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Effects of an Integrated Electronic Health Record on an Academic Medical Center

Kenneth E. Koppenhaver II
Walden University

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Walden University

College of Management and Technology

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Walden University
2016

Abstract

Effects of an Integrated Electronic Health Record on an Academic Medical Center

by

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MS, University of Maryland, Baltimore, 2003

BS, Pennsylvania State University, 1999

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Management

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August 2016

Abstract

The debate about healthcare reform revolves around a triple aim of improving the health of populations, improving the patient experience, and reducing the cost of care. A major tool discussed in this debate has been the adoption of electronic health record (EHR) systems to record and guide care delivery. Due to low adoption rates and limited examples of success, the problem was a lack of understanding by healthcare organizations of how the EHR fundamentally changes an organization through the interactions of people, processes, and technology over time. The purpose of this case study was to explore the people, processes, and technology factors that change as a result of an EHR implementation. Complexity theory was used as the lens to evaluate the effects of the EHR on the holistic system of healthcare. Data were collected using semistructured interviews and observations of physicians, nurses, and administrators, as well as document reviews of organizational documents related to the EHR. Data were analyzed using open coding to identify themes and patterns of usage that redesign or restructure institutional resources. The results of this study demonstrated positive changes in the interactions of healthcare providers with increasing collaboration on process changes and reliance on EHR for communication. These findings may positively affect government policy and the organizational approach to adoption and ongoing use of EHRs to create organizational change beyond the implementation of such systems, thus benefiting both health care employees and patients.

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Dedication

I dedicate this study to all of the patients and family of patients that depend on the U.S. Health Care system to take the best care of them. Excellent health care is a right for all humans and each should receive the best that the science and art of human caring can provide.

Acknowledgments

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Table of Contents

List of Tables	v
Chapter 1: Introduction to the Study.....	1
Background	2
Problem Statement	5
Purpose of the Study	6
Research Questions.....	7
Conceptual Framework.....	7
Nature of the Study	8
Definitions.....	9
Assumptions.....	11
Scope and Delimitations	12
Limitations	13
Significance of the Study	14
Significance to Practice.....	14
Significance to Theory	15
Significance to Social Change	15
Summary and Transition.....	16
Chapter 2: Literature Review.....	17
Literature Search Strategy.....	17
Conceptual Framework.....	18
Complexity Theory	19

Evaluation Frameworks	24
Literature Review.....	27
Appreciation for the System	27
Understanding Variation.....	39
Psychology.....	42
Theory of Knowledge	44
Summary and Conclusion.....	46
Chapter 3: Research Method.....	47
Research Design and Rationale	47
Role of the Researcher	53
Methodology.....	54
Participant Selection Logic.....	54
Instrumentation	56
Procedures for Pilot.....	57
Procedures for Recruitment	57
Procedures for Participation.....	58
Procedures for Data Collection.....	59
Data Analysis Plan.....	60
Issues of Trustworthiness.....	63
Credibility	63
Transferability.....	64
Dependability.....	64

Confirmability.....	65
Ethical Procedures	66
Summary	70
Chapter 4: Results	72
Pilot Study.....	73
Research Setting.....	74
Demographics	76
Data Collection	77
Data Analysis	80
Evidence of Trustworthiness.....	88
Credibility	88
Transferability.....	89
Dependability	90
Confirmability.....	90
Study Results	90
Research Question 1	93
Research Question 2	102
Research Question 3	111
Research Question 4	116
Summary	122
Chapter 5: Discussion, Conclusions, and Recommendations	125
Interpretation of Findings	126

Limitations of the Study.....	130
Recommendations.....	132
Implications.....	135
Significance to Practice.....	136
Significance to Theory	137
Significance to Social Change	137
Conclusions.....	138
References.....	140
Appendix A: Interview Protocol.....	167
Appendix B: Observation Protocol.....	168
Appendix C: Informed Consent	169
Appendix D: Community Partner Letter of Cooperation and Data Use Agreement	175
Appendix E: Emails to Participants	180
Appendix F: Confidentiality Agreement	183

List of Tables

Table 1. Framework Comparison	26
Table 2. Interview and Observation Data	77
Table 3. Document Data Collection Summary	80
Table 4. Coding Hierarchy.....	85
Table 5. Role Oriented Matrix	87
Table 6. Themes and Definitions for Research Question 1	93
Table 7. Themes and Definitions for Research Question 2	103
Table 8. Themes and Definitions for Research Question 3	111
Table 9. Themes and Definitions for Research Question 4	117

Chapter 1: Introduction to the Study

Health care reform has been a critical social and political topic for over a decade. Rising costs and inconsistent quality have been key points in the debate since the institution of the Medicare and Medicaid programs in the 1960s (Iglehart, 1999; Keehan et al., 2011). With health insurance costs tied to employee benefits, employers and employees as patients alike feel the effect of increasing health care costs (Auerbach & Kellerman, 2011). Containment of health care costs and the provision of quality health care to all Americans remains a significant goal of health care policy makers and has had a profound effect on each American as well as the national economy (Berwick, Nolan, & Whittington, 2008). Many past federal policies have targeted cost containment such as managed care (Iglehart, 1992), aiming to increase competition based on price, and the conversion to diagnosis-related groups (DRGs) for benchmarking reimbursement across institutions to limit reimbursable costs based on typical costs for specific diagnoses (Chassin & Loeb, 2011). The outcomes of these initiatives did not result in sustainable gains in cost containment or address the issues of quality and access that might be affected by decreasing costs (Blumenthal, 2006; Fuchs, 2012). Lessons from these attempts at reforming health care costs led to multifaceted approaches in current policy initiatives.

Current policies to address the triple aim of health care reform—improve the health of populations, improve the experience of care, and decrease the per capita cost of care have targeted health information technology (HIT) as part of the solution (Berwick, Nolan, & Whittington, 2008). The triple aim is intended to avoid the myopic solutions of

the past and foster balance in health care organizations across the three dimensions (Berwick, Nolan, & Whittington, 2008). This concept of integrated care delivery identifies information technology as a foundational facilitator across the complex health care landscape (Chaudhry et al., 2006). In 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act committed 19 billion dollars in incentives to individual medical providers and hospitals for the implementation and meaningful use of an electronic health record (EHR) according to Blumenthal (2009). However, the unaddressed problem in this new policy was the holistic system level effects of EHR systems. As adoption rates for EHRs had been disappointingly low (Jha et al., 2011), these effects are poorly understood due to the focus mainly on adoption and implementation of such systems. This problem was framed within the context of several conceptual models to highlight the differing aspects of a complex adaptive system, such as a health care service organization, including the people, processes, and technology needed for health care delivery reform. The following sections including the background of the study, and the problem and purpose statements, highlight the details of a new policy to incentivize the adoption and use of electronic health record (EHR) systems intended to improve quality, efficiency, and cost. These sections also identify the limitation of the evidence to support the effects of the EHR on these goals.

Background

Addressing the issues of cost alone in health care resulted in failed policy and growing concerns over quality. The Institute of Medicine, (IOM) report in 1999 surprised the nation with an assertion that up to 98,000 deaths a year were attributable to medical

errors. The authors attributed those errors to a decentralized and fragmented care delivery system that did not allow for comprehensive care delivery:

Health care is composed of a large set of interacting systems—paramedic, emergency, ambulatory, inpatient care, and home health care; testing and imaging laboratories; pharmacies; and so forth—that are connected in loosely coupled but intricate networks of individuals, teams, procedures, regulations, communications, equipment, and devices that function with diffused management in a variable and uncertain environment. Physicians in community practice may be so tenuously connected that they do not even view themselves as part of a system of care. They may see the hospitals in which they are attending as platforms for their work. In these and many other ways, the distinct cultures of medicine (and other health professions) add to the idiosyncrasy of health care among high-risk industries. (IOM, 1999, pp. 158-159)

In a second IOM report in 2001, the authors outlined a framework for reform that included six goals to close the quality gap in the U.S. Health Care system (IOM, 2001). Inconsistencies in care delivery were attributed to rapid advances in medical science and increased longevity changing the needs of the American people from episodic health care visits to chronic diseases requiring more complicated and coordinated care (IOM, 2001). The authors of this IOM report argued that the health care delivery system was badly in need of a major redesign focused on the patient experience, patient-centered care, and increased information flow (IOM, 2001). To achieve these goals, massive investments in information technology infrastructure were needed to provide improved knowledge and

information sharing, as well as coordination of care between the increasing numbers of care providers involved in each patient's care.

EHR system implementation was identified as a major goal of this information technology infrastructure that could provide major improvements to a health care system's efficiency and quality goals but evidence of these improvements was mixed and in need of further investigation. Buntin, Burke, Hoaglin, and Blumenthal (2011) cited a preponderance of the literature from 2007 to 2010 demonstrating positive overall effects of EHRs on one or more aspects of care. Efficiency demonstrated a decrease in total office visits per member and an increase in secure messaging and scheduled telephone encounters with patients were also attributed to the use of an electronic EHR to proactively manage patient needs (Chen, Garrido, Chock, Okawa, & Liang, 2009). These positive findings drove the consensus for the need to implement EHRs in all health care settings.

Other findings, however, limited the generalizability of quality and efficiency gains resulting from the use of an EHR system. Chaudhry et al. (2006) found that the majority of documented empirical evidence on the quality effects of EHRs came from a small number of academic medical institutions who had developed an EHR in-house gradually over many years. The authors were troubled in the review of the existing literature by the lack of generalizability of such results to institutions with fewer means for development of robust solutions (Chaudhry et al., 2006). The authors of other later studies using a national sample found similar inconsistencies in quality gains for organizations with and without an EHR (DesRoches et al., 2010; Himmelstein, Wright,

&Woolhandler, 2010; Kazley & Ozcan, 2008). In addition, some unintended consequences were observed that could jeopardize patient safety through the systematic interactions of technology such as electronic medication orders with existing processes for confirming the right patient and right time for treatments and medications (Adelman et al., 2012; Borycki, Kushniruk, & Brender, 2010). Users of the electronic health record system at the veterans administration (VA) hospitals outlined many benefits such as improved communication between clinicians but also highlighted the negative aspects of the system, including increased time to enter information taking time away from the patient (Bonner, Simons, Parker, Yano, & Kirchner, 2010). The challenge, therefore, becomes understanding the organizational changes brought on by EHR systems and identifying the interactions of people, processes, and technology that improve the potential of EHR systems in achieving the IOM aims (IOM, 2000) while limiting the introduction of new factors that would take organizations further away from these goals.

Problem Statement

The problem was a lack of understanding of how the EHR fundamentally changes an organization through the interactions of people, processes, and technology over time and what prerequisite or concomitant factors need to be present to achieve positive outcomes across all of these three factors. The findings of DesRoches et al. (2010) and Elnahal, Joynt, Bristol, and Jha (2011) indicated inconsistency of results when the EHR was viewed as the only change in health care systems. Understanding how an EHR changes an organization by changing people's roles and responsibilities, business, and clinical processes, and the technologies people use becomes paramount to evaluating

whether the government policy focus on accelerating adoption of EHRs will meet with greater success or not (Cresswell & Sheikh, 2014). Cresswell, et al. (2014) pointed out that little research has been done on organizations to understand the longer-term effects after the implementation stabilization period. Ammenwerth, Graber, Herrman, Burkle, and Konig (2003) also highlighted that evaluating the effects of HIT on an organization has many challenges that have not been completely resolved with past research efforts. Exploring this gap in understanding through the experiences of the users of a system assists future organizations adopting EHR systems to plan adequately and achieve greater results.

Purpose of the Study

The purpose of this qualitative case study was to explore the people, processes, and technology factors that change as a result of an EHR implementation. The outcome was a summative evaluation of the effects of a comprehensive, integrated EHR system on a large urban academic medical center at the organizational level. The documentation of the interactions of these three factors can provide a clearer roadmap for health care organizations otherwise narrowly focused on implementation of an EHR system as a single solution to the issues of cost, quality, and patient experience (Payton & Pare, 2011). The case in this study was an academic medical center having adopted an enterprise-wide integrated commercial EHR system and focused on evaluation of summative outcomes of the implementation. My goal was to identify opportunities for transformation that occurred as a result of the implementation and adoption of the system,

as well as missed opportunities. This was achieved through interviews, observations, and review of documents generated before, during, and after the implementation.

Research Questions

The research questions focus on the people, processes, and technology factors and how they change.

1. How do the interactions of people change as a result of an EHR implementation?
2. How do organizational processes change as a result of an EHR implementation?
3. How do technologies change as a result of an EHR implementation?
4. What are the summative outcomes of an integrated EHR system at an organizational level?

Conceptual Framework

Considering that the aim of this case study was retrospectively to evaluate the organizational effect of a comprehensive EHR, Rippen, Pan, Russell, Byrne, and Swift's (2013) organizational framework provides a good fit to contextualize the findings. This organizational framework consists of five elements: technology, use, environment, outcomes, and temporality (Rippen, et al., 2013). This framework was chosen over many others due to Rippen et al.'s focus on answering the question of whether a HIT was successful or not. Temporality was also included as a component which allows for study of the EHR in multiple time frames of preimplementation, during implementation and postimplementation supporting the direction of this research in identifying a summative

evaluation of the EHRs effects on an academic medical center postimplementation.

Further review of this framework compared to other current frameworks being used for evaluation of EHR systems will be described in Chapter 2.

In addition to this framework, complexity theory was used to explore the interactions of these elements. Complexity theory arose in the 1980s from the works of multiple researchers representing a variety of disciplines at the Santa Fe Institute in New Mexico (Waltrop, 1993). Complexity theory varies from the traditional mechanistic view of organizations, in which understanding of the parts enables understanding of the whole (Miller & Page, 2007). Uhl-Bien, Marion, and McKelvey (2007) argued that organizations are presented with complex problems that cannot be solved through top-down planning alone but warrant a greater understanding of the interactions of the parts of the organization. This theoretical approach links well to Rippen et al.'s use of the five components and can be used to explore the interaction. The perspective of complexity allows for a more holistic view of health care organizations that can be used to explore the effects of the EHR further in the context of a complex adaptive system. Further description of the combination of complexity theory with Rippen's five components of a health care system was explored in Chapter 2.

Nature of the Study

The nature of this study was qualitative with a focus on the use of the case study design to explore the people, processes, and technology affected by EHR system use within an academic medical center. Yin (2009) argued the case study design is most appropriately used to address research questions focused on how and why, in which the

researcher has little control over the environment and the focus is on a contemporary phenomenon. The unit of analysis for this study was an academic medical center as an organization having adopted an EHR as a means to achieve transformative change. Data were collected primarily through interviews of the members of the organization with additional data collection from organizational artifacts such as progress reports, intuitional documents, and quality scores. Three categories of people were focused on separately—administrators as organizational decision makers, physicians, and nurses as primary users of the EHR to elicit commonalities or differences in perceived effects of the EHR. A total of 23 participants were recruited for this study. Creswell (2014) described data saturation as when the themes or categories of data are filled, and further data collection does not result in any new insights into the phenomenon being studied. Saturation was achieved with 20 participants. The additional three participants were included to ensure similar numbers from each of the three categories.

Definitions

Basic electronic health record: The full implementation in at least one clinical unit of a computerized system(s) for patient demographics, physician notes, nursing assessments, patient problems and medication lists, laboratory and radiologic reports, diagnostic test results and order entry for medications (Jha et al., 2011).

Complex adaptive system: A system made up of multiple individual entities whose actions are interdependent and affect the behavior and actions of other entities in the system in unpredictable ways (Plsek, 2003).

Comprehensive electronic health record: Includes all the functionalities of a basic system and 14 additional clinical functions with the major difference that the functionalities are fully implemented in all clinical units (DesRoches, et al., 2010).

Electronic health record (EHR): Is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports (Jha et al., 2006)

Health care reform: Is defined in many ways. Clancy, Anderson, and White (2009) defined health care reform as a “system that rewards improved patient outcomes” (p. 479). Berwick, Nolan, and Whittington (2008) used the triple aim as the goal of health reform, and Porter and Lee (2013) used the term value to define the goals of health care reform. Each of these definitions has applicability to this study and the effects of the EHR on an academic medical center.

Health care value: The health outcome per dollar spent, which should be focused on the consumer (Porter & Teisberg, 2006).

HIMSS Davies Award: Award established by the Health Information Management Systems Society in 1994 to recognize organization for outstanding achieving in the use of information technology in improving patient care while demonstrating high quality return on investment of the technology (HIMSS, 2016).

HIMSS Electronic Medical Record Adoption Model (EMRAM): HIMSS (2014) developed tool to benchmark the level of adoption within an organization of an electronic

health record system. The scale is from 0 to 7 with 0 being no evidence of EHR use and 7 being a nearly complete adoption and use of advanced EHR functionality throughout an entire organization.

Meaningful use (MU): Of an EHR was the key element of the HITECH Act that described the criteria for certification of EHR systems as well as the usage by organizations and physicians that would be applied to measure the use of the EHR required to qualify for the incentive funds (Blumenthal & Tavenner, 2010).

Quality of care: Donabedian argued that two definitions of quality combine to provide firmer ground for evaluation, processes of care in comparison to established guidelines and settings of care involving the structure of the care delivery. (Donabedian, 2005).

Triple Aim: Berwick, Nolan, and Whittington (2008) defined this as the goals to improve the patient experience of care, improve the health of populations, and reduce the cost of care.

Assumptions

An assumption was made that all participants in this study provided honest and thoughtful answers to the interview questions to the best of their ability given assurances of confidentiality. Also, participant guidance was relied upon to identify the key potential participants within the organization for data collection. Due to the size of the organization and the limited time available for finding appropriate participants, each participant was relied upon to provide insight into the organizational structure including identification of

the key stakeholders in the organization who may hold valuable information on the EHR effects on the institution over time.

Scope and Delimitations

The scope of this research was limited to a single academic medical center and the interactions of people, processes, and technology related to the use of the EHR. The findings of this study are limited in application to academic medical centers and are not representative of other health care institution structures such as community hospitals or for profit health care entities. The focus of this study was not on the functionality or usability of the EHR system itself with an assumption being made that the system meets all minimum standards required by law and also meets the minimum threshold of usability and functionality acceptable for the institution. The areas of research around adoption of EHRs and implementation approaches were not addressed in this research due to the current volume of research being done elsewhere on these topics. While this qualitative analysis may not be generalizable to all academic medical centers, the findings of this research may have some transferability to other organizations in the postimplementation phases of an EHR system and should provide a foundation for further research into the areas of change necessary to achieve transformative change in health care delivery systems. An academic medical center was chosen for this study because it represents a higher level of complexity than community hospitals resulting in more interactions of people, processes, and technology.

Limitations

This study was performed at one well-established large academic medical institution employing thousands of employees. This study used a purposeful sampling technique to locate and collect data from the key personnel that can inform the established research questions. The goal was depth of information gathering and not breadth, which was certainly not be inclusive of all clinical disciplines. The focus was on three large groups that represent major stakeholders within the organization: physicians, nurses, and operational leaders. The number of organizations chosen in this study was intentionally small due to the methodology and depth of data to be collected; this limitation did affect the generalizability of the findings. The focus on academic medical centers also limited the findings usability in community and for-profit health care facilities. External pressures on the organization were detailed as general contributors to change but may represent a limited local effect in some cases due to the geographic location of the institution.

The most important potential bias in this study was me as the researcher and also an employee of the organization to be studied. As this study focused on the clinical and operational leadership of the organization, my role as a senior leader in the information technology department had a minimal effect on the data collection due to limited interaction with most potential participants other than the senior operational leaders. For any of the senior operational leaders who participate in the study from my organization, explicit guidelines for information sharing, confidentiality expectations, and process were reviewed to avoid any concerns.

Significance of the Study

With growing inertia behind the adoption of HIT to improve patient safety and reform rapidly growing health care costs, understanding the effects of HIT and especially EHRs is becoming increasingly critical. Billions of dollars of federal stimulus money are now being funneled into health care to increase adoption of EHRs, yet the IOM report on HIT and Patient Safety (IOM, 2012) demonstrated that the presence of an EHR alone does not guarantee improvements. The larger sociotechnical environment including people, processes, and technology affect the outcomes of EHR implementation and adoption and ultimately the achievement of reform goals. Therefore, uncovering the deeper relationships between technology, people, and processes in health care becomes paramount to realizing the triple aim of health care reform.

Significance to Practice

Few examples of the qualitative effects of an EHR on organizational structure and process exist in the current literature. Bonner, Simons, Parker, Yano, and Kirchner (2010) described the effects on the VA system, an early adopter of an integrated EHR system, concluding that the EHR was merely the first step in the improvement process, and much work was needed to achieve the goals of health care reform. Kaushal, Barron, and Abramson (2011) concluded through the comparative evaluation of two electronic medication prescribing systems that the system integrated in an EHR demonstrated less improvement and challenged further research in this area to understand other factors affecting outcomes of EHR use. A detailed review of a complex academic medical center

recently adopting an EHR provided needed insight into the technology, process, and people changes needed in order to achieve health care reform initiatives.

Significance to Theory

Quality improvement strategies in health care have been historically based on methods borrowed from manufacturing industries. Litaker, Tomolo, Liberatore, Strange, and Aron (2006) argued that the use of methodologies such as continuous quality improvement focus on a mechanistic view of health care delivery that views variation as bad and needing to be limited. Using the Rippen et al. (2013) organizational framework allowed for categorization of these effects and reinforces an approach for further evaluation studies.

Application of complexity theory provides a new perspective on the health care delivery system as comprised of many entities adapting to local environments and pressures. Use of complexity theory as the lens to evaluate the application of the EHR to health care provides an opportunity to modernize the perspective of health care delivery systems while also providing a different scale for weighing the benefits of the EHR as an innovation.

Significance to Social Change

Health care viewed as a commodity and governed by market forces has led to a dysfunctional and fragmented system badly in need of redesign. Historical policy fixes have resulted in limited change to the complex settings in which health care is delivered (Chassin & Loeb, 2011; Iglehart, 1992). New federal government policies incentivizing adoption of the EHR as a tool to achieve the triple aim are resulting in the investment of

billions of dollars into the recalcitrant health care system and rapidly increasing adoption of EHR systems with limited research into the larger system effects of such systems (Nguyen, Bellucci, & Nguyen, 2014). This case study of a large academic medical center's transformation through the adoption of an integrated commercial EHR system provided depth of understanding beyond the implementation and adoption aspects of these systems.

Summary and Transition

Adoption and implementation of EHR systems have been a national imperative for the last decade to address the triple aim of improving health, improving the patient experience and reducing the per capita cost of care (Bipartisan Policy Center Task Force on Delivery System Reform and Health IT, 2012) yet little progress had been made in achieving these goals. Incentive programs established in 2009 have turned the tides of adoption and implemented criteria to ensure demonstration of meaningful use of the technology and standardization of the functionality across multiple vendor systems (Jha, et al., 2011). However, little has been done to investigate and understand the holistic system level changes in health care organizations that result from EHR adoption to further our understanding and guide future initiatives to achieve transformative results. A comprehensive review of the literature related to this problem is presented in Chapter 2 and a proposal for the design of a study to close this gap in understanding and provide insight into the people, processes, and technology needed for repairing the American health care system is presented in Chapter 3.

Chapter 2: Literature Review

EHR systems have been proposed as a tool to improve the quality, efficiency, and cost of health care. Evidence, while predominantly positive in local cases (Buntin, Burke, Hoaglin, & Blumenthal, 2011), has been mixed in large scale research when looking at the consistency of improvements across a variety of health care delivery organizations (DesRoches et al., 2010; Himmelstein et al., 2010; Kazley & Ozcan, 2008). With the U.S. government investment of billions of dollars into the adoption of EHRs to meet the health care reform agenda (Blumenthal, & Tavenner, 2010), an understanding of the factors influencing success is critical. The purpose of this study was to explore the interactions of people, processes, and technology at one academic medical center after the implementation of an EHR to elicit the elements of the interactions that change with EHR use and are critical to achieving the health care triple aim.

The organization of the remainder of this chapter outlines the conceptual framework used as the lens for interpretation of findings and the literature search strategy. The review of the literature follows a framework outlined by Deming provided to allow for the systematic analysis of complex problems by dividing the analysis into four areas of focus: appreciation for the system, theory or theories of knowledge, psychology, and understanding of variation (Deming, 1994).

Literature Search Strategy

Articles and references for this review were obtained from the Walden Library databases including Academic Search Complete, Medline, and Cinahl. The specific search terms originated with *electronic health record* and *electronic medical record* and

evolved to include cross-referenced terms with *health care quality, safety, and cost*. The search continued to evolve through the review of references of germane articles and established authorities in the field such as the federal government publications on HIT and the Institute of Medicine. Due to the rapidly evolving nature of this area of study other online sources were used to track newly occurring research such as the Commonwealth Fund as well as professional organizations such as the Health Information Management System Society (HIMSS), the Advisory Board Company and the American Medical Informatics Association (AMIA).

Conceptual Framework

Historically, health care has borrowed the concepts and methods of the airline industry, hotel management, and manufacturing to devise tools for interpreting and improving the experiences and quality of care delivery. Each of these borrowed concepts focuses on a mechanistic view of a system composed of multiple parts that when taken apart, examined, and changed can lead to a better understanding and ultimately improvement of the whole system (Hales, Terblanche, Fowler, & Sibbald, 2008). In recent years; however, researchers have realized that health care systems are more than the sum of their parts and demonstrate complex behaviors due to the makeup and interactions of the constituent parts of the system (Litaker et al., 2006). This realization requires a different theory of systems to allow for broader understanding of health care organizations and the innovations that are implemented with the goals of improvement.

One of the innovations that has been a major focus for more than a decade has been HIT (McCullough, Parente, & Towne, 2014). More robust understanding of the

environment of health care as well as tools to evaluate the uses of HIT to improve the quality, cost, and efficiency is a critical necessity for health care reform. Using both the lens of complexity and a framework of evaluation methods for gathering and comparing data, insight can be gained into the effects of the EHR on health care systems. Both the concepts of complexity theory as well as the evolution of evaluation frameworks is described in the following sections.

Complexity Theory

Health care organizations differ from other industries due to the predominance of knowledge workers that make up the complex structures of health care organizations (Nagle, & Yetman, 2009). Health care is comprised of knowledge workers who are professionally licensed to provide health care services in some manner based on a variety of disciplines (Nagle & Yetman, 2009; Walker, 2000). As an outcome of these independently licensed care providers' interactions with patients, organizational structures, and each other, the processes of a health care organization evolve to meet the changing environment and pressures of care delivery (Nugus, Greenfield, Travaglia, Westbrook, & Braithwaite, 2010). Understanding the adaptability and evolution of interactions within the health care structure can provide insight into how change is accepted or rejected by an organization or system of entities (Tsisis, Evans, & Owens, 2012). This change in perspective from health care organizations as mechanistic systems with interchangeable parts to interconnecting and self-organizing entities forms the foundation of necessary thinking to address health care reform.

Complexity theory provides this different perspective to understand health care organizations. Complexity theory focuses on the interactions of multiple entities within a system in defining the macro structures of an organization through simple rules and adaptation to the environment (Plsek, 2001). Much of the original work around complexity originated from the Santa Fe Institute in New Mexico in the 1980s (Waltrop, 1993). The concepts of complexity evolved from the work of many researchers primarily from the physical sciences as an attempt to understand the nonlinear evolution of biological systems (Holden, 2005). Many of these same principles can also be foundational for understanding social systems such as organizations.

The foundations of complexity are a large number of entities capable of interacting with the local environment and being influenced by other entities in their environment resulting in adaptation. This capability to interact and adapt results in the phenomenon of self-organization and emergent behavior not present when individual components of the system are viewed in isolation (Litaker et al., 2006). The concept of a complex adaptive system (CAS), which is defined as a bounded system of multiple entities that are interdependent and affect each other through adaptation to the behaviors of the other entities (Plsek, 2003) provides the context to examine an organization using complexity concepts. When examined closely, complex adaptive systems are governed by simple rules that guide behavior (Holland, 2005). Plsek (1999) argued that these rules already exist in health care and focus on understanding and changing these simple rules will have a greater effect on the whole of health care delivery than creation of more

complex rules with the hopes of system manipulation. This concept makes complexity useful as a lens for the evaluation of health care delivery organizations.

A complex adaptive system (CAS) is a concept developed to further the understanding of systems such as biological systems that adapt to their surroundings in sometimes unpredictable ways. Holland (1995) described CAS as a system, either biological, or social, made up of multiple agents with free will capable of interacting with each other, adapting to their environment and governed by simple rules of these interactions. CAS theory was developed as an alternative method of viewing and studying these systems that allowed for the concept that the whole is greater than the sum of its parts and understanding the capabilities of the individual agents had to be combined with the interactions of the agents to understand the holistic view of the system (Holland, 1995). Holland (1995) made the observation that in a CAS often small changes could have large effects on the whole system while large change could have relatively small effect. He posited that CAS theory could be used to identify the levers within the system by which these effects were generated (Holland, 1995).

The first aspect of the CAS described by Holland (1995) was the agent. He described the agent as an autonomous element that actively interacts with the environment and other agents within the system and is capable of adapting to its local environment. However, this adaptation, Holland found was not complex and was often guided by simple rules that governed the actions of each agent. Understanding these simple rules in a CAS could be used to understand higher-level behavior of the system.

Second, Holland (1995) identified several properties that were common among CAS.

Aggregation is the first property that allows for similar agents to be grouped together and categorized by like actions (Holland, 1995). Holland argued that aggregation could be used both as a tool to model CAS but also as a concept to explain the difference in behaviors between the individual agents and the system or organization as a whole.

Holland used the example of the individual ant and the ant colony as an example of aggregation. In the health care setting individual care provider versus a clinical unit or academic department could also be described using this concept of aggregation. Another property of CAS identified by Holland was that of nonlinearity. This concept, derived from mathematics emphasizes that the sum of the parts does not equal the whole. Each of the agents in a CAS is capable of adaptation to the local environment and is influenced by interactions with other agents, which leads to changes that are dependent on the specific interactions (Holland, 1995). Flow is also a property of CAS that describes either the multiplier or recycling effect of some element through the CAS between the agents (Holland, 1995). Flow could be raw materials, information, or patients in the example of health care. This concept was used to describe the changes to the CAS as changes in flow across the network occur (Holland, 1995). Applying these concepts to health care can allow for a different perspective and a better understanding of the actions that will have a modifying effect on health care reform.

Since the incorporation of complexity theory concepts in the IOM report by Plsek (2001), many researchers have used it as a lens to evaluate health care processes and visions for the future. Litaker et al. (2006) identified the CAS concepts of understanding

interconnectedness of the local environment and coevolution at a VA clinic to explain how top-down changes to improve scheduling were unsuccessful. The authors explained the local variation that contributed to individual patient delays and the importance of this understanding in designing interventions to make improvements (Litaker et al., 2006) Mathews and Thomas (2007) and Paina and Peters (2012) also highlighted how the local context of a large-scale change promulgated from top down was unsuccessful due to lack of understanding of relationships and interconnectedness at the local level. In each of these studies, the authors highlighted information sharing contexts that were highly relevant to the dissemination of knowledge and adoption of change (Litaker et al., 2006; Mathews & Thomas, 2007; Paina & Peters, 2012). Complexity theory adds a perspective to the evaluation of healthcare that values the local context and interactions agents when HIT innovations are introduced.

Changes from a mechanistic view of health care as a machine have fostered researchers to relook at the elements of change necessary for the organization. Boustani et al. (2010) viewed organizational learning for treatment of dementia patients through the lens of complexity and identified the incidence of missed diagnosis in primary care related to ineffective methods of dissemination of knowledge due to lack of understanding of the local context and interconnectedness of the staff in sharing of information. Kannampallil, Schauer, Cohen, and Patel (2011) emphasized that the number of components in a CAS is not as relevant to the complexity as the degree of interrelatedness of the components. The authors eschew the concept of functional decomposition of a large CAS in order to be able to identify the relationships of interest

by using examples of health care activity in an ICU during resuscitation of a patient as well as an emergency department during a mass casualty incident (Kannampallil, Schauer, Cohen, & Patel, 2011). Each of these examples demonstrates changing the lens of evaluation to one using the complexity concepts of interrelatedness, coevolution, and dependency, which supports the necessary change in EHR evaluations as a top-down initiative expected to have standardized outcomes.

Evaluation Frameworks

Health care organizations are complex adaptive systems that are continuously changing due to multiple forces including regulatory, competitive, and reimbursement factors (Plsek, 2003). To understand the effects of the EHR on a complex system, many conceptual lenses have been used to evaluate organizations preimplementation, during implementation, and post implementation of the EHR (Jones, Adams, Schneider, Ringel, & McGlynn, 2010; Rippen et al., 2013). While finding a standard for evaluation has been challenging, most frameworks have a foundation of Donabedian's structure, process, and outcome model initially developed to describe and foster quality evaluation of physician-specific interactions (Donabedian, 1988). Some; however, like the DeLone and McLean (2003) model for IS success and the composite index model proposed by Otieno, Hinako, Motohiro, Daisuke, and Keiko (2008) are system focused without consideration of the environment or processes in which the technology was implemented. As evaluation techniques and understanding of health care organizations have evolved, more robust frameworks have also evolved.

The more current frameworks (see Table 1) have acknowledged the evolution of the health care environment to include many other factors influencing the outcomes of care delivery for example four levels of a health system, environment, organization, microsystem and patients, and caregivers (IOM, 2001). Ancker, Kern, Abramson, and Kaushal (2012) included four areas of technology, organization, provider, and patient in evaluating quality and safety of HIT. Carayon, et al., (2006) proposed expanding the structure element of Donabedian's work to include work systems that include five elements of person, tasks, tools and technologies, physical environment, and organizational conditions. Sittig and Singh (2011) and Cresswell and Sheikh (2014) advocated for the use of the sociotechnical framework for evaluating HIT systems with the use of eight perspectives including hardware and software, clinical content, human-computer interface, people, workflow and communication, internal organizational policies, procedures and culture, external rules, regulations and pressures, and system measurement and monitoring. Each of these frameworks demonstrates an evolution of thinking to broaden the focus from a pure technology perspective to one in which a more global perspective of the effects of HIT can be examined within the greater context of the organization where they are implemented. However, each remains narrowly focused on individual processes or systems without a more holistic organization level perspective.

Table 1

Framework Comparison

	Date	Elements	Purpose	Health care
Donabedian – SPO	1988	Structure, process, and outcome	Evaluation of physician-centric quality (no technical focus)	Yes
IOM Crossing the Quality Chasm	2001	Environment, organization, microsystems, patients and caregivers	General quality improvement focus (no technical focus)	Yes
Triangle Model Ancker, Kern, Abramson & Kaushal	2012	Technology, organization, provider, and patient	Focus on quality and patient safety related to technology for specific areas of effect	Yes
SEIPS Model Carayon, Schoofs, Hundt, Karsh, Gurses, Alvarado, Smith & Brennan	2006	Person, tasks, tools and technology, physical environment, organizational conditions	Focus on quality and patient safety related to technology	Yes
Delone & McLean Model for Information System Success	1992 (revised in 2003)	Information quality, system quality, service quality, intention to use, use, user satisfaction, net benefits	Technology centric	No
Sociotechnical Model Sittig & Singh	2011	Hardware-software, clinical content, human-computer interface, people, workflow and communications, internal organization policy, procedure and culture, external rules, regulations and pressures, system measurement and monitoring	Technology centric with expanded focus on non-technology factors affecting quality and safety of technology systems	Yes
Composite Index Otieno, Hinako, Motohiro, Daisuke, Keiko	2008	System quality, information quality, service quality, use, user satisfaction	Quantitative composite benchmark for technology system comparison across organizations. Technology centric	Yes
Organizational Framework Rippen, et al.	2013	Technology, use, environment, outcomes, temporality	Focuses on the organizational impact of technology systems	Yes

Note. Data compiled from each of the source articles listed

To get a more organizational level perspective in the retrospective evaluation of the effects of an EHR on an academic medical center, a framework would need to allow for the inclusion of not just technology assessment but also the environment, outcomes, and timing in relation to the implementation. Rippen et al.'s (2013) organizational framework allowed for this flexibility while also posing the fundamental question of whether the system implementation was a success or failure. The authors provided a robust framework with subcategories within each element that complement the use of complexity theory to explain the interactions between the categories (Rippen et al. 2013). Combining this framework with the elements of complexity theory such as coevolution of entities within a system will provide insight not only into the static point of evaluation but also the evolution of an EHR system in a dynamic complex adaptive system.

Literature Review

Appreciation for the System

The overarching health care service organization (HSO) is made up of many systems including but not limited to HIT systems, health care delivery systems, provider networks made up of primary care and specialty care, organizational structures, and payor relationships as well as many other entities that all combine into a complex adaptive system for delivery of care. A hallmark of complex adaptive systems is resilience and adaptability to a changing environment resulting in multiple interconnections between different points in the system (Edgren & Barnard, 2012). Understanding the entities both within and external to a HSO is critical to understanding the current critical need for health care reform. The following sections describe the major systems involved in the

CAS of an academic medical center and how they interact in the provision of care to patients.

Health care system. The health care system of the United States is composed of many different entities including ambulatory physician practices, acute care hospitals, long-term care facilities, and a variety of types of organizations both public and private providing health insurance. This system differs markedly from other countries in several aspects including basic health care services being funded through a variety of private and public insurance offered through employers and available for those who can afford to pay with only a few exceptions (Anderson, Reinhardt, Hussey, & Petrosyan, 2003). Schoen, Osborn, Squires, Doty, Pierson, and Applebaum (2010) argued that the U.S. health care insurance system is unique in how it segregates coverage based on income and age, which leads to increased complexity in gaining access to care and coverage of costs for essential care. Employer-based health insurance has been a contributor to this coverage disparity by not providing coverage to the unemployed or part time employed and has led to the belief of health care being a privilege of those who are willing to work for it (Gable, 2011). Also, unique to the U.S. health care system is the overall costs of delivery far outweigh other countries without a concomitant increase in healthy outcomes (Anderson & Frogner, 2008). For this reason, as well as the persistent increases in costs year over year health care reform has become a prominent topic of political discourse and policy development (Anderson et al., 2003). To understand why these differences in the health care structures exist for the United States, the historical perspective needs further exploration.

The historical evolution of health care organizations in the United States has not only included the providers of care such as physicians, hospitals, and long-term care facilities but has also included both public and private insurance companies. This evolution espoused the same principles of capitalism as other industries with health care being a commodity and fostering structures that were independent of each other and narrowly focused on profits (Leibert, 2011). The growth in health care costs since 1950 has been dramatic with an increase in percent of gross national product (GDP) from health care increasing more than 12% in the 60 years from 1950 to 2009 (Fuchs, 2012). The major contributors to this are the rapid increase in medical technology including medications as well as other diagnostic and treatment modalities with the greatest percent of technologies being those without a proven benefit on outcome (Chandra & Skinner, 2012). This increase in medical technology also fostered a boom in the development of physician specialization fragmenting care delivery among an increasing number of providers (Fuchs, 2012). Concomitantly the wide spread of insurances both public and private decreased the out of pocket costs of health care increasing the moral hazard of increasing demand without a realization of actual costs of care (Fuchs, 2012). These increases in spending can be put into perspective when compared to growths in other countries and when compared to health outcomes.

The Organization for Economic Cooperation and Development (OECD) produced statistics comparing the U.S. health care spending with 30 other industrialized nations. When compared to other countries, health care spending in the U.S. per capita is nearly double that of the median of the top 30 industrialized nations (Anderson & Frogner,

2008). Despite this disparity in spending, when health care value is examined, benefit over dollars spent, the U.S. does not fare well and often resides in the bottom quartile of developed countries in the measures of life expectancy and preventable illness (Anderson & Frogner; Tchouaket, Lamarche, Goulet, & Contandriopoulos, 2012). Auerbach and Kellerman (2011) made the case that despite modest increases in the use of services, that the intensity of services have increased dramatically in the first decade of the twenty-first century with limited effect on overall outcomes when measured by decreases in mortality from treatable conditions compared to other developed countries. Bradley, Elkins, Herrin and Elbel (2011) further differentiated across the OECD countries by percent spent on health care (e.g., treatment of disease compared to social spending such as housing supplements, unemployment and other preventative programs) found to have a greater influence on health outcomes. Bradley et al. found that the U.S. exceeded all other countries in the portion of overall spending on health care over social spending. Insight into the spending on health care and the differences between the U.S. and other countries can be gained by looking at the infrastructure for funding.

Health insurance is intended to shield consumers from catastrophic costs, which may occur from unexpected illnesses. The employer-based health insurance program was started after World War II as a means of compensating employees during a time when a national wage freeze was in effect (Blumenthal, 2006). This approach was considered an alternative to the universal health care coverage that was not well supported by the American Medical Association and others at the time (Blumenthal, 2006). This connection to employment has led to the unique situation of disparities in health coverage

based on income, employment, and age, with the advent of the Medicare program to cover those over 65 years of age (Schoen et al., 2010). Cost increases described earlier have therefore had the greatest effect on employers as they take the brunt of the cost for insurance premiums, which resulted in the many attempts to control costs.

Managed care arose from the needs of employers to manage the increasing costs of health care for their employees. Managed care, established in the 1990s, was intended to control cost through direct contracting with the providers of health care to increase competition based on who could keep cost down through limiting services as much as possible (Fuchs, 2012; Iglehart, 1992). As the majority of insurance for Americans was employer based through commercial companies during this time, the outcome was effective, leveling off cost increases throughout the 1990s. However, the backlash was great from consumers and physicians due to limits on choice and decreasing autonomy (Fuchs, 2012). By the early 2000s, managed care in the form of strict health maintenance organizations was waning in favor of less strict management resulting in a resumption in health care cost increases (Blumenthal, 2006). The other change at this time was a growing proportion of public funding as a percentage of insurance coverage through the expansion of the Medicaid program (Truffer, et al., 2010). As this transition moved more of the health spending to public accounts while also increasing, albeit at a slower rate the costs to private employer-based insurances, the public policy debate on health care increased.

At around the same time in the early 2000s the authors of the Institute of Medicine report (IOM, 1999) argued that the segmented structure of health care leading

to fragmented care was not able to keep up with the evolving complex health care needs of the American public and contributed to an increased incidence of medical error. Not only was this detrimental to the public trust in health care but it impacted overall cost by \$17 to \$29 billion a year (IOM, 2000) This expanded the conversation around health care to include not only costs but also quality and consistency of care delivery (IOM, 2001). The authors of both IOM reports (1999, 2001) were quick to point out that errors and improvements in quality would not be achieved through assigning blame and the view was that this was a system and process issue that needed to be addressed and not poor performance by individuals within the health care system. This propensity for error, as well as the increasing costs over time, has been a major driver of health care reform efforts.

Early efforts at reform post-2000 focused on experimentation with structures and processes to address the dual concerns of quality and cost control. Wang, Hyun, Harrison, Shortell, and Fraser (2006) found many challenges in achieving successful changes in health care delivery systems including changing the care team from physician-led to team led, incorporation of quality improvement processes into the care process such as clinical guidelines, and accelerated adoption of information technology into clinical practice. The results of the study by Wang et al. (2006) concluded that a system level perspective was necessary and that incremental change was not going to be sustainable to effect transformational change in health care. By 2008, Berwick argued that while some individual successes had been made, overall, health care reform was not making much progress. Berwick (2008) continued to outline a triple aim for health care that provided

broad vision with linked objectives to address the health of populations, the overall experience of care, and the cost per capita for health care. A system level perspective was necessary to achieve the goals outlined by the IOM report in 2001 and having goals that linked objectives across all aspects of care was critical to achieving transformational change in health care.

From the policy perspective, many continued attempts have been made to institute reform through policy changes. The Clinton health care plan in 1990 met with severe resistance from multiple perspectives and ultimately failed to achieve universal coverage or any significant change (Hecl, 1995). When the Patient Protection and Affordable Care Act (PPACA, often referred to as ACA) of 2010 was proposed, there was much skepticism about whether success was likely (Rak & Coffin, 2012). Health care reform while fundamentally agreed upon by the majority of Americans stimulated vehement debate about funding of insurance exchanges, and single payer discussions raised tensions with commercial insurance carriers. The eventual passing of this program established some clear processes for experimental health care structures such as the accountable care organization (ACO) that would place responsibility for the total coordination of care for populations of patients back on physician or hospital groups who would assume the cost risks of poor management (Berenson & Burton, 2012). Concurrent with this policy change, was the focus on value-based purchasing that would change the fee for service model to one based on value, health benefit over unit of cost as a measure for reimbursement, as well as measurement of performance (Fineberg, 2012). This shift mitigates the incentive to increase the volume to offset decreases in reimbursement. All

of this change in the years since 2011 has sparked health care leaders to look hard at the structure of health care that will be needed to survive in the future.

Changes in reimbursement and different metrics for judging quality have sparked proactive changes in health care structures resulting in increased horizontal and vertical integration of physician practices and hospitals. Mergers and acquisitions (M&A) have increased dramatically in the years since the passages of ACA in preparation for a pay for performance environment where health care organizations are required to manage the total care for populations of patients and assume the risks of poor outcomes (Hood, & Lawrence, 2012). As a result of this M&A activity, health care organizations are expanding horizontally, combining like function services across an area, and vertically, combining different function services, integration which increases the complexity of an organization. (Moses, Matheson, Dorsey, George, Sadoff, & Yoshimura, 2013). To achieve success in the triple aim of providing for the health of populations, different organizational structures will be necessary to manage the complexity of integrated systems of care and the ACA has provided one type of structure for organizations to start this redesign.

One of the new organizational structures encouraged by ACA was the development of accountable care organizations (ACO) responsible for the health and overall care of a population of Medicare beneficiaries. Over 300 ACOs have been formed across the nation usually as part of an integrated health network (Moses et al., 2013). The model of the ACO a group of physicians and other providers responsible for the overall care, quality and costs of a population of patients who are then able to share in the cost

savings (Berenson & Burton, 2012). The intent was to shift the thinking from a pure volume driven incentive to one where coordination of care across complex health institutions is the responsibility of the providers within the ACO (Berenson & Burton, 2012). This was just one of the many initiatives in the ACA to move away from fee for service that incentivized quantity over quality to one of pay for performance that emphasizes not only quality but value calculated as benefit over cost (James, 2012). The foundation for success of these models of care delivery was easy access to information about these populations for monitoring and quick action to prevent expensive events such as readmission to the hospital soon after discharge or preventable complications. This requires the use of integrated information technology solutions also incentivized through the Health Information Technology for Economic and Clinical Health (HITECH), which is discussed in the next section on the development of the EHR as a tool to transform health care.

Electronic health record system. Despite a call to action for major investment in information technology infrastructure in the IOM reports (1999, 2001), ongoing generalized resistance to adoption of HIT and specifically EHRs persisted for nearly a decade. The slow EHR adoption rates found by Jha et al. (2011) with only 11.5% of nonfederal acute care hospitals adopting a basic EHR, reflected the lack of confidence health care organizations had with EHRs as a solution to their complex problems (Ward, Stevens, Brentnall, & Briddon, 2008). Ford, Menachemi, Peterson, and Huerta (2009) pointed out that the resistance to adoption increased after 2004 when the first Presidential

imperative to adopt EHRs was announced. The change needed to overcome this resistance would require a policy intervention and incentives to promote adoption.

By 2009, this call to action was answered in the form of legislation intended to encourage adoption and use of EHRs. The passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act as part of the American Recovery and Reinvestment Act (ARRA) committed \$19 billion to first incentivize the adoption and meaningful use of EHRs and then to penalize those organizations lagging behind with reimbursement reductions starting in 2015 (Blumenthal, 2009). The passage of this legislation established an imperative to define what an EHR system must include through a certification process as well as a definition of what it meant to adopt meaningfully and use an EHR. Many variations of EHR systems had evolved either through the work of individual institutions or through development by commercial vendors anxious to fill a need in the health care industry (Classen & Bates, 2011). The hope was that the initial program would provide guidance and incentive in system selection and offset the costs of EHR systems sufficiently to spur implementation and provide a more consistent platform for health care reform.

To standardize the definition of an EHR as well as use of these systems, the Office of the National Coordinator for Health Information Technology (ONCHIT) worked with multiple agencies to develop standards for certification of EHR systems and administered the certification process. ONCHIT additionally developed a list of meaningful use criteria intended to establish a standard set of requirements for how an organization used the EHR with the intended result being uniform use that would limit

variation and improve quality (Appari, Johnson, & Anthony, 2013). Jha et al. (2011) described the elements of meaningful use Stage 1 as including 14 core objectives and at least five of 10 menu objectives that can be selected by the organization. The focus on these first stage measures was to encourage basic use of the EHR to capture information (Appari et al., 2013). ONCHIT reported that by 2011 adoption or intent to adopt rates for a basic EHR had increased to nearly 35% from 11.5% in 2010 (Jha et al., 2011) with many more organizations planning to attest to basic meaningful use criteria in the coming year. This rapid leap in adoption from previous years, 7.2% in 2008 and 9.2% in 2009 (Jha et al.) indicated success in the program's intent to stimulate adoption of EHR systems in physician practices and hospitals.

Continually evolving meaningful use stages were intended to push organizations to evolve and change in their use of EHR systems towards the greater goals of increased quality and efficiency. In September of 2012, the final rule for Stage 2 of meaningful use compliance was released requiring each hospital meet a total of 16 core objectives and at least three of six menu objectives (Medicare and Medicaid Programs, 2012). Objectives increasing the need for electronic communication between a health care provider and a patient focused on improving patient engagement in their care while other changes focused on leveraging the advanced functionality of EHR systems such as decision support for clinical care (CMS, 2012). While continuing incentive money for achieving Stage 2 meaningful use drives further adoption and forces organizations attesting to MU Stage 1 in 2010 to meet Stage 2 requirements, many organizations are struggling with the increased thresholds for Stage 2 related to transitions of care and patient engagement

(The Advisory Board Company, 2014). Without providing a roadmap for organizations to follow in modifying processes or the people necessary to achieve these increasingly demanding objectives, many organizations are unclear how to achieve next steps in the meaningful use journey or ultimately to achieve the triple aim. .

EHR system certification and meaningful use criteria intend to instill quality and efficiency into organizational processes, but there has been little research identifying the interactions of people, process, and technology inherent in the complicated adoption of an EHR within a complex sociotechnical organization such as an academic medical center. The majority of current research in the area of electronic health records focuses on the demonstration of specific quality gains on a local scale (Cebul, Love, Jain, & Hebert, 2011; Chaudhry et al., 2006). Yet studies that have taken a broader view of EHRs' effect on improving quality across multiple institutions have demonstrated inconsistent results (DesRoches et al., 2010; Elnahal et al., 2011; Kazley & Ozcan, 2008). The researchers (2012) from the Advisory Board in conjunction with the Health Information Management System Society (HIMSS, 2012) argued that these inconsistencies could be explained by process immaturity as well as lack of development of more advanced functionalities within the EHR namely clinical decision support tools. Given these findings, adoption of an EHR was not the end state for benefits realization; there are other more intrinsic factors within health care organizations that must be explored to leverage the EHR as a tool to achieve quality and efficiency gains.

Most of the recent research on EHRs has focused on the adoption (Angst, & Agarwal, 2009; Blavin, Buntin, & Friedman, 2010; Castillo, Martinez-Garcia, & Pulido,

2010; Gagnon et al., 2010; Hudson, Neff, Padilla, Zhang, & Mercer, 2012; Jang, 2011; Kumar & Bauer, 2011; Powers, 2011; Stream, 2009), and implementation approaches (Brooks & Grotz, 2010; Carayon, Smith, Hundt, Kuruchittham, & Li, 2009; Cresswell, Morrison, Crowe, Robertson, & Sheikh, 2011; Hollar, 2009; Murphy, 2011; Yoon-Flannery, Zandieh, Kuperman, Langsam, Hyman, & Kaushal, 2008) as key to the success of EHRs. Recent studies on the medium term impact of EHR on the organization have been inconclusive on identifying positive organizational effects and even highlighted some safety concerns created by the interaction of technology and current work processes (Cresswell et al., 2014). Regardless of these inconsistencies though, the imperative for change continues as health care costs continue to rise, and quality concerns persist. Since the passage of the HITECH Act in 2009 with meaningful use incentives, adoption rates have increased rapidly, and 44% of eligible hospitals have adopted at least a basic EHR system. (DesRoches, Charles, & Furukawa, 2013). The incentives offered to hospitals and providers for adopting EHR systems provided the needed stimulus but this accelerated adoption argued by many (Cresswell & Sheikh, 2012; Thompson, Kleinberg, & Mohan, 2013) comes at a cost both financial as well as potential adverse effects in the interaction of technology with existing processes inadequately modified due to rapid transition.

Understanding Variation

Variation in health care organizations and provider performance was one of the main contributors to increasing costs and variations in quality. Sirovich, Woloshin, and Schwartz (2011) found that 42% of primary care providers felt that patients in their

practice were receiving too much care driven by financial incentives that support overtreatment and not enough time spent with patients. When viewed from a national level, Fisher, Bynum, and Skinner (2009) found wide variation in Medicare spending across different U.S. regions indicating a range of practice patterns without effect on patient outcome or quality of care. Berwick and Hackbarth (2012) argued that focusing on areas of waste could have a tremendous effect on costs over time without the need to ration appropriate care. Use of EHRs to identify and address these variations in health care delivery was possible, but the implementation and use of EHRs was also faced with variation that need to be addressed.

Successful introduction of EHRs into health care faces many challenges including the variety of systems available, varying from basic to comprehensive EHRs and many more variations in organizational structure and culture in the health care organizations where these systems are being implemented. Albadvi, Keramati, and Razmi (2006) argued that in their examination of information technology's impact on firm performance in a manufacturing plant that mediating factors affected the level of improved performance observed. Moreover, Markus (1983) argued that a misunderstanding of the culture and environment in which an information system was applied can mean the difference between success and failure. In health care, differences in subcultures based on discipline can also lead to differing perceptions of the EHR as a tool for accomplishing needed tasks (Callen, Braithwaite, & Westbrook, 2008). Each element of culture and organizational structure adds variables to the value equation for the EHR in accomplishing the goals of health care reform therefore, describing the system being

studied in as much detail as possible improves the level of transferability of the knowledge gained (Rippen et al., 2013). To achieve the lofty expectations of technology when applied to health care, implementation and adoption are only the first steps (Sittig & Classen, 2010). Further understanding of the interactions of technology with processes and people becomes a critical factor and one that needs to be closely examined to understand the effects of technology on the U.S. Health Care system as adoption rates are quickly rising.

To provide a close comparison across health organizations and EHR systems, a scale that indicates the level of system components present and its use should be used. The Health Information Management System Society (HIMSS), a purposed based nonprofit professional organization, developed an Electronic Medical Record Adoption Model (EMRAM) for use in standardizing EHR adoption levels by function and process changes (HIMSS, 2014). This model provides for eight levels of EHR functionality acceptance providing a method of comparison across organizations to account for the variation in EHR system capabilities and organizational decisions around adoption (Jarvis, et al., 2013; Shea, Weiner, & Belden, 2012). Factors affecting the adoption of EHR functionality within the organization are often dependent on organizational characteristics that also demonstrate wide variation in multiple factors.

With the evolution of quality, efficiency and reimbursement regulations in the last five years, health care organizations have been forced to adapt in a variety of ways through mergers and acquisitions, as well as affiliations, to achieve stability. Pina et al., (2014) described a framework to understand the evolving structure of health care delivery

organizations through the use of six factors, capacity, organizational structure, finances, patients, care processes and infrastructure, and culture. The authors argued that this framework could be used for comparative effectiveness research across organizations when evaluating interventions to improve the quality, efficiency, and cost. Shea et al. (2012) identified a framework using people, process, and technology as categories to assess the capacity of organizations to achieve the meaningful use of EHR systems. The authors found that most ambulatory practices have the requisite people capacity; however, there were deficiencies in the process and technology areas that affected their ability to achieve meaningful use criteria.

Psychology

The medical system in the U.S. has grown out of a cottage industry initially focused on single practitioners caring for individual patients often at home. This entrepreneurial spirit has been an inherent attribute of the growth of medicine throughout the last century as medical technology has evolved, and the number of medical specialties and subspecialties has exploded (Fuchs, 2012). As health care reform initiatives have been proposed the American Medical Association (AMA) has been a stalwart defender of the autonomy of physicians often at the expense of reform initiatives such as universal health care or single payer systems due to the potential effect on physician reimbursement (Blumenthal, 2006). This backdrop has limited the possible options for health care reform in a complex environment with many special interest groups having trenchant perspectives to defend.

While having a different history, nurses also provide a critical service in the health care organization and collaboration with physician partners is essential to the holistic care of the patient. Often this collaboration has been troubled by a variety of factors including an unequal status as the decision maker and often feeling subordinate to the physician (Johnson & Kring, 2012). The differences between professional groups both in education and practice, have led to divergent processes of care delivery as well as methods of capturing clinical knowledge (Hall, 2005; Stein-Parbury & Liaschenko, 2007). Further, advent of the nurse practitioner role to fill the gap in primary care as a more independent practitioner at a lower cost has met with resistance from the medical community as a threat to autonomy (Donelan, DesRoches, Dittus, & Buerhaus, 2013). These differences and tensions pose a challenge to EHRs to ensure that processes of care are supported for both professions, and a balance is found in shifting responsibilities for information capture and knowledge generation.

Physician and nurses perceptions of EHR technology differ in the usefulness in practice as well as risks to care quality Callen et al. (2008) found that the subcultures of medicine and nursing affect perceptions of computerized physician order entry systems on the overall quality improvement of such systems with nursing being more positive and physicians being more negative. DesRoches, Miralles, Buerhaus, Hess, and Donelan (2011) found in a national survey of nursing a predominantly positive attitude towards HIT effects on nursing workflows. Physician perceptions of HIT are often framed in the context of adoption rates and barriers to adoption with the focus on time to learn the system, time to enter information and impacts on productivity being the major barriers

(Boonstra & Broekhuis, 2010). Each of these group perceptions affects the usage and ultimately the effect of an integrated EHR on organizational structure, process, and outcomes.

Theory of Knowledge

The randomized control trial, as a method of knowing, was the gold standard for medicine to determine the effects of selected treatments on the patient's outcome. This cause and effect method of study was difficult if not impossible to design on an organization-wide basis that involves many social and technical variables (Keller, Gare, Edenius, & Lindblad, 2010). Typical randomized control trial studies for the evaluation of EHRs focus on usability of system features and effects on the user (Lobach & Detmer, 2007). Another common method of understanding the effects of HIT on health care delivery is the preintervention and post-intervention study focusing on quantifying the outcome of the HIT intervention on the environment (Poissant & Pereira, 2005; Westbrook, Li, Georgiou, Paoloni, & Cullen, 2013; Zlabek, Wickus, & Mathiason, 2009). Much of the earlier research on EHRs focused on quantitative studies looking at the cause and effect relationship between specific independent variables of the EHR and clinical or operational dependent variables (Greenhalgh, Potts, Wong, Bark, & Swinglehurst, 2009). While this research aim focused on the technology, the lack of inclusion of the environmental context hampered the holistic understanding of EHRs on organizations.

After 2009 and the passage of the HITECH Act that stimulated adoption through financial incentives, the focus of research shifted to usability, unintended consequences and the qualitative experiences of use. Kaushal, Barron, and Abramson (2011) described

the local organizational findings of a comparison of a standalone eprescribing system and one integrated into an EHR system and highlighted the workflow context as affecting the instance of medication prescription errors. Qualitative research done by Cresswell et al. (2014) identified limited medium term effects of order entry and clinical decision support systems on two hospitals emphasizing the need for broader understanding of these systems in a variety of clinical settings over longer periods of time. King, Patel, Jamoom, and Furukawa (2014) found; however, that in a national survey that physician perceptions were the EHR improved patient care overall. The variation from local organizational findings and national comparison studies while showing differences in findings highlight a shift in research to operationalizing EHRs that are more widely adopted due to national incentives. While there has been a shift in EHR system research since the passage of the HITECH Act, methods of understanding continue to focus on a single aspect of change without taking a holistic organization level view of the effects of an EHR. Greenhalgh et al. (2009) argued that this focus on the EHR as tool lends itself to the positivist ontology of cause and effect and the effects of the EHR being predictable and measurable. Greenhalgh et al. (2009) continued that a more interpretivist perspective holds the EHR as a social construct and actor that interacts with users and environmental context to result in fewer predictable outcomes, which require broader understanding of the organization to understand the effect. Taking this interpretivist approach provides a broader perspective in viewing the effect of the EHR on the organization as a complex adaptive system.

Summary and Conclusion

The health care system is a complex adaptive system with many components that are interconnected and evolve over time in reaction to the local environment both internal and external to the system. A fundamental change in the view of health care delivery as a machine with interchangeable parts to one similar to a living organism was necessary to understand how change occurs in health care and to inform health policy at both the national and local levels in driving the triple aim of health care reform. EHR systems can provide needed structure for linking the multiple facets of a health care delivery organization together and allowing for more integrated and coordinated care but there are many challenges to achieving this success that have yet to be explored in depth.

In Chapter 3, the methods for evaluation of an academic medical center recently adopting an EHR system are outlined using the framework from Rippen et al. (2013) as well as the lens of complexity to understand how the local interactions change with the additional of the EHR. Further details are described for participant recruitment, participation, and data collection with additional focus on the trustworthiness of the study approach.

Chapter 3: Research Method

The purpose of this qualitative case study was to explore the people, processes, and technology factors that change as a result of an EHR implementation. The outcome was a summative evaluation of the effects of a comprehensive, integrated EHR system on a large urban academic medical center at the organizational level. Much of the knowledge around EHRs has focused on their implementation and adoption due to governmental incentive programs that have stimulated organizations to purchase or build their own systems (Charles, Gabriel, & Furukawa, 2014). As with any system, changes in one area (such as the use of an EHR), could have unforeseen effects on intrinsic elements. These effects can result in emergent behaviors that are unexpected (Harrison, Koppel, & Bar-Lev, 2007). Understanding the changes to the organization that results from the implementation and adoption of an integrated EHR system, therefore, becomes important in the evaluation of whether EHRs can be used as a tool to achieve health care reform.

The following sections in this chapter include research design and rationale with emphasis on the qualitative case study approach, role of the researcher, methods including participant selection, processes for recruitment, procedures for data collection, the plan for data analysis, and finally issues of trustworthiness and ethical considerations. Each of these sections outlines the foundations of the study to be performed and emphasize the appropriateness of this approach to the subject matter.

Research Design and Rationale

The research questions focus on the people, processes, and technology factors and their interactions to achieve change.

1. How do the interactions of people change as a result of an EHR implementation?
2. How do organizational processes change as a result of an EHR implementation?
3. How do technologies change as a result of an EHR implementation?
4. What are the summative outcomes of an integrated EHR system at an organizational level?

EHR adoption and use in health care has increased dramatically in the last 5 years since the passage of the HITECH Act (Jha et al., 2011) and despite a variety of research studies over the last decade or more indicating the positive effects of the EHR on clinical outcomes, efficiency and cost (Butin, Burke, Hoaglin, & Blumenthal, 2011) the real benefits have been difficult to quantify (Cresswell et al., 2014). When looking at the quantitative results of an EHR on the care of a specific chronic condition like diabetes, some positive effects on clinical outcomes have been achieved (Cebul et al., 2011). Other authors have identified modest gains in clinical outcomes through quantitative analysis of hospital data on the treatment and outcomes of diseases such as heart failure and pneumonia as well as decreases in the process variation resulting in surgical site infection (Himmelstein et al., 2010; Jones & Rudin, 2014). These findings have been refuted by other authors as not generalizable to the broader health care community due to the differences in organizational structure and processes that affect the outcomes (Chaudhry et al., 2006). Further limitations on quantitative studies at the organizational level are the sheer number of variables to be controlled (Lobach & Detmer, 2007). In order to identify the variables of interest in a cause and effect relationship many authors have looked at national aggregate data to evaluate the quantitative effects of EHRs on quality, cost and

efficiency (Appari et al., 2013; Elnahal et al., 2011; McCullough, Casey, Mosovice, & Prasad, 2010; Patel, Jamoom, Hsiao, Furukawa, & Buntin, 2013). These quantitative studies lack the local context that ultimately drives the outcomes of EHRs in an organization. Considering these findings, quantitative research methods were considered but ultimately rejected as a means to answer the research questions for this study.

Mixed methods as a research approach blend the quantitative and qualitative approaches to achieve a more tightly defined result while also incorporating the depth and ambiguity of perceptions and experiences in the real world. The challenge with this approach in studying the effects of an EHR on an organization are the limited direct effects of the EHR on patient outcomes; often researchers are required to substitute proxy variables as measures of outcomes in quantitative analysis (Lobach & Detmer, 2007). Therefore, blending the quantitative and qualitative approaches becomes difficult especially when looking at the organizational level. Some authors have used mixed methods by combining survey data with interviews and observations to determine the usability of specific EHR systems (Doran, Reid-Haughian, & Cafazzo, 2012; Pirnejad, Niazkhani, Van der Sijs, Berg, & Bal, 2009). These authors focused on specific aspects of clinical care, however did not address the organizational level changes with the EHR implemented in a HSO. Without having a clear hypothesis to test the organizational effects of an EHR and after some consideration designing a research study using mixed methods would be difficult and not meet the purpose of this study therefore mixed methods was also rejected as a research method for this study.

In order to address the more holistic perspective of organizational changes, the local context and depth of understanding was needed which can only be provided through a qualitative approach that may then lend itself to more quantitative or mixed methods approaches to further understand the phenomenon. Understanding the qualitative sociotechnical changes in an organization with the implementation of an EHR could provide a broader insight into the changes that occur. Qualitative research methods allow for a deeper and broader understanding of the local context in which studied activities occur. Qualitative research involves data collection using three methods: open-ended interviews, observations, and review of documents (Patton, 2002). Kaplan and Maxwell (2010) argued that qualitative methods offer an opportunity to examine the processes involved in a changing environment as opposed to the quantitative focus on understanding the static structures of a concept or event. With the rapidly changing health care landscape and the coevolution of EHRs to meet the changing needs of health care, the qualitative research method provides more appropriate tools to further a deeper understanding of the summative effects of the EHR on the organization. Qualitative methods were therefore selected as the most appropriate research method for this study.

There are many qualitative designs that provide varied perspectives in gathering data that will be explored in the following paragraphs. Qualitative research design includes narrative, phenomenology, ethnography, grounded theory, and case study (Creswell, 2014). Each of these designs provides a particular insight into the study of information systems; therefore careful selection was necessary to achieve the optimal result. Creswell (2014) defined the narrative design as telling the story of one or more

individuals' lives to highlight a specific attribute. As this approach has a narrow focus on one or more individuals and dives deeply into the lives of the individuals, it does not lend itself to the study of an organization. The phenomenological research design focuses on the lived experiences of a group of individuals experiencing a specific phenomenon (Moustakas, 1994). This approach more closely matches the needs for evaluation of an organizational effect of an EHR system, but the focus was on the individuals' experiences and not the summative effects at the organizational level. Ethnography as a research design is focused on the culture of a group of individuals and the evolution of this culture over time (Patton, 2002). Patton (2002) pointed out that this method of study has been used for program evaluation with the ultimate purpose of changing the program culture. Often this method is undertaken over prolonged periods of time to understand subtle changes in culture and parse out the influencers of change (Patton, 2002). Considering the rapidly changing environment of health organizations and the effects of EHRs, this method while useful does not fit the intended purposes of this study. Grounded theory is a research approach that focuses on the development of a theory to explain a phenomenon or event through inductive reasoning (Strauss & Corbin, 1998). Patton describes this as building from the ground up. Many researchers have used the grounded theory approach to understand the intricacies of EHR adoption and implementation with some success (Embi, Yackel, & Logan, 2004; Huryk, 2010; Yoon-Flannery et al., 2008). This research approach is also attractive for the research on the organizational effects of the EHR but due to the complexity of HSOs there may be too many confounding effects to develop one unifying theory of how the organization was affected by the EHR. The remaining

qualitative research design, case study was chosen for this study and is described in more detail in the follow section.

Case study, as a research design, can cross methods from quantitative to qualitative and can be used for exploratory, descriptive, or explanatory purposes. Yin (2009) argued that there are three variables that need to be addressed when choosing a research method: (a) type of research question, (b) the amount of control the researcher has over the behavior of the participants, and (c) whether or not the concept to be studied is contemporary or historic. The author explained that specifically the case study approach can be useful for how and why research questions and refutes the assumption that case study research can only be used for exploratory preliminary research (Yin, 2009). The case study approach allows for data collection through observation, and interviews as well as documents or artifacts that are present as part of the object of study (Yin, 2009). Crowe et al., (2011) described the case study approach as a well-established method of studying in depth the phenomenon of interest. Case studies, as described by Yin (2009), are also flexible in the unit of analysis and can focus on an individual, a decision, a program, or an organization experiencing a specific phenomenon. This flexibility in case definition allows for a holistic view of the health care organization as the object of study and according to Anderson, Crabtree, Steele, and McDaniel (2005) aligned well with complexity theory in understanding health care organizations as complex adaptive systems.

Role of the Researcher

The role of the researcher in this qualitative case study was to collect the data through semistructured interviews, observations, and document review. I functioned as the research instrument through the design and execution of an interview and observation protocol comprised of interview questions to gather information to answer the research questions and explain the effects of an EHR system on an academic medical center as the unit of analysis. I was responsible for validation of data collection through triangulation of data from different sources and member checking to ensure consistency in interpretation of responses. I also identified applicable documents that provide an insight into the research questions. These documents were carefully logged to track inclusion in this study.

To identify and mitigate any research bias, I must disclose that I am an employee of the organization to be studied. Currently, I am a senior director in the information technology department responsible for the deployment and maintenance of the EHR. I have been employed at the institution to be studied for the duration of the EHR implementation (since 2005) and have many formal and informal relationships with other members of the organization. This study is intended to focus on the clinical and operational effects of the EHR on the organization as a whole. While I am known to many of the senior level administrative officers of the organization, there was no direct reporting or supervisory relationship with any of the intended participants in this study. The other groups to be included, the physician and nursing disciplines, will most likely

not be known to me but may include some participants where previous collegial relationships existed.

All of these relationships hold the potential for biasing me in the data collection processes of this study. I maintained a log of thought processes involved in participant selection as well as avoided any potential biased relationships. Each participant was ensured confidentiality of the information that was shared to further support truthful information exchange intended solely for the furtherance of research knowledge about the effects of the EHR on a complex adaptive system such as an academic medical center.

Methodology

The proposal for this research study was submitted to the Walden University IRB for approval. Approval number 04-16-15-0148499 with conditional approval pending community partner approval. After some further discussions with the hospital, it was determined that IRB approval through the hospital was also needed. This approval was obtained on August 3, 2015, GCO # 15-03248 with the requirement that I use the hospital consent form for the informed consent. This was submitted to the Walden University IRB as a change in procedure and was approved on August 24, 2015. No data was collected prior to both IRB processes and the change in procedure being completed. An extension to the Walden IRB approval was granted on April 13, 2016 for 1 year if needed. Final documents closing the study with the hospital IRB were submitted on June 21, 2016.

Participant Selection Logic

The unit of analysis or case in this study was a single academic medical center located in the northeast of the United States in a large urban setting. The population was

all staff, faculty, and voluntary physicians providing care and using the EHR at this academic medical center. This population represents approximately 2,500 physicians, 2,000 nurses, 1,000 residents, and 2,000 additional staff. The goal of this study was to focus on the primary users of the EHR either for the provision of patient care or organizational decision making. The sampling design for this study was intended to be nonprobability and purposive to ensure the most salient aspects of the organizational changes with EHR use are highlighted in this case study. Three general groups were targeted for inclusion, physicians (both faculty and voluntary), nurses, and senior administrators such as the C-Level officers of the organization. These three groups represented differing perspectives and goals in care delivery and represented variation across the unit of analysis (Nugus et al., 2010). Patton (2002) argued that the sample size in the qualitative study is elusive and not guided by specific rules but is driven by what knowledge is sought. For this study, a minimum sample of 20 participants was selected to provide adequate insight into the three categories of EHR users. During this sampling, I monitored for redundancy of data collection and reached saturation at 20 participants.

Purposive snowball participant selection was used to identify participants across a range of disciplines within the academic medical center. Patton (2002) pointed out that participant selection is one of the primary differences between quantitative and qualitative research with the goal of the latter being to locate a small number of information-rich participants that can provide information on the topic being studied. Hence, the purposive selection methods are not intended to be random but more focused on finding those participants most likely to provide insight into the research questions.

Patton (2002) also described snowball sampling as a technique of identifying new potential participants from each participant interviewed by asking them who else might have insight into the identified problem or question. Using this approach to participant selection allowed for quick identification of the most information-rich participants as well as documents to review as part of this study.

Every attempt was made in this study to cover the following disciplines, nursing, physician, and senior administrative officers. Initial identification of participants was made through analysis of primary stakeholders in the use or planning of the EHR. The goal was to identify commonalities and differences in perspectives on the effects of the EHR both planned and post implementation. The selection process also included perceived outliers such as voluntary physicians who send their patients to the hospital for acute care who may have differing perspectives than faculty physicians.

Instrumentation

An interview protocol was developed (see Appendix A) based on the work of Creswell (2014) that included a heading, instructions for the interviewer, the questions, and probes to use as follow up. All interviews were digitally recorded for further analysis with the participants' permission. I paid a transcriptionist to transcribe the recorded interviews verbatim for incorporation into NVIVO 10. In addition, a log was kept of all documents to be reviewed from the organization. Participants were asked if they are aware of any documents or other participants that may further the understanding of the effects of the EHR on the organization.

An observation protocol was developed (see Appendix B) based on Creswell (2014) including demographic data on the location and or setting of the observation, participants in the observation, time, and date. The remaining page was divided into two sections with descriptive notes on the left used to explain what was observed in an objective manner and the right side used for my reflective notes and assumptions of what was observed. All observations notes were transcribed into electronic format for further analysis.

Procedures for Pilot

In order to ensure the appropriateness of the interview protocol, a pilot study was performed with two participants. The purpose of the study was explained. These participants were used to understand if the interview protocol (including interview questions) achieved the necessary depth of information around the main case study. The pilot study participants had the information from the interviews provided back to them for review to check for accuracy and modifications to questions that were not felt to be necessary. Yin (2009) argued that the pilot study is important in case study research to hone data collection methods as well as to ensure the content of the data collection furthers the research purpose. In addition, the pilot study can provide needed insight into the participant selection for the main study by identification of primary roles in the evaluation of the EHR effects.

Procedures for Recruitment

The participants for this research study were members of a single academic medical center located in an urban environment. The participants were from different

disciplines including nursing, physicians, and senior administrative leadership within the organization. The senior administrative leadership was easily identified by roles in the organization such as the chief financial officer, chief nursing officer, and chief operating officer. To identify the other groups, subgroups were identified to ensure breadth of coverage where possible. First, for the physician discipline the subgroups included, faculty attending physician, resident, and voluntary attending physician. For nursing, the subgroups included adult critical care nurse, adult medical/surgical nurse, and maternal child health nurse. For each of these subgroups in each discipline, I first contacted the leadership for each group to explain the purpose of the study and the requirements for participation and then asked for identification of potential participants.

Procedures for Participation

Participants were asked to join an individual interview session to last from 45 minutes to 1 hour. Each participant had the purpose of the study explained and informed consent completed. Each participant was given the opportunity to stop the interview at any time if necessary or to refuse to answer any particular question.

A semistructured approach to interviewing was used based on the interview protocol in Appendix A. The intent was to structure the interview more as an informal conversation to elicit the depth of personal experience with the EHR. Patton (2002) identified this method as conversational but related to a set of issues that are preestablished. This approach allowed for both the collection of the interview protocol questions as well as allowed flexibility in the identification of adjacent and congruent streams of thought.

Procedures for Data Collection

The purpose of this qualitative case study was to explore the people, processes, and technology factors that change as a result of an EHR implementation. The outcome was a summative evaluation of the effects of a comprehensive, integrated EHR system on a large urban academic medical center at the organizational level. Semistructured interviews with participants were conducted to collect data on individual experiences with the EHR and the effects on the organization. I kept a self-reflective journal to identify and factor out any bias in data collection and ensure reliability of data collection.

Twenty-one participants were identified in total representing the three groups of stakeholders outlined above. After each interview, analysis was performed on the content received, and the quality of data was evaluated in finding answers to the established research questions. I looked for saturation in themes and categories of data collected. Patton (2002) described saturation as the point at which no new insights are obtained from new data collection. I also looked for disconfirming evidence to improve the trustworthiness of the study and provide as full a picture as possible.

Yin (2009) pointed out that in case study research multiple types of data are collected. These include documentation, archival records, interviews, direct observations, and physical artifacts. Yin (2009) continued on to say that interviews are one of the most important methods of data collection in case study research and other elements such as documentation and archival records can be used to corroborate or disconfirm the data collected during interviews. This use of triangulation in case study research is essential to improving the credibility of the data collected.

I used multiple types of triangulation during this study to increase credibility and gain accurate insights into the effects of the EHR. Patton (2002) described four types of triangulation that include: investigator, data, theory, and methodological. I was the only investigator in this study thus focus was on the remaining three types of triangulation. Data triangulation was achieved through identification of multiple sources of data including award submissions, operational reports and publications, and organizational changes since the implementation of the EHR. Data were also collected through interviews with a variety of personnel within the organization from different disciplines and perspectives to highlight differences, as well as consistencies. Inclusions of observations in the use of the EHR in daily work also provided methodological triangulation used by others authors to increase credibility (Yusof, Kuljis, Papazafeiropoulous, & Stergioulas, (2008).

I sought out specific documents that may provide evidence of the effects of the EHR on the institution such as documents and records indicating the achievement of the EMRAM certification levels and other professional association awards requiring documented evidence of EHR use and outcomes. Participants were also queried to determine if other documents are available for this purpose as well. Each document or archival record was logged to track its content and use.

Data Analysis Plan

Yin (2009) described the data analysis portion of case study research to be one of “the least developed and most difficult aspects of doing case studies” (p. 127). Given this challenge understanding the approach to data analysis must be determined before data

collection beginning (Yin, 2009). Creswell (2014) argued that case study data analysis need to include rich detail of the setting and individuals that is then analyzed for themes and patterns. Patton (2002) also supported the need to identify patterns in the data and specifically for case study research, the multiple sources of data need to be collated, and condensed into a coherent package for analysis. Patton referred to the process of condensing data as content analysis. The next paragraphs outline the steps that were taken in this study to condense and bring meaning to the data collected.

The data collected for this study were transcribed into NVIVO 10 for analysis. Exact documentation of interviews transcribed by a transcriptionist and all documents and archival data were imported into this tool for analysis. This approach also included research notes and journal entries. The next step was to code the data by identifying common descriptions in the data; labeling each with a summary or category for further analysis (Creswell, 2014). I made efforts to identify commonalities and differences in the interview data from each of the respective groups of participants, administrators, physicians, and nurses. Commonalities in responses were grouped together and coded for further analysis, and differences were used to understand where further gaps in understanding exist, needing additional exploration, and perhaps data collection. As each interview was completed, data analysis was done, which influenced the understanding and direction of further data collection. Miles, Huberman, and Saldana (2014) described two levels of coding with first cycle codes used to initially identify labels that describe chunks of data and second cycle codes being used to further condense data into patterns and themes. The authors described an example of first cycle coding as descriptive. This

approach was used to provide high level categories to the data collected in this study such as efficiency, improvement, change, or complexity. Second cycle coding evolved from the first cycle codes as a method to further condense and bring meaning to the data collected. Huberman et al. described second cycle coding as generation of patterns between data sources to identify higher-level themes. This analysis allowed me to analyze the relationships between participants in the study. The second cycle coding was also used to identify the rules that govern the actions of the agents in this study. This process of multiple cycle coding was used inductively to identify patterns and themes across the organization that can be used to understand the organizational changes occurring with the EHR implementation the complex adaptive system.

Yin (2009) pointed out that while computer software can be helpful in organizing research data, the coding and analysis requires the researcher to develop an analytic framework that links back to the research questions and conceptual model used for the study. I used the matrix approach advocated by Miles and Huberman (1994) to play with the data by aligning codes and themes into a matrix where data can be added. Rippen et al.'s (2013) categories were used to populate this matrix as a framework for analysis. Yin argued that aligning the analysis with the theoretical propositions is the most preferred method of data analysis in case study research. This allowed for identification of missing data as well as further illuminated relationships and themes in the data collected. The categories from Rippen et al. (2013) were used to guide this categorization of the data for further analysis of themes and to identify gaps in data collection. Data saturation can be identified when data from interviews becomes redundant, and each cell in the matrix is

filled with data. To avoid confirmation bias, I identified outliers in the data and examined all aspects of interpretation to explain the findings using the literature and my knowledge to provide an objective analysis of the findings. Yin (2009) argued that there are four elements needed for high quality analysis of case study research: all evidence must be considered, all major rival interpretations must be explored, the analysis must address the most significant aspects of the study, and the researcher's prior expert knowledge should be used in the interpretation. Each of these approaches was used in the analysis of the data from this study to further the understanding of the effects of the EHR on an academic medical center.

Issues of Trustworthiness

Validity and reliability are terms used in quantitative research to describe the level at which research findings accurately represent reality and are repeatable. In qualitative research, there is much debate on the level at which these can be achieved (Creswell, 2014; Miles et al., 2014; Patton, 2002). To address these concepts without blurring the context of the quantitative definition, alternative concepts have been identified to support the usefulness and solidity of qualitative approaches. The following sections outline the elements incorporated into this study to achieve these goals.

Credibility

Credibility linked to the concept of validity in quantitative research is used to describe the level of truthfulness that comes from the research findings. As qualitative research comes from deep and rich descriptions of people's experiences, variation may occur across different groups of people in different settings. This was one of the core

issues in the works done by Litaker et al. (2006) and Mathews and Thomas (2007) on complexity in health care indicating that local context matters when evaluating the effects of the EHR on processes and structure. Houghton, Casey, Shaw, and Murphy (2013) argued that credibility in observations come from prolonged and persistent engagement in the environment to ensure full comprehension of the environment. The methods in this study to assure credibility included the use of rich descriptions of the context of EHR use, member checking to ensure that data were accurately captured and triangulation of multiple data sources as much as possible (Miles et al., 2014). Additional efforts were made to link findings to current literature and seek out disconfirming evidence to present a balanced picture of the findings.

Transferability

While the findings of this qualitative case study may not be completely transferable to other settings that do not have the same characteristics, I made every effort to ensure the specific characteristics of the case are described in detail and categories of analysis follow consistently with other research described in the literature. The techniques of data collection and temporality of the data collection are approaches that can be transferred to other research studies and would build upon the deeper understanding necessary to guide future policy steps driving the use of EHRs in academic settings.

Dependability

Reliability is the antecedent of dependability. As the reliability is based on repeatability in different settings, qualitative research struggles considering the changes

in context that affect the rich data involved in qualitative research. Miles et al. (2014) made the point that dependability in qualitative research can be obtained through the clear articulation of research questions, the researcher's role in data collection and interpretation being explicit and data quality checks being incorporated into the research design.

The research questions and role of the researcher were clearly defined by the alignment with current literature in Chapter 2 and explicit description of the researcher role and potential bias in the sections above. Data quality checks including keeping a research journal to highlight perceptions of the researcher after each interview, member checking of data and triangulation of data sources were all incorporated into the design of this study to improve dependability.

Confirmability

The final element of trustworthiness is confirmability or objectivity, which requires the researcher to be explicit about methods used in gathering, analysis and forming conclusions about the topic of study. Miles et al. (2014) explained that confirmability could be increased in qualitative studies through the explicit description of methods and clear linkages from conclusions to data collection and analysis.

The elements of this study design reflected these concepts through the use of a researcher journal to capture perceptions of the researcher of each interview and data element analyzed. In additional processing of the data through data matrices, coding, and pattern identification were explicitly described to allow for auditing of the approach and ultimate conclusions.

Ethical Procedures

Ethical considerations in research range from the proper treatment of human subjects to the responsible handling of participant and organizational data obtained as part of the research process. Creswell (2014) encouraged researchers to consult with professional organizations for codes of ethics that may guide the performance of research in a specific field. The American Medical Informatics Association (AMIA, 2014) is a professional organization dedicated to providing leadership in the transformation of health care through the application of information science and education. AMIA published a code of ethics to guide members in ethical considerations of daily responsibilities, as well as research endeavors related to health care information technology (Goodman et al., 2012). Specific elements of this code of conduct that apply to this study include the concepts that professionals performing research or working in the field of clinical informatics often have multiple roles with differing responsibilities, one for the direct care of patients and the other for development and/or research in the information science field. The authors point out that in all circumstances the care and treatment of the patients must take priority even if the work of the researcher or professional is not directly related to care delivery. An additional element of this code of conduct is the duty to never disclose biomedical information and protect the confidentiality of the patient at all times (Goodman, 2012). Each of these elements provide an overarching code of ethics to professionals in the field of clinical informatics and were carefully considered in the execution of this research study by avoidance of

patient-centric data in the data collection approach and careful consideration in data collection methods to prevent impedance of patient care activities.

Goodman et al. (2012) also pointed out that during activities of research or otherwise a professional may be made aware of defects or processes that might cause a patient safety concern. It is, therefore, the obligation of the researcher to communicate such findings to the respective leadership in the organization to ensure these findings are investigated further to avoid patient harm. Finally, Goodman (2012) pointed out that employers have certain requirements of employees to protect the interests of the organization through guarding of intellectual property as well as other information that could be damaging to the organization. Commercial EHR systems also have proprietary rights to protect intellectual property. During the performance of this research study, confidentiality was maintained for participants as well as the organization and vendor to protect these rights.

Treatment of human participants. Each participant in this study was provided an explanation of the study including an informed consent form for signature prior to participation. This informed consent included identification of the researcher, sponsoring institution, purpose of the study, benefits and risks of participating, guarantee of confidentiality and assurances that the participant can withdraw at any time without consequences (Creswell, 2014). A copy of the informed consent form is included in Appendix C. All efforts were made to incorporate the concepts of honesty, trust and respect into this research study as outlined by the National Institutes of Health (NIH) *Protecting human research participants* (NIH, 2011) program.

In addition to the university institutional review board process, organizational permission for this study was obtained through the presentation to the organizational intuitional review board to ensure all conflicts of interest are explored and mitigated. Approval forms are included in Appendix D.

Ethical concerns with recruitment and data collection. Recruitment of participants in this research study was voluntary with no coercion to participate or consent. Explanations of the purpose of the study were communicated honestly with no deception. All attempts were made to include major populations of EHR users within the scope of this research study including nurses, physicians, and administrators without excluding any particular group or subgroup from participation. Participants were informed of the purpose of the study as well as the potential for publication. Participants were assured of confidentiality of all data provided with any documents being de-identified.

During data collection, the setting and length of interviews was arranged to not interfere with daily work efforts or patient care activities. Participants were selected in a manner that avoids any authoritative power over or between the researcher and the participant. Data collection was limited to information necessary to gain answers to the stated research questions and avoided questions that may be considered harmful to the organization or the participant (Creswell, 2014). All participants were given the option of not answering specific questions or rescinding their consent to participate in the study at any time. I identified participants until saturation of data is achieved. Any participant

withdrawing from the study or refusing to participate or answer questions were replaced by other participants.

Treatment of data. Data collected from participants was kept confidential, and the individual roles of participants were kept confidential. While this was easily achievable for most participants such as individual nurses and physicians, the executive level roles were harder to keep confidential due to a limited number of people in roles such as the chief nursing officer (CNO) or chief financial officer (CFO). I kept the names of these participants confidential but argue that the identification of role in this circumstance was important to the overall outcome of the data analysis as the perspectives of business-oriented roles such as the CFO and the clinical orientation of the CNO can be quite different and potentially valuable. This differentiation was made clear to these participants during the informed consent process to allow for autonomous decision-making as to whether to participate or not. Overall the confidentiality of the organization was maintained as well to prevent any negative repercussions from research findings. All findings were analyzed with the intent of improvement of EHR use and effects and not from the perspective of assigning blame or culpability to the specific organization.

Data collected during this study were kept confidential in secure computer files and paper documents were not be identified with specific participant names or identifiers. I was the only person with access to the data collected and all data collected including any documents will be destroyed 5 years after publication. Specific permission was

obtained for any institutional documents or archival data that is identified or used in this case study. Records of these permissions will be maintained for 5 years after publication.

Other ethical concerns. One ethical element pointed out by Yin (2009) was the importance of avoiding bias toward previously accepted outcomes because the case study researcher must have familiarity with the environment and issues to be studied. In this research study, I am an employee of the organization to be studied, and this may present a conflict of interest. I hold a position as senior director in the information technology department responsible for the implementation and support of the EHR system. The summative evaluation of this system proposed in this study was intended to illuminate the gaps in understanding of the effects of the EHR on a complex adaptive system such as an academic medical center. The system implementation in this organization has been considered very successful by all leadership both internal and external to the organization in question so there was no existing motive by myself to increase the reputation of the organization or any involved in executing this study. Identification of the gaps in understanding of such system will further future initiatives in other like settings. To further mitigate the effects of myself as the research instrument, a detailed research journal was kept with entries included after each interview or data collection event to elicit researcher perceptions and biases so they can be identified and prevented from affecting the objectivity of the research findings.

Summary

The methods used in this research study followed the qualitative case study approach in order to gain depth of understanding of the effects of the EHR on a complex

adaptive system through semistructured interviews and review of organizational documents. The case study approach provided a good fit for the purpose of this study and allowed for the flexibility necessary to evaluate the summative effects of the EHR on the organization. The selection of participants in this study was critical to obtaining the information necessary to achieve my goals. A specific interview protocol was developed to guide the data gathering process and specific tools have been outlined for the data analysis that began after the first data collection and extend throughout the data collection process.

Issues of trustworthiness have been outlined to increase the credibility of the results of this research and to allow for further building upon the findings of other researchers. Ethical considerations have also been outlined in order to make explicit the methods of protecting the human participants, as well as the organization from harm. My role in the organization has also been made explicit in order to establish procedures to mitigate bias and ensure quality results. Chapter 4 includes the results of the research findings as well as limitations of the data collected.

Chapter 4: Results

The purpose of this qualitative case study was to explore the people, processes, and technology factors that change as a result of an EHR implementation. The outcome was a summative evaluation of the effects of a comprehensive, integrated EHR system on a large urban academic medical center at the organizational level. Much of the knowledge around EHRs has focused on their implementation and adoption due to governmental incentive programs that have stimulated organizations to purchase or build their own systems (Charles et al., 2014). As with any system, changes in one area (such as the use of an EHR), could have unforeseen effects on intrinsic elements. These effects can result in emergent behaviors that are unexpected (Harrison et al., 2007). Understanding the changes to the organization that results from the implementation and adoption of an integrated EHR system, therefore, becomes important in the evaluation of whether EHRs can be used as a tool to achieve health care reform.

The research questions focus on the people, processes, and technology factors and their interactions to achieve change.

1. How do the interactions of people change as a result of an EHR implementation?
2. How do organizational processes change as a result of an EHR implementation?
3. How do technologies change as a result of an EHR implementation?
4. What are the summative outcomes of an integrated EHR system at an organizational level?

The following sections describe the finding of this research study including the pilot study, research setting, demographics, data collection, data analysis, evidence of trustworthiness and study results.

Pilot Study

The pilot study for this research included semistructured interviews of two participants, one physician and one administrator. No observations were completed with the pilot study participants. The pilot was intended to ensure that the interview protocol would elicit information pertinent to the research questions for this study and guide future participant identification. The interview protocol addressed questions of each participants' role in the planning and use of EHR as well as the effects of the EHR on their daily activities, interactions with peers, access to information, and impact to care delivery. The interview protocol was weighted with questions more specifically to a direct caregiver and user of the EHR so the inclusion of an administrative role in the pilot was important to ensure applicability of the questions with modifications for that role.

The interview protocol was effective at eliciting comments about the changes in process and people in the organization related to the electronic health record system use. Each of the participants related the questions to their specific perspective of the EHRs effect on their daily work as well as to the institution as a whole. However, the later was more difficult to elicit due to each participant having a narrow view of the use of the system as either a direct user or overseeing a department with a narrow focus on quality. Both positive and negative statements were collected that represented the perspectives of

the physician and administrator interviewed. No specific changes to the interview tool or study protocol were identified during the pilot study.

Research Setting

The research setting for both the pilot and full research study was an urban academic medical center. The institution is a tertiary teaching hospital with an associated medical school situated in an area adjacent to both a very affluent as well as extremely poor section of the city. This location has been a stimulus for many of the clinical programs as well as a driver of the culture of the organization. The original scope of the research study focused on only the main hospital in this system despite there being a separate community hospital also within the city limits. The organization has a long and well respected reputation both in the local area as well as internationally with over one million outpatient visits a year and more than 60,000 inpatient discharges a year. The organization has a very complex structure with the physicians having an academic appointment as well as a hospital designation and often times separate title and responsibilities. The nurses interviewed as part of this study all were employees of the hospital. The administrative participants ranged from association with just the hospital to spanning the structure of both the hospital and the medical school.

All of the participants were associated with this organization through employment at some level. All participants had been employed throughout the implementation of the EHR at this institution and have some role in the use, planning, or direction setting for the EHR at the institution. There was a varying degree of institutional longevity that was mentioned by some of the participants however this variable was not collected as part of

the study. Several of the participants' roles evolved from staff to leadership during the time span from initial implementation to when this study data were collected. This became evident in the depth of information provided by some participants on the historical perspective of the organization before the EHR implementation. This did not affect the overall quality of the information given on the effects of the EHR on the organization in the current time.

None of the participants were voluntary providers that had clinical practices outside of the institution. While some participants had other experiences with EHRs that differed from the EHR at the institution in prior positions outside of this institution, this did not affect the information provided, as the focus was the effects on the institution and not the specific functions of the EHR effectiveness.

In 2013, the institution merged with another local hospital system that included five additional hospitals. These additional hospitals functioned more on the level of community hospitals and did not have an accompanying medical school. As the merger evolved staff, physicians, and administrators have expanded and travelled to different locations of the health system. Each of the newly added facilities have legacy EHR systems and, in order to prevent any confounding effects from the different systems on the data collection for this study, no participants whose role or responsibility changed to require legacy EHR system use were included in this study. No other changes in the setting were identified that would have an effect on this research study.

Demographics

The participants in this study were identified from three broad groups, physicians, nurses, and senior administrators at the institution. Within each of these groups, a variety of different clinical specialties or areas of responsibility were targeted with the goal of identifying as diverse a sample as possible. Many of the participants were identified through snowball purposive selection as each participant was asked for any others that might have good insight into the effects of the EHR at the institution. Other than the need to have enough longevity at the institution to provide perspective on the changes occurring since the EHR implementation, no other demographic information was collected, for example age, gender, or race, as these were not considered pertinent to this research study's goals.

Despite attempts to gain participation from other subgroups specifically voluntary physicians who use the EHR for admitted patients but otherwise have an independent practice outside of the institution, no participants were identified from this group. In addition, other physician extenders such as nurse practitioners and physician assistants were intended to be included but were not successfully recruited. The initial plan for participant selection included C level executive administrators in the institution. While several of most senior organizational officers were successfully recruited, several key roles were not able to be included, namely nursing. In order to avoid leaving a gap in understanding the next layer of senior nursing administration was included and successfully recruited to participate in the study. In total, there were seven physicians, seven nurses, and seven administrators identified and successfully recruited to participate

Data Collection

The participants in this study were divided into three major groups, physicians, nurses, and administrators. Including the two participants recruited for the pilot study, a total of 23 participants were successfully recruited with seven participants in each category for the full study. The nursing group was further divided into clinical nurse manager and staff nurse, to more accurately describe the subgroups of individuals who participated. Table 2 includes the breakdown of participants for the pilot, full study and the number of participants interviewed and observed.

Table 2

Interview and Observation Data

	# of interview participants pilot	# of interview participants full study	# of observations
Physicians	1	7	2
Administrators	1	7	
Nurses			
Clinical Nurse Manager		3	
Staff Nurse		4	1

The pilot participants were identified through recommendations from contacts at the institution after the research study was socialized among my contacts. Each participant was contacted via email initially and then through a follow up telephone call

to confirm the objectives and schedule a time to meet. This deviated slightly from the approach outlined in Chapter 3. The plan was to use the email communications outlined in Appendix E but for most participants the initial email was all that was needed to gain assent to schedule the interview. After the first pilot participant was recruited the follow up background email was no longer used. This process was also followed for the full study participants as well. The only variation from this was for the senior level administrator where communication was done through their administrative assistant to gain agreement to participate and to set up the scheduled time.

Each of the participants was interviewed using the interview protocol in Appendix A in a place of their choosing, which typically was an academic office or conference room near their primary job responsibilities. Each participant was given an overview of the study and asked to sign the informed consent form. The interaction with each participant was a single session lasting from 20 to 35 minutes. The interviews were recorded using a digital recorder with the participants' consent. The only variation in data collection was for one interview of a nurse where two nurses insisted they wanted to do the interview together. This was allowed as each one answered the interview questions after completing the informed consent.

In addition to the semistructured interviews, the plan was to also perform observations of participants using the observation protocol in Appendix B. Due to limitations imposed by the IRB, these interviews, which were intended to be performed in the clinical settings, were restricted to observations of a single participant outside of the clinical setting. This limited the usefulness of this form of data collection because the

underlying research questions revolved around understanding of the people and process changes that involve groups of individuals. Despite this limitation though, three observations were performed. The data from these observations were recorded through hand written notes on the observation protocol form and later transcribed to electronic format. These observations were used as credibility checks to confirm information collected in the interviews. For two of the observations, participants being interviewed demonstrated specific tasks or processes in the EHR to emphasize the points that they were making and for the third an additional participant was identified to demonstrate a specific workflow mentioned by an interview participant at her request.

The third type of the data collection performed was the identification and collection of existing documents that provided insight into the changes that occurred in the organization since the implementation of the EHR. Table 3 includes a summary of the types of documents collected for analysis.

Table 3

Document Data Collection Summary

	# internal documents	# external documents
Return on Investment Analysis	1	
Press releases		3
Davies Award Case Studies		5
Project documents	2	
Organization website		1
Published article on organizational results		1

Note. Internal documents indicate those documents created internal to the organization and not shared publicly. External documents were publicly available through the internet or through scholarly sources.

Data Analysis

Once all of the data were collected for this study from the 23 participants, the interview recordings, transcripts, and documents were imported into NVivo 10 for analysis. Transcripts were reviewed and cleaned up to remove interview nonvalue statements such as *yeah*, *um*, and so on and to ensure that participant statements were captured correctly by the transcriptionist. Further cleanup was done to keep participant thoughts together without the researcher interruptions of normal conversation. An initial list of descriptive codes was identified from the research questions including the terms interaction, process change, technology, and outcomes. A quote from a senior leader in

the HIMSS Davies Award documents supports the use of interactions as a critical element in EHR use by saying:

[The EHR] is important to [the organization] on interrelated dimensions serving as an integrated backbone of care. One doctor knows what the other doctor has done and everyone sees the same medical record, which enhances the satisfaction of patients, as they know their doctors are all communicating with each other.

Another senior leader, P4 supported the concept of process change as a key objective in EHR use stated during the interview:

As we talk about things we want to change, how do I want to get more from it? How do I want to improve quality? Always in the middle of that conversation is the [EHR]. And I think it's become such an important tool as an organization, to move us forward.

These early findings supported the use of the coding terms from the research questions but a more thorough review of the data was needed to develop additional coding.

As the transcripts were reviewed and compared to the digital recordings additional codes were identified to expand on the initial codes and group related statements or concepts. These included some concepts from the literature review on EHRs that highlighted common benefits to health care organizations. This list included efficiency, patient safety, errors, productivity, and quality. These codes were common among the interview data as highlighted by one senior physician leader, P8.

So when we went on [the EHR], it was a huge transformation for us, and a marked improvement in our ability, my ability as a practicing physician, to keep

on top of what's going on, especially getting back consults, because I wouldn't have to wait to get back the consult. As it rolled out to other specialties, I could just look on mine, and see what happened. Same thing with everything else, lab tests, radiology imaging. It became much more streamlined. I could just go to one place, one-stop shopping, to get what I needed, whereas before I had to go onto a whole bunch of different, disparate systems to check stuff.

These common elements from the literature were used in coding to elevate the level of credibility by demonstrating that the findings in this study aligned with other researchers' findings when evaluating EHR effects.

The transcripts were reviewed in the order that they were performed while also reviewing and adding to the journal notes that were documented after each interview. This allowed for reflection on my thoughts during the interview and identification and limitation of any bias that may have occurred during the process. The chronologic review process allowed me to compare and contrast content from each of the three major groups of participants, physicians, nurses, and administrative leaders. This resulted in a wide range of codes some of which only applied to one or two of the groups of participants. Statements from the most senior administrative officer, P4, of the organization focused on the competitive environment and managing the day-to-day operations of the larger organization, "But, what became clear, especially at an academic medical center, teaching hospital, or any other hospital, that you need an electronic medical record to be competitive." Whereas the physician and nursing participants focused more on the daily activities of care delivery including access to information, variations in use and decision

making. Access to information was by far the most common coded concept supported by many of the participants including a physician leader, P19.

Everything is there, instantaneously, where before it would require hours, sometimes days, to get information-from the inpatient perspective, to get it from down in Medical Records. From the outpatient perspective, there was a dearth of information, and now [the EHR] has enhanced it tremendously.

As well as a staff nurse, P20, who had been working at the facility for 15 years and experienced many iterations of electronic and paper based clinical documentation systems.

I definitely think we have more access to things-test results, doctors' reports from, say, Radiology. In the past we'd have to go into a different system to even see lab results, or see the reports from X-ray. So you definitely have a lot more of the patients' information available to you.

Except as noted with the administrators' focus being different from that of the physicians and nurses interviewed, there were no discrepant cases. All participants had positive and negative perspectives on the EHR effects on the organization but none had purely one or the other and all had commonalities in both aspects of their comments.

Once I completed the first pass of all of the interviews as well as the collected organizational documents, I was able to review the nodes created in NVivo 10 and evaluate the next level of commonalities. At first the commonalities focused on individual codes used in the first round of coding with an attempt to group the nodes into

a higher-level pattern or theme. Some of these first approaches group the nodes into themes of care delivery, secondary data use, and outcomes.

After further review of the codes and the hierarchy that was developing, the inductive process became clearer and the structure for the higher level codes was identified as the conceptual framework that was already established for this study. Rippen et al.'s (2013) organizational framework provided the construct for the higher-level themes needed to group the first level codes beneath. Rippen et al. outlined the concepts of technology, use, environment, outcomes, and temporality as a structure for capturing data about the implementation and effects of the health IT systems.

After coming to this conclusion, the first level coding done on all of the data collected for this study was easily grouped under one of the categories outlined in the organizational framework of Rippen et al. (2011). Some of the categories were more heavily populated than others with the largest grouping being for outcomes and use while environment, technology, and temporality were sparsely populated with codes and references from the data collected. This aligned well with the overall purpose of the study to focus more on the outcomes of use and less on the implementation, adoption or specific technology used for the EHR.

Table 4

Coding Hierarchy

2 nd Level	1 st Level	# of sources
Technology	Devices	2
Use	Access to information	21
	Care delivery	19
	Decision making	14
	Variation in use	1
	Data collection	4
	Data analysis	1
Environment	Competitive	1
	Regulatory	10
Outcomes	Efficiency	19
	Errors	11
	Interactions	20
	Patient focus	20
	Productivity	1
	Process change	24
	Quality	22
Temporality	Adoption	1
	Proficiency	2

Note. # of sources was obtained from NVivo 10 indicating the number of data sources where content was coded for that specific node.

In Chapter 3, the proposal was to use a matrix to compare the elements of the Rippen et al. (2013) organizational framework to the processes of care within a hospital, patient admission to the hospital, care delivery while admitted, transitions of care, continuity of care from inpatient to outpatient follow-up, and completeness of care documentation. After completing data collection, I realized that the data collection and participant selection did not ensure that all of these care processes were covered by the interview protocol. Further analysis resulted in the processes of care being removed from the analysis for this research study because the data were incomplete and not necessary for answering the research questions associated with this study. In place of this matrix, the organizational framework elements from Rippen were compared against the three groups of participants with data summarized from each of the groups in Table 5.

Table 5

Role Oriented Matrix

	Technology	Use	Environment	Outcomes	Temporality
Physician	Variation in use Limits system functions Multiple systems sharing info Integrated system	Attending/supervisor Time away from patients Overhead to make changes Data visualize important	Teaching setting Move to pop health Some areas info dense	Improved communications Decreased ownership of info, med list Improved workflow Access to info	Initial improvement Changes as others start using EHR Incremental implementation limits effects
Admin	Capture discrete data Administrative adoption Necessity for robust decision support missing Blood admin/critical values/early intervention	Electronic view feels less comprehensive Data and use governance Constant drive for further adoption Balance access vs privacy Info overload	Interaction with external agencies Reporting Driving discrete data Env. of fragmented data;	Improved efficiency Change behavior Facilitated conversations No assistance with data analysis	Move from resistance to dependence
Nurse	Mobile devices barrier Tech can't replace physical contact Wow's pull focus	Finding info takes practice Inc. expectation for documentation Multiple places to document	Multi discipline Interactions more visible with pharmacy Interactions with physician less visible Primary and secondary data uses	Inc. collaboration Inc. efficiency of care Changes in relationships between people Ongoing changes in workflow ad hoc Com and access to info	Initial use versus use over time

Note. Key words obtained from interviews and organizational documents

Evidence of Trustworthiness

Credibility

In order to demonstrate credibility in this study a wide range of people were included as potential participants. Each person who agreed to participate was instructed on the confidentiality of the information that they would share and also made aware of my role as both the researcher and an employee at the institution. This was explained as two separate roles and that my role as researcher would be objective and I would not be bringing any of my perspective to their responses. Where possible responses were compared across participants to ensure some alignment of concepts and many commonalities were identified despite being no relationship between the information provided from each participant. Information from interviews was also confirmed with observations of specific workflows in the EHR in some cases and compared with institutional documents for ensure alignment.

In addition to the suggestions of each participant for additional people who might hold valued perspectives on the EHRs effect, conscious decisions were made to seek out participants with wide perspective such as chief medical officer, and others with disconfirming perspectives on the value of the EHR. Some people recommended from participants with documented disconfirming perspectives were pursued for participation but did not respond to attempts to recruit them for this study.

One of the major methods of triangulation that was planned for this study was the observation of participants in the clinical setting using the EHR. Due to issues of consent for all potential participants in a clinical setting where observations were to be held, this

approach was changed to observations on individuals' use of the EHR. This approach limited my capability to gain broader observations of the EHR in use but did allow for confirming specific processes changes with specific workflow changes in the EHR. Triangulation was also performed by comparing perspectives of participants from different care settings or administrative responsibility such as ambulatory and inpatient ICU to ensure the effects of the EHR were evaluated from a variety of viewpoints. Also inclusion of different clinical and administrative disciplines also assisted with the triangulation of results for example the quality director's experience with use of the EHR for regulatory compliance was different from a clinical nurse or physician. Finally, member checking through follow up discussions with participants on the interpretations were not possible given the time commitment needed from the participants to accomplish this task. Despite this limitation, findings from the interviews were compared to institutional documents and current literature to ensure accuracy of the information collected.

Transferability

While transferability of this qualitative case study research was limited to the context of the organization where it was performed, the interview protocol and types of documents collected could be replicated in future studies in other organizations to gather comparable results. The organization used as the unit of analysis for this case study was described in enough detail to identify comparable organizations for and the grouping of participants for this study, physicians, nurses and administrators, was also standard and could be replicated in future studies.

Dependability

The first elements of dependability focus on clear research questions and clear explanation of the role of the research in the study. The research questions in this study have been clearly stated and focus on the changes in people, processes and technology related to the use of an electronic health record system at an academic medical center. The role of the researcher in this study has been as primary data collector, and analyzer as well as employee of the organization being studied. To avoid bias in data collection, role separation between researcher and employee was clearly explained to each participant. As many of the participants were familiar to the researcher prior to the study, a research journal was maintained to highlight any bias or perceptions of the researcher after each interview. In addition, data collected during interviews were confirmed where possible through triangulation with existing organizational documents and member checking.

Confirmability

As described in an earlier section, a research journal was used to record researcher perceptions of each interview to increase identification of bias and settings allowing for confirmability of the research findings. In addition, data collected are described in detail through the use of data matrices and coding schema described in detail to provide clear linkage between data analysis and conclusions.

Study Results

The unit of analysis for this study was one academic medical center located in a large densely populated urban setting in a highly competitive environment with multiple competing organizations within a 10-mile radius. The organization is comprised of

approximately 1100 inpatient beds, 183 hospital based outpatient practices, 5000 active physicians, residents and fellows, and 2000 nurses. The organization has nearly 70,000 inpatient admissions annually, 100,000 emergency department visits and 1.3 million ambulatory visits in hospital clinics and faculty practice associates. The organization also has a top tier medical school with 500 medical students annually and is consistently highly ranked in the best hospitals in the U.S. News and World Report annual report.

The organization achieved the HIMSS EMRAM Level 6 (HIMSS, 2014) certification in 2011 after the completion of the inpatient implementation of the EHR and received recognition in 2012 with the HIMSS 2012 Davies Enterprise Award (HIMSS, 2016) for demonstration of return on investment and improvement of patient outcomes related to the implementation of the EHR. Prior to the implementation of the integrated EHR referenced in this study, the organization had a myriad of fragmented systems with incomplete and inconsistently adopted functionality including lab results review and order entry in the inpatient setting. In the outpatient setting, multiple EHRs had been partially implemented with little success in integrating care across individual practices and care settings. The background of the organization was outlined in the Davies award case study.

[This organization] is among the nation's leading health systems to achieve EMR Adoption Model (EMRAM) Stage 6 (application for Stage 7 is planned for 2013) and has successfully attested to Meaningful Use Stage 1. The original fragmented network of clinical systems consisted of the ED system (IBEX), inpatient ordering (TDS), medication reconciliation (eMedRec), and a handoff communications

application for use between residents (SignOut). The Epic EHR replaced all of these systems with a seamless and single integrated EHR platform across the inpatient, ambulatory, and clinical research settings.

This academic medical center was a part of a two-hospital system with a community hospital during the initial implementation of the EHR. In 2013, there was a merger with a local five-hospital system with facilities located throughout the urban area. This system had multiple other legacy EHR systems, which have not been consolidated yet to one integrated system.

The implementation of the EHR of record for this research study started in 2005 with a comprehensive system selection process and began the implementation in the ambulatory setting. After early successes with implementation and adoption the scope of the implementation was expanded to include the inpatient hospital setting in 2010 with the activation of the system in 2011. The EHR implemented at this organization focused on the clinical aspects of care including, clinical documentation, physician order entry, results review, and patient education tools. The EHR system had multiple modules with specialized tools for each care setting, including emergency department, ambulatory, OB/GYN, inpatient medical surgical and pharmacy. While available some clinical modules were excluded from implementation in lieu of keeping existing legacy systems namely for the perioperative areas. There was also a strategic decision made by the organizational leadership to implement only the clinical aspects of the system and not to include an enterprise installation that would include integrated business modules for registration and scheduling of patients and billing functions. The following sections

address each of the research questions for this study and include reference to the data collected from the participants during interviews as well as organizational documents both internal and external.

Research Question 1

How do the interactions of people change as a result of an EHR implementation?

The first research question addressed changes in the interactions of people with the use of the EHR. This was one of the areas that elicited one of the highest numbers of responses during the interviews but was addressed only to a limited extent in the organizational documents that highlighted the implementation success. The themes identified in the results for this question are summarized in Table 6.

Table 6

Themes and Definitions for Research Question 1

Theme	Definition
Interactions	This theme captured several types of responses including, changes to the interactions between disciplines such as nursing, physicians, and pharmacy as well as intradisciplinary interactions. The interaction theme also captured the interactions of the organization with external regulatory agencies.
Access to Information	This theme was both positive and negative. The positive was related to the more comprehensive knowledge of the patient's medical history and perspectives of other healthcare providers. The negative perception was related to the pull of this larger amount of information of the healthcare provider away from direct care of the patient. Both nursing and physician participants identified this effect of the EHR on their daily activities.

One of the organizational documents was a case study submitted for the Davies award in 2012 that focused on change management activities. This case study focused on the organizational impact of the EHR implementation with the intent of planning for these changes in advance instead of being reactive to unexpected consequences. This document was part of the submission for the HIMSS Davies award and focused on the changes identified during the implementation of the EHR and not the ongoing changes occurring in the organization.

Interactions of people in the organization were closely related to access to information which was also highly ranked in responses from the interviews. Several aspects of interactions were highlighted. The first was the result of access to too much information pulling the provider, either nurse or physician, away from the patient to be more focused on the computer. Senior physician administrator, P19, highlighted this in his statement.

I think that trainees, especially—well, everybody—who uses the EMR has become much more focused on the computer screen, and has to actively think not to stay focused on the computer screen when there's a patient present. That's especially true in the outpatient setting, and people are much more in the rooms where people interact with the attendings. And then on the inpatient floors, I think it has removed some of the personal activity that used to be on the floor. That's because people have to find computers. So if there's not enough computers on the floor for the number of people, the residents go to the team room, and sit in there

and do the work, because the work has to be done via computer. So in some ways, it has removed people from being present on the floors.

This was also observed by nursing staff that patient interactions were affected by the use of workstations on wheels (WOW) for access to information and documenting care.

Nurse participant, P18, commented,

I feel as if we're glued to our WOWs for the whole day. At any given time, you constantly see a nurse going around the unit, pushing a WOW. And it does take away time from patient care. They try to implement new things on the floor, like our daily sit-down with our patients, but it's impossible. It takes away that human connection that you actually have with that patient, because I feel as though, like, you're more focused on the computer, and doing things, rather than actually taking care of that patient. That's kind of why I feel as though the whole five-minute sit-down has come into play. Prior to that we didn't need a five-minute sit-down, because we never used to bring a computer into the room. We were always talking with the patients, and so forth. But now, that computer kind of just created like a blockade for that.

These findings in the inpatient setting were contrasted by the findings in other setting within the health system.

In the ambulatory setting, several physicians interviewed commented on the positive effects of the access to information on patient interactions.

For patients, and family members, [the EHR] is also really helpful, because in the outpatient-which I don't do anymore-but in the outpatient setting, I used it a lot to

say, “Come look. This is what we did. Here are the results.” And any question they had, I would at that point say, “Great question. Let’s go check it out. We’ll answer it together.” So we can trend, and say, “Well, here’s what your hemoglobin levels were over the past 3 years. And they’ve actually been stable, so it’s not a problem,” because someone was worried or anything like that. So it was a good way to bring them in. (P13)

Especially, I think the most critical way it has [affected patient interactions] is outside of the patient encounter, because when a patient used to call, you wouldn’t have, really, any information, except what you could either remember, or understand from the patient. But now, you pull up the medical record, and you have everything you need at your fingertips, with the patient on the phone, and can make clinical judgments, and perform clinical-and order activity, whether it be medication, or a future order, right there. (P19)

It also enabled me-as a geriatrician, a lot of the work I did was outside of the office visit. And so me and my colleagues in geriatrics do a lot of clinical, important work that’s on the phone, that’s after hours, that’s with the caregivers, adult children, VNS, whoever, and we really weren’t documenting those interactions in any meaningful way, because we had no easy ability to do it. And so with [the EHR] we began to much more use telephone encounters, and updates, and in real time, and be able to better service the patients, too, after hours, because we had access to information that we had no access to before. (P5)

These differences in findings between the inpatient and ambulatory settings supported the concept that local context is important in the planning and evaluation of the EHR has a transformational change.

In addition to these effects on interactions between the provider and the patient, other types of interactions have also become apparent with the use of the EHR. One nurse manager, P6, identified the EHR as a catalyst for collaboration among different disciplines.

I think that because with the way that the [EHR] is set up, the decisions that we make about the documentation, or the placing of the orders, affect so many different disciplines within the hospital, that it really causes us to really have to work together, all coming to the same table: Nursing, MDs, Pharmacy, every group who's going to be involved, the educators, IT. So it's kind of created this cohesive workforce.

An internal medicine physician, P19, also described an interaction with a specialist that had changed due to EHR use.

It was a patient care event, where a patient of mine who I share with a neurologist, the neurologist got the phone call that the patient had been admitted for a subdural, and so saw the patient. And then, through [the EHR], let me know, through a message, that the patient had had a subdural, and what his labs were, and whether or not it was okay. It actually did affect critical decision-making, because the question was: is it okay to put him on a steroid, decadron, in his condition, from your perspective? Before I do, I want to hear what you have to say. So, it did, and that was something that may have required previously a phone

call, that then I would-maybe two days' worth of phone tag, where this was done that day

The variety of interactions affected by the EHR in this organization supported the use of complexity as a lens for the evaluation of the EHR in a CAS.

Other, subtler changes were also observed by nurses on the inpatient floors with mixed reactions as to whether this was a positive or negative effect of the EHR.

I sometimes think, with myself and the nurse practitioners, there's always verbal communication, but I sometimes think that there's not as much verbal communication with the doctors. Like everything, they just put everything in the note, but they don't actually come and touch base with you first. (P20)

We kind of lose that interaction with some of our doctors, and they'll put in orders but they're not around the floor; they're in some distant location. So if there is any question about it, we have to get on the phone, and that face to face isn't the same as them putting it through the system, and us just completing the tasks. (P18)

[The EHR] hasn't really impacted that much on how I deal with my coworkers.

With other disciplines, it does help, like I said, with communications of what their thoughts are. I don't have to reach out to them by calling them, because they usually write their note with their plan. And I only have to reach out to them if I have an issue that's acute, that needs immediate attention. (P9)

This perception of the nurses was confirmed by the observations of one physician, P19, as well noticing that fewer physicians were present on the inpatient floors.

[The EHR has] removed people from the floors. It's very obvious that there's less—except for the designated times of like rounding, team rounds, or something, it's obvious that there's less people on the floors, less physicians on the floor, providers, for sure.

Other physician-to-physician interactions have also been affected by the EHR in a variety of ways that came out in the interviews.

There are fewer doctor-to-doctor phone calls for things of medium importance, and almost none, now, for things of small importance, within the health system.... Whereas, the minor stuff never got a phone call anyway, this sort of intermediate stuff, or moderately important stuff, would have more phone calls, had more phone calls, in the past. The severe stuff that requires a phone call, my sense is that that still happens with the same frequency, and/or urgency, when it's needed. And so I think that the communications around patient care have certainly changed in those areas. (P22)

So first as a practicing physician, with other physicians on the care team, it's just a great facilitator for communication, because I can, again, instantaneously read what people are writing when I'm asking for advice, or consults, etcetera. It saves time, too. Even somebody will send me a text and say, 'Saw your patient. Call me if you have questions. Note's in the chart.' And then I would say, 'Oh, great.' I'd read everything. 'Oh, that makes sense. I should do that.' Or then I can give a call, and have a much more efficient conversation, because I've already read through

what they found, and what they thought was important, because that's what they documented in the record. So for colleagues, it's extremely helpful. (P5)

These individual agent interactions combine to affect the behavior of the organization as a whole with findings at the organizational level.

From a more organizational level perspective, the EHR also played a role in meeting the requirements from external regulatory bodies by providing tools that changed the interactions between staff charged with changing the behavior of physicians.

I guess the other thing with [the EHR], too, was our ability in the Population Health world—we started with our MSSP ACO [Medicare Shared Savings Program Accountable Care Organization], with Medicare, July, 2012, and one of the initial requirements that prioritized was going out to the physicians, explaining what this was about, and getting their buy-in on those quality measures. So they had 33 quality measures, and it's core to the program. And if we're successful in saving money, you have to do all the quality in order to get the money. And so, how do we know how they're doing? That was built all through [the EHR], too. So as the clinical lead in the ACO, I was able to work with folks [in IT], too, to build us reports that are physician-level, practice level physician-level, and then actual quality-metric performance level, with the gaps and the detail behind it on who doesn't meet that criteria, so they can take action and work on improvements. None of that could have been possible without an EHR, period. (P5)

A physician leader (P5) in the organization responsible for the clinical documentation quality improvement program emphasized a transformational change in the interactions his staff had with physicians with the use of the EHR.

A clinical documentation specialist, pre[EHR], was going to the floor, let's say nine to five, roughly. And they were assigned floors, and they were looking for charts, and they were trying to find a space to sit, too, which they couldn't find, and a computer to get on, which they couldn't get on, to check things that weren't in the chart, like labs and other stuff, on EDR. And then they would read through the record, somewhere-standing at the nurses' station, or sitting if they had a corner, writing a query by hand on a sticker, putting it in a chart, keeping a copy of it in their own books. And that was their workflow. And then they would go back the next day, and look to find those charts that they put some queries in. Did they get answered? Read through the notes, and then if not, re-query, or page, and do their thing. So they were on the floor. [The EHR] changed their day, so that they don't go to the floors, right. We came up with some other ways for them to interact with the physicians, by going and joining them on rounds, which are a real help, right. Just on the team rounds, and contributing that way, and having the face time.

Whether the interaction was between the patient and a health care provider or between health care providers, the EHR has had a profound effect on the people involved in the provision of health care as well as the patients receiving that care. This supports Greenhalgh et al.'s (2009) argument of the EHR being a social construct that interacts

with users and the environment with unpredictable results. Unlike the focus of the study performed by Cresswell et al. (2014), the findings related to Research Question 1 of this study focused on the interactions of healthcare providers and not the individual effects on each as a user of the EHR. This change in focus highlights the complexity lens used for this study. This focus uncovered changes including both positive and negative experiences that will continue to evolve over time as the EHR settles into the substrate of the health care environment. A scan of current literature related to provider interactions affected by the EHR resulted in no additional findings.

Research Question 2

How do organizational processes change as a result of an EHR implementation?

The EHR can affect potentially thousands of different processes within a complex adaptive system like an academic medical center. The interview question posed to gather information on these changes focused on changes to participants' daily activities and also questions about whether they perceived of any organization wide changes since the implementation of the EHR. Table 7 highlights the themes for Research Question 2.

Table 7

Themes and Definitions for Research Question 2

Theme	Definition
Quality	This theme focused on the secondary use of data from the EHR to influence change in process to improve standardization of processes and improve quality. This theme also captured the use of the EHR for monitoring or quality assurance activities by the nurse managers on the inpatient units.
Patient Safety	Improved processes to ensure safety in medication administration, medical supervision of residents, and improved documentation were identified in as a theme across all three disciplines of participants.
Productivity	This theme captured the improvement of clinical processes from better information display for decision making as well. A negative aspect of these theme was also identified as expanding processes of care documentation because of the ease of adding it to the EHR for the nurse or physician to perform.

One of the case studies submitted for the Davies award summarized this by saying, “This was not a technical installation but a process transformation and implementation where the human dimension would determine how successful the program was.” The first area where process change was evident was in the measurement and eventual improvement of quality measures. One of the physician leaders, P5, in the organization responsible for improvement of physician quality metrics said this:

So for me to drive improvements in, for example-another good example: screening for depression. We submitted the first year, and our screening rates for depression were, like, two, because nobody did it, because we had no standard way to document it. We didn’t know how we were doing, and so we built, again,

with [the EHR], a workflow, and a [decision support reminder], around depression screening, so that it was user-friendly. It's what the clinicians wanted, and then had the elements that were required. And our screening rates went to over 50% in just a year, which was better than the national average.

Information from the EHR was also leveraged through reports to facilitate process change with informed discussions about performance and identifying areas where good performance approaches could be shared.

So I went out to all the practices every quarter, met with the physicians, showed them their data, and talked about how to improve, and had the ability to say, "Doctor So-and-so, you're doing amazing. About 95% of your patients got flu shots already. How do you do it?" Because everybody else is at 50, or the guy next to you is at 20. "What is it that-you're doing great, and what are the struggles?" And that's been really useful. And again, without [EHR], we would just not be able to get that information. (P5)

This approach was driven by the shift of health care from episodic care and managing sickness to a population health approach where the goals are to manage the health of the patient through proactive monitoring. The chief medical officer, P22, highlighted this approach with the following,

We used [EHR] to find the patients who have poorly controlled diabetes, and based on those [EHR] reports of who had uncontrolled diabetes, we referred them to diabetes educators, and made appointments for them. So we were able to target

the resources at the folks that needed it the most, and that was sort of making decisions on what we want to do, and where we want to focus, using [the EHR].

On an inpatient unit level, process change is also evident as a result of the EHR.

Nursing participants highlighted several changes in process that resulted from deliberate modifications made to the EHR to ensure patient safety and improve the nursing practice.

The medication process is a lot easier to document. The scanning of the patient's ID band, the scanning of the medications themselves. The prior system, we had to look at a paper, get all the medications, then go back into the computer and administer them. All our documentation is now in one place. We're not documenting medications in one area, lab results in another area, and note in the chart. (P7)

There are so many medications out there, and it's hard for every nurse to know every medication, and interactions with the medications. So there's a lot of high-risk medications, that a newer nurse might not know that it's not okay to administer this medication. And in our system, everything has to be verified by Pharmacy, and we know if it's verified by Pharmacy or not. So if it's not verified, that medication won't be administered. Or in the past, as my fellow nurses have told me, when they were hand written, it didn't really go through the same process. (P10)

I used to work at another hospital where it was all paper charting. It was when I came here I was introduced to the electronic charting. So the doctors, they can put orders into the system, where it's readily available. You can see it right away.

Whereas with the paper charting, you have to wait for them to come down to the floor, and write it in the chart, and take it over to Pharmacy. And then, are there errors? And there's like delays and things. So in that sense, it helps facilitate the flow, the flow of information, like if you're putting in orders, or medications for the patients. So it also minimized some of the delays that I used to see with paper charting. (P 20)

A specific example would be heparin drips. It's a high-risk medication, and its low frequency on a lot of floors. And the nurses titrate the medication; there's an algorithm that's put in. So we had many different nurses make errors with their math, or their comprehension of the algorithm, or whatever it is, that caused adverse events in our patients. So the nurses really advocated for a co-sign. They're doing their best; they're well intended. They obviously don't want to make that mistake, but they're making that mistake anyway. They felt they needed somebody to kind of back them up on the decision they were making, so what we did was we formalized a co-sign. So any time you have to change the rate on that particular medication, another nurse has to come, look at everything, assess the whole situation, and verify that the decision you're making is the correct decision (P 6)

A nurse manager, P12, emphasized the changes that the EHR made to her daily activities of monitoring activities on the inpatient unit.

I think it makes my job easier. Everything's becoming more functional now that we have access to reports, and things like the Dashboard. I use that every day,

multiple times a day, to watch what the staff are doing, maintain quality indicators, things like central lines, making sure the dressings are getting changed-things like that, clinically. So rather than having to go back through the entire record and find the information, a lot of things I can find in that snapshot. That, to me, has really just improved. Also I think medication safety is a big thing. We've improved so much on that, with the scanning. [The EHR] tells you when you're making an error. It says, "Oops." I think that's such a big thing for Nursing. Nurses can't make errors anymore unless they're taking shortcuts.

A physician in the intensive care unit, P14, identified the process change facilitated by the EHR when making rounds on the patients in the surgical intensive care unit.

Another nice thing that I recognized early on: a lot of the calculators facilitated our work, to the point that our rounding on the nutrition service, which formerly we see the patients, we discuss what you need to do with the order, and then we write an order. That order was on a triplicate sheet; it has a table, where I each component of each of the TPN order. We look at the day before, and we try to make our adjustment, but we hand write everything-this one, this one, this one; how much? Ten milligrams, 50 milligrams, ten units, twenty units-and you made the adjustment on that basis. When we went to the EMR, with the design that we had, it was prepopulating the previous order, and only make the changes. And also incorporated the labs and the orders. It was nicely done.

Other physician participants indicated the benefits of electronic documentation in improving the supervision of residents and fellows.

As an attending in an academic medical center, where you have residents, the ability to co-sign the tests much later. So sometimes with paper, you would see a patient, and you kind of write your attending part at the bottom of the note, and then have them fill in the rest, which is not really how it's supposed to be done. You're supposed to read the whole note and make sure it's accurate, and then sign it; I never liked doing that, and I always waited for them to finish. But this allowed me to more easily go home, and go back and co-sign for the work we had done in a more thoughtful type of manner. (P2)

Both nursing and physician participants indicated a downside to process change as well with the EHR decreasing the barriers to change by providing an easy medium for organization wide change, some without adding perceived value.

But I think the biggest change was trying to be more compliant, documentation wise, and there's a lot of boxes being checked, and things being brought into the notes, and a lot of information that previously you may have forgotten to do. So I felt like documentation-wise, there was a lot more. I was kind of being forced to do a lot of screening questions that I was being asked to do that I would never do before. But how meaningful that was, and how seriously I took it, I can't always say. With smoking cessation, for example, if someone said they smoked, I would

say, “Well, that’s terrible. You should stop smoking.” How much counseling went into it, I can’t really say. (P2)

And what we find, especially within Nursing, is that nobody has really come to take a look at the work flow, and see how it’s really impacted patient care, and how it’s impacted RN engagement, and the ability of the nurses to carry out work throughout their day. So for example, the original build, whatever it was, then someone else might come with one initiative, and a work group works together and creates a new build that the nurse has to document in there. And then things aren’t flowing into each other, so the nurse might have to document the same content maybe three different times throughout the day. (P6)

Another nursing senior leader, P8, identified where the EHR had not done enough process change in handling the notification of physician of critical lab labs for a patient.

And I remember one of the things that still comes to mind was when the part about the lab results, that would still—that did not solve what I was hoping would be solved at that point, and that is: take away the nurses as middle-men, middle-people, in the paper results, that I was hoping that when I lab result is resulted, it goes into EPIC, and that the physicians would be responsible for looking at the data. But to this day, it’s still the nurses calling, and getting those critical values

As one of the anesthesiologists, P11, involved in much of the performance improvement activity summarized though,

I like to call-and this is really informal, but I like to call [the EHR] “The Matrix.” If you put something in The Matrix, then like there are so many possibilities, and your imagination is the limit, but there’s always gravity. So there are always some limitations, and I do find that when we create these builds, and we create the work flows, inevitably we’ve got to create some kind of workaround, because EPIC can’t do what we want to.

The responses from participants related to Research Question 2 highlight the richer details gathered by this qualitative inquiry in the areas of quality, patient safety and secondary data use. Quantitative analysis across a national sample of hospitals found inconsistent results in quality improvements (DesRoches et al., 2010; Elnahal et al., 2011; Kazley & Ozcan, 2008) but the findings of this study highlight the local quality effects of process changes as a result of the EHR system. Similar to the findings of Cresswell et al. (2014), the findings in this study found EHR related changes fostered both positive and negative consequences related to patient safety. Cresswell also found that secondary data use from the EHR was a critical benefit to the organizations and while Creswell’s study focused on limited function systems, this study demonstrated that effect with a comprehensive EHR system.

More recent studies on the effects of the EHR on healthcare have found similar links to improved quality, a greater focus on decision support tools to assist with changing behavior and clinical processes and a deeper focus on patient safety related to the EHR. Enriquez et al. (2015) found slight decreases in the incidence of Heparin overdosing in hospitals with partially or fully implemented EHR systems which aligns

closely with the qualitative findings of this study that highlighted the process changes associated with the Heparin administration using the EHR. Kern, Edwards, Pichardo, and Kaushal (2015) also identified quality improvements over time when looking at ambulatory visits over 3 years post EHR implementation.

Research Question 3

How do technologies change as a result of an EHR implementation?

A comprehensive integrated EHR is a huge technological innovation for any health care organization. In an academic medical center with many diverse services and needs, the level of technological complexity is already high from both the operational and information technology perspective. Technology has become an integral part of this complexity and each health care professions work.

Table 8

Themes and Definitions for Research Question 3

Theme	Definition
Integrated systems	Participants identified the obvious gaps in integration of information technology systems and the value of adding more modules from one integrated EHR system rather than disparate best of breed systems.
Devices	Devices were identified in a negative theme by participants ranging from WOW's as an additional method of infection transmission to technical problems with devices pulling clinicians away from patient care.
Advancing technology	Comparisons were made to consumer technology and the need for more mobile devices to allow for increased flexibility and asynchronous care delivery. This also included engagement of patients in their medical care through access to medical records.
Variation in use	Variation in EHR use by physicians was identified as a limiting factor in achieving full value from the EHR.

One nursing leader, P8, emphasized the magnitude of the change that the EHR brought to the organization.

But what [the EHR] does, I think, demonstrate to me is how much technology and the EMR is now so a part of what nurses do. It's so part of their nursing practice. It's like, when I was a nurse, a long time ago, didn't have that. I mean, like, that wasn't anywhere in the equation. And now, if you're looking at something like how to prevent, say, sepsis, right. You can't have that conversation anymore without including the EMR, without including EPIC

The scope of the EHR implementation at this academic medical center was focused on the direct patient care clinical settings resulting in many other information systems needing to be connected to share information. The first of these was the registration and scheduling system. While the initial decision on this scope was wise in this complex environment as the EHR expanding to cover all clinical areas the lack of some other technologies limited the possibilities for clinical transformation. One internal medicine physician, P6, explained this limitation.

I find [the EHR] has a lot of great features, as far as communication with colleagues, now that everybody's onboard. The big down side is we don't have [EHR] registration, so it's hard, when you're trying to do something as a whole multidisciplinary team, to involve the registration staff, because we have two different systems.

Another senior leader, P 17, in the organization and anesthesiologist identified the missing perioperative module from the EHR has a barrier to continuity of care and quality efforts.

Well, I think not having peri-op in place, which we have good economic reasons for not having done so. I think that it impairs our ability to truly follow the patient as we'd like. I mean, yes, there's enough, in terms of having personally worked with Anesthesia records there, and a little bit of excerpt of Anesthesia, you can certainly see little bits and pieces of what goes on in the OR. But that, and the absence of demographic, and flow, and through-put, integrated with the EHR, I think, are examples that hold me back as a hospital administrator, from being able to use it optimally.

As overall technology advances are made such as smart phones, smart watches and a myriad of other mobile health apps, the EHR has to keep pace making access to the EHR through mobile devices important for mobile physicians. One internal medicine physician, P6, identified this necessity to maintain productivity.

I think it's made me much more efficient, I mean, especially now with a lot of the phone app capabilities, where I can e-prescribe from my phone if a patient call. I can quickly check their allergies and their other medications, so from a safety perspective it's very helpful.

Technology is also pushing health care organizations to be more transparent with patients about what was in their medical records. A physician leader, P19, in the

organization identified increased patient engagement with their medical care due to the access they have to their medical record through a patient portal.

I think that's just beginning, with patients having more access to information. I don't think enough patients-there's definitely not enough patients are using it in that way. But, the patients that are using it are responding, and sort of saying, "Why is this number, this number?" and understand the diagnosis. So it's sort of making-it's making the patient's understanding of their own health much crisper.

The downside of technology is the devices can interfere with patient care and potentially be a cause of infection. As mentioned in the section on people interactions, the inpatient nurses use WOWs for their clinical documentation and for the administration of medications using a bar code scanner. The director of quality, P1, indicated some challenges with these devices on the inpatient units.

WOWs are "vector for infection," and they don't get clean. And then we have the issue with the privacy, and then we have the issue with the WOWs are bulky, and if you walk around during Joint Commission rounds, everything but the kitchen sink is stashed in the WOWs, including syringes, medications, and outdated supplies that people forget about, food on top of them.

Nurses also identified the WOWs as a limitation to patient care when there are technical problems.

Like, you're in a patient's room and you're trying to give medication, and your computer freezes. Or you're in the middle of writing a note; the computer freezes.

So it's not so much an EMR issue. It's like the technology issue, or lack of enough Wi-Fi in this area. (P18)

A physician leader, P11, in the organization identified the focus on technology especially when there are technological challenges as a barrier as well to providing patient care.

I think sometimes there are, like, work flow obstructions. There's a lot of workflow facilitation, like we had described. But at times, there are challenges, in that it is possible for care to not be delivered, because they get-because practitioners get stuck, and on like an ordering piece in EPIC, they can't get the order in. So let's say, for example, hypothetically, if a practitioner were to put in an order; the nurse couldn't release it. They keep trying to put in the order, and the nurse can't release it. Now the patient's not getting the medicine. And that's the whole point, is to give the patient the medicine. And people lose track of that, and get focused on that workflow.

Overall the EHR modernizes the health care environment in ways that other businesses experienced decades ago. The challenge with any technology though is taking full advantage of the functionalities of the system that are available. One physician leader, P22, compared this to other common office software packages.

And I think that also I, like others, have, relatively speaking-I don't want to say a rudimentary knowledge, but it's the same frustrations, or the same lack of taking advantage of this awesome tool that I have, that I feel about the Microsoft Office products. It's like, "Gosh, I only know about ten percent of Excel. I wish I had,

like, a 90% knowledge of what's in there." Because half the menu items, and half of the tabs that are up there, and icons that I could press on to do certain things-I don't even know what they are. And I have that same feeling about [the EHR] as well. Where I would find the time to be trained, and to improve? I don't know. But I almost wish that there was, or that I had availed myself to more and better training. Because I feel like it's this great Ferrari that I'm really just driving 35 miles an hour, trying not to hit anybody.

The changes in technology that an EHR brings to a complex adaptive system such as an academic medical center are significant and often are underestimated. Cresswell et al.'s (2014) study of provider order entry and clinical decision support systems showed a vast underestimation of the effects and time it takes for process change to occur. The study of the academic medical center in this study echoed those findings and demonstrated the continuously evolving needs of the clinicians and administrators. Current literature continues to focus on understanding the cognitive workload of users (Colligan, Potts, Finn, & Sinkin, 2015) as well as the variations in use of the EHR systems across the organization that can limit positive gains from the EHR implementation (McGeorge et al., 2015).

Research Question 4

What are the summative outcomes of an integrated EHR system at an organizational level?

Review of all of the organizational documents collected for this academic medical center resulted in many indicators of a successful implementation and adoption of a

comprehensive integrated EHR. A return on investment (ROI) analysis that was done several years after the implementation identified areas of process improvement and cost reduction broken into two categories hard ROI and soft ROI. The hard ROI included reduction in transcription costs, reduction in medical records staff and space for storage, and reduction in the cost of paper forms. The soft ROI focused on significant evidence of increased revenue per encounter and per FTE, increased charges for emergency department visits, improved documentation quality, more accurate coding of visits and reductions of payment denials. These soft ROI elements were considered soft due to the potential influence of other factors in addition to the EHR to the outcomes. Many of the themes identified for this research question overlap with those from previous questions. Table 9 identifies the themes for Research Question 4.

Table 9

Themes and Definitions for Research Question 4

Theme	Definition
Quality	Quality for this research question focused on improvements in quality realized through process change with the EHR. The examples included decreasing readmissions of patients, and increasing the rate of patient vaccinations against preventable diseases.
Access to information	This theme was recurrent and identified as a major contributor to the value of the EHR in daily use of the EHR.
Variation in use	Variation in use of the EHR was again identified as a limiter to value for the whole organization due to limited to each providers' time to develop expertise in all of the tools within the EHR.

In the 2012 Davies Award case study on clinical value several elements were identified that indicate the positive effects of the EHR on this organization.

The Clinical Decision Support of the EHR functionality was fully utilized to provide predictive screening alerts relating to many areas including early identification of sepsis cases. Prior to Epic, clinicians manually accessed patients for signs of sepsis requiring them to be experts in this area. The “Triage Screening Sepsis” best practice alert (BPA) was launched in the ED with an algorithm that evaluates eight criteria of sepsis infection based on by Greater New York Hospital Association (GNYHA) criteria. The BPA fires if any three of the eight variables are present, alerting clinicians that the patient has been screened positive for a possible sepsis infection. When the BPA fires, it prompts nursing and providers to place orders to initiate early, aggressive sepsis care. The patient is then monitored in [the EHR] every four to six hours. The EHR continues to monitor vital signs and fires additional alerts to prompt reassessment for sepsis if vital signs are abnormal. Similar functionality supports early nursing identification of potential severe sepsis on medicine inpatient units.

Prior to the [EHR] go-live, monitoring patient vaccinations was especially problematic because immunizations were occurring in both outpatient and inpatient settings. Without a unified database, clinicians were often forced to rely on the patient’s memory for immunization history. To solve this issue, vaccination compliance was monitored and tracked in the EHR beginning at the time of go live and ensured nursing on both the inpatient and outpatient units could access and view a patient’s vaccination history. Once the order is entered, the system reminds nursing every 24 hours to administer the vaccination until it is

completed. In the event a vaccination is not administered, the discharge process cannot be completed until the vaccination is given. The EHR workflow has resulted in close to 100 % vaccination compliance.

The PACT [Preventable Admission Care Team] Program at MSMC had been using admission history data for nearly the past two years to identify and target for intervention of patients at high risk of a 30-day readmission to the inpatient setting. Without an integrated EHR, this identification process was very labor intensive and required a concentrated review of manual paper documents....

Integrating this risk prediction score into [the EHR] not only makes it possible to easily and quickly identify patients at high risk for readmission, it also improves the awareness of services being provided to the patients.... [The organization] reported a 56% reduction in 30-day readmission rates (baseline 39% to 17%) in 2011. While the [organization] is only held to reducing 30 day readmissions, these gains were sustained at both the 60 and 90-day mark. [The organization] also measured overall utilization. On a subset of 111 patients, using each patient as their own control, MSMC measured hospitalization and ED visits for six months prior to the PACT intervention and for six months after the PACT intervention. [The organization] had a 43% reduction in hospitalizations and a 54% reduction in ED visits (for the 6-month period). Ninety-one percent of patients enrolled in PACT (n= 615) had seven to 10 day follow up appointments made and 84 percent of patients kept their appointment.

Throughout the interview of participants, the overwhelming sentiment was that the EHR has had more positive than negative influences on the provision of patient care, provider interactions and overall processes of care. A senior physician leader, P22, indicated this about the overall experience.

So I think both the quality of the information, and the ready accessibility of that information, and the breadth and completeness of it, has been a great improvement. And at this point, I think, it's only slowing me down a little, not a lot.

Another physician leader, P19, had this to say about the EHR's effects on the overall organization.

We're able to, I think, push the organization towards better quality, because we're able to measure things on a sometimes-daily basis, or even a basis of every shift, and to focus people on the important metrics. That's sort of a major positive.

Nursing, P10, also had overall positive thoughts about the EHR's effects on clinical workflows.

I feel like there's more improvements in care because of it. Things happen a little bit faster, and there's less, like, error, room for error, because everything is right there.

Despite the overall positive outcomes of the EHR use at this organization, there are definitely challenges and unexpected consequences of the EHR's incorporation into the complexity of an academic medical center. Variation in use of the system may

prevent attaining some quality and efficiency goals as described by an internal medicine physician, P6.

Because, for example, if you free-text your entire HPI, and your entire past medical, past surgical, family and social history, you're not using [the EHR]. And you have to retype it every time you see the patient. Whereas, if you put it in the appropriate fields the first time you see a patient, then it's always going to be there, and it's always going to be visible to anybody who sees the patient, and it's going to automatically populate your note.

Some of these variations could be explained but varying amounts of comfort with system use. One senior physician leader, P22, used the driving analogy to describe a use of the EHR.

There's actually truly a speed limit out there on the road that we're on that would allow me to drive 200, and do cool stuff, but I'm driving 35. And there is that sense that I'm not fully harnessing the power or robustness of this great system.

Other challenging aspects of the EHR have been described in other sections namely information overload and pulling focus away from the patient. A senior physician executive, P17, summarized this in the following way.

The downsides, I think, are the downsides that all EHRs have. They're probably not as secure as they need to be. There's too much access to too much information, so you can get lost in it. There's no good summary. The coordinating primary care physician, who knows just enough about every individual patient, is probably still the person you have to go to, to get a good summary, because if

someone's a frequent [organization] flyer, and there are 50 notes to review, you're not going to know which ones to look at.

As the literature review of the overall effects of an EHR demonstrated, the findings in this study were mostly positive with an indication for additional work being needed in areas of patient privacy and variations in use. Buntin et al. (2011) found that the majority of studies done on EHR system demonstrated positive or mixed positive effects. Cresswell et al. (2014) found that prior research had typically been done on home grown systems and the focus on commercial systems was important for broader understanding of the EHR effects. The study I performed also helps to further this understanding of commercial EHR systems and echoes the mostly positive effects on the organization. Current literature focuses on deeper understanding of decision support tools (Goldzweig, et al., 2015) and explores the privacy concerns that arise from electronic health record systems (Bayer, Santelli, & Klitzman, 2015).

Summary

The research questions in this study focused on the changes to people, processes, and technology associated with the use of the EHR in an academic medical center. For each of these areas there were positives and negatives in the findings from documents reviewed as well as interviews of a cross section of physicians, nurses and administrators in the organization. While some potential participants were identified as outliers to the perception of the EHR as a positive innovation, several of these people did not respond to invitations for participation. Only one participant expressed overwhelming negative perspectives of the effects of the EHR on the organization. This was steeped in historical

perspective of healthcare using paper charts and the loss of the personalized story of the documentation. This sentiment was not echoed throughout the other participants' responses. Overall, the summative analysis included as the last research question provided an overall perspective not on the implementation and adoption of the EHR but on the longer-term outcomes of the EHR at this organization.

The interactions of people in this organization were affected in some expected and unexpected ways. Communications between physicians, nurses and other health care disciplines increased with the use of the EHR by making transparent the work of each in the EHR. Access to all of this information also had the effect of pulling attention away from the patient to focus more on the EHR as a source of data about the patient. Nurses noticed physicians were less present on the inpatient floors and nurses and administrators noticed nurses more focused on the WOWs than their patients at times. Other observations in the outpatient settings demonstrated the value of access to a patient's clinical information from anywhere when interacting with the patient outside of a face to face encounter. Physician interactions were also positive using the EHR to collaborate on the care of a patient between primary care physician and specialist.

The second research question focusing on organizational process change identified areas of EHR effect in facilitating changes in workflows to improve compliance with clinical screening tools and improvement in general quality metrics. Processes for engaging with the patients were used to proactively manage patients with chronic diseases such as diabetes. And nursing identified the EHR has a tool to ensure safer medication administration both through safety checking of medications with bar

code scanning and build in algorithms for high risk medication administration. Nursing also identified the challenge the EHR presents of making process change too easy through adding another click or flow sheet and the adverse impact this has on the overall workflow and efficiency of nursing in providing care to patients.

The third research question focused on technology changes associated with the EHR. The EHR in itself is a large scale technology change for any health care organization but with it comes multiple other challenges for access to data from mobile devices to engaging patient more in their health care through access to their medical records through a patient portal. Finally, as adoption spread throughout the organization the appetite for more strongly integrated technology solutions also grew with a demand for integrated patient registration, scheduling, billing and circling back to clinical areas on the different EHRs to incorporate them into one enterprise solution.

Lastly, the fourth research question was a summative evaluation of the EHR effects at this organization. Overall, the sentiments of those interviewed and of the organizational documents reviewed were that EHR use has positive effects on the organization's processes and laid the foundation for the future of health care reform. Variation in use of the EHR provided continued challenges as well as balancing access to information over the need for privacy and maintaining patient focus. All of these findings provide interesting discussion in Chapter 5. The focus will be on providing conclusions of the data analysis as well as recommendations for further study.

Chapter 5: Discussion, Conclusions, and Recommendations

The purpose of this qualitative case study was to further the understanding of the effects of a comprehensive, integrated EHR on an academic medical center. The interactions of people, processes, and technology in a complex adaptive system have not been well documented in the literature due to only recent increases in implementation and adoption of EHRs in health care. Understanding how technology affects the health of populations, the patient experience and the reduction in the cost of care is a necessary step in achieving the triple aim of health care reform and EHR systems have been advertised as a necessary tool in this journey.

The findings of this study have identified some expected and unexpected effects of the EHR on a complex system including the known increases in communication and access to information. The unexpected result was the amount of time that the EHR has consumed of caregiver time in evaluation of the information available. Shifts in physician availability on the inpatient floors were also identified by several nurses as a result of access to patient information from anywhere. A myriad of process of changes were also identified ranging from the ability to drive improvement with EHR data for quality metrics such as diabetes monitoring and smoking cessation counselling to nursing implementing tools within the EHR to ensure safer medication administration. The downside to the capability to make process changes so easily was identified as increasing the volume of documentation tasks added to the nurses' daily work in often-haphazard ways that caused redundancy. Overall, the effects of the EHR on the organization have been positive though and have laid the foundation for shifts in health care to population

health and more preventive proactive management of patients even outside the walls of the organization. The EHR technology has driven the organization for more technology and more advanced solutions that are able to ingest data and present smarter decision support to physicians and nurses. That process gaps initially left open in the EHR implementation for the perioperative services have been a critical need for the organization to close. There also has been an increased desire to have a single integrated system with the EHR for business functions like registration, scheduling, and billing to provide a single platform for organization wide process changes to be made. The overall findings of this study have indicated positive effects of the EHR on the institution but also highlighted the areas to watch and the needs of the organization to focus on improved use of the system by individual and to implement measures to prevent the patient from getting lost in the technology.

Interpretation of Findings

The findings from this study reinforce the concepts of health care providers as knowledge workers responsible for ingesting and analyzing huge amounts of data in the care of patients every day. Nagle and Yetman's (2009) forecast of the need for nursing practice transformation in the age of the EHR becomes apparent in the findings that nursing participants found themselves tied to the WOWs throughout their shift so they could remain informed of new physician orders, patient results, and other changes to the plan of care for their patients. This was supported by the research of Kossman and Scheidenhelm (2008) who found that despite recognition of the positive benefits of the EHR to patient safety and access to information, the EHR consumed a large part of their

clinical time. The changing interactions of the different health care disciplines was also evident in the findings of this study as some participants found the physicians less present on inpatient units due to access to the EHR being available from remote locations. This was a surprising finding that was not expected or present in any of the literature reviewed for this paper. This change may support the move to more team based care management advocated by Nugus, Greenfield, Travaglia, Westbrook, and Braithwaite (2010) but it were unclear from the findings of this study and will probably continue to evolve over time.

The EHR system adds to the level of connectedness of health care providers across all care settings. This was demonstrated in the findings by several of the participants who expressed having greater access to the notes of other disciplines and for example having a more informed understanding of the role of the pharmacy in verification of medications because of the prominence of this workflow in the EHR. The participant responses also supported the use of the EHR to improve quality through initiatives to inform physicians with quality data from the EHR and to find the bright spots of providers or care areas that are doing well. The findings of the changes to daily activities for each of the participants demonstrate the potential of the EHR as a disruptive innovation that can provide an opportunity to rethink standard practices and roles. This supports Wang et al.'s (2006) belief that in order to achieve the goals of the triple aim that system level change was necessary.

Other findings related to people interactions included changes in engagement with patients. Some physician participants highlighted the increased transparency of care

afforded by the EHR through sharing the computer screen to educate patients on health and disease processes. Other methods of data sharing with patients were also communicated by the participants with the use of the patient portal. Incorporation of the patient as part of the care team in this way directly impacts the experience of care for each patient.

In Chapter 2, one of the new health care organizational structures created by the ACA was the ACO to push organizations to focus on holistic care of patients and not just the episodic care when the patient presents to the physician office or the emergency department (Berenson & Burton, 2012). Participants in this study articulated how the EHR was foundational in this organization's ability to meet the regulatory quality metrics by reporting on care gaps and educating physicians on the health of their population of patients. Some quality metrics were demonstrated to have marked increases in compliance as a result of being able to have fact based discussions with physicians on their performance. Secondary data use from the EHR has become a pivotal success factor in managing the changing health care environment.

Decision support tools built into the EHR have become a focus for improving the consistency of quality improvements with the EHR. Several participants including all three groups, physicians, nurses and administrators raised the use of the EHR to guide care process improvements. Examples included the use of the EHR to ensure patient safety with nurse administration of high-risk medications, ensuring physician ordering is supported with calculators and views of influencing data such as lab tests. Flatow et al., (2015) found in a study of the surgical intensive care unit at this institution postEHR

implementation a dramatic decrease in the incidence of central line blood infection rates and patient mortality rates that was attributed to the quality checklists built into the EHR for physicians to use to ensure consistency in care delivery. Despite these findings in the positive benefits of decision support within the EHR, several participants also highlighted the risk of alert fatigue resulting in ignoring all alerts. Other senior leadership identified the need to make the EHR system smarter to be able to analyze large amounts of complex patient data and produce predicative alerts for patients potentially on a path for critical health concerns. His analysis was that the EHR is not at a point where it is able to do this and needs to further evolve in this area to continue to improve the quality of patient outcomes while hospitalized.

Overall, the effects of the EHR on the academic medical center that was the focus of this study were positive. Participants highlighted the changes in practice that improved safety and quality initiatives throughout the organization. Creswell et al. (2014) performed a similar qualitative case study on two UK hospitals 2 years after the implementation of electronic systems for physician ordering and clinical decision support. The authors of that study were focused on the medium term benefits of these systems on the organizations and found similar focus on safety measures that improved with medication administration. The authors also included system usability as study factor many of their findings focused around computer availability and the potential errors that are possible with electronic ordering systems such as selecting the wrong patient. While these elements of usability and potential for data entry errors were not part of the elements for this study in this paper, similarities in findings around medication

administration increase the credibility of findings. The study in this paper extends the results of Cresswell et al. (2014) first by collecting data in a U.S. based academic medical center and also be focusing on a comprehensive integrated commercial system designed specifically for the American health care system. Second, this study extends the findings to areas not anticipated by the identification of the issues around cognitive focus being pulled away from the patient due to EHR use and the changes in physician nurse relationships on the inpatient units. The study outlined in this paper was also performed 5 years after the implementation of the EHR system and could demonstrate the continuing coevolution of the EHR to meet organizational needs.

The final area of findings for this study focused on the technology aspects of the EHR. The unexpected findings voiced by several of the participants were the need for further implementation of same vendor integrated tools for other functions such as registration and scheduling that were felt to be integral to further process improvement across all disciplines including front desk and administrative staff. Other areas that were expected were the need to fill the gaps where the single integrated EHR was not the system of record such as the perioperative areas. Participants involved in care delivery in these areas voiced the extreme difficulties and need for workarounds due to disparate systems in these areas and the potential benefits of a single system to continuity of care and regulatory compliance.

Limitations of the Study

The limitations of this study stem from the narrow focus on one academic medical center and the purposive sampling of participants within this large organization that was

not representative of all members of the organization. There were three groups of participants targeted for this study, physicians, nurses, and administrators. Some of the participants crossed between these two groups such as a physician in a senior administrator role or a nurse in a senior administrator role. In each of these instances the participant was asked to share their perspectives from both their clinical discipline as well as the administrator role especially if they had primary responsibility in each of these two roles during the time since the EHR was implemented. Not all varieties of roles within these groups were included in as participants primarily due to nonresponse to request to participate in the interview process.

The other limitation of this study was the potential bias of me as the researcher and also an employee of the organization. The intent of the participant selection was to focus mostly on participants who were not directly known to myself as the researcher. Due to difficulty in recruiting participants with the limitation established by the IRB many of the physicians agreeing to participate had some relationship with me as the researcher. For nursing, I was able to leverage several contacts in the department of nursing to recruit nurses as participants that were unknown to me as a researcher. To mitigate this potential bias in data collection with the physician, each participant was informed of my role as an employee and how that was separate from my role as a researcher for this study. Due to the types of questions and responses, I have no reason to believe that this previous relationship biased the information that was provided by any of the participants.

The limitations of this study focused on the narrow focus of the research on one academic medical center as well as the myself as the researcher. Future research that replicates this study at yearly increments post implementation as multiple organization using the multi case study approach could further extend the understanding of the effects of the EHR on an academic medical center. Cresswell et al. (2014) was also able to include both usability and observations as part of the deeper analysis that was performed on two institutions in England. Further exploring the possibility of incorporation of these aspects into a qualitative research case study could deepen the understanding of the topic. Finally, a mixed methods approach that identified quantitative data such as medication error rates, quality score changes in combination with qualitative data could provide additional useful information in this area.

Recommendations

The U.S. health care system is changing through regulatory pressure for costs to be closely tied to value and consumer demand for more transparency. Variation in health care practices are being targeted as inefficient and wasteful (Berwick & Hackbarth, 2012). EHR implementations, while providing a tool for improving quality and efficiency of health care processes, also provide a mechanism to collect and analyze data unlike anything previously possible with paper records. Determining how and what to measure are critical decisions that need to be made both for the evaluation of EHRs and health care reform outcomes. Hospital executives, hospital information technology executives, and vendor leadership should pay special attention to this research and assist in driving further research in this area to understand the evolving effects of the EHR in healthcare.

This qualitative case study was aimed at the evaluation of the EHR effects on one academic medical center through the analysis of participant interviews and organizational document review. A recommendation for further research would be to consider a mixed method approach to combine quantitative time study data on workflows as well as quality improvements with user perceptions of the effects of the EHR. Cresswell et al. (2014) recommended a mixed methods approach as well to compare user perceptions of the lack of timesaving with quantitative evidence.

Other quantitative data around improvements of efficiency could also be studied based on findings from this study that indicate variations in use of the EHR affect the overall value of the EHR system. This was not a variable that was considered for this study but arose from the participant interviews. Ancker et al., (2014) identified physician personal patterns of use of the EHR as a factor that should be considered in doing research of the effectiveness of EHR systems. Further research could be done on whether these variations are the result of lack of knowledge of systems features, or just individual preferences. Jordan, Lanham, Anderson, and McDaniel (2010) cautioned researchers though not to focus entirely on consistency in actions of agents within a complex system but rather explore further the outliers for potential positive variations.

Finally, the conceptual framework for this research was based on the work of Rippen, et al (2013) and this framework also provides direction for future research as well. The authors highlighted that a common missing facet of EHR evaluation is temporality (Rippen, et al. 2013). Health care organizations change over time and EHR system coevolves with the systems in which they are implemented, therefore, it is

important that research focus on the effects of the EHR over time. Cresswell et al. (2014) focused on evaluation of the order entry and CDS systems 2 years post implementation. I have focused on an organization that was 5 years post implementation with some similarities in findings. Cresswell pointed out that some predictions are that it takes 4-9 years to start seeing a return on investment for EHR systems possibly due to the maturity of secondary data use. Cresswell also included two facilities with the same order entry and clinical decision support system for their study. Future research on academic medical centers would also benefit from the inclusion of multiple organizations using the same commercial comprehensive integrated EHR system to identify any organizational differences that may affect the overall changes that the EHR introduced to the organization.

Another area of focus for future research could be the inclusion of patients as participants to understand their perceptions of the EHR as it relates to their care. Several aspects of this could be studied further including the ambulatory care setting in face to face encounters, out of business hours contacts with their physicians, and then inpatient experiences with nurse and physicians. Each of these areas could be explored further to determine if the technology of the EHR, WOWs or just the presence of a computer in an exam room detracted or added to their experience of care.

The findings of this study add to the current industry knowledge of EHRs effects on health care organizations. Cresswell, et al's (2014) focus on the medium term effects of the EHR are expanded through this study with a time period of 5 years post implementation being used. This also factors well into the organizational framework

element that was missing is many studies evaluated by Rippen et al (2014) of temporality. The findings from this research could be disseminated through the publication of the findings, after revision, in a peer review industry appropriate journal. In addition to this, presentation of findings at professional organization conferences such as the Health Information Management System Society annual conference would assist with dissemination of the findings of this study.

Implications

There are implications of this research on a variety of levels, individual for providers of health care, patients as consumers of health care as well organizations either implementing or evolving EHR systems and at a national policy level to address the needs of organizations to continue to evolve as the health care environment changes. The EHR is a disruptive innovation that has a myriad of effects on institutional processes (Brockstein et al., 2011). Taking a deeper dive into these changes to understand the changes in people, processes and technology as well as the interactions of the three is vital to both mitigating the adverse consequences of the change as well as achieving transformative positive change.

While plans for implementation and adoption of EHR systems have been the primary focus of researchers in the last several decades, the results of the HITECH Act have rapidly boosted adoption from hospital and individual physician practices. Researchers now have a social obligation to study the ongoing effects over time of these systems on the organizations where they are implemented and the people who use them. Going beyond the efforts of Brokel and Harrison (2009) in understanding the immediate

effects of EHR implementation, provided insight into how EHR systems need to evolve. As newer generations of physicians and nurses who have grown up as digital natives graduate and become the primary care providers, the demands for EHR systems to be more sophisticated and automate more processes will continue to increase. Complex adaptive systems theory proposes that organizational behavior is a result of the interaction and adaptation of the agents within the organization and development of simple rules that guide behavior. This study begins to delve into the understanding of these simple rules of interaction with the EHR and other agents within the system to ensure that the resulting outcomes move the organization and health care in general towards positive health care reform goals.

Significance to Practice

Undertaking an EHR implementation is a major investment with multiple points of failure for any organization, so a focus on implementation and adoption is imperative to ensure success. Adequate planning is often one of the elements identified as a reason for failure when looking back on implementation projects that have failed (Thompson, 2006). However, the planning for EHR implementation has to extend far beyond just the implementation phase to include the evaluation of the program both immediately after as a summative evaluation and also as ongoing formative evaluation as the system continues to evolve with the organization to ensure that the ongoing needs of the organization and individual care givers are supported (Jones, Swain, Patel, & Furukawa, 2014). The research done in this paper illuminated some of these ongoing needs and areas where

organizational focus was needed to address gaps in provider knowledge of the system as well as potentially harmful distractions of nurses by the information burden of the EHR.

Significance to Theory

The organizational framework of Rippen et al. (2013) was used in the research of this study to guide data collection and to organize the findings. This study added to the evidence that this framework was an effective method for evaluation of the EHR in the organizational context. Each of the elements of this framework was captured in the data collection and the use of this tool furthered the understanding of the effects of the EHR on a complex organization. Continued use of this tool for evaluation purposes will provide more standardized data for larger scale generalizability across institutions which was missing from the current literature due to the variety of methods used to approach the evaluation of EHR systems.

This research also extends the work of Cresswell et al. (2014) by extending the evaluation time period to 5 years post implementation. Ongoing evaluation to build upon these findings is also critical to continue to extend the understanding of the EHRs effects on an organization. Jordan, Lanham, Anderson, and McDaniel (2010) emphasized the need to not only focus on the goal of standardization of use but also on the outliers to deeper understanding of the simple rules that affect user behavior in relation to the EHR.

Significance to Social Change

All of us have been or will be consumers of health care services in our lifetimes. Improving the processes of health care delivery is a laudable goal and will have far reaching effects on society as a whole. Due to the complexity of the health care

environment in the U.S. and a history of failed interventions, careful and informed qualitative and quantitative research is critical to understanding the impact of EHRs on the complex adaptive systems of health care. The research in this study focused on the qualitative evaluation of an EHR on a complex academic medical center and has identified many areas of effect warranting further investigation and organizational action to address potential safety issues as well as further improve the performance of a significant capital investment.

This research will also inform other organizations planning for EHR implementations or post implementation evaluation of EHR effects on their organizations. Changing the perception of organization leadership to include the need for ongoing evaluation post implementation will ensure the coevolution of EHR systems and drive system vendors to continuously improve and innovate systems to meet the ongoing challenges faces by health care organizations.

Conclusions

Metcalfé's Law states that the value of a network grows as the square of the number of users (Metcalfé, 2013). This also seems to apply to the EHR when implemented in a complex health care system. A single integrated EHR used consistently across all care settings within an organization adds value that is exponential to disparate best of breed systems tailored specifically to each care area. The HITECH Act has stimulated the implementation and adoption of EHRs throughout the nation with the hopes of driving efficiency, quality, and cost containment. As organizations continue to expand and become more complex (Kocher & Sahni, 2011) the challenge of coordination

of care will also increase and become more complex. EHRs will continue to be critical tools as a catalyst for change in health care.

The findings from this study extend the knowledge in the field by supporting the use of complexity theory and an organizational framework for evaluation of EHR performance. In addition, this study also uncovered the ongoing challenges of information burden and lack of expertise on the users of the system. Elements such as these are critical to be surfaced and addressed to achieve maximum performance from the EHR as an investment and the improvement of patient care. Jones, Heaton, Rudin, and Schneider (2012) made the comparison of information technology's effect on productivity on business in the 1970s with the effects being experienced today in health care as the EHR systems are being implemented. The authors found the productivity increases were not immediately apparent in business sections for years after the implementation of information technology innovation. They argue that there are three reasons for this that apply to the health care experience, usability of systems, poor capabilities to measure improvement and time. Each of these elements were evident in this study of the effects of the EHR at an academic medical center and provide a call to action to continue to investigate the effects over time and drive the evolution of EHR systems to meet the needs of health care organization.

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Appendix A: Interview Protocol

Interview Protocol Project:

Time of interview:

Date:

Interviewer:

Interviewee:

Position of Interviewee:

Instructions:

- Review informed consent and assurances of confidentiality for information given
- Explain that summary data will be returned to the participant for accuracy checking

Questions:

1. Describe your role in the planning/use of the EHR.
2. How do you think that the EMR has changed your daily activities?
3. How has the system affected your interactions with other peers?
 - a. Is there any change to how you interact or how information is shared?
 - b. Have you seen any changes in practice for your peers or other colleagues?
4. How has your access to information changed? Positive or negative
 - a. What information do you have access to now that you did not prior to the EHR implementation?
 - b. Has this changed your approach to decision-making?
5. How do you feel the system has changed care delivery?
 - a. Have you seen any changes in the structure of care delivery such as new models, different expectations or changes in relationships between people?
6. Do you have a specific experience where the EMR played a critical role either positive or negative in clinical/administrative decision-making?
7. What organization-wide effects do you perceive related to the EMR implementation? Positive or Negative
8. Do you have anyone that you think I should talk to that has specific or important insight into the EMR impacts on the organization?

Appendix B: Observation Protocol

Observation protocol project:

Location/setting of observation:

Time of interview:

Date:

Observer:

Participants:

Position of participants:

Instructions:

- Review informed consent and assurances of confidentiality for information given
- Explain that summary data will be returned to the participant for accuracy checking
- Table B1

Descriptive Notes:	Reflective Notes

Appendix C: Informed Consent

**THE MOUNT SINAI HEALTH SYSTEM
 CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
 AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
 ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI**



Page 1 of 6

Study ID #: GCO #15-03248

Form Version Date: 4/1/15

TITLE OF RESEARCH STUDY:

Title: Effects of an Electronic Health Record System on an Academic Medical Center

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:**WHAT IS A RESEARCH STUDY?**

A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others.

People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay.

Someone will explain this research study to you. Feel free to ask all the questions you want before you decide. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

PURPOSE OF THIS RESEARCH STUDY:

The purpose of this study is to better understand the changes in the institution that occur after the implementation of an electronic health record system. The researcher is inviting physicians, physician extenders, nurses, and senior administrators to participate in the study. You have been invited to participate in this study because of your role in the organization and potential insight you have in the changes that have occurred since the implementation of the EHR at this facility. This form is part of a process called "informed consent" to allow you to understand this study before deciding whether to take part. This study is being conducted by a researcher named Kenneth Koppenhaver, who is a doctoral student at Walden University. You may already know the researcher as a senior director in the information technology department, but this study is separate from that role.

You may qualify to take part in this research study because of your experience working at Mount Sinai Hospital with the electronic health record system and being in one of three categories of participants, physician, nurse or administrator.

Funds for conducting this research are provided by the Mount Sinai School of Medicine

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Form Approval Date: 8/3/2015

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AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI**



Page 2 of 6

Study ID #: GCO #15-03248

Form Version Date: 4/1/15

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study is expected to last for the length of a 45 to 1 hour interview.

The total number of people expected to take part in this research study including the pilot and full study is a minimum of 22 and a maximum of 30.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

- Participate in a single semi-structured interview with this researcher lasting 45 minutes to an hour that will be digitally recorded. The location will be at a place of your convenience at the Mount Sinai Hospital. Individual digital recordings will be made of the interview and transcribed for data analysis. Each recording will be kept confidential by identifying each by your role at the institution and not by name.
- Participate in an observation of your use of the EHR system in typical daily activity lasting for approximately 30 minutes. This will be done in a place of your convenience at the Mount Sinai Hospital and outside of the clinical care areas. Notes of this observation will be taken by the researcher and kept confidential by labelling the notes only with your role.

At any time during the interview or observation process, you may decide to stop the process or refuse to answer a specific question if you are uncomfortable.

At the end of the interview process, a summary of the responses will be reviewed with the participant to ensure the accuracy of the responses. In addition, an executive summary of the findings will be presented back to all participants to further ensure credibility of the findings.

Here are some sample questions:

1. Describe your role in the planning/use of the EHR.
2. How do you think that the EMR has changed your daily activities?
3. How has the system affected your interactions with other peers?

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things:

Agree to a mutually acceptable time to meet for the interview.

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 CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
 AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
 ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI**



Page 3 of 6

Study ID #: GCO #15-03248

Form Version Date: 4/1/15

Show up for the interview on time with enough time to complete the interview (45 mins to 1 hour).

Provide honest and thoughtful responses to all questions from your own experiences with the electronic health record system at Mount Sinai Hospital.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for participating in this research study. Being in this research study will not lead to extra costs to you.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be contributing to the understanding of the electronic health records effects on health care.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

Being in this type of study involves some risk of the minor discomforts that can be encountered in daily life, such as time away from daily work or added stress. Being in this study would not pose a risk to your safety or well-being.

If you are a senior leader in the organization such as CFO, CNO or COO, identification by role may unintentionally identify you as a participant in this study. It is important that specific roles are identified for this study to understand the perspectives being shared. If this potential identification is not acceptable you may refuse to participate in this study at any time.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

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CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI**



Page 4 of 6

Study ID #: GCO #15-03248

Form Version Date: 4/1/15

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff.

You may also withdraw your permission for the use and disclosure of any of your protected information for research.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason.

CONTACT PERSON(S):

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator at phone number [REDACTED]

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than \$5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at <http://icahn.mssm.edu/> where Mount Sinai publicly discloses the industry relationships of our faculty.

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 AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
 ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI**



Page 5 of 6

Study ID #: GCO #15-03248

Form Version Date: 4/1/15

MAINTAINING CONFIDENTIALITY

As you take part in this research project it will be necessary for the research team and others to use and share some of your private information.

The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Any information you provide will be kept confidential. The researcher will not use your personal information for any purposes outside of this research project. Also, the researcher will not include your name or anything else that could identify you in the study reports. The only identifier that will be used is your role at the institution. Data will be kept secure by password protecting all electronic files and limiting identification of participants in hand written notes to just initials. Data will be kept for a period of at least 5 years, as required by the university .

No protected health information will be collected as part of this research study.

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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 CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
 AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
 ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI



Page 6 of 6

Study ID #: GCO #15-03248

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Signature Block for Capable Adult

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

DO NOT SIGN THIS FORM AFTER THIS DATE →

8/2/2016

Signature of subject

Date

Printed name of subject

Time
[required if used for FDA
documentation purposes]

Person Explaining Study and Obtaining Consent

Signature of person obtaining consent

Date

Printed name of person obtaining consent

Time

Witness Section: For use when a witness is required to observe the consent process, document below (for example, subject is illiterate or visually impaired, or this accompanies a short form consent):

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process

Date

Printed name of person witnessing consent process

Time

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Appendix D: Community Partner Letter of Cooperation and Data Use Agreement

LETTER OF COOPERATION

LETTER OF COOPERATION

Mount Sinai Hospital
Kumar Chatani
EVP & Chief Information Officer
Mount Sinai Health System
One Gustave L. Levy Place, Box 1000
New York, NY 10029

Date: April 23, 2015

Dear Kenneth Koppenhaver,

Based on my review of your research proposal, I give permission for you to conduct the study entitled Effects of an Electronic Health Record System on an Academic Medical Center within the Mount Sinai Hospital. As part of this study, I authorize you to collect interview and observational data from members of the organization through word of mouth snowball recruitment and referrals from other participants. Interviews will be held in Mount Sinai Hospital facilities and observations will be of participants using Mount Sinai Hospital IT systems, specifically the electronic health record system. In addition, access to a limited data set related to the return on investment studies and other documents created to outline the value of the electronic health record system can be used for the purposes of this research study. (See attached data use agreement)

Participants will be provided the transcriptions of interviews and/or observation notes to check for accuracy and summary results will be provided back to the organization. Individuals' participation will be made clear to be separate from regular work activities and voluntary at their discretion. Since the researcher is also an employee of this institution all activities authorized with this consent will be kept separate and apart from typical work activities.

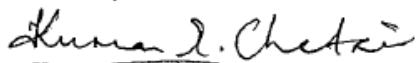
We understand that our organization's responsibilities include: allowing the use of conference or meeting rooms to conduct interviews that will be reserved through the normal process. No specific supervision will be required by the facility personnel. We reserve the right to withdraw from the study at any time if our circumstances change.

The student will be responsible for complying with our site's research policies and requirements, including getting Icahn School of Medicine IRB approval for this research, not using patient information or any information in any of Mount Sinai Hospital clinical databases, and focusing on personal opinions of those interviewed as well as other factual information in documents obtained with consent.

I confirm that I am authorized to approve research in this setting and that this plan complies with the organization's policies.

I understand that the data collected will remain entirely confidential and may not be provided to anyone outside of the student's supervising faculty/staff without permission from the Walden University IRB.

Sincerely,



Kumar Chatani
EVP & Chief Information Officer
Mount Sinai Health System
One Gustave L. Levy Place, Box 1000
New York, NY 10029

Walden University policy on electronic signatures: An electronic signature is just as valid as a written signature as long as both parties have agreed to conduct the transaction electronically. Electronic signatures are regulated by the Uniform Electronic Transactions Act. Electronic signatures are only valid when the signer is either (a) the sender of the email, or (b) copied on the email containing the signed document. Legally an "electronic signature" can be the person's typed name, their email address, or any other identifying marker. Walden University staff verify any electronic signatures that do not originate from a password-protected source (i.e., an email address officially on file with Walden).

DATA USE AGREEMENT

This Data Use Agreement ("Agreement"), effective as of 4/1/2015 ("Effective Date"), is entered into by and between Kenneth Koppenhaver ("Data Recipient") and Mount Sinai Hospital ("Data Provider"). The purpose of this Agreement is to provide Data Recipient with access to a Limited Data Set ("LDS") for use in research **in accord with laws and regulations of the governing bodies associated with the Data Provider, Data Recipient, and Data Recipient's educational program.** In the case of a discrepancy among laws, the agreement shall follow whichever law is more strict.

1. Definitions. Due to the study's affiliation with Laureate, a USA-based company, unless otherwise specified in this Agreement, all capitalized terms used in this Agreement not otherwise defined have the meaning established for purposes of the USA "HIPAA Regulations" and/or "FERPA Regulations" codified in the United States Code of Federal Regulations, as amended from time to time.
2. Preparation of the LDS. Data Provider shall prepare and furnish to Data Recipient a LDS in accord with any applicable laws and regulations of the governing bodies associated with the Data Provider, Data Recipient, and Data Recipient's educational program.
3. Data Fields in the LDS. **No direct identifiers such as names may be included in the Limited Data Set (LDS).** In preparing the LDS, Data Provider shall include the **data fields specified as follows**, which are the minimum necessary to accomplish the research: return on investment data re to the electronic health record system including hard and soft costs and changes to processes and structures within the organization related to the EHR system. No personal health information (PHI) will be accessed as part of this study.
4. Responsibilities of Data Recipient. Data Recipient agrees to:
 - a. Use or disclose the LDS only as permitted by this Agreement or as required by law;
 - b. Use appropriate safeguards to prevent use or disclosure of the LDS other than as permitted by this Agreement or required by law;
 - c. Report to Data Provider any use or disclosure of the LDS of which it becomes aware that is not permitted by this Agreement or required by law;
 - d. Require any of its subcontractors or agents that receive or have access to the LDS to agree to the same restrictions and conditions on the use and/or disclosure of the LDS that apply to Data Recipient under this Agreement; and
 - e. Not use the information in the LDS to identify or contact the individuals who are data subjects.
5. Permitted Uses and Disclosures of the LDS. Data Recipient may use and/or disclose the **LDS for its Research activities only.**

6. Term and Termination.

- a. Term. The term of this Agreement shall commence as of the Effective Date and shall continue for so long as Data Recipient retains the LDS, unless sooner terminated as set forth in this Agreement.
- b. Termination by Data Recipient. Data Recipient may terminate this agreement at any time by notifying the Data Provider and returning or destroying the LDS.
- c. Termination by Data Provider. Data Provider may terminate this agreement at any time by providing thirty (30) days prior written notice to Data Recipient.
- d. For Breach. Data Provider shall provide written notice to Data Recipient within ten (10) days of any determination that Data Recipient has breached a material term of this Agreement. Data Provider shall afford Data Recipient an opportunity to cure said alleged material breach upon mutually agreeable terms. Failure to agree on mutually agreeable terms for cure within thirty (30) days shall be grounds for the immediate termination of this Agreement by Data Provider.
- e. Effect of Termination. Sections 1, 4, 5, 6(e) and 7 of this Agreement shall survive any termination of this Agreement under subsections c or d.

7. Miscellaneous.

- a. Change in Law. The parties agree to negotiate in good faith to amend this Agreement to comport with changes in federal law that materially alter either or both parties' obligations under this Agreement. Provided however, that if the parties are unable to agree to mutually acceptable amendment(s) by the compliance date of the change in applicable law or regulations, either Party may terminate this Agreement as provided in section 6.
- b. Construction of Terms. The terms of this Agreement shall be construed to give effect to applicable federal interpretative guidance regarding the HIPAA Regulations.
- c. No Third Party Beneficiaries. Nothing in this Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.
- d. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- e. Headings. The headings and other captions in this Agreement are for convenience and reference only and shall not be used in interpreting, construing or enforcing any of the provisions of this Agreement.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf.

DATA PROVIDER

Signed: Kumar S. Chatri
Print Name: KUMAR CHATRI
Print Title: EVP/CIO

DATA RECIPIENT

Signed: KK
Print Name: Kenneth
Koppenhaver
Print Title: Co investigator

Appendix E: Emails to Participants

PRELIMINARY EMAIL

To: x
From: Ken Koppenhaver
Subject: Preliminary request to participate in a research study

Dear x,

I am writing to invite you to participate in a research study of the effects of an electronic health record system on an academic medical center. This research study is being done as part of doctoral dissertation research through Walden University. Permission has been gained through the IRB at Walden as well as through the IRB at the Icahn School of Medicine at Mount Sinai. Participation would involve the involvement in a semi-structured 45 min interview with questions dealing with your experiences with the electronic health record system and its effect on the academic medical center.

Please contact me at the below email address or phone number if you are willing to participate in this study. Further information will be provided on the background and purpose of the study should you wish to participate. Thank you for your consideration.

Sincerely

BACKGROUND PILOT STUDY EMAIL

To: x

From: Ken Koppenhaver

Subject: Request for participation in research pilot study

Dear x,

The initial pilot of this research will involve participation in a 45 minute semi-structured interview focused on understanding how the interactions of people, processes and technology within an organization change and ultimately change the organization after transitioning to an integrated, comprehensive electronic health record system.

The pilot for this research study will involve interviews for 2-3 people to ensure that the interview questions appropriately garner information to answer the research questions for this study. After the pilot data is analyzed, further refinement of the interview questions may be done.

In addition to interview data, each participant will be asked if they have knowledge of other potential participants who may have knowledge that would further the understanding of the research topic.

All participation in this study is voluntary and unrelated to employment at Mount Sinai hospital for both the researcher and any potential participants. All information collected will be kept confidential, and any reference to participants or the institution will be removed from the final study. Each participant will be asked to complete an informed consent that outlines the risks and benefits of the study, and each participant can withdraw at any time from the study.

Each participant will be provided a transcript of the interview to check for accuracy. Thank you for reviewing this request and please let me know if you would be willing to participate in this study and we can determine a mutually acceptable time for the interview. My contact information is listed below.

Sincerely

BACKGROUND FULL STUDY EMAIL

To: x
From: Ken Koppenhaver
Subject: Request for participation in full research study

Dear x,

This research will involve participation in a 45 minute semistructured interview focused on understanding how the interactions of people, processes and technology within an organization change and ultimately change the organization after transitioning to an integrated, comprehensive electronic health record system.

This research study will involve people from three different groups including, nursing, physicians, and senior administrators to gather each group's experiences with the electronic health record system.

In addition to interview data, if there are elements of the discussion that might be easier to convey with observation of the use of the EHR observation of the participant interacting with the EHR will be discussed and a mutual agreed upon time arranged. Each participant will be asked if they have knowledge of other potential people who might have useful knowledge or experiences and be willing to participate.

All participation in this study is voluntary and unrelated to employment at Mount Sinai hospital for both the researcher and any potential participants. All information collected will be kept confidential, and any reference to participants by name or the institution will be removed from the final study. Each participant will be asked to complete an informed consent that outlines the risks and benefits of the study, and each participant can withdraw at any time from the study.

Each participant will be provided a transcript of the interview to check for accuracy. Thank you for reviewing this request and please let me know if you would be willing to participate in this study. My contact information is listed below, and we can determine a mutually acceptable time for the interview.

Sincerely

Appendix F: Confidentiality Agreement

CONFIDENTIALITY AGREEMENT

1

CONFIDENTIALITY AGREEMENT
Ken Koppenhaver Transcription ProjectName of Signer: *Heidi J. Muir*

During the course of my activity in transcription of data for this research: "The Effects of and Electronic Health Record on an Academic Medical Center" I will have access to information, which is confidential and should not be disclosed. I acknowledge that the information must remain confidential and that improper disclosure of confidential information can be damaging to the participant.

By signing this Confidentiality Agreement I acknowledge and agree that:

1. I will not disclose or discuss any confidential information with others, including friends or family.
2. I will not in any way divulge, copy, release, sell, loan, alter or destroy any confidential information except as properly authorized.
3. I will not discuss confidential information where others can overhear the conversation. I understand that it is not acceptable to discuss confidential information even if the participant's name is not used.
4. I will not make any unauthorized transmissions, inquiries, modification or purging of confidential information.
5. I agree that my obligations under this agreement will continue after termination of the job that I will perform.
6. I understand that violation of this agreement will have legal implications.
7. I will only access or use systems or devices I'm officially authorized to access and I will not demonstrate the operation or function of systems or devices to unauthorized individuals.

Signing this document, I acknowledge that I have read the agreement, and I agree to comply with all the terms and conditions stated above.

Signature: *Heidi J. Muir*Date: *03/26/2015*

DBA Mediascribe