Engineering an EMR System in the Developing World

Necessity is the Mother of Invention

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While Electronic Medical Record (EMR) systems continue to improve the efficacy of healthcare delivery in the West, they have yet to be widely deployed in the developing world, where more than 90% of the global disease burden exists. The benefits afforded by an EMR notwithstanding, there is some skepticism regarding the feasibility of operationalizing an EMR system in a low-resource setting. This dissertation challenges these preconceptions and advances the understanding of the problems faced when implementing EMR systems to support healthcare delivery in a developing-world setting.

Our methodology relies primarily on eight years of in-field experimentation and study. To facilitate a better understanding of the needs and challenges, we created a pilot system in a large government central hospital in Malawi, Africa. Learning from the pilot we developed and operationalized a point-of-care EMR system for managing the care and treatment of patients receiving antiretroviral therapy, which we put forth as a demonstration of feasibility in a developing-world setting.

The pilot identified many unique challenges of healthcare delivery in the developing world, and reinforced the need to engineer solutions from scratch rather than blindly transplant systems developed in and for the West. Three novel technologies were developed over the course of our study, the most significant of which is the touchscreen clinical workstation appliance. Each of the novel technologies and their contribution towards successful implementation are described in the context of both an engineering and a risk management framework. A small comparative study to address data quality concerns associated with a point-of-care approach concluded that there was no significant difference in the accuracy of data collected through the use of a prototype point-of-care system compared to that of data entered retrospectively from paper records. We conclude by noting that while feasibility has been demonstrated the greatest challenge to sustainability is the lack of financial resources to monitor and support EMR systems once in place.

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1.0 INTRODUCTION

1.1 BACKGROUND

Three decades of research have gone into the development of electronic medical record (EMR) systems. With few exceptions, however, these systems have been created for and deployed in healthcare settings in the developed world, essentially limiting the contribution of their many benefits to less than 10% of the world's population. We foresee that the benefits afforded by electronic medical record systems will inevitably be leveraged to improve healthcare delivery in developing countries. Given that the global burden of disease exists predominantly in the developing world, such benefits should have greater marginal utility in these resource-poor settings. However, cultural, geographical and socio-economic differences as well as differing presentations of morbidity seen between the developed and developing world have implications for the form an EMR system suitable for a developing country should take. It would be presumptuous to assume that systems created to address the needs of Western medical facilities could simply be transplanted into resource-poor settings. In this dissertation we built an argument for the necessity to engineer an EMR solution in response to a thorough understanding of the real-world context and demonstrate feasibility that such systems can be both operationalized and sustained in a developing-world setting.

1.2 RESEARCH QUESTION

The goal of this research is to investigate the feasibility of deploying a point-of-care electronic medical record (EMR) system in resource-poor settings. The development and deployment of an EMR system in a developing country was undertaken to facilitate a better understanding of the

needs and challenges of putting an EMR in to practice in such settings. We shall consider the EMR to have demonstrated feasibility if it can meet all of the following three conditions:

- Does the system do what it was intended to do?
- Has the system been extended to at least two additional sites beyond the pilot site (speaking to the generalizability of the solution)?
- Has the system run for at least two years beyond completion of the pilot?

1.3 IMPORTANCE OF THIS WORK

The greater burden of morbidity and mortality exists in the developing world, yet little emphasis has been placed on applying electronic medical records to improving healthcare delivery in such settings.

The medical community is becoming increasingly convinced that the use of EMR systems can contribute to increases in efficiency and effectiveness of healthcare delivery (1). Recognition of this fact notwithstanding, the rate with which EMR systems are being deployed is slow. Slow uptake results partially from a lack of understanding of how to "operationalize" EMR systems in the healthcare delivery setting. This lack of understanding is apparent by the high number of documented failures in deploying EMR systems (2). The problems associated with operationalizing EMR systems have and continue to be studied (3). A body of research that focuses on operationalizing systems in a Western setting however does not adequately address the challenges of deploying EMR systems in resource-poor settings where the challenges are arguably greater.

Lack of understanding of the problems and challenges surrounding the delivery of healthcare in resource poor settings inhibits the development of information systems to address these unique needs. Documenting these needs and providing real-life examples of systems that can and do function in these settings will provide a body of knowledge upon which others can design, implement and deploy systems more efficiently and effectively and with decreased risk of failure.

1.4 CONTRIBUTION TO KNOWLEDGE

This research will contribute to and extend the current level of knowledge surrounding the design, implementation and deployment of electronic medical record systems for developing-world settings in three areas:

- Differentiate the needs of electronic medical record systems between developed and developing countries, establishing a justification to engineer new systems to meet the unique needs of resource-poor settings rather than transplanting existing systems created with the needs of developed countries in mind
- Describe technologies and philosophical approaches developed over an eight year period spent designing, implementing and deploying systems in Malawi
- Describe findings from an analysis of data accuracy from a point-of-care system developed and deployed in Malawi in a HIV care and treatment setting.

1.5 GUIDE TO THE READER

In Chapter 2 we describe a first approximation of an EMR solution from the perspective of an "embedded" developer in the form of a case study.

In Chapter 3 we supplement findings from the case study with a more detailed description of the differences and challenges of delivering healthcare in a developing-world setting, we provide an overview of the evolution of electronic medical records in a the developed West, and conclude with a summary of the landscape of EMR projects of significance in the developing world.

In Chapter 4 we summarize development of the system following the pilot phase completed in 2001 and provide a detailed description of technologies developed up to 2009. We present two frameworks, borrowed from engineering and risk management, which we found useful in examining our system design decisions in the context of determinants of successful

implementation. We conclude this chapter with a brief description of seven projects that have built on aspects of this work as of 2009.

In Chapter 5 we address the issue of data quality. We describe a study comparing the accuracy of data entered by clinicians at the point-of-care with that of data entered retrospectively by nurses.

We conclude in Chapter 6 with a discussion of the findings drawn from eight years of system development and implementation in Malawi, our conclusions drawn from these findings together with key recommendations for improving outcomes for EMR deployment in developing-world settings, and a description of future work we propose to undertake.

In the next chapter we use a case study to describe the development of a pilot system developed in Malawi in 2000-2001. We present this case early in the dissertation as it provides a real-life context for what follows. The case study highlights several aspects of the unique challenges and characteristics of healthcare in the developing world.

2.0 ENGINEERING A DEVELOPING-WORLD EMR: A FIRST APPROXIMATION

This dissertation is somewhat unorthodox in many senses. It describes lessons learned and technologies developed over an eight year period. This chapter is a case study describing a pilot project I undertook over a period of nine months starting in August 2000. The pilot aimed to create a first approximation of an EMR system for the developing world, grounded in the realities of a real-life setting, and from the perspective of an "embedded" developer. However, the story actually began four years earlier.

2.1 BACKGROUND TO THE PROBLEM

In 1996 I had the privilege of volunteering with the Health Information Systems (HIS) branch of the Ministry of Health of Malawi. Malawi is a landlocked country in sub-Saharan Africa with a population of approximately 13 million people (Figure 2). The country was, and continues to be stricken with poverty and ill health. The World Health Organization (WHO) ranks Malawi 189 out of 191 countries studied in disability-adjusted life expectancy (DALE) and 185 out of 191 in overall health system performance. Infant mortality is among the highest in the world. The WHO data for 2004 shows that one out of every eight children dies before reaching 12 months of age and one in four dies before reaching five years of age. Roughly 14% of the population is HIV positive and the country is slow to respond with prevention measures. There are approximately 80,000 new cases of HIV every year and a similar number of HIV-related deaths. Malawi, like most developing countries, is hampered in its ability to provide healthcare by a severe shortage of medical staff, medications and diagnostic resources.

Figure 1: Geographical location of Malawi

During the first four months of my tenure with the HIS branch I assisted with the compilation and reporting of national health statistics that attempted to describe the patterns of morbidity and mortality for the nation. While undertaking this process I was struck by the gross lack of completeness of the data provided by health facilities as well as the high percentage of errors introduced into the data during transcription from paper into electronic form. Of the more than 750 health facilities registered in Malawi at that time less that 25% submitted health statistics to HIS on a regular basis.

The method for collecting morbidity and mortality data in Malawi relied on the completion of pre-printed forms by clinicians, nurses and clerks. Outpatient diagnoses are recorded on a monthly tally sheet. A tally sheet is essentially a table with one row for each day of the month and one column for each diagnosis being captured. Clinicians are supposed to place a check in the appropriate cell after seeing each patient in the outpatient clinic. Inpatient data is collected using three-part discharge forms. Nurses complete discharges forms at the time of discharge and give the original to the patient. Tally sheets and a carbon copy of all discharge forms are supposed to be submitted to HIS for data entry on a monthly basis.

After some research I determined there were a number of shortcomings with this system. Inadequate funds to pay for printing costs left some health facilities without data collection forms for weeks and sometimes months each year. This resulted in huge gaps in data. Health facilities frequently allowed their inventories of forms to be exhausted before re-ordering more. Re-ordering of forms, distribution of new forms and collection of completed forms were severely hampered by the country's poor communication infrastructure. Even when forms were available they frequently did not get completed. Clinicians argued that the high patient-to-physician ratio resulted in them being over-burdened with patient care, and consequently they had less time for paperwork that was not directly related to the management of the patient. When a genuine attempt was made to complete forms certain fields were frequently left blank. Completed forms often accumulated for months before being transported to HIS for data entry. Once the forms arrived at HIS there were further delays before entering data into the computer. These delays resulted from having too few data entry clerks to enter the data arriving from health facilities. Some forms were lost either at the health facility or at HIS before ever being entered.

Auditing demonstrated that data entry errors occurred frequently. Data entry was usually performed by clerks with little or no medical background or training in medical terminology. During data entry clerks were required to code free-text diagnoses (e.g. Malaria) into ICD9 codes (e.g. 084). The combination of a lack of controlled vocabulary, poor handwriting and little or no medical training on the part of the clerks resulted in a high percentage of errors. Inconsistencies in the data (e.g. John Phiri with a diagnosis of vaginal bleeding) were rarely resolved, or worse, were resolved "arbitrarily" (John became Jane or vaginal became rectal). On occasion when essential fields on a form had been left blank data was fabricated. The resulting data set, albeit incomplete and inaccurate, was used to generate reports that attempted to describe the state of morbidity and mortality of the population. Regrettably, these reports were only processed and distributed once a year. Furthermore, the reports were so summary in nature that they were of little or no value to individual health facilities. Huge backlogs in data entry resulted in reports being compiled months and sometimes years later making them of little value for planning purposes.

To better understand these problems I visited Kamuzu Central Hospital (KCH), one of the two large government central hospitals in Malawi at that time. KCH was only two miles away from the HIS headquarters. However, the HIS unit had not received data from KCH for

several years. KCH was opened in the late 1960's to serve as a referral hospital for Malawi's central and northern regions. Regrettably, due to the absence of a district hospital in the Lilongwe district and a lack of adequately resourced health centers in the immediate area, KCH was forced to take on the additional responsibility of providing primary care. The 700+ bed hospital was operating with less than 40% of its required complement of staff.

After meeting with the hospital administration I discovered that a small cadre of ward clerks was employed to maintain admission registers on the wards. Using a large generic register book, clerks maintained a double-spaced list of admissions detailing the patient's name, age, sex, and date of admission. On discharge the final diagnosis would be added along with the discharge date. Examination of several registers revealed a great deal of incomplete entries. Furthermore, a census revealed patients currently on the ward who were not in the register, some of who had been there for several days. The clerks explained that patients admitted outside regular working hours (8:00 am – 4:30 pm), or on weekends when the clerks were not there, were commonly not entered into the register. Patients who were discharged outside regular business hours, patients who absconded, and patients for whom the medical chart could not be found, rarely had the final diagnosis or date of discharge recorded in the admission register. In summary, the registers were grossly incomplete. An informal cross reference of diagnosis between the register and the patient's chart revealed numerous discrepancies, putting the accuracy of the data contained in the register into question.

Observations at the nursing station revealed why carbon copies of discharge forms were not being submitted to the HIS unit. Discharge forms were printed in books with two forms to a page. The three-part form comprised a white, yellow and pink sheet. The form was supposed to be completed using carbon paper with the white original going to the patient, the pink copy staying at the health facility and the yellow copy going to the HIS unit. However, nurses frequently experienced shortages in forms. Patients were accustomed to receiving a discharge form and complained to the nursing staff when the forms were not available. Nurses quickly realized that they could keep the patients happy and make the forms last three times as long if they treated the yellow and pink parts of the form as originals in addition to the white part. The lack of follow-up from the HIS unit perpetuated this problem.

A visit to the pediatric outpatient clinic shed light on the use of the tally sheets. The pediatric outpatient clinic sees 200+ children each day. The clinic is typically staffed with one

senior clinical officer, one junior clinical officer and one or two medical students depending on the time of year. Clinicians spend as little as three minutes with each child. Some clinicians reported that after a long day in the clinic they completed morbidity tally sheets from memory after seeing 80+ patients that day. Others reported not completing tally sheets at all, particularly the students. Very few tally sheets were actually completed at the time of seeing the patient.

After visiting several other departments in the hospital I came to the following conclusions:

- Ward clerks were incapable of collecting complete data without working weekends and potentially evening shifts.
- Ward clerks were incapable of capturing accurate information without training in medical terminology.
- Ward clerks in general lacked motivation, most likely due to a lack of supervision and a perceived lack of interest from anybody in the data they collected.
- Clinicians were over-burdened with patient care.
- Clinicians perceived documentation for "statistical" purposes as outside the scope of clinical work and therefore not part of their responsibilities.

I speculated that other health facilities shared the same problems. In light of these problems it seemed appropriate to place greater emphasis on improving the completeness and accuracy of data collected at health facilities before putting resources into aggregating and reporting data, which would only perpetuate a "garbage in – garbage out" scenario.

After presenting my findings to the hospital core management team I was approached by a pediatrician and invited to tour the pediatric wards. Pediatrics was the only department in the hospital with a functional medical records department. The adult wards essentially collected patient charts on discharge and stored them in a room in the basement of the hospital. Charts were stored in no particular order, which made retrieval almost impossible. Pediatrics on the other hand had a conveniently located medical records office with patient records dating back roughly 10 years. Files were organized by admission number and retrieval of files was not only possible, it was standard practice when patients could be identified on re-admission. The absence of any national patient identifier did make identifying returning patients challenging,

hence the importance of the patient maintaining their discharge form from a previous admission. Three senior pediatricians worked in the pediatric department (two Malawian and one German). They clearly understood the value of having morbidity and mortality data at the department level and asked if I could help them to establish a simple data entry system. I proposed using the same data entry software the national health information systems office was using (DBase IV application), and we resurrected an old computer on which the software could run. The two pediatric ward clerks were trained and data entry commenced. Clerks typically entered data during the afternoon hours when the load of processing patient discharges was minimal. After a few weeks, several months of historical data had been entered from the admission register and some basic morbidity and mortality reports were generated.

Unfortunately my tenure with the Ministry of Health finished before I had time to evaluate the data entry process or consider other solutions to the data collection problems I had seen throughout the hospital. I left Malawi in July 1997 with a strong believe that there was great potential for improving the collection of health-related data, but there were clearly many challenges, some of which were unique to this resource-poor setting. It would be three years before I returned to Malawi.

In mid 2000 after completing a Masters degree in information science with an area of concentration in medical informatics, I returned to Malawi to re-examine the problems I had identified three years earlier in the context of my newly acquired skills. A recent initiative to reform the collection of health data had replaced the generic admission registers found on the wards with new standardized registers. Inpatient data for national reporting purposes was now collected from the registers rather than from discharge forms. Clerks were still working regular 8-hours shifts five days a week. In addition to capturing basic admission data clerks were required to record the drugs given on discharge. Emphasis was placed not on reporting diagnoses but mapping diagnoses into indicators. The task of mapping diagnoses into one of approximately fifty indicators fell upon the ward clerks. Examination of the registers combined with a ward census revealed the same kinds of problems observed three years prior. The shift from ICD9 (a 1-to-1 relationship) to indicators (a many-to-1 relationship) further exacerbated the problem of clerk's unfamiliarity with medical terminology. Finally, clerks were required to manually aggregate the data onto a summary sheet for submission to HIS. This manual aggregation made the process prone to simple arithmetic errors not possible in the previous

system where the data was aggregated by computer. Evidence of these errors was found in the registers along with incorrect mapping of diagnoses into indicators.

In the outpatient setting registers similar to those used on the wards had replaced the tally sheets. Clinicians were expected to complete the registers, now with additional information over and above just the diagnosis. It was no surprise to see that clinicians had resisted this additional work. In the KCH pediatric outpatient department clerks had been assigned to complete the registers on behalf of the clinicians. In a setting such as this where two or more clinicians were seeing patients at once, patients were directed to a single clerk after seeing the clinician. Clinicians were supposed to write the patient's diagnosis and treatment in a small patient-kept booklet called a health passport. The health passport, similar in size to a travel passport, contains roughly 14 blank pages to be used by clinicians to document patient encounters. The passport serves as a patient-kept medical record. Passports were introduced in Malawi in 2000 at several mission hospitals and rolled out in government hospitals in 2001/2002. Printing costs for the first batch of passports were provided through donor support. Passports are sold to the public at a cost of roughly ten cents and the money goes back into a revolving fund to pay for the next round of printing. In the pediatric outpatient clinic at KCH the clerk was assigned to transcribe the visit details from the patient's health passport into the outpatient register. In reality many patients left the clinic without their information being captured. Furthermore, many patients were treated empirically with only signs and symptoms written in their passport. This confounded the clerk, who in many cases was doing word pattern matching. I observed many cases where fever was coded as yellow fever and cough coded as whooping cough. After a three-year initiative to overhaul the data collection process some problems were solved and others made worse in my opinion. Overall the situation was still very problematic.

Having re-familiarized myself with the problems I discussed my interest to work on a solution with one of the pediatricians whom I had worked with during my time Malawi in 1997. Now the hospital director, but still maintaining his clinical responsibilities in the pediatric department, he was open to suggestions. I made the following assertions to be taken into consideration while formulating possible solutions to the problems described above:

- Clinicians rather than clerks were the best people to capture clinical information based on their understanding of medical terminology

- Clinicians complete documentation as part of healthcare delivery (e.g. writing prescriptions, ordering diagnostic tests, complete admission sheets).
- Morbidity and mortality information is a subset of the information typically documented by clinicians as part of the healthcare delivery process
- Information recorded at the time it was observed (e.g. while seeing the patient, performing the x-ray, running the lab test) is likely to be more complete and accurate than data recorded retrospectively (hard to resolve missing or contradictory data after the patient has gone)
- Clinicians would not tolerate additional work
- Clinicians operated with limited information (past medical history, previous lab results, availability of specific drugs in the pharmacy).
- Transcribing information from paper to electronic form provides an opportunity to introduce errors
- Entering information directly into the computer at the point-of-care instead of transcribing from paper facilitates computerized data-validation resulting in fewer errors and provides a platform on which to build decision support

After further discussions with other clinicians at the hospital it became apparent that no matter how complete and accurate the data collected, it was of little value to clinicians' main mission of providing patient care. Absent of a significant increase in human resources, clinicians could not provide quality care to their patients without additional tools.

2.2 PROPOSED INTERVENTION

Western medicine has recognized the benefits of electronic information systems to improving the efficiency and effectiveness of healthcare delivery (4, 5). I hypothesized that an electronic information system designed to meet the needs of delivering healthcare in a resource-poor setting would provide clinicians' with tools that would augment their ability to efficiently and effectively deliver healthcare while collecting complete and accurate data as a transparent

byproduct of system use. I proposed the idea of a patient management information system (PMIS) that would be used by clinicians in real-time at the point-of-care. This would provide the infrastructure for realtime decision support; a system feature that could potentially be leveraged to compensate for many of the shortcomings of healthcare delivery in resource-poor settings. Recognizing that this was an ambitious undertaking even by Western standards I performed a literature review but found no reported examples of similar initiatives in the developing world at that time (2000).

In collaboration with the KCH hospital director and head of the pediatric department I developed a proposal for funding to conduct a pilot of the PMIS in the pediatric department. Pediatrics was chosen based on my earlier experiences with the department and their keen interest. The pediatric department delivers both inpatient and outpatient services. The outpatient clinic is located close to the main entrance of the hospital in a covered but unsecured area (Figure 2). Clinicians sit at concrete desks and patients wait on concrete benches to be seen. Portable equipment such as weighing scales are locked away in a storage room at night and only brought out when the clinic is in progress.

Figure 2: Pediatric outpatient clinic at 10am on a typical Monday

The clinic runs from approximately 8:00am to 4:30pm. Patients arriving outside these hours go directly to the ward for care. The inpatient wards are located at the back of the hospital. The wards are covered by three nursing stations and comprise 216 beds in total. As few as five nurses cover the pediatric wards during the day (as few as two in the evening). Three or four clinical officers and a senior doctor round on patients following the morning handover meeting. One clinical office is on call throughout the night. During the rainy season when malaria and diarrheal diseases spike as many as 60 admissions and six deaths occur each day. Many deaths occur in the early hours of the morning.

The proposal was submitted to the UK Department for International Development (DfID) in October 2000 and funding was approved in January 2001 in the amount of GBP 19,250 (~$27,500).

2.3 REQUIREMENTS ANALYSIS

Based on the limited human and financial resources available to conduct the pilot it was decided that the functionality of the PMIS would be limited to patient registration, admission/discharge/transfer (ADT) processing, and outpatient management. To replicate the current processes and workflows as closely as possible it would be necessary to study each in detail.

I perceived the primary threat to the successful implementation of the proposed electronic information system to be the lack of adoption by the target user group. In light of the many challenges healthcare workers face in their day-to-day duties, a system that was unintuitive and cumbersome to use would almost certainly fail to be adopted. This has held true in Western implementations and I saw no reason to believe this setting would be any different. It was agreed that the time taken to perform tasks using the PMIS should be no longer than the time taken to perform the task manually and significantly shorter wherever possible.

Due to the real-time nature of PMIS use at the point-of-care, high system accessibility was considered to be essential. The nature of healthcare delivery is such that multiple users need access to the PMIS from a variety of locations. During the outpatient clinic at KCH, up to three clinicians concurrently see patients while others are being registered. At the same time,

admissions, transfers and discharges are taking place on the paediatric wards at the opposite end of the hospital.

Given that patients could arrive and would need to be treated at any time during the day or night, the PMIS should be available for use 24 hours a day year-round. Like many developing countries, the power in Malawi is unreliable. Some form of power backup system would be required to keep the PMIS running during power failures.

2.3.1 Registration Module

From the early stages of the project it was evident that there was no systematic mechanism of assigning unique patient identifiers. The ability to re-identify patients on return visits to the hospital is essential if continuity of care is to be achieved. Maintaining continuity of care is critical when treating chronic illnesses such as HIV, diabetes and hypertension that require lifelong treatment. Electronic information systems designed to be used in Western settings typically rely on a patient's social security number or other identifiers to uniquely identify patients. Unfortunately Malawi has no form of national registration. If historical records were to be retrieved and continuity of care maintained it would be necessary to create a patient registration system that would be capable of issuing nationally unique identifiers to patients. Patient registration appeared to be a fundamentally essential core requirement upon which all subsequent clinical modules would build.

The pediatric department used the paper-based registers issued by the Health Management Information Unit to document patient visits. The notion of patient registration was an attribute of the visit rather than the patient. Separate registers were used for inpatient and outpatient visits. There was a significant amount of redundancy in the collection of patient demographic details, not only across visits but also within visits. If a patient presented in the outpatient clinic their complete demographic data would be captured regardless of how many previous visits they had at the same hospital. Furthermore, if they could not be managed as outpatients and were admitted for care, demographic information would be collected yet again on the ward. While the process was grossly redundant it did establish a basic set of demographic characteristics from which an electronic patient registration system could be based.

The basic requirements of the patient registration system would be: 1) to capture patient demographic information electronically such that it could be linked to clinical data collected for that patient, and 2) to issue a unique patient identifier that would facilitate the linking of clinical data across time, clinical departments and ultimately health facilities.

2.3.2 Admission/Discharge/Transfer Module

Workflow in capturing admission and discharge data centered around the existing inpatient paper-based registers. Clerks were accustomed to the task of capturing admission and discharge dates and corresponding discharge diagnoses, the issues of completeness, accuracy and timelines notwithstanding. The ADT module would be required to replace the paper-based register while maintaining the same set of data elements previously collected.

2.3.3 Outpatient Module

The outpatient department used a similar register to collect visit details. Unlike the inpatient setting, a diagnosis was frequently never determined and the patient had to be treated empirically. Consequently there were large gaps in diagnoses recorded. After discussion with three senior pediatricians experienced in tropical medicine we agreed that a limited amount of clinical data relating to the history of the present illness and the physical findings would be captured. A consensus was reached among the pediatricians that cough, fever, diarrhea, convulsions, abdominal distension, pallor, dyspnea and edema would be recorded in addition to a presumptive diagnosis. An additional requirement of the outpatient module was that visit summaries should be printed and inserted into the patient health passport. The expectation was that this would reduce the burden of documentation for the clinician and therefore save them some time.

2.4 ADDRESSING CONSTRAINTS& LIMITED RESOURCES

A number of constraints were identified that would impact the design of the PMIS and are discussed below.

If the findings of the pilot implementation indicated the PMIS was sustainable and added value we anticipated that the Ministry of Health might endorse a scale-up. There have been many successful systems developed that never extended beyond the pilot phase due to high system cost. We recognized that it be would necessary to demonstrate affordability as well as feasibility. Furthermore, funds for the pilot would need to be secured. Given the lack of track record of the developers and the relatively risky nature of the project it was anticipated that funds would be limited.

The supply of electrical power at the hospital was extremely unreliable, particularly during the rainy season from November to April. This also coincided with the time of greatest morbidity resulting from increased Malaria and diarrheal diseases. Some form of backup power would be essential to ensure system availability. The lack of reliable power would constrain the types of hardware that could be operated from backup power.

The lack of computer literacy among the target users posed a threat to PMIS adoption. Traditional mouse and keyboard interface has been a barrier to system adoption in many Western settings where computer literacy is generally high. It was anticipated that a traditional mouse and keyboard user interface would prove to be too cumbersome for users, particularly in light of the decision to use the PMIS in real-time.

The PMIS design and implementation would need to be done during the remaining six months of my one-year leave of absence from my PhD program. Additionally I would be required to do all the systems analysis, software development, hardware development, testing, system deployment, and user training myself. Consequently, the scope of the project would need to be narrowly focused and a relatively small intervention.

A pre-analysis of the processes and workflows suggested that they were not ad-hoc, but had developed and evolved over a period of time to meet the demands of providing healthcare in a resource-poor setting. It was felt that any changes to existing processes and workflows would not only be counter-productive, but would reduce the likelihood of adoption of the PMIS by the users.

The decision to install a system to be used in real-time would require that workstations be located at the point-of-care. This posed two challenges. The high accessibility of the system would potentially increase the access to confidential patient information to unauthorized as well as authorized users. Some form of user authentication would be essential. Additionally, with clinical care being provided in unsecured areas within the hospital the risk of theft posed a serious concern. Hardware would need to be secured wherever possible to minimize the risk of theft.

2.5 FUNCTIONAL SPECIFICATION

2.5.1 Patient Registration Module

The high levels of illiteracy and redundancy of names (multiple John Bandas and Sam Phiris) in Malawi make the use of first and last names impractical to use as patient identifiers. Additionally, many adults do not know their date of birth. It would be necessary to establish a set of patient attributes that could be used to identify patients as uniquely as possible before any patient data could be captured. The patient registration module would capture these patient details and assign a unique patient identifier to each patient. The basic set of demographic indicators collected in the paper-based registers comprised first name, last name, sex, day, month and year of birth. These were augmented with the area where the patient was currently living, and the patient's traditional authority (TA, the village their family originally came from) to increase the uniqueness of the patient's registration number. Once the patient registration data had been entered the PMIS would automatically generate a unique patient identifier. To facilitate patient retention of the number an adhesive label would be printed and affixed to the patient's health passport. The label would display all the information collected with the exception of the area where the patient was currently living (dynamic), the newly assigned patient ID, and a barcode representation of the patient ID number.

Operationally, patients would queue at an existing patient registration window in the outpatient waiting area. Clerks would sit inside the registration office and serve patients as they presented at the window. Many patients already had health passports with much of the

demographic information completed on the front cover by hand. In this case the clerk would transcribe the details into the PMIS, print the label and affix to the passport covering the handwritten details. When new health passports are issued (sold for ~10c from the same office) the details would be captured directly from the patient.

Patients presenting at the registration window could be classified as either having an ID or needing an ID. Once the registration went live virtually all patients would require IDs to be issued. This was likely to place an increased burden on the registration staff for a period of time until a significant portion of the population was registered. Consequently, it would be necessary to increase the number of clerks working in the registration office during this period to prevent the registration process from becoming a bottleneck.

2.5.2 Admission/Discharge/Transfer Module

The ADT system would be designed to replace the admission registers. Clinicians would admit patients and nurses would discharge patients using the ADT module. The Health Management Information Unit agreed to forego the requirement to complete the paper registers provided the PMIS could produce the necessary information. So as not to increase the workload of the nursing staff the PMIS would print a discharge summary in place of the discharge slips previously issued to patients upon discharge.

The admission process would entail the user scanning the patient's barcode or manually entering the patient's national ID number (the same number issued by the registration process). Once the patient had been identified in the PMIS the user would assign the patient to a particular ward within the pediatric department. The user would select the admitting ward using a graphical presentation of the ward floor plan (Appendix B, Figure 26). To discharge a patient the user identifies the patient in the ADT system either using the barcode or manually entering the patient's ID as before, or selects the patient from a list of admitted patients.

2.5.3 Outpatient Module

The PMIS would collect diagnoses, making the paper-based registers no longer necessary. Clinicians would use the outpatient module as they saw patients in the clinic. Clinicians would

identity the patient in the outpatient module either by scanning their barcode or by selecting them from an outpatient waiting list. Once the patient was identified a growth chart would be presented to the clinician showing all known patient weights plotted against patient's age. From here the clinician would continue by recording eight symptoms and/or physical findings and a presumptive diagnosis. So as not to increase the workload of the clinician a summary of the information captured for each visit would be printed out and included in the patient's health passport removing the necessity for the clinicians to document the encounter manually.

2.6 DESIGN SPECIFICATION

When an information-system based solution is identified as an appropriate approach systems analysts are faced with the dilemma of whether to buy or build the software. Using commercial off-the-shelf (COTS) software has many advantages. It is generally cheaper to buy software than to write it from scratch. Additionally, COTS software has more established long-term support and can be deployed relatively quickly. COTS software has been referred to as an 80/20 solution in that it gives 80% of the desired functionality at 20% of the cost. While this is a gross generalization it highlights the trade-offs between cost and functionality that must be considered when deciding whether to buy or build. As information systems attempt to address more esoteric problems the choice of COTS software becomes limited and the compromises one would be required to make increase.

With respect to the functional specification described above, there were no obvious choices for COTS software packages that could meet the needs at that time. Consequently, I decided that building a system from scratch was the better option. This had some additional benefits in that it would allow the system to be introduced incrementally, the design would involve users, which would increase the chances or user adoption, and in this case the cost would be lower as the programming time was being donated.

2.6.1 General Design/Implementation Decisions

To maximize the chances of user adoption it was decided that the PMIS must mimic existing processes and workflows so as to be as minimally invasive as possible. Furthermore, the PMIS should attempt to replicate the metaphor of the familiar paper documents and other forms traditionally used in healthcare delivery. Given the unfamiliarity of the target user group with computer technology and particularly their lack of skill in typing, two design decisions were made regarding the user interface that differentiated the solution from information system implementations traditionally seen in healthcare settings. The first decision related to screen design and the method of data entry. As computer displays and screen resolutions have increased in size system developers have had a tendency to increase the amount of information contained on a single screen. This often results in overly complex screens, which can be overwhelming and harder to navigate for the user.

A touchscreen-based graphical user interface would be used for human computer interaction. Button size and inter-button spacing would be optimized for ease of use with a finger rather than a mouse.

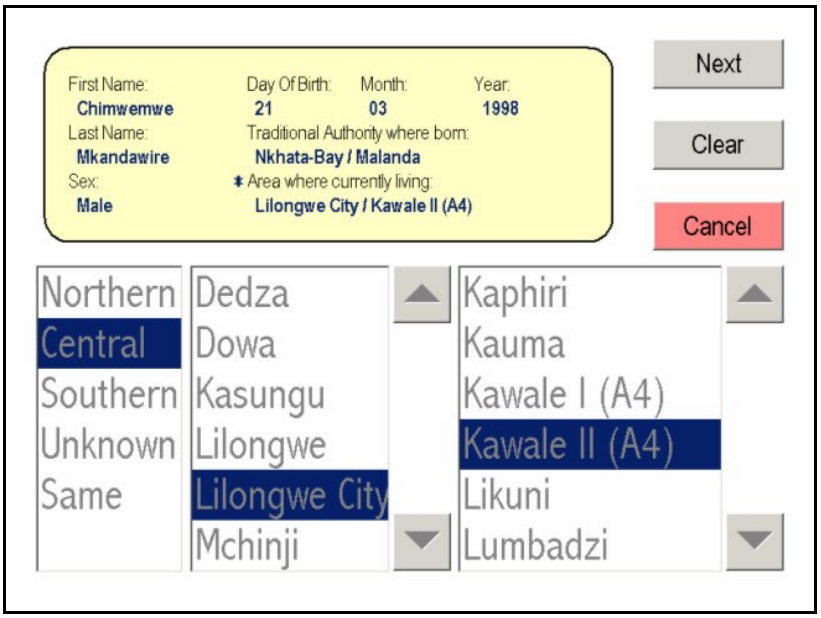


Figure 3: Sample screen shot representing a prototypical layout of controls

User interfaces should be designed to match the skills, experience and expectations of the anticipated users. The decision was made to use a "wizard-like" approach to capturing

information. Rather than having multiple data entry fields on a single screen, each screen would be dedicated to collecting a single piece of data.

Generally speaking screens would be designed with the upper portion of the screen displaying the set of data elements being captured for the particular task at hand and the lower portion of the screen providing data entry options for each data element. In the sample screen shown in Figure 3, the upper portion shows the information being collected to register a patient. In the lower portion a hierarchically organized list of geographical locations is shown allowing the user to complete the data field for the indicating the location where the patient currently resides. This motif would be used throughout the application for consistency.

The second design decision related to the method of human-computer interaction. It was decided that a touchscreen interface would provide the optimal solution in usability. While touchscreen technology had been around for more than 15 years, it has only been adopted in limited vertical applications. Touchscreens lend themselves to applications more focused on information retrieval than information gathering. Using a touchscreen in place of a keyboard greatly limits the capacity to enter free text. However, considering the focus on collecting categorical data the touchscreen seemed to be a perfect choice. A small amount of free text would be necessary, for example entering patient names. To accommodate for this a virtual keyboard would be displayed on the screen.

To meet the need for high system accessibility multiple workstations would need to be deployed. It was decided that three workstations would be deployed in the outpatient area, one at the patient registration area adjacent to the outpatient clinic, one in the pediatric medical records office and one at each of the three nursing stations on the pediatric wards, for a total of eight workstations.

To accommodate the necessity for mobility in the outpatient area wireless networking would be employed. A wireless access point was installed in the outpatient area.

To protect against power failures that would prevent workstations from functioning, a large (96 Amp Hour) deep-cycle battery would be connected to each workstation. The capacity of the battery would need to be sufficiently large to enable workstations to run continuously for more than 12 hours from a single charge. Both the main server and the network electronics would need to be backed-up with an uninterruptible power supply (UPS). This backup

arrangement was not required to run the PMIS for long periods of time, just sufficiently long for the hospital generator to come online.

A client-server architecture was chosen. A failure of the server would cause the entire system to fail. Consequently measures would need to be taken to maximize the reliability and availability of the server.

Theft of equipment was considered to be a serious threat to the success of the PMIS. To protect against theft, the server would need to be located in a highly secure room. The medical records office would also need to be secured. Given that workstations would be more accessible they would be at greater risk of theft. Increasing the security of workstations by locking them in rooms away from patients confounded the goal of having workstations used in realtime at the point-of-care. It was decided that no data would reside on the workstations to eliminate the risk of loss of data should a workstation be stolen.

While the PMIS emphasized the collection of categorical data over free text, patient names could not reasonably be picked from a list and would need to be entered using some form of keyboard. An onscreen keyboard would be developed for this. Given the high frequency of particularly common Malawian names, particularly surnames, a list box containing approximately 1,000 common names was displayed onscreen to allow for auto-completion purpose. Given the low levels of computer literacy among the target users there seemed to be little advantage to using the QWERTY format for the keyboard. Consequently an alphabetic layout was adopted.

The barcode 39 (3-of-9) format was chosen for use on the adhesive labels as it can represent both alphabetic and numeric characters and is able to be read by the vast majority of barcode scanners on the (used) market.

2.6.2 Hardware Selection

Having identified user adoption as a critical success factor the clinical workstation design was of great importance. Limited space available in the clinics and at the nursing stations made a small footprint device preferable to a conventional desktop computer. Given the decision to use a touchscreen interface the selection of available hardware was limited to devices produced for the point of sale (POS) market. However, these devices ranged in price from $1,000 to $1,800 and

were well above our budget. Moreover, at that cost the PMIS would not be affordable in broader use. An alternative was to develop a piece of low-cost custom hardware. A device called a Netpliance I-Opener was identified as a platform that may provide a suitable basis for a clinical workstation. The I-Openers was originally marketed as an Internet appliance by a company called Netpliance. The company sold the device inexpensively but charged for Internet access as a means of generating a stream of income. The device used a proprietary operating system and was incapable of connecting to a generic Internet service provider. The company folded in 2000 leaving a large quantity of product with little use.

A sample I-Opener was purchased and a prototype workstation constructed. The original I-Opener is based on a 266 MHz Intel Pentium platform with 32 MB of RAM and a 10.4" LCD display capable of a screen resolution of 800 x 600 pixels. It has a single USB port installed, parallel port, and no external serial ports. There are two internal serial ports with an internal 56Kbps modem connected to one of them. There is no conventional hard drive installed. Rather, a 16MB SanDisk flash memory chip located on the motherboard is seen by the computer as drive C. The motherboard has a connector for attaching an IDE device, however the pin configuration is reversed from the conventional IDE connector. It is unclear whether this was done intentionally to prevent people from adding an IDE drive, or if the connector was accidentally installed on the wrong side of the circuit board.

The modifications required to convert the I-Opener into a clinical workstation are as follows:

1. A MicroTouch Systems ClearTek 3000 capacitive touchscreen sensor is added over the 10.4 inch 800 x 600 pixel active matrix display
2. The internal modem is removed and a MicroTouch Systems USB touchscreen controller is added in its place (mounting holes matched coincidentally)
3. A SanDisk 256 MB Compact Flash (CF) memory card is used in place of a conventional hard disk to reduce current consumption and increase the robustness of the Workstation (a custom circuit board was designed for accommodate the CF card)

4. An additional USB socket is added in a vacant position on the motherboard (this was just a matter of installing a connector in existing holes and removing a blanking cover to make it accessible)
5. A D-Link DSB-650TX 10/100 MBPS USB Ethernet adapter is added

The finished product provides the functionality of a POS terminal at approximately one third of the cost (~$350).

The hardware chosen for the server incorporated two fault-tolerant features. The first feature is the presence of three hard drives in a Redundant Array of Inexpensive Drives (RAID) configuration. This allows for the server to continue running without any downtime or loss of data in the event of a catastrophic failure of any single drive. The second feature is the presence of two power supplies connected in a failsafe configuration such that if the first power supply fails, the second will take over before power to the system is interrupted. The server chosen was a Dell PowerEdge 2400 900MHz. computer with dual redundant power supplies and four 9GB hard disks configured as RAID level 5.

Two network switches would be required, one to serve the outpatient department and the second for the pediatric wards. Linksys EtherFast II 24-port 10/100 network switches were selected. These are unmanaged switches and at the time were readily available on the used market at very reasonable prices.

The underlying philosophy of the PMIS was not intended to replace paper but to enhance it. This was to be achieved by capturing data electronically and then printing it out rather than capturing it on paper. To accommodate printing in the outpatient setting small receipt printers were use. These printers use three-inch wide receipt paper and required a ribbon. A single laser printer was installed for printing reports. The printer was located in the pediatric medical records office from where the clerk could produce monthly morbidity and mortality reports from the PMIS.

2.6.3 Software Development

Software development started in October 2000. The limited capacity of the chosen hardware platform required an operating system with a small footprint. Linux was the preferred choice;

however, I did not possess the necessary skills at that time to perform the customization that was required to configure Linux for the platform. The alternative was to use an early version of Microsoft Windows. Windows 95 did not have the native support for USB devices. USB functionality was critical as the touchscreen controller used in version 1 of the clinical workstation used a USB interface. Windows 98 was chosen. A custom installation script for Windows 98 called 98-Lite was used to minimize the size of the install. 98-Lite, developed by Brooks Engineering, converts many of the standard Windows 98 features to optional features. When Windows 98 is installed without these optional features the operating system footprint is approximately 50 MB.

Consideration was given to the development of the PMIS in a cross-platform language. Java was an obvious choice, however I had no previous experience in Java programming and there was no obvious integrated development environment (IDE) or graphical user interface (GUI) builder. Microsoft Visual Basic (VB) version 6.0 was chosen for the development of the user interface and its rapid prototyping features.

One of the early challenges was the problem of the inadequate target size of list box scroll bars with respect to the size of the human finger; the pointing device of choice for this application. While button sizes could be easily adjusted to a size sufficiently large to be selected easily with the finger, native scrollbar arrows were not adjustable in size. Visual Basic has the capability of binding individual native controls together with a set of behaviors to form “custom controls”. These are really objects in an object oriented programming context. The first control to be built was a “touchscreen list box”. This control combined a visible list, a hidden list and two buttons to make a list box with scroll buttons sufficiently large to be operated by a human finger.

The power of Visual Basic to create these user controls was used extensively to build other controls such as location pick-lists, diagnosis pick-lists, touchscreen keyboards and keypads, date selectors, etc. This greatly improved code reusability and reduced programming time considerably once the controls were created. In total, more than 50 user controls were created over the course of the software development.

2.7 PMIS DEPLOYMENT

The deployment of the hardware started in March 2001. The PMIS went live on May 21, 2001 with the patient registration (Figure 4) and admission/discharge modules. An outpatient module was deployed the following month.

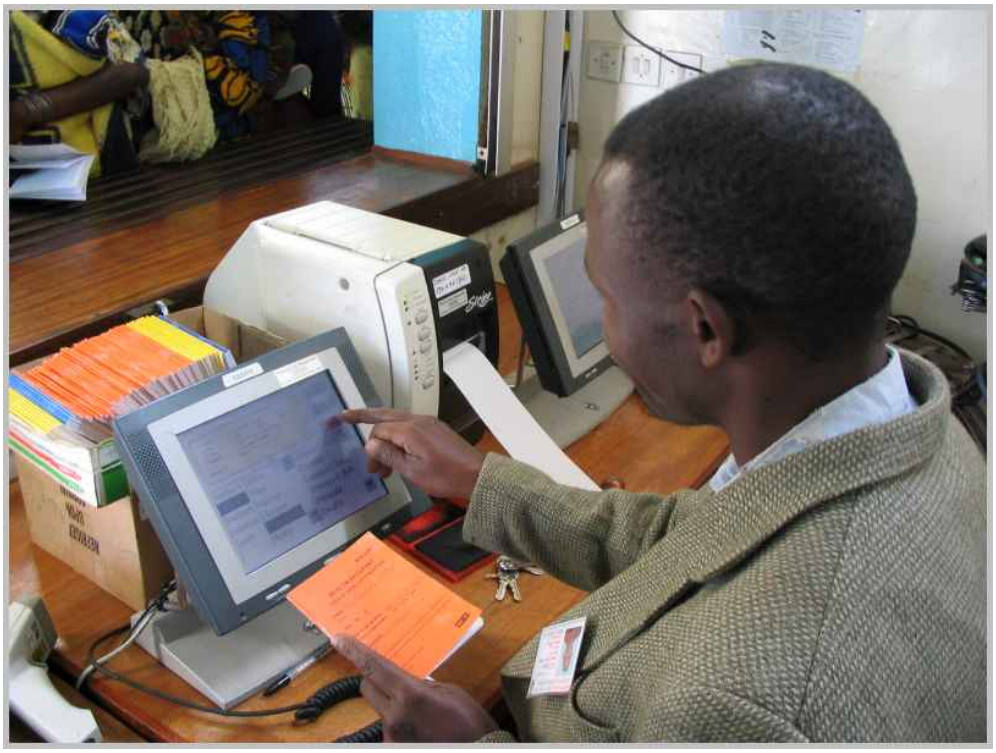


Figure 4: Clerk operating patient registration system

Hospital staff had emphasized the likelihood of equipment theft. Finding a secure location to be used as a server room was the first concern once I arrived on-site. Suitable space was limited. A small room located on the pediatric ward used to store orthopedic supplies was released for use as a server room. A steel security door was fabricated and installed along with steel bars for two small windows. A dedicated electrical feed was installed back to the main circuit breaker panel on the pediatric ward.

The server was installed and connected to the dedicated electrical feed from the main circuit breaker panel. This feed was tied indirectly to the hospital generator; however there is a period of approximately 10 seconds between power failure and the generator coming online. To

bridge this gap a 650VA uninterruptible power supply was installed. Power fluctuations were reported to be common and had resulted in damage to electrical equipment. An automatic voltage switch (AVS) was installed to remove the power from the equipment if the mains voltage became dangerously high or low.

Installing equipment in the pediatric outpatient clinic proved a challenge. The clinic is held in an unsecured area. Clinicians sit at concrete desks and patients wait on concrete benches to be seen. Portable equipment such as weighing scales are locked away in a storage room and night and only brought out when the clinic is in progress. Without securing the entire area it would not be possible to leave computer equipment in the outpatient clinic overnight. To address this problem, small mobile desks were built on castor wheels (Figure 5).

Figure 5: Plywood desk containing workstation, printer, battery and charger

Desks were constructed of plywood by a local carpenter and had a paint finish. Each desk had a clinical workstation and small documentation printer permanently fixed to it. A deep-cycle 12-volt battery (similar to a car battery) and a battery charger were mounted in the base of each desk and provided power to the workstation and printer. Wireless networking adapters were used to provide connectivity back to the server. At the start of clinic three workstation desks were wheeled out onto the floor where the outpatient clinic takes place. At the end of the

clinic, the desks were locked in a secure room and the battery chargers plugged in to boost the batteries for the clinic the following day. Given the relative success of this "packaging" of equipment and power backup system, and the obvious benefits of commonality of configuration, it was decided that the same setup would be used at each of the three nursing stations and in the patient registration office.

The pediatric department maintains their inpatient and outpatient services at opposite ends of the hospital. Two 24-port network switches were installed; one in the outpatient area and the second on the server room located on the pediatric wards. The two switches were separated by a cable run of approximately 270 meters. Standard 10/100Mbps Ethernet segments are limited by cable runs of no more than 100 meters in length. Consequently, two intermediate network switches needed to be installed. Small 5-port switches were used at the intermediate points and were powered using power over Ethernet (PoE) from the server room and the outpatient area.

Given the mobility of the workstation desks, wireless networking was necessary in the outpatient area. A single wireless access point was installed to service the three workstations. While mobility was less of a requirement on the wards wireless was used there too so as not to preclude workstations from being moved around and to make workstations used on the wards and in the outpatient area interchangeable. A wireless access point was installed at each of the three nursing stations. All wireless access points were powered using the same homemade power over Ethernet solution. Workstations in the patient registration area and medical records office were hardwired.

Running Cat-5 Ethernet cable between network switches, workstations and wireless access points was labor-intensive and time consuming. All cables were run inside plastic conduit. Numerous holes had to be dilled through concrete walls up to 10 inches in thickness necessitation specialized tools. Two cordless hammer drills and spare batteries proved invaluable, as many of the locations had limited access to power.

There were a number of challenges in getting the PMIS online and working stably. Most problems were solved with minimal effort. However, some problems could not be solved and alternatives had to be found:

- The version of SQL Server had some bugs that prevented TCP/IP from being used as the primary connection protocol. This was never resolved so NetBeui was used instead of TCP/IP.
- Wireless access points were operating unreliably. After researching the problem it was determined that early versions of the firmware had a bug that caused the access point to lock up. Downloading and flashing the latest version of the firmware solved the problem.
- The battery charging system was not working properly and was causing the electrolyte in some of the batteries to boil and vent from the battery. This was ultimately resolved when the batteries were eliminated from the system and workstations connected to an existing generator.

2.8 USER TRAINING

While the PMIS was designed to be extremely simple to use, some orientation would be required. Initial training was done one-on-one with the nursing staff. Training sessions typically lasted between 10 and 20 minutes per user culminating in a demonstration of competency, after which a PMIS password was issued to the user. As new users came into the pediatric department they were commonly given an informal orientation on the PMIS by colleagues, greatly reducing the time taken to train new staff. A small group of clerks who had been involved with the PMIS development from the early stages became extremely proficient in the use of the system. These clerks voluntarily ran group-training sessions for medical students rotating through the hospital.

2.9 OPERATION AND MAINTENANCE

A local computer specialist was hired to maintain the pilot system using funds budgeted for in the initial grant. Start-up problems stabilized over a period of several months and by the time funds for the computer specialist had been exhausted the PMIS was sufficiently stable that it

could be supported by email with the help of a locally employed assistant. Problems that could not be easily resolved had to wait until one of my many subsequent visits.

The case study described above is intended to provide a real-life context to the challenges of healthcare delivery in the developing world. In Chapter 3 we expand on examples from the case study, providing a more rigorous background in the areas of electronic medical records and challenges of delivering healthcare in a developing country.

3.0 BACKGROUND

Much of the pilot project described in the case study presented in the previous chapter was based on a somewhat limited understanding of electronic health records and the unique characteristics of healthcare in the developing world. In this background chapter, we describe the evolution of electronic medical records in a Western healthcare setting, discuss characteristic of healthcare in the developing world, and present the efforts of others who have sought to develop electronic medical record systems to meet the demands of these challenging environments.

3.1 OVERVIEW OF ELECTRONIC HEALTH RECORDS IN WESTERN MEDICINE

I recognized that moving forward beyond the pilot would require the synthesis of lessons learned from the pilot with lessons learned in the electronic medical record community. I undertook a systematic review of the literature to better understand the history and current status of the evolution of the electronic health record. This section summarizes my findings.

3.1.1 Introduction to Electronic Health Records

The 1960s saw the introduction of computers in healthcare for administrative and financial functions. At the same time, early work in medical informatics focused on the use of computers to improve medical diagnosis and reduce medical error through improved access to procedure results, relevant medical literature, and through the application of decisions support functionality such as alerts and reminder (6-10). Early systems focused on providing access to patient information such as encounter notes (e.g. progress notes and discharge summaries). Exemplars

of such systems include the HELP system developed at LDS hospital in Utah, the COSTAR system developed at Massachusetts General Hospital, the TMR system developed at Duke and the Regenstrief Medical Record System developed at the University of Indiana (11-14). These early systems are recognized as models for the electronic medical record.

A major focus of informatics research in the 1980s focused on developing expert systems to support clinical diagnosis. Exemplars of such systems include QMR developed at the University of Pittsburgh, DXPLAIN developed at Mass. General and ILIAD developed at LDS (15-17). Other research focused on the contribution of using reminders in electronic medical records and several evaluations demonstrated that incorporating reminders could reduce healthcare costs (18-21).

In 1991 the Institute of Medicine released a report titled "The Computer-based Patient Record: An essential technology for health care" (4). The report explored three aspects; uses and users, technology, and policy and implementation. The report concluded that simply recreating the medical record in electronic format would not be sufficient to meet the emerging needs of healthcare and that a total rethinking would be necessary with particular emphasis on moving the record from being medicine-centric to being patient-centric. This new model of record was referred to in the report as the computer-based patient record (CPR), but is now more widely referred to as the electronic health record (EHR). The report described twelve functions for CPR summarized as below.

The CPR should …

1. contain a problem list that clearly delineates the patient's clinical problems
2. support systematic measurement and recording of the patient's health status
3. states the logical basis for all diagnoses and conclusions
4. be capable of linking with other clinical records of a patient
5. address patient data confidentiality
6. be accessible for use in a timely way
7. allow selective retrieval and formatting of information by users
8. be capable of linking to local and remote knowledge bases
9. assist in clinical problem solving by providing decision analysis tools

10. support structured data collection and store information using a defined vocabulary
11. help individual practitioners manage and evaluate the quality and cost of care
12. be sufficiently flexible and expandable to support evolving needs

In 2003 the Institute of Medicine released a follow up report titled Key Capabilities of an Electronic Health Record System (5). In this revised report they summarized the eight core functions of an electronic health record as:

- health information and data
- result management
- order management
- decision support
- electronic communication and connectivity
- patient support
- administrative processes and reporting
- Reporting and population health

These functions are still believed to be relevant and comprehensive. While not described here explicitly there is an increasing expectation that the EHR will meet the information-seeking needs of clinicians in real-time.

The report stimulated the development of national strategies for electronic health records in Europe, Canada, Australia and New Zealand. In the United States the Veterans Administration (VA) developed and deployed the VISTA system at more than 150 sites across the country (22, 23). Adoption in the private sector was limited to a small number of organizations such as the Kaiser Health System (24, 25).

A number of vendor (commercial) systems are available with varying degrees of functionality. EMR Experts, a portal primarily dedicated towards the commercial EMR vendor industry, lists more than 200 vendors of EMR system (26). This is not a comprehensive list and vendors need to sign up to exhibit. It does give a sense of the large number of EMRs available. However, of those listed only a handful (e.g. EpicCare, GE Centricity, Cerner) are considered “enterprise” class systems suitable for large institutions. There are no notable reviews of commercial vendor systems in the peer-reviewed literature.

3.1.2 Clinical Decision Support Systems

There is no universally accepted definition of clinical decision support systems (CDSS), or decision support systems in general in the literature. Coiera describes CDS as a form of 'cognitive prosthesis' that supports healthcare workers in a variety of tasks (27). Sittig et al. define clinical decision support broadly as "clinical information" that is either provided to you or accessible by you, from the clinical workstation (28). In this context clinical workstation refers to the network-attached computer the clinician uses to access the clinical information system (CIS).

CDSSs fall into several broad categories. Event monitoring systems periodically look at data to identify pattern of significance that when brought to the attention of a care provider may inform decision-making in a constructive way (29, 30). Reasoning systems combine clinical knowledge and clinical findings to assist clinicians in diagnosis or treatment planning (15). Clinical practice guidelines encoded into the EMR can be more easily navigated through transparent branching compared with the use of traditional paper-based guidelines (31-34). Access to generic or context sensitive clinical knowledge in the form of medical literature, particularly evidence based, is also considered a form of decision support. The presentation of clinical data in enhanced (e.g. graphs) or context sensitive ways (e.g. showing weight for height for a child but showing body mass index for an adult, both derived from weight and height observations) can enhance clinicians' decision-making process. Performing routine but nonetheless potentially error-prone clinical calculations such as calculating BMI, dosage calculations or creatinine clearance are a form of decision support. Wagner notes that even the most primitive form of electronic medical record has benefit as it provides a framework within which decision support can be deployed (29).

The degree to which clinical decision support can be beneficial (reduce errors, improve patient outcomes, contain costs) is determined somewhat by the degree to which clinicians interact directly with the CIS. The electronic medical record can be populated with clinical information in a number of different ways. At one end of the spectrum the clinician does not interact with the clinical information system directly. In this scenario all clinical data is entered

by a third party, commonly medical transcriptionists, who retrospectively enter data into the CIS that was captured on paper or dictated by the clinicians during or after the clinical encounter. Clinical information is fed back to the clinician via printed reports such as rounding sheets. At the other end of the spectrum clinicians interact directly with the clinical information system in real-time, frequently at the point-of-care.

3.1.3 Computerized Physician Order Entry (Care Provider Order Entry)

Computerized physician order entry (CPOE) is a mechanism that allows physician orders to be entered directly into the CIS. This is increasingly being done by the physicians themselves, but is still predominantly done by unit clerks. Many CPOE systems provide a mechanism for augmenting medication ordering by checking correct dosage, checking for contraindications and for drug-drug interactions. CPOE systems are able to quickly communicate orders to the pharmacy thereby reducing the time taken to deliver the medication to the patient.

As with all interventions unintended negative consequences can occur. In the EMR arena this effect is referred to as e-iatrogenesis (35-38). A study conducted at Children's Hospital Pittsburgh noted an unexpected increase in mortality coinciding with the implementation of CPOE (39).

3.1.4 Point-of-Care

Point-of-care (PoC) represents the highest level of interaction between in the clinician and the information system in that it (generally) requires that the interaction take place in real-time during the clinical encounter. For PoC systems to be successfully adopted into workflow it requires both a high level of competency in the use of the CIS by the clinician as well as a CIS that is "user friendly or "highly usable". In addition to providing CPOE functionality PoC is used by the clinician to document the patient assessment. PoC systems provide the optimal infrastructure for leveraging clinical decision support in that they allow the clinician to have direct access to decision support tools while formulating their hypotheses for diagnoses and their care plan for the patient.

Carter describes one of the first applications of a point-of-care approach to bedside computing in 1986 (40, 41). Several more were described shortly thereafter (42-47). Stefanchik points out in 1989 that despite considerable interest of hospital managers in bedside/point-of-care systems cost justification remains an obstacle to purchase decisions (46). However, the mix and cost of available technologies have changed significantly in the last 20 years.

Most early point-of-care solutions in the inpatient setting use computers mounted to small mobile carts that could be wheeled from patient to patient. In many cases the team leaves the cart in the hall, using the computer to review lab and other clinical data prior to entering the room, and then use the computer to enter orders after completing the assessment and leaving the patient's room. Handheld computers and table PCs were later introduced.

Drazen in 1995 describes point-of-care moving beyond the bedside and into ambulatory care (48). Murphy in 1997 describes the increased use of point-of-care systems in the exam room by nurses for logging patient vitals (49). Murphy points out that a significant amount of process reengineering was required for the implementation.

For systems to be used in realtime while seeing patients in an ambulatory care setting computers must be located at each point-of-care (exam room). Since there are many points of care in the hospital this has necessitated an increase in the amount of hardware deployed. Hardware deployed for the purpose of providing clinicians with access to the CIS is generally referred to in the literature as a clinical workstation.

3.1.5 The Clinical Workstation

Lenhard, et al. describe the development and deployment of a clinical workstation at Johns Hopkins Hospital in 1990, referring to it as a tool that moves technical support for medical decision making from the computer room to the nursing station (50). In 1993 Safran describes the use of clinical workstations at Beth Israel Hospital (51). He describes four main attributes of a clinical workstation as 1) display patient information rapidly and flexibly, 2) must be patient-centered, 3) having a uniform interface for all functions, and 4) providing a single-entry solution for all data elements. In a subsequent article in 1994 Safran provides a functional definition as 1) providing support for administrative tasks, 2) facilitating communication, and 3) providing decision support at four levels; access to literature, access to databases, clinical calculation, and

'synthetic vision,' or different views of patient data (52). These functions closely fit those described for the CPR in the Institute of Medicine report published three years earlier (4).

Kolodner describes functional workstation requirements as defined by VA clinicians as falling into five categories: general environmental capabilities, input methods, display features, output abilities, and miscellaneous functionality and features. He notes that clinical workstations meeting these functional requirements can offer a significant enhancement over existing hardware interfaces, and that the use of these workstations by healthcare providers could improve their willingness to directly enter data into clinical information systems, increasing the benefits of such systems (53).

Several articles have included recommendations for computer hardware for the clinical workstation. This has typically represented medium to high level hardware available at the time of publication. None of these articles refer to input methods other than traditional mouse and keyboard. Given the many challenges associated with using a computer in real time at point-of-care it seems reasonable to focus on optimizing usability. Limited keyboarding skills have been cited as a significant barrier to the realtime us of systems at point-of-care (54, 55). While the touchscreen is recognized as the optimal form of human-computer interaction in many applications (56), it is notable that the literature contains no references to clinical workstations that utilize a touchscreen-based user interface. We recognize that free text still plays a major part of the medical record in most systems world wide, and acknowledge the limitations of the touchscreen to efficiently capture free text as the most likely explanation for their lack of use to date.

3.1.6 Use of Touchscreen Technology in Healthcare

The touchscreen is considered the most usable form of human-computer interaction (56). However touchscreens are not widely used in EMR systems. Touchscreen use has largely been limited to patient-administered computerized questionnaires (53-73) and patient education (57-67). Many of these systems have been delivered using kiosks (68-75). A small number of prototype systems have been developed around ICU and other critical care settings (76-80). To date, the only commercial EMR vendor offering touchscreen functionality as a standard feature is JMJ Technologies (http://www.jmjtech.com/) (81).

Lowes differentiates between stylus-based touchscreen systems such as tablet PC and PDA (iTouch notwithstanding) and finger-based touchscreen systems (82). He points out that larger buttons and other on-screen controls are required to accommodate a finger compared to stylus-based systems. These larger controls give the impression of a simpler less-crowed user interface than commonly seen on an EMR, which can have the effect of making the systems seem less intimidating to a user. Silvey et al. point out that developing software suitable for a touchscreen user interface requires a different approach than developing traditional interfaces and that programming tools are not widely available (83).

Colle, et al. report on the importance of optimizing button size and inter-button spacing for touchscreen use at a kiosk (84). Harada et al. conducted similar experiments and reached the same conclusions (85, 86). These findings supported Lowes' comment that larger buttons are necessary when using a finger as a pointing device.

King cites the touchscreen as dramatically improving the casual user's ability to input data into the computer system for a monitoring system used in Anesthesiology at Vanderbilt (80). Chisolm et al. describe the assessment of a touchscreen-based patient intake system. The authors found that patients and staff across levels of computer experience found the system easy to use and were highly satisfied with the experience (87).

Touchscreens are cited by Arkoff as a possible source of cross infection (88). However, keyboards and mice still require touching and would be equally effective in contributing to cross infection but much harder to clean than a simple flat sheet of glass.

Touchscreens do not lend themselves to efficient input of free text (89). On-screen keyboards can be used for capturing limited amounts of free text but the upper limit of speed does not approach that achieved when using a conventional keyboard. Free text is widely used in progress notes and discharge summaries. However it cannot be reliably validated or analyzed. Some structure can be extracted from free text through the application of natural language processing. Kruger reviewed 103 articles and 70 abstracts on benefits of structured data in the electronic medical record. Research shows that structured electronic medical records can result in faster data entry and improved data quality. Furthermore doctors and nurses preferred structured data entry (90). However, this is not a universal finding. Webster advocates the use of structured data entry in a workflow-enabled electronic patient record and argues that a touchscreen is the optimal way of capturing structured data (81).

3.1.7 Rate of Adoption and Barriers to Adoption in the West

Despite anticipated benefits of EHR systems adoption has been slow. A review article from 2005 attributes slow adoption to a number of factors including technology immaturity, health administrator focus on financial systems, application "unfriendliness", and physician resistance (91).

In 2008 DesRoches, et al. conducted a national survey of 2,758 physicians in the United States representing a 62% response rate (92). Only 4% of physicians reported having an extensive fully functional electronic records system. Thirteen percent reported having a basic system. Primary care physicians and those practicing in large groups, in hospitals or in medical centers, and in the Western region of the United States were more likely to use electronic health records. Common barriers to adoption were cited as high capital costs (66%), not finding a system that met their needs (54%), uncertainty about their return on investment (50%), and concern that a system would become obsolete (44%).

Among physicians currently not using an electronic health record facilitators to adoption were cited as financial incentives for the purchase of and EHR system (55%) and payment for the use of the system on an ongoing basis (57%). These physicians also reported that protecting physicians from personal liability for record tampering by external parties could be a major facilitator of adoption. Of those physicians already using an EHR system, facilitators to adoption were cited as financial incentives for the purchase of and EHR system (46%) and payment for the use of the system on an ongoing basis (52%).

3.2 UNIQUE CHARACTERISTICS OF HEALTHCARE IN DEVELOPING COUNTRIES

There are well in excess of 200 commercial EMR systems available for organizations to adopt (26). While each may be different in one way or another, the functionality is very similar, and almost entirely geared to address the needs of medicine as practiced in the West. While healthcare is a worldwide endeavor, cultural, geographic and socio-economic variations can

greatly affect the manner in which healthcare is delivered from country to country. Unique situations often require unique solutions. To build an EMR tailored to address the needs of healthcare delivery in the developing world requires that we examine the unique characteristics of medical care in such settings.

Described below are 12 characteristics common to most developing countries that should be taken into consideration when formulating a model for an EMR to be used in these settings. These characteristics represent the "realities" we need to design toward when building EMR systems for developing-world settings. In describing each characteristic I have chosen to draw observations from Southern African settings because that is where I have focused my work.

3.2.1 Low Literacy Rates

The literacy level of both patients and healthcare workers should be taken into consideration when creating EMR systems to be used in developing countries. EMR systems created for use in a Western healthcare system assume high levels of literacy of the healthcare team and medium level of literacy for the patient.

The UNDP estimates the average literacy rate for developing countries to be 76.6% and the average literacy rate for Sub-Saharan Africa to be 60.3% (only three out of every five people are literate). It may seem unintuitive that a person could rise to the position of a healthcare worker and not be literate. However, due to the shortage of staff (addressed in this chapter) many lower-level positions are filled by less qualified people. These positions often include clerks, whose responsibility it is to deal with recordkeeping, typically in the form of inpatient and outpatient paper-based registers.

Table 1 below shows literacy rates for the United States and United Kingdom as well 11 countries in Sub-Saharan Africa. Each country is ranked out of a total of 177 countries reported.

Table 1: Comparison of literacy rates

Country	Rank (out of 171)	Literacy Rate
USA/UK	18	99.0%
Zimbabwe	92	89.4%
South Africa	114	82.4%
Lesotho	116	82.2%
Botswana	118	81.2%
Swaziland	124	79.6%
Kenya	131	73.6%
Tanzania	136	69.4%
Zambia	140	68.0%
Uganda	144	66.8%
Rwanda	145	64.9%
Malawi	146	64.1%
Mozambique	169	38.7%

3.2.2 Absence of Unique Patient Identifiers

Continuity of care is essential when managing patients with chronic illness. This is particularly challenging in developing countries where patients tend to seek treatment from multiple providers rather than the Western model where patients have a primary care provider. Maintaining continuity within the same healthcare facility requires that the patient can be re-identified each time they come to the hospital. This can be challenging in a country without a national registration system or identity cards, as patients literally have no form of unique identification. Many Western countries use driver's license numbers or numbers issued by the government to track employment (social security number, social insurance number) as a unique identifier to maintain continuity of care. Unfortunately, the absence of such government systems and the low percentage of drivers' license holders in developing countries make these approaches unfeasible.

The problem is compounded by the fact that levels of literacy are extremely low in many developing countries (discussed above). Many patients when providing their name can only provide it verbally, not in writing. Consequently any representation of their name is subject to the interpretation of the listener. Many older patients do not know their date of birth. This complicates tasks as simple as creating a master patient index.

Patient registration has proven challenging with duplicate registration being a common occurrence. Tools to coalesce records when duplicate registration occurs are an essential component of an EMR designed to work in this setting.

3.2.3 HIV/AIDS Pandemic

The widespread effect of HIV/AIDS has a huge impact on healthcare in developing countries. Figures from UNAIDS for the end of 2007 estimate approximately 33.2 million people are living with AIDS of which 68% live in Sub-Saharan Africa alone. Second to Malaria, HIV/AIDS and associated opportunistic infections are the leading cause of adult mortality and the second leading cause of morbidity in the developing world.

To effectively address the needs of HIV/AIDS patients, an EMR would need to facilitate the diagnosis, treatment and monitoring patients and management of opportunistic infections. At a minimum the EMR would need to keep track of CD4 counts, viral loads, radiological findings, dermatological findings, and be linked to the pharmacy for prescribing.

The recent availability of affordable antiretroviral (ARV) drugs in developing countries poses certain logistical problems. How will the management of ARV therapy be handled? Additionally, there is a threat of developing drug resistance due to poor adherence. Follow-up of patients defaulting from ARV therapy will be essential if drug resistance is to be minimized. However, follow-up poses its own set of challenges. Many patients live in rural settings where house numbers and street names are not used. There has arguably never been a more important time to be able to find patients at their home. Table 2 below gives a breakdown of the prevalence of HIV in selected countries in Sub-Saharan Africa. Prevalence in the United States is show for comparison purpose.

Table 2: People living with HIV/AIDS 15 – 49 age group

Country	HIV Prevalence
Unites States	0.4%
Zimbabwe	20.1%
South Africa	18.8%
Lesotho	23.2%
Botswana	24.1%
Swaziland	33.4%
Kenya	6.1%
Tanzania	6.5%
Zambia	17.0%
Uganda	6.7%
Rwanda	3.1%
Malawi	14.1%
Mozambique	16.0%

An EMR system would have to accommodate some mechanism for locating patients geographically. This might include recording the patient's proximity to one or more of a set on well-know landmarks (e.g. churches, schools) that have previously been geo-coded.

HIV/AIDS is placing an increased strain on healthcare delivery, an area where human resources are already inadequate to meet the demand for healthcare. As a result much of the healthcare delivery process has been delegated to lower cadres (clinical officers doing doctors work, nurses doing clinical officers work, medical assistants doing nurses work). An EMR with realtime decision support features might provide support to a workforce that is under-trained for its current responsibilities.

3.2.4 Low Levels of Computer Literacy Among Health Workers

Computers are not as ubiquitous in many developing countries as they are in the West. This is particularly true in sub-Saharan Africa and especially outside of major cities. Many healthcare

professionals and support staff have little or no training or experience with computers. An EMR suitable for a developing country would function best using an extremely intuitive and easy to use interface.

3.2.5 Under-Trained and Inexperienced Clinicians

With few exceptions (Cuba) clinicians in developing countries are under-trained. This frequently results in poor diagnostic accuracy. Misdiagnosing patients causes delays in getting them on the correct therapy during which time their condition can worsen, potentially exposes them to therapies that are unnecessary and hospital-acquired infections, and may result in more medication being used and a greater length of stay than was necessary. One solution to this has been the extensive use of protocols such as the Integrated Management of Adult / Childhood Illness (IMAI/IMCI) developed by the World Health Organization (WHO). The contribution to improving the use of protocols and the value of decision support is described in 3.1.2. Realtime decision support for diagnosis and encoded practice guidelines would be a valuable component of an EMR for developing countries.

3.2.6 Limited Healthcare Budget

Most developing countries spend very little on healthcare. The government of Malawi for example spends about US$22 per capita per year (2005). Of the 53 countries that comprise the continent of Africa 34 countries spend less than the $34 per capita minimum spending limit recommended by the Commission on Macroeconomics and Health (CMH) (93). It may be hard to convince nations to invest in an EMR when the pharmacy shelves are half empty. In the context of limited healthcare budgets, an EMR system would need to demonstrate cost benefits such as pharmaceutical inventory control, mitigating implementations and support costs.

3.2.7 Low Staffing Levels

Limited healthcare budgets to pay staff, generally low salaries in the health sector and brain-drain of health professionals to developed countries all contribute to low staffing levels in healthcare in developing countries. In Malawi, low staffing levels have also been attributed to high death rates among healthcare workers (94). High rates of morbidity combined with low staffing levels result in a staggeringly high patient-to-provider ratio. In Malawi in 2006 the patient-to-provider ratio was approximately 50,000:1. At the opposite end of the scale the ratio in the United States is roughly 400:1, or put in the context of Malawi, 125 times as many doctors for the same number of patients. The high volume of patients seen in both the inpatient and outpatient setting means clinicians can only spend a few minutes with each patient. Any EMR introduced to this setting would need to be extremely easy to use. A system that was too cumbersome for clinicians to use would undoubtedly fail eventually.

Figure 6: Population per doctor

3.2.8 High Turnover Among Staff

Due to a variety of factors there is high turnover of healthcare staff in developing countries, particularly in sub-Saharan Africa. Among these factors are staff moving on to "greener pastures", transfers, or early death as is seen more and more commonly now (94). The implementation of an EMR not only has a significant capital cost but often requires investments in training individuals as well. Any system that places significant emphasis on a small group of individuals in order to function is therefore at risk of failure based on this reason alone. For an EMR to be successful it would need to be designed in a way that decentralizes the work across a number of people, any one of whom could reasonable do the job of any of the others (a fault tolerant approach). This would require that the system be simple, easy to learn, and easy to use too minimize the training required.

3.2.9 Inadequate Security / High Risk of Theft

In general, there is a high risk of equipment theft in developing countries. This may be due in part to poor security combined with an increased rate of crime based of high levels of poverty.

The technology chosen to implement an EMR must be sufficiently fault tolerant that it can continue to function in the event of a component being stolen. With respect to servers this can be achieved through the redundant configuration of multiple servers such that no one server is a single point of failure. With respect to workstations, which are much more accessible to the public, using a technology that does not look like or function like a conventional computer would decrease the appeal thereby reducing the chance of it being stolen. Employing technologies that lend themselves to being stolen easily (e.g. PDAs) may be a poor choice for this reason alone.

3.2.10 Absence of Electrical Power in Many Health Facilities

The greatest burden of illness occurs in the rural areas, many of which are off the main electrical grid. This prevents or greatly limits the use of diagnostic equipment that requires electricity. In many cases health centers do not even have a microscope with which to diagnose malaria. Some

hospitals are equipped with diesel-powered generators. However, the logistics required to keep them fueled and maintained is too great in many cases leaving generators inoperable.

Figure 6 from the World Bank report on Africa's development shows the number of days per year business suffer from power outages in 30 developing countries (95). The report indicates that of all enterprises surveyed across the African continent 60 percent indicated that the lack of electricity is their top constraint.

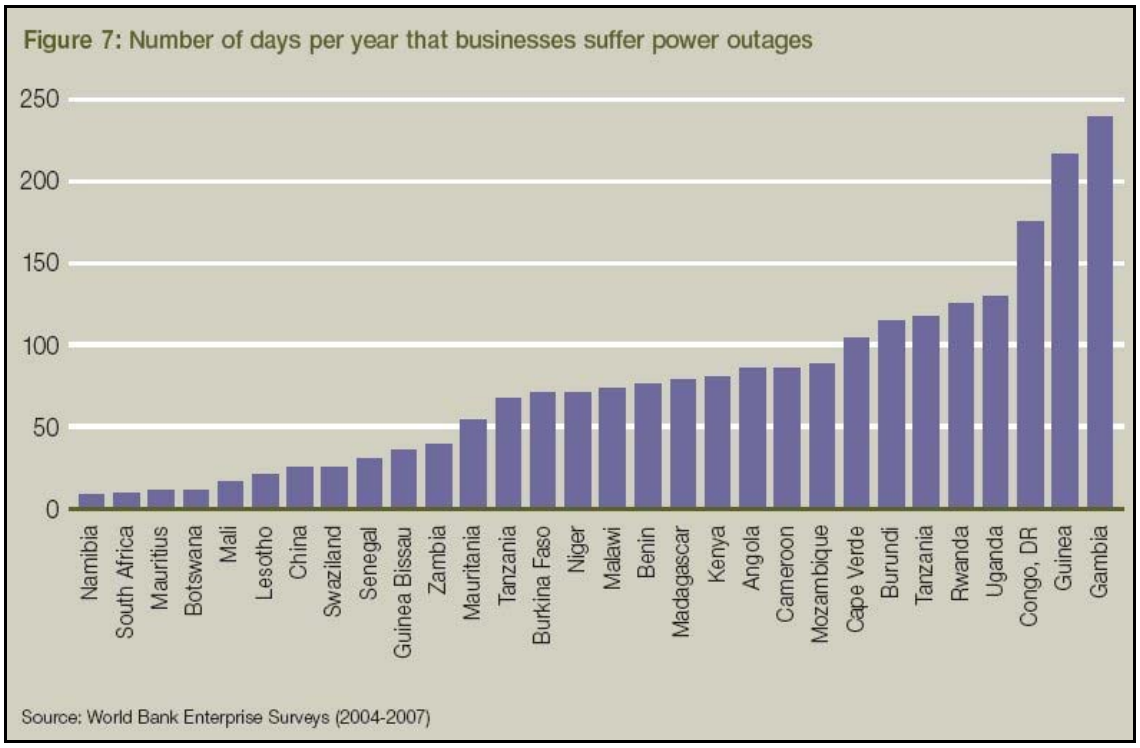


Figure 7: Number of days per year that businesses suffer power outages

Any EMR system developed to work in this setting would need to be capable for running reliably in the absence of reliable power or entirely off the grid.

3.2.11 Inadequate Infrastructure for Equipment Maintenance

While donors regularly support healthcare development through the donation of medical and computer equipment they rarely provide funds to pay for maintenance contracts or repairs. In-

country capacity is commonly inadequate to meet the demands for equipment repair. Availability of spare parts is minimal. As a result rooms can be found filled with broken equipment awaiting repair (when some doctors don't even have an office). Gatrad remarks that 50% of anesthesia equipment in developing countries is not in use because of lack of maintenance or spare parts, because it is too sophisticated, or because local personnel do not know how to use it (96).

The inability to maintain basic hospital equipment should be seen as a red flag for lack of capacity to maintain computer equipment as its role in healthcare delivery increases. The early signs of inability to maintain computer equipment are not promising. Some problems arise from the poof fit of donated hardware in this setting. Computers donated from the United States (110 Volts) sit with burned-out power supplies as a result of being plugged in to the wrong voltage (240 Volts). Broken UPSs are regularly used as doorstoppers. Similarly computers often less than one year old sit indefinitely with damaged power supplies, non-functional floppy drives or something as simple as a broken mouse or keyboard. Equipment can sit for months at a rural site for lack of transportation to take it to be repaired. Private computer repairs services are available. However, they are expensive, many technicians are poorly qualified, and have a reputation of returning the computer with half the memory removed. Such technicians have a habit of treating all hard drive problems by reformatting the drive and reinstalling the operating system, with no thought to the value of data that might be lost in the process. Any EMR system would need to employ robust and highly durable hardware if it were to be sustainable in this kind of environment.

3.2.12 Role of Routinely Collected Data in M&E of Public Health Initiatives

Many developing countries have implemented health facility level data collection to inform the monitoring and evaluation of public health initiatives (e.g. malaria, TB, HIV/AIDS). Government health facilities in Malawi are required to submit standardized reports to the Health Management Information Unit (HMIU) of the Ministry of Health (97). Data is collected using paper-based registers and manually aggregated to produce these reports. There is generally some attempt within each country to collect data based on agreed upon case definitions and a controlled vocabulary. An EMR developed in this setting should try to harmonize with

established standards within the country and support the infrastructure already in place through the generation of required reports. Any system that required parallel paper reporting would increase the burden of effort which would compromise the successful adoption of the EMR.

3.3 CURRENT EMR SYSTEMS IN DEVELOPING COUNTRIES

There is a paucity of literature describing EMR systems in developing countries. A recent systematic review of evaluations conducted on EMR systems for developing countries found only one quantitative study of an EMR system in Sub-Saharan Africa (98).

Five exemplars of systems created for developing countries in Sub-Saharan Africa are described below. The following criteria for selection were used:

- Use of the system should have extended beyond the pilot phase for a minimum of 12 months
- The system was deployed in at least one more site in addition to the pilot site
- No two systems are from the same developer

3.3.1 Partners in Health Suite of EMR Applications

Partners in Health (PIH) developed an EMR system to support patient care (99). The system was first deployed in Peru in 2001 to support the treatment of patients with multi drug resistant tuberculosis (MDR-TB). The PIH-EMR is an example of a web-based EMR based on open-source technology and backed by an Oracle database. The system is viewable in both English and Spanish and currently has over 42,000 patients, 12,000 of which have received treatment. The PIH-EMR includes a clinical record with initial history, physical examination, laboratory results and medications on all patients receiving individualized treatment for MDR-TB. The

custom medication order entry system provides advice on potential problems and feedback to the clinical personnel. There is an extensive suite of web-based analysis tools for reporting and outcome monitoring (100). Analysis tools are used to assess drug requirements based on the medications prescribed and perform operation research. It is also linked to a pharmacy inventory and dispensing system. While the system is essentially designed to manage TB patients it contains some HIV data including CD4 count and viral load as many TB patients have HIV as a co-infection. Evaluations of modules of this system have shown that the medication order entry system produced significantly fewer errors than the previous paper and spreadsheet approach. Drug usage prediction tools have been shown to match the usage data in the pharmacy to within 3% and are used routinely is drug ordering. Further modules have been added to the PIH-EMR to collect and communicate TB laboratory data. A personal digital assistant (PDA)-based system to collect TB lab data from laboratories and health centers without internet was shown to reduce processing delays from 30 to eight days, reduce errors by 60%, and to be preferred by users (101).

The Peru system was later modified in 2003 for use in Haiti to support patients on antiretroviral therapy for HIV (102). The HIV-EMR system has been implemented in all nine PIH sites and as of end of 2007 has over 12,000 patients; 3,051 of which are receiving ART. The system records clinical data including history, physical examination, social circumstances and treatment prescribed. Decision support tools provide allergy and drug interaction warnings and generate warning emails about low CD4 counts. Staff also keep paper records, but they can use the EMR to check for up to date lab results and drug regimen data and monitor patients' follow-up status. A suite of reporting tools allow staff to create key reports, such as for the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), and automatically generate the reports monthly. There is also a full pharmacy inventory system and tools for drug regimen analysis. The inventory system allows pharmacy staff at all clinics to enter stock levels and request drugs and track shipments. This system is used to track about 450 products supporting care for 1.78 million patient visits annually. During 2006 drug stock-outs fell from 2.6% to 1.1% and 97% of stock requests delivered were shipped within one day.

In 2004 the MDRTB system was installed in several clinics in the Philippines. The system is used in English. Some modifications were required to meet the needs of the different setting. The system currently maintains approximately 4,000 patient records.

In 2005 a variation on the Haiti HIV EMR system was installed in a number of clinics in Rwanda. This system was adapted to the local work flow and ran for one year before being replaced by an OpenMRS version.

Though both the PIH-EMR and the HIV-EMR are web-based, a set of off-line modules were developed in the HIV-EMR to provide partial functionality when connectivity is disrupted. Concerned about the problems associated with maintaining servers in a hostile environment (dusty, humid, unsecured, unreliable power), PIH chose to maintain the servers for Peru and Haiti at their head offices in Boston, USA, though the Philippines server is in the Philippines. This required that remote sites had connectivity in order to use the EMR. Connectivity for the Peru sites was provided using modem and subsequently broadband technologies available in Lima, the capital. Haiti and Rwanda sites use satellite-based technology for connectivity. This was an additional reason for locating the server in the US – the latency of connecting through two satellite links was prohibitive for live use of the web site.

While the systems deployed at each of the four sites described above provide different functionality, they are very similar in their design and implementation.

3.3.2 Mosoriot Medical Record System / AMPATH

This system was developed by a team from the Regenstrief institute at the University of Indiana. The pilot implementation took place at the Mosoriot Rural Health Centre (MRHC) located about 25 kilometers outside Eldoret, the fifth largest city in Kenya (103-105). The health centre serves a patient population of approximately 40,000. Services provided are mostly limited to ambulatory care. However the health centre does have 20 beds for inpatients. The Mosoriot Medical Record System (MMRS), initially deployed in 2001, has gone through a number of incarnations. These changes reflect improvements resulting from in increased understanding of the needs and challenges of creating an EMR system for the developing world.

Four barriers to establishing an electronic medical record system are described: 1) maintaining clean and reliable electrical power, 2) lack of computer literacy among the target user group, 3) lack of unique patient identifiers, and 4) making the transition from paper to the electronic medium.

MMRS later developed into the Academic Model for the Prevention and Treatment of HIV/AIDS (AMPATH) (106).

3.3.3 SmartCare

The primary aim of the SmartCare project is the continuing development of an electronic medical record (EMR) suitable for use in Zambia and developing nations around the world (107). The project takes advantage of Smart Card and touchscreen technology to enhance the reliability and usability of the system. The Smart Card is used to store and transport patient's data electronically. The touchscreen user interface is used for ease of clinician adoption. While touchscreen functionality is provided the system can also work using a keyboard and mouse that are deployed alongside the touchscreen monitor. The decision to use touchscreens was made by the project leader after his visit to Malawi in 2004 to see sites using touchscreens for voluntary counseling and testing (VCT) and the management of patients receiving antiretroviral therapy (108).

SmartCare currently has seven modules: Voluntary Counseling & Testing, Antenatal Care (ANC), Delivery, Pharmacy, Antiretroviral Therapy (ART), Labs and Tuberculosis (TB). The ART module is the most highly developed and as of January 2007 there are over 65,000 patients whose ART care is managed and recorded by the SmartCare system (107). Of these ART patients the greater portion are receiving care and treatment from the Center for Infectious Disease Research in Zambia (CIDRZ) established and operated by the University of Alabama at Birmingham.

The system is designed on the premise that linking sites electronically would not be possible for some time and having patients carry their data on a Smart Card would address this problem. Nothing has been published on this system in the peer-reviewed literature.

The developers formulated several models for how data would be entered into the system. "E-First" is a point-of-care model where the clinician interacts directly with the clinical information system. "E-Fast" is a point-of-care model where dedicated clerks enter data into the system in the clinic room. Both approaches are designed to ensure that data is captured before the patient leaves the clinic.

The system has been deployed extensively in and around the Zambian capital of Lusaka and is now being deployed in other parts of Zambia. The Ministry of Health has endorsed SmartCare and requires it be used at all sites providing antiretroviral care in Zambia.

The SmartCare project is described as a joint effort between the Zambian Ministry of Health (ZMoH), the Elizabeth Glazer Pediatric Aids Foundation, the Centre for Infectious Disease Research in Zambia (CIDRZ), the Centers for Disease Control and Prevention (CDC), the University of Alabama at Birmingham (UAB), and Dimagi (a US-based for-profit software development organization). The application is developed in C# on a .Net framework and uses Microsoft SQLServer for the underlying database. Neither the software application nor the database and operating system upon which it runs are open source.

3.3.4 FUCHIA

FUCHIA is used by Medicins sand Frontieres (MSF) to track patient data of ART (109). MSF is an independent, international medical humanitarian. The FUCHIA system is used in approximately 20 of the 60+ countries in which MSF operates. The system is developed in Microsoft Access by EpiCenter, the epidemiological branch of MSF based in Paris.

3.3.5 Zambia Electronic Perinatal Record System

The Zambia Electronic Perinatal Record system (ZEPRS) was developed by Research Triangle International for use by the Center for Infectious Disease Research in Zambia (CIDRZ) (110, 111). ZEPRS is a web-based system that is designed to be used at point-of-care. The system was first deployed in 2006 and is currently is in use at roughly 35 sites in Lusaka and surrounding areas.

3.3.6 OpenMRS-based Initiatives

OpenMRS is a free and open source framework for building a forms-based electronic medical records system launched in 2006. OpenMRS was born from a collaboration between the MMRS/AMPATH development team from the Regenstrief Institute and Partners in Health, (both described above) and subsequently the South African Medical Research Council. OpenMRS provides a data model encapsulated in an application programmer interface (API), and uses Microsoft InfoPath to create forms for inputting data into the system, although an open source forms tool was released in early 2009. There is a modular structure allowing new components to be added by developers around the world and a set of reporting and data export tools. The system can be used "off-line" with synchronization of data to a central server.

OpenMRS is becomingly increasingly widely adopted. The OpenMRS website lists 14 ongoing projects spanning eight countries where OpenMRS is being implemented (http://openmrs.org/wiki/Summary_of_OpenMRS_Implementation_Sites). All new system development by both Partners in Health and the Regenstrief team is now built on top of OpenMRS. The Government of Rwanda is currently considering using OpenMRS as its national medical record system.

4.0 SYSTEM DEVELOPMENT & DETERMINANTS OF IMPLEMENTATION SUCCESS

In this chapter we describe the current state of the work that has occurred since the completion of the pilot in 2001. We follow with a summary of technologies we developed to address the specific challenges we faced over this eight-year period. Then we introduce two existing frameworks for understanding the criteria for successful systems that we have used to systematically examine the contributions of our design and implementation decisions in meeting the many challenges inherent in healthcare in the developing world. The chapter concludes with a brief description of the impact and influence of this work on other stakeholders working in this field, both within Malawi and internationally.

4.1 SUMMARY OF POST-PILOT SYSTEM MILESTONES

In the eight years that followed the pilot, several donors funded the development of new system modules covering ancillary services including radiology, specimen labeling and pharmacy as well as clinical modules including voluntary counseling and testing, and antiretroviral therapy. Concurrently, the work of one individual evolved into the Baobab Health Partnership, an organization with the goal of creating a paradigm shift in healthcare delivery in Malawi through the application of information technology and the principles of medical informatics. In early 2008, with the goal of creating greater indigenous ownership the organization was reborn as the Baobab Health Trust; a Malawi-based organization with a predominantly Malawian board of trustees. By the end of 2008 the trust had approximately 25 fulltime employees managed by a seasoned country director.

Major milestones in the development of the Baobab organization and the core system architecture include:

- 2002 - Deployed first point-of-care application using touchscreen (detailed pediatric admission module)
- 2003 - Migrate to MySQL database management system (from MS SQL Server)
- 2004 - Moved to Linux on the server side (Linux on the client in 2007)
- 2005 - Recruited professional software developer to manage Malawi-based team
- 2006 - Abandoned existing data model in favor of OpenMRS
- 2006 - Dropped Visual Basic, shifted development to Ruby on Rails and delivering as a browser-based application (entirely open source software stack at this point)
- 2007 - Baobab ART (BART) point-of-care system certified by Ministry of Health
- 2008 - Moved to small-footprint server: running from DC, low power, replace RAID with latest Solid State Disk (SSD) technology
- 2008 - Deployed two sites totally off the electricity grid running from Solar and wind
- 2008 – Recruited professional country director and established Baobab Health Trust, an indigenous organization with Malawian trustees
- 2009 - Piloted first feasible off-the-shelf solution to the next generation hardware for touchscreen workstations (J2-580).

The creation and deployment of new software application modules is described as follows:

2002 - Comprehensive pediatric admission module (Appendix B, Figures 23,24,25)

2002 - Specimen labeling module (Appendix B, Figures 21, 22)

2003 - Prototype Antiretroviral Therapy (ATR) System – Lighthouse Specification

2004 - Voluntary Counseling & Testing data management system (eVCT)

2004 - Radiology module

2006 - Pharmaceutical Inventory Control System (ePICS)

2006 - Antiretroviral Therapy System – Ministry of Health Specification

2007 - Browser-based Antiretroviral Therapy System – Ministry of Health Specification

As of December 2008, seven years after the pilot system went live in the KCH pediatrics department, variations of the Baobab system have been installed at 14 sites spanning Mzuzu, Lilongwe and Blantyre, Dedza, Kasungu and Salima (Figure 5), with more than 160 clinical workstation appliances installed in total. Of all the systems deployed to date we perceive the Baobab Antiretroviral Therapy (BART) system to be the most significant in terms of current and potential future deployment. As of December 2008 more than 18,400 patients across five sites were being managed using the BART system. This represents roughly 15% of the total patients receiving ART in the country. In terms of sheer volume of patients touched by a Baobab system the patient registration system has issued more than 800,000 unique patient identifiers since it went live back in March 2001. All other Baobab-developed systems are currently functional with the exception of the detailed pediatric admission module. Due to lack of funding we were unable to sustain this beyond 2003.

Figure 8: Dots represent cities where Baobab technologies are deployed

4.2 TECHNOLOGIES DEVELOPED FROM THIS WORK

Approaches to developing information systems to support healthcare delivery in the developing world thus far have largely attempted to integrate existing technologies. We believe that current technologies used to build EMRs for the Western setting are not sufficiently versatile to meet the challenges in a developing-world setting. We have engineered new technologies and reengineered existing technologies to address these needs.

Three key technologies have been developed over the course of the last eight years. The touchscreen clinical workstation appliance was developed to address the challenges of operationalizing a point-of-care system in a developing-world setting. The centralized power backup system was engineered to address developing-world challenges of maintaining a reliable source of power to maintain the high level of system availability required by point-of-care systems. The extension of the Power over Ethernet standard to power clinical workstations was developed to address the needs for easy of deployment in settings where power infrastructure is limited. Below we describe each of these in detail.

4.2.1 Touchscreen Clinical Workstation Appliance

Our touchscreen clinical workstation appliance was first conceived during the initial pilot work in 2000 and has been refined over the years. It is based on the notion of a clinical workstation introduced by Safran et al. and discusses in 3.1.5 above (51). We introduced both hardware and software features into the design of the device to optimize it for reliability, serviceability, usability and installability in a developing-world setting. A summary of the mix of technologies used on the touchscreen clinical workstation appliance are shown in Figure 8 below.

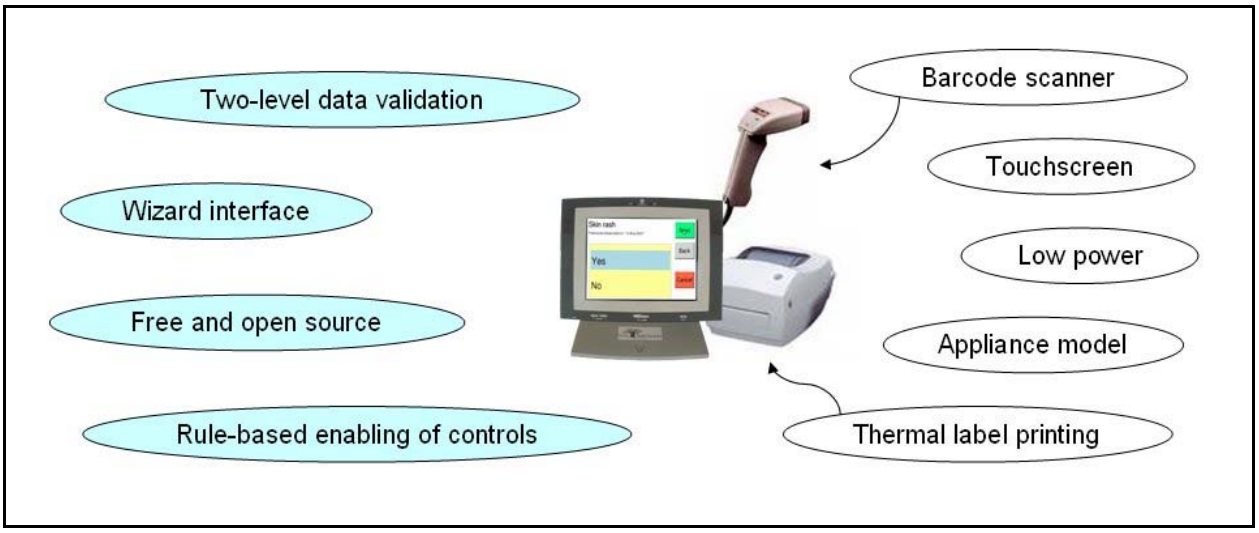


Figure 9: Touchscreen clinical workstation appliance: Mix of technologies employed

4.2.1.1 The Touchscreen as a Choice of Input Modality

The touchscreen replaces alternative pointing devices such as a mouse or stylus. Stylus-based systems are common on tablet computers, which we see playing an increasing role in healthcare in some settings. Styluses can be easily lost/stolen making them less suitable for the developing world. Styluses also require the user to pick it up and put it down, so are more invasive than using a finger. Mice in general have a low mean time between failure (MTBF), require greater hand to eye coordination, and require a flat surface on which to operate.

A touch screen offers a higher level of usability than a stylus-based system or a mouse driven system. Laughlin cites the touchscreen as the most optimal method for human computer interaction (56). Touchscreens have been around for almost 20 years. However, until recently they have not been widely adopted. The introduction of the Apple iPhone released in 2007 has spurred consumer electronics manufacturers to take a second look at the touch interface. More than 10 million iPhones sold in the first year of release. The Consumer Electronics Show (CES) held in Las Vegas in January 2009 has marked 2009 as the "Year of the Touch Screen".

During the initial development of the Baobab prototype touchscreen clinical workstation appliances we paid roughly $64 for the 10.4" touchscreen sensor and $46 for the touchscreen controller. More recently, we can buy 10.4" sensors from China for $26 each and controllers for $6 each in 100-lot quantities. We have found the sensors to be very robust. We have only had

one broken sensor in over 160 deployed units. Ironically the cost of replacing the sensor is less than the cost of replacing the LCD display, so the sensor acts as a display protector as well.

4.2.1.2 Appliance Model

Norman introduces the notion of an information appliance in his book "The Invisible Computer: Why Good Products Can Fail, the Personal Computer Is So Complex, and Information Appliances Are the Solution" (112). The notion of "invisible" here tries to convey the idea of the computer disappearing. This happens when the computer is no longer perceived to be one. Many devices we use in everyday life are appliance model computers. Examples include the X-Box video game unit, TIVO and the ipod.

The appliance model has a number of benefits. Desktop computers are designed to address multiple needs; the jack of all trades but master of none. Appliances are optimized for one particular task. They contain only the necessary components to achieve the specific goal. Consequently they are less expensive to manufacture. Furthermore their form and function is optimized for usability.

Figure 10: An information appliance approach

We have designed the touchscreen clinical workstation as an appliance model computer. The device is applied to the sole purpose of running the clinical application. When the device boots the user is taken directly a web browser running in full-screen mode and a default webpage is loaded showing the login screen to the clinical application. In Figure 9 above our clinical touchscreen workstation is shown top and center. Here we challenge the perception that the workstation is a computer by asserting that it is more akin to a kitchen appliance (electric kettle) than a laptop computer.

4.2.1.3 Wizard Interface Design

The concept of the "wizard" was first introduced by Microsoft in its Windows 95 operating system. The most commonly used wizard was the Internet Connection Wizard, which stepped the user through a series of dialog boxes, each dialog capturing a piece of information about the user's internet service provider.

We find this approach of spread the task across several screens as opposed to putting it all on one screen highly usable. It reduces information density and number of decisions that need to be made (Hick's law) on each screen. It allows for arbitrarily large tasks to be represented as a series of steps (not possible with conventional form-based screen design). Screens require some form of global navigation ("Back", "Next" and "Cancel" controls). The wizard also allows for more transparent branching where data elements that do not apply are never shown rather than just skipped and grayed out in the more traditional form approach to data collection. Virtually every on-line ordering system, customer-operated store checkout and passenger-operated flight check-in uses the wizard approach.

When determining optimal size for user controls on a graphical user interface (GUI) a number of factors need to be taken into consideration. Onscreen controls such as buttons, check boxes and list boxes require the user interaction. For example, in the context of a button the action may be a click or double-click, and for a scroll bar the action may be select and slide.

Fitts's law is a model of human movement that predicts the time required to acquire a target (user control in this case) (113). The time required increases as the distance the point needs to travel increases and as the size of the target decreases. Consequently, larger targets can be activated faster.

Minimum control size is a function of the selection device. Fine pointing devises such as the mouse and stylus can reliability activate small controls that a finger could not. For finger-based touchscreen systems larger buttons are required to accommodate the finger size. Optimal button size and inter-button spacing specifically for touchscreens was investigated by Harada and Coll (84-86).

4.2.1.4 Rule-based Enabling of Interface Controls

Hick's law describes the time it takes for a person to make a decision as a function of the possible choices he or she has (114). The fewer the choices the faster the decision can be made. In the context of an interface, the decision may be which user control to activate for the next operation out of the total number of user controls available on the screen. Rule-based enabling and disabling of user controls at appropriate times reduces the time to find the correct target. This principle is the premise of a popular book on user interface design called "Don't Make Me Think" (115). It has the additional benefit of reducing the chance of selecting a target in error thereby increasing the quality of data entered by reducing the overall error rate.

Below we show two keypads (Figure 10), the first (left) with all buttons enabled, and the second (right) with only the 1, 2, 3 and 0 buttons enabled. The keypad on the right is waiting to accept the first digit of a two-digit number representing a patient day of birth (range 01 – 31, exact range determined by year and month entered previously).

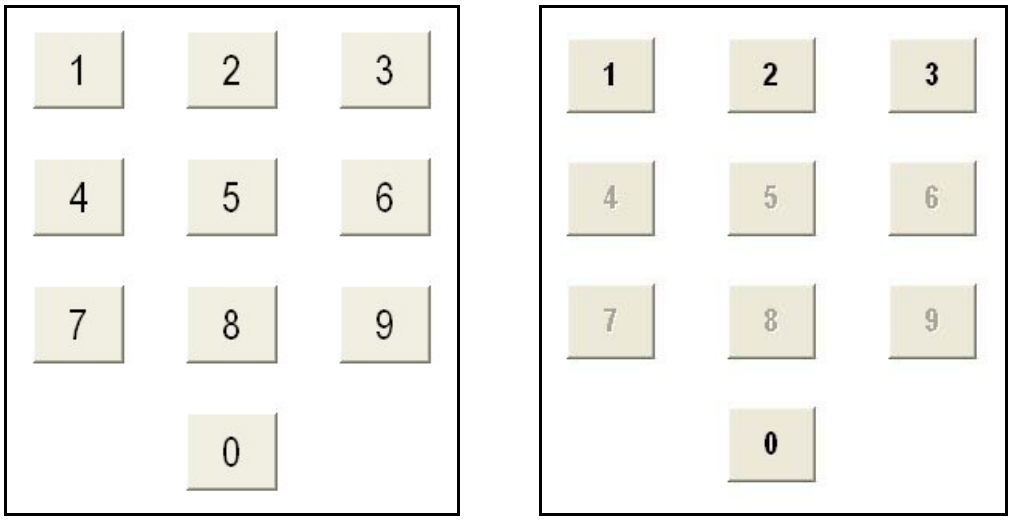


Figure 11: All Keys Enabled (left) and Keys Selectively Enabled (right)

We apply this principle to global navigation controls ("Next", "Back", "Clear") on our wizard interface. Enabling the "Next" button only once the user has entered the necessary information is a way of communicating to the user that they have completed the current task. We recognize that there is some potential for confusing the user if controls they expect to be enabled are "grayed out" and they are unable to proceed. In our experience to date we have found that users quickly develop and understanding of the problem. However we do recognize that creating an understanding of exactly how novices adapt to this technique warrants additional research. This feature was widely used in the earlier modules written in Visual basic. However, we have yet to carry this over as part of our philosophy in our new browser-based applications.

4.2.1.5 Two-level Data Validation

The ability to perform data validation during the time of entry can significantly improve data quality. Traditional approaches to validation use range checking. Upper and lower limits are set and data outside the range is disallowed. Increased accuracy can be achieved using dynamic range checking. Here, the upper and lower limits are not fixed. Rather the limits move dynamically based on a rule or set of rules. For example, in Figure 11 below you can see a "Value out of range" warning indicating the valid range for the patient's weight is between 28 and 76 Kgs. This range is calculated using the patient's date of birth and a look-up table of weights for upper and lower limits for a patient of a specific age to the closest year.

A major limitation of this approach to range checking is that if it is too constrained then the system may actually prevent the user from entering an extreme but valid data value. To get around this problem we have implemented two-level range checking. Here we create two ranges. The first range traps values in the traditional way, preventing unfeasible values from being entered. The second range traps values that are unlikely but plausible if they were valid outliers. This technique slows the user down, forcing them to look closely at what they have entered. If they recognize they have made a transposition error for example typing 27 instead of 72, then they can clear and reenter the correct value. However, if the value is truly 27, then the user can "Authorize" allowing the data to be saved. We believe the process of slowing the user down and forcing them to take a second look at the data value improves data accuracy. However, we have not evaluated this technique yet.

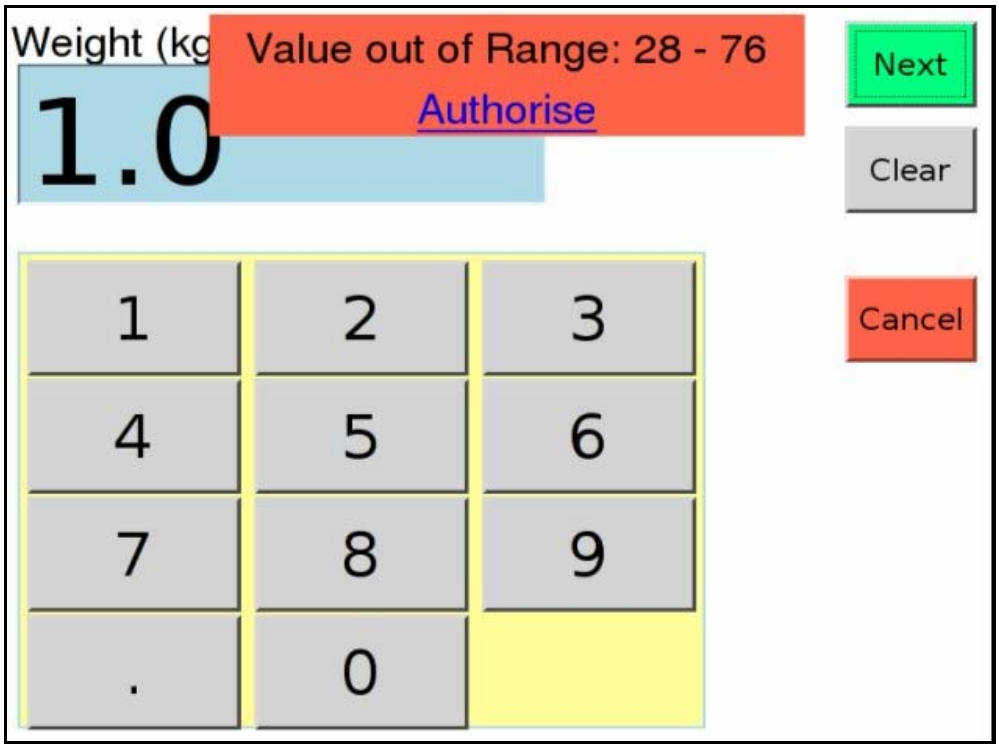


Figure 12: Screen shot demonstrating range validation

4.2.1.6 Low Power System

Early discussions with the Ministry of Health in Malawi sensitized us to the fact that the vast majority of care is not delivered in the central or district hospitals. Rather it is delivered through the many health centers scattered around the country, as significant number of which are off the main electrical grid. Recognizing that the ultimate goal was to get our technology into these sites, we focused on optimizing our hardware to consume as little power as possible. This philosophy paid off in September 2008 when we operationalized two health centers on the outskirts of Lilongwe that are off the grid using a combination a hybrid solar/wind solution.

Dedza District hospital is one of the BART pilot sites in Malawi. In October 2008 an electrical fire gutted part of the hospital where the main electrical panel is located. It took two days to restore power to the hospital during which time no lighting or electrical outlets were functional. Despite this prolonged power outage, the BART system functioned without interruption running entirely from our battery backup system. This level of endurance was only possible due to the power considerations during system design.

The ability of the system to perform under these extreme conditions was an important design consideration. While electrical fires as not so common, power cuts occur frequently, and with increased regularity during the rainy season. Conversely, load shedding, the practice of scheduled rotating blackouts to conserve power, is common during the dry season for countries that rely heavily on electrical power. Hospitals and health centers are not exempt. In South Africa load shedding is a part of everyday life now as the country is experiencing an unprecedented shortage of hydropower.

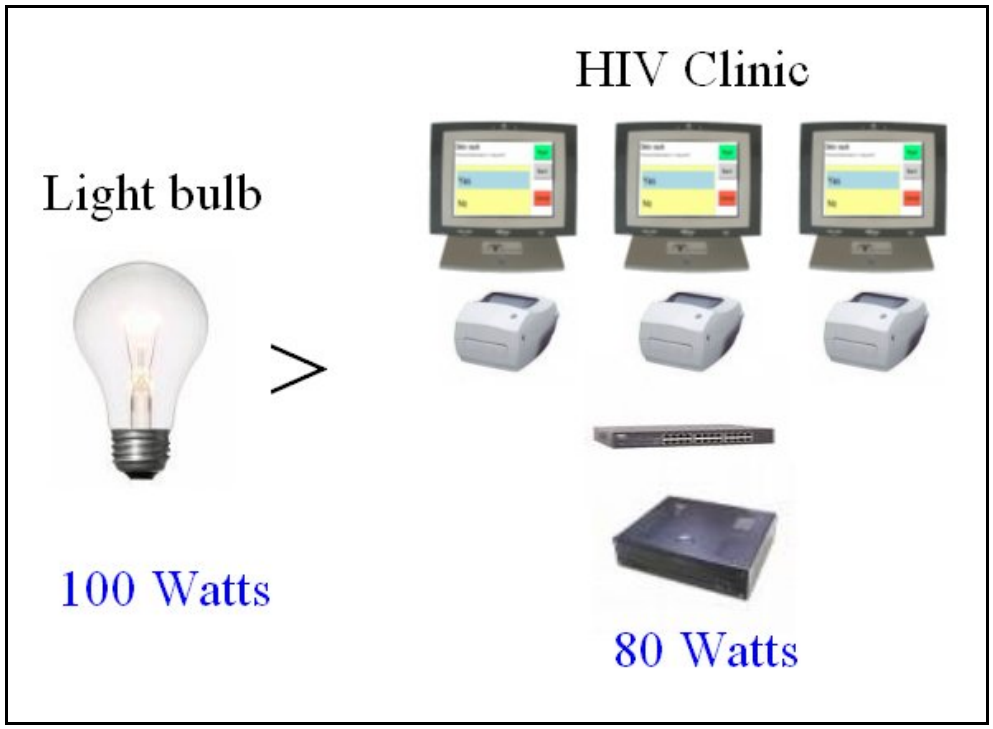


Figure 13: A typical BART deployment consumes less power than a 100 Watt light bulb

Using our current technology hardware we are able to run three touchscreen clinical workstations appliances complete with thermal label printers, a network switch and a server with the combined power consumption lower than a single 100 Watt light bulb (Figure 12).

The decision to optimize for low power significantly closes the technology design-reality gap for using for using an electronic system in health centers absent of electricity.

4.2.1.7 Choice of Barcodes as Machine-Readable Media

The use of barcodes has greatly simplified the use of the system, reducing data entry time and errors commonly associated with manual data entry. Users master the technology quickly. We do note that wrinkles and imperfections in the barcode can render it unscanable, or worse, generate an output that does not match the encoded data, potentially accessing information for a different patient. Based on this finding we decided to introduce a check digit into the barcode. Assuming printing of some form is taking place as part of the patient care process adding barcodes to documents or labels adds no additional cost and is relatively trivial to implement. Barcode scanner cost in the range of $130 - $150 and interface easily to most hardware through an option of ports including PS/2, serial, and now more commonly USB. Handheld scanners are made for harsh environments and seem to stand up well in developing-world healthcare settings. We have deployed more than 150 barcode scanners in Malawi since we first started patient registration in 2001. These were used scanners purchased on ebay at the time. To date we cannot report a single scanner failure.

4.2.1.8 Use of Thermal Labels as a Choice of Printing Technology

There are a variety of printing technologies to choose from including laser, thermal, dot matrix and inkjet. Inkjet printers are typically cost prohibitive to operate as replacement ink cartridges are very expensive. In a Western healthcare setting laser printing is the technology of choice. Experience has demonstrated that laser printers do not stand up well in developing-world setting. Laser printers utilize a mechanically complex set of gears, rollers and pulleys to move the paper from the input tray, through the toner path, across the fuser and into the out-feed tray. It is not uncommon to find excessive amounts of dust and debris inside laser printers. Additionally the significant amount of heat generated by the fuser attracts insects. I have found dead cockroaches and small ant nests inside many laser printers.

We believe thermal label printing is a highly suitable technology for printing in developing-world healthcare settings. There are two types of thermal printing technology. Direct thermal requires special heat-sensitive labels. These labels fade over time making them unreadable in a matter of months. These work well for things like labeling things that have a short life such as specimen tubes. The advantage direct thermal technology is that no printing ribbon is required, making it easier to support. The second type of thermal technology is called

thermal transfer. The technology uses conventional labels but requires a wax ribbon. Heat transfers the wax from the ribbon onto the label. These labels are long lasting and highly resilient. Labels are available in different materials providing a wide range of characteristics such as water resistance and ability to withstand extremely low temperatures (required for labeling specimens in a freezer). Labels generally come on a spool. Depending on the size of the label spools can accommodate several thousand labels. Many label printers are designed for harsh environments like warehouses and loading bays making them ideal for developing-world settings.

4.2.1.9 A Philosophy of Developing and Using Free and Open Source Software

We are committed to using free and open source software (FOSS) for our entire software stack, both as developers and consumers. Software costs only account for a fraction of the entire projects cost when taking into consideration hardware, deployment, maintenance and support. These costs can be significant nonetheless. The open source software community builds and maintains robust operating systems, database management systems and web browsers and web servers that adequately meet the needs for any software development project. We have standardized on Linux as our operating system of choice, MySQL as our database management system, Firefox as our web browser (which delivers the application), and Mongrel/NginX as our web/proxy server.

Another benefit of using FOSS is that it's globally distributed nature is a robust model for sustainable support software. Support channels are often informal, and generally highly assessable in the form of web-based list servers and news groups. This strategy of accessing support is highly suited to the developing world, where in-country support is typically not available and the cost of international calls to a help desk is prohibitive. Our development team relies on these resources, but also contribute to providing support for others by answering questions in IRC and on blogs, fully participating in the open source community.

4.2.2 Centralized 48-Volt Power Backup System

Power interruptions in Malawi can be frequent and prolonged, particularly during the rainy season (Nov – Apr). When a system is used in real-time it must be highly available. Backup

power is an essential prerequisite to keeping a system running when the supply of electrical power is unstable or unreliable. Choices for backup power are somewhat limited. Gas or diesel-powered generators can be used to provide power during a power interruption. Generators have several limitations. Due to the noise when running, generators need to be placed outside a building. This poses a risk of theft. They require periodic maintenance to run reliably and require fuel to run. These are significant challenges in a resource-poor setting. Since generators only come online once the power has failed there will be a period of a few seconds when no power is available. This would cause all computers to reboot, which can be disruptive and cause a loss of information. The use of a generator also requires a mechanism for the procurement and ongoing supply of fuel, which can be challenging in a resource-poor setting.

An alternative method of keeping computers running in the event of a power interruption is the use of uninterruptible power supplies (UPS). Under normal operating conditions the mains AC power passes through the UPS directly to the computer while simultaneously keeping a battery internal to the UPS on charge. In the event of a power failure the battery is used to power a small inverter inside the UPS that generates AC power to keep the computer running. UPSs come in a variety of sizes and are rates in Watts. The appropriate size is determined by the amount of power the computer (or other device) consumes and the desired run time after the mains power has failed. A 350-Watt UPS purchased in the United States costs in the order of $75 however they are heavy and shipping costs are expensive. The same model of UPS purchases in Malawi costs over four times as much. A UPS of this size can keep a small computer running for 30 to 45 minutes and a server class computer for 15 – 20 minutes only. Larger UPSs can be purchased to provide longer up-times, but at much greater expense.

Storage of electricity through the use of large deep-cycle batteries is a cost effective solution. The cost of a 12V, 7 Amp-hour (Ah), Gel Cell battery for a UPS is approximately $25 in Malawi (~$3.58 per Ah). A 12V, 96 Ah deep cycle battery is approximately $60 (~63 cents per Ah), a factor of 5.7 times cheaper based on storage capacity. Additionally the local capacity to repair UPSs in Malawi is extremely limited.

Power from the deep-cycle batteries can be utilized in two ways; 1) powering an inverter that turns the direct current (DC) from the battery into alternating current (AC) to power the computer, or 2) provide direct DC power to run the computer. Most computers run from DC but have an AC input and an internal power supply. If the computer requires AC (as most desktop

computers do) then the inverter solution may be the only option. Unfortunately, this is very inefficient. The inverter will have a conversion efficiency of no more than 87%. Once the AC reached the power supply internal to the computer it is again turned back into DC with a similar degree of inefficiency. The combined losses can reduce the capacity of the stored energy in the battery by 25% or more. The implication of this being that a set of batteries holding sufficient capacity t run a system for 10 hours will only run it for 7.5 hours or less. This is a significant loss of power.

The telecommunications industry has been around far longer than the computer industry (relatively speaking) and has a number of valuable lessons to share. Telecom has standardized on –48Volts DC in their switching stations (phone lines all over the world carry –48VDC). Certain hardware vendors (Dell, IBM, Compaq) make special DC power supplies for some of their server class computers to meet the needs of the telecommunications industry. We were able to procure dual redundant –48VDC power supplies for our Dell PowerEdge 2650 server, which we powered from a set of deep-cycle batteries. In a typical installation at a small site the server and network electronics (switch) are co-located in a steel cabinet for security and protection. In an adjacent cabinet a set of 4, 12Volt, 96 Ah deep-cycle lead acid batteries connected in series and connected to a 48Volt battery charger (Figure 13).

Figure 14: Steel cabinets housing server and battery system

The batteries are constantly providing power to the server and are on charge as long as mains AC power is present to power the charger. When an interruption in power occurs the

batteries continue to keep the server running without interruption (and associated rebooting) as long as sufficient charge remains in the batteries. When power is restored the charger restores the batteries to their original level of peak charge over a period of several hours.

Many other products are available to run from –48VDC, including network switches. The cost of an off-the-shelf –48VDC network switch is cost prohibitive however (>$1,000). To address this problem we standardized on a particular model of Dell 24-port switch (PowerConnect 2324) that had an internal power supply with an output of 5VDC to run the internal electronics of the switch. The switch costs less that $150 new from Dell and is widely available on the used market for roughly $75. With little effort we manufactured a circuit board that housed a 48Volt to 5 volt DC to DC converter and mounted on the same holes as the original power supply. The total cost of the modifications was approximately $25 per switch.

While this method of power backup worked extremely well for the server and network switch the workstations would also require backup power if the entire system as a whole was to function during a power interruption.

4.2.3 Extending Power over Ethernet to Run Workstations

Network-connected devices commonly use a data cable. The most common type of cable is called unshielded twisted pair (UPT). The cable contains four pairs of wires. In a standard 10Mbps or 100Mbps connection one pair is used for transmitting data and a second pair for receiving data. The two remaining pairs are unused (all four pairs are used in Gigabit Ethernet however, but there are still variations of PoE that allow power and data to be on the same wire). Power over Ethernet (PoE) describes a method of using the two unused pairs in the data cable to feed power to a device.

The main benefit of PoE is that it allows certain types of network devices such as wireless access points and web-cams to be installed away from power outlets, providing greater flexibility and reducing the cost of deploying such equipment. PoE does have some limitations. If power is injected into a device that is not PoE compatible it may cause damage to the device depending on how the manufacturer chose to handle the unused connections. If the unused connections are left open there will be no damage. However, if the manufacturer tied the unused

pins on the Cat-5 connector to ground (a common practice) this would short the cable resulting in damage and even possibly fire in extreme cases.

To address some of the challenges associated with deploying PoE the Institute of Electrical and Electronic Engineers (IEEE) developed the 802.11af standard that incorporates a handshaking protocol to prevent power from being provided to devices that were not PoE compliant. The standard has been useful in promoting the development of interoperable PoE devices of which there are currently many on the market (www.poweroverethernet.com).

One of the limitations of 802.11af is the restriction the standard imposes on the power that PoE devices can draw. The standard limits power to 12.75 Watts, above which the power injector will stop supplying power to the device. Engineering calculations based on a maximum Ethernet segment length of 100 meters and 26 gauge wire used in Cat-5 cable safely put the maximum possible power consumption at well over three time the 802.11af limit. It is not known why the limit was specified at such a conservative level. The information technology community has recognized that there is a range of devices that could be safely powered if the 802.11af power limitation were exceeded. Some manufacturers are already making 30-Watt and 60-Watt PoE injectors to meet this demand (www.phihongusa.com/html/midspans.html).

While there were a limited number of commercial devices available on the market at that time nothing was available in Malawi. In early 2001 we deployed homemade PoE solutions to run small network hubs and wireless access points. In late 2004 we formulated the concept of running a clinical workstation appliance using PoE. Eight prototypes were constructed and deployed in a VCT center in Mzuzu (northern Malawi) in May 2005. The prototypes worked well and the system demonstrated proof of concept for PoE powered computing devices. In early 2006 a prototype circuit board was designed that incorporated the PoE equipment within the clinical workstation appliance. The circuit board design went through three revisions and in May 2006 a production run of 50 circuit boards was manufactured.

Converting the clinical workstation appliances to use PoE has a number of significant advantages:

Installing a workstation no longer requires that a power receptacle be accessible. In earlier installations where power was not readily available an electrical socket, conduit and wire had to be purchased and an electrician had to be employed to install it. This was costly. We also discovered that during the winter when the nights were cold nurses on nightshift would unplug

the computer so they could plug in an electric heater, or a kettle to make tea, after which the computer rarely managed to get plugged back in again. Consequently we ended up installing a double socket to ensure that there would be a spare for other "appliances".

Installing additional sockets was not only costly but could double the amount of time required to do an installation. Installations can be disruptive for the host organization and attempts are made to install equipment outside regular business hours to minimize disruption. This further stresses the need to keep installation time as brief as possible.

Arguably the single largest benefit to using PoE in this setting is the ability to centralize power for all the workstations. In the PoE model the power to all workstations is fed from a central location. This is typically the point at which all network cables converge in the building; the location of the network switch. Power from the set of batteries is injected into the network cables leading to each workstation. This is a very cost-effective solution as it negates the necessity to have individual UPSs installed at each workstation. Furthermore, it provides a single point of connection between the mains AC power and the system, making it easier to monitor the power for fluctuations and noise spikes (lightning) that could potentially be harmful to the equipment.

The "single cable" solution also simplified troubleshooting and swap-out of equipment by non-technical personnel. "Is it plugged in? Yes or No".

The benefits described above notwithstanding we have noted two limitations of this approach:

- The RJ-45 connectors used for UTP Cat-5 cable are not very robust. The plastic locking tabs frequently break off, leaving the connector loose in its socket and making it susceptible to poor connection.
- We have observed that the quality of UTP Cat-5 cable locally available in Africa is poor. To save cost, many manufacturers substitute thinner wire for the two pairs that are traditionally unused. This does not appear to have a noticeable effect on data transmission. However, it does significantly reduce the capacity of the cable to carry power.

4.3 DETERMINANTS OF SUCCESSFUL SYSTEM DESIGN AND IMPLEMENTATION

We describe two complementary frameworks that can be used both at the design phase, as well as to evaluate existing systems. RASUI is an engineering framework that focuses on the "quality" of the system without consideration to the specific environment. The Design-Reality Gap (D-R Gap) model is a framework that assesses and supports the management of the risk of a particular implementation by examining how well the system design fits the realities of the current situation in each of seven dimensions. We use these frameworks to systematically assess the technology design decisions that were made as we developed the Baobab systems.

4.3.1 RASUI : An Engineering-oriented Framework

Systems engineering is an interdisciplinary approach and means for enabling the realization and deployment of successful systems. This approach established around WWII to manage the development of highly complex projects revolves around a set of non-functional requirements commonly referred to as "-ilities". Industry has identified an important subset of these metrics to characterize the quality of a system: Reliability, Availability, Serviceability, Usability, and Installability, collectively referred to as RASUI (116). We have included accessibility as a 6th metric. Accessibility is a key factor in the adoption of an EMR. This is critically important when the EMR is used in realtime at point-of-care. We briefly describe each metric below:

- Reliability: the ability of a system to perform and maintain its functions during routine as well as hostile or unexpected circumstances.
- Availability: the proportion of time a system is in a functioning condition
- Serviceability: the degree of ease with which technical staff can identify, troubleshoot and repair a system
- Usability: the ease and speed with which a user can become proficient at using a system
- Installability: the degree of easy with which a new system can be deployed at a site
- Accessibility: the degree of ease with which a user can access the system from their current location.

Inter-dependencies exist between these metrics. Serviceability, installability and usability involve design decisions, but can potentially be achieved without incurring additional costs. The developer must determine which metrics are of greatest importance in the context of the system being developed and adjust the design accordingly.

4.3.2 Design-Reality Gap Model: A Risk Management Framework

Heeks describes the design-reality gap; a framework used to score the likelihood of success or failure of specific implementations (117). The design-reality gap model has seven dimensions summarized by the acronym ITPOSMO and shown below.

1. Information – Are you planning to collect significantly more/different information that you did previously?
2. Technology – Can you work with the technology already in place or will additional equipment be required?
3. Processes – Will there be significant changes to processes or work flow?
4. Objectives and values – To what degree does the new system conflict with the objectives and values of the stakeholders?
5. Staffing and skills – Will there be additional staff or significant training required?
6. Management systems and structures – will there be a significant change to lines of reporting or levels of power or influence?
7. **O**ther resources: time and money – How likely will the necessary funding be available for the successful completion of the project in the allotted timeframe?

Each dimension is scored on a scale of 0 to 10 as follows: 0 = no change between the design proposal and current reality; 5 = some degree of change between the design proposal and current reality; 10 = complete and radical change between the design proposal and current reality. Summing the scores of each dimension provides a score of expected success or failure of the system. The higher the overall score the greater the risk of failure.

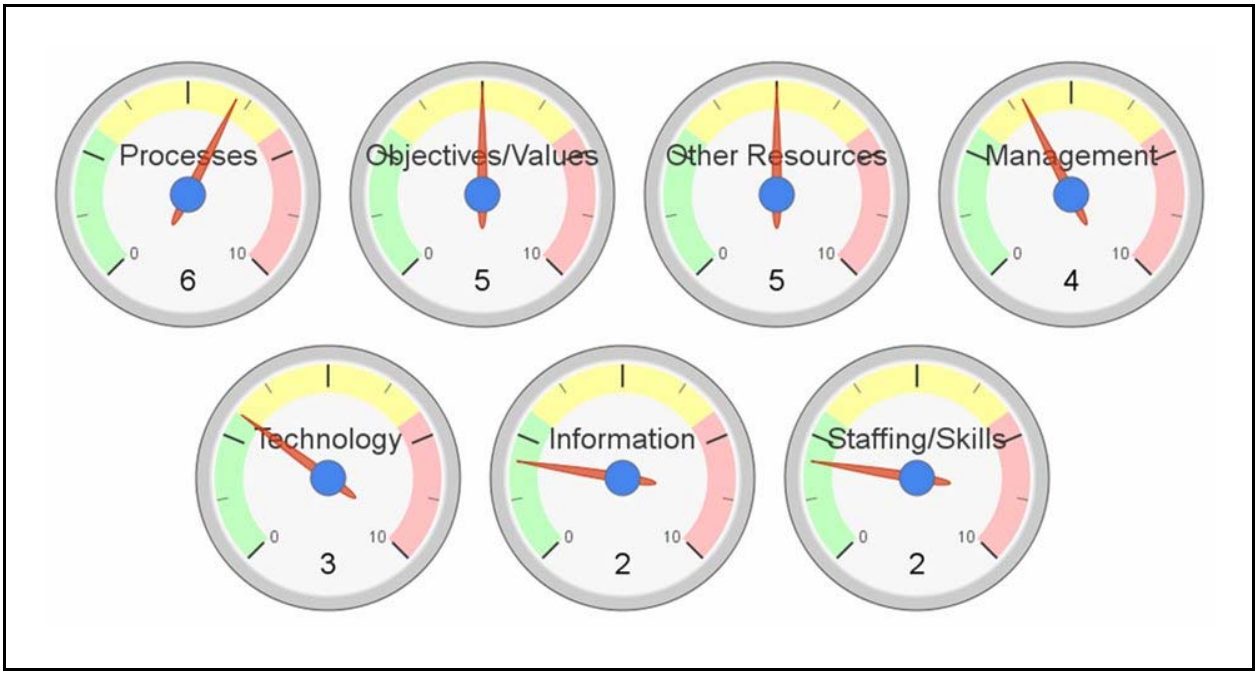


Figure 15: Sample Design-Reality dash board

4.3.3 Applying the Frameworks to Technology Choices

In Table 3 below we describe each of the technologies used and their contribution to implementation success with respect to the two frameworks described above.

Table 3: Technology choices in the context of RASUI and D-R Gaps

Touchscreen clinical workstation appliance	See each of the nine components below.
Touchscreen	In Chapter 3 we cite low levels of computer literacy among healthcare professionals. We recognize that introducing computers into the healthcare delivery process represents a large design reality gap, particularly when used at point-of-care. The high usability of the touchscreen over a traditional mouse and keyboard approach greatly reduces both the process and the staff and skills D-R Gaps.
Appliance model	In Chapter 3 we describe both an inadequate infrastructure for

	equipment maintenance (staff and skills D-R Gap) and limited budgets for healthcare (time and money D-R Gap). The appliance model is generally a more cost effective solution and requires less maintenance that a traditional desktop computer as it has generally fewer components and in optimized for reliability. Appliances are also more serviceable and installable than generic computers as they require no configuration. Since appliances are single purpose devices they can never be unavailable due to a user performing some non-related task on the system. This greatly increases the accessibility of the hardware.
Wizard Interface	The wizard approach generally simplifies the use of the system increasing its usability for users with low levers of computer literacy and also a better fit for point-of-care application where the user has to focus on both the computer as well as the process of patient care. This helps to reduce the process D-R Gap.
Rule-based enabling of interface controls	Low staffing levels, low levels of computer literacy among healthcare workers and high turnover of staff all demand that a system be highly usable. Rule-based enabling of interface controls help guide the user through the software application making the system more usable.
Two-level data validation	Systems that do not enforce data validation are prone to data quality problems. Constraining values excessively will prevent users from entering valid outlier values, resulting in user frustration. Two-level data validation provides a mechanism to ensure high data quality while giving the user options to enter valid outlier values. This greatly increases the usability of the system.
Low power systems	When systems are used in real-time at the point-of-care high system availability is paramount. Given the unreliable nature of the electrical grid in the developing world some form of backup power is essential to mitigate power outages. The use of low power devices can greatly increase system runtime in backup mode, maintaining high system availability. Being able to maintain the same workflow, unaffected by the power outages greatly reduces the process D-R Gap.

Barcoding	In Chapter 3 we raise the issue of the absence of patient identifiers in many developing countries. As described earlier, we believe some form of standardized national patient identifier is fundamentally necessary to maintain continuity of care. Barcodes used in combination with label printers (described below) can significantly reduce the design-reality gap in both the process and the staff and skills dimensions.
Thermal label printing	We recognize that documentation is a necessary component of healthcare delivery. Clinicians need to perform a variety of documentation tasks such as completing lab order forms, writing prescriptions and filling out discharge forms. If we ask clinicians to use information technology at the point-of-care while continuing to do manual documentation we will only increase the burden of work they have to perform. However, if we can capture all the information we need electronically and reproduce it easily on labels we can significantly reduce or even eliminate manual documentation entirely. The use of the labels to support documentation reduces the process design-reality gap considerably. Thermal technology is a highly reliable method of printing especially suited for harsh environments.
Free and open source software (FOSS)	The point-of-care approach requires an increase in the number of workstations, and consequently software licenses. Significant cost savings can be realized when using FOSS on a large scale deployment reducing the financial D-R Gap. Additional savings are realized as support is generally provided by the open source community.
Centralized 48-Volt power backup system	A centralized power back up system provides many benefits. Overall system availability is increased as power management is done at a "system" level rather than at the individual workstation level. The cost of installing a centralized system is amortized over the total number of devices supported, thereby reducing the financial D-R Gap.
Power over Ethernet to	Many sites lack adequate electrical infrastructure to support the

run workstations	installation of an electronic system. Power over Ethernet greatly increases the installability of a system as it make no assumptions about the availability of electrical outlets in clinic rooms, and does not require a qualified electrician to install.

4.4 WIDER IMPACT OF TECHNOLOGIES DEVELOPED

Since the early work in the pediatric department at KCH in 2001 we have shared ideas with a number of international organizations doing similar work in this field. My colleagues and I have collectively presented this work at more than 40 different venues spanning 11 countries. In some cases we have been influenced by what we have seen and incorporated aspects of the work of other groups into our own (e.g. adopting the OpenMRS data model in 2006). In other cases we have influenced the trajectory of developments in other groups. Some of these are described below.

4.4.1 Kenya Malarial Anemia Study

In 2003 following a presentation I gave at the University Of Pittsburgh Graduate School Of Public Health I was approached by a faulty member undertaking a large NIH-funded malarial anemia research study in Kenya at that time. At his request he we recruited a programmer (Zach Landis Lewis) for him, did technology transfer, and provided hardware. They subsequently deployed a version of the point-of-care pediatric admission system we had created in 2001 in a district hospital in Kisumu Kenya for the purpose of collecting data for the research study (118).

4.4.2 SmartCare incorporating a touchscreen user interface into their ANC system

In 2004 the project leader for the development of SmartCare in Zambia (see Section 3.3.3) visited Malawi to see the Baobab Voluntary Counseling & Testing system deployed at MACRO

and the Antiretroviral Therapy system deployed at the Lighthouse clinic. Following this visit the SmartCare system was refactored to include a touchscreen user interface component.

4.4.3 PIH piloting touchscreen system for patient registration in Malawi

In March 2007 the Partners in Health site in Neno, Malawi launched a variation of the Baobab patient registration system. The hardware deployed in Neno matches a standard Baobab site deployment. The software has been modified to work against a newer version of the OpenMRS data model and runs along side a full OpenMRS stack receiving data from other sources via InfoPath data input forms. The Neno site is running a Baobab server, power backup system and full power over Ethernet.

4.4.4 CIDRZ adopting a low-power think client approach for ZEPRS

In June 2007 Baobab was approached to assist the Center for Infectious Disease Research in Zambia (CIDRZ) in getting their Zambia Electronic Perinatal Record System (ZEPRS) application running on think client hardware (see 3.3.5). Over the past 18 months the electrical power grid in Lusaka, the region of Zambia where CIDRZ operates, has become extremely unreliable. CIDRZ require their nurses to enter data into ZEPRS immediately after the patient visit. The unreliability of the power grid was extremely disruptive to continuous system use.

In August 2008 the head of the CIDRZ information systems team spend two days with us in Lilongwe during which time (and with some assistance from RTI, the developers of ZEPRS) we were able to achieve proof of concept running ZEPRS on our low-power clinical workstations (with mouse and keyboard, not touchscreen) and a low-power server. CIDRZ is currently piloting this at one of their sites in Lusaka, running the system entirely from solar power.

4.4.5 MSF France opt to install BART over FUCHIA in Malawi

In October 2007 we were contacted by Médecins sans Frontières (MSF) to discuss alternatives to using FUCHIA at their network of sites in Malawi. MSF was the first site to dispense antiretroviral therapy in Malawi and has a cohort in excess of 15,000 patients on ART across its main site at Chiradzulu district hospital and nine satellite health centers. In December 2008 representatives from MSF in Malawi met with the Ministry of Health HIV Unit and expressed their wishes to pilot the Baobab ART system at four of their sites in Malawi's Chiradzulu district in 2009. Discussions regarding the specifics of the implementation are ongoing.

4.4.6 Intl. Union Against TB & Lung Disease Collaboration on NCD

In February 2009 in collaboration with the International Union Against Tuberculosis and Lung Disease (IUATLD) we started to develop and pilot a prototype touchscreen-based system for managing patients with diabetes and hypertension. This is a two-year initiative that will result in the development, deployment and evaluation of a system at two large central-hospital based clinics in Malawi.

4.4.7 Partners in Health to Pilot Touchscreen Patient Registration in Rwanda

In February 2009 at the request of the PIH-Rwanda team we procured two next generation touchscreens computers for them to do prototyping work. PIH plans to undertake a pilot deploying a touchscreen-based patient registration system at 25 sites in Rwanda in late 2009.

In this chapter we have described the landscape of EMRs in the developing world, the mix of technologies we developed and employed in creating systems for Malawi, and spin-off from this work in terms of influence on other organizations doing similar work internationally. We recognize that a point-of-care approach to using an EMR represents a paradigm shift, and with any radical change in process there can be both positive and negative impact. In medicine

the term iatrogenic refers to the negative impact of a therapy or treatment. The informatics community has coined the term e-iatrogenic to refer to any negative impact of introducing information technology into the healthcare delivery process (38). Concerns were raised as to the potential negative impact on data quality when using a system at point-of-care. We recognize that incorporating technology into existing workflow is challenging, and could have a negative impact in several areas. However, in Chapter 2 we articulate a position that data quality is already greatly compromised when data entry is delegated to clerks with no training in medical terminology, typically entered retrospectively, and transcribed from paper. To better understand the impact of point-of-care systems on data quality we conducted as small study comparing the accuracy of data entered at point-of-care with the accuracy of that same data entered retrospectively. We describe this study and our findings in Chapter 5 below.

5.0 IMPACT OF REALTIME POINT-OF-CARE USE ON DATA QUALITY

To better understand the contribution of a realtime point-of-care approach on data quality a study was designed and conducted. The point-of-care approach has documented benefits in a Western setting including realtime data validation, decision support and protocol guidance. We believe these benefits can be extended to the developing-world setting. However, we need to ensure that there is no negative (e-iatrogenic) impact in data quality as a result (38). The study described below contrasts the level of accuracy of data collected using touchscreen clinical workstation appliances and two different data entry paradigms; entry at point-of-care vs. retrospectively entered data. We choose our null hypothesis to be that there is no difference between the accuracy of the data collected at the point-of-care and data collected retrospectively from a paper chart.

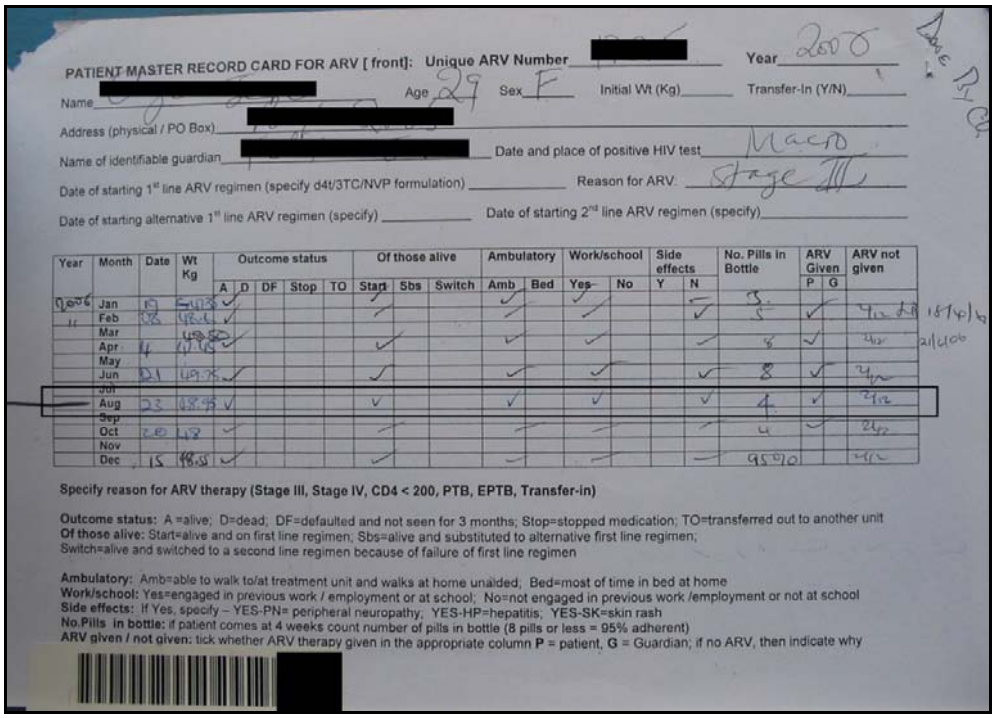
5.1 BACKGROUND OF DATA QUALITY STUDY

In Malawi, the Ministry of Health has adopted a nationally standardized approach to delivering HIV care and treatment. Underpinning this approach is a fundamental requirement for uninterrupted drug supply, patient adherence to therapy, and compliance with follow-up (119). The absence of complete and accurate data for monitoring and evaluation (M&E) could result in treatment failure paving the way for drug-resistant viral strains (120).

Malawi had 214 public sector sites delivering ART as of September 2008. The ability of the HIV Unit to conduct efficient and effective monitoring and evaluation is critical to the success of Malawi's ART program. At high-burden sites in Malawi (starting 150 or more new patients on ART per month) site supervision by the HIV Unit is largely focused on manual

auditing of patient records to ensure accurate statistics. This leaves little time to focus on specific clinical care issues.

Malawi's national HIV program uses a paper record to document the patient encounter. This record, know as the patient master card, is completed by hand (Figure 14). The document is formatted as a simple table with rows representing visits and columns representing clinical variables. This master card represented the primary record. All MoH staff working in HIV care and treatment receive training in how to complete the form. The master card serves as both a clinical document for longitudinal patient care, as well as a record from which cohort analysis was conducted for programmatic monitoring and evaluation.



PATIENT MASTER RECORD CARD FOR ARV [front]: Unique ARV Number [redacted] Year 2006

Name [redacted] Age 29 Sex F Initial Wt (Kg) Transfer-In (Y/N)

Address (physical / PO Box) [redacted]

Name of identifiable guardian [redacted] Date and place of positive HIV test Macro

Date of starting 1st line ARV regimen (specify d4t/3TC/NVP formulation) Reason for ARV: Stage III

Date of starting alternative 1st line ARV regimen (specify) Date of starting 2nd line ARV regimen (specify)

Year	Month	Date	Wt Kg	Outcome status					Of those alive			Ambulatory		Work/school		Side effects		No. Pills in Bottle	ARV Given		ARV not given
				A	D	DF	Stop	TO	Start	Sbs	Switch	Amb	Bed	Yes	No	Y	N		P	G	
2006	Jan	10	49.5	✓					✓			✓		✓			✓	5	✓		4m 18/4/06
"	Feb	08	48.6	✓					✓			✓		✓			✓	5	✓		
	Mar		49.5	✓					✓			✓		✓			✓	8	✓		4m 21/4/06
	Apr	14	47.7	✓					✓			✓		✓			✓				
	May																				
	Jun	01	49.5	✓					✓			✓		✓			✓	8	✓		4m
	Jul																				
	Aug	03	48.95	✓					✓			✓		✓			✓	4	✓		2m
	Sep																				
	Oct	20	48	✓					✓			✓		✓			✓	4	✓		2m
	Nov																				
	Dec	15	48.5	✓					✓			✓		✓			✓	95%0			4m

Specify reason for ARV therapy (Stage III, Stage IV, CD4 < 200, PTB, EPTB, Transfer-in)

Outcome status: A =alive; D=dead; DF=defaulted and not seen for 3 months; Stop=stopped medication; TO=transferred out to another unit
Of those alive: Start=alive and on first line regimen; Sbs=alive and substituted to alternative first line regimen; Switch=alive and switched to a second line regimen because of failure of first line regimen

Ambulatory: Amb=able to walk to/at treatment unit and walks at home unaided; Bed=most of time in bed at home
Work/school: Yes=engaged in previous work / employment or at school; No=not engaged in previous work /employment or not at school
Side effects: If Yes, specify – YES-PN= peripheral neuropathy; YES-HP=hepatitis; YES-SK=skin rash
No.Pills in bottle: if patient comes at 4 weeks count number of pills in bottle (8 pills or less = 95% adherent)
ARV given / not given: tick whether ARV therapy given in the appropriate column **P** = patient, **G** = Guardian; if no ARV, then indicate why

[redacted]

Figure 16: Patient master card

The HIV Unit relies on quarterly cohort analysis as their main tool for monitoring and evaluation. It is the responsibility of each site to compile their reports. The process of compiling reports requires staff on site to manually update the site ARV register (one per site) by reviewing master cards of all patients receiving treatment during the prior three-month cohort period. Once the ARV register has been updated to reflect the status of each patient at the end of the cohort period, outcomes are manually tallied from the register and recorded on an aggregate summary

sheet. A quarterly cohort report, cumulative cohort report and a survival analysis are compiled every three months. These reports are then reviewed and audited by a supervision team from the HIV unit during quarterly site visits. Supervision teams observed at many sites that as the burden of patients receiving ART at grows beyond roughly 1,500 the effort required to compile reliable quarterly cohort reports becomes too great. This resulted in delays in getting reports and unacceptably high levels of error thereby compromising the HIV Unit's ability to monitor its programme effectively (121).

In 2005, at the request of the HIV Unit, a task force was created to investigate the feasibility of introducing computers to capture patient data and produce cohort reports automatically. A number of electronic medical record systems (EMRs) have been developed and applied to care and treatment of HIV/AIDS in the developing world (102, 105, 109, 122-124). Many of these systems rely on clerks to retrospectively enter data from paper-based records. Data entry may occur anywhere from minutes to weeks after the event. Intuition suggests that the combined effects of the time lag between data collection and data entry, the potential for transcription error and the effect of having data entered by a third party (frequently a non-clinical person with no training in medical terminology) could have a negative impact on data quality. A recently published study on ART data quality conducted by the ART-LINC collaboration looked at ART data collected in 15 countries across Africa, South America and Asia (Malawi included). The study concluded that the quality of data collected by ART treatment programmes is generally unsatisfactory for many sites involved in the scale-up of ART in resources-limited settings, including some that use electronic medical records for data management (125).

Over the course of several task force meetings two models for how computers could be incorporated into HIV clinics were proposed. The first model comprised a single desktop computer used by a dedicated clerk to enter patient information retrospectively from patient master cards. The second model comprised touchscreen computers located in every clinic room connected to a central server where data is stored. With the latter model doctors, clinical officers and nurses would use the touchscreen workstations to enter patient information at the point-of-care. The latter point-of-care model was chosen based on prior successes using touchscreen computers in similar settings in Malawi (108, 126). With the assistance of the task force, the HIV Unit created a specification document to describe the required functionality of the proposed system.

In 2006 the Centers for Disease Control made funds available to the HIV Unit to conduct a pilot implementation. Due to the high burden of patients receiving care at Queen Elizabeth Central Hospital in Blantyre (QECH) the HIV Unit requested that the site be the first site to receive an electronic system designed to meet the national specification established by the taskforce. In April 2006 we deployed a prototype touchscreen-based computer system in the HIV clinic at QECH. The intent of this system was to replace the recording of patient information on paper master cards. However, it was decided that the paper system would be maintained until there was sufficient evidence that the computer system was working reliably, had been incorporated into daily use, and was institutionalized within the clinic.

QECH operates a pediatric ART clinic on Mondays and Tuesdays and an adult clinic Monday through Friday. Treatment protocol within the ART clinic requires that clinicians (doctor or clinical officer) see complicated patients and those patients who have not been seen by a doctor or clinical officer in more than three months. Clinicians do not dispense medications however, so patients are sent to see a nurse to receive their antiretroviral drugs after the clinician visit. The remaining patients accounting for about 60 percent of all patient visits are managed entirely by nurses trained in providing ART.

In October 2007 the computerised ART system installed in the ART clinic was upgraded to a new browser-based version (described in 3.11.1 above). This upgrade required that existing data in the old system be migrated to a new format (OpenMRS data model). In the process of moving the data over to the new system it was discovered that some patient visits had been entered twice. Ordinarily this should not have been possible. However there was a bug in the prototype that allowed this to happen. From discussions with clinic staff we concluded that the duplicate records were most commonly created when a nurse dispensing medications retrospectively entered visit details from a patient's master card unaware that the clinician who saw the patient in the clinic room had already done so. Analysis of system user ID codes and electronic time stamps on duplicate pairs supported this scenario as the cause of double entry.

Preliminary analysis identified 1,938 pairs of duplicates. Of these, roughly 1,026 of the pairs were identical. The remaining 912 records differed between the first and second entry on one or more field. Duplicates were limited to only those visits where the first entry was done by a clinician (doctor or clinical officer) and the second entry was done by a nurse based on user ID

codes and time stamps recorded in the system. For the purpose of this study we refer to information entered by the clinician while seeing the patient as the *point-of-care entry* (PoC) and information entered by the nurse after the clinician visit was completed as the *retrospective entry* (Ret). After filtering a total or 805 duplicate visit pairs remained and of those 725 (80%) visits differed on one or more fields. This discordance indicates that either the one or both records are incorrect.

During a preliminary analysis of the data it was determined that discordance was significantly high on three fields; weight, pill counts, and side effects. Discordance was greatest on patient weights differing in 44% of cases, however mostly in the decimal place limiting the impact to care of infants. Pill counts (proxy for adherence) are second with 39% disagreement followed by side effects with 18% disagreement. Additional analysis revealed that many weights differed by only 0.1 Kgs (e.g 67.5Kgs vs. 67.4Kgs). This scenario is most likely explained by the fact that the electronic scale used in the clinic reported weight to two decimal places and rounding was being done (sometimes rounding up and other times rounding down) during data entry.

5.2 STUDY OBJECTIVES

The specific objectives of this study are as follows:

- To estimate and access the difference in the accuracy of data entered into the touch-screen workstation at point-of-care versus accuracy of data entered retrospectively among staff working at the ART clinic at QECH
- To identify possible predictors of error (e.g person entering the data, day of week, etc.)
- To characterize the nature and frequency of numerical errors
- To assess whether an error of one kind makes other errors more likely

Approval for this study was obtained from both the University of Pittsburgh Institutional Review Board and the University Of Malawi College Of Medicine Research Ethics Committee (COMREC).

5.3 STUDY DESIGN

Data was extracted from the ART system database. Duplicate visits were determined by looking for patients who had exactly two visits recorded on any given day where the first visit was done by a clinician (doctor or clinical officer) and the second visit done by a nurse based on user ID.

5.3.1 Establishing a Gold Standard

The use of the master card was maintained in the clinic as a backup mechanism after the introduction of the EMR, with the intention of discontinuing use once the EMR had been validated. Since the master card represents the closest approximation to the "truth" in this setting it has been used as the gold standard for the purpose of this study.

When deploying the Baobab Antiretroviral Therapy system the ministry of Health had requested that we back-enter all historical data from paper records. To facilitate this, a small browser-based data entry application was created that allowed data to be captured from digital images of patient master cards. All data was double entered and cleaned to improve accuracy. This application was repurposed and used to create an electronic version of the gold standard.

5.3.2 Establishing Representativeness

This study compares the accuracy of data entered into an electronic ART system at point-of-care (PoC) with data entered into the same system retrospectively. The data being analyzed is a convenient sample of 805 records that were double-entered by mistake from a total of more than 79,000 records in the system.

We believe the PoC (first) entry was done by the clinician (doctor or clinical officer) in the same way as all other PoC records. Consequently the data being analyzed is considered to be representative of the larger set of data entered by clinicians at PoC.

The retrospective (second) entry into the system was done by a nurse from a patient master card that had been completed by a clinician during the clinic visit. Nurses also see patients autonomously and are required to enter the visit details into the system. Nurses report that they frequently defer the entry of patient master cards until later in the day due to the high volume of patients seen by nurses in this clinic. Consequently we believe the retrospective data being analyzed here is representative of data retrospectively entered by nurses in this clinic.

5.3.3 Unit of Measurement:

Of the 805 duplicate records analyzed in this study, 725 have at least one field discordant between the data captured by clinicians at point-of-care and data captured by nurses retrospectively. For the purpose of this study the unit of measurement is the individual field, not the entire record. Each record contains the following fields:

- UserID (person entering the data into the EMR, de-identified)
- Patient sex (from demographic record, not visit record)
- Patient age (from demographic record, not visit record)
- Visit date
- Time stamp when the record was entered into the system
- Patient Outcome (alive, dead, transfer-out, stop)
- Regimen (start/sub/switch)
- Patient weight at visit
- Pill count (number of previously dispensed pills remaining)
- Side effects (none, SK-skin rash, HP-hepatitis, PN-peripheral neuropathy)
- ARVs given to (patient, guardian)
- Patient ambulatory (y, n)
- Patient able to attend work/school (y, n)

5.3.4 Data Analysis

The underlying database management system used by the ART system and the double entry system is MySQL™. To facilitate data analysis, the demographic data, point-of-care record, retrospectively entered record, and gold standard record for each patient were pivoted into a single table containing one record per visit.

To facilitate statistical analysis specific fields of the table was imported into Stata™ using the Stata's ODBC connectivity functionality. Both MySQL and Stata were run on the Ubuntu Linux operating system.

All queries have been stored in a text document so the results can be easily reproduced.

5.4 RESULTS OF DATA QUALITY STUDY

Of the 805 duplicates identified, four had missing ARV numbers and consequently the corresponding patient master cards could not be located for validation.

The distribution of the remaining 801 patients by age and sex is shown below.

Table 4: Duplicate visits by age and sex

	Male	**Female**	**Total**
14 years and younger	53	53	106 (13%)
15 years and older	251	444	695 (87%)
	304 (38%)	497 (62%)	**801**

To complete the analysis we attempted to retrieve the corresponding master cards from the medical records office to establish the gold standard data set. Of these 801 duplicate patient

visits we were only able to find master cards for 705 (88%) visits. Visit dates range 20th June 2006 to 25th October 2007.

The distribution of age and sex of the discordant visits is described in Table 5 below.

Table 5: Duplicate visits by age and sex for visits where a patient master card was retrieved

	Male	**Female**	**Total**
14 years and younger	35	37	72 (10%)
15 years and older	230	403	633 (90%)
	265 (38%)	440 (62%)	**705**

The retrieval rate for master cards broken down by sex and age is shown in Table 6 Below. Regrettably we were not able to retrieve 32% of the pediatric files.

Table 6: Retrieval rate for master cards by sex and age

	Duplicates	**Located**	**Missing**
Child, Male	53	35	18 (34%)
Chile Female	53	37	16 (30%)
Total Child	**106**	**72**	**34 (32%)**
Adult, Male	251	230	21 (8%)
Adult, Female	444	403	41 (9%)
Total Adult	**695**	**633**	**62 (9%)**
Total	**801**	**705**	**96 (12%)**

The retrieval of master cards was confounded in two significant ways:

- Medical records office (Figure 15) is very small, has only one filing cabinet supplemented by wooden shelving. The office is greatly understaffed, with only two clerks managing more than 8,000 patient files. It is common for master cards to get misfiled.

- The clinic keeps the patient master card in a folder along with clinical notes. Files are frequently taken out of the clinic for chart review during clinical meetings. This is true for both adult and pediatric files. However, this is apparently more prevalent for pediatric patients according to clinic staff.

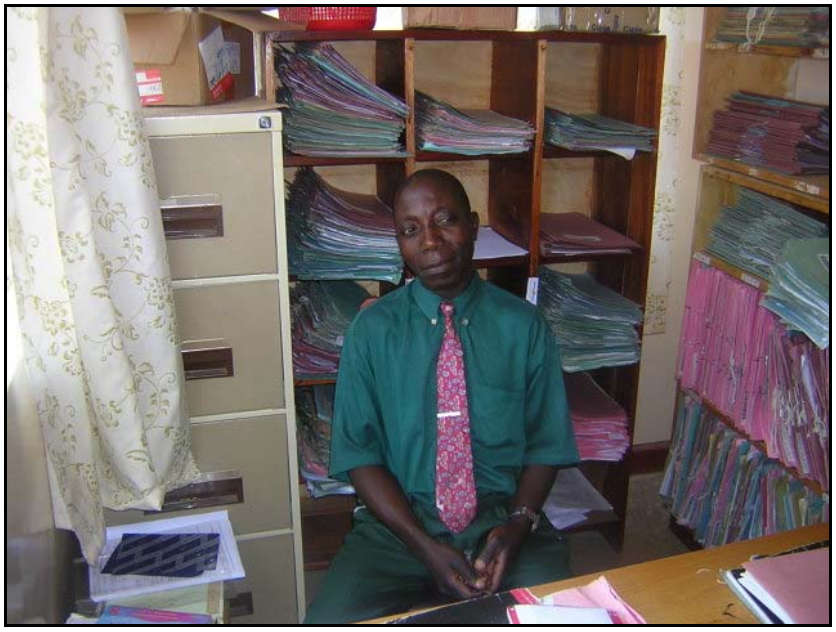


Figure 17: ART Clinic Medical Records office at QECH

For the purpose of this study we elected to restrict the analysis to the adult patients only for the following reasons:

- Only 66% of the master cards could be retrieved for the pediatric patients. We believe that the missing 34% may represent more complicated patients and were missing from the clinic because they had been taken for chart review. Based on this we question the representativeness of the 72 pediatric patients we were able to locate.
- The master card was designed with adult patients in mind. There are specific fields that when applied to a child do not make sense (e.g. able to attend work/school, ARVs given to patient or guardian, alternative regimens for pediatric patients). Based on this we felt the overall accuracy of the dataset would be compromised by including the pediatric records.

After dropping the 72 pediatric records we remained with 633 records for adult patients. The frequency distribution of visits by month is show in Figure 16 below.

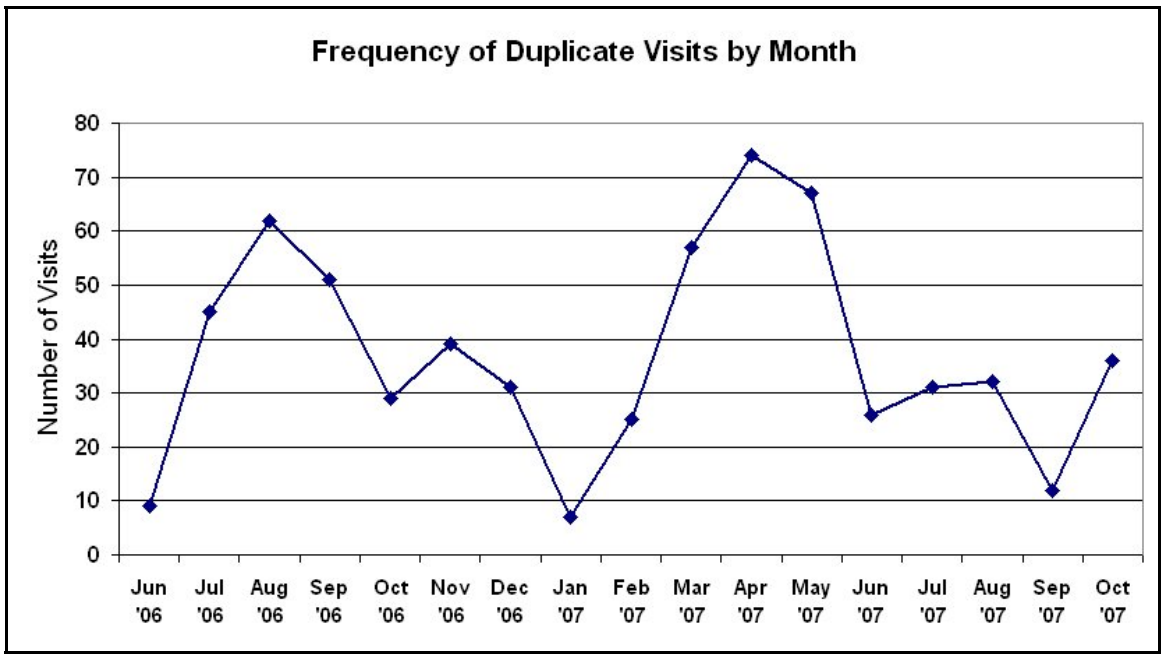


Figure 18: Frequency of duplicate visits per month

The significant variation in duplicates from month to month caused some concern as to the representativeness of the data. We believe the variations in duplicates are created by a combination of the following factors:

- The system went live at the end of April 2006. Training took place for a period of several weeks. We made it very clear to clinicians and nurses that patient care was the first priority and should not be compromised by the need to get the data entered into the system. We employed two staff to help clinicians with gaining proficiency, answer questions and report problems or bugs in the system. At the end of each day all patient files were checked to ensure that they had been entered into the system. For the first three months a significant amount of back entry had to be done to capture visits that had been missed. We believe the low number of duplicates (nine) for Jun 2006 is a result of slow uptake among clinicians to use the system at the point-of-care.

- When the system was first deployed in April 2006 the intent was to remove the use of master cards once proof of concept had been demonstrated. Unfortunately, no clear criteria had been established as to what constituted success. Consequently, both the electronic system as well as the master cards continued to be used. In mid 2007 discussions among the clinic staff resulted in a meeting with clinic management where they presented their position as a group that they wanted to use only one system. By late 2007 the use of the system by clinicians has dwindled significantly, with nurses and clerks picking up the missed clinician visit entries. Consequently the number of duplicates generated during this period was low.
- The number of overall clinic visits generally increases through the 17 month period, with the exception of a significant drop in September 2007. This is consistent with a low number of duplicates created in that month (11).
- One two occasions we had problems with the power backup system and eventually had to upgrade. We attribute the low number of duplicated in January 2007 to power problems during this period preventing the clinicians from using the system at point-of-care.
- Due to the high turnover of clinicians in the clinic it was hard to ensure that new clinicians were trained and given passwords on arrival. Nurses were aware that while the system was supposed to be used at point-of-care, many new clinicians were not actually using the system in the clinic room. A core group of nurses in the clinic, committed to ensuring that the data get entered, got into the habit of entering the record when they were not sure the clinician had done so.

Given the slow uptake in system use and the fact that this was only the second month the system had been used (and first month duplicates appeared in the data), we consider the nine duplicate visits from June 2006 to be non-representative and have dropped them from the analysis, leaving a **total of 624 visits to be analyzed**.

5.4.1 Description of the Dataset Under Analysis

The system users responsible for the point-of-care entry comprise both doctors and clinical officers. Clinical Officers (CO) are somewhat equivalent to Physician Assistants (PA) in

the US. The data set contains entries from 19 distinct doctors and nine distinct clinical officers. The 19 doctors account for 289 (46%) of the visits and the nine clinical officers account for 335 visits (54%). Of these 335 visits done by clinical officers 300 (90%) were completed by just three of the nine COs. The system users responsible for the retrospective entry belong to the nursing cadre. The dataset contains entries from 11 distinct nurses, with three nurses accounting for 482 (76%) of all visits entered. Frequencies are shown in Table 7 below.

Table 7: Frequency of Visits by Doctor, Clinical Officer and Nurse

Doctor (User #)	Num. of Visits
4	47
24	41
23	29
31	28
18	23
11	22
26	20
21	20
20	12
29	9
10	8
8	8
7	8
16	5
19	3
22	2
13	2
14	1
28	1
Total	289

Clin. Off. (User #)	Num. of Visits
1	122
2	108
3	70
5	11
6	8
12	6
30	6
17	2
15	2
Total	335

Nurse (User #)	Num. of Visits
1	253
2	139
3	81
4	63
5	45
6	30
7	5
8	3
9	3
10	1
11	1
Total	624

The patient load in the clinic varies throughout the week. An adult clinic runs Monday through Friday. A pediatric clinic is run on Mondays and Tuesdays. While the doctors and clinical officers are scheduled to cover their respective adult and pediatric clinics, a core of clinic-based nurses cover both the adult and pediatrics, making Mondays and Tuesdays very high load days for the nursing staff. Fridays are reportedly busy. Many patients, realizing they will run out of medication on the weekend, come to the clinic for refills. The clinic remains close for the morning one Thursday each month for meeting and to take care of general housekeeping issues. Consequently the lower number of visits seen on Thursday underestimates the relative workload that day, since it is only seven half-days per month compared to eight on other days. Figure 17 below shows the total number of visits per day at the clinic over the months during which the duplicates being analyzed were created. Figure 18 shows the total number of visits by month.

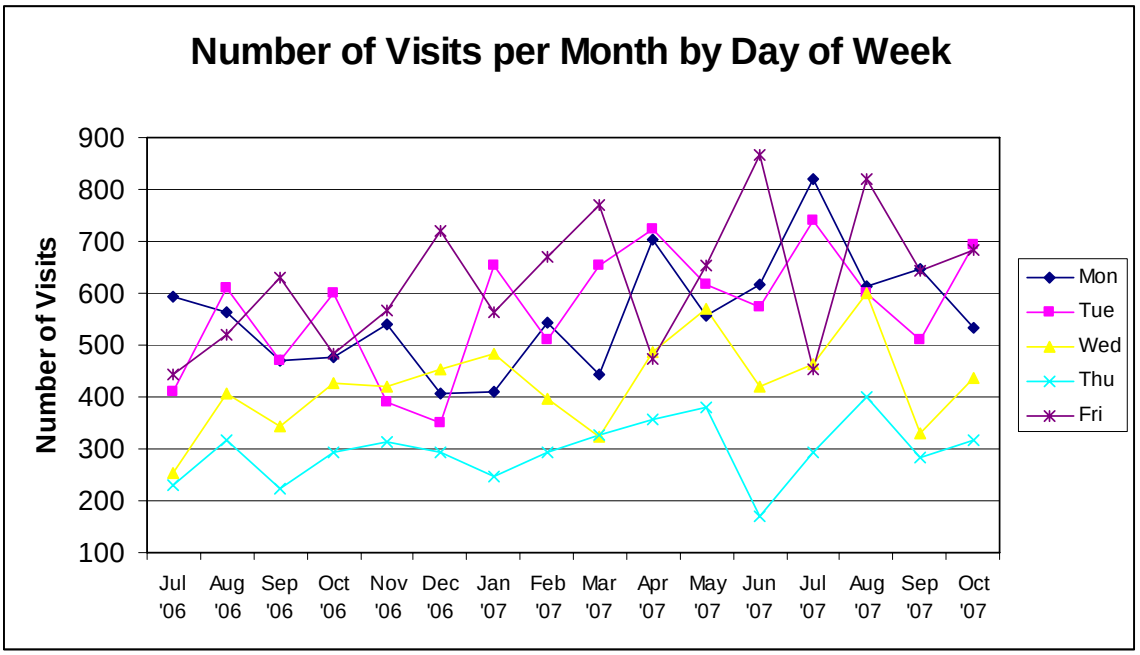


Figure 19: Total number of visits per month by day of week

Figure 20: Total visits per month

Figure 18 above shows the total number of visits per month.

Table 8 below shoes the distribution of visits by weekday in the dataset under analysis.

Table 8: Distribution of visits by weekday

Day	# of Visits
Monday	165
Tuesday	138
Wednesday	84
Thursday	111
Friday	126

For all duplicate pairs being analysed, the point-of-care entry and the retrospective entry took place on the same day. Distribution of time between first and second entry is shown in Table 9 below.

Table 9: Distribution of time between first and second entry

Duration (mins)	# of Visits
Less than 10	203 (32%)
10 – 20	217 (35%)
20 - 30	85 (14%)
30 - 40	47 (8%)
More than 40	72 (11%)
Total	663 (100%)

Figure 19 below shows the distribution of visits based on start time.

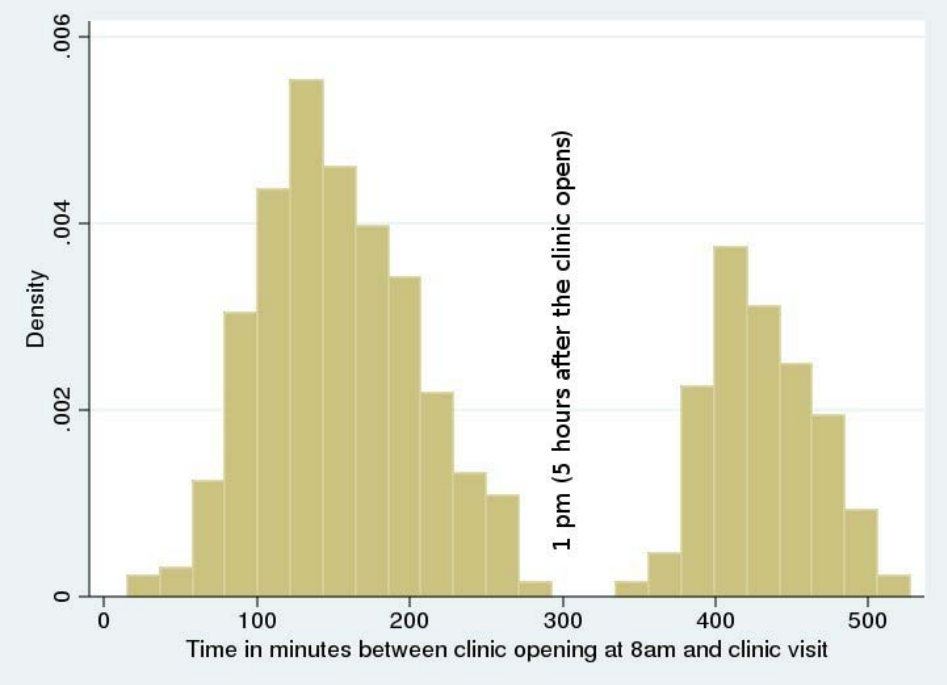


Figure 21: Distribution of visits based on start time

Table 10 below shows the distribution of visits where the point-of-care entry was done before 1pm (300 minutes from clinic opening), derived from Figure 19 above as a natural cut point.

Table 10: Frequency of visits before and after 1pm

PoC Visit	# of Visits
Before 1pm (300mins)	417 (67%)
After 1pm	207 (33%)

5.4.1.1 Master Card Data Elements

Patient Weight was largely completed on the master card as show in Table 11 below.

Table 11: Frequency of completed and blank weight entries on the master card

Weight	# of Visits
Indicated	604 (97%)
Blank on M.C.	20 (3%)

Table 12 below shows the distribution of regimens recorded on the master card.

Table 12: Frequency of ARV regimens recorded on the master card

Regimen	# of Visits
Start	575 (92%)
Substitute	33 (5%)
Switch	2 (<1%)
Blank on M.C.	14 (2%)

Table 13 below shows the distribution of patient outcomes recorded on the master card.

Table 13: Frequency of patient outcomes recorded on the master card

Outcome Status	# of Visits
Alive	602 (96%)
Transfer Out	5 (<1%)
Default*	1 (<1%)
Blank on M.C.	16 (3%)

*Default refers to patients who do not return to the clinic for their next visit.

Table 14 below shows the distribution of the patient's ambulatory status recorded on the master card.

Table 14: Frequency of the patient's ambulatory status recorded on the master card

Is Ambulatory	# of Visits
Ambulatory	600 (96%)
Bed	9 (2%)
Blank on M.C.	15 (2%)

Pill Count (pills remaining from previous dispensing) were largely completed on the master card as show in Table 15 below.

Table 15: Frequency of completed pill counts on the master card

Pill Count	# of Visits
Indicated on M.C.	501 (80%)
Blank on M.C.	123 (20%)

Table 16 below shows the distribution of the patient's working/attending school recorded on the master card.

Table 16: Frequency of completed for work/school field on master card

Is Working	# of Visits
Yes	565 (91%)
No	36 (6%)
Blank on M.C.	23 (3%)

Instructions for recording side effects are printed on the bottom of the master card as follows:

"Side Effects: If YES, specify – YES-PN = peripheral neuropathy; YES-HP = hepatitis; YES-SK = skin rash"

To better understand side effects details written on master cards we reexamined 624 master cards and documented the free text. The nature and frequency of the text is shown in Table 17 below.

Table 17: Frequency of Handwritten Side Effects noted on Master Card

Handwritten notation on MC	Frequency
PN	95
Lipodystrophy	4
Mild PN	2
joint pains	1
PN + lipodystrophy	1
abd pains	1
diarrea	1
neuropathy	1
SK	1

Table 18 below shows the distribution of patients recorded as having peripheral neuropathy recorded on the master card.

Table 18: Frequency of master cards with peripheral neuropathy hand written

PN	# of Visits
Not indicated	525 (84%)
Indicated	99 (16%)

The most common free text notation was PN (peripheral neuropathy). It is interesting to note the high percentage of patients reported as having PN (99 = 16%). We recognize that this sample of visits is not representative of a typical patient visit at the clinic, since all these patients have been seen by a clinician, indicating that they are non-typical visits (in general roughly 60% of patients have a nurse-only visit). We isolate all PN visits in the dataset and

report the levels of accuracy of the point-of-care entered data and the retrospectively entered data below.

Table 19 below shows the distribution of recipients of the ARV drugs (Patient / Guardian) recorded on the master card.

Table 19: Frequency of ARV Recipient completed on master card

ARVs Give To	# of Visits
Patient	515 (83%)
Both	24 (4%)
Guardian	13 (2%)
Blank on M.C.	72 (11%)

Note the high number of entries left blank on the master card (72) as well as 24 instances of both patient and guardian being checked. The high number of blanks may be an indication that the clinic staff do not see this variable as important. The purpose of the field was to record whether the patient presented at the clinic in person, or whether the patient was represented by his/her guardian. This is not really conveyed in the data. If both the patient and the guardian are present and the nurse physically hands the meds to the guardian this would be recorded as a guardian visit, which is inconsistent with the underlying intention of collecting this data. Based on the high number of blanks and "both" entries in the data we concluded that the meaning of this field is not well understood by clinic staff and elected to remove this field from the analysis.

5.4.2 Analysis of Data Accuracy

Accuracy is determined on a variable by variable basis for both the data entered at point-of-care (PoC) as well as the data entered retrospective. Accuracy levels are reported for weight, ART regimen, pill count, attend work/school and peripheral neuropathy. In the following subsections, raw accuracy data are displayed in 2x2 tables for each variable.

5.4.2.1 Weight

Of the 624 visits 20 have the patient's weight left blank on the master card. Consequently these visits will be excluded from analysis. During analysis we noted that a very high level of discordance existed among the weight values recorded in the dataset. Further analysis revealed that of those discordant a high percentage differed only by 0.1 Kg. On inspection of the master cards we noted that weights were generally recorded to two decimal places. We subsequently confirmed that the electronic scale in the clinic does report weights to two decimal places, but the data input screen in the software application is designed to accept only one decimal place. Based on this we realize that the discrepancy of 0.1Kg is most likely accounted for by inconsistent rounding to one decimal place. Consequently, for the purpose of determining concordance, we consider two values to be concordant if they differ by no more than 0.1 Kg.

There are 14 occurrences where a weight is not entered at the point-of-care but is recorded on the master card and captured electronically during the retrospective entry by the nurse. We suspect that the patient was seen by the clinician prior to being weighed and therefore was unable to enter the weight into the system. We recognize that this is a systemic problem and not a data entry error. Consequently we exclude these visits from the analysis of accuracy for weight. To compare accuracy for the weight field we tabulate levels of concordance of both point-of-care data and retrospectively entered data with the master cards below. A total of 587 were considered in the analysis.

Table 20: Comparing point-of-care and retrospective errors for patient weights

Weight		*Point-of-Care data*	
		Concordant*	Discordant*
Retrospective Data	Concordant*	424	64
	Discordant*	65	34

* Concordant/Discordant referrers to the agreement/disagreement of the field in the point-of-care record and retrospective record with the master card.

5.4.2.2 Outcome Status

We recognize that master cards get updated after the visit to reflect changes in patient outcome of death and transfer out. Five occurrences of visits that are concordant between the point-of-

care and retrospectively entered dataset but discordant with the master card. They comprise three "transfer out", one death and one default. Additionally, we note very little variability in the data ("Alive" 96% of visits). Based on these observations we exclude outcome status from our analysis.

5.4.2.3 ART Regimen

Of the 624 visits 14 have the regimen field left blank on the master cards. Consequently these visits will be excluded from analysis. To compare accuracy for the ART regimen field, we tabulate levels of concordance of both point-of-care data and retrospectively entered data with the master cards.

Table 21: Comparing point-of-care and retrospective errors for ART regimens

ART Regimen		*Point-of-Care data*	
		Concordant	Discordant
Retrospective Data	Concordant	589	7
	Discordant	12	2

5.4.2.4 Pill Count

Of the 624 visits 125 have pill counts recorded as 0 from the master cards. Unfortunately we did not undertake to keep track of blank pill count fields on the master card when capturing the data electronically. Consequently a 0 in the pill count column in the study dataset can mean either a pill count of 0, or that the field was left blank on the master card. For the purpose of analysis we exclude all 125 visits with a pill count of 0 in the dataset transcribed from the master card. We also eliminate four additional visits based on the presence of a "-1" in the field placed in there by the ARV system to indicate "Unknown" at the time of data entry.

To compare accuracy for pill count we tabulate levels of concordance of both point-of-care data and retrospectively entered data with the master cards below.

Table 22: Comparing point-of-care and retrospective errors for pill counts

Pill Count		*Point-of-Care data*	
		Concordant	Discordant
Retrospective Data	Concordant	392	47
	Discordant	42	14

5.4.2.5 Work / School

Of the 624 visits 23 have the ambulatory field left blank on the master cards. Consequently these visits will be excluded from analysis. To compare accuracy for the work/school field we tabulate levels of concordance of both point-of-care data and retrospectively entered data with the master cards below.

Table 23: Comparing point-of-care and retrospective errors for work/school

Work / School		*Point-of-Care data*	
		Concordant	Discordant
Retrospective Data	Concordant	551	16
	Discordant	19	15

5.4.2.6 Side Effects

Of the 624 visits 17 have the side effects field left blank on the master cards. Consequently these visits will be excluded from analysis. To compare accuracy for PN we tabulate levels of concordance of both point-of-care data and retrospectively entered data with the master cards below.

Table 24: Comparing point-of-care and retrospective errors for peripheral neuropathy

PN (Peripheral Neuropathy)		*Point-of-Care data*	
		Concordant	Discordant
Retrospective Data	Concordant	489	42
	Discordant	75	1

Given the low occurrence of side effects other than PN in the data we see no value in reporting on them.

5.4.2.7 ARV Recipient

Of the 624 visits 73 have the "ARV recipient" field left blank on the master cards. An additional 24 master cards indicated ARVs had been dispensed to both the Patient and the Guardian. We believe this data is of extremely low quality, possibly confounded by different interpretations of what the data is supposed to represent. Based on these observations we exclude outcome status from our analysis.

5.4.2.8 Summary of Results for Data Accuracy

We summarize the overall error rates and PoC vs. Ret differences for five variables in Figure 22 below.

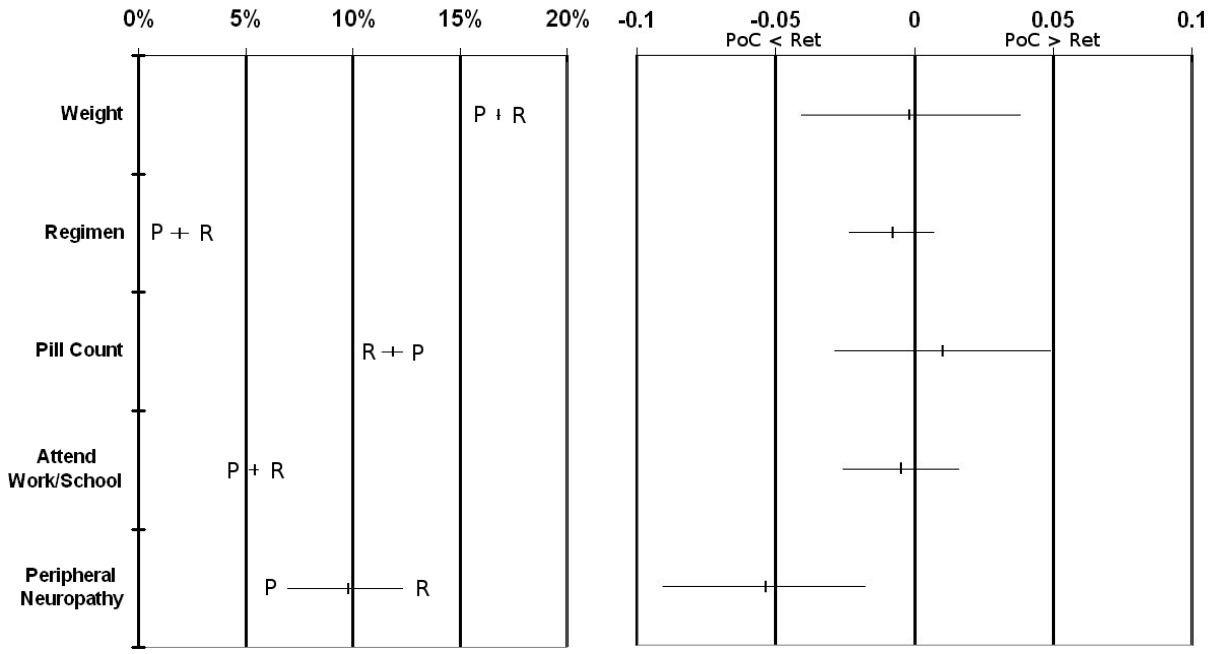


Figure 22: Overall error rates and Difference (PoC - Ret)

Left: Overall error rates; Average, PoC (P), Ret (R)

Right: Difference between PoC error rates and Ret error rates with 95% confidence intervals

(Statistically significance for Peripheral Neuropathy, P =0.0023)

5.4.3 Predictors of Data Errors

Logistic regression was performed to identify possible predictors of error in the data. The following candidate predictors were tested:

- Person entering the data (de-identified, coded numerically)
- Day of week of visit
- Mo+Tu vs. rest of the week (Mo+Tu being peds clinic days and very busy)
- Mo+Tu+Fr vs. rest of the week (Mo+Tu being peds clinic days and very busy, also Fr busy due to increased demand for refills before the weekend)
- Visit before lunch break or after (based on the time stamp of the PoC record)
- Patient age (included a quadratic variable)
- Patient sex
- Patient on first line or other ART
- Time between entry of PoC and retrospective record (included a quadratic variable)
- Time between clinic opening and first visit (included a quadratic variable)
- Cadre at point-of-care (doctor vs. clinical officer)

5.4.3.1 Variation in Error Rate Across Users

In the analysis of accuracy of patient weight we examine 587 visits collectively entered retrospectively by nine distinct users. Four users account for retrospective entry of 513 (87%) of the 587 visits. We describe the error rates for each of these users below in Table 25. We observe a wide range in error rates across the four users.

Table 25: Error rate for individual users on retrospective entry of patient weight

User	# Visits	# in Error	Error Rate	OR wrt U1	95% CI
1	238	54	23%		
2	132	15	11%	0.45	0.24 - 0.85
3	81	14	17%	0.69	Not significant
4	62	5	8%	0.26	0.10 - 0.71

In the analysis of accuracy of pill counts we examine 499 visits collectively entered at point-of-care by 29 distinct users. Four users account for retrospective entry of 272 (55%) of the 499 visits. We describe the error rates for each of these users below in Table 26. We observe a wide range in error rates across the four users.

Table 26: Error rate for individual users on point-of-care entry of pill counts

User	# Visits	# in Error	Error Rate	OR wrt U1	95% CI
1	101	5	5%		
2	86	11	13%	3.30	1.05 - 10.23
3	55	8	15%	5.05	1.37 - 18.62
4	30	2	7%	0.15	Not significant

5.4.3.2 Variation in Error Rate Based on Day of Visit

In the analysis of accuracy of pill counts we examine 499 visits entered retrospectively. Of these 269 (54%) had been entered on a Monday or a Tuesday.

Table 27: Error rate for MT vs WRF users on retrospective entry of pill count

DoW	# Visits	# in Error	Error Rate	95% CI
M,T	269	39	14.5%	10.5% - 19.3%
W,R,F	230	16	7.0%	4.0% - 11.1%

5.4.4 Nature of Numerical Errors

Below we describe the nature of numerical errors identified in both pill counts and patient weights. We recognize that the person entering the data is not necessarily the one who recorded the data on the master card. Consequently there is potential for error resulting from mistaking

specific digits for others (transcription error). Three common errors are mistaking the digits 3 and 8, digits 1 and 7, and digits 2 and 7.

We look at errors resulting from both omitting a digit and including one or more extra digits. Omitting a digit frequently results from a key-press not registering. This can be due to the user narrowly missing the target (onscreen key), or miscalibration of the touchscreen. Repeated key errors generally occur from a slight hesitation by the user when removing the finger from the key.

Transposition errors result when two digits in a string of digits are interchanged. For example, 36.2 being recorded as 32.6. We examine and describe occurrences on transposition errors in the data.

5.4.4.1 Transcription Errors

Table 28: Common transcription errors

	Total Obs	3/8 error	1/7 error	2/7 error	Total
Pill Count (PoC)	499	0	0	1	1
Pill Count (Ret)	499	0	0	0	0
Weight (PoC)	587	7	7	1	15 (2.5%)
Weight (Ret)	587	6	3	4	13 (2.2%)

5.4.4.2 Omitted / Repeat Digit Errors

Table 29: Frequency of omitted digit and repeat digit errors

	Total Obs	Omitted Digit	Repeat Digit
Pill Count (PoC)	499	2	1
Pill Count (Ret)	499	1	1
Weight (PoC)	587	0	0
Weight (Ret)	587	1	0

5.4.4.3 Transposition Errors

Table 30: Frequency of transposition errors

	Total Obs	Transposition
Pill Count (PoC)	499	0
Pill Count (Ret)	499	0
Weight (PoC)	587	0
Weight (Ret)	587	3

The following transposition errors were found in the weight dataset recorded at point-of-care:

- 74.6 recorded as 76.4
- 45.2 recorded as 54.2
- 47.7 recorded as 74.7

5.4.4.4 Other Errors of Note

One example 40.4 recorded as 40440.4 by a clinician … this is a case of not hitting the decimal on the first try, then pressing "clear" but not clearing (maybe missing the key) and them typing 40.4 and "Next". Two other error similar errors were detected, 54.6 recorded as 4454.4, and 59.8 recorded as 588.8, both entered by a nurse.

5.5 DISCUSSION OF DATA QUALITY STUDY RESULTS

Of the five variables analyzed, only peripheral neuropathy (PN) has a statistically significant difference in accuracy between the data captured at point-of-care by clinicians and the data captured retrospectively by nurse. The error rate of PN data collected by clinicians at the point-of-care (6.9%) is significantly lower than that entered retrospectively by nurses (12.3%). We recognize that the users in the point-of-care group comprise both doctors and clinical officers. When we rerun the analysis for doctors and clinical officers separately we find no evidence of a

difference in the accuracy in any of the five variables for the clinical officers. However, the difference in accuracy for peripheral neuropathy in the doctor group is highly significant. While the clinical office cadre is made up entirely of Malawian trained clinicians, the composition of clinicians in the doctor cadre comprises both Malawian and foreign trained (expatriate) clinicians. Unfortunately we are not able to separate out the two groups as we did not include this in our dataset.

With respect to the two numerical data fields, we note that error rates are high in both weight (16.7% - 16.9%) and pill count (11.3% - 12.3%). Given that these are numerical fields, the likelihood of error resulting from transcription or transposition are greater than in binary fields (e.g. Yes / No) or categorical fields with limited selection (e.g. start / sub / switch). This data is considered to be free text and consequently harder to validate. In general, we should expect to see higher error rates in fields that comprise longer strings of digits. This is consistent with the higher error rate observed in weight vs. pill count described above. A detailed description and classification of types of numerical errors in the dataset follows below.

Of the five variables we analyzed patient weights had the highest level of error. We believe that the value of collecting patient weights is perceived by clinicians and nurses as being somewhat nebulous. Weights are recorded on the master card but there are no clearly articulated rules as to how to use this data. Of all data collected on the master cards this is one of two pieces of data that does not translate into an indicator of one form or another on the quarterly reports. One wonders what value nurses and clinicians find in knowing the patient's weight. Changes in weight can be used as an indicator for treatment success or conversely treatment failure. However, this is not applied in any systematic way when using the master card. We hypothesize that this perceived lack of value in collecting this data element contributes to the high rate of error observed.

Pill counts have the second highest rate of error of the five variables we analyzed. This variable represents the number of unused ARV tablets the patient has from their previous visit. The purpose of measuring this is to determine adherence to taking the drugs. Instructions to the clinician/nurse are written on the master card as follows … "No. Pills in Bottle: if patient comes at 4 weeks count number of pills in bottle (8 pills or less = 95% adherence". Pill counts were left blank 20% of the time. Occasionally other notations such as >95% were used, or just a tick mark. There are significant limitations to using the number of pills remaining an accurate measurement of

adherence. It is common for patients to have their next visit a few days earlier or later than 28 days. Many patients have pills remaining from a previous visit, so those "hanging pills" increase the number of pills available to them and could be interpreted as extra pills implying that the patient had missed taking their drugs. As more patients are becoming stable, clinics are increasingly putting them on two-month and three-month visit schedules to reduce traffic in the clinic and make space for new patients to start treatment. These factors all confound the process of accurately measuring adherence using a paper-based system. However, with the electronic system we are able to determine the actually number of days since the last visit, calculate in the number of pills dispensed at that visit as well as the number of pills the patient had remaining at that time to accurately calculate adherence.

Based on a significant level of incompleteness and inconsistency in the data for "ARVs give to" observed on the master card we elected to exclude this variable from the analysis. No indication was given as to whether the drugs were given to the patient or the guardian in 11% of the master cards and an additional 4% indicated that drugs had been given to both. We suspect there is widespread misunderstanding about what "ARV given to" really means. We believe this variable it is intended to reflect whether the patient attended the clinic in person or whether a guardian came to collection medication on the patient's behalf. It is unclear whether the question is asking who did the clinician/nurse physically hand the drugs to? To what degree does it reflect whether the patient was present or not at the clinic. This piece of data does not translate into an indicator in the cohort report.

We examined error rates in patient weight retrospectively entered by the four users. Error rates varied from 8% to 23 %. We can see for the odds ratios (Table 24) that there is a statistically significant difference in the error rates between User 1 and User 2, and between User 1 and User 4. In examining the errors in recording weight by User 1 we observe that nine of the 54 errors exceeded 10% of the weight recorded on the master card, and consequently could be validated by a rule based on patient weight from last visit. Of these nine errors one was caused by an omitted digit (7.7 vs. 77.7), a second a result of transposition error (45.2 vs. 54.2) and a third a result of a 7/1 error (51.1 vs. 57.1). Of the 45 remaining visits 30 differed by less 1 Kg between what was entered into the system by the user and what was written on the master card, greatly diminishing any potential impact of the error. With respect to the regimen, pill count,

work/school and peripheral neuropathy we found no evidence of significant differences in error rate among users when entering the data retrospectively.

We performed a similar analysis of error rates in pill counts entered at point-of-care by four users. Error rates varied between 5% and 15%. We determined that there is a statistically significant difference between User 1 and User 2, and between User 1 and User 3 when entering pill count data. With respect to the regimen, patient weight, work/school and peripheral neuropathy we found no evidence of significant differences in error rate among users when entering the data at point-of care.

A physician from the ART clinic at the study site noted that the clinic was particularly busier on Mondays and Tuesdays as both adult and pediatric clinics took place on those days. Based on this we questioned whether the busyness of the clinic might impact accuracy. We analysed error rates for all five variables both for data entered at point-of-care and for data entered retrospectively. We found a statistically significant difference in the error rate of pill counts entered retrospectively based on the day of week. The error rate for pill counts on Mondays and Tuesdays was 14% compared to 7% for the rest of the week. A clerk at the clinic had noted that Fridays were particularly busy as many patients came for refills, afraid they would run out of medications on the weekend. We analyzed error rates on Fridays compared to the rest of the week and found no significant difference.

We tested all five variables to see if there is a significant difference in accuracy between data captured by doctors vs. data captured by clinical officers. We found no significant difference in error rates between these two cadres.

The rate of transcription errors is noticeably higher in weights than in pill count in both the point-of-care and the retrospectively entered data. Weights are generally three digit numbers and are reported to one decimal place. Pill counts are generally single digit numbers and occasionally two-digit numbers. However, the cell provided to record pill count on the master card is approximately 60% longer than that provided for weight. This is a common flaw in form design, where the designer is more influenced by the space required to accommodate the column heading (e.g. |wt Kg| vs. |No. Pills in Bottle|) than by the size of the data that will be recorded in that column. A second problem we see with the form design is the limited height of the rows on the master card. Due to this space restriction we frequently see cell entries where the top and

bottom of the digit touch the line above or below. This can have the effect of obscuring the horizontal stroke of a 7 making it appear at a glance to be a 1, or the lower horizontal stroke of 2 making it appear to be a 7. With respect to recording patient weight, we observed the majority of the transcription errors occurring in the decimal digit. We hypothesize this is due to the limited amount of space on the master card making it hard to accommodate a three-digit number (with decimal point), with the greatest impact on the right-most digit. On most master cards this digit spills over into the next cell. We are pleased to note that in the revised version of the master cards being released in February, 2009 the size of cells has been adjusted and row height increased to better accommodate the nature of the data recorded in each cell.

In examining error rates from transcription we observe an error rate ranging from 2.5% in the point-of-care data to 2.2% in the retrospective data resulting from incorrectly transcribing digits that appear similar(3/8, 1/7, 2/7). We argue that by eliminating the paper record entirely, thereby eliminating the transcription process, there will be a small increase in accuracy realized. In the case of patient weights, we strongly advocate for the use of an electronic scale that would allow for direct transfer of data to the computer via a serial or similar connection, thereby eliminating manual data entry entirely. However, such scales are in the price range of $800 and consequently would only be affordable in larger urban clinics.

The occurrence of transposition errors in the dataset is low. Of the three transposition errors encountered only one of these was sufficiently different in value (47.7 recorded as 74.7) that a validation rule for weight based on patient age would have caught it. A second error (45.2 recorded as 54.2) could have been caught by a validation rule based on weight recorded during a previous visit. The third error (74.6 recorded as 76.4) would be extremely hard to detect through a validation rule.

Errors resulting from a failed attempt to clear a partial entry occur only three times in the dataset (e.g. 40.4 entered as 40440.4). Nonetheless, these should have all been eliminated with a validation rule.

5.6 DATA QUALITY STUDY CONCLUSIONS & RECOMMENDATIONS

We hypothesized that there was no significant difference between the accuracy of data collected by doctors/clinical officers at point-of-care compared to data collected retrospectively by nurses in the ART clinic at QECH. Based on this small study we conclude that there is no difference in the accuracy of weight, ARV regimen, pill count, and the patient's ability to attend works or school. With respect to the presence of the side effect peripheral neuropathy, data accuracy was significantly higher ($P = 0.002$) when entered by the doctor/clinical officer at point-of-care than when entered retrospectively by the nurse. Based on these findings we see no deficit to data quality incurred by collecting data at the point-of-care where all the benefits of alerts and reminders, protocol guidance and decision support can be realized.

The monitoring and evaluation (M&E) community has traditionally thought about the implications of poor data quality as having some general impact on reports. However, they have not considered the impact on the individual patient. M&E efforts would benefit from thinking more broadly about the implications of poor data quality. A single incorrect piece of data in 50 pieces of data represents a 2% error rate in a report. Many would consider this to be an acceptable margin of error. However, that single incorrect piece of data when used for patient management may have serious negative consequences, in extreme cases resulting in a life threatening outcome. Consider a scenario where a child whose weight is 3.7Kg is being dosed based on a recorded weight of 7.3Kg due to a transposition error that occurred during data entry. This error may result in the child being given twice the appropriate dose, with potentially serious adverse consequences. Incorrect data may trigger rules causing alerts or reminders to fire when not warranted, or worse, not to fire when they should. As we start to use data to inform and support individual patient care we need to place greater emphasis on maximizing data quality through whatever mechanism are available to us. The use of rule-based data validation techniques delivered through a point-of-care interface is one of the best tools we have at our disposal to improve data quality.

The primary reason the Ministry of Health decided to introduce the point-of-care system into HIV care and treatment was to improve the cohort reporting capabilities for large sites (Appendix A: Sample Cohort Repot and Survival Analysis). Thus far little thought has been given beyond this to consider additional benefits. We recommend reevaluating this, placing

greater emphasis on doing more with the data at sites that have an electronic system. Recommendations falls into three broad areas: increased reporting, operational research, and enhancing decision support for the user.

- We recommend producing reports with greater frequency and with broader scope. We suggest that short reports should be produced on a weekly basis for review. These should include both aggregate-level reports for program management (reviewed by the clinic manager / district health officer), as well as patient-level reports alerting clinical staff to patients who may need follow-up or consultation. Thus far both adult and pediatric patients have been reported as a single group despite the significant differences between the two groups. At QECH we have observed attempts by the pediatric team to establish a parallel reporting system. Creating a separate set of reports for adult and pediatric patients will greatly increase the ability of the respective care teams to monitor and evaluate the performance of their departments.
- The volume of electronic patient-level data is large and growing rapidly as existing sites take on more patients and new sites come online. We recommend conducting operational research in the form of data mining and knowledge discovery using this data. Of specific interest would be the identification characteristics of the data that might help clinicians predict treatment failure, increased rate of defaulting, or ultimately death.
- Some decision support already exists in the system in terms of alerts. For example we alert a clinician to refer a patient to nutritional counseling based on a system-calculated body mass index (BMI) of less than 18.5. Based on the findings of operational research (described above) we should add to the suite of automatic alerts in the system to notify clinicians when patients exhibit potential risks, such as poor adherence, treatment failure or toxicity.

We strongly recommend changing the master card to remove reference to “ARVs give to” and have two columns for “Patient present” and “Guardian present”, if that is what we are trying to determine.

For new sites, move away from conventional master cards immediately after the system goes live. However, we do recognize the value of maintaining some paper audit trail (a paper enhanced rather than a paperless system). The latest version of the system prints a summary of

the encounter on an adhesive label to be placed in the patient's health passport. We recommend printing a second label and affixing it to a new style card designed for the purpose.

Based on the significantly higher error rates in pill counts observed on Mondays and Tuesdays compared to the rest of the week we recommend reviewing the work load of the nursing staff and performing some form of load balancing between adult and pediatric patients to even out the workload throughout the week.

5.7 DATA QUALITY STUDY LIMITATIONS

We attempt to determine whether capturing data at point-of-care vs. capturing data retrospectively from a paper record will have an impact on data accuracy. However, our analysis is confounded in several ways.

- The point-of-care data is entered by doctors and clinical officers whereas the retrospective data is entered by nurses. Any difference in accuracy resulting from the data entry paradigm (point-of-care vs. retrospective) could be confounded by differences in training and other characteristics between the different cadres.
- Within the point-of-care setting data entry is done by both doctors and clinical officers. The doctors comprise a mix of Malawian and expatriate. We might expect expatriate doctors to have a greater level of experience using information technology, which could affect their levels of data accuracy. Any difference in accuracy resulting from the data entry paradigm could be confounded by other differences between the two groups.

Queen Elizabeth is a teaching hospital. Findings from this study may not be generalizeable to smaller hospitals or health centers.

The sample of data used in this study is not representative of all patients attending the clinic. For approximately 40% of patient visits at the QECH ART clinic the patient is seen first by a clinician. These are typically the sicker or more complicated patients. Consequently the findings of this study may not be generalizeable to the entire patient population of the clinic.

While the range in error rate (5% - 15%) in users entering pill counts at point-of-care is wide, the large number of distinct users at point-of-care (29) and overall relatively small sample

of visits (624) make it hard to determine statistical significance in differences in error rates among users.

6.0 CONCLUSIONS

We have received some skepticism as to the feasibility of the point-of-care approach in a developing-world setting. We recognize that a traditional model of recording clinical data on paper and back entering data is less invasive with respect to existing workflow and therefore less likely to negatively impact the delivery of clinical care. However, the impact of protocol guidance and decision support features on patient-level clinical care will not be achieved if a clerk is the one using the computer.

6.1 FEASIBILITY

The primary goal of this research was to investigate the feasibility of a point-of-care approach to designing an electronic medical record system for use in a developing-world setting. We demonstrated feasibility through examples of several successful Baobab systems that have been deployed across multiple sites and have functioned for several years beyond the pilot phase.

The most significant example of the application of our technology is the Baobab patient registration system. Versions of this system are installed on more than 35 touchscreen clinical workstation appliances across 10 sites in Malawi. Two of these sites are off the electrical grid entirely. From the first deployment at Kamuzu Central Hospital in 2001 the system had been used to issue more than 800,000 unique patient identifiers by the end of 2008. While this system is used in real-time, it is not used in the clinical context per se, so is not a point-of-care system strictly speaking.

Of the three point-of-care systems created since the pilot, the Baobab ART (BART) system is the most developed and widely deployed. The first version of the system was deployed at the Lighthouse Clinic in Lilongwe in 2003. Since then the software has gone through two

major revisions and is now endorsed by the Ministry of Health for widespread rollout pending the availability of funds. More than 18,400 patients across six sites were being managed using the BART system by the end of 2008.

We developed two systems to support ancillary services. The radiology system, while never deployed beyond the pilot site, has functioned with minimal need for support since 2004. We were able to easily support this system in the absence of dedicated funds to do so as it was generally low maintenance, and was operating on the same hospital campus we are based, so did not require time and money for transportation when support was necessary. By the end of 2008 the system contained records of more than 470,000 x-ray and ultrasound investigations. The specimen labeling system created and developed in 2002 in the pediatric department was extended to two additional sites. The system was deployed to all adult wards in the main hospital (eight nursing units). The nurses found that having the system located at the nursing station was a poor fit for their workflow and stopped using the system over a period of a few months; however, this system is currently in use on a daily basis at two high burden sites used primarily in HIV and TB care and treatment.

While the majority of the systems we have put in place have been sustained, some have not. The point-of-care system we created for pediatric admissions in 2002 could not be sustained beyond 15 months after going live. We attribute this to lack of technical support and the increased need for support due to the high turnover of students moving through the department. It is interesting to note however that the version of this system modified for use in the malarial anemia research study in Western Kenya in 2004 was still in use as of the end of 2008.

The Voluntary Counseling and Testing system deployed at the Malawi AIDS Counseling and Resources Organization (MACRO) ran for more than three years across four sites. However, the system is currently not in use at three of the four sites due to a combination of factors. Lack of foresight to budget for equipment replacement and ongoing maintenance over time resulted in significant downtime. Two of the four sites were more than four hours drive away making it costly and time consuming to support. Downtime caused users to loose confidence in the system. An additional factor was the shift in counseling from being 80% static to 80% mobile. The touchscreen system did not match the data collected on outreach, and consequently became an increasingly poor fit.

While success is mixed, we conclude overall that feasibility has been demonstrated by the BART system. In Chapter 1 we define a successful demonstration of feasibility as meeting all of the following: 1) does the system do what it was designed to do, 2) has the system been extended to at least two additional sites beyond the pilot site, and 3) has the system run for at least two years beyond completion of the pilot? BART was commissioned by the Ministry of Health to collect patient-level data at HIV clinics and deliver quarterly cohort and survival analysis reports to support monitoring and evaluation (Appendix A). The system is currently meeting this goal at five Ministry of Health HIV Clinics in Malawi, three of which have been running for more than two years.

6.2 SUSTAINABILITY – LESSONS LEARNED

Having established feasibility we consider the lessons learned from the work done thus far and examine the threats to system sustainability. Over the eight years of development and deployment we have revised our opinions of the threats to sustainability. We no longer perceive poor reliability or indeed absence of power in health facilities to be a risk factor. Currently all the systems we have deployed in Malawi, including two sites off the grid entirely, function reliably in the presence of severe power interruptions.

We do not perceive low levels of computer literacy to be a threat to sustainability. More than 75 doctors, clinical officers, nurses and clerks use a Baobab touchscreen system on a daily base, and over 420 users have been exposed to the technology over the last eight years.

Thus far low staffing levels do not appear to be a threat to sustainability with possibly one exception. In 2004 we installed a prototype dispensing module in the pharmacy at Kamuzu Central Hospital. At that time the pharmacy was operating with only five of the 16 human resource posts filled. The dispensing system was entirely barcode driven and was extremely simple to use. However, due to the shortage of staff, pharmacy technicians said they were unable to meet the demand for dispensing during peak times of the day while using the system. After three months of use we concluded that the negative impact of requiring technicians to use

the system against their better judgment would ultimately be counterproductive and we voluntarily discontinued the use of the system to respect the views of the users.

Inadequate infrastructure to maintain equipment and perform routing maintenance has contributed to the failure of at least one Baobab system (VCT). Supporting an infrastructure for maintenance requires national commitment both in terms of political will and financial resources. The Ministry of Health struggles to support an infrastructure to maintain medical equipment for government hospitals. Unless a robust and efficient infrastructure for support can be established we are likely to see significant challenges in three to five years time as equipment deployed today approaches end of life.

Not surprisingly, a point-of-care system that is a poor fit to existing workflow is a threat to sustainability, as evidenced by our experiences with the specimen labeling system on the adult wards. This problem is cited as a significant risk factor in deploying systems in the West, and we need to learn from the growing body of research in this area.

We do not perceive the high risk of equipment theft to be a threat to sustainability. Through the use of locally fabricated steel cabinets we have been able to adequately protect servers, network electronics and power backup systems. Over eight years and 14 sites we have only had one instance of equipment theft. We believe the clinical workstation appliances are not perceived as valuable due to their proprietary nature and therefore less prone to theft (an additional benefit of the appliance model).

We recognize limited healthcare budgets as probably the most significant threat to sustainability. While the donor community is willing to invest in infrastructure they are rarely willing to pay for ongoing costs. From a total cost of ownership perspective, support costs represent a significant proportion. Consequently these costs need to be addressed up front and not be overlooked as a problem to be solved later. If consumables, maintenance and support can not be procured, system will not be sustained beyond the initial pilot. If EMR systems are to be scaled nationally greater efforts need to be made to identify viable financial models that justify the use of the technology. In the case of the Baobab ART system (BART) the primary goal of the system from the Ministry of Health's perspective is to support monitoring and evaluation (M&E). The National AIDS commission (NAC) recommends spending roughly 6% of a program budget on M&E. However, based on current calculations the cost of installing and maintaining BART is in the range of 10% to 12%. Greater emphasis needs to be placed on

finding ways of using systems to save costs in other areas. For example, can we quantify the benefits of leveraging decision support? Can we determine costs saved by forgoing second line regimen drugs by getting defaulters back into care earlier so as to keep them on first line regimen? Can the technology infrastructure be leveraged to support continuing medical education for clinicians and nurses? If so, what are the costs and benefits? We consider finding such synergies to be essential to creating a financial model for sustainability.

6.3 FUTURE WORK

Ball et al. cite lack of understanding the value proposition for stakeholders as contributing to the failure to provide clinicians with useful IT systems (127). After eight years of working in the field we still have a poor understanding of the value proposition for many of the stakeholders. The Ministry of Health HIV Unit has clearly articulated many of their needs, and to a large degree these have been met. However, we believe it is fundamentally important to understand the value proposition for the users if long-term sustainability is going to be achieved. This kind of information is hard to elicit. We propose to undertake research to better understand user's needs. We are in the process of seeking funding for this through the International Development Research Center (IDRC).

The study described in Chapter 5 suggests that there is no negative impact on data quality from using the EMR at point-of-care. The study has several limitations that question the generalizability of the findings beyond the study site. However, the analysis has brought up numerous issues that will greatly inform a more rigorous study. We propose to conduct a prospective multi-site study of data accuracy based on the findings of this descriptive study. We are in the process of seeking funding for this through IDRC. The results of the data quality study also indicated that opportunities exist to improve data quality collected at point-of-care (e.g., rule-based validation) and to increase the value of data collected (e.g., more frequent and targeted reporting, the addition of decision support that is derived from analysis of actual clinical data.)

We believe the point-of-care approach can have a significant impact on improving clinician adherence to clinical protocols. Safran looked at protocol adherence in Western HIV

care and treatment setting (128). We propose to evaluate the impact of protocol guidance supported by the BART system across sites using BART in contrast to sites that do not have BART. We are in the process of seeking funding for this through IDRC.

There is evidence of a silent epidemic of non-communicable diseases in the developing world (129-131). Harries et al. propose to use the quarterly cohort analysis model developed for TB and HIV in Malawi to perform monitoring and evaluation of non-communicable diseases such as diabetes and hypertension (132). Since no paper-based M&E system exists for these diseases we propose to go directly to an electronic point-of-care solution modeled on the BART system. Two years of funding has already been secured for this project.

Several early systems we created were implemented using the Visual Basic programming language. We have now moved entirely away from Microsoft Windows (required to run Visual Basic applications). We intend to reimplement the specimen labeling system and the radiology system as browser-based applications that are consistent with out current software stack, as funding becomes available.

This dissertation has demonstrated feasibility of a point-of-care approach to using an electronic medical record system in a developing-world setting. We have made contributions to knowledge in three key areas. We have differentiated the needs of electronic medical record systems between developed and developing countries, establishing a justification for engineering new systems to meet the unique needs of resource-poor settings rather than transplanting existing systems created with the needs of developed countries in mind. We have described technologies and philosophical approaches developed over an eight year period designing, implementing and deploying systems in Malawi. Lastly, we have described findings from an analysis of data accuracy from a point-of-care system developed and deployed in Malawi in a HIV care and treatment setting.

APPENDIX A: SAMPLE COHORT REPORT AND SURVIVAL ANALYSES

Queen Elizabeth Central Hospital Quarterly Cohort Analysis - 01 Oct 2008 to 31 Dec 2008

Case Data	# of patients
Total registered	538
Patients transferred in on ART	118
Patients newly initiated on ART	420
Males (all ages)	229
Non-pregnant Females (all ages)	292
Pregnant Females (all ages)	17
Adults (15 years order at ART initiation)	451
Children (18 months - 14 years at ART initiation)	63
Infants (0 - 17 months at ART initiation)	24
Reasons for starting	
WHO Stage III	199
WHO Stage IV	74
CD 4 Count	243
Other	22
Indicate number started because of:	
KS	21
TB	61
Pregnant women started on ART for PMTCT	17
Outcome Data	
Alive and on ART	514
Alive and on first line regimen (Start)	481
Alive and on alternative first line regimen (Substituted)	27
Alive and on alternative first line regimen AZT+3TC+NVP	7
Alive and on alternative first line regimen d4T+3TC+EFV	19

Alive and on alternative first line regimen AZT+3TC+EFV	1
Alive and on second line regimen (Switch)	6
(Zidovudine Lamivudine Tenofovir Lopinavir/Ritonavir Regimen)	0
(Didanosine Abacavir Lopinavir/Ritonavir Regimen)	0
Other Regimen:	0
Died	6
Defaulted	0
Stopped	1
Transferred out	17
Of those Alive and On ART	
Ambulatory	490
At work/school	482
Side effects	3
PN	0
HP	0
SK	3
Adults on 1st line regimen with pill count done in the last month of quarter	296
With pill count in the last month of the quarter at 8 or less	277
Of those who died	
In month 1	5
In month 2	1
In month 3	0
After month 3	0

Note that some of the totals are hyperlinks (blue and underlined). When viewed as an on-screen report the user can tunnel down to look at specific patients in many instances. For instance, in the report above, clicking on the "5" for patients who dies in month one after starting treatment will show a list of those patient names. We believe this will significantly help the Ministry of Health HIV Unit site supervision teams validate the totals if they can see the actual underlying data.

Survival Analysis

12 month survival: outcomes by end of December 2008	
New patients registered for ART between October 2007 to December 2007	314
Number Alive and on ART	306
Number Dead	1
Number Defaulted	1
Number Stopped Treatment	0
Number Transferred out	6
24 month survival: outcomes by end of December 2008	
New patients registered for ART between October 2006 to December 2006	273
Number Alive and on ART	268
Number Dead	2
Number Defaulted	0
Number Stopped Treatment	0
Number Transferred out	3
36 month survival: outcomes by end of December 2008	
New patients registered for ART between October 2005 to December 2005	221
Number Alive and on ART	217
Number Dead	0
Number Defaulted	0
Number Stopped Treatment	1
Number Transferred out	3
48 month survival: outcomes by end of December 2008	
New patients registered for ART between October 2004 to December 2004	149
Number Alive and on ART	147
Number Dead	1
Number Defaulted	0
Number Stopped Treatment	0
Number Transferred out	1

Children Survival Analysis

12 month survival: outcomes by end of December 2008	
New patients registered for ART between October 2007 to December 2007	26
Number Alive and on ART	26
Number Dead	0
Number Defaulted	0
Number Stopped Treatment	0
Number Transferred out	0
24 month survival: outcomes by end of December 2008	
New patients registered for ART between October 2006 to December 2006	17
Number Alive and on ART	17
Number Dead	0
Number Defaulted	0
Number Stopped Treatment	0
Number Transferred out	0
36 month survival: outcomes by end of December 2008	
New patients registered for ART between October 2005 to December 2005	9
Number Alive and on ART	9
Number Dead	0
Number Defaulted	0
Number Stopped Treatment	0
Number Transferred out	0
48 month survival: outcomes by end of December 2008	
New patients registered for ART between October 2004 to December 2004	12
Number Alive and on ART	11
Number Dead	1
Number Defaulted	0
Number Stopped Treatment	0
Number Transferred out	0

APPENDIX B: SAMPLE PICTURE AND SCREEN SHOTS FROM PILOT SYSTEM

Figure 23: Nurse using the specimen labeling system in pediatric treatment room

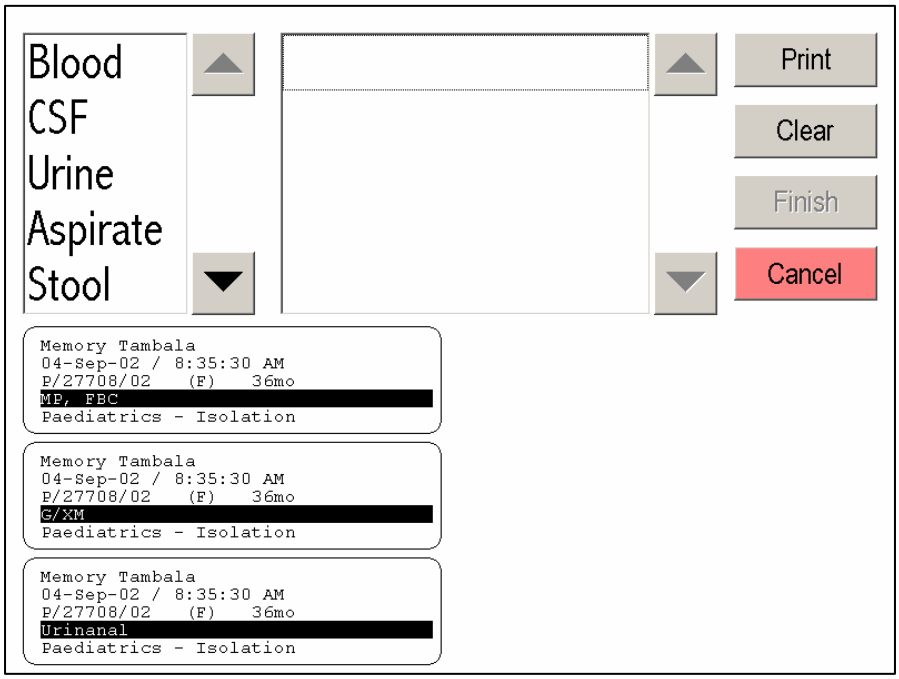


Figure 24: Screenshot of interface used to select specimens

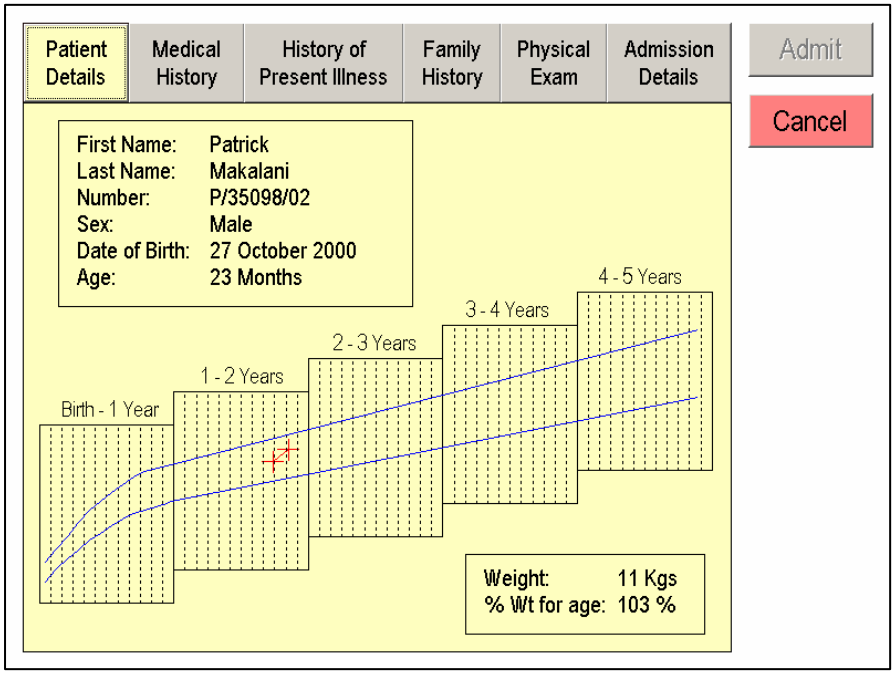


Figure 25: Screenshot of detailed admission module with patient details tab visible

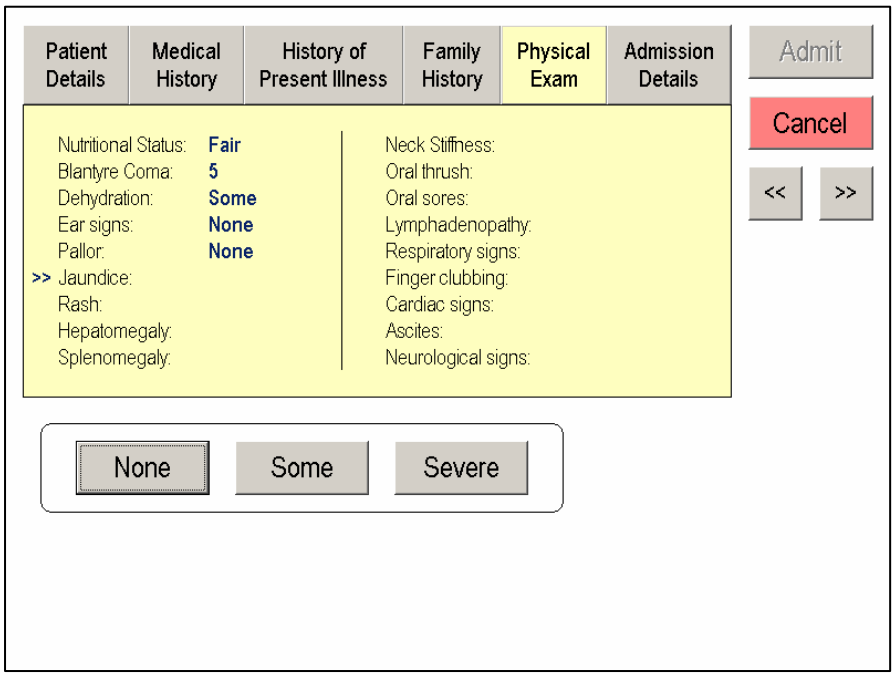


Figure 26: Screenshot of detailed admission module with physical exam tab visible

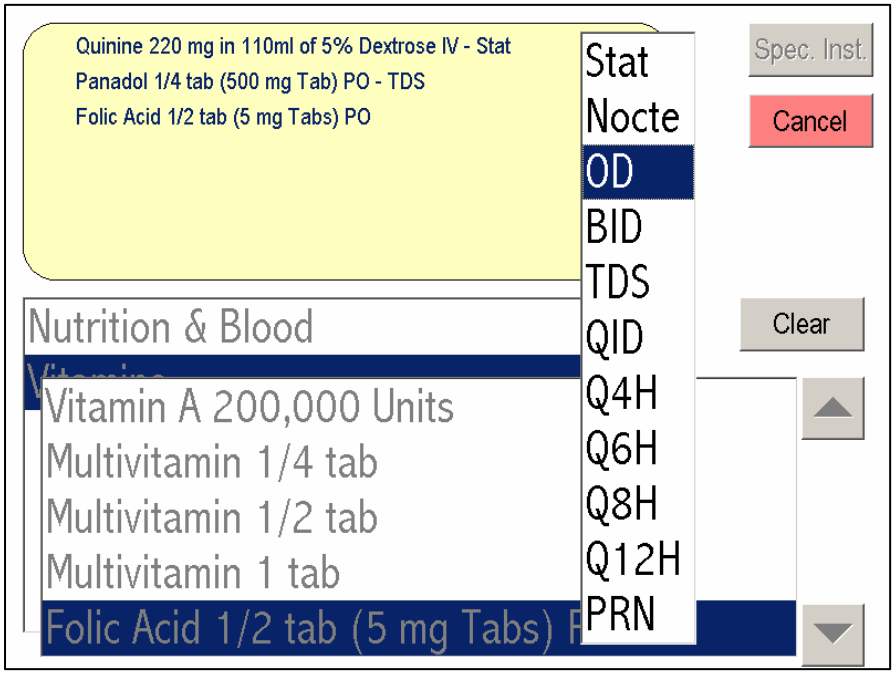


Figure 27: Screenshot for detailed admission module with prescribing tab visible

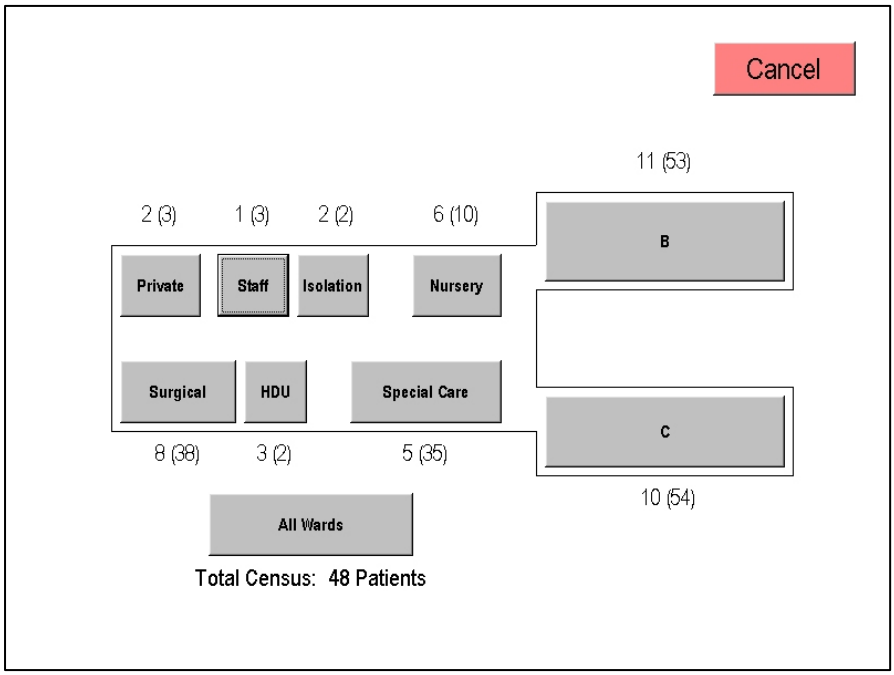


Figure 28: Screenshot showing census on pediatric Ward A

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