USER-CENTERED DESIGN AND EVALUATION OF RXMAGIC: A PRESCRIPTION MANAGEMENT AND GENERAL INVENTORY CONTROL SYSTEM FOR FREE CLINIC DISPENSARIES

by

Arielle Marie Fisher

Bachelor of Arts, Bucknell University, 2013

Master of Science, University of Pittsburgh, 2015

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This dissertation was presented

by

Arielle Marie Fisher

It was defended on

July 11, 2017

and approved by

Dr. Harry Hochheiser, Assistant Professor, Biomedical Informatics

Dr. Julia Driessen, Assistant Professor, Health Policy and Management

Dr. Lauren Jonkman, Assistant Professor, Pharmacy and Therapeutics

Dr. Vladimir I. Zadorozhny, Associate Professor, Information Science and Technology

Dissertation Advisor: Dr. Gerald P. Douglas, Assistant Professor, Biomedical Informatics

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Arielle Marie Fisher, PhD

University of Pittsburgh, 2017

Medication management is a complex and expensive multistage process that covers the prescribing and ordering, order communication, dispensing, administering, and monitoring and use of prescription medications. While challenges in medication management are ubiquitous across all settings, they can be particularly exacerbated in a free clinic that serves a medically vulnerable population. These patients suffer from financial constraints, poor health literacy, multiple chronic conditions, and medication non-adherence. Clinical pharmacists play an integral role in the provision of healthcare services to these patients and could benefit from the use of medication management information technology (MMIT) to provide efficiencies in the tracking, provision, and use of medications. While MMITs exist, they are not designed to support the unique needs of pharmacists in these settings.

To address challenges related to medication management in this setting, and the inability of existing technologies to alleviate them, we developed a system for Prescription Management And General Inventory Control, or RxMAGIC, in collaboration with the Birmingham Free Clinic (BFC) in Pittsburgh, PA. RxMAGIC is an interoperable, web-based dispensary management information system designed to streamline the dispensing process and improve inventory control in a free clinic dispensary. This research describes the process employed to create, deploy, and evaluate RxMAGIC in the BFC. We used a range of evaluation studies and methods to

understand challenging aspects of the pharmaceutical workflow, design a system that alleviates those challenges, and evaluate it to ensure that it does.

We assert that this research is significant in several ways. First, we developed a medication management tool for free clinic dispensaries that pharmacists in this setting do not currently have. Second, we demonstrated the importance of various levels of evaluation throughout the system development process to ensure successful adoption. Third, we utilized health data standards to achieve functional and semantic interoperability with an electronic health record. Lastly, RxMAGIC is freely available and amenable to customization, which makes it an attractive solution for low-resource settings.

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PREFACE

"Knowing is not enough; we must apply.

Willing is not enough; we must do."

-Johann Wolfgang von Goethe

1.0 INTRODUCTION

Medication management is a complex and expensive continuum that covers all aspects of prescription medications. Bell et al. model this continuum in five main phases: prescribing and ordering, order communication, dispensing, administering, and monitoring [1]. Each phase has high potential for both benefit and harm. While prescription drugs can improve patients' health and well-being, their rising significance in healthcare systems has come with access, safety, and cost challenges [2,3]. Many of these challenges are exacerbated in medically vulnerable populations such as low-income individuals, uninsured persons, immigrants, racial and ethnic minorities, and the elderly. These patients often suffer from multiple chronic conditions, the need for several medications, poor health literacy, and medication non-adherence; they also have difficulty accessing appropriate healthcare services altogether [2,4,5].

The availability of healthcare services by safety net providers is essential to improve our nation's health. Many underpinnings of patient-centered care models – individualized planning and delivery of pharmaceutical services, monitoring medication use, and interdisciplinary team care – are often absent in safety net care [6]. Free and charitable clinics strive to provide a medical home for the underserved in a setting that enables the establishment of a respectful relationship between patient and provider. However, these clinics face severe challenges due to a lack of resources, such as essential medicines, medical equipment, and available providers [7]. These challenges, coupled with poor medication-use in underserved populations [8], may

contribute to medication utilization errors and ultimately less than optimal patient outcomes [5,7]. Health information technology (health IT), particularly medication management information technology (MMIT), holds great potential to improve care associated with medication management and provide efficiencies for the tracking, provision, and use of medications in free clinic settings [2].

The use of MMIT applications to support the medication management continuum is not a new concept. Pharmacists have a history of early information system adoption, with the first MMIT application published in 1979 as a decision support system to help in prescribing appropriate antibiotics [9]. However, pharmacists are often left out of the discussion when it comes to informatics research, design, and decision-making [9]. Further, while many groups have studied the effects of new and old MMIT applications on components of the medication management process, their role in free and charitable clinics remains understudied and underutilized. MMIT can play a critical information support role in these unique healthcare environments if they are designed to meet pharmacists' workflow and information needs.

1.1 DESCRIPTION OF THE PROBLEM

Few tools currently exist for pharmacists, and those that do are primarily designed for use in hospital and/or retail community pharmacies [9]. Most of these systems are offered as integrated modules within electronic health records (EHRs)[1] or are stand-alone systems capable of

[1] Electronic medical record (EMR) and EHR are used somewhat interchangeably in the literature, although differences between the two are recently being defined. For the purposes of this research, EMR and EHR may be used interchangeably throughout this document.

receiving prescription data from EHRs [10]. While homegrown options may exist, they may not be generalizable and are typically unable to connect with other systems in an enterprise. As there is a need for accurate and timely health information exchange (HIE) between disparate systems (i.e. EHRs) within an enterprise [11], a system's inability to share data with an EHR is a recipe for redundancy and implementation failure [9].

Although EHRs have made their way into several free clinics due to donations by larger hospital systems [12,13], many clinics cannot afford the additional modules and/or product suites needed to support their dispensing processes. Further, EHR pharmacy modules may only provide support for preparing and dispensing medications [9], as those are the primary responsibilities of a pharmacy department in a hospital setting. Medication administration and monitoring activities are responsibilities of nurses and physicians, and pharmaceutical purchasing may be handled by an entirely separate department altogether [14]. Thus, pharmacy modules within an EHR may not accommodate the multiple workflows of a clinical pharmacist in a free clinic setting who is involved in all stages of the medication management continuum, from medication procurement to monitoring activities.

Most retail community pharmacies purchase stand-alone MMIT applications from technology companies like McKesson or Surescripts or, in the case of large pharmacy chains, they utilize homegrown software [15]. These systems are designed to support the business of pharmacy rather than a clinical practice. Although they can receive electronic prescription data, the exchange is not seamless and typically requires manual data entry from one system to another, a process that is redundant and labor-intensive for pharmacists [16]. Further, these systems are transactional and include billing frameworks and forms to submit claims for reimbursements to third party payers [15]. These features are not needed in a MMIT for free

clinics because medications are provided to uninsured patients for free. Unnecessary functionality would burden the user experience in a free clinic setting.

1.2 SIGNIFICANCE OF THIS RESEARCH

Overall, existing MMIT applications may not be viable implementation strategies for free clinics due to several challenges [13], such as cost, poor integration with existing systems, unnecessary functionality (i.e. insurance/billing screens, additional data entry), and their inability to accommodate multiple workflows (i.e. dispensing, inventorying, etc.). Clinical pharmacists are an integral part of the healthcare team, especially in free clinics, and could benefit from a user-centered MMIT effectively designed to alleviate challenges associated with all stages of medication management in these settings. The success of this system relies on a sophisticated understanding of the problems it is designed to address, its ability to support multiple workflows and processes, a low-cost implementation that is amenable to customization, and its ability to receive electronic prescription data from an EHR. I call this system RxMAGIC, or a system for **P**rescription **(Rx) M**anagement **A**nd **G**eneral **I**nventory **C**ontrol. This dissertation describes the process used to design, develop, and evaluate RxMAGIC, as guided by Friedman and Wyatt's evaluation framework [17], from needs assessment to problem impact, culminating in its deployment in a local free clinic.

2.0 BACKGROUND

In this section I discuss relevant topics that pertain to this research. These topics include free and charitable clinics and the role of clinical pharmacists in the medication management continuum; existing MMIT applications in several healthcare settings; the importance of standards to achieve interoperability; systems thinking and lean management principles; and lastly, usability and user-centered design in health informatics, in the context of the fundamental theorem of biomedical informatics.

2.1 FREE AND CHARITABLE CLINICS

Implementation of the Affordable Care Act (ACA) has transformed the American healthcare landscape. However, this landmark law does not provide universal access to healthcare, and numerous barriers to health care access continue to exist for many [6]. The non-partisan Congressional Budget Office estimates that 29-31 million Americans will remain uninsured following the full implementation of the ACA [6]. However, at the time of this writing, there is much uncertainty regarding the future of the ACA as the new administration attempts to reform the health law. While we are unsure of the implications of a potential repeal of the ACA, researchers are certain there will be a significant increase in the number of uninsured citizens in the coming years [18,19].

Despite the reforms made by the ACA, significant health disparities persist in vulnerable populations due to a variety of intersecting economic, social, and geographical factors [6]. For many Americans, a lack of health literacy and proper education has comprised their healthcare [4]. Further, many low- and moderate-income families report that, even if they have health insurance, out of pocket health costs remain a significant barrier to receiving medical care and purchasing prescription drugs [20,21]. Perhaps one of the largest contributing factors to health disparities in these populations is their inability to access healthcare services [22]. This is particularly true for patients living in rural areas, and the 11 million undocumented immigrants who are legally prohibited from participating on the healthcare exchanges created under the ACA [6].

The provision of healthcare services by safety net providers is essential to improve our nation's health. Free and charitable clinics remain the only healthcare providers to provide services regardless of the patient's ability to pay, filling the gaps in the US healthcare system. Sometimes that gap is urgent care, sometimes bridge care, and sometimes it is primary care; all free clinics are different [23]. Free clinics provide comprehensive services that may include medical, dental, pharmacy, vision, mental health, substance abuse treatment, and even health education [24]. Most free clinics provide treatment for routine illnesses or injuries, such as strep throat or the flu, in addition to managing long-term chronic conditions like diabetes and hypertension in the adult population. In addition to these services, clinics regularly serve as advocates for their patients, playing a major role in helping individuals and families secure affordable healthcare [24].

There are currently more than 1,200 clinics within the United States conducting an estimated 5 million patient visits each year [6]. These non-profit organizations receive little-to-

no state or federal funding and rely heavily on the generosity of individual donors, foundations and grants to acquire medications and medical supplies [6]. While demand for their services has increased in the last two years, donations to free and charitable clinics have fallen by 20% [6]. Further, a growing shortage of physicians is likely to impact disadvantaged communities and the clinics that serve them due to a lack of compensation. Providers receive greater incentives when practicing within higher-income populations. [7].

Most challenges in a free clinic can be attributed to a lack of resources, and meeting the pharmaceutical needs of patients is often one of the most prominent [8,22,24]. The rising cost of prescription drugs has been causing pain and hardships for millions of Americans, especially lower income residents lacking drug coverage [22,25]. Uninsured Americans are more likely than their insured counterparts to go without prescription medications or skip doses because of cost [20,21]. Providing prescription drugs to patients who cannot afford them is perhaps one of the most important services a free clinic can offer. Most free clinics obtain drugs through a variety of channels, including the donation of drug samples from licensed practitioners (from pharmaceutical companies, physician practices, and partnering hospitals), discounted bulk purchases, state prescription drug return, reuse, and recycling laws, and, especially, private drug companies' Patient Assistance Programs (PAPs) [19,24].

2.1.1 Patient assistance programs

Some pharmaceutical companies offer PAPs. These programs provide prescription medications for free or at a greatly reduced cost to those who cannot afford them [20,24]. Many free clinics work to qualify patients on behalf of these programs and greatly assist them in the application process, which often requires one full-time, non-pharmacy staff person. Navigating the different

and often variable eligibility requirements and application procedures for PAPs is time-consuming and labor-intensive [26]. However, these programs fill a major gap in health insurance coverage and are necessary to enhance access to cost-effective medicines for patients meeting certain eligibility criteria [24,26,27]. Further, research shows improved medication compliance and significant cost savings for clinics and patients when PAPs are employed systematically [24]. In many cases, this means that the clinic is responsible for receiving and dispensing the medications to qualifying patients on-site.

2.2 THE ROLE OF CLINICAL PHARMACISTS

Pharmacists are in expanded clinical roles of direct patient care in many clinical settings, practicing independently or in collaboration with other healthcare professionals [9]. Clinical pharmacy is defined as providing patient care to optimize medication therapy and promote health, wellness, patient safety, and disease prevention [28]. Within the system of healthcare, clinical pharmacists are experts in the therapeutic use of medications and invaluable in the provision of team-based healthcare [29]. The role of a clinical pharmacist extends far beyond the traditional dispensing role, a task that can be done by a pharmacy technician, to include regular consultations with patients and healthcare professionals regarding medication therapy evaluations and recommendations [9,29,30]. These services are typically referred to as medication therapy management (MTM), where the focus is more patient-centered as opposed to individual product-centered. The MTM service model includes five core elements: medication therapy review, personal medication record (i.e. access and review of the patient's health record), medication-related action plan, intervention and/or referral to other services, and documentation

and follow-up [31]. These services are dependent upon pharmacists working collaboratively with physicians and other healthcare professionals to optimize medication use.

Integrating these services into interdisciplinary patient care at free and charitable clinics is particularly effective in improving access to prescription drugs and resolving medication related problems [29,30]. Challenges with medication adherence are especially pronounced in vulnerable populations due to cost and poor health literacy [5,32]. Clinical pharmacists are in an optimal position to directly educate patients on the importance of appropriate medication use, monitoring one's disease state, and improved lifestyle recommendations. Research also shows that clinical pharmacy services can support improvement in clinical indicators such as blood pressure, A1C and LDL-C readings [24,30,33]. Further, the environment of a free clinic enables pharmacists to develop a trustful relationship with patients and increased communication with prescribers, both of which are typically absent in community pharmacies. These patient-pharmacist relationships allow pharmacists to carefully observe medication utilization and patient behavior over time, which is critical in preventing prescription drug abuse [34]. Similarly, the enhanced prescriber-pharmacist relationship is beneficial to patient care, particularly in a free clinic setting [35].

Free clinics provide pharmacists and student pharmacists with a unique opportunity to expand their clinical role and utilize their expertise in all stages of the drug management continuum [23]. This role can be different from clinic to clinic. Clinical pharmacists can establish a medication dispensary within a free clinic under the auspices of a physician's license [36]. They are responsible for developing a site-specific medication formulary and an appropriate payment structure, in addition to determining how pharmaceuticals will be stored, inventoried, and dispensed [19]. Ensuring an uninterrupted drug supply to their patients is often

the sole mission of free clinics [6,19,24], and pharmacists must be prepared to identify inexpensive medication alternatives to optimize medication therapy. This relies on their specialized therapeutic knowledge, knowledge of the patient population, and ability to determine appropriate stock levels and average consumption rates to avoid stockouts [9,37].

Appropriate management support technologies can reinforce clinical pharmacists at each stage of the drug management continuum, especially in a free clinic setting. However, few tools exist for pharmacists, and many of them fail to support a clinical pharmacists' cognitive needs and workflow [9,38]. Moreover, pharmacists are not currently considered eligible providers by the Centers for Medicare and Medicaid Services (CMS), and do not receive incentive funds through Meaningful Use [9,39]. There is a critical need for pharmacists in informatics and informatics in clinical pharmacy, so that better tools can be developed to support a multidisciplinary health care team. The pharmacy profession needs to articulate requirements for tools that will meet their cognitive needs, and informaticists must study and understand the realities of the pharmacy workflow to design tools that support the entire clinical practice, not just electronic prescribing.

2.3 EXAMPLES OF PHARMACY INFORMATICS

Pharmacists have a history of early information system adoption; the use of technology and automation to support pharmacy practice predates back to the 1970s [9]. While there is an increasing demand for accuracy, safety, and efficiency in medication use, the pace of medication-use-supporting technologies adoption remains slow, understudied, and underutilized [9,10]. These technologies are often described within the framework of an EHR and include, as

envisioned by the Institute of Medicine: Computerized Provider Order Entry (CPOE) and clinical decision support systems, pharmacy systems, medication reconciliation systems, and medication administration systems [10,40]. These technologies have been tailored to support specific roles and responsibilities, as healthcare professionals have traditionally practiced within their functional silos.

This mindset has created fragmented solutions that focus on departmental tasks rather than the comprehensive process of healthcare delivery [10]. This is even more problematic if only some of the listed core medication-use systems are implemented (i.e. just CPOE), or the technologies are unable to interoperate within the framework of an EHR and/or communicate to other MMITs. Standalone medication management solutions that are unable to communicate with disparate systems are not realistic implementation strategies in a time where accurate and timely health information exchange is necessary to improve medication safety. These strategic and technical challenges are just a few examples of fragmentation and poor system integration [41].

This notion of MMIT can differ depending on the implementation setting, i.e. community pharmacy or hospital pharmacy, because the medication management process is very different between the two sites. In hospitals, prescriptions are entered into systems at the same place they are filled, whereas in ambulatory care, the information is fragmented across several sites [42]. Perhaps one of the most significant differences between these two settings is the pharmacist's involvement in EHR use [9]. Although some community pharmacies (i.e. Walgreens) are beginning to integrate EHRs into their practice [16,43], they are predominately absent in these settings. Contrary to community pharmacies, pharmacists in a hospital setting are active users of the EHR. They are involved in processes such as medication reconciliation, CPOE, clinical

decision support, immunizations, and patient evaluation and monitoring [9]. Differences in EHR access and use between these two settings has a large impact on the design and utility of pharmacy information systems in practice.

I discuss these differences and how they contribute to the application of pharmacy information systems in US hospital pharmacies, community retail pharmacies, and free clinics. Further, I discuss examples of medication-use-supporting technologies in low-income countries, as the literature describing pharmacy informatics in these settings is more dense and descriptive. Free clinics represent an interesting environment in US healthcare as they share similarities with all three settings, especially if they utilize an EHR: prescriptions are entered into systems at the same place they are filled, yet they are technically an outpatient facility. Thus, lessons can be learned from the implementation of pharmacy information systems in all settings, which I discuss at the end of this section.

2.3.1 US hospital pharmacies

A national survey done by the American Society of Health-System Pharmacists (ASHP) in 2013 assessed the use of pharmacy informatics in US hospitals, which includes the use of information, information technology, and automation in the medication-use practice. The ASHP focuses on the use of technology in the following processes related to medication-use: prescribing, transcribing, dispensing, administration, monitoring and follow-up, and MTM [44]. In 2013, 80% of hospitals with an EHR (partial or complete) that allowed pharmacists to view some component of the record also allowed pharmacists to document and make recommendations in the EHR [44]. The number of hospitals allowing pharmacists to document in the EHR has

increased from 56.7% in 2007 [41], which may be attributed to the documented benefits that pharmacist-prescriber communication has on patient care [16].

The survey concluded that 75% of hospitals reported having a CPOE system, and 61.4% of these hospitals used concurrent clinical decision support for inpatient orders [44]. Nearly 60% of survey respondents reported that their hospital used electronic prescribing (e-prescribing) to communicate outpatient medication orders to community pharmacies [44]. Further, fewer than 15% of respondents reported a purely electronic medication reconciliation process, with most respondents using a paper-based method or a hybrid paper and electronic method [44]. Thus, in 2013, most hospitals were only 'partially implemented' sites in terms of core medication-use technologies [44].

Most relevant to this research, however, is the use of transcribing and dispensing technology in US hospitals (i.e. pharmacy computer systems). Transcribing typically refers to the use of medication ordering and receiving technology (i.e. for procurement and inventorying) and dispensing includes medication dispensing, distribution, and storage technology. Fox et al. found that US hospitals' pharmacy computer systems are primarily purchased and integrated as a suite of products from a single vendor (56%) or are interfaced with other systems but not necessarily components of a suite (28.3%) [44]. Approximately 10% of systems are homegrown or standalone systems that may only support information transfer with other applications within their institution; this is particularly true in specialty hospitals and all Veterans Affairs hospitals [44]. While nearly all hospitals reported ordering medication products online from their primary wholesalers, only 39% of them used barcoding for inventory control [44]. This response surprised the researchers as they consider barcoding a critical technology that has a positive impact on the medication-use process [44]. There are a variety of technologies that exist to

support dispensing, such as dispensing robots, carousels, and automated dispensing cabinets [44]. Amongst these, automated dispensing cabinets were the most common and found in 80% of US hospitals [44].

Most hospitals utilize technology for medication administration, as it is a primary focus area for safe medication use in hospitals. A variety of technologies were found among all hospitals to address medication safety during medication administration, such as barcode-assisted medication administration (75%) and smart pumps (75%) [44]. In regard to MTM services, the survey does not discuss any form of technology to support these processes in an outpatient setting. As MTM services have become an important aspect of pharmacists' activities, the ASHP makes recommendations for an ideal MTM documentation system that includes features to support workflow, regulatory compliance, and patient care activities.

Overall, the results from this survey demonstrate the variability in the use of tools to support pharmacists' activities toward safe, effective, and efficient medication-related care. Further, as there are so many individual technologies that comprise the medication-use process, these results emphasize the importance of sharing structured data across disparate systems [40]. While much of pharmacy informatics is focused on prescribing and administration, as driven by government initiatives like Meaningful Use, it is important that all aspects of the medication-use process are considered. MMIT could be better utilized in areas of extended-duration medication counseling, such as MTM and disease state management, which are primarily done in community pharmacy settings [16].

2.3.2 Community pharmacies

Compared to US hospital settings, the use of pharmacy informatics in community pharmacies is both limited and understudied. While software programs have been in wide use in community pharmacies, the literature revealed few publications regarding the experience of community pharmacies and medication-use technologies. Several technology companies have created products or systems for use in pharmacies, such as Computer Rx, McKesson and Surescripts, which manage the business and clinical workings of a pharmacy [15]. What product, or portions of a product, that a community pharmacy purchases varies greatly depending on its needs; there may not be a one-size-fits-all system. In addition to these vendors, many large chain pharmacies have created their own pharmacy management systems that are customized for certain locations [15].

While functionality varies between different installations, these systems are mostly capable of receiving and verifying e-prescriptions, managing inventory and ordering, and facilitating the dispensing workflow (i.e. tracking which employee completed which steps and when and when prescriptions have been picked up and paid for) [15,45]. They can also be used to review and submit claims for reimbursement to third-party payers. More sophisticated systems may help manage clinical tasks, such as MTM interactions, and track adherence data.

Apart from electronically receiving e-prescriptions, there is little connectedness between pharmacy dispensing information systems and the EHR [16]. Further, although pharmacy systems are 'interoperable,' the exchange of information is not seamless and requires manual entry of data from one system to another; pharmacists typically print the e-prescription before entering it into their dispensing system [16,46]. In some cases where pharmacies do have shared EHR access with a physician practice, they still have to print out the information they need from

the EHR and manually enter it into the pharmacy's own system by hand (i.e. medication order, billing codes, etc.) [15]. This is essentially an error detection process because the dispensing and prescribing are done at two different sites, and because approximately 9% of e-prescriptions have medication errors [46]. Many pharmacists report that this detection process is time-intensive and disruptive, especially when they have to call the prescriber to verify the prescription [16]. The American Medical Association (AMA) has stated that inquiries related to prescription verification are disruptive to the practice of medicine in general, however many of these inquiries may be required for billing [16]. Moving forward, shared EHR access and bidirectional systems are necessary to enable the seamless sharing of information between prescriber and pharmacist [16,40].

2.3.3 Free and charitable clinics

A literature search revealed few MMIT solutions for free clinic dispensaries. A research group at Vanderbilt University has developed a pharmaceutical tracking system for a local free clinic that facilitates the acquisition and efficient management of medications [47]. While this system facilitates the restocking of medications and inventory management, it is not capable of interoperating with a prescribing system. Thus, manual data entry is required to dispense medications.

Similarly, AmeriCares, a non-profit disaster relief and global health organization, has recently piloted an inventory management program for selected free and charitable clinics in the US [48]. The proposed software does offer integrated functionality and support for the pharmaceutical workflow, but is incapable of interoperability, does not adhere to standard prescribing vocabularies, and will require an implementation fee.

2.3.4 Low income countries

Much of the research regarding medication-use-supporting technologies in low-income countries has focused on the development of electronic medical records to support drug management for specific treatments, such as HIV and Tuberculosis (TB), pharmacy dispensing systems, inventory control applications, or quantification tools [49]. Levison et al. reviews available computer-assisted technologies for pharmacies in developing countries and concludes that many applications operate primarily as independent systems. I discuss some of these applications below, and Table 1 (adapted from Levison et al.) provides an overview of existing software and their functionality as it relates to the four medication-use-supporting technologies: EMR, inventory control, dispensing, and quantification.

Table 1: Overview of sampled software and their functionality for developing countries adopted from Levison et al. [49]. Pluses indicate partial functionality or functionality in development.

Software package	EMR	Inventory	Dispensing	Quantification
PIH-EMR	✔		✔	✔
HIV-EMR	✔			✔
FUCHIA	✔			MSFH Order Tool
MMRS	✔			
BART	✔		✔	
CAREWare	✔		✔	
OpenMRS	✔			✔
mSupply (Dispensing)		✔	✔	
iDart	+	✔	✔	
RxSolution	+	✔	✔	✔
ADT			✔	
SIGMED		✔		FoCaMed
ORION		✔		
mSupply (Warehouse)		✔		
HIV-EMR Pharmacy system		✔		
Navision		✔		
Syspro		✔		
ePICS		✔	+	

Douglas et al. in collaboration with Baobab Health demonstrate the effective use of touchscreen, point-of-care EMR system to support and monitor antiretroviral therapy and TB in Malawi, and how this platform can be expanded to support other chronic diseases (e.g. hypertension and diabetes). The Baobab Anti-Retroviral Therapy (BART) system is open-source and runs on rugged, low-power appliance hardware [49,50]. To effectively engineer this solution, Douglas et al. first developed a system to issue unique patient identifiers to manage continuity of care within the country. This patient management information system has expanded its functionality to support order entry for medications, laboratory and radiology tests [51].

Fraser et al., a research team at Partners In Health (http://www.pih.org/), has developed a web based EMR to support a treatment programme for drug resistant tuberculosis in Peru (PIH-EMR) [52], and an HIV-EMR to support HIV treatment in rural Haiti [53]. Both of these applications are open source, web-based systems that focus on drug supply management to ensure uninterrupted drug supplies to specific patient populations in these two countries. The HIV-EMR supports two methods of determining medication use: 1) manual calculation of total requirements for a patient group for a specified period based on their prescribed regimen; 2) calculating the amount of drugs that enter and leave the warehouse each month [53]. While these methods may be effective at avoiding most stockouts, they do not support dispensing functionality at the health center level and thus cannot accurately quantify consumption data.

Building on the experiences of the EMR team at Partners In Health, OpenMRS was developed as a robust open-source EMR platform intended to be adopted and modified by different organizations, and is used in over forty countries across every continent [54,55]. OpenMRS is a platform for the creation of medical record systems in developing countries that consists of an open source data model, a set of core application functions, and a default

implementation [56]. Implementation sites are given the opportunity to implement additional modules to support functions that may be unique to their organization. For example, a simple inventory module was developed to manage and track items in a stockroom [57]. An order entry module is currently under development to support simple outpatient orders, focusing on medication orders and laboratory tests [58]. While this module is designed to support medication ordering, the fulfillment of these orders will be managed by applications external to the EMR (e.g. prescriptions dispensed by a pharmacy system interacting with an inventory system) [58]. Thus, OpenMRS provides modules to support inventory management and order entry, but fails to integrate the actual dispensation process, which is necessary for effective medication management.

Levison et al. describe several pharmacy dispensing systems, such as mSupply, iDart, and RxSolution, which have been developed for use in developing countries [49]. These systems, all developed by different groups, enable pharmacists to enter medication orders from paper prescriptions, dispense appropriate regimens, and deduct this dispensed quantity from the stock levels [49]. mSupply was primarily designed for use in a warehouse but has a 'dispensing mode' that allows pharmacists to dispense medication if desired; although it may have been open-source at one point, mSupply is no longer free to download [49,59]. Although iDart is open-source and able to print multilingual barcode labels which has significantly improved pharmacist efficiency, it is designed to only support the dispensing of antiretroviral therapy (ARV) drugs and does not interface with a medication ordering system [49,60]. RxSolution offers additional functionality, such as inventory control, consumption-based ordering, and recording patient regimen information, but is close-sourced which makes customization and technical support difficult and costly [49,61]. While each of the dispensing systems described by Levison et al. are

problem-driven and appropriate for their implementation setting, an integrated system that receives prescription orders from an EHR, facilitates the dispensing process, uses a standard vocabulary, and manages inventory levels would provide the most accurate stock levels and greatest workflow enhancements in a low-resource setting.

A literature search uncovered only two relevant articles describing possible stand-alone inventory programs to support procurement of essential medicines in a third world country. Berger et al. developed a web based stock tracking system that is intended to provide a communications link between pharmacies as well as recording local stock levels [62]. Pharmacy staffs at nine clinics in rural Haiti are able to enter stock levels, request drugs, and track shipments from a central warehouse. Pharmacists are reminded to request drugs when their stock balances fall below predetermined minimum stock alert levels. These levels are based on consumption data that is manually calculated by the pharmacists. The researchers conclude that stockouts have decreased from 2.6% to 1.1%, and that they plan to implement the same software in Rwanda, Malawi, and Lesotho [62]. However, to the best of our knowledge, there is no additional research regarding implementation of this specific pharmacy stock tracking system in other countries.

Holm et al. developed a similar system for medication supply chain management in a Haitian hospital pharmacy [63]. This pharmacy computerized information program (PCIP) is a web-based system that enables nursing staff to view how frequently certain medications are requested (from the central warehouse) and how much the pharmacy currently has on hand of certain medications. If a nurse wants to place a request for a drug order, it is electronically sent to the pharmacy and the pharmacist must verify the current stock count and approve or deny the drug request. The authors conclude that this system allows real-time knowledge of inventory

status as well as forecasting, increases availability of medications at the point of care, reduces waste and shortages, and provides a deterrent to drug diversion. While results from system implementation are optimistic, this system only provides support for inventory management and fails to integrate drug dispensing and order entry, which may lead to inaccurate stock counts in the future.

2.3.5 Lessons learned

These examples demonstrate the variability of pharmacy informatics in different settings. While the settings described here each share similarities with a free clinic, the tools utilized to support the medication-use process are not designed to effectively meet the needs of free clinic pharmacist for several reasons. First, many of the pharmacy informatics interventions in US hospitals are expensive and fragmented, which are not viable implementation strategies for free clinics with financial and strategic challenges. Second, the software used in community pharmacies is designed to support the business of pharmacy, and not pharmacists who are active users of the EHR, which may be the case at a free clinic. Further, the transactional framework and billing screens are not necessary in a free clinic setting and would burden the user experience. Lastly, while medication-use-supporting technologies for low-income countries have proven to be helpful, most have been developed in isolation and do not effectively make use of data standards to enable the sharing of health information between disparate systems.

While helpful in their own context, the MMITs described in this section may not be suitable implementation strategies for free clinics. However, due to their relative success, certain attributes of these MMITs should be considered in the development of a similar system for a free clinic setting. Some of these attributes may include:

- A minimalistic design that is easily implemented (i.e. web-based) and adapted to user needs and workflow in a specific setting;
- A system design that is focused on improving health worker efficiency and patient outcomes;
- Identification of the value proposition for the user to achieve sustainability;
- A system that supports the entire medication management cycle, i.e. integration of different clinical processes such as order entry, dispensing, and inventory control, which improve real-time overview of stock counts;
- The use of health data standards and open-source software to achieve data sharing between independent systems.

2.4 HEALTH DATA STANDARDS IN PHARMACY INFORMATICS

Health data standards are required to enable interoperability, which is the extent to which disparate systems can exchange, interpret, and display data in a way that makes sense to human users [64]. Generally, this data must be built upon data elements and terminology, structures, and organizations to make it usable and shareable within and across hospitals, pharmacies, laboratories, outpatient clinics, patients, etc. There are many types of standards that can be used to support interoperability in health information management. Functional interoperability is the capability to reliability exchange information without error, and semantic interoperability refers to the ability to interpret and make effective use of the exchanged information. In this research, we achieved functional and semantic interoperability using Health Level-7 (v 2.3) and RxNorm.

Health Level Seven International is one of the leading organizations for standards development in the healthcare arena. Health Level-7 (HL7) provides a framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information [65]. To define how information is packaged and communicated from one party to another, HL7 standards define the language, structure, and data types required for integration between systems. While other alternatives exist, HL7 standards are recognized as the most commonly used in the world to support clinical practice and the management, delivery, and evaluation of health services [65]. Its messaging standard has been widely used to support the exchange of clinical and administrative data enabling departmental hospital systems to communicate with one another.

2.4.1 RxNorm in ambulatory e-prescribing

Ambulatory e-prescribing requires the use of reliable standards to represent drug names in prescriptions. In the domain of pharmacy informatics, drugs in e-prescriptions are identified using the Food and Drug Administration's (FDA) National Drug Code (NDC) Directory, which enumerates prescription drug products at the level of distinct manufacturers and packaging [66]. Despite its overwhelming use, NDC Identifiers have been criticized for several shortcomings relative to their application in e-prescribing as these granular distinctions have little clinical meaning [67]. A single e-prescription drug concept (i.e. drug name, strength, and dosage form) can have multiple assigned NDC identifiers, which can be restrictive and problematic if the receiving dispensing system does not contain a particular NDC identifier in its database [68]. Further, the NDC Directory has been shown to be unreliable and poorly maintained [66]. One study found that 27% of the 123,856 codes in the Directory were erroneous, and an additional

14,337 prescription drug products were missing codes [69]. Although there are documented challenges with using NDC identifiers, it continues to be used as the primary nomenclature in most vendor e-prescribing systems.

RxNorm, developed and maintained by the US National Library of Medicine (NLM), is the first publically available standardized nomenclature of prescribable clinical drugs in the US [70]. Early work that led to the development of RxNorm was motivated by efforts of the HL7 vocabulary technical committee to facilitate the semantic interoperation between various systems that use different drug vocabularies [71–73]. RxNorm includes multiple components – medication names (generic and non-proprietary brands), dosages, forms, ingredients, and packaging - that are linked together through a relational file structure that is easily portable into a database format [72,73]. These components are structured to represent prescribable concepts as unique triples {drug, strength, dose form}, i.e. Fluoxetine 10 mg Oral Tablets, that are independent of non-clinical elements such as inert ingredients [70].

The RxNorm data model is organized by concepts to provide a set of clinically relevant drug names and relationships based on 11 different external source vocabularies [70]. Each concept, or clinically distinct drug, is assigned a unique and permanent Rx concept unique identifier (RXCUI) and a normalized name (i.e. Normalized name = Azithromycin 250 mg Oral Capsule, RXCUI = 141962). These concepts most closely resemble the drug products that are familiar to clinicians and pharmacists [67]. Drugs that map to the same RXCUI are synonyms that are each assigned an RXAUI, or atom unique identifier [70]. Each RXCUI is linked to at least one, but potentially many, RXAUIs, however each RXAUI is only linked to one RXCUI [70]. Table 2 shows sample data from an RxNorm file that represents synonymous drug names of the same concept. Only a portion of the total fields in this RxNorm file (RXNCONSO.RRF) are

shown in this table for simplicity. By providing links to the source vocabularies, RxNorm can mediate messages between systems using different vocabularies.

Table 2: Synonymous drug names from the same concept. The RxNorm normal form is indicated in bold.

RXCUI	RXAUI	Source	Name
141962	2407920	FDB MedKnowledge	AZITHROMYCIN@250mg@ORAL@Capsule (HARD, SOFT, ETC.)
141962	**944489**	**RXNORM**	**Azithromycin 250 MG Oral Capsule**
141962	944502	SNOMED CT	Azithromycin 250mg capsule (product)
141962	944496	VANDF	AZITHROMYCIN 250mg CAP

Each of the sources used to create the RxNorm vocabulary (i.e. SNOWMED CT, FDB MedKnowledge, etc.) provide NDC codes in a different format, which makes it difficult to assess consistency in NDCs across sources. RxNorm normalizes all received NDC data into the 11 digit, no dashes HIPAA NDC format [70]. When the data is available, RxNorm assigns "correct" NDC identifiers as attributes to clinical drug concepts in its data model. "Correctness" of a NDC assignment essentially means that there is consistency among the various sources in the association of a clinical drug concept with a particular NDC [70]. Similar to RXAUIs, a RXCUI may have several NDCs assigned as attributes, however a single NDC is expected to be assigned to only one RXCUI [73].

RxNorm has been recommended as the preferred alternative to the NDC identifier scheme for use as a standardized nomenclature in e-Prescribing applications, as it more closely approximates an "ideal" system of drug identifiers [68,74]. Bell et al. describe an "ideal" system of drug identifiers as one where clinically distinct drugs each have their own unique identifier [67]. Clinically distinct refers to differences that matter when a drug is administered to a patient, as opposed to differences that matter in production or distribution (i.e. NDCs) [67]. Several

different RxNorm applications have been documented. It has been found to be a suitable terminology for capturing medication history in live EHRs, supporting its use in the medication reconciliation process [72], and its identifiers have been used as a mediation between the disparate drug vocabularies of the U.S Department of Veterans Affairs and the Department of Defense [73].

Several groups have evaluated RxNorm's completeness in ambulatory e-prescribing. RxNorm was demonstrated to have a 99.995% coverage rate for nearly 20,000 prescribed clinical drugs in a real-world sample of e-prescriptions [69]. In this sample, NDC identifiers automatically mapped to 98.8% of RXCUIs in RxNorm, and 1.2% were manually mapped [69]. However, when using the vendor's proprietary nomenclature instead of RxNorm, 0.5% of identifiers failed to automatically translate from the NDC to the vendor's proprietary, non-RxNorm prescribable concept [69]. These 'missing concepts' prevent pharmacists from relying on representative NDC identifiers to auto-populate their dispensing systems, which creates extra work for the pharmacists. This further supports claims that the NDC Directory is unreliable in ambulatory e-prescribing [66].

Although RxNorm has been found to be highly-complete in representing prescribable concepts, researchers have identified some areas of caution [69]. For example, in 3.4% of the e-prescriptions described above, two non-identical CUIs were mapped to distinct NDCs; only one unique CUI should be mapped to distinct NDCs [69]. This implies that there are errors in some NDC-to-CUI mappings in RxNorm due to the existence of two concepts having the same meaning. Although these mismatches were of low clinical significance (i.e. involving minor differences in dose forms, salts, or inhaler canister sizes), it is important to maintain the completeness and accuracy of mapping NDC-to-CUIs [67,69]. Eliminating nonspecific terms

from RxNorm may reduce ambiguity and facilitate more complete mappings. Further, drug manufacturers could contribute to this maintenance process by ensuring that the FDA has complete and accurate information for each drug they make available on the market [69].

The RxNorm distribution is updated monthly with new RXCUIs, some of which replace existing concepts [68,70]. Although RxNorm maintains documentation of old RXCUIs, they are essentially retired and not included in the primary prescribable dataset. An evaluation of the RxNorm concept replacement rate found that 8.1% of RXCUIs used in April 2009 were replaced with new CUIs six months later, however researchers were able to forward-map 100% of these replaced CUIs to their current representation using RxNorm's archival table for retired concepts [69]. While this forward-mapping rate is optimistic, retired CUIs could be problematic in practice depending on the implementation of RxNorm [68].

Although several challenges remain unresolved, as evidenced by several evaluation studies, RxNorm has demonstrated its potential to improve drug identification in ambulatory e-prescribing [67–69,73]. Compared with the current use of representative NDCs, RxNorm could improve the ability of e-prescribing systems to accurately and unambiguously represent the clinical drug intended by physicians, which will also be beneficial for pharmacists [69]. However, much of this research is focused on the application of RxNorm in e-prescribing, and its use in electronic dispensing (e-dispensing) is understudied. Further, the e-prescriptions sampled in these evaluation studies demonstrate high-coverage in a primary care setting, but how will it perform in other settings with different prescribing patterns? The RxNorm documentation states that it contains the names of many over-the-counter (OTC) drugs available in the US, however it has not been evaluated in a setting, i.e. a free clinic, that frequently prescribes these products.

While RxNorm is described as a terminology for use in e-prescribing, its application in e-dispensing is inherently related, yet there are limited studies investigating this relationship. If RxNorm improves the ability to identify prescribable clinical concepts in e-prescriptions, how will this translate to a pharmacy information system using a local medication terminology? As vendor EHR systems move toward using RxNorm as the standardized vocabulary in their own systems [73], it is important that departmental systems, specifically in pharmacy, utilize RxNorm similarly to support semantic interoperability. Thus, for the many reasons described here, RxNorm was chosen as the standardized nomenclature for use in RxMAGIC. Although there are uncertainties around the use of RxNorm in an e-dispensing system in a free clinic setting, as it has not been discussed in the literature, it should be effective at supporting semantic interoperability if implemented appropriately. The implementation described in this research provides potential avenues for evaluation of RxNorm in this setting, which would be a significant contribution to the field of pharmacy informatics.

2.5 LEAN HEALTHCARE AND SYSTEMS THINKING

The US healthcare system is discussed as having gaps in quality, safety, equity, and access [75]. Moreover, rising healthcare costs impact all members of a healthcare organization, including employers, payers, and patients. Changing the way healthcare is delivered requires process redesigns that improve quality and reduce cost growth at the same time, thereby making healthcare more efficient. To address this, some healthcare institutions have adopted lean management, a quality improvement philosophy and set of principles originated by the Toyota Car Company [76]. Lean is an approach to process improvement and organizational excellence

focused on eliminating waste and redundancy and providing value for customers, and has been adopted by many organizations across service industries (e.g. automobile and airplane manufacturing) [77]. Waste can be defined as anything that does not add value in the eyes of the customer [78].

The key elements of lean involve determining the value of any given process as identified by the customer, distinguishing value-added steps from non-value-added steps (a process called "value stream mapping"), and eliminating waste so that every step ultimately adds value to the process [76,78]. Lean describes primary and internal processes. Primary processes serve the external customer, such as patients and their families, while internal processes serve healthcare staff and other internal customers, such as hospitals and insurers, in support of the primary processes. Primary processes are typically easier to see, particularly in healthcare, however internal processes are necessary to create value in the primary process [79].

The ultimate goal of lean is to transform the behavior and culture of an organization over time through employee empowerment, standardized work, and incremental improvement, all with use of efficient resources [78], which is particularly important in an under-resourced environment. Healthcare organizations in several continents have demonstrated their use of lean principles to design effective interventions (not necessarily technological) that improve process efficiency and better utilization of health worker time, reduce costs, patient outcomes, and the overall financial health of the organization. These four metrics — time, satisfaction, quality, and financial — represent the lean value diamond (Figure 1). Each metric should experience improvement through reduction of waste in individual processes [78,80].

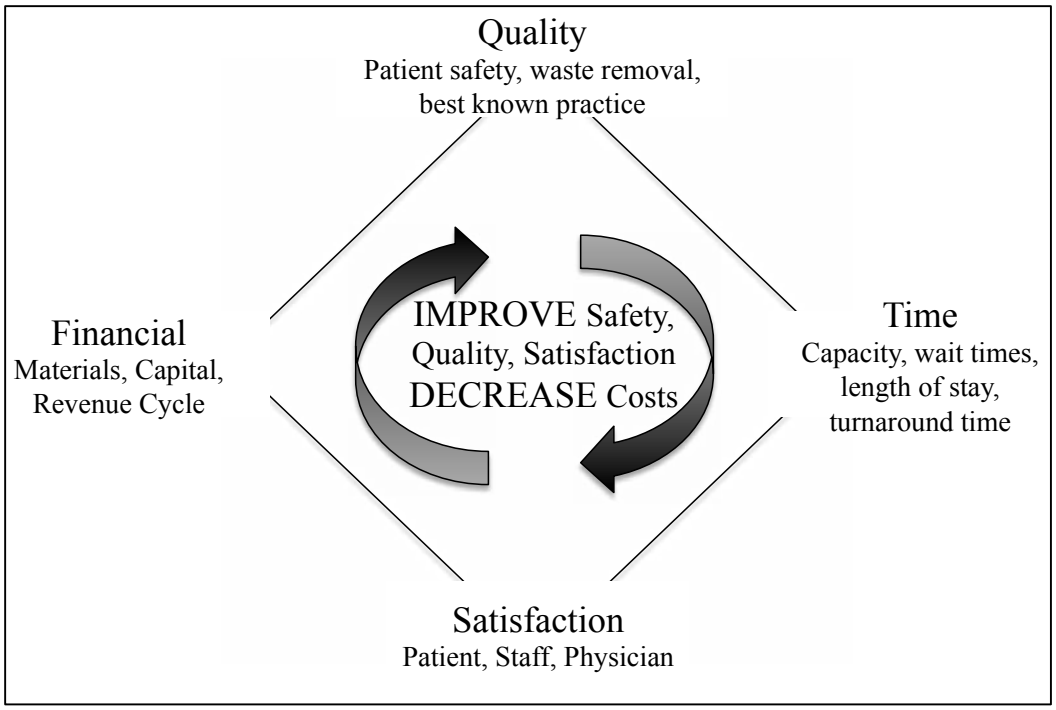


Figure 1: Lean value diamond. Adapted from [80].

The literature discusses several examples of process improvement with use of the lean value diamond metrics as outcome measures. A case study conducted in East Africa describes many examples of simple process improvements as a result of lean implementation [77]. For example, researchers decreased the internal time to procure goods in Rwanda from 27 days to 14 days by eliminating redundant reviews and approvals. Likewise, the annual costs of goods (e.g. mosquito nets, office supplies) in Burundi was decreased by 30% by changing the procurement planning and sourcing tasks. Similar studies in the literature summarized improvements in operational costs, organizational efficiencies, and employee satisfaction in the US [78,81,82].

Lean methodology was effectively used to improve operating room efficiency in 12 hospitals across Saudi Arabia [83]. The Saudi Ministry of Health (MoH) developed the Surgical Pathway Improvement (SPI) initiative to improve patient flow through the surgical pathway, increase operating room (OR) utilization, and improve overall quality of care, while ensuring

increased patient and staff satisfaction. External consultants trained local healthcare professionals and hospital staff members on the principles of lean methodology to design the SPI initiative, which evaluated the current surgical pathway in each hospital using value-stream mapping. In summary, the SPI initiative was developed using existing resources, including: 1) the creation of visual dashboards that facilitate case start times; 2) computerized surgical list management to optimize use of the OR; 3) optimization of time allocation to enhance OR productivity; and 4) creation of pamphlets and other documents summarizing hospital procedures to reduce cancellations. Implementation of the SPI initiative resulted in hospital improvements, such as on-time start time for cases, decreased OR turnover times, and improvements in OR time utilization to reduce overrun cases [83].

A research group in Seattle applied lean methods to improve the quality and safety of surgical sterile instrument processing at Virginia Mason Medical Center. Errors in the processing of these instruments can lead to increased operative time and costs in addition to detrimental patient outcomes [84]. Blackmore et al. employed lean to identify and categorize errors in sterile instrument processing, which were used as outcome measures in their study. The intervention consisted of several components that utilized checklists to monitor packaging of surgical instruments, redefinition of roles and standard work, staff training toward formal sterile process certification, physically changed space, and continuous feedback through weekly team discussions. As a result of the intervention, errors in instrument processing decreased by half in surgical cases, and improvements were measured in the rate of assembly errors and presence of foreign objects in packaging [84].

These examples demonstrate successful use of lean methods to improve various processes in hospital and public health settings. The heterogeneity of lean is also evident from

these studies in which a variety of implementation methods, research designs, and outcome measures are used. This further demonstrates that lean is not a strict methodology, but rather a set of operating philosophies and principles that can be employed to maximize value for a variety of customers, whether it is the patient or the healthcare worker.

2.5.1 Systems thinking

Many quality improvement specialists draw similarities between lean principles and systems thinking. Particularly in healthcare, systems thinking provides a framework to which we can approach problems and design solutions, which focuses on the integrated nature of health systems [85]. This approach is opposite to that of 'silo thinking,' which currently drives the design of most health IT, as evident in the interventions described previously in the medication-use process (Section 2.3.1). Many technological solutions in healthcare are developed and deployed vertically, in that they do not consider synergistic aspects of a health system [86,87]. For example, deploying an e-prescribing system in a health practice without deploying a pharmacy system to receive the information and dispense medication does not consider all processes comprising the therapeutics value stream in system design. This type of vertical, simplistic culture can breed isolationism, redundancy, and error [87].

A systems thinking approach considers the multifaceted and interconnected relationships among health system components, such as order entry and dispensing, and how they all affect the same goal of safe healthcare delivery [85,88]. Health IT interventions must consider the complex dynamics of a clinical event so that they optimize the performance of individual components to maximize the overall output. There are an extensive number of theories, methods, and tools that explain the utility of systems thinking and how it can be used to design and implement cross-

cutting interventions [85]. Moreover, there are a number of different terms used to describe these theories, and their means of implementation and use can be variable.

2.5.1.1 The sociotechnical model

One framework that is relevant to this research is the sociotechnical model for studying health IT proposed by Sittig and Singh [89]. This 8-dimensional model is specifically designed to address the socio-technical challenges involved in the design, development, implementation, use, and evaluation of health IT. While many conceptual models of user interaction, acceptance, and evaluation exist [90,91], they are relatively limited in scope which limits their utility to address the full range of factors that should be considered at all stages of the system development life cycle [89]. The model proposed by Sittig and Singh has eight interdependent, interrelated concepts that span the socio-technical spectrum, including: hardware and software computing infrastructure; clinical content; human computer interface; people; workflow and communication; internal organizational policies, procedures, and culture; external rules, regulations, and pressures; and system measurement and monitoring.

This model is comprehensive in that it provides a framework to address challenges that exist in complex relationships between the intervention itself, its information content, its human-computer interface, and its users. Similar to the systems thinking approach, these dimensions must be studied in relationship to one another, as they are not independent, sequential steps. As such, several of the model's components are more tightly coupled than others. For example, the 'technology' components, which include the hardware, software, content, and user interface are all dependent on one another. However, this model specifically represents these items independently to enable researchers to dissect out the causes of particular implementation

problems [89]. While challenges may not occur in all 8 dimensions of the model, its segmented framework encourages researchers to carefully monitor the impact, effectiveness, and unintended consequences of an intervention.

The sociotechnical model motivated components of this research to understand challenges and facilitators for successful adoption and use of RxMAGIC. Its multi-dimensional approach was appropriate because it considers several user interactions, workflows, organizational policies, and external pressures - all of which are relevant in a free clinic setting. From our experience, we found that problems could, and often do, occur in most dimensions of the model. To address these problems, it is important their solutions are interrelated as well. Solution creation and implementation is not explicitly discussed by Sittig and Singh, however the language they use to describe various solutions is similar to the language used in change management techniques.

Change management is the process by which an organization moves toward its future state by empowering its individuals to champion organizational change [92]. Change management specialists emphasize that, just as we manage technological change, it is also important to understand peoples' needs and manage the natural resistance to change. Health IT should not disrupt workflow, but rather enhance the quality of work life and increase responsibility, empowerment, and motivation so that users feel empowered to think creatively and solve problems. These principles are the foundation of many change management techniques that we found to be useful in this research. Further, these techniques share many similarities to lean healthcare principles, as they both focus on staff empowerment and incremental improvement. Many of the models and principles described in this section are complementary

(i.e. lean healthcare, the sociotechnical model, and change management), thus we have used aspects of all of them in this research.

2.6 EVALUATION METHODS IN BIOMEDICAL INFORMATICS

In this section I focus on the importance of evaluation in informatics, with many references to the book *Evaluation Methods in Biomedical Informatics* by Friedman and Wyatt [17]. I specifically focus on the usability of health IT, which measures how well a resource performs the function for which it was designed [93]. Nielsen identified five facets of usability that include: learnability, efficiency, memorability, errors, and satisfaction [93]. A new user of an informatics resource should learn how to use it quickly, be highly productive using the resource quickly, remember how to use the resource early, not experience many errors in using the resource, quickly recover from errors that do occur, and be subjectively pleased with the experience. Particularly in the design of health IT, it is necessary to optimize these usability factors to ensure the system effectively meets the needs of the user that the developers sought to address.

Research has demonstrated the importance of displaying unambiguous and actionable information in the right way at the right time, particularly in the design of clinical information systems [94]. The benefits of health IT are not often recognized by clinicians due to poor system design, incorrect implementation, and its inability to integrate into the cognitive and clinical workflow [95]. This is particularly true in the design of drug alerting systems. Usability flaws in these systems typically include poor information presentation, quality and content, information density, lack of consistency between disparate systems, and a lack of flexibility to support a range of user types (i.e. physicians, pharmacists, nurses, etc.) [94–96]. These challenges are just

an example of the types of interaction problems users encounter when navigating a new system, and it is essential that they are understood and addressed through careful evaluation at all stages of system development.

As health IT takes on an increasingly central role in healthcare, reliable methods for evaluation are more and more imperative [17]. Methods for evaluation are important to understand user requirements, system usability, and the impact or side effects of health IT in both laboratory and field settings. There are a range of techniques, methods, study designs, and analysis methods that can be applied across a range of evaluation problems. Friedman and Wyatt describe different types of evaluation problems as they pertain to five major aspects of an information resource that can be studied, which include: the need for the resource, the design and development process, resource static structure, resource usability and dynamic functions, and resource effect and impact [17]. The authors further expand these five areas into nine important evaluation study types that are described in the table below (Table 3). These study types help researchers determine "what" should be studied, and although these nine study types comprise a theoretically "complete" evaluation, it is rarely necessary to be so comprehensive in the 'real world' [17]. We used several of the nine study types in this research, which are indicated in bold in Table 3, and described below. We selected these study types to ensure that they span the five focus areas listed above and could be employed sequentially, albeit some more formally than others.

Table 3: Classification of nine generic evaluation study types by broad study question and version of resource studied. The items in bold indicate the studies used in this research. The numbers in 'Aspect studied' refer to: 1) Need for resource; 2) Design and development process; 3) Resource static structure; 4) Resource dynamic usability and function; 5) Resource effect and impact. Adapted from [17].

Study type	Aspect studied	Example study question	Version of resource
Needs assessment	**1**	**What are the problems?**	**None (or one that will be replaced)**
Design validation	2	Is the development method in accord with accepted practices	None
Structure validation	**3**	**Is the resource appropriately designed to function as intended?**	**Prototype or released version**
Usability test	**4**	**Can intended users navigate the resource to complete certain functions?**	**Prototype or released version**
Lab function study	4	Does the resource have the potential to be beneficial?	Prototype or released version
Field function study	4	Does the resource have the potential to be beneficial *in situ*?	Prototype or released version
Lab user effect study	5	Is the resource likely to change user behavior?	Prototype or released version
Field-user effect study	**5**	**Does the resource change actual user behavior in ways that are positive?**	**Released version**
Problem impact study	**5**	**Does the resource have a positive impact in the original problems (uncovered in the needs assessment)?**	**Released version**

User-centered design principles are rooted in ethnographic and cognitive science, which focuses on the need to gather evidence for system design by observing healthcare workers in their automatic environment rather than purely laboratory-based design ideas that are removed from daily practice [94,97,98]. Thus, to understand the nature of the problems the resource is intended to address, a needs assessment study that utilizes a subjectivist approach is helpful. These methods include passive observation, key-informant interviews, informal discussion, and

workflow modeling to understand user information needs, abilities, expectations, and workflows [17,99]. During the design and implementation stages, it is important that the intervention is thoroughly evaluated in the laboratory to ensure it is functioning as designed and not violating any usability requirements. Once the system is in use, the focus switches from the resource itself to its effects on users and the healthcare organization. It is important to understand how the resource impacts the behaviors and actions of its users to facilitate a seamless integration and adoption; this is the field-user effect study. Lastly, to understand if the resource has a positive impact on the initial problems uncovered in the needs assessment studies, a problem impact study is critical.

2.6.1 The "fundamental theorem" of biomedical informatics

Further emphasizing the importance of evaluation methods in biomedical informatics, we discuss a "Fundamental Theorem" of informatics as proposed by Charles Friedman [100]. The fundamental theorem of biomedical informatics states that "a person working in partnership with an information resource is 'better' than that same person unassisted." A resource, for example, can be an information system, an algorithm, a dataset, or even a new method of standardized work; in this research, RxMAGIC represents the 'resource.' This theorem is illustrated in Figure 2 and referenced several times throughout this research. Friedman describes three important corollaries to the theorem that offer a finer depiction of what informatics is and is not. We found these corollaries to hold mostly true as this research progressed, with some exception to the second corollary. I briefly describe these corollaries below.

Figure 2: The 'fundamental theorem' of biomedical informatics proposed by [100].

Corollary 1: Informatics is more about people than technology. This corollary reminds us that, as informaticians, we are developing resources for the benefit of the users. This was particularly important in this research as it is grounded in user-centered design principles. Users were engaged at every stage of the design and development process to ensure that the resource effectively meets the pharmacists' needs. Further, this corollary emphasizes the importance of what informatics is not: automation. The goal of this research was to deliver a resource that augments the pharmacy workflow and requires user intervention to be successful, rather than something that replaces the user altogether. While automation certainly plays a role in health IT, it is important that resources do not compete with their users.

Corollary 2: In order for the theorem to hold, the resource must offer something that the person does not already know. It is important that an information resource is informative and capable of incrementing the knowledge of the user in some way. While we believe this to be true, it is not the only indicator of success. It is possible that an information resource does something that can already be done, but does it better. The resource should offer users information and assistance they did not previously have in a way that adds value to the process.

Corollary 3: Whether the theorem holds depends on the interaction between person and resource, the results of which cannot be predicted in advance. This final corollary explains the importance of evaluating a resource once it is in steady use in a user's authentic

work environment. While it is important to understand a user's needs and expectations, the resource itself, and how the user interacts with the resource in a controlled environment, it is just as important to study this interaction *in situ*. Further, it is necessary to revise the resource if it does not have a positive impact on user behavior and outcomes. We found this corollary to be especially true in this research, which we further elaborate upon in Aim 2 (see Section 5.2).

3.0 RESEARCH DESIGN

We have collaborated with the Birmingham Free Clinic (BFC) in Pittsburgh, Pennsylvania to conduct this research. In this section, I discuss the characteristics of the study setting and the motivation behind this research. Further, I provide an overview of the individual studies that comprise this dissertation as guided by three specific aims.

3.1 SETTING: BIRMINGHAM FREE CLINIC

This research focuses on challenges associated with the medication management continuum as typified by the BFC, which is the only free, non-federally-funded, walk-in health clinic in Pittsburgh [24,101]. The BFC was founded in 1994 through the Program for Heath Care to Underserved Populations (PHCUP) with the goal of placing free, compassionate healthcare services within the Pittsburgh community to provide a safety net of care for homeless, uninsured, and medically indigent individuals. The PHCUP was developed under the auspices of the University of Pittsburgh Medical Center (UPMC) in response to medically vulnerable individuals being discharged from hospitals without proper follow-up care. The mission of the Program is "to facilitate, provide, and improve access to high-quality care for those in need, through community partnerships, volunteerism, service learning, and advocacy" [101].

The BFC is the PHCUP's longest-running initiative and "envisions a community were every individual has access to high-quality, compassionate healthcare" [101]. They use of a community-campus partnership model to achieve this. The BFC receives support from the Salvation Army, generous donations, and the Division of Internal Medicine at UPMC [101]. Further, they leverage relationships with the University of Pittsburgh School of Pharmacy / School of Medicine to provide educational experiences for students. A mostly volunteer team of physicians, pharmacists, nurses, health professional students, and other allied-health professionals donates over 2,000 hours of clinical service annually. These services, in addition to medications, are provided for free to approximately 1,100 uninsured and medically underserved individuals annually. In addition to these volunteers, the BFC hosts AmeriCorps National Service members who act as patient advocates in the clinic. Amongst other duties, their primary responsibility is to manage the PAP application process.

The BFC focuses on continuity, prevention, and education with the goal of forming and maintaining a positive, trusting relationship with their patients. Their services include primary and acute medical care, medication access, medical and social services, case management, and insurance navigation services. They utilize an interdisciplinary team-based approach to provide a wide range of clinical services, including the identification and prevention of disease, management of chronic conditions, as well as extensive health and social service referrals. The services that are offered vary depending on the day of the week. For example, clinical pharmacists conduct a smoking cessation clinic on Thursday mornings, while Saturday afternoons may be a student-run clinic for walk-in, pediatric patients. Likewise, the clinic offers more specialized services, such as dermatology or optometry, on certain Monday evenings.

An on-site medication dispensary enables access to essential medications for free during every clinic session. Volunteer clinical pharmacists work collaboratively with the medical team to provide in-depth MTM and disease state management for patients with chronic diseases. Most medications are donated by UPMC, purchased in bulk at significantly discounted rates, or acquired for specific patients through PAPs. Approximately 20% of the patient population at the BFC receive prescription medication through PAPs. A study done by BFC pharmacists in 2009 reported an average savings of $243 USD per patient per month because of these programs [24]. Pharmacists assist patients in applying for PAPs, and receive and dispense the medication to patients on-site.

3.2 MOTIVATION

3.2.1 A paper-based workflow

Like many medical practices before the introduction of health IT, the BFC utilized paper charts to document patient visits. They standardized use of paper forms by creating customized charts, intake forms, and medication labels that adhered to certain regulations. The workflow was straightforward and consistent; a paper chart would follow the patient from intake to the dispensary. Physicians would handwrite medication orders and personally deliver and discuss them with pharmacists before dispensation. Although paper charts and handwritten documentation tasks were inefficient, labor-intensive and prone to human error, they facilitated collaborative team-based care. Physicians would often consult the pharmacist to determine

treatment plans based on stock availability before placing medication orders, which standardized communication between the medical and pharmaceutical services.

3.2.2 A hybrid EHR-paper workflow

UPMC donated their outpatient EHR system, EpicCare, to the BFC with the goal of enhancing the continuity of care within their enterprise. The introduction of an EHR has improved the quality and efficiency of several clinical processes, such as the ability to electronically view patient laboratory results and order medications using CPOE. However, pharmacists report that it has not benefited their productivity as it is unable to accommodate their workflow. The EHR essentially automates the medical services while failing to fully support the pharmaceutical practice, particularly dispensing and inventory tracking.

While pharmacists at the BFC are active users of the EHR, they continue to use a paper-based system for dispensing, inventory tracking, and monitoring medication use. Pharmacists play a key role in many processes related to the EHR at the BFC such as medication reconciliation, CPOE, patient evaluation, and other documentation tasks. While they recognize the benefits that the EHR provides, this hybrid EHR-paper system has created a culture of redundancy in the dispensary that is both inefficient and prone to error. Rather than providing efficiencies and improved time management, the partial support of the EHR has exacerbated many of the inefficiencies that existed due to the use of paper charts [102].

The challenges described here, which are further elaborated upon in Aim 1 (see Section 4.0), were the motivation for this research. The BFC pharmacists could benefit from an automated dispensary management information system that improves the efficiency of their dispensing workflow. This system should provide workflow efficiencies, safer and more

standardized dispensing, and strengthened supply chain integrity. Further, to avoid continued redundancy, this system should integrate with the EHR to receive electronic prescription data entered via CPOE [102].

3.3 APPROACH

The goal of this doctoral research is to understand challenging aspects of the pharmaceutical workflow at the BFC, design and deploy a system that directly alleviates these challenges, and iteratively evaluate the system (both in the field and the laboratory) to ensure that it does. That system is RxMAGIC.

This research involved a combination of studies guided by Friedman and Wyatt's evaluation framework, from needs assessment to problem impact. We have used a variety of methods including qualitative and quantitative data analyses, information system design and implementation, user-centered design, and multiple evaluation techniques. We began by qualitatively understanding the pharmaceutical workflow at the BFC and the specific challenges that pharmacists encounter. Having identified a set of workflow challenge themes, we quantified their impact on pharmacist time utilization to help prioritize intervention design. We used these data to design a novel dispensary management information system with functional components that could be directly linked to the challenges they are to alleviate. We employed a prototype-and-test approach to ensure completeness and feasibility. After testing this prototype with potential users, we supervised development and iteratively evaluated the system for usability. We deployed RxMAGIC at the BFC, trained users, and observed initial use to diagnose and resolve functional and organizational challenges. Finally, after steady use, we evaluated the impact of

RxMAGIC on pharmacist time utilization and satisfaction, and inferred its effect on quality of care and cost.

This process is described in several studies that are guided by the following research questions, and associated study types as described by Friedman and Wyatt [17]:

1. **NEEDS ASSESSMENT:** What are the information needs and workflow challenges pharmacists encounter at the BFC, and what can we design to alleviate them?
2. **STRUCTURE VALIDATION / USABILITY:** Does this information system design have the potential to meet those needs, and how can it be improved?
3. **FIELD-USER EFFECT:** How do pharmacists interact with RxMAGIC once deployed, and how can we resolve problems related to system functionality and workflow organization?
4. **PROBLEM IMPACT:** How does RxMAGIC impact pharmacist time utilization and satisfaction?

3.3.1 Dissertation overview

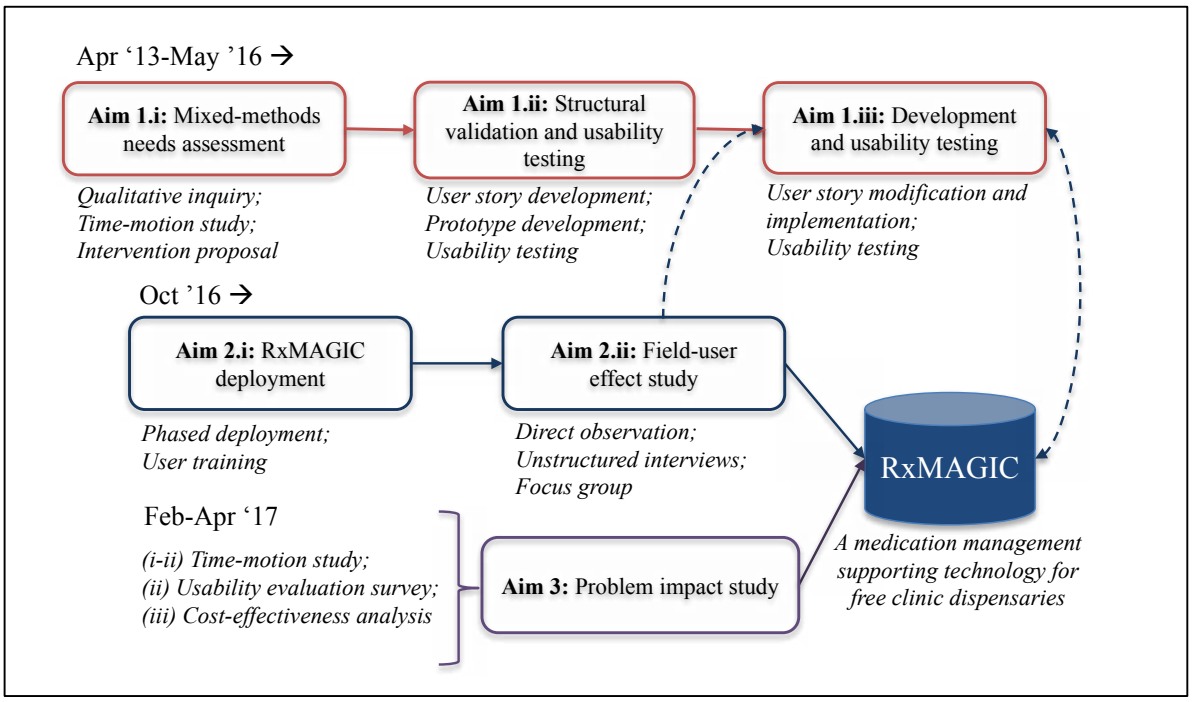


Figure 3: Dissertation overview.

Figure 3 provides an overview of this dissertation research that consists of three specific aims that are associated with the research questions defined above:

AIM 1: To design a production version of RxMAGIC and evaluate it in a laboratory setting.

Aim 1.i: Understand workflow challenges at the BFC and propose the initial framework for RxMAGIC.

Aim 1.ii: Develop a prototype version of RxMAGIC and test it with potential users to guide the design of a production system.

Aim 1.iii: Use results from Aim 1.ii to design a production system and evaluate its usability in a laboratory-based environment.

AIM 2: To identify and resolve post-deployment implications related to system design and workflow organization.

Aim 2.i: Deploy components of RxMAGIC in two locations and train all users through a tutorial video and on-site instruction.

Aim 2.ii: Conduct passive observations and a focus group with primary users to identify, understand and resolve post-deployment challenges.

AIM 3: To evaluate the impact of RxMAGIC in the clinic within the framework of the lean value diamond.

Aim 3.i: Measure changes in pharmacist time utilization.

Aim 3.ii: Utilize results from Aim 3.i to infer changes in the quality of services provided.

Aim 3.iii: Measure users' perceptions about the usability of RxMAGIC.

Aim 3.iv: Assess the cost-effectiveness of RxMAGIC as a prospective new intervention being considered for implementation by a free clinic.

4.0 AIM 1: DESIGN RXMAGIC AND CONDUCT USABILITY TESTING

Aim 1 focuses on the user-centered design process employed to develop RxMAGIC. Identifying the need for an information resource before it is developed is an important precursor to any developmental effort. Thus, we began this research by conducting two needs assessment studies at the BFC to identify problems that may be amenable to a solution (Aim 1.i; see Section 4.1-4.2). Both needs assessment studies are published separately in BMC Health Services Research [102,103]. Keeping with the user-centered design process, we developed a proof-of-principle prototype that captured enough functional aspects of the desired system to support user research and structure validation (Aim 1.ii; see Section 4.3). Results from the prototype usability evaluation guided the design and development of a production version of the system, which we iteratively tested for usability in a laboratory environment (Aim 1.iii; see Section 4.4).

4.1 QUALITATIVE NEEDS ASSESSMENT

We conducted a qualitative investigation utilizing contextual inquiry to document the dispensary workflow and identify processes that may benefit from introduction of an informatics intervention. Holtzblatt et al. designed contextual inquiry as a user-centered, social method aimed to identify and understand users' needs and unarticulated knowledge about work processes [104]. This methodology users direct work observation, informal interviews, and four graphical

models to describe all aspects of workflow and provide highly detailed data about the structure of work practice. Contextual inquiry differs from other qualitative methods, such as interviews and focus groups, because it does not just rely on the user's ability to clearly articulate his/her needs, which can be a difficult task for any user [104,105].

4.1.1 Methods

We performed three contextual inquiry sessions at the BFC dispensary during clinical care according to the guidelines suggested by Holtzblatt et al. [104]. Each session lasted approximately four hours and included direct work observation and unstructured questions about work tasks. We observed a wide range of pharmaceutical tasks including pharmacist-physician consultation, prescription preparation and dispensation, and patient counseling and education. The University of Pittsburgh Institution Review Board approved this study as exempt (PRO15010330). This research was published in BMC Health Services Research in February 2016 [102].

Notes representing user-provided data such as key user needs, information sources and flow, physical artifacts, activities, and regulatory tasks were captured during contextual inquires. We also identified 'breakdowns' in the workflow, which are defined as anything or anyone that interrupts the pharmacist during task completion. As part of the contextual inquiry process, we used these data to create four graphical models (physical, artifact, sequence, and cultural) to facilitate data visualization and interpretation. The physical model captured the actual layout of the BFC to portray different components of the environment that may support or hinder pharmacist's work. The artifact model documented and described any physical objects (i.e. documents or forms) that are necessary to understand the workflow. The sequence model

illustrated the main steps pharmacists take to perform certain work tasks, and described how workflow strategies may differ between users. The cultural model illustrated the expectations, goals, values, and general policies that may influence how the pharmacists accomplish their work and coordinate information flow with co-workers. The models were validated for accuracy and completion during a member-checking discussion with the pharmacists. The discussion lasted one hour and was audio-recorded.

We used a pattern coding approach to categorize the qualitative data and develop a set of themes summarizing the primary workflow challenges encountered by the pharmacists. Pattern coding is used to identify trends and repetitive patterns in a dataset. It allows the use of the same codes, which may describe themes or categories, to be used repeatedly throughout a qualitative dataset. To focus the design of an intervention on problems most amenable to a technological solution, we asked the pharmacists to rank the themes by level of importance. We used a weighted ranking technique by assigning scores to each ranked item, where the highest-ranked item received the greatest score (equivalent to the total number of ranked items) and the lowest-ranked item received the lowest score (i.e. a score of 1). The scores for each ranked item were added across the datasets and ranked in descending order to produce a new, harmonized set of themes. We then proposed informatics interventions to address the five highest-ranking workflow challenges that received the greatest aggregate scores during the ranking process. Figure 4 provides an overview of the methodology employed in this study; this figure is adapted from a study done by Turner et al [106].

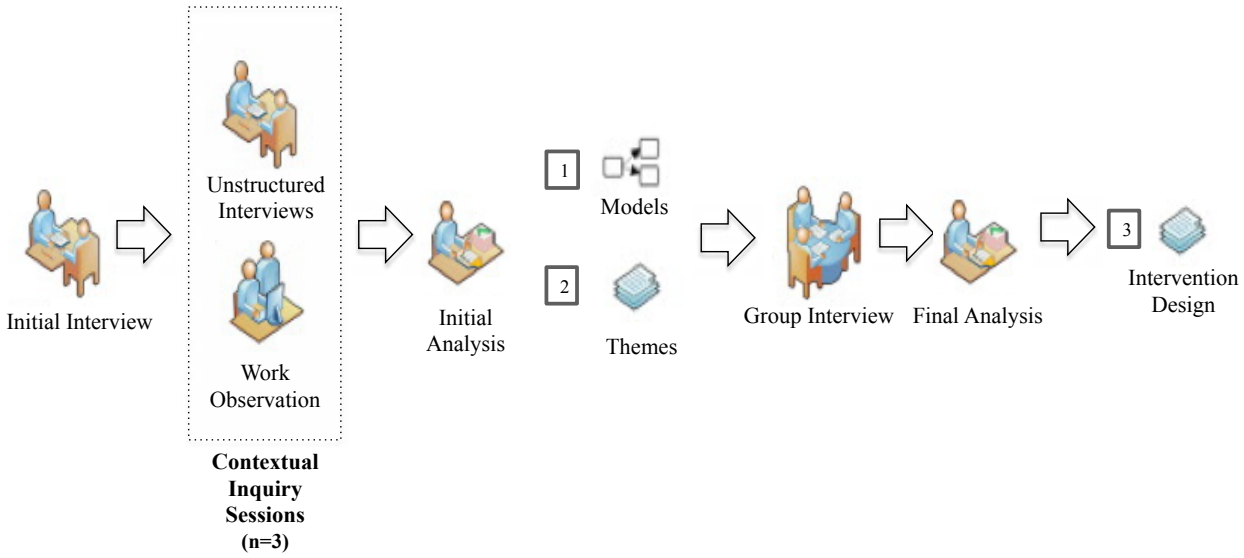


Figure 4: Overview of methodology used in the qualitative inquiry. Adapted from Turner et al. [106].

4.1.2 Results

Three pharmacists participated in this study, all with varying levels of experience volunteering at the BFC. Figure 5, the physical model, is an approximated floor plan of the BFC to provide some context as to the physical location of the on-site dispensary. The cultural model (Figure 6) shows the degree to which different organizations, general policies, values, and relationships within the clinic influence the pharmacists primary goal of medication management. For example, this model shows that providers have limited knowledge of the available formulary which may lead to errors in CPOE and negatively impact the pharmacist's ability to efficiently dispense medication and counsel patients.

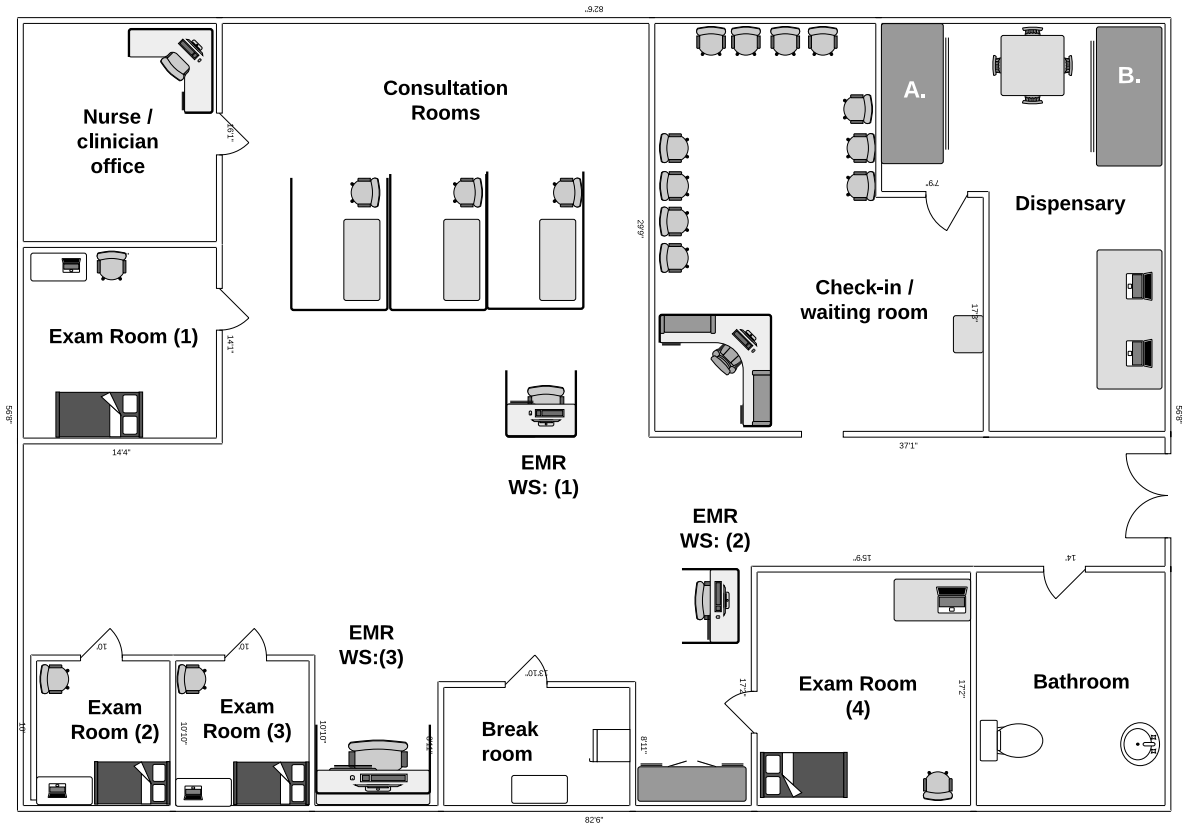


Figure 5: Birmingham Free Clinic floor plan (physical model). WS = workstation, A = PAP medication cabinet, B = general stock medication cabinet.

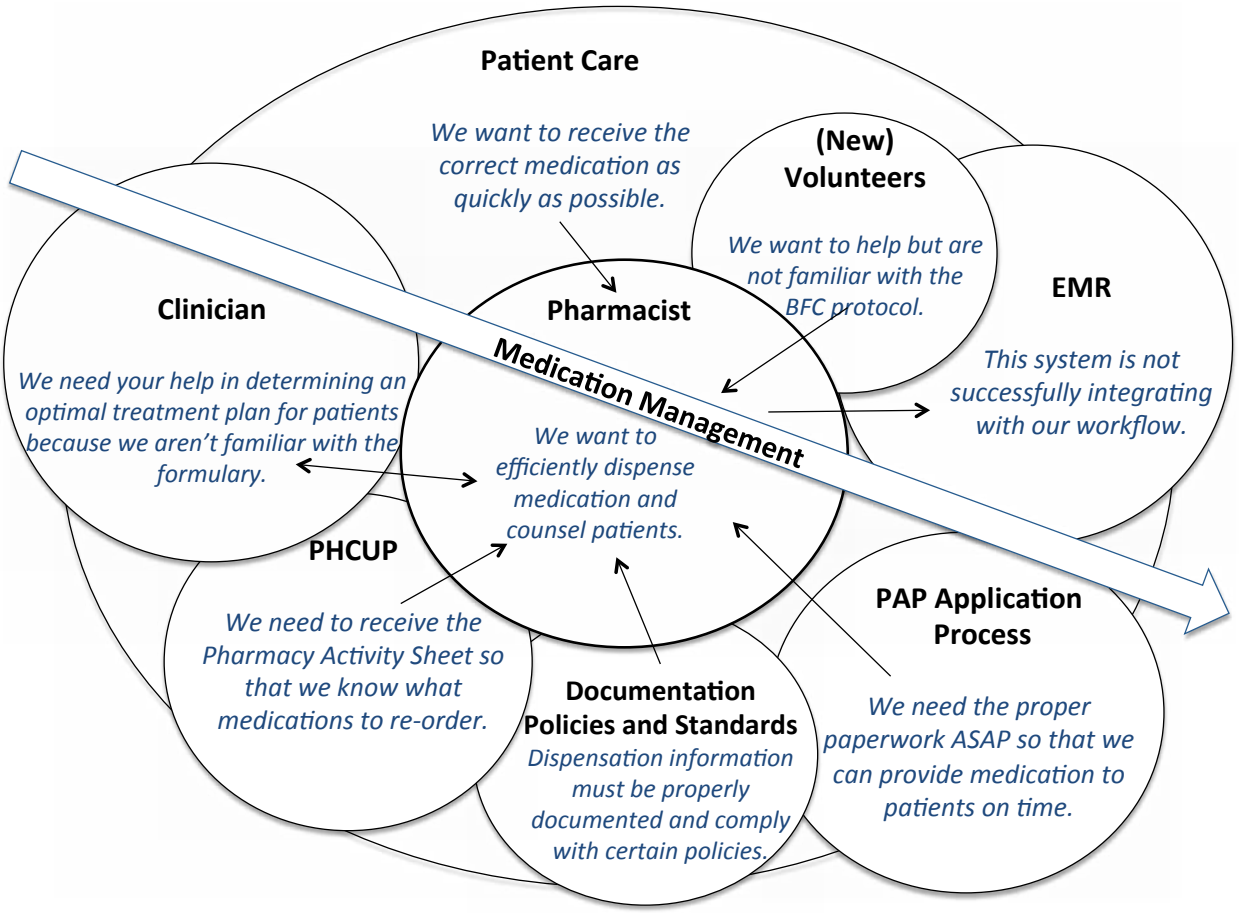


Figure 6: Cultural model. The size of the circle indicates the degree of influence, and the text in italics describes the primary concerns of each influencing factor.

We used the sequence model (Appendix A) in conjunction with the qualitative data to identify 12 themes that describe workflow challenges in the BFC dispensary. Table 4 lists these themes in order of importance as ranked by the pharmacists. The five highest-ranking workflow challenges, which are indicated in bold in Table 4, include handwritten medication labeling, insufficient process notification, redundant documentation, challenges related to CPOE, and knowledge of the medication formulary. We recognized that the latter two themes were symptomatic challenges related to the same root problem: poor inventory control. Thus, these themes were coalesced and renamed as poor inventory control. To provide a better understanding of the

workflow, I describe these four themes in detail and the interventions we proposed to address them below:

Table 4: Workflow challenges uncovered in the qualitative inquiry. The items in bold indicate the five highest-ranking workflow themes to which we focus our intervention design.

Theme	Definition
Labeling	**The labeling of medication bottles is time-consuming, redundant, incomplete, and can lead to inaccuracies.**
Insufficient process notification	**The EMR has an inefficient method of alerting the pharmacist that a patient is ready for dispensary services due its reliance on the clinician's memory.**
Triple Documentation	**The pharmacists currently document patient prescription/dispensation information in three separate documentation forms (i.e., medication labels, Pharmacy Activity Sheet, and the EMR).**
Challenges with CPOE	**Frequent errors in clinician ordering due to confusion around available inventory and patients' financial capabilities.**
Knowledge of formulary	**Clinicians have no visibility into the available medication stock at the BFC dispensary.**
Dispensing	The EMR is only capable of supporting the prescribing process at the BFC and does not provide a similar structure for dispensing practices.
Patient Validation	The dispensary lacks an explicit method to validate that the right medication is being dispensed to the right patient.
Inventory Maintenance	The dispensary is unable to use prescription information in EMR to track medication inventory and dispensing history in real-time.
Drug-Drug Interactions	The dispensary lacks an explicit method for checking potential DDI's at the counseling site due to the inability to readily access past dispensation records.
EMR Accessibility	Pharmacists cannot readily access the EMR at relevant locations, such as the patient counseling location.
EMR Complexity	Volunteer pharmacists and clinicians are not familiar with the specific protocol when ordering medications to the BFC dispensary in the EMR which leads to incorrect EMR order entries.
PAP Application Process	The PAP application process is challenging and time consuming due to the large amount of paperwork involved and the wide variation in application format and patient requirements.

Insufficient process notification

After a physician places a medication order in the EHR using CPOE, he must change the patient status to 'ready for dispensary services' on the EHR dashboard. This notifies the pharmacist that he may begin preparing the prescription; however, the pharmacist must be continually checking the dashboard to notice this update. Changing the patient status following CPOE may be an unfamiliar step to many volunteering clinicians as it is not part of their workflow at their typical medical practice. Thus, in conjunction with a high patient burden, this step is easily overlooked, which may result in unnecessary patient delays and limited time for the pharmacist to counsel the patient on appropriate medication usage.

- ➢ *Intervention proposal:* Implement a dashboard that displays pending prescriptions in order of their receipt via CPOE.

Poor inventory control

Once an order is placed in the EHR, the pharmacist may determine that the medication is currently unavailable or that the BFC typically does not carry this medication. The clinician was likely unaware of this because, as an infrequent volunteer, he is not familiar with the limited formulary at the BFC and how it differs from a typical retail community pharmacy formulary. Further, the clinician lacks visibility into this unique inventory from his prescribing location, which results in incorrect medication orders and extra work for the pharmacists to correct this mistake. The underlying cause of these challenges is a lack of automated inventory control, which can lead to unreliable monitoring of medication utilization, uninformed CPOE, and drug stockouts.

- ➢ *Intervention proposal:* Use electronic dispensing to establish a system of automated inventory reduction that will update inventory counts in real-time. Using past

consumption data and expiry information, we can alert pharmacists of low-inventory items and medications approaching expiry. This will remind pharmacists to reorder high-usage medications and dispense expiring medications first, which will help keep critical drugs on the shelves and may reduce wastage of low-usage drugs due to expiry. The inventory will be visible to clinicians by a web-browser that they can view on the same computer as the EHR, resulting in a more informed patient-provider conversation during the patient visit.

Handwritten medication labeling

The pharmacist begins to prepare the prescription by handwriting medication labels for all medications the patient is receiving that day. These labels contain similar information to those on prescription bottles from a typical community pharmacy (i.e. medication name, strength, directions for consumption, prescriber). The artifact model in Appendix B describes this label in more detail. This handwritten process is labor intensive, prone to human error, and lacks scalability if patients are receiving multiple medications that day.

- ➢ *Intervention proposal:* Use computer-generated barcode labels to streamline and standardize the dispensing process. Each laptop in the BFC dispensary will receive a barcode scanner and thermal label printer to produce patient medication labels upon dispensation. This scalable method will maintain dispensation records for each BFC patient, and will replace the paper-based filing system used at the clinic.

Triple documentation

After patient care has ended, the pharmacist handwrites information summarizing each dispensation that day (i.e. the same information written on the patient labels) on another

document, the activity sheet, that is delivered to the PHCUP office. The artifact model in Appendix B describes the activity sheet in greater detail. Any low-inventory medication items must also be written on this document so that they can be replenished. Use of the activity sheet represents this notion of redundant work.

- ➢ *Intervention proposal:* Generate automated reports based on the information previously used to produce computer-generated dispensing labels. Low-inventory items can be automatically added to electronic reports when they fall below a certain threshold, so that the pharmacist does not have to recall low-inventory items at the end of the day.

4.1.3 Discussion

To our knowledge, limited research exists on the challenges pharmacists encounter in free clinic settings. While the BFC workflow has undergone many refinements since its inception, we noted much inefficiency and redundancy in the dispensing process. It was obvious that inefficiency was at the core of many workflow breakdowns. We identified five main challenges that may be amenable to a technological solution: insufficient process notification, challenges related to CPOE, knowledge of formulary, handwritten medication labeling, and triple (redundant) documentation.

In proposing individual interventions designed to address these challenges, we recognized that many of the problems shared the same root cause, and thus their interventions would be dependent on one another. For example, electronic dispensation and automated inventory control are somewhat synergistic; they can certainly exist on their own, but they would be more successful if working together. It was necessary to consider these dependencies so that we could design a 'systems thinking' solution that would act as an umbrella under which

multiple performance improvements to occur. This solution evolved into a framework for a dispensary management information system, RxMAGIC, that was grounded in these individual interventions.

4.1.4 Limitations

We recognize that contextual inquires by a single researcher is a limitation of this study. However, the pharmacists were actively involved in model development and theme validation. We believe this level of user engagement is critical to sustain innovation, although we still wanted to validate these results with quantitative data. We planned to conduct a time-motion study to measure pharmacist time utilization and understand the magnitude of these workflow inefficiencies. This would help to prioritize the design of RxMAGIC to focus on the tasks that were most inefficient tasks and amenable to improvement. Further, as efficiency is the outcome for which RxMAGIC is intended to improve, it was necessary that we acquire a baseline measurement to eventually ensure that it does.

4.2 QUANTITATIVE NEEDS ASSESSMENT

The qualitative investigation provided a somewhat broad understanding of the workflow inefficiencies that may be alleviated through introduction of an informatics intervention. However, it did not provide any insight into the relative impact of relevant inefficiencies in the current workflow. A more quantitative understanding of pharmacist time allocation was necessary to determine where to focus RxMAGIC so that it maximizes value for its users. We

conducted a continuous observation time-motion study informed by lean principles to quantify pharmacists' time expenditures on defined tasks. The goal of this study was to quantify time invested in non-value-added tasks, or tasks pharmacists thought were amenable to efficiency improvements, and to focus RxMAGIC on reducing redundancy in these areas.

Time-motion studies are business efficiency techniques that have been adopted in the biomedical domain to evaluate the adoption of health IT systems and how they impact the quality, efficiency, and cost of healthcare [107]. Using time-motion observations to quantify healthcare workers' time expenditures on different clinical activities can provide valuable insight into system specifications and workflow redesign. Improving process efficiency may benefit staff productivity and other related organizational challenges such as communication and process transparency.

4.2.1 Methods

Two researchers conducted time-motion observations in the BFC dispensary on tasks that comprise the pharmaceutical workflow. The University of Pittsburgh Institutional Review Board reviewed this study and approved it as exempt (PRO14020120). This research was published in BMC Health Services Research in September 2016 [103].

Codebook development and pilot studies

We developed an initial set of ten task subcategories, or codes, describing pharmacist activities based on data from the qualitative investigation. We conducted a pilot study to test these codes for completeness and calculated Cohen's kappa to determine inter-rater reliability. Both researchers observed the same pharmacist for the duration of the data collection session and

documented the amount of time he/she took to complete tasks; these data were not analyzed. Questions about the appropriateness of certain categorizations following the pilot study resulted in several modifications in the codebook. We also clustered related subcategories into higher-level workflow categories to assist with broader analysis. Due to these changes, we conducted a second pilot study to measure inter-rater reliability with the new coding system.

Data collection and analyses

Each researcher observed a different pharmacist during a three-hour shift, which began approximately 30 minutes before the first patient appointment. This allowed the researchers to document pre-work tasks, such as pending medication orders in the EHR. Data collection continued through general care hours until onsite care was completed. Each session lasted roughly three hours.

We collected data using the Time Motion Study application by Graphite Inc. (www.graphiteinc.com) for Android devices. This software allowed the observer to create a list of motions, i.e. task subcategories, to track pharmacist activity. Timing began as soon as the task was selected and ended upon selection of a new task. Data was recorded in comma separated value files where each row summarized the duration of a single task selection. We used RStudio 0.98 (RStudio Inc., www.rstudio.com) and R 3.1 to analyze the accumulated time invested in each subcategory, and hence each major category, over the entire dataset. We created bar charts to help visualize these data.

Value stream mapping

The core idea of lean is to maximize value for the customer while minimizing waste, or simply, to create more value for customers with fewer resources. To do this, we must first identify value

as perceived by the customer and then distinguish non-value-added tasks from value-added tasks; in lean language, this is the value stream mapping phase [78]. While we recognize that there are many customers affected by the therapeutics value stream, and that the patient represents our final customer, it is the pharmacist who is immediately involved in the processes described here. Thus, we identified BFC pharmacists as the internal customer in this study, and they specified efficiency as the value they desired. Efficiency is defined as the ability to accomplish a task with the minimum expenditure of time and effort. Pharmacists classified the tasks described in this study as non-value-added and value-added, thereby indicating non-value-added tasks as potential areas for efficiency improvements through waste reduction.

We used these value categorizations to calculate the value quotient for each dataset. The value quotient is a metric for determining the efficiency of a workflow; it calculates the percentage of value-added time over the total time [108]. This metric provides insight into the amount of time pharmacist spend completing tasks they consider to be non-value-added, time that can be redirected to focus on more patient-centered tasks. Our goal is to increase the value quotient by decreasing the amount of time invested in non-value-added tasks. The value quotient formula is shown below:

Value Quotient: (value-added-time / total time)

The numerator was calculated by summing the total time spent performing value-added-tasks for the entire dataset. The denominator represents the total time collected.

4.2.2 Results

Time-motion data was collected during three independent clinic sessions between September and November 2014 for a total of approximately 16.5 hours. These sessions occurred on a Friday; the

clinic sees a mix of general walk-in patients and scheduled MTM patients on Fridays. Two pharmacists were observed during each session, which is the total number of working pharmacists at any given time. Cohen's kappa for the first pilot session was found to be $\kappa = 0.806$, indicating strong agreement between raters. We made several changes to the coding system after the first pilot session: two subcategories were added for completeness (consulting clinician and traveling); the definition of dispensing medication was broadened to accommodate a multiple-step process; and strict initiation and termination times were defined for each subcategory. The final codebook and value categorizations are shown in Table 5 and a complete list of the subcategories, definitions, and their intuition/termination protocols is in Appendix C. After modifying and finalizing the codebook, we recalculated Cohen's kappa to be $\kappa = 0.808$ for the second pilot session. This coefficient further indicates strong agreement between raters.

Table 5: Final codebook for the pre-deployment time-motion study. Items in bold indicate changes made to the codebook after the first pilot study. NVA = non-value-added, VA = value-added.

Major task category	Minor task subcategory	Value categorization
Prescription (Rx) Preparation	Hunting for medication	NVA
	Traveling	**NVA**
	Dispensing medication	NVA
	Labeling medication bottles	NVA
	Duplicate documenting	NVA
Clinician Interaction	**Consulting clinician**	**VA**
	Teaching	VA
Patient Interaction	Counseling patients	VA
	PAP [application] initiation	VA
	PAP [application] discussion	VA
EMR Operations	EMR Operations	NVA / VA
Other	Other	NVA

We compare pharmacist time investment between the five main categories described in Table 5 above: Prescription (Rx) preparation, clinician interaction, patient interaction, EMR operations, and other tasks. Figure 7 shows pharmacist time utilization by each major workflow category, which are deconstructed into their associated subcategories for the entire dataset (16.5 hours). These data are further explained below.

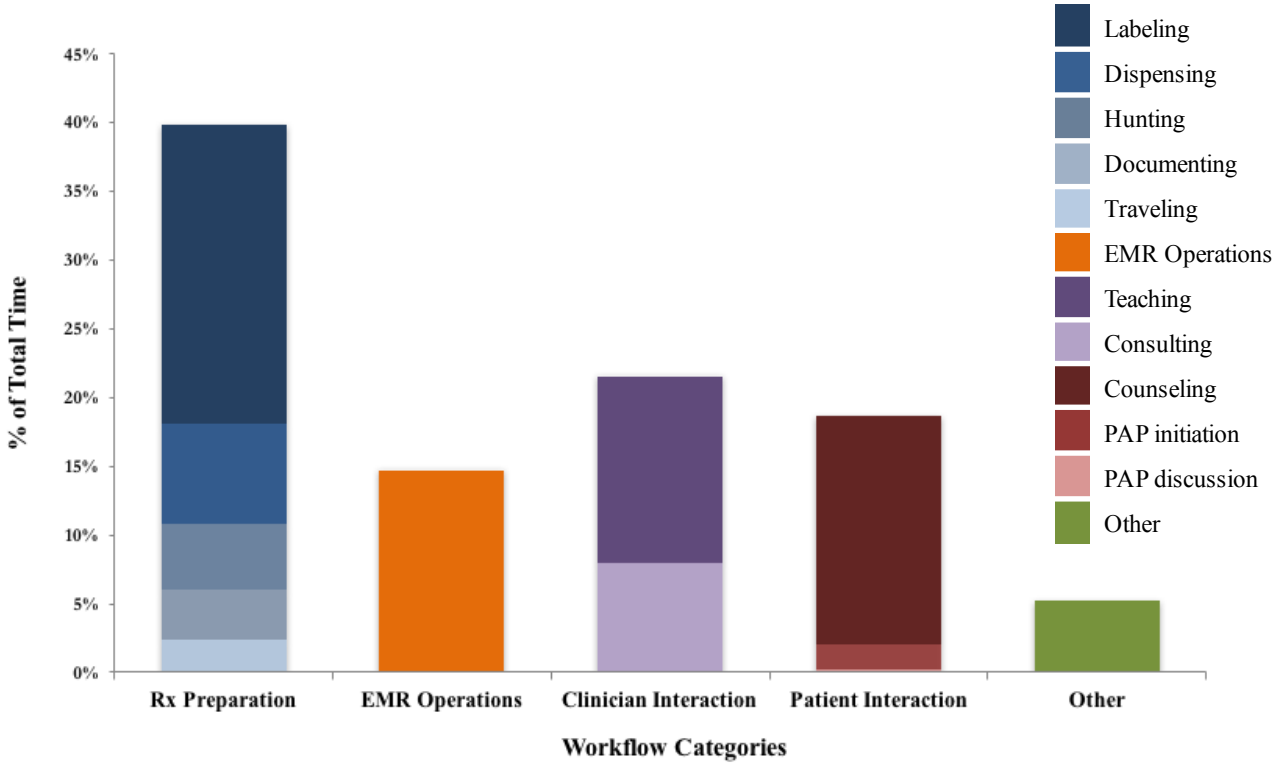


Figure 7: Percent total time investment by major workflow categories and their associated subcategories.

Prescription preparation

Pharmacists invest 39.8% of their time into preparing prescriptions for dispensation. This category includes five subcategories: traveling (2.4%), duplicate documenting (3.6%), hunting for medication in the stock cabinets (4.8%), dispensing medication (7.3%), and handwriting medication labels (21.8%). The pharmacists identified these tasks as non-value-added because they are inefficient and amenable to improvement, potentially via automation. It was difficult to classify dispensing medication, however the pharmacists believed that the process of determining

what to dispense based on what was ordered via CPOE could be more efficient if the orders were presented to them in a single view. For example, using a dashboard that is updated in real-time to display all pending prescriptions. Similarly, while these documentation tasks are necessary steps in the prescription preparation process at the BFC, they consume an unnecessary amount of pharmacist time and resources, in addition to underutilizing their clinical expertise.

EMR operations

Our results indicate that pharmacists spend 14.8% of their time using the EMR. These activities include reviewing relevant patient information, pending medication orders, and modifying incorrect orders entered by physicians via CPOE. The CPOE process is somewhat different at Birmingham and may be unfamiliar to volunteer physicians. For example, the clinic does not allow medication refills and will only dispense a month's worth of medication during a given patient visit. These reasons, in addition to prescribing a drug that is out of stock, may lead to incorrect order entry. The pharmacists report that this correction process can be cumbersome and hinders their productivity. While they recognize that the EMR is both necessary and beneficial for clinical care, it often creates redundant work when combined with their paper-based processes.

It was difficult for the observers to differentiate productive versus nonproductive use of the EHR without interrupting the pharmacist. For this reason, the value quotient was calculated twice for each dataset, once with this task considered to be value-added, and once with it classified as non-value-added.

Clinician interaction

Clinician interaction consumes more than a fifth (21.5%) of pharmacist time. This includes clinician consultation (8%) and teaching students and/or volunteers (13.5%). Due to the limited formulary at the BFC, physicians often utilize the pharmacist's expertise to determine an appropriate and affordable treatment plan. This clinician consultation also provides a teaching opportunity for students, which is a valuable component of the clinic's community-campus model. The pharmacists consider both tasks in this category to be value-added.

Patient interaction

Pharmacists spend 18.7% of their total time interacting with patients, which includes direct pharmacist-patient counseling (16.7%) and initiation and discussion of PAP applications (1.8% and 0.2%, respectively). Initiation of a PAP application occurs when a patient needs a prescription medication and lacks insurance/drug coverage. This process typically beings with the pharmacist or AmeriCorps worker filling out sections of the paper application. The application is discussed with the patient during counseling, as personal financial information must be obtained from the patient. The pharmacists identified all tasks related to patient interaction as value-added, as they are integral to patient education and chronic disease state management.

Other

Tasks unrelated to any aspect of the pharmacist's job, such as casual conversation or using the restroom, consume 5.2% of pharmacist time. These tasks were considered as non-value-added in the value quotient calculation.

Value quotient

Based on the value categorizations made by the pharmacists, the value quotient range for the entire dataset is 40.3% - 54.8% (Table 6). The lower bound represents the value quotient when the EHR was considered a non-value-added task, whereas the higher value includes EHR operations as a value-added component.

Table 6: Value quotients for each dataset. Each figure is calculated when EMR=NVA and EMR=VA.

Session	Value Quotient (%) [EMR = non-value-added]	Value Quotient (%) [EMR = value-added]
1	39.3	56.5
2	43.6	51.4
3	38.0	56.5
Overall	40.3	54.8

4.2.3 Discussion

The pharmacists at the BFC are in expanded clinical roles of direct patient care that extend beyond dispensing medication. While documentation and other administrative activities are necessary, it is important these tasks are completed efficiently so the pharmacists can contribute fully to individual patient care. Our results indicate that pharmacists at the BFC allocate roughly 40% of their time to prescription preparation, most notably the handwritten labeling of medication bottles and related documentation tasks, which is not an optimal utilization of pharmacist time and expertise. The value quotient further supports the conclusion that pharmacists devote more than half of their time to tasks they consider to be inefficient.

The results from this time-motion study act as a data validation component to the results from the qualitative inquiry. Handwritten medication labeling, redundant documenting, and poor inventory tracking were among the most significant workflow challenges uncovered in the

qualitative study. The time-motion data clearly capture the magnitude of this inefficiency for tasks like handwritten labeling and redundant documentation, and identify them as potential areas for improvement through automation. Although perhaps not explicitly, the time-motion data also support claims describing poor inventory tracking as a potential area for improvement. While it was difficult to quantify the challenging aspects of inventory control, we know it contributes to the time invested in hunting for medications and the non-productive use of the EHR (i.e. correcting order entries), which are both symptomatic problems of poor inventory control.

The non-value-added tasks comprising the prescription preparation category in this study represent the main drivers of inefficiency in the BFC. Focusing an informatics intervention on alleviating these challenges, such as computer generated labeling and automated inventory control, may reduce the amount of time pharmacists invest in their completion. Decreasing time invested in non-value-added tasks should produce time savings for the pharmacists. While we cannot be certain how pharmacists will utilize this extra time, we believe their behavior will evolve to focus on more patient-centered tasks, thereby improving the value quotient.

4.2.4 Limitations

It is difficult to assess the generalizability of these findings. The pharmacists observed in this study each have more than seven years of experience at the BFC and understand how the EHR has changed their workflow. These pharmacists often used workarounds, or temporary solutions to bypass a recognized problem, to optimize the amount of time spent on different tasks, thereby minimizing their time investment on non-value-added tasks. We recognize that introducing new

volunteers into the workflow is common practice for free clinics, and that these volunteers may take longer to complete the same tasks due to a learning curve.

Measuring the variability between pharmacists could be a useful study, yet this would be difficult at the BFC because the pharmacists do not evenly divide the task load (i.e. one pharmacist will do all the medication labeling, while the other focuses on counseling). These data maintain consistency across clinic sessions and measures time investment of the most experienced BFC volunteer pharmacists. Thus, the calculated value quotients may be an overestimate, because less experience pharmacists are likely to spend more time on non-value-added tasks due to not having the opportunity to develop efficiency workarounds. To address this, it is necessary to engage pharmacists with varying levels of BFC experience during the user-centered design process.

4.3 PROTOTYPE AND TEST

The mixed-methods needs assessment studies provided us with a greater understanding of the interactions and synergies of the dispensary workflow. At this stage of the research, we understood the specific problems pharmacists encounter at the BFC, proposed problem-driven interventions to address them, and articulated the outcome for which we were optimizing: efficiency. The individual interventions we proposed as part of the qualitative investigation would provide the foundation for a dispensary management information system, or RxMAGIC.

We proposed a framework for RxMAGIC that was grounded in the interventions described above. The goal was to deliver a pharmacist-facing tool that would improve their ability to efficiently deliver medication services at the BFC. At a high-level, we intended for

RxMAGIC to standardize the dispensing practice, strengthen supply chain integrity, and enhance process efficiency and transparency between the pharmaceutical and clinical services at the BFC. We recognized that RxMAGIC would be most effective if it could receive e-prescription data from the EHR, which would require the use of health data standards and vocabularies. Lastly, to maintain the low-cost, potentially generalizable model of implementation, we proposed the application as an open-source, web-based system that would be flexible, cheap, and amenable to customization.

Before considering the more technical aspects of the implementation (i.e. health information exchange and an open-source framework), we wanted to ensure that it was feasible to deploy a system like RxMAGIC at the clinic, and that the proposed functional requirements were complete from the perspective of the users. Continuing with the contextual user-centered design process, we involved users early in the development process. We built a proof-of-concept prototype that captured enough of the proposed system functionality to support user testing. This allowed us to iteratively refine system design, acquire an even greater technical understanding of the problem, and understand the utility of the system for different users.

In this section, I discuss the creation and validation of system requirements which took the form of user stories. User stories are high level statements that describe desired software features and their benefits from an end-user perspective [109]. We chose a subset of the user stories to build the RxMAGIC prototype, which we showed to potential users in laboratory environment. I discuss the results of this usability test and how they guided incremental expansion of the prototype system.

4.3.1 Methods

4.3.1.1 User story development and prioritization

We transformed data from the needs assessment studies into user stories that describe software features from the perspective of three user roles at the clinic. User stories are an agile approach to facilitate system planning, prioritize functional components, and most importantly, integrate the end user's perspective into the development plan at the earliest stages [109]. We used the following template to format the user stories:

"As a <role>, I want <desired feature> so that <benefit>."

We wrote 44 user stories for three different roles: pharmacists (28), physicians (6), and clerical staff (10). These are the three primary user groups at the clinic who are involved in patient care; all three groups have access to the EHR. We asked a representative user from each group to modify and approve the user stories. This validation process ensured that the proposed system design was complete and in line with users' expectations.

We selected a subset of the user stories to develop a proof-of-concept prototype to ensure RxMAGIC was technically feasible. As user-centered approaches suggest, we planned to implement the remaining user stories and any additional functionality after prototype development and testing. We focused on the pharmacists' user stories as they are the primary users of RxMAGIC, and thus all other user stories depend on their successful implementation. We chose 13 of the 28 pharmacist user stories to implement as part of prototype development which are shown in Table 7. These user stories were selected because they capture the minimum set of requirements for RxMAGIC, which include inventory tracking, computer generated labels (i.e. electronic dispensation) and some basic PAP functionality.

Table 7: User stories selected for prototype implementation.

As a pharmacist (goal)…	**…so that (benefit)**
I want to know when a clinician has prescribed a medication for a new BFC patient…	…so that I can ensure that this drug is in stock prior to end of patient/clinician visit.
I want to have visibility into the current medication inventory…	…so that I can inform AmeriCorps staff of low medication stock levels.
I want to have visibility into the current medication inventory…	…so that I don't physically waste time looking for medications that we do not have.
I want to have visibility into the current medication inventory…	…so that I can efficiently aid clinicians in determining what medication and dosage we are currently able to dispense to patients.
I want to have visibility into the distinct inventories maintained by the dispensary (i.e. PAP and general stock) …	…so that, when a drug is in stock, I know whether to look in the PAP cabinet or general stock cabinet.
I want to attach preprinted adhesive labels to dispensed medications…	…so that my documentation tasks become more efficient.
I want to attach legible labels to dispensed medications…	…so that the patient clearly understands how much medication to take and when throughout the duration of the prescription.
I want to attach detailed labels to dispensed medications…	…so that all labels are complete with the necessary information required for adherence to dispensing standards.
I want to know the expiration date of all medications…	…so that I can prioritize dispensation of near-expiry drugs to reduce medication wastage.
I want to know the lot number of all medication in stock…	…so that I can quickly respond to medication recalls by identifying patients who have received medications from a specific batch.
I want to view past medication dispensation from the BFC, by patient…	…so that I can more easily identify potential drug-drug interactions and be reminded of any differences between what was prescribed and dispensed.
I want electronic dispensation to update drug inventory in real-time…	…so that I am informed of low stock levels in the *timeliest* fashion.

I want to be able to identify patients who are currently enrolled in a PAP program…	…so that I can efficiently locate that particular medication by patient name in the PAP inventory.

We created a logical data model for RxMAGIC with a graphical schema utilizing an entity-relationship (ER) model that was generated in MySQL Workbench. The prototype was developed using a relational database model and SQL; phpMyAdmin, a free software tool written in PHP, was used to handle administration of MySQL over the web. We used HTML and PHP to build a functional web interface, and a 1D barcode scanner and Eltron Programming Language (EPL) compatible printer to produce medication labels. The prototype did not include the desired health data standards to achieve interoperability (i.e. RxNorm and HL7 messaging); we manually curated a representative medication list to support user testing.

4.3.1.2 Prototype functionality

The primary objective behind building the RxMAGIC prototype was to elicit reactions from potential users regarding certain functional components of the desired system. Thus, functionality was limited and the interface was not optimized for usability. I describe basic elements of the prototype below and show some screenshots to provide more context.

Automated inventory control

RxMAGIC maintains two separate inventories for the general and PAP medications to reflect the physical layout of the dispensary. Users can enter inventory items into the general stock by selecting a medication name from the dropdown list and completing the fields for medication lot number, expiration date, and received quantity. Once the entry is saved, a label is printed with a

barcode that encodes a unique inventory identification number for each unit of medication in the inventory.

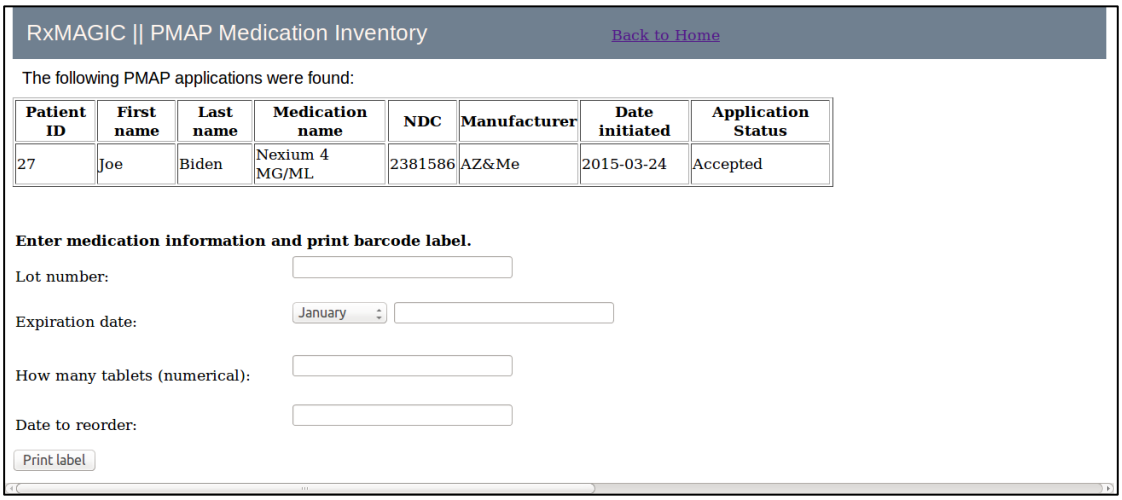


Figure 8: Inventory entry screen for PAP medications.

Entering items into the PAP inventory has a slightly different workflow because each medication is tightly coupled to a patient name. Users are first prompted to search for the appropriate patient who is enrolled in a PAP[2] before entering the medication details displayed above (Figure 8). In addition to these fields, users are also required to enter a 'date to reorder' the medication. Currently, the AmeriCorps member writes this date on each medication item with a marker. While not implemented in the prototype, this field will eventually be used to remind the pharmacists to reorder this PAP medication.

Electronic dispensing

The prototype includes a 'prescription dashboard' that lists pending prescriptions to be filled by the pharmacists (Figure 9A); this is a simulation of the desired functionality. Eventually, this

[2] At the BFC, pharmacists refer to PAPs as PMAPs, which is why PMAP is used within the RxMAGIC application as shown in the screenshots.

dashboard will be populated with e-prescriptions that are sent from the EHR. Once a prescription is selected, the user is prompted to scan the barcode on the label of the medication from which she is dispensing and enter the appropriate quantity to dispense (Figure 9B). The user selects 'print label' to print the prescription label once complete.

Patient management

The prototype also includes some basic patient management functions such as patient registration and search capabilities. We also implemented a function that allowed users to identify patients in PAP applications and update application status within RxMAGIC, although these features were not intended to replace the actual paper process of PAP applications. These functions were implemented to help us understand how best RxMAGIC could support the PAP process, if at all, as this was not sufficiently capture this in the needs assessment studies.

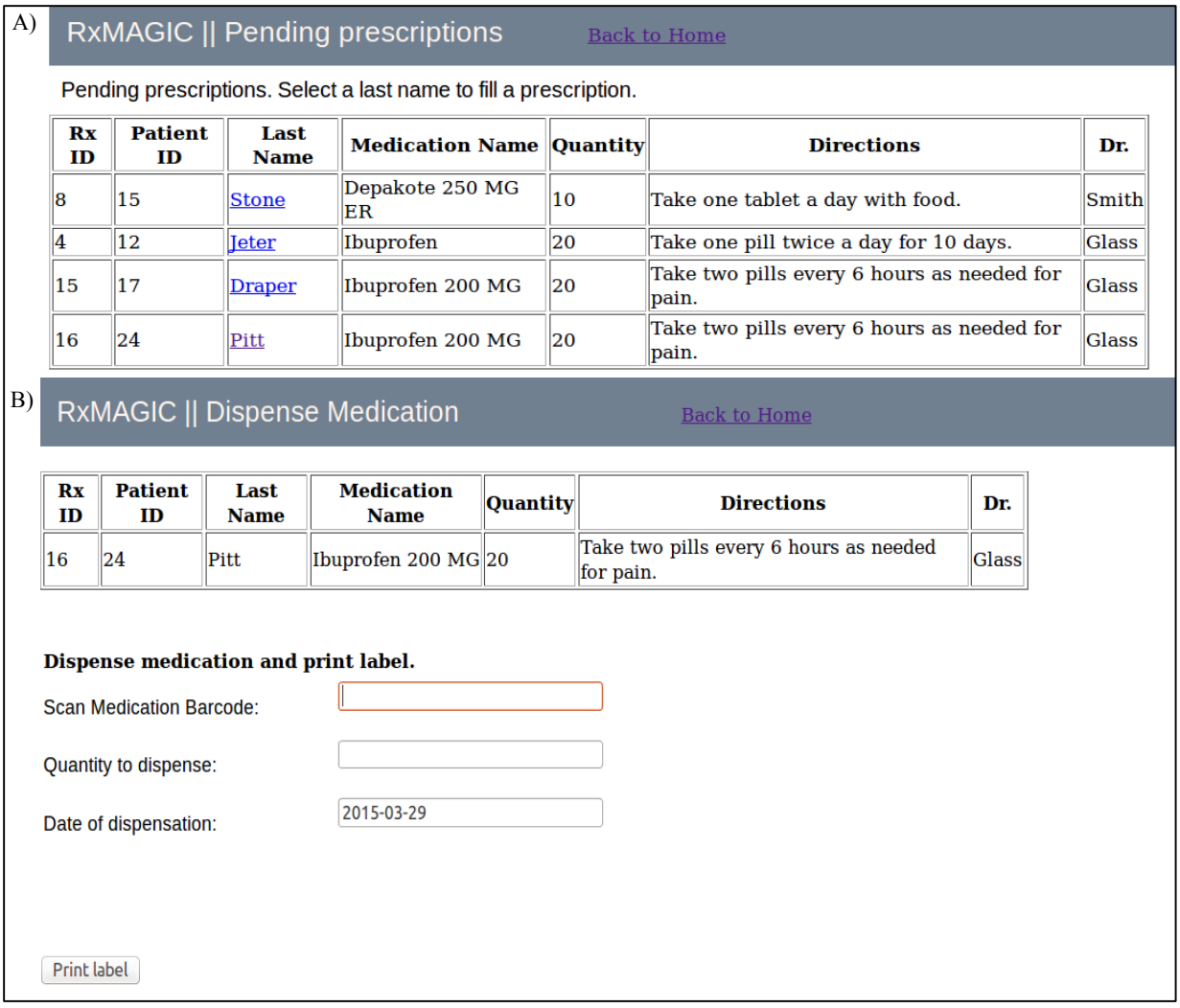


Figure 9: Electronic dispensing screens in prototype. A) Prescription dashboard with queue of prescriptions. Selection of patient name brings user to (B) patient-specific dispensing screen. User completes fields to print prescription label.

4.3.1.3 Usability testing

To verify that RxMAGIC has the potential to effectively meet pharmacists' needs and expectations, we conducted a laboratory-based usability evaluation with potential users. We recruited four pharmacy students and one resident pharmacist to participate in the usability study. All participants were affiliated with the University of Pittsburgh School of Pharmacy with an emphasis in underserved care and global health, and had experience volunteering at the BFC or a similar low-resource health center. Pharmacy students were an ideal group for initial user testing

as they frequently rotate at the clinic, thus their feedback would provide insight into the potential learnability of the system for new users. The University of Pittsburgh Institution Review Board approved this study as exempt (PRO15010330).

We conducted a think-aloud study in which participants were asked to complete five tasks within the system while discussing their perceptions of different features. These tasks included patient registration, inventory entry (general and PAP), medication dispensing, and PAP application initiation. For example, participants were given a bottle of Ibuprofen 200 mg oral tablets and asked to enter that item into the medication inventory. To complete this and print an inventory label, they had to enter the lot number, expiration date, and quantity into RxMAGIC. Additional details of these tasks are in Appendix D. We conducted the study in an office environment (Department of Biomedical Informatics) outside of the clinic, and used fake patient data to facilitate task completion. We passively observed each participant during the study and captured qualitative data in the form of participant comments. These data were used to identify positive and negative features of the system as described by the participants.

4.3.2 Results

Participants completed all five tasks without any failures or observed/reported confusion. They provided mostly positive feedback regarding the feasibility of the system at the BFC and the potential impact it would have on improving inefficient aspects of their workflow. Three of the four users praised the “clean interface” design and its lack of unnecessary clicking, screens, and dialogue boxes. These comments were often supplemented with comparisons to the cumbersome EHR interface. Further, they emphasized the importance of maintaining two separate inventories

for the general and PAP medications, as they consider these to be distinct inventories in the clinic.

A commonly reported interface suggestion was the inconsistent method by which dates were entered within the application. There were three different instances where users were required to enter a date: expiration date, date to reorder PAP items, and patient birthdate. We only used a standard date-picker widget for the latter because we were unsure how best to represent the other two fields. As expiration dates are typically listed as MM/YYYY on most medication bottles, we just required the user to select a month from a dropdown menu and manually enter a year (Figure 8). However, the date to reorder field did not specify how the date should be entered which confused all participants (Figure 8). We recognized that all date fields should be consistent in the application and with the user's mental model. Most users indicated that they prefer the use of a standard date-picker widget (i.e. selecting a date from a calendar) when interacting with date fields. We have incorporated these preferences in the production version of the application.

Some other commonly reported suggestions included the ability to print medication directions in Spanish and save patient language preferences within the application. Further, participants found it difficult to locate low-inventory items within RxMAGIC. Most participants suggested this idea of an alert feed that would tell them when a medication item fell below a certain threshold, indicating that item should be reordered. They noted that other alerts could be present on this hypothetical alert feed as well, such as medication items approaching expiry and new prescription alerts. Lastly, many participants suggested the use of colors or icons to increase the visual appeal of the RxMAGIC interface, as other applications leverage certain colors to

indicate meaning. For example, participants suggested the use of green buttons to indicate the printing function and red font to indicate low inventory items.

Although limited functionality was implemented in the prototype to support the PAP application process (i.e. initializing an application), we realized that it would not be feasible to address all aspects of the PAP application process. Most participants claimed that the PAP functionality in the prototype would likely create redundant work for them without making these tasks easier or more efficient. Therefore, we decided to not incorporate significant PAP functionality because it may decrease the perceived usefulness of RxMAGIC from the perspective of the AmeriCorps. However, results from the usability study did provide insight as to how RxMAGIC can assist pharmacists and AmeriCorps with this process. Participants suggested that a report summarizing PAP medications to be reordered would be useful, which will be addressed in the production version. User stories regarding the PAP process will be modified to reflect these results.

4.3.3 Discussion

The results from the 'prototype and test' phase of this research demonstrate the feasibility of deploying RxMAGIC at the BFC, while also providing a greater technical understanding of the problems at the clinic. The participants' suggestions about desired interface components and the burdensome PAP functionality inform continued development of RxMAGIC, and user stories were modified to reflect these changes. Specifically, the use of an alert feed to update users of poor inventory levels, expired medications, and PAP reorders will be a significant component in the development of the production version of RxMAGIC.

The prototype included a subset of the desired functionality to facilitate inventory tracking and dispensing. Although the results were generally positive, there were still some important problems that needed to be addressed before implementation. In addition to the remaining user stories, these included, but are not limited to, improving the user interface, implementing reporting features, addressing Spanish-speaking needs, and incorporating data standards. Use of data standards are necessary to operationalize RxMAGIC so that it is interoperable with the existing EHR. In addition to achieving interoperability, implementing the 'alert feed' that would update in real-time required significant changes to the schema and potentially additional data collection. For example, to generate alerts for low inventory items, we needed to understand the minimum amount of inventory that should be on the shelves for high-usage medication items. This required access to data that summarizes medication consumption patterns at the BFC.

While the prototype was developed in PHP, discussions with colleagues demonstrated the importance of using a potentially superior framework to develop web applications. Thus, in addition to the functional changes described above, we planned for the final application to be developed using Ruby on Rails. I further elaborate upon this in Section 4.4 below.

4.4 EVALUATE USABILITY OF THE PRODUCTION VERSION

To improve aspects of the prototype, we conducted additional contextual inquiry sessions in the BFC dispensary to update our understanding of certain processes. We directly observed two pharmacists in the dispensary over the course of five three-hour sessions. Both pharmacists that

were observed participated in the prototype usability study and provided feedback during the observations to inform continued development.

Results from the prototype usability evaluation, in addition to these observations, uncovered more technical challenges that were not addressed in the prototype system such as the ability to dispense medication from multiple bottles. In addition to some of the functional modifications previously described (i.e. interoperability, the real-time alert feed, and an optimized user interface), we chose to develop the production version in Ruby on Rails rather than PHP. While PHP provided a quick and easy entry point for a prototype system, the RxMAGIC development team was most familiar with Ruby on Rails. To reduce the learning curve for the primary software developer, we developed the production version of RxMAGIC using Ruby on Rails, using the prototype as a skeletal starting point. We loosely adopted an agile methodology to facilitate development, thus most of the terms and artifacts I use in this section are taken from agile practices.

In this section, I discuss the artifacts used for the development of RxMAGIC, which was implemented with Ruby (v 2.2.3) on Rails (v 4.2.0), MySQL, bootstrap, and jQuery. I also describe the use of health data standards to achieve interoperability. As a fully functional application is the result of user story implementation, I discuss features of the RxMAGIC application in the results component of this study. Lastly, I discuss the laboratory-based usability evaluation we conducted with pharmacists from the BFC to understand and resolve potential interaction challenges.

4.4.1 Methods

4.4.1.1 Modifying product requirements

We significantly modified the user stories to reflect a deeper understanding of the challenges at the clinic and the intended RxMAGIC functionality. This process resulted in a new set of 47 user stories that spanned all three user roles: pharmacists (34), physicians (5), AmeriCorps (8). We grouped related user stories into distinct epics, which, in agile methodologies, are used to define larger feature requirements. Epics are used to describe a specific scope of work and typically are comprised of 5-10 user stories [109]. Eight epics were implemented that include: 1) View and maintain inventory through a web-based browser, 2) Use electronic dispensation to update drug counts in real time, 3) Produce computer generated labels upon dispensation, 4) Automatically alert pharmacists of new medication orders after CPOE, 5) Provide soft stop[3] alert feed functionality that is updated in real time (five different alert types), 6) Automatically generate the activity sheet and enable PDF creation, 7) Provide medication reordering support for the PAP application process, and 8) Establish a user management framework. Table 8 shows an example of an epic in this context and its related user stories; a complete list of the epics and user stories is in Appendix E.

Table 8: Eight epics used to describe large feature requirements.

Epics used in RxMAGIC development
Epic 01: View and maintain inventory through a web-based browser
Epic 02: Use electronic dispensation to update drug counts in real time

[3] A soft stop alert requires minimal or no action/acknowledgement of the alert on the part of the user to proceed within the system.

Epic 03: Produce computer generated labels upon dispensation
Epic 04: Automatically alert pharmacists of new medication orders after CPOE
Epic 05: Provide soft-stop alert feed functionality that is updated in real-time (five types)
Epic 06: Automatically generate the activity sheet and enable PDF creation
Epic 07: Provide medication reordering support for the PAP application process
Epic 08: Establish a user management framework

Table 9: Example of an epic and its associated user stories from the pharmacist perspective.

Epic 05: Provide soft-stop alert feed functionality that is updated in real time (five alert types)	
User Story 01:	As a pharmacist, I want to know the approaching expiration date of all medications so that I can prioritize dispensation of near-expiry drugs to reduce wastage.
User Story 02:	As a pharmacist, I want to know when medications are expired so that I can keep patients safe by deleting them from the inventory.
User Story 03:	As a pharmacist, I want to know the lot number of all medications so that I can quickly respond to medication recalls and keep patients safe.
User Story 04:	As a pharmacist, I want to customize par levels (i.e. medication thresholds) so that I am in control of low inventory alerts.
User Story 05:	As a pharmacist, I want to know when a medication item has fallen below a par level so that I can add the item to the activity sheet and avoid stock outs.
User Story 06:	As a pharmacist, I want to know when a PAP patient hasn't returned to the clinic in six months so that I can decide if I should transfer the medication item to the general stock.

We prioritized the user stories within each epic so that the pharmacist user stories would be implemented first; we also prioritized implementation of individual epics. We created wireframes using Mockingbird (https://gomockingbird.com/home) to supplement certain user stories and guide initial interface design. We then developed acceptance criteria or additional specifications for most user stories that were not implemented in the prototype version. Acceptance criteria provide a more detailed scope of the requirement and act as a checklist of parameters to ensure the user story is completed and working [109]. We recognize that this approach of developing acceptance criteria was somewhat non-traditional and that they acted more as a list of defined specifications. This was partly due to the previous development of a functioning prototype. These criteria included a step-by-step description of end-to-end user flow, the impact of user stories on other features, the output of artifacts after completion of a user story, and any potential negative scenarios of the functionality. Table 10 shows an example of the acceptance criteria we defined for User Story 05 from Table 9.

Table 10: Acceptance criteria for User Story 5 for E5.

Epic 05: Provide soft-stop alert feed functionality that is updated in real time (five alert types)

User Story 05: As a pharmacist, I want to know when a medication item has fallen below a given par level so that I can promptly add the item to the activity sheet and avoid stock outs.

Acceptance Criteria:

- Alert should be generated when the drug count is < = the defined threshold (thresholds defined in separate document).
- Alert should be generated at two time points in the day as requested by pharmacists.
- Alert should use identical icon as general inventory and be titled General: Low Inventory.

- Alert should read '[Medication Item] stock below par level.'
- Alert should have two options: 1) dismiss and 2) add to activity sheet.
    - Dismiss: Alert should be removed from the alert feed but reappear the next day.
    - Add to activity sheet: When user selects this option, the medication item should be automatically added to the 'stock meds to be replenished' section of the activity sheet. Upon selecting this option, a validation message should appear that reads '[Medication item] has been successfully added to the activity sheet.'
- The alert should not reappear if the user has added it to the activity sheet.
    - User will have alternate route of adding items to activity sheet should they need to repeat this process.

The epics, user stories, acceptance criteria and wireframes comprised a product requirements document that constantly evolved throughout the duration of the development process. In addition to these items, we created several user scenarios to ensure RxMAGIC would meet varying user expectations and requirements once deployed. Further, we reproduced the physical artifacts from the qualitative study, i.e. inventory/dispensation labels and the activity sheet, to illustrate their new representation within RxMAGIC.

Health data standards

As the BFC is within the UPMC network, all components of the RxMAGIC application (e.g. database server, application server) must be within the UPMC network and adhere to all necessary privacy and security requirements. Thus, as part of the development process, we worked with several teams (i.e. UPMC and EpicCare) to ensure that all necessary steps were taken in order to meet these requirements. One of the first requirements for deployment was that RxMAGIC authenticates users using UPMC's active directory services. To this end, RxMAGIC

supports a lightweight directory access protocol (LDAP) that allows users to access the application using their UPMC credentials. All RxMAGIC users have valid UPMC accounts.

RxMAGIC leverages HL7 (v 2.3) messaging and RxNorm to achieve functional and semantic interoperability with the EHR. HL7 messaging was chosen because there was already an outgoing HL7 framework in place at the clinic, and these messages included all the information RxMAGIC needed to facilitate dispensation. We use Mirth, a cross-platform HL7 interface engine, to receive HL7 messages and transform them into a standard format that is written to the RxMAGIC database. While Mirth allows bi-directional communication of HL7 messages, RxMAGIC does not send HL7 messages back to the EHR because the EHR is not technically "listening." Thus, this connection is unidirectional. RxMAGIC uses RxNorm as its drug nomenclature to achieve semantic interoperability with the EHR, which uses the vendor's proprietary NDC nomenclature. The NDC of a drug product in an HL7 message is mapped to the appropriate concept in RxNorm. Drugs must exist in RxNorm to be inventoried in RxMAGIC.

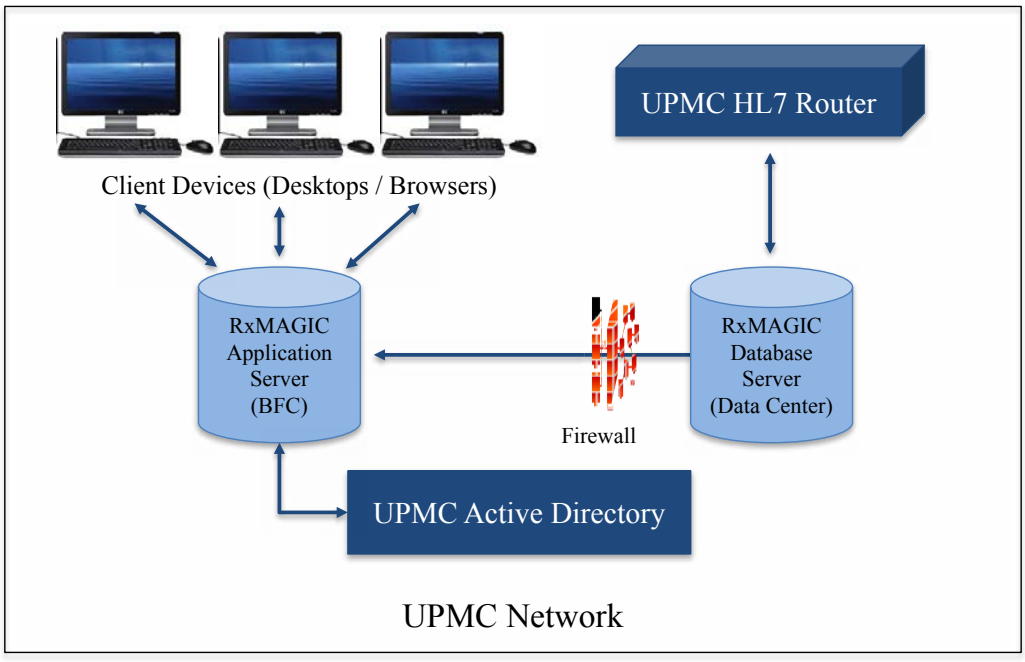


Figure 10: Network diagram of the RxMAGIC implementation.

The network diagram in Figure 10 illustrates the various components of the RxMAGIC application. All machines are located within the UPMC network. The RxMAGIC application itself is hosted on a web server that is physically located in the BFC, whereas the database is hosted on a virtual server in a UPMC data center. This was done to adhere to certain security requirements within the UPMC enterprise, however, other configurations are possible depending on the security requirements of the organization.

4.4.1.2 Usability testing

We iteratively tested the production system throughout the development process, typically after implementation of an entire epic, to ensure user stories functioned as designed. To complete functional testing for each epic, we identified functions that RxMAGIC was expected to perform and created fake input data based on the function's specifications (i.e. Table 10). We defined specific steps for completion of each function, which we referred to as 'test tasks.' After execution of each test task, we compared the actual output to the expected results that should be achieved upon completion of the test task. This allowed us to check whether the application works as per the original design specification. Any discrepancies between the actual and expected results were investigated and the specifications were modified as necessary. For example, we tested the first specification in Table 10 that states "alert should be generated when the drug count is < = the defined threshold" by creating an inventory entry with a stock count that is lower than the threshold for that item. The expected result of this test task is an alert that notifies pharmacists to reorder this specific item. If the alert was not generated, then this specification was not implemented properly.

Upon implementation of all user stories, and multiple rounds of functional testing, we conducted a second laboratory-based usability evaluation with pharmacists who were actively volunteering at the BFC. Our goal was to diagnose potential interaction problems and ensure RxMAGIC performed the functions for which it was designed. Identifying these challenges before deployment would allow us adequate time to resolve them through careful redesign.

Similar to the preliminary usability evaluation, we conducted a think-aloud protocol to gain a realistic understanding of how pharmacists navigate the system without any training on how to do so. We recruited pharmacists and AmeriCorps from the BFC via email to participate in the study, which took place in an office (Department of Biomedical Informatics) location outside of the clinic. During the study, we asked each participant to complete 11 tasks that were slightly tailored to their user role, as views and functionality in the application vary depending on the user role. Participants rated each task on a five-point scale to indicate its ease of completion, where 1 = "very difficult" and 5 = "very easy." We calculated an average score for each task at the completion of the study.

We used Kazaam Screencaster for Ubuntu (https://launchpad.net/kazam) to record on-screen action and audio into a video file. Each file was annotated using ChonoViz [110] to identify commonalities amongst participant responses describing positive and negative features of the system, potential interaction problems, and suggestions for improvement. We used these data to compile a report of modifications to be implemented before deployment, which were prioritized using the MoSCoW method [111]. This is a technique used to prioritize requirements into four categories: *Must have, Should have, Could have, Won't have*. Requirements labeled as *must have* are both important and required changes before deployment; requirements labeled as *should have* are important but not vital (i.e. the solution is still viable without them);

requirements labeled as *could have* are desirable but not necessary in the first release. We did not use the *won't have* category in this analysis.

4.4.2 Results

RxMAGIC is a web-based dispensary management information system that is designed to focus on processes associated with medication management in a free clinic setting. The application supports these processes with four high-level features, including: automated inventory tracking and reduction, electronic dispensing and labeling, automated reporting and alerting, and support for the PAP reordering process. RxMAGIC is a freely available application; the source code can be downloaded from GitHub (https://github.com/amf022/RxMAGIC). Once implemented, the application can be accessed through any web browser. RxMAGIC has minimal requirements in terms of additional hardware, which are in the form of an EPL compatible printer and 1D barcode scanner. At the BFC, there are two workstations in the dispensary, both of which are used to access RxMAGIC (Figure 5). Thus, each workstation has a barcode scanner and printer.

4.4.2.1 Production functionality

I describe how these four features support aspects of the medication management process at the BFC. These stages include inventory tracking, order communication and interoperability, dispensing, and alerting and reporting. Not all possible screens of the application are illustrated in the following screenshots.

Inventory tracking

RxMAGIC provides automated inventory control and visibility by tightly coupling each medication item to a unique barcode. The inventory features of the production version are similar to the prototype, however they are optimized for usability and interoperability (i.e. validation messages, colored buttons, use of RxNorm). When new 'general stock' medications arrive, pharmacists or AmeriCorps log their receipt by entering medication details (i.e. name, expiration date, lot number, and received quantity) in RxMAGIC. For PAP medications, users must first navigate to the patient profile screen before entering the medication item into the distinct PAP inventory (Figure11). In addition to the details described above, users also enter a 'date to reorder' the medication and an appropriate pharmaceutical company. This entry creates a unique barcode label that is affixed to the medication item and used to identify that item during dispensation. Users can view details of all stock items and are able to edit stock quantities, reprint inventory labels, or delete items from the inventory.

The inventory screen also includes a stock summary panel that provides a high-level view of low-inventory items, well-stocked items, items approaching expiry, and expired items; this is a new feature of the production version (Figure 12). When selected, these features provide a more detailed understanding of the inventory to facilitate efficient and accurate management. Stock availability is determined by comparing the current drug count to a pre-determined par level. Par levels indicate the minimum amount of stock that should be on the shelves at any time. We calculated par levels for fast-moving drugs based on pharmacist expertise and a year's worth of consumption data from the BFC (i.e. activity sheets). These levels are customizable and can be created for new medication items within the application

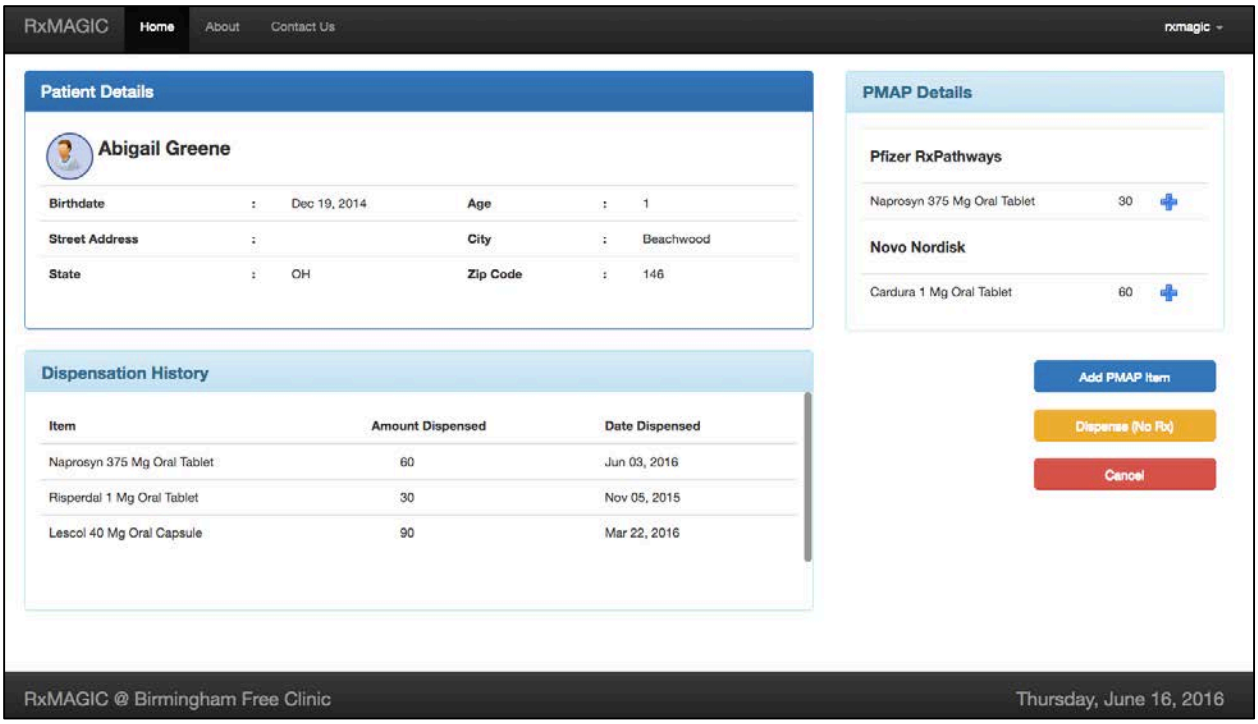


Figure 11: Patient profile screen. Users can add new PAP items by locating a patient and selecting either 'add PMAP item' or the blue plus sign next to an existing application.

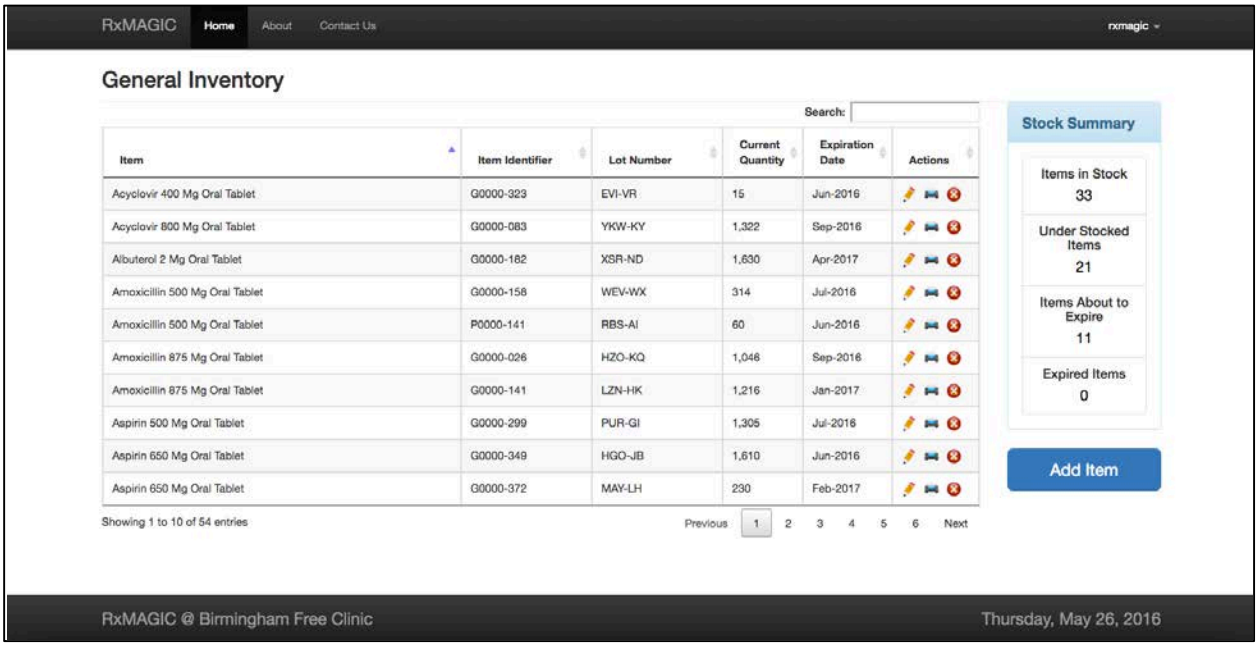


Figure 12: General inventory screen. Users can add new items to this inventory by selecting ‘add item.’

Order communication and interoperability

RxMAGIC does not have a direct impact on the medication ordering process; physicians continue to see patients and prescribe medication in the EHR using CPOE. However, like pharmacists, physicians can also view the available inventory within RxMAGIC at the point of prescribing (Figure 12).

When a medication order is entered in the EHR, it is packaged as an HL7 message, electronically transmitted and transformed by Mirth into a format that is accepted by RxMAGIC, and loaded into the RxMAGIC database. The patient demographic information in the HL7 message is used to create a patient record within RxMAGIC, if one does not already exist, and records the associated prescriptions. These prescriptions are stored in the RxMAGIC patient profile so that pharmacists can view a patient's dispensation history at the BFC (Figure 11).

Incoming prescriptions are added to a dashboard screen within the application and prioritized based on their receipt which initiates the dispensing process (Figure 14). In addition to this screen, a 19.5-inch dashboard that runs on a Raspberry Pi mini-computer is mounted in between the two pharmacist workstations to display pending prescriptions (Figure 13). This dashboard was implemented to alleviate challenges with insufficient process notification in EpicCare.

Pending Prescriptions — Birmingham Free Clinic

Patient Name	Prescribed Medicine	Quantity	Type
Harry Conn	aspirin 500 MG Oral Tablet	60	PMAP
Jenny Walker	aspirin 500 MG Oral Tablet	90	General
Darlene Osburn	amoxicillin 500 MG Oral Tablet	30	General
Theo Dunn	isoniazid 100 MG Oral Tablet	15	General
Pablo Alfonso	Zestril 5 MG Oral Tablet	60	PMAP

Figure 13: Information displayed on the 19.5-inch dashboard screen. Users cannot interact with this dashboard.

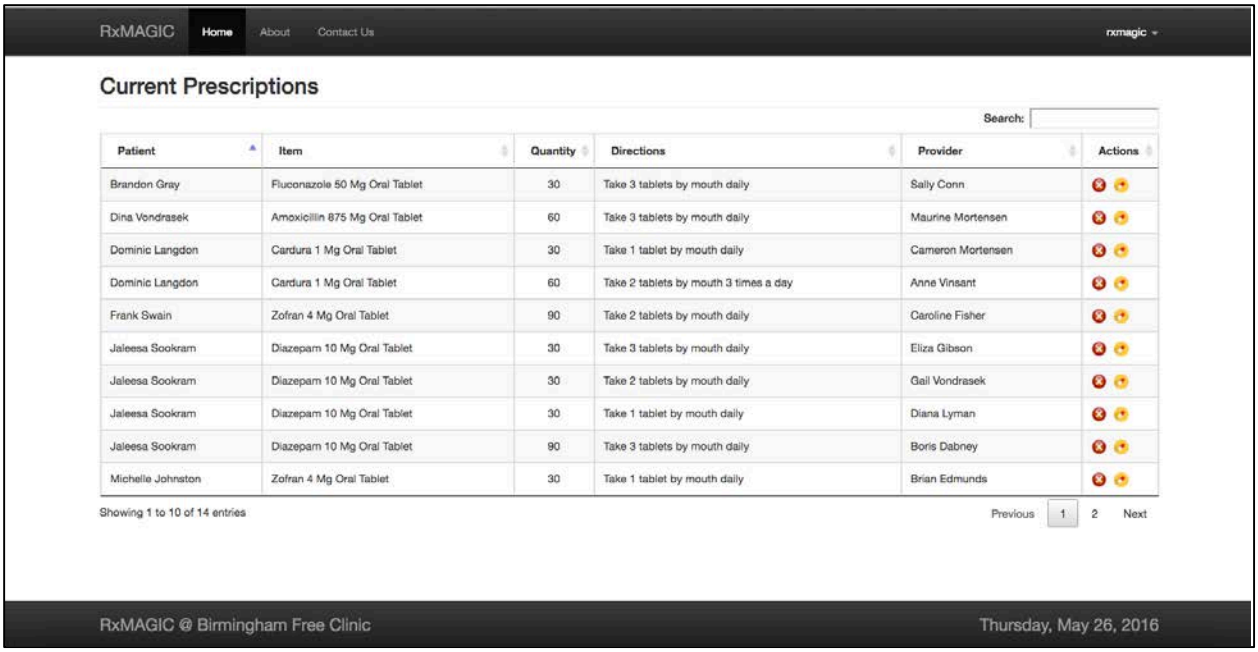


Figure 14: Prescription dashboard within the RxMAGIC application. Users select a prescription to fill by selecting the pill icon in the 'action' column.

Dispensing

Pharmacists electronically dispense medications by selecting a prescription from the prescription dashboard (Figure 14). Selection of a prescription brings them to the patient-specific dispensing screen (Figure 15). Here, pharmacists can review the prescription and select the preferred patient language (English or Spanish) which will determine how the medication directions are printed. Currently, if Spanish is the selected language, the medication directions will not print on the label so that the pharmacist can manually translate them.

The dispensing screen also provides inventory suggestions based on expiration date and inventory type (i.e. PAP or general). Items closest to expiry will appear at the top of the list to encourage pharmacists to dispense medications that may be wasted due to expiry. The pharmacist scans the barcode label of the stock medication and enters the dispensed quantity; if the dispensed quantity does not equal the prescribed quantity, RxMAGIC assumes the pharmacist is dispensing medication from a second bottle. Once these two values are equal, a label is automatically printed and the stock counts are adjusted appropriately within RxMAGIC.

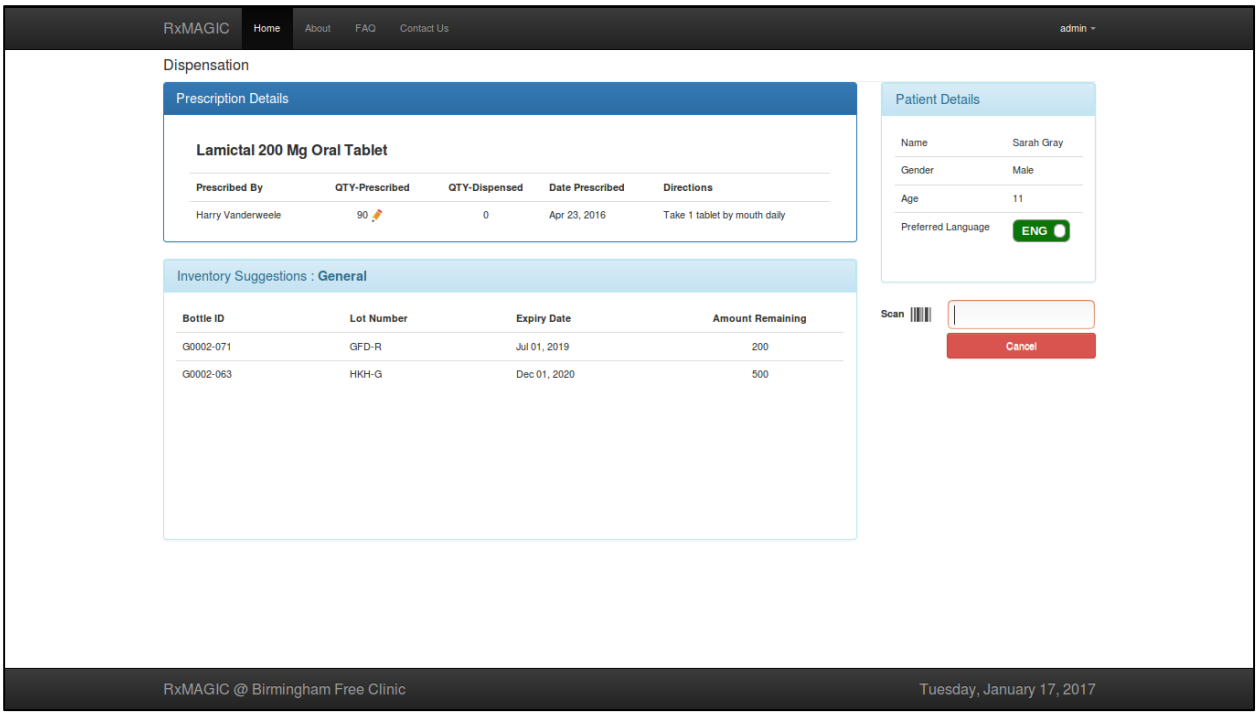


Figure 15: Patient-specific dispensing screen. Users are brought here after selecting a prescription in Figure 14.

Alerting and reporting

As suggested in the preliminary usability study, an alert feed was implemented on the home screen of the application that initially included five different alert types (Figure 16). These are soft-stop alerts in that they don't interrupt and prohibit the user from completing a task; however, they are actionable. Pharmacists are alerted of new prescriptions, items approaching expiry, expired items, low-inventory items (PAP and General), and underutilized PAP items. Alerts for underutilized PAP items are generated when a PAP-receiving patient has not returned to the clinic in six months. This is intended to encourage the pharmacist to contact the patient or transfer the item to general stock so that it can be used for another patient.

Alerts for low-inventory items are generated using the same query that creates the stock summary panel. However, the alert provides instant access to information that allows the pharmacist to efficiently determine a course of action at the point of care (i.e. add the item to the activity sheet). The activity sheet is automatically populated with each dispensation and can be

accessed at any point during clinical care (Figure 17). This document can be exported as a PDF or saved within the application. All historical activity sheets are stored in the application and able to be viewed at any time. In addition to the activity sheet, RxMAGIC creates a report for the AmeriCorps member to facilitate the PAP reordering process. Users can select an appropriate date range within the application to understand which PAP medications are due for reordering.

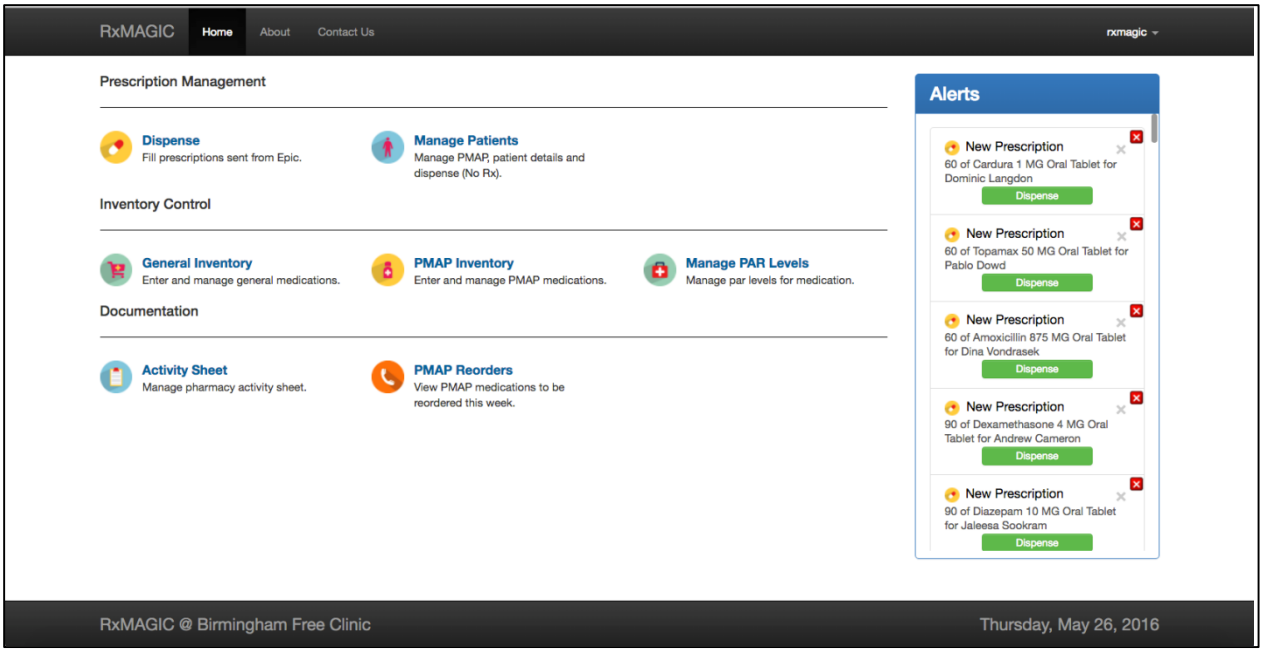
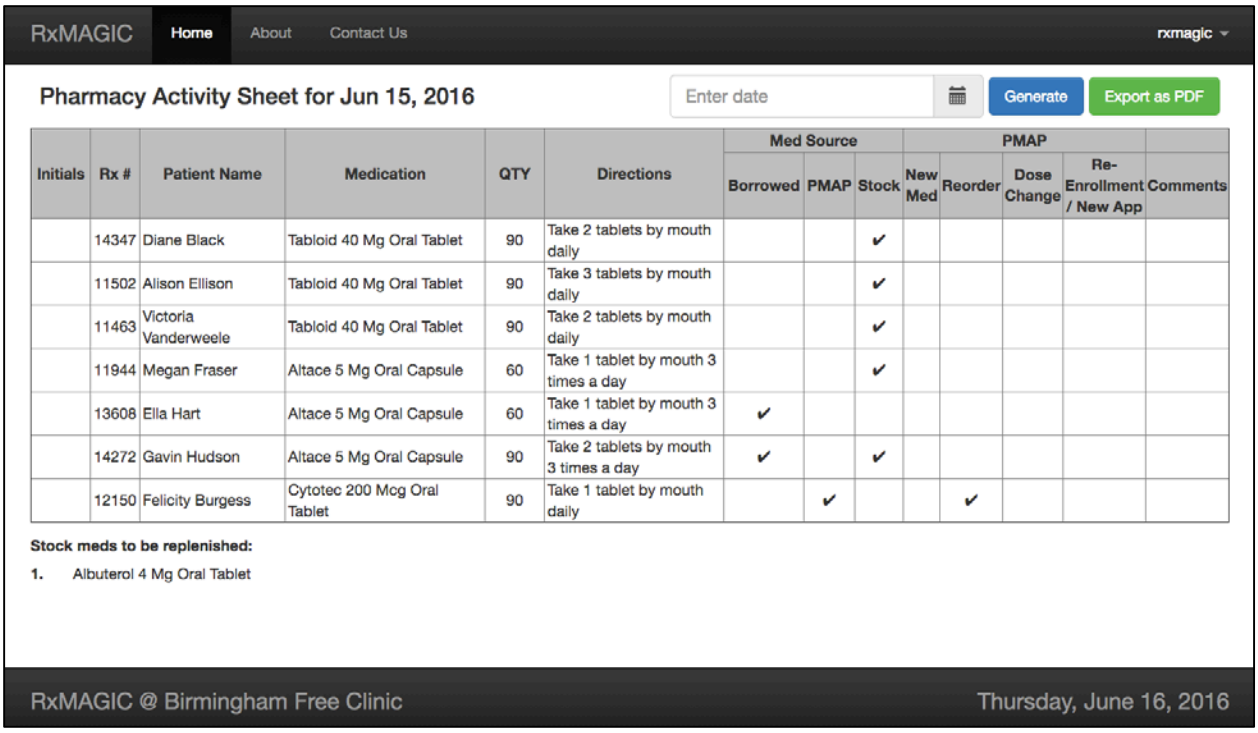


Figure 16: RxMAGIC home screen. Users can act on alerts as they appear in the feed on the right side of the screen (all alert types are not pictured). The two reports can be accessed from this screen under documentation.



Initials	Rx #	Patient Name	Medication	QTY	Directions	Med Source			PMAP				
						Borrowed	PMAP	Stock	New Med	Reorder	Dose Change	Re-Enrollment / New App	Comments
	14347	Diane Black	Tabloid 40 Mg Oral Tablet	90	Take 2 tablets by mouth daily			✔					
	11502	Alison Ellison	Tabloid 40 Mg Oral Tablet	90	Take 3 tablets by mouth daily			✔					
	11463	Victoria Vanderweele	Tabloid 40 Mg Oral Tablet	90	Take 2 tablets by mouth daily			✔					
	11944	Megan Fraser	Altace 5 Mg Oral Capsule	60	Take 1 tablet by mouth 3 times a day			✔					
	13608	Ella Hart	Altace 5 Mg Oral Capsule	60	Take 1 tablet by mouth 3 times a day	✔							
	14272	Gavin Hudson	Altace 5 Mg Oral Capsule	90	Take 2 tablets by mouth 3 times a day	✔		✔					
	12150	Felicity Burgess	Cytotec 200 Mcg Oral Tablet	90	Take 1 tablet by mouth daily		✔			✔			

Figure 17: Example of the pharmacy activity sheet. (Fake patient data is used).

4.4.2.2 Usability testing

Six participants completed the usability evaluation, which is a representative sample of the total volunteer population at the clinic. These participants included four BFC volunteer pharmacists and two AmeriCorps representatives. We also asked two non-users (i.e. colleagues recruited as a convenience sample) to complete the evaluation prior to the beginning of the study to pilot the protocol and data collection tools; their data was not included in the analysis. The study took place in May 2016. At the time of this usability evaluation, RxMAGIC was not receiving prescription data from the EHR; thus, the database was populated with simulated patient data to support user testing.

Overall, five of the six participants completed each task without any failures in the software. Of the 11 tasks, all of them averaged a score of four or five on the ease of completion scale. Tasks three and five had the greatest standard deviation, 1.67 and 1.26, respectively. One

participant was unable to complete task three due to a complication with the printer which was resolved immediately (i.e. a printer jam). Two participants struggled to complete task five, which asked the user to dispense medication without receipt of an order (i.e. it did not appear on the prescription dashboard), because they were unable to quickly locate this function in the software. A complete list of the tasks and their mean scores and standard deviations are in Appendix F.

The participants supplemented these ratings with mostly positive feedback regarding the simplicity of the system, its high learnability, and the potential benefit it will have on their productivity at the clinic. They all expressed satisfaction with their user experience and articulated specific benefits and efficiencies the system would provide. I show some direct user quotes that support these claims.

> *"It's [RxMAGIC] really modern, it's very easy to use, like it reminds me of my Gmail inbox [application], it's very intuitive, just with the look of how it is. I know what to expect with each click."*
>
> *"Honestly, all of this was really easy, it's very simple, I think somebody new would have no problem, actually, I don't know if you'd even need to train new people, you can pretty much just figure it out [laughter]."*
>
> *"Wow, this would've saved a lot of time last week! Not only that, it just makes me feel safer, I don't know, like I'm doing a better job."*

In addition to the positive feedback, there were several commonly reported suggestions to improve interface design. I discuss these results in the context of the MoSCoW prioritization technique.

Must have

While participants liked the idea of the alert feed, they all commented that some alerts were irrelevant and that they may overshadow more important alerts. Specifically, participants did not

think it was necessary to include a low-inventory alert for PAP items as the AmeriCorps are alerted of this in other places within the application. They also thought it was unnecessary to alert them that an item is approaching expiry, as they can look in the stock summary panel within the inventory to view medications approaching expiry. Further, some participants thought the 'new prescription' alert would be redundant once the system is interoperable, as the dashboard will display new prescriptions. The participants were most interested in alerts for low-inventory items (general stock), expired items, and underutilized PAP items.

There were several required additions to be made on the labels produced during dispensation. These included the phone number of the BFC, the date of the dispensation, the manufacturer of the dispensed item, and some type of unique identifying number (i.e. Rx #) so that they could link dispensed items to the automated activity sheet. To this end, changes to the activity sheet were also required. In addition to adding a unique Rx #, the activity sheet was not scrollable, so users were unable to view low-inventory items listed at the bottom of the sheet. Participants also wanted the ability to export the activity sheet to a word document in addition to a PDF, so that they can type comments if necessary.

Participants also made suggestions to improve interface design in several places. They specifically noted that the word 'cancel' had several different meanings in the application, and that that could be confusing for a new user. Sometimes, the 'cancel' button terminated the current activity and redirected the user to the home screen, while in certain dialogue boxes, the word 'cancel' simply closed the dialogue box. Participants suggested the term 'close' be used instead of 'cancel' in the latter scenario. Further, participants thought some of the validation messages, i.e. 'Metformin 500 mg has successfully been added to the inventory', could be more specific to include the lot number of the medication. Lastly, in screens where icons are used to

indicate actions such as edit and print (Figure 12), participants tried to hover over the icon before selecting it to understand its meaning. They noted inconsistency in the application as some icons had clear definitions when they hovered, whereas others did not.

Should have

Participants made several suggestions that we categorized as *should haves* as they were not as critical or time-sensitive to the deployment deadline. First, participants were confused when they attempted to sort medication names by expiration date in the general inventory view. When selecting the expiration date column, the application sorted dates by the letter of the month, not the date itself. All six participants were expecting this feature to sort by date, where the first item on the list was the one closest to expiry.

Participants also seemed confused when selecting the appropriate medication name from the filtered dropdown menu populated by RxNorm. RxNorm utilizes a certain capitalization pattern that confused the participants, as they were expecting to see words listed in title case. Lastly, participants consistently searched the screen for some type of feature that would allow them to toggle between different views within the application. Most features within the application can only be accessed from the home screen; participants found this frustrating when they wanted to quickly toggle between different views in the inventory.

Could have

There were few suggestions we classified as *could haves*, and these items would likely be implemented after the first release of the system. Participants suggested that, rather than alerting users of underutilized PAP items, this information could be included in the stock summary panel on the PAP inventory screen. This way, they could select this item in the stock summary panel

and have a more high-level view of all underutilized PAP items. Further, some participants recognized the importance and quality of the dispensation data that RxMAGIC would produce once deployed. They suggested some type of reporting framework within the application that would allow them to easily understand prescribing and dispensing patterns over a long period.

4.4.3 Discussion

Results from this round of usability testing demonstrated the importance of having real users interact with an application before deployment. The functional testing we conducted throughout development demonstrated that all user stories were implemented and functioning as designed. However, although the results were generally positive, we recognized several design flaws that did not align with users' expectations. For example, the definition of the word 'cancel' in different places in an application and how items should be sorted in various fields. Resolving these somewhat minor flaws in the application would improve the utility and satisfaction with the system once deployed, and that would only facilitate system adoption and continued use.

Using the MoSCoW technique to prioritize requirements facilitated results reporting and continued development. As the method suggests, items in the *must have* and *should have* category should be implemented prior to deployment, these categories just prioritize implementation so that items that are more complex are implemented first (*must have*). Thus, all items listed as *must have* and *should have* were implemented prior to deployment. These included the reorganization and elimination of some alerts (i.e. new prescription, item approaching expiry, low PAP inventory), changes to the labels and activity sheet, more specific validation messages, sorting based on expiration date, harmonizing 'cancel' and 'close,' defining hovering actions, a menu feature to easily toggle between screens, and utilizing title case in

RxNorm. Further, the suggestion to incorporate the underutilized PAP items in the stock summary panel was also implemented. We continued to conduct functional testing as changes in the application were made.

4.4.4 Limitations

The results from the laboratory-based usability evaluation were promising, however, as this study was done in a controlled environment, we knew that user interaction would likely change once the system was in use at the clinic. This is particularly true as the interoperability component was not tested in the laboratory setting, and this would likely create new challenges that had not been considered during development. Thus, understanding how users interact with RxMAGIC once deployed, and this level of interaction, would be critical to ensure a seamless integration with the BFC workflow.

5.0 AIM 2: IDENTIFY AND RESOLVE POST-DEPLOYMENT CHALLENGES

Aim 2 focuses on the deployment of RxMAGIC. Although some hardware components were deployed previously (i.e. the dashboard in June 2016), system deployment started in October 2016. We were prepared to deploy RxMAGIC in June 2016, however, challenges with achieving interoperability continued to delay this timeline. These challenges were more bureaucratic than technical due to our collaborations with several groups within UPMC that were working on other high-priority projects. For example, it took several months to establish a virtual server in a UPMC data center due to procedural delays.

In Aim 2 I discuss the several stages of system deployment, including user training and materials, and the identification of challenges regarding the impact of RxMAGIC on user behavior and vice versa. We used the sociotechnical model proposed by Sittig and Singh to inform the categorization of different challenges [89]. For the purposes of reporting the results in Aim 2, I discuss these challenges as either functional or organizational, where functional challenges refer to actual system design and use and organizational challenges describe implications on workflow and behavior.

5.1 SYSTEM DEPLOYMENT

5.1.1 Delays

We experienced delays in deploying RxMAGIC due to several reasons. First, the laptops at the BFC used Internet Explorer as their web browser; RxMAGIC did not function properly in Internet Explorer due to challenges with communicating to an EPL compatible printer. As Internet Explorer was not an option, UPMC required that the RxMAGIC application be accessed through Google Chrome for security reasons. As RxMAGIC was developed and tested in Firefox, ensuring the application functioned properly in Google Chrome caused delays. We then needed to install Google Chrome on the BFC laptops, which took a significant amount of time because application installation requires administrative privileges on devices within the UPMC network. Thus, the BFC clinic director had to submit several requests to UPMC before Google Chrome was successfully installed. A similar process was required to install the thermal label printers at the BFC, as printer installation also required administrative privileges. Together, these installations delayed the deployment timeline.

In addition to these delays, we also experienced challenges with establishing interoperability. There were several different steps to ensure the RxMAGIC server was receiving HL7 messages from the EHR at the clinic. While these steps are not technically complex, they depend on successful communication between different groups within UPMC that are all managing multiple projects; RxMAGIC was not necessarily a top priority for many of these teams. Once functional interoperability was established with the EHR, we experienced a final delay in receiving access to a service account that supports LDAP within RxMAGIC. As UPMC

required that users must have UPMC credentials to access RxMAGIC, deployment was delayed until access was granted and the user management framework was established.

5.1.2 Phased deployment

All hardware was installed during the summer of 2016 (i.e. dashboard, server, printers, scanners); interoperability and LDAP access were successfully achieved in September 2016. RxMAGIC was deployed in October 2016, which happened in three consecutive stages: 1) PAP inventory component (PHCUP office), 2) stock counts and data entry, and 3) electronic dispensing. Conceptually, all medication items in the BFC inventory cabinets had to be physically counted and electronically entered into the RxMAGIC inventory before the electronic dispensing component could be deployed. It was important that these stages occurred consecutively, so that the physical counts were accurate in RxMAGIC when electronic dispensation was deployed. I describe these stages below:

Stage 1: PAP inventory component [October 12, 2016; ~2 hours]

We first installed a thermal label printer at the PHCUP office in UPMC Montefiore where the AmeriCorps staff receives all PAP medications; most general stock medications also come through the PHCUP office before being delivered to the BFC. This was done to ensure that all medications are entered into the RxMAGIC inventory and labeled at the PHCUP office before being delivered to the BFC so that they are prepared for dispensation. AmeriCorps users have limited privileges in RxMAGIC so that they can only enter and view inventory information; they do not have access to the dispensing component.

Stage 2: Stock counts and data entry [October 13 –15, 2016; ~10 hours]

Two pharmacy students at the BFC were tasked with physically counting all medication items in the BFC inventory. We scheduled data entry to occur during the longest break in time between two clinic sessions (Thursday AM – Saturday AM). All medication items were counted during a Thursday morning smoking cessation clinic; the dispensary does not typically dispense medication during this clinic. Data entry began after patient care ended Thursday morning and lasted until Friday evening, before patient care began Saturday morning, which was the planned deployment date for the dispensing component. The large volume of medications to be entered coupled with poor query optimization in RxMAGIC caused the application to slow down tremendously, and data entry was not completed before Saturday morning. Thus, data entry was prioritized so that all high-usage medications were entered before Saturday morning. The pharmacists continued to enter the remaining medications as needed, which was much easier once the query bottleneck in RxMAGIC was alleviated.

Stage 3: Electronic dispensing [October 15, 2016; ~8 hours]

The electronic dispensing component went live on Saturday, October 15, 2016. The clinic did not limit the number of patients they accepted, so the patient volume was comparable to any other Saturday walk-in clinic. Pharmacists used RxMAGIC to dispense medications to nine patients; 37 total prescriptions were dispensed. RxMAGIC was used throughout the duration of onsite patient care. While there were some initial challenges during deployment that I will discuss in Section 5.2, there were no significant challenges that caused us to turn off the system and resort back to the paper dispensing process. RxMAGIC has been used for every clinic session since its deployment on October 15. At the time of this writing, RxMAGIC has been in use for 9 months and has 15 active users.

5.1.3 User training and materials

Although many pharmacist users had interacted with RxMAGIC during usability testing, some training was required. We conducted one-on-one training sessions at the BFC before onsite patient care began; sessions typically lasted between 10 and 20 minutes per user. I trained ten users during the first two months of system use. Approximately five new users that volunteered in the dispensary after the first two months of system use were trained by their colleagues. A small number of pharmacist users who had been involved with RxMAGIC development from the early stages quickly became proficient in system use. We identified one of these users as a 'champion' of the system, and she continues to train new pharmacy students and volunteers that rotate through the dispensary.

In addition to the one-on-one onsite training, we prepared a tutorial video that demonstrates and explains system use (RxMAGIC Tutorial Video). We published this video on YouTube and the link was distributed to all BFC volunteers. The video link is also posted in the 'About' section within the RxMAGIC application. As some users were not able to watch the video during patient care, we also created a Frequently Asked Questions (FAQ) document based on questions we received during the first few weeks of system use. The FAQ document is hanging in the BFC dispensary and all questions are listed under 'FAQ' within the RxMAGIC application. This document includes relevant YouTube links that demonstrate how to properly refill the printer labels and ribbons.

5.1.4 Physician use of RxMAGIC

We consider the pharmacists and AmeriCorps to be the primary users of RxMAGIC, which is evident in the description of the deployment process. While we wrote five user stories from the perspective of the BFC physicians, we consider them to be secondary users of the system. Their user privileges are comparable to the AmeriCorps in that they can just view the inventory (i.e. they do not have access to the dispensing functionality). Although they were included in system design, they were not trained on how to access RxMAGIC from their computers. This was discussed and agreed upon with the pharmacists. Our goal was to ensure that the pharmacists and AmeriCorps were confident using the system before demonstrating its use to the physicians. Once RxMAGIC was being used routinely, we planned to show the physicians how to access the inventory from the computers in the exam rooms. I further elaborate upon physician use of RxMAGIC in Section 5.2.2.2.

5.2 FIELD-USER EFFECT STUDY

While we consider the deployment of RxMAGIC to be successful, there were some initial challenges encountered during the first week of system use. These challenges demonstrated that it is difficult to predict how users will interact with a system once deployed, which is the third corollary to the fundamental theorem of biomedical informatics. In addition to evolving user requirements, this can be attributed to a variety of factors. For example, during the evaluation studies, users did not have to address interruptions, manage actual patients and prescriptions, or use the system for extended periods of time. Further, we were unable to effectively test the

interoperability component of RxMAGIC before deployment. We knew that RxMAGIC was receiving HL7 messages successfully, but it was difficult to assess their completeness and accuracy outside of the clinic setting. For these reasons, we conducted a field-user effect study to understand post-deployment implications.

Field-user effect studies focus on the behaviors and actions of users, and not the consequences of these actions on patient outcomes. These studies provide an opportunity to understand if and how a system is being used, if this usage is appropriate, if users retrieve correct information from a system, and if the system is causing any problems. The questions asked and methods employed in a field-user effect study can vary depending on the scenario. In this study, the evaluation questions emerged during the deployment process and evolved in the days following. Our goal was to determine how the pharmacists and AmeriCorps were using RxMAGIC and when physician usage would be appropriate. Further, we planned to identify and resolve any challenges associated with RxMAGIC.

We used the sociotechnical model developed by Sittig and Singh to facilitate the identification of challenges in the different dimensions of health IT use [89]. This model is grounded in the idea that these different dimensions are inherently related and significantly influence one another. As such, many of the challenges we uncovered could be classified into several dimensions in the model. Thus, I discuss these challenges in two primary categories: functional and organizational. Functional challenges are more technical and relate to hardware and software, clinical content, and the design of the system interface. I group these challenges together as they are more tightly coupled and their solutions are dependent on one another. Organizational challenges, however, focus on the more social end of the socio-technical spectrum. These challenges relate to system users, workflow and communication, and

organizational policies. While I discuss these challenges separately, it is important to note that many social components exert strong influences on technical components.

In this section I discuss the subjectivist approach we used to understand post-deployment challenges. This included passive observations, member-checking discussions, and a structured debriefing with primary users to validate our findings. We used these qualitative data to understand specific challenges related to RxMAGIC, which we classified as either functional (i.e. software, clinical content, human computer interface) or organizational (i.e. user behavior, workflow, communication). Most functional challenges were resolved immediately, specifically if they were caused by bugs in the application. However, some functional challenges were a product of previously unarticulated user requirements, and these solutions were not as urgent. As organizational challenges were not as straightforward, because they required changes in people and workflow, we used lean healthcare principles that empowered users to develop "standard work" to accommodate RxMAGIC.

5.2.1 Methods

Continuing with the contextual inquiry process, we passively observed pharmacist users during patient care at the BFC and AmeriCorps users at the PHCUP office. Most of the BFC inventory is entered into RxMAGIC at the PHCUP office, so it was important that we also document any challenges with this interaction. To understand the immediate impact of RxMAGIC on the dispensary workflow, we observed users on the first clinic session following deployment. We attended every clinic session for an entire week; each session lasted approximately four hours. In addition to data collection, these observations allowed us to train new users as they rotated in the dispensary during the first week of system use.

Open-ended discussions with users were frequent during these observations. These discussions often focused on specific challenges users were encountering, most of which were considered bugs in the application. As the week progressed and users became more comfortable with RxMAGIC, they often suggested new features (functional challenges) or workflows (organizational challenges) that would further improve their medication services. Suggestions that were not complex or time intensive were implemented immediately so that they could be tested and refined through member-checking sessions. These incremental improvements in system design and workflow organization facilitated the development of "standard work," which is a core principle of lean healthcare.

After the observations, we categorized the qualitative data into functional or organizational challenges. Solutions to functional challenges were prioritized and implemented as soon as possible, particularly those related to interoperability. We conducted a focused debriefing with five primary users who were actively involved in system development. This semi-structured debriefing allowed the users to discuss their experience using RxMAGIC, both positives and negatives, and provide suggestions for improvement. Additionally, we demonstrated new features within RxMAGIC that resulted from the observation sessions. Together, we discussed organizational challenges and how they could be alleviated through standard work and solutions were communicated appropriately to other BFC volunteers.

5.2.2 Results

We observed users at the BFC for approximately 25 hours in the week following deployment. During this time, we trained and observed six RxMAGIC users. Data from these observations informed the development of functional and organizational challenges, which were discussed in

a one-hour audio recorded focused debriefing with three pharmacists and two AmeriCorps users. These results are explained in detail below as they pertain to functional or organizational challenges. I also attempted to classify them as they pertain to the individual dimensions of the sociotechnical model in Table 11, however, it is important to note that there is significant overlap between challenges and dimensions (i.e. some challenges could be classified into multiple dimensions). Further, two dimensions were not addressed in this study: external rules, regulations, and pressures, and system measurement and monitoring. We studied system measurement and monitoring in Aim 3 of this research.

Table 11: Results classified by the different dimensions of the sociotechnical model. Challenges of the first three dimensions are discussed as functional challenges and the latter three are organizational.

Sociotechnical model dimension	Challenge	Description
Hardware and software	1) NDC-to-RxNorm mappings 2) Duplicate HL7 messages	Some NDCs used in the EHR could not be mapped to related concepts in RxNorm.
		Two HL7 messages were generated for one order (discontinuation and new order).
Clinical content	1) Scope of RxNorm 2) Mismatched par levels	Some items were out-of-scope of RxNorm (vitamins, non-medication items).
		The term types used to match par levels to inventory items were too narrow.
Human computer interface	1) Delete/reprint labels 2) Dispensing less than what is prescribed	The process whereby users delete/reprint items was unnecessarily complex.
		Users were unable to efficiently dispense less than the prescribed quantity.
People	Implications of inaccurate stock counts	Users did not trust the automated inventory due to minor errors introduced during data entry.
Workflow and communication	1) Pre-work activities and impacts on prescribing 2) Inventory management	Pharmacists needed physicians to enter medication orders before they could dispense.

		Variation in data entry regarding confusion around stock quantities.
Organizational policies and procedures	Assigning new responsibilities	New tasks were not being completed appropriately due to confusion around who was responsible.

5.2.2.1 Functional challenges

Several functional challenges were uncovered and resolved during deployment; bugs in the software were fixed before new features were implemented. For example, some medication names were so long that they disrupted the barcode on the inventory label, which made it unreadable by the barcode scanner. This was a bug that was fixed immediately. New features were implemented once a use case was observed, such as the ability to void dispensed items and reprint labels. While new feature requests were important, we focused on challenges with interoperability (i.e. RxNorm and HL7) as these were the most critical to the field of informatics.

Scope of RxNorm

We encountered several problems with the completeness of RxNorm once RxMAGIC was deployed. RxNorm includes all prescription medications that are approved for human use in the US; it does not include non-prescriptions, non-drug items such as supplies and equipment, and multivitamins, which are partially represented [69]. The RxNorm documentation states that OTC medications will be added to the vocabulary when reliable information about the medication can be found [70]. The BFC dispenses many of these out-of-scope items, so we recognized that RxNorm might not be complete for their purposes. Also, RxNorm is designed to be used in electronic prescribing applications, and its use in electronic dispensing has not been adequately

studied. We discussed this with the pharmacists prior to deployment and decided that RxNorm was the most suitable vocabulary to ensure semantic interoperability with the EHR.

As expected, there were several items not included in the RxNorm vocabulary (mostly vitamin and dermatological products), and the pharmacists did not know how to inventory them. Several solutions were considered, like a specified medication list for OTC items, however this did not seem sustainable. The pharmacists identified certain active ingredients in OTC products that were included in RxNorm (i.e. partial representation). This was not a perfect solution, but it became the new standard for entering these products. Further, we concluded that non-medication items would not be inventoried and dispensed with RxMAGIC, as they are often not prescribed by the physician via CPOE. While this may not be ideal, the benefits of using a standard vocabulary such as RxNorm significantly outweighed these negatives. Although initially frustrating, the pharmacists realized that a customized medication list would not facilitate interoperability, sustainability, or generalizability, which are all critical to RxMAGIC's success.

NDC-to-RxNorm mappings

Challenges with OTC medications were not limited to inventorying. We realized that the HL7 messages for some e-prescriptions were not successfully transferring to RxMAGIC. This was confusing because the physician could prescribe these medications in the EHR, which meant the HL7 message included a NDC for that prescribed item. A thorough investigation of this specific interoperability failure proved that some NDC codes used in the EHR were unable to be mapped to a prescribable concept in RxNorm. For example, RxMAGIC was not displaying e-prescriptions for Aspirin 81 mg tablets, although this concept is included in RxNorm. We found that the NDC used in the HL7 message is not the same NDC used in RxNorm for this item. As

RxMAGIC matches the NDC identifier in the HL7 message to one in a RxNorm concept, it was unable to transform and write this prescription to the RxMAGIC database.

This challenge can be attributed to RxNorm's process of retiring CUIs [69]. We assume that the NDC used for Aspirin 81 mg in the HL7 message is no longer used in the most current RxNorm concept for that item. Although this was initially problematic, pharmacists were still able to electronically dispense OTC medications in RxMAGIC because it has a feature that allows users to dispense medication to patients without a prescription from the EHR. This feature was implemented for two reasons: 1) in the case that we encountered challenges with interoperability, and 2) to ensure aspects of RxMAGIC could be generalizable to clinics without an ordering system.

While this workaround was helpful at the time, it could be problematic as the pharmacists become more reliant on RxMAGIC to display all pending prescriptions. We implemented a specific solution to alleviate this problem. When RxMAGIC receives an HL7 message with an 'invalid' NDC in RxNorm, it extracts the medication name of the prescribed item and matches it to a medication name in the RxMAGIC inventory. This suggested matching is displayed in the form of an alert that reads 'missing drug reference.' Users select this alert and validate the suggested matching, or suggest a new one that is more appropriate (Figure 18). Once the match is confirmed, the HL7 message is written to the RxMAGIC database and added to the queue of pending prescriptions as per usual. Users only have to do this once for a given medication, as this matching applies to all subsequent HL7 messages containing the invalid NDC.

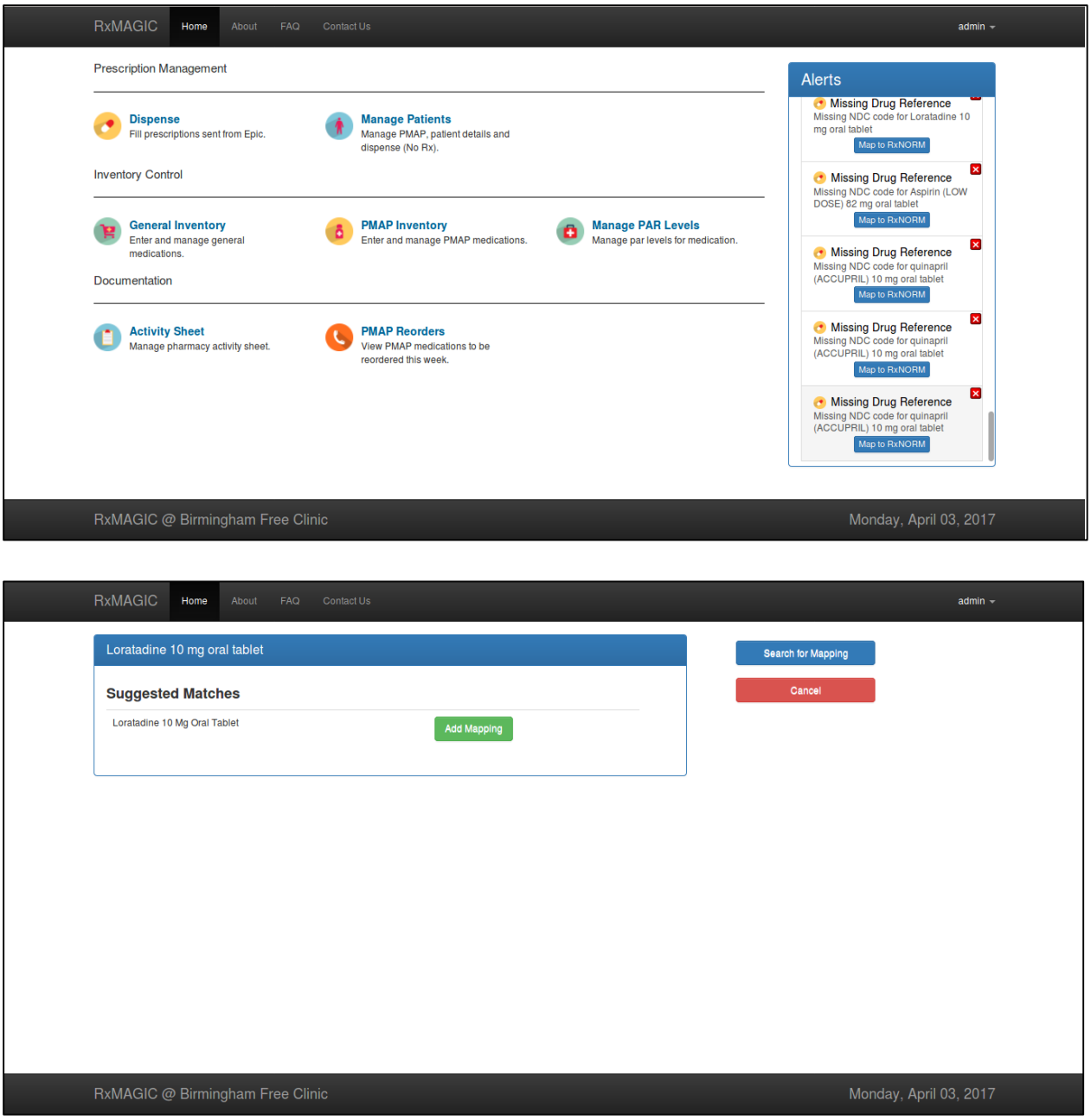


Figure 18: NDC-to-RxNorm mapping alert. Users select 'Map to RxNorm' from the alert shown in the above figure. Below, users can approve the suggested mappings or search for a more appropriate one.

Duplicate HL7 messages

While some HL7 messages were not appearing in RxMAGIC at all, others were appearing in duplicate. The same exact prescription would be listed in the queue twice. While the pharmacists recognized that the prescriptions were duplicates and reacted appropriately, they were frustrated

that the duplicate orders were cluttering the prescription dashboard. RxMAGIC is designed to update a prescription if it receives identical HL7 messages (same provider, same medication, same dose, etc.), which should have resolved a problem of this type. Therefore, there had to be something in the HL7 messages that was different between the duplicate prescriptions. We also noticed that the duplicate prescriptions were only appearing for patients who had been to the clinic previously, and that prescriptions placed for new patients were appearing appropriately.

An investigation of the duplicate messages in Mirth revealed that the EHR sends two HL7 messages per one medication order. The first message is a discontinuation of the medication if it was prescribed previously, and the second is the initiation of the new medication order, although all aspects of the refill are the same. There is a field in each HL7 message that identifies it as a 'discontinuation/historical order' or a 'new medication order.' A filter was applied to all incoming HL7 messages so that only those encoding new medication orders are written to the RxMAGIC database, which immediately resolved the problem.

Similarly, RxMAGIC would occasionally receive and display prescriptions to be filled at a community pharmacy. When a provider at the BFC orders a medication in the EHR, he/she is supposed to select a certain option ('no printout') that indicates the prescription is to be filled by the BFC dispensary. Medication orders that do not use 'no printout' are sent to the patient's local pharmacy. This indication is encoded in the HL7 message. We applied a filter to all incoming HL7 messages so that only those identified as 'no printout' are displayed in RxMAGIC.

Mismatched par levels

RxMAGIC compares the aggregate stock quantity of an inventory item of the same name to its associated par level to determine its stock availability. For example, if the par level for Fluoxetine 10 mg oral tablets is 1000 and RxMAGIC lists three separate bottles of Fluoxetine 10

mg oral tablets each with quantities of 200 (total stock = 600), then this drug would be considered under-stocked (600 < 1000). The successful aggregation of similar inventory items and the matching of these items to their associated par level relies on their semantic representation in the RxMAGIC database, which depends on the term types (TTYs) and CUIs used in the RxNorm implementation. RxNorm uses TTYs to indicate generic and branded drug names at different levels of specificity (Table 12); different TTYs have different RXCUIs for the same drug product. When RxMAGIC was deployed, both the par level and inventory features used the prescribable name (PSN) and the semantic clinical drug (SCD). Further, par levels were matched to inventory items based on their RXAUI. While this worked during testing, it was not successful once RxMAGIC was in practice.

Table 12: RxNorm TTYs that are relevant to this research. RxNorm describes 20 total TTYs.

TTY	Name	Definition	Example	RXCUI
PSN	Prescribable Name	Given for clarity and display purposes in prescribing applications. Only one PSN per concept	Leena 28 Day Pack	749148
SCD	Semantic Clinical Drug	Ingredient + Strength + Dose Form	Fluoxetine 4 MG/ML Oral Solution	310386
SBD	Semantic Branded Drug	Ingredient + Strength + Dose Form + Brand Name	Fluoxetine 4 MG/ML Oral Solution [Prozac]	104850
SBDC	Semantic Branded Drug Component	Ingredient + Strength + Brand Name	Fluoxetine 4 MG/ML [Prozac]	563784
SCDC	Semantic Clinical Drug Component	Ingredient + Strength	Fluoxetine 4 MG/ML	315953

During usability testing, we ensured that all medication items were represented similarly in RxMAGIC by specifically creating par levels based on medication names in the inventory (i.e. par level medication name = Fluoxetine 10 mg oral tablets, inventory medication name =

Fluoxetine 10 mg oral tablets). However, we realized that the logic used to match par levels to inventory items was too specific, and RxMAGIC was incorrectly classifying items as under-stocked. For example, items were inventoried using their brand names (i.e. Prozac 10 mg oral tablets), or some other representation (i.e. Fluoxetine HCl 10 mg oral tablets), but par levels were created using generic names (i.e. Fluoxetine 10 mg oral tablets), different dose form (i.e. Fluoxetine 10 mg oral capsules) or some form of synonym. To improve the par level functionality, we needed to understand how pharmacists would use this information in practice and which TTYs would best meet these needs.

We modified the TTYs used to create par levels to enable a broader mapping between different semantic representations of the same medication in the database. This took multiple attempts, but we found that the semantic clinical drug component (SCDC) and semantic branded drug component (SBDC) to be most successful for the par level feature. This means that par levels created for medication names just include the drug name and strength, but not the dose form (i.e. tablet, capsule, etc.). Also, rather than matching items based on their RXAUI, we match items by RXCUI to broaden the matching potential. Now, when users create a par level for Fluoxetine 10 mg, it is compared to items with the name Fluoxetine 10 mg oral tablets, Fluoxetine 10 mg oral capsules, Prozac 10 mg oral tablets, etc.

Ability to delete/reprint labels

The pharmacists typically received medication orders and prepared a patient's prescription before bringing the patient into the dispensary for counseling. In some instances, the patient no longer needed or requested the medication that had been ordered and dispensed. Because the pharmacist had already completed this dispensation in RxMAGIC, the dispensed item was added to the activity sheet and the dispensed quantity was subtracted from the stock quantity. The

pharmacist was unable to delete this dispensation within RxMAGIC, so she would manually edit the stock quantity to add back the quantity she had dispensed. Further, there was no way to delete this dispensation from the patient's record in RxMAGIC or the activity sheet.

In addition to deleting dispensed items, pharmacists also wanted the ability to reprint dispensation labels. This would be useful in the case where the label ripped during the dispensing process or if the dispensed items were separated into different containers. To resolve these problems, we implemented a feature that allows users to delete a dispensed item which automatically replenishes the inventory within RxMAGIC. Deleting the dispensed item also removes it from the activity sheet and the patient's record. Further, we updated the system to include a reprint feature so that users can print a second dispensation label. Both options appear as action icons next to each dispensation on the patient profile page.

Dispensing less than is prescribed

RxMAGIC allows users to dispense medication from multiple bottles to fill a prescription. When a user is dispensing, RxMAGIC does not print a label until the dispensed quantity matches the prescribed quantity. This was done to ensure the prescription is filled completely. While this was a necessary system requirement uncovered in the usability testing, there were some instances where the pharmacist did not want to dispense the total prescribed quantity (i.e. they had insufficient stock). We noticed that the pharmacists created a workaround to achieve this by dispensing the necessary quantity to print a label, and then retrospectively editing the stock counts to reflect what they dispensed. This was not only extra work for the pharmacists, but it would likely contribute to inaccurate stock counts and information regarding past dispensations.

The pharmacists wanted to be able to edit the prescribed quantity in RxMAGIC so that the dispensation records were accurate and complete. After much discussion with the

pharmacists about their reasoning for this feature, we implemented the ability to edit the prescribed quantity on the patient-specific dispensing screen (Figure 15). Users select the edit icon to update this value and then proceed with dispensation as usual.

5.2.2.2 Organizational challenges

We expected RxMAGIC to change the medication management services. However, managing the people dimension of this technological change is critical to health IT adoption. Although we had our own vision of how RxMAGIC would be used in practice, it was important that the pharmacists and AmeriCorps felt empowered to optimize their own workflow to use RxMAGIC. We relied on their judgement to facilitate incremental changes in their workflow that realized the full potential of RxMAGIC.

Inventory management

It was important that the pharmacists managed data entry so that medication items were represented in a way that made sense to them and their practice as they would be responsible for entering all medications moving forward. Several different pharmacy students entered most of the medication items into the inventory during deployment and there was much variability in the way these items were entered. Some of this variability was resolved by modifying the RxNorm TTYs described above (i.e. brand name versus generic name), however there were questions on how best to enter items such as inhalers, topical ointments, and insulin. For example, should the stock quantity of an inhaler indicate the number of doses (or puffs) in the inhaler? Or should each inhaler be entered as a quantity of one? Likewise, for topical ointments, do we enter the stock quantity as the volume of the tube (i.e. 28 g)? It was obvious that some form of standard work was necessary to ensure consistency and accuracy in the inventory.

Physician prescribing patterns ultimately determined this standard. Nearly all medications are prescribed in their generic form, so the pharmacists made a group decision that all inventory items should be entered in the same way to maintain consistency. For inhalers, it was decided that the number of doses should be included in the drug name, i.e. 200 ACTUAT Albuterol 0.09 MG metered dose inhaler, and that each inhaler should be entered as a quantity of one. Developing a standard for topical ointments, though, was a bit more complex. These items are typically prescribed by volume (i.e. grams), so they could not be inventoried as a quantity of one because RxMAGIC would assume there is insufficient quantity to dispense. The pharmacists decided that all topical creams/ointments/gels be inventoried by volume, and that the volume should be rounded up to the nearest ten (i.e. 28.2 g = 30 g). Insulin pens were also inventoried by volume (ml).

The original philosophy of RxMAGIC was that each medication item would be barcoded with a unique inventory ID, and this barcode would be utilized for electronic dispensing. This would ensure that all dispensable units are tightly coupled to a single entity in the inventory that can be defined by its drug name, lot number, and expiration date. This is the process by which items were inventoried when RxMAGIC was initially deployed. However, the pharmacists ultimately chose to group similar medication items together by lot number and expiration date, and enter all of these items into the inventory under one unique inventory ID. For example, there were 15 inhalers of the same type (200 ACTUAT Albuterol 0.09 MG metered dose inhaler) with the same lot number and expiration date. Rather than enter each item individually as a quantity of one, the pharmacists chose to enter all 15 inhalers in one transaction, so that the total stock quantity was 15. While this was not how we intended the system to be used, the pharmacists

considered this to be the most efficient means of inventory tracking, which made it the new standard method for data entry.

Pre-work activities and impacts on the prescribing process (CPOE)

Before RxMAGIC was deployed, some pharmacists would prepare medications to dispense before the physician entered any orders in the EHR. This was mainly done for patients with chronic conditions who were coming to the clinic monthly. The pharmacists reported that these pre-work tasks were necessary because the labeling process was so time-intensive. Once RxMAGIC was deployed, the pharmacists were frustrated that they could not begin preparing medication labels until the physician placed the order in the EHR. Previously, the ordering and dispensing processes were completely decoupled. With RxMAGIC, however, the physician must sign and enter the medication order in the EHR to initiate the dispensing process, which was an organizational change in the dispensary.

Over time, the pharmacists realized that these pre-work activities were not as necessary with RxMAGIC, as the actual dispensing process was much more efficient. However, this notion of needing the physician to enter medication orders in the EHR to initiate electronic dispensing was still a frustration. The pharmacists at the BFC often enter and sign medication orders in the EHR as a time-saving tactic, amongst other reasons, which is a practice they encourage. The EHR only allows one user to be in the patient order screen at a given time. While this was not a new problem, it was amplified now that the pharmacists needed medication orders to be entered to initiate electronic dispensing in RxMAGIC. Previously, they could dispense items and enter them in the EHR later.

During our observations, the pharmacists frequently had to find the physician and ask him/her to exit the patient's order entry screen so that they enter orders and proceed with

dispensation. Because the physicians were not involved with the RxMAGIC deployment, they did not understand what had changed and that this was suddenly a problem. We realized that it was necessary to include all volunteer personnel of this organizational change, so the physicians were given a brief orientation on RxMAGIC and how it may impact the prescribing workflow. Specifically, they were instructed to enter medication orders as soon as possible, or exit the order screen in the patient's EHR. This demonstrated the importance of all clinicians working cohesively in an organization to accomplish patient care.

Implications of inaccurate stock counts

There are many factors that caused inaccurate stock counts during the first weeks of deployment. First, due to the magnitude of medication items to be entered, there were opportunities for error in the data entry process (i.e. counting, transcription). Second, given the nature of a free clinic, it is not uncommon for pharmacists to dispense a few tablets of Ibuprofen, for example, to a patient who has a headache. Prior to RxMAGIC, these trivial dispensations had no major implications on inventory control. However, pharmacists learned the importance of accountability and recording all stock movement in RxMAGIC, which was a new aspect of their workflow. In addition to these challenges, some first-time users did not use RxMAGIC for every dispensation. For example, one pharmacist became overwhelmed during his/her first time using RxMAGIC and decided to dispense medications by hand and used RxMAGIC retrospectively once on-site care had ended.

For these reasons, some stock quantities were incorrect in RxMAGIC, which caused users to distrust the automated inventory. In addition to this distrust, inaccurate stock quantities led to other challenges, such as the inability to electronically dispense from a bottle that has insufficient inventory. This is particularly frustrating when the pharmacist knows the that there is

physically enough inventory to dispense, but the stock quantity is incorrect in RxMAGIC. Thus, harmonizing physical stock counts with their automated representation continues to be a necessary component of the medication management process. While automation may have made the inventory more transparent, its benefits will not be fully realized if it is poorly maintained and inaccurate.

Distrust in the automated inventory was evident as the pharmacists rarely utilized RxMAGIC when consulted by physicians to determine what is in stock. Initially, this lack of utilization was likely due to the novelty of RxMAGIC and its potential to inform discussions about stock availability. However, remarks made by the pharmacists during the focused debriefing uncovered that they do not feel comfortable relying on the automated inventory because it has been inaccurate in the past. As a result, they specifically requested that we do not show physicians how to access the inventory in RxMAGIC as originally planned. They were concerned that this access would hinder clinician communication and cause confusion around stock availability at the point of CPOE, potentially causing more incorrect medication orders. Further, the pharmacists stated that the physicians would likely prefer a higher-level overview of the medication inventory rather than an itemized description of each medication unit. It is possible that these concerns would have been realized and addressed if we included the physicians in the earlier contextual inquiry studies. However, at the time of this writing, RxMAGIC continues to be a pharmacist-facing application, with no plans of expanding its use to the physicians at the BFC.

Assigning new responsibilities

The introduction of a new system brings new tasks and responsibilities that did not previously exist. There were two situations that demonstrated the importance of defining new work tasks

and user roles, the first being how to handle the activity sheet. Previously, pharmacists would complete the handwritten activity sheet and leave it in a bin on the patient registration desk. The sheet would eventually be transported to the offices at UPMC Montefiore. Now that the activity sheet is automated, the AmeriCorps can access it from their computer at UPMC Montefiore. Some pharmacists continued to print the automated sheet while others assumed the AmeriCorps would print it at UPMC Montefiore, which created confusion for pharmacists and AmeriCorps alike. In a group meeting, the pharmacists decided that the AmeriCorps would be responsible for printing the document unless the pharmacist needed to add something to it (i.e. a non-medication item).

Responsibilities were similarly confused when it came to removing expired medications from the stock cabinets. Pharmacy students typically accessed RxMAGIC to see which medications were expired and would then physically remove them from the stock cabinets. However, they would often forget to electronically delete those removed items from RxMAGIC. This caused problems when pharmacists were looking for certain medications in the stock cabinet that were listed as 'well-stocked' in RxMAGIC. Clarifying the responsibility of the pharmacy student to ensure that items are both physically and electronically deleted alleviated confusion around this task.

5.2.3 Discussion

Observing user interaction after deploying RxMAGIC proved the third corollary following the "Fundamental Theorem" to be true: whether the theorem holds depends on an interaction between person and resource, results of which cannot be predicted in advance [100]. Although the results from the earlier usability studies were helpful in alleviating potential interaction

challenges before deployment, new and different challenges were realized once RxMAGIC was in practice. It is unlikely that these challenges could have been identified and resolved before deployment, particularly those related to health data standards and interoperability. Similarly, the social components of system use, which exert strong influences on the technical components, may not have been predicted before *in situ* interaction.

The benefits of using a reliable, rigorously structured standard vocabulary like RxNorm significantly outweigh the challenges uncovered in this study, especially as vendor EHR systems like EpicCare intend to use RxNorm in the future [73]. However, there are still some areas in RxNorm that could benefit from further refinement to improve its completeness such as maintaining accurate and current NDC-to-RxNorm mappings. The results from this study demonstrate that there are inconsistencies between the prescribable concepts in RxNorm and a vendor's proprietary nomenclature, which is an area of caution that has been documented in the literature [68,69]. Likewise, the challenges we encountered associated with mismatched par levels highlights cases of synonymy or ambiguity in RxNorm; eliminating nonspecific terms is another area for improvement. Maintaining the completeness of RxNorm in addition to accurate NDC-to-RxNorm mappings is critical as RxNorm continues to expand its vocabulary, which would improve its utility in a setting like the BFC.

In addition to problems associated with the adoption of health data standards, the results from this study demonstrate the importance of managing organizational change, which has both emotional and situational components. Although several pharmacists were involved in the planning and evaluation of RxMAGIC, its specific impact on people and processes in the BFC were difficult to predict before deployment. It was most surprising to observe this user distrust in the automated inventory and how that negatively affected the physician's potential use of

RxMAGIC. While this result was unexpected, we believe that new user behaviors will emerge to enable the realization of RxMAGIC's potential to be helpful. However, these findings demonstrate that, although RxMAGIC has the potential to improve efficiency and time utilization, a problem impact study is required to determine its effects once it is in steady use. This study is discussed in Chapter 6.

5.2.4 Conclusions

While there were no significant design flaws that prohibited pharmacists and AmeriCorps from using RxMAGIC, the deployment process emphasized this notion of evolving user requirements and multiple levels of evaluation. It was important to prioritize bugs in the application before new feature requests so that RxMAGIC was successful in supporting dispensing tasks in practice. However, it was also important that new features were continually implemented to sustain innovation, which did not end with the conclusion of this study. At the time of this writing, we continue to make changes to RxMAGIC to further accommodate user needs and provide a resource that brings maximum value to the medication management services at the BFC.

6.0 AIM 3: PROBLEM IMPACT STUDY

The results from the field-user effect study demonstrated that, however promising the results from the previous levels of evaluation, an impact study is necessary to determine the ultimate effects of RxMAGIC once rolled out into routine practice. RxMAGIC was and continues to be iteratively updated following deployment to accommodate the evolving needs of the pharmacists and AmeriCorps. For example, as requested by the pharmacists, a new report was recently implemented that summarizes dispensation information at the level of the medication item for any period of time desired by the user (i.e. daily, weekly, monthly). This report is intended to help the pharmacists understand consumption, discrepancies in prescribed versus dispensed items, and inform medication ordering.

The field-user effect study was instrumental in understanding how RxMAGIC impacts user behavior in addition to identifying and resolving facilitators and barriers of success regarding RxMAGIC adoption. However, we were now interested in studying whether RxMAGIC successfully addressed the original problems for which it was designed. This is a problem impact study. Problem impact studies are similar to field-user effect studies in many aspects, but differ significantly in what is being explored. The original need that motivated the design of RxMAGIC was improved efficiency, specifically during the prescription preparation process (i.e. labeling). Thus, understanding changes in pharmacist time utilization was a driving factor behind the problem impact study.

RxMAGIC was designed in the context of a lean intervention, and we used many lean principles throughout this research. Time utilization is one metric of the lean value diamond, which is used to understand the impact of interventions on four metrics: time, quality, satisfaction, and financials [79]. These four metrics are inherently related and each metric affects the others in some way. We are interested in exploring how changes in time utilization, as a result of RxMAGIC, may impact the other three metrics of the lean value diamond. Although measuring time utilization was perhaps the biggest component of the problem impact study, we also directly measured the impact of RxMAGIC on the financial health of the BFC in addition to pharmacist satisfaction. Further, we used results from these evaluation components to understand potential changes in the quality of patient-centered services provided by the pharmacists. I discuss each of these separate evaluation components, and how they relate to one another, in the following sections.

6.1 TIME UTILIZATION

In Section 4.2 we conducted a pre-deployment time-motion study as part of the needs assessment (November 2014) to quantify pharmacist time investment in 12 tasks that comprise the dispensing workflow in the BFC; these are the baseline results for comparison (see 4.2). To measure changes in time utilization after deployment of RxMAGIC, we performed a post-deployment continuous observation time-motion study once the system was judged to be in a steady state of use (February 2017). At that time, RxMAGIC had 21 active users (i.e. pharmacists, AmeriCorps, and pharmacy students) and was used daily in the dispensary for all clinic sessions and dispensations with no major problems.

The objective for this study was to measure changes in pharmacist time utilization to understand if RxMAGIC alleviated the challenges for which it was designed. Further, if time invested in non-value-added tasks decreased, we were interested in understanding how this time was redirected. Ideally, pharmacists would spend more time completing patient-centered, value-added tasks.

6.1.1 Methods

To ensure the most accurate pre-post comparison, we attempted to mimic the parameters from the pre-deployment study. However organizational changes in the clinic made it difficult to reproduce all aspects of the pre-deployment study. Most notably was the type of clinic that was observed during data collection sessions. In the pre-deployment study, we collected data during Friday sessions, which includes a mix of general walk-in and scheduled MTM patients. Since this study, the clinic has reduced the amount of Friday clinic sessions due to difficulties scheduling an attending physician for this day. Thus, in the post-deployment study, data was collected during Wednesday afternoons, which is a clinic only available to nonscheduled walk-in patients. I will later discuss how the difference in clinic sessions affects the results of this study.

The same researcher that assisted with the pre-deployment study helped with data collection for this study. This allowed us to each observe an independent pharmacist during observations. The University of Pittsburgh Institutional Review Board reviewed this study and approved it as exempt (PRO14020120).

Codebook development and pilot study

The 12 task subcategories, or codes, used in the pre-deployment study were restructured to accommodate a new workflow that had evolved due to RxMAGIC implementation. These 12 subcategories are grouped into five major workflow categories (e.g. Rx Preparation, EMR Operations, Clinician Interaction, Patient Interaction, Other). To maintain consistency with the earlier study, the five major categories were not modified, although a new major category was introduced (Inventory). New subcategories were introduced under the major categories to account for new workflow tasks, or to facilitate a more granular analysis due to limitations realized during analysis of the pre-deployment study. Similarly, subcategories that were no longer relevant were removed.

We conducted a pilot study to test the restructured codes for completeness and to calculate Cohen's kappa to determine inter-rater reliability. Both researchers observed the same pharmacist for the duration of the pilot study and documented the amount of the he/she took to complete the coded tasks; these data were not included in the final analysis. Questions about the appropriateness of certain categorizations following the pilot study resulted in very minor changes to definitions in the codebook (Table 13).

Table 13: Final codebook for the post-deployment time-motion study. Items in bold indicate new categories/subcategories as compared to the pre-deployment codebook. NVA = non-value-added, VA = value-added.

Major task category	Minor task subcategory	Value categorization
Prescription (Rx) Preparation	Hunting	NVA
	Traveling	NVA
	Rx Management	**VA**
	Dispensing	NVA
	Labeling	NVA
Inventory	**Inventory**	**VA**
Clinician interaction	Consulting clinician	VA
	Teaching	VA

Patient interaction	Counseling	VA
	PAP initiation	VA
	PAP discussion	VA
EMR operations	**Patient care**	**VA**
	Order correction	**NVA**
Other	Other	NVA

Data collection and analyses

Each researcher observed a different pharmacist during data collection, which began approximately 30 minutes before the first patient appointment. This allowed researchers to document any pre-work tasks that, such as reviewing patient information in the EHR. Data collection continued through general care hours until onsite care was completed. Each session lasted roughly three hours.

Data was collected using the Time Motion Study application (Graphite Inc., www.graphiteinc.com) for Android devices, which was the same application used in the pre-deployment study. With this software, we created a list of motions, i.e. subcategories, to track pharmacist activity. Timing began as soon as the task was selected and ended upon selection of a new task. Data was recorded in comma separated value (CSV) files where each row summarized the duration of a single motion selection. We used RStudio 0.98 (RStudio Inc., www.rstudio.com) and R 3.1 to analyze the total time invested in each subcategory, and hence each major category, over the entire dataset. Bar charts were created to help visualize these data. Additionally, like the pre-deployment study, we used these data to calculate the value quotient for each dataset.

6.1.2 Results

Cohen's kappa for the pilot session was found to be $\kappa = 0.651$, which indicates substantial agreement between raters. The codebook used in the pilot study was the same codebook used during data collection. Time-motion data was collected during three independent clinic sessions in February 2017 for a combined total of approximately 16.5 hours (not including the pilot study data). Two pharmacists were observed during two of the three clinic sessions. Due to scheduling changes, only one pharmacist was observed during the third data collection session in addition to a pharmacy student. Because their roles differ in the clinic (pharmacist and student), the data from the student observation is analyzed and reported separately. Thus, the overall dataset represents approximately 13.5 hours of observation, and the student dataset is approximately 3 hours of observation.

The final codebook (Table 13) for the post-deployment study includes 14 subcategories clustered into six major categories; the new category 'Inventory' does not include any subcategories. In addition to Inventory as a new major category, there are few differences between the pre/post codebook, which are indicated in Table 13. Two changes have been made to Rx Preparation: 1) the subcategory 'duplicate documenting' was removed as a result of automation; 2) 'Rx Management' was introduced as a subcategory, which describes the pharmacist's use of RxMAGIC to dispense prescriptions. Further, the 'EMR Operations' category now includes two subcategories to allow for a more granular analysis. Previously, this category did not contain any subcategories, and it was difficult to distinguish value-added from non-value-added time regarding EMR usage. To address this, two subcategories were introduced (patient care and order correction) to categorize this distinction. Lastly, some subcategory

definitions were modified to accommodate the new workflow. The complete codebook, including definitions and initiation/termination protocols, is in Appendix G.

I describe the results as they compare to those from the pre-deployment time-motion study. Figure 19 shows the percent total time invested in each of the five main categories, which are deconstructed into their associated subcategories for the entire post-deployment dataset (13.5 hours). Figure 20 compares the percent total time invested in the shared workflow categories as they pertain to the pre- and post-deployment studies. The category 'Inventory' that was introduced in the post-deployment study is not included in Figure 20. Changes in time utilization between the pre- and post-study are also shown in Table 14.

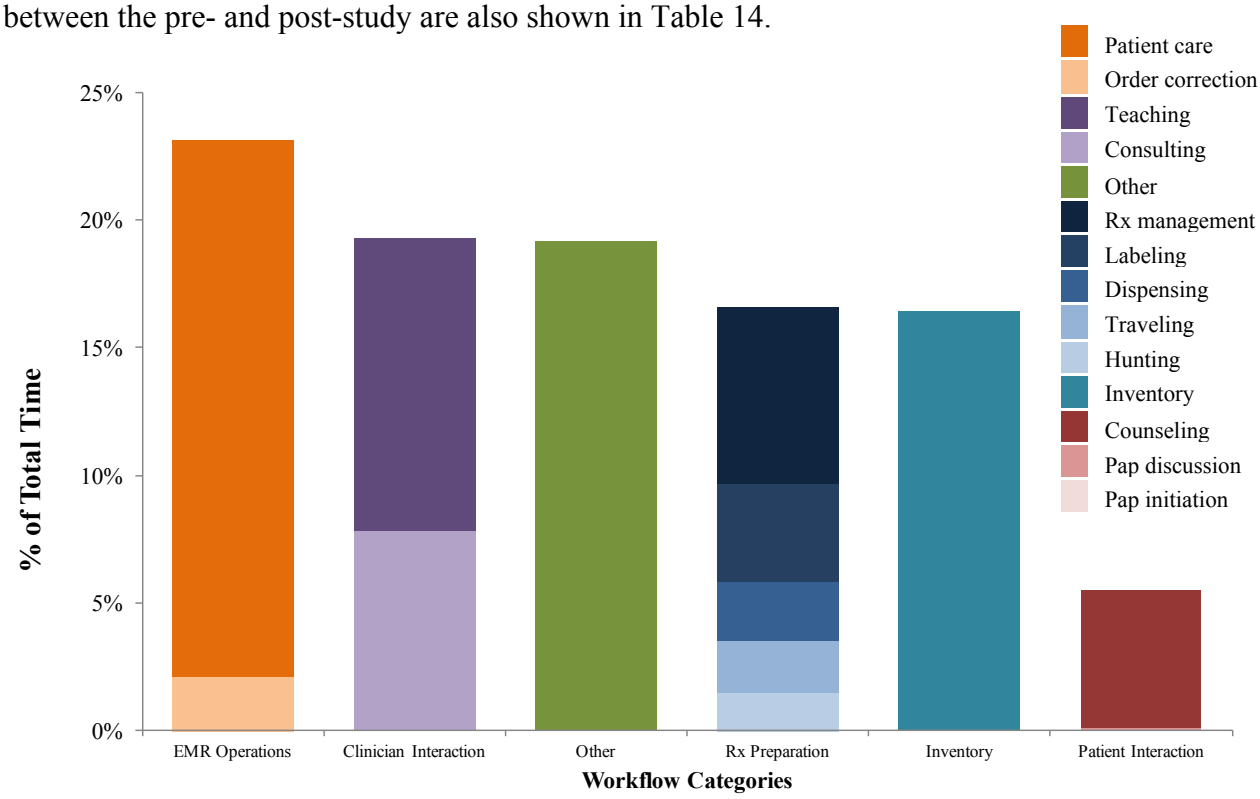


Figure 19: Percent total time investment by major workflow categories and their associated subcategories.

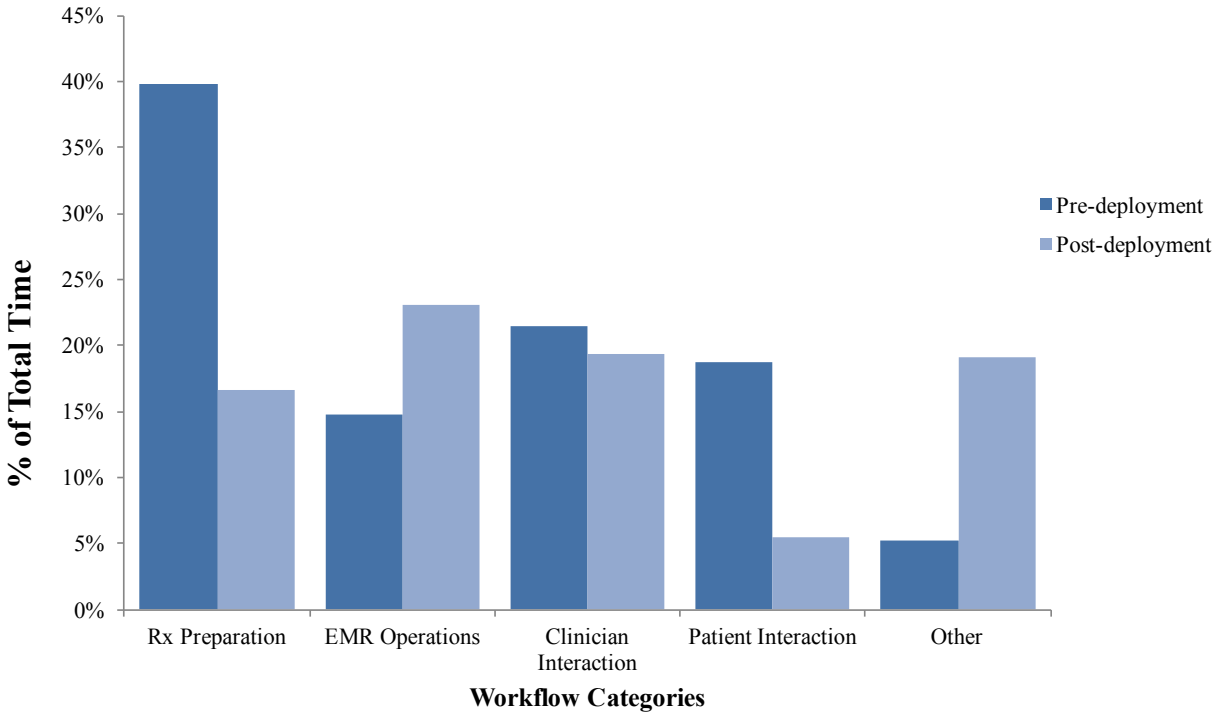


Figure 20: Comparing time investment by major task category between the pre- and post-deployment studies.

Table 14: Comparing percent total time investment between the pre- and post-deployment studies. Subcategories followed by (+) are new to the post-study; subcategories followed by (-) have been eliminated in the post-study.

Workflow categories	Pre (% total time)	Post (% total time)
Rx Preparation	**39.8**	**16.6**
Hunting	4.8	1.5
Traveling	2.3	2.1
Dispensing	7.3	2.3
Labeling	21.8	3.8
Rx management (+)	--	6.9
Duplicate documenting (-)	3.6	--
EMR Operations	**14.80**	**23.1**
Patient Care (+)	--	21.0
Order Correction (+)	--	2.1
Clinician Interaction	**21.50**	**19.3**
Consulting	8.0	7.9
Teaching	13.5	11.4
Patient Interaction	**18.70**	**5.5**
PAP initiation	1.8	0.0009

PAP discussion	0.2	0.1
Counseling	17.7	5.4
Inventory (+)	**--**	**16.4**
Other	**5.2**	**19.2**

Prescription preparation

Post-deployment, pharmacists invested 16.6% (SD = 6.3) of their time into preparing prescriptions for dispensation, which has decreased from 39.8%. This category includes five subcategories: traveling (2.1%), hunting for medication in stock cabinets (1.5%), dispensing medication (2.3%), automated labeling (3.8%), and Rx management (6.9%). Apart from Rx management, which is a new subcategory, the percent total time invested in each subcategory has decreased post-deployment. The most significant decrease was noted in the labeling task (previously 21.8%), which can be attributed to RxMAGIC use. Although 'Rx management' consumed the largest proportion of pharmacist time within prescription preparation, the pharmacists categorized it as a value-added task because of the impact it has had on all other tasks, particularly labeling. Further, this task essentially replaced 'duplicate documenting,' which consumed 3.6% of pharmacist time in the pre-deployment study. All other tasks in this category remain classified as non-value-added.

EMR operations

The results indicate that pharmacists spent 23.1% (SD = 4.9) of their time using the EMR compared to 14.8% pre-deployment. Difficulties in classifying EMR operations as value-added or non-value-added in the pre-deployment study required a more granular depiction of the tasks that comprise this category. As a result, EMR operations includes two subcategories: patient care (20.97%) and order correction (2.12%). Patient care included activities such as reviewing patient information and pending medication orders, which are tasks the pharmacists considered to be

value-added. Order correction, however, is a non-value-added task. This task is related to challenges with CPOE and occurred when the pharmacist had to correct a medication order in the EMR for a variety of reasons that may be unique to this setting (i.e. the physician indicated a refill).

Inventory

Pharmacists invested 16.4% (SD = 11.2) of their time managing the inventory within RxMAGIC, which is a category that did not exist in the pre-deployment study. This primarily included the entry and labeling of new medication items. Although components of this task may be non-value-added, like harmonizing automated stock quantities with physical counts, the pharmacists identified this task as value-added because it is necessary to utilize the dispensing component.

Clinician interaction

Clinician interaction consumed approximately a fifth (19.3%; SD = 11.4) of pharmacist time. This value is comparable to the pre-deployment study, which was 21.5%. Clinician interaction included clinician consultation (7.9%) and teaching students and/or other volunteers (11.4%). These tasks were both considered to be value-added.

Patient interaction

The amount of time pharmacists invest into patient interaction has decreased from 18.7% to 5.5% (SD = 3.8) post-deployment of RxMAGIC, which is a value-added category. This category was primarily comprised of patient counseling, as the PAP initiation and discussion categories consume a trivial amount of time, 0.0009% and 0.1%, respectively. Thus, the reduction can be attributed to a decrease in the amount of time invested in patient counseling, which has fallen

from 17.7% to 5.4%. The pharmacy student observation data, collected during the third clinic session, can potentially describe this discrepancy. Figure 21 shows that the students invested a third of their active time (12.93%) counseling patients. These results demonstrate that, during walk-in clinics, the pharmacy students do most of the patient counseling, and may explain the decrease in the time pharmacists invested in this subcategory.

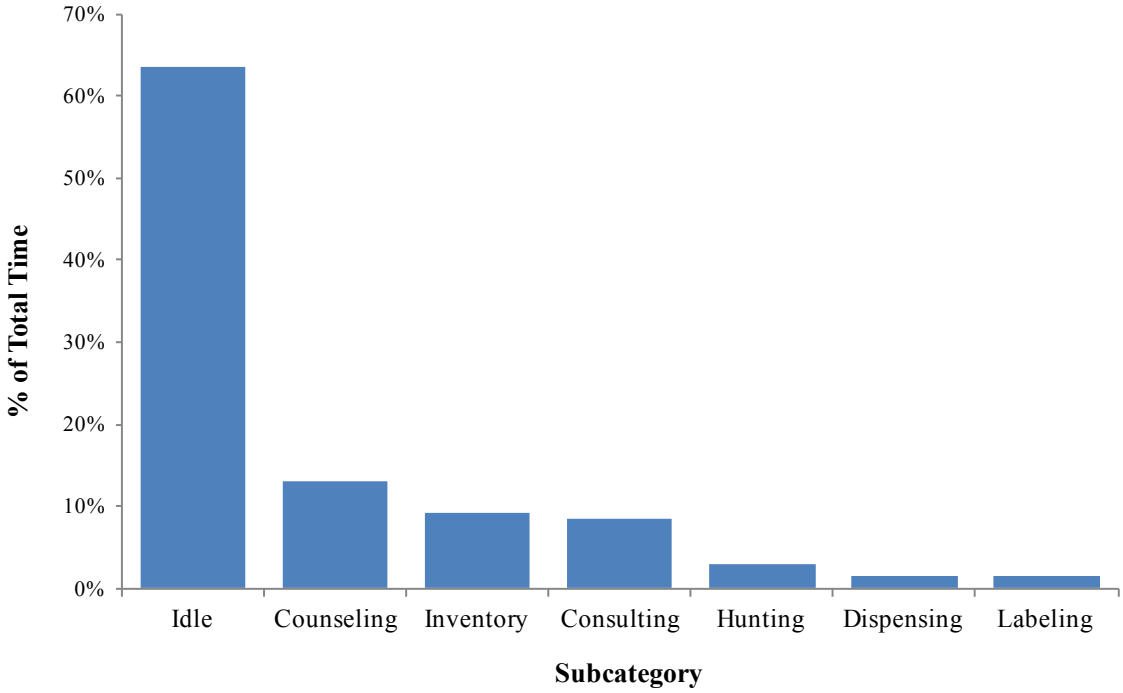


Figure 21: Percent total time invested by pharmacy student.

Other

Pharmacists invested 19.15% (SD = 8.2) of their time in this category, which has increased from 5.2%. In the pre-deployment study, tasks that were classified as 'other' included using the restroom or casual conversation. In the post-deployment study, however, in addition to using the restroom and casual conversation, new tasks were classified as 'other' that did not have a specific code because these behaviors were not noticed previously. For example, we noticed that the pharmacists spent more time consulting the literature to investigate a patient's disease state.

Although this is a value-added task, we classified this major category as non-value-added to maintain consistency with the pre-deployment study.

Value quotient

Based on the value categorizations made by the pharmacists, the value quotient for the entire dataset is 69.6% (Table 15). However, it is likely that this is a conservative calculation because other tasks, which comprised 19.2% of pharmacist time, were considered non-value-added. The overall value quotient may be greater if our analysis of 'other' tasks was more granular, as some of these tasks were value-added. These values have increased from the pre-deployment study, where the range was 40.3% - 54.8%, indicating that the amount of value-added time in the dispensary workflow has increased.

Table 15: Value quotients for each dataset.

Session	Value Quotient (%)
1	71.4
2	70.3
3	63.5
Overall	69.6

6.1.3 Discussion

This study evaluated how RxMAGIC use affected time utilization by pharmacists. We found that compared to the pre-deployment results, RxMAGIC reduced the amount of time pharmacists invest in non-value-added tasks, thereby making these tasks more efficient. Further justifying this claim, the results indicated that the pharmacists spend 70% of their time completing tasks

they consider to be value-added. Possibly having the largest impact on this value is the decrease in time invested in the prescription preparation category, which has decreased by more than half. This change can be attributed to the nearly tenfold decrease in the total time invested in the labeling process, as the differences in the other subcategories are trivial in comparison. The tasks in this category were the main drivers of inefficiency at the clinic [103], specifically the labeling process, and RxMAGIC was designed to reduce waste and maximize efficiency of these tasks.

In an unstructured interview with the pharmacists following the study, they stated that the results met their expectations. They expected to see a significant decrease in labeling, and minor decreases in dispensing and hunting, as RxMAGIC has improved the efficiency by which they determine which medications they have in stock. However, although RxMAGIC provides a means for checking the stock quantity of a medication, the pharmacists reported that they will continue to physically check the inventory in addition to RxMAGIC. It is a typical pharmacy behavior to check both the physical and automated inventory. This behavior also encourages the pharmacists to continually harmonize physical counts with those in RxMAGIC.

Although it is a value-added task, the amount of time that pharmacists invested in the inventory category is surprising. Apart from the initial data entry that was done when RxMAGIC was deployed, the AmeriCorps typically receive all medication (both PMAP and general stock) to their office at UPMC Montefiore. Medications are entered into the inventory and labeled at Montefiore before they are brought to the clinic, thus inventory entry is not a primary task for the pharmacist. The pharmacists also agreed that the proportion of time invested in inventory was unusual, and that they rarely enter medication items into the inventory. They explained that, during the first two clinic sessions, a large donation of dermatology samples had just been delivered to the clinic as opposed to Montefiore. Although this is not the typical workflow, the

pharmacists entered these medications into the inventory themselves, which explains the 16.4%. During the third data collection session, the pharmacist invested under 1% of his total time in this category, which further justifies the 16.4% as atypical behavior. This also justifies the value quotient being less for this clinic session compared to the others (63.5%).

It is also important to note that entering items into the inventory is an asynchronous task. That is, it is a flexible task that can be completed independently of all other tasks; it is not time-sensitive or necessary to dispense medication and counsel patients at the time of its completion. On the contrary, the activities described in Rx Preparation are synchronous tasks in that they must be completed before moving on to another task. These tasks are time-sensitive and many other activities are dependent on their timely completion such as patient counseling. It is likely more important to provide workflow efficiencies for synchronous tasks compared to asynchronous tasks, as efficient synchronous tasks will provide more flexibility in a workflow to complete other potentially asynchronous tasks.

Time spent in direct patient care activities such as counseling patients decreased post-RxMAGIC implementation, which is a disappointing result. However, conversations with the pharmacists justified this decrease as being unrelated to RxMAGIC use. The pre-deployment study was conducted during Friday afternoon clinic sessions. On these days, the clinic sees a mix of both MTM and nonscheduled walk-in patients. MTM patients are scheduled to see only the pharmacist and do not have a typical physician examination before receiving their medications. These patients receive extensive counseling on their disease state, lifestyle decisions, and other medication-related needs [5,31,112]. MTM patient encounters are different than walk-in patient encounters because the pharmacist is the only clinician the patient will see that day, thus they are inherently more time-intensive [31]. At the BFC, the attending pharmacist or resident will

counsel all MTM patients. For general walk-in patients, however, the pharmacy students do most of the counseling as it is more straightforward; this is a teaching opportunity for the pharmacists [113]. These patients have already met with the attending physician and understand what medications are being prescribed that day, so the patient interaction is expected to be less for walk-in patients. This was the case in the post-deployment study which was conducted on Wednesdays. Thus, differences in clinic type influence the level and type of pharmacist-patient interaction, which justifies the discrepancy in the pre/post results.

The amount of time pharmacists spend doing 'other' tasks has increased, which was also discussed with the pharmacists following the study. Again, this difference can be partially attributed to the difference in clinic types. There are typically a wide variety of patient encounters during walk-in clinics. These patients may have never been to the clinic before, so pharmacists may take more time to investigate their disease state by consulting the literature. Pharmacists also make greater use of the EHR to understand patient history, a value-added task, which may explain the increase in EHR operations post-deployment. The observational data further supports this claim. This behavior was not noticed in the pre-deployment study, however, as MTM patients have been coming to the clinic for months and the pharmacists are familiar with their disease state; this time is instead spent counseling. While there were likely other unrelated job activities that were classified as 'other', researching a patient's disease state and looking for inexpensive medication alternatives were prominent tasks.

6.1.4 Limitations

The difference in clinic days is an obvious limitation of this study. Amongst other organizational changes at the BFC (between 2014 and 2017), this made it difficult to statistically compare the

pre/post results. We were unable to conduct the time-motion observations during Friday clinics because the BFC does not always have a scheduled attending physician, which affects the volume of the patient population. Although observing MTM encounters would have made for a more accurate pre/post comparison, it was more important to observe how RxMAGIC use affects time utilization when there is a large volume of patients. We recognize that collecting data during MTM encounters may have increased the amount of pharmacist-patient interaction, which would have also improved the value quotient. The student data and further discussions with the pharmacists helped put the post-deployment results in perspective, particularly in regard to patient interaction and inventory entry.

It could be useful to understand changes in the amount of time invested per patient, however these data were not collected previously. This would allow for greater comparisons across the pre/post results, although the difference in clinic days observed would have also affected these data and their implications. The effect of continued experience is also not explicitly evaluated in this study. RxMAGIC may affect time differently depending on the level of experience with the system. However, of the two pharmacists observed, one had been using RxMAGIC since its deployment and the second was a new resident. Although the variability between these two pharmacists was not measured, the observational data confirmed that both pharmacists easily navigated the system, and that differences in experience did not affect time utilization.

6.1.5 Conclusions

This component of the problem impact study focused on how RxMAGIC use affects pharmacist time utilization. We conclude that, compared to the pre-deployment results, RxMAGIC has

decreased the amount of time pharmacists invest in tasks they consider to be non-value-added. RxMAGIC has addressed the problems for which it was designed (i.e. reducing waste in labeling, documentation, etc.) and improved the value quotient, which indicates improvement in workflow efficiency. This study demonstrates that RxMAGIC introduces value-added hours into the dispensary workflow, which is a claim further justified by the pharmacist. While the results do not describe how the pharmacists redirect this additional time, the observational data confirmed that new patient-centered behaviors have evolved. Further studies are needed to understand these new behaviors and how RxMAGIC affects other aspects of the lean value diamond.

6.2 QUALITY

The results from the time-motion study demonstrate that RxMAGIC has had a positive impact on pharmacist time utilization. As a result, it is possible that pharmacists redirect additional time toward other activities, specifically those that are patient-centered. Many of these benefits are not quantifiable in the context of the time-motion study, nor are they in the scope of this research. For example, reduced wastage of medication due to expiry, as RxMAGIC prioritizes dispensation of medications closest to expiry. However, the literature strongly supports that improved time management and the elimination of tasks that have little or no financial value can enhance the quality of services provided [112,114–116], which is why ‘quality’ is included in the lean value diamond. Quality is defined as the degree to which healthcare services increase the likelihood of desired health outcomes [117]. Thus, although we did not directly measure changes in health outcomes, the improvement of pharmacist time utilization may correlate with improved

outcomes. Data from the time-motion study in addition to unstructured interviews with pharmacists following the study informed potential changes in the quality of services provided.

In free clinic settings, patient counseling and MTM services have been correlated with improved medication adherence and patient outcomes [5,31,118,119]. Study results indicate that enhanced patient-pharmacist interactions can increase adherence from 37% to 81% for respiratory therapies and from 67% to 92% for cardiovascular therapies, as well as reduce first-fill abandonment by 90% [120]. First-fill abandonment occurs when a patient receiving a chronic medication fails to fill his/her prescription after the first month's supply. This may be due to financial limitations, a lack of understanding of the chronic condition, or limited availability of healthcare services. Similarly, the National Association of Boards of Pharmacy reports that counseling by pharmacists increased the adherence rate of elderly patients taking three or more medications by 43% and of patients suffering from heart failure by 46% [121]. These improved adherence rates are of obvious benefit to patients in regard to better medical outcomes and fewer trips to the hospital, which could result in cost savings for patients and providers alike [122]. Although the results of the time-motion study may not reflect enhanced pharmacist-patient interaction, the pharmacists report that the dispensing process is safer and more standardized. Further, due to efficiency gains during the dispensing process, the pharmacists feel that patient counseling is no longer rushed, and that they have ample time to discuss proper medication use with patients. As new behaviors continue to evolve, the pharmacists may have additional time to dedicate to patient-centered tasks.

Also contributing to this notion of 'safer' dispensing procedures is the use of computer-generated prescription drug labels (as compared to the handwritten labels used previously). The Institute of Medicine (IOM) cited poor or illegible medication labeling as a central cause of

medication errors [123,124], as it may lead to miscommunication of medication information and poor patient outcomes. A study has shown that 33% of all medication errors are attributed to packaging and label confusion [125]. This is further exacerbated in a population with poor health literacy and multiple chronic conditions [5,7,8], as these patients may take more medications which can lead to increased mistakes and decreased medication recall [126,127]. Improving the legibility of drug labels (i.e. electronically-generated labels) can have the same effect on reducing medication errors and improving the quality of patient safety as e-prescribing has [123,124,128,129]. Further, the use of a standardized nomenclature to clearly and effectively communicate a drug product to patients via prescription labels is important [123]. The literature suggests that dispensing pharmacies utilize health IT that is integrated with the prescribing system to complete and print labeling components. This could reduce variability in formatting and the risk that medication directions become lost in conversion [124,126]. Thus, because of the reasons listed here, it is likely that RxMAGIC has improved the legibility and standardization of drug labels, which may improve medication adherence at the BFC.

Observational data from the time-motion study also indicates potential improvements in the quality of services provided. As discussed previously, there was an increase in the amount of time pharmacists invest in completing 'other' tasks. The pharmacists reported that this is time they did not previously have, which makes this increase a representation of the time savings potentially created by RxMAGIC. Several behaviors were noticed during the time-motion study that were classified as 'other.' For example, pharmacists spent more time consulting the literature to understand a patient's disease state. They often compared different medication therapies and researched less expensive alternatives for patients. The pharmacists also researched and discussed the importance of receiving the appropriate vaccinations before traveling abroad.

Further, one pharmacist, who was not observed in the time-motion study, reported that she now sits-in on the clinical encounter with the physician as time permits, which she was not able to do as frequently at the BFC pre-RxMAGIC implementation. While many of these behaviors cannot be directly attributed to RxMAGIC, it is likely that that its use has created additional time that can be redirected toward value-added tasks [112] such as patient interaction and inventory maintenance.

In addition to changes in the quality of services provided, the pharmacists also report an improvement in their quality of work life. The pharmacists used to come to the clinic an hour before on-site care began to prepare medications for dispensation. Similarly, they used to leave nearly an hour after on-site care has ended (and the physicians have left) to finish counseling patients and complete any remaining paper documentation. Post-RxMAGIC implementation, the pharmacists reported that they no longer feel the need to complete pre-work tasks and that they are able to leave when on-site care has ended. Further, the BFC has noticed a decrease in their turnover rate of pharmacist volunteers. Previously, pharmacists were hesitant to volunteer because the dispensing process was labor-intensive and overwhelming. Post-RxMAGIC implementation, pharmacists are more eager to volunteer because the workflow is more efficient and less stressful. I further elaborate upon quality of work life in the next section.

6.3 SATISFACTION

The post-deployment time motion study quantified the impact of RxMAGIC on pharmacist time utilization, however it did not evaluate the pharmacists' perceptions of the system and their new workflow. Although the results indicate that RxMAGIC has improved pharmacist efficiency,

they do not provide any insight on user experience or perceived utility. If RxMAGIC supports achievement of certain tasks, but fails to impact higher level expectations such as job satisfaction, user acceptance will be variable. Ensuring that the pharmacists find RxMAGIC useful and important are necessary to facilitate its continued adoption. It is important that the pharmacists find value in using RxMAGIC so that they want to use it to support their medication services.

To measure the perceived usability of RMAGIC, we customized the previously validated Health Information Technology Usability Evaluation Scale (Health-ITUES) [130,131]. Health-ITUES was developed as a customizable questionnaire to subjectively evaluate usability of informatics tools and various health IT characteristics. The questionnaire includes 20 items grouped into four question domains: quality of work life, perceived usefulness, perceived ease of use, and user control. We chose this questionnaire because it measures perceptions as they pertain to different levels of user expectation, all of which are included in Nielsen's five facets of usability [93]. Quality of work life represents higher expectations of system impact, whereas perceived usefulness refers to the pharmacists' perception of RxMAGIC's ability to help them preform their job better [131,132]. Both user control and perceived ease of use capture user-system interaction, the ease by which users can recover from errors and how difficult RxMAGIC is to learn in relation to its benefits, respectively [131,132].

6.3.1 Methods

We customized the Health-ITUES to address the type of tasks that pharmacists are expected to perform while using RxMAGIC. Each questionnaire item was motivated by a pharmacist user story so that they were tightly coupled to the functions and benefits originally desired by the

pharmacists (Table 16). The questions were randomly sorted so that they were not grouped together by the four domains described above. Pharmacists were asked to rank their agreement with each statement on a scale of 1 to 5 where 1= "Strongly Disagree" and 5= "Strongly Agree." The survey was administered using Qualtrics, which is a Web-based service that allows you to create a survey, collect and store data securely, and analyze responses (Qualtrics Inc., http://www.qualtrics.com/). Mean scores and their standard deviations were calculated for each statement. The University of Pittsburgh Institution Review Board approved this study as exempt (PRO17020591). No personally identifiable information was collected as part of the questionnaire.

Following completion of the time-motion study, the clinic director emailed the survey link to the core pharmacist distribution list. Recipients were instructed to only participate in the survey if they have used RxMAGIC at the clinic. The survey link was active for one month (March 30, 2017 – April 30, 2017). The AmeriCorps member was not invited to complete the survey as the statements focused on pharmacist use of RxMAGIC. We conducted an unstructured interview with the AmeriCorps staff member to understand her perceptions of RxMAGIC and how it has affected inventory management.

6.3.2 Results

The questionnaire was sent to pharmacist volunteers after the system was in steady use for five months. Of the 15 pharmacists on the core pharmacist distribution list, 11 pharmacists responded to the survey (73%), which represented the active users at that time. Overall, the pharmacists agreed/strongly agreed that RxMAGIC is both useful and easy to use, with mean scores of 4.47 and 4.31, respectively. Further, pharmacists perceived that RxMAGIC has had a positive impact

on their quality of work life (4.79); all participants agree that RxMAGIC has been a positive addition to their medication management services. Pharmacists were more neutral in regard to user control (3.61). For the purposes of discussing these results, both 'agree' and 'strongly agree' indicate a positive response, and 'disagree' and 'strongly disagree' are negative.

In regard to perceived usefulness, pharmacists were generally satisfied with RxMAGIC for making their workflow more efficient (10/11, 91%, Q.8). They found it particularly useful for efficiently producing complete and legible prescription labels (11/11, 100%, Q.12) and providing a more standardized process for dispensing medication (10/11, 91%, Q.7). Pharmacists were mostly in agreement with their increased ability to focus on patient-centered tasks (8/11, 73%, Q.5), with one participant disagreeing with this statement. The most variation in participant responses in this dimension was noted in statements related to improved inventory control, with Q.11 having the only mean score less than 4. Less than half of pharmacists perceived that RxMAGIC makes it more likely they ensure an uninterrupted drug supply (5/11, 46%, Q.11), with five pharmacists indicating neutral agreement and one pharmacist disagreeing with this statement. There was a similar distribution for Q.9. Most pharmacists were in agreement-to-neutral that RxMAGIC clarifies current stock availability (10/11, 91%, Q.9); one pharmacist disagreed with this statement.

Table 16: Summary of the Health-ITUES results.

Statement		**Mean (SD)**
Quality of work life		**4.79 (0.05)**
1.	It has been a positive addition to the medication management services.	4.82 (0.39)
2.	It is an important part of our dispensary services.	4.73 (0.45)
3.	It has been a positive addition to the Birmingham Clinic.	4.82 (0.39)
Perceived usefulness		**4.47 (0.41)**

4.	It makes it easier to dispense medication and manage stock levels.	4.64 (0.48)
5.	It increases my ability to focus on patient-centered tasks.	4.00 (0.95)
6.	It enables me to produce labels during dispensation more quickly.	4.82 (0.39)
7.	It provides a more standardized process for dispensing.	4.64 (0.64)
8.	I am satisfied with it for making my workflow more efficient.	4.45 (0.66)
9.	It helps me understand current stock availability.	4.18 (1.03)
10.	I label dispensed medications in a timely manner.	4.82 (0.39)
11.	It makes it more likely that I ensure an uninterrupted drug supply.	3.73 (1.05)
12.	It is useful for efficiently producing complete and legible prescription labels.	4.91 (0.29)
Perceived ease of use		**4.31 (0.23)**
13.	It is easy for me to become skillful at using it.	4.64 (0.48)
14.	I can always remember how to log on and use it.	4.27 (0.96)
15.	I find it easy to use.	4.36 (0.64)
16.	I am comfortable with my ability to use it.	4.27 (0.62)
17.	Learning to use it has been easy for me.	4.00 (0.74)
User control		**3.61(0.73)**
18.	It provides error messages that clearly tell me how to fix problems.	2.82 (0.83)
19.	I recover easily and quickly if I make a mistake using it.	3.73 (0.62)
20.	It provides clear information (i.e. stock counts, activity sheet).	4.27 (0.86)

The pharmacists positively perceived the system's ease of use. It was a bit more difficult to evaluate the pharmacists' perception of system learnability. While all participants agreed that it is easy to become skillful at using RxMAGIC (11/11, 100%, Q.13), only 73% of pharmacists agreed that learning to use RXMAGIC was easy (8/11, 73%, Q.17). However, no participants disagreed with this statement. Only one participant disagreed with a statement in this dimension, that he/she can always remember how to log on and use RxMAGIC, with most pharmacists supporting system memorability (9/11, 82%, Q.14).

The statement receiving the lowest mean score was in the user control dimension. While most pharmacists were in neutral agreement (6/11), some pharmacists did not think RxMAGIC provides clear error messages that tell them how to fix problems (3/11, 27%, Q.18). However, most pharmacists agreed that they easily recover after making a mistake using RxMAGIC (7/11, 64%, Q.19), with the remaining participants indicating neutral agreement.

In addition to the questionnaire, we conducted an unstructured interview with the AmeriCorps to ensure all user perceptions were evaluated. The AmeriCorps does not have access to the dispensing functionality in RxMAGIC but is responsible for ensuring the clinic is sufficiently stocked with medications. The responses were overly positive in regard to how RxMAGIC has improved the medication ordering and restocking process, the PAP reordering process, and overall time management. The AmeriCorps claimed to use all stock features in RxMAGIC daily, especially the par level feature that allows users to identify medications that are understocked. Further, the report that summarizes which PAP medications need to be reordered each week is the most helpful. Previously, the AmeriCorps had to scan a several page excel spreadsheet to identify which medications were to be reordered. This process was incredibly time intensive and would sometimes consume a day's work. Overall, the AmeriCorps perceptions of RxMAGIC were generally positive, which is supported by this direct quote:

> *"I'm really quite fond of it [RxMAGIC], and I think it's so useful. It makes my job easier and faster, I get things done more quickly and feel like I use it a lot, even if I don't need to. I don't know how we did things before it, honestly."*

6.3.3 Discussion

The Health-ITUES subjectively evaluated pharmacists' perceptions of RxMAGIC as they relate to different dimensions of usability: quality of work life, perceived usefulness, perceived ease of use, and user control. Analysis of the questionnaire shows that the pharmacists had a positive perception of three of the four dimensions, with user control being the only dimension receiving a mean score less than 4. Overall, these results indicate that pharmacists found RxMAGIC to be useful for improving their workflow efficiency, particularly tasks related to medication labeling, and providing a more standardized process for dispensing. Further, they perceived it to have had a positive addition to their dispensary services and are satisfied with its ease of use.

The pharmacists' perceptions of usefulness of RxMAGIC were slightly higher than their perceptions of ease of use, albeit not by much. The latter may be attributed to the turnover rate of volunteers at the BFC, especially in regard to remembering how to log on and use the system. Of the pharmacists who volunteer at the BFC and responded to this survey, most of them are frequent volunteers and use RxMAGIC several times a week. However, some volunteers are more infrequent, and may only have used RxMAGIC once or twice before completing this survey. Thus, the different levels of pharmacist experience with using RxMAGIC may have contributed to the variation in responses related to memorability and learnability. Regardless of varying levels of experience, the mean scores in this dimension indicate strong usability related to these two facets of usability. Moreover, a significant body of literature on technology acceptance suggests that perceived usefulness more strongly predicts intention to use and actual use of technology than perceived ease of use [132–134].

While the results regarding perceived usefulness were generally positive, the variation of responses related to inventory management were surprising. It is clear that the pharmacists find

RxMAGIC to be most useful for producing complete and legible labels in a timely manner, however the potential benefits RxMAGIC could have on improving inventory control are not as realized. There are several factors that may contribute to this. First, managing inventory at the level of individual units of dispensation is a new task for the BFC pharmacists, and one that is still being learned and optimized after only five months of system use. Second, it is possible that some pharmacists, particularly those that don't volunteer as frequently, find this task to be more burdensome than beneficial. As discussed in Aim 2, inaccurate stock counts in RxMAGIC prohibit the user from dispensing medication from that bottle, even if the bottle physically has sufficient stock. The frustrating task of harmonizing the physical and automated counts may hinder other inventory benefits provided by RxMAGIC. Lastly, as stock management is one of the AmeriCorps's primary responsibilities, its benefits may not be realized by the pharmacists that responded to this survey. The qualitative feedback from the AmeriCorps supported this claim.

It is difficult to assess the pharmacists' perceptions of user control due to the variation in responses. User control concerns the ease by which a user can correct or navigate back from an error [135]. It is somewhat difficult to make an error that is realized by RxMAGIC. For example, a user can dispense a medication that does not match the name of the prescribed medication; RxMAGIC does not currently check to ensure the medication names match before dispensing. This was done intentionally and in agreement with the pharmacists. If the user does make this error, they can easily void the dispensation and correct the mistake (i.e. recover easily and quickly, Q. 19), however RxMAGIC does not provide an error message. RxMAGIC provides few error messages altogether, which may explain the number of neutral responses to this statement (6/11, 55%, Q.18). We recognize that the error messages RxMAGIC does provide are

somewhat unclear, as they are the result of a bug in the application that has been difficult to understand. This has been discussed multiple time with pharmacists at the BFC. We continue to investigate this problem with the goal of alleviating incorrect error messages.

6.3.4 Limitations

It may be difficult to generalize these results to other settings as RxMAGIC was developed in collaboration with the BFC. However, we did not personally train all pharmacists that responded to this survey, and they may have little free clinic experience, yet the results indicate strong learnability and efficiency. The sample size may also limit the generalizability of the results, but it is a representative sample of the population of volunteer pharmacists.

6.3.5 Conclusions

The results of the usability questionnaire are generally positive and indicate that RxMAGIC addresses Nielsen's five facets of usability (i.e. learnability, efficiency, memorability, errors, and satisfaction) [93]. Pharmacists claimed that learning to use RxMAGIC was easy, they found it to be useful for the tasks it was designed, they were satisfied with its ability to improve workflow efficiency, they remembered how to log on and use it, and they recovered quickly and easily from mistakes. Optimizing these usability factors early in the design process was important to ensure user acceptance, which has contributed to the overall success of RxMAGIC.

6.4 COST

Reforming the US healthcare delivery system to improve the quality and value of care is essential to address increasing costs and the number of Americans without health insurance coverage. Although often debated, economic assessments are necessary components of evaluation because they can support decision makers in prioritizing interventions, allocating resources, and maximizing value [136]. Among the four metrics of the lean value diamond, demonstrating a decrease in costs associated with improved benefits may be the most difficult, as there are ethical issues regarding the monetization of health outcomes [136,137]. For example, critics of economic evaluations in healthcare believe that these methods hide assumptions about the goals of treatment, the selection of treatment, and the role of the patient [137]. These factors play an important role in healthcare delivery and should not be ignored even when providing patient care, regardless of the cost-benefit tradeoff.

Moreover, many argue that willingness-to-pay methods, which determine the maximum amount an individual or healthcare organization is willing to sacrifice to accrue a desired benefit, is unethical as it assigns a value to human life. Many believe this value can be influenced by income level, age, or pre-existing conditions (i.e. should we assign greater value to a child's life than an elderly adult?) [137]. In the unique case of a free clinic, it is even more difficult to assign costs to items that are donated, such as medication and clinician time. Thus, a cost-benefit analysis (CBA), which monetizes both the costs and benefits of an intervention, is often difficult to perform in healthcare; cost-effectiveness analysis (CEA) are more commonly used [138–140].

Both CBA and CEA assign monetary values to all project costs. However, a CEA is distinct from a CBA because the benefits are not monetized, but rather measured as a single unidimensional outcome such as illnesses prevented or years of life gained [141,142]. CEA

studies may be appropriate when there is only one type of physical outcome that is sought as a result of the intervention. The CEA is typically expressed in terms of a ratio where the denominator is a gain in health from a measure expressed in physical units and the numerator is the cost associated with that health gain. Because the numerator and denominator are incommensurable, they cannot be added or subtracted to obtain a single value. Therefore, CEA studies provide a source of unbiased information that offers insight into the tradeoffs and consequences of certain choices. CEA data is not, however, sufficient for making complex resource allocation decisions because it cannot incorporate all of the values that may be important (i.e. equity, feasibility, or overall budgetary impact) [143].

Many CEA studies compare the costs and health effects of prospective new interventions with current practice in that area. Evaluating the economic impact of open-source solutions is difficult because the costs incurred for development are one-time costs, while all subsequent adoptions of the solution can use the existing source code for free. The availability of free and ready-made components can significantly reduce or eliminate software development costs, depending on how future implementers utilize the source code. While development costs may be eliminated, it is likely that a second implementation site will incur greater costs for deployment and training as these tasks will not be tightly coupled to the development process. These costs may include downloading and customizing the source code for use in a particular setting. It is difficult to estimate these costs for a novel open-source solution that has yet to be implemented in a second site.

To explore potential cost savings as a result of utilizing open-source software, we performed a CEA of implementing RxMAGIC in the BFC and from the perspective of a second free clinic. The costs used in the model describing the BFC implementation accurately depict the

costs incurred to develop and deploy RxMAGIC at the BFC. The second CEA model describes the cost-effectiveness of RxMAGIC as a prospective new innovation from the perspective of a second implementation site. We assumed that the second site utilizes the freely available source code, thereby eliminating the cost for development from this model. I describe the assumptions used in both models below.

6.4.1 Methods

We created two models to demonstrate the CEA of RxMAGIC usage: the first model is from the perspective of the BFC and the second is from the perspective of a subsequent implementation site. The primary outcome measure for both models was cost per additional hour of value-added time during a one-year period. A one-year time horizon was chosen because all expenditures and benefits are realized in the near-term. The models were framed from the perspective of the healthcare organization, and the reference strategy was their previous paper-based dispensing process.

6.4.1.1 The BFC implementation

Costs

There are two categories of costs associated with RxMAGIC implementation: direct implementation costs and operational costs (Table 17). Direct implementation costs are those related to all means of production that are used to implement the system (i.e. hardware, software development, and deployment); indirect costs are not included in this model (i.e. administrative support). Operational costs are those related to the ongoing use and maintenance of the

intervention, such as materials and technology support. These figures accurately reflect the costs incurred to develop, deploy, and support RxMAGIC at the BFC and are based on receipts of purchase.

Table 17: Costs of RxMAGIC used in BFC implementation model.

Items	Quantity	Unit cost	Base Value
Direct Implementation Costs			
Hardware			
Dashboard monitor	1	$ 190.00	$ 190.00
Thermal label printer	2	$ 53.14	$ 106.28
Barcode scanner	2	$ 14.50	$ 29.00
Raspberry pi	1	$ 30.00	$ 30.00
Server	1	$ 1,210.00	$ 1,210.00
Computer	0	$ 350.00	$ 0.00
Development	400 hours	$ 44.60	$ 17,840.00
Deployment	20 hours	$ 44.60	$ 892.00
Direct Implementation Costs			**$ 20,297.28**
Operational Costs			
Labels			
Dispensed labels	9,100	$ 0.008	$ 78.91
Inventory labels	1,040	$ 0.008	$ 9.02
Printer ribbon	7	$ 5.52	$ 38.23
Power supply			$ 30.00
Training and support	15 hours	$ 44.60	$ 669.00
Operational Costs			**$ 825.16**
Total Costs			**$ 21,112.44**

Hardware costs were calculated to be $1,565.28 for the implementation at BFC. We decomposed the hardware costs into their individual components for transparency. The hardware acquired for the BFC implementation included: one 19.5-inch dashboard monitor with a HDMI signal input, two Zebra TLP 2844 thermal label printers, two Symbol Motorola LS2208 barcode

scanners (with interface cable and stand), one Raspberry Pi 2 Model B, and an application server (custom core i5 Mini-ITX computer) to host RxMAGIC at the BFC.

We purchased most hardware items 'used' and in bulk from eBay or Amazon, which significantly decreased the hardware costs overall. The BFC already had two laptop computers in the dispensary that were donated by UPMC during the EHR implementation, which is why the cost for a computer is listed as $0.00 in this model. We included this item as a direct implementation cost because we recognize that a clinic may need to purchase computers to utilize RxMAGIC. The pharmacists wanted to access RxMAGIC from both computers, thus we decided to set up two RxMAGIC workstations (i.e. two printers, two barcode scanners, etc.).

Development costs, calculated to be $17,840.00, included the costs of developing RxMAGIC, establishing interoperability to the EHR, and periodic system upgrades. We did not keep a rigorous timetable of the hours invested to develop RxMAGIC; in addition to an estimate given by the actual RxMAGIC developer, we based this figure on the expert opinions of two open-source software developers with access to the RxMAGIC source code on GitHub. We concluded that development of RxMAGIC consumed 10 weeks of work (40 hours/week) at $44.60/hour, which was the actual hourly wage of the RxMAGIC developer. We used the same hourly rate to calculate the cost of deployment, which included installing hardware at the clinic and inventory data entry. This figure was based on the total time invested in the three-phase deployment process described in Aim 2.

The cost of labels used per year was calculated to be $88.00, which includes both prescription labels and inventory labels. This figure was based on the average number of dispensations per day, which was obtained from RxMAGIC, and the average number of

inventory labels used per week. The cost of printer ribbons used per year was calculated to be $38 and based on the total number of labels used per year (i.e. one ribbon = 1464 labels).

The cost for powering the new hardware was nominal at $30.00 and was calculated using the Appliance Energy Calculator at energy.gov (https://energy.gov/energysaver/maps/appliance-energy-calculator). Training and support costs, calculated to be $669.00, included 15 hours of change management, user training, and ongoing maintenance and support. We assumed the same hourly rate for the calculation of this figure.

Benefits

The outcome measurement was additional hour of value-added time. This figure was calculated based on differences in the value quotient between the pre- and post-deployment time-motion studies. The value quotient describes the percentage of value-added time in a workflow. For the purposes of this calculation, we used the lower bound of the value quotient range for the pre-deployment study (40.3%). The difference in value-added time between the pre- and post studies is 0.3 hour per hour of value-added time, or 18 minutes value-time gained per hour. Based on data from the BFC, we assumed that there are 364, 3 hour clinics per year. However, two pharmacists were independently observed during each clinic session in the time-motion studies. Each dataset per clinic observation was approximately 6 hours, thus we assumed each clinic is 6 hours to reflect two working pharmacists. The benefits were calculated to be 728 additional value-added hours per year; this figure was used in both models. The calculation used to arrive at this figure is shown below:

$$\frac{18\ min}{(clinic)\ hour} \times \frac{364\ clinics}{year} \times \frac{6\ hours}{clinic} = \frac{39312\ min}{year} = 655\ hours/year$$

6.4.1.2 Subsequent implementations

It is difficult to generalize the results described in the BFC implementation for several reasons. First, while the development costs were substantial in this model, they were a one-time cost and will not be incurred at this magnitude for a subsequent implementation because RxMAGIC is an open-source solution. Thus, assuming a second implementation site utilizes the freely available source code, development costs should not be a factor from the perspective of a new free clinic. Second, given the collaborative nature of this project, software development was tightly coupled to the deployment and training processes. Many of the pharmacist users were involved in the development of the system which may have reduced the amount of training needed during deployment. It is likely that the costs for deployment and training/support will be greater for subsequent implementations. This may include downloading and customizing the source code for a particular setting and establishing interoperability with existing systems. These costs will vary depending on the existing health IT infrastructure in a second implementation site. Third, the hardware costs used in the BFC model may not be generalizable because we purchased them in 'used' condition and in bulk. This greatly reduced the cost for the thermal label printers and barcode scanners. Thus, the condition of the hardware purchased and the quantity of items needed may influence the CEA for a second site.

We attempted to capture this variation in a second model that describes the cost-benefit tradeoff from the perspective of a second implementation site. In this model, we assumed that the site requires one unit of each piece of hardware, as if they are setting up one RxMAGIC workstation (i.e. one monitor, one printer, one barcode scanner, etc.). The base values for hardware items in this model represent the expected cost for purchasing each item in new

condition. We estimated these figures based on the current value of hardware items on Amazon and similar sites.

Table 18: Costs of RxMAGIC used in subsequent implementations model.

Items	Quantity	Unit cost	Base Value	Range
Direct Implementation Costs				
Hardware				
Dashboard monitor	1	$ 190.00	$ 190.00	$ 0.00 – 249.00
Thermal label printer	1	$ 389.99	$ 389.99	$ 0.00-780.00
Barcode scanner	1	$ 89.00	$ 89.00	$ 0.00-178.00
Raspberry pi	1	$ 30.00	$ 30.00	
Server	1	$ 1,500.00	$ 1,500.00	$ 0.00-3,000.00
Computer	0	$ 350.00	$ 350.00	$ 0.00-1,000.00
Deployment	40 hours	$ 44.60	$ 1,784.00	$ 892.00-3,568.00
Direct Implementation Costs			**$ 4,332.99**	
Operational Costs				
Labels				$ 43.97 – 175.86
Dispensed labels	9,100	$ 0.008	$ 78.91	
Inventory labels	1,040	$ 0.008	$ 9.02	
Printer ribbon	7	$ 5.52	$ 38.23	$ 19.12-76.46
Power supply			$ 30.00	
Training and support	30 hours	$ 44.60	$ 1,338.00	$669.00–2,676.00
Operational Costs			**$ 1,493.93**	
Total Costs			**$ 5,826.92**	

Costs

Hardware costs were calculated to be $2,198.99 for the model describing subsequent implementations. We assumed a quantity of one for all items in this model; the costs represent the hardware items in ‘new’ condition. Perhaps the greatest component of variation in these costs

is the quantity of items an implementation site will need to utilize RxMAGIC. In the sensitivity analysis, the costs of items were varied to reflect changes in quantity, with a quantity of two being the most items needed for implementation. These values are in the last column of Table 18. The lower bound of all hardware items is $0.00 because it is possible that a clinic may already have the appropriate hardware, like the laptops at the BFC. This is particularly relevant for items such as the dashboard monitor, which is not a necessary item to utilize RxMAGIC.

The upper bound for each hardware item in the sensitivity analysis was varied to represent a clinic needing a quantity of two of each item, which was 200% of the baseline cost. For the dashboard monitor, the upper bound represents a 23-inch screen as opposed to the 19.5-inch screen, which is captured in the base value. A larger screen may be appropriate for a clinic that has a larger dispensary or more space between the workstations. For the server, we estimated the base value to be $1,500.00, however there is much variation in this cost depending on the sophistication of the server that is acquired. Further, if a clinic already has a dedicated server, or is able to use a virtual server for the entire application at no direct cost to them, then there may not need be a need for a server altogether. This is represented in the lower bound in the sensitivity analysis. Likewise, for computers, we estimated that one computer may cost a clinic $350.00. There is also much variation around this cost that depends on the current hardware in the clinic, the sophistication of the computer that is purchased, or the quantity needed. We attempted to demonstrate how this variation effects the CEA in the sensitivity analysis, however all upper bound values are estimates.

The cost for development is not included in this model as those costs are not a factor for a second implementation site. However, because of the factors described above, we have doubled the cost for deployment in the second model ($1,784.00). This figure includes customization,

installing hardware, interfacing with other systems, and periodic system upgrades. Similarly, we have doubled the cost for training and support in the second model ($1,338.00). We expect that these costs will be greater for a second implementation site as they are not tightly coupled to the development process. As these values are estimates and not based on evidence, we varied these costs from 50% to 200% of the base value in the sensitivity analysis.

Apart from changes to training and support, all other operational costs remained the same in the second model. We varied the cost of labels and printer ribbons from 50% to 200% of the base value as these figures may change depending on the patient volume at a second implementation site.

Sensitivity analysis

To understand which parameters have the greatest influence on the outcome, we performed a one-way sensitivity analysis using the ranges shown in Table 18. This is a deterministic sensitivity analysis in which the input parameter is varied across the indicated range of values, while other input variables are held constant. The CEA ratio was calculated twice for each parameter using the minimum and maximum values in Table 18 as inputs. A tornado diagram is used to depict the results of the sensitivity analysis, where each bar depicts the overall effect on the CEA ratio.

6.4.2 Results

In the one-year CEA model for the BFC implementation, the cost per additional hour of value added time was $32.25. This ratio directly reflects the cost-benefit tradeoff experienced at the BFC. As expected, costs for development were the most significant in this model. The CEA ratio

for the second model was $8.90 for each additional hour of value-added time; this figure is more generalizable from the perspective of a second implementation site as development costs were eliminated. The model was most sensitive to variations in server costs, which ranged from $6.61 to $11.19 (Table 19, Figure 22). Variations in deployment costs had the second largest effect on the CEA ratio ($7.53-$11.62). The model was least sensitive to variations in costs for printer ribbons and labels, in which the CEA ratio ranged from $8.87 to $8.95 and $8.83 to $9.03, respectively. Variations in most parameters did not have a large effect on the CEA ratio. We show the range of CEA ratios as they pertain to each cost included in the sensitivity analysis (Table 19).

Table 19: CEA ratios for items varied in the sensitivity analysis.

Item	**CEA Lower Bound**	**CEA Upper Bound**
Printer ribbons	$ 8.87	$ 8.95
Labels	$ 8.83	$ 9.03
Barcode scanner(s)	$ 8.76	$ 9.03
Dashboard monitor	$ 8.61	$ 8.99
Thermal label printer(s)	$ 8.30	$ 9.49
Computer(s)	$ 8.36	$ 9.89
Training and support	$ 7.88	$ 10.94
Deployment	$ 7.53	$ 11.62
Server	$ 6.61	$ 11.19

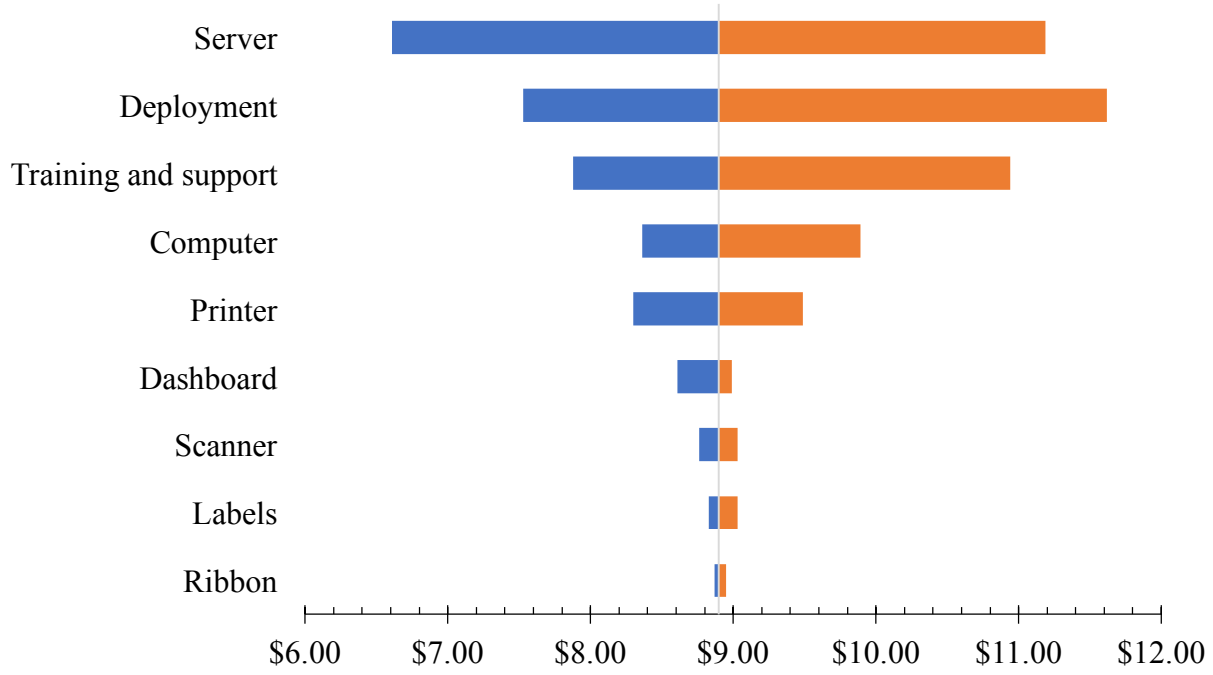


Figure 22: Tornado diagram showing the one-way sensitivity analysis of one-year CEA model. Each bar depicts the overall effect on the model as that input is varied across the indicated range of values, while other inputs are held constant. The vertical line indicates the base case ($8.90).

6.4.3 Discussion

This analysis demonstrates the potential cost savings of using open-source software, which is an important part of this research. While the CEA ratio for the BFC implementation is $32.25 per additional hour of value-added time, it is nearly $25 lower from the perspective of a second implementation site ($8.90). We report this value because it is more generalizable, as it assumes use of the freely available source code, which is an important component of this innovation. Further, the sensitivity analysis indicates that the CEA ratio is relatively stable across a wide range of assumptions. This is particularly important as it is difficult to estimate costs for hardware items, which may vary depending on the condition of the item or the quantity needed. This is evident in the model describing the BFC implementation, where the costs for printers and

scanners are significantly reduced. Likewise, as RxMAGIC has not yet been utilized by a second free clinic, it is difficult to estimate customization, deployment, and training costs. The model is robust in that the CEA ratio does not deviate far from the base value when the upper bounds of the deployment and training costs were considered. We expect these costs to be the most variable for a second implementation site.

The main objective of this CEA analysis is to provide unbiased information about an implementation scenario so that interested free clinics can reproduce this model and understand potential cost implications. The sensitivity analysis includes appropriate ranges for variations in cost of hardware components, however there could be even greater variation than what is represented in this model. For example, the BFC had two computer workstations in the dispensary thus requiring two printers and two barcode scanners. The amount of equipment needed to support RxMAGIC in a different setting can vary based on the quantity needed and the status of the purchased equipment (i.e. new or used). Purchasing used equipment may significantly reduce the amount of implementation costs, which is important in a low-resource setting.

It is also important to note that many of the system costs included in this model are one-time costs, meaning that they will only be incurred at the time of implementation. While we only developed the model for a one-year time horizon, it is likely that the CEA ratio would improve in consecutive years as the benefits will remain constant but the costs will decrease. Only operational costs will be relevant in consecutive years, which are trivial in this model, thus potentially overestimating the CEA ratio in both scenarios. Many models typically include the cost for replacing hardware every three years, in which case those costs would be incurred repeatedly over a longer time-horizon. Further, this model does not include costs for a potential

network installation or establishing a data feed from an EHR, which should be considered if this model is to be reproduced.

Given the nature of a CEA, the benefits described in this model are unidimensional. It may be difficult to interpret what additional hours of value-added time means in this setting. The goal of RxMAGIC was to improve workflow efficiency so that pharmacists had increased time to focus on other tasks, particularly those that are more patient-centered. The results from these evaluations demonstrate significant time savings, however how that additional time is redirected is not as clear. There is a significant body of literature that discusses the importance of pharmacy involvement in direct-patient care to improve medical outcomes and decrease associated costs (i.e. hospitalizations and emergency department visits) [112,120–122], and particularly how effective, time-saving health IT can contribute to this goal [144]. Pharmacy staff can be redirected in a free clinic setting to serve more patients or just improve their existing interactions. Thus, there are many other potential areas of cost savings associated with implementing an intervention such as RxMAGIC that are not included in this model. These savings may include, but are not limited to, avoidable drug waste [145], transcription errors [146], and improved medication adherence [122].

Not all benefits of RxMAGIC are measurable in financial terms: other benefits include improved quality of work life and quality of care, reduced medical errors, and better access to information of good quality [147,148]. The latter has been found to improve decision-making and reduce physical and cognitive workload in a community pharmacy setting [42,148]. A CEA analysis is only one component of a complete evaluation of the effects of implementing RxMAGIC in this setting. These data alone are not sufficient for making complex allocation decisions as they do not consider all values that are likely important such as feasibility or overall

budgetary impact. Total budget impact tends to be of importance for technologies in general, but especially in a free clinic setting where resources are already limited. The majority of a free clinic's budget is dedicated to procuring essential medicines for their patients, which is why a low-cost intervention that may result in savings can be beneficial.

6.4.4 Limitations

This CEA study has several limitations, most of which are covered in the context of the discussion. There may be other costs associated with implementation of RxMAGIC. For example, system integration costs (i.e. receiving electronic prescription data from an EHR) may be significant at other free clinics and are not included in this model. However, benefits can likely be realized even without this component. Likewise, the cots for deployment and training may be even greater than what is included in this model. It is difficult to estimate these costs as this is a novel open-source solution that has yet to be implemented in a second setting. Interpreting the results of a CEA can be difficult because there are many other factors that contribute to the decision-making process, such as budget impact, which may impact the generalizability of these results. Similarly, it is difficult to estimate an organization's willingness to pay as it pertains to RxMAGIC, which is the maximum amount they are willing to sacrifice to accrue the benefits described.

6.5 CONCLUSIONS

The results from Aim 3 describe the impact of RxMAGIC *in situ* as it pertains to the four metrics of the lean value diamond: time utilization, quality, satisfaction, and cost. Each component of this comprehensive problem impact study provides a different perspective on how RxMAGIC has effected the BFC. Together, these studies show that RxMAGIC has addressed the original problems that motivated its creation.

The pre- and post-deployment time-motion study demonstrates a quantified improvement in pharmacist workflow efficiency, in which pharmacists spend less time completing non-value-added tasks such as labeling and documenting. These results are further supported by the Health-ITUES questionnaire results, that indicates pharmacists perceive RxMAGIC to be useful for the tasks it supports and an overall positive impact on their dispensary services. The implications of time savings are addressed in Section 6.2, which discuss potential improvements to the quality of services provided. Although we cannot explicitly claim that RxMAGIC has improved the pharmacist-patient relationship, it is possible that pharmacists will redirect time savings to focus on more patient-centered tasks, thereby resulting in improved medication outcomes. We attempt to compare the benefit of this additional value-added time with the cost of implementing RxMAGIC in Section 6.4. These benefits are described in the context of the BFC implementation in addition to the perspective of a second implementation site; the results from the latter are of greater interest as they are more generalizable for subsequent adoptions. While the study has several limitations, these results aim to provide information about a potential cost-efficiency tradeoff because of RxMAGIC.

7.0 DISCUSSION AND FUTURE WORK

This dissertation describes the process used to design, develop, and evaluate RxMAGIC, a dispensary management information system, as guided by Friedman and Wyatt's evaluation framework [17]. We have used a combination of studies and methods to support the system development process, beginning with a needs assessment and ending with a problem impact study. While RxMAGIC is the obvious physical contribution of this research, the approach described in this research demonstrates the importance of user-centered design principles, health informatics standards, and multiple levels of evaluation. With this approach, we were able to achieve the three specific aims we set out to achieve in Section 3.3:

AIM 1: To design a production version of RxMAGIC and evaluate it in a laboratory setting.

- We proposed an initial framework for RxMAGIC based on a careful understanding of the specific workflow challenges encountered in the BFC.
- We developed a prototype version of the system and tested its usability with potential users to guide its continued development.
- We used these results to expand and improve the prototype version of RxMAGIC and, again, tested its usability with actual pharmacists from the BFC.

AIM 2: To identify and resolve post-deployment implications related to system design and workflow organization.

- We deployed aspects of RxMAGIC in two locations (UPMC Montefiore and the BFC) and trained all users.
- We performed a field-user effect study to understand how pharmacists interact with RxMAGIC in practice, and identified and resolved both functional and organizational challenges.

AIM 3: To evaluate the impact of RxMAGIC in the clinic within the framework of the lean value diamond.

- We performed a post-deployment time-motion study to measure changes in pharmacist time utilization.
- We used these results to infer potential changes in the quality of care provided.
- We administered the H-ITUES to understand pharmacists' perceptions of the perceived usefulness and ease of use of RxMAGIC.
- We assessed the cost-effectiveness of RxMAGIC in terms of additional hours of value-added time as a prospective new intervention being considered for implementation by a free clinic.

7.1 NEEDS ASSESSMENT AND USABILITY

We began by qualitatively understanding the pharmaceutical workflow at the BFC and the specific challenges that pharmacists encounter in the dispensary. Having identified a set of workflow challenge themes, we quantified their impact on pharmacist time utilization to help prioritize intervention design and provide a baseline for post-deployment comparison. We used these data to map workflow challenges to individual interventions, which informed the initial

framework of a dispensary management information system, or RxMAGIC. We used a prototype-and-test approach to ensure the prototype had the potential to meet pharmacists' needs, and used these results to modify the design and expand the prototype. The production version was evaluated for usability in a laboratory-based environment and these results continued to inform changes to the system before deployment.

7.2 DEPLOYMENT AND FIELD-USER EFFECT

To prepare for deployment, health data standards including RxNorm and HL7 messaging were implemented to achieve functional and semantic interoperability with the EHR at the clinic. RxMAGIC was deployed in the BFC dispensary in October 2016 and inventory components were deployed in UPMC Montefiore. At the time of this writing, RxMAGIC has 21 distinct users and is used daily at the BFC (approximately 5,000 dispensations to date). On average, pharmacists dispense 25 prescriptions per clinic and the inventory includes nearly 800 stock entries (approximately 300 distinct medications).

In the week following deployment, we performed a field-user effect study to understand barriers to successful adoption. These challenges were classified as either functional or organizational. Functional challenges were related to the design and content of the system; these were mostly focused on problems with interoperability. Organizational challenges were those related to people, workflow organization and communication. While challenges were resolved in the context of this study, we continue to make changes to RxMAGIC so that it brings the most value to the dispensary services.

7.3 PROBLEM IMPACT

Once RxMAGIC was in steady use, approximately four months after its deployment, we evaluated its impact on the four metrics of the lean value diamond: time utilization, quality, satisfaction, and cost. We used a combination of evaluation methods including a time-motion study, usability evaluation survey, and economic analysis. The results demonstrated that RxMAGIC has addressed the problems uncovered in the needs assessment studies. Specifically, it has improved workflow efficiency and the amount of time pharmacists invest in value-added tasks by streamlining the dispensing process. Per the H-ITUES results, pharmacists perceived RxMAGIC to be both useful and easy to use, having a positive impact on their dispensary services. We discussed how improvements in pharmacist time utilization can result in improved patient outcomes such as medication adherence. Lastly, we assessed the economic impact of RxMAGIC as an open-source solution as it relates to efficiency gains from the perspective of a free clinic. Together, these results proved that RxMAGIC has effectively met the pharmacists' needs at the BFC, which can be attributed to the comprehensive process that was employed to create it.

7.4 FUTURE WORK

This research uncovers many potential areas of inquiry that future work could explore. Perhaps the most obvious direction for this research is to understand the generalizability of RxMAGIC in other free clinic settings. Although we do not intend to use the RxMAGIC source code for commercial purposes, we have filed an invention disclosure with the University of Pittsburgh

Innovation Institute. Our goal is to acquire an open source license that is approved by the Open Source Initiative (OSI). In brief, a license would allow our program to be freely used, modified, and shared; technically, we cannot call RxMAGIC "Open Source" if we do not have an approved license. At the time of this writing, we are still in the early phases of the licensing process.

We have been exploring potential possibilities for implementation both domestically and internationally. Recently, as part of a collaboration with a non-profit, non-governmental organization called Shoulder to Shoulder, we have forked the original RxMAGIC code to create an independent and distinct application for a primary care clinic in rural Honduras. This version of the application runs on a touchscreen workstation and primarily utilizes dispensing and inventory features based on those in the original system. We were unable to use RxNorm in this implementation because it could not sufficiently support the medications used in this setting; this has proved to be challenging and further emphasizes the importance of health data standards and interoperability. In addition to the collaboration in Honduras, we have been contacted by a physician from Healthcare for the Homeless in Houston, Texas who is interested in using RxMAGIC in their pharmacy. We are currently in discussions with several people from this group as they attempt to establish interoperability with EpicCare in their clinic.

There are several ways in which RxMAGIC can be improved and expanded. The process of therapeutic interchange has been shown to decrease drug expenditures and other related healthcare costs [149,150]. Therapeutic interchange is the practice of replacing, with the prescribing physician's approval, a prescription medication originally prescribed with a chemically different medication [149]. RxMAGIC could accommodate this process by providing preferred medications as a guide for dispensing when alternative medication products are available to treat a patient's condition. This could be particularly useful in a low-resource setting

that serves patients with poor medication adherence. The suggested alternative medication may be more convenient for patients to take. For example, the medication could be less expensive, cause less side effects, or only need to be taken twice a day rather than for times a day. Implementing this type of therapeutic substitution process could improve RxMAGIC's generalizability and utility from the physician's perspective. Likewise, RxMAGIC could incorporate a process that detects potential prescriptions errors in regard to drug-drug interactions (DDI) or drug dosing. Given the limited formulary in a free clinic setting, research is needed to understand what types of DDIs are most relevant in this setting.

The implementation of RxNorm in this setting is another avenue of future research. Many studies have evaluated RxNorm in ambulatory electronic prescribing to understand its completeness [67,68]. Further, some studies have evaluated the content of prescribing errors from the perspective of the community pharmacist, however they may not focus on challenges with RxNorm [42,46,148]. To my knowledge, there is little research done on the use of RxNorm in a free clinic setting or in a pharmacy dispensing system. The implementation of RxNorm in RxMAGIC at the BFC can allow researchers to assess the completeness of the vocabulary, the success rate of NDC-to-CUI mappings, and its ability to effectively support pharmacists' needs and intents in a dispensing system. This could be an interesting research area as RxNorm continues to be widely adopted by enterprise EHR systems, which may have implications on dispensing systems in community pharmacies. Further, as we were unable to use RxNorm in the Honduras application, establishing some form of standard terminology for use in international settings is certainly an area of interest from the perspective of global health informatics.

Other potential research ideas can leverage the consumption data in RxMAGIC. After one year of use, RxMAGIC could provide a decent dataset summarizing dispensation patterns in

a medically vulnerable population. Although the BFC does not dispensed controlled substances, this type of data could be useful in understanding prescribing patterns and potentially investigating drug use and addiction if implemented in a setting that does dispense narcotics. Medication consumption data is also useful for inventory modeling, which can have a significant impact on reducing pharmaceutical expenditures. Effective pharmacy stock modeling is particularly important in developing countries where stockouts are frequently encountered and can have severe detrimental effects on patient care (i.e. poor outcomes and drug-resistance). Thus, as evidenced by the Honduras implementation, there is certainly a place for RxMAGIC in resource poor areas of the world.

7.5 CONCLUSIONS

This work has been motivated by challenges in the free clinic dispensing process, as articulated by the BFC pharmacists prior to the beginning of this work, by Friedman and Wyatt's evaluation methods, and by the fundamental theorem of biomedical informatics. The obvious physical contribution of this research is RxMAGIC, an interoperable, web-based resource that is designed to streamline the dispensing process and improve inventory control in a low-resource dispensary.

RxMAGIC is novel in that it was designed with user-centered principles to effectively meet the needs of pharmacist in these settings; it is comprised of problem-driven interventions that directly link to the challenges they are designed to alleviate; it is able to support multiple user groups including pharmacists, AmeriCorps, and physicians by providing visibility into the clinic's formulary; it is an open-source program (pending licensing) that lends itself to customization; and it is capable of electronically receiving e-prescriptions from a vendor

enterprise EHR system. We believe that the process employed to create RxMAGIC has significantly contributed to its success at the BFC. Further, we think it holds high potential for improving processes associated with medication management in a free clinic setting that enable pharmacists to provide the best care possible.

APPENDIX A

SEQUENCE MODEL FROM QUALITATIVE INQUIRY

The sequence model decomposes all workflow activities into their individual tasks. The activity is described as having an intent (i.e. goal), trigger (i.e. what initiates the task), and an abstract strategy (i.e. alternative ways other pharmacists complete the task).

Activity ***Intent/Trigger/Abstract Strategy***	**Tasks**	**Breakdowns**
Intent: Prepare 'General' prescription to be dispensed. ***Trigger:*** Clinician places a medication order (non-PAP). ***Abstract Strategy:*** To expedite the process, pharmacist prepares medication orders for patients with chronic conditions prior to clinician examination.	**T1.** Scan EMR dashboard to see if patient status has changed. **T2.** Receives prescription information in EMR. **T3**. Scans stock cabinets for medication.	**B1**. Clinician failed to update patient status after examination. **B2**. The dispensary does not have the prescribed medication.

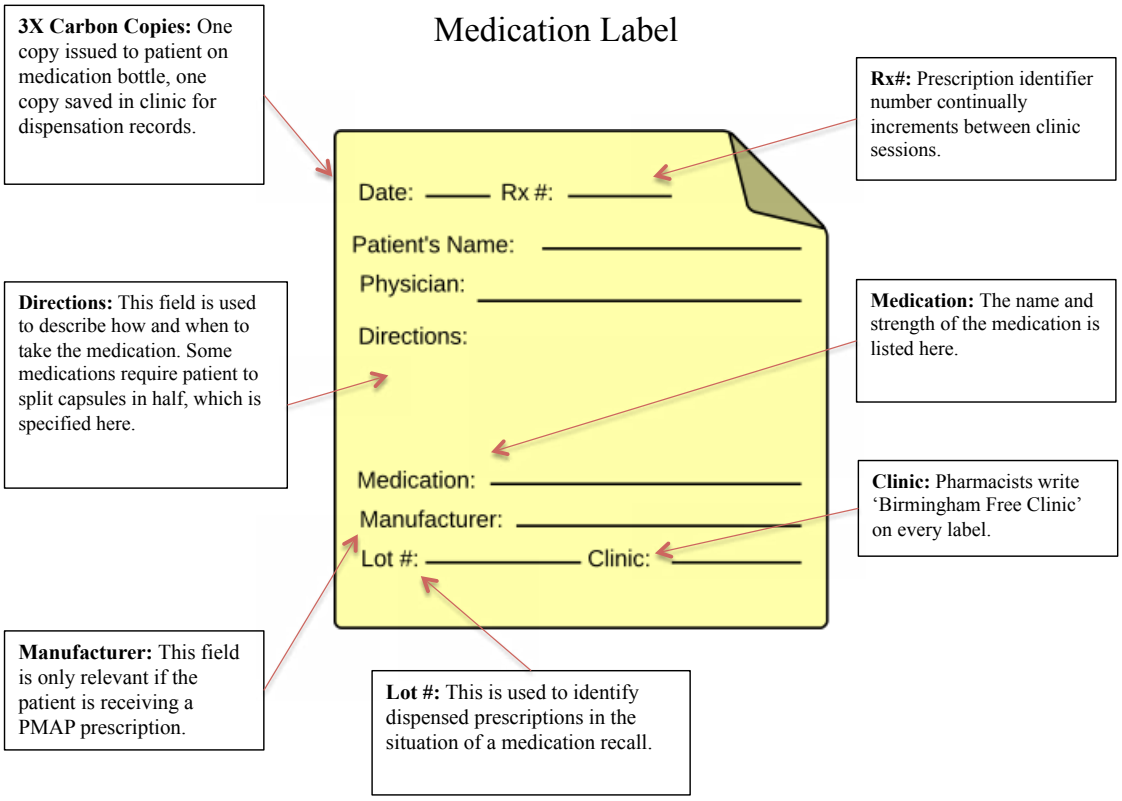
Intent: Prepare PAP medications to be dispensed. ***Trigger:*** An PAP patient has checked in at the clinic and has met with the pharmacist.	**T1**. If patient is a monthly scheduled patient, then pharmacist has a one-on-one counseling session with the patient in an exam room. **T2.** Medications are retrieved from PAP cabinet. **T3.** Medication labels are prepared and taped on top of previous labels. **T4.** Medications are dispensed immediately to patient (patient only requires clinician examination every three visits).	**B3**. PAP medications have not been re-ordered. **B4.** Patient was due for an annual program re-enrollment but paperwork has not been processed.
Intent: Discuss new medication plan with clinician. ***Trigger:*** Clinician prescribes a medication that the dispensary does not have. ***Abstract Strategy:*** Pharmacist feels comfortable determining a new treatment plan for the patient without consulting the clinician	**T1.** Find clinician in the clinic during clinic session. **T2.** Consult clinician to discuss the problem. **T3**. Determine new treatment plan with clinician. **T4**. Scan medication cabinets for new medication. **T5**. Correct EMR entry to adjust for the new order.	**B5**. Pharmacist must leave his/her workspace to interrupt a clinician while he/she is with a new patient. **B6**. Clinician does not remember all the details from a recent patient and must refer to EMR. **B7**. The prescribed medication is required and patient must buy the medication from community pharmacy. **B8.** EMR order correction process is cumbersome and time-consuming.
Intent: Dispense medications. ***Trigger:*** Patient prescriptions are prepared and ready to be filled	**T1**. All medication stock bottles are located and retrieved from cabinets. **T2**. New patient-medication bottles are retrieved from drawers. **T3.** Pharmacist counts the pills to be dispensed. **T4**. Pills are filtered into new medication bottles. **T5**. Medication labels are written and affixed to bottles.	**B9**. There are not enough pills in the current stock bottle. **B10**. The pharmacist miscounted and needs to start over. **B11**. There is an error transcribed on the medication label and it must be re-written. **B12**. Wrong medication label is taped on the medication bottle

Intent: PAP application initiation. ***Trigger:*** A patient qualifies for prescription medication from a pharmaceutical manufacturing company.	**T1**. Pharmacist explains the PAP application process to the patient. **T1**. Pharmacist locates correct PAP application. **T2**. Patient fills out required fields. **T3**. Pharmacist and patient discuss what materials the patient must bring in to receive the medication (i.e. W2 form). **T4**. Application is placed in a bin to be processed.	**B13**. There are no copies of the correct PAP application. **B14**. Patient is unable to provide income documents.
Intent: Complete the Pharmacy Activity Sheet. ***Trigger:*** The last patient has been counseled. ***Abstract Strategy:*** *Pharmacists complete the document throughout the clinic session.*	**T1**. Pharmacist retrieves new document from a binder. **T2**. Pharmacist transcribes dispensed medication information from that clinic session to the form. **T3**. Transcribes low inventory alerts to the proper section of the form. **T4.** Deposits form in specified outgoing bin located in the check-in room.	**B15**. There are no copies of the Pharmacy Activity Sheet. **B16**. Pharmacist forgets to transcribe low-inventory medication. **B17.** There is insufficient time to fill out the form in its entirety.

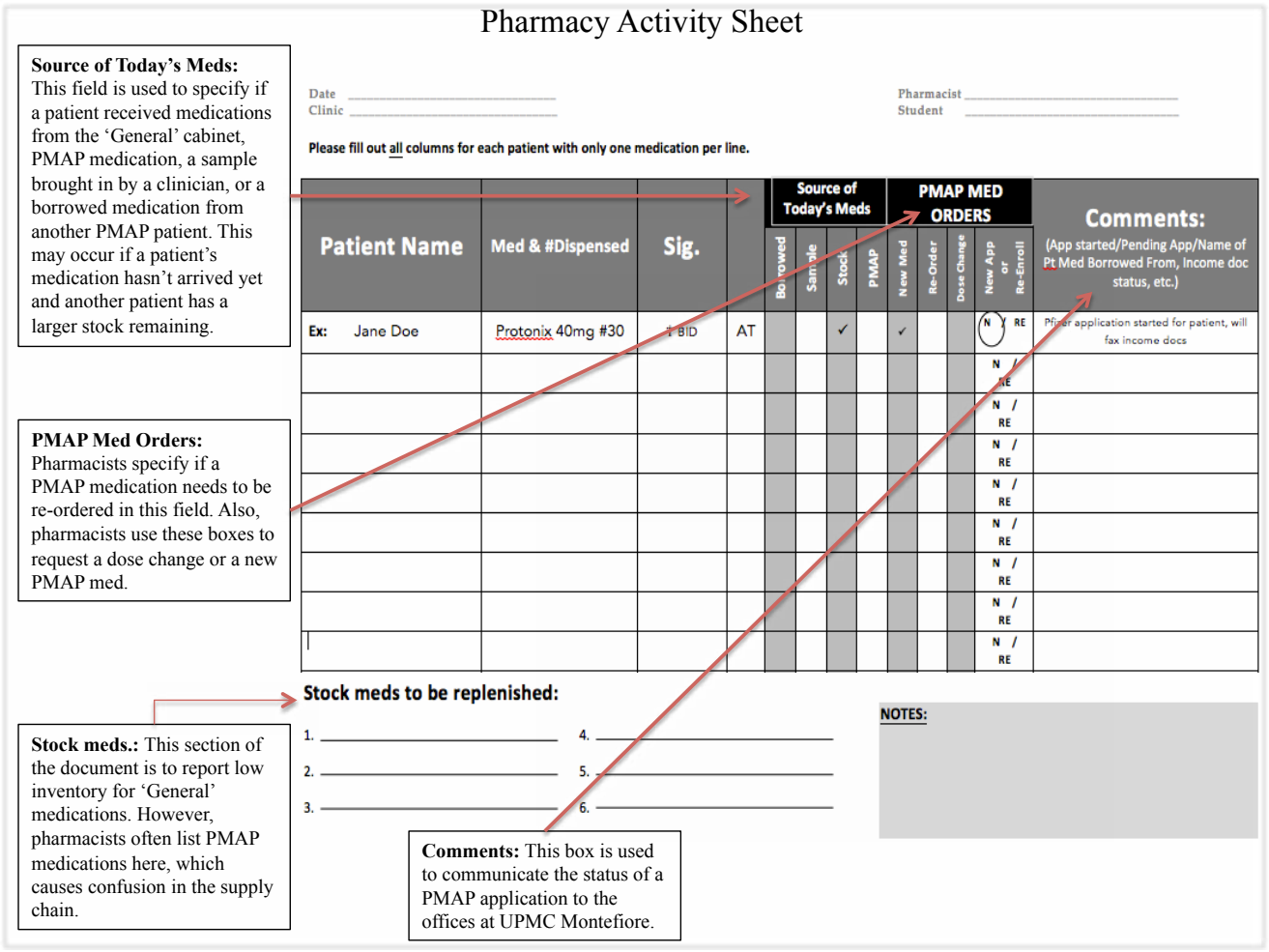
APPENDIX B

ARTIFACT MODELS FOR QUALITATIVE INQUIRY

Two artifact models were created during the qualitative inquiry. The first is a replication of the handwritten prescription label pharmacists affix on patient bottles. These labels adhere to dispensing laws within the state of Pennsylvania. Each field is explained in the figure below.



The second artifact is a copy of the activity sheet. This is completed at the end of each clinic session and describes each dispensation that day in addition to any low-stock medications that need to be replenished. Completion of this document adheres to certain regulations for free clinics in Pennsylvania. An example is shown on the first line of the sheet. All fields are described in the model below.



APPENDIX C

CODEBOOK FOR PRE-DEPLOYMENT TIME-MOTION STUDY

Category	Subcategory	Definition	Value definition
Rx Prep	Hunting for medication	The physical search for stock medication in the cabinets. **Begin:** When pharmacist slides open cabinet door to initiate search. **End:** When pharmacist closes the door and/or found the medication.	NVA
Rx Prep	Labeling medication bottles	The manual process of writing individual medication labels for patient bottles. **Begin:** When pharmacist starts writing on a label. **End**: When pharmacist finishes taping the label on the bottle.	NVA
Patient interaction	Counseling patients	Explaining medication and administration instructions to patient during dispensation. **Begin:** When pharmacist calls patient into the dispensary. **End:** When patient exits the dispensary.	VA
EMR	EMR operations	Any time spent in the EMR (i.e. entering & correcting orders, retrieving patient information, managing patient status). **Begin:** When pharmacist turns to the computer and opens Epic. **End:** When pharmacist isn't actively using Epic.	NVA/VA

Rx Prep	Duplicate documenting	Filling out the Pharmacy Activity Sheet with dispensation information. **Begin:** When pharmacist starts writing patient information on PAS. **End:** When pharmacist completes the document.	NVA
Clinician interaction	Consulting clinician	Consulting physician to discuss patient treatment plans or answer questions regarding formulary. **Begin:** When physician physically enters the dispensary and/or when pharmacist talks to physician in exam room. **End**: When physician leaves dispensary and/or when pharmacist finishes conversation with physician.	VA
Patient interaction	PAP initiation	Deciding to initiate a PMAP program with patient and beginning application process. **Begin:** When pharmacist starts filling out application. **End:** When pharmacist finishes working on application.	VA
Patient interaction	PAP discussion	Talking to patient about bringing in missing application materials. **Begin:** When pharmacist brings up PMAP during counseling. **End:** When they stop talking about the application.	VA
Clinician interaction	Teaching students/clinician volunteers	Teaching sessions with pharmacy students and new volunteers. **Begin:** When pharmacist initiates teaching session by asking questions of students. **End:** When the interaction ends.	VA
Rx Prep	Dispensing medication	Retrieving empty medication bottles, counting pills, and filtering medication into bottles. **Begin:** When pharmacist either begins counting pills or reaches for an empty medication bottles. **End**: When pills are filtered into bottle.	NVA
Rx Prep	Traveling	When pharmacist moves between locations in the entire clinic (i.e. walking to exam room) and in the dispensary alone. **Begins:** When pharmacist gets up from the desk. **Ends:** When pharmacist returns.	NVA
Other	Other	Any arbitrary tasks that are unrelated to work tasks. For example, casual conversation or using the restroom.	NVA

APPENDIX D

USABILITY TASKS FOR PROTOTYPE TESTING

Participants were asked to complete the following tasks within the RxMAGIC prototype. All necessary information was provided to them to complete these tasks.

(1) Register a patient. Please register the following patient: Jack Smith, DOB: 04/20/1956, Address: 332 Park Avenue, Pittsburgh, PA, 15232.

(2) Enter medication into general inventory. Please enter Ibuprofen 200 MG Oral Tablets into the general inventory (quantity: 100, expiration date: Jul/2017, lot number: 78AD889)

(3) Enter medication into PAP inventory. Please enter Depakote 250 MG Oral Tablets into the PAP inventory for Jack Smith. (expiration date: Sept/2018, lot number: AD113)

(4) Dispense medication. Please select a prescription of your choice from the dashboard and dispense the appropriate medication. You may use any of the medication bottles you see in front of you.

(5) Initiate a PAP application. Please enter a new PAP application for Jack Smith. Company: Abbott Pharmaceuticals; Medication: Depakote 250 MG Oral Tablets.

APPENDIX E

EPICS AND USER STORIES

Epic 01: View and maintain inventory through a web-based browser. (10)	
Pharmacist	I want to have visibility into the medication inventory so that I can inform appropriate staff of insufficient inventory and facilitate reordering.
	I want to have visibility into the medication inventory so that I don't waste time physically searching for medications in the cabinets that we don't have in stock.
	I want to have visibility into the specific inventories maintained by the dispensary so that I know which cabinet to access when consulted about stock availability.
	I want to enter new medication items into the inventory so that I can attach a unique inventory ID barcode to all stock medications.
	I want to be able to edit drug counts in the inventory so that I can ensure they are accurate at all times.
	I want to be able to reprint inventory ID labels so that each medication item has a legible barcoded label (should one become detached).
	I want to be able to delete items from the inventory so that I can cleanse the inventory of expired medication.
Physician	I want to have visibility into the current formulary during patient visits so that I can have an informed discussion with the patient about their treatment plan without interrupting the pharmacist.
	I want to know if a patient is enrolled in a PAP program so that I know I can prescribe certain types of medications.
AC	I want to enter items into the inventory from my own office so that I can deliver them to the clinic labeled and reduce the pharmacist workload.
Epic 02: Use electronic dispensation to update drug counts in real time. (6)	

Pharmacist	I want electronic dispensation to update drug counts in real time so that stock counts are updated accurately and immediately.
	I want electronic dispensation to update drug counts in real time so that I am informed of low-inventory levels in the timeliest fashion.
	I want to be able to electronically dispense medication without a medication order from the EHR so that I can maintain accurate drug counts for OTC medication too.
	I want to know the history of a dispensation for a certain patient (medications patients are prescribed and taking) from the BFC so that I can avoid drug-drug interactions during dispensation.
	I want to understand specific stock availability at the point of dispensation so that I ensure we prioritize dispensation of medications approaching expiry.
Physician	I want to know the history of dispensation for a certain patient from the BFC so that I can prevent an adverse drug event during ordering.
Epic 03: Produce computer generated labels upon dispensation. (3)	
Pharmacist	I want to attach preprinted adhesive labels to dispensed medication so that my documentation tasks become more efficient.
	I want to attach preprinted adhesive labels to dispensed medication so that the patient clearly understands the medication directions throughout the duration of the prescription.
	I want to attach preprinted adhesive to prescription medication so that they are complete with all necessary information required for adherence to dispensing standards.
Epic 04: Automatically alert pharmacists of new medication orders after CPOE. (6)	
Pharmacist	I want to be alerted immediately when a physician has entered medication orders so that we can efficiently initiate the dispensing process and reduce patient wait times.
	I want to be alerted immediately when a physician has entered medication orders so that I can ensure that the drug is in stock prior to the end of the patent visit.
	I want to know when a physician is confused during CPOE so that we can resolve the problem and correctly update the order in EpicCare.
	I want incoming prescriptions to be automatically added to a list in order of their receipt so that I prioritize dispensation to the longest-waiting patients.
	I want incoming prescriptions to be automatically added to a visible dashboard so that I do not need to continually check the patient dashboard in EpicCare.
Physician	I want the pharmacist to be alerted immediately when I enter a medication via CPOE so that patients aren't waiting for long periods of time if I forget to update their status.
Epic 05: Provide soft-stop alert feed functionality that is updated in real time. (6)	

Pharmacist	I want to know the expiration date of all medications so that I can prioritize dispensation of near-expiry drugs to reduce wastage.
	I want to know when medications are expired so that I can keep patients safe by deleting them from the inventory.
	I want to know the lot number of all medications so that I can quickly respond to medication recalls and keep patients safe.
	I want to customize par levels so that I am in control of low inventory alerts.
	I want to be know when a medication item has fallen below a given threshold so that I can promptly add the item to the activity sheet to avoid stock outs.
	I want to know when a PAP patient hasn't returned to the clinic in six months so that I can decide whether should transfer it to general stock to reduce waste.
Epic 06: Automatically generate the activity sheet and enable PDF creation. (8)	
Pharmacist	I want electronic dispensation to populate the activity sheet so that my documentation tasks are more efficient.
	I want to be able to search and view all old activity sheets within RxMAGIC so that I understand consumption patterns.
	I want to be able to print the activity sheet so that it gets to delivered to the PHCUP.
	I want to know when a patient has one month or less of a PMAP medication in stock so that I can indicate its due for reorder on the activity sheet.
	I want low inventory medications to be automatically added to the activity sheet so that I don't have to remember low-stock items throughout the entire clinic session.
AC	I want to view an automated copy of the activity sheet daily so that I know it is accurate, legible, and on time.
	I want to view an automated copy of the activity sheet so that I know which medications to reorder.
	I want to be able to export and print the activity sheet so that I can save it for my own records.
Epic 07: Provide medication reordering support for the PAP application process. (5)	
Pharm	I want to know the details of a patient's PAP application so that I can ensure their medication is up-to-date and reordered.
	I want to ensure a patient is enrolled in a PAP application before adding their medication to the inventory.
AC	I want to know the 'date to reorder' a patient's medication so that I can ensure an uninterrupted supply of PAP medications.
	I want to view a report of all medications to be reordered in a certain time period so that I don't forget to reorder a patient's medication.

	I want to know the specific pharmaceutical company program in which a patient is enrolled so that I know who to contact for reordering.
Epic 08: Establish a user management framework. (3)	
ALL	I want to be able to login to RxMAGIC with my UPMC credentials so that I don't need to create another set of credentials.

APPENDIX F

USABILITY TASKS FOR PRODUCTION TESTING

Six participants completed the following tasks within RxMAGIC. Each participant rated the ease of completion of each task, where 1 = "very difficult" and 5 = "very easy."

	Task	Mean (SD)
1.	A new shipment of medication just arrived at the clinic, and you want to enter an item into the general inventory (non PMAP) and give it a barcode label. Please enter the following medication: Ibuprofen 200 MG Oral Tablet, Lot No: 8BE1288, EXP: 12/17, QTY: 100)	4 (0.63)
2.	Oops! You meant to enter 200 tablets rather than 100 for that last bottle of ibuprofen. Find your entry, edit the quantity, and print a new label.	5 (0)
3.	One of the clinicians just placed an order in Epic for 30 tablets of Amoxicillin 500 MG Oral Tablet for Fidelia Butler. Dispense medication to this patient.	4 (1.67)
4.	Another order was just placed in Epic for 90 tablets of Naprosyn 500 mg oral tablets for Arlie Swain. Dispense medication to this patient, taking the expiry dates into consideration. You may dispense from multiple bottles if there is insufficient inventory in one bottle.	4 (0.89)
5.	A patient is planning on purchasing her medication from Giant Eagle, but she can't pick it up until Friday. You want to dispense medication to hold her over, although no prescription exists for this. Dispense 10 tablets of Ibuprofen 200 MG oral tablets to Theresa Starin (q6h prn).	4 (1.26)

6.	Can you tell me how many medications are about to expire in the General Inventory? Please name a few.	4.3 (0.82)
7.	How many medications are understocked in the general inventory? Select one and add it to the activity sheet. Check to make sure it added correctly. What else is on the activity sheet?	4.8 (0.41)
8.	Let's look up Theresa Starin and view her details. Can you tell me about her past dispensations?	4.8 (0.41)
9.	You realize that you have been dispensing a lot of Azithromycin 500 mg oral tablets lately and want to make sure you don't run out in the future. Set a new par level for this medication so that you will receive low inventory alerts. Par level: 500 tablets.	4.5 (0.84)
10.	Looking at the alert feed, what are some things you think you should do? Choose an alert of your choice and act on it. Please check on its outcome.	4.7 (0.52)
11.	Dominic Langdon receives Cardura 1 mg oral tabs through PMAP, but he hasn't been to the clinic in over 6 months. Transfer this item to the general inventory, and check to make sure it is there.	4.3 (0.82)

APPENDIX G

CODEBOOK FOR POST-DEPLOYMENT TIME-MOTION STUDY

Category	Subcategory	Definition	Value definition
Rx Prep	Hunting for medication	The physical search for stock medication in the cabinets. **Begin:** When pharmacist slides open cabinet door to initiate search. **End:** When pharmacist closes the door and/or found the medication.	NVA
Rx Prep	Labeling medication bottles	The process of printing and affixing adhesive label to bottle (includes reprinting). **Begin:** When pharmacist completes dispensation form in RxMAGIC. **End**: When pharmacist finishes affixing the label on the bottle.	NVA
Patient interaction	Counseling patients	Explaining medication and administration instructions to patient during dispensation. **Begin:** When pharmacist calls patient into the dispensary. **End:** When patient exits the dispensary.	VA
EMR	Patient Care	Pharmacist interacts with EMR to assess patient history and/or enter medication orders. **Begin:** When pharmacist is actively using Epic to view patient info. **End:** When pharmacist completes action.	VA

EMR	Order correction	Pharmacist corrects CPOE (i.e. changes quantity, removes refill). **Begin:** When pharmacist opens a CPOE and modifies it. **End:** When new order has been entered.	NVA
Clinician interaction	Consulting clinician	Consulting physician to discuss patient treatment plans or answer questions regarding formulary (also includes pharmacist interaction). **Begin:** When physician physically enters dispensary; when pharmacist goes to exam room; when two pharmacists discuss. **End**: When interaction is complete.	VA
Inventory	Inventory	Interacting with the inventory within RxMAGIC; adding items to the activity sheet; adjusting par levels; adding items to inventory. **Begin:** When pharmacist selects icon from home screen. **End:** When pharmacist completes inventory activity.	VA
Patient interaction	PAP initiation	Deciding to initiate a PMAP program with patient and beginning application process. **Begin:** When pharmacist starts filling out application. **End:** When pharmacist finishes working on application.	VA
Patient interaction	PAP discussion	Talking to patient about application and/or missing materials. **Begin:** When pharmacist brings up PMAP during counseling. **End:** When they stop talking about the application.	VA
Rx Prep	Rx Mgmt	Using RxMAGIC dashboard to select and complete dispensation form; also includes manual entry of prescription info. **Begin:** When pharmacist selects a prescription from the dashboard. **End:** When pharmacist completes form.	VA
Clinician interaction	Teaching students/clinician volunteers	Teaching sessions with pharmacy students and new volunteers. **Begin:** When pharmacist initiates teaching session by asking questions of students. **End:** When the interaction ends.	VA

Rx Prep	Dispensing medication	Retrieving empty medication bottles, counting pills, and filtering medication into bottles. **Begin:** When pharmacist either begins counting pills or reaches for an empty medication bottles. **End**: When pills are filtered into bottle.	NVA
Rx Prep	Traveling	When pharmacist moves throughout the clinic **Begins:** When pharmacist gets up from the desk. **Ends:** When pharmacist returns.	NVA
Other	Other	Any arbitrary tasks that are unrelated to work tasks. For example, casual conversation or using the restroom.	NVA

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