Design, Development, and Evaluation of a Laboratory Order Entry and Results Review Application for a Low-Resource Inpatient Setting.

by

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Estimated to be the basis of up to 70% of all clinical decisions, laboratory testing is an important component of the clinical diagnostic process. However, the laboratory testing process is often negatively affected by events that delay or prevent laboratory tests from being performed or the results of those laboratory tests from being utilized in the clinical context i.e. laboratory errors. While laboratory errors are ubiquitous across health facilities, low-resource settings are particularly susceptible to high incidence rates due to shortage of both human and material resources, frequent power outages, and inadequate infrastructure to meet the demand of laboratory testing in these settings.

Appropriate application of technology provides opportunities for reducing the occurrence of laboratory errors by addressing gaps in the laboratory testing process. To this end, we conducted a series of studies at Kamuzu Central Hospital, a referral hospital in the central region of Malawi, a low-income country. These studies were conducted to understand the laboratory testing process in this setting, identify the gaps in the laboratory testing process that could cause specimens to not be analyzed due to various reasons for non-viability, and measure the magnitude of specimen rejections and the reasons for rejection. We then designed and implemented two interventions aimed at reducing the number of specimens rejected as being non-viable for testing. First, we deployed a specimen collection cart with a paper job aid to address gaps in knowledge during specimen collection. The second intervention was an electronic system designed to support the

process of ordering laboratory tests and collecting specimens. Both interventions were evaluated to assess their impact on the rates of specimen non-viability.

We assert that this research contributes to knowledge in several ways. First, it provides descriptions of the current laboratory testing process and its gaps. We provide accurate and current measures of the magnitude of specimen rejection rates in this setting. Third, we describe our experience implementing the first clinician facing system in the inpatient setting at Kamuzu Central Hospital. Lastly, all software and hardware developed in this study is freely available for customization and use in other health care settings.

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Preface

I would like to acknowledge several people who played a part in my journey to completing the doctoral program in Biomedical informatics. To my family, thank you for encouraging me and being so understanding during the past 5 years. You have been there for me through all the difficult moments and have always been patient with me.

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Abbreviations

CAD: Computer aided design

CNC: Computer numerical control

COW: Computer on wheels

CPOE: Computerized provider order entry

EHR: Electronic health record

EMR: Electronic medical record

HIT: Health information technology

ICU: Intensive care unit

KCH: Kamuzu central hospital

LED: Light emitting diode

LIS: Laboratory information system

LMIC: Low- and middle-income country

MHDU: Medical high dependency unit

MSS: Medical short stay

POCT: Point of care testing

WOW: Workstation on wheels

1.0 Introduction

Estimated by some pathologists and clinicians to be the basis for up to 70% of all clinical decisions, clinical laboratory testing is an integral part of patient care [1]–[4]. Primarily, laboratory testing is used in medicine to diagnose disease, monitor progression of disease and treatment, screen for certain conditions, and for clinical research [5]. Results of clinical laboratory testing and the decisions made based on them can often have life-altering impacts such as surgical procedures and prescription of medications.

Despite its essential role in clinical decision making, laboratory testing is often negatively affected by laboratory errors [6]. Bonini et al. define laboratory errors as defects in the testing process from ordering tests to reporting results and appropriately interpreting and reacting to them [7]. We extended this definition to add emphasis on the impact and clarity to the occurrence of laboratory errors. A laboratory error is any event that delays or prevents laboratory tests from being performed or the results of those laboratory tests from being utilized in the clinical context [8].

When they occur, laboratory errors often increase healthcare costs through repetition of laboratory tests, delays in diagnosis and treatment, or wrong clinical decisions causing harm to patients [9]. A 2005 study of laboratory tests performed at the Queen Mary Hospital clinical immunology laboratory in Hong Kong found that up to 16.78% of all tests valued at US$ 132,151 were unnecessary [10]. Another study found that more than 11% of ordered tests were repeated, overutilized or unnecessary [11]. A multi-institutional study of 147 institutions found that approximately one in every 1,087 specimen labels had a labeling error [12]. Another study also found that misidentification of patients occurs in approximately 0.005% to 1% of laboratory

samples [13]. Errors in the laboratory testing process are more common than previously thought [14].

Laboratory errors can occur at various points during the laboratory testing process with rates varying between hospitals based on the challenges that exist at each facility [15]. The total testing process provides a model for thinking about clinical laboratory testing where the process begins and ends with patient care [16]. In this model, the various steps of the laboratory testing process are categorized into one of three phases; the pre-analytical phase, the analytical phase, and the post analytical phase as depicted in Figure 1 [17].

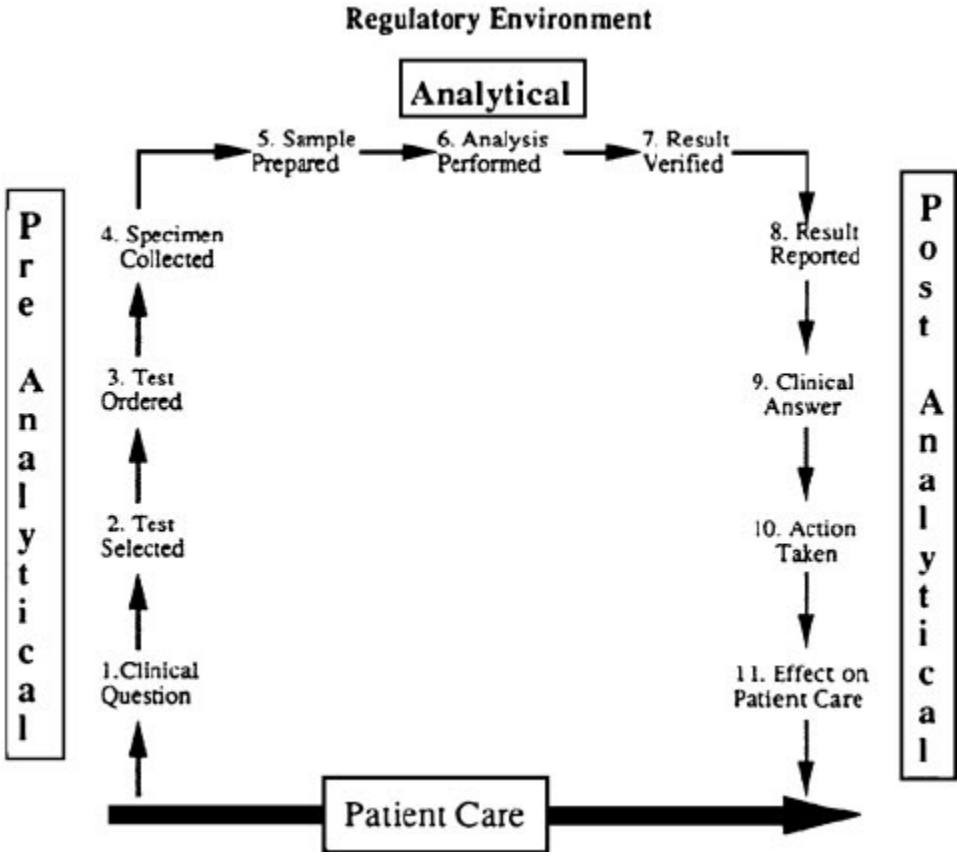


Figure 1: An overview of the total testing process as described by [17].

The pre-analytical phase encompasses all activities from when a clinician decides to order a laboratory test to when the specimen is transported to the laboratory. An underlying assumption of patients and those taking care of them i.e. guardians, is that the clinician will order a test that is relevant to their diagnosis and treatment [18]. However, this is not always the case. Ordering an inappropriate test is one of the errors that can occur in the pre-analytical phase. Similarly, clinicians can also order tests that are not available and cannot be performed at a health facility. This is particularly true in low-resource settings where shortage of staff, reagents and faulty instruments often result in certain tests being unavailable on any given day [19]. Most times, these specimens are not analyzed, leading to delays in provision of treatment or diagnosis of the patient. Several other errors can occur in this phase of the total testing cycle such as collection of the specimen in the wrong container, in insufficient volume of specimen for the instrument to analyze reliably, with the wrong technique resulting in hemolyzed specimens, or failure to legibly label the specimen [20]. All these errors can lead to a specimen not being analyzed when it is received in the laboratory. The general consensus is that most laboratory errors occur between the ordering of the laboratory test and the arrival of the specimen in the laboratory for analysis; affecting the amount of time it takes for a laboratory result to be available or whether the specimen is analyzed at all [7], [21] [7], [8].

The receipt of the specimen in the laboratory marks the initiation of the analytical phase. The analytical phase of the total testing process comprises the various steps and processes between when the specimen is received in the laboratory to when the results of the analysis are released. While significant gains have been made in reducing the occurrence of errors in the analytical phase, the possibility of laboratory errors in this phase has not been eliminated [22]. The most common

errors in the analytical phase include failure to adhere to correct testing protocols, instrument malfunction, failure to detect quality control issues, and mix-up of specimens [23], [24].

In the post-analytical phase, the results generated from analyzing the specimen are transmitted to the clinician for their review and clinical decision. This phase ends with the clinician making a decision on the basis of the new information provided by the laboratory test result. However, challenges in the process can lead to a test result being misplaced and unavailable for review by the clinician. Furthermore, the presence of the laboratory test result doesn't imply that the correct interpretation of the results will be made or that the right results are available as transcription errors can lead to the wrong results being sent to the clinicians [25].

As summarized by Hammerling, automation is one of the necessary steps in a comprehensive plan for preventing pre-analytical errors [26]. Appropriate application of technology provides opportunities for reducing the occurrence of laboratory errors by addressing gaps in the process. This has the potential to improve the laboratory testing process. The use of technology is not new in the laboratory testing process as electronic laboratory information systems (LIS) have a long history of use in clinical laboratories [27]–[30]. Of further note are the significant contributions of automation to the reduction of errors and improvement of processes in the analytical phase [25]. However, the clinical setting, a significant part of the laboratory testing process as modeled by the total testing process, has often been left out of technology applications designed to improve the laboratory testing process [27], [31], [32]. This is in part due to the complexity and myriad of interactions and requirements for systems in the clinical setting. As a result, the manually tasking activities of the pre-analytical phase which happen in the often chaotic clinical setting and are thus particularly more susceptible to errors, have mostly been neglected in traditional LIS implementations [33], [34].

Electronic medical record systems (EMRs) can have a wide range of functionality. The HIMSS EMR adoption model defines seven stages of implementation of EMR capabilities [35]. Radiology, Pharmacy, and Laboratory information systems are considered part of the first stage of EMR implementations. However, the functionality required to facilitate the performance of activities in the pre-analytical phase of the testing process is often not part of traditional LIS implementations. This functionality is often included as part of the computerized provider order entry (CPOE) capabilities which are in the fourth stage of EMR implementations as prescribed by the HIMSS EMR adoption model, CPOE is therefore advanced functionality that is mostly found in more fully-fledged EMR implementations.

Unfortunately, full-fledged EMRs have low penetration in low- and middle-income countries which share the combined misfortunes of having the highest disease burden and the lowest global share of health-care resources [36], [37]. While laboratory errors are ubiquitous across health facilities, low-resource settings are particularly susceptible to high incidence rates and could benefit from the appropriate use of technology. EMRs with CPOE functionality linked to the laboratory testing process could help address challenges in the pre-analytical phase of the laboratory testing process thereby improving the process.

1.1 Dissertation Goal

This research was undertaken with the aim of improving the laboratory testing process at a referral hospital in a low-resource setting. Improvements to the laboratory testing process were done through understanding the current state of the process, identifying and quantifying challenges

in the process and addressing the gaps and challenges through the design and implementation of interventions. To assess the impact of the interventions, an evaluation was conducted to measure any effect on non-viability of specimens collected at the hospital.

1.2 Research Hypothesis and Specific Aims

1.2.1 Hypothesis

This research assessed the effects of two interventions on the non-viability rates for specimens. We hypothesize that the interventions when implemented should lead to a reduction in specimen non-viability rates.

1.2.2 Specific Aims

1. Describe current workflows in laboratory test ordering and specimen collection processes in different hospital departments and wards.
2. Study and measure the effects of deploying a specimen collection cart, designed to facilitate bringing of specimen collection supplies to the bedside, and a paper job aid, designed to address knowledge gaps on specimen collection, on the viability of specimens that are collected and the workflows used to collect the specimens.
3. Design, develop, and implement an electronic laboratory order entry system designed with digital job aids for improving the test ordering and specimen collection processes.

4. Evaluate the impact of the electronic laboratory order entry system on the viability of specimens that are collected and the workflows used to collect the specimens.

1.3 Significance of this Research

Laboratory testing plays a significant part in clinical decision making and patient treatment. Reliable laboratory services are essential for prevention and treatment of both current and future infectious and chronic diseases [38]. However, years of minimal investment in the laboratory infrastructure in sub-Saharan Africa poses a significant threat to global efforts to combat infectious disease and the associated antimicrobial resistance [39], [40]. Poor communication systems, process gaps, and infrastructure challenges often limits the effectiveness of laboratory test results in low-resource settings. Some of these challenges can be overcome through the application of appropriate and sustainable technologies. Several studies have reported the implementation and use of informatics interventions, often in the form of EMRs in low-resource settings. The potential of EMRs to improve availability of medical records, processes, and decision making can have tremendous impact in low- and middle-income countries (LMICs) where two thirds of the world population reside and the greatest burden of disease lies [41], [42]. However, there is a dearth of knowledge on the systematic use of technology to improve the total testing process in low-resource laboratory settings.

This research is motivated by the recognition of the challenges to laboratory testing in low-resource settings and the role that information technology can play in addressing these challenges. Clinicians can benefit from a system that provides visibility into the status of the various laboratory tests which they ordered and the results of those tests. Furthermore, a system that facilitates the

reduction in the number of non-viable specimens and improves the communication between the laboratory personnel and clinicians could result in timely delivery of patient care and reduction in healthcare costs. This dissertation describes the development, implementation, and evaluation of two interventions aimed at addressing the challenges to laboratory testing in low-resource settings.

1.4 Dissertation Outline

In Chapter 2, I present an overview of pertinent topics and prior work relevant to this research. Chapter 3 describes the overall research design and describes the setting where the research was conducted and the approach used to conduct it. Chapter 4 describes a study aimed at understanding the current workflows for diagnostic testing workflow at the research site. In Chapter 5, a study to measure the magnitude of specimen non viability at the research set is described and the results are presented. In Chapter 6, the first intervention, a specimen collection cart and paper job aid, aimed at improving the specimen collection process and reducing specimen non viability is presented. The chapter describes the intervention, its deployment in the clinical setting and an evaluation of its impact on the laboratory testing process. The second intervention, an electronic laboratory order entry and results review system, aimed at improving the testing process is introduced in Chapter 7. This chapter describes the concepts used to design the intervention and the realization of the design choices. In Chapter 8, the electronic laboratory order entry and results review system is piloted in the clinical setting and the level of user adoption is assessed. Chapter 9 describes a study to assess the impact of the electronic laboratory order entry and results review system on the laboratory testing process and user intentions towards continued

use of the system. Chapter 10 summarizes the dissertation and highlights the lessons and contributions from this research.

2.0 Background and Related Work

In this chapter, I review the relevant literature and provide the background on pertinent topics and concepts to this dissertation. Section 2.1 provides an overview of diagnostic testing; the process, its challenges, and the opportunities that exist to improve the process. In Section 2.2, I introduce concepts from biomedical informatics and how they can be used to improve the total testing process. Section 2.3 introduces the lean healthcare framework that has shown promise in improving health care delivery. Section 2.4 discusses the uniqueness of LMICs and the challenges faced in this setting. A context for the work described in this dissertation is established and the concepts previously described are applied to this setting. Section 2.5 discusses the role of information technology in healthcare and the use of electronic systems to improve the delivery of care. The chapter concludes with Section 2.6 where the gaps in prior work are presented and the contributions of this dissertation are highlighted.

2.1 Diagnostic Testing

The role of the laboratory in the continuum of patient care cannot be overemphasized. Physicians use laboratory tests to diagnose, treat, manage or monitor the condition of a patient [43]. Diagnostic testing can happen at the point of care or in the laboratory. Point of care testing (POCT) enables quick medical decisions as the tests tend to have a relatively short turnaround time [44]. Recent advances have improved reliability of most POCT devices with the accuracy of results comparable to laboratory-generated test results [45]. Despite longer turnaround time, laboratory-

based testing tends to be more robust as most laboratory instruments have higher levels of sensitivity and specificity as opposed to POCT devices and the laboratory testing process has a well-defined quality assurance program [46], [47]. As a result, the majority of diagnostic testing is still performed in the clinical laboratory.

Despite the importance of diagnostic testing in health care, clinical laboratories face several challenges. To begin with, clinical laboratories face a global shortage of qualified technologists [48], [49]. Reasons for the reduced workforce include retirement, increased demand for laboratory services, and changes in practice due to technology advances [50]. Workforce capacity for pathology and laboratory medicine is one of the gaps that needs to be closed to achieve universal health coverage, a sustainable development goal [48], [51], [52].

Apart from achieving universal health coverage, the health-related sustainable development goals also seek to substantially increase health financing [52]. For a critical component of health care, the clinical laboratory often accounts for a small proportion of total hospital expenditures [53]. Forsman estimates that laboratory services may account for only 5% of hospital budgets even though laboratory test results influence up to 70% of all clinical decisions [2]. This disproportionate availability of resources severely undermines clinical laboratory operations.

Lack of adequate funding combined with workforce capacity has an effect on the total testing process. Lack of adequate financial resources limits the capacity of most clinical laboratories through frequent unavailability of testing kits and reagents, failure to maintain and upgrade laboratory equipment, and inability to provide continuous professional training of the workforce on new equipment and methods.

Laboratories play a critical role in health care. To ensure that minimum standards are being met, accreditation has become a preferred framework for quality improvement in medical laboratories particularly in LMICs [54], [55]. External quality assessment is essential for measuring and identifying gaps in laboratory performance [56]. Closing the gaps identified in these and similar assessments is vital for the continued well-being of society. Various tools exist that could be used to help close these gaps.

2.2 Biomedical Informatics

Biomedical informatics as defined by Bernstam et al. is the science of information applied or studied in the context of biomedicine [57]. Though often involving computers, the focus of biomedical informatics is not to computerize health care but rather to improve it [57]. In this context, computers are merely a tool for improvement. The tools used are not more important than the work itself [58]. Further, computers are not the only tools that can be used to improve healthcare. In his proposed fundamental theorem for biomedical informatics, Friedman uses the term `information resource' as opposed to computers to describe the essence of biomedical informatics where an information resource is "any mechanism capable of providing knowledge, information, or advice to support the person's task completion" [59]. He further describes the work of informaticians as creating and supporting information resources, which when used by a person to support their work, the resulting work is better than the same person working unassisted [59].

Primarily, biomedical informatics is more about people and not tools or technology [59]. The goal is to improve health care leading to better health outcomes and not to increase use of technology. This is achieved through understanding the process, problems, and the culture in

health care [57], [60]. As a science, Biomedical informatics therefore provides tools for understanding problems and other phenomena.

Understanding and measuring the magnitude of problems provides a mechanism for assessing the impact of any tools that can be built. Friedman and Wyatt refer to these assessments as evaluations and describe nine different types of evaluation studies that can be done [61]. Even with good intentions, implementations of technology in health care do not always lead to improved outcomes and can sometimes introduce new types of errors and unintended consequences [62], [63]. The dynamic nature of the clinical setting results in continued occurrence of unintended consequences and underscores the need for evaluation when implementing informatics projects [64].

2.2.1 Informatics in the Clinical Laboratory

Clinical laboratories were early adopters of information technology in health care. Descriptions of use of computers and automation in laboratories can be found from as early as the 1960s [30]. This was largely necessitated by the large volume of specimens analyzed by clinical laboratories and the accompanying documentation and reporting needs [65]. The specialized application of information technology to optimize and extend laboratory operations is called laboratory informatics [33].

Based on area of application, classifications have been developed to describe the type of informatics work being conducted. Informatics work aimed at facilitating patient management through an interdisciplinary approach is called clinical informatics [66]. This field covers a range of applications including clinical decision support and provider order entry systems [67]. Laboratory informatics is often limited to the laboratory and the analytical phase of the testing

process even though the main consumers of laboratory information are clinicians who operate outside of the laboratory [33]. This research brings together clinical informatics and laboratory informatics on the basis of trying to improve laboratory testing which cuts across both informatics classifications.

Communication between the laboratory and clinicians is often a challenge in the laboratory testing process [68]. Clinicians may not be fully cognizant of the expectations that the laboratory has of them in relation to the performance of tasks related to the laboratory. The clinicians have expectations of getting results of a certain quality from the laboratory within a reasonable amount of time, an expectation that has often led to negative attitudes toward the laboratory from clinicians [39]. Improving the communication between these two parties in the laboratory testing process could improve the entire laboratory testing process.

2.3 Lean Healthcare

Lean healthcare is a set of methods or tools adapted from the Toyota Production System that seek to improve the efficiency and reduce the cost of healthcare [69], [70]. Universal health coverage as part of the sustainable development goals seeks to reduce financial risk for people accessing health services [52]. To achieve this, people must either have enough money to afford health services or, more realistically, the cost of health care must be reduced so that everyone can afford it. Lean methodologies applied to healthcare, i.e. lean healthcare, have been shown to improve processes, eliminate delays, improve patient care, and reduce costs [71]. The lean approach seeks to create value for the customer quickly, efficiently and with minimal waste [72],

[73]. Waste in healthcare can take one of eight forms: defects, overproduction, transportation, waiting, inventory, motion, over processing, and untapped human potential [74].

As defined by Bonini et al. laboratory errors are defects and fall under the category of one of the forms of waste in healthcare [7]. Similarly overutilization of laboratory tests (overproduction), delays in transporting specimens to the laboratory, and delays in reporting laboratory results are all forms of waste in health care that could be addressed through lean health interventions [11], [26], [75].

The application of lean healthcare methodologies shows potential in improving the laboratory services by eliminating different forms of waste. Inal et al. report using the lean methodology of define, measure, analyze, improve, and control (DMAIC) to reduce turnaround time of urgent tests and the steps prone to medical errors in the laboratory reception area [76]. Sanders and Karr were able to cut in half the utilization of specimen containers and the number of unused specimens [77]. 5S, a lean methodology for creating a clean, organized, and efficient working environment was used together with other lean methodologies by Rutledge et al. to reduce turnaround time for creatine from 54 to 23 minutes [78]. Further, Mitchell et al. had success in even reducing the expenditure from purchasing reagents used for laboratory testing using lean methodologies [79]. These and similar findings have direct impact on the laboratory testing process and costs incurred. Utilizing lean methodologies to replicate similar successes in low-resource settings could have tremendous impact and free up some of the much-needed resources.

2.4 Low- and Middle-Income Country Settings

In 2017, a 3.9% growth health care expenditure resulted in 3.5 trillion USD being spent on health care goods and services in the United States [80]. In the following year, the net cost of health insurance grew by 13.2% resulting in a 4.6% increase in expenditure and a total of 3.6 trillion USD (11,172 USD per person) spent on healthcare in the United States [81]. In contrast, the average current health expenditure per capita for LMICs was 884 USD. Fifty-three countries were classified as lower-middle income by the World Bank with a gross national income of under 3,995 per capita [82]. A further 31 countries were classified as low-income countries with a gross national income of under 1,025 per capita.

Health systems globally face some common challenges such as the rise in non-communicable diseases and antimicrobial resistance [83]. The high burden of disease and severe shortage of both human and material resources further complicates the challenges of health systems in LMICs [84]. Low access rate to electricity and high rates of power outages adds further complexities to delivery of health care in LMICs [85], [86].

In the context of laboratory testing, LMICs experience further challenges in the form of inadequate supply of trained personnel, lack of reagents to perform certain tests and frequent service interruptions due to broken down equipment and power outages, and unavailability of redundancies for performing certain tests [87]. These challenges can have an effect on the laboratory testing process resulting in compromised health care delivery. For example, lack of adequate laboratory personnel can cause analysis of certain specimens to be delayed thereby compromising the quality of the tests. Prolonged downtime of laboratory equipment often results in waste of resources as several specimens may be collected but not analyzed during that time. These are some of the challenges in providing health care in LMICs.

2.5 Health Information Technology and Electronic Systems

The myriad of challenges faced by health systems in LMICs present an opportunity for innovation and generation of evidence for different solutions and approaches. One area that shows promise for improving health care delivery in LMICs is the use of electronic health record systems (EHRs) [88].

Since the early 2000s, the adoption and use of EHRs has been steadily increasing globally. In 2008, four out of seven industrialized countries surveyed had EHR adoption rates above 90% for general practices [89]. By 2015, the United States had achieved 84% EHR adoption in contrast to just 9% in 2008 [90]. While these trends have not been replicated in LMICs, various publications have reported EHR implementations in these settings [88]. The use of health information technology (HIT) has the potential to improve performance of health care providers, reduce costs, and improve quality [91].

Unlike in the United States where the uptake in adoption of EHRs has been driven by availability of federal funding to implement these systems, the scarcity of resources in LMICs necessitates that expenditure on health information technology should be grounded in evidence or theory of efficacy and effectiveness [92], [93].

2.6 Our contributions

Several studies have reported the implementation and use of EHRs in LMIC settings. These implementations have predominantly been in outpatient settings. Published literature on the implementation and use of EHRs in LMIC inpatient settings is scarce. Further, historical work in

laboratory informatics mostly centered on aiding the analytical side for the testing process. Gaps still remain in our understanding of how best to implement EHRs in LMIC inpatient settings and whether investing in such implementations is the best use of the limited available resources. This research aims to reduce this gap in knowledge by measuring the utility of a minimally viable HIT intervention in a LMIC inpatient setting.

3.0 Research Design

The research described in this dissertation was carried out at Kamuzu central hospital (KCH), a referral hospital in the capital city of Malawi. We collaborated with the hospital management and the laboratory personnel to understand and improve laboratory testing processes.

3.1 Setting: Kamuzu Central Hospital

KCH is a government-run 780-bed facility which serves the entire central region of the country and offers specialized care for cases that cannot be treated at district and most privately-owned hospitals in Malawi. The hospital had a bed occupancy of 83% in 2010 and treated 275,880 patients in that year alone [94]. The laboratory at KCH is responsible for analyzing specimens for outpatients, inpatients and referrals from other hospitals. Between July 01, 2010 and June 30, 2011, the laboratory at KCH performed 242,242 laboratory tests [95].

Three key factors make KCH an ideal location to conduct this research. To begin with, previous work that this research builds upon was conducted at this facility [95], [96]. The proposed research is therefore a continuation of that work and a testimony of the good rapport we enjoy with the administration of the hospital. Second, KCH as a referral hospital has a relatively busy inpatient setting and a laboratory that performs a high volume of laboratory tests. This allows us to see effects and trends relatively earlier than would be the case at a low volume facility. Finally, the hospital currently has several electronic information systems that are deployed and in use. These include a patient registration system that records patient demographic records and assigns patients

a nationally unique patient identifier. This identifier is used to retrieve patient records in all the other EMR modules at the facility to promote completeness of the patient record and continuity of care. The facility also has a radiology module that supports the processes in the hospital's radiology department. The laboratory at KCH has a functional electronic LIS that tracks specimens and tests through the analytical phase of the total testing process. This system has been in use since June 2016 and stores all records of the tests that have been performed at the facility. These pre-existing systems provided a foundation upon which the electronic intervention envisioned in this research could be built upon.

3.2 Process Improvement Approach

Systematic errors as opposed to random errors and blunders often indicate weakness in policies and processes [97]. Changes are often necessary to reduce or eliminate these types of errors. This requires a detailed understanding of the current process and procedures. Our approach to process improvement encourages making refinements to existing processes such as the laboratory testing process as opposed to wholesale introduction of policies or new procedures. Process refinements are made through small additions and changes to the process that can be measured and make it easy for the users to adhere to policies and complete the relevant process activities. These additions and changes often fall in one of two categories: Job aids and value propositions.

A job aid is an external resource that supports work and activity by directing, guiding, and enlightening performance of a task [98]. A job aid can take several forms including a checklist, how-to directions, flowcharts or an infographic and equips the performer of a task with the

information necessary to successfully complete the task by reducing memory and possibly training requirements [99]. The concept of a job aid is referenced several times in this dissertation often with a descriptor of being digital or paper-based. A digital job aid is any resource that has been encoded in a computer program with the aim of facilitating the performance and completion of a task.

A value proposition is an incentive for a consumer that makes them prefer one product or process over another. With value propositions, the focus is primarily on the individual and their preferences. A value-proposition attempts to steer the individual into preferring one thing over another. It addresses the question, "What value can the consumer get from using this product or process that they would not have otherwise". This is not dissimilar to the second corollary of a fundamental theorem for biomedical informatics as proposed by Friedman; for an individual working with an information resource to be better than the same individual working alone, the information resource must provide something that the individual doesn't already possess i.e. the information resource must provide value [59].

A common theme in low-resource healthcare settings is high ratios of patients to providers. This implies that providers in these settings are relatively overworked. One obvious role of biomedical informatics in this setting is maximizing the efforts of these providers by ensuring that their efforts are not wasted by frequently performing non-value adding tasks or incorrectly performing the tasks that add value.

To identify tasks that add value, we must first understand the process in its entirety and the goals of each action. Furthermore, to prevent value-adding tasks from being done incorrectly, we must identify and investigate the root causes of errors in the process. The magnitude of errors must be measured and deliberate measures must be designed and implemented to eliminate or reduce

the errors. Deliberate measures or actions made with the aim of reducing the incidence and likelihood of errors are called interventions.

Our approach is therefore grounded in concepts from biomedical informatics which seeks to facilitate processes by providing information resources, lean methodology which improves processes by adding value and eliminating waste, and implementation science which seeks to develop evidence and promote systematic uptake of proven methods and tools in routine practice [59], [100]–[102]. We seek to improve the laboratory testing process at KCH by understanding the process, measuring the magnitude of errors, and introducing interventions in the form of job aids that will address reasons for specimen non-viability while offering value to the clinicians involved in the laboratory testing process.

The studies described in dissertation were approved by the University of Pittsburgh Institutional Review Board (STUDY19040269) and the National Health Sciences Research Committee in Malawi (Protocol #: 19/05/2342). We were also given permission to conduct the study at KCH by the hospital management.

4.0 Understanding the Current Diagnostic Testing Workflow at Kamuzu Central Hospital

4.1 Introduction

The field of medicine as described by Callahan, seeks to relieve pain and suffering, promote health, prevent disease, forestall death, and cure or manage disease [103]. Key to achieving these goals is a detailed understanding of disease that allows clinicians to classify a given presentation of symptoms and complaints into a pre-existing set of categories agreed upon by the medical profession that can then be treated or managed i.e. making a diagnosis [104]. A timely and accurate diagnosis improves the chances of a positive health outcome as the right treatment and management can be provided based on the patient's condition [105].

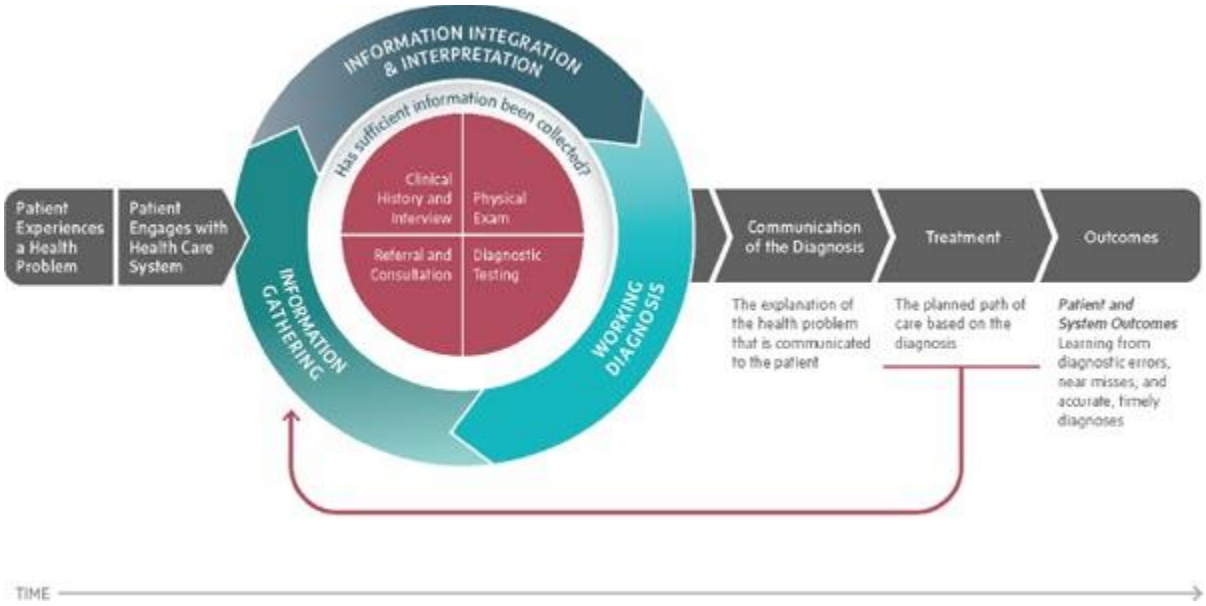


Figure 2: A summary of the diagnostic process as presented by [106]

Figure 2 provides a conceptual model of the process used to make a diagnosis [106]. While fairly robust and reproducible, sometimes the diagnostic process can produce errors leading to missed, delayed, or wrong diagnosis [107]. Failure to provide an accurate and timely diagnosis or communicate an explanation of the patient's health condition to them is called a diagnostic error [108]. Causes of diagnostic errors are often categorized into cognitive and system-related [109]. Cognitive errors can be identified in a majority of diagnostic error cases [109]. However, Graber et al. found that diagnostic errors are often multifactorial in origin and involve both cognitive and system related factors [107].

A synthesis of three studies in the United States estimated that up to 12 million adult Americans experience one diagnostic error each year with half of these errors potentially leading to adverse events and outcomes [108]. Diagnostic errors can cause harm to patients and waste valuable health system resources. A 25 year analysis of malpractice claims in the United States found that diagnostic errors were the most costly and frequent type of claims accounting for US$ 13.6 billion inflation-adjusted payouts [110]. Data on incidence of diagnostic rates in LMICs is not readily available but the rates are expected to be much higher due to limited access to diagnostic testing, inadequate human resource, and challenges in maintaining accurate patient records [109].

Diagnostic testing plays an important role in the diagnostic process. While some tests happen at the point of care, the majority are performed in a clinical laboratory. Diagnostic testing using the clinical laboratory happens across two distinct settings in healthcare namely, the clinical setting and the laboratory setting and follows the total testing process.

The significance of laboratory test results in the clinical decision-making process suggests that laboratory errors are a likely source and contributor to some diagnostic errors. However,

laboratory errors have often been neglected in the discussion about diagnostic errors partly due to the number of steps and the amount of time between laboratory testing, clinician actions, and patient outcomes [22]. The increasing demand for reliable laboratory services and the prominent role of laboratory tests in clinical decision making necessitates that laboratory errors are no longer neglected as errors in the process can be costly both to patients and the health system.

Reducing the probability and incidence of laboratory errors provides a significant opportunity for improving health care delivery and reducing costs. However, before any changes can be made to improve the process, we must first understand the current process. This provides a baseline for measuring any impact that the changes may have on the process.

4.2 Methods

To understand the entire diagnostic testing process as it exists at KCH, we conducted direct field observation in both the laboratory and the different hospital wards. KCH has four clinical departments: medical (internal medicine), obstetrics and gynecology, pediatrics, and surgery. Each department runs one or more outpatient clinics to treat ambulatory patients and has several wards under their management. The laboratory at KCH has seven departments: parasitology, biochemistry, serology, hematology, blood bank, and microbiology. To understand the expectations that the laboratory had of the clinical personnel, we began our observations in the laboratory. This was done to get an understanding of the reasons why specimens are rejected. Understanding these reasons helped us identify circumstances in the clinical setting that could lead to specimens being rejected.

4.2.1 The Laboratory

Direct work observations of laboratory personnel were conducted to understand the workflows within the analytical phase of the total testing process. These observations were preceded by an introduction of the research to the laboratory manager and the laboratory personnel during the weekly laboratory meeting. Laboratory personnel were briefed on the aims of the research and the research activities that would be conducted.

To understand the journey of a specimen from when it is received in the laboratory to the releasing of a laboratory result, the primary researcher observed laboratory personnel for three consecutive days. Our observations begun in the laboratory reception which is the entry point of all specimens into the laboratory. To understand the process within the departments in the laboratory, specimens belonging to each of the departments were followed to the department and the process observed. Where possible, the laboratory personnel were asked to clarify procedures and actions that were not clear. Notes from the observations were used to create workflow models illustrating the processes and any breakdowns in the process that could affect the viability of the specimens.

4.2.2 The Clinical Setting

To understand the total testing process workflow in the clinical setting, the primary researcher shadowed clinicians as they were conducting ward rounds. Before shadowing clinicians in each department, we first briefed the head of the clinical department about the research that we were conducting and the goals that we were seeking to achieve. This was followed by a briefing

of the clinical staff in that department during morning handover meetings which we attended daily for the course of direct observations in each department.

We utilized the morning handover meetings to also recruit clinicians to shadow for that day. Following the meeting, we approached clinicians who were on duty and were going to conduct ward rounds that morning. To ensure completeness of the observations, we shadowed more than one team or unit of clinicians in each ward.

In the clinical setting, decisions to conduct laboratory tests are often made during routine patient reviews or when emergency situations arise. These decisions are often preceded by a physical exam and a review of the patient's past laboratory test results if they are available. By shadowing the clinicians for the entire ward round, we were able to sequentially observe the pre- and post- analytical phases of the laboratory testing process in each of the four distinct clinical departments at KCH.

Observation notes from each clinical department were used to create a process diagram for the pre- and post-analytical aspects of the total testing process. Differences in processes between departments and between clinicians in the same department were incorporated in the same diagram to provide a complete description of the processes within the clinical setting.

4.3 Results

Direct field observations were conducted to understand current total testing process workflows at KCH. Laboratory and clinical personnel were observed while conducting various activities that form the total testing process. Our observations begun in the laboratory at KCH.

4.3.1 The Laboratory

Three direct work observation sessions of the laboratory reception at KCH were conducted to understand the workflow for receiving specimens and the challenges encountered in the process. Cumulatively, the laboratory personnel were observed for 16 hours over three consecutive days. Tests received at the laboratory and going to different departments within the laboratory were also followed to understand the processes within the different laboratory departments.

4.3.1.1 Personnel and resources

The laboratory reception at KCH is staffed by two cadres of personnel. The first cadre is the laboratory receptionists. This group is responsible for receiving and registering specimens as they arrive, conducting preliminary checks for viability, sorting specimens into the appropriate departments, and delivering the specimens to the department where it will be analyzed. Currently, three people serve in this capacity at the KCH laboratory reception. The laboratory receptionists work from 8am to 4pm on week days.

The second cadre is the client officer. This is a recently introduced role that is filled by a laboratory technician for a week at a time. A schedule is produced by the laboratory management assigning a laboratory technician from one of the departments of the laboratory to the role of client officer for one week. To ensure that the technician is not overwhelmed with work during that week, the technician is excused from all duties in their department while serving as a client officer.

Client officers are primarily responsible for retrieving laboratory results from the electronic system or the various departments and releasing them to the clients of the laboratory. Due to their training as laboratory technicians, the client officers are able to interpret laboratory results and notice if there are any discrepancies in the results. Furthermore, they are also able to explain

specific details of the laboratory testing process that may not always be known by the laboratory receptionists.

To ensure that the laboratory reception is open from 7:30am to 4:00pm, one of the laboratory receptionists has different work hours from their peers. This laboratory receptionist is responsible for opening the laboratory reception window and starts work at 7:30am, works through the official lunch hour and is allowed to leave work early. The other two laboratory receptionists start work at 8am and work until 4:00pm with an hour lunch break from 12:00pm to 1:00pm. This arrangement leaves the laboratory reception with two receptionists for a large part of most afternoons. On the days that the first receptionist is unavailable, the laboratory reception is closed during the official lunch hour and emergency specimens are received through the blood bank. The blood bank is a department within the laboratory that is always supposed to have at least one person working there at all times. Due to this unique qualification, it also serves as a secondary laboratory reception when the main reception is closed i.e. at night, on public holidays, and when there is no one to cover the main laboratory reception during lunch hours.

The laboratory reception is equipped with four computers, three of which are all-in-one touchscreen computers equipped with a thermal label printer and a barcode scanner. These are used to register new specimens in the electronic laboratory information system. The fourth computer is another all-in-one computer without a touchscreen. This computer is primarily used by the client officer for checking results and status of tests in the LIS.

4.3.1.2 Workflow

The laboratory serves two types of clients grouped according to their roles in the health system. The first group consists of clinical personnel who will often bring specimens for patients

admitted in the wards to the laboratory for analysis. Patients utilizing ambulatory hospital services at the facility are the second type of client for the laboratory.

To facilitate the different needs of these two groups, the laboratory reception personnel separate specimens based on client type. Patients and clinicians are encouraged to form two separate lines based on their role so that they can be assisted in a timely fashion with clinicians being given priority. However, orderly queuing is not always possible especially when there are many clients waiting to be served by the laboratory reception. Furthermore, people queuing at the laboratory reception are usually there for one of two reasons: to drop off specimens or collect results of laboratory tests. Since receipt of specimens and releasing laboratory test results is done by two separate cadres of people at the laboratory, this necessitates that two different lines are formed based on the reason for being at the laboratory reception. Overall, four different lines must be formed to cater to all the reasons and client types at the laboratory reception. This often results in a crowded reception area as the windows where the lines can be formed are narrow.

Figure 3 depicts the analytical phase of the testing process at KCH starting from when the specimen is received to when the result is available. The process begins with the receipt of specimens at the laboratory reception. It is recommended that a specimen with its requisite laboratory order form be handed over to the laboratory receptionist. However, this is not always possible. Due to crowding at the laboratory reception, clients, especially clinical personnel, just leave specimens on the reception counter sometimes without the laboratory order forms. This makes it difficult to match forms to specimens and can lead to rejection of the specimens due to missing laboratory order forms. Further, in cases of incomplete documentation, the person bringing the specimen has the opportunity to provide the missing information and prevent rejection of the

specimen if they are present. However, when the specimen was just left on the counter and not handed over to a laboratory receptionist, this is not possible.

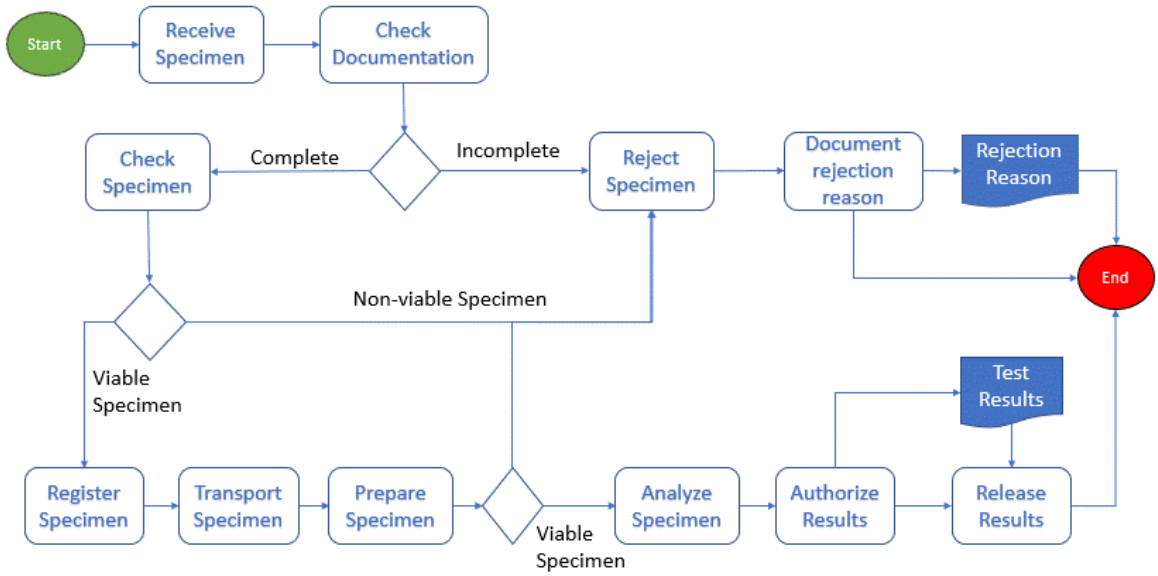


Figure 3:The analytical phase process as observed at KCH.

Upon receipt of a specimen, the laboratory receptionist checks the specimen and the order form to make sure that all the identifying details are present and correspond to each other. Furthermore, the assessment verifies that the right specimen type for the test ordered was collected and that all the necessary fields have been filled on the order form. If everything is in order and the workload is low or an urgent test result is required, the laboratory receptionist will register the specimen in the KCH LIS immediately. Otherwise, the specimen together with the form is placed, in order of arrival, on a specimen rack dedicated to test from one laboratory department. These specimens are often registered once the workload has eased and the laboratory receptionists are no longer predominantly receiving specimens.

Registering a specimen in the LIS generates an accession number for the specimen that is used to uniquely identify the specimen in the laboratory. The accession number represented in both human-readable form and as a barcode is printed on an adhesive label, which is affixed to the specimen container and laboratory order form. The specimen and laboratory test requisition form are then brought to the right laboratory department for analysis. Each laboratory department has a designated specimen receiving area where recently registered specimens are left. The laboratory technician in that department will collect specimens from this area and start processing them. Once the analysis is complete, the laboratory technician enters the results in the LIS manually if the instrument used for analysis is not interfaced with the LIS. If the instrument is interfaced, the laboratory technician fetches the result from the instrument through the LIS and reviews them to ensure that all the parameters were retrieved. Once the results have been entered or fetched, the laboratory technician can save them and the test is marked as complete. However, this result cannot be printed or released to a client until it has been authorized by another laboratory technician as recommended by international laboratory practices [111]. This is done as a verification step to ensure that the results being released from the laboratory are not erroneous. Once authorized, the results can be printed and released to the clients.

Releasing of results is done in two ways. For outpatients, the name of the patient is called out in the laboratory reception and the result is handed over to them if they are available. For patients that are not available, the result is placed in the outpatient results pigeon holes within the laboratory reception. Inpatient results are placed in the inpatient pigeon holes according to the ward from which the laboratory test request came. Clinical personnel are encouraged to first check these pigeon holes for the laboratory results of their interest before asking the client officer.

4.3.1.3 Challenges in Process

Several challenges exist in the processes within the analytical phase of the total testing process at KCH. The first challenge is the late delivery of specimens at the laboratory. Due to the walking distances involved, specimens are often collected and kept in the wards until there is a person available who is heading in the general direction of the laboratory. This results in specimens being dropped off as people are going to lunch or leaving work as the laboratory is on the route out of the hospital premises. Unfortunately, many specimens arrive at the laboratory around the time that the laboratory personnel are leaving their duty stations. As a result, specimens are sometimes left overnight to be registered the next morning because they arrived late in the laboratory.

To preserve specimens that have not been registered and will not be tested on the same day, some specimens are moved to departments for preservation. This is common for biochemistry specimens that have to be separated and refrigerated for preservation. Due to this break in normal process, sometimes specimens can be found in laboratory departments without being registered and can be lost to follow up.

Another challenge within the laboratory is the delays in retrieving results from the LIS. This is a result of several factors but key among them were transcription errors that meant that the client officer had to search several permutations of the patient name before identifying the results for the patient. After several unsuccessful attempts to get results, the patient or clinical personnel will often have to collect another specimen for analysis.

4.3.2 The Clinical Setting

4.3.2.1 Personnel and resources

The clinical setting at KCH has numerous configurations for personnel. Generally, there are 4 cadres of people working in the clinical setting: doctors, nurses, students, and patient attendants/maids. Predominantly, nurses and patient attendants are assigned to specific wards. Due to inadequate staffing, some patient attendants cover more than one ward.

Doctors are assigned to specific clinical departments and to a team or unit within the department. A unit or team is composed of a consultant/specialist, a registrar and intern medical/clinical officers based on availability. The pediatric department is an exceptional case in that instead of teams or units, doctors are assigned to specific wards. A team or unit is responsible for managing care for any patient that they admitted to any of the wards in their department. Furthermore, they are responsible for assessing patients which they admitted that have been moved to the intensive care unit.

Students who do rotations in the hospital as part of their training form the last cadre in the clinical setting. At least four schools have their students from different programs doing rotations at KCH. Students doing rotations at KCH are often from Nursing, Medicine, and clinical officer training programs.

4.3.2.2 Workflow

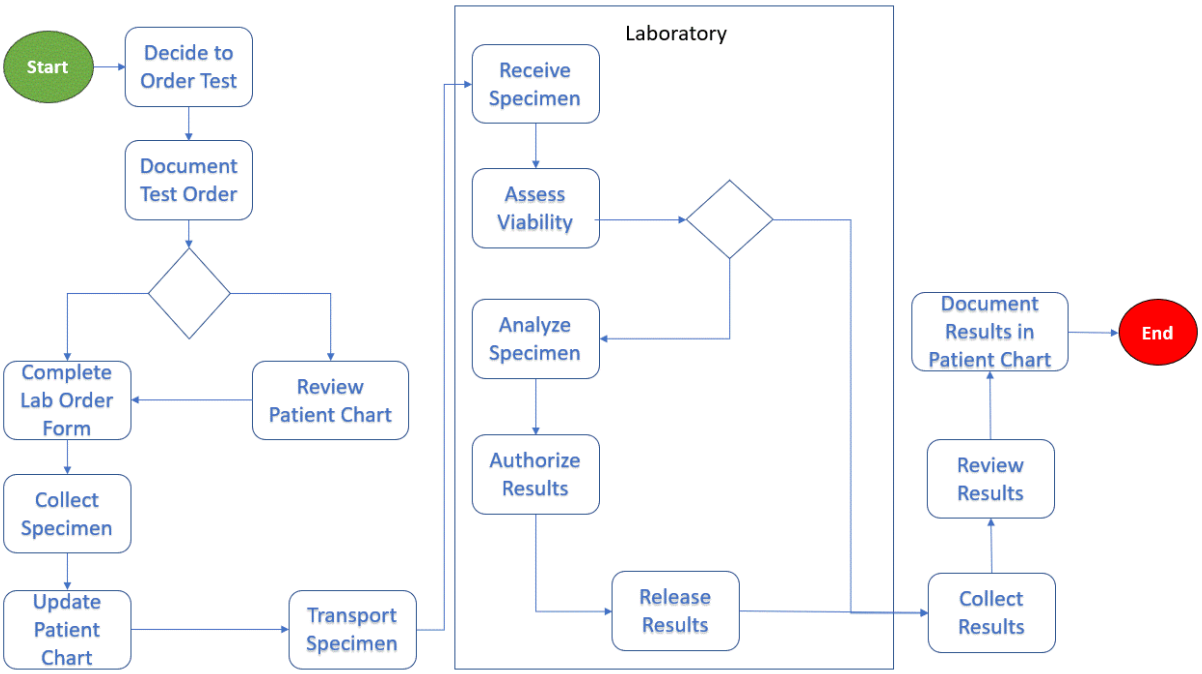


Figure 4: The laboratory order, specimen collection and transportation processes as observed at KCH.

Figure 4 gives an overview of the process for ordering laboratory tests, collecting specimens, and transporting the specimens to the laboratory. Most laboratory tests are ordered during ward rounds by writing the order for the test in a patient paper chart. An unchecked box next to the name of a laboratory test is often used to indicate an order. A check mark is added to the box when the specimen has been collected either by a doctor, nurse or student. Once collected, the specimen is either brought directly to the laboratory or left in a specimen holding location for transport to the laboratory. In most departments, it is expected that the patient attendant will bring the specimens to the laboratory. However, this often leads to delays as the patient attendants have a wide range of duties in their portfolio.

Several compositions of rounding teams and specimen collection processes were observed while shadowing the different clinical teams. The composition of rounding teams and associated specimen collection processes were as follows:

1. Doctor(s) rounding alone and referring patients to a central location for specimen collection. This configuration was observed in the pediatric department and in some wards in the Obstetrics and Gynecology department where patients would go to the nurse station to have specimens collected.
2. Doctor(s) with nurse or nursing students going from bedside to bedside together. In this composition, specimens were often collected by the nursing team by looking in the patient chart or through verbal communication.
3. Doctor(s) and nursing teams rounding separately. The doctor would document test orders in the patient chart and either collect the specimen or leave it for the nursing team to collect. The nursing team would come to the patient bedside after one or all the units or teams of doctors had completed the ward rounds to collect and return patient charts to the nursing station. The charts would be checked for any new orders and the specimens would be collected if a laboratory test was ordered.

4.3.2.3 Challenges in the Process

Communication within the clinical setting was one of the major challenges observed during the ward rounds. Checkboxes next to the name of laboratory test or procedure in the patient chart is used for communicating orders to other clinical personnel. However, this means of communication is liable to be missed or not updated as seen in almost all inpatient observation sessions. In one particular instance, the checkbox had not been checked but the patient claimed that a sample had been taken. This challenge in communication can lead to unnecessary repetitions

of laboratory tests or delays availability of laboratory test results. To combat this problem, most doctors often resort to collecting the specimen themselves and bringing it to the laboratory to prevent such occurrences. In other cases, doctors, particularly intern medical and clinical officers maintain a list of all the orders for procedures and laboratory tests on a piece of paper. This list of tasks or jobs is used to ensure that the orders have been done by the next ward round.

Another aspect of communication that was observed as being a challenge in the laboratory testing process was communication across departments regarding laboratory orders. Patients are often admitted to a ward through an outpatient clinic. Sometimes, laboratory test orders are indicated as having had the specimen collected and brought to the laboratory when that is not the case. In other cases, specimens are collected but are either not brought to the laboratory or are brought late. One contributing factor to this could be a workaround used by clinicians where specimens from the wards or for patients that are being admitted are sent as outpatient test specimens. This is based on a perception that the turn-around time for outpatient laboratory tests is shorter than for inpatient tests.

Further challenges in communication exist between clinicians and patients. Certain laboratory tests such as urine and stool analysis require patients to collect the specimens themselves and ensure that they are brought to the laboratory. Incomplete and unclear instructions often result in these specimens coming late to the laboratory leading to rejection or the specimens not being collected at all. For example, we observed a case where a patient was not given a sterile container to collect sputum for testing until the next ward round thereby delaying the testing process. Another case involved a patient who brought a urine specimen in an empty soft drink container because they had not been given any specimen container but had been told to bring a

specimen to the laboratory. These incidents could have been avoided with sufficient and clear communication.

Unclear and incomplete instructions are further complicated by having non-standard workflows. The hospital has various partnerships, some of which have to do with laboratory testing. For example, CD4 count, viral load testing, and cryptococcal antigen testing (CrAg) are handled by hospital partners and not the hospital laboratory. However, specimens for these tests still come to the hospital laboratory for testing. The same is true for biopsy samples which sometimes are brought to the main hospital laboratory and not the histopathology laboratory that is run by a hospital partner at the same facility but is located in a different building.

Ideally, all patients must be reviewed by a doctor during ward rounds. Doctors often identify patients belonging to their team or unit based on the color of the folder on the patient's bed. These folders contain the patient charts and are brought from the nursing station and placed on the patient's bed before the start of the ward rounds. The process of leaving these folders on the beds often requires that the patient or their guardian indicate when their name is called out so that they get the folder. It is not uncommon that patients don't get their folders before the ward round and consequently do not get reviewed due to, among other things, not being in their bed at the time the folders were being distributed.

Unavailable stationary was another challenge observed in the laboratory testing process at KCH. Each laboratory department has its own laboratory order forms with the parameters of interest for the tests conducted in that department. However, these forms are not always readily available in the wards and clinical setting. As a workaround, clinicians often improvise and order tests on a laboratory order form for tests done in another department of the laboratory. Furthermore, because of the different designs of the forms, clinicians often forget to fill in some

details because the fields do not have prominent positioning on the form. Failure to provide all the necessary information often leads to rejection of a specimen. Another reason for failing to provide all the information on a laboratory order form is lack of visibility of certain fields on form. Due to having been photocopied multiple times, certain fields of the form have faded and are not easily visible. This often leads to incomplete test order documentation which is one of the reasons for rejecting a specimen if a required field is not provided.

Access to information around laboratory testing was another challenge that was observed. More than once, clinicians were heard discussing which test tube to use and the volume of a specimen needed for a particular laboratory test. While a manual exists cataloguing all the laboratory tests performed at the facility, we did not see it nor observe its use in the clinical setting. In the absence of such a guide, it is easy for incorrect information to spread resulting in poor viability of specimens brought to the laboratory.

Finally, specimen collection at the bedside was often done using stainless steel trays (Figure 5) which did not have enough space to bring specimen collection supplies for multiple specimen draws and other equipment to the bedside. Used specimen collection supplies such as cotton swabs and syringes often need to be safely disposed of. However, when using a tray for specimen collection, the used syringes and cotton swabs are often placed in the same tray thereby posing a safety risk. Further, the limited space on the tray makes it difficult to bring other equipment such as a blood pressure meter, which is often used during ward rounding, together with specimen collection supplies to the bedside. As a result of not having all the supplies and equipment that they need at the bedside, clinicians often have to make several trips to the nursing station to collect the items that they need.

Figure 5: An example of the specimen collection tray used at KCH.

In some wards, we found stainless steel carts such as the ones shown in Figure 6. However, these were few and far in between. Clinicians would often collect supplies that they thought they would need during the ward round and place them on the cart. Specimens collected during the ward round were placed on the cart pending transport to the laboratory.

Figure 6: An example of a specimen collection cart being used to collect a CSF specimen (left). A steel cart used for specimen collection at KCH (Right).

Of note is that the supplies for collecting specimens were often available with the exception of two cases where the available specimen collection tubes were expired and a 25 ml syringe and cannula had to be used to collect 4 milliliters of blood due to lack of smaller syringes being unavailable.

4.4 Discussion

Several challenges that could result in breakdown of processes and non-viable specimens were identified in this study. While the majority of challenges were identified in the clinical setting,

each part of the total testing process at KCH had several challenges that could reduce the likelihood of the right test result making it in time to a clinician for clinical decision making.

Some of these observed challenges are not new. A previous study by Petrose et al. found shortage of stationary to be one of the perceived challenges to laboratory testing [96]. Unfortunately, stationary shortages have persisted and continue to affect the laboratory testing process at KCH. Similarly, challenges around communication, delays in sample delivery, and delays in results processing have continued. These challenges have the unwanted effect of causing delays in treatment for the patients and causing specimen to be rejected thereby wasting the scarce available resources

In the years since the previous study was published, an electronic information system has been implemented in the laboratory, serving the analytical phase of the total testing cycle while ignoring the pre- and post-analytical phases. An attempt to close the gap for the other phases was done but administrative issues derailed the pilot implementation [8]. The downside of only implementing an information system in the analytical phase of the total testing process is the failure to maximize the benefit of the available technology such as the use of the information system to reduce the impact of stationary shortages and incomplete documentation on laboratory test requisitions.

To cater for the lack of an electronic information system in the pre-analytical phase, all specimens are registered at the laboratory reception. The laboratory at KCH received an average of 389 specimens per day between August 26, 2019 and March 1, 2020. The laboratory reception often struggles to register all the specimens in time for them to be analyzed on the day they have been received. With the current implementation, the laboratory reception has become a bottleneck in the testing process.

While the system for registering specimens was designed to allow the scanning of patient identifiers in barcode form to retrieve their demographic information from the master patient index, this feature is best utilized at the point of care. Consequently, this feature is not used at the laboratory reception. Further probing for explanation for this observation highlighted process challenges involved in taking patient health passports as a barrier to use of this feature. Furthermore, specimens received at the laboratory reception are not always immediately registered in the LIS. Therefore, using the barcode on the health passport would require the laboratory receptionist to keep the health passport for a prolonged period of time until the patient's specimen had been registered.

In place of using the master patient index to get the patient demographic details, the demographic details are entered into the system for every specimen that is received. This often introduces transcription errors that make it difficult to efficiently retrieve patient results when they are available. Approximately 30 seconds are spent per specimen to transcribe the laboratory order details into the LIS. The current setup provides an opportunity for significant gains in speed and accuracy of the records by improving or task shifting the specimen registration process.

Results from a four-week specimen quality audit at KCH from 2009 indicated that 54% of all specimens were either compromised or discarded [95]. However, preliminary data from the LIS used at the KCH laboratory indicated an average monthly non-viability rate for specimens around one percent. Observing the workflow at the laboratory reception provided an explanation for these extreme differences. Specimens that are deemed non-viable are often not registered at the reception since they are going to be discarded anyway. These rejected specimens account for the majority of non-viable specimens received at the laboratory reception. The LIS at KCH can therefore not be relied upon to provide accurate counts of rejected specimens at the health facility in its current

form. Further improvements to the information system can help capture this and other import performance indicators that are not being accurately captured such as the turnaround time for specimens.

Current evidence in the study of laboratory errors shows that the pre-analytical phase could be responsible for as much as 75% of all laboratory errors [6]. Among the most common sources of these errors are incomplete laboratory requisition forms, wrong patient identification, specimen collection errors, and delayed transportation of specimens to the laboratory [16], [48]. The observations of the total testing process at KCH suggest that most of these errors are likely to be prevalent in this setting. However, since most of these errors are not captured, data on the magnitude of these errors is not readily available. To this end we proposed a study to measure the magnitude of specimens that were rejected at KCH and designed an intervention to address some of the challenges faced by clinicians in the testing process.

4.5 Limitations

KCH is a teaching hospital with high turnover of staff and a lot of transient staff in the form of students and interns. We recognize the fact that the workflows observed during this study may not reflect the natural workflows that occur when there are no students. To the best of our ability, we tried to observe only permanent KCH staff and confirm the workflows with permanent staff if students were involved in the processes we observed.

5.0 Measuring the Magnitude of Specimen Non-viability at Kamuzu Central Hospital: A Descriptive Analysis

5.1 Introduction

Often erroneously attributed as the Hippocratic Oath, “first, do no harm” is an idea central to the physician-patient relationship [112]. This idea acknowledges the potential for injury that exists in the provision of healthcare. Published among a growing body of patient safety publications, the 1999, “To Err is Human: Building a Safer Health System” report by the Institute of Medicine is widely credited with reinvigorating interest and research into improving safety in healthcare [113]. This publication succeeded in bringing to light the extent and impact of errors in healthcare and calling stakeholders to action on reducing medical errors by 50% in 5 years [113], [114].

A key takeaway from the “To Err is Human” report is that patient safety is an attribute of the system of care implemented by a healthcare provider [115]. Unfortunately, this doesn’t bode well for LMICs where the health systems face a multitude of barriers and struggle to provide high quality primary healthcare. One area of healthcare in LMICs that suffers from systematic challenges leading to errors is the clinical laboratory.

Laboratory errors have various outcomes including delays to analysis of the specimen, failure to analyze specimens, and wrong results being given to clinicians. Of primary concern is the number of specimens that cannot be tested due to various laboratory errors. The rates and reasons for non-viability vary across facilities. We therefore decided to measure the magnitude of specimen non-viability at KCH.

5.2 Methods

To quantify the number of specimens that were classified as being non-viable and the reason for non-viability, we conducted a six-week study at the KCH laboratory. The primary researcher joined the laboratory receptionists in receiving specimens at the laboratory reception and applying the laboratory's specimen rejection criteria provided in Table 1 to determine which specimens were non-viable.

Table 1: Specimen rejection criteria as defined by the KCH laboratory.

Specimen rejection criteria for the KCH Laboratory
No Age / date of birth on request form
No ward on request form
No patient name
Failure to label the specimen correctly
Failure to send a correct request form
Insufficient quantity of specimen
Wrong tube or container
Leaking or contaminated sample
Clotted sample (where applicable)
Delayed transport of specimens to the laboratory / Old Sample

Specimens received at the laboratory reception are first assessed for viability before being registered in the LIS. As a result, non-viable specimens are often not recorded in the LIS since they will be discarded. Further, some of the reasons for rejecting specimens as non-viable have to

do with required fields in the specimen registration process. This prevents these specimens from being registered in the LIS. Therefore, to record the number of specimens that were non-viable, we utilized a specimen rejection log book that was provided by the researcher. Specimens that were rejected for non-viability were recorded in the log book at the time of rejection detailing the date that the specimen was rejected, the ward where the specimen was collected, and the reason for rejection.

Specimen rejection counts were aggregated on a weekly basis. The counts were aggregated by ward and then by department since the departments were the unit of analysis. To calculate the weekly specimen non-viability rate, we retrieved weekly counts of the number specimens received from each ward from the LIS. Weekly non-viability rates were then calculated as follows:

$$non\ viability\ rate = \left(\frac{\#\ of\ rejected\ specimens}{\#\ of\ accepted\ specimens + \#\ of\ rejected\ specimens}\right) * 100$$

Data for this study was collected from August 26, 2019 to October 6, 2019. This was followed by analysis of the data where descriptive statistics were compiled on the reasons for specimen non-viability and the relative distribution of non-viable specimens across the different hospital wards and departments.

5.3 Results

The laboratory at KCH received 9,335 specimens to conduct 14,736 tests over the six-week study period. Multiple tests can be performed on a single specimen hence the higher number of tests for the received specimens. Figure 7 shows the distribution of all the specimens received and

the setting from which they were collected. 6,031 of all the specimens received were from the inpatient setting at KCH, representing 64.61% of all specimens received. Tests from external health facilities i.e. referrals and specimens for whom no source was given due to missing documentation, contributed the least number of specimens at 0.8% (78 specimens) each.

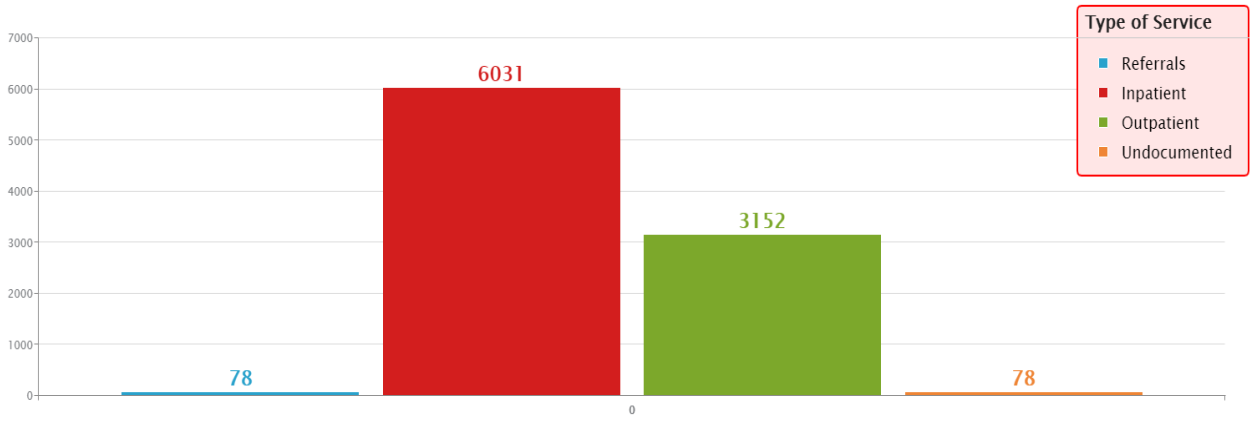


Figure 7:Distribution of specimens based on type of service.

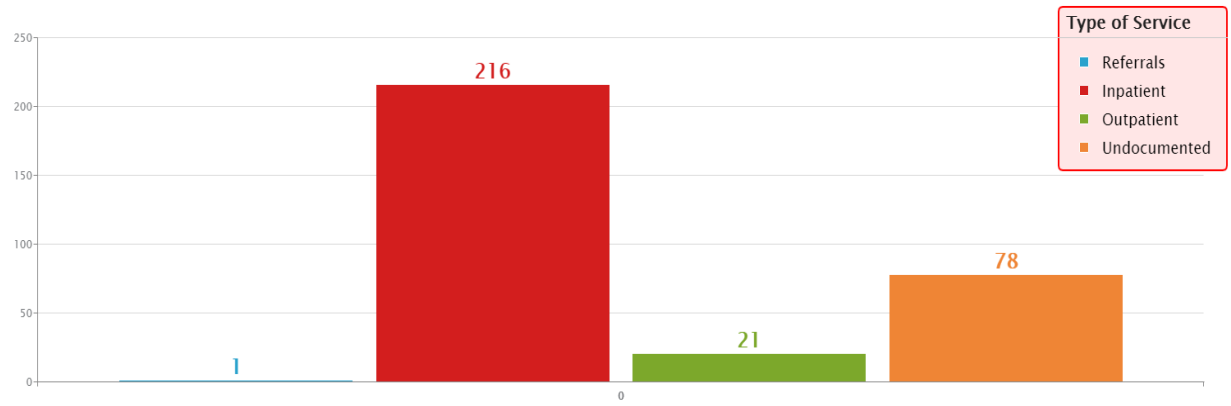


Figure 8: Distribution of non-viable specimens based on type of service.

Of all specimens received at the laboratory reception, 316 were rejected at the laboratory reception, representing a 3.38% rejection rate of specimens at the laboratory reception. Most of

the rejected specimens (68.4%) were from the inpatient setting as shown in Figure 8. This is not surprising as the inpatient setting was also the source of the highest proportion of specimens. Undocumented specimens were the second highest contributor to the number of non-viable specimens surpassing even the outpatient setting.

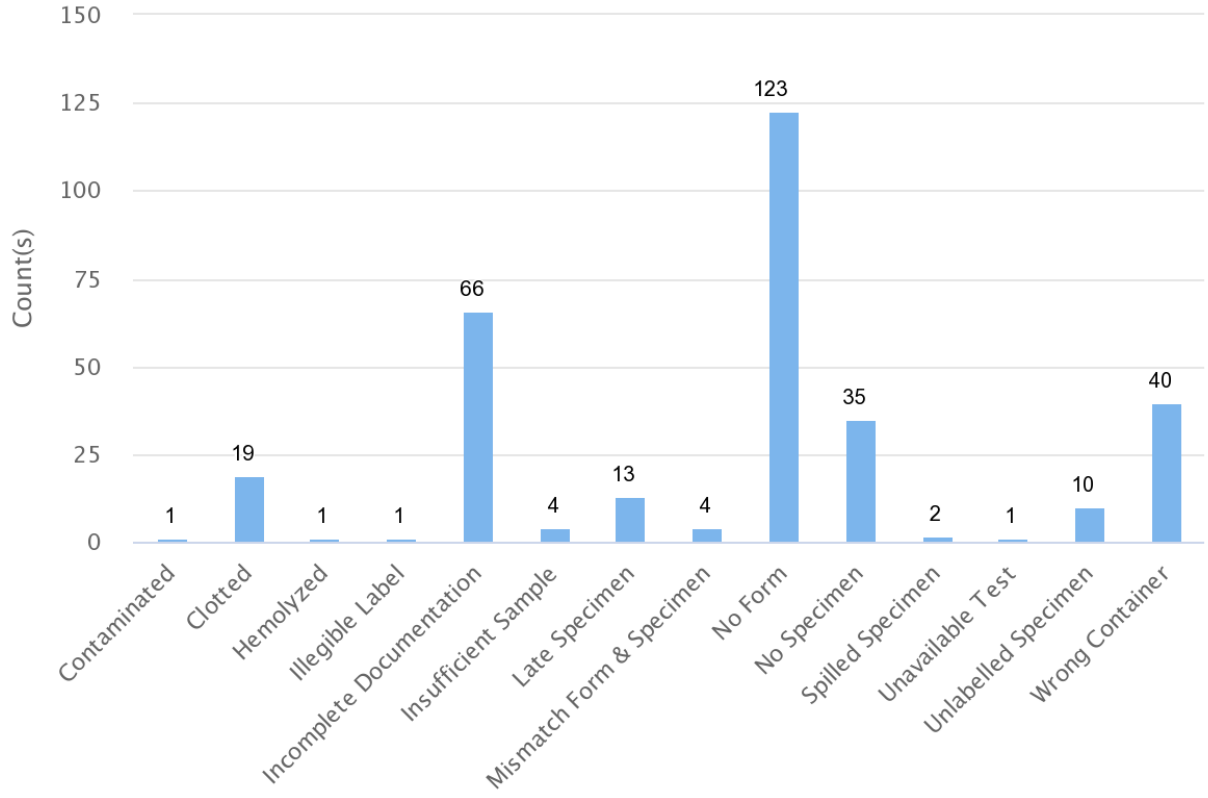


Figure 9: Distribution of reasons for rejection of specimens August 26, 2019 and October 6, 2019 (n= 316).

The majority of non-viable specimens were rejected for arriving at the laboratory reception without laboratory order forms. This reason accounted for 38.92% of all the specimens that were rejected at the KCH laboratory reception. Incomplete documentation was the second highest reason for specimen rejection at 20.89%. The majority of specimens with incomplete documentation had a single field, mostly the age, missing among the required fields. However,

46.97% of all specimens with incomplete documentation had two or more missing required fields. A histogram is shown in Figure 9 of the distribution of the reasons for specimen rejections.

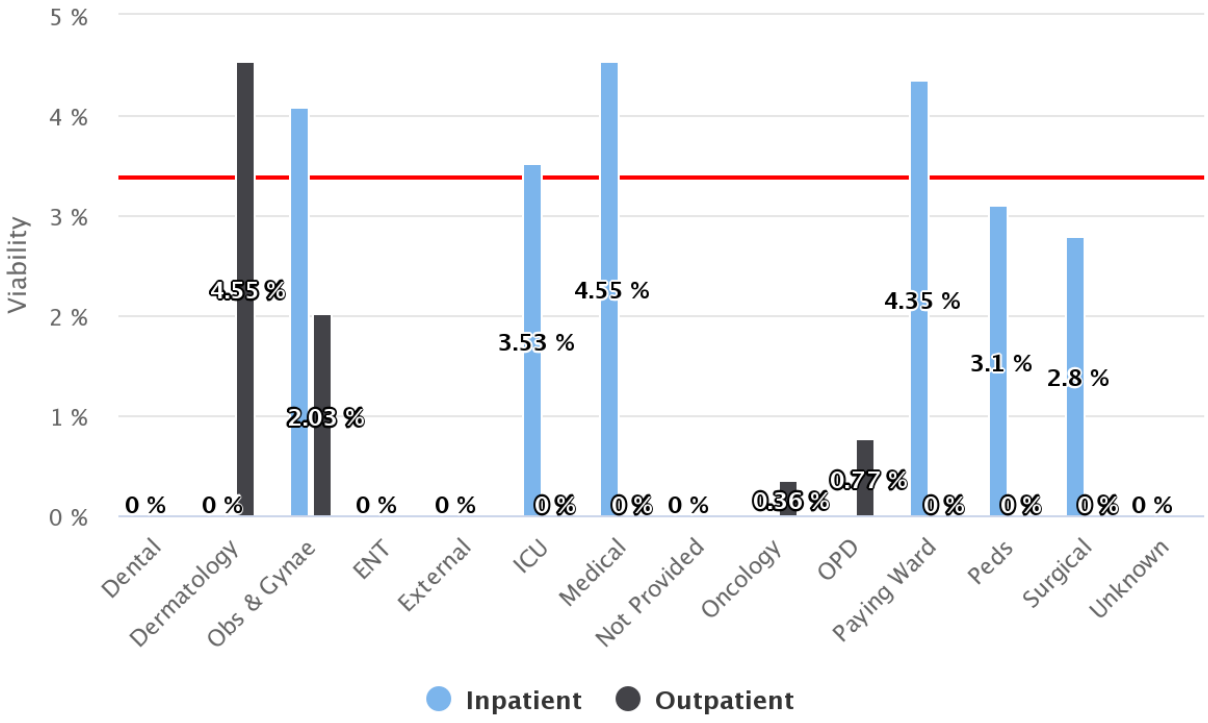


Figure 10: Non-viability grouped by departments and service types.

Five departmental settings had higher than average nonviability as seen in Figure 10. The Medical department was the highest with regards to the number of specimens coming from the inpatient setting followed closely by the general paying ward, the obstetrics and gynecology department, and the intensive care unit (ICU) in that order. Dermatology had the highest rate of non-viability in the outpatient setting. However, the Dermatology clinic did not have a high utilization of laboratory tests during this period.

Despite having one of the highest numbers of specimens delivered to the laboratory, Oncology had relatively few specimens that were rejected as being non-viable. This could likely be a result of the limited number of types of laboratory tests often ordered by the oncology staff.

5.4 Discussion

Specimens received over six weeks were assessed for viability at the laboratory reception at KCH. On average, 1,555 specimens were received each week during the period of study with the majority of specimens coming from the inpatient setting. Comparatively, the four-week specimen quality audit conducted at KCH in 2009 had an average of 887 specimens received per week [95]. Albeit focusing mainly on specimens going to four laboratory departments, the difference in the average number of specimens received suggests an increase in demand for laboratory services, a trend that is being seen elsewhere [116].

This study highlighted the challenges with documentation that exists in the laboratory testing process at KCH. Many specimens were received at the laboratory without forms. Our previous observations of the total testing process suggest that this could be a result of one of two scenarios. First, the specimens could have been left on the laboratory reception counter as opposed to being handed over to a laboratory receptionist. The laboratory receptionist usually checks that each specimen they receive has complete documentation. However, since these samples arrived without documentation, it is likely that the laboratory receptionist did not get the chance to match the specimens to a form in the presence of the person who brought the specimens. Alternatively, the specimens could have arrived with laboratory order forms but they were misplaced at the

laboratory reception. However, this is unlikely as the number of forms without specimens was substantially lower than the number of specimens without forms.

Wrong container and incomplete documentation, while not as high as absence laboratory order forms, were the second and third most frequent cause of specimen non-viability respectively. Since no stock-outs of supplies were reported during this time, these reasons put together suggest some lack of knowledge on the side of the clinical personnel with regards to documentation required by the laboratory for each laboratory test. Student rotations through the different hospital departments may explain some of the wrong containers used for certain tests. However, sometimes experienced clinicians collect specimens in two different containers as a redundancy when they are not sure which container to use for a particular test. The laboratory has a long list of tests that it offers. It is easy to imagine that a clinician cannot remember the right combinations of the test type, volume, specimen type, and the right container for the test. Improving the accessibility of information regarding the right combinations of the test type, volume, specimen type, and the right container for the test, during the collection of specimens could help address this gap in knowledge in the clinical setting.

The high number of specimens without wards and laboratory order forms makes it difficult to accurately quantify which department has the highest proportion of non-viable specimens. The outpatient setting is especially more difficult to differentiate between departments as clinics under the different departments often use the non-distinguishing “OPD” to indicate that the patient is from the ambulatory setting rather than from a specific clinic.

Despite this limitation, the medical department and obstetrics and gynecology were the highest in terms of the number of non-viable specimens. These two departments also had the high utilization of laboratory services based on volume of specimens received from the department. Of

particular interest is the finding that both the inpatient and outpatient settings of the obstetrics and gynecology had higher levels of non-viable specimens. Most of the non-viable specimens from this department were a result of specimens arriving at the laboratory without having forms.

Another limitation of this study is that it did not measure the number of tests that were ordered but not performed. Salvagno et al. report that 49.3% of all pre-analytical phase problems in their study were a result of unfulfilled laboratory test orders where tests ordered by the doctor were not done [117]. We therefore may have missed out on a portion of laboratory errors that could unnecessarily prolong a patient's stay in the hospital. The amount of resources needed to accurately measure these unfulfilled test orders across the hospital and the privacy implications of such an undertaking made it difficult for us to measure this aspect of laboratory errors.

Continued global efforts to manage HIV and other infectious diseases require routine laboratory testing. As a result, the demand for laboratory tests is expected to continue growing. Reducing errors in the total testing process presents a significant opportunity to improve a vital health service, minimize waste, and accrue financial savings in healthcare.

6.0 Design, Deployment, and Evaluation of a Specimen Collection Cart and Paper Job Aid to Improve Specimen Collection

6.1 Introduction

The previous study aimed at understanding the total testing process at KCH identified several challenges in the process that had the potential to make specimens non-viable. A follow-up study measuring the magnitude of laboratory errors identified at the laboratory reception found that 3.38% of all specimens received were rejected as being non-viable for several reasons. No documentation, incomplete documentation, and wrong container type were the three most frequent reasons for specimen non-viability.

We previously observed a lack of access to information around laboratory testing as a challenge to the laboratory testing process. Information regarding the type of specimen to collect for particular laboratory tests and the minimum specimen volume were not easily accessible to clinicians in the inpatient wards. The lack of access to this information often results in the use of wrong containers during specimen collection or the collection of insufficient specimen volumes. Both of these situations result in the specimen being rejected for analysis in the laboratory.

Further, we observed that unavailability of stationary often led to improvisation of laboratory order forms and use of plain paper as laboratory order forms. We believed this to be one of the factors leading to high counts of incomplete documentation on laboratory order forms.

Clinicians could benefit from an information resource that provided essential information around laboratory testing. We hypothesized that making such information easily accessible to clinicians during specimen collection could help reduce the frequency of specimens being rejected

at the laboratory reception. The rest of this chapter describes the design, deployment, and evaluation of this intervention at KCH.

6.2 Methods

6.2.1 Design of a paper-based job aid for specimen collection

We designed a paper-based job aid to address the most common problems in the specimen collection and transportation stages of the laboratory testing process. Hammerling and Naz et al. highlight the most common errors in the pre-analytical phase which include [26], [118]:

1. Inappropriate laboratory test requisition
2. Incomplete laboratory forms
3. Wrong patient identification
4. Wrong labeling of the containers
5. Specimen collection errors e.g. inadequate volume, hemolysis, lipemic specimens, wrong containers
6. Delayed transportation of specimens
7. Errors in specimen preparation

To ensure comprehensiveness of the paper job aid, we incorporated information targeting most of these common errors in the pre-analytical phase with details on the most frequently performed laboratory tests at KCH. For the 20 most ordered tests, we listed the full name of the test, the correct short name, the correct specimen type, the minimum volume of specimen required, and the right specimen container type. We also provided a list of all the details that have to be

available on the laboratory order form. Further, we included a reminder for clinicians to bring specimens to the laboratory as soon as possible and a checklist of all the things to avoid to ensure specimen viability. A copy of the paper job aid is provided in Appendix A.

The paper job aid as an information resource is only beneficial if it is available when clinicians are collecting specimens. To ensure that the job aid was accessible when needed and address challenges around bringing specimen collection supplies to the bedside, we provided a specimen collection cart.

The specimen collection cart was specifically designed to reduce the chances of clinicians fetching for supplies during ward rounding due to limited carrying capacity. This was one of the challenges observed with the use of stainless-steel trays for specimen collection. The specimen collection cart has two drawers with two containers each for carrying supplies. Four wheels attached to the base allow the cart to be pushed and moved around easily. A closed compartment at the bottom of the cart has a waste basket and sharps container where used supplies and needles can be stored until they can be safely disposed of. These features were deliberately included to simplify and minimize effort required in specimen collection.

The paper job aid was affixed on top of this cart to provide clinicians with the information necessary for specimen collection. We hypothesized that by providing visual cues through the paper job aid and simplifying the process of specimen collection through reducing the need to fetch for supplies during specimen collection and the number of things carried to the bedside for specimen collection, we could attain lower non-viable specimens stemming from errors in the pre-analytical phase. A picture of the specimen collection cart with the paper job aid is provided in Figure 11.

Figure 11: A picture of the specimen collection cart with the paper job aid.

6.2.2 Deployment of the specimen collection cart and paper job aid

To manage the logistics around deploying the specimen collection carts and the paper job aids, we used a phased deployment strategy. Specimen collection carts were deployed in two phases with two clinical departments receiving the specimen collection carts in each phase. Deployment of this intervention was preceded by communication with the clinicians in each department during daily morning handover meetings and through senior nursing officer in each ward. To observe the natural evolution of the workflows associated with the use of the specimen collection cart, we deliberately decided not to be prescriptive in how the cart should be used. Instead, clinicians were told that the specimen collection cart was an addition to their repertoire of tools in the wards and to use it as they saw fit. They were however briefed on the presence of the paper job aid for specimen collection that was affixed on the top of the cart.

Ideally, the order of deploying the carts to the departments was supposed to be random. However, other constraints and developments in the environment meant that we had to deploy the carts to the medical and pediatric departments first. The medical department had been chosen as the pilot site for a subsequent intervention around the laboratory testing process. To ensure that we had enough time to observe the effects of the specimen collection cart and paper job aid, the intervention had to be deployed in this department in the first phase.

True to the ever-changing landscape in healthcare, the pediatric department KCH planned to open a satellite laboratory for analysis of pediatric specimens in late 2019. To reduce the possibility of this development confounding our findings, we again decided to deploy the specimen collection carts and paper job aids to the pediatric department in the first phase.

Deployment of the specimen collection carts in the clinical setting was done on Sunday afternoons in readiness for the new work week. The carts were brought to each ward and the nurse-

in-charge in the ward was briefed on the development and asked to find a suitable location in the ward for easy access to the cart by other clinicians.

A total of 26 specimen collection carts with paper job aids were deployed to the inpatient wards at KCH. Six carts were deployed to the medical department, seven to the pediatric department, six to the surgical department, and seven to the wards managed by the obstetrics and gynecology department. No specimen collection cart was deployed to any outpatient setting as this did not fall under the scope of the study.

6.2.3 Evaluating the impact of the specimen collection cart and paper job aid

6.2.3.1 Data Collection

We hypothesized that the specimen collection carts and the paper job aids would affect both how clinicians collected specimens and the number of non-viable specimens received at the laboratory reception. Direct field observations were used to evaluate the impact of the specimen collection carts and paper job aids on how clinicians collected specimens. Weekly visits were made to each ward after the specimen collection carts and paper job aids had been deployed to chart the evolution of the workflows. Of special interest was how the different wards organized their carts to effectively do their work. Observation notes were collected to compare different uses and arrangements of the specimen collection carts.

The impact of the specimen collection carts on the non-viability of specimens in each clinical department was evaluated using weekly departmental non-viability rates as the primary metric. Since the paper form for recording rejected specimens is not routinely used and the majority of non-viable specimens were not registered in the LIS, a research assistant was assigned to the laboratory reception to record each specimen that was rejected. A record for a specimen rejection

included the reason for rejection, date of rejection, and the ward from which the specimen came from.

To calculate the weekly non-viability rate for each department, we divided the total number of specimens from a particular department that were rejected by the total number of specimens that were received in the laboratory from that department. The total number of specimens received in the laboratory from a particular department was retrieved for the KCH LIS while the total number of specimens rejected from a clinical department was calculated from the specimen rejection log recorded by our research assistant. Data for this study was collected from August 27, 2019 to March 1st, 2019. All non-viability rates were recorded weekly.

6.2.3.2 Data analysis

We started our analysis by conducting exploratory analysis of our data to familiarize ourselves with it. The non-viability rates were plotted in a graph to visually inspect for any patterns in the data.

A time-series analysis with a linear regression model of the weekly non-viability rate, using time, intervention status, and the interaction between time and the intervention, was used to assess the impact of the paper job aid and specimen collection cart on the non-viability of specimens in each department. The model for this part of the research is defined as follows:

$$Y_t = B_0 + B_1T_t + B_2X_t + B_3X_tT_t + e_t$$

Where the terms are:

- Y_t is the observed rate of non-viability of specimens in week t.
- T_t is the number of weeks since the start of the study.
- X_t is an indicator variable for whether the intervention is implemented at time t.
- X_tT_t is the interaction term between the presence of the intervention and time.

- B_0 is the baseline level of specimen non-viability.
- B_1 is the change in rate of non-viable specimens per unit time interval (weekly).
- B_2 is the level of change in non-viability of specimens following the introduction of the intervention(s).
- B_3 is the difference in gradient or slope after the intervention.

The hypotheses that will be tested in this part of the study are:

1. H_0: $B_2 = 0$ vs H_A: $B_2 \neq 0$
2. H_0: $B_3 = 0$ vs H_A: $B_3 \neq 0$

The satellite laboratory in the pediatric department was a potential confounder for our study as a significant number of pediatric specimens were no longer coming to the main laboratory at KCH. We accounted for this in our analysis by excluding specimens recorded as being tested in the pediatric laboratory from our study.

6.2.3.3 Power Calculation

To determine the ability of our study to accurately detect the effect of the interventions, we estimate the statistical power for our model. The calculations were conducted at 5% significance level. Variance of non-viability of the specimen is estimated from system data for the previous year. The sample size is predetermined based on the number of observations. Preliminary data from the LIS at KCH between January 2017 and June 2018 gave us an estimated variance of 0.0000658 (SD = 0.0081) for the rate of non-viable specimens. The lag-one autocorrelation of 0.1 was also calculated from the same preliminary data. Using the formula given by McLeod and Vingilis, the calculated power for the study to detect 2 standard deviations is 95.54% for 26 time

series points in each department with 6 occurring before the intervention [119]. While 2 standard deviation represents a very large effect, this is reasonably consistent with our goal of developing an intervention that will have a large impact on the viability of specimens.

6.3 Results

Over the period in which the study was conducted, a total of 74,758 specimens were registered in the LIS at KCH as received for analysis in the laboratory. Of these, 2,879 specimens were received at the pediatric laboratory and were not included in the analysis. Of the specimens that were received and registered for analysis, 598 specimens were later rejected as being non-viable for different reasons. A total of 1,521 specimens were received but not registered due to being non-viable for analysis based on the laboratory's specimen acceptance/rejection criteria. The proportion of specimens that got to the laboratory but were deemed to be nonviable over the course of the study were 2.95%.

Missing laboratory test order forms accounted for 35.54% of all rejected specimens. 17.27% of all specimens were said to be clotted. A summary of all the reasons for rejection and the proportion of specimens rejected is presented in Table 2.

Table 2: A summary of the reasons for specimen non-viability.

Reason for Non-Viability	Count	Proportion (%)
No form	753	35.54
Clotted Blood	366	17.27
No specimen	181	8.54
Insufficient Sample	154	7.27
Wrong container	119	5.62
Late sample	128	6.04
No age	55	2.60
Incomplete documentation	103	4.86
Duplicate specimen received	41	1.93
Unlabeled specimen	68	3.21
Mismatch form & specimen	37	1.75
Inappropriate specimen for the test	32	1.51
Hemolysis	24	1.13
Unavailable test requested	9	0.42
No Sample in the Container	9	0.42
Leaking	23	1.09
Over saturation	5	0.24
illegible labeling	5	0.24
Damaged sample	3	0.14
Serum rings	2	0.09
Request form contaminated with specimen	2	0.09

6.3.1 Impact of Specimen Collection Cart and Paper Job Aid on Workflow

Specimen collection carts were deployed to the inpatient wards at KCH with the expectation that clinicians would organize their supplies in an optimal way. We noted a variety of specimen collection cart organization patterns. Some wards mixed different types of specimen containers in one compartment of the specimen collection cart. The majority however kept only items of one type in a compartment. We were particularly pleased to find one ward where the clinicians had labelled the different compartments with the type of items that should go in each compartment (Figure 12). We helped this ward further standardize and sustain this practice by providing them with adhesive stickers that clearly showed what should go in each compartment (Figure 13).

Figure 12: Cart with labels for each compartment.

Figure 13: Standardized labels for the compartments

To learn how the specimen collection carts were being used, we observed clinicians in the wards as they were going about their work and checked the carts to see if there was any evidence of use. In all carts, we found that the waste basket had contents indicating use. However, we could not tell whether the waste was from the same day. Further, the containers in most drawers had supplies providing further evidence of use. We observed that the carts had more than one use case in the wards as shown by Figure 14 and Figure 15.

Figure 14: : A cart used primarily for specimen collection.

Figure 15: A specimen collection cart being used for documentation in the ward..

The specimen collection carts were used by both nurses and doctors. However, we also observed some clinicians that preferred to use the old stainless-steel carts when performing their tasks. Figure 16 provides an example of a doctor using one of the old carts.

Figure 16: Stainless-steel cart being used to move patient charts during ward rounds.

The pediatric emergency zone ward was particularly interesting in that the clinicians did not use the specimen collection carts to go to the bedside. Rather, they took advantage of having a second specimen collection cart to create a new stationary specimen collection point. Patients came to one of the stationary specimen collection points for specimen draws. The specimen collection carts were kept fully stocked at each of these specimen collection points.

6.3.2 Impact of the Paper Job Aid on Specimen Non-viability

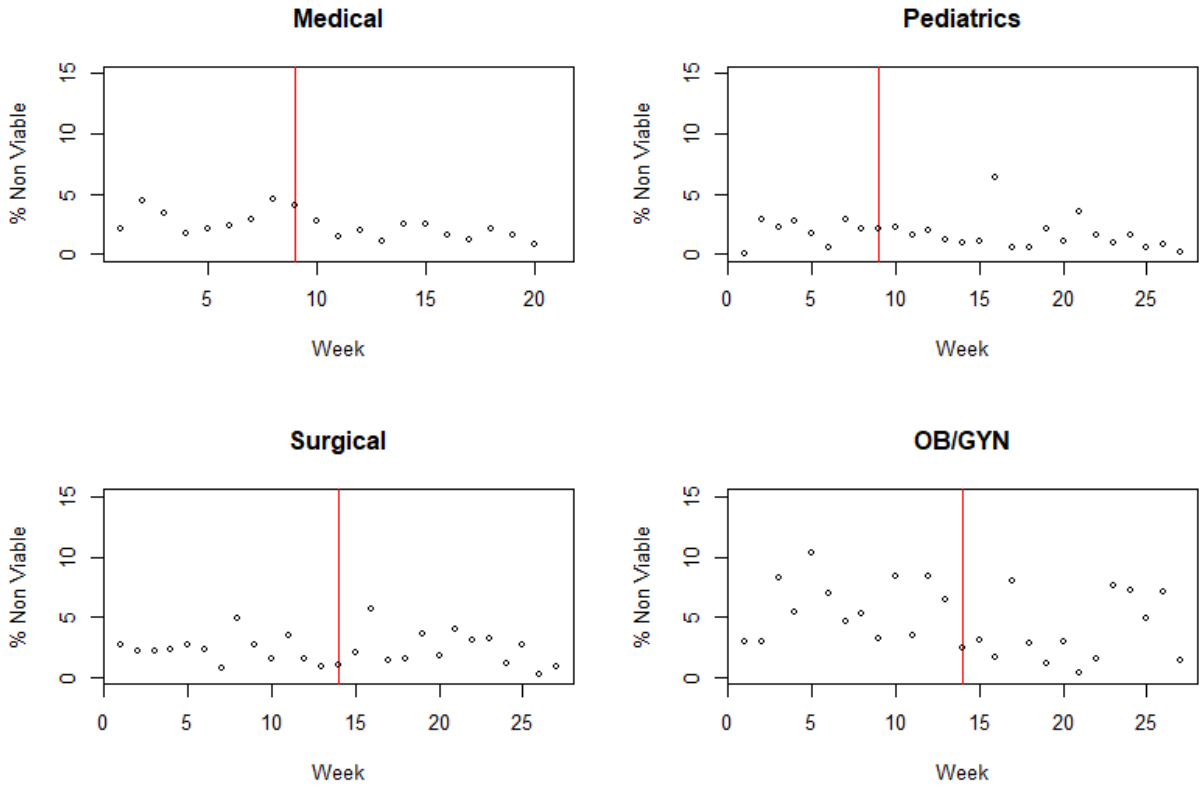


Figure 17: Plots of the non viability rates for each department.

We conducted exploratory data analysis of our data and plotted the nonviability rates for each department over the time that we conducted the study as shown in Figure 17.

Table 3: A summary of the the findings from the segmented time series analysis for each department.

Medical Department

Coefficient	Estimate	P-value
Intercept	1.16116	0.079
Time	0.02758	0.825
Intervention	-1.00712	0.375
Time*Intervention	0.04866	0.726

Pediatrics

Coefficient	Estimate	P-value
Intercept	0.5874	0.285
Time	0.0640	0.553
Intervention	1.0204	0.194
Time*Intervention	-0.1130	0.316

Obstetrics & Gynecology

Coefficient	Estimate	P-value
Intercept	2.013522	< 0.0001
Time	-0.028624	0.481
Intervention	-0.001883	0.998
Time*Intervention	0.003563	0.948

Surgical

Coefficient	Estimate	P-value
Intercept	1.326549	< 0.0001
Time	-0.009293	0.796
Intervention	0.031400	0.966
Time*Intervention	-0.004825	0.920

A time series analysis was used to assess the impact of the paper job aid and specimen collection cart on non-viability of specimens from each department. A summary of the findings from the time series analysis is provided in Table 3. The specimen collection cart together with the paper job aid did not have any effect on the non-viability of specimens in any of the departments in which they were deployed.

6.3.3 Other Changes During the Study Period

Several changes happened in the KCH laboratory in the course of this study. As earlier discussed, a satellite laboratory was opened for the pediatric department in late 2019. Further changes occurred with the laboratory at KCH aimed at improving service delivery. The first change was a reorganization of the laboratory staff with some laboratory technologists moving to different departments within the laboratory. To further improve the service in the laboratory, laboratory technologists agreed to authorize and print out results once the analysis was complete. This was supposed to reduce the amount of waiting for laboratory results by the clients of the laboratory. However, this change did not last as the LIS in the laboratory became slower over time. Laboratory technologists gradually moved towards a model where only test results that were being followed up were being printed out and released to save time.

6.4 Discussion

We deployed specimen collection carts in all inpatient wards of the four main clinical departments at KCH. We hypothesized that by providing clinicians with this tool, they would

organize their supplies in an efficient manner to aid in the specimen collection process. We wanted to observe if different wards would converge towards similar organizations of the specimen collection carts. To this end, we deliberately chose not to be prescriptive about how the clinicians should use the specimen collection cats. While common patterns such as dedicated compartments for different types of supplies were observed, only one way had put in place measures to ensure that this separation was maintained. In this ward, the clinicians organized the supplies on their specimen collection cart in a manner similar to that described by the 5S lean method [120]. Each compartment was labelled with the type of supplies that were going to be kept in it. This was particularly interesting as it was achieved without any external input from the research team.

The use of a paper job aid and a specimen collection cart was meant to reduce the number of specimens that were non-viable. However, after months of observation and data collection, the evidence does not provide enough evidence to suggest this intervention had any effect on the number of non-viable specimens. While this is disappointing, we recognize this as a step towards the next iteration of the intervention.

The number of specimens without laboratory forms continued to be the primary reason for specimen rejection. As previously discussed, there are several reasons why laboratory order forms get misplaced or do not come with the specimen. Tightly coupling the specimen to the laboratory order form seems to be the most effective way to ensure minimal misplacement of the laboratory order forms. Ning et al. reports success in using automated sample labeling connected to a CPOE system to resolve identification errors in both inpatient and outpatient settings [121]. Issuing accession numbers in the clinical setting that can be linked to records in the laboratory would address the missing laboratory order form problem. However, this requires an integrated system between order entry and the laboratory information system.

Our observations showed that the old carts from the hospital were still in use during the course of the study. While we did not expect clinicians to simply discard the old carts, we hoped that they would prefer the new specimen collection carts. However, we learnt that the steel carts were lighter and thus required less effort to move around. Further, the stainless-steel carts worked better to move folders of patient charts around because they had more flat surfaces area than the specimen collection cart.

The major limitation of this study was the extent with which we were able to control for confounders and other factors in the departments that the intervention was deployed in. A more controlled study could have potentially led to different outcomes. The work described in the rest of this dissertation is restricted to one department where we could manage some of the confounders and limit their impact on the findings.

7.0 Design and Development of an Electronic Order Entry and Results Review System for KCH

7.1 Introduction

In this chapter we describe the design and development of the hardware and software used to operationalize an electronic laboratory order entry and results review system at KCH.

Laboratory order forms provide a means of communication between users of laboratory services such as clinicians and the clinical laboratory [122]. Failure to complete all the required details on a laboratory order form can lead to a specimen not being analyzed. Despite the importance of complete and accurate details on laboratory order forms, incomplete documentation and missing forms continue to be commonplace in most low-resource laboratory settings [122], [123]. Incomplete and missing documentation accounted for more than 40% of all rejected specimens over a period of 6 weeks at KCH.

Several factors could be responsible for the high occurrence of incomplete and missing laboratory order forms. Incomplete forms could indicate poor design of the laboratory order form itself. Poor placement of fields on the form and failure to indicate which fields are required can often lead to that information not being provided. Redesigning laboratory order forms could help improve the level of completeness of the information provided [122]. However, this is a continuous process. The laboratory order forms have undergone several iterations of redesign and yet this problem still persists.

Missing forms could be a result of poor handling of the paper form in the laboratory or failure to complete forms in the clinical setting. Since most laboratory order forms are often loose

pieces of paper transported together with the specimens, it is not uncommon for forms to be lost during transport to the laboratory. Further, since the specimen and paper forms are separate, the person transporting the specimen could easily deliver the specimen and forget to leave the forms at the same time.

To address the problem of missing and incomplete laboratory order forms, we conceived the idea of a "self-contained specimen". A self-contained specimen is a specimen having everything that is needed for analysis and doesn't require any external documentation. With a self-contained specimen, all the necessary information required for analysis, including the patient details, clinical history and the details of the person who ordered the test, is part of the specimen itself and not on an external paper.

We implemented the idea of the self-contained specimen by designing and implementing an electronic laboratory order entry system that allows clinicians to order laboratory tests and document specimen draws which result in a self-contained specimen. We describe here the concepts used in the design of this intervention and the final prototype that was built.

7.2 Methods

7.2.1 Design Concepts

7.2.1.1 Positive Patient Identification

Misidentification of patients is one of the most common errors in medicine [124], [125]. In the laboratory testing process, misidentification of a patient or specimen can both cause harm to a patient [126]. Failure to identify the right patient for a laboratory test order can result in the

wrong patient going through the non-trivial process of submitting a specimen for testing. Misidentification of a patient and collecting a specimen for an unnecessary test can be considered as waste in the process and should be minimized to improve the process.

Positive patient identification refers to the correct initial identification of a patient and the tight coupling of all subsequent orders, procedures, medications, and specimens to the patient's identifier [127]. This concept has been used with great success in the administration of medication where a patient's barcode and the medication package barcode are both scanned before administering medication to ensure that the right patient is receiving the medication [128], [129]. Morrison et al. report using similar technology to reduce specimen identification errors [127]. Linking patient test orders and specimens to a unique patient identifier reduces the chances of the results going to the wrong patient. Further, associating all of a patient's individual laboratory tests to their unique identifier creates a historical record of the laboratory tests for the patient thereby facilitating continuity of care.

KCH has a long history of electronic patient registration where patients are assigned a unique identifier that is printed on an adhesive label in barcode and human readable forms and affixed to a paper artifact owned and kept by the patient [130]. A patient registration system has been in use in one form or another at KCH since 2001 [131]. The facility was also one of the sites included in a pilot implementation of a national master patient index [132]. These unique identifiers from the patient registration system at KCH provide an identifier that can be used for positive patient identification in any electronic system at the facility.

7.2.1.2 Point of Care and Mobility

For a positive patient identification to work effectively, use of the interventions has to happen at the point of care with the patient present. To facilitate this, the electronic laboratory

order entry and results review system has to be accessible by clinicians at the bedside as they are conducting patient reviews and assessments. This requires the presence of a computer at the bedside and a network infrastructure to support the exchange of information. Cost and usability were key factors in determining the type of hardware to be used in our implementation.

Several studies have reported the use of both personal and hospital-owned mobile devices for provision of healthcare [133]. Due to the high penetration of smartphones in LMICs, most clinicians already bring personal mobile devices to the bedside [134]. This provides an opportunity to use such devices for positive patient identification, literature searches, clinical communication, and other uses. However, personal devices cannot be relied upon for the performance of professional tasks and duties. Hospital-owned devices would be better suited for this role. Further, specimen labeling requires the use of a label printer to generate a label for the specimen container. This functionality is limited to a small group of custom mobile devices and is not readily available on most personal mobile devices. While these labels can be printed remotely to a central printer, this would require that the clinician leave the bedside and walk to the printer to retrieve the label. The time spent walking back and forth is considered non-value-added time and introduces inefficiencies in the specimen collection process. There is therefore a need for a dedicated, reliable, and secure computer and the necessary peripheral devices that can be brought to the bedside for performing these tasks at the bedside.

Computers and workstations on wheels (COWs and WOWs) provide a reasonable alternative to mobile devices for bedside computer access in the clinical setting. These devices have the added advantage of allowing the addition of peripheral devices such as a label printer and barcode scanner. However, the cost of a commercially available off-the-shelf solution is prohibitive for most LMIC settings with prices per unit ranging from 2,600 USD to as high as

4,000 USD [135]. Such high costs would make the initial costs of implementation unfeasible for most low-resource settings. Furthermore, even if the initial implementation could be afforded, subsequent purchases to replace broken hardware could make implementation unsustainable due to financial reasons. A low-cost, locally-available, and maintainable alternative to the commercially available off-the-shelf COW would be better suited for implementation in low-resource settings.

7.2.1.3 Digital Job Aids

Ordering laboratory tests and the review of laboratory test results are routine tasks in patient care management. However, insufficient adequately-trained human capacity in LMICs often leads to these tasks being performed by people with varying levels of training and proficiency. The role of clinical informatics in this setting is therefore to bridge the knowledge divide and ensure that routine tasks and processes are performed in a standard way. One way of achieving this is through the use of job aids that facilitate the performance of a task or process.

Several gaps exist in the laboratory testing process that could be addressed through the use of job aids. Previously, we designed a paper job aid that was affixed to a specimen collection cart to provide a quick reference for requirements for different laboratory tests and ways of preventing common laboratory errors such as wrong specimen containers. To further improve the process, these and other interventions targeted at ensuring completeness of laboratory test order documentation were built into the electronic laboratory order entry and results review system as digital job aids.

7.2.2 Design Goals

Several frameworks exist defining the requirements or properties that systems can possess and the dimension on which they can be evaluated [136]. IBM introduced the RAS framework for assessing hardware using three important -ilities namely: reliability, availability, and serviceability [137]. From a more exhaustive list of -ilities, usability and installability were added to this model creating the RASUI framework [138]. Douglas extended the framework to RASUI+A when describing the properties for systems in LMICs [139]. We further add sustainability as another of the -ilities that best address the common problems faced in implementing HIT in LMICs.

7.2.2.1 Reliability

The measure of the level of risk and potential for application failures [140]. Systems with low reliability have high application downtime, application outages, and errors. Rigorous testing can identify causes of errors when using the system. Handling the potential sources of errors can improve reliability of a system. Reliability can be further improved by a quick turnaround of updates for detected problems [137].

7.2.2.2 Availability

Error messages and dropped network connections are a source of frustration for system users [141]. In healthcare, system failure can contribute to patient safety incidents and do more harm than good [142]. Ensuring that any system deployed in a clinical setting is available for use even in the remote corners of the hospital is of great importance. Several factors contribute to the availability of a system. In LMICs, network and power outages are significant barriers to HIT implementation and often lead to system unavailability [143]. A client-server architecture without

redundancy is highly likely to suffer from high unavailability when the network is unreliable as is the case in many low resource settings. Similarly, devices with high power consumption are likely to deplete power backup reserves quickly resulting in prolonged system downtime. A distributed system which does not require real-time network access and a network infrastructure with built in redundancies would provide better availability for systems.

7.2.2.3 Serviceability

Serviceability is the measure of the ease with which one can identify why a system failure happened and how to resolve it in a reasonable amount of time. This is often linked to competencies of the team or individuals supporting the system. A serviceable system should allow locally available human resources to return the system to a functional state without requiring expert assistance in most cases. Local capacity building is essential in ensuring a serviceable system especially in LMICs [144].

7.2.2.4 Usability

KCH is a teaching hospital with high turnover of staff. Any system requiring extensive training will either fail or require dedicated resources for continuous training. Both of these outcomes are undesirable. The system would therefore need to have a short learning curve so that users would easily become proficient in its use without formal or extensive training. Further, the system must ease the effort required to perform a task either by making it faster and/or simpler. One way this can be achieved is through reusing previously captured information such as patient demographic details to minimize data capture thereby reducing the amount of typing required.

7.2.2.5 Installability

Often done by implementers, how the system is setup has a bearing on how well the system performs. Installability refers to the level of difficulty in setting up the system. Ensuring that the system can be easily installed helps improve consistency of performance across multiple installations. One way to do this is through the use of checklists and automation of the software installation process. Clear guidelines and how-to documents also help to improve the installability of a system.

7.2.2.6 Accessibility

The degree to which the users can easily and readily access the system from their work location can affect the success of the system. To provide an accessible system in a clinical setting, clinicians must have access to the system at the point of care which in an inpatient setting is often the bedside [145]. Users must have access to the system in order to use it. Providing enough access points for the system such that users have access to the system when and where they need it improves the accessibility of the system.

7.2.2.7 Sustainability

One criticism of digital health implementations in LMICs is the failure to move past pilot implementations and scale-up due to flawed business models and failure to plan beyond current project funding [146], [147]. With competing interests for the small amount of financial resources available, health information technology is unlikely to be a priority amongst the needs for a hospital. This is particularly true when the cost for implementing and maintaining the technology is comparable to a few months of human resource salaries or medication supplies. One way to

make HIT feasible for low-resource hospitals is to use reliable low-cost technology that can be maintained locally for insignificant costs.

7.2.3 Design Reality Gaps

We utilized the design-reality gap framework to assess potential barriers to successful implementation and use of the envisioned intervention. Heeks proposes seven dimensions that have to be assessed and managed to prevent failure of HIT implementations [148]. The seven dimensions of the design-reality gap framework are information, technology, processes, objectives and values, staffing and skills, management systems and structures, and other resources. We assess the envisioned intervention in the context of each dimension.

7.2.3.1 Information

This dimension has to do with the amount and use of data that will be collected using the envisioned system against the data that is currently collected and used. The system will be designed to facilitate the creation of laboratory orders and the review of results. Data will be captured to create the laboratory orders. However, the use of positive patient identification means that patient data can be reused in the order and doesn't have to be re-captured. In this regard, the amount of data entered manually in the envisioned system is less than what is currently required when completing a paper laboratory order form.

7.2.3.2 Technology

Some parts of the technology needed for the electronic laboratory order entry and results review application already exists. A wired Ethernet connection to other systems exists in the

targeted deployment locations. However, since the computers would have to be used at the bedside, a wireless network is needed to facilitate information exchange and communication. This is the first gap in the technology dimension.

Further gaps exist in that the implementation will require COWs which have not been used before in this clinical environment. This hardware will have to be procured or developed and deployed in this setting. A power solution will also have to be purchased or developed to ensure that the COWs are available for use when required.

7.2.3.3 Process

Some changes to the process will be necessary to accommodate the use of the system. We envision role-based functionalities that will allow doctors to order tests and nurses to see what has been ordered and collect specimens. This process will depend upon positive patient identification requiring that all patients in the targeted implementation sites should have patient identifiers. The current process does not require or use patient identifiers. This presents a gap between the current situation and the design that will have to be managed. One possible way to manage this will be the enumeration of all possible entry ways into the targeted implementation sites and deployment of patient registration capabilities in each of those pathways.

7.2.3.4 Objectives and values

As earlier described, it is estimated that laboratory test results form the basis of up to 70% of all clinical decisions [2]. The availability of laboratory test results is therefore a critical piece in ensuring that clinicians are able to meet their core objectives of relieving pain and suffering, promoting health, preventing disease, forestalling death, and curing or managing disease [103]. However, results of laboratory testing are not the only information gathered and used in the

diagnostic process [104]. Details of physical examination and past clinical history also contribute to clinical decision making [104]. The electronic laboratory order entry and results review system will not, in the pilot stage, cater to the performance of other clinical functions such as physical examinations or the recording of the outcomes from these activities. However, while the system does not provide a complete set of information that can be used for clinical decision making, it is expected to provide information contributing to at least 70% of clinical decisions. The proposed system can thus be said to be aligned with the objective and values of clinicians and not having a significant design reality gap.

7.2.3.5 Staffing and Skills

Computers are not in use in the targeted implementation sites. It is difficult to ascertain the competency of the targeted users with information technology solutions. However, the envisioned system is being designed to be highly learnable and easy to use for novice users. This should reduce the need for extensive training. The system is further designed to assist the current personnel in performing their routine duties. Extra personnel will not be required to use the system thereby mitigating any gaps that exist in this dimension.

7.2.3.6 Management structure and systems

The system is not expected to shift the balance of power between the various cadres of healthcare workers or affect any reporting lines. However, the system may expose the performance of the laboratory, for which there are currently no clear performance indicators that are shared with the clinicians. The system may increase the scrutiny that the laboratory faces and cause the laboratory to be held accountable by the clinical personnel. To the best of our knowledge, no other significant design-reality gap exists in this dimension.

7.2.3.7 Other resources

To sustain the system, the hospital will eventually need to start paying for consumables in the form of thermal labels. These may not be locally available and may prove to be a both a logistical and financial problem for the hospital. Further, the hospital will be expected to eventually take over maintenance of the system. This may also require some extra financial resources. Driessen et al. describe a return on investment model that hypothesizes that a system with job aids similar to the ones included in the proposed systems would in the long run save the hospital money [94]. We hope that by the time the hospital starts paying for the implementation, there will be sufficient evidence to show that the system provides value and reduces waste leading to financial savings. This will help limit the design-reality gap that exists in this dimension.

7.3 Results and Discussion

Informed by the design-reality gap and the extended RASUI frameworks, we designed an electronic system intended to be run on a custom COW to facilitate point of care laboratory order entry in a low-resource inpatient setting. Two main artifacts were produced in this process, the software and hardware. The reset of this chapter describes the software and custom hardware that was developed and provides a description of the proposed workflow for the system.

7.3.1 System Architecture

7.3.1.1 Software

We designed and developed the electronic laboratory order entry and results review software to provide clinicians with the ability to order laboratory tests electronically and review results of the same. The software consists of three main components: a user interface, web

framework, and a database. The user interface was built using HTML, CSS, and JavaScript. We utilized Flask, a micro web framework written in python, to communicate between the user interface and the database which was implemented in CouchDB [149], [150].

To account for intermittent network connection and increase availability of the system, we utilized a distributed system architecture which required no real time connectivity with other external systems. We took advantage of the robust replication functionality within CouchDB to synchronize data between each workstation and a CouchDB node on the LIMS server, thus maintaining up to date records on each workstation. Laboratory orders and results are pushed to each workstation to create a local cache and allow clinicians to access them even when the workstation that they are using may be temporarily out of wireless network range.

To eliminate the need for the electronic laboratory order entry and results review system to be tightly integrated with the hospital master patient index, we modified the output of the patient registration system. A QR-code was added to the details printed out on the adhesive label produced after patient registration. We maximized the size of the QR code to improve scanning while maintaining sufficient room on the first line of the label to accommodate long patient names. As opposed to the linear barcode that only has the national patient identifier, the QR-code contains a complete patient demographic record. Scanning the QR-code in the electronic laboratory order entry and results review application creates a patient record with the same demographic details if one doesn't already exist. This achieved integration with the master patient index without a need for real time communication between the systems. A comparison of the old and new adhesive labels is provided in Figure 18.

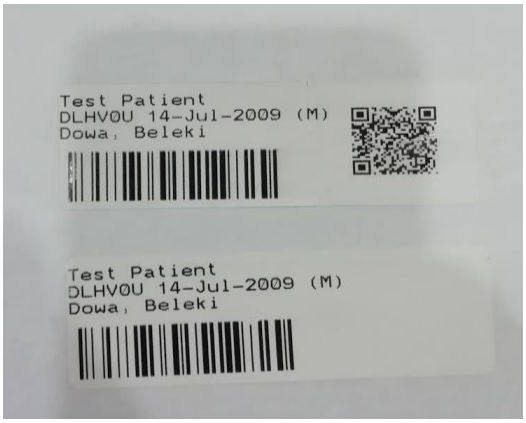


Figure 18: Picture highlighting changes between the old patient registration label without a QR-code (bottom) and the new patient registration label with a QR-code (top).

Further changes were made to the laboratory specimen registration application which is used to register specimens and assign them accession numbers as they arrive at the laboratory reception. Functionality was added to allow parsing of information scanned from a 2-dimensional (2D) barcode produced by electronic order entry and results review application to create a laboratory test order and assign an accession number to the specimen. The additional functionality also generates a laboratory order form which is printed on thermal paper for use within the laboratory. This form has the same information as the paper forms that will continue being used in the areas where the electronic system would not be deployed.

Finally, to update the status of laboratory test orders and make the results of laboratory tests available in the electronic laboratory order entry and results review system, we developed a laboratory test result synchronization service. This service is responsible for routinely updating the status of the tests order through the electronic laboratory order entry and results review system. Figure 19 provides a description of all the pieces of software used in the laboratory testing process at KCH and how they all fit together.

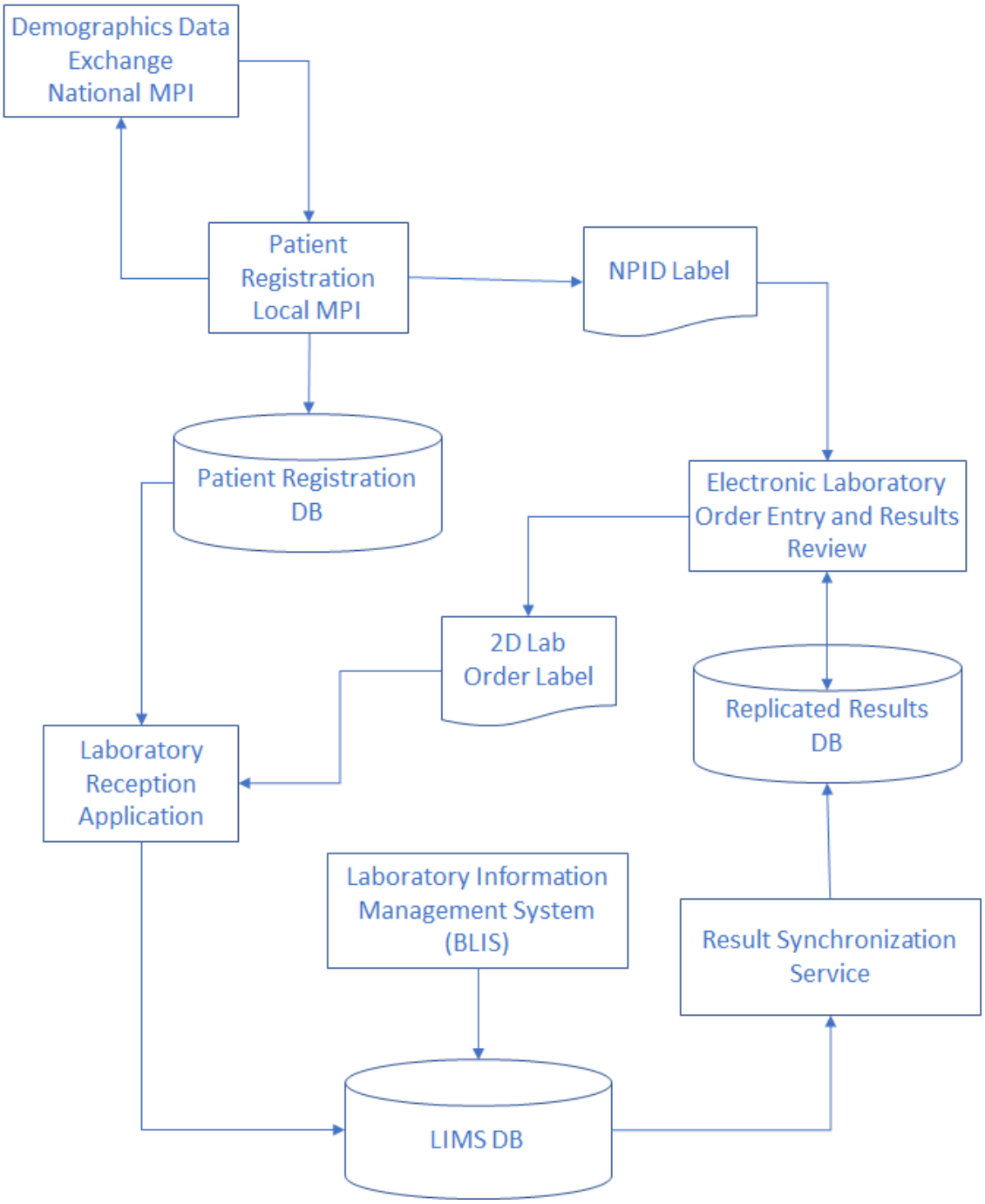


Figure 19: Overview of the laboratory testing software ecosystem at KCH.

7.3.1.2 Hardware

Three different types of computing hardware platforms were considered for use at the bedside. We chose to use COW hardware as opposed to fixed computers and mobile devices for several reasons.

The COW hardware platform provides sufficient space to allow multiple peripheral devices to be connected which was a core requirement in this case. Further, the COW platform provides the necessary infrastructure for streamlining the specimen collection process. Apart from bringing the computing device to the bedside, a good cart design can be used to pack specimen collection materials and bring them to the bedside thereby reducing trips to fetch supplies. A well-designed cart could also facilitate the safe disposal of any used supplies by providing a sharps box and a waster bin.

To minimize the cost, improve maintainability, and ensure sustainability of the implementation, we locally designed and assembled a custom COW. The total cost of putting together the custom COW was 422 USD. We further brought down the cost of each COW by using second hand printers that we procured at 25 USD, a quarter of the cost for a new printer. This is in comparison to 2,600 USD reported by Jen et al. for a COW with fewer peripheral devices [135]. A detailed description of the materials used to assemble the COW and their costs is available in Appendix B. A commercial off-the-shelf product with high cost of purchase and the possible need for foreign expertise to maintain makes it difficult to sustain in a low-resource setting such as the one at KCH.

Custom hardware has the potential to be less sustainable and maintainable than commercial Off-the-shelf hardware. A supplier of custom hardware often maintains a market monopoly for the hardware; a paradigm known as vendor lock-in [151]. This could be a significant risk for a project.

In our case, we developed custom hardware that adheres to the free hardware design ideology [152]. The way the carts were assembled and detailed instructions on how to build your own will be provided for free to allow other implementers the opportunity to build this hardware platform by themselves and reduce dependence on us as the innovators and suppliers of this hardware paradigm.

Previously, we compared the usability of a commercial Off-the-shelf POS touchscreen computer with a custom 10-inch workstation that we had designed and assembled [153]. We utilized similar low-cost single board raspberry pi computers as our primary computing platform in this design [154], [155]. The raspberry pi foundation offers a 7-inch touchscreen display which we combined with a 32GB SD card and a raspberry pi model 3B+ board to make a fully-fledged computer with a touchscreen for information display and user interaction.

For printing the specimen labels, we utilized a direct thermal Zebra LP 2824 printer which requires no ribbon or cartridge for printing when heat-sensitive labels are used [156]. This was done to reduce the number of consumables needed to run the workstation. An embedded 2D barcode scanner completes the list of peripheral devices used by our COW. This was included to allow scanning of patient identifiers in the form of QR codes for positive patient identification.

All the various pieces of electrical components are powered by a locally-sourced 12-volt sealed lead-acid battery, commonly used in uninterruptible power supplies. A custom circuit board was designed to facilitate the electrical connection of all these devices along with a real-time clock and circuitry to charge the battery.

Docking stations were designed to charge the battery in the COW when the COW was not in use. Magnetic contacts on the COW and the docking station attract when the COW is in close

proximity with the docking station. When these contacts come together, an electric circuit is completed and the battery begins to charge at a constant current.

Figure 20: A fully assembled custom assembled mobile touchscreen clinical workstation in use at KCH and a prototype of the docking station.

To secure and house all these parts, we designed and built a plastic enclosure using computer aided design (CAD) software. We utilized plastic cut from PVC pipes and flattened into manageable pieces to assemble the various parts that we needed for the enclosure. The parts for the enclosure were cut from the flattened plastic pieces using a computer numerical control (CNC) machine. A picture of a fully assembled workstation is provided in Figure 20.

The electronic order entry and results review system requires a network connection to facilitate asynchronous information exchange with the other workstations. To make this possible, we utilized Mikrotik wireless router boards to create wireless access points in each of the targeted implementation sites. The wireless routers were connected to the pre-existing hospital network for EMRs allowing communication with other systems that were deployed at the facility.

7.3.2 Proposed Workflow

The system is designed to facilitate the total testing cycle at KCH by providing functionality to order laboratory tests, label specimens, track the status of the laboratory test, and review the results of the test once they are available. Once logged in, a doctor or physician can use the barcode on a patient's health passport to positively identify the patient and retrieve their record. This gives them access to all the patient's past laboratory tests and provides an option to create a new laboratory order. A screenshot of this interface is shown in Figure 21.

The system provides an interface design to guide the user through all the required information fields if they choose to order a laboratory test. These fields include the type of test, urgency of the test, and the clinical information associated with the test. Once all the information has been entered, a new laboratory order is created and the doctor or physician can indicate if they are collecting the specimen at that time or not. The created laboratory order is visible to all members of the team to which the doctor belongs and to the nursing staff on that ward when they login into the system.

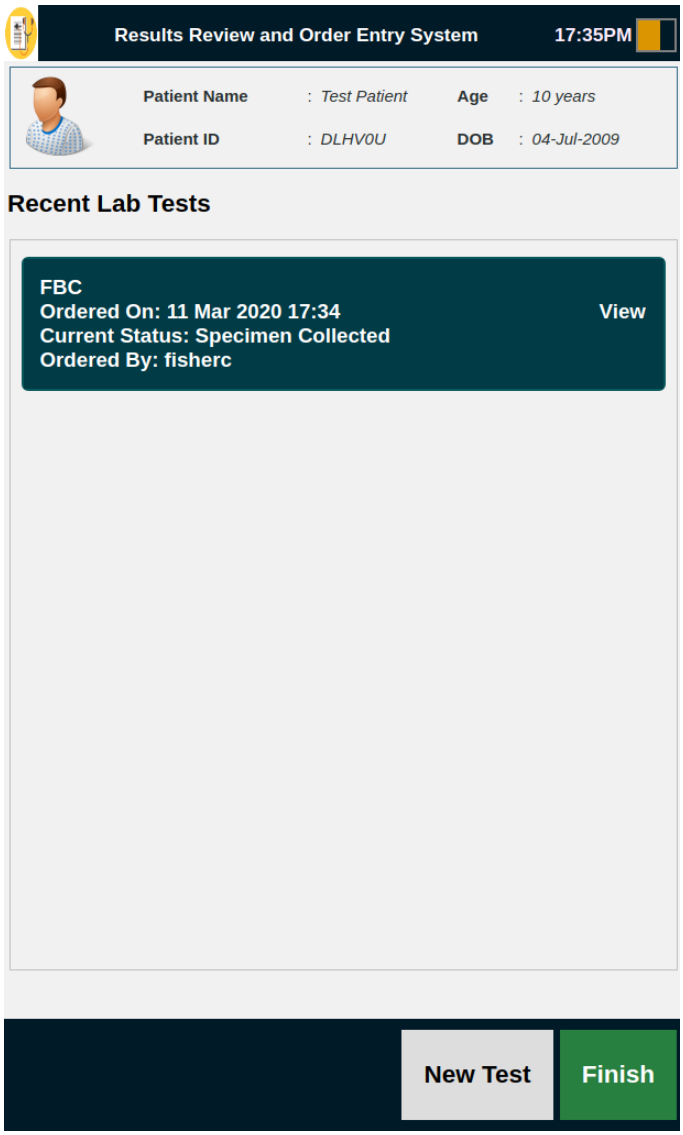


Figure 21: Screenshot of the patient record in the electronic order entry and results review application.

Specimen collection and labeling is done from within the open patient record. Pressing the "Draw Samples" button, which appears any time a patient has a pending order, opens a modal dialog box with details of all uncollected specimens as shown in Figure 22. Pressing the "Draw Sample" button next to a test order updates the status of that test to "Specimen Collected" and prints out an adhesive label with a PDF417 formatted barcode and the name of the patient, their date of birth, and the short names of the tests that have to be run on the specimen. The PDF417

barcode format was chosen due to its linear form which allows it to be read when placed lengthwise on curved surfaces such as those of most specimen containers [157]. The adhesive label has to be affixed to the specimen container as shown in Figure 23.

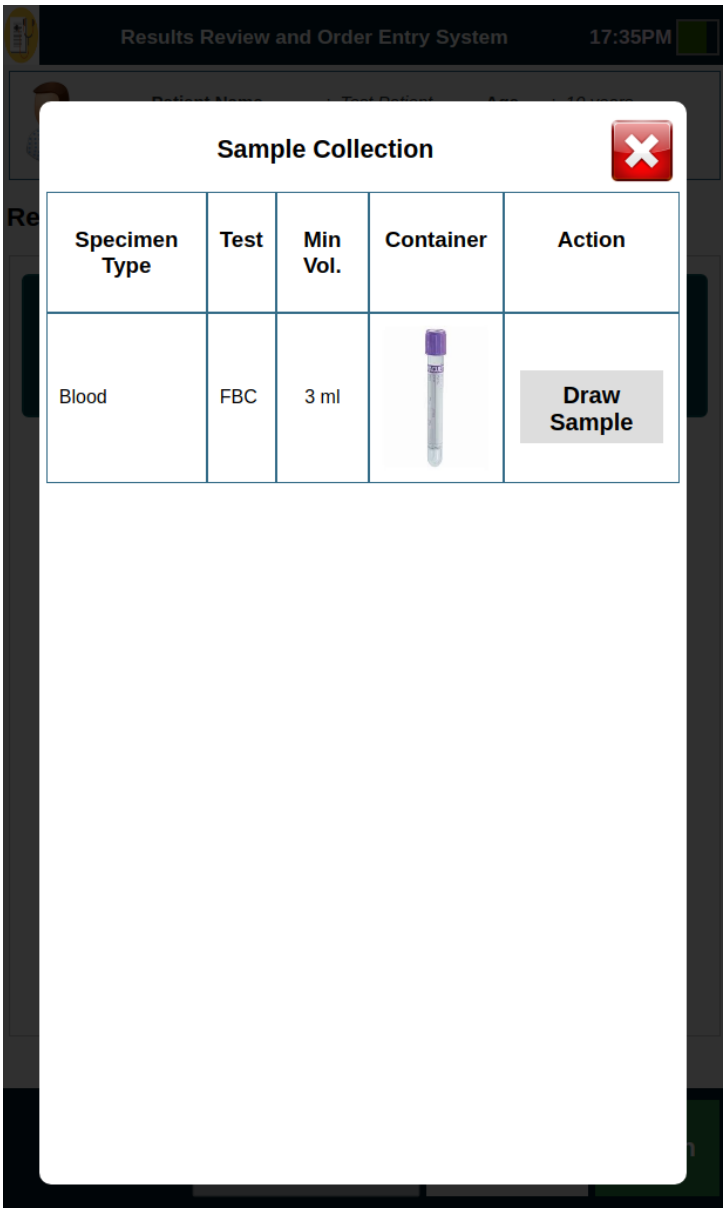


Figure 22: A screenshot of the specimen drawing screen with guides on minimum specimen volume and the right specimen container.

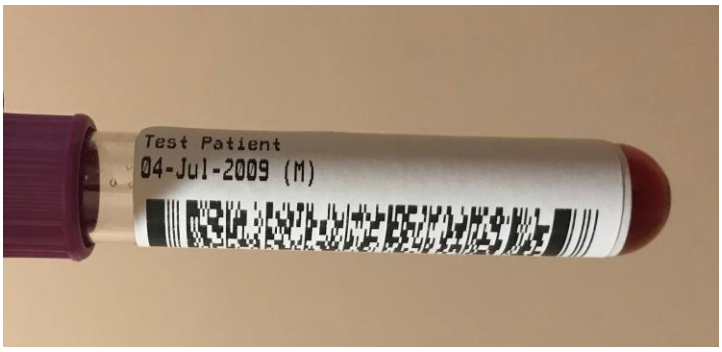


Figure 23: An example of the self-contained specimen with the laboratory order details encoded in a PDF417 barcode.

When the collected specimen(s) are brought to the laboratory, a laboratory receptionist scans the barcode on the specimen container which creates a record of the specimen and laboratory test order in the LIS. This process also assigns an accession number to the specimen as described in 4.3.1.2 with the only exception that in this case, a system generated laboratory order form is printed on thermal paper. The system generated laboratory order form is used within the laboratory to schedule some tests and retrieve records in the LIS for fetching results from the instruments or authorizing of results that have been fetched from the instrument. Further, the accession number on this form is used to schedule analysis of specimens in some departments such as biochemistry, where the analytical instruments process specimens in batches that could have multiple combinations of analytes that need testing. An example of the system generated laboratory order form is shown in Figure 24.

One limitation of the system developed in this phase is the failure to use standard controlled vocabularies. Standard vocabularies allow interoperability with other systems and promote reuse of applications in different settings. The system developed here did not use any standards due to the overhead required to make all the other systems in the ecosystem compliant with the standards.

While this may be sufficient for the pilot implementation, any plans to scale the application further must be preceded by a refactoring to utilize standards where possible.

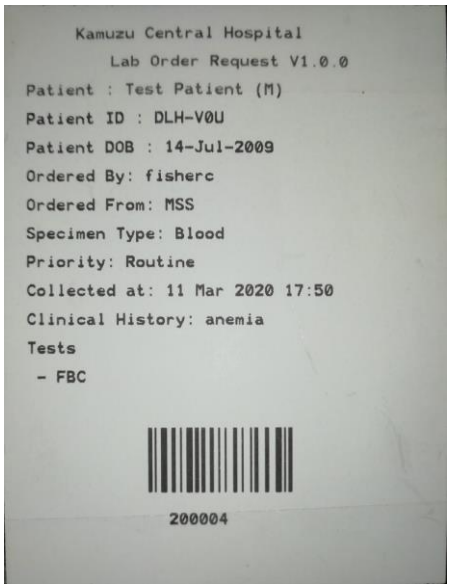


Figure 24: An example of a system generated laboratory order form. This is printed after scanning a laboratory order barcode.

8.0 Implementation of An Electronic Laboratory Order Entry and Results Review System

8.1 Introduction

Five years after the first attempt to implement a system that supported the total testing process at KCH, we piloted an electronic order entry and results review system [8]. The system was designed with several digital job aids aimed at addressing challenges in the total testing process.

Specifically, the system aimed to address challenges in documentation of laboratory order forms by ensuring that forms are legible, complete, and cannot be misplaced during transport and sorting in the laboratory. Further the system aimed to improve communication between clinicians and laboratory personnel by keeping an updated record of the status of each test and specimen. In doing this, the system would also improve the turnaround time of laboratory results by making them accessible in the inpatient setting as soon as they were available and the COW was in the wireless network range.

The electronic laboratory order entry and results review system was designed with job aids for specimen collection. The right specimen container, specimen type and the minimum volume of the specimen required to perform the test were displayed to the clinician before printing an adhesive label with all the test details. This was done to ensure that the number of specimens rejected due to using the wrong container or having insufficient volume was reduced.

We hypothesized that the system when implemented in a low-resource setting would reduce the number of non-viable specimens. This chapter describes the approach used to implement this system and the initial evaluation of the system's adoption and use.

8.2 Methods

8.2.1 Setting

We conducted a pilot implementation of the electronic laboratory order entry and results review system in the Medical department inpatient wards at KCH. We chose to pilot in this department due to the wide variety and high volume of laboratory tests ordered by this department. The medical department at KCH has 4 inpatient wards; medical short stay (MSS), medical high dependency unit (MHDU), female medical ward (4A), and male medical ward (4B).

8.2.2 System Deployment

We utilized a parallel implementation strategy to pilot the electronic order entry and results review system. Clinicians maintained the option of using either the old paper-based laboratory order process or the electronic order entry process. This was done to minimize the impact of the pilot on the laboratory testing process in the medical department at KCH.

In the first week, all the hardware necessary for the operation of the electronic order entry and results review system was placed in the clinical setting. Six COWs were deployed in total; one in medical short stay, two in male medical ward, and three in female medical ward. COWs were allocated to wards based on bed occupancy and the level of utilization of laboratory tests. We introduced the system to the clinicians during the first daily handover meeting that week and collected names for all clinicians present to create user credentials. We took advantage of the rest of the week to conduct one-on-one orientation sessions on how the system was supposed to work and ensure that all prospective users in the medical department had credentials.

The second week was designated as the official go-live week where full-scale use of the system was expected. This week also coincided with a new rotation of medical students joining the medical department. The system went live in the medical department on January 20, 2020.

This implementation utilized COWs with a 12-volt sealed lead-acid battery as the mobile power source. Initially, we had planned for these batteries to be charged through docking stations that were going to be deployed in all the targeted implementation wards. However, the docking stations were not ready by the scheduled deployment date. To ensure that there was enough charge to keep the system running in the absence of the docking stations, we devised a temporary solution of rotating batteries between use in the COW and charging in a dedicated battery charging station shown in Figure 25. Batteries were changed twice a day, in the morning and late afternoon, including on weekends This was in lieu of deploying a docking station that could charge the batteries without having to remove the batteries.

Figure 25: The battery charging station at KCH used to ensure that batteries have enough charge to run the COW.

8.2.3 Measuring Adoption and Use

Two metrics were used to assess adoption and use of the system in the clinical setting. The first metric was the proportion of tests from the medical department that were ordered using the electronic system as opposed to paper forms. In the absence of any hindrances to using the system, this measurement captured the user's preference to use the electronic system as opposed to the pre-existing paper order form which was still in use. This measurement served as a proxy for user's preference of the electronic system.

To measure use of the system, we recorded the number of registered users with completed tasks in the system. While similar evaluations have used system logins as a proxy for system use, we did not think this was an accurate measure. Logins may capture an attempt to use the system. However, they do not capture meaningful use of the system. System use is best captured by the user performing a task with the system. Since each transaction in the system had an identifier for the person who completed it, we opted to count the unique user identifiers from the various transactions as a measure of system use.

8.2.4 Workflow Changes and Post-deployment Issues

We hypothesized that implementing a system like the one described here would affect the workflow in the clinical setting. We used direct field observations to assess whether there was any effect on the workflow in the medical department and identify challenges in using the system once it had gone live.

The electronic laboratory order entry and results review system was deployed in the medical department wards on January 13, 2020. Full scale use of the system started on January 20,

2020, three months after the paper-based intervention had been implemented in the medical department at KCH.

8.3 Results

Since full scale use of the electronic system started at KCH on January 20, 2020, a total of 1797 tests have been ordered using the electronic system as of March 24, 2020. From the perspective of the total testing process, each test order has a life-cycle with multiple possible end points. Figure 26 summarizes the current state of each test that has been ordered at KCH using the electronic system.

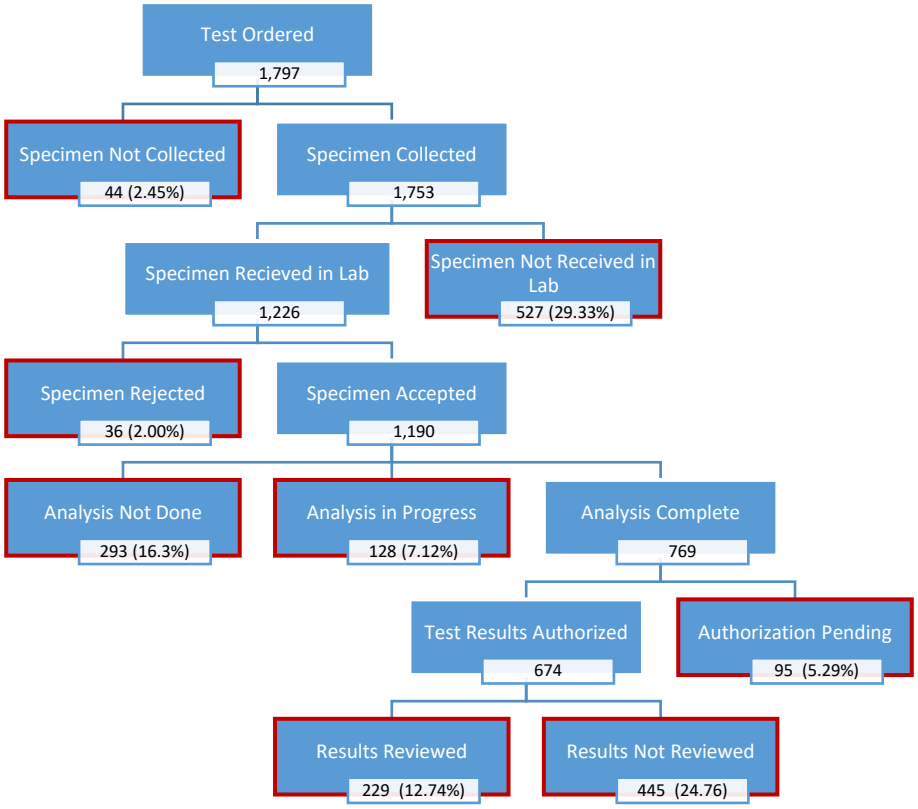


Figure 26: The state of all the tests ordered using the electronic laboratory order entry and results review system from January 20, 2020 to March 15, 2020.

We further assessed the number of electronic test orders made per week that resulted in orders being recorded in the LIS at KCH. At its peak, 83.93% of all tests ordered in the electronic laboratory order entry and results review system were recorded in the LIS as being received in the laboratory at KCH. However, a downward trend in these proportions ensued with the last reported reading showing only 34.43% of all orders made electronically being recorded in the LIS at KCH. This was despite the electronic laboratory order entry and results review system showing that high numbers of test having specimens collected with the lowest reading being 95.94% of all the tests ordered electronically (Figure 27).

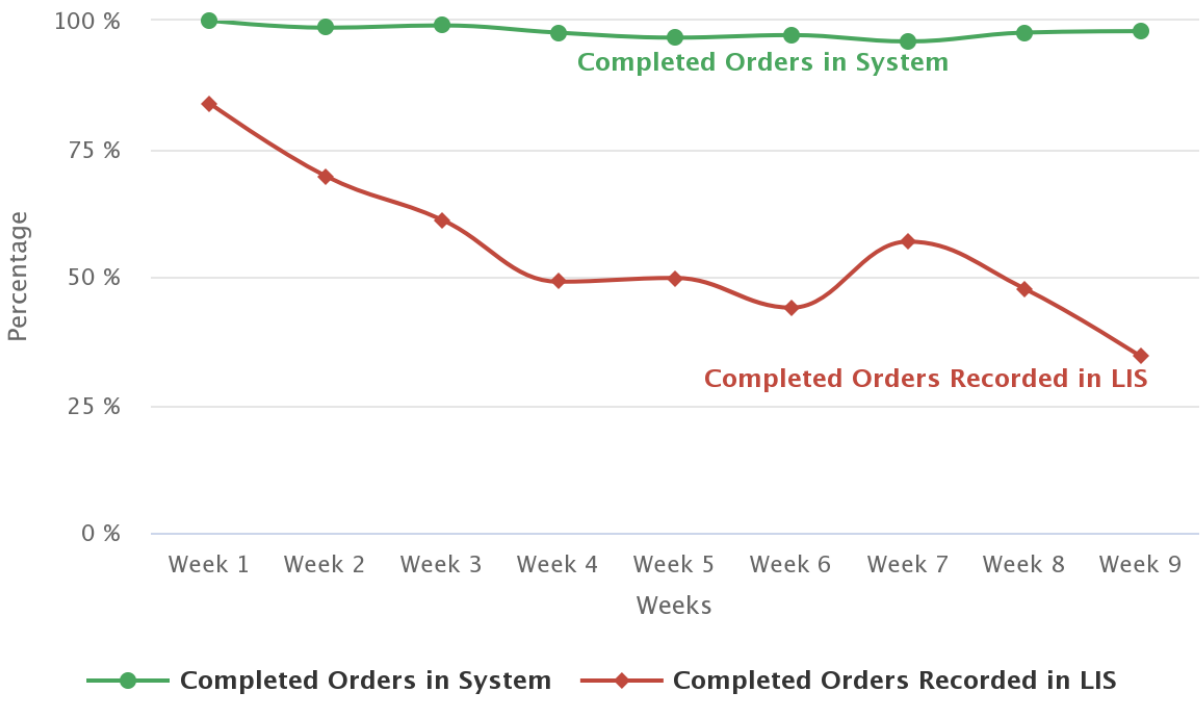


Figure 27: An overview on the amount of completed laboratory orders based on status of tests in the electronic laboratory order entry and results review system and records in the LIS.

8.3.1 System Adoption and Use

In the first week of full system use, 56 tests were ordered using the system by eight different doctors. In the same week, 460 tests were ordered from the inpatient wards of the medical department. A total of 271 specimens were received in the laboratory from the medical department inpatient wards. Of these, 42 specimens were linked to electronic laboratory orders representing 15.5% of all specimens. Out of the 460 tests, 47 were linked to electronic laboratory orders representing 10.22% of all tests ordered from the medical department inpatient wards. The majority of these tests were ordered from 4A, the female medical ward.

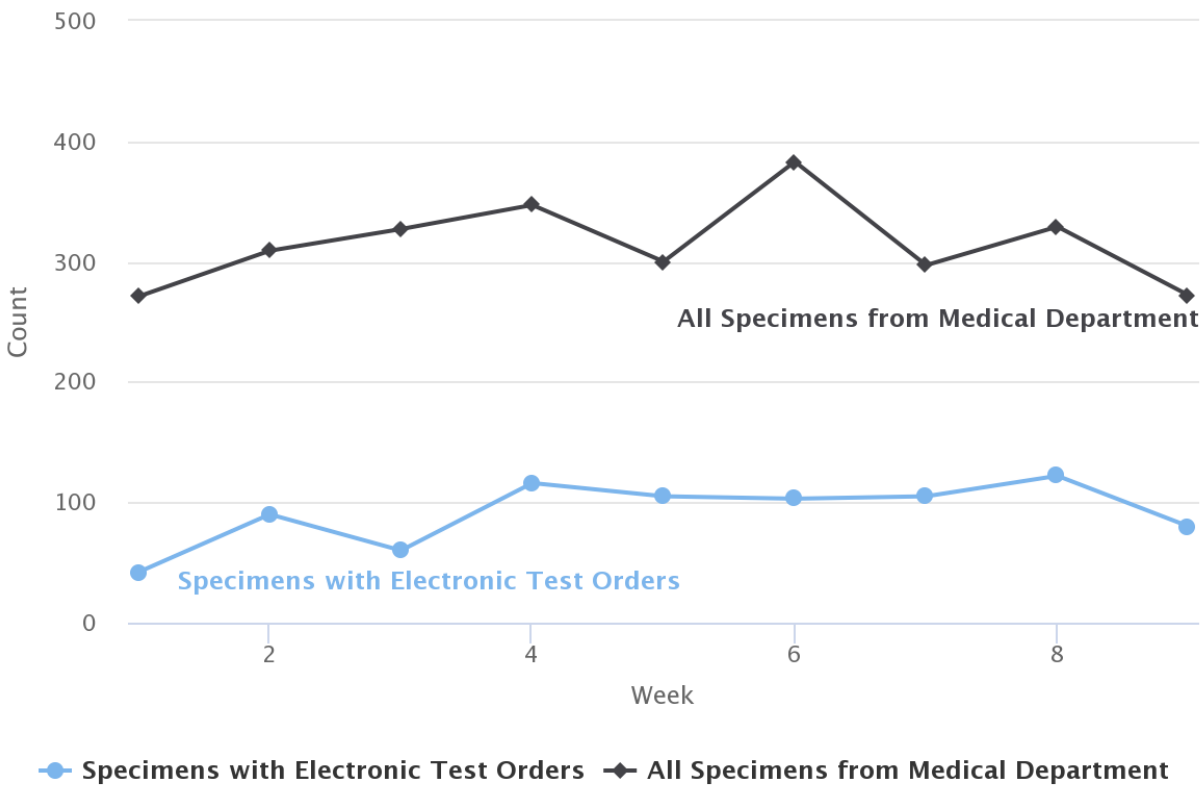


Figure 28: The number of specimens linked to electronic orders in comparison to all specimens received from the medical department inpatient ward.

In the second week, three new doctors ordered laboratory tests using the system but another three from the previous week did not order any tests using the system. A total of 145 tests were ordered through the system in that week of which 101 tests linked to electronic laboratory orders were registered in the LIS. Out of the 460 tests recorded in the LIS as coming from the medical department in patient wards, 101 were linked to electronic orders representing 20.61% of all tests from the inpatient wards of the medical department. The 460 tests were run on 309 specimens of which 90 (29.13%) were linked to electronic orders.

Figure 28 and Figure 29 provides a graphical representation of the number of specimens received in the laboratory that are associated with electronic laboratory orders in comparison to all the specimens from the medical department inpatient wards.

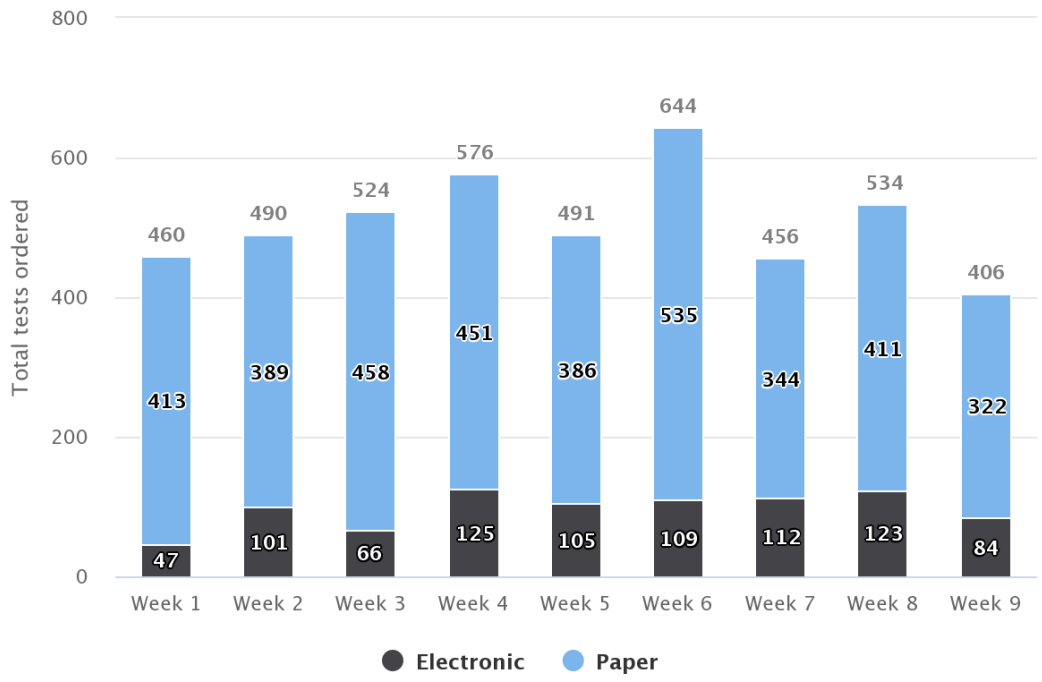


Figure 29: A graphical comparison of the number of tests ordered electronically as opposed to those ordered by paper.

Since the deployment of the system, 201 unique user credentials have been issued with the majority of users being students. 135 (67.16%) of all users have performed and completed a task using the system. Table 4 provides the distribution of the user roles and the proportion of users within each group who have successfully used the system.

Table 4: The distribution of users based on roles.

Role	Number of Users	Users with Successful Tasks	Proportion with Completed Tasks (%)
Clinical Officer	5	4	80.00
Medical Doctor	51	49	96.08
Nurse	43	19	44.19
Student	102	63	61.76
Total	**201**	**135**	**67.16**

8.3.2 Workflow Changes and Post-deployment Issues

The proposed workflow for the COWs was that clinicians would bring them to the bedside and use them as they were reviewing patients. However, in the first two weeks post deployment, we noticed that clinicians preferred to have access to the carts but not bring them to the bedside. Ordering of tests in the system was often made by taking a patient's health passport to the cart and entering the details. This was often done after the specimen had already been collected. Furthermore, clinicians continued to mostly order tests using paper forms as shown in Figure 29. Some doctors simply wrote their orders in the paper chart and nurses were responsible for filling out the paper laboratory order forms.

Based on this observation, we made an alteration to the proposed workflow and user rights in the application. Nurses who previously were not allowed to create laboratory orders were given access to this feature with one alteration; they had to enter the name of the doctor who ordered the test. This modification to the software was made available in the clinical setting at the beginning of the third week post deployment of the system.

Several post-deployment challenges were encountered after the system had gone live at KCH. The first challenge had to do with the barcode scanning process required for creating and retrieving patient records. We observed that several workstations could not detect the barcode due to poor lighting conditions primarily in male and female medical departments. We addressed this challenge through two iterations of hardware and software modifications. In the first iteration, we addressed this challenge by adding a light emitting diode (LED) to the workstation to improve the lighting in the vicinity of the barcode scanner. The LED was turned on in software when the user was on the main application page from which they could scan the patient barcode. This approach was partially successful but did not completely eliminate the problem, leading to the second iteration of designing and implementing a solution to address the challenge of poor lighting affecting barcode scanning. We had more success in the second iteration where we used the barcode scanner's own internal lighting to trigger the motion sensing and initiate barcode scanning. This was done by making a modification to the scanner to turn the LED on independently of the embedded motion sensor.

During the time when we were resolving the challenges with barcode scanning, we lost two barcode scanners to unexplained hardware failures. These scanners simply stopped responding and any attempts to fix them were unsuccessful. These were replaced with new scanners of the same model, which have not presented any problems since.

The need for high coverage of the patient demographics and identifiers printed in QR code format was highlighted in the design reality gap analysis as a challenge to the system. While efforts were made to facilitate patient registration by clerks in all the medical department wards, many patients admitted to these wards still did not have the patient demographics in QR code form. When the clerk is present, such patients have been registered and issued patient identifiers. However, there are many times when the clerk is absent. Further, clerks only work five days a week during the day time. There are no clerks on the wards at night or on weekends. The poor coverage of patients with patient identifiers continues to present a barrier to using the system to order laboratory tests for these patients as positive patient identification is required.

All mobile workstations were powered by 12-volt sealed lead acid batteries that kept the COWs running for at least eight hours at the beginning. However, over time with increased system use, we noticed a reduction in battery life. We attributed this to the frequent charge/discharge cycles which decrease the usable capacity of a battery [158].

8.4 Discussion

In the nine weeks of since the system was made accessible to clinicians, users have had the chance to interact with the system and perform tasks with it. Many user accounts have been created with the majority belonging to students doing rotations in the department. The number of users whose accounts are linked to successful task completion has been increasing while the number of specimens received in the laboratory that were ordered electronically has been consistent around the 30% mark.

An overview of the status of the different tests in the system shows that a significant proportion of specimens collected in the wards are not making it to the laboratory. This is reflected both in the number of specimens that show as being collected but not received in the laboratory in

Figure 26 and the number of laboratory tests completed as recorded in the LIS (Figure 28). There are several plausible explanations for this phenomenon.

In the first place, a predominant part of user training is now done peer-to-peer amongst clinicians. While this has the benefit of reducing the amount of resources needed for training, it can also lead to spurious records being created during user orientation, which in turn results in inflated figures. Currently, there is no way to identify and delete such records. Providing a mechanism for users to void these records could potentially provide a better picture of the true nature of orders in the electronic laboratory order entry and results review process.

Challenges in using the system could also explain the reason for many specimens having the status of being collected but not received in the laboratory. Issues with labels not printing for one could lead to the clinician re-entering the order thereby creating duplicate records. Further, there are also challenges with certain tests that are handled uniquely at KCH. For instance, Prostate-specific antigen testing is available at KCH for a fee unlike other tests that are done free of charge. When these tests are ordered, the specimen is usually kept until the fee has been paid. A potential gap in communication may exist between the laboratory and all clinicians regarding this unique process. Tuberculosis testing is another test that has a unique procedure for specimen collection and transport. To begin with, the patient collects the specimen by themselves. Whether the specimen was collected or not is thus unlikely to be indicated in the system since patients do not have access. Sputum specimens are brought to the outpatient tuberculosis screening office from where they go directly to the microbiology department. Special tuberculosis testing forms, filled in the tuberculosis screening office, are used to register these specimens in the LIS. The barcode label affixed to the specimen container is unlikely to be transferred to the form in this process.

This results in the specimen being entered without association with the national patient identifier and thus the link with the electronic laboratory test order is severed.

Another alternative explanation to the same is that specimens are being marked as being collected before they actually are collected. Specimen collection may fail due to different reasons such as not finding the vein to draw blood. The system currently has no way of indicating a failed attempt to collect a specimen. Adding this functionality could potentially elucidate the number of times that this happens. This also raises the question of whether the specimens are then later collected and brought to the laboratory with paper forms. In the case where the specimen is brought with paper form, the link between the test and the patient is often not maintained due to the unique patient identifier not being entered in the routine order entry at the laboratory reception. It is also possible that specimens are being collected and lost in the transport between the inpatient wards and the laboratory. However, the steady decline in the proportion of electronic tests orders that are being recorded as not being received in the LIS points to a more systemic problem. All possible explanations for the current status quo warrant further investigation.

Nurses appear to be the group of users with the lowest task completed in the system. However, this could be a result of students taking a leading role in specimen collection as this is a key part of the tasks that students perform during their rotations. Similarly, doctors appear to be associated with a high number of successful tasks in the system. This in and of itself doesn't imply that doctors have taken to the system. The ability to let nurses and students enter laboratory test orders made by different doctors means that doctors can be linked with tests even though they themselves did not use the system. A more accurate description of this finding is that laboratory tests ordered by most doctors have been labeled using the system.

The unpredictable results of the interaction of a user with an information resource determines whether the user working with the information resource is better than the user working alone as described in the "fundamental" theorem for biomedical informatics [59]. In this study, we expected clinicians to use the electronic system from the bedside. However, we observed that most of the clinicians did not use the system this way. When asked why they were not bringing the COW to the bedside, several clinicians cited the limited number of COWs available as a reason for not bringing the COW to the bedside. The COW was not brought to the bedside to ensure that everyone had access to it during ward rounding. Due to limited resources, we did not provide extra COWs to see if this explanation would hold when they had more COWs.

Ensuring that all patients have a patient identifier printed as a QR code continues to be a barrier to system use. Some clinicians have been oriented on how to use the patient registration system accessible in the patient wards to issue new patient identifiers. However, this is not consistent with the objectives and values of their daily work. Many other clinicians have not been oriented on using the patient registration system. Efforts continue to identify and implement a better mechanism for ensuring higher patient registration numbers.

The innovative solutions used to address the post-deployment challenge with the barcode scanners highlight the value of local capacity in HIT implementations. Two quick iterations were made on a solution to address the problem and reduce the impact on system use. The first iteration identified the problem and had a tested and working solution that was implemented on all COWs within six hours of the problem being reported. This was only possible because people were available on the ground who had the technical skills to diagnose and remedy the problem. Building similar and more comprehensive capacity continues to be a barrier to sustainable HIT

implementations in LMICs [143]. Further action is needed to close this gap in LMICs to ensure that this setting has sustainable benefits from HIT.

Further innovation has been required with regards to the power solution for the COWs and the rapidly degrading battery capacity. A replacement battery pack made from locally-available lithium ion batteries is being tested with the aim of replacing the sealed 12-volt, lead-acid battery currently in use in the COW. From the results of the preliminary testing, we believe that this new power solution will have better performance and provide continued power for the cart lasting for approximately 9 hours per single charge thereby provide a sustainable option for the continued operation of the system in this setting.

In this study, we used the number of users with completed transactions in the system as a measure of system use. This measurement did not capture users who were unsuccessful in their attempt to perform a task using the system. This was a limitation of our study and did not allow us to capture users that may have been frustrated by the system. To remedy this, a survey was conducted eight weeks after the system was deployed to capture user attitudes, experiences, and views.

9.0 Assessing the Impact of the Electronic Order Entry and Results Review

9.1 Introduction

We developed and modified several pieces of software to ensure that clinicians could order laboratory tests, track the status of the test, and review laboratory results when they are available. Three key functions provided by the system were regarded as the key benefits that clinicians would attain from using the system. We refer to the benefits that clinicians would attain by using the system as value-propositions. The first value proposition was the ability to review laboratory results electronically and faster if the test order was done through the system.

The second value proposition was the ability to track the status of specimens through the laboratory testing process. Previously, the only way to check the status of a laboratory test was by going to the laboratory and asking the client officer. However, this is not always possible and can often be time consuming due to the high volume of people seeking to access laboratory services. As part of the functionality within the electronic laboratory order entry and results review system, any change in status of the laboratory test is visible across all workstations. Clinicians were now empowered with knowledge of the status of the laboratory test that they ordered.

The final user value proposition was the elimination of the paper laboratory order form. Stationary shortages meant that a significant amount of time could often be spent looking for a blank laboratory order form which sometimes is not available and leads to improvisation with a laboratory test form for another laboratory section or just using plain paper. However, when an improvised form is used, the probability of making errors resulting in incomplete documentation is high. Incomplete documentation makes the associated specimen non-viable for testing and the

specimen is rejected. The elimination of the paper form therefore could provide significant benefits to the clinicians and reduce the number of rejected specimens.

One of the criticisms of several years of implementing electronic systems in healthcare is the failure to generate objective evidence of the benefits to support the continued use and implementation of these systems in healthcare [88], [159]. Our value propositions were grounded in observations and hypotheses around the interventions that could improve the laboratory testing process at KCH. To assess whether the interventions indeed addressed the challenges in the laboratory testing process and improved the process, we evaluated the impact of the interventions on the laboratory testing process.

9.2 Methods

To assess whether this intervention had the hypothesized effect, we conducted a problem impact evaluation study. The multifaceted nature of the intervention necessitated that we evaluate the intervention from different perspectives. Previously, we looked at the impact of the intervention on the workflow; whether the clinicians started bringing the COW to the bedside for laboratory test ordering, specimen collection and labeling. In this study, we assess the impact of introducing the COW on specimen viability and the type of errors. Further, we assess the attitudes and intentions of the clinicians for whom these interventions were developed.

9.2.1 Specimen Non-viability

An interrupted time series analysis using segmented regression was used to assess whether the implementation of the electronic order entry and results review system had an impact on the number of non-viable specimens from the medical department inpatient wards. We used data collected from the ongoing study on assessing the impact of the specimen collection carts to get the daily count of non-viable specimens from the medical ward. These were used to calculate the non-viability rates as a percentage of all the specimens received at the laboratory from the inpatient wards of the medical department. The data used in the analysis was from October 1, 2019 to March 15, 2020, 9 weeks after the electronic order entry and results review system was in use by the clinicians. We excluded data from the transition week where users where being oriented on how to use the system and data from the week of March 20, due to outage of the LIS at KCH that affected the processing of specimens.

The model for the effect of the electronic system on nonviability of specimens is defined as $Y_t = B_0 + B_1T_t + B_2X_t + B_3X_tT_t + e_t$ where the terms are:

- Y_t is the observed rate of non-viability of specimens in week t.
- T_t is the number of weeks since the start of the study.
- X_t is an indicator variable for whether the intervention is implemented at time t.
- X_tT_t is the interaction term between the rate of non-viability of specimens.
- B_0 is the baseline level of specimen non-viability.
- B_1 is the change in rate of non-viable specimens per unit time interval (weekly).
- B_2 is the level of change in non-viability of specimens following the introduction of the intervention.
- B_3 is the difference in gradient or slope after the intervention.

9.2.2 User Attitudes and Intentions Towards the System

We utilized the Unified Theory of Acceptance and Use of Technology (UTAUT) questionnaire to assess the attitudes and intentions of clinicians towards continued use of the system. The UTAUT model is a validated tool for assessing the likelihood of success of new information technology and the factors that drive adoption of the same [160]. We removed one of the performance expectancy questions since use of the system in this setting is in no way connected to remuneration. A five-point scale ranging from “strongly disagree” to “strongly agree” was used as the response scale for the questionnaire items. Further, we added two open-ended questions to the questionnaire to solicit open-ended responses on things that users would like to see changed in the system and any feedback that they had regarding the system. We also added age range, gender, role in the clinical setting, and level of use of the system as items to be collected in the questionnaire. A copy of the full questionnaire is provided in Appendix C. The questionnaire and a cover letter were handed out to participants during morning handover meetings and at the nursing stations.

Thematic analysis was conducted on the open-ended questions to gather common themes arising from user responses. A codebook was generated from the survey responses enumerating codes for the common themes, descriptions of the theme, and examples (Appendix D). The codebook was then used to analyze the survey responses to identify the most frequent themes.

9.3 Results

9.3.1 Effect of Electronic Laboratory Order Entry and Results Review on Specimen Viability

Table 5 : A summary of specimens received by the laboratory from the medical department inpatient wards (October 1, 2019 – March 15, 2020)

	Pre-Intervention	**Post-Intervention**	**Total**
Accepted Specimens	6,049	4,173	10,222
Rejected Specimens	135	44	179
Total Specimen	6,184	4,217	10,401

We analyzed specimen viability data from the medical department inpatient wards to assess the impact of the electronic laboratory order entry and results review system that was implemented in this setting (Table 5). A total of 10,401 specimens were received at the laboratory reception from the medical department over the entire duration of the study. A total of 6,184 specimens were received in the period before the intervention was deployed with a nonviability rate of 2.18%. Of the specimens that were received following the implementation of the electronic laboratory order entry and results review system, 44 were rejected representing a non-viability rate of 1.04%. In the period after the electronic laboratory order entry and results review system was implemented in the medical department inpatient wards, the non-viability rate for the other departments was 1.85%.

Laboratory order forms without specimens were the most frequent reason for specimens from the medical inpatient departments that were rejected after the intervention was implemented.

Forms with no specimens and wrong specimen containers were the second and third most common reasons for specimen rejection respectively. A summary of the distribution for all the reasons for specimen rejection during the post implementation period is presented in Figure 30. Note that paper laboratory order forms were still being used in the medical inpatient wards during the post implementation period.

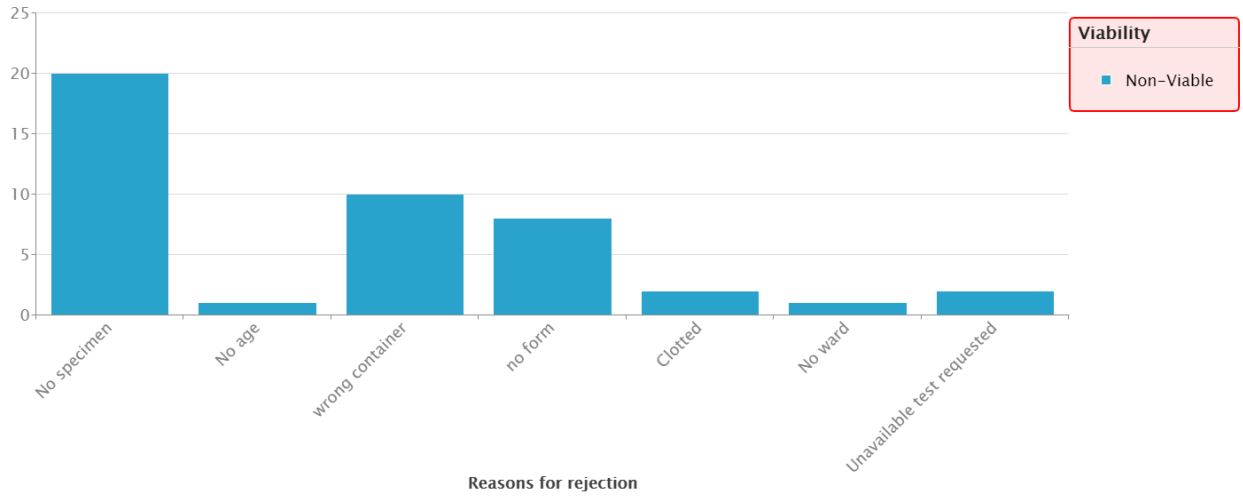


Figure 30: A histogram of the reasons for nonviability of specimens in the medical after the intervention was implemented.

To assess the impact of the intervention on the number of non-viable specimens, we utilized a segregated time series analysis where the non-viability rate was the target variable with a dummy variable representing when the intervention was deployed and a time variable indicating how long the study had been going for as the predictors. We did not find significant evidence of an immediate or gradual effect of the electronic laboratory order entry and results review application on nonviability of specimens as shown in Table 6.

Table 6: Findings from segmented regression for the effect of the electronic system on on specimen nonviability.

Coefficients	*Estimate*	*Std. Error*	*P Value (α= 0.05)*
Intercept	2.39963	0.17014	< 0.00001
Time	-0.93736	1.17594	0.4254
Intervention	-0.03274	0.01880	0.0816
*Time*Intervention*	0.04474	0.05792	0.4398

9.3.2 User Attitudes and Intentions

Out of the 50 questionnaires that were handed out, 33 were completed and returned representing a response rate of 66%. However, two questionnaires that were completed have not been included in the analysis. The first questionnaire was discarded for being incomplete and the other for not being internally consistent. The summary of the characteristics of the respondents to the survey is provided in Table 7.

Overall, the users of the system found that using the system helped them perform better in their tasks as shown by their responses to the performance expectancy questions in the UTAUT survey. The question with the lowest average response had a mean of 3.97 and was in response to whether the system improved the user's productivity. Responses to question on behavioral intention to use the system were positive with most users reporting intention to use the system in the next week. We negated one question in this section to ensure internal consistency of the responses. Most respondents disagreed when asked whether they did not plan to use the system in the next week. This indicates the intentions of the clinicians to continue using the system.

Table 7: Descriptive statistics of survey respondents (n=31)

Category		Number of Respondents	Percentage (%)
Age	< 25	12	38.7
	26 - 35	14	45.2
	36 - 45	5	16.1
	46 - 55	0	0
	> 56	0	0
Gender	Female	13	41.9
	Male	18	58.1
Role	Clinical Officer	2	6.5
	Doctor	8	25.8
	Nurse	12	38.7
	Medical Student	4	12.9
	Nursing Student	5	16.1
	Other	0	0
Frequency of System Use	Never	2	6.7
	Less than 10 times	9	30
	10 - 20 times	17	56.7
	> 20 times	2	6.7

Facilitating conditions and self-efficacy were of particular interest as uses were trained one-on-one without any special training conferences. Most users agreed to having the necessary resources to use the system (mean = 3.90) and disagreed when asked if they did not have the knowledge necessary to use the system (mean 2.16). Most users agreed that someone was available to help them if they had any problem with the system (mean = 4.03) pointing to a good support structure for the system. With regard to self-efficacy, most respondents agreed to being able to complete tasks in the system if they had help.

When asked to assess the level of ease with regards to using the system, most respondents agreed that the system was relatively easy to use with an average response of 4.00 (agree) to all positively worded questions. When asked if it was difficult to become skillful at using the system, most users disagreed with a mean response of 2.58. All social influence factors pointed to a belief among users that people important to them believe they should use the system with respondents agreeing to all positively worded questions and disagreeing to the negated questions. Respondents also demonstrated positive attitudes towards use of the system with all questions on their attitudes toward technology reporting high positive averages of 4 and above.

Finally, responses when asked on their level of anxiety when using the system, most users indicated being apprehensive about using the system with an average response of 3.97. Users were mostly neutral when asked if they were scared of losing data while using the system with an average response of 3.34. On the other hand, users disagreed with being hesitant to use the system or being intimidated with the system. A summary of the detailed responses from all the questionnaires is provided in Table 8.

Table 8: Summary of responses to the UTAUT survey.

Category	Statement	Mean (SD)
Performance Expectancy	I find the system useful in my job.	4.39 (0.80)
	Using the system enables me to accomplish tasks more quickly.	4.45 (0.85)
	Using the system increases my productivity.	3.97 (1.02)
Behavioral Intention to Use the System	I intend to use the system in the next week.	4.23 (0.97)
	I predict I will use the system next week.	4.03 (0.80)
	I do not plan to use the system in the next week.	2.21 (1.18)
Effort Expectancy	My interaction with the system is clear and understandable.	4.06 (0.89)
	It was difficult for me to become skillful at using the system.	2. 58 (1.09)
	I find the system easy to use.	4.19 (1.01)
	Learning to operate the system is easy for me.	4.40 (1.07)
Attitude Toward Using Technology	Using the system is a good idea.	4.68 (0.48)
	The system makes work more interesting.	4.23 (0.88)
	Working with the system is fun.	4.16 (0.82)
	I like working with the system.	4.03 (0.93)
Social Influence	My colleagues and management think that I should use the system	4.32 (0.75)
	People who are important to me think that I should not use the system.	1.63 (0.93)
	The senior management of this institution has been helpful in the use of the system.	3.63 (1.07)
	In general, the institution has supported the use of the system.	3.81 (0.95)
Facilitating Conditions	I have the resources necessary to use the system.	3.90 (1.03)
	I do not have the knowledge necessary to use the system.	2.16 (1.37)
	The system is not compatible with other systems I use.	2.89 (1.20)
	A specific person (or group) is available for assistance with system difficulties.	4.03 (0.91)
Anxiety	I feel apprehensive about using the system.	3.97 (1.08)
	It doesn't scare me to think that I could lose a lot of information using the system by hitting the wrong key.	3.34 (1.08)

	I hesitate to use the system for fear of making mistakes I cannot correct.	2.06 (1.03)
	The system is somewhat intimidating to me.	1.97 (0.98)
Self-efficacy	I could not complete a lab order and review a test result using the system if there was no one around to tell me what to do as I go.	2.35 (1.23)
	I could complete a lab order and review a test result using the system if I could call someone for help if I got stuck.	3.55 (1.12)
	I could complete a lab order and review a test result using the system if I had a lot of time to complete the job for which the software was provided.	3.00 (1.14)
	I could complete a lab order and review a test result using the system if I had just the built-in help facility for assistance.	3.39 (1.17)

9.3.3 Thematic Analysis

To ensure that we got extensive feedback from the users, we added two open ended questions to the questionnaire asking respondents for the changes they would like to see made to the system and any other feedback that they had regarding the system. Using the codebook generated from the responses, we analyzed the responses and classified them into common themes.

Overall, users were positive in their feedback regarding the system and provided suggestions on how to improve the system as shown in two direct quotes below:

"It's a brilliant idea"

"A well thought out system that will be super helpful if the minor glitches are sorted"

Thematic analysis of the survey responses highlighted resolution to errors/crashes, availability of results, and the usefulness of the system as the most frequent themes. From these

themes, resolution to system errors/crashes and availability of test results point to areas of further improvements for the deployed system. Usefulness of the system points to the benefits that the system Some respondents also suggested scale up of the implementation to other departments and the ability to access other services such as radiology on the same devices.

9.4 Discussion

In this study, we hypothesized that the deployment of an electronic order entry and results review application in the medical department inpatient setting would reduce the number of nonviable specimens that we got from those wards. When we assessed the impact of the intervention on the nonviability of specimens, we found no significant effect of time and the intervention on the nonviability of specimens even though there was a numerical decrease in proportion of errors observed before and after the intervention. The medical department also had a smaller proportion of non-viable specimens as opposed to the other departments.

At the time of this assessment, laboratory test orders were being made through either the electronic system or using paper laboratory order forms. The concurrent use of these modalities for laboratory order entry continued throughout the duration of this study and the electronic system had not been fully adopted for processing all laboratory orders. The proportion of specimens coming through the electronic laboratory order entry and results review application was less than half as shown in 8.3.1. This is further reflected in the reasons of specimen rejection after the intervention had been implemented. Of the seven distinct reasons that led to specimens being rejected after the intervention, only two, clotted specimens and requesting unavailable tests, would likely remain if the electronic system was in full use as intended. The rest of the reasons for

specimen rejection would also be eliminated if specimens were labelled using the electronic system. We believe that this contributed to the lack of significant results in the interrupted time series analysis.

While the low adoption rate of the electronic system could explain the lack of significant results in the interrupted time-series analysis, it raises key questions as to why clinicians preferring the paper-based method as opposed to the electronic system. One plausible explanation is that clinicians are still getting used to having the system and adoption will increase over time. However, this explanation is not well supported by the data as shown in Figure 29. The number of tests ordered electronically appears to have plateaued at around 30%. Further investigations will have to be made to ascertain why this is the case. Informal conversations with clinicians suggest that the change from conducting ward rounds with just a clipboard, paper, and pen, to wheeling a COW from bed to bed is difficult. We hypothesize that not having the cart at the bedside results in clinicians doing things the way they have always done them in the past, using paper order forms.

One strategy that has been used by other implementers of EMRs in inpatient settings is the use of scribes [161], [162]. Scribes accompany the rounding team to perform clerical tasks such as documenting consultations and tests using computers stationed in patient rooms or COWs that they bring to patient rooms [163]. While the need for scribes has been attributed to poor designs for EMRs, scribes have played an essential role in adoption of EMRs in settings such as emergency medicine [164], [165]. Their presence has been associated with financially significant productivity gains for some emergency physicians [166]. In the context of the implementation at KCH, scribes would be responsible for wheeling the cart to the bedside and recording orders in the system. However, Walker et al. estimated the cost of training a competent medical scribe at 6,317 USD [167]. While training cost could be lower in LMICs, the expense of training scribes in these settings

would strain the limited financial resources available and affect the purchase of other essential healthcare needs. Employing scribes also requires further financial resources that have to be offset by an increase in revenue making scribes financially unviable for most settings including KCH [168], [169].

Previously, we also discussed the idea of using mobile devices that clinicians bring to the bedside for laboratory order entry and results review (7.2.1.2). Allowing clinicians to use their personal mobile devices would overcome the barrier of pushing a COW from bed to bed. A possible customization of the system could involve adapting the system functionality based on the type of device that is being used to access the system. For instance, specimen drawing and labelling could potentially only be available on the COW, where a thermal printer is available to print a specimen label.

The suggestion of letting clinicians use personal mobile devices also prompts a question of whether we should have had more than one design and type of COW implemented in the inpatient clinical setting at KCH. The COW currently deployed at KCH is designed to allow placing of laboratory orders and the collection of specimens. However, some clinicians do not collect specimens at the same time that the laboratory order is made. For these clinicians, using the COW as it is currently designed may be unappealing. An alternative design would remove the aspects of the COW that had to do with specimen collection. This would potentially reduce the footprint of the COW and make it lighter to move around. This design would potentially be more appealing to some clinicians and would potentially be better suited and have higher adoption.

The difficulties with the COWs highlight a limitation of this study. We did not conduct field function testing of the COW with the clinicians. Failure to conduct a field function study deprived us of an opportunity to address problems in the design of the COW itself. Feedback from

conducting such a study would have potentially given us insight into challenges with the current COW design.

Unlike issues with the design of the COW, problems with the software are easier to resolve with frequent system updates. One of the common themes from the survey was the need to resolve system errors and crashes. While these have largely been resolved, we believe that during the time when users encountered these errors, it affected the ability of clinicians to use the system and could have also negatively affected their perception of the usefulness of the system. Coupled with the diminished capacity of the batteries to power the COWs for the entire day, this could have contributed to the low adoption of the electronic system.

While the quantitative analysis was not as positive as we had hypothesized, the responses from the survey that we conducted showed promise for the electronic laboratory order entry and results review system. Users showed positive attitude towards the system and responses pointed towards an intention to continue using the system.

Of particular note in this implementation was the training model used to orient the users on how to use the system. Unlike other implementations that require days of training and financial remuneration for users before they start using the system, we conducted on the job training, one-on-one with users. The effectiveness of this approach in this setting was unknown before this study. We are happy to report that most survey respondents said that they had sufficient skills and knowledge to use the system. Only one comment in the open-ended questions of the questionnaire mentioned the need for a formal training session.

In this research, one confounding factor to the acceptance of the electronic intervention was the delays in fetching and authorizing results in the laboratory. Since the system was meant to

improve the availability and turnaround time of laboratory results at the bedside, these delays were interpreted as the system not performing to the required standard.

9.4.1 Limitations

Implementing a system that shows the status of each specimen exposes the black box that is the laboratory process to the clinical staff. One limitation of this study was that this change in availability of information in the medical department was not followed by changes within the laboratory. This was particularly seen in the delays to release test results for tests that had been run but whose results had not been fetched from the instrument into the LIS. While several factors contributed to this challenge, most clinicians interpreted this as the system not working. This was further exacerbated by the fact that when the clinicians did not come to the laboratory to retrieve the result, the laboratory technicians would not fetch the results from the instrument and print them out. While the completion of this process made the results also available in the electronic system, the results at this point had already been reviewed on paper.

10.0 Discussion

10.1 Dissertation Summary

This dissertation describes efforts to improve the laboratory testing process at KCH using two interventions designed to address the reasons for non-viability of specimens in the pre-analytical phase of the total testing process. Four different studies were carried out to understand the laboratory testing process at KCH, measure the magnitude of non-viable specimens received at the laboratory reception, and to evaluate the impact of the two interventions that were deployed in the inpatient wards at KCH. Both interventions used in this study were designed around the concept of a job aid to provide information on specimen collection guidelines and processes.

In this research, we were guided by the hypothesis that interventions designed to improve the laboratory testing process would lead to a reduction in the number of specimens rejected in the laboratory as being non-viable. To this end, we defined four specific aims to explore and assess the veracity of our hypothesis:

Aim 1: Describe current workflows in laboratory test ordering and specimen collection processes in different hospital departments and wards.

Aim 2: Study and measure the effects of deploying a specimen collection cart, designed to facilitate bringing of specimen collection supplies to the bedside, and a paper job aid, designed to address knowledge gaps on specimen collection, on the viability of specimens that are collected and the workflows used to collect the specimens.

Aim 3: Design, develop, and implement an electronic laboratory order entry system designed with digital job aids for improving the test ordering and specimen collection processes.

Aim 4: Evaluate the impact of the electronic laboratory order entry system on the viability of specimens that are collected and the workflows used to collect the specimens.

10.2 Insights and Contribution to Knowledge

In this research, we gave clinicians tools that we designed to help address challenges around specimen collection and associated laboratory testing tasks and requirements. However, we were not prescriptive about how the users ought to use the tools. We wanted to observe the natural evolution of the workflows and see if clinicians within and between departments would converge to common workflows. Our findings show that despite the tools being designed to point the clinicians towards bedside usage, there is still a lot of variation in how clinicians go about the laboratory testing process. Questions still remain on whether standardizing workflow across all wards and departments is the best way to eliminate variation in the process and resolve systemic challenges. However, the varying level of both human and material resources between the different wards and departments continues to be a barrier towards standardizing workflows.

Any information system that doesn't adequately address the present problems or provide a platform for the future is a waste of money and resources [170]. Emphasis on cross-cutting HIT interventions will have a significant role in moving the needle on healthcare delivery in LMICs. However, for this to happen there is a need for a networking and communication infrastructure

amongst the different systems operating at a hospital or health facility. Maintaining such infrastructure requires resources in finances and personnel that are not always available in LMICs.

In this research, we have utilized 2D barcodes as an alternative form of transporting information around as opposed to real time data transmission over networks. This approach has required some investment in barcode scanners, which are much cheaper compared to setting up a reliable network infrastructure. This model has practical applications in other areas of healthcare. For instance, patient identification across multiple health facilities has been a challenge in most LMICs for several years. Using 2D barcode technology, a patient would only have to register once and carry their patient identifier with them on the next hospital visit. As long as the hospital has a 2D barcode scanner, the patient's identification details can be retrieved from the identifier and used.

While a 2D barcode can be used to get the correct patient identifier and demographic details, the clinical information from the last hospital visit will not be available if the subsequent visit is to a different health facility. Previous approaches have used patient visit summaries to transport this information in human readable form. This approach limits the potential impact of any clinical decision support system that includes past clinical history in its algorithm on the hospital visit. Printing the patient visit summary both in human readable form and as a 2D barcode provides an opportunity to close this gap.

Interoperability and integration of systems is key to further unlocking the potential of HIT [171]. The ability to share data across systems allows patient data to be more accessible at the time that it is needed. In this dissertation project, we did not implement a real-time interoperability model where systems are in active communication with each other. This notwithstanding, the electronic laboratory order entry and results review system contributes to the laboratory testing

ecosystem at KCH. The electronic laboratory order entry and results review application provides input to the laboratory testing process in the form of a laboratory order in 2D barcode format. The system also makes use of the master patient index at KCH. Our work here showcases the potential for interoperability in low-resource setting where real time network connectivity is often unavailable. Innovative ways are required to ensure continuity of care even when network availability is not possible.

Sustainability of HIT interventions is an important aspect of successful implementations. Several aspects of the current implementation would not work well without the continued presence of the research and the support team. There is a need to transition the ownership and maintenance of the implementation to the hospital's own IT department. One area where this need is apparent is the issuing of user credentials. Our current model for creating user credentials depends on us identifying any new personnel in the medical department or them approaching us with a request for access. KCH is a teaching hospital with high turnover of personnel and the current approach is likely to leave other people without credentials. Further, the current model is not ideal for any hospital-wide scale up. A more sustainable approach would be for the user management to be managed by the ICT department of the hospital and for user credentials to be institutionalized as part of the onboarding process for new personnel.

10.3 Future work

This research was intended to be the first foray into the use of HIT in the inpatient setting at KCH. The most obvious next step for this work would be to expand the electronic intervention to other clinical departments at KCH. As earlier described, the workflow and behaviors for the

clinical laboratory testing process differ between and within departments. It would be interesting to see if the introduction of this intervention standardized or further differentiated the workflows in each department. To this effect, discussions have been initiated with the pediatric department at KCH as a potential location for the expansion of this implementation.

In this research, we introduced the notion of computerized provider order entry for laboratory tests. However, laboratory tests are not the only thing that can be ordered in medical practice. Other things such as radiology exams, medications and procedures can be ordered in the same way. Since KCH has a functioning radiology system, use of electronic ordering to streamline the radiology testing process for inpatients is the proverbial low hanging fruit. We therefore intend to build on the pre-existing infrastructure and hardware deployed in this research to explore this application.

Curating electronic records tied to specific users who performed certain tasks provides new opportunities for further research and interventions. Clinicians could benefit from interventions that provide feedback to them based on individual performance. Supervisors could also benefit from information on the performance of their sections and departments. Such information could lead to informed personal and departmental development goals which should eventually lead to the improvement of healthcare delivery. Electronic records on laboratory tests could also be used to facilitate informed conversations between the laboratory and clinicians on the performance of the laboratory and the laboratory's expectations of clinicians. Such conversations would help to further improve the laboratory testing process at KCH.

Further, the availability of electronic clinical records provides an opportunity for strengthening research and teaching at KCH. Providing access to deidentified records for researchers and students can provide further insight into the processes at KCH and potentially lead

to further interventions that could improve the delivery of care. We would like to facilitate these conversations on secondary use of clinical data by engaging the KCH management on setting up a data preprocessing pipeline and repository that could be used for research.

Finally, all this work is being done with the intention of improving healthcare delivery at KCH. However, the only way to know if we are having the desired effect is through continuous evaluation. While an evaluation of this pilot implementation was conducted as part of this research, more rigorous evaluations are needed to justify the continued outlay of resources in this area. To this end, we plan to revisit prior work on return on investment modelling and build a net present value model for the interventions described in this dissertation. We further intend to continue utilizing concepts and frameworks from biomedical informatics, implementation science, lean healthcare and health economics to build and evaluate interventions for healthcare delivery at KCH.

10.4 Final remarks

The research described in this dissertation builds upon 18 years of prior work trying to understand and address challenges in the laboratory testing process at KCH. We first introduced the concepts of paper job aids for specimen collection along with specimen collection carts in all inpatient wards at KCH. This was followed by the implementation of an electronic laboratory order entry and results reviewing system with digital job aids in the medical department inpatient ward.

This research highlights the complexity of the laboratory testing process and the variations that exist within a single facility in the performance of the tasks associated with this process. Minimizing the variability of such processes continues to be a challenge and will be important in

further efforts to improve the process. The specimen collection carts deployed in this study present an opportunity for beginning to standardize these workflows by prescribe how the carts should be used.

We demonstrated in this research the attitudes and intentions of clinicians towards adoption of technology in their work. Despite its limited scope, clinicians were keen on using the system and felt that it helped them perform their job better. The willingness of clinicians to adopt HIT presents an opportunity for further improving healthcare delivery in this setting through HIT interventions.

Further, we designed, developed, and piloted a custom COW which was locally manufactured at costs lower than commercial off-the-shelf alternatives. We believe that providing a local hardware platform for HIT interventions in LMICs will open new opportunities and make previously financially unfeasible interventions possible.

Appendix A Paper Job Aid for Specimen Collection

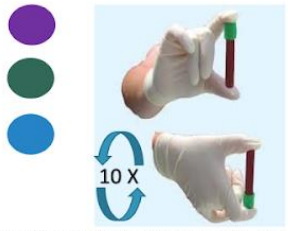
TEST REFERENCE

	Test Name	Specimen Type	Min. Volume	Container Type
GXM	ABO Blood Grouping	Venous Blood	3 ml	
	Cross Match (XM)	Venous Blood	3 ml	
	Blood Culture	Venous Blood	5 ml	
	Blood Film (BF) / Malaria Screening (MPS)	Venous Blood	3 ml	
	Cell Morphology (PBF)	Venous blood	3 ml	
	CSF Analysis (CSF)	CSF	3 ml	
U&E	Electrolytes (E)	Venous blood	3 ml	
	Renal Function Test	Venous blood	3 ml	
	Erythrocyte Sedimentation Rate (ESR)	Venous blood	3 ml	
	Full Blood Count (FBC)	Venous blood	3 ml	

	Test Name	Specimen Type	Min. Volume	Container Type
	Hepatitis B Test	Venous blood	3 ml	
	Hepatitis C Test	Venous blood	3 ml	
	Liver Function Test (LFTs)	Venous blood	3 ml	
	Lipogram	Venous blood	3 ml	
	Minerals	Venous blood	3 ml	
	Uric Acid	Venous blood	3 ml	
	Syphilis Testing (VDRL)	Venous blood	3 ml	
	Urine Analysis	Urine	15 ml	
	Sputum Tb microscopy	Sputum	3 ml	
	Stool Analysis	Stool	2 gm	

NOTES

- Ensure specimen has sufficient volume.
- Check that specimen is in the correct container type.
- Make sure all documentation is filled. One Specimen, One Form
- Label the specimen clearly.
- Deliver all collected specimen to the lab as soon as possible.
- When in doubt, consult the lab or lab manual for wards.



Gently invert the tube with purple, green or blue top 8-10 times to prevent clotting.

Ensure each test request form has the following:

1. Test ordered
2. Person who ordered test
3. Department or ward
4. Patient name
5. Patient age or date of birth
6. Patient gender
7. Date on which specimen was collected

Remember, specimens degrade over time. Deliver all collected specimens to the laboratory as soon as possible

Appendix B A Cost Sheet of All the Parts for the Custom COW

ELECTRICAL AND MECHANICAL COMPONENTS FOR CART-TOP		
Component Name	**Qty**	**Price**
Resistor 10 K, ¼ Watt	5	$0.25
Resistor 1 K, ¼ Watt	3	$0.15
Resistor 220 Ω, ¼ Watt	2	$0.10
Resistor 330 Ω, ¼ Watt	1	$0.05
Real time clock module, DS3231	1	$3.00
Lithium Battery 3V, CR2032	1	$0.50
Transistor 2N2222	2	$1.00
Relay 12V, JQC-3FF-S-Z	1	$1.00
2 pin Terminal Block	3	$0.50
3 Pin Terminal Block	1	$0.50
Zener Diode 12V	1	$0.10
Zener Diode 3V	1	$0.10
Rectifier Diode (4A)	3	$0.75
Buck DC-DC XL4015	2	$6.00
Boost DC-DC XL6009	1	$3.00
Raspberry Pi 3B+	1	$52.90
Raspberry Pi Female GPIO header	1	$2.00
Raspberry Pi 7” Display	1	$68.48
Barcode Scanner, Aibecy 2D/QR/1D Embedded	1	$50.94
Micro-SD card, 32G	1	$10.00
Zebra thermal printer, LP2824	1	$100.00
Male and Female Connector, Molex, 2 contact	1	$2.00
Battery 12 V @ 4.5Ah	1	$18.00

Battery Terminal	4	$1.00
Ring Terminal	2	$0.50
Analogue to Digital converter, MCP3002	1	$5.00
Analogue to Digital converter socket, 8-pin DIP	1	$0.50
2D scanner Light control PCB (34 mm X 24 mm)	1	$2.00
Cart-top Main PCB (125 mm X 83 mm)	1	$7.00
Charging control PCB (115 mm X 32 mm)	1	$3.00
USB Cable, Type-A to Right angle USB Type-B connector	2	$3.00
Spacer (16 mm) and Screw	2	$0.50
Spacer (3mm) and Screw	2	$0.50
Magnet (1.26-inch x 0.2-inch Neodymium disk, hole countersunk)	1	$2.00
Magnet Bolt and Nut, M4	1	$1.00
Door Lock, 1 7/8-Inch, Cam	1	$2.90
Press fit nuts and screws, M3 x 12mm	4	$4.00
Screws, 60mm, countersunk	6	$1.50
10mm PVC	9	$20.00
Total (Workstation)		**$375.72**

ELECTRICAL AND MECHANICAL COMPONENTS FOR DOCKING STATION		
Component Name	**Qty**	**Price**
Reed Switch (3A)	1	$5.61
Magnet (1.26-inch x 0.2-inch Neodymium disk, hole countersunk)	1	$2.00
Magnet Bolt and Nut	1	$1.00
Ring Terminal	1	$0.50
Bolt and Square Nut	1	$1.00
Power supply, 19 Volts at 3 Amps, with power cable	1	$14.00
M8 X 20mm Bolt	2	$1.00
M8X 30mm Bolt and Nut	2	$1.00

Screws, 60mm, countersunk	18	$4.50
10mm PVC	13	$15.00
Total (Docking Station)		**$45.61**
Grand Total		**$421.33**

Appendix C A Copy of the UTAUT Survey Instrument

Appendix C.1 Page 1 of the Questionnaire

Select Age Range: ○ < 25 ○ 26 - 35 ○ 36 - 45 ○ 46 - 55 ○ > 56

Select your gender: ○ Female ○ Male

Select the choice that best describes your role at KCH:

○ Clinical Officer ○ Doctor ○ Nurse

○ Medical Student ○ Nursing Student ○ Other (Specify): _____

How would you rate your level of use of the system?

○ Never ○ Less than 10 times ○ 10 – 20 times ○ > 20 times

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
I find the system useful in my job.	○	○	○	○	○
I intend to use the system in the next week.	○	○	○	○	○
A specific person (or group) is available for assistance when I experience system difficulties.	○	○	○	○	○
I find the system easy to use.	○	○	○	○	○
The system makes my work more interesting.	○	○	○	○	○
My colleagues and management think that I should use the system	○	○	○	○	○
I could complete a lab order and review a test result using the system if I had only the built-in help facility for assistance.	○	○	○	○	○
My interaction with the system is clear and understandable.	○	○	○	○	○
Working with the system is fun.	○	○	○	○	○
The system is not compatible with other systems I use.	○	○	○	○	○
In general, the institution has supported the use of the system.	○	○	○	○	○
Learning to operate the system was easy for me.	○	○	○	○	○
I feel apprehensive about using the system.	○	○	○	○	○
Using the system enables me to accomplish tasks more quickly.	○	○	○	○	○

Appendix C.2 Page 2 of the Questionnaire

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
I predict I will use the system next week.	○	○	○	○	○
I could not complete a lab order and review a test result using the system if there was no one around to tell me what to do as I go.	○	○	○	○	○
I like working with the system.	○	○	○	○	○
It was difficult for me to become skilful at using the system.	○	○	○	○	○
I could complete a lab order and review a test result using the system if I had a lot of time to complete the job for which the software was provided.	○	○	○	○	○
People who are important to me think that I should not use the system.	○	○	○	○	○
Using the system increases my productivity.	○	○	○	○	○
I do not plan to use the system in the next week.	○	○	○	○	○
I have the resources necessary to use the system.	○	○	○	○	○
The senior management of this institution has been helpful in the use of the system.	○	○	○	○	○
Using the system is a good idea	○	○	○	○	○
It doesn't scare me to think that I could lose a lot of information using the system by hitting the wrong key.	○	○	○	○	○
I could complete a lab order and review a test result using the system if I could call someone for help if I got stuck.	○	○	○	○	○
The system is somewhat intimidating to me.	○	○	○	○	○
I hesitate to use the system for fear of making mistakes I cannot correct.	○	○	○	○	○
I do not have the knowledge necessary to use the system.	○	○	○	○	○

What changes would you like to see made to the system?

_____

_____

What other feedback do you have regarding the system?

_____

_____

Thank you for your participation

Appendix D Codebook for UTAUT Survey Responses

Code	Description	Example
Resolve Errors/Crashes	Request to resolve errors leading to system crashes	Update the system regularly to eliminate crashes.
Results Availability	Comments regarding the amount of or the timeliness laboratory results that can be reviewed electronically	Results should be coming in good time.
Results Review	Statements about the ability to review laboratory	There should be an option for nurses also to review result tested …
Scale-Up	Request to increase functionality of the system or deploy it in more departments.	Needs to be distributed to the other departments.
Specimen Labeling	Suggestions on the labels that the system produces	To group together lab investigations tests using one sticker
Specimen Tracking	Recommendations on how the specimen states are updated in the system.	Update on whether blood samples are still pending or

		have been discarded by the lab.
Speed Improvement	Request to improve the speed of the system	Improve on speed of the system
System Availability	Comment on system downtime.	Sometimes it is out of service.
Test Catalog	The number or type of tests that can be recorded or reviewed using the system.	There are other laboratory tests that are not available for usage in the system.
Test Priority	Discussion on the different priorities of tests in the system.	…I don't see any difference between a routine and stat order…
Time Saving	Comments about how the system can save the users time when performing tasks.	The system helps save time as you can view results whilst in the ward other than going to the lab.
Training	Request for training on how to use the system.	Management should make arrangement to train us on how to operate the machine
Troubleshooting and Error Recovery	Request for features that will allow users to recover from a system crash/failure.	If it had a reset button because sometimes it gets stuck in the absence of a technician to fix

Usability	Comment on the degree with which it's easy to use or learn how to use the system.	Its user friendly makes my work easier
Useful and Helpful	Description of the system as a useful addition to the workplace.	The system has been a great experience and so helpful.
No Changes	Comments indicating no need to change anything with the system.	Nothing I feel like all is well.

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