Patient Engagement to Improve Medication Safety in the Hospital

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ABSTRACT

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Purpose: There is a pressing need to enhance patient safety in the hospital environment. While there are many initiatives that focus on improving patient safety, few have studied engaging patients themselves to participate in patient safety efforts. This work was motived by the belief that patients can contribute valuable information to their care and when equipped with the right tools, can play a role in improving medication safety in the hospital.

Methods: This research had three aims and used a mixed-methods approach to better understand the concept of engaging patients to improve medication safety. In order to gain insight into whether patients could beneficially contribute to the safety of their hospital care, my first aim was to understand current perspectives on the sharing of clinical information with patients while they were in the hospital. To accomplish this aim, I conducted surveys with clinicians and enrolled patients in a short field study in which they received full access to their clinical chart. In Aim 2, I conducted a study to establish that the Patient Activation Measure (PAM), a common measure of patient engagement in the outpatient setting, showed reliability and validity in the inpatient setting. Building on the knowledge from Aim 1 and using the PAM instrument from Aim 2, my third aim evaluated the impact of providing patients with access to a medication review tool while they were preparing to be admitted to the hospital. Aim 3 was achieved through a randomized controlled trial (RCT) involving 65 patients I recruited from the emergency department at Columbia University Medical Center. I also conducted a survey of admitting clinicians who had patients participate in the trial to identify the impact on clinician practices and to elicit feedback on their perceptions of the intervention.

Results: My research findings suggest that increased patient information sharing in the inpatient setting is beneficial and desirable to patients, and generally acceptable to clinicians. The clinician survey from Aim 1 showed that most respondents were comfortable with the idea of providing patients with their clinical information. Some expressed reservations that patients might misunderstand information and become unnecessarily alarmed or offended. In the patient field study from Aim 1, patients reported perceiving the information they received as highly useful, even if they did not fully understand complex medical terms. My primary contribution in Aim 2 was to provide sound evidence that the Patient Activation Measure is a valid and reliable tool for use in the inpatient setting. Establishing the validity and reliability of the PAM instrument in inpatient setting was essential for conducting the RCT in Aim 3, and it will provide a foundation for future clinicians and research investigators to measure and understand hospital patients' levels of engagement.

The results from the RCT in Aim 3 did not support my primary hypothesis that clinicians who had patients participate in their medication review process using an informatics tool would make more changes to the home medication list than clinicians who had patients in the control group. However, the results did suggest that most hospital patients are knowledgeable, willing, and able to contribute useful and important information to the medication reconciliation process. Interestingly, the clinicians I surveyed seemed far less convinced that their patients would be able to beneficially participate in the medication reconciliation process due to low health literacy and other barriers. Nevertheless, the clinicians did seem to believe that in theory, at least, patient involvement in the medication reconciliation process could have positive impacts on their workflow and potentially save them time.

Conclusion: The overall theme resulting from my research is that patients can be a valuable resource to improve patient safety in the hospital. Patients are generally knowledgeable and willing to more actively participate in their hospital care. By developing the structures and processes to facilitate greater patient engagement, hospitals can provide an extra layer of safety and error prevention, particularly with

respect to the medications patients take at home. As with any medical treatment, active participation in patient safety efforts may not be possible for all patients. However, I believe that if the culture of a hospital encourages openness and transparency, and if patients are given the proper tools and information, the quality and safety of hospital care will improve.

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Acknowledgements

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I feel so lucky, and am extremely thankful to all of you.

Dedication

To my parents, Jane and Jerry Prey, without whose unfailing support none of this would have been possible. You've always believed in me and provided me with everything I could ever ask for to thrive. I am so grateful.

Chapter 1: Introduction and Significance

1.1 Introduction

The Institute of Medicine estimated in 1999 that medical errors in the hospital contribute to between 44,000 and 98,000 deaths in the United States each year.(Institute of Medicine, Kohn, Corrigan, & Donaldson, 2000) Newer estimates suggest there are at least 210,000 deaths yearly associated with preventable harm in hospitals.(James, 2013) Healthcare providers have undertaken a variety of initiatives to improve the quality of patient care in hospitals. Many initiatives focus on the provider side, such as deploying workflow changes, implementing clinical decision support, and automating processes. A complementary option is engaging patients themselves to be part of safety-improvement initiatives. Currently, few hospital patients play a significant role in planning and managing their care. This lack of patient engagement is a missed opportunity for quality and safety improvement. Weingart and colleagues (2011) found that patients with greater participation in their healthcare were less likely to experience adverse events, and as a result, were more likely to report high quality of care. Additionally, other research has found that patients are able to report many events that are not documented in the medical record,

and some of these events are serious and preventable.(Weissman et al., 2008) These results suggest there may be an opportunity to engage patients in their care, particularly while they are in the hospital, to help contribute to improving patient safety.

In recent years there has been a growing interest in the general concept of patient engagement. Patient engagement is often described as encompassing a number of related concepts including 'patient-centered care' and 'shared decision-making' that focus on the idea of involving patients as partners in their care.(Herrin et al., 2015) Involving patients in their care by providing them with access to their clinical information, having them participate in shared decision-making, and encouraging self-efficacy, has been shown to increase levels of satisfaction, understanding of care, participation in health improving behaviors, and also to improve health outcomes.(Nelson et al., 2004; Street & Millay, 2001; Tang & Lansky, 2005; Tang & Newcomb, 1998; Verlinde, De Laender, De Maesschalck, Deveugele, & Willems, 2012) However, most patient engagement initiatives to date have not focused on engaging the patients in patient safety initiatives. A 2016 article in the New England Journal of Medicine suggested that it is time for a "patient-driven health information economy" and remarked upon patients' unique ability to act as "reporters" and an "additional pair of eyes" to "identify and correct errors in the medical record".(Mandl & Kohane, 2016)

Despite a growing interest in patient engagement, there is a lack of evidence on the methods and impacts of patient engagement in the inpatient setting.(Prey et al., 2014) In light of the positive findings regarding patient engagement in the outpatient setting, it is important to understand the impact patient engagement can have on the quality and safety of inpatient care. Research in this area is nascent, and there is "insufficient high-quality evidence" informing whether patient engagement can impact patient safety.(Berger, Flickinger, Pfoh, Martinez, & Dy, 2014)

Medication Safety

The Agency for Healthcare Research and Quality (AHRQ) encourages patients to "Be a Partner in Your Care."(Agency for Healthcare Research and Quality, 2013) A process that could potentially be improved by better involving patients as partners in care is medication reconciliation. In the most basic definition, medication reconciliation is the process of comparing a patient's medication orders to all of the medications the patient has been taking.(Vawdrey, Chang, Compton, Tiase, & Hripcsak, 2010) The primary purpose of medication reconciliation is to avoid medication errors. It is an important, but time-consuming, and complex task with many stakeholders and decision-makers.(Plaisant, Wu, Hettinger, Powsner, & Shneiderman, 2015)

Because of the complexity of medication reconciliation, medication lists are often inaccurate, and resulting errors can greatly impact the quality of patient care.(Poon, 2009; Poon et al., 2006; Pronovost et al., 2003) The current system most healthcare delivery organizations use to identify patients' medications, particularly upon admission to the hospital, is rushed, error-laden, and offers patients limited or no visibility into the final record that results. As noted in the Society of Hospital Medicine 2010 Consensus Statement,(Greenwald et al., 2010) medication reconciliation efforts are often resource-intensive and must overcome several challenges, including the disjointed nature of American healthcare, the need to maintain up-to-date and accurate medication lists across different patient care venues, and the difficulty in identifying and maintaining roles and responsibility in the process.

Currently, there are gaps in the literature as to the methods for, and the benefits and potential harms associated with, engaging patients in the hospital. Considering the challenges in managing patient medications across care settings, and the importance of accurate and complete medication reconciliation for patient safety, the ability to engage patients to contribute to the medication reconciliation process has potential advantages, but this proposition has not been rigorously evaluated.

The purpose of this research was to increase understanding of how patients can be engaged in the inpatient setting to improve medication safety. To achieve this, I (1) explored patient and clinician perceptions of inpatient engagement in general, (2) provided evidence on the validity of a tool for measuring engagement in the inpatient setting, and (3) evaluated an intervention that provided patients with direct access to participate in the medication review process.

1.2 Overview of Aims

This thesis consists of three aims. Table 1.1 provides an overview of the research aims, the study design, and the methods used to address each aim. First, the concept of providing patients in the inpatient setting with access to their information was explored in a two-part study with both patients and clinicians (Aim I, Chapter 3). Next, the reliability and validity of a method of measuring patient engagement in their care for the inpatient setting was analyzed (Aim II, Chapter 4). Finally, an informatics intervention was evaluated on its ability to allow patients to contribute to the medication reconciliation process to improve medication documentation (Aim III, Chapter 5).

Table 1.1 Outline of Research Aims and Components

	Aim I (Chapter 3)		**Aim II** (Chapter 4)	**Aim III** (Chapter 5)	
	I-A	I-B	II	III-A	III-B
Study	Discover clinician perspectives on sharing clinical information with patients	Discover patient perspectives on receiving full access to their clinical records	Determine if the Patient Activation Measure (PAM) is a reliable and valid measure for inpatient use	Discover what contributions patients can make to improving the medication reconciliation process	Determine the impact patient-generated medication review has on clinicians
Design	Survey	Prospective field study	Known-group differences analysis	Randomized controlled trial	Survey

	Aim I (Chapter 3)		**Aim II** (Chapter 4)	**Aim III** (Chapter 5)	
	I-A	I-B	II	III-A	III-B
Subjects	53 inpatient clinicians from NYP	8 patients from the cardiology ward at NYP	100 patients from cardiology and oncology wards at NYP	65 patients who were marked to be admitted from the ED at NYP	21 clinicians whose patients participated in part III-A of this aim
Resources	R statistical software	Printouts from NYP EHR	▪ Qualtrics survey software ▪ Stata SE v 14.0	▪ Inpatient medication reconciliation portal tool ▪ Tablet computers (Apple iPads) ▪ Qualtrics survey software ▪ Stata SE v 14.0 ▪ R statistical software	Qualtrics survey software
Instruments	Survey instrument	Semi-structured interview questionnaire	▪ PAM-13 ▪ PROMIS Global Health measures ▪ Health literacy questions ▪ Demographic questionnaire	▪ PAM-13 ▪ Health literacy questions ▪ Demographic questionnaire	Survey instrument
Procedures	▪ Recruit clinicians to fill out one-page survey ▪ Aggregate data from clinicians using Microsoft Excel ▪ Analyze data	▪ Recruit patients to participate in study ▪ Provide patients with daily printouts of their EHR data for 4 days ▪ Conduct semi-structured interviews with patients	▪ Recruit patients with both planned and unplanned admissions to participate in the study ▪ Administer the PAM-13 and other survey questions ▪ Analyze the survey responses	▪ Recruit patients in the ED to participate ▪ Randomize patient to Control or Intervention arm ▪ Execute protocol for arm: ▪ Intervention: patients review home medications and allergies, print out	▪ Send email invitation to participate in survey to clinicians who had patients participate in 3.1. ▪ Send follow-up reminder to those clinicians who had not responded

	Aim I (Chapter 3)		Aim II (Chapter 4)	Aim III (Chapter 5)	
	I-A	I-B	II	III-A	III-B
		▪ Transcribe patient interviews ▪ Thematically analyze interview transcriptions		review and give to patient to provide to their clinician. ▪ Control: wait one day (or until OR completed by admitting team), have patient then complete home medication and allergy review.	7 days after initial invitation ▪ Analyze data of survey responses
Analysis	Quantitative analysis of responses to calculate descriptive statistics and analyze trends across groups	Qualitative content analysis by two researchers	Quantitative analysis of responses to calculate reliability, validity, and identify predictors of low activation	Quantitative analysis of patient and clinician medication changes	▪ Quantitative analysis of survey responses ▪ Qualitative content analysis of free-text responses by two researchers

1.2.1 Aim I: Understand perceptions of sharing clinical information with patients in the inpatient setting

As noted in a recent New England Journal of Medicine article, there is a trend toward fully-transparent medical records.(Walker, Darer, Elmore, & Delbanco, 2014) Patients are increasingly demanding, and receiving access to their clinical charts. However, evaluations of patients accessing their medical information have been primarily limited to the outpatient setting. This study aimed to better understand perceptions surrounding the sharing of clinical information with patients while they were in the hospital.

Objective

To understand both patient and clinician perceptions of hospital patients receiving access to their clinical information.

Research Questions

- What are clinicians' perceptions about sharing clinical information with patients in the hospital? What benefits or difficulties do they expect may occur as a result of increased information sharing?
- How will hospitalized patients respond to receiving an unedited, daily copy of their medical records?

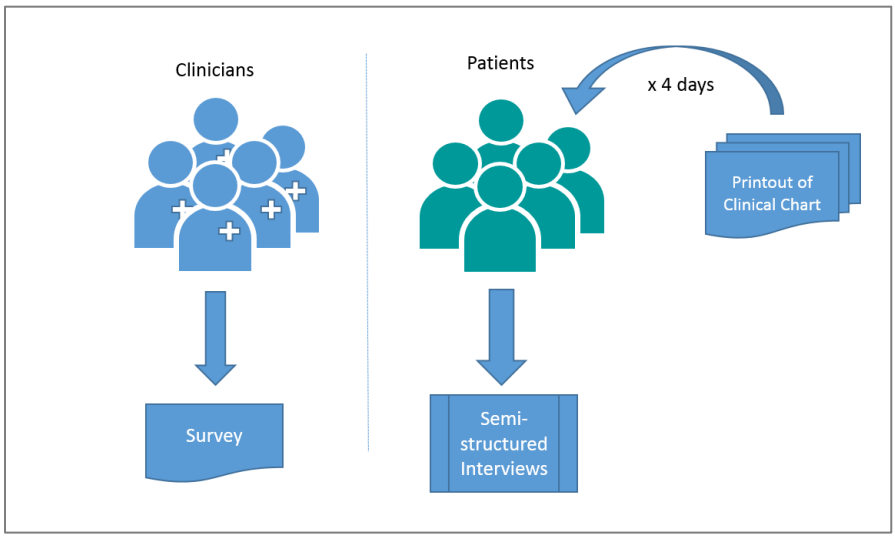


Figure 1.1. Overview of Aim 1 methods

Methods

This study consisted of two parts; a survey administered to clinicians as well as a complementary field study conducted with patients in the hospital. The clinician perspectives on providing increased access to information to patients were studied through a survey. Survey questions were used to determine clinician preferences on the types of information to be shared with patients and the potential impacts clinicians believed increased information sharing could have. In the field study, patients received once daily, paper

printouts of their medical chart for a period of four days, and then participated in semi-structured interviews to discuss their experiences. The reports included data concerning items such as laboratory test results, clinician notes, radiology reports, etc.

The results of this study helped informed the design and scope of the next aims, and provided the motivation to continue studying how patients can be engaged in their care while they are in the hospital.

1.2.2 Aim II: Measure the reliability and validity of the Patient Activation Measure with hospitalized patients

There is no single definition of the term "patient engagement", nor is there a universally agreed-upon tool for measuring this concept. To date, the most frequently used instrument for measuring patient engagement is the Patient Activation Measure (PAM).(Hibbard, Mahoney, Stockard, & Tusler, 2005; Hibbard, Stockard, Mahoney, & Tusler, 2004; Masterson Creber et al., 2016; O'Leary et al., 2015; Toscos et al., 2016) While the PAM has become a widely used tool in outpatient care settings, (Fowles et al., 2009; Skolasky et al., 2011; Stepleman et al., 2010) its applicability to patients in the hospital is not well established.(Schmaderer, 2015)

Objective

To determine if the Patient Activation Measure (PAM-13) is a reliable and valid measure of patient engagement for use with hospitalized patients.

Research Questions

- What is the internal consistency reliability of the PAM-13?
- What is the construct validity of the PAM-13?
- What are the predictors of low PAM-13 levels?

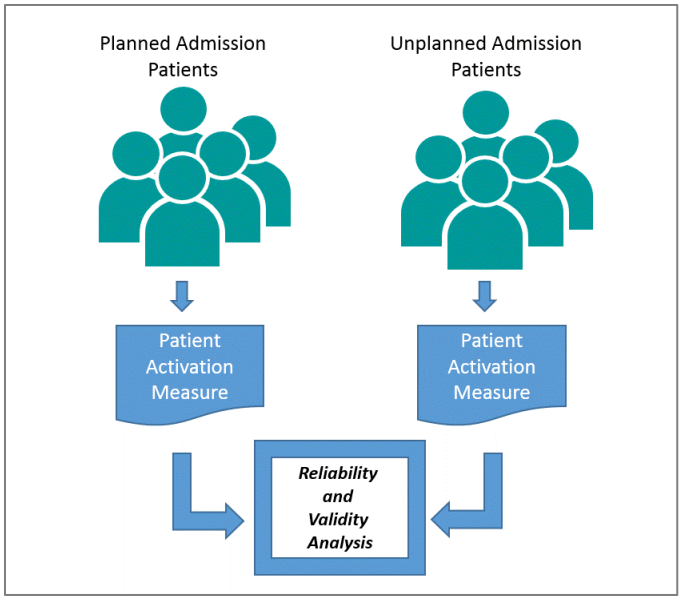


Figure 1.2. Overview of Aim 2 methods

Methods

This study collected and analyzed data to describe the internal consistency reliability and construct validity of the PAM-13 for hospitalized cardiology and oncology patients and to examine the predictors of low patient activation in the same population. One-hundred patients from cardiology and oncology wards at an academic medical center were recruited and asked to respond to the 13-item PAM, the 10-item Patient Reported Outcomes Measurement Information System (PROMIS) Global Health short form questions (Hays, Bjorner, Revicki, Spritzer, & Cella, 2009), and demographic questions. Patients were recruited from two groups; those who had planned admissions and those with unplanned admissions. Internal consistency reliability of the PAM-13 was analyzed as well as the construct validity. The construct validity of the PAM-13 was assessed using two approaches: expected known-groups differences of PAM-13 levels and convergence of PAM-13 levels with other measures. The known-group differences analysis was based on the supposition that patients who had planned admissions would have higher PAM levels than patients with unplanned admissions.

The results of this aim provided a tool that could be used to measure engagement of patients involved in studies in the inpatient environment. In the next aim, I utilized the PAM to measure the levels of engagement of the patients who participated in an inpatient study.

1.2.3 Aim III: Evaluate the impact of using a novel informatics tool to engage patients in the medication reconciliation process at hospital admission

Objective

To determine if having patients directly participating in the medication reconciliation process increased the number of changes made (i.e., medications added, medications removed, or medication details adjusted) by the admitting provider to the documented home medication list.

Hypothesis

H1: Patients in the emergency department (ED) who participate in the admitting medication reconciliation process by receiving access to an electronic medication review tool prior to their admission to the hospital will have more changes made by their admitting clinician to the home medication list during the admitting medication reconciliation process than patients who are not given access to the review tool.

Research Questions

- What types of changes do patients who are being admitted to the hospital make to the hospital's pre-existing home medication lists (i.e., add medications, delete medications, edit medication details) to reflect what they actually take at home?
- What is the potential for harm and severity of harm of the changes clinicians and patients make to the home medication lists?

- How does the Patient Activation Measure (PAM) level relate to the medication information a patient provides in the medication review tool?
- What are admitting clinicians' perceptions of the impact of the patient-generated medication review on the admitting medication reconciliation process?

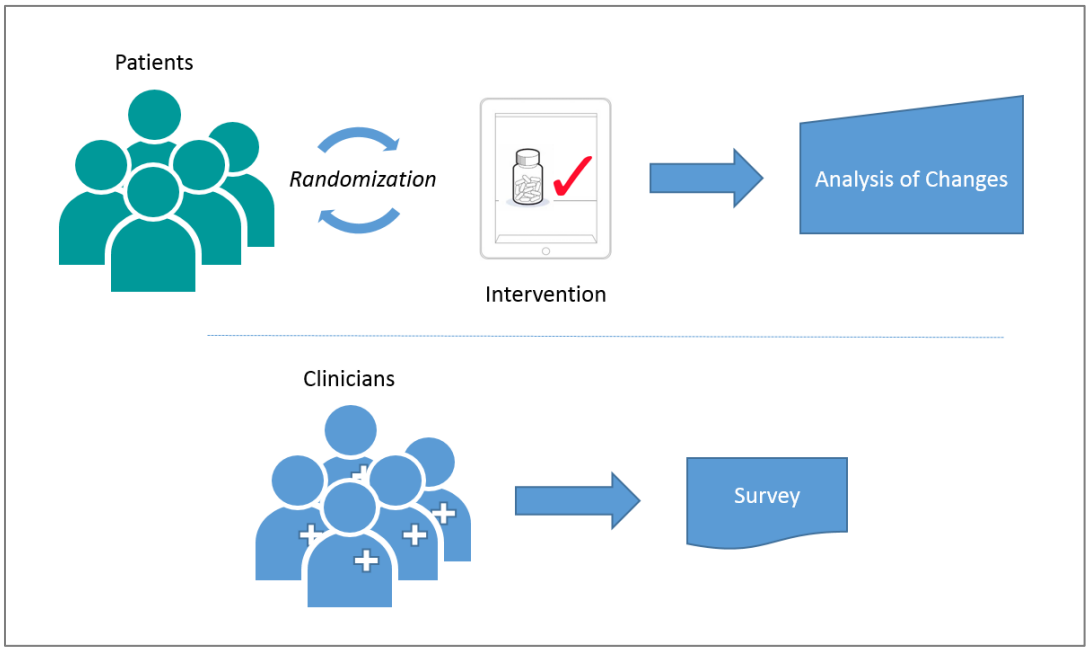


Figure 1.3. Overview of Aim 3 methods

Methods

This was a two-part study. The first part was a stratified, randomized controlled experiment. Patients who were preparing to be admitted to the hospital were recruited from an academic medical center's ED. Patients were stratified across three groups based on the number of home medications they had listed in the hospital's electronic health record (EHR) at time of recruitment. Intervention patients were asked to review their home medications and allergies using an electronic medication review tool, and to respond to survey questions including the PAM-13. The patient responses to the medication and allergy review were printed and given back to the patient to provide to their admitting hospital team, typically a medical resident, physician assistant, or hospitalist. Control patients were enrolled at the same time, but did not use the application to review their data in the ED. The following day, after the admitting team had

completed the admitting medication reconciliation process, control patients were followed-up with and asked to use the same medication review tool to review their admitting-clinician completed medication list and respond to the survey questions.

Data were analyzed to determine if those patients who were in the intervention group had more changes made to their home medication lists during admitting medication reconciliation by the admitting clinician than patients who were in the control group. Changes were defined as medications added, removed, or changed in any way (e.g., dose, route, frequency). Additional analysis assigned the changes that patients identified into severity categories of potential for harm and severity of harm.

The second component of the study was a survey to obtain clinician perspectives on the impact of this patient-generated medication and allergy review. All clinicians who had a patient participate in the intervention group of the randomized, controlled trial were invited to participate in a short, online survey via email. The topics of the survey included querying whether the clinicians received the patient-generated printout from their patients, whether the information was useful and accurate, the perceived impact of the intervention on the amount of time required to complete the admission medication reconciliation, and general feedback on the intervention, design and workflow.

1.3 Significance and Contributions

Patient engagement is a growing trend in healthcare. While it is receiving significant attention, the concept of engagement is not well-understood, particularly with regards to engagement in the hospital setting. The work in this dissertation adds new knowledge of the perceptions of both patients and clinicians on increased information sharing to engage hospital patients, demonstrates the reliability and validity of a tool that can be used to measure patient engagement in the hospital, and evaluated an approach to combat the significant patient safety issue of medication errors by engaging patients in the medication reconciliation process.

The optimistic preliminary results of patient engagement in the outpatient setting provide motivation to leverage this valuable concept within the hospital as well. Engaging patients can be a difficult task, particularly in the inpatient setting. Patients are often quite sick, have varying levels of health literacy, self-efficacy, and desire to participate in their care, and are in unfamiliar surroundings. Additionally, privacy and security are important considerations when developing any application to share personalized health information. Continued research on patient engagement in the hospital setting will mean that the design and implementation of future interventions can be better informed. The work in this thesis builds on an existing infrastructure to engage patients in the hospital and is one of the first to explore the viability of engaging patients in the hospital to improve medication safety.

Patients are the "sole subject matter experts on themselves,"(Goetz, 2011) and as such, they are an essential component to establish a complete patient safety network. Currently, patients in the hospital can be viewed as "untapped resources" in participating in improving patient safety.(Laurance et al., 2014) This work showed a potential method of "tapping into" the wealth of knowledge that patients can contribute, and showed the beginning of what potential effects patient engagement could have.

Chapter 2: Review of the Literature[1]

2.1 Introduction

Medical errors, particularly in the hospital environment, contribute to unnecessary patient harm and death. A 2013 study in the United States estimated that 210,000 deaths per year are associated with preventable harm in hospitals.(James, 2013) There have been many efforts to reduce preventable errors including the use of computerized physician order entry with clinical decision support(Ranji, Rennke, & Wachter, 2014), teamwork training,(Kemper et al., 2016; Salas & Frush, 2012) and checklists(Russ et al., 2013). However, there is still significant room to improve the safety and quality of care patients receive, especially within the hospital. A promising effort in the campaign to reduce preventable medical errors is

[1] This chapter expands on the work originally published in Prey, J. E., Woollen, J., Wilcox, L., Sackeim, A. D., Hripcsak, G., Bakken, S., … Vawdrey, D. K. (2014). Patient engagement in the inpatient setting: a systematic review. *Journal of the American Medical Informatics Association*, *21*(4), 742–750. http://doi.org/10.1136/amiajnl-2013-002141 and Prey, J. E., Polubriaginof, F., Kuperman, G. J., Tiase, V., Collins, S. A., & Vawdrey, D. K. (2016). International perspectives on sharing clinical data with patients. *International Journal of Medical Informatics*, *86*, 135–141. http://doi.org/10.1016/j.ijmedinf.2015.11.007

to increase patients' engagement in their care. I posit that more engaged patients can aid in the identification and mitigation of potential errors before they occur, if they are given the proper information and tools to do so.

The objective of this review of the literature is to provide some background on patient safety efforts and patient engagement efforts, to show how patient engagement might be used to improve patient safety, specifically medication safety, in the hospital. The review is presented in four sections:

1) A brief background on the current patient safety landscape in the hospital and some associated models,
2) a research study on the global landscape of how patients are being engaged in their care through the sharing of clinical data,
3) a systematic review of the literature on patient engagement in the inpatient setting, and
4) a description of the current state of patient engagement efforts to improve patient safety during inpatient care.

2.2 Patient Safety

Since the publication of the Institute of Medicine reports, 'To Err is Human' and 'Crossing the Quality Chasm'(Institute of Medicine, 2003; Institute of Medicine et al., 2000), considerable focus has been placed on quality improvement and patient safety in the American healthcare system. Particular focus has been placed on examining the cause of medication errors, which are the most frequent cause of adverse events.(Morimoto, Gandhi, Seger, Hsieh, & Bates, 2004)

Identifying causes of errors and resulting accidents is a challenging undertaking, particularly in healthcare, where the complex environment involves many participants and frequently changing tasks and priorities. In 1990, James Reason proposed a model of accidents. The model illustrates how accidents occur, and how these accidents are a result of interrelations between latent conditions and unsafe acts by operators

(Figure 2.1).(Reason, 1990) This model was based on the "Swiss Cheese Metaphor," which suggests that there are multiple contributors (the holes in the cheese slices) that must be aligned for an adverse event to occur, and there was a failure at each barrier (each slice) that would have otherwise prevented an accident from occurring.(Reason, Hollnagel, & Paries, 2006).

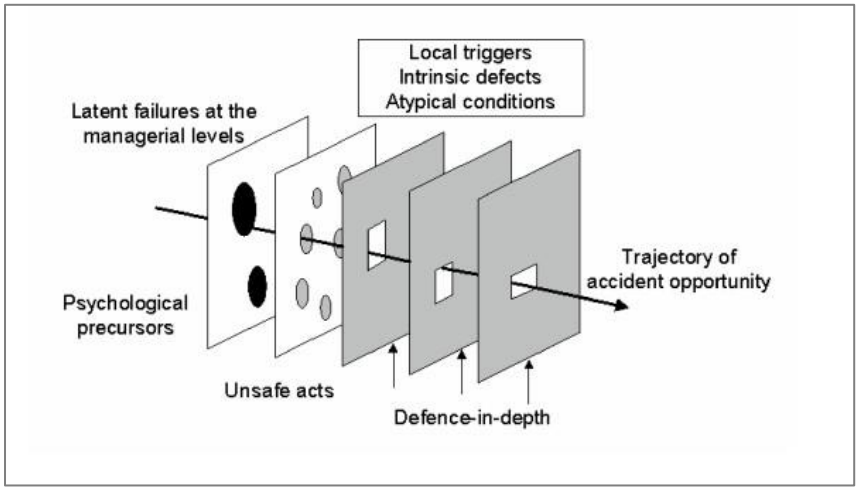


Figure 2.1 Reason's model of accidents (Reason, 1990)

Reason's model has been updated multiple times,(Reason, 1995, 1997) and adapted to analyze various safety situations across many different industries, including the military,(Leveson, Allen, & Storey, 2002) aviation,(Shappell & Wiegmann, 2012) and railway transportation.(Baysari, McIntosh, & Wilson, 2008) Of note, it has also been adapted for use in the healthcare domain.(Avery et al., 2002; Carthey, de Leval, & Reason, 2001; ElBardissi, Wiegmann, Dearani, Daly, & Sundt III, 2007; Vincent et al., 2000) For example, Avery and colleagues developed a model of how medication management errors occur in the primary care setting (Figure 2.2). This shows how there are multiple steps, across multiple systems and stakeholders, in which specific circumstances involving an error must occur for a patient to suffer an adverse event.

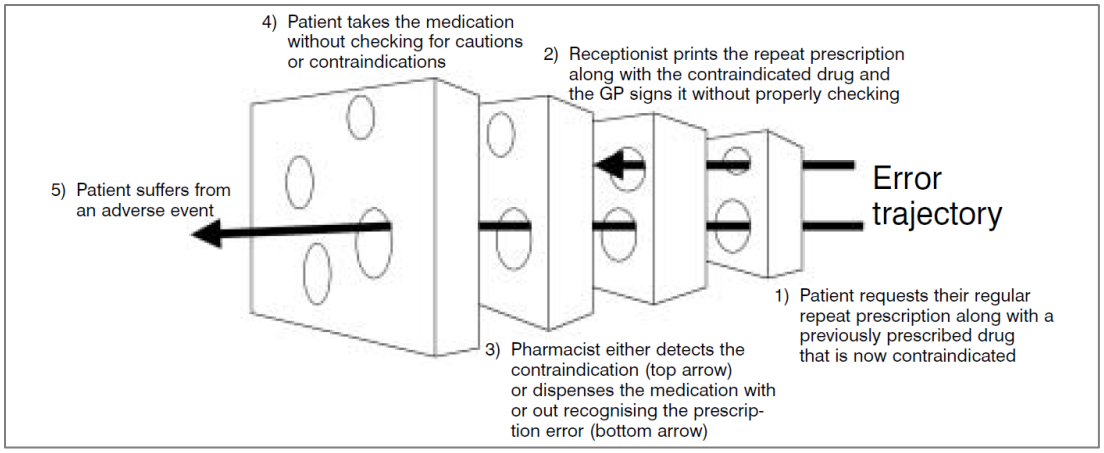


Figure 2.2 Swiss cheese model of errors in the medication management process (Avery et al., 2002)

In the inpatient setting, there are multiple lines of defense, or barriers, that prevent errors from occurring. Increased training on teamwork,(Salas & Frush, 2012) the implementation of checklists,(Russ et al., 2013) and standardization of care delivery(Coppedge, Conner, & Se, 2016; Doyle et al., 2014) are just a few examples of methods that aim to catch errors and reduce adverse events before they occur in the hospital. In terms of the Reason model, these methods are attempting to reduce the number of "holes" in each slice of cheese, or to add an additional "slice" in the case of the checklists.

In recent years, technology has been a key contributor to increase patient safety. The implementation of electronic health records (EHRs) has reduced prescribing errors due to legibility issues, enabled automatic clinical decision support to alert clinicians to errors such as drug-allergy problems and dosage mistakes, and allows for increased availability and search of past patient health records.(Buntin, Burke, Hoaglin, & Blumenthal, 2011; Radley et al., 2013; Zlabek, Wickus, & Mathiason, 2011)However, as is the case in any environment with human-computer interaction, technology alone cannot identify all errors that may occur.

I believe that patients themselves are an important and underutilized resource for reducing errors, and that they can provide another layer of "Swiss cheese" in the error causation framework. Dr. Warner Slack, an American informatician at Harvard University, has commented that "the largest and least used

resource in medicine is the patient."(Goetz, 2011) Engaging patients more directly in their own care can enable them to provide important details on their health history and self-care activities, and improve the quality of the data in the EHR. These activities will then lead to a clearer picture of the patient's health status, and allow for more errors to be identified and fewer adverse events to occur.

2.3 Patient Engagement and Information Sharing

2.3.1 Background

Increasing the engagement of patients in their care is a phenomenon that has gained significant interest in recent years. The aim of patient engagement is to encourage patients to participate and be valuable resources and partners in their health care. It has been shown that engaged patients have higher levels of satisfaction, increased understanding of their care, more engagement in health improving behaviors, and improved health and outcomes.(Nelson et al., 2004; Street & Millay, 2001; Tang & Lansky, 2005; Tang & Newcomb, 1998; Verlinde et al., 2012) "Engaged" patients receive more patient-centered care,(Street & Millay, 2001) and have increased levels of trust of, better relationships with, and more confidence in their physicians.(Tang & Newcomb, 1998) Additionally, increased patient engagement has been shown to have a positive correlation with reduction in overall expenditure and reduction in litigation against health professionals.(Entwistle, Sheldon, Sowden, & Watt, 2009; Hibbard, Greene, Sacks, Overton, & Parrotta, 2016) As a result of these findings, the phenomenon of patient engagement has been referred to as being equivalent to the next "blockbuster drug."(Dentzer, 2013)

While most patient engagement interventions have focused, as the name indicates, on involving the patient, there are also interventions aimed at engaging the patient's "care partners".(Sarkar U & Bates DW, 2014) A care partner is someone who assists the patient with their health, potentially from afar; this could include one's spouse, parents, adult children, friends, or relatives. These care partners frequently work together with the patient and often access clinical information for the patient to "bridge patients'

health literacy deficits and lack of technology experience".(Wolff et al., 2016) Illustratively, some have suggested that the term "patient engagement" be expanded to "patient and family engagement" (PFE).(Herrin et al., 2015)

Multiple national initiatives in the United States have focused on patient engagement. The maxim "nothing about me without me" (Delbanco et al., 2001) has been used to summarize the principles of patient-centered care and shared decision-making.(J. Finkelstein et al., 2012) The Agency for Healthcare Research and Quality sponsored a national public service advertising campaign "Questions Are the Answer" to encourage patients to ask questions of their care providers,(Agency for Healthcare Research and Quality, 2012) and for clinicians to "treat patient inquiries not as an impediment to care but as an opportunity to enhance it."(Clancy, 2008) The Joint Commission and National Quality Forum have also started their own initiatives surrounding patient engagement(Commission, 2009; Forum, 2003), and the National Research Council emphasized use of health IT for the "empowerment of patients and their families in effective management of health care decisions," to educate individuals about health, and to support communication with care providers.(Stead & Lin, 2009)

In researching patient engagement initiatives, there was little information found that summarized the state of patient engagement projects from around the world. To address this gap, interviews were conducted with experts from around the world to discover more about how they were attempting to increase patient engagement, specifically focusing on how they shared clinical information with patients.(Prey et al., 2016)

2.3.2 Methods

This study was a cross-sectional survey conducted via telephone or videoconference during November and December 2014. Semi-structured interviews were conducted to learn about clinical information sharing practices across the globe.

The list of interview participants was created using a convenience method of sampling in which research team members identified individuals around the world who had knowledge of patient engagement and data-sharing initiatives in their respective countries. These individuals were contacted by email and asked whether they felt qualified to comment on the local and national trends regarding patient engagement and clinical data sharing in their countries. If they did not feel qualified to comment, a referral to a better source was sought. Participants who were not conversant in English were excluded from the study.

Once the final list of potential participants was compiled, research team members sent emails to the remaining participants, inviting each individual to participate in the voluntary study. The email invitation included a description of the information the interview was seeking. Upon receiving acceptance to participate, individual telephone or videoconference calls were scheduled. Follow-up emails were sent to those individuals who did not respond to the initial query. Institutional Review Board approval for conducting the study was obtained from Columbia University Medical Center. Individuals were informed of the intent to publish the results of this study, and verbal consent was provided by all participants.

The semi-structured interview consisted of five topic areas, and participants were asked to provide information regarding their specific country's current status and views on (1) the maturity of the concept of patient engagement and patients' involvement in their care; (2) what, if any, government incentives existed to encourage sharing of clinical information with patients; (3) who was seen as having 'ownership' of clinical data (i.e., patients themselves or the clinical institutions providing care); (4) what technologies were being used to share clinical information with patients; (5) if technologies were in place, what data were being shared, how were they being shared, and what additional capabilities were offered to patients. For the first topic, regarding patient engagement, as there is not one single definition of the term, the participants were asked if they knew of, and used, the term patient engagement, what that meant to them, and whether they believed it was considered an important concept in their country. In addition to the five topic areas, interviewers gathered information describing each country's financing model and if a

national patient identifier exists. In terms of financing models, they are described below in terms of the healthcare system model (public and/or private, national health insurance model, etc.), whether there was universal coverage for all citizens (universal healthcare), and the type of payment model (single-payer or multi-payer).

Data from the interviews (notes, audio-recording transcripts) as well as information derived from a supplemental literature review were aggregated and analyzed. Themes were generated based on the original five topic areas identified to be of interest. Data were reviewed by two researchers to ensure the accuracy of the labeling. The reviewers went through the transcripts to label information relevant to each topic area, countries were then grouped based on similarity of characteristics and compared across each of the themes.

2.3.4 Results

Thirty-two people from 28 different countries were invited to participate in the study. Of the 32, 19 individuals representing 19 unique countries (response rate = 59%) responded. Interviews were conducted with individuals from 16 countries representing 6 continents (Figure 2.3); the remaining 3 were not conducted due to competing priorities. The countries represented were from Europe (Austria, England, the Netherlands, Portugal, Switzerland), Asia (Iran, Israel, Japan, South Korea), South America (Argentina, Brazil, Uruguay), North America (Canada, the United States), Australia, and Africa (Kenya).

Figure 2.3 Map of interview-participant home countries

Most individuals who participated in the study were involved in the biomedical informatics research community. Ten participants were from academic institutions, four worked in industry or clinical institutions, and two participants worked for policy groups or governmental agencies such as a ministry of health. Participants from each country responded to interview questions across the five topic areas described above, a summary of the results can be seen in Table 2.1.

Maturity of patient engagement

Overall, the interviews revealed that the concept of patient engagement existed in most countries, and there was on-going work to develop patient-centered healthcare systems. Patient engagement initiatives in these countries focused on encouraging patients to participate in their healthcare decisions, educate themselves on their health conditions, communicate with their providers, and as described in this study, receive access to their clinical data. Interview participants' perceptions of the importance of this topic varied depending on the country. These stages of maturity were classified into three levels: Established, Emerging, and Limited.

Countries with ‘Established’ levels of maturity include Israel, England, Canada, Australia, and the United States. These countries have the earliest national strategies for patient data access, some dating to the early 2000s, and as such have been conducting work focused on patient engagement for many years.

Countries such as Austria, Argentina, Brazil, the Netherlands, Portugal, South Korea, Switzerland, and Uruguay have expanded their efforts in patient data sharing in recent years, and have been classified as being in the ‘Emerging’ state of maturity. The interviews suggested that awareness of patient engagement is growing in each of these nations, but is a more recent trend. The Austrian participant framed increased patient engagement as a recent “paradigm shift” among the medical establishment there.

Countries with ‘Limited’ maturity of patient engagement include Iran, Japan, and Kenya. Interview participants from these countries reported less of a focus on patients themselves accessing clinical data. Each of these nations seemed to be more focused on the implementation of EHRs rather than the development of patient-targeted applications. While these countries are currently classified as having limited maturity of patient engagement, there was the suggestion that there would be an increased focus on patient engagement in the future, particularly in Japan.

Table 2.1 Overview of patient-information sharing by country

	Country	Maturity of Patient Engagement	Government Involvement	Patient Portal Strategy	Healthcare Financing Model	National Patient Identifier (NPI)	NPI Details
Europe	*Austria*	Emerging	Major	National	Public, private; universal healthcare	Yes	National Insurance Number
	England	Established	Moderate	Institutional*	Public; universal healthcare, single-payer	Yes	NHS number and Spine (for all of England)
	Netherlands	Emerging	Moderate	Limited†	Public, private; universal healthcare, multi-payer	Yes	Social-fiscal number
	Portugal	Emerging	Major	National	Public, private; universal healthcare, multi-payer	Yes	
	Switzerland	Emerging	Moderate‡	Regional	Public, subsidized private, private; universal healthcare; multi-payer	No	Project in progress
Asia	*Iran*	Limited	Minor	Limited†	Public, private; universal healthcare	Yes	Only some citizens have NPI
	Israel	Established	None	Regional	Public, subsidized private; universal healthcare	Yes	Regional by HMO
	Japan	Limited	None	Limited†	Public, private; universal healthcare, multi-payer	No	
	South Korea	Emerging	None	Institutional	National health insurance model; universal healthcare; single-payer	Yes	

	Country	Maturity of Patient Engagement	Government Involvement	Patient Portal Strategy	Healthcare Financing Model	National Patient Identifier (NPI)	NPI Details
South America	*Argentina*	Emerging	None	Institutional	Public, private, social security; universal healthcare	Yes	
	Brazil	Emerging	None	Institutional	Public, private; universal healthcare	No	
	Uruguay	Emerging	Minor	Limited[†]	Public, private; universal healthcare	Unknown	
North America	*Canada*	Established	Moderate	Regional	National health insurance model; universal healthcare; single-payer	Yes	Care card number by province
	United States	Established	Major	Institutional	Mixed market; multi-payer	No	
Australia	*Australia*	Established	Major	National	Publicly funded, subsidized private; universal healthcare	Yes	
Africa	*Kenya*	Limited	None	None	Government-funded;	Yes	AMPATH ID

[*]Early stages of implementation, [†]Research or chronic disease focused, [‡]Local level of government

Government incentives and regulations

The interviews suggested that the majority of countries in the study did not have government initiatives directly tied to sharing clinical information with patients. The few exceptions were Australia, Austria, and Portugal. Each of these were reported to have government funding and infrastructure to facilitate the development of a national patient portal. Additionally, the United States' Meaningful Use program ties a portion of clinician reimbursement to the action of providing patients with access to their information. The Kenyan Ministry of Health is facilitating the implementation of OpenMRS in clinics across the country, but this effort focuses primarily on giving access to information to clinicians, not to patients. While this is currently the case, the provision of information to patients in Kenya may increase and change over time with increased e-health implementations, particularly as one of the five key pillars in the Kenyan e-health strategy was identified as being the delivery of "Information for Citizens".(Ministry of Medical Services & Ministry of Public Health Sanitation, 2011)

Most countries had funding available through government programs to facilitate patient engagement research in general, but the funding is not directly tied to specific implementation of data-sharing interventions. Countries that reported having such funding include Canada, England, Iran, the Netherlands, and Uruguay. In Switzerland, patient engagement initiatives are reportedly funded on a local level, with individual cantons contributing their work that is then fed into the national system in a 'bottom-up' structure.

The representatives from South Korea, Japan, Argentina, Israel and Brazil reported that these countries did not have specific government initiatives for this type of patient-centered work. In these countries, projects were developed by the provider institutions themselves rather than being motivated by government incentives.

Ownership of data

Policies around the ownership of health data can often be complex. Patients may expect that their clinical data should belong to them. Healthcare providers may feel that information in medical records is owned by those who collect and maintain it. Regardless of actual ownership stake, in the majority of countries involved in this study, patients were guaranteed access to their medical records through government legislation. Historically, these records were delivered via paper printouts and often patients were required to pay for duplication costs. This process was difficult, slow, and cumbersome according to respondents.

With the development of technologies to provide electronic access to patient information (e.g., patient portals), countries must decide whether individuals must register to have their data included, or whether data for the entire population is automatically included unless patients opt out. Only two countries in this study were found to have opt-out policies: Israel and Austria. The rest of the countries with portal solutions required patients to sign up to receive access. Australia was reported to be considering an opt-out strategy to encourage greater adoption of their system.

Interestingly, the Netherlands was the only country in this study in which patients were able to "delete" their record or portions of their record—even information created by clinicians—as a fundamental right. In most other countries, patients could only amend data that was created by them, not clinical data created independently by a provider. The only similar country is Australia, in that a patient is allowed to 'hide' documents from other providers, but not from the provider who created the document, and it cannot be removed permanently. A full exploration of patient-control of data was beyond the scope of this analysis but is being explored elsewhere.(Blumenthal & Squires, 2015)

Technology

Health information technology infrastructure varied across the countries represented in this study. Three countries reported having nationwide patient portals. Seven countries had well-established institutional

portals, but these were used on a more local level. Five of the countries represented in the study were still in very early stages of patient engagement and system development. These countries had very few portals and were targeted to more specific populations (e.g., disease-specific groups). Kenya focused on sharing information through a primarily paper-based system.

Austria, Portugal and Australia were the only countries in the study that had national initiatives for patient portals. Austria had developed the infrastructure for their portal (Elektronische GesundheitsAkte (ELGA)), but patient data were not yet in the system at the time of this study. Portugal's Patient Access to Patient Summary portal was being used, but only included data from the outpatient setting. Australia's personally controlled electronic health record (PCEHR), launched in 2013, has seen limited adoption by patients.

The majority of portal systems discussed in the interviews were in the beginning stages of deployment, with low percentages of patients enrolled in the systems. Two exceptions were Israel and Argentina. In the Israeli system, three-quarters of the population in the Health Maintenance Organization (HMO, one of four in the country) of the subject used the patient portal, and have for many years. The Argentine portal, in one non-profit health system, has high adoption with 160,000 registered patients and 100,000 active members. This system was also used directly by patients to request 80% of their medication prescriptions instead of having to come in or call the clinician.

In Switzerland, portal development has taken place at the local level, with Geneva being a pioneer in their country. Canada has a similar organizational structure in that each province is working to develop portals for their population, as opposed to a single national product.

The United States, South Korea, and Brazil appear similar in that patient portal deployment has been done on a per-institution basis. Because of the Meaningful Use EHR incentive program, the U.S. seems to be ahead of Brazil and South Korea in the number of institutions that are working on patient portals.

The participants from the Netherlands and England each commented that while there have been a few portal projects within their respective countries, they have yet to attain broad adoption. Both countries reportedly have sponsored research projects where chronic disease patients received access to their clinical data. Participants from Iran, Japan and Uruguay indicated that portals within their countries were very limited and available to very few people today.

The OpenMRS system (Wolfe et al., 2006) in Kenya allows patients to receive a paper-based care summary after each visit. This use of paper is a low-tech example of patient involvement in the care process.

Data available to patients and methods for access

Depending on the implementation choices and technical capabilities of the various patient portals discussed in this study, patients were able to access different portions of their medical records. In more sophisticated portals, patients were able to see information such as medication lists, allergies, lab results, discharge summaries, problem lists, and reports (pathology, radiology, etc.). The countries classified in this study as having more sophisticated portals were Argentina, Israel, Austria, Australia, Switzerland, Canada, Portugal, South Korea and the U.S. This is not to say that all portals within these countries have these capabilities, but that at least one institution in each of these countries seems to have made significant progress in developing a system for making medical information available to patients. Of note, the portals in Austria and Australia provide access only to document-based information, but a variety of document-types are accepted.

Electronic sharing of care providers' notes through patient portals is not common. In the U.S., the OpenNotes project has successfully provided thousands of patients with access to their outpatient notes at a small number of institutions.(Delbanco et al., 2010; Leveille et al., 2012; Trossman, 2013; Walker et al., 2011) It has been extremely well-received, and the project has been expanded and implemented by places such as the U.S. Department of Veterans Affairs (VA).(Nazi, Turvey, Klein, Hogan, & Woods, 2015)

No other country included in the study reported having this type of functionality. Mobile-access was a feature present in only a limited number of portals, specifically one in South Korea and one in Argentina. The VA has also created the Blue Button initiative that allows patients to download a simple, readable version of their electronic records with the click of a button.(Turvey et al., 2014; U.S. Department of Veterans Affairs, 2015)

Patient portals in Brazil were reported to provide patients with access to data from external resources, such as laboratory results, images, and pathology results. Before the creation of electronic portals, Brazilian patients were already responsible for retrieving the results from these external resources and taking them back to their care providers. As such, patient access to this type of information is not new, it is merely now available via portals rather than exclusively on paper.

The release of information in almost all countries was immediate; as soon as a clinician can see the data, the patient can do so as well. In a few countries, including Portugal and Brazil, informants suggested that patients may even see their information before a healthcare provider does. Two exceptions to the practice of immediate information release were the U.S. and Israel. Both countries have delays or blocks preventing the release of potentially sensitive information such as pathology reports and HIV test results.

In a few countries (Israel, U.S., South Korea, Australia, Argentina, Austria), some institutions provide patients with the ability to add information into the portal themselves. In the facilities represented by the South Korean and the Argentine study participants, these patient-generated data are integrated into the institutions' EHRs and are reviewed by the clinicians when the patient comes in for a visit. Examples of the data added by the patient are personal notes or videos, glucose values, blood pressure tracking, and shared patient-generated problem lists.

Along with the sharing of clinical information with patients, some of the portals contained ancillary features such as secure messaging (Argentina, U.S.), appointment scheduling (Argentina, Portugal, U.S.), and prescription renewals (Argentina, Portugal, U.S., Japan).

2.3.3 Discussion

The results of these interviews show that the ability to share personal, clinical information directly with patients is a concept of growing global importance to engage patients in their care.

Among the 16 nations represented in this study, there were a variety of strategies for enabling patients to access their clinical information. These strategies were shaped by the maturity and focus of patient engagement, government incentives, healthcare payment models, and availability of technology. One of the key technologies that is redefining the way patients participate in their healthcare is patient portals.

The interoperability problem of sharing information between institutions, and across countries, has not been adequately addressed in any of the countries represented in this study. A few countries had patient portal systems that were available across institutions, all within one local province or county. More extensive networks for health information exchange are developing slowly, though the reasons for gradual adoption are unclear. Some have pointed to poor adherence to standard terminologies and data communication protocols as a reason for local health information fragmentation.(Adler-Milstein & Jha, 2012) An initiative that is working to connect electronic medical records on an international scale (from the European Union (EU) to the U.S.) is the Trillium Bridge project.(“Trillium Bridge,” 2014) Additionally, within the EU, the epSOS project is working to connect electronic medical records across European countries.(“epSOS,” 2014) As these projects are implemented and successful in sharing patient records between countries for clinicians, there could be lessons to learn on how to connect patient portals as well.

More generally speaking, along with the described benefits of engagement come some ethical considerations. Patient preferences do not always coincide with clinicians’ judgments about the relative

effectiveness of treatments, therefore, it is necessary to discuss whether to "promote efficient and effective health care, sometimes at the expense of patient choice" or to always respect patient desires.(Entwistle et al., 2009) Additionally, research has shown that patients do not always make rational decisions, which can result in pressure on practitioners who then prescribe illogically in response.(Henwood, Wyatt, Hart, & Smith, 2003) There is also the question of what information patients can readily understand, and whether adverse consequences, such as an increased disease burden, may result. Health literacy levels of patients can vary significantly, and make sharing of clinical information difficult.(Kessels, 2003; Schillinger, Bindman, Wang, Stewart, & Piette, 2004; Weiss, Reed, & Kligman, 1995) Additionally, there is a tradeoff between making health information more freely available and patient privacy, particularly in thinking about sharing information with patients' care partners.(Brown et al., 2016) These considerations must be taken into account in designing engagement interventions.

In thinking about patient engagement, there are a variety of frameworks one could employ. Researchers studying patient engagement have utilized general frameworks like the Theory of Planned Behavior as done by Schwappach and colleagues,(2010), Rasumussen's Taxonomy of Human Performance as done by Unruh and Pratt,(2007) and Roger's Diffusion of Innovation Model as done by Emani and colleagues.(2012) Patient engagement-specific frameworks have begun to be developed. Househ and colleagues (2014) developed a framework for the "Meaningful Use of Personal Health Records" that shows the associated challenges that may hinder meaningful use of engagement technologies by patients. Additionally, Graffigna and colleagues (2014) developed a "Toolkit for eHealth Interventions Aimed at Promoting Patient Engagement" that shows four stages a patient may go through to become engaged (from disengagement, to arousal, to adhesion, and then to "eudaimonic project" (i.e., self-realization and fully functioning)) and the role of eHealth interventions at each stage. The Consumer Role Model developed by Hibbard (2003) delineates three roles that the patient can take on to participate in their care: "evaluators" who report their perspectives on quality, effectiveness, and satisfaction of their care,

"informed choice" where patients choose to go to high performing clinicians or hospitals, and "coproducers" where patients are engaged and contribute expertise about their symptoms and actually participate in making decisions about their treatments.

Efforts to improve patient engagement and access to clinical data are active on a global-scale. There are many open questions about best practices and much can be learned by adopting an international perspective to guide future implementation efforts. Additionally, research involving patient engagement to date has mainly focused on the outpatient setting. Most interventions have focused on providing patients with access to some of their clinical information through personal health records (PHRs). As mentioned, there is considerable evidence indicating the benefits of providing patients with access to their health information including increased patient participation in health-related decision-making, decreased decisional conflict, and increased adherence to care.(Greenfield, Kaplan, Ware, Yano, & Frank, 1988; Hack, Degner, & Dyck, 1994; Kaplan, Gandek, Greenfield, Rogers, & Ware, 1995) With the success so far of interventions to provide patients in the outpatient setting access to their information to increase their engagement in their care, it seemed a natural step to expand that engagement effort to the inpatient setting. The following work was conducted to provide insight into the current state of patient engagement initiatives in the inpatient setting.

2.4 Patient Engagement in the Inpatient Setting

There are 35 million hospital admissions each year in the United States.(Centers for Disease Control and Prevention, 2010) Historically, patient engagement has been limited within the hospital setting. Often patient information needs are not met, despite evidence linking better health outcomes with the provision of information, especially within the hospital setting.(Hibbard, 2003; Kaziunas, Hanauer, Ackerman, & Choi, 2015; Larson, Nelson, Gustafson, & Batalden, 1996; Skeels & Tan, 2010; Tang & Lansky, 2005) For many patients, hospitals are unfamiliar, isolating places filled with anxiety and unanswered questions. Being a hospital patient has been called "one of the most dis-empowering situations one can

experience in modern society."(Bickmore, Pfeifer, & Jack, 2009). Furthermore, patients often do not even know their health care providers' names contributing to the confusion and dis-engagement.(Clever, Jin, Levinson, & Meltzer, 2008; Elwyn, Edwards, Kinnersley, & Grol, 2000; O'Leary et al., 2010) To reverse the dis-empowering nature of the inpatient experience providing information to, and engaging, patients within the hospital is an important priority.

To better understand patient engagement in the inpatient setting, I conducted a systematic review.(Prey et al., 2014) Advances in technology have enabled new methods for patient engagement. The spread of EHR systems within care organizations, and the proliferation of mobile devices, provide the opportunity to employ technology to increase engagement.

2.4.1 Methods

This review followed the methods outlined in the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement.(Moher, Liberati, Tetzlaff, & Altman, 2009) The search was conducted across four electronic databases: PubMed, Association for Computing Machinery (ACM) Digital Library, Institute of Electrical and Electronics Engineers (IEEE) Xplore, and the Cochrane database in February 2013. A three-part terminology search was used to identify studies that (1) discussed patient engagement ("self-efficacy", "patient empowerment", "patient activation", or "patient engagement"), (2) involved health information technology ("technology", "games", "electronic health record", "electronic medical record", or "personal health record"), and (3) took place in the inpatient setting ("inpatient" or "hospital"). Exclusion criteria were non-English language publications. MeSH terms were not used in the search criteria as there is not a consistently used MeSH term to describe patient engagement.

The search strategy involved determining appropriate search keywords and then aggregating results from the four databases. Two investigators screened the results and determined based on title and abstract whether to include each article for full review. Full review consisted of in-depth analysis of the identified

articles to summarize the findings of each. Additional candidate articles were identified by reviewing references of the included articles. Articles were then categorized by content and grouped for discussion.

NOTE: Nine additional articles have been added to the results published in the systematic review to provide an update to the literature. These are primarily articles that were published after the review was conducted. The additional articles are noted within the text, but were not added to the search result numbers or PRISMA diagram so as not to confound the systematically-retrieved results.

2.4.2 Results

In total, 546 results were found; 92 from PubMed, 94 from the ACM digital library, 226 from IEEE Xplore, 126 from Cochrane and eight from citations within the found articles. Of the 546 results found, 22 qualified for full review; excluded articles dealt with outpatient care settings or did not involve information technology (IT) interventions (Figure 2.4). Of those that qualified for full review, 17 were included in the final results, five articles were excluded, again, due to their lack of inpatient focus or non-technological interventions. Of the 17 included, three were randomized controlled trials (RCTs), 11 employed a quasi-experimental design, and three were qualitative analyses (Table 2.2). Of these results, three articles identified design requirements for inpatient engagement technology. The remaining 14 articles, which described interventions, were placed into four categories: entertainment, generic health information delivery, patient-specific information delivery, advanced communication tools, and personalized decision support.

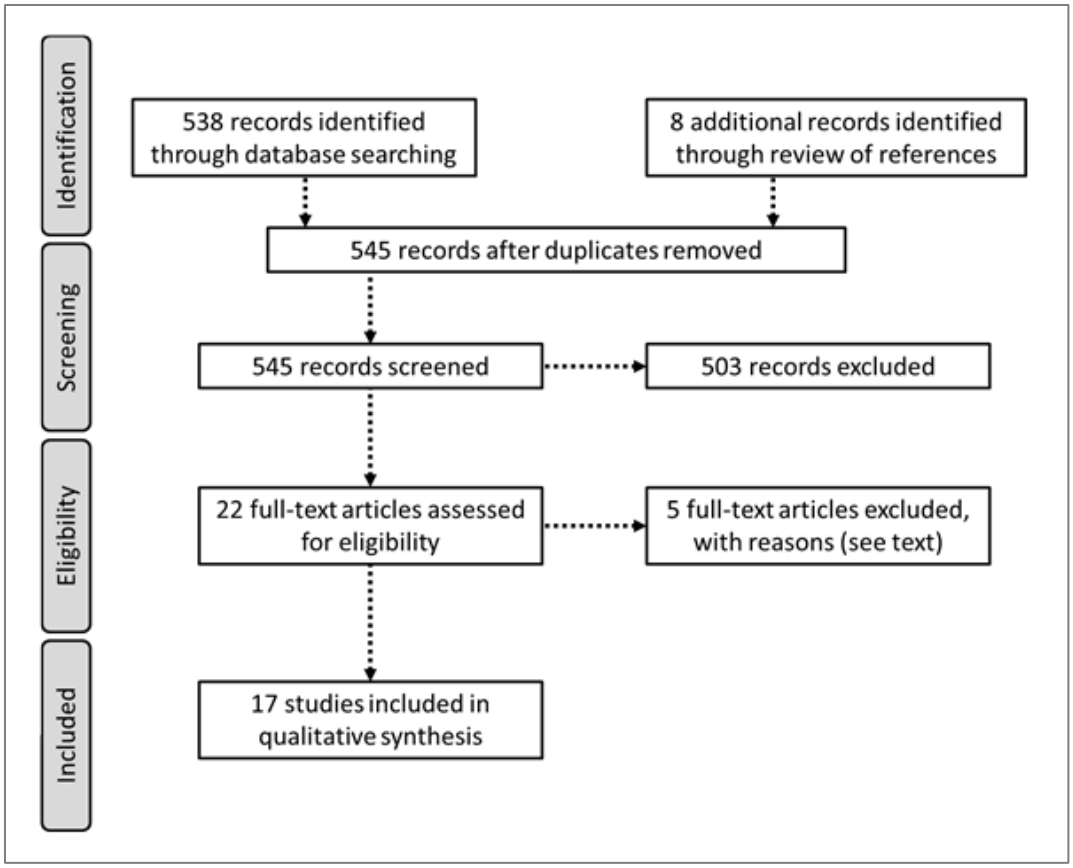


Figure 2.4 PRISMA diagram of systematic review results

Table 2.2 Studies of inpatient patient engagement using IT by category

Category	Author	Brief Description	Experimental Type	# of Participants	Outcomes
Design Reqs	Wilcox et al. (2012)	Interviews with patients and nurses in a cardiology step-down unit to determine common trends in medication information needs.	Interviews	17	Semi-structured interviews found a desire to keep track of current medications and trends. Patients desired additional educational information about their medications in the hospital. Found common themes on information content valued.
Design Reqs	Skeels & Tan (2010)	Conducted interviews with patients and visitors to discover opportunities to improve the inpatient experience.	Interviews	16 patients, 5 visitors	Semi-structured interviews found opportunities for improved communication and awareness as well as provision of social connectedness and entertainment.
Design Reqs	Morris & Karlson (2011)	Discussion of hospital-specific requirements for delivery of information.	Position Paper	-	Discuss how hospital patients be treated as situationally-impaired computer users, currently receive much information verbally, have many changing care team members and could benefit from accessibility research.
Design Reqs*	Kendall et al. (2015)	Used observations and an online questionnaire to understand information needs of hospitalized patients.	Observations, Survey	118 hours of observation; 157 questionnaires	Discovered that patients and caregivers have information they desire, like the plan of care and the schedule of activities, that are difficult to access as needed in a hospital setting.
Design Reqs*	Kaziunas et al. (2015)	Field observations and interviews of pediatric hematopoietic stem cell transplantation patients to identify unmet information needs.	Observations, Interviews	20 hours of observation; 17 patients	Found four recommendations for information provision: to provide patients/caregivers with real-time access to EHR data, to provide information about clinical trials the patient is enrolled in, provide care team information, and provide information to prepare patients for discharge.

Category	Author	Brief Description	Experimental Type	# of Participants	Outcomes
Entertainment	Bers, Gonzalez-Heydrich, & DeMaso (2003)	Explored usage of a computer-based application, Zora, in a pediatric hemodialysis unit in order to facilitate coping with chronic physical illnesses.	Quasi-experimental	7 patients, 4 staff	Results found that use of computational environments can provide an opportunity for pediatric patients and their caregivers to communicate and help with coping of chronic illnesses. Overall patient satisfaction was high (mean = 5.3 out of 7, sd = 1.3), enjoyment (5.7, 1.6), low harm (1.4, 1.1); staff had even more pleasing results: satisfaction (6.5, 0.5), safety (5.6, 1.4), harm (1.0, 0.0).
Entertainment	Das et al. (2005)	Studied the use of Virtual Reality games in reducing pain felt by children with burn injuries during burn management procedures.	Randomized Controlled Trial	9	Using the Face Scale Pain Scores, found lower average pain scores (4.1 (SD: 2.9) to 1.3 (SD: 1.8) when add VR to use of pharmacological analgesia. Nurse interviews had high satisfaction/appreciation
Entertainment	Dvorkin et al. (2009)	Used a haptic/graphic paradigm to improve attention and concentration of Traumatic Brain Injury patients.	Quasi-experimental	9	Subjects tolerated technology and showed increased # targets (higher attention) on day 2 of using the intervention. Found it engaging and enjoyable.
Generic Info	Mahler & Kulik (1998)	Evaluated use of three types of videotapes to assist in preparing patients for coronary artery bypass grafts.	Randomized Controlled Trial	268	Using a survey, found that viewing any videotape resulted in feeling better prepared for recovery, higher self-efficacy for using spirometer and speeding recovery, higher use of spirometer, released more quickly (shorter LOS). Three video types seemed relatively equal in effectiveness.
Generic Info	Stevens et al. (1993)	Multi-part inpatient intervention including counseling, videotapes, self-help materials and a phone call to encourage ex-smokers to continue to avoid use of tobacco.	Randomized Controlled Trial	1119	Using surveys and taking saliva samples, found use of intervention increased ex-smokers by 50% (9.2% to 13.5%), testing done at 3 and 12 month intervals.

Category	Author	Brief Description	Experimental Type	# of Participants	Outcomes
Generic Info	Yin, Ring, & Bickmore (2012)	Prototyped the effects of using a visual novel game to improve hospital patients' confidence in managing their own care.	Quasi-experimental	36	Found significant impact on increase of self-efficacy (measure by modified Generalized Self-Efficacy Scale (10-item) when combined with Flow State as co-variate, p = 0.004
Generic Info	Cook et al. (2014)	Provided a surgical population with access to educational modules using a tablet computer.	Quasi-experimental	149	Found that age, hospitalization, and major surgery were not significant barriers to effective patient education, and that mobile technology was an effective delivery mechanism even with older patients.
Patient-Specific	Bickmore, Pfeifer, & Jack (2009)	Testing of an animated, empathic virtual nurse who assists in educating and counseling patients at discharge.	Quasi-experimental	30 (Group 1) + 19 (Group 2) = 49	Preliminary User Study: 92% of patients comfortable with receiving health information this way. Hospital User Study: Felt like virtual nurse cared about them, 74% preferred VN to their doctors/nurses. System was easy to use, high satisfaction, prefer to use; like authority of information.
Patient-Specific	Varduloukais et al. (2012)	Provided mobile phones with access to dynamic, interactive reporting to patients within the emergency department.	Quasi-experimental	25	Using interviews, found improved patient awareness (more calm/less anxiety). Found few barriers to deployment. Useful for updating visitors about their current health status and care plans.
Patient-Specific	Vawdrey et al. (2011)	Used tablet computers to allow patients within a cardiothoracic surgery step-down unit to access personal health record information.	Quasi-experimental	5	Using interviews and a survey containing the Telemedicine Satisfaction and Usefulness Questionnaire (25-item), found improved satisfaction and engagement. Patients believed in the usefulness of application.
Patient-Specific*	Wilcox et al. (2016)	Explored the design and usefulness of patient-facing tools supporting inpatient medication management	Quasi-experimental, Interviews	20 patients, 17 clinician interviews	The provision of inpatient medication tracking tools can be a useful method to increase patient participation in their own care and improve patient-provider communication during the hospital stay.

Category	Author	Brief Description	Experimental Type	# of Participants	Outcomes
		and tracking to increase patient participation.			
Patient-Specific*	Masterson Creber et al. (2016)	Use of tablet computers to provide patients with access to a personalized patient portal.	Randomized Controlled Trial	140	This study is still enrolling participants, but is measuring changes in patient engagement and satisfaction from the use of a patient portal while admitted to the hospital. The portal provides access to care team information, medications, lab results, and pain management tracking
Patient-Specific	Dykes et al. (2013)	Pilot testing of an electronic bedside communication center to facilitate access to health information.	Quasi-experimental	11	In focus groups and interviews, patients expressed interest in using tool, liked tailored education content and access to information.
Patient-Specific*	Dalal et al. (2015)	Recruitment of medical intensive care and oncology unit patients and their care givers to use a web-based patient-centered toolkit.	Post-test only	239	Care givers were frequent users for those patients in the ICU. Many patients used a daily and overall goal as well as the educational content for medications and test results. However, there are many barriers to the adoption and use of inpatient portals.
Patient-Specific	Wilcox et al. (2010)	Wizard-of-Oz study in an emergency department (using large manually-updated poster prototypes) to assess patient and care provider responses to in-room information displays.	Quasi-experimental	18	Overall positive response to displays, high subjective satisfaction found through user interviews.
Patient-Specific*	O'Leary et al. (2015)	Provided intervention patients with access to a mobile patient portal application. Assessed patients' ability to correctly name their clinicians, tests, and medications.	Randomized Controlled Trial	202	Patients in the intervention group showed more knowledge of their physician names and roles than those patients in the control group. Patient activation was not associated with knowledge of clinicians' names and roles.

Category	Author	Brief Description	Experimental Type	# of Participants	Outcomes
Patient-Specific*	Pell et al. (2015)	A small cohort study that provided patient participants with access to a tablet computer to access parts of the EHR. Clinicians were surveyed before and after their patients received the intervention.	Pre-post study	50 patients, 44 clinicians	The suspected risks that clinicians had concerning the repercussions of sharing information with patients did not bear out. Patients answered more positively to empowerment questions after being given access to their data.
Patient-Specific*	Greysen et al. (2014)	A pilot study on the use of tablet computers to deliver interactive educational videos and promote engagement in discharge planning.	Post-test only	30	This pilot study demonstrated the viability of using tablet computer to improve inpatient education and patient engagement in discharge planning.
Patient-Specific*	Palma et al. (2012)	Conducted surveys to study the impact of providing a daily patient update letter, Your Baby's Daily Update, with data from the EMR to increase parent engagement on a level II neonatal intensive care unit.	Pre-post survey	57	The implementation of an EMR-based parental letter was feasible and provided parents with increased perceived competence to manage information in the NICU.
Communication	Safran (2003)	Use of BabyCareLink, a secure collaborative environment, to allow parents greater access to information concerning their infants in the NICU.	Quasi-experimental	300	300 people accessed the Baby CareLink more than 11,000 times in one year; median use of 17 separate sessions for parents. Strong utilization even in Medicaid populations.

Category	Author	Brief Description	Experimental Type	# of Participants	Outcomes
Communication	Anthony et al. (2005)	Offered collaborative rounds for family members and multimedia sources to review patient conditions, results and plans of care. Allowed for virtual meetings with off-site care team.	Quasi-experimental	57	Using focus groups and the Critical Care Family Satisfaction Survey (internally developed), results found the majority of respondents felt the program improved patient safety (64%) and response times (86%).
Personalized Decision Support	Weyand et al. (2011)	Testing of a personalized parent decision support tool for a neonatal intensive care unit.	Quasi-experimental	8	Usability testing showed the tool to be useful and easy to use.

*Article not included in original systematic review findings

Design Requirements

The hospital environment presents special challenges for implementing IT to support patient engagement. Wilcox and colleagues used inpatient interviews to explore requirements for medication information technology.(L. Wilcox et al., 2012) They found patients were often confused by frequent changes in medication therapies, and desired verbal briefings be supplemented with electronic information. In particular, patients thought having a record available would help them gauge therapeutic progress. Patients also desired the ability to read educational information about their medications and to be able to validate a list of their home medications.

Skeels & Tan conducted interviews in four different hospital units to examine opportunities to use technology to improve the inpatient experience.(Skeels & Tan, 2010) The authors asserted that patients desired the ability to send more information with the nurse call button so nurses could prioritize their calls. Patients hoped a personalized board could show a progress bar with important steps as well as past and future events (e.g., a doctor's upcoming visit). Participants also wanted to track "medications, pain scale data, and billing information," and be able to look up medical information about their condition and living a healthy lifestyle. Patients expressed a desire for general activities such as music, movies, television, games, and video conferencing. Also noted were the difficulties of limited mobility and reclining postures of inpatients, and suggestions made for the use of voice commands. These results were confirmed by Kendall and colleagues (2015) who discovered through observations and surveys that being hospitalized creates specific challenges for patients, and it is difficult for patients to obtain information such as a patient's care plan for each day. Additionally, patients wanted to be able to track "key aspects of their experience," and this functionality was not available in any inpatient portals. Kaziunas and colleagues(2015) also used observations and interviews to identify information needs in the hospital setting, this time with pediatric hematopoietic stem cell transplantation patients. Their results note the asymmetry of information between caregivers/patients and providers and suggest the need to close this

gap through the provision of real-time patient-access to EHR data, information about clinical trials the patient is enrolled in, as well as information concerning the patient's care team and planning for discharge. Morris and Karlson asserted that a "hospital patient should be treated as a situationally-impaired user,"(Morris & Karlson, 2011) and noted that impairments are highly dynamic in nature. Patients may feel disoriented by sights, sounds, smells, and frequent staff changes. Because verbal information is easily forgotten, it is important to have computer-based memory support in the hospital. They recommended leveraging information stored in a patient's EHR to help evaluate the patient's cognitive status. This evaluation could then help "inform dynamic adaptation" and potentially affect privacy permissions on the patient's data to allow family members access when the patient is not cognitively sound.

Entertainment

As early as 2003, researchers anticipated the benefits of virtual reality (VR) or gaming on improving patient engagement through entertainment. An 11-participant pilot study conducted by Bers and colleagues provided children undergoing dialysis treatment with a computer-based application that allowed them to create "characters, stories and spaces while communicating in real-time."(Bers, Gonzalez-Heydrich, & Demaso, 2003) The application engaged "both patients and staff in the creation of a virtual community-support network." Patients could communicate privately and the application helped some patients "voice personal concerns without the burdens of face-to-face or real-time conversation."(Bers et al., 2003) Results of the study showed high satisfaction and safety ratings, and support the use of computational systems to promote dealing with chronic physical illnesses.

A similar usage of VR with children was completed within a burn unit by Das et al. This nine-patient randomized controlled trial (RCT) studied a VR game used by children aged 5–18 years who were receiving treatment for burn injuries.(Das, Grimmer, Sparnon, McRae, & Thomas, 2005) Use of the game was shown to significantly lower average pain scores and decrease anxiety. This study supported findings that VR-

based games can reduce physical pain “with minimal side effects and little impact on the physical hospital environment.”(Das et al., 2005)

VR technology was used by Dvorkin and colleagues during inpatient rehabilitation.(Dvorkin, Zollman, Beck, Larson, & Patton, 2009) The group used a 3-D haptic/graphic system in the rehabilitation of Traumatic Brain Injury (TBI) patients. In this study, nine participants (six with TBI, three without) used this ‘Virtual Reality and Robotic Optical Operations Machine’ to reach for a visual target. They found the VR-haptics intervention to be “effective, well-tolerated and highly motivating.”(Dvorkin et al., 2009)

Generic health information delivery

Several studies used video presentations to increase patient engagement during hospitalization. A RCT of video usage was by Mahler and Kulik.(1998) Video recordings were shown to patients in preparation for their surgeries. Results of the trial found that patients who viewed the videos felt “significantly better prepared for the recovery period” and had higher reported self-efficacy beliefs. They also had significantly shorter intensive care unit (ICU) stays and were released from the hospital more quickly than patients in the control group. Similarly, Cook and colleagues (2014) used a tablet computer to deliver “just-in-time” education modules to elder adults following cardiac surgery. They found that mobile technology was a successful method of delivering this information, even to the elderly, and that age, hospitalization, and major surgery are not barriers to effective patient education.

Stevens and colleagues used videotapes as part of an intervention to encourage patients who had given up smoking while in the hospital to continue to do so after they left.(Stevens, Glasgow, Hollis, Lichtenstein, & Vogt, 1993) This RCT of over 1,000 participants was conducted across two hospitals. Results showed that the intervention group had a 50% increase in smokers who did not relapse into previous smoking behavior.

Yin and colleagues developed an intervention to improve the confidence patients had in managing their hospital stays.(Yin, Ring, & Bickmore, 2012) Thirty-six participants walked through an interactive visual novel concerning helping a family member avoid a fatal heart attack. This study found a significant effect when using flow score as a composite covariate, the more engaged in the novel the participant became, the more confidence they gained.(Yin et al., 2012)

Patient-specific information delivery

In addition to simply providing the same information to all patients, several studies focused on the provision of patient-specific information to increase patient engagement.

Bickmore and colleagues developed an "animated, empathetic virtual nurse interface for educating and counseling hospital patients with inadequate health literacy" at Boston Medical Center.(Bickmore et al., 2009) This study of 49 patients found the system was easy to use, resulted in high levels of patient satisfaction, and most participants preferred receiving information from the virtual nurse over their actual doctor or nurse. They believed the system provided authoritative information and appreciated the time the virtual nurse spent with them. Some patients felt the system helped them become more involved in their care.

With the proliferation of mobile phones and tablet computers, new approaches of presenting health information and engaging patients in their healthcare are being introduced. Varduloukais and colleagues developed a mobile phone application that provided patients with "a dynamic, interactive report on their progress, care plan, and care team throughout their emergency department stay."(Vardoulakis et al., 2012) Patients found the information helped reduce anxiety and "regain some semblance of participation in their own care." Patients valued the educational component, reported greater awareness of their care teams, and appreciated the system's ability to maintain privacy. The study found the system helped in

"improving awareness, promoting patient empowerment, and enhancing ownership of medical information in hospitals."(Vardoulakis et al., 2012)

Similar to the work of Varduloukais and colleagues., Vawdrey and colleagues developed a patient-facing tablet computer application that linked their institution's EHR and PHR systems.(Vawdrey et al., 2011) This application enabled five test patients to access information such as their care team profiles and hospital medication records. Through semi-structured interviews, patients reported the application was useful as a memory aid, improved medication tracking ability, and fostered personal connections through care team member photographs. The tablet application was perceived to be a "useful tool for providing information and increasing patients' engagement in their care."(Vawdrey et al., 2011) This tablet application was also used in a separate study to provide patients with access to information about their medication regimens while they were in the hospital. The study found that "inpatient medication-tracking tools, when designed to meet patients' needs, can play an important role in fostering patient participation in their own care and patient-provider communication during a hospital stay."(L. Wilcox et al., 2016) This tablet application is also currently being used in a randomized controlled trial in a hospital to determine its effect on patient satisfaction and engagement.(Masterson Creber et al., 2016) The information provided includes care team information, medication administrations, clinical orders, and vital signs, as well as the ability to document of pain information and notes, and send messages to clinicians. This work will more definitively report on whether providing patients with access to their clinical information while in the hospital changes patient activation.

Dykes et al. (2013) conducted another study that used a tablet device to provide patient-specific information. The authors led focus groups and used a participatory process to design an electronic bedside communication center. The tool allowed patients to access tailored patient information and educational content. Usability testing results showed high satisfaction and high perceived value. This research group followed-up on their initial study with a larger enrollment of patients from medical ICU and oncology units

to use this web-based application.(Dalal et al., 2015) They found that the educational content that was accessed the most frequently was for medications and test results, and clinical messages contained themes related to health concerns, needs, preferences and questions. Additionally, they identified multiple barriers to adoption and use including security and technological difficulties, recruitment issues, and lack of clinician knowledge concerning the inpatient portal.

Recently, O'Leary et al. (2015) published research showing that the provision of a mobile patient portal application to hospitalized patients was able to increase the patients' knowledge of physician names and roles. However, improvement in knowledge of nursing names, planned tests, procedures, and medications was not significantly different. Pell et al. (2015) also gave patients in the hospital tablet computers to provide access to information like the patient's real-time medication schedule and test results. They used pre- and post-intervention surveys to evaluate caregiver workload, patient confusion and worry, patient empowerment, errors detected and discharge planning. They found that expected increases in workload and patient worry did not bear out. Additionally, patients answered more positively to empowerment questions. Tablets were also used by Greysen et al. (2014) to improve patient engagement through the provision of interactive videos to improve patient education and to provide access to a PHR to allow patients to participate in discharge planning. They found that tablet computers were an effective way of delivering this information, and inpatients were highly satisfied with the use of tablets and that minimal timing was necessary for training of either patients or staff.

A study by Wilcox and colleagues assessed the usefulness of large in-room information displays in an emergency department.(L. Wilcox, Morris, Tan, & Gatewood, 2010) The displays included personalized information such as medications, vital signs, allergies, and care team details. Results of the 18-patient study showed a positive response, and patients found having the information calming. The displays facilitated information sharing and promoted discussion with care providers. Patients also reported "the benefits of an in-room information display outweighed any privacy concerns."(L. Wilcox et al., 2010)

An example of parental engagement in the inpatient setting was studied by Palma et al., (2012) in which they provided parents of children in the neonatal intensive care unit with a daily, printed care plan. Families found these daily updates useful, and showed trends towards improved communication and parents feeling more competent in managing information related to the status of their babies.

Enhancing communication

In addition to more traditional technology, there is some research into current abilities to provide information and data access in new ways. Baby CareLink, described by Safran in 2003, was a web-based application used by 300 parents to remotely follow the hospital care of their premature infants.(Safran, 2003) The system allowed parents to see "daily reports, doctor's notes, and a baby growth chart" as well as research materials, messages from the night shift care team, and photographs. Safran reported a 75% reduction in quality-of-care problems, illustrating the potential this type of collaborative tool offers in keeping families informed and involved.

In addition to its application in neonatal care, video conferencing was utilized to allow patients to communicate with family members and clinicians who are geographically distant.(Anthony et al., 2005) A project at Lehigh Valley Hospital used IT to allow patients' family members to join on rounds in the ICU and facilitate "virtual meetings between family members and an off-site intensivist during nonprime hours." Such family meetings involved multimedia sources to review patient conditions, results, and plans of care including digital radiology films and trends from vital sign readings. A survey conducted with 57 staff members found the majority of the people who utilized the system believed it improved patient safety and staff response times.

Personalized decision support

In addition to improving the provision of information within healthcare, there are efforts to help patients and parents of patients make tough, personalized decisions. Weyand and colleagues designed a computerized decision support tool for parents with children in a neonatal intensive care unit

(NICU).(Weyand, Frize, Bariciak, & Dunn, 2011) The tool assisted parents in making informed decisions, allowed for greater communication with the physicians, and provided information on ethically challenging situations. Initial studies, of eight parents, showed this tool offered potential benefits to both future parents and physicians working in the NICU.

2.4.3 Discussion

This review shows that research on patient engagement in the inpatient setting is in its beginning stages, but it is a growing area of research interest, as indicated by the recent increase in related research studies. Studies were found across a variety of methods and were classified into the model shown in Figure 2.5. A pyramid structure was chosen to represent the perceived quantity of interventions at each level of engagement. The entertainment category at the base encompasses basic technologies such as television and internet access (which were not found in the literature), as well as entertainment options for medical purposes (e.g., pain management through distraction (Das et al., 2005)). Generic health information refers to the provision of health-related content to patients, including tailored information for a particular diagnosis or treatment. Patient-specific information implies unique content delivered to each individual, such as laboratory test results or medication administration records. Advanced communication technology facilitates communication between patients and care team members. Personalized decision support aids patients and families in making decisions about treatment options. It was theorized that as the complexity of interventions increases, expected patient usage decreases, or viewed the other way, that simpler interventions will likely have greater utilization. However, the clinical impact that interventions at these varying levels of complexity may have is still unknown, and will likely relate to each tool's usefulness for patients across the varying stages of their care.

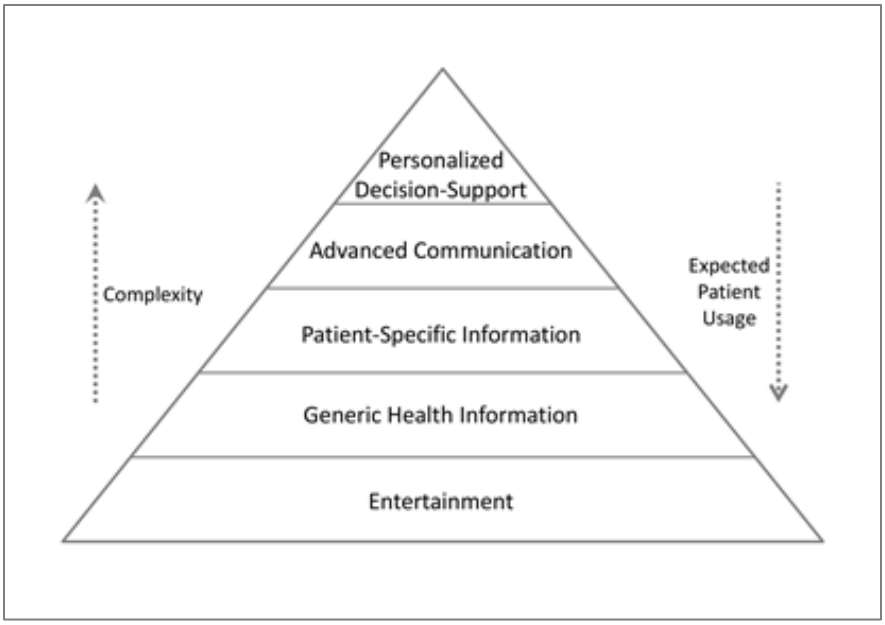


Figure 2.5 Categories of information technology-enabled patient engagement

These technology-enabled patient engagement devices are slowly making inroads into the hospital environment. Advances in technology have enabled new methods for patient engagement. The spread of electronic medical record systems within care organizations, and the proliferation of mobile technology, provides the capability to employ technology to increase engagement.

The majority of studies found in this review followed quasi-experimental designs using interviews and surveys to measure the success of each intervention, with a few of the more recent studies now reporting some results from randomized controlled trials. This suggests that the quality of the evidence base for this domain is underdeveloped and could benefit from further, more rigorous analysis. Results of all of the RCTs found had some positive results, indicating the potential of future work. Success was most often defined as increased user satisfaction. Various metrics were employed to measure satisfaction, including the Critical Care Family Satisfaction Survey (Safran, 2003) and the Telemedicine Satisfaction and Usefulness Questionnaire.(Vawdrey et al., 2011) Overall, studies found positive impact the through use of engagement technologies, with some studies demonstrating lower average pain scores, (Das et al., 2005) increased self-efficacy and engagement,(Dvorkin et al., 2009; Mahler & Kulik, 1998; Vardoulakis et

al., 2012; Vawdrey et al., 2011; Yin et al., 2012) and increased patient knowledge.(O'Leary et al., 2015) Various measures of self-efficacy were used, including a modified Generalized Self-Efficacy Scale,(Yin et al., 2012) and a self-efficacy scale based on the work of Condiotte and Lichtenstein(1981) and Sallis and colleagues.(1988) Only two studies measured clinical outcomes; one evaluated smoking cessation,(Stevens et al., 1993) and the other measured length of hospital stay.(Mahler & Kulik, 1998) Future work should focus on use of RCTs to further evaluate effects of engagement technologies on patient outcomes.

The studies identified in this systematic review provide valuable lessons for designers and implementers of technology. Notably, engagement within the inpatient setting presents challenges that are less salient in the outpatient world. For example, if electronic devices are provided to patients, there are issues regarding infection control,(Morris & Karlson, 2011) data security and privacy,(Brown et al., 2016) physical management of the devices (e.g. who distributes and collects them), and ergonomic issues.(Skeels & Tan, 2010) It can also be challenging to provide the same information within the inpatient setting to the patient once s/he has left the hospital. Such issues have yet to be fully addressed, and future research is warranted to ensure patient engagement in the inpatient setting is optimized and tailored to each patient's specific needs.

To gain more insight into inpatient engagement needs, research and lessons learned from outpatient projects like Project HealthDesign can be utilized. Project HealthDesign is a multi-site project that employs user-centered design processes to create computer-based applications to support health across patient types.(Brennan, Downs, & Casper, 2010) The project focused on using PHRs as "platforms for action" and encouraged patient self-management of their health. A trend to consider in designing new engagement interventions is the spread of patient-owned mobile devices. Future interventions could potentially leverage the increased availability of devices and design applications that run on multiple platforms (i.e. tablet computers and mobile phones of varying operating systems). Utilization of a web-interface over a

custom-built platform-specific application could provide for more seamless access to information in transitioning from the inpatient to the outpatient realm.

Inpatient patient engagement and satisfaction are of growing importance to hospitals as patient satisfaction scores will soon affect reimbursement rates. Starting in fiscal year 2013, the Patient Protection and Affordable Care Act put into place a Value-Based Purchasing plan that determines hospital performance and pay based in part on Consumer Assessment of Healthcare Providers and Systems (HCAHPS) scores.(Buhlman & Matthes, 2011) HCAHPS includes satisfaction measures across eight domains including items such as communication with nurses, pain management, and new medicines being explained. HCAHPS publicly reports patients' perspectives of hospital care. Thus, further research analyzing the efficacy and usefulness of inpatient engagement is important. With the spread of electronic health records and emergence of PHRs, healthcare institutions are positioned well to provide patients access to their personal health information.

One obstacle in researching patient engagement is the relative lack of standard terminology and measurement techniques. There is no specific MeSH term for patient engagement. Terms such as "patient participation", "patient activation", "patient satisfaction", and "self-efficacy" are often used without consistency. In addition to the various engagement measures mentioned above, a well-known instrument for measuring patient engagement, is the Patient Activation Measure (PAM) developed by Hibbard and colleagues.(Hibbard et al., 2005, 2004) The PAM is a 13-item questionnaire that measures the activation of a patient in managing his/her health. The PAM has been used in multiple patient engagement studies,(Masterson Creber et al., 2016; O'Leary et al., 2015) but no one true measure of patient engagement has been established. Future research would benefit from the development of an ontological framework for describing and measuring patient engagement to provide a common vocabulary for research in this area.

Limitations of this review include the potential exclusion of relevant articles due to incomplete search terms. As noted above, there is a lack of standard terminology surrounding the subject of patient engagement and no consistently utilized MeSH terms. Additionally, only English language studies were reviewed. As with all literature reviews, the result set may be influenced by publication bias.(Vawdrey & Hripcsak, 2013) No formal 'grey literature' searches were conducted, but conference proceedings and papers found within the search databases were included.

The results of this review demonstrate that knowledge gaps exist regarding patient engagement in the inpatient setting. Much work remains to be done in this area. As Henwood and colleagues (2003) noted, "the informed patient will not emerge naturally or easily within existing structures and relationships." Future studies should focus on identifying optimal methods for engaging patients and rigorously examining the impact of these methods on healthcare delivery process. Specifically, there is a clear need for both methodological and practical research on inpatient engagement that addresses health outcomes and cost-effectiveness. While some work is being done to engage patients in their care by providing them with access to their clinical information, there has been less work in engaging patients as part of the patient safety process. As the patient is the "one true constant in care, actively and consistently collecting observations about the healthcare experience",(A. King et al., 2010) they can provide a valuable perspective for improving patient safety.

2.5 Patient Engagement to Improve Patient Safety

The Institute of Medicine reports, "To Err is Human" and "Crossing the Quality Chasm",(Institute of Medicine, 2003; Institute of Medicine et al., 2000) placed significant focus on the need to improve patient safety. While important strides have occurred in the past ten years, there are still gaps in care quality and safety that need to be addressed. Medication errors in particular have been identified as an area that needs improvement. However medication errors can be difficult to target, as current data suggest that

information provision, recognition and possibly interception of medication errors occur largely unsystematically 'at random'.(Schwappach & Wernli, 2010)

A 2008 study by Pippins and colleagues found that unintentional medication discrepancies are common, and discrepancies may be more often due to errors in taking an accurate medication history than errors reconciling this history with patient orders. Similarly, Shepherd and Schwartz (2009) found that medication history obtained at triage was missing at least one medication in 48% of patients. Poor communication of medication information is especially important at care transitions (e.g., from emergency department (ED) to inpatient admission or ED to home) and was estimated to be responsible for 46-60% of medication errors in hospitals.(Barnsteiner, 2005; Rozich & Resar, 2001) To combat these medication discrepancies, the process of medication reconciliation was created. Medication reconciliation is the process of "identifying the most accurate list of all medications a patient is taking… and using this list to provide correct medications for patients anywhere within the health care system."(Resar & Midelfort, 2004) However, as a result of the variety of care settings each individual patient interacts with, along with polypharmacy, the process of collecting a patient's current medication list can be a complex, resource-intensive task.

A physician from a New York City hospital illustratively stated, "Everyone owns 'med rec', and nobody owns 'med rec'." This lack of ownership results in errors being created and propagated, potentially for long periods of time. Studies have found that 48-87% of patients in the ED have at least one medication discrepancy.(Caglar, Henneman, Blank, Smithline, & Henneman, 2011; Shepherd & Schwartz, 2009) Ziaeian et al. detected either a medication error or a lack of patient understanding about a medication change in approximately 80% of older patients at discharge.(Ziaeian, Araujo, Van Ness, & Horwitz, 2012) Coleman et al. (2005) reported that 14% of recently discharged patients experienced a medication discrepancy. More than half of patients evaluated in a Gleason et al. (2004) study had discrepancies in

their medication histories and admission medication orders, with 22% of discrepancies that could have resulted in patient harm during hospitalization and 59% may have resulted in patient harm if the error continued beyond discharge.

In 2005, The Joint Commission identified medication reconciliation as a National Patient Safety Goal in an effort to minimize adverse events caused during care transitions.(The Joint Commission, 2005) However, actually meaningfully and systematically implementing medication reconciliation across all care settings turned out to be extremely difficult for healthcare institutions to implement.(Greenwald et al., 2010) More recently, the American Pharmacists Association and the American Society of Health-System Pharmacists jointly issued a white paper entitled "Improving Care Transitions: Optimizing Medication Reconciliation".(Steeb & Webster, 2011) This paper described a new system of medication reconciliation, "composed of multiple processes that together reduce medication errors, support safe medication use by patients, and encourage community-based providers and those practicing in hospitals and health systems to collaborate in organized medication reconciliation programs to promote overall continuity of patient care".(Steeb & Webster, 2011) This suggestion relates back to James Reason's model of accidents in considering that layering multiple processes and checks together will help create a safer environment.(Reason et al., 2006)

Most medication reconciliation improvement research has focused on provider practices and/or improved electronic medical record interfaces.(Murphy, Oxencis, Klauck, Meyer, & Zimmerman, 2009; Plaisant et al., 2015; Pronovost et al., 2003; Schnipper et al., 2011; Smith, Coleman, & Min, 2004; Vawdrey et al., 2010) A systematic review of hospital-based medication reconciliation practices found limited data on the most effective practices of inpatient medication reconciliation, and a lack of rigorously designed controlled studies comparing different medication reconciliation approaches with each other.(Mueller, Sponsler, Kripalani, & Schnipper, 2012) Mueller and colleagues also noted that taking an accurate

medication history and communicating with post-discharge providers are important steps, particularly for reducing post-discharge health care utilization.

I believe that patients can be a key contributor to the medication reconciliation process, and are currently being underutilized as a resource in this regard. Based on the successes of patient engagement interventions in the outpatient setting, and those positive preliminary results in the inpatient setting, I believe patients can employed to participate the complex process that is medication reconciliation, and be another "slice of Swiss cheese" to help reduce medication errors. In order to engage patients more actively in the medication reconciliation process, they need to receive greater transparency into what is in their medical records. In a survey of hospital patients conducted by Cumbler and colleagues, 90% of respondents said they wanted to review their hospital medication list for accuracy, but only 28% were given the opportunity to do so.(Cumbler, Wald, & Kutner, 2010) As Schwappach and Wernli (2010) note, "a central and crucial element for patients' ability and effectiveness to participate in error identification is information."

Giving patients a larger role in the medication reconciliation process will not only allow for improved accuracy of the medication list, but also allow for patients to give their feedback more directly to clinicians in regards to their personal preferences concerning the medication regimen. Generally, institutions have no defined methods for storing rules about individual patient preferences or customized care needs, and it therefore has a high potential to be lost.(Schwappach & Wernli, 2010) By providing patients with direct access to data from their clinical record, and allowing them to annotate and update the information, clinicians could have greater access to patient's adherence to their medications and understand patient habits and care preferences more easily.

Some investigators have reported on patients' ability to play a role in patient safety and error reduction.(Davis, Sevdalis, & Vincent, 2011; Friedman, Provan, Moore, & Hanneman, 2008; A. King et al.,

2010; Schwappach, Frank, & Davis, 2013; Schwappach & Wernli, 2011; Unruh & Pratt, 2007) Most of this body of work has focused on the general ability of patients to contribute to the patient safety process, and the evidence suggests that patients are willing and able to contribute. However, there are several barriers inhibiting participation, including both patient attributes and effort required. Additionally, clinicians' approval of patient-involvement with safety-related interventions was found to be generally high, however clinicians expressed varying levels of support depending on the type of intervention (e.g., clinicians had more favorable attitudes concerning patients intervening about a medication error rather than hand sanitation).(Schwappach et al., 2013)

A few studies have focused specifically on the patient's ability to contribute to the medication review process, with mainly positive results. One group at a Boston teaching hospital provided patients with drug safety information and their personalized hospital medication list, while a control group had only drug safety information.(Weingart et al., 2004) While there were no significant results, the process was considered to be a "promising strategy" and 29% of nurse respondents indicated at least one medication error was prevented when a patient or family member identified a problem. Additionally, at some US cancer centers, patients are provided with a card listing their medications, which they can update as they receive treatment at different sites and physicians are instructed to ask for medications at every visit.(J. B. Finkelstein, 2006)

A recent study used a combination approach of pharmacists and an ePHR to help patients conduct the medication reconciliation process once they were discharged from the hospital.(Kogut, Goldstein, Charbonneau, Jackson, & Patry, 2014) The investigators reported this to be an effective method to identify medication-related problems. In the outpatient setting, Dullabh and colleagues (2014) provided patients with access to a patient portal where participants could review their medications prior to a visit, and submit feedback directly to their providers, was able to improve the accuracy of the medical record. Dullabh showed that patients were providing mostly accurate information, and a gold-standard review by

pharmacists accepted 68% of changes submitted by the patients. They concluded that building a workflow and technological infrastructure to support this type of partnership is needed. A similar study conducted in Boston asked patients to review their documented medications and identify discrepancies at home prior to clinical visits.(Schnipper et al., 2012) This controlled trial found that patients in the intervention group had fewer unexplained medication discrepancies than patients in the control group. Additionally, the intervention group had a lower potential for severe farm than control patients. These results showed that if a patient uses the tool, there can be improved concordance between documentation and patient-reported medication regimens, and that there is a reduction in potentially harmful medication discrepancies.

In addition to viewing the incidence of errors using the Reason model of accidents, there are several frameworks that have been developed that focus specifically on engaging patients as partners for patient safety. Longtin et al. (2010) created a conceptual model of factors that influence patient participation in preventing errors. These factors include both patient-related factors and healthcare worker-related factors, showing the importance of not just the patient, but also the surrounding system of care team members and environment. Effective communication and the sharing of power and responsibility were noted as key components influencing patient participation in the error prevention process. Schwappach (2010) developed a structural model of “Intention to Act and Engagement in Safety-Related Behaviors” (Figure 2.6) based on the Theory of Planned Behavior. The model was created based on the results of a systematic review and is meant to provide a conceptual model of relevant factors and latent structures that seem to affect the intentions and behaviors of patients to participate in a preventive safety action.

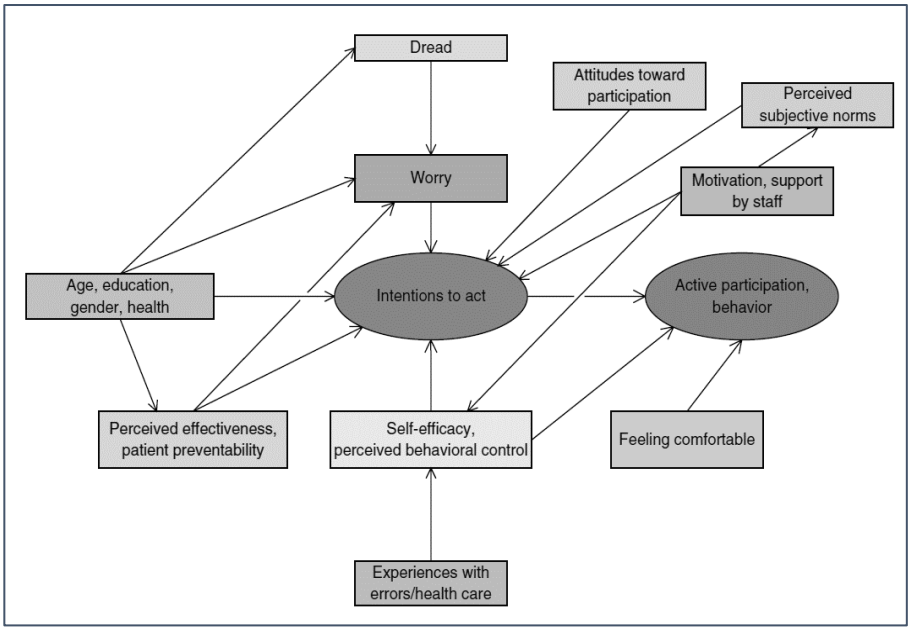


Figure 2.6 Structural Model of Intention to Act and Engagement in Safety-Related Behavior (Schwappach, 2010)

Further, it shows that self-efficacy, behavioral control beliefs, the preventability of incidents by patients and the perceived effectiveness of actions seem to be the key forces in engaging patients in their safety, moderated by socio-demographic characteristics.(Schwappach, 2010) There are other more general models that could also be considered when implementing an intervention in the healthcare setting, especially one that uses technology, including the Unified Theory of Acceptance and Use of Technology (UTAUT), PRECEDE-PROCEED, and RE-AIM.(Bakken & Ruland, 2009; Green & Kreuter, 1993; Holden & Karsh, 2010)

2.6 Summary

This review of the literature started with the consideration of patient safety initiatives. There are many opportunities for improvement within the healthcare environment to increase patient safety. I believe that engaging patients is an innovative and practical way to improve safety, particularly with respect to medication management. This review described how patients are currently being engaged around the world through the sharing of clinical information. The trend is going toward “fully transparent medical

records",(Walker et al., 2014) and patients have seen positive outcomes as a result of this increased sharing and engagement. I believe these optimistic results, especially when combined with those from the inpatient setting, have set the stage for the engagement patients to participate in patient safety efforts. Patients are in a prime position to participate in reviewing their health information and as they are the ones who are actually taking their medications at home, should be well-suited to review this type of information when admitted to the hospital.

Chapter 3: Providing Patients with Access to Their Medical Records[2]

3.1 Introduction

Being in the hospital has been called "one of the most dis-empowering situations one can experience in modern society."(Bickmore et al., 2009) Patients often feel isolated, anxious, and concerned that they do not have control over their care. They often do not know what medications they are taking, details of their treatment plans, or even the names of the members of their care teams.(Cumbler et al., 2010; Makaryus & Friedman, 2005; O'Leary et al., 2010) Therefore, there is a need to engage hospital patients and facilitate greater participation in their care.

Engaging patients has received significant attention in recent years. In contrast to the traditionally paternalistic doctor-patient relationship, consumers increasingly expect direct and fast access to their

[2] This chapter expands on the work originally published in Prey, J. E., Restaino, S. W., & Vawdrey, D. K. (2014). Providing Hospital Patients with Access to Their Medical Records. In AMIA Annu Symp Proc (pp. p. 1884–93). Washington, D.C.

health records.(Collins, Vawdrey, Kukafka, & Kuperman, 2011; Mandl & Kohane, 2016) In the beginning of 2016, the Obama administration in the United States released new guidelines to remove barriers to patients gaining access to their medical records.(U.S. Department of Health and Human Services, 2016) This sharing of information and engagement of patients not only helps the patients feel more involved, but also can lead to improved health outcomes.(Hibbard & Greene, 2013; Hibbard, Greene, & Overton, 2013) The Institute of Medicine (IOM) recommended that individuals receive opportunities to be the source of control in their care, and that they should be given access to medical information and clinical knowledge.(Institute of Medicine, 2003) The Meaningful Use financial incentive program in the United States stipulates requirements for the provision of access by patients to their clinical summaries, electronic messaging with their providers, patient-specific educational resources and online access to their personal health information (including content such as care team members, medication lists and history, laboratory results, and problem lists).("HealthIT.gov," 2014) Further, the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Hospital Survey, which collects patients' perspectives of hospital care, impacts hospital reimbursement from the Centers for Medicare and Medicaid.(Buhlman & Matthes, 2011) Despite a growing interest in patient engagement, little work has been conducted to study patient engagement in the inpatient setting.(Prey et al., 2014)

Aim 1: Understand perceptions of sharing clinical information with patients in the inpatient setting

This aim assessed patient and provider opinions of increased information sharing with hospital patients. Writing in the New England Journal of Medicine, Walker and colleagues pointed out that while providing patients with access to information is becoming more common, doing so in the inpatient setting is particularly complex.(Walker et al., 2014) When I undertook this study, no one had studied the impact of providing patients in the hospital with full access to their medical record, including medications, laboratory results, radiology and pathology reports, clinical summaries, operative/procedure reports and

progress notes. In this aim, I conducted a two-part study to understand the clinician perspective on increased patient access to clinical information, as well as to study the patient experience in receiving greater access to their information while in the hospital. My hypothesis was that providing patients with full access to their clinical chart would increase engagement in their care.

Research Questions

- What are clinicians' perceptions about sharing clinical information with patients in the hospital? What benefits or difficulties do they expect may occur as a result of increased information sharing with patients?
- How will hospitalized patients respond to receiving an unedited, daily copy of their medical records?

3.2 Methods

This research consisted of two parts (Table 3.1, Figure 3.1): a survey administered to clinicians, and a complementary field study conducted with patients in the hospital.

Table 3.1 Overview of Aim 1 methods

Study	Participants	Analysis	Outcomes
Clinician Survey	Physicians, PAs, Nurses, ancillary care providers (e.g., nutritionists)	Descriptive statistics, Kruskal-Wallis analysis	Characterization of clinician perspectives on information sharing
Patient Field Study	Cardiology patients	Thematic content analysis of semi-structured interviews	Overview of patient experience in receiving access to their full medical chart

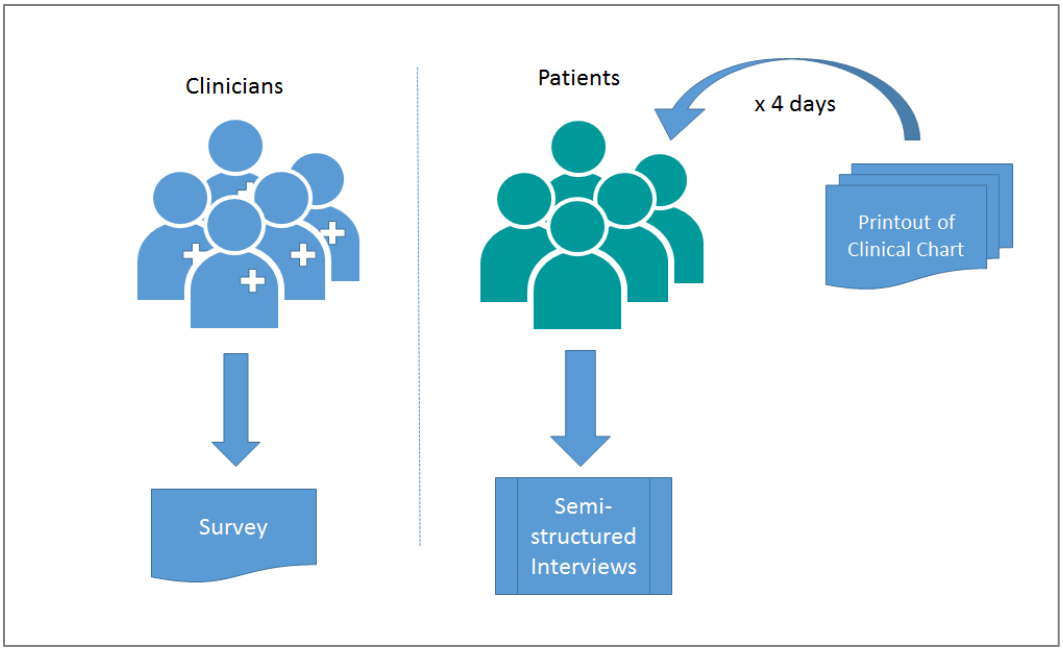


Figure 3.1. Overview of Aim 1 methods

3.2.1 Clinician Survey

Study Design

We conducted a prospective survey to discover clinician perspectives on increased sharing of clinical information with patients. The survey consisted of two parts; first, a set of questions that focused on clinicians' perceptions of sharing different types of information with patients (e.g., medication information, clinical notes), and a second set of questions that asked about potential consequences of increased patient access to information.

Setting

The study was conducted at Columbia University Medical Center (CUMC), a large urban academic medical center that is part of NewYork-Presbyterian Hospital.

Subjects

The survey was distributed to clinical staff in a cardiac step-down unit, mostly comprised of nurses and physician assistants (PAs). It was also distributed at a monthly meeting of CUMC's Housestaff Quality

Council, a group of resident physicians representing each clinical department at the medical center. Additional surveys were collected from clinical staff on the cardiology floor. This research was approved by the medical center's human subjects institutional review board.

Data Collection

The survey was administered to all subject groups on paper. It was a single-page survey that respondents filled out by hand. The data were then entered from the paper forms into a spreadsheet for analysis.

Measures

All survey questions were evaluated on a 5-point Likert-type scale with responses ranging from 'Strongly Disagree' to 'Strongly Agree'. Questions used negatively and positively worded stems to guard against acquiescence.(Barnette, 2000)

Clinicians were asked one over-arching question, "In general, I am comfortable with patients having some level of access to their electronic medical record." They were then asked how comfortable they were with patients having access to specific elements in the medical record: medication information, care team profiles, lab results, radiology results, pathology results, operative/procedure reports, progress notes, and consultation notes. They were also asked to report whether they believed they would change the way they wrote their clinical notes if they knew a patient could easily view them.

The second set of questions asked the clinicians to provide their opinions on what they believed the impact of increasing patients' access to their medical information would be. Potential areas of impact included changes to time at the patient bedside, patient misunderstanding of information, patient anxiety, increased concern about legal liability, additional work as a caregiver, changes in patient health behaviors, changes in quantity of patient questions, changes in patient-clinician communication, and changes influencing patient engagement in decision making.

A final question provided a free-text box to allow for clinicians to elaborate on their potential concerns and perceived burdens or benefits that may result from providing patients with this increased access to their clinical information.

Data Analysis

Responses to the survey were tabulated and analyzed using both Microsoft Excel 2010 and the R Statistical program.(R Core Team, 2013) A descriptive summary of the data consisted of calculating frequencies, medians, and inter-quartile ranges (IQRs). Kruskal-Wallis analysis was completed, and a Bonferroni correction used for post-hoc analysis to look for differences between types of respondent (i.e., physician, physician assistant (PA), nurse, or other).(Cabin & Mitchell, 2000)

3.2.2 Inpatient Field Study

Study Design

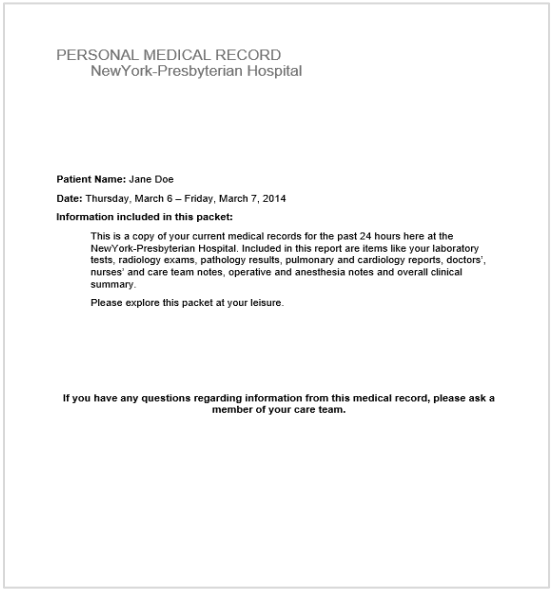
The second component of this aim was a prospective, quasi-experimental design in which patients were provided with a daily printout of their hospital care, printed from the institution's electronic health record (EHR).(A. B. Wilcox, Vawdrey, Chen, Forman, & Hripcsak, 2009) After four consecutive days of receiving this printout, in-situ semi-structured interviews were conducted with each participant to elicit his/her feedback.

Setting

This study was conducted in the same institution as the clinician survey, Columbia University Medical Center – NewYork-Presbyterian Hospital.

Intervention

After providing consent, the patient received a daily printout of his/her medical record, which included new information added to the EHR in the previous 24 hours. Specifically, the printout contained laboratory test results, physician progress and consult notes, radiology reports, pathology reports, cardiology test results, discharge planning materials, operative reports, nutrition notes, the medication administration record, and other nursing documentation.



PERSONAL MEDICAL RECORD
NewYork-Presbyterian Hospital

Patient Name: Jane Doe

Date: Thursday, March 6 – Friday, March 7, 2014

Information included in this packet:

This is a copy of your current medical records for the past 24 hours here at the NewYork-Presbyterian Hospital. Included in this report are items like your laboratory tests, radiology exams, pathology results, pulmonary and cardiology reports, doctors', nurses' and care team notes, operative and anesthesia notes and overall clinical summary.

Please explore this packet at your leisure.

If you have any questions regarding information from this medical record, please ask a member of your care team.

Figure 3.2 Cover page for patient printout

Minor editing was performed to remove phone numbers and social security numbers, and to delete unnecessary white space. No additional changes were made to the documents. A cover page describing the potential contents of the printout was added (Figure 3.2). The report was printed and hand-delivered each morning to each of the participants. The reports ranged from 5–40 pages each; 10–15 pages each day was typical.

Subjects

Medically stable patients on a cardiology floor were approached for potential participation based on their ability to speak English and their anticipated date of discharge. In line with the institutional policies, their attending physician described the study and referred interested patients to the primary researcher (JP), who obtained informed consent.

Data Collection

After receiving daily reports for four days, a semi-structured interview was conducted. This interview was audio-recorded. In addition to basic demographic questions, patients were asked to describe various experiences related to receiving their clinical information. Topics that were discussed included:

- Patients' use of the printout (e.g., frequency, time spent)
- Patients' perceived capacity to understand the information
- Preferences regarding structure/format of the information
- Patients' desire to receive such information in the future
- Behavior changes as a result of having the information (e.g., asking more questions)

Data Analysis

The audio-recordings of the patient interviews were transcribed internally. As done in previous studies by this research team,(Vawdrey et al., 2011; Woollen et al., 2016) transcripts were analyzed using a qualitative analysis approach.(Burnard, 1991) As the primary researcher, I independently reviewed all the data, and iteratively generated a coding scheme. I independently coded the data, and the Principal Investigator (DKV) reviewed the coding. The two researchers then discussed the coding to reach a consensus and finalize themes.

3.3 Results

3.3.1 Clinician Survey Results

Approximately 65 surveys were distributed and 53 clinicians responded: 21 physicians (40%), 20 nurses (38%), seven physician assistants (13%), and five allied health professionals (e.g., nutrition specialists, social workers) (9%). Data for this study were collected from January to March 2014. Responses are shown in Table 3.2 along with frequency, median, and IQRs in ordinal number format (1=Strongly Disagree; 5=Strongly Agree). Only the first question (sharing some information in general) had an IQR equal to zero.

Six questions had an IQR of two. The Kruskal-Wallis test was used to analyze differences between the groups (physicians versus PAs versus nurses versus other). Only the question on note-writing behavior was statistically significantly different between groups (p=0.033); however, post-hoc pairwise analysis of between group differences with a Bonferroni correction did not find any significance. The survey results are also presented using diverging stacked-bar graphs in Figures 3.3–3.5.(Robbins & Heiberger, 2011)

Table 3.2 Summary statistics of clinician survey on attitudes toward inpatient information sharing

	Disagree	Strongly Disagree	Neutral	Agree	Strongly Agree	No Response	Range	Q1	Median	Q3	IQR	Kruskal-Wallis
I am comfortable with patients having access to:												
Some information from their EHR (in general)	0 (0%)	0 (0%)	6 (13%)	28 (62%)	11 (24%)	9 (20%)	3-5	4	4	4	0	0.458
Medication Information	0 (0%)	0 (0%)	1 (2%)	23 (45%)	27 (53%)	3 (6%)	3-3	4	5	5	1	0.336
Care Team Profiles	3 (0%)	0 (6%)	8 (15%)	23 (44%)	18 (35%)	2 (4%)	2-5	4	4	5	1	0.419
Lab Results	2 (2%)	1 (4%)	3 (6%)	23 (44%)	23 (44%)	2 (4%)	1-5	4	4	5	1	0.511
Radiology Results	3 (2%)	1 (6%)	5 (10%)	21 (40%)	22 (42%)	2 (4%)	1-5	4	4	5	1	0.088
Pathology Results	2 (2%)	1 (4%)	3 (6%)	24 (46%)	22 (42%)	2 (4%)	1-5	4	4	5	1	0.211
Operative/Procedure Reports	1 (2%)	1 (2%)	6 (11%)	27 (51%)	18 (34%)	1 (2%)	1-5	4	4	5	1	0.345
Progress Notes	10 (6%)	3 (19%)	11 (21%)	19 (36%)	10 (19%)	1 (2%)	1-5	2	4	4	2	0.092
Consultation Notes	7 (4%)	2 (13%)	12 (23%)	20 (38%)	12 (23%)	1 (2%)	1-5	3	4	4	1	0.233
In my opinion, providing patients increased access to their medical information will result in:												
Increased time at bedside	9 (4%)	2 (17%)	15 (29%)	20 (38%)	6 (12%)	2 (4%)	1-5	3	3	4	1	0.97
Increased patient misunderstanding of information	15 (2%)	1 (28%)	11 (21%)	20 (38%)	6 (11%)	1 (2%)	1-5	2	3	4	2	0.541
Increased patient anxiety	14 (10%)	5 (27%)	13 (25%)	14 (27%)	6 (12%)	2 (4%)	1-5	2	3	4	2	0.638
Increased legal liability	11 (2%)	1 (21%)	16 (31%)	16 (31%)	8 (15%)	2 (4%)	1-5	3	3	4	1	0.784
More work for me as a caregiver	16 (0%)	0 (31%)	14 (27%)	18 (35%)	4 (8%)	2 (4%)	2-5	2	3	4	2	0.333
Increase in patient questions	5 (2%)	1 (10%)	17 (33%)	25 (49%)	3 (6%)	3 (6%)	1-5	3	4	4	1	0.198
Improved health behaviors	16 (4%)	2 (31%)	6 (12%)	26 (50%)	2 (4%)	2 (4%)	1-5	2	4	4	2	0.14
Enhanced patient-clinician communication	1 (0%)	0 (2%)	18 (35%)	30 (58%)	3 (6%)	2 (4%)	2-5	3	4	4	1	0.301
Increased patient engagement in decision making	2 (0%)	0 (4%)	16 (31%)	28 (54%)	6 (12%)	2 (4%)	2-5	3	4	4	1	0.57
I would change the way I write my clinical notes if I knew a patient could view them:	15 (4%)	2 (31%)	12 (25%)	15 (31%)	4 (8%)	6 (13%)	1-5	2	3	4	2	0.033*

The survey results indicated that clinicians viewed information sharing with patients favorably. For clinicians, the sharing of objective data in particular seemed to provoke little controversy. The sharing of more subjective data, such as progress notes and consultation notes, was less agreeable to survey respondents, but still, the majority were comfortable with sharing this information.

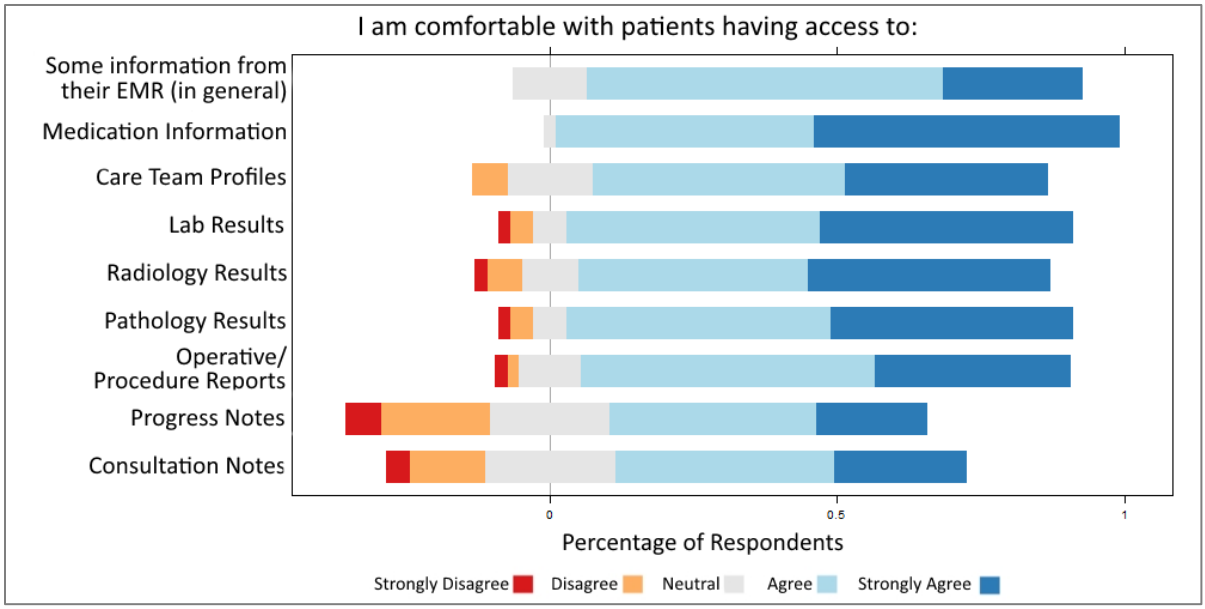


Figure 3.3 Clinician perspectives on patient information sharing

Clinicians' expectations of the consequences of inpatient information sharing were mixed. Most were optimistic that sharing information would enhance communication and increase patient engagement in decision-making. However, some survey responses reflected concerns about increased patient anxiety and misunderstanding of information.

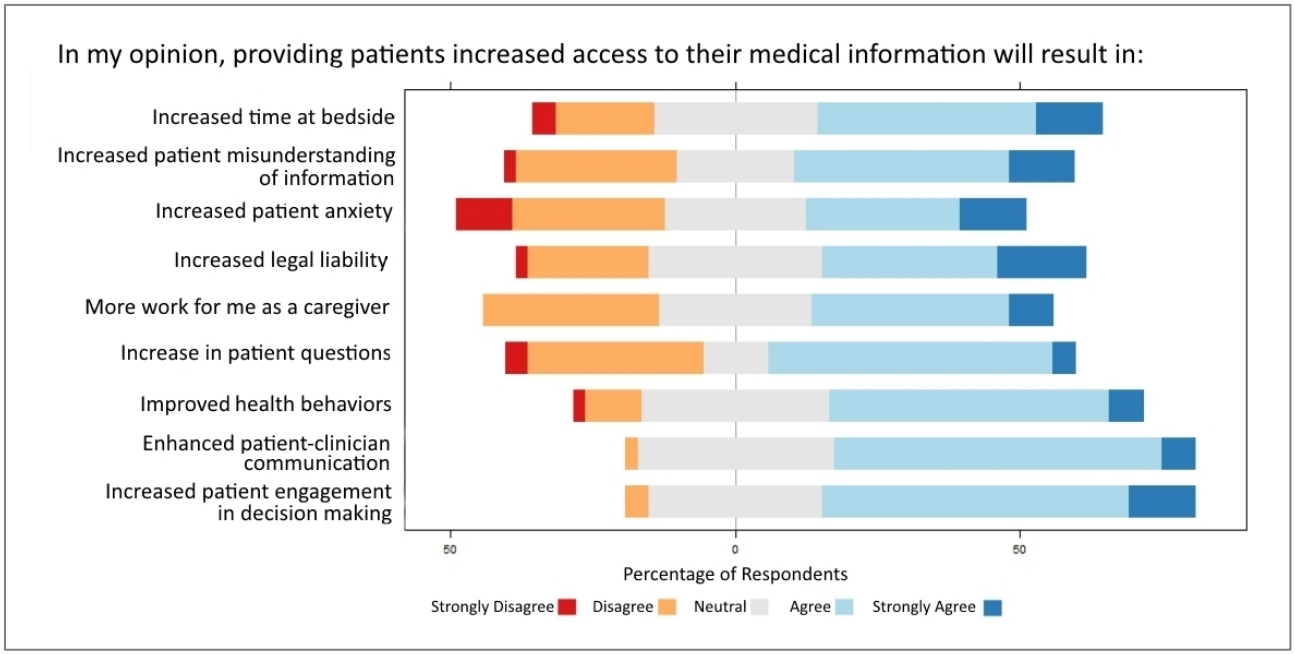


Figure 3.4 Clinician perspectives on consequences of increased patient information sharing

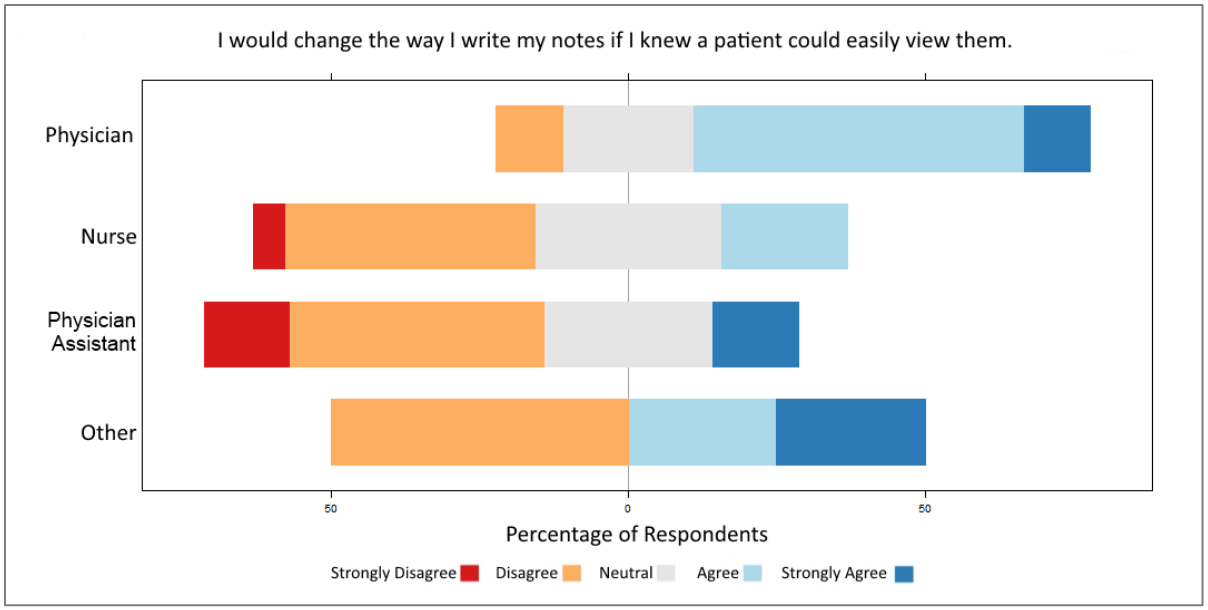


Figure 3.5 Clinician perspectives on expected changes in note-writing with increased patient information sharing

3.3.2 Inpatient Field Study Results

Eight patients consented to participate in the field study (Table 3.3) from January to March 2014. Seven completed the follow-up interview after receiving printouts of their hospital record for four days. The eighth participant was discharged prior to completing four days of receiving his records.

Table 3.3 Participant demographics of inpatient field study

	Sex	Age	Admission Reason	Presenting Chief Complaint	LOS*	Highest Level of Education	Internet for Health§
P1	F	87	Congestive heart failure exacerbation	Shortness of breath	6 days	High School	No
P2	M	56	Diarrhea, atrial fibrillation	Diarrhea, shortness of breath	22 days	Some College	Yes
P3	M	65	Septic Shock	N/A†	8 days	Graduate School	Yes
P4	M	43	Myocardial infarction	Chest pain	4.5 months	College Graduate	No
P5	M	35	Hemoptysis	Hemoptysis, shortness of breath	5 days	College Graduate	Yes
P6	M	54	Awaiting Heart Transplant	N/A‡	5 weeks	Associates Degree	Yes
P7	M	54	Ventricular tachycardia	Shortness of breath	5 weeks	Some College	No

*Length of stay at time of interview, †Transferred because of fevers from inpatient acute rehab, ‡Admitted for heart transplant listing, §Patient reported using the internet to look up health information

Overall, participants' feedback on receiving the daily printouts was positive. Out of the seven participants interviewed, six participants indicated that they would want to receive this type of information again if they had to return to the hospital. All six expressed a desire to continue receiving the printouts for the remainder of their current stay. Key themes that emerged from the semi-structured interviews were variations in use, difficulty understanding medical jargon, appreciation for having the information, suggestions for improvement, changes in interaction with clinicians, and changes in engagement.

Variation in Use

There was variability in the use of the printout. Two participants stated that they did not look at the printout (P5 and P7), P4 looked at it on two of the four days, and the remaining patients reported looking at it every day. The scope of use also varied. Some participants reported only skimming the information, while others read it in detail and even added their own annotations. For example, P2 commented, "I take a look, and if I see something that's not [in range], I just mark it."

Difficulty Understanding Medical Jargon

The printouts were created from the EHR without any substantive changes made to the content or format. Participants discussed having particular difficulty with certain medical terms and acronyms. P3 stated, "I read until I found technical stuff, and then I would jump over it…the parts I read, and I understood, were interesting and beneficial." P2 said, "Most of the things I understand, but some of the other things…like letters in combination, 'WT' or whatever… [were] not of use to me."

Several participants reported looking for specific items which they knew about. P1 specifically asked about her creatinine values and searched for the results of a sonogram performed the previous day. P5 expressed difficulty with understanding some material, but was planning to use the Internet to supplement his knowledge: "I'm familiar with some stuff," he said, "but…some of the terms I'm not familiar with, so once I have my laptop I'm probably going to take another look at it."

Appreciation for Having the Information

Participants expressed appreciation for having access to information about their care that they wouldn't normally receive. P7, who did not review the printouts at all, reported that it was important to him to simply "have a file." P2 said it was "very, very neat…because they give you all the details," and P5 stated, "Notes help a lot too, to see if the doctors are interpreting what I say… and they're pretty right on. And just [to see] what they thought as far as the possible diagnosis."

Suggestions for Improvement

In addition to wanting more explanation around medical terms and acronyms, participants expressed ideas regarding changes to the process that would make the intervention more helpful. For instance, P5 requested that there be a more clear delineation of the author of notes, "Sometimes I see a bunch of comments, and I don't see exactly which doctor said it." P3 expressed the desire for more descriptive information, "If you could give me more information describing my condition and my situation…more than the technical stuff…more information as far as what the doctors are finding, and what the doctors are doing."

We also discussed the possibility of presenting the information to patients via a computerized interface. Most participants (four of the five who viewed the printouts) expressed an interest in being able to view their information on a tablet computer or laptop.

Changes in Interaction with Clinicians

We asked participants if having access to their information prompted them to ask follow-up questions. Only one of the seven participants (P5) mentioned asking a clinician anything related to information in his printout. Several participants acknowledged the busy clinical workload of the providers and did not want to further impose on their limited time. P2 said, "[My doctors] have one or two minutes, [then] they're running all the time."

Changes in Engagement

Participants expressed feeling more informed about their health as a result of receiving the daily printouts. P2 mentioned that "if you don't ask, you don't receive [information], but with that paper, I am very on top of the situation." P5 said, "Instead of just listening to the doctor…I should pay attention to myself too" and believed the printouts could help him to do so.

In addition to feeling more informed, multiple participants mentioned the ability to act as a 'fact checker' of the information. P1 reported finding a prior procedure that was recorded with an incorrect date. P5 said it was, "neat to see the notes because sometimes during the interviews with the doctors, they'll write things down that I said, and well I didn't really mean it exactly that way." P5 also said, "I see the hospital medications…that's important I guess, just in case there are any discrepancies…between what stuff I think I should be taking, and [that] which they didn't give me here, and I'm like why, not?" P2 and P6 mentioned noticing discrepancies between when medications were documented as administered and when they believed them to have actually been administered.

3.4 Discussion

While patient engagement has recently been a topic of considerable interest(Bird & Walji, 1986; Cohen, 1985; Elwyn et al., 2000; Fisher & Britten, 1993; Greenfield et al., 1988; Jimison & Sher, 1995; Maly, Bourque, & Engelhardt, 1999), research in the inpatient setting is lacking.(Prey et al., 2014) This study was one of the first to evaluate the effect of providing patients with access to their entire charts, including physician notes, during their hospital stay. The most important findings were that information sharing (1) was perceived as desirable to patients and acceptable to clinicians, (2) allowed patients to more actively participate in their hospital care, and (3) may impact clinician behavior in terms of workload, communication, and note-writing practices.

The results suggest that greater information sharing with hospital patients can be beneficial. Of the seven patients interviewed, six of them requested to continue receiving the daily printouts. Patients appreciated seeing the details of their hospital care even in the raw, unfiltered format that came from the EHR system. I believe that a more tailored format, though difficult to actualize, could have even greater potential to increase patient engagement. The survey results indicated that clinicians also viewed information sharing with patients favorably. For clinicians, the sharing of objective data in particular seemed to provoke little controversy. The sharing of more subjective data, such as progress notes and consultation notes, was less agreeable to survey respondents, but still, the majority were comfortable with sharing this information.

Clinicians' expectations of the consequences of inpatient information sharing were mixed. Most were optimistic that sharing information would enhance communication and increase patient engagement in decision-making. However, some survey responses reflected concerns about increased anxiety and misunderstanding of information. Though the sample was small, none of the patients interviewed expressed that they felt additional anxiety from viewing their records. On the contrary, several patients commented that receiving the daily printout made them feel more informed and better able to understand the details of their care. Additionally, having access to their information allows patients to act as another 'line of defense' to identify incorrect information and potentially decrease medical errors.

In the outpatient setting, the OpenNotes project has explored the effects of giving patients the ability to read their doctor's office visit notes.(Delbanco et al., 2010) The project has been successful enough that the three institutions involved continued sharing notes with patients after the study ended. Additionally, the project has expanded to other institutions, including the Department of Veterans Affairs (VA).(Trossman, 2013) Although physicians had worries that opening their notes would result in more confusion, worry or patients taking offense, these concerns did not materialize for the OpenNotes partners; fewer than eight percent of doctors reported taking more time in order to address patient questions outside of visits (via email or phone calls), and fewer than 20 percent of doctors reported taking

more time to write their notes.(Delbanco et al., 2012) Although further study of information sharing in the hospital setting is warranted, the results suggest that the OpenNotes concept may also be applicable to inpatient care.

OpenNotes investigators reported that increased access to physician notes by patients may change note-writing behavior.(Delbanco et al., 2012) Comments from the clinician survey suggested that this was a concern at this institution. For example, patients may be offended by reading certain descriptions in their charts (e.g., "obese", "disheveled"). Moreover, notes often contain expressions of uncertainty, frightening differential diagnoses, and findings that lack interpretation. If notes are readily accessible to patients, clinicians might avoid using certain terms, or omit clinically relevant details to protect patients from anxiety. On the other hand, because so much of what clinicians currently document is not easily understandable by patients, they may be inclined to write in a manner that is more intelligible to patients (e.g., by using fewer acronyms).

Design Considerations for Inpatient Engagement

Beyond a pilot study, printing and hand-delivering daily reports as was done in this study is likely not a feasible option for most hospitals. However, a recent study from a neonatal intensive care unit described delivering a one-page paper handout to parents each day of their baby's stay.(Palma et al., 2012) The handout included information on the baby's care team, respiratory status, nutritional status, medications, most recent lab results, and care plan. Similarly, the VA began providing inpatients with access to limited information through the *Daily Plan* project. The *Daily Plan* is a printout delivered to patients containing their medications, appointments and diagnostic tests that nurses review with the patients each day.(B. King, Mills, Fore, & Mitchell, 2012) We (Masterson Creber et al., 2016; Vawdrey et al., 2011) and others (Dalal et al., 2015; Dykes et al., 2013; Greysen et al., 2014; O'Leary et al., 2015) are working to deploy online patient engagement solutions for hospital patients. So far, these projects have provided tablet computers to patients in the hospital on a small scale and with limited information—excluding clinical

notes, for example. Major results of these studies are still forthcoming, but initial work has shown some ability for these tools to improve knowledge of care team members.(O'Leary et al., 2015)

Future work should investigate how to present patient-specific medical information in a more patient-friendly manner. Appealing to diverse populations of patients, including those with low health literacy, low literacy in general, and non-native English speakers is a particular challenge. Using resources such as the Consumer Health Vocabulary and MedlinePlus may help to make complex medical terminology more understandable.(Medicine, 2011; Zeng & Tse, 2006) Additionally, use of visualizations has been shown to help patients better understand health information, especially for individuals with low health literacy.(Ancker, Senathirajah, Kukafka, & Starren, 2006; Arcia et al., 2013; Gaissmaier et al., 2012; Garcia-Retamero, Okan, & Cokely, 2012) Research on the creation of visualizations that explain inpatient data is warranted.

Another challenge to providing increased access to patient information is addressing privacy and security concerns. As discussed previously, Bates and colleagues discussed the need for "care partner" access to patient data.(Sarkar U & Bates DW, 2014) Restricting access to certain types of data may be a feature necessary for the privacy of sensitive topics like testing for drug use, HIV status, or pregnancy in teenagers.

3.4.1 Limitations

This study was limited by a relatively small sample size for the clinician survey (n=53), and similarly by a small sample size of hospital patients who participated in the inpatient field study (n=8). Of the eight patients in the inpatient field study, one was discharged prior to the interview and two additional patients had not read through their records. Thus, the sample size was insufficient to achieve thematic saturation. Nevertheless, the results shed light on the understudied topic of engaging hospital patients in their care and provide a foundation for future research. The study was conducted at a single site, an academic medical center in an urban setting, and the findings may not generalize to other settings. More specifically,

the study was focused primarily in the domain of cardiology, and different results may be found in other patient populations. For example, patients with cardiac disease may have higher baseline engagement levels than patients with less chronic diseases, and thus may be more interested in seeing their data. Future work should explore whether differences in settings or patient populations exist with respect to inpatient engagement.

3.4.2 Conclusion

Healthcare delivery organizations are moving towards greater sharing of information with patients and consumers are increasingly expecting to have access to their data. As noted in *The Patient Checklist*, Elizabeth Bailey observed that "once a patient enter a hospital for treatment of any kind, what he or she needs most of all is knowledge – what is happening to him, and why."(Bailey, 2011) This study found that clinicians were mostly comfortable with increased information sharing, and patients benefitted from receiving daily printouts of their hospital care record. Increased access to information will enable patients to more actively participate in their hospital care. The results of this study provided motivation to continue studying how patients can be engaged in their care while they are in the hospital.

Chapter 4: Reliability and validity of a patient engagement measure for hospitalized patients[3]

4.1 Introduction

Patient engagement is a concept that has received increasing attention in recent years (Dentzer, 2013). It is a construct that includes self-efficacy, behavior, and knowledge, and has been shown to predict a variety of health behaviors (Hibbard, Mahoney, Stock, & Tusler, 2007). Engaging patients in their care is the focus of many public- and private-sector initiatives and programs (Delbanco et al., 2001; "Meaningful Use | Policy Researchers & Implementers | HealthIT.gov," 2012, "Speak Up Initiatives," 2002). There is no single definition of patient engagement, nor is there a universally agreed-upon tool for measuring this concept.

[3] This chapter expands upon a paper, currently under review by the Journal of Patient Education and Counseling. The full author list for this publication is: Prey, J. E., Qian, M., Restaino, S. W., Hibbard, J., Bakken, S., Schnall, R., Rothenberg, G., Vawdrey, D. K., Masterson Creber, R. (2016). Reliability and validity of the Patient Activation Measure in hospitalized patients.

To date, the most frequently used instrument for measuring patient engagement is the Patient Activation Measure (PAM) (Hibbard et al., 2005, 2004; Masterson Creber et al., 2016; Toscos et al., 2016).

The PAM-13 is a 13-item self-reported measure designed to assess patients' knowledge, skills and confidence in managing their health. The PAM-13 also describes the extent to which patients are informed and involved in their healthcare (Hibbard et al., 2004). The PAM-13 has been validated in multiple outpatient populations including multi-morbid older adults and multiple sclerosis patients, and in relation to employee health characteristics (Fowles et al., 2009; Skolasky et al., 2011; Stepleman et al., 2010). It has strong psychometric properties, with high internal consistency and construct validity (Fowles et al., 2009; Skolasky et al., 2011; Stepleman et al., 2010). Recent studies involving the PAM have found that higher patient activation levels were correlated with improved health outcomes over time including better clinical indicators (e.g., not being obese, having high-density lipoprotein and triglycerides in normal ranges), more healthy behaviors, better self-management, greater use of preventive screening tests, and lower use of costly healthcare services (Greene, Hibbard, Sacks, Overton, & Parrotta, 2015; Hibbard, Greene, Shi, Mittler, & Scanlon, 2015).

While the PAM has become a widely used tool in outpatient care settings, its applicability to patients in the hospital is not well established (Schmaderer, 2015). Validating the PAM-13 in the inpatient setting is important as there are over 35 million hospital admissions each year (Centers for Disease Control and Prevention, 2010) and interventions to impact patient engagement in the hospital are becoming more commonplace (Dalal et al., 2015; Greysen et al., 2014; Masterson Creber et al., 2016; O'Leary et al., 2015). The purposes of the research described in this chapter are (1) to describe the psychometric properties (internal consistency reliability and construct validity) of the PAM-13 for hospitalized cardiology and oncology patients; and (2) to examine the predictors of low activation in the same population.

Aim 2: Measure the reliability and validity of the Patient Activation Measure with hospitalized patients

Objective

To determine if the Patient Activation Measure (PAM) is a reliable and valid measure of patient engagement for use with hospitalized patients.

Research Questions

- What is the internal consistency reliability of the PAM-13?
- What is the construct validity of the PAM-13?
- What are the predictors of low PAM-13 levels?

4.2 Methods

4.2.1 Study design

First, internal consistency reliability of the PAM-13 in the inpatient setting was evaluated. The construct validity of the PAM-13 was then assessed using two approaches: expected known-groups differences of PAM-13 levels and convergence of PAM-13 levels with other measures (Figure 4.1).

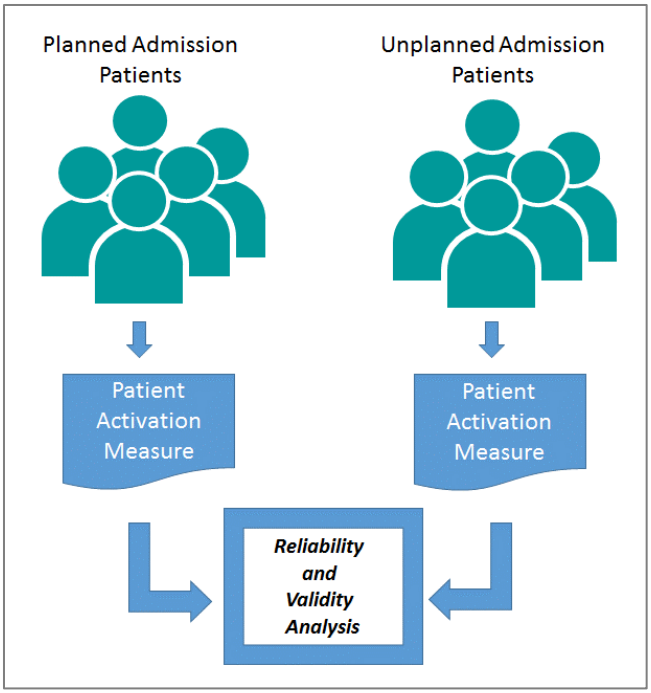


Figure 4.1. Overview of Aim 2 methods

The purpose of validation using known-group differences was to systematically evaluate whether the PAM-13 instrument would discriminate between two known groups (unplanned admissions versus planned admissions) expected to differ on the constructs that the instrument is intended to measure (Davidson, 2014; Netemeyer, Bearden, & Sharma, 2003; Portney, 2009). These groups were chosen based on the hypothesis that patients with a planned hospitalization would have a higher PAM level (reflecting higher activation) than patients with an unplanned admission. The rationale behind this assumption was that patients who have planned admissions are more likely to be actively managing their healthcare and have been able to schedule the procedures and treatments for their care ahead of their admission. It was believed these patients would be different than those admitted through the emergency department with an unplanned admission for an emergent problem. Additionally, I hypothesized that this difference would be apparent among both cardiology and oncology patients.

Convergent validity was examined by correlating the PAM-13 levels with quality of life measures, specifically, the Patient Reported Outcomes Measurement Information System (PROMIS) Global Health

short form scores (Cella et al., 2010). It was conjectured that participants with higher activation levels would also have higher mental and physical quality of life scores. The hypothesis was that these quality of life measures would be positively correlated with the PAM-13 level. This hypothesis was based on prior findings of modest correlation between the PAM-13 and a multiple sclerosis quality of life measure (r= 0.42) (Stepleman et al., 2010).

Predictors of low activation were also examined according to PAM-13 levels and scores. Differences by age, education, health literacy and primary clinical service lines (oncology and cardiology) were tested for based on prior literature (Fowles et al., 2009; Hibbard & Cunningham, 2008; Hibbard et al., 2005; Stepleman et al., 2010). Then, PAM-13 levels found in this inpatient study were compared to those previously reported in other settings.

4.2.2 Subjects

The evaluation of known-group differences was based on data collected from 100 participants recruited from cardiology and oncology units at a large, urban, academic medical center. Criteria for inclusion were 18 years or older and English speaking. Exclusion criteria were inability to perform the interview in English, and severe cognitive or psychiatric impairment. Participants were compensated $10 for their time, typically around 15 minutes. The research protocol was approved by the medical center's Institutional Review Board.

In total, 50 cardiology participants (25 planned and 25 unplanned admissions) and 50 oncology participants (25 planned and 25 unplanned admissions) were recruited from July to October 2015. On the cardiology service, recruitment for planned admissions was conducted among those patients with a known disease (e.g., aortic stenosis) undergoing a planned heart valve repair or replacement (e.g., a transcatheter aortic valve replacement). Unplanned cardiology participants came through the hospital's emergency department and were diagnosed with ST-segment elevation myocardial infarction, non-ST

segment elevation myocardial infarction, or acute coronary syndrome. On the oncology unit, the planned-admission participants came in for chemotherapy or another planned treatment. Unplanned oncology participants came through the hospital's emergency department and were admitted with diagnoses such as fever and respiratory failure.

4.2.3 Data Collection

Each participant's admission status of planned versus unplanned was collected by reviewing the electronic health record (EHR). Data were collected by surveying each participant and storing the results in a secure database. Participants elected whether to be asked the questions verbally by the research coordinator, or to respond directly to the survey using a tablet computer provided to them by the research coordinator.

4.2.4 Measures

Sample characteristics

Sample characteristics were collected through a demographic form completed at enrollment. These questions included information on age, gender, race, ethnicity, education level, and technology use. Technology-use questions asked about the patient's experience using the internet, what devices they used to access the internet, and how much they used the internet on a daily basis. Income was measured with the question, "*Financially, would you say you are… comfortable; have enough to make ends meet; or do not have enough to make ends meet?*" as traditional questions using numerical income scales have been fraught with a wide range of bias (Horowitz & Manski, 1995) and random error (Moore, Stinson, & Welniak, 2000).

Patient activation

Patient activation, was measured using the PAM-13. The responses to each of the 13 items range from 1 (strongly disagree) to 4 (strongly agree). Scores were calculated by summing the responses, weighted to a scale of 0 to 100, and then converting the score to a PAM level (1-4) using the PAM scoring spreadsheet.

The four PAM levels are 1) Disengaged and overwhelmed (indicated by a score of 0.0-47.0) 2) Becoming aware, but still struggling (47.1-55.1), 3) Taking action (55.2-72.4), and 4) Maintaining behaviors and pushing further (72.5-100).

Quality of life

Quality of life was measured using the 10-item Patient Reported Outcomes Measurement Information System (PROMIS) Global Health short form questionnaire (Hays et al., 2009). PROMIS was developed to provide instruments that allow for the efficient, flexible, and precise measurement of patient-reported outcomes (Cella et al., 2010). The Global Health short form includes mental and physical health components as well as a single item on general health status, "In general would you say your health is…". Participants respond to each item using a 5-item Likert-type scale. Previous tests of construct validity for the PAM have shown strong associations with other functional status measures, including the SF-36(Brazier et al., 1992) and the SF-12(Gandek et al., 1998). The PROMIS questionnaires were chosen because they are freely available and capture the same information as legacy measures with fewer items (Cella et al., 2010; Fries, Bruce, & Cella, 2005).

Health Literacy

Study participants answered three health literacy questions developed by Chew et al. (Chew, Bradley, KA, & Boyko, EJ, 2004). These questions facilitate the identification of patients with "inadequate health literacy." Each question has differing sensitivity and specificity based on the cutoff selected by the researchers. Cutoffs were selected to optimize the sensitivity and specificity tradeoff based on the findings of Chew and colleagues (Chew et al., 2004).

4.2.5 Analysis

Baseline characteristics of participants in the planned and unplanned admission groups were compared using two-sample *t*-tests for continuous variables and chi-squared tests for categorical variables.

Internal consistency (reliability) of the PAM was assessed using Cronbach's alpha. An alpha of at least 0.80 was considered evidence of good internal consistency.

Construct validity was evaluated through a known-group differences analysis of the PAM levels between planned and unplanned admissions. PAM levels were dichotomized into 'low activation' (PAM levels 1 and 2), and 'high activation' (PAM levels 3 and 4). The known groups were then analyzed using a chi-square test. Logistic regression was used to determine the odds ratio of having low activation between the known groups (unplanned versus planned admissions). Forward and backward step-wise selection was conducted using all collected variables (with entry and removal criterion of $p = 0.2$) to identify those variables associated with low activation.

To analyze differences across service lines (cardiology versus oncology), the median PAM-13 levels between unplanned versus planned admissions were compared using Wilcoxon rank-sum tests, and the proportions of 'low activation' were compared using chi-squared tests. In addition, average PAM-13 scores (0-100) between services lines and admission type were also compared using a two-sample Student's *t*-test.

Convergent validity was assessed by correlating the PAM-13 with the PROMIS Global Health short form measures. A Spearman rank correlation between each of the PROMIS Global Health measures and the four PAM-13 levels was calculated. This correlation was also completed using the continuous PAM-13 scores. An ANOVA was conducted to determine the strength of the association between the PROMIS scores and activation level.

Predictors of low activation and PAM-13 scores were analyzed through chi-square tests for categorical variables and ANOVA for continuous variables. All baseline demographic data was included in the analysis.

PAM levels from the inpatient setting were compared with four published studies in other settings (Greene & Hibbard, 2012; Hibbard & Cunningham, 2008; Mitchell et al., 2014; Stepleman et al., 2010)

using Wilcoxon rank-sum tests. The four studies that were selected reported sample size and the distribution of participants across the four PAM-13 levels.

Analyses were completed using Stata version 14 (StataCorp, 2015) and R version 3.0.2 (R Core Team, 2013).

4.3 Results

Participant characteristics are described in Table 4.1. The average age in the cohort was 64 years, (range = 22–102). The majority of the participants were male (65%), 13% were black, 9% were Asian, 9% reported their race as "other" or were multi-racial, and 16% were Hispanic/Latino. Almost one-fifth (18%) of the participants reported their income level as "not having enough money to make ends meet".

Table 4.1 Baseline demographics and analysis of predictors of low activation

Variable	Overall (n=100)	Low Activation (n=40)	High Activation (n=60)	*p*-value
Age	64.1 (1.69)	65.7 (16.0)	63.1 (17.6)	0.447
Sex, Female	35 (35%)	12 (30%)	23 (38%)	0.392
Country of Origin*				0.530
Dominican Republic or Puerto Rico	7 (7%)	3 (7.5%)	3 (5%)	
United States	72 (72%)	27 (67.5%)	45 (75%)	
Other	20 (20%)	10 (22%)	11 (18.3%)	
Education				0.832
Some high school or less	11 (11%)	5 (12.5%)	6 (10%)	
High School, some college, or Associate's degree	51 (51%)	19 (47.5%)	32 (53.3%)	
College or more	38 (38%)	16 (40%)	22 (36.7%)	
Race				0.769
Asian or Pacific Islander	9 (9%)	5 (12.5%)	4 (6.67%)	
Black or African American	13 (13%)	5 (12.5%)	8 (13.3%)	
Other, multi-race, or prefer not to answer	14 (14%)	6 (15%)	8 (13.3%)	
White	64 (64%)	24 (60%)	40 (66.7%)	
Ethnicity				
Hispanic, Latino or Spanish Origin	16 (16%)	6 (15%)	10 (16.7%)	0.215
Income				0.948
Comfortable	50 (50%)	21 (52.5%)	29 (49.2%)	
Have enough to make ends meet	31 (31%)	12 (30%)	19 (32.2%)	

Variable	Overall (n=100)	Low Activation (n=40)	High Activation (n=60)	*p*-value
Do not have enough to make ends meet	18 (18%)	7 (17.5%)	11 (18.6%)	
Chew et al. Health Literacy Screen				
1. How confident are you filling out medical forms by yourself?				
Inadequate Health Literacy	38 (38%)	18 (45%)	20 (33.3%)	0.239
2. How often do you have problems learning about your medical condition because of difficulty understanding written information?				
Inadequate Health Literacy	14 (14%)	8 (20%)	6 (10%)	0.158
3. How often do you have someone help you when you read hospital materials?				
Inadequate Health Literacy	30 (30%)	15 (37.5%)	15 (25%)	0.181
Technology Use				
Yes, I use the internet	68 (68%)	26 (65%)	42 (70%)	0.600
Length of daily internet use (of internet users)				0.433
Less than 30 minutes	27 (39.7%)	11 (27.5%)	16 (26.7%)	
1-2 hours a day	17 (25%)	9 (22.5%)	8 (13.3%)	
3-4 hours a day	14 (20.6%)	4 (10%)	10 (16.7%)	
5 or more hours a day	10 (14.7%)	2 (5%)	8 (13.3%)	
Use IT to look up health information				
Yes	57 (57%)	22 (55%)	35 (58.3%)	0.742
Family member looks up health information online	63 (63%)	28 (70%)	35 (58.3%)	0.236
Device use (of those who use the internet)				
Desktop	38 (56%)	13 (32.5%)	25 (41.7%)	0.355
Laptop	32 (47%)	15 (37.5%)	17 (28.3%)	0.336
Smartphone	33 (49%)	12 (30%)	21 (35%)	0.602
Tablet	21 (31%)	4 (10%)	17 (28.3%)	**0.027**

Abbreviations: SD: standard deviation, n: number

For continuous variables, mean (SD) were reported, and p*-values were calculated using two sample* t*-tests. For categorical variables, n (%) were reported, and* p*-values were calculated using chi-squared tests.*

**Percentages do not add to 100% as not all participants provided a response.*

4.3.1 Psychometric results (Reliability, construct and convergent validity)

The PAM demonstrated adequate internal consistency overall (Cronbach α = 0.81). There was a statistically significant difference in the PAM-13 levels of participants who had planned compared to unplanned admissions. Among participants with unplanned admissions, 56% had low activation compared

to 24% of participants with planned admissions (p = 0.001). This difference confirmed the hypothesis that the PAM-13 instrument is able to differentiate between the two known groups. Overall, patients with unplanned admissions were more likely to have low activation compared to patients with planned admissions (unadjusted OR = 4.03, p = 0.001; Table 4.2). The difference remained significant after adjustment for baseline covariates (adjusted OR = 5.7, p = 0.008). The final model included age, sex, race, ethnicity, education, income, and use of a tablet computer to access the internet (Table 4.2).

Table 4.2 Description of logistic regression models

	OR	95% CI
Model 1		
Unplanned/planned	4.03	1.71 – 9.49*
Model 2		
Unplanned/planned	5.72	2.06-15.9*
Age	1.01	0.98-1.05
Race	1.30	0.44-3.82
Income	1.29	0.65-2.57
Ethnicity	1.43	0.46-4.46
Gender	0.49	0.18-1.32
Education	0.95	0.45-1.97
Tablet	0.33	0.59-1.28

**statistically significant at p < 0.05*

There was a higher proportion of participants with low activation in the unplanned admission group. This finding was consistent across both the oncology and cardiology service lines (Table 4.3). Both the median (interquartile range) PAM-13 levels and mean (standard deviation) PAM-13 scores were lower in the unplanned admission group (Table 4.4). There was no statistically significant difference in PAM-13 level between oncology and cardiology service lines.

Table 4.3 Proportion of patients with low activation by service and admission type

Patients with Low Activation*	Unplanned (n=25, 25)	Planned (n=25, 25)	p-value
Low Activation Cardiology	15 (60%)	8 (32%)	0.047
Low Activation Oncology	13 (52%)	4 (16%)	0.007

*Low activation is defined as having a PAM level of 1 or 2

Table 4.4 PAM-13 levels and scores by service and admission type

	Unplanned PAM-13 Level*	Planned PAM-13 Level*	*p*-value	Unplanned PAM-13 Score†	Planned PAM-13 Score†	*p*-value
Overall (n=100)	2 (2-3)	3 (3-4)	**0.001**	57.0 (12.6)	66.2 (13.4)	**0.001**
Cardiology (n=50)	2 (2-3)	3 (2-4)	**0.032**	57.0 (12.0)	65.9 (14.7)	**0.023**
Oncology (n=50)	2 (2-3)	3 (3-4)	**0.012**	57.1 (13.4)	66.5 (12.2)	**0.013**
			0.221‡			0.888‡

*Median (IQR) are reported, *p*-values were calculated using Wilcoxon-rank sum tests.
†Mean (SD) are reported, *p*-values were calculated using 2-sample *t*-tests.
‡Difference between cardiology/oncology overall

The PAM-13 was modestly correlated ($p < 0.001$) with each of the three PROMIS Global Health components used in this study (global, physical and mental health) (Table 4.5). Analysis of correlations using the PAM-13 scores (instead of levels) were consistent. The results of the ANOVA comparing PROMIS global, physical and mental quality of life measures across participants with low and high activation demonstrated that lower scores on PROMIS measures were associated with low activation (Table 4.6).

Table 4.5 Correlations between PAM and PROMIS measures

(n = 96)	**PAM Level** r (*p*-value)	**PROMIS Global Health**	**PROMIS Physical Health**	**PROMIS Mental Health**
PAM Level	---			
PROMIS Global Health	0.4003 (0.0001)	---		
PROMIS Physical Health*	0.396 (0.0001)	0.660 (<0.0001)	---	
PROMIS Mental Health*	0.447 (<0.0001)	0.4307 (<0.0001)	0.437 (<0.0001)	---

Correlations and p-values were calculated using a Spearman Rank correlation
**Measures were converted into T-scores prior to analysis*

Table 4.6 Associations between PROMIS measures and PAM levels

PROMIS measures	Low-PAM	High-PAM	*p*-value
Global health question†	2.05 (0.75)	2.66 (1.04)	0.0019
Physical health*	37.6 (8.42)	42.98 (8.84)	0.0033
Mental health*	41.5 (6.54)	46.1 (6.11)	0.0006

Mean (SD) were reported, and p-values were calculated using one-way ANOVA.
† Failed Bartlett's test for homoscedasticity, unequal variances across groups
**PROMIS measures are reported as T-scores*

4.3.2 Identifying predictors of low activation

Differences across demographic variables between participants with low and high activation are described in Table 4.1. The results of this analysis indicated that use of a tablet computer to access the internet was the only significant predictor of low activation (p = 0.027), but it was no longer significant when included in the stepwise logistic regression model. When using the continuous PAM-13 scores, statistically significant differences by use of a tablet computer (p = 0.038) and mean number of participants with inadequate health literacy (based on the health literacy question, "How often do you have problems learning about your medical condition because of difficulty understanding written information?"; p = 0.043) were found.

4.3.3 Comparison to outpatient studies

The PAM-13 levels of this patient population were significantly lower than the PAM-13 levels of the four other PAM-related studies reviewed (Figure 4.2, Table 4.7). The four studies included three studies in the outpatient setting (a study in a multiple sclerosis clinic in the southeastern U.S.(Stepleman et al., 2010), a national survey (Hibbard & Cunningham, 2008), and a study in primary care clinics in Minnesota (Greene & Hibbard, 2012)), and one inpatient study of cardiac patients in Boston (Mitchell et al., 2014). Sample sizes ranged from 196 to over 25,000.

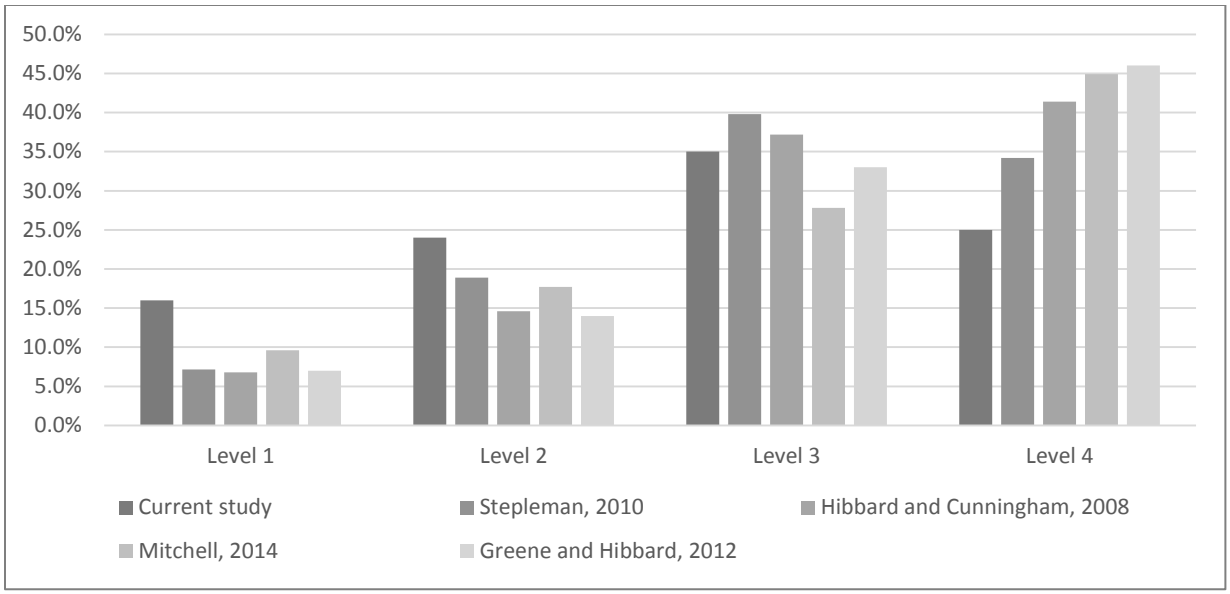


Figure 4.2 PAM-13 levels across studies

Table 4.7 Comparison of outpatient PAM-13 levels to the inpatient PAM-13 levels

Individual Studies	Sample Size	PAM-13 level Mean (SD)	*p*-value*
Stepleman, 2010	196	3.01 (0.91)	0.005
Hibbard and Cunningham, 2008	17,800	3.13 (0.90)	<0.0001
Mitchell, 2014	695	3.08 (1.00)	<0.0001
Greene and Hibbard, 2012	25,047	3.18 (0.92)	<0.0001

*p-value comparison of each study to this study's PAM-13 levels based on Wilcoxon rank-sum test.
The mean (SD) of this inpatient PAM study was 2.69 (1.02).

4.4 Discussion

This study provides evidence for the internal consistency reliability and the construct validity of the PAM-13 instrument for use in the inpatient setting. The study also confirms that type of admission is important to consider when analyzing PAM levels. There was a significant difference in PAM levels between hospitalized patients with unplanned compared to planned admissions, no differences in the PAM levels between cardiology and oncology service lines, and specific demographic variables were not predictive of low activation.

The results complement the findings from a recent study by Schmaderer et al. (2015) that documented the psychometric properties of the PAM for use in hospitalized multimorbid patients. These results build

on the Schmaderer study by demonstrating the importance of admission type in predicting low patient activation. These results are important for current and future investigations that use the PAM-13 to measure patient activation in inpatient randomized controlled trials (Masterson Creber et al., 2016; O'Leary et al., 2015).

A study conducted by Hibbard and Cunningham (Hibbard & Cunningham, 2008) suggested that patients with cancer had a slightly higher average PAM score than patients with hypertension (65.8 versus 63.5). The results of this study did not identify a statistically significant difference in PAM scores between patients on the cardiology versus oncology services (61.5 versus 61.8, respectively; p =0.888). In contrast to this study, which was conducted in an urban, inpatient, academic setting, Hibbard and Cunningham performed a nationwide survey, with a sample size of over 17,800 participants in the outpatient setting.

This study found a modest correlation between PAM-13 levels and quality of life (measured with the PROMIS Global Health short form), further supporting the validity of the PAM-13. The PROMIS mental health measure had the strongest correlation with activation, which was consistent with other studies that have analyzed the relationship between PAM levels and quality of life measures (Stepleman et al., 2010).

Only one significant predictor of low activation was found among the demographic characteristics measured, the use of a tablet computer to access the internet. Age, sex, race, ethnicity, income, and education were not found to be predictive of low activation. One of the three questions used to identify patients with inadequate health literacy was found to be correlated with the PAM-13 scores; however, it was not found to be a predictor of low activation. Implications of this finding are that health literacy should not be used as a proxy measure of patient activation. Additional research by Hibbard and colleagues,(Hibbard et al., 2008) also indicates that activation is not simply a marker for socioeconomic

status. These are important findings as they suggest that if someone is economically or socially disadvantaged it is not necessarily an indicator that they have low activation.

This study assessed differences between the PAM-13 levels of hospitalized patients versus those from the literature. The PAM-13 levels of the hospitalized patients in this study were found to be significantly lower than those in the four other studies analyzed. One difference between this study and the others is that patients in this study were older (average age of 64.1), whereas average ages reported in the other studies ranged from 46 to 50. The results may suggest that there could be changes in PAM levels when patients enter the hospital. Being a hospitalized patient has been called one of the most "dis-empowering situations one can experience in modern society," (Bickmore et al., 2009) and this change in environment could contribute to decreasing patients' PAM levels. Upon hospitalization, measures should be taken to address patient-specific activation during that time period.

Use of the PAM-13 in the inpatient setting could allow for a more customized approach to tailoring interventions, preparing appropriate education, and follow-up after hospital discharge. Knowing the activation level of a patient in the hospital could also support clinicians' efforts to tailor their communication and materials to potentially increase the patient's knowledge, self-efficacy, and engagement. For example, knowing that a patient has lower activation and needs a more thorough explanation of a medication schedule could allow a clinician to prioritize spending extra time with the patient while he or she is in the hospital. Improved patient-provider interaction could enable patients to experience a more seamless discharge process, potentially help to reduce readmissions, and facilitate the improvement of patients' clinical outcomes and overall health.

4.4.1 Limitations

Strengths of this study are that it was conducted in a large, urban, academic medical center with a diverse population. While non-English speaking patients were not included in this study, 16% the participants

identified as Hispanic/Latino. Validation of the PAM-13 among a diverse population of hospitalized patients contributes to the generalizability of the study findings.

Additionally, this study was conducted at a single site. While the PAM-13 was valid in this setting, there is the potential that these results may not be broadly generalizable to other inpatient settings.

4.4.2 Future research

Future steps for research include validating the Spanish version of the PAM in the inpatient setting and identifying interventions that are successful for improving activation for patients with low PAM scores.

4.5 Conclusion

This study demonstrated that the PAM-13 is a reliable and valid measure to be used in the inpatient setting. It has also shown that knowing the admission type is an important predictor of patient activation. Understanding a patient's level of activation is important for being able to optimize inpatient communication. By measuring patient activation with the PAM-13, clinicians and researchers can more accurately understand their patients and provide tailored communication and care strategies to meet patients' needs and allow patients to participate in their care.

Measuring patient engagement is also an important concept for researchers so they may better study the usefulness of interventions across different levels of engagement. In the next aim I used the Patient Activation Measure with hospital patients who participated in a study to determine if use of the intervention changes across different levels of activation.

Chapter 5: Engaging patients in the medication reconciliation process

5.1 Introduction

It is estimated that there are more than 210,000 deaths each year resulting from preventable medical errors in the United States.(James, 2013) Adverse drug events constitute a significant portion of preventable medical errors, and have been shown to add an average of 4.6 days in length of stay, and $5,857 in extra costs.(Bates, Spell, Cullen, & et al, 1997) Unintentional medication discrepancies, or differences in documented medication regimens across different sites of care, make up an important cause of adverse drug events among patients in the Emergency Department (ED).(Schnipper et al., 2011) Studies have shown that the number of patients with at least one medication discrepancy ranges from 48-87% in the ED,(Caglar et al., 2011; Shepherd & Schwartz, 2009) and 22-54% on hospital admission.(Coffey et al., 2009; Cornish, 2005; Gleason et al., 2010) Recognizing a need to reduce

medication errors caused during care transitions, the Joint Commission identified medication reconciliation as a National Patient Safety Goal beginning in 2005.(The Joint Commission, 2005)

Medication reconciliation entails "a systematic and comprehensive review of all the medications a patient is currently taking to ensure that medications being added, changed, or discontinued are carefully evaluated with the goal of maintaining an accurate list."(Greenwald et al., 2010) Reconciliation is complex, involves many participants, and many issues often occur during the medication reconciliation process including records being incorrect or incomplete due to data entry errors, and medication histories that are unavailable or inaccessible.(Plaisant et al., 2015) A rigorous approach to medication reconciliation can take over one hour, which is not feasible for most patients.(Meguerditchian, Krotneva, Reidel, Huang, & Tamblyn, 2013) This amount of time could result in estimated pharmacists costs of up to $44 per patient, and could translate into "11 full-time personnel obtaining medication histories for a hospital with 23,500 annual admissions."(Pevnick, Shane, & Schnipper, 2016)

Medication reconciliation should be conducted at every handoff of care, including the intake of a patient into the ED, admission to the hospital, and again at discharge. As a result of its time-consuming nature, rigorous medication reconciliation is often neglected. As one physician in our hospital institution illustratively stated, "Everyone owns 'med rec', and nobody owns 'med rec'." The stakes for getting medication reconciliation right are particularly high in the ED-to-inpatient ward transition. Poor communication of medication information is responsible for 50% of medication errors and 20% of adverse drug events in hospitals.(Barnsteiner, 2005; Rozich & Resar, 2001)

There have been many different types of medication reconciliation interventions to facilitate the accurate collection of medication data.(Mueller et al., 2012; Murphy et al., 2009; Poon et al., 2006; Vawdrey et al., 2010) However, the vast majority of these interventions have not directly involved patients themselves to complete any medication review. I believe that leveraging informatics methods to engage patients in

the medication reconciliation process can increase error recovery, improve quality of care, reduce adverse events, and improve medication safety. An integral component of the current medication reconciliation process is verbal confirmation of exactly which medications are being taken by the patient.(Rozich & Resar, 2001) The information given by patients to their clinicians is typically not visible to the patients, and patients are not able to see a confirmation of what they described.(Unruh & Pratt, 2007)

Informatics interventions can allow patients to provide information that can contribute to the medical record, and can lead to an increased amount of patient-specific information collected. There is evidence that patients are sometimes more honest with providing information to a computer-interface rather than speaking directly to a clinician, particularly if they are not abiding by the "doctor's orders".(Kobak, Greist, Jefferson, & Katzelnick, 1996; Kurth et al., 2004) Further, patients who participate in the medication reconciliation process may be able to provide personal information and specific adherence details, such as why they are no longer taking a particular medication.

A knowledge gap exists regarding patients' ability to directly contribute information about their own health situations using information technology, particularly with respect to medication use. In the time-pressured clinical environment of the ED, it is important that technology be leveraged to elicit patient-generated data conveniently and systematically without adding additional burden on the clinical teams. By providing patients with direct access to an electronic interface to participate in the medication reconciliation process, they might be able to more accurately report their actual medication regimen and identify errors in or changes to previous documentation by healthcare providers.

Some evidence supporting patients' ability to participate in reviewing medications was reported by Weingart et al. (2004), who provided inpatient medication lists and medication information to patients while they were in the hospital in hopes that patients themselves would be able to assist in preventing drug ordering and administration errors. While Weingart and colleagues did not find a significant

difference in errors between their intervention and control groups, they did find that patients were willing to participate, nurses found the intervention unobtrusive, and patients and clinicians believe that patient participation in care can prevent errors.(Weingart et al., 2004) This inpatient intervention showed the potential of this type of patient engagement in medication review, but it was limited because it did not provide a clear way for patients to deliver information back to the clinical information system. Moreover, the intervention examined the inpatient medications patients were taking rather than focusing on the reconciliation of home medications.

A more recent study on involving patients in the review of their home medications was conducted by Dullabh and colleagues.(2014) In this study, clinic patients were provided with access to a patient portal in which they were asked to review their medication lists prior to a doctor's visit. The investigators found that patients were eager to provide feedback on their medications and that the feedback they provided was useful and accurate. Based on the findings from these studies, I designed an experiment to investigate the contributions that ED patients preparing to be admitted to the hospital could make to the admitting medication reconciliation process through use of an electronic, patient-facing medication reconciliation tool.

I hypothesized that involving patients more directly in the medication reconciliation process, using a novel informatics tool, could increase transparency, efficiency, and effectiveness. Additionally, I believed that providing hospitalized patients with access to their medication lists allows them to have the opportunity to ask questions about their medications while they have more frequent direct access to their care providers.

Aim III: Evaluate the impact of using a novel informatics tool to engage patients in the medication reconciliation process at hospital admission

Objective

The objective of this aim was to determine if having patients directly participate in the medication reconciliation process increased the number of changes made (i.e., medications added, medications removed, or medication details adjusted) by the admitting provider to the documented home medication list.

Hypothesis

H1: *Patients in the ED who participate in the admitting medication reconciliation process by receiving access to an electronic medication review tool prior to their admission to the hospital will have more changes made by their admitting clinician to the home medication list during the admitting medication reconciliation process than patients who are not given access to the review tool.*

In addition to this primary hypothesis, I investigated the following research questions.

Research Questions

- What types of changes do patients who are being admitted to the hospital identify in the hospital's pre-existing home medication lists (e.g., add medications, delete medications, edit medication details) to reflect what they actually take at home?
- What is the potential for harm and severity of harm of the discrepancies between the hospital version and the patient-generated version of the home medication lists?
- How does the Patient Activation Measure (PAM) level relate to the medication information a patient provides in the medication review tool?
- What are admitting clinicians' perceptions of the impact of the patient-generated medication list on the admitting medication reconciliation process?

5.2 Methods

This aim included two parts (Figure 5.1): (1) a randomized, controlled trial of patients who used the electronic medication review tool, and (2) a survey of clinicians whose patients participated in the randomized trial to identify the clinicians' perceptions and experiences with having patients participate directly in the admitting medication reconciliation process.

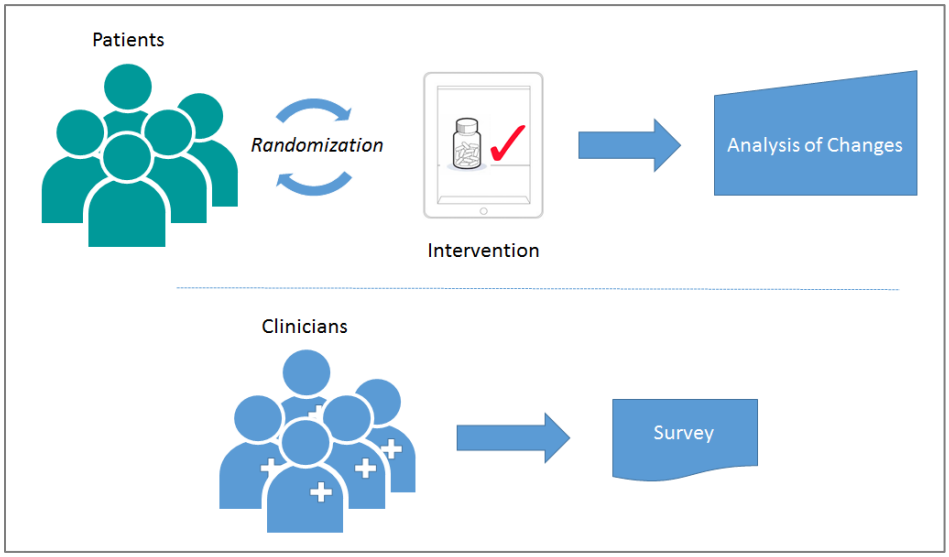


Figure 5.1 Overview of Aim 3 methods

5.2.1 Randomized, controlled trial of patients

Study Design

I conducted a prospective, stratified, randomized controlled study in which intervention patients who were admitted to the hospital from the ED were given access to a personalized, electronic medication review tool. Patients were stratified for randomization based on the number of medications on their initial home medication list at the time of recruitment across three groups: 'No medications', 'Few medications' (one to five medications), and 'Many medications' (six or more medications).

In the hospital's current admitting medication reconciliation process, when it was decided that a patient would be admitted from the ED, an admitting team was assigned from the hospital. It was the duty of that

admitting team to complete an 'admission medication reconciliation'. This process involved the admitting team coming to the ED and speaking with the patient prior to his or her being transferred to the hospital unit. One admitting clinician, typically a medical resident or physician assistant (PA) then completed the admission medication reconciliation in the electronic health record (EHR). For this study, participants were recruited prior to their admitting team completing the admission medication reconciliation process. Intervention-group participants were provided access to the electronic medication review tool via a tablet computer. These participants could review their medications and allergies at their own pace in an attempt to optimize recall of their medication regimen (Figure 5.2). After reviewing their medications and allergies, participants were asked to complete a short survey. A report of the patient-reviewed medication and allergy information was printed on brightly colored paper and given to the intervention participants. The participants were instructed to provide the brightly colored summary report to their admitting clinician to aid him or her in completing the admission medication reconciliation process in the EHR.

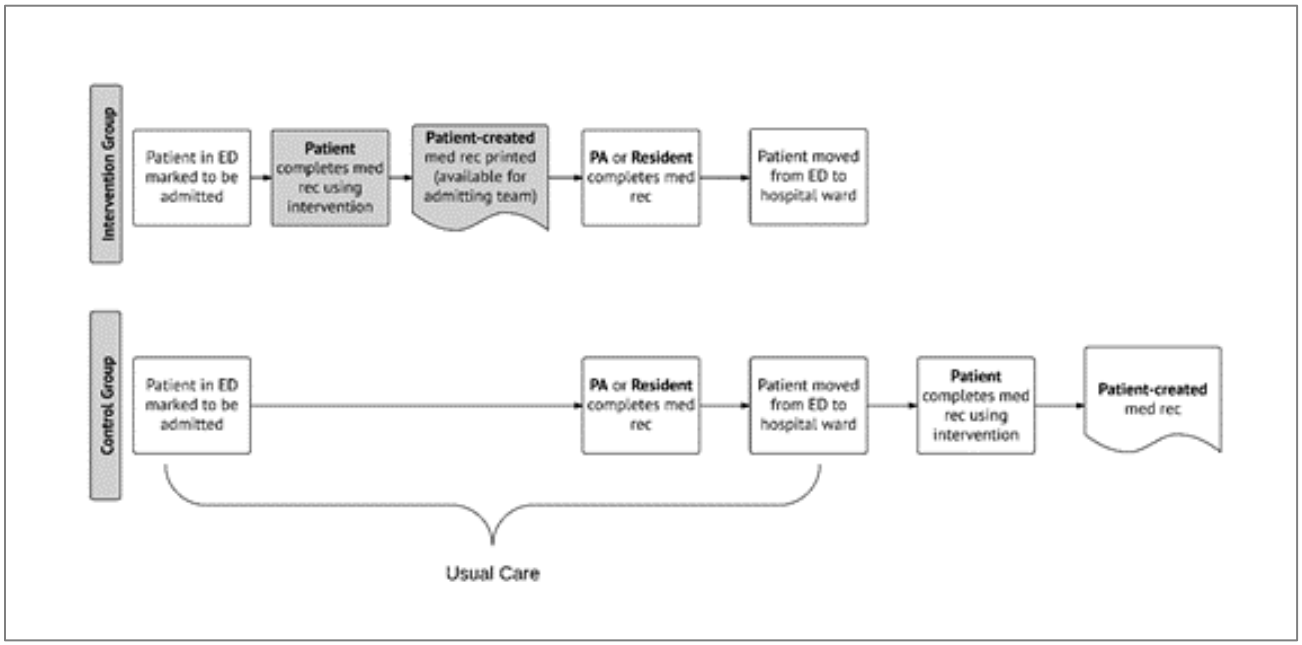


Figure 5.2 Study design process flow of Aim 3

Control participants were consented at the same time as the intervention patients, but they did not use the medication review tool prior to their admitting medication reconciliation. The day after consenting to

participate, a member of the research team followed-up with the control participants and asked them to review their medications using the same tool the intervention participants used prior to the admitting medication reconciliation. The medication list the control participants reviewed was the updated, ostensibly 'reconciled' list created by the admitting clinician during the admitting medication reconciliation process. The patient-generated review was documented for the research team, but not printed out for the clinical team, as the admission medication reconciliation had already occurred by the time the patient review was performed.

Setting

Subjects were recruited from the ED at a large, urban, academic medical center.

Intervention

The intervention was a patient-facing medication review tool accessed using a tablet computer. After logging in with a personalized username and password (provided by the research team), the tool displayed the patient's current list of home medications and allergies as documented in the hospital's EHR (Allscripts Sunrise Clinical Manager). The medication review tool was web-based and was developed using the Microsoft ASP.NET Web application framework (Figure 5.3). Data displayed by the tool were securely stored in a SQL Server 2008 database.

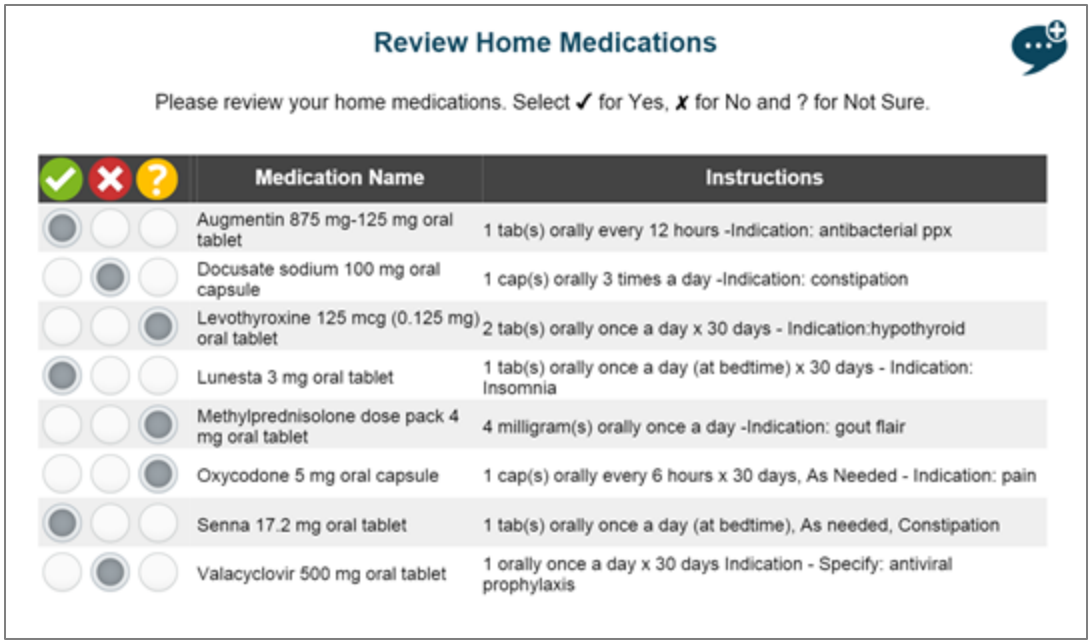


Figure 5.3 Patient-facing medication review tool accessed on tablet computers

The medication review tool listed each home medication with dose, route, and frequency instructions, and allowed participants to record “Yes” if they were still taking the medication at home, “No” if they were not, and “Not Sure” if they did not know the medication, or if they wanted to edit something about the medication details (e.g., the medication name was correct, but the dosage was incorrect). After this initial review, participants were given the opportunity to provide comments, and to input any medications that were missing from the list. For those medications marked as “incorrect”, patients were given the option to provide a reason as to why they were not taking that medication, or what was incorrect about the details shown. Alternatively, if the patient was not confident on the specific details of his/her medication list, more general information concerning the medication regimen could be entered as free-text on the next screen (e.g., “I take my eye medication in the morning.”). Of note, patients were able to ask their family, friends, or outside healthcare providers for assistance with this process if they were available in person or by phone. Allergies and associated symptoms were reviewed in a similar fashion to the medications.

Subjects

Patients who were approached to participate in the study were in the ED, were being prepared for admission to the hospital, and did not yet have an admission note written by the admitting team in the hospital's EHR. Criteria for inclusion were 18 years or older and English speaking. Exclusion criteria were inability to speak English fluently, or a known history of psychosis, dementia, or other cognitive impairment that would preclude participants from completing study activities.

Sixty-five patients were to be recruited to find an effect size of 0.378 (two-tailed hypothesis, $\alpha = 0.05$, $\beta = 0.1$) as calculated using the program G*Power.(Faul, Erdfelder, Bucher, & Lang, 2009) This was estimated based on previous studies on medication reconciliation (Caglar et al., 2011; Coffey et al., 2009; Cornish, 2005; Gleason et al., 2010; Shepherd & Schwartz, 2009) including a paper by Owens and colleagues (Owen, Chang, Chong, & Vawdrey, 2011) showing that 72% of the medication lists they analyzed had at least one medication discrepancy.

Eligible patients were approached by study personnel who explained the nature of the study and asked patients to provide written informed consent prior to conducting any study activities. After receiving written consent, patients were randomized to either the intervention or the control group based on the stratification by the number of medications on the patient's home medication list. This randomization was completed using physical envelopes for each randomization group with an equal number of intervention and control patient assignments on individual paper slips. Participants were compensated $10 for their time, typically around 15 minutes, received upon study completion. The research protocol was approved by the medical center's Institutional Review Board.

Data collection

Data for this study were collected using tablet computers (Apple iPad Air 2) that were provided to the participants by the study personnel. The tablet computers were charged by the research team, and secure

Wi-Fi (802.11a/b/g/n) network access was available using an existing hospital network. Rubberized cases and theft-deterrent software were used to protect the tablet computers. Infection control precautions were strictly adhered to, including the use of disposable chemical wipes suitable for sanitizing mobile electronic devices between patients. The intervention tool was accessed using the tablet computer's web-browser, Safari. Upon completion of the medication and allergy review, participants answered a brief survey. Survey data were also collected using the tablet computer by accessing an online, HIPAA-compliant survey application (Qualtrics).

Measures

Clinician medication changes: The changes made to the patient's home medication list during admission medication reconciliation by the healthcare provider. These medication changes were obtained from the hospital's EHR and were quantified by additions, deletions, and modifications/edits.

Patient-generated medication changes: Changes that the study participants made to their home medication list using the intervention tool; categorized as additions, deletions, and modifications/edits.

Sample characteristics: Sample characteristics were collected through a demographic form completed as part of the survey. These questions included information on age, sex, race, ethnicity, marital status, education level, and technology use. Technology-use questions asked about the patient's experience using the internet, what devices they used to access the internet, and how frequently they used the internet. Income was measured with the question, "*Financially, would you say you are… comfortable; have enough to make ends meet; or do not have enough to make ends meet?*" as traditional questions using numerical income scales have been fraught with a wide range of bias (Horowitz & Manski, 1995) and random error (Moore et al., 2000).

Health literacy: Health literacy was assessed using the simplified screening technique of three health literacy questions developed by Chew and colleagues.(2004) This technique requires little time and compares favorably against the gold standard Short Test of Functional Health Literacy in Adults (STOFHLA) (area under the curve 0.87; 95% CI = 0.78–0.96).(Chew et al., 2004) These questions facilitate the identification of patients with limited health literacy. Each question has differing sensitivity and specificity based on the cutoff selected by the researchers. Cutoffs were selected to optimize the sensitivity and specificity tradeoff based on the findings of Chew and colleagues.(Chew et al., 2004)

Patient activation: Using the measure validated in Aim 2, patient activation was measured with the PAM-13. The responses to each of the 13 items ranged from 1 (strongly disagree) to 4 (strongly agree). Scores were calculated by summing the responses, weighted to a scale of 0 to 100, and then converted to a PAM level (1-4) using the PAM scoring spreadsheet. The four PAM levels are (1) Disengaged and overwhelmed (indicated by a score of 0.0-47.0), (2) Becoming aware, but still struggling (47.1-55.1), (3) Taking action (55.2-72.4), and (4) Maintaining behaviors and pushing further (72.5-100).

ED Level of severity: Each patient was assigned a level of severity, called an Emergency Severity Index (ESI) upon admission to the ED to assess patient acuity. The scale ranged from level 1 (most urgent) to level 5 (least resource intensive).

Table 5.1 Variables and methods of collection for Aim 3

Variables	**Method of Collection**
Number of changes made by clinician during admission medication reconciliation	Retrieved from EHR
Number of patient-made changes (medications added, removed, edited)	Application logs
Types of medication discrepancies	EHR, Application logs, Clinical review

Variables	Method of Collection
Potential for harm and severity of medication discrepancies	EHR, Application logs, Clinical review
Patient activation measure (PAM-13)	Survey
Demographic characteristics (age, sex, race, ethnicity, income, education)	Survey
Health literacy questions (Chew et al. brief health literacy screen)	Survey
Technology use questions	Survey
ED level of severity (ESI)	Retrieved from EHR

Data Analysis

The analysis of this aim involved the comparison of changes identified during medication reconciliation at three different parts of the study, depicted as the diamond shapes A, B, and C in Figure 5.4, with A corresponding to the primary research hypothesis.

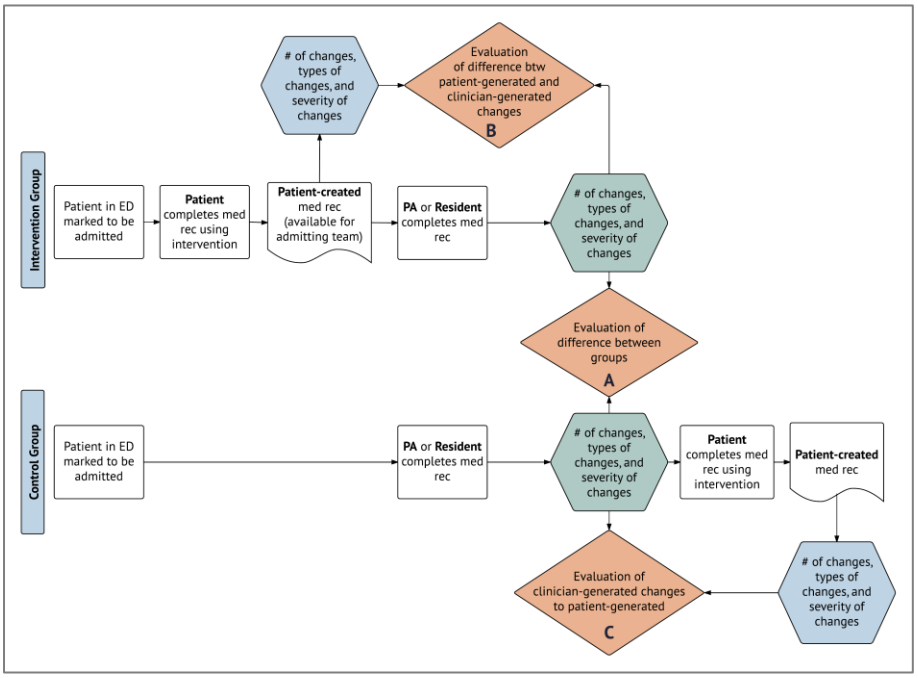


Figure 5.4 Flow diagram and analysis of Aim 3

As inputs to complete these comparisons, each of the changes made by the patients or clinicians (each hexagon in Figure 5.4) were categorized. These changes were defined as any inconsistency or discrepancy between what was listed in the medication list the patient or clinician was shown and the changes documented in the tool or in the admitting medication reconciliation document (by the clinician). These changes included additions, deletions, or modifications/edits to the medication list (see Table 5.2 for an example).

Table 5.2 Example medication list changes

Documented home medications	**Patient-generated list in intervention tool**	**Clinician-entered admitting medication reconciliation note**
Famotidine 20 mg oral tablet; 1 tab(s) orally every 12 hours	Famotidine **40** mg oral tablet; 1 tab(s) orally every 12 hours	Famotidine **40** mg oral tablet; 1 tab(s) orally every 12 hours
Ferrous sulfate 325 mg (65 mg elemental iron) oral tablet; 1 tab(s) orally 3 times a day	~~Ferrous sulfate 325 mg (65 mg elemental iron) oral tablet; 1 tab(s) orally 3 times a day~~	~~Ferrous sulfate 325 mg (65 mg elemental iron) oral tablet; 1 tab(s) orally 3 times a day~~
Finasteride 5 mg oral tablet; 1 tab(s) orally once a day	Finasteride 5 mg oral tablet; 1 tab(s) orally once a day	Finasteride 5 mg oral tablet; 1 tab(s) orally once a day
Levothyroxine 75 mcg (0.075 mg) oral tablet; 1 tab(s) orally once a day Multiple vitamins oral tablet; 1 tab(s) orally once a day	Levothyroxine 75 mcg (0.075 mg) oral tablet; 1 tab(s) orally once a day Multiple vitamins oral tablet; 1 tab(s) orally once a day	Levothyroxine 75 mcg (0.075 mg) oral tablet; 1 tab(s) orally once a day Multiple vitamins oral tablet; 1 tab(s) orally once a day
	Coumadin 2mg oral tablet; 1 tablet once a day	Coumadin 2mg oral tablet; 1 tablet once a day
	Levoxyl 75 mcg oral tablet; 1 tablet once a day	~~Levoxyl 75 mcg oral tablet; 1 tablet once a day~~
Changes from Documented medications: *Unaccepted Changes from Patient-generated:*	**4** - 1 modification, 1 deletion, 2 additions --	**3** - 1 modification, 1 deletion, 1 addition **1** - 1 deletion

Baseline characteristics of participants in the intervention and control groups were compared using two-sample t-tests for continuous variables, and chi-square and Fisher's exact tests for categorical variables. The categorization of changes had two components (Table 5.3) and was done for each medication change on each medication list (again, all hexagons shown in Figure 5.4) for all patients. First, descriptive statistics were calculated to describe the number of changes entered, types of changes (i.e., additions, deletions,

modifications), and the average number of changes made per patient. Changes were categorized for their potential for harm and severity of harm based on work from Pippins and colleagues, (2008). Each change was assigned a scale of confidence as to the potential to cause at least significant patient harm (levels one through six; from "little to no confidence" up to "virtually certain confidence"), and one of four levels of severity (life-threatening (e.g., incorrect dose of units of insulin as 100 units instead of 10 units), serious (e.g., incorrect listing of blood pressure medications that a patient is no longer taking resulting in hypotension when medications are provided in the inpatient setting), significant (e.g., omission of glaucoma eye drops from medication list), or insignificant (e.g., daily multi-vitamin missing from list)). This evaluation of harm potential and severity was completed by two pharmacists who independently coded the medication changes. Inter-rater agreement was calculated using a weighted Cohen's Kappa.

Table 5.3 Data analysis for Aim 3 patient study

Analysis	**Statistics**
Descriptive statistics of changes	Frequency, median, mean, standard deviation, Wilcoxon rank-sum analyses
Potential for harm using Pippins et al. categorization: Six levels of confidence Four levels of severity	Descriptive statistics, Cohen's Kappa (inter-rater agreement), Mixed-effect models

In addition to assessing the number of home medication changes made by patients and clinicians, the percentage of medications that were changed was also calculated. This was done, for clinicians, by taking the sum of the total number of changes clinicians made to the home medication lists across all patients, divided by the total number of medications on initial lists in the EHR. Similarly, for patients, the overall number of changes all patients made in the review tool were summed and divided it by the total number of medications displayed on the medication lists. Sub-group percentages were calculated for each type of change (i.e., additions, deletions, modifications), and comparison across groups (intervention versus control) were analyzed using tests of proportions.

Once the baseline characteristics of the changes made to the medication lists were described, the comparisons between groups were conducted (diamond shapes A, B, and C in Figure 5.4). Wilcoxon rank-sum analyses were used to evaluate differences between groups (intervention versus control) of changes made to the medication lists by both clinicians and patients. Mixed-effects models were used to analyze differences in the potential for harm and severity of harm of the changes. Bonferroni corrections were used for post-hoc analyses to account for multiple hypotheses.(Cabin & Mitchell, 2000)

- First, the difference in the number of changes made to the medication lists by clinicians in the intervention compared to the control group was evaluated (Comparison A in Figure 5.4).
    - This calculation allowed for the analysis of the primary research hypothesis (H1): *Patients in the ED who participate in the admitting medication reconciliation process by receiving access to an electronic medication review tool prior to their admission to the hospital will have more changes made by their admitting clinician to the home medication list during the admitting medication reconciliation process than patients who are not given access to the review tool.*
- Next, the difference in changes made to the medication list by the intervention group patients to those changes made by the clinician after receiving the patient's list was evaluated (Comparison B in Figure 5.4).
    - This analysis showed how many of the changes made by patients were then accepted by the clinician and added to the medical record.
- Then, the changes that control group patients made to their medication list after their clinician had completed the standard medication reconciliation process was evaluated (Comparison C in Figure 5.4).

- This analysis shows what changes the clinician may have missed by using the standard medication reconciliation process, and what information patients can contribute even after the admitting medication reconciliation has occurred.

Summary statistics were also calculated for changes identified in the allergy portion of the review tool. Additional analyses were completed to categorize the types of allergies reported (i.e., medication, environmental (including food), or other).

Using the evaluation results from comparing both the intervention and control patient changes to those of the clinician groups (Comparisons B and C), the relationship between changes made by the patients and their PAM levels was analyzed. A Spearman rank correlation analysis was conducted to determine if the number of changes made by the patient (e.g., "4" from the middle column of Table 5.2) was associated with the PAM level of the participant. It was anticipated that patients with higher PAM levels would contribute more changes to the medication list than those participants with lower PAM levels. This analysis was repeated for the relationship between PAM score (0-100) and number of changes the participant made to the medication list through a pairwise correlation.

Additional analysis was conducted to determine if other demographic characteristics were associated with the number of changes made to the medication lists by patients. Linear regression and Spearman rank correlation were used for ordinal characteristics (e.g., education level), and pairwise correlation analysis for continuous variables (e.g., age).

5.2.2 Clinician methods

I conducted a survey of clinicians who had one or more patients in the intervention arm of the randomized trial to understand the impact of the intervention on the admitting medication reconciliation process. The topics of the survey included querying whether the clinicians received the patient-generated printout

from their patients, whether the information was useful and accurate, the perceived impact of the intervention on the amount of time required to complete the admission medication reconciliation, and general feedback on the intervention, design and workflow.

Setting

This survey was conducted in the same hospital as the patient field study, a large, urban, academic medical center.

Sample

This study recruited clinicians who had patients in the intervention group in the patient field study. The identity of the clinicians was obtained by reviewing the hospital's electronic health record system to identify the clinician who had completed the patient's admitting medication reconciliation. Clinician participants were then recruited via email invitation to complete the survey. The IRB of the medical center approved this study and waived the need for written consent.

Data collection

Clinicians who wished to participate, clicked on the survey link included in the email invitation. Each participant responded to seven or eight questions total, depending on their responses (Table 5.4). Clinicians were asked whether they had received the patient-generated medication list from the intervention patients. If the clinician had received the intervention list, they were asked questions focused on its usefulness and accuracy, any effect on time to complete the admission medication reconciliation process, and their perceptions of their patients' knowledge of their medications. Clinicians who had not received the patient-generated medication list were asked to report their beliefs on the usefulness, accuracy, and impact on time to complete admitting medication reconciliation if they were provided with a patient-generated review first. An additional question asked for feedback on the intervention and suggestions for improvement from all clinicians. Clinicians were also asked their role (i.e., Attending

Physician, Resident Physician or Fellow, Physician Assistant, or Other) and the number of years they had worked in that role.

Table 5.4. Clinician Survey Questions

Received Intervention	How useful did you find the patient-generated home medication and allergy information to be?				
	Extremely useful	*Very useful*	*Moderately useful*	*Slightly useful*	*Not at all useful*
	How accurate did the patient-generated home medication and allergy information seem to be?				
	Extremely accurate	*Somewhat accurate*	*Neither accurate nor inaccurate*	*Somewhat inaccurate*	*Extremely inaccurate*
	What was the effect on time to complete medication reconciliation by having the patient-generated home medication and allergy information?				
	Saved a lot of time	*Saved a little time*	*Did not save or add time*	*Added a little time*	*Added a lot of time*
	Patients who completed this medication reconciliation on their own seemed to know their medications and allergies better than patients who had not used the intervention				
	Strongly agree	*Somewhat agree*	*Neither agree nor disagree*	*Somewhat disagree*	*Strongly disagree*
Did Not Receive Intervention	How useful would having patients complete their home medication and allergy review on their own, using technology, be to your admitting medication reconciliation process?				
	Extremely useful	*Very useful*	*Moderately useful*	*Slightly useful*	*Not at all useful*
	How accurate do you think a patient-generated home medication and allergy review would be?				
	Extremely accurate	*Somewhat accurate*	*Neither accurate nor inaccurate*	*Somewhat inaccurate*	*Extremely inaccurate*
	Having patients review their own medications and allergies using technology would save me time on completing the admission order reconciliation.				
	Strongly agree	*Somewhat agree*	*Neither agree nor disagree*	*Somewhat disagree*	*Strongly disagree*

Data Analysis

Responses to the survey were tabulated and analyzed using Microsoft Excel 2013, Stata SE v 14.0 , and the R Statistical program.(R Core Team, 2013; StataCorp, 2015) A descriptive summary of the data consisted of calculating frequencies, medians, and inter-quartile ranges (IQRs). Differences across roles and by experience were examined using Kruskal-Wallis analysis. Qualitative comments and feedback that were provided as free-text were analyzed using a qualitative content analysis approach, and frequency of topics were quantified. Two researchers developed a coding system deductively based on the

implementation dimension of the RE-AIM framework.(Glasgow, Vogt, & Boles, 1999) The RE-AIM framework is used to evaluate the factors involved in assessing the impact of interventions in complex, real-world, healthcare settings. These factors focus on 'reach', 'effectiveness', 'adoption', 'implementation', and 'maintenance'. RE-AIM is used broadly across the healthcare domain and has been adapted for use with clinical informatics.(Bakken & Ruland, 2009) The implementation dimension was selected after initial review of the clinician comments and deemed appropriate. Data were classified into the categories within the implementation dimension (i.e., predisposing and enabling factors). Then themes were inductively generated to further characterize the data. Data were then coded by the two reviewers to ensure the coded data fit the agreed upon definitions for the categories and themes.

5.3 Results

5.3.1 Randomized, controlled trial results

Sixty-five patients were recruited from the ED to participate in this study; 36 in the intervention arm, and 29 in the control arm. Seventy-six patients in total were approached, eleven patients declined to participate (decline rate of 14%). Participant characteristics are described in Table 5.5. The participants had an average age of 49 years (range = 20–88). Participants were equally split among male and female (51% female), and the majority were single (65%). Participants were racially and ethnically diverse; 35% Black or African American, 31% White, 31% of other or unknown race, and 35% identified themselves as Hispanic or Latino. Patients were evenly distributed across both the control and intervention group based on other demographics characteristics.

Table 5.5 Participant demographics of patient medication review study

	Overall (n = 65)	**Control** (n = 29)	**Intervention** (n = 36)	***p*-value**
Age	48.8 (18.99)	44.7 (17.4)	52.1 (19.8)	0.118
Sex, Female	33 (50.8%)	18 (62.1%)	15 (41.7%)	0.102
Race				0.613
Asian	2 (3.08%)	0 (0%)	2 (5.71%)	
Black/African American	23 (35.38%)	9 (30%)	14 (40%)	
White	20 (30.77%)	10 (34.5%)	10 (27.8%)	
Other/Unknown	20 (30.77%)	10 (33.3%)	10 (28.6%)	
Ethnicity				0.567
Hispanic or Latino	22 (33.85%)	9 (30%)	13 (37.14%)	
Not Hispanic or Latino	29 (44.6%)	12 (40%)	17 (48.57%)	
Unknown	14 (21.54%)	8 (27.6%)	6 (16.7%)	
Preferred Language				0.544
English	51 (78.46%)	21 (72.4%)	30 (83.3%)	
Spanish	9 (13.85%)	5 (16.67%)	4 (11.43%)	
Other/Unknown	5 (7.69%)	3 (10%)	2 (5.71%)	
Religion				0.334
Christian or Catholic	39 (60%)	20 (69%)	19 (52.8%)	
Other/Unknown/Not Religious	18 (27.6%)	7 (24%)	11 (30.5%)	
Jewish	4 (6.2%)	0 (0%)	4 (11.1%)	
Islamic	3 (4.6%)	2 (6.9%)	1 (2.8%)	
Buddhist	1 (1.5%)	0 (0%)	1 (2.8%)	
Marital Status				0.791
Single	42 (64.6%)	19 (65.5%)	23 (63.9%)	
Married	16 (24.62%)	7 (23.3%)	9 (25.71%)	
Divorced	3 (4.62%)	2 (6.67%)	1 (2.86%)	
Widowed	4 (6.15%)	1 (3.33%)	3 (8.57%)	
Education				0.304
Some high school or less	11 (17.2%)	5 (16.7%)	6 (17.7%)	
High school, some college, or associate's degree	36 (56.3%)	14 (46.7%)	22 (64.7%)	
College or more	16 (25%)	10 (34.5%)	6 (17.1%)	
No response	1 (1.6%)	0 (0%)	1 (2.9%)	
Income				0.229
Comfortable	21 (35.6%)	13 (44.8%)	8 (26.7%)	
Have enough to make ends meet	27 (45.8%)	10 (35.7%)	17 (54.8%)	
Do not have enough to make ends meet	11 (18.6%)	5 (17.2%)	6 (20%)	
Birth country				0.125
United States	40 (62.5%)	19 (65.5%)	21 (60%)	
Cuba, Dominican Republic, Puerto Rico	11 (17.2%)	7 (23.3%)	4 (11.8%)	
Other	13 (20.3%)	3 (10%)	10 (29.3%)	

	Overall (n = 65)	**Control** (n = 29)	**Intervention** (n = 36)	***p*-value**
Use the Internet				0.112
Yes	48 (75%)	25 (86.2%)	23 (65.7%)	
No	13 (20.3%)	4 (13.8%)	9 (25.7%)	
Prefer not to answer	3 (4.7%)	0 (0%)	3 (8.6%)	
Time spent on internet per day*				0.149
Less than 30 minutes	8 (15.7%)	5 (16%)	5 (15.4%)	
1-2 hours a day	14 (27.5%)	5 (20%)	9 (34.6%)	
3-4 hours a day	15 (29.4%)	6 (24%)	9 (34.6%)	
5 or more hours a day	13 (25.5%)	10 (40%)	3 (11.6%)	
Prefer not to answer	1 (2%)	0 (0%)	1 (3.85%)	
Device used to access the internet*				
Smartphone	37 (75.6%)	22 (88%)	15 (62.5%)	0.038
Desktop	18 (37.5%)	9 (36%)	9 (39.1%)	0.823
Laptop	25 (51%)	14 (56%)	11 (45.8%)	0.477
Tablet	15 (30.6%)	9 (36%)	6 (25%)	0.404
Health Literacy (HL)				
HL1 - Confident filling out with medical forms				
Inadequate HL	7 (10.8%)	2 (6.9%)	5 (13.9%)	0.447
HL2 - Problems learning about medical condition because of difficulty understanding written information				
Inadequate HL	13 (20%)	7 (24.1%)	6 (16.7%)	0.454
HL 3 - Help reading hospital materials				
Inadequate HL	20 (30.8%)	9 (31.0%)	11 (30.6%)	0.967
PAM Level				0.452
1	6 (9.4%)	1 (3.5%)	5 (14.3%)	
2	10 (15.6%)	6 (20.7%)	4 (11.4%)	
3	36 (56.3%)	17 (58.6%)	19 (54.3%)	
4	12 (18.8%)	5 (17.2%)	7 (20%)	
Average PAM score	62.8 (1.79)	63.3 (2.42)	62.4 (2.61)	0.800
ESI				0.376
2	27 (42%)	10 (34.48%)	17 (48.57%)	
3	36 (56.25%)	17 (60.7%)	19 (52.8%)	
4	1 (1.56%)	1 (3.45%)	0 (0%)	
Average ESI	2.59 (.526)	2.68 (0.548)	2.53 (0.506)	0.664
Median days since last visit	31.5 (8-115)	28 (13-120)	58.5 (8-192.5)	0.735
Number of drugs on list	6.65 (6.15)	7.89 (6.98)	5.6 (5.28)	0.143

For continuous variables, mean (SD) or median (IQR) were reported, and *p*-values were calculated using two sample *t*-tests. For categorical variables, n (%) were reported, and *p*-values were calculated using chi-squared tests or Fisher's exact tests for groups with small sample sizes.

*Percentages based on those participants who reported using the internet.

Two pharmacists independently evaluated the severity of the changes made by both the clinicians and the patients, evaluating for both the potential for harm and the severity of harm. Inter-rater agreement was 91.7% (K = 0.715) for the potential for harm, and 90.9% (K = 0.647) for severity of harm for the changes made by clinicians, and 90.0% (K = 0.694) for the potential for harm, and 90.1% (K = 0.643) for severity of harm for the changes made by patients.

Analysis of clinician changes to the home medication list

On average, clinicians made two changes to the home medication list during their admitting medication reconciliation process per patient. The average number of changes made by clinicians was not different between the two groups (Comparison A, intervention versus control) (Table 5.6). Thus, the null hypothesis that intervention patients would have the same number of changes made to their medication lists as control patients could not be rejected.

Table 5.6 Average number of clinician changes to medication list by group

	Overall (n = 65)	**Intervention** (n = 36)	**Control** (n = 29)	***p*-value**
Average number of changes	2.09 (2.95)	2.28 (2.70)	1.90 (3.27)	0.488
Additions	0.87 (2.12)	1.06 (2.33)	0.69 (1.85)	0.793
Deletions	1.11 (1.74)	1.11 (1.56)	1.10 (1.97)	0.819
Edits	0.11 (0.31)	0.11 (0.32)	0.10 (0.31)	0.922

Mean (SD) are reported, *p*-values were calculated using Wilcoxon rank-sum.

Further analysis was conducted to review the average percentage of changes made to medication lists by clinicians (Table 5.7). Overall, clinicians updated 137 out of 420 (32.6%) medications they reviewed during the medication reconciliation process, and there were no differences in the percentage of changes to medications between groups (intervention versus control).

Table 5.7. Average percentage of clinician changes to medication list by group

	Overall (n = 420)	**Intervention** (n = 203)	**Control** (n = 217)	***p*-value**
Total changes	137 (32.6%)	82 (40.4%)	55 (25.3%)	0.200
Additions	58 (13.8%)	38 (18.7%)	20 (9.2%)	0.279
Deletions	72 (17.1%)	40 (19.7%)	32 (14.7%)	0.598
Edits	7 (1.7%)	4 (2.0%)	3 (1.4%)	0.854

Number(percentage of total medications by column) are reported, p-values were calculated using a proportions test

In looking at the changes clinicians made during their admitting medication reconciliation process (Table 5.8), there was a difference in the potential for harm by modification type (i.e., add/delete/edit) (p = 0.015), and by severity of harm (p = 0.021). Post-hoc pair-wise analysis of between type differences with a Bonferroni correction found a significant difference only in the add-delete pairwise comparison for potential for harm with an difference of 0.684 (p = 0.024), showing a higher potential for harm for those changes clinicians added.

Table 5.8 Potential and severity of harm of clinician medication changes by type

	Overall (n = 135)	**Add** (n = 58)	**Delete** (n = 69)	**Edit** (n=8)	***p*-value**
Potential for harm (1-6)	3.57(0.16)	3.96(0.21)	3.28(0.18)	4.10(0.44)	0.015
Severity of harm (0-3)	1.08(0.08)	1.26(0.11)	0.91(0.10)	1.35(0.23)	0.021

Values reported are least squares mean (standard error). *p*-values were calculated from a mixed-effect model.

There was no difference in potential for harm (p = 0.505) or severity of harm (p = 0.907) between the two groups (intervention versus control). The potential for harm (p = 0.787) and severity of harm (p = 0.578) were not significantly different based on the role of the clinician (MD or PA).

Analysis of intervention-patient changes to the home medication list

Twenty out of 36 participants (55%) in the intervention group made changes to their medication lists. On average, intervention participants made almost three changes to their medication lists, changing almost half (52.6%) of their documented home medications (Table 5.9). Intervention participants added an

average of 1.36 medications to their list, typically deleted one of those medications listed, and edited less than one. Out of all the intervention patients (n=36), just two patients reported being unsure about the medications displayed on the list or those that they took at home (e.g., one patient knew he took a medication for his blood pressure, but was unsure of the name or dose).

Table 5.9 Changes made by intervention patients (n =36) to medication lists

	All Changes	Additions	Deletions	Edits
Average number of changes, n (SD)	2.75 (2.73)	1.36 (2.52)	1.14 (1.42)	0.25 (0.87)
Medication changes (n = 192)	101 (52.6%)	49 (25.5%)	43 (22.4%)	9 (4.7%)

The average potential for harm of changes that intervention patients made to their medication lists was 3.42, this put it between the "less than 50-50" chance and "more than 50-50 chance" of occurring, and the severity of harm of these changes was close to level 1, "significant" harm. There was a difference in the severity of harm by modification type (add/delete/edit) (p = 0.016, Table 5.10). Post-hoc pair-wise analysis of between type differences with a Bonferroni correction found a significant difference in severity of harm between added changes and deleted changes of 0.427 (p = 0.022), with added changes having a higher severity of harm than the deleted changes.

Table 5.10 Potential for harm and severity of harm of medication changes made by Intervention patients

	Overall (n = 95)	Add (n = 44)	Delete (n = 41)	Edit (n=10)	*p*-value
Potential for harm (1-6)	3.42 (0.17)	3.76 (0.24)	3.10 (0.23)	3.4 (0.46)	0.124
Severity of harm (0-3)	1.09 (0.08)	1.29 (0.11)	0.86 (0.11)	1.29 (0.22)	0.016

Values reported are least squares mean (standard error) and *p*-values from the mixed-effects models.

We analyzed the difference between the changes that participants made within the intervention tool and those changes that were made by the clinicians during the intervention patients' admitting medication reconciliation process (Comparison B). On average, 40% of the changes that patients noted in the tool were then also made by the clinician in the EHR. Patients had an average of 1.6 changes that they entered

into the intervention tool that were not made by the clinician. Additionally, clinicians made an average of 1.06 changes to the mediation list that were not recorded by the patient using the review tool.

Of the 53 medication changes that were identified by intervention participants but were not entered by their clinicians during the admitting medication reconciliation process, there was an average potential for harm of 3.09(SD = 1.47) and average severity of 1.01(SD = 0.73), indicating a less than 50-50 chance for harm, but a close call, and a significant severity of harm.

Analysis of control-patient changes to medication list

Sixteen of 29 participants (55%) in the control group made changes to their medication lists. These medication lists reviewed by the control group had already been updated through the admitting medication reconciliation process. Still, control group participants made an average of 2.34 changes to their medication list (Table 5.11). Participants added an average of almost one (0.86) new medications to their medication list, and removed an average of one (0.97 (SD=1.48)) medications off the list. One patient in the control group marked one medication on the list as "not sure" as to whether they s/he was taking it.

Table 5.11 Changes made by control patients (n = 29) to medication lists after admitting medication reconciliation

	Total changes	**Additions**	**Deletions**	**Edits**
Average number of changes, n (SD)	2.34 (3.10)	0.86 (2.23)	0.97 (1.48)	0.52 (1.21)
Medication changes (n = 218)	68 (31.2%)	25 (11.5%)	28 (12.8%)	15 (6.9%)

The changes control patients made were based on the medication lists that the clinicians submitted after completing admitting medication reconciliation, and can be viewed as those medication changes that were potentially "missed" by the admitting medication reconciliation process. The average potential for harm of these changes was 3.54/6 and average severity of harm 1.26/3. There was a difference in both potential for harm and severity of harm by modification type (add/delete/edit) (Table 5.12). Post-hoc pair-wise analysis of between type differences with a Bonferroni correction for both potential for harm and

severity of harm found a significant difference only for the severity of harm between deleted changes and edited changes of -0.914 (p = 0.005), with deleted changes having a lower severity of harm than the edited changes.

Table 5.12 Potential for harm and severity of harm of medications changes made by control patients

	Overall (n = 67)	**Add** (n = 25)	**Delete** (n = 41)	**Edit** (n=10)	***p*-value**
Potential for harm (1-6)	3.54(0.24)	3.99(0.38)	2.86(0.33)	4.28(0.43)	0.001
Severity of harm (0-3)	1.26(0.11)	1.51(0.21)	0.84(0.18)	1.76(0.24)	0.003

Values reported are least squares mean (standard error) and *p*-values from the mixed-effects models.

Comparison of patient changes in intervention group to control group

Secondary analysis was completed to compare the patient-generated changes between the intervention and control group. A comparison of the number of changes made by patients in the intervention versus the control group was not found to be significant (p = 0.289). The percentage of medications changed was higher for the intervention group (52.6%) than the control group (31.2%), however this difference was only significant at $p < 0.1$ (p = 0.083). This pattern is as expected as it indicates that the clinicians are completing a medication reconciliation that improves the accuracy of the patient's medication lists, thereby leaving fewer changes for the control patients to make.

Additionally, while the overall number of changes was not significantly different across the two groups, the number of medications that the patients confirmed as corrected (marked "Yes" in the tool) was significant at $p < 0.01$ (p = 0.063, Figure 5.5), with the participants in the control group confirming more

medications than the participants in the intervention group. This again makes sense and indicates that the clinicians are creating a more accurate medication list that the patients are then able to confirm.

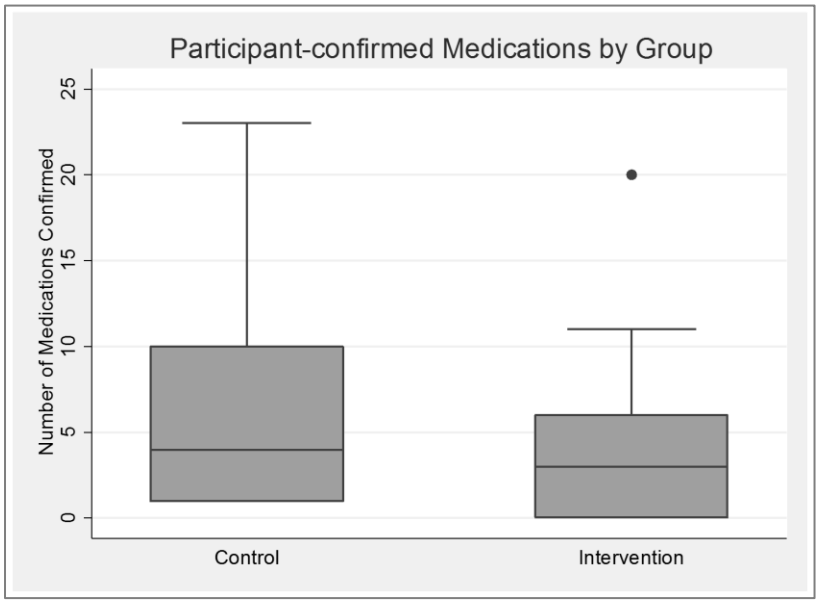


Figure 5.5 Box-plot graph of number of medications confirmed by group

There were no differences in the potential for harm ($p = 0.561$) nor the severity of harm ($p = 0.325$) of the medication changes made between the two groups (intervention versus control).

Analysis of patient-made changes to allergy list

All patients who participated in the study (both intervention and control groups) reviewed their list of allergies as documented in the EHR. In total, 63 allergies were reviewed, with 52 of the allergens marked as correct (82.5%).

Eight participants added allergies that were not previously documented in the EHR (five of whom previously had no allergies listed at all). Of these eight, there were three medication allergies; specifically, an allergy to ACE inhibitors, to codeine, and to an "antibiotic given yesterday". In the case of the antibiotic, it had been given to the patient while she was in the ED the day before she enrolled in the study, her allergic reaction had not been added to the EHR by the time of her participation in this study. Five participants added environmental allergens (e.g., grass, pollen, trees, or food allergies).

Two participants had allergies listed that they stated were incorrect; one participant who was documented as having a morphine allergy and another as having an allergy to "Tape: Plastic". Four participants made a total of nine edits to their allergy lists, primarily to edit the reaction they experienced from the allergen or to specify the allergy as an intolerance rather than a full-blown allergy.

Association of patient changes to PAM and other demographic measures

Overall, the number of changes patients made to their medication lists was not associated with their individual PAM levels (r_s = -0.037, p = 0.774) or PAM scores (r_s = -0.041, p = 0.645). Additionally, no correlation was found between the number of changes and PAM score within the intervention group (r_s = -0.058, p = 0.742) nor the control group (r_s= -0.015, p = 0.939) individually.

We analyzed the other demographics collected in this study to determine if any individual demographic characteristic was associated with the number of changes that a patient made to his/her medication list. Education, health literacy, income level, birth country, sex, race, ethnicity, preferred language, religion, internet use, and use of a smartphone, laptop or desktop, were not associated with the number of changes the patient made to the medication list.

Age was moderately positively correlated with total number of changes patients made (r = 0.362, p = 0.003; Figure 5.6), suggesting that older patients may make more changes to their medication list.

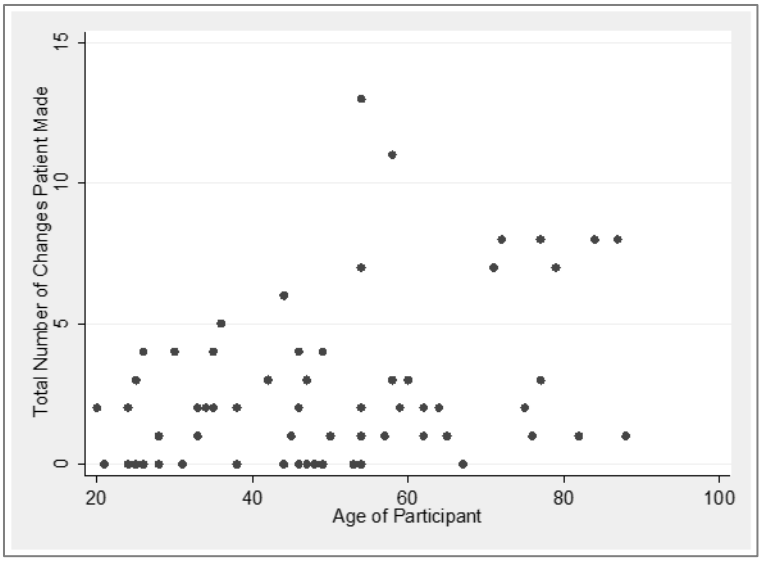


Figure 5.6 Scatterplot of age versus number of medication changes made by patients

Previous use of a tablet computer to access the internet was modestly correlated with the number of medication changes (r_s = 0.366, p = 0.010) by patients. Additional demographic characteristics that modestly correlated with the number of changes of medications made by patients were birth country (r_s = 0.2514, p = 0.045) and ESI (r_s = -0.292, p = 0.018; Figure 5.7).

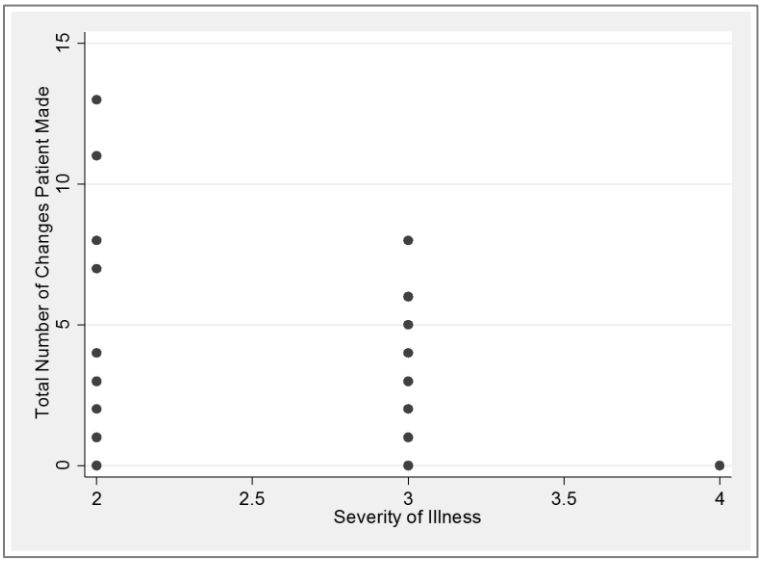


Figure 5.7 Scatterplot of ESI versus number of medication changes made by patients

There was no significant relationship between the changes that patients identified on their allergy lists to either their PAM scores or PAM levels. PAM score and level showed no ability to predict if a participant would make a change to their allergy list (p = 0.192 and p=0.167, respectively), nor did they have a relationship with how many changes the participant would make (p = 0.748 and p = 0.948, respectively). No specific type of change (add, delete, or edit) had any relationship with the PAM score or level of the participant.

5.3.2 Clinician results

Twenty-one clinicians responded to the survey out of 34 invited (response rate of 62%). Respondents included 12 residents or fellows, six physician assistants, and three attendings (Table 5.13). Clinicians took as little as 30 seconds or up to eight minutes to complete the survey. Out of the 21 clinicians who responded, only one clinician reported having received the intervention print-out from a patient.

Table 5.13 Experience of clinician survey respondents (n = 21)

	n	< 1 year	1-2 years	2 or more years
Attending	3			3
Physician Assistant	6		2	4
Resident/Fellow	12	4	3	5

Clinicians who did not receive the intervention responded to questions regarding what effect they believed a patient-generated medication reconciliation might have on their admitting medication reconciliation process (Table 5.14).

Table 5.14 Clinician (who did not receive intervention) survey responses (n = 20)

Usefulness	***Not at all useful*** 0 (0%)	***Slightly useful*** 1 (5%)	***Moderately useful*** 5 (25%)	***Very useful*** 11 (55%)	***Extremely useful*** 3 (15%)
Accuracy	***Not at all accurate*** 1 (5%)	***Slightly accurate*** 5 (25%)	***Moderately accurate*** 12 (60%)	***Very accurate*** 2 (10%)	***Extremely accurate*** 0 (%)
Save time	***Strongly disagree*** 0 (0%)	***Somewhat disagree*** 2 (10%)	***Neither agree nor disagree*** 2 (10%)	***Somewhat agree*** 9 (45%)	***Strongly agree*** 7 (35%)

Most clinicians believed this type of intervention would be moderately or very useful (Figure 5.8). The majority stated they believed the medication list from patients would be moderately accurate (Figure 5.9). Additionally, 80% of respondents somewhat or strongly agreed that having patients complete their own medication reconciliation would save them time (Figure 5.10). Results were not significantly different across role type (Resident/Fellow, Attending, or Physician Assistant), nor by time in role (less than one year, one-to-two years, or two or more years).

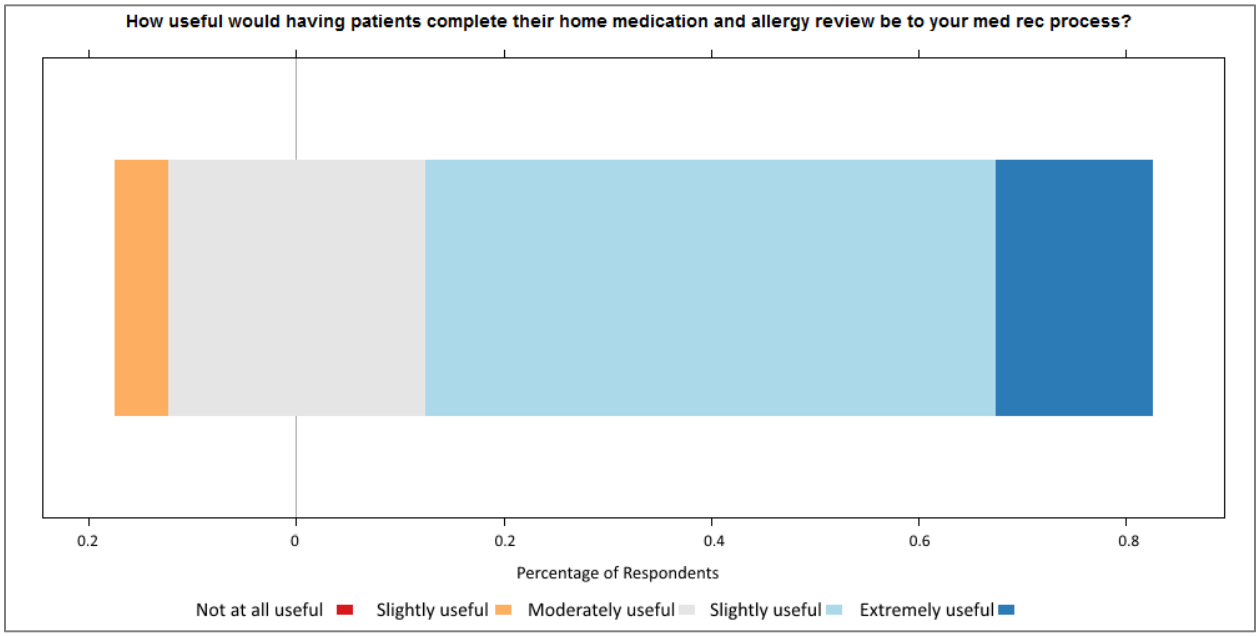


Figure 5.8 Clinician belief of patient-generated medication reconciliation usefulness

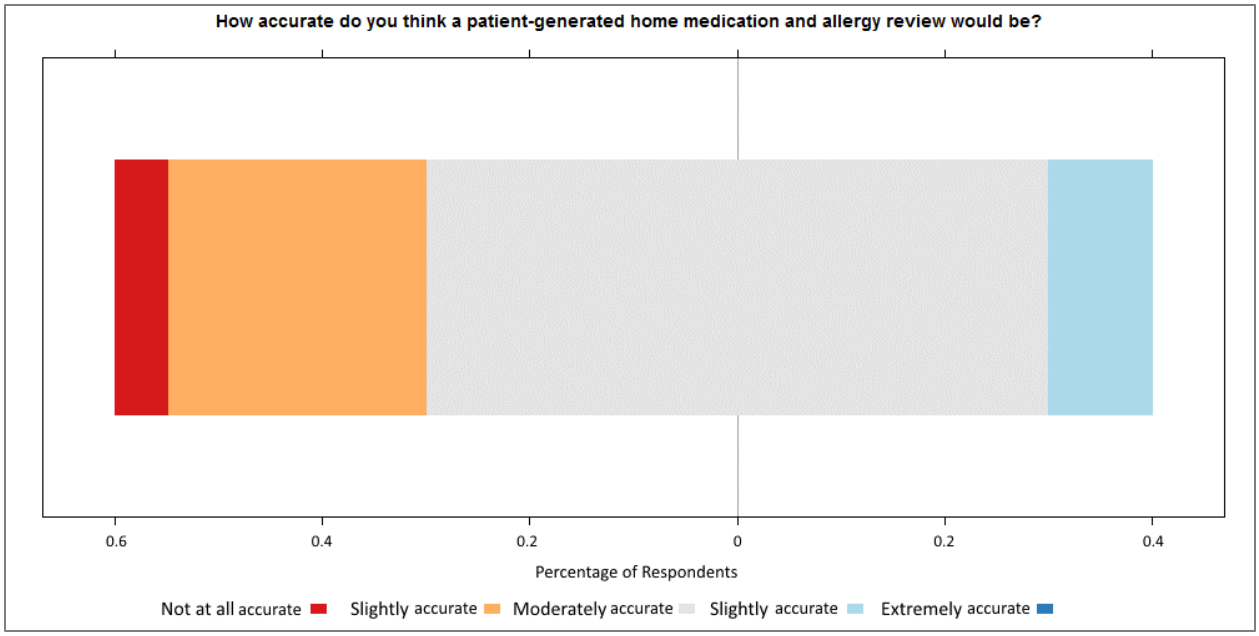


Figure 5.9 Clinician belief of patient-generated medication reconciliation accuracy

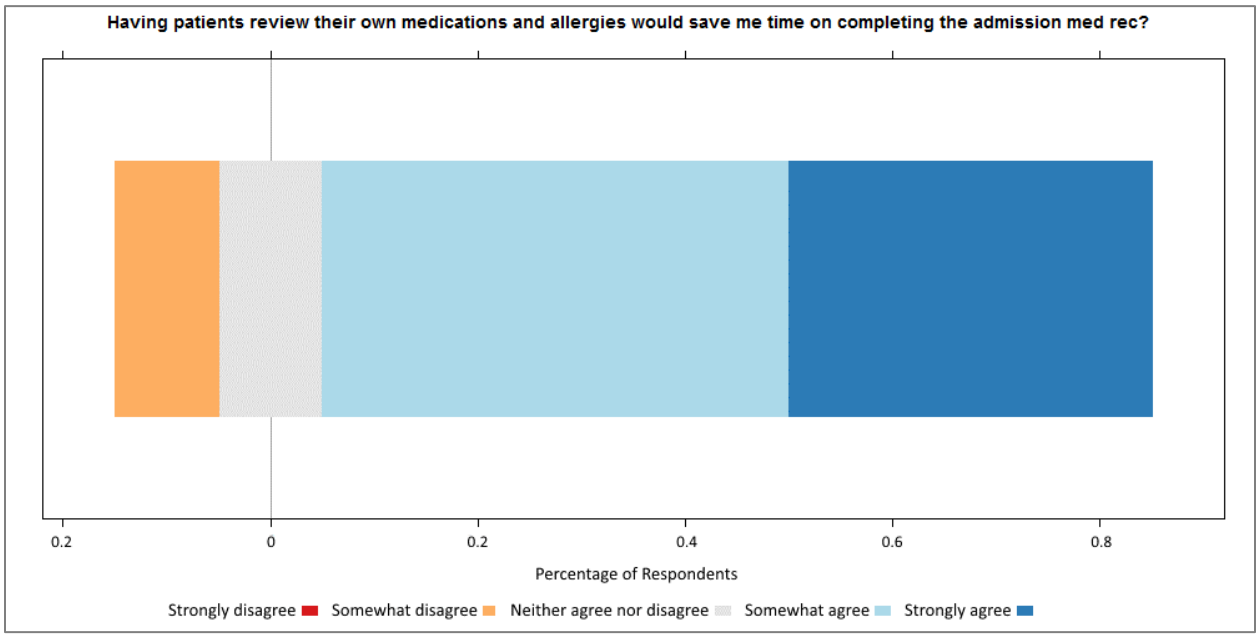


Figure 5.10 Clinician belief of patient-generated medication reconciliation effect on time

Ten clinicians (labelled as C1-C10) provided comments in the free-text space at the end of the survey that asked for feedback. The emerging themes included categories of both predisposing and enabling factors. The frequency of each theme is depicted in Figure 5.11.

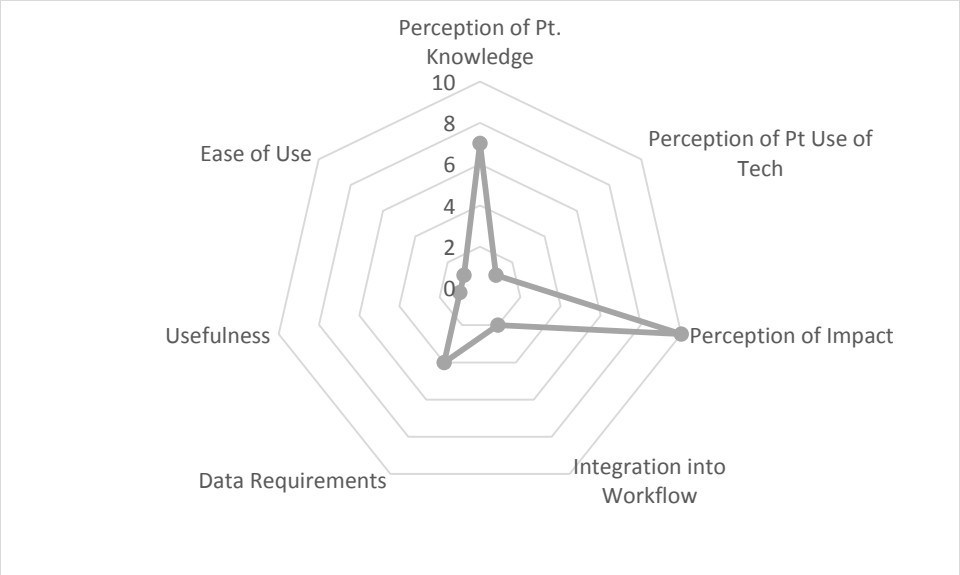


Figure 5.11 Frequency of themes in clinician survey by individual comment

Clinicians provided comments across a variety of themes related to the implementation of this type of intervention. These themes were categorized into predisposing factors and enabling factors (Table 5.15). The most frequent categories of comments related to patient's knowledge of their medications and clinician perceptions of the impact this type of intervention might have. Most (six of the ten clinicians who provided comments) expressed concern over the potential difficulty patients would have to remember their medications, or their lack of health literacy to participate in this type of intervention.

Table 5.15 Themes of clinician survey comments (n=10)

Implementation: extent and consistency to which a program is delivered across programs and settings as intended after it is implemented.		
Predisposing Factors: Occur before a behavior and influence motivation to undertake a particular behavior (knowledge, attitudes, beliefs, values, self-efficacy, behavioral intentions and existing skills), can occur at both the	*Perception of Patient Knowledge*	"Our patient population's health literacy likely limits the utility of having patients do their own med rec. They often just don't know and I would bet that most don't remember how to write it down, let alone doses." [C1] "Unfortunately most patients don't know the names or the dosages of the medications they take…" [C9] "For some patients self-service is possible, but for the vast majority of patients on the hospitalist service this is impossible." [C6]

individual or organizational level		"Most times (at least most patients admitted to the medicine service) patients do not remember what meds they take so we have to rely on collateral--family members, PMD, their pharmacy to figure it out." [C3]
	Perception of Patient Use of Technology	"They either don't know their medications or are incapable of using the technology." [C6]
	Perception of Impact	"This is a great idea and would certainly save us time." [C4] "This is a very valuable tool in all settings, but especially if the patient were to be admitted." [C3] "Any intervention to have the medication reconciliation be performed as early in the ED process as possible would be great." [C6] "Wonderful idea in theory…" [C2] "The home med list would be most time-saving and helpful for an admitting team, who does the med-rec and often has to call the pharmacy, outpatient MD, or family member." [C5] "This would be helpful if patients (or family) are familiar with their medications." [C7] "I think having patients complete a med rec, would help expedite the process but not eliminate it." [C8]
Enabling factors: Support the behavior, also precede behavior, include institutional commitment and central leadership support, integration of system into organizational context, time to allow learning, investment in change process and adequate user training	*Integration into Workflow*	"Unless the electronic document they fill out is linked to our EMR, I'm not sure it would speed up the admissions ordering process." [C1] "Admission orders reconciliation is such that if med rec is not done within 12 hours, we get locked out and cannot place orders until the med rec is done." [C3]
	Data Requirements for Intervention	"It also would be helpful if they could list their pharmacy and/or PMD." [C7] "Perhaps breaking up medications by type (anti-hypertensives, lipid-lowering, oral hypoglycemics etc.) because patient tend to remember their medications best by lumping them into different categories." [C10]

		"It would also be helpful to know if patients input information that they are uncertain about." [C6] "Make sure there are Spanish versions of the interface (paper, electronic med rec, etc.) with proper translations." [C10]
	Usefulness	"I honestly don't remember if this was helpful or not." [C5]
	Ease of Use	"An assistant would be needed [if patient couldn't use technology] in these cases." [C6]

Eight clinicians made ten comments regarding their perceived impact of this type of intervention. Most clinicians made optimistic statements, believing that the intervention could have a positive impact on medication reconciliation and save them time. Others were somewhat skeptical and thought the impact may be limited based on the patient population who uses it, their knowledge, and circumstances.

5.4 Discussion

This study was one of the first to evaluate the concept of having patients contribute directly to the medication reconciliation process while in the hospital. While there was no evidence from this study to support the primary hypothesis that clinicians who had patients participate in their medication review process using the informatics tool would make more changes to the home medication list than clinicians who had patients in the control group, the results do demonstrate that hospitalized patients are knowledgeable, willing, and able to contribute useful and important information to the medication reconciliation process, and some potential difficulties associated with implementing this type of intervention were discovered. Interestingly, there were not many demographic factors found that seemed to affect the number or quality of medication list changes that patients identified. Additionally, while clinicians were skeptical of the practical value of this type of intervention, they did seem to believe it could have positive impacts on their workflow and potentially save them time.

I could not identify any existing studies where patients in the hospital were asked to participate directly in the admitting medication reconciliation process. Previous studies have leveraged patient health portals to elicit patient feedback on the medications that they take at home. A study at Geisinger Health System found that outpatients using a portal were eager to provide feedback on their medication lists, and requested changes in 89% of cases.(Dullabh et al., 2014) Of those changes, pharmacists confirmed the accuracy of 68% of the patient requests, showing the validity of the patient-generated changes. The Geisinger results complement work from Schnipper and colleagues,(2012) who found "concordance between documented and patient-reported medication regimens and reduction in potentially harmful medication discrepancies can be improved with a PHR medication review tool linked to the provider's medical record". These results build on the foundation laid by Dullabh and Schnipper; showing that patients are able to contribute useful knowledge and information to the medication reconciliation while in the hospital.

Implementation of interventions in the hospital come with specific challenges. The results of the clinician survey show that having patients provide a printed form of their medication review may not be an effective way of communicating this information. While there is no exact evidence for why clinicians in this study did not receive the printed mediation review, it can be speculated that a variety of issues may have contributed including the possibility that patients were moved to a different area within the ED prior to their admission and possibly lost their paper before they could give it to the clinician, or perhaps the participants did not know to whom to give the paper as the clinicians were unfamiliar to them. An additional issue might have been that the staff did now know to look for the printout so were not able to prompt the participant for it. This issue was exacerbated by the slow recruitment process as on each day there were fewer than five participants total who would have a printout to provide, so clinicians were unlikely to get used to the process.

The qualitative analysis shows that clinicians have different pre-disposing and enabling factors that may affect their views and use of this type of intervention. I believe that having the data integrated into the EHR would be the most beneficial and efficient delivery mechanism so that clinicians could use the information directly while they are putting in medication orders and updating the medication lists. This EHR integration was not completed for this study as I wanted to discover the usefulness of the patient-generated information first without completing time-consuming development within the EHR. Consideration should be given to the design of the user interface within the EHR so that the patient-generated data is easily available to clinicians and well integrated with their workflows and mental models. However, while the instinct is that having this information integrated into the EHR would make for a smoother process, there are some unexpected positive traits of having the details printed on paper. For one, in today's complex EHR world, it is likely this information would be held within a web of sub-menus within the EHR and would take significant effort to navigate to and therefore clinicians might never actually find it. Having the information on paper also provides the details in a separate location, not taking up space on often crowded computer monitors, making for easy reference. Additionally, clinicians would have the ability to "mark-up" what the patient has provided, and then hand the paper back to them, which could be extremely valuable. These traits show that deciding on whether to integrate something in the EHR is not straight forward. Technology has limitations, as do paper-based solutions, and as such, these points affirm the importance of thorough consideration of how to provide information in the right way, at the right time, in a useful manner that is appropriate for the task, be that using a technological interface or not.

Although admitting clinicians did not use the paper printout from the participants, I believe the results are still valuable. Participants in both the intervention and control group identified changes necessary to their medication lists. Even in the control group, participants still made changes to their medication lists, indicating these could be changes that were missed during the clinician medication reconciliation process.

Additionally, the changes that patients identified were rated as having some potential significant harm. Only three patients involved in the study marked any medications as being "unsure" as to whether they were taking them, and most seemed confident in reviewing their medications and were able to make changes. Very few patients declined to participate in the study, perhaps demonstrating a strong willingness of patients to review their medications and allergies. Patients were also successfully able to use a tablet computer to complete this type of review, albeit, there was a research coordinator at hand, who would assist with occasional entry problems. As more people become comfortable using mobile technology, I believe this method of delivery to have great potential going forward.

Surprisingly, the PAM level was not found to be associated with the number of changes that patients made to their medication lists. The initial assumption was that patients with higher PAM levels would identify more changes in their medication lists than patients with low PAM levels. I believe this finding shows that patients of all activation levels should be engaged to participate in this type of intervention. Often patients will bring in their medications with them to their hospitalization, and therefore by giving them a simple interface to review their medications, they can utilize their pill bottles to review medications at a more leisurely pace than if a clinician were waiting. Further study is required to identify if there are different solutions that may be more beneficial to facilitate the medication reconciliation process for patients of varying PAM levels, but this study indicates patients of all PAM levels have information to contribute.

Overall, clinicians were optimistic about the usefulness of this intervention. They also expressed positive feelings about the potential effect of the intervention on time. However, as shown by the responses to the accuracy question and through the analysis of the clinician comments, clinicians seem concerned about the ability and knowledge of patients to provide this type of information. I believe that the study results should provide some clarity around this point. While the changes the patients identified were not specifically analyzed for accuracy, over 40% of changes that the intervention patients made were also made by the clinician (likely, with the clinician not having seen the patient-generated list). Additionally,

the control patients were able to identify changes that were not made by the clinicians during their admitting medication reconciliation. Going forward, there may need to be some clinician education on the ability of patients to complete this type of review to increase the potential effectiveness of this type of intervention.

5.4.1 Limitations

This study was conducted over a period of three months and with a paper-based implementation of the medication and allergy review. This paper-based method was chosen based on the desire to quickly implement a protocol without having to develop a tool within the institutional EHR. I believe that this paper-based method may have contributed to the lack of receipt of the intervention information by the admitting clinicians. Going forward, significant consideration to the correct implementation of this type of project should be conducted. Integrating the patient-generated data into the EHR could greatly increase its availability and its likely use by the care team.

This was an exploratory study and did not have a large sample size. The effect size calculated for these 65 patients was 0.378, and as stated earlier was based on data from other medication list review studies. Clinically speaking this means, based on the standard deviation found in the number of changes in this study, the clinicians in the intervention group would have to make an average of one additional change to their patient's medication lists than the clinicians in the control group. There is question of whether this difference would be clinically significant, and a larger sample size could be justified in future research.

The design for this study did not include the use of a pharmacist or other clinician to provide a gold-standard for whether the changes made by the patient are truly accurate in real-time. I cannot be sure of the validity of the changes that the patients marked in the medication review tool. However, this information reflects the information that a clinician would otherwise receive verbally. Clinicians

conducting medication reconciliation with their patients will not have a gold-standard to use to complete their work and will use the patient's input as their primary method of contribution.

The clinician surveys were distributed at the end of the recruitment cycle for the study. This means for those clinicians who only had patients participate in the beginning of the study, it might have been up to two months after their patients participated that they received the survey. This could have had an effect on clinicians' memory and therefore their responses to the survey as they might have forgotten if they did receive the intervention months prior.

Additionally, this study was conducted with research coordinators who interacted one-on-one with the participants while they filled out their medication and allergy review. This enabled the coordinator to assist the participant with the entering of information and to clarify any questions the participants might have had. Even patients who were not necessarily comfortable using a tablet computer were more likely to participate with one-on-one assistance than they might be if they were asked to fill out the information on their own. This again points to the need to focus on specific implementation considerations, not only on the clinician-side, but with the patients to ensure they will actually understand and use the tool.

This study was conducted in a large, urban, academic hospital, the results may not generalize to other settings. Workflow processes in other environments could differ and may find different results. Additionally, testing of the medication reconciliation intervention was only completed using one design of the software, and therefore may be limited by the usability and functionalities found therein. It was also only conducted with English-speaking participants, so may need additional tailoring for other languages and cultures.

5.4.2 Conclusions

I evaluated the use of a patient-facing tool that allowed patients to directly participate in the medication reconciliation process. While I did not find a significant difference in the primary outcome of the number

of changes clinicians made during admitting medication reconciliation, I have shown that patients are willing to participate in reviewing their medications and allergies, report medication changes that are not fully captured by the current medication reconciliation process, and showed the changes they do report could have significant effect on the safety of their care while in the hospital. I also found that clinicians are optimistic on the impact and usefulness of this type of intervention. Additionally, I have found that implementation decisions for this type of intervention are critical. Data integration, varying types of workflows, ergonomics, and user interfaces on both the clinician and patient sides should be considered to successfully deploy this type of intervention on a larger scale.

Chapter 6: Conclusions and Future Work

6.1 Summary of Work

The body of research represented in this dissertation investigated the concept of engaging patients in their care to improve medication safety in the hospital. Increasing patient safety is a goal that has broad implications and can be approached from a variety of angles. My research applied an innovative approach of empowering patients to access their hospital medical records in hopes of improving patient safety and reducing adverse events. The current state of the literature shows that the phenomenon of patient engagement is rapidly growing, and that initiatives are being developed on a global scale (Chapter 2). Additionally, preliminary evidence points to increased patient satisfaction, reduction in expenditures, and suggestions of improved health outcomes when patients participate more actively in their care. Engaging patients is a concept that has received attention across care settings. Engagement in the inpatient setting comes a unique set of challenges, but multiple groups have begun studying how to most effectively allow

patients to participate in the hospital care process. Based on the existing evidence, and motivated by the imperative to improve patient safety, I explored the concept of patient participation in the medication reconciliation process.

As was described in previous chapters, patient safety initiatives have focused on using a variety of different methods. Over the last two decades there has been an especially focused effort to reduce medical errors to improve patient safety.(Braithwaite, 2015) Efforts to improve team training have shown some positive effects, but have not been proven to cause a significant change in outcomes as stand-alone interventions.(Kemper et al., 2016) There have been many initiatives to use various functions built into electronic health records to help improve patient safety. However, a study by Ranji and colleagues (2014) found that computerized provider order entry with clinical decision support does not reliably prevent clinical adverse drug events, and that "despite more widespread implementation over the past decade, it remains a work in progress." The existing need to find other ways to improve patient safety is what inspired this work. As it is unlikely that one solution will be able to mitigate all errors, I hoped to show that adding patients themselves to be part of the patient safety network could help improve safety efforts, that patients could be another layer of "cheese" in the Swiss cheese model of accidents.(Reason et al., 2006) Patient engagement efforts have gained increasing attention in recent years.(Dentzer, 2013; Herrin et al., 2015) Engaged patients have been shown to have increased medication adherence, (Wright et al., 2015) and higher satisfaction, (Kruse, Bolton, & Freriks, 2015) and there is evidence to suggest it can improve health outcomes and lower costs.(Greene et al., 2015)

While patient engagement has grown in importance, the focus of the majority of initiatives has been on the outpatient setting. Engagement for patients within hospitals has been perceived to be more difficult with the typically acute nature of patient illness, foreign surroundings, perceived loss of autonomy and the multitude of people involved.(Morris & Karlson, 2011; Prey et al., 2014; Skeels & Tan, 2010) However, recent efforts have started to make inroads into the complex inpatient territory. Multiple institutions have

set about engaging hospital patients through the use of tablet computers that provide access to varying parts of the electronic health record and to health-related information.(Dalal et al., 2015; O'Leary et al., 2015; Pell et al., 2015; Woollen et al., 2016) One particular study described by Masterson Creber and colleagues (2016) is fully evaluating the efficacy of such interventions through a randomized controlled trial. These interventions are focusing on the valuable and necessary goals of increasing access to information in the inpatient setting and facilitating communication between patients and providers.(Kaziunas et al., 2015) The work in this dissertation focused on a related but different goal, to understand how patients could participate in patient safety efforts within the hospital.

To accomplish the goal of engaging patients to improve medication safety in the hospital, I first explored how patients would react to receiving full access to their clinical information (Chapter 3). I also wanted to understand clinician perceptions of this increased information sharing with patients. By sharing daily, printed versions of the medical record with a small subset of patients, I found that patients had a strong desire to receive this type of information, even in a format that was not patient friendly. Patients appreciated being more informed and frequently checked the information they talked about with their doctors. While they did not understand everything in the printed record, patients still derived value from having it.

Clinicians reported a relatively high level of comfort regarding clinical data sharing with patients, particularly with respect to objective data like laboratory test results. The sharing of clinical notes with patients was viewed with some hesitancy, but the majority of clinicians were still open to sharing this type of information. Additionally, while clinicians thought that patients would experience increased anxiety from receiving access to their clinical information, the results of this small study suggested the opposite--that having access to their information made patients feel more comfortable and able to understand the details of their care. Overall, the study described in Chapter 3 showed that increased patient information sharing was beneficial and desirable to patients, and generally acceptable to clinicians. These findings

provided us with the confirmation that sharing information with patients while in the hospital could be a viable method of engaging them to help improve medication safety.

With the understanding that patients in the hospital were open to receiving and reviewing their clinical information, an instrument was needed that could measure a patient's level of engagement to evaluate the impact of various engagement interventions. As described in Chapter 4, I measured the validity of the Patient Activation Measure to determine its suitability for use in the inpatient setting. Using a known-group differences analysis I showed the reliability and validity of the PAM for use with hospitalized patients. The PAM showed adequate internal consistency and construct validity. Construct validity was shown using both the known-group differences method mentioned, but also with convergence on other measures such as the PROMIS Global Health components. Additionally, I showed that the PAM was significantly different across patient groups based on their type of admission, either planned or unplanned. Patients with planned admissions were almost six times as likely to have low activation as compared to patients with unplanned admissions. This finding not only informed Aim 3 of my research but it provides insight into important characteristics that need to be considered in other types of investigations involving patients participating in their hospital care. Simply put, admission type may significantly affect the success of an intervention based on the activation levels of the patients.

By showing that the PAM is a reliable and valid measure for use in the inpatient setting, it can be used to help evaluate the impact of many interventions that are conducted in the hospital. For instance, if patients are administered the PAM when they enter the hospital, their care teams may be able to tailor their communication and patient education strategies. There is additional work to be done in studying how a patient's PAM level may change over time. There is very little evidence regarding the potential changes that may occur longitudinally over a patient's lifetime and with regard to their disease state. It seems quite possible that a specific PAM level is actually a 'state' rather than being an inherent trait to that patient, and a patient's PAM level may change over time and is related to their current diagnoses and

experience with their health conditions. There is a need for test-retest longitudinal studies to analyze how patients' PAM levels change over time to discover if it is in fact a fairly fluid measure, if it is fairly steady and unlikely to be affected by changes in disease severity or condition, or perhaps if it varies noticeably with the onset of a new health indication but can be changed back to the baseline value through education and interventions. My study provided evidence to show the validity of the PAM in the inpatient setting, but there are still open questions as to how PAM changes throughout a patient's lifetime and changing disease states. After establishing some of the benefits and desirability of sharing clinical information with patients and providing evidence to support the reliability and validity of a measure to assess patients' the level of engagement, I conducted a study designed to improve the process of medication reconciliation and increase medication safety (Chapter 5). This study was conducted in the Emergency Department (ED) of a hospital as it is a great interface between inpatient and outpatient care. There are a variety of patients who enter the hospital through the ED and they often have time in which they are stable and waiting to be admitted to the hospital floor that provides a good environment for patient initiatives. It is also the beginning of an inpatient visit for those patients who are admitted and can therefore be an optimal time to familiarize these patients with patient engagement initiatives in the hospital. I discovered that the intervention involving electronic review by patients and paper printouts for clinicians was not successful in terms of facilitating the direct exchange of pertinent home medication information from the patient to the clinician (i.e., only one clinician recalled seeing the paper summary). However, I discovered that the patients who participated in the randomized trial were knowledgeable and willing participants in the medication reconciliation process. Patients contributed medication knowledge that was not otherwise found by clinicians, and it was important in terms of its potential for harm and likely severity of harm. Participants in the randomized trial were also able to identify pertinent allergy information that was not otherwise documented in the electronic health record. These contributions display how technology can act as a mediator and provide affordances to the patients to provide insight that they might otherwise

not have been able to. To enable participants for whom there is a gulf between their ability and the task at hand, one can either decrease the competency of the task or increase the ability of the user. In this case, we hoped to decease the competency necessary for the task of medication reconciliation, and to do so we used the affordances given by access to technology. A framework related to this concept is the "technology affordances and constraints theory" (TACT) whose essential premise is "that to understand the uses and consequences of information systems, one must consider the dynamic interactions between people and organizations and the technologies they use."(Majchrzak & Markus, 2013) The theory shows that it is not simply a person or a technology that matters, but the relationship between the two. The theory of "affordances of technology" helps describe this point.(Putnam, 2008) Putnam's theory has four affordances, "Providing Access to Information", "Automating, Simplifying, and Transforming Tasks", "Representing Knowledge and Thinking", and "Communicating and Collaborating with Peers and Experts". By providing patients with access to their medication lists using tablet computers, I was able to "upskill" the users. The patients were given access to information they would not have had access to otherwise, it was presented in a simple, and automatic way, it allowed patients to contribute their thinking in multiple ways, and facilitated communication with their care providers. All of these functions relate to the four technology affordances. There is often hesitation by providers that their patients would not be knowledgeable enough to participate in these types of activities, as indicated by the results of the clinician survey. However, based on this experiment, when provided with a seemingly useful technological resource, patients were able to provide information and contribute in ways that are not appreciated nor expected. While this study did not analyze actual knowledge of the patients using a gold standard, patients were asked to indicate if they were unsure about any of the information they were providing. Very few patients actually used this capability and the vast majority indicated they were confident in the information they were providing, showing the perceived knowledge was very high. I believe the results of this experiment show that while patients require the right tools to provide greater value, when they are

engaged in the right ways, they can be seen as important resources of information and participants in patient safety.

Additionally, I found that clinicians were optimistic on the potential impact of this type of intervention, and believed it could save them time. A key lesson from this study was that the end-to-end workflow is extremely important to consider in evaluating and implementing interventions. This study showed that, when given the right tools, patients can beneficially participate in medication reconciliation, and therefore can contribute to improving the safety and quality of their care.

6.2 Contributions

My research is a novel contribution for understanding how engaged patients can contribute to improving medication safety in the hospital. Each study I conducted provided insight into new areas of exploration that had not been previously reported in the biomedical literature. Chapter 3 was the first study I could identify that reported on sharing of all aspects of patients' clinical records while they were in the hospital. My study provided evidence that hospitalized patients desire this type of information, and also that clinicians may be fairly open to this type of sharing. Chapter 4 established the reliability and validity of the Patient Activation Measure for use with hospitalized patients. This is an important contribution, as a valid measure is needed to identify patients' potential to participate actively in their hospital care. I hope that care providers will ultimately be able to readily identify patients with low activation so that their education, communication, and delivered interventions can be appropriately tailored. In Chapter 5, I conducted what may be the first study to engage patients in the hospital medication reconciliation process using information technology, demonstrating the affordances that technology can provide. The most notable contributions of this study may simply be the demonstration that patients are willing and able contributors to medication safety.

6.2.1 Implications for Biomedical Informatics

The studies I conducted suggest that the area of engaging patients to participate in medication safety efforts, and patient safety in general, is ripe for study. This is a new and promising field of study that should garner significant interest in coming years. The contribution of providing evidence for the reliability and validity of the Patient Activation Measure means that it can be leveraged in future studies to better understand patient populations, and what interventions work best at different levels of activation. The PAM is rarely looked at routinely and measures an attribute separate from health literacy. Both PAM and health literacy are important characteristics to take into account when interacting with and treating a patient. Additionally, they are especially important to understand in evaluating patient engagement interventions. Health literacy and numeracy receive significant attention in research,(Ancker et al., 2006) but the PAM is less frequently collected. The hope of this work is that I have shown the importance of the PAM and its potential use in the inpatient setting so it can be utilized in other studies and in patient care going forward to better understand patients and study participants. I have also described several methods for evaluating interventions, and have shown that conducting studies in a clinical environment yields practical lessons that may not be learned through more structured laboratory experiments. I also encountered and documented some of the challenges and shortcomings of implementing interventions in a hospital environment.

I have shown that strategic deployment of mobile technology can be an effective method of engaging patients with their clinical data. The development of interactive tools that provide personalized, tailored, clinical information to patients is an important area of research. Developers of these types of tools should understand the entire patient-clinician-hospital eco-system, including the activation level of patients, their health literacy, human-computer interfaces, and overall clinical workflow. Technology can be applied to improve patient-clinician communication and engagement, and as shown in this work to help improve patient safety. The pairing of technology with patients provides affordances to upskill the

patients and allows them to participate in ways they would not be able to on their own. However, there are barriers to overcome in allowing this patient participation in that clinicians have preconceived notions, expectations and hesitations regarding the ability of patients. There is a need to educate both patients and providers on the possibilities of these new patient roles.

An important implication for biomedical informatics that can be taken from this research is the potential for the reuse of clinical information (generated by clinicians) for use by patients. Standard practice is that the majority of information that is collected and created by clinicians stays in the clinicians' hands. The studies in this dissertation have shown the potential for reusing that clinical data to empower patients and enable them to participate more fully not only in their care in general, but in patient safety practices as well.

6.2.2 Implications for Clinical Care

My dissertation research shines an optimistic light on the concept of having patients contribute to improving medication safety. My results indicate that patients are willing to participate and have pertinent clinical information that is not otherwise captured. If properly directed, patients are highly motivated and capable of improving the quality and safety of their care. The key is for tools to be built that provide patients with the right information and the right feedback loops so that their knowledge and input will actually contribute to the clinical process. These tools will also need to take patient state into consideration, and the ergonomics and general environment of being in a hospital. Additionally, a culture change needs to occur so patients are encouraged to contribute this type of information. By the same token, clinician culture must change so that clinicians are open to receiving this type of information from patients in order to foster a truly collaborative environment.

6.3 Limitations

This work is not without limitations. There is a potential limited generalizability of this research as all studies were conducted at only one institution--a large, urban, academic medical center. Additionally, all studies only involved English-speaking participants and had fairly small sample sizes. My research centered on the use of engagement methods to involve patients in their care but did not emphasize tailoring based on the health literacy levels of participants. There is a large body of research on the optimal ways of presenting information to people of varying levels of health literacy. While my research did not specifically focus on these presentation mechanisms, health literacy should be considered along with activation in the deployment of patient-facing interventions.

The ever-changing information technology landscape also affects the generalizability of the results. The comfort level that patients have with different types of technology (e.g., tablet computers) increases and over time. Studies using technology must adapt to the current environment of use, and be pragmatic in studying different interventions. It is possible that in the future, tablet technology will not be the best mechanism for the delivery of information to patients, and as such, the results of this body of research will need to be adapted.

6.4 Future Work

The findings from this work can be expanded in multiple areas.

Immediate next steps for the future work of the medication review intervention are to improve the user interface and develop a system so that the information entered by the patients is made available for clinicians within the electronic health record. Prior to the next round of development, it would be beneficial to conduct focus groups with clinicians and patients independently to gather the design requirements desired by each group. Knowing the specific workflow and mental models of how both patients and clinicians could use systems when thinking about medication regimens would be helpful in

designing future iterations of the intervention. Once a more robust system has been developed, a larger study should be conducted to evaluate the actual impact patient-generated medication lists can have on clinicians' medication reconciliation processes. Another randomized controlled trial across a broader swath of patients would be especially beneficial, particularly to include non-English speaking patients. Independent studies could be conducted using varying interface design mechanisms to study if patients of different levels of activation respond differently to a range of designs.

Additional work should be conducted to identify other areas of the clinical record to which patients could contribute valuable information. While this study used patients to review medications and allergies, symptom information, family history, patient demographics, and health history are all areas of the clinical record in which most patients would have intimate knowledge. Another aspect of research will be to study not only what information patients can review and add to specifically with an electronic health record of a hospital, but what personally-generated health data patients may have that would be of use in the inpatient setting to improve patient safety, and how patients could best share that information with clinicians. Allowing patients to contribute data they have collected would need to be done carefully so that information that clinicians view is curated to be only information that is clinically useful. This type of summarization will be of vital importance in order to obtain benefits.

Greater alignment may be needed so that both patients and clinicians expect and desire for patients to participate in their healthcare, specifically for patient safety purposes. Interventions should be developed and evaluated that help encourage this culture change. I believe patients can contribute valuable information in the inpatient setting; it will be of vital importance to understand how to convince clinicians, and patients themselves, of this.

Longitudinal studies should be conducted to quantify the actual clinical impact of patient engagement strategies in the hospital. Short-term studies may be able to identify a reduction in adverse events, but it

will be important to understand actual, long-term outcomes such as changes in mortality. These longitudinal studies could then also focus on the "return on investment" of these interventions. The initial upfront costs of the development, hardware, and additional workflows would need to be quantified and compared against any improved outcomes that are found.

6.5 Conclusion

Overall, I believe this body of work has shown that patients are willing, and able to participate in medication safety efforts in the hospital. It is important that patients are provided with the right tools, with the right level of information, at the right time, in the right "way", similar to the nine rights of medication administration, (Elliott & Liu, 2010) to allow them to be effective at contributing information. Like any medical treatment, encouraging patients to participate in patient safety efforts may not be possible for all patients. However, I believe that if the culture of a hospital encourages openness and transparency, and if patients are given the proper tools and information, the quality and safety of hospital care will improve. Patients are currently an underutilized resource, and the results of this body of research suggest that there is an opportunity to leverage patient time and knowledge through the use of technology to help facilitate improved patient-provider communication and medication safety in the hospital.

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