	
ALT/SGPT		
Measures	Column Width (%)	
ALT/SGPT	10	38

Figure 14: Custom worksheet creation form for lab administrators

language translation in BLIS operates, in further detail.

3.4 Flexibility

This section describes the various technical innovations incorporated in C4G BLIS to ensure flexibility of the system and allow end-user customization.

3.4.1 Flexible Schema Design for Custom Fields

Variation between different countries and sometimes even within a single country, with respect to the usage of patient and specimen identifiers, field names and data types, entailed the need for keeping BLIS database schema flexible. To achieve this purpose, BLIS utilizes Entity-Attribute-Value (EAV) [17] model to enable addition

Modify Language	
Target Language Francais 💽 Categor	ry General Terms
Default	Francais
Tips	Conseils
Username	Username
Password	Password
Temp Password	Temp Password
Reset Password	Reset Password
Name	Name
Phone No.	Phone No.
Email	Email
Login	Login
Search	Search
Submit	Submit
Submitting	Submitting

Figure 15: User-driven Language Translation

of new fields for patient and specimen records. EAV model has previously found some use in biomedical databases and medical record systems [15] [16], primarily for efficient storage of data fields which are sparse in nature.

Figure 16 shows a sample layout for employing EAV model in the schema design. Client table consists of fields ClientID, FirstName, LastName which are default fields. DataTypes table stores metadata about various allowable types of custom fields. Attributes table contains a list of all custom fields that have been created, with DataType field linking to the corresponding metadata entry in DataTypes table. Each custom field value that is assigned to a client is now analogous to a mapping between Client table and Attributes table. Each such mapping along with actual value for the field is stored in ClientAttribute table.

3.4.2 Multi-lingual Support

The variation in terminology used and the need to provide a French version to some participating laboratories in Cameroon led to the inclusion of multi-lingual support



Figure 16: EAV Model for Flexible Schema Design

in BLIS. In general, there are two possible approaches to making a web-based system multi-lingual–

- Code Replication Same source code gets replicated to multiple versions where each version differs only in terms of the actual text it prints in the generated HTML pages.
- Key-Value Mappings A single copy of the source code is maintained with library calls to fetch and plug in appropriate text string, based on the language currently in use.

Approach 1 has the disadvantage of having to maintain multiple copies of source code which are functional clones of each other. However, it is generally faster as additional time for resolving mappings is not required. On the other hand, Approach 2 negates the need for multiple source code copies but requires additional time for resolving mappings. We have opted for Approach 2 in the preliminary versions of BLIS and describe the design and performance results of the same.

Each time any text is generated by the server-side script (PHP in the case of BLIS), the actual text string is replaced by a mapping call. For example, instead of

writing-

<h1>Search</h1>

we now write-

```
<h1><?php echo LangUtil::$mapping[$EARCH]; ?></h1>
```

XML representation is used for persistent storage of language mappings.

For example-

```
<?xml version="1.0"?>
```

```
<termlist lang="en" descr="English">
```

<term>

<key>SEARCH</key>

<value>Search</value>

</term>

<term>

<key>SUBMIT</key>

<value>Submit</value>

</term>

```
</termlist>
```

The corresponding XML file for French would be -

```
<?xml version="1.0"?>
```

<termlist lang="fr" descr="French">

<term>

<key>SEARCH</key>

<value>Chercher</value>

</term>

<term>

<key>SUBMIT</key>

<value>Soumettre</value>

</term>

</termlist>

In our initial tests, mappings being retrieved repeatedly from XML data resulted in visibly slower page load times. Hence, this feature was modified to generate corresponding language representation in the form of PHP associative arrays [18] every time the language strings are updated. This reduces the mapping resolution time as values are now present in program variables instead of an external XML file. The corresponding PHP representation of the above XML file would be –

```
$mapping = array {
```

```
"SEARCH" => "Chercher",
"SUBMIT" => "Soumettre"
```

```
}
```

Table 1 shows the degree of increase in page generation times observed after the introduction of language translation in BLIS. These were average values recorded on localhost with 250 http pings per page (each time pairwise on translation and non-translation version). It is inferred that the recorded increase in page generation time is tolerable as it did not result in any visible delays at the user end during the test runs. Page load times on the web browser are independent of the use of translation as the mapping process takes place only at the server side. However, this does present a case to further evaluate system performance if BLIS eventually runs as a connected system hosted remotely.

3.4.3 Packaging for Offline Use

Deploying a web-based system for offline use requires the web server to be installed on the local machine along with the appropriate server-side scripts. However, to reduce the system deployment and setup time, BLIS required a stable solution that would work with minimal or no installation steps needed on the laboratory computer. The

Page	Average Increase (secs)	Average % Increase
Homepage	0.0031	4.9
Patient Lookup	0.0013	1.64
Patient Registration	0.0022	4.0
Specimen Registration	0.0051	7.2
Results Entry	0.0033	6.77
Results Verification	0.0040	2.63
Search	0.0037	5.9
Patient Profile	0.0040	6.79
Results Entry	0.0041	5.77
Reports	0.0010	1.56

 Table 1: Effect of language translation on HTML page generation time



Figure 17: Page generation times for succesive http requests

portable offline version of BLIS is built using the Server2Go Framework [19] which enables packaging of Apache web server, PHP runtime, and MySQL database engine into a single entity requiring no installation. This enables use of the system in a portable manner on local hard disk or flash drives.

3.4.4 Data Merging

With multiple local instances of C4G BLIS running in a group of laboratories, merging and synchronization of data is essential to obtain a notion of connected between laboratories as well as keeping a backup replica of data from nearby laboratories in the regional or central offices. Figure 18 shows a basic scheme for data merging to



Figure 18: Data Merging Scheme

be considered for use with BLIS. Patient data gets entered at laboratories and is sent for periodic backups to a central or regional office. Data can be modified at the regional office as well. Hence, the merging scheme needs to account for two way synchronization of records.

Timestamp based approach might not necessarily work due to differences between the actual system clocks being used at the sites. Hence, a parameter like Edit Number which is an indicator of the age of a record needs to be considered. Last Sync Age has to be tracked denoting the last time a merging operation was performed. For each synchronization operation, Sync log would contain all records that were added, deleted or modified after Last Sync Age. Merging of records where at most one copy was updated after Last Sync Age is straightforward. However, instances when both the copies were updated require input from the user for determining which copy has a higher priority. All merging decisions made at the regional office need to be reflected back at the laboratories by the use of a Resync Log.

3.5 Scalability

With the ongoing pilot phase, the focus is primarily on ensuring that a stable version of C4G BLIS is obtained at the end of the one-month intensive testing period. The purpose is also to gauge the scalability of the system as the size of collected data builds up along with usage. The following are some of the parameters against which future scalability needs to be measured–

- Number of records As the number of records increase, insertion and retrieval time for records gets affected. Use of appropriate indexing on the database table fields can help in reducing the degradation of data retrieval time.
- 2. Number of users BLIS presently runs as a standalone instance within the laboratory. However, connected deployments would be required for the larger facilities which house two or more separate sections or rooms. Under such an environment, multiple users will be accessing the system simultaneously and it is important to ensure that the response times are not adversely affected.
- 3. Concurrent accesses A networked implementation would also entail concurrent read or write access to the same portion of database tables. To ensure consistency the resulting data, database locking and transaction control play an important role.
- 4. Network maintenance In the event of BLIS being run on a Local Area Network (LAN), additional local expertise would be required to perform maintenance and service in case of failures. Also, network setup effort and time needs to be reduced as much as possible.

In addition to these technical aspects, supplementary use of paper-based methods would be required as long as constant power supply is not guaranteed to the servicedelivery laboratories. Under such circumstances, providing data availability as well as maintaining close coherence between BLIS and paper forms used at the facility is essential to ensure laboratory data quality is not adversely affected. BLIS allows for printing of section-wise or test-wise pending test worksheets for laboratory staff, which are closely aligned with the fields and format of the corresponding results entry form on the system. BLIS also enables printing out daily or periodic logs containing all records entered on the given day or during the period. This can serve as a backup for retrieving data in the absence of power. Additionally, lab configuration settings like test catalog, list of user accounts, list of registration fields in use, reports customization etc. can be exported and printed out for quick reference. While use of paper forms and logs is out of a necessity to contend with power supply issues, appropriate practices can be put in place to ensure that the resulting overhead is as low as possible.

CHAPTER IV

PRELIMINARY EVALUATION

This chapter presents preliminary data collected using initial surveys and questionnaires, user evaluation activities and some qualitative observations.

4.1 Survey and Qualitative Observations

When starting out with the requirements gathering phase, surveys with a small set of questions were used to gather relevant information about the laboratories and gain a perspective of the kind of environment BLIS would be required to work in. Table 2 lists the initial survey questions used during requirements gathering phase. Changes and additions to the system design were made based on those survey responses. During the review phase, participating laboratories were asked to complete a follow-up survey on phone or via email. As shown in table 3, this survey consisted for further questions and information which was not available after the end of the first survey exercise.

The following observations were made based on these survey responses-

- Majority of the 22 participating laboratories did not have internet connectivity. Among laboratories which had internet, only two described their internet connectivity as constant. Others stated that internet goes down for roughly 3-4 days a week.
- A few of the laboratories did not have computers at their facility. Among those that had computers, the lab administrator would use it to generate reports for printing.
- A policy of non-disclosure of private patient information was in place, especially

Sr. No.	Survey Question
1.	What tests are handled in your laboratory?
2.	What samples are handled in your laboratory?
3.	What specific machines are used in your laboratory? Please list
	details about the machine and tests for which they are used.
4.	How is the output of the machine recorded? What format? Please
	send sample outputs for each machine and test.
5.	How would you describe the internet connectivity in your labora-
	tory – Constant, Intermittent, or No internet?
6.	Does your laboratory currently have computers? If yes, how many,
	what type (desktop, laptop, etc) and what are they primarily being
	used for?
7.	What are the monthly averages for the number of patients and
	number of test samples handled by the laboratory?
8.	How are test results and reports sent back to the originator (doc-
	tors, patients, health centers)?
9.	Are test results or summary results reported to regional or national
	headquarters? If so, please elaborate.
10.	Any other feedback on the current version of C4G BLIS?

 Table 2: Survey questions used for initial requirements gathering

for tests for HIV/AIDS. However, within the laboratory premises, all technicians had implicit access to patient information like name, age, gender as those were entered in logbooks along with result indicators.

- The terminology used at the various facilities differed, sometimes even within the same country. For example, some facilities used "Lab No." for sequencing of patients and specimens while others used terms like "Patient Number" or "Patient ID".
- Depending on the facility, these number sequences were reset at the end of each day or week or month. This led to the need of providing configuration identifiers to patients and specimens, different from the database primary key used internally by the system.
- Test nomenclature varied from country to country. Moreover, even result values and reference ranges differed depending on the facility or region. For example,

Table 3:	Survey	questions	used	during	review	phase	
----------	--------	-----------	------	--------	--------	-------	--

Sr. No.	Survey Question
1.	What is the lab/country policy on patient data privacy and which
	of the lab personnel have access to private information?
2.	What information about the patient and test results is reported
	back?
3.	What are various means (postal mail, email, phone, etc.) by which
	results are reported back to patient/hospital?
4.	Please list all of the statistical and printable report types generated
	on a regular basis at your lab facility.
5.	What are the major data fields that are recorded for patients, sam-
	ples, test results?
6.	Please list all machines/equipment used at your labs along with
	the tests they conduct. You can also send us sample output files
	by email if possible.
7.	How are pending samples assigned into different batches? What
	are the batch sizes for each and how are batch results obtained and
	recorded?
8.	What sort of worksheet is provided to a staff member who does the
	testing? Feel free to send us sample worksheets by email if possible.
9.	What are the access levels/categories for lab personnel at your fa-
	cility?
10.	Are test results verified by another technician before publishing
	them?
11.	If using portable version of BLIS, would you prefer running it from
	one designated computer in a lab, or from multiple computers?
12.	Please list any other missing features that you require in order to
	start using BLIS.
13.	Any other general comments on BLIS.

result for malaria smear test was entered either in discrete format like Negative or 1+ or 2+, or using the actual numeric value. These factors led to the inclusion of customizable test catalog for lab administrators to add or edit existing tests, allowable values, reference ranges and compatible specimens.

- Cross-verification of test results is often limited to certain critical tests or not performed at all due to the lack of adequate time and personnel.
- Batching of pending specimens depends on the workload on the particular day. It also depends on whether the test involves use of an automatic equipment that accepts specimens in batches for calculating indicators.
- Monthly averages for a typical testing facility ranged from between 1200 to 1500 patients.
- Although a physician orders for certain tests to be done on the patient, the results report is returned back to the visiting patient in a paper slip or an envelope.
- Patients are sometimes turned back or referred to another facility due to factors like shortage of reagents, power cuts or equipment awaiting maintenance.
- The Ministry of Health in respective countries formulate the template to be used for monthly reports of infection counts which are periodically sent from each service-delivery laboratory to the ministry. Additionally, some funding programs also require periodic reporting of infection trends.

4.2 User Evaluation Results

Heuristic evaluation [20] of the user interface was performed as a means of obtaining insights about usability problems and possible solutions. A list of tasks for the laboratory staff was used to obtain gauge the ease of use of the system [21]. The expected

Table 4: User evaluation - Lab technician tasks		
Sr. No.	Task	
1a.	Register a patient with the given name, age and gender.	
1b.	Assign a sample type and specified tests for this patient.	
2.	Enter test results for the patient registered in task 1.	
3.	Verify all ALT/SGPT tests, making corrections if any.	
4.	Generate individual specimen report for the specimen	
	registered in task 1.	
5.	Generate worksheet for pending Hematology tests.	

difficulty and actual difficulty levels for each of those tasks were recorded on on a Likert scale of 1-5 when appropriate, with 1=very easy, 2=easy, 3=neither easy nor difficult, 4=difficult and 5=very difficult. Additional user comments associated with each task were also noted. Progress of users while performing the task was observed in order to identify the difficult or confusing parts of the task.

Tables 4 and 5 list the evaluation tasks that were used in Cameroon and Uganda in preparation for the launch of the pilot phase. Table 6 lists the mean observed difficulty values from user evaluations performed in Cameroon and Uganda on eight laboratory technicians. Figures 19 and 20 show the mean difficulty values with corresponding standard deviation.

The observed difficulty values were consistently less than or equal to the anticipated difficulty. Testing for the hypothesis *observed difficulty is less than anticipated difficulty*, yeilded the following results–

p-value < 0.01, for N = 40

It was observed that overall the difficulty ratings where higher in the labs in Uganda. Specifically, variation was noted in the way technician tasks number 4 and 5 were approached by staff in Cameroon vis-a-vis Uganda. The task of creating pending test worksheets (task 5) was not immediately clear to the technicians in Uganda as use of worksheets is not a common practice in those laboratories. On the other hand, technicians in Cameroon were able to instantly identify with the worksheet related task. Similarly, the task of generating specimen report (task 4) required some time

Sr. No.	Task		
1	View the current configuration of your lab and update		
	as indicated below.		
1a.	Add specimen type "Whole Blood EDTA" to the con-		
	figuration.		
1b.	Add test type "Complete Blood Count" to the configu-		
	ration.		
	Ensure that your lab configuration is updated.		
2.	View the turnaround time for the period between Jan-		
	uary 1, 2009 and December 31, 2009.		
3.	View the specimen count report for the period between		
	January 1, 2009 and December 31, 2009.		
4.	Add new technician user account with username		
	'new_tech' and password 'tech123'.		
5.	Add a new specimen custom field named "Hospita"		
	Type" with allowed option values "National" and "Re-		
	gional".		

 Table 5:
 User evaluation - Lab administrator tasks

 Table 6:
 User evaluation - Observed mean difficulty values

Task	Cameroon	Uganda
1	1.6	3.0
2	1.6	2.33
3	2.0	3.0
4	2.0	4.0
5	1.8	3.66

to be comprehended by technicians in Uganda. Participating laboratories in Uganda follow the practice of returning the results back to patients by writing them down in the same registration slip that the patient turns in at the reception stage, instead of filling out a separate form meant for patient report.

As the BLIS project moves forward, we plan to perform further qualitative and quantitative usability studies based on existing Human Computer Interaction (HCI) methodologies [20] like co-operative evaluation and post-task walkthroughs. Measurement of HCI parameters like accuracy, recall, emotional response and user frustration rates would be useful in further determining the quality of end-user experience and general usability of the system.



Figure 19: Lab technician evaluation tasks from Cameroon



Figure 20: Lab technician evaluation tasks from Uganda

CHAPTER V

CONCLUSIONS AND FUTURE WORK

C4G BLIS in its current version enables the laboratories to initiate and evaluate the adoption of an ICT solution to aid in better management of clinical data and timely dissemination of aggregate trends. A one-month pilot phase has been launched in Cameroon with similar efforts going on in Ghana, Uganda, Tanzania. Throughout this pilot phase, emphasis is on working on feedback as it is received and sending out regular, incremental updates to the pilot laboratories. By the end of this one-month period of testing with realistic volume of clinical laboratory data, we hope to obtain a stable version of the system. This period is to be followed by a six-month test phase with quantitative measurements of benefits, usability and sustainability of C4G BLIS as an effective tool for laboratory information management. If favorable results are obtained at the end of this phase, the system can be gradually scaled up to other laboratories within the participating countries.

In addition to the focus on arriving at a stable system through intensive testing periods and refinement during the pilot phase, a number of open avenues exist for consideration as future work. Firstly, a robust method for synchronizing country-wide data in the absence of internet connectivity is an essential requirement as described earlier. With the initial focus on getting C4G BLIS to run efficiently within laboratories, one of the next goals is to have a connected system that does not assume a reliable internet backbone. Secondly, the ability to interface BLIS with lab equipment can further reduce manual transcription steps and bring about an extra level of automation to avoid transcription errors. Thirdly, the observation that a majority of target users in the low-resource laboratories have limited prior experience with computers, touch-screen data entry can be a possible way of negating the need for training with keyboard and mouse. Touch-screen interfaces would be more intuitive and can be an interesting possibility to consider as the BLIS further develops. Designing and building inexpensive low-power touchscreen computers like the ones being used in the Baobab project [23] in Malawi can further enhance user experience.

Moving forward, implementing partners like GHSS and AFENET play an important role in making the C4G BLIS initiative sustainable as they would be the ones in constant and close interaction with end users, providing technical assistance and gathering detailed feedback for continuous refinement. The CDC with its presence in PEPFAR-supported countries can act as a key enabler for bringing together various stakeholders in these countries and lay the groundwork for scaling up and expanding BLIS to other laboratories. CDC country offices play a crucial role as they can closely monitor the progress of this initiative in liaison with the respective Ministries of Health, our implementing partners on field and funding programs that could benefit from increased efficiency within the laboratories, and the timely reporting of infection-related statistics and trends.

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