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ASSESSING THE PERFORMANCE DIFFERENCES BETWEEN HOSPITALS WITH AND WITHOUT MEANINGFUL USE OF ELECTRONIC HEALTH RECORDS ON CARE OUTCOMES

ΒY

Joseph G. Conte

Submitted in partial fulfillment of the

requirements for the degree of Doctor of Philosophy in Health Sciences

Seton Hall University

2016

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Assessing the Performance Differences between Hospitals with and without Meaningful

Use of Electronic Health Records on Care Outcomes

By

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Submitted in partial fulfillment of the requirements for the degree of

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2016

ACKNOWLEDGEMENTS

Many individuals deserve acknowledgement for their support and contributions to the journey, the completion of this study and the achievement of this Ph.D. First I would like to acknowledge my dissertation committee members.

Dr. Cahill, your untiring support throughout this process made the difference in achieving this end result. The work is materially better for the many hours spent challenging me to improve the end product. I am extremely grateful for your guidance and fortitude. I know that the academic perspective of this material is in great measure due to your guidance.

Dr. Battaglia, I am extremely grateful to have the benefit of your experience in reviewing the clinical aspects of this paper in supporting the effort. Your timely advice and willingness to contribute to its completion were very important to its content.

Dr. Zhang, as the "big data" expert of this committee I am most appreciative of your formative guidance in assembling the datasets and content. Your expert guidance provided an invaluable focus on managing such a robust and large data base.

Dr. Ong, as a colleague and friend your support has been invaluable in pursuit of this Ph.D. Your stature in the health informatics community was a

constant reminder to me of how important this work was in putting a lens of electronic health records.

A special thanks to Dr. Deluca and Dr. Zipp, both members of the original faculty who interviewed me upon my application to the program. You are a special example to all the students in your integrity, diligence and intellectual rigor. I would also like to recognize Joann Deberto for her special help in navigating the maze of University requirements at each step of this long process.

To all my friends who have supported and encouraged me through this arduous and sometimes uncertain path, it is with great pride I can say your trust was not misplaced.

Lastly, and most important I would like to thank my family members who have been dragged along through this process. Through thick and thin you have never been anything but a great cheer leading section and understanding of the sacrifice that was needed to cross the finish line. When life intrudes on your path it is those closest to you that keep everything in balance.

DEDICATION

This dissertation study is dedicated in memory of my sister Anita Rose Conte. A formidable personality and one of the most impactful people in my life. Her perseverance and dedication to those things that she held to be important is a constant reminder that only the best is good enough. Gone far too soon but never forgotten.

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ABSTRACT

Assessing the Performance Differences between Hospitals with and without Meaningful Use of Electronic Health Records on Care Outcomes

Joseph G. Conte

Seton Hall University, 2016 Dissertation Chair: Terrence F. Cahill, Ed.D. FACHE

Background and Purpose of the Study: The U.S. healthcare system at \$3 trillion, is the sixth largest economy in the world. The federal government is the largest purchaser of healthcare in the country. In the past decade it has been on a quest to refocus its purchasing from volume to value. While spending nearly double per capita than every other industrialized nation, U.S. healthcare outcomes are consistently in the lowest quartile for every major indicator from life expectancy to ambulatory sensitive conditions. The Crossing the Quality Chasm Report (IOM) focused a lens on the dearth of electronic health record (EHR) systems nationally. Resultant legislation, the HITECH Act, funded a \$50 billion investment to close this gap along with promulgation of standards known as Meaningful Use (MU) to achieve interoperability. This investment and related MU protocols for implementation warrant a careful examination to establish if the intended improved outcomes have been achieved.

Methods: The study is a cross-sectional, retrospective design; it employs two cohorts, Meaningful Use (MU) vs Non-MU hospitals. Publicly reported data on clinical outcomes, cost and safety from 4221 or 95% of the nation's hospitals were included in the analysis to identify if there is a difference in outcomes between the hospital cohorts.

Results: 2315 of the 4221 or 55% hospitals who were included in the study met MU standards by 2013. The profile of an MU hospital was a non-teaching (70%), geographically southern (40%), not-for-profit hospital (61%). Non-Mu hospital had a similar profile, 78% non-teaching, 35% Southern and 60% not-for-profit. Those hospitals who met MU had statistically lower mortality (p<.05) rates for all three clinical conditions (heart attack, heart failure, pneumonia) and statistically lower cost per discharge of \$327 (p<.05). The improved outcomes suggest a reduced cost of over \$6 billion and 21,000 fewer deaths.

Conclusion: The HITECH Act that committed over \$50 billion in subsidy incentive funds has dramatically increased EHR adoption nationally from 8% in 2009 to over 50% by 2013. The results from this suggest hospitals that had implemented EHRs' that meet MU standards demonstrate mortality and cost outcomes that result in statistically significant cost and clinical care benefit.

CHAPTER 1

INTRODUCTION

BACKGROUND OF THE PROBLEM

The United States spends nearly double per capita what every industrialized nation does on health care per the Organization for Economic Cooperation and Development (Figure 1). However, ranks in the lowest quartiles of performance for infant mortality, life expectancy, male and female healthy life expectancy and nearly every major health indicator (Figure 2). These outcomes, coupled with an abysmal patient safety record (IOM, 1999; Bates, 2001; Shekelle, 2011) underlie systemic flaws in the system. The need to identify effective levers for change began to evolve from government, industry and health economist in academia (Porter, 2006). The gaps identified were not the absence of evidence based best practices, clinical guidelines, competent practitioners or academic rigor but a misaligned payment model and a dearth of electronic health records in the nation's hospitals (IOM, 2001).

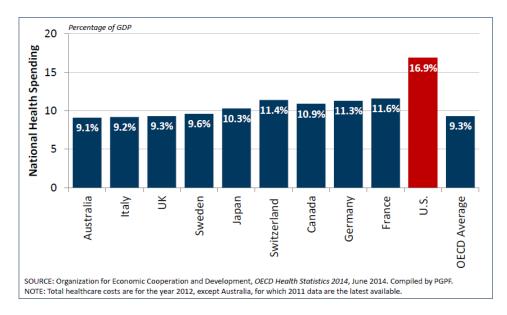


Figure 1. Healthcare Spending Per Citizen Compared to U.S.

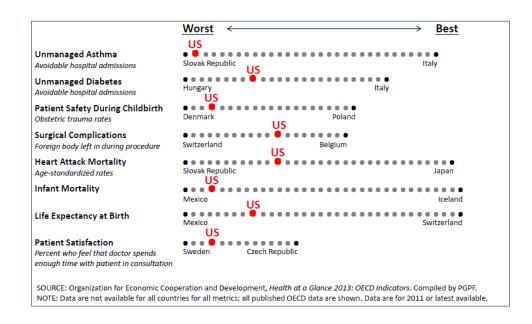


Figure 2. Healthcare Indicators - International vs U.S.

In the search for solutions to the value inequity in American healthcare, the report *"Crossing the Quality Chasm: A New Health System for the 21st Century"*

(IOM, 2001), focused national attention on electronic health records (EHR). The report highlighted structural shortcomings of the existing healthcare delivery system, a major one being the "absence of real progress...toward applying advances in information technology" (p. 115). The report stated that all healthcare organizations should set goals for improvement, specifically that healthcare should be: safe, patient-centered, efficient, effective, timely and equitable. In support of the IOM findings, the Health Information Technology for Economic and Clinical Health Act (HITECH) legislation was created to stimulate the adoption of health information technology. This \$50 billion investment, coupled with excitement generated by literature (Hillestad, 2005) that suggested that nearly \$80 billion in savings would accrue from EHR adoption nationwide spurred a rush to EHR adoption (Desroches, 2013).

While electronic health record systems (EHR) existed in hospitals for decades, they functioned in isolation as departmental reporting and record keeping tools. Laboratory, pathology, imaging, pharmacy and other ancillary programs without interconnectivity left valuable information isolated and inaccessible to multidisciplinary team users, resulting in excess utilization, ineffective prescribing and safety lapses (Bates, 2001). An interconnected, cohesive electronic health record platform with access to the most current evidence base, clinical decision support and safety features to prevent errors was lacking in over 92% of hospitals as late as 2008 (DesRoches, 2010).

In addition to the focus on the EHR gap, payment reform is another lever being utilized to change the fundamental economics driving health cost, quality and the wide variations in care utilization trends (Fisher, 2009). The endgame in healthcare purchasing is not strictly one of cost control nor one of quality improvement in isolation; it is a search for value (Porter, 2006; McHugh, 2010). Value in healthcare is defined as health outcomes achieved per dollars spent (Porter, 2006). Different models of payment reform such as Pay for Performance, Value Based Purchasing, Accountable Care Organizations (shared savings or risk models) and patient Centered Medical Home programs are all in play in the search for sustainable models balancing patient centered care with cost and quality outcomes (Eldridge, 2011). Ultimately, value-based purchasing is part of a much broader policy "experiment" to advance value as a remedy for spiraling health benefit costs and quality concerns in US healthcare. The implementation of payment reform in parallel with the HITECH Act support for EHR has created a naturally occurring experiment in which to study the difference between hospitals that have adopted EHR technology and attested to Meaningful Use (MU) standards versus those that have not. Meaningful Use is the set of standards for EMR adoption and functionality as defined by the Office of the National Coordinator (ONC). ONC not only defines the standards but also governs the assessment process employed to evaluate eligible providers' and hospitals' implementation progress to earn incentive payments.

The HITECH Act legislation committed a combined \$50 billion in federal and state funds to support the rapid expansion of EHR capability in the nation's hospitals and physician practices. The problem is that this legislation, while bold and strategic, was designed without empirical evidence that the investment would yield improved outcomes in population health, cost and safety. The belief that EHR adoption represents a significant component of the solution to modulate annual cost trajectory of healthcare and solve the quality and safety dilemma rests on conflicting research which is at present inconclusive and depending on measurement parameters, time periods included and available survey data (Hillestad, 2005; Buntin, 2011; Blumenthal, 2010; Desroches, 2010; Rudin, 2014).

Further not only does the HITECH Act commit \$50 billion in public funding, the criteria to earn the subsidy payments require substantial investments by hospitals and healthcare systems. To obtain subsidy funding, which began in 2011, healthcare providers had to demonstrate MU of electronic health records (EHR). As stated above, MU is the set of standards for EHR adoption and functionality as defined by the Office of the National Coordinator (ONC). ONC not only defines the standards but also governs the assessment process employed to evaluate eligible providers' and hospitals' implementation progress to earn incentive payments. The opportunity to qualify for payments began in 2011 for hospitals attesting to meaningful use standards. In 2015, CMS began withholding between 1 and 3% of Medicare payments to those hospitals that failed to meet the MU requirements. It is estimated that the private funding required for the nation's hospitals could top well over \$100 billion (Rand, 2005)

PURPOSE OF THE STUDY

This study was undertaken to focus a lens on the impact of EHR adoption, a major health policy initiative under the HITECH Act (2009). HITECH was implemented in parallel with Value Based Purchasing, the CMS program designed to realign payment with value and away from the fee for service structure focused on volume. This study is needed because these 2 policy decisions created an intersecting impact on the healthcare system and have created a major gap in the literature that this study was designed to address. The purpose of this research therefore is to study whether there is a difference in publicly reported outcomes of quality, safety and cost per discharge between hospitals that have adopted EHR's and achieved MU status versus those that have not achieved MU in the era of value based purchasing.

As the healthcare payment system transitions to VBP, outcomes measures focusing on quality and cost are the key indicators to assess improvement and progress (VanLare, 2012; McHugh, 2010; Ranawat, 2009; James, 2012). Prior studies focused solely on process measures for quality measurement. These measures assess compliance with steps in care protocols, while a proxy assessment of quality (Donabedian, 1988, 2005; Mant, 2001) they do not align with current Value Based Payment models where hard outcomes linked to expenditure such as readmission, cost per discharge, infection and mortality rates drive reimbursement schema. Cost calculations were not standardized and therefore not comparable from study to study (Himmelstein, 2009; Chaudry, 2006; DesRoches, 2010; Appari, 2009; Agha, 2011). This study included safety, quality outcomes and cost per discharge measurements to assess whether MU adoption of EHR systems makes a difference in these outcomes.

Numerous studies (Himmelstein, 2009; Chaudry, 2006; DesRoches, 2010; Appari, 2009; Agha, 2011) have demonstrated that EHR adoption has a generally positive impact on process measures of quality. Most however, have found negative to neutral outcomes on cost of care. Much of this research was conducted prior to the creation of MU criteria (Himmelstein, 2009; Chaudry, 2006) or standardized cost per episode of care. This gap indicates that this research approach, outcome vs process is necessary to more closely focus a lens on how MU standards can improve cost and value as organizational maturity and experience with EHR evolves.

Therefore, in the context of value based purchasing (VBP), the secondary purpose of the study is to utilize outcome measures such as mortality, readmission and cost per episode of care linked to Value Based Payment models as opposed to process measures to evaluate the differences in performance in clinical quality and cost. These and other outcome measures are the foundation of payment under the VBP methodology. The challenge to the validity of the program is utilizing reliable quality indicators and a sound cost rubric (Wachter, 2006; Rudin, 2014, Kazley, 2009). Therefore, an underlying goal of this study is to bring a level of consistent outcome measurement to the literature in the MU era. This will stand in contrast to the inconsistent and complicated systems of performance measurement previously applied when comparing results between organizations outcomes and their MU status.

Study Variables

The independent variables selected for this research have been utilized consistently in the literature focusing on EHR adoption (Chaudry, 2006; Jha, 2009; Himmelstein, 2009; Agha, 2011; Ding, 2011; DesRoches, 2013). The variables are teaching status, case mix index (CMI) or acuity, region, discharge volume and owner status (Table 1). Teaching status describes whether a hospital participates in graduate medical education of physicians as defined by Council of Teaching Hospitals and Health Systems (COTH). Teaching hospitals characteristics include tendency toward more complex care, service for the underprivileged, greater cost per discharge and urban locations (Shahian, 2014).

Table I: Study Variables

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Variable	Measurement	Туре
EHR Status	MU vs non-MU	Independent Variable
Total Discharges	Number cases	Categorical
Acuity	Risk adjusted case mix index rate	Categorical
Teaching Status	Yes or No	Categorical
Ownership Type	Government, Proprietary, Voluntary (coded 1-3)	Categorical
Region	Midwest, Northeast, South, West (coded 1-4)	Categorical

Case mix is an extremely important variable in that it reflects the complexity of care across various diagnostic related groups (DGR), but also includes factors that account for regional variation in cost of services. DRG are assigned by the primary reason for hospital care but also include a patient's age, sex race as well as co-morbidities. Co-morbidities are pre-existing medical conditions that affect how care is provided and ultimately weigh on the total cost of service and likelihood of a favorable outcome of care. CMI is represented as a numeric value with a normalized base of 1.0. This represents the "average hospital" CMI, a value greater than 1.0 reflects higher complexity of care and cost of service, with the opposite holding true. In the VBP context CMI is a very important hospital factor for reimbursement.

Region is a geographic construct coded 1-4 applied to mirror the 4 regions recognized by the Center for Medicare coding system. Discharge volume reflects total number of cases discharge from the hospital included deaths. Obstetrical and pediatric cases are not included in Medicare calculations. Ownership status falls into the three categories, not-for-profit, for-profit, governmental.

In order to address cost, quality and safety measurements, the dependent variables for this study are cost per inpatient discharge, morbidity and mortality rates for heart attack, heart failure and pneumonia and a standardized patient safety score (Table 2).

Table II: Dependent Variables

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Indicator	Measurement	Measure	Domain
Heart Attack	Mortality	Rate	Quality
Heart Attack	Readmission	Rate	Quality
Congestive Heart Failure	Mortality	Rate	Quality
Congestive Heart Failure	Readmission	Rate	Quality
Pneumonia	Mortality	Rate	Quality
Pneumonia	Readmission	Rate	Quality
Safety	Composite	Score (0-1)	Safety
Cost per Discharge	Adjusted Cost per Discharge	Dollar Value	Cost

Research Questions

These are the five research questions:

Is there a difference in clinical outcomes between hospitals that have achieved Meaningful Use (MU) for their EHR systems verse hospitals that have not achieved MU as measured by mortality and readmission rate for Heart failure?

Is there a difference in clinical outcomes between hospitals that have achieved Meaningful Use (MU) for their EHR systems verse hospitals that have not achieved MU as measured by mortality and readmission rate for Heart attack?

Is there a difference in clinical outcomes between hospitals that have achieved Meaningful Use (MU) for their EHR systems verse hospitals that have not achieved MU as measured by mortality and readmission rate for Pneumonia?

Is there a difference in clinical outcomes between hospitals that have achieved Meaningful Use (MU) for their EHR systems verse hospitals that have not achieved MU as measured by Agency for Healthcare Research and Quality Patient Safety Indicator

Measurement?

Is there a difference in cost per discharge between hospitals that have achieved Meaningful Use (MU) for their EHR systems verse hospitals that have not achieved as measured by the CMS standardized cost per discharge metric?

Significance of the Study

There are over 4000 hospitals in the US confronted by what is essentially a federal mandate to achieve MU adoption of their EHR systems, i.e. incur penalties for non-adoption of 2% of gross Medicare revenue by 2016. Given the magnitude of the investment required by hospitals and the \$50 billion in governmental subsidy available to transform healthcare in the US to an interoperable EHR platform objective measurement of its efficacy is essential. This study applies outcome not process measures that align with core VBP indicators to evaluate whether EHR adoption under the MU guidelines can achieve the promise of quality, cost and safety improvement highlighted in the Crossing the Quality Chasm report (IOM, 2001).

In 2015, over \$1.5 billion was withheld from hospitals that failed to achieve the specified performance outcomes and then reallocated to hospitals based on their overall performance on a set of outcome measures in clinical, cost and satisfaction measures (www.cms.gov/VBP). The paradigm shift of moving away from paying for volume of services to linking payment with outcomes for the 100 million Americans covered by Medicare is transformational. This is the most significant change in US healthcare since government sponsored health insurance came into being. Because commercial Medicare managed care plans and Medicaid programs in each of the states are adopting this very same payment methodology, the influence of value based purchasing in US healthcare is an attempt at transformation on a grand scale (VanLare, 2012; Eldridge, 2011).

Operational Definitions

There are three main constructs used in this study that are identified in the literature. These three constructs are Meaningful Use, Value Based Purchasing and Quality/Outcomes Measurement. Meaningful Use (MU) refers to the criteria developed by the Office of the National Coordinator (ONC) that defines the interconnectivity standards and technical performance requirements necessary to achieve MU designation under one of the three progressive levels to be eligible for federal subsidy payments. Value-based purchasing (VBP), links payment directly to the quality of care provided, it moves the focus from volume to value (Porter, 2009). CMS has made VBP (www.cms.gov/Medicare/Quality-Initiatives) the focus of its effort under the Affordable Care Act, to transform the current payment system by rewarding providers for delivering high quality, efficient clinical care based on value, not volume. The methodology most favored when assessing quality of care in the hospital setting has been to use process measures (Donabedian, 1988). The shift to outcome measures like mortality, readmission, infection rates, etc. has occurred in parallel (VanLare, 2012; Ranawat, 2009; Porter, 2009) with the need to shift from adherence to standards. to risk adjusted outcomes of care where value not volume is the driver.

CONCEPTUAL MODEL

The measurement of outcomes is at the core of the analysis to determine if there is a relationship between MU adoption of EHR systems and improvements regarding quality of care and/or safety, and/or cost of care." This study draws on two theoretical frameworks, one focused on clinical care measurements and the other focused on healthcare economics. The Donabedian Model is the dominant paradigm for assessing the health care. It focuses on structure, process and outcome to measure quality. The second is the Value Based Purchasing theory advanced by an economist Michael Porter in his seminal work, Redefining Healthcare (2006). The Porter model argues that the US healthcare system's inherently misaligned payment methodology resulted in the pursuit of high volume, high margin services without a focus on the outcomes of health for the population being served or the total cost of care incurred.

The successful adoption of EHR's under the Meaningful Use (MU) criteria developed by the CMS Office of the National Coordinator is based upon achieving, both process and outcome milestones. The Donabedian model therefore is uniquely suited to function as an overall theoretical model as it incorporates the assessment of multiple process steps to achieve MU while at the same time including the care outcomes as a core domain. How the domains of EHR implementation processes and measures for the outcomes of quality and cost of care align to form the theoretical measurement approach to assess the difference in outcomes for MU and non-MU hospitals is illustrated in Figure 3.

Dimension	How Measured
Structure ➤ EHR	➤ ONC Certified EHR System
Process	≻ Meeting CMS per Criteria ≻ MU Criteria
Outcomes > Mortality > Readmission > Cost > Safety	 > Rate > Rate > CMS Cost per discharge > AHRQ Safety Score

Figure 3. Application of Donabedian Model Assessment of EHR

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Figure 3 illustrates the Donabedian structure, process, outcome matrix as applied in this study to EHR adoption. Under structure, it encompasses the physical facility, equipment, and human resources, as well as organizational characteristics such as staff training and payment methods. The Process elements include technical processes for EHR implementation, compliance with ONC criteria under MU and provision of services influenced by EHR protocols. And of course the outcome domain contains all the effects of healthcare on patients or populations, including changes to health status, behavior, healthrelated quality of life. This theoretical model, while oriented to process measures as proxies for outcomes such as achieving MU status process criteria, is also as flexible enough to incorporate outcome indicators into measurement criteria.

In fact, nearly thirty years ago Donabedian (1988) made an astute observation that is at the core of the dilemma of the inexorable cost trajectory in healthcare. He noted that "it is believed that as one adds to care, the corresponding improvements in health become progressively smaller while costs continue to rise unabated" (p. 1745). Consistent with current payment reform focus on value, he postulated that it is possible to separate quality from inefficiency by analyzing each added bit of expected usefulness against its corresponding cost. Those providing care without regard to cost, he terms maximalist. Those who provide care with a focus on weighing each additional bit of expected usefulness against its corresponding cost, he terms optimalist.

Donabedian captures the essence of current healthcare reform debate by focusing on the maximalist vs optimalist approaches to care and their respective impacts on cost and health benefits. This value dilemma, excessive cost coupled with inferior population health and safety outcomes, positions the US healthcare system to search for systemic, effective solutions. What the Donabedian model lacked was an economic framework to embody this concept into a system with functional regulatory and financial underpinnings. This is where the work of Porter with its emphasis on value, cost and outcome created the underpinning for the value based purchasing paradigm.

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Porter's seminal work Redefining Healthcare (2006) focused on the misaligned reimbursement model as the root cause for out of control cost and poor health outcomes. He highlighted how the entrenched pay for volume rather than payment for value system encouraged high cost, high volume care rather than a focus on population health. In Figure 4. the change associated with current to future state evolution in VBP is represented.

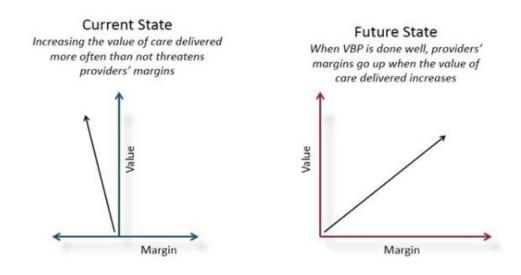


Figure 4. Current State vs. Future State Evolution in VBP

Source: New York State Value Based Roadmap, 2015

Porter also rejected reliance on compliance with process measures as an effective measure system to govern reimbursement methodology preferring the IHI inspired Triple Aim (IHI, 2006) outcome measures rubric. The current VBP system informed by Porter's work has shifted reimbursement from former pay for volume to a focus on outcomes of care and total cost of service. After a transition

period, 2011-2013, where process measures dominated payment, outcomes of care and cost now account for 90% of reimbursement for the program in 2016.

These two conceptual models, the Donabedian triad model of structure, process and outcome, coupled with the Porter value based payment model are the theoretical pillars adopted by this study to measure the impact of EHR systems on hospitals. In order to bring a more detailed focus on the research to date as well as the theoretical concepts and developments of EHR implementation in the MU era, the literature on the topic is reviewed in the next Chapter.

Chapter II

LITERATURE REVIEW

The early excitement on the potential quality and cost improvements benefits, associated with EMR adoption was fueled by literature funded by the Rand Corporation (Hillestad, 2005) that suggested that nearly \$80 billion in savings would accrue from EHR adoption nationwide. This estimate was based on savings associated with efficiency, clinical decision support and safety improvements. When added to the anticipated savings from improvements in preventative and chronic disease management the estimated benefit increased to the \$100 billion level.

Prior to the adoption of the HITECH Act (2009), which included over \$50 billion in federal Meaningful Use (MU) funding, the US seriously lagged other industrialized nations in EMR adoption. In 2008, prior to the advent of MU incentives, fewer than 9% of US hospitals had even basic EMR systems (DesRoches, 2013). The benefit of MU incentives and threat of penalties (HITEC Act, 2009) jump started EMR adoption and by 2010 the proportion of US hospitals with basic EMR jumped to 15% (DesRoches, 2013). Once financial incentives under MU began flowing in 2011, the adoption of EHR systems nearly doubled to 27% (AHA IT Survey, 2013). The American Hospital Association data (IT Survey, 2013) identified that EHR adoption was most robust in large urban and teaching hospitals.

As the \$30 billion HITECH Act (2009) subsidy to stimulate EHR into US healthcare over the past 10 years has accelerated, the effort to assess its effectiveness

has grown. However, the literature (Chaudry, 2006; Himmelstein, 2009; DesRoches, 2010; Ding, 2011; Appari, 2012) that has investigated the association between the investment in EHR and its effect on quality, safety and cost domains reveal mixed results at best. Individual hospital, ambulatory practice and even health system reviews illustrate improvements in domains such as medication safety (Bates, 2001; Poon, 2012) or quality scores (Lindenauer, 2007), yet the results are far from conclusive. Other recent studies have demonstrated little if any benefit in quality and none in cost control (Ding, 2011; Himmelstein, 2009).

Appari, et al. (2012) reviewed HIT and quality data for a four year period (2006-2010) for 3,921 non-federal hospitals. They measured quality by analysing process measure compliance for pneumonia, heart attack and heart failure. Statistical analysis was conducted using fixed effects linear panel regression models over a 5 year period, 2006-2010. Their study entitled "Meaningful Use of Electronic Health Record Systems and Process Quality of Care: Evidence from a Panel Data Analysis of U.S. Acute-Care Hospitals", found adoption of EHRs did improve hospital process quality measures for AMI, heart failure and pneumonia. This improvement was especially true for hospitals that started with scores in the lowest quartile of performance. In an unexpected finding, hospitals with EHRs that upgraded their basic systems to more advanced functionality experienced a quality score decline. This finding prompted a cautionary conclusion "technology implementation alone is not sufficient to produce quality improvement" (p. 17). As stated earlier, a limitation in this and other studies is that it was conducted before MU criteria were codified by the Office of the National Coordinator. Their evaluation of MU compliance was based on self-reported capabilities from the AHA annual IT survey not assessment of MU compliance as required under the HITECH Act (2009). Neither cost nor safety was included in the analysis critical factors when the value of services are evolving into central theme in healthcare policy.

Spencer (2010) utilized a national cohort study based on primary survey data about hospital EHR capability and publicly reported quality data. A regression analysis was used to assess the relationship between EHR adoption and quality improvement for heart attack, heart failure and pneumonia care. To evaluate the association between quality improvement over time and the availability of an EHR, they compared hospitals that maintained a system with those that reported having no system. The results were striking for significant increase in quality scores for heart failure, less for heart attack and none for pneumonia scores. Unlike the findings from the Appari, et al. (2012), implementation of advanced systems did not result in decreased quality scores but did result in smaller gains for AMI and heart failure.

Ding et al., (2011) examined the effects of EMR on the clinical, financial and operational outcomes of U.S. hospitals. They utilized publicly reported data on EHR adoption from 2006-2008 (the pre-MU era). The information was obtained from the Health Information Management (HIMSS) database, the Hospital Quality Alliance for quality scores and the American Hospital Association database for performance metrics. The focus of the study was to test the effects of EMR adoption over time within a hospital. This is a unique analysis moving away from EMR adoption as a binary variable, i.e. EHR vs no EHR, to one looking at the effect of the adoption overtime.

Using simultaneous regression models they found that EMR adoption has a positive and significant effect on cost and quality. Specifically, adoption history, the time an organization was operational with an EMR, was associated with reduced cost per patient day but not on length of stay. Therefore, overall cost per discharge were essentially unchanged. The improvement in process quality measures for AMI, heart failure and pneumonia clinical outcomes likewise increased over time. When comparing the effect size, they found the impact on operational and financial outcomes more significant than that on clinical quality measures.

Himmelstein (2009) linked data from an annual survey of computerization at approximately 4,000 hospitals for the period from 2003 to 2007 with administrative cost data from Medicare Cost Reports and cost and quality data from the 2008 Dartmouth Health Atlas. Higher overall computerization scores correlated weakly with better quality scores for acute myocardial infarction ($r_0.07$, $P_..003$), but not for heart failure, pneumonia, or the 3 conditions combined. Utilizing multivariate analyses, more computerized hospitals had slightly better quality. However, in comparing a hospital's overall computerization score, more computerized hospitals had higher total costs in the 2003-2007 period and a more rapid increase in computerization was associated with a faster increase in computerization costs. Himmelstein, et.al (2009) concluded that as currently implemented, hospital computing might modestly improve process measures of quality but does not reduce administrative or overall costs. Further, hospitals that increased their computerization more rapidly had larger increases in administrative costs. As significant federal and state financial resources continue to be committed to

EHR adoption, the investments, as per Himmelstein, "rest on scant data" and "Recent Congressional Budget Office reviews have been equally skeptical..." (pg. 2).

Value Based Purchasing

Payment reform is a lever being utilized to change the fundamental economics driving health cost, quality and wide variations in care utilization trends (U.S Department Health and Human Services, 2007; Eldridge, 2011). The endgame in healthcare purchasing is not strictly one of cost control nor one of quality improvement in isolation; it is a search for value. This means a movement away from payment for volume to one of payment to reward quality outcomes that contain cost. Different models of payment reform such as Pay for Performance, Value Based Purchasing, Accountable Care Organizations (shared savings or risk models) and patient Centered Medical Home programs are all active strategies in a search for sustainable models balancing patient centered care with cost and quality outcomes (James, 2012; VanLare, 2012) Ultimately, value-based purchasing is part of a much broader policy "experiment" to advance value as a remedy for spiraling health costs and quality concerns in US healthcare.

Regardless of the vehicle(s) chosen, until incentives to providers are aligned in local or regional arrangements with population health as an ultimate measure of value, the current siloed approach under fee-for-service will continue to promote perverse resource utilization (VanLare, 2012). As demonstrated over the past 20 years by Dartmouth Atlas reports (Fisher, 1999) regional variation in health care costs have no correlation to differences in quality outcomes, acuity of care or cost of care delivery. The report identified that in high cost regions (Fisher, 2009) utilization patterns by physicians and others respond to the availability of high cost alternative services that have no greater efficacy, including discretionary referrals to specialists. The payment for volume of services provided which was the predominant model by which discretionary service was delivered resulted in high cost care with no quality difference.

The current system of care drives destructive competition not competition on value (Porter, 1999). Pro-competitive and outcome oriented care such as Value-based purchasing (VBP), links payment directly to the quality of care provided, it moves the focus from volume to value (Porter, 2009). Based upon similar mounting evidence regarding the unsustainable cost trajectory and lack of association with value, CMS has made the focus of its efforts to transform the current payment system by rewarding providers for delivering high quality, efficient clinical care (James, 2012; Affordable Care Act, 2010). Through a number of public reporting programs, demonstration projects, pilot programs, and voluntary efforts, CMS has launched VBP initiatives in hospitals, physician offices, nursing homes, home health services, and dialysis facilities (CMS Hospital Pay-for-Performance Workgroup, 2007). In 2006, Congress passed the Deficit Reduction Act of 2005 (DRA), which authorized CMS to develop a plan for VBP for Medicare hospital services commencing FY 2009.

An early effort at incentives for publicly reporting process quality measures was Medicare's Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program. This is a pay-for-reporting (P4R) program that uses Medicare payment as an incentive for hospitals to publicly report on the care they provide all adults, regardless of

payer. As originally mandated under the 2003 Medicare Modernization Act (MMA), the RHQDAPU provision required that PPS hospitals report on a specified set of 10 clinical performance measures in order to avoid a 0.4 percentage point reduction in their Annual Payment Update (APU) for inpatient hospital services. This is the source of the self-reported quality data for the Hospital Compare website, <u>www.hospitalcompare.gov</u>.

Payment reform has resulted in multiple reimbursement methodologies being experimented with to identify provider preference and reduced cost. These include bundled payments programs (innovation.cms.gov/initiatives/bundled-payments) where a group of providers split a single payment by episode of care. Examples include joint replacement or cardiac surgery have shown promise (VanLare, 2012). The Geisinger coronary bypass program, known as ProvenCare, is designed as a flat fee payment for surgery and all related care for 90 days after discharge. At Geisinger health care system, these programs demonstrated a 10% reduction in readmissions, shorter average length of stay, and reduced hospital charges. Perhaps most importantly, the program achieved a 44% drop in readmissions over a course of 18 months (Bertko, 2010).

When P4P objectives are aligned with national best practice evidence as in the CMS/Premier Quality Incentive Demonstration (HQID), process quality measures improved significantly over a matched control group of non-participating hospitals (Lindenauer, 2007). The study enrolled 266 participants in the HQID who were matched with 406 Hospital Quality Alliance (HQA) controls. Hospitals needed to have a minimum of 30 cases per condition (heart failure, heart attack, pneumonia, cardiac and

orthopedic surgery measures) annually to be eligible for the demonstration. For each of the clinical conditions, hospitals performing in the top decile on a composite measure of quality for a given year received a 2% bonus payment in addition to the usual Medicare reimbursement rate. Hospitals in the second decile received a 1% bonus. Bonuses averaged \$71,960 per year and ranged from \$914 to \$847,227. A participation requirement was that all hospitals accept a risk of financial penalty. These penalties ranged from 1 to 2% of Medicare payments for the conditions under evaluation. They applied if by the end of the third year of the program they ranked in the lowest two deciles of hospitals. This is one of the earlier programs in which providers demonstrated a willingness to accept risk based agreements (CMS, VBP, 2010) this is an important but largely forgotten fact.

Gain sharing, once controversial but now in popular use, is another approach to reward incentivized behavior. Gainsharing arrangements, particularly those used in hospital and integrated delivery systems, provide bonus payments to physicians and other providers, to reward cost savings resulting from their efforts to reorganize delivery of clinically appropriate care at a lower cost (Eldridge, 2011). The benefit for Medicare is that CMS shares in 50% of the reduced payments. Accountable Care Organization (ACO) type programs, where total cost of care for a population is assigned to the participating practitioners, has now evolved more towards a value based paradigm. In the new ACO/gain sharing scenarios providers now have down side risk if they overspend the funds allocated to their population which often is calculated as the prior 3

year average per capita spend (<u>https://www.cms.gov/Medicare/Medicare-Fee-for-</u> Service-Payment/ACO/index.html).

Regardless of the foregoing, Porter (2006) is critical of payment reform methodologies such as P4P which do not seek to keep the focus on value. He criticizes their emphasis on compliance with evidence based guidelines and algorithms because they lack focus on outcomes of care such as readmission, mortality, cost per discharge, etc. More important is that they do not discourage excess utilization. Donabedian described clinicians as maximalist when their approaches to incremental care result in little change in outcome, Porter expressly discourages reward for P4P in these programs. A financing incentive linked to process measure improvement, P4P, rewards providers for achieving pre-established performance objectives in defined medical conditions and procedures. However there is some evidence that at least process quality improved in at least one large national study (Lindenauer, 2007).

PROCESS VERSUS OUTCOME - ASSESSING QUALITY IN THE MEANINGFUL USE & VALUE BASED ERA

The correct method to select in order to objectively assess quality and cost outcomes, the two basic components of the value equation, remain very much in debate. The current practice for evaluating EMR impact on healthcare is the analysis of its impact on cost and quality. The most widely applied method to evaluate quality performance is the use of process measures (Donabedian, 1988; Mant, 2001; Mainz, 2003; Lilford, 2007). However, as Pronovost (2004) notes, the IOM defines quality as "the degree to which health services for individuals and populations increase the likelihood of desired *health outcomes (emphasis added)* and are consistent with current professional knowledge." As CMS enters its third year of the Value Based Payment Program for Medicare (CMS, 2010) the focus is clearly on cost and outcome measures. The emphasis on process measures has diminished from 60% to 10% of the reimbursement methodology. Numerous proponents (VanLare, 2012; Ranawat, 2009; Porter, 2009) of the outcome measures emphasize the need to shift from mere adherence to standards, to risk adjusted outcomes of care where value not volume is the driver.

However, from the clinical standpoint Liford (2007) and Mant (2001) support the contrary premise that process measures are direct measures of the quality of health care, provided that a link has been demonstrated between a given process and outcome. In addition, they advocate for process measures because they are well defined, easily measured, sensitive, specific and easy to interpret. Their construct validity is derived from professional societies such as American Heart Association, American College of Cardiology, etc. and therefore well vetted and form the community standard of practice. The controversy of process versus outcome measures is a consistent theme of quality literature (Pronovost, 2004; Mant, 2001; Liford, 2007). The acuity of patient's conditions, their compliance with care plans, their financial and sociologic backgrounds, referred to as social determinants of health, all influence important outcomes such as readmission, mortality and control of chronic disease. In

these circumstances it would be as Mant (2001) notes a "misnomer" to refer to outcome measures as performance indicators since this would indicate a "barometer" of population health. In an insightful and pertinent reference to the usefulness of outcome measures, Mant notes outcome data should be used to "inform upon wider aspects of health policy", which Value Based Purchasing is a central theme. (p. 479)

The current reliance on process measures is not based solely upon concerns with the potentially confounding factors referenced above. Experts in quality have postulated that the triad of structure-process-outcome forms the foundation of quality improvement processes. Donabedian (1966, 1988), a practicing physician, emphasized the importance of both process and outcome measures. He stated "we cannot claim either for measurement of process or measurement of outcome an inherently superior validity, since the validity of either flows to an equal degree from the validity of the science that postulates a linkage between the two. But process and outcome do have, on the whole, some different properties that make them more or less suitable objects of measurement for given purposes" (p. 1746).

Mainz (2003), also supports a strategy to employ both process and outcome measures depending on the purpose. Process measures are especially useful when quality improvement initiatives are being initiated as they can be applied to small samples and are sensitive to small differences making them desirable for departmental and local analysis. The foundation of the application of these measures is that they be valid, requiring rigorous testing to produce the desired outcome, which he refers to as "outcome validated", and therefore represent direct measures of quality.

Outcome measures are more suited to assess the effectiveness of process and as end points of care (Lilford, 2007; Mant, 2001). Examples of hospital specific outcome measures include mortality, infection and readmission rates. However, outcome measures have the added feature of being able to encompass broad public health measures such as cancer, influenza and cardiac disease prevalence. As Mainz (2003) notes, it can be recommended that the broader the perspective required, the greater the relevance of outcome indicators." (p. 527) It is therefore not surprising that CMS, as the largest payer of healthcare in the United States, has moved towards the implementation of outcome measures as a yardstick for quality performance and payment.

Table III: Examples of Indicators Related to Structure, Process & Outcome © 2016 Joseph G. Conte

Structure	Process	Outcome		
Diabetes Self Management	Staff, Enroll, Educate	Control Hemoglobin A1C;		
Program	Diabetes Patients	Micro Albumin		
Developed Care	High Risk Patients identified	Reduction Avoidable ER &		
Coordination Program	and enrolled	Hospital Admission		
Availability of Cardiac Intervention	Timing of Emergent PTCA for Patients with AMI	AMI Mortality Rate		
Asthma Management	At-Risk Patients Identified &	Compliance with Medication		
Program	Enrolled	Eliminate ER Use		
Substance Abuse Disorder Program	Referral & Treatment Peers & Counselors	Reduce BH Admission Percent Complete Detox Program		

Illustrated in Table III are indicators for conditions such as stroke, asthma, heart attack care, women's health and ICU care. What can be discerned from each of the indicators is the continuity between the structural component, the process to be employed and the desired outcome to be achieved. As Mainz (2003) astutely observed, process measures are especially usefully for evaluating compliance with standards of care and feedback on departmental performance. The outcome measures on the other hand, are more a check on the effectiveness of the implementation of the standards and broader public health or policy objectives that are desired to be achieved. CMS, the largest payer of health care in the three trillion dollar U.S. health system, has evolved from a passive payer of services to a more demanding consumer seeking to achieve a balance between cost and quality; hence the advent of Value Based Purchasing Program (Federal Register, 2011).

SUMMARY OF THE LITERATURE TO DATE

There are three distinct but related areas of literature being utilized to inform the parameters of study on EHR impact on quality cost and outcome. They are literature that assess the impact EHR adoption has on healthcare performance, literature that utilizes differing measurement philosophies to measure performance (process vs outcome) and the literature on the payment reform programs.

While the need to improve quality and safety outcomes is of paramount importance (IOM, 1999; IOM 2001) the \$3 trillion cost associated with the U.S. healthcare systems is an unsustainable financial burden for the government (Porter, 2006; Darling, 2010)) and individuals (Polsky, 2009). The need to clearly identify what, if any, cost savings can be associated with the adoption of EMR under MU guidelines, has therefore received great attention. The review of the payment reform literature details the shift away from fee for service or volume based care to payment for value (Porter, 2006; Ranawat, 2009; Eldridge. 2011; James, 2012; VanLare, 2012). One focus of this study will be to identify what if any connection exists between EHR adoption and improved cost. As previously noted numerous studies (Himmelstein, 2009; DesRoches, 2010; Appari, 2009; Agha, 2011) have demonstrated that EMR adoption while having generally positive impact on process measures of quality have negative to neutral outcomes on cost of care.

GAPS IN THE LITERATURE

To make the connection between EHR adoption, MU standards and shift towards value and improved outcomes a measurement redesign is required. The underpinning of the EHR literature analysis conducted to date has been the reliance on process measures to assess performance difference on quality, safety and cost (Chaudry, 2006; DesRoches, 2010: Buntin, 2011; Jones, 2014). Whether compared within or between hospitals before and after EHR adoption or between hospitals that have or have not adopted the technology, reliance on process measures has been the standard measurement rubric. This method while accepted professionally (Donabedian, 1988; Mant, 2001; Mainz, 2003; Lilford, 2007) is in direct conflict with the measurement paradigm used for the various VBP payment models. Since the parallel lever for healthcare transformation, payment reform, is being simultaneously implemented with MU standards for EHR adoption the linkage with outcomes that influence direct cost

such as cost per discharge, readmission, preventable ER use, complication rates, etc. Further the cost variable used from study to study was inconsistent with some study using cost estimates derived from annual cost reports (Himmelstein, 2009) or financial and operational data from the American Hospital Directory (Ding, 2011). The fact that much of this research was conducted prior to standard MU definitions being available, i.e. the pre-MU era, also confounded reliability of the adoption stage of EHR technology estimated by hospitals. None of the estimates of adoption were based on the MU criteria and all data was based on survey responses which at best resulted in 50% response rates. This lack of consistency between studies dictates that continued research is necessary to more closely focus a lens on how MU standards for interoperability, provider order entry (CPOE), and decision support can improve cost and value as organizational experience with EMR evolves (Ding, 2011).

The gaps that this study will address impact both methodological and analytical domains. Previous studies ignored the advent of value based purchasing on the measurement paradigm. No prior study utilized the actual achievement of MU status as measured by CMS as a sorting method to cohort MU and non-MU hospitals. Early approaches relied on incomplete and self-reported survey data applying a HIMSS electronic health record functionality algorithm. Another major methodological gap this study will bridge is the prior approach to measure quality. When assessing the impact EHR had on clinical performance prior studies relied solely on process measures not outcome measures. This study also bridges the gap between the prior studies that used non-standardized cost measures.

The question to be explored in this research is whether achieving meaningful use status (MU) of EHR technology is associated with achieving a more favorable relationship between cost, safety and improved healthcare outcomes. The difference between this study and prior research that attempted to make this connection is that this study will use standardized cost values calculated by the CMS which risk adjust for acuity, regional cost variation and teaching status. Therefore, all cost values will be uniform and consistent between hospitals. In addition, all MU criteria will be judged by the ONC criteria for MU standards so that each response is internally valid and consistent between hospital responses. In prior research, self-reported survey data with response rate as low as 50% were used to rank MU performance. This study will not be affected by survey response bias since all hospitals must respond to achieve their MU incentives and those that do not are automatically categorized as non-MU.

Chapter III

RESEARCH METHODS

RESEARCH DESIGN

The study is a cross-sectional, retrospective design; it employs two cohorts, Meaningful Use (MU) vs Non-MU hospitals. This research seeks to assess the impact of EHR adoption on publicly reported outcomes for quality, safety and cost in the value based purchasing era. As many as half of U.S. hospitals (DesRoches, 2013) did not have a basic EHR system as of 2012 and far fewer had attested to MU standards. The implementation of healthcare payment reform as a component of the Affordable Care Act (ACA) in parallel with the HITECH Act created a naturally occurring experiment in which to study the difference between hospitals who have adopted EHR technology and attested to MU standards versus those who have not but have been equally impacted by the Value Based Purchasing program without attesting to MU with EHR adoption, the independent variable. Since there was no human subjects or individual level personal health information the Seton Hall Institutional Review Board (IRB) concluded that the study did not fall under the requirement for IRB review (See Appendix A).

Sample

Two cohorts were created from the Center for Medicare and Medicaid Services (CMS) Hospital database. One cohort will represented hospitals that had not attested to the MU adoption of certified EHR technology as of 2013. The second cohort were hospitals that had attested to MU. For this study, data on EHR adoption followed strict

inclusion criteria for meeting MU adoption standards promulgated by the Office of the National Coordinator (ONC). The actual records were drawn from the CMS payment documentation file that records which hospitals received meaningful use payments and in what years it was paid. Therefore, there was no need for proxy mapping (Appari, 2012; Furukawa, 2010) to interpret hospital survey responses previously required in other studies to establish whether existing EHR met MU core standards as proscribed by the ONC.

This study utilized MU payment as the inclusion criteria for EHR adoption with MU standards. To receive meaningful use payments, hospitals had to meet the predetermined Office of the National Coordinator (ONC) performance criteria and then "attest" to the technology adoption. Through December 2015, Federal payments of \$21,095,328,473 have been paid to all eligible providers with nearly \$13 billion going to acute care hospitals (<u>https://www.cms.gov/Regulations-and-</u>

<u>Guidance/Legislation/EHRIncentivePrograms/Downloads/December2015_MedicareEH</u> <u>RIncentivePayments.pdf</u>).

The MU data file is the most current and accurate database of hospitals attesting to and being verified as meeting Meaningful Use standards as well as payments being issued based on performance validation. This current study includes a sample of 4,221 hospitals or 94% of hospitals nationwide. In comparison, the American Hospital Association annual survey of 4,474 acute care hospitals had an IT supplement response rate of 2,796, or 62.4%. This response rate while relatively high, results in a

loss of data for 1425 hospitals. As discussed in Chapter 5 this may have a material impact on accuracy and validity of the information.

DESCRIPTION OF STUDY VARIABLES

Cost per Discharge

In order to assess the difference in cost per discharge between MU and non-MU hospitals, this study utilized standardized cost per discharge value from the CMS database publicly reported through Hospital Compare (www.hospitalcompate.gov). Importantly, this data file contains cost per discharge adjusted for unique characteristics of hospitals, historically identified as confounding variables preventing meaningful cost comparisons. The formula adjusts for differences among hospitals in geographical location and in certain hospital-specific attributes. The latter include higher costs of carrying on an approved teaching program, higher costs of care associated with a payer mix that includes a higher percentage of low-income Medicare and Medicaid patient populations, and special pass-through payments for unusual capital and other costs. This study utilized the specific hospital data to conduct a MU vs Non-MU cohort level comparison to assess cost impact in the value based purchasing context, no other study utilized this approach.

Quality Outcomes

Under the Value Based Purchasing Program (Federal Register, 2011), CMS has tied performance on clinical outcomes to reimbursement. The methodology employed in measuring clinical quality performance in this study is the analysis of risk adjusted mortality and readmission rates for three clinical conditions developed by CMS for

national reporting purposes from the outset of the program. The clinical conditions measured include: heart failure, community acquired pneumonia (pneumonia) and myocardial infarction (heart attack). In order to introduce this evolving approach to quality measurement, an underpinning is required to attempt to control the confounding factors and risk adjustment. The CMS database utilized to report facility outcomes has adopted a risk adjustment methodology that creates a level playing field for organizations to be compared to one another on this important outcome metric (Pitches, 2007; Roberson, 2015).

Safety Indicator

This study utilized Patient Safety Indicator 90 (PSI 90) an Agency for Healthcare Research and Quality composite value utilized by Hospital Compare website as a safety measure proxy measurement (www.qualityindicators.ahrq.gov/Modules/psi_resources). Importantly for comparison purposes, the measures of serious complications reported on Hospital Compare are risk adjusted to account for differences in hospital patients' characteristics. The rate for each PSI is calculated by dividing the actual number of outcomes at each hospital by the number of eligible discharges for that measure at each hospital, multiplied by 1,000. The composite value reported on Hospital Compare (https://www.medicare.gov/hospitalcompare/data/serious-complications.html) is the weighted averages of the component indicators.

Hospital Demographics

Endogenous variables that are associated with hospital performance (CMS, 2014; Lin, 2014; Appari, 2012) were identified for each hospital included in the analysis.

These variables include hospital teaching status, hospital ownership category, and acuity of care, as measured by the case mix index (CMI), hospital region, and activity level as measured by annual discharges. Categorized by their MU status, each hospital individually and the respective hospital cohort (MU vs non-MU) performance were measured against its own performance for the baseline period 2009 versus 2013.

DATA COLLECTION

The analytic sample was comprised of 4,221 non-federal acute care hospital U.S. hospitals using data reported from 2011 through 2013. Data was drawn from three publicly reported national databases with respect to hospital's technology status, costs and performance on publicly reported clinical outcomes, functional characteristics and demographics.

These databases are the only source utilized by CMS for reimbursement and public reporting purposes when determining which organization had achieved EHR implementation that meets MU standards, risk adjusted quality outcomes and identification of standardized costs controlling for multiple variables. The majority of data utilized on the previous assessment of EHR adoption and its impact on quality, safety and cost by other large national studies (Appari, 2010; Ding, 2011; Agha, 2011, Himmelstein, 2009; Jones, 2014), relied either on self-reported survey data, non-risk adjusted clinical performance and cost report data that was not standardized for multiple hospital specific or regional variables.

DATA ANALYSIS

Measurement Methodology

The Hospitals were assigned to control and treatment cohorts based upon their EMR adoption status. The respective hospitals unique Common Identification Number (CIN) number was used as a linking code to compile the information accurately from the 3 publicly reported databases utilized for the study. Each hospital's publicly reported performance data referred to above, for the respective pre and post MU attestation periods, was be obtained.

Due to the large number of hospitals, over 4000, wide geographic dispersion and other disparate attributes, the subject hospitals vary widely in numerous ways. To identify and report on these variables each hospitals'_demographics profile information, most frequently associated with likelihood to adopt EHR technology was identified from the respective publicly reported data bases. These variables include: teaching status which identifies if the hospital trains residents, acuity which is measured as a function of case mix index, discharge volume measured as Medicare discharges and geographic regions. The hospital region was coded numerical as 1-4, to comply with the CMS methodology for identifying hospitals.

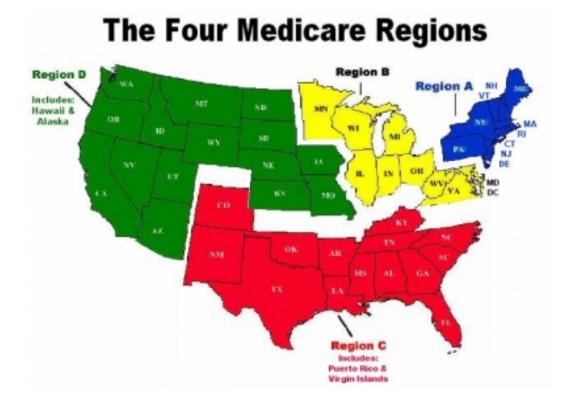


Figure 5. The Four Medicare Regions

Source: https://www.cms.gov/About-CMS/Agency-

Information/RegionalOffices/RegionalMap.html

The clinical outcome, safety and cost values all were risk adjusted to account for variations age, sex, severity of patient condition (CMI), indirect medical education cost associated with teaching status, operating expense associated with geographic location and payments for treating uninsured known as disproportionate share or DISH payments.

As stated above, all of the outcome measures selected were risk adjusted by the respective agency that reported the data, thereby normalizing the values across hospitals. For the clinical outcomes the 3M risk adjustment methodology was utilized by

CMS. For the standardized cost per discharge CMS developed an internal cost adjustment methodology in conjunction with statistical experts from Acumen LLC (http://www.qualitynet.org/dcs) and the Agency for Health care Research and Quality (AHRQ) devised the safety composite score approach (http://qualityindicators.ahrq.gov/Downloads/Modules/PSI/PSI_Composite_Developmen t.pdf.)

DATA ANALYSIS METHODS

This study used the publicly reported data available through the Office of the National Coordinator for MU status as well as the CMS clinical, cost and safety data set (https://data.medicare.gov/data/hospital-compare). It separated the hospitals into MU and non-MU status and then combined each of the 4221 hospital's risk adjusted outcome data and categorical variables into the master data set resulted in over 287,000 data elements for analysis. This robust data base combined with the risk adjustment scheme for the outcome indicators supported a unique and detailed statistical analysis of the difference in performance between MU and non-MU hospitals.

The statistical analysis was conducted on the outcomes of the two independent cohorts, MU and non-MU to establish whether there a difference between hospitals that implemented EMR and those that did not on important outcome variables. The data was statistically analyzed utilizing SPSS version 22. The analysis included: Levene's Test of Equality of Error Variances; Tests of Between-Subjects Effects; T-Test. All of the data was analyzed at a minimum alpha of at least 0.05.

Based upon these parameters a T-test is the appropriate statistical test. It satisfies the following criteria:

Assumption #1: The dependent variable is be measured on a continuous scale Assumption #2: The independent variable consists of two categorical groups.

The data analysis methodology includes both descriptive statistics and inferential statistical analysis. Descriptive statistics in the form of frequencies, means, medians and standard deviations were constructed and utilized to examine specific characteristics of the hospital research population. There is one independent variable - MU with two categories and eight dependent variables, analyzed separately. There are 8 dependent variables: 3 readmission rates (heart attack, heart failure and pneumonia) and 3 mortality rates (heart attack, heart failure and pneumonia) a safety measure and the cost per hospital discharge.

There are five descriptive variables for the sample (Teaching, region, ownership, acuity and number of discharges). The five categorical variables are not integrated into the research design.

This study was the first to gather "big data" utilizing publicly reported information which was not reliant on voluntary survey responses, included a standardized cost per discharge metric, without being reliant on a proxy measures gathered via voluntary survey responses to identify MU status. Therefore, the results presented in the next chapter utilize a new lens with which to determine how electronic health records with MU capabilities impact cost, quality and safety.

Chapter IV

RESULTS

INTRODUCTION

The purpose of this study was to evaluate whether there is a difference in hospital performance between organizations that have adopted meaningful use of electronic health records and those that have not. This chapter focuses on the statistical analysis of the data assembled on the outcomes of 4221 hospitals.

CHARACTERISTICS OF THE SAMPLE

After the application of exclusion criteria, data was assembled on 4221 hospitals. There were 560 hospitals eliminated from the study because they had less than 50 discharges per year, or less than at least 30 discharges per category of clinical performance. Outcome measures were identified from publicly reported data sources, the performance year selected for study was 2013.

The profile of a hospital is comprised of demographic and operational characteristics. These characteristics or endogenous variables (CMS, 2014; Lin, 2014; Appari, 2012) were identified for each hospital included in the analysis. The variables include hospital teaching status, hospital ownership category, acuity of care as measured by case mix index (CMI), hospital region which was coded consistent with CMS regions and labeled 1-4 depending on state geography and activity level as measured by annual discharges. In Table IV. the teaching status, region and

ownership are illustrated for each of these characteristics in the respective cohorts, MU and non-MU.

Characteristic	All Hospitals	Meaningful Use=YES	Meaningful Use=NO
	(N=4221)	(N=2315)	(N=1906)
Teaching Status			
No	3127 (74.1)	1637 (70.71)	1490 (78.17)
Yes	1094 (25.9)	678 (29.29)	416 (21.83)
Region			
Midwest	1239 (29.4)	666 (28.77)	573 (30.06)
Northeast	575 (13.6)	361 (15.59)	214 (11.23)
South	1579 (37.4)	915 (39.52)	664 (34.84)
West	780 (18.5)	373 (16.11)	407 (21.35)
Owner			
Government	479 (20.7)	444 (23.3)	479 (20.7)
Physician	11 (0.5)	28 (1.5)	11 (0.5)
Proprietary	697 (16.5)	412 (17.8)	285 (15.0)
Voluntary	2547 (60.3)	1406 (60.7)	1141 (59.9)

Table IV: Frequencies and Percentage of Total by Categorical Variables

In the MU cohort, 2315 or 55% of hospitals had attested to MU by 2013. Seventy-one % or 1637 were non-teaching facilities, with the majority (40%) located in the South, followed by the Midwest, 29%, West and Northeast at 16% each. The predominant ownership model was 61% voluntary, not for profit status, followed by governmental 23%, proprietary 18% and physician owned 1.5%.

For the non-MU cohort, 1906 or 45%, had yet to attest to MU. Seventy eight % or 1490 were non-teaching facilities, with the majority (35%) located in the South,

followed by the Midwest, 30%, West 21% and Northeast at 11%. The predominant ownership model was 60% voluntary, not for profit status, followed by governmental 21%, proprietary 15% and physician owned 0.5%.

DEPENDENT VARIABLE RESULTS

The differences in outcome performance between meaningful use (MU) and nonmeaningful use (Non-MU) hospitals were analyzed through T-Test. The level of significance utilized was P =.05. The dependent variables results describe mortality and readmission rates for heart failure, heart attack and pneumonia, cost per discharge and the AHRQ aggregate safety score.

In Table V. the number of hospitals who reported by condition and the mean performance of the respective dependent variables is illustrated for all hospitals, MU and non-MU cohorts. The "N" of each subset is a function of how many hospitals met reporting criteria per variable. Minimum reporting thresholds were 30 discharges annually per condition. What should be highlighted is that the difference in mean performance in mortality is consistently in favor of the MU hospitals, as is the difference in cost per discharge. The readmission rate is lower for all three conditions in favor of the non-MU hospitals. It must be noted that the readmission data is calculated as all-cause readmission. Therefore, readmission is not directly tied to the condition for which the patient was initially discharged from the hospital. The PSI 90 or AHRQ safety score is identical between cohorts. Further analysis of each variable and the statistical significance of the differences between cohorts will be described later in this chapter.

			All Hospital (N=4221)			Meaningful Use= YES (N=2315)			Meaningful Use= NO (N=1906)		
	Dependent Variable	Ν	Mean	S.D.	Ν	Mean	S.D.	Ν	Mean	S.D.	
1.	Heart Attack Readmit Rate	2238	18.31	1.19	1426	18.35	1.20	812	18.23	1.16	
2.	Heart Attack Mortality Rate	2510	15.14	1.46	1587	15.11	1.47	923	15.21	1.45	
3.	Heart Failure Readmit Rate	3694	23.06	1.80	2156	23.10	1.86	1538	23.00	1.70	
4.	Heart Failure Mortality Rate	3625	11.81	1.57	2126	11.75	1.58	1499	11.90	1.55	
5.	Pneumonia Readmit Rate	3900	17.61	1.41	2221	17.66	1.45	1679	17.54	1.34	
6.	Pneumonia Mortality Rate	3888	12.02	1.85	2217	11.93	1.84	1671	12.14	1.86	
7.	Safety	3163	0.60	0.14	1960	0.60	0.14	1203	0.60	0.13	
8.	Cost per Discharge	3134	7975.73	1820.86	1955	7852.86	1587.14	1179	8179.47	2138.44	
Mean Dis	Mean Discharges		7535.07	9856.88	2315	8727.68	10308.86	1906	6086.53	9072.48	
Case Mix Index Acuity Score (> number = more complex patient acuity)		4204	1.36	0.34	2313	1.39	0.31	1891	1.34	0.38	

Table V: Mean Performance Data by Care, Cost and Safety Variables

In Table VI. the summary of the T-test results are depicted. The mortality rates are listed consecutively for the 3 clinical conditions of interest, heart attack, heart failure and pneumonia. A statistically significant difference in favor of the MU hospitals was identified for each condition. For the readmission measure a statistically significant difference was found in favor of the non-MU hospitals. With respect to cost, MU hospitals had a difference of \$327 less per discharge using the CMS standardized discharge metric. There was no difference between the hospital cohorts for the AHRQ safety score. The following sections will describe in detail the clinical, cost and safety results for each condition illustrated in Table VI.

				t-Test for Equality of Means (one-tail)		ns (one-tail)	
	Meaningful Use	Ν	Mean	S.D.	t	df,	P
Heart Attack Readmit	No	812	18.232	1.164	-2.293	2236	0.011*
Rate	Yes	1426	18.352	1.199	-2.293	2236	0.011
Heart Attack Mortality	No	923	15.210	1.454	4 775	0500	0.044t
Rate	Yes	1587	15.105	1.467	1.735	2508	0.041*
Heart Failure Readmit Rate	No	1538	23.005	1.705	-1.644	2452.4	
	Yes	2156	23.104	1.859		3469.4	0.048*
Heart Failure Mortality	No	1499	11.896	1.553	0.776	2622	a aaatt
Rate	Yes	2126	11.750	1.576	2.776	3623	0.003**
Pneumonia Readmit Rate	No	1679	17.544	1.344	0.000	2720.0	
Pheumonia Readmit Rate	Yes	2221	17.662	1.448	-2.602	3738.9	0.004**
Deserves and the second second	No	1671	12.137	1.856	2 202	2005	a coatt
Pneumonia Mortality Rate	Yes	2217	11.935	1.842	3.383	3886	0.000**
S-f-t-	No	1203	0.597	0.131	0.116	2722.4	0.454
Safety	Yes	1960	0.598	0.143	-0.116	2722.4	0.454
Cast and Discharge	No	1179	8179.470	2138.442	4.544	1000 2	0.000**
Cost per Discharge	Yes	1955	7852.860	1587.144	4.544	1960.3	0.000++

Table VI: T-test Results on Quality Variables by Meaningful Use Status

*p<.05 **p<.01

RESULTS BY DEPENDENT VARIABLE

The following analysis is ordered according to the research questions initialy presented

in Chaper I.

Heart Attack Mortality and Readmission

The research question was: Is there a difference in clinical outcomes between hospitals that have achieved Meaningful Use (MU) for their EHR systems verse hospitals that have not achieved MU as measured by mortality and readmission rate for Heart attack?

These results are reported from the CMS data base for Medicare discharges with a primary mortality cause (cause of death) of heart attack. Medicare heart attack mortality rates were aggregated from 2510 hospitals that reported data. As illustrated in Table VII and Figures 6 and 7, the overall national rate was 15.14%. The Non-MU hospital rate was 15.21% versus the MU hospital rate of 15.11%. This study found that there was a statisistically significant difference was in favor of the MU hospital (P<.041).

A functional illustration of the implication of this finding would be its impact on overall deaths per 500 thousand admissions for the specific condition. Nationally in 2013 there were approximately 3,000,000,000 Medicare discharges for heart attack, heart failure and pneumonia. With nearly 500,000 of these discharges for heart attack. There was an estimated reduction of 500 deaths in this condition associated with MU.

					T-test for Equality of Means (one-tail)		
	Meaningful Use	Ν	Mean	S.D.	t	df	р
Heart Attack	No	923	15.210	1.454			
Mortality Rate++	Yes	1587	15.105	1.467	1.735	2508	0.041*

Table VII: T-test Results on Heart Attack Mortality by Meaningful Use Status

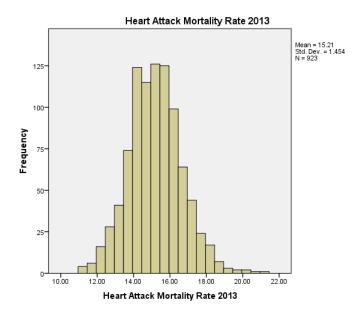


Figure 6. Histogram of Heart Attack Mortality Rate 2013 – Hospitals (MU=NO)

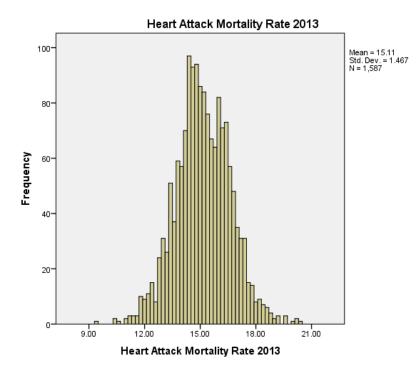


Figure 7. Histogram of Heart Attack Mortality Rate 2013 – Hospitals (MU=YES)

The following readmission results are reported from the CMS data base for Medicare discharges. The patient has to have an initial or index admission of heart of heart attack. The case was categorized as readmission if the patient was readmitted within 30 days from the index admission with any diagnosis. This measurement is know as all-cause readmission rate and is how CMS calculates the metric.

There were 2238 hospitals that reported on heart attack readmission rates, 1426 were from the MU cohort amd 812 from the non-MU cohort. As illustrated in Table VIII and Figures 8 and 9, the overall mean readmission rate was 18.31% with non-MU hospitals reporting a lower overall rate of 18.23 % versus the MU hospital rate of 18.35%. The difference was statisistically significant in favor of the non-MU hospital (P<.011). In this condition with approximately 110,000 heart attack readmissions nationally at least 300 readmission were avoided.

				I-te	st for Equa (one-		ans
Meaningful Use	Ν	Mea	an S.D).	t d	ť	р
Heart Attack	No	812	18.232	1.164	-2.293	2236	0.011*
Readmit Rate⁺	Yes	1426	18.352	1.199	-2.235	2230	0.011

Table VIII: T-test Results on Heart Attack Readmission by Meaningful Use Status T-test for Equality of Means (one-tail)

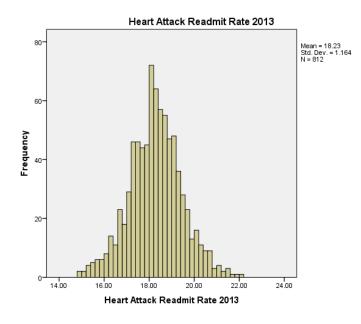


Figure 8. Histogram of Heart Attack Readmit Rate 2013 – Hospitals (MU=NO)

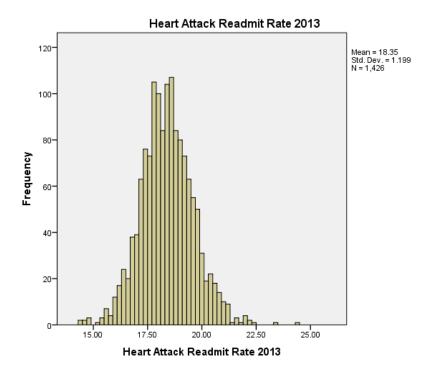


Figure 9. Histogram of Heart Failure Readmit Rate 2013 – Hospitals (MU=YES)

Heart Failure Mortality and Readmission

The research question was: Is there a difference in clinical outcomes between hospitals that have achieved Meaningful Use (MU) for their EHR systems verse hospitals that have not achieved MU as measured by mortality and readmission rate for heart failure?

These results are reported from the CMS data base for Medicare discharges with a primary mortality cause (cause of death) of heart failure during the admission. Heart failure mortality rates from 3625 hospitals were reported. As illustrated in Table IX and Figures 10 and 11, the overall national mortality rate was 11.81%. The Non-MU hospital rate was 11.90% versus the MU hospital rate of 11.75%. The difference was statistically significant in favor of the MU hospitals (P<.003). With approximatelt 1,200,000 heart failure discharges annually the reduced mortality associated with the benefit of MU adoption is approximately 2000 lives.

					_	T-test for	Equality (one-tail)	
	Mean Us	ingful se	Ν	Mean	S.D.	t	df	р
-	Heart Failure	No	1499	11.896	1.553	0.770	0000	0.000**
Mortality Rate**	Yes	2126	11.750	1.576	2.776 3623		0.003**	

Table IX: T-test Results on Heart Failure Mortality by Meaningful Use Status

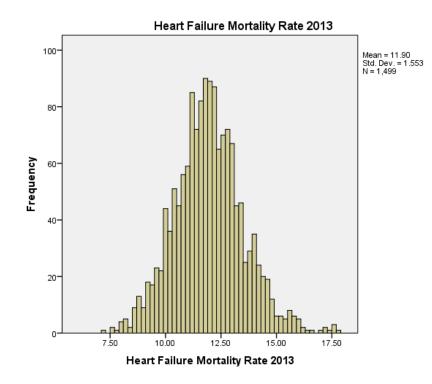


Figure 10. Histogram of Heart Failure Mortality Rate 2013 – Hospitals (MU=NO)

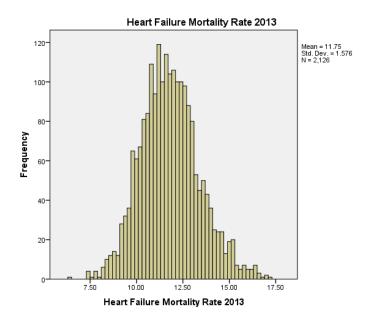


Figure 11. Histogram of Heart Failure Mortality Rate 2013 – Hospitals (MU=YES)

These results are reported from the CMS data base for Medicare discharges with an index admission of heart of heart failure. The patient was categorized as readmission if they were reamitted within 30 days from the index admission with any diagnosis. This measurement is know as all cause readmission rate and is how CMS calculates the metric. In the heart failure readmission analysis there were 3693 hospitals reporting data, 2156 were MU hospitals and 1538 were non-MU hospitals. As illustrated in Table X and Figures 12 and 13, the overall national mean readmission rate was 23.06 % with non-MU hospitals reporting a lower overall rate of 23.00 % versus the MU hospital rate of 23.10%. The difference was statisistically significant in favor of the non-MU hospital (P<.048). The lower readmission rate was associated with approximately 330 less readmissions.

Table X: T-test Results for Heart Failure Readmission by Meaningful	Use Status
---	------------

				_	T-test for E (0	quality of N one-tail)	leans
Meaningful Use		Ν	Mean	S.D.	t	df	р
Heart Failure	No	1538	23.005	1.705		0.400.4	0.0.40*
Readmit Rate	Yes	2156	23.104	1.859	-1.644	3469.4	0.048*

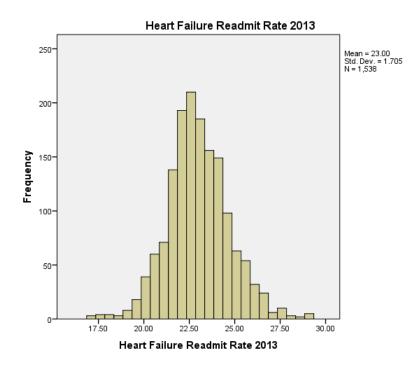


Figure 12. Histogram of Heart Failure Readmit Rate 2013 – Hospitals (MU=NO)

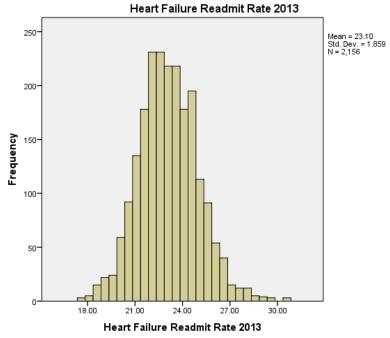


Figure 13. Histogram of Heart Failure Mortality Rate 2013 – Hospitals (MU=YES)

The research question was: Is there a difference in clinical outcomes between hospitals that have achieved Meaningful Use (MU) for their EHR systems verse hospitals that have not achieved MU as measured by mortality and readmission rate for Pneumonia?

These results are reported from the CMS data base for Medicare discharges with a primary mortality cause (cause of death) of pneumonia. Pneumonia mortality rates were reported 3888 hospitals. As illustrated in Table XI and Figures 14 and 15, the overall national mortality rate was 12.02%. The Non-MU hospital rate was 12.14% versus the MU hospital rate of 12.04%. The difference was statistically significant in favor of the MU hospital (P<.000). With over 1,200,000 pneumonia discharges annually the reduced mortality associated with MU adoption is approximately 2400 lives. Table XI: T-test Results on Pneumonia Mortality by Meaningful Use Status

				_	T-test for E	quality	
	Meaningful Use		Mean	S.D.	t	df	р
Pneumonia	No	1671	12.137	1.856			
Mortality Rate++	Yes	2217	11.935	1.842	3.383	3886	0.000**

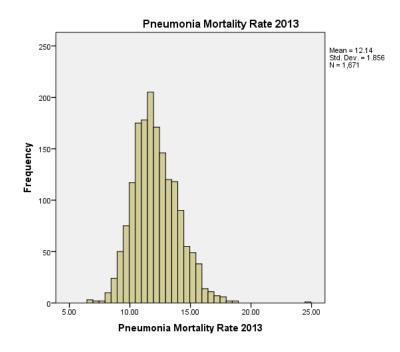


Figure 14. Histogram of Pneumonia Mortality Rate 2013 – Hospitals (MU=NO)

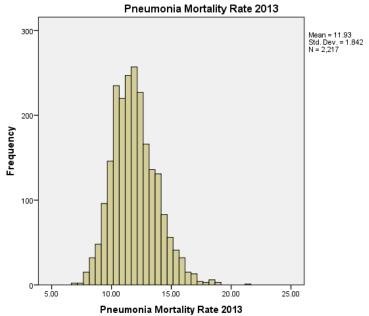


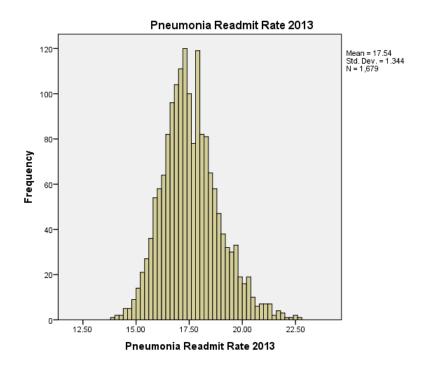
Figure 15. Histogram of Pneumonia Mortality Rate 2013 – Hospitals (MU=YES)

These results are reported from the CMS data base for Medicare discharges with a primary admission cause of pneumonia. The patient was categorized as readmission if they were reamitted within 30 days from the index pneumonia admission with any diagnosis. This measurement is know as all cause readmission rate and is how CMS calculates the metric.

In the pneumonia readmission analysis there were 3900 hospitals reporting data, 2221 were MU hospitals and 1679 were non-MU hospitals. As illustrated in Table XII and Figures 16 and 17, the overall mean readmission rate was 17.61 % with non-MU hospitals reporting a lower overall rate of 17.54 % versus the MU hospital rate of 17.66%. The difference was statisistically significant in favor of the non-MU hospital (P<.004).

Table XII: T-test Results on Pneumonia Readmission by Meaningful Use Status

				_	T-test for Equality of Means (one-tail)		
	ningful Jse	Ν	Mean	S.D.	t	df	р
Pneumonia Readmit Rate**	No Yes	1679 2221	17.544 17.662	1.344 1.448	-2.602	3738.9	0.004**





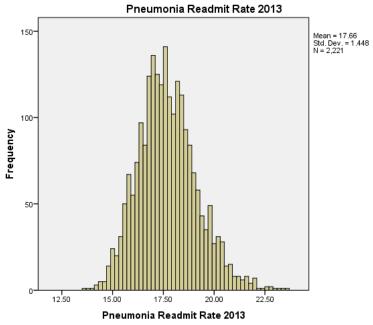


Figure 17. Histogram of Pneumonia Readmit Rate 2013 – Hospitals (MU=YES)

Patient Safety Composite Score

The research questions was: Is there a difference in clinical outcomes between hospitals that have achieved Meaningful Use (MU) for their EHR systems verse hospitals that have not achieved MU as measured by Agency for Healthcare Research and Quality Patient Safety Indicator Measurement?

For AHRQ composite safety score, 3163 hospitals reported data. As illustrated in Table XIII and Figures 18 and 19, there were 1960 MU hospitals reorpting an overall score of 0.60 and 1203 non-MU hospitals reporting and identical score of 0.60. there was no statstically significant difference between the MU and non-MU hospital outcomes.

(one-tail) Meaningful t Ν Mean S.D. df р Use 1203 0.597 No 0.131 -0.116 Safety++ 2722.4 0.454 Yes 1960 0.598 0.143

Table XIII: T-test Results on Composite Safety Score by Meaningful Use Status T-test for Equality of Means

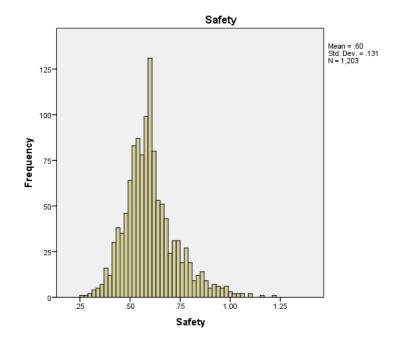


Figure 18. Histogram of Safety – Hospitals (MU=NO)

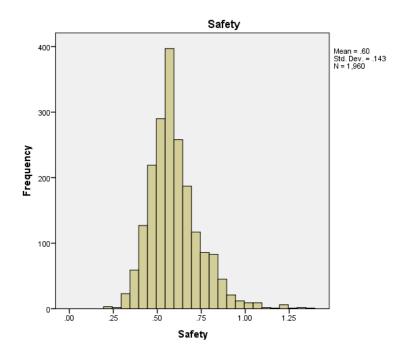


Figure 19. Histogram of Safety – Hospitals (MU=YES)

COST PER DISCHARGE

The research questions was: Is there a difference in cost per discharge between hospitals that have achieved Meaningful Use (MU) for their EHR systems verse hospitals that have not achieved as measured by the CMS standardized cost per discharge metric?

For the standardized cost per discharge there were 31634 hospitals reporting data. As illustrated in Table XIV and Figures 20 and 21, the national mean Medicare discharge cost was \$7975. There were 1955 MU hospitals reporting with a mean discharge cost of \$7852. There were 1179 non-MU hospitals reporting with a cost per discharge of \$8179. The difference in mean cost per discharge was \$327 in favor of MU hospitals which was statistically significant (P<.000). With over 20,000,000 Medicare discharges annualy an estimated cost reduction associated with MU is over \$6 billion. This very significant finding, the implications of the cost of EHR adoption and potential future trajectory of savings associated with MU will be discussed in detail in Chapter 5.

Table XIV: T-test Results on Standardized Cost Per Discharge Metric by Meaningful Use Status

				T-test for Equality of Means (one-tail)			S
Meaningful Use	Ν	Mean	S.D.	t	df		р
Cost per Discharge**	No Yes	1179 8179. 1955 7852.		38.442 37.144 4	.544	1960.3	0.000**

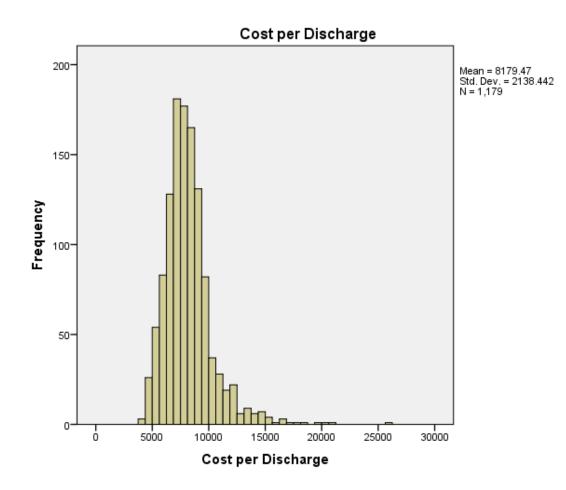


Figure 20. Histogram of Cost per Discharge – Hospitals (MU=NO)

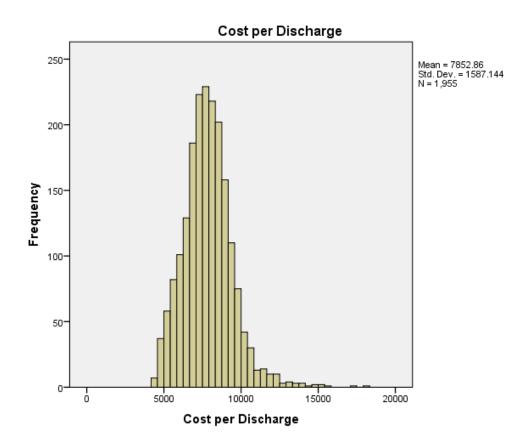


Figure 21. Histogram of Cost per Discharge – Hospitals (MU=YES)

SUMMARY

There are favorable mean scores for the Meaningul Use hospitals for heart failure, heart attack and pneumonia mortality. In addition, the average standarized cost per discharge is lower for MU hospitals by \$327. There is no difference in mean safety score (PSI 90) between hospital cohorts. The readmission results reveal that non-MU hospital had lower all-cause readmission rates in all three clinical domains. While the differences are not large in comparing the raw rates when assessing the difference based upon the number of discharges impacted the number of lives saved and cost reduced is substantial. From the cost perspective wiith the cost per discharge difference of \$327 and the 20,204,517 discharges included in the research, the dollars saved amount to over \$6.6 billion. In lives saved the data is likewise impactful. When applying the improved mortality rate to the over 20,000,000 Medicare discharges from the nation's hospitals a reduction in mortality of over 20,000 lives is associated with MU adoption. The finding regarding readmission rates in favor of non-MU hospitals was unexpected. The phase1 MU guidelines are substantially focused on inter-facility integration and interoperability. As the phase 2 MU guidelines take hold with their focus on care plan integration, E-prescribing and related data sharing with external, non-hospital providers, a positive impact on readmission rates is expected.

Table XV illustrates the results for the Levene's test. The equality of variance test results were accepted for heart attack readmit and heart attack mortality rates, heart failure and pneumonia mortality rates. The equality of variances results were rejected for heart failure and pneumonia readmission rates, safety and cost measures. In the cases where the equality of variance was rejected the alternate degrees of freedom and t-test scores were utilized to properly calculate statistical significance of the measurements.

	Variances				
	F	Sig.			
Heart Attack Readmit Rate	.939	.333*			
Heart Attack Mortality Rate	.310	.578*			
Heart Failure Readmit Rate	17.484	.000^			
Heart Failure Mortality Rate	1.771	.183*			
Pneumonia Readmit Rate	9.830	.002^			
Pneumonia Mortality Rate	.181	.670*			
Safety	9.093	.003^			
Cost per Discharge	45.419	.000^			

Table XV: Levene's Test for Equality of Variance of Quality Variables (2 sample t-test) Levene's Test for Equality of

*equality of variance assumed ^ equality of variance rejected

*Equal variances not assumed for the t-test

**Equal variances assumed for the t-test

*p<.05 **p<.01

Chapter V

DISCUSSION

BACKGROUND

From a health policy perspective, the \$50 billion CMS committed to the HITECH Act is a substantial investment in the implicit belief that EHR adoption will transform the U.S. healthcare system. While the program's stated purpose was to support and stimulate the adoption of EHRs' in healthcare, addressing the value inequity between cost and outcomes in the \$3 trillion U.S. healthcare system is an outcome of great interest (IOM, 2001). Simultaneously, Value Based Purchasing, VBP, is realigning the reimbursement paradigm by shifting payments from fee for service to payment for value. In this scheme, outcome and cost are the respective numerator and denominator to measure value, inexorably linking these two initiatives (Porter, 2006).

Early studies undertaken to assess EHR impact on clinical and financial outcomes were primarily undertaken in the pre-MU era (Chaudry, 2006; Ding, 2011; Himmelstein, 2009; DesRoches, 2010). Those studies used process measures to assess impact and cost estimates were generally derived from various sources such as cost reports, AHA survey responses, financial filings, etc. The assessments of safety were generally focused on hospital centric studies on important indicators such as medication error, falls and infection rates (Bates, 2010; Poon, 2010). Due to the complexity of identifying these outcomes from administrative data these results were difficult to validate and replicate across large numbers of organizations. The need to validate the interim progress that MU has on clinical outcomes and cost requires a revised measurement paradigm aligned with Value Based purchasing concepts of outcome and cost (Porter, 2006) with a global focus on patient safety (AHRQ, 2006).

The purpose of this research was to evaluate whether there is a difference in hospital performance *outcomes* in organizations that have implemented electronic health records that meet Meaningful Use (MU) standards. The use of a revised measures paradigm, one focused on publicly reported outcome measures, not process indicators, is in alignment with payment reform under the Affordable Care Act. The outcomes of interest, as stated, were mortality and readmission rates, cost per discharge and aggregate safety score. With a national healthcare bill of over \$3 trillion, the American healthcare system spends nearly double the amount of every industrialized nation on a per citizen basis. Ironically, the U.S. has the lowest life expectancy and the highest infant mortality rate of the group (OECD, 2014). In addition, the Institute of Medicine estimates that the third leading cause of death in America is related to patient safety lapses (Squire, 2012). The need for a realignment of cost, outcome and patient safety is of paramount importance.

This study sought to ascertain whether there is a relationship between Meaningful Use of EHRs' and quality, cost and safety outcome measures. In reviewing the study findings, after analyzing outcome data on 4221 hospitals the conclusion is that there is a statistical difference for mortality rates for all three conditions for meaningful use hospitals; heart attack, heart failure and pneumonia. Further, meaningful use hospitals demonstrated statistically significant difference in terms of standardized cost

per discharge. As discussed in greater detail later in this chapter, when extrapolating the mortality difference achieved at MU hospitals there were over 20,000 lives saved. This is a powerful finding and one further magnified when taken in the context that over \$6 billion in cost per discharge was achieved by the same cohort (MU).

These results are the first definitive endorsement of MU capability in clinical quality and cost savings. When considering that the lead time for adopting complex technology is estimated at between two and five years (Ding, 2011), the fact that mortality differences and cost savings were demonstrated in the first two years after the initial attestation period, 2013, is support of the CMS investment. Other potential explanations for outcomes improvements aside from MU implementation will be discussed later in this chapter.

DISCUSSION

Impact of the HITECH Act

The implementation of basic EHRs' in the nation's hospitals stood at just 8% in 2008 (Jha, 2009). With the passage of the HITECH Act in 2009, ushering in both monetary incentives and penalties for EHR adoption that had to meet MU standards, a veritable rush for implementation impacted the healthcare industry. In fact by the time the first incentive payments were available in 2010-2011 period there was an over threefold increase of EHR adoption to nearly 27% of hospitals (DesRoches, 2013). The initial uptake, according to the American Hospital Association annual IT survey, was in large, urban and teaching hospitals. The research suggested that this hospital cohort,

large, urban, teaching hospitals, was twice as likely to have adopted an EMR and that approximately 44% could meet MU standards (DesRoches, 2013). The AHA survey response rate at just over 60% did not include the many hospitals, at least 1500, and the actual results from this study discussed below differed materially.

By analyzing the actual 2013 MU attestation data file, the current study found that the percentage of hospitals that had actual MU certified EHRs' had jumped from 8% to 55%, or 2315 of 4221 hospitals nationally. In contrast to the DesRoches (2013) study, the majority of hospitals that had actual MU certified functionality, 1637 of the 2315, or 71% of the attesting cohort, were actually non-teaching facilities. The majority (40%) located in the South, followed by the Midwest, 29%, West and Northeast at 16% each. The predominant ownership model was 61% voluntary, not for profit status, followed by governmental 23%, proprietary 18% and physician owned 1.5%. The difference in the data reported by DesRoches (2013) and the actual CMS data results just one year later may be interpreted in several ways.

One reason for the difference in actual versus reported uptake in MU certified EHRs s that the Desroches (2013) study relied on voluntary survey data with a 61% response rate. A large number of hospitals, over 1500, did not reply, many of whom were likely not AHA members or have seen the value in completing the survey. To receive MU payments it was mandatory for hospitals to attest and to be certified as MU compliant, therefore the CMS data file used for the current study had the most current and accurate data. The other reason, also aligned with a payment incentive, is that hospitals clearly moved very quickly, a 7 fold uptake, to advance their basic EHR capability once the MU criteria was finalized in order to capitalize on the HITECH funds. Therefore the financial incentive seemed to have clearly increased the number of EHR installations by those meeting the criteria. In the first year over \$6 billion was awarded to hospitals.

Clinical Quality

However, the most striking aspect of this study is that the clinical outcomes reported reveal statistically significant difference in mortality rates in all three clinical conditions, heart attack, heart failure and pneumonia for hospitals who achieved MU recognition for their EHR systems. This critical finding represents both a quality and reimbursement benefit to hospitals. The pressure to move away from fee for service reimbursement to value, driven by the VBP model has refocused the quality discussion to one centered on clinical outcomes and away from process measures. Previous research (Ding, 2011; Appari, 2012; Himmelstein, 2009; Chaudry, 2006; Spencer, 2012) did not demonstrate this level of clinical improvement either in magnitude of change or uniformly across conditions. It is important to discuss the focus on process versus outcome as a measurement paradigm in this prior research to understand the different outcomes of the studies.

The community standard for measurement of clinical quality since 2003 when the first publicly reported data by CMS (www.medicare.gov/hospitalcompare.gov) and the Joint Commission (www.JCAHO.org) has been the utilization of aggregated process measure data. As discussed in the literature review, individual quality experts such as Donabedian (1988, 2003) as well as institutional authorities on quality measurement

such as the National Quality Forum, advocated for process measure standards. Indeed, the theoretical support for process measures is strong (Mant, 2001; Mainz, 2003; Lilford, 2007). However, the process measure philosophy is tied to the linkage between process and clinical standard validity and best suited for practitioner feedback and performance improvement. However, the focus on population health inherent to VBP requires a measurement lens of broader scope and one oriented to informing wider aspects of health policy (Mant, 2001), that being outcomes. Outcome measures such as mortality, readmission and infection are discrete events. By focusing on mortality and readmission as quality endpoints, consistent with new VBP measures, this current study was able to report results less subject to such data management concerns (Mant, 2001; Rubin, 2001).

Procedurally, the utilization of process measures requires data be abstracted from administrative systems. This method is attractive since it is automated for large data sets, less expensive and efficient. It does have validity issues, however, these limitations are a function of the completeness and accuracy of the individual documentation of each clinical intervention as transposed into the hospital record and billing systems (Billings, 2003; Grosse, 2010; Tollefson, 2011). Each aggregate quality measure for the clinical conditions under study has at least 8 sub processes that must be performed and documented to achieve a "passing grade" for the clinical encounter. The variability of the documentation and data management associated with the process measures approach to quality measurement creates opportunity for error. The outcome measure methodology utilized in the current study and discussed below alleviates these

Meaningful Use

Another issue requiring elaboration is the utilization of actual Office of National Coordinator (ONC) criteria to create the two cohorts used for analysis. The research reported in this study utilized the ONC database of actual MU achievement utilized for awarding MU status and distribution of payments. The information was validated and audited by CMS prior to awarding a MU certification or making payments. All of the prior studies mentioned in the literature review utilized proxy measures based on either a Health Information Management Services Society (HIMSS) or AHA Information Technology voluntary survey instrument to establish if a hospital had implemented an EHR that was capable of meeting MU specifications. These studies relied on selfreported capabilities from either of the HIMSS or AHA hospital surveys. The accuracy and response rate create a question as to the accuracy of categorizing a hospital in a specific cohort, MU or non-MU. Further, as mentioned above in any given survey response year a large number of hospitals, over 1500, did not reply omitting a significant number of organizations from their analysis. The impact of the inclusion of many non-surveyed hospitals in the current study significantly affected the true total of organizations meeting MU standards in the first 2 years, and affected how the cohort performed in the cost savings described below.

Cost

The fact that a statistically significant difference in cost per Medicare discharge between MU and non-MU hospitals of \$327 was found in this study provides support for the \$50 billion investment of the HITECH Act. In one year, with just over 50% of the nation's

hospitals participating, the current study suggests over \$6 billion in savings will have accrued from MU adoption. The focus on whether EHRs' demonstrated a relationship to cost in the \$3 trillion U.S. healthcare system was a significant focus on this study. The pressure for policy change to create a value driven healthcare system under the American resource and Recovery Act (AARA) of 2009 was supported by economist Porter (2006). CMS sought to bend the cost curve and align payment with value by implementing VBP and shifting the original reimbursement equation weighted 90% in favor of process to the current 2016 formula which is 90% outcome oriented (https://www.medicare.gov/hospitalcompare/data/total-performance-scores.html).

Prior studies have utilized various methods for detecting the impact of an EHR on hospital costs. Himmelstein (2009) used Hospital Medicare Cost Reports to assess an organization's overall administrative cost. Ding (2011) used American Hospital Association survey data to create two financial indicators, operating cost per day and operating cost per admission. DesRoches (2010) and Agha (2011) utilized Medicare Provider Analysis and Review File and Medicare Inpatient Impact File. Other researchers excluded cost entirely choosing to focus on quality or utilization approaches, consistent with practice guidelines without commenting on costs (Jones, 2014; Appari, 2012). What is clear from the literature is that past studies utilized multiple approaches and data sources, some overlapping, others unique, utilized to assess if EHR adoption had an impact on healthcare costs. This lack of consist measures limits the external validity of these studies on the cost domain.

The difference with the current study is that none of the prior research utilized a normalized cost per discharge approach. The current study used the CMS spending by claim file (www.data.medicare.gov/Hospital-Compare/Medicare-Hospital-Spending-by-Claim) that calculates a normalized Medicare spending per discharge by hospital. The multiple characteristics of a hospital's overall cost structure, union versus non-union staff, urban versus rural, ownership models, payer mix, teaching status create such variability that without an adjusted cost per discharge approach there can be no meaningful cost comparison between the cohorts, MU and non-MU hospitals. By utilizing the CMS Medicare spending per beneficiary file cost per discharge this barrier to cost analysis has been removed in this study. This same standardized metric approach was utilized to assess the final and critically important safety domain.

Safety

The previous research on EHR impact on safety outcomes focused on specific initiatives in local hospital or health systems (Poon, 2012). The seminal study *To Err is Human* (1999) identifying between 44-98,000 deaths annually from errors was followed by numerous other studies (Bates, 2001; Poon, 2010; Shekelle, 2011). As identified in the cost per discharge issue, the study of safety and EHR impact on improving overall results were not undertaken on broad enough levels to create an endorsement of technology as the hoped for change agent. Some studies actually found that EHR created its own error prone process problems and a caution flag was raised (IOM, 2012; Sittig, 2012). Few if any broad based studies were focused on this topic because of the

complexity in measuring and identifying agreed upon community standard for analysis. The AHRQ (2010) safety metric PSI 90, changed this barrier.

Yet, while this new measurement paradigm was significant in its breadth of measurement and ability to be extracted from administrative data the results failed to reveal a difference in outcome between MU and non-MU hospitals in this study. One reason may be that the indicators selected for the composite score are not well aligned with clinical interventions that EHR can specifically impact. There are 11 indicators, 9 of which are surgery related, followed by pressure ulcers and blood stream infection. In order to better assess the impact of EHR on patient safety a different indicator set more effective in impacting safety issues such as medication errors, timing of antibiotic for procedures, pneumonia care or management of sepsis (Bates, 2001; Poon, 2010) would be more sensitive measures.

THEORETICAL IMPLICATIONS

This study drew upon two theoretical frameworks, one focused on clinical care measurements and the other focused on healthcare economics. The Donabedian Model focuses on the structure, process and outcome to measure quality. The second was the Value Based Purchasing theory advanced by economist Michael Porter in his seminal work, Redefining Healthcare (2006). The Porter model argues that the US healthcare system's inherently misaligned payment methodology resulted in the pursuit of high volume, high margin services without a focus on the outcomes of health for the population being served or the total cost of care incurred.

The Donabedian quality measurement theory remains a consistently applied and valid approach to measuring quality from a process perspective. The CMS hospital compare program, Joint Commission and National Quality Forum utilize and endorse quality measurement at the process level. However, the measurement framework is best applied at the practice feedback level. For example assessing performance and giving feedback re compliance with or missed care opportunities, such as administration of therapy within proscribed time frames such as aspirin within 60 minutes for heart attack patient, antibiotic within 30 minutes for pneumonia patients in the ER. Mainz states simply "process indicators assess what the provider did for the patient and how well, it was done" (p. 525). This approach is in contrast to outcome measures with their focus on population and endpoint measurement.

Process measures are at best useful in a Pay-for-Performance approach such as the Premier/CMS Project (Lindenauer, 2007) that aligned payment with achieving the highest levels of compliance with care guidelines. It was ultimately concluded that the program improved compliance but never decreased cost, reduced safety errors, or changes endpoints in mortality or readmission. So while the process measurement theory remains a valid and useful tool in quality improvement efforts, for the purposes of validating broader population measures such as mortality rates, readmission and safety metrics the greater the relevance of outcome measures (Mainz, 2003). Most importantly however, process measurement is methodologically unsuitable for measuring outcomes and hence out of sync with the Value Based Purchasing

reimbursement paradigm implemented by CMS where 90% of current payments are focused on outcome and not process measures.

LIMITATIONS

As with all studies, this study has several limitations. First, hospitals cannot be randomly assigned to control and treatment groups as in a randomized control trial but they could be assigned to cohorts based upon their EMR adoption status. Due to the large number of hospitals, 4221, resulting in wide geographic dispersion and other disparate attributes, the subject hospitals vary widely in numerous ways: teaching status, urban vs rural, large vs small discharge volume, union status and related social determinants of patients. This is a potential threat to the generalizability of the study conclusions. To control for this threat, all of the outcome measures selected were risk adjusted thereby normalizing the values across hospitals.

The data utilized for this study was abstracted from sources that utilized administrative data. As discussed above there are inherent limitations to this data source, however, outcome measures such as mortality, readmission and infection are discrete events. By focusing on mortality and readmission as quality endpoints, consistent with new VBP measures, this study was able to report results less subject to such data management concerns. In addition, the 3M risk adjustment methodology applied by CMS for the clinical outcome measures while the current standard for risk adjustment in the industry is subject to the criticism of all such formulas (Rubin, 2001). The standardized cost metric utilized for assessing cost per discharge was developed by CMS. The cost is calculated from hospital specific data and then risk adjusted for a number of variables, medical education, geographic cost allowances, etc. affecting a hospital's operating expense (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/). As such this metric is prone to all criticisms that any risk adjusted value may be subject. The actual cost savings calculated in this study is based upon this value and may not be directly linked to actual reduced hospital operating expenses. It is also focused solely on standardized hospital discharge cost not total cost of care per episode attributable to the population.

FUTURE RESEARCH

This study was undertaken to focus a lens on EHR adoption, a major health policy initiative under the HITECH Act (2009). The \$50 billion investment was aimed at transforming healthcare by accelerating the adoption of EHRs. Future research is required to assess the ongoing impact EHR adoption under MU guidelines will have on clinical, cost and safety outcomes as larger and larger numbers of hospitals meet the requirements or face penalties. This is especially true as Meaningful Use Phase 2 places greater focus on connectivity between providers, E-prescribing, care plan exchange, greater utilization of evidence based guidelines and patient engagement via portal use is now being implemented.

As more care is being directed toward lower cost settings, the ambulatory care platform will assume greater importance in overall healthcare spending. Therefore, future research could include additional studies aimed at evaluating how and if, the increasing adoption of EHR by non-hospital providers such as physician practices,

therapist offices, nursing homes, home care agencies, pharmacies and other ancillary providers has the potential to result in increased clinical and cost benefits. Specifically, a focused examination of how readmission within 30 days of an index hospitalization can be impacted by EHR adoption and interoperability when the constellation of providers mentioned above have facilitated electronic communication.

Another area requiring future research is the continued refinement of patient safety indicators that can be measured within the EHR platform of hospitals and other providers. This study utilized the AHRQ, PSI 90 patient safety composite score which revealed no significant difference between the cohorts under study. Their appeared to be low sensitivity between the indicators that comprise the score to processes that are affected most directly by EHR functionality, i.e. medical management versus surgical interventions.

The issue of cost continues to be a prominent one in discussing the future state of the U.S. healthcare system. Future research that identifies the impact of specific EHR functionality on total cost of care is required to identify, refine and expand the functionality that maximizes the cost benefit of healthcare dollars expended.

As noted earlier, legislation affecting both the community physician practices and hospitals under the Medicare Access and CHIP Reauthorization Act released in April of 2016 is focused on how adoption and outcomes should be aligned with payment reform. In the new reimbursement paradigm payment for value not volume is an underpinning of healthcare transformation (Porter, 2006). Therefore, further research is

required to see how these intersecting forces, EHR systems and VBP, impact a new era in which fee for service medicine recedes payment for value ascends.

CLOSING COMMENTS-FUTURE INDUSTRY TRENDS

The future improvement in the healthcare system will require additional cooperation and integration between hospitals, community based providers, continuing care organizations, home care agencies, ancillary testing providers and others. The electronic health record information linkages between the providers, the payers, and oversight agencies are critical to improving quality outcomes, and reducing overall cost of care. The infrastructure of the National Health Information Network may be a powerful tool in this pursuit.

At the center of all of this change is the patient. For change to be meaningful and lasting, culturally competent care must be provided to patients by a competent workforce motivated to improvement. Technology, including EHR, is a tool that can support these efforts and the evidence assembled by this study suggests that it is a powerful one. As discussed above, future research is required to understand the implications of EHR in conjunction, not in isolation, of other initiatives. Improvements in hospital outcomes of care are a national responsibility of the healthcare system from a regulatory, professional and fiduciary perspective.

In conclusion, this study found that there is a positive difference in cost per discharge and clinical outcomes between hospitals that have and have not adopted MU technology in their day to day operations. As concepts of interoperability between hospitals, physician practices and out-patient providers advance in the next stage of MU implementation more gains are possible. Based on the current study over 21,000 lives were saved and up to \$6.6 billion dollars in expenditure avoided related to MU implementation. As the remaining hospitals across the nation close the gap in adopting EHRs' with MU functionality further benefits may accrue if this trajectory of improvement holds.

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APPENDIX A

Seton Hall University: Institutional Review Board (IRB) Approvals



June 11, 2015

Joseph G. Conte

Dear Mr. Conte,

The IRB is in receipt of the application for your research entitled "Assessing the Impact of Meaningful Use of Electronic Health Records on Publicly Reported Outcomes of Care - A National Study."

Your research does not fall under the requirement for IRB review. Use of anonymous, aggregate data from a publically available site does not meet the requirement of research with human subjects nor research with identifiable individual data.

Please proceed with your research.

Sincerely,

Mary F. Ruzicka, Ph. D. Mary F. Ruzicka, Ph. D.

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Professor Director, Institutional Review Board

cc: Dr. Terrence Cahill

Office of Institutional Review Board

Presidents Hall · 400 South Orange Avenue · South Orange, New Jersey 07079 · Tel: 973.313.6314 · Fax: 973.275.2361 · www.shu.edu

APPENDIX B

DEFINITIONS

ARRA – American Recovery and Reinvestment Act 2009, is the parent legislation that authorized the funds for electronic health record subsidy for the HITECH Act

AHRQ - Agency for Healthcare Research and Quality is a fully funded division of the Department of Health and Human Services. Their stated mission is "The Agency for Healthcare Research and Quality's (AHRQ) mission is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used"

(http://www.ahrq.gov/cpi/about/mission/index.html)

CMS – Center for Medicare and Medicaid Services. CMS is a federal agency that administers health insurance programs for 100 million Americans. CMS sponsors the healthcare website, <u>www.cmshospital</u>compare.gov that provides a portal into healthcare services rating hospital and provider performance.

EHR system– Electronic Health Record refers to a system of interconnected electronic health care record platforms. These systems create a platform and repository for such functions as physician order entry, nursing record keeping, pharmacy, radiology,

surgery and anesthesia charting, ER and Transport systems. The system is capable of having a outward facing portal for patient engagement, transfer of care plans and discharge information to providers outside the hospital such as nursing homes as well as connecting to local and national Health Information Exchanges.

HITECH Act - Health Information Technology for Economic and Clinical Health Act was enacted under the ARRA legislation specifically to spur adoption of EHRs. The HITECH Act set Meaningful Use of interoperable EHRs systems as a critical national goal and incentivized EHR adoption. Penalties for non-adoption were also a part of the program.

Interoperability – The complex US health care system is comprised of numerous electronic health record (EHR) products. Interoperability refers to the architecture or standards that make it possible for diverse EHR systems to work compatibly in a true information network exchanging information between providers.

Meaningful Use - The Meaningful Use aspect of the HITECH Act is part Medicare and Medicaid EHR Incentive Programs that sets out specific performance and compliance criteria for providers to demonstrate that their certified EHR technology meets specific measurement thresholds that range from recording patient information, accessing clinical evidence, patient portal, external data transmission, syndromic surveillance capability all as structured data.

Mortality – is a measure that calculates actual death during a hospital stay, it does not include hospice services. For this study the data is risk adjusted, it does include

hospitalizations for Medicare beneficiaries 65 or older who were enrolled in Medicare for 12 months before their hospital admission.

Readmission - measures that are calculations of unplanned readmission to an acute care hospital in the 30 days after discharge from a hospitalization. Patients may have had an unplanned readmission for any reason. For this study the data are risk adjusted. (https://www.medicare.gov/HospitalCompare/Data/30-day-measures.html)

Risk adjustment- To accurately compare hospital performance, the CMS readmission and death measures adjust for patient characteristics that may make readmission or death more likely. These characteristics include the patient's age, past medical history, and other diseases or conditions known as comorbidities the patient had when they were admitted that are known to increase the patient's chance of dying or having an unplanned readmission.(https://www.medicare.gov/HospitalCompare/Data/30-daymeasures.html)

VBP - Hospital Value-Based Purchasing (VBP) is part of the Centers for Medicare & Medicaid Services' (CMS') effort to link Medicare's payment system to a value-based system to improve healthcare quality, including the quality of care provided in the inpatient hospital setting. The program attaches value-based purchasing affecting payment for inpatient stays in over 3,500 hospitals across the country. Participating hospitals are paid for inpatient acute care services based on the quality of care, not just quantity of the services they provide. Congress authorized Inpatient Hospital VBP under the Affordable Care Act. (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html)