Medical Errors / Patient Safety: Hospital Medication Errors Pre- & Post-Electronic Health Records (EHR) / Meaningful Use Act

Emmanuel C. Chukwudi

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MEDICAL ERRORS / PATIENT SAFETY:
HOSPITAL MEDICATION ERRORS PRE- & POST- ELECTRONIC HEALTH
RECORDS (EHR) / MEANINGFUL USE ACT

BY

Emmanuel C. Chukwudi

A doctoral project submitted to the faculty of the Medical University of South Carolina
in partial fulfillment of the requirements for the degree
Doctor of Health Administration
in the College of Health Professions

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Abstract of Doctoral Project Presented to the
Doctoral Program in Health Administration & Leadership
Medical University of South Carolina
In Partial Fulfillment of the Requirements for the
Degree of Doctor of Health Administration

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Emmanuel C. Chukwudi

Chairperson: Abby Swanson Kazley, Ph.D.
Committee: James A. Johnson, Ph.D., M.P.A., M.Sc
Kit N. Simpson, Dr.P.H.

Abstract

Introduction:

The current dissertation study analyzes whether the volume of medication errors in which years *prior* to the adoption and implementation of the HITECH / Meaningful Use Act or the EHR (2007-2010) was higher, lower, or remained unchanged versus in which years *after* implementation of the Meaningful Use Act / HITECH Act (2011-2014). The study employed secondary data sources from the Center for Drug Evaluation
and Research (CDER) / Healthcare Cost and Utilization Project (HCUP). A time series analysis was used to assess the effect of the regulation implementation.

**Purpose:**

Medical errors ranked as the third top leading cause of all hospital deaths in the United States, and as many as 400,000 patients are harmed annually, as a result of preventable medical errors. This problem creates the need to enhance patient safety in the US.

**Methods:**

Medication error was measured using the monthly recorded Rxper OE variable (medication error percent as a % of the total non-medication medical errors of the month). The Rxper OE was recorded from 2007-2014, and data analyzed to make an inference as to whether the volumes of medication errors increased, decreased, or stayed the same between the years 2007 to 2014.

**Scope:**

Medical errors, a major challenge facing the US healthcare system, are found in every region of the country. To address this problem as well as improve the overall quality of care, the US government implemented the HITECH Act / Meaningful Use Act on February 17, 2009.

**Results and Findings:**

Although medication errors in the U.S. increased as a proportion of all medical errors after the implementation of the HITECH Act (6.78% versus 7.98% Averages), those proportional increases were due to a decrease in non-medication / other types of medical errors, while the rate of the medication errors overall remained stable.
This trend was further explored, and found to only increase by \textit{6%/year} after 2011, with a \textbf{p-value of (p=0.6397)}, which is not statistically significant.

**Conclusion:**

The study findings do not support the hypothesis that there was a change in the volume or levels of in-hospital medication errors between the Pre-and Post-Electronic Health Records (EHR) timeframe.

**Recommendations:**

Recommendations included the following 7 ideas: Employee (re)training and Awareness campaigns; strategic recruitment; effective policy; problem acknowledgment and transparent reporting; patient-centeredness; problem solving / documentation, and being proactive (versus reactive).

**Keywords:**

Medical Errors, Medication Errors, Patient Safety, Electronic Health Record (EHR), Meaningful Use, Health Information Technology for Economic and Clinical Health (HITECH) Act, Electronic Medical Records (EMR), Patient Harm, In-Hospital Medication Errors, Problem Solving, Patient-Centeredness, DHA, Doctor of Health Administration, and Preventable Medical errors.
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CHAPTER I
INTRODUCTION

Background and Need

Annually, 200,000 American lives are lost due to preventable medical errors, and as many as 400,000 patients are harmed annually, as a result of preventable medical errors (James, 2013). The estimated cost due to this problem in 2008 was $19.5 billion (Andel et al, 2012). Medical errors are a potentially avoidable problem that can lead to serious consequences, including unnecessary deaths.

The issue of medical errors has been plaguing United States health systems, especially, hospitals for over three decades (Andel, Davidow, Hollander, & Moreno, 2012; IOM, 2000; Yang, 2005). A Johns Hopkins University study by Daniel & Makary (2016) suggested that 9.5% of all hospital admission deaths in the U.S. are due to medical errors. The same study confirmed that medical errors, which are usually under-reported, ranked as the third top leading cause of all hospital deaths in the Unites States. In addition, the main causes of medical errors were traced to systemic problems.

Disagreements regarding the actual level or amount of medical error are ongoing. Some researchers argued that the estimated figures should be lower, while others have contended that the actual number of people harmed is even higher (ASHRM, 2018). Regardless of differences in the estimated numbers, all the above evidence indicates that far too many patients are being harmed. Physicians and healthcare institutions are still uncomfortable discussing medical errors, yet medical insurance companies are increasingly moving to reward quality versus quantity of care (US News, 2016).
Although medical errors pose a great challenge to patient safety (Grober & Bohnen, 2005), evidence have shown that the rate of errors in medicine is still significantly high (Brennan et al, 1991; Leape et al, 1991; Wilson, Runciman, Gibberd, Harrison, & Hamilton, 1996; and Thomas et al, 2000).

To reduce medical errors and enhance process capabilities in the healthcare industry, the US government enacted the Health Information Technology for Economic and Clinical Health (HITECH) Act on February 17, 2009, which necessitated the use of an Electronic Medical Record (EMR). The Center for Drug Evaluation and Research (CDER) established a medium for collecting medication errors (FDA, 2016) as well as establishing the Medication Errors Subcommittee in 1992 to address challenges related to medication errors, drug safety, and other associated responsibilities.

The current dissertation study utilizes patients’ Electronic Records and (Information) Technology, which make it imperative to define and clarify the major differences between an Electronic Medical Record (EMR), and an Electronic Health Record (EHR), early in this research. Evidence by HealthIT, Garrett & Seidman (2017) showed that these two words have been used loosely and interchangeably for quite some time. EHR, which is broader in scope, is the preferred choice for this study versus EMR, which refers to the electronic version of clinical paper records, charts, and data generated in a particular provider’s location. The EHR includes far more than those clinical records and can be made accessible to a broader network of authorized clinicians (HealthIT, Garrett & Seidman, 2017; Practice Fusion, 2017; Athenahealth, 2018). Evidence showed that EHR has been referenced far more often than the EMR (Athenahealth, 2018) and is also a preferred choice by both the Centers for the Medicare & Medicaid Services, CMS,
and the Office of the National Coordinator for Health Information, ONC, respectively (Garrett & Seidman, 2017).

The results from most previous studies of medical errors have been mixed and complicated because there is no universally accepted definition of the term *medical error* (Tamuz, Thomas, & Franchois, 2004); moreover, there are only a few studies that measured medical errors directly (Grober & Bohnen, 2005). How medical errors are defined in clinical studies affects the results as well as the interpretations given to them. However, most studies in medical errors have utilized surrogate measurements that depend mostly on injury or adverse outcomes (Grober & Bohnen, 2005).

On the specific issues of medication errors, evidence by Lisby, Nielsen, Brock., & Mainz (2010), revealed that the definitions given to medication errors are inconsistent as well as having over 26 different terminologies for medication error in a given systemic Literature Reviews searches by the same researchers, (WHO study, Payne et al., 2016; Lisby et al., 2010). These different returned definitions generated by Lisby et al., (2010) varied in content and/or meanings, came from searches in PubMed, Embase, PsychINFO and CINAHL databases, and were conducted in nine (9) different countries. The researcher’s view is that the issue of not having a general consensus on the true definition of medication error, considering the above disagreements and medication error definitions may hinder the creation of effective solutions to this problem.

To help clarify which next stage research is warranted, the current study analyzes whether the adoption and implementation of the HITECH / Meaningful Use Act or the EHR has resulted in an increase or decrease in reported medication errors, or has had no impact on the reported incidence of such errors in the US. Existing secondary data
sources were employed in the study, and came primarily from a government agency, specifically, the Center for Drug Evaluation and Research (CDER) / Healthcare Cost and Utilization Project (HCUP). Such collected data were assembled, analyzed, and used in making inferences for the current analysis.

**Problem Statement**

The Centers for Disease Prevention and Control (CDC) has indicated that medical errors still rank among top major causes of death in the United States (CDC, 2017). Yang (2005) demonstrated that despite increased public reporting about hospital performance, the results still indicated that even the top performing hospitals report between 10,000 to 50,000 medical error related deaths per million.

According to a Columbia Broadcasting Station (CBS) news report (Collins, 2003), a North Carolina teenager and a heart-lung transplant recipient died after receiving the organs from a donor with the wrong blood type, which her body rejected immediately. In another case, a 17-month-old baby received an incompatible liver transplant from her father, instead of her mother, resulting in a lawsuit filed against two Dallas hospitals and three surgeons. Her mother’s blood type was O, while the father’s was type A. The laboratory that identified the blood type made a mistake by incorrectly identifying the father as the correct donor. Part of the father’s liver was removed at Baylor University Medical Center and was taken to the Children’s Medical Center, where it was transplanted into the baby. The mistake was not discovered until the 19th day after surgery when the child developed serious complications and then died the next day.

Hospitals and other health services organizations are morally obligated to act in the best interest of the patients. When patients are sick, they tend to rely heavily on hospitals
and health services organizations to provide them with the best available care for their ailment – medically, physically, psychologically and otherwise. Patients’ sole expectations during serious medical circumstances are recovery versus injury and possible death due to clinical negligence or medical error. When that purpose cannot be achieved, patients expect to be in the same or better condition as when they leave the facility, instead of leaving in a life-threatening conditions as a result of preventable medical errors.

Reducing or possibly eliminating medical errors, while enhancing patient safety is a critical component to delivering patient-centered care (Heath, 2017; Epstein & Street, 2011), which is closely linked to patient satisfaction. Information from selected documentaries like Dangerous Prescription (Fanning, 2003); PBS video - Escape Fire: The Fight to Rescue American Healthcare (Heineman & Froemke, 2012), and “Sicko” (Moore, 2007), also highlights the alarming number of medical errors and their consequences in the United States. For example, an Electronic Health Records error issued a particularly dangerously flawed instruction that a small child weighing as little as 44 pounds be given a sedative 10 times beyond the clinically required and safe dosage (Kaiser Health News, 2016). Such a situation is scary, very dangerous, and raises a lot of concern about patient safety and unintended consequences of the EHR, in general.

In particular, medication errors are a central focus of this research. According to The United States National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP, 2018), medication error can be defined as:

“any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional,
patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.”

According to the World Health Organization (WHO), a majority of medication errors are preventable (WHO, Payne, Franklin, Slight, & Avery, 2016).

For example, the medical errors discussed in the above scenarios were preventable and would have saved lives if appropriate measures and precautions had occurred. For several decades, the healthcare industry has been battling medical errors and publishing extensively on the dangers (IOM, 2000) yet the issue of medical error, especially, the medication errors is not yet under control. One reason may be that most medical organizations have not collaborated sufficiently to reduce medical errors for healthcare stakeholders in the US. A lot is still yet to be done in efforts to enhance patient safety and reduce medical errors to a manageable level.

Scope of The Problem

Medical errors are a major challenge facing the United States and found in every region of the country. A study by James (2013) challenged previous low estimates of medical errors in the U.S., as well as indicating that the actual levels of medical errors are between 210,000 to 400,000 deaths resulting from preventable medical errors. On a global level, the World Health Organization, WHO, Payne et al. (2016) indicated that some countries estimated the rate of medication errors at 7% of hospital admissions, and
shockingly, about 70% of such errors are preventable (Patel et al., 2007; Pirmohamed et al., 2004; and Alexopoulou et al., 2008).

Medication errors are also of a major global concern since no part of the globe is completely free from the threat of medication errors.

Research Questions

a. What is the impact of Electronic Health Records (EHR) on patient safety, as measured by medication errors, following the HITECH Act?

b. Was there an increase or decrease in the number or levels of in-hospital medication errors from 2007 to 2010, and after the implementation of The Meaningful Use Act / Electronic Health Records (EHR) from 2011 to 2014?

c. Were there no significant changes between those two periods (pre- and post-Electronic Health Records (EHR) era?

Research Hypotheses

The Null Hypothesis: there is no difference in the volume or counts or the trends of the medication errors between 2007 and 2014 as indicated in the presence of ICD 9 CM Codes that identify medication errors) between the Pre- and Post- EHR eras).

The alternate Hypothesis: there is a difference in the volume or counts or pattern of the medication errors (those ICD 9 CM Codes used for identifying medication errors).
CHAPTER II

REVIEW OF THE LITERATURE

Introduction

The healthcare industry has been struggling with the issue of reducing medical errors for some time, creating the need for a better solution. A better solution must involve rigorous, in-depth research that will explore a variety of sources in order to arrive at a well-rounded solution that will not only be beneficial to the healthcare industry, but also be beneficial to the entire humankind. This is one of the core goals of this research.

Focusing only on one type of source of research materials will not only negate, but will also defeat the purpose of arriving at rich and balanced results. This was one of the key reasons for broadening the source type of materials utilized in this study. The study utilized evidence-based sources that highlighted various issues, and proposed effective multi-disciplinary ideas that will lead to better understanding of medical errors, while offering effective possible solutions. However, on the specific issue of medication errors, the 2016 WHO study (Payne et al., 2016), indicated that there is still no consensus as to the real classification and/or definition of medication errors. Consequently, estimating the prevalence of medication errors has been very complex, as indicated in that WHO study.

The current study involved a rigorous review and synthesis of numerous / broad sources which included (but are not limited to) empirical scholarly materials, books,
scholarly journals, articles, reviews, online resources, documentaries, digital and several other diverse sources.

Physicians and other medical practitioners face the arduous work of taking care of patients with all levels of care needs, and that the human body is a very complex system. Despite those challenges, it is still necessary today to promote patient safety to ensure that only minimal or possibly NO harm occurs to the patients. Reducing preventable medical harms of both omission and commission should be the top priority of all healthcare professionals and organizations that provide care to patients. This point is extremely important, considering that many improvements can still be made to reduce preventable clinical errors, which happens to be most of the medical errors that cost the patients their lives, as indicated in this research. Evidence showed that negligence is also responsible for about 17% of adverse events, especially in surgeries (Leape et al., 1991; Thomas et al., 2000).

The focus of this study is not to place blame on physicians and other medical professionals, but rather to highlight several issues of critical importance relating to patient safety, in such a way that all stakeholders can work synergistically and collaboratively to proffer solutions for addressing this canker worm that is drastically eating deep into the fabric of the healthcare industry. Such a situation is not far-fetched and can definitely be attained if solutions and appropriate measures are taken, including possible solutions to be provided in this research.
Patient Harm & Safety

Donaldson, Corrigan, & Kohn (2000) indicated that patient safety is a critical issue of national importance. It is important not only in the U.S., but also on a global level. It is very important to deliver care in both a timely and safe manner to patients. There are serious consequences for not following such recommendations. Several studies by the RAND Corporation indicated alarming levels of medical practices that are harmful to patients (Goldman & McGlynn (2005).

Masters in Healthcare (2018) elaborated on a few varieties of astonishing medical errors, as indicated in the following cases described below:

(a) Accidental Medication Overdose given to Babies: Instead of administering the recommended (ten) 10 units of a medication, a deadly dose of (ten thousand) 10,000 units were administered to newborn twin babies of a prominent US Actor.

(b) Performing a Surgery on the Wrong Side of the Brain, by Neurosurgeons at Rhode Island Hospital, RI.

(c) Transplanting the Wrong Heart and Lung, at Duke University Hospital, North Carolina: Although the surgeon, the surgeon who transplanted the organ with the wrong blood type tried to correct the problem, it was too late since the 17 – year old patient had already suffered severe brain damage while her body was shutting down. She eventually died, as a result of such medical error, that could have been prevented.

(d) Erroneously Removing the Wrong Testicle of a US Air Force veteran in a Los Angeles VA Medical Center, California: This medical error resulted in a vigorous lawsuit filed by the veteran’s wife, joined by the enraged patient.
(e) Removing Kidney instead of a Gall Bladder in an 84-year old woman, in Milford Regional Medical Center, Massachusetts, MA.

(f) Mistakenly Amputating a Wrong (Healthy) Leg of a 52-year old, instead of the diseased leg.

(g) Double Mastectomy was Erroneously Performed on 35-year woman, who did not even have breast cancer.

The United States spends over $1.6 trillion in healthcare (Crane & Crane 2006), and yet the rate of medical error is considerably very high. The US healthcare system is plagued with medication errors, and some studies indicated that the U.S. has one of the highest medical error rates among the industrialized nations of the world (Heavey, 2005; Schoen et al., 2005). The Institute of Medicine (IOM) provided an earlier estimate on number of people that die from preventable medical errors to be as much as 98,000 deaths per year (Donaldson, Corrigan, & Kohn, 2000). A later study by James (2013) refuted the IOM’s purported low estimate claim of 98,000 deaths from medical errors, indicating that true number was actually 4.5 times higher (Becker’s Hospital Review, 2013).

The United States Food & Drug Administration, FDA, (FDA, 2016) showed that approximately 1.3 million people are harmed annually in addition to at least one death per day in the US due to various medication errors that ranged from prescribing, repackaging, dispensing, administering, or monitoring. According to Shahrokhi, Ebrahimpour & Ghodousi, (2013), medication errors, amongst many others, are the most common medical error category that results in patient complications. Additional research
by Ebrahimipour et al (2016) supported the claim that medication errors are the most common medical errors that pose significant threat to patient safety. Walker et al (2008) inferred that several studies showed that Electronic Health Records (EHR) contribute to numerous unintended consequences that result in patient harm, posing a significant challenge to patient safety, globally. Farley, et al. (2013), also confirmed the above postulation and referenced numerous studies that highlighted the unintended consequences associated with the use of EHR (Bloomrosen & Detmer, 2010; Blumenthal, 2011; Handel, Wears, Nathanson, & Pines, 2011; Kellermann & Jones, 2013; Mandl & Kohane, 2012). Some of the medical errors can be attributed to negligence, which has been an issue of both national and global importance that requires utmost attention.

With the above highlighted concerns with medical errors, especially medication errors, there is a dire need to find effective solutions that will enhance patient safety in the United States. The sole reason for such a solution being that there is a widespread use of both prescription and non-prescription medications in the United States, as was indicated by Mayo Clinic (Wittich, Burkle, & Lanier, 2014). Medication error is a major concern and threat considering the risks and associated adverse impacts on the American society. A surprising study revealed that 81% of US population took medications within a single week, when a large national survey was conducted (Kaufman, Kelly, Rosenberg, Anderson, & Mitchell, 2002), and that 50% of them consumed a minimum of one prescription medications.

Diagnostic error rates in the US contribute to a significant causes of patient harm, and the prevalence is alarmingly high (Graber, 2011; ECRI, 2018). According to the National Academies of Sciences, Engineering and Medicine in their publication –
‘Improving Diagnosis in Health Care,’ released in September, 2015: “the best estimates indicate that all of us will likely experience a meaningful diagnostic error in our lifetime” (Ball & Balogh, 2016, p. 59). Diagnostic error was defined in the same study as (a) failing to accurately determine or ascertain clinical problems in a timely manner or (b) failure to translate that explanation to the patient. Such inability to accurately establish or communicate the health conditions of patients is a great risk to the patients and the entire healthcare industry since treatment is directed to the wrong medical problems while the true cause still torments the patients, in some cases eventually killing the patients.

The Emergency Care Research Institute, ECRI, confirmed that amongst the institute’s Top 10 List of Patient Safety concerns in 2018, Diagnostic Errors ranked #1, topping the entire list (ECRI, 2018). Shockingly, such ranking also included Leadership Engagement in patient safety. This is a clear pointer that the upper management of health service organizations must increase their level of support and engagement towards the effort to find effective solutions to the malaise of medical errors. An earlier study by Kirch & Schafii (1996) which placed diagnostic error at a minimum rate of at least 10% also indicated that diagnostic errors were a major concern of the health care industry as well as posing a significant threat to patient safety, at all levels.

A 2005 study (Graber, Franklin & Gordon, 2005) found that in most diagnostic errors that resulted in death, the key contributory factors to such errors were chiefly cognitive factors (from the physician), followed by system-related factors (from the concerned health service organization), respectively, amongst other causes. Although, overconfidence has been proven to be one of the specific cognitive reasons for diagnostic errors (Berner & Graber, 2008), such cognitive faults are not usually due to lack of
knowledge on the physician’s part. Rather, it is mostly due to failing to gather or consider necessary information, or misinterpretation of that information. Conversely, clinical areas that rely heavily on visual judgment, like pathology and radiology, have slightly lower rates of medical error, except in the situations where other clinicians that are not well-trained interpret such results instead of the radiologists (Berner & Graber, 2008; Fitzgerald, 2001).

**The United States Healthcare System, Complexity and Patient Safety**

The United States healthcare system is unique. A study by Emanuel (2015) indicated that it is very complex (James, 2013; Zilberberg, 2011) in addition to its associated concerns of the Costs of Poor Quality (COPQ). The issues of cost of poor quality and complexity are strongly tied to the social scientists’ concept of *path dependence*, explaining how the U.S. healthcare system evolved over a period of 100 years, and several systems built upon one another. All U.S. new healthcare decisions are built on longstanding ones over a period of time, thereby creating complexity, even though some of the ideas may still not be relevant in the present health systems environment.

For instance, the level of complexity of the U.S. healthcare system can be seen from the fact that five different previous U.S. presidents (Theodore Roosevelt, Franklin D. Roosevelt, Harry Truman, John Kennedy, and Richard Nixon) - all tried but failed in their efforts in providing Universal Health Coverage to the U.S. citizens (Emanuel, 2015). The Affordable Care Act (ACA) was finally signed into law by President Obama on March 23, 2010 and upheld by the Supreme Court on June 28, 2012, in order to address the burden created by the long-standing challenges of the U.S. health system.
Some aspects of the ACA touched immensely on the issue of patient safety. Also, Emmanuel (2015) inferred that the ACA has gained great historical success, as well as being one of the most remarkable U.S. healthcare reforms since the 1965 Medicare Act by Lyndon B. Johnson. Nonetheless, it is imperfect, requiring some tweaking despite positive results.

On the issue of the high cost of the U.S health system, according to the data from Organization for Economic Co-operation and Development (OECD), the U.S. spends about twice as much on healthcare compared to other countries, while those that spent less ranked higher than the U.S. in multiple measures of health (Bradley, Taylor & Bradley, 2015).

**The Level of Medical Harm in the United States**

Numerous past studies, which included The Harvard Medical Practice Study Group (1990) and Leap, et al (1991) has expressed serious concerns on the level of medical errors, in addition to stating that a lot of work is needed to address the problem of medical errors. Initial figures provided by the Institute of Medicine (IOM, 2000) extrapolated the level of medical errors at between 44,000 to 98,000 deaths per year. More recent studies have aggressively rebutted the above earlier figure provided by the Institute of Medicine by highlighting numerous flaws in the study, and indicating that the actual figure should be much higher – as much as 4.5 times higher (ASHRM, 2018; Carroll, 2016; Daniel & Makary, 2016; James, 2013). A 2016 Johns Hopkins study by Daniel & Makary (2016) demonstrated that the level of medical harms to patients is
actually higher than past extrapolations, thereby making medical error the #3 cause of
death in the United States.

James’ study (2013), which utilized a weighted average of 4 studies, indicated a low
estimate of 210,000 deaths per year from medical errors. However, considering the
methodological limitations of the study, the estimate still showed that death from
preventable medical errors could be as high as 400,000+ deaths per year. The above
figure translates into about 4+ Million preventable deaths over a period of 10 years,
which seems significantly very high! James (2013) indicated that the major causes of
such medication errors are due to such issues like communication, omission, commission,
or even wrong diagnosis. However, the fact that such high number of deaths could have
been avoided or prevented is also very disturbing.

When examining these conflicting medical error casualty figures in the above
referenced studies as a neutral party, it seems that it does not really matter if the earlier
estimates were very low, high, correct or even incorrect. The important observation and
key point is that lots of patients’ lives are being lost, which could have been prevented.
The target should be zero harm to the patients, wherever possible.

Even with the lowest estimates, these figures are still troubling, considering that most
of these cases are preventable. Time and energy should not be wasted in debating,
fighting over the correct figures or volume of people that lost their lives from medical
errors. Rather, the same energy should be well channeled, targeted, focused, and geared
appropriately towards solving the actual problem and challenge at stake - which is
medical error. Collaborative efforts amongst all stakeholders are required in order to
achieve this common goal. All hands should be on deck in order to solve the crippling situation that has been ravaging the health care industry for several decades.

**Categorization of Medication Errors: The Agency for Health Research and Quality, AHRQ**

The Agency for Health Research and Quality, AHRQ (2012) categorized medication errors into nine major groups:

(i) no error, but, capacity to cause error; (ii) error that was not able to get to the patient; (iii) error that reached patient but improbable of causing harm; (iv) error that reached the patient that may require intervention and/or monitoring to in order to prevent harm; (v) error that could lead to temporary harm; (vi) error that could cause temporary harm resulting in some form of hospitalization; (vii) error that could lead to permanent harm; (viii) error that could require intervention in order to sustain life and, (ix) error that could lead to death.

**Tracking Adverse Events in Hospitalized Patients**

According to Classen, et al. (2011), the three major methods for tracking adverse medical events in the United States are voluntary reporting; Quality’s Patient Safety Indicators, and the Agency for Healthcare Research. Those methods are critically flawed to the extent that they miss or fail to capture 90 percent of most medical errors. Voluntary
reporting was also shown as a risky measure, since it promotes misleading patient safety data, information, and conclusions in the United States.

Conversely, when compared with other detection methods, the Global Trigger Tool, by The Institute for Healthcare Improvement, found adverse events ten times more than other methods (Classen, et al., 2011).

The Health Information Technology for Economic and Clinical Health (HITECH Act of 2009) / Meaningful Use Act, and Health Information Technology (HIT)

The four notable characteristics of the US health care system, according to Emanuel (2015) are as follows: (a) Very Costly (b) Prone to Errors, (c) Very Complex, and (d) Inefficiency. Other concerns highlighted by Emmanuel (2015) also included the following: lack of transparency in cost and quality; medical malpractice; the cost of being uninsured; the economic cost of high health care costs; and the cost of poor quality of care.

Social Determinants of Health

According to Bradley, Taylor & Bradley (2015), United States healthcare is characterized by high costs, bad health outcome, little spending in social, behavioral, and environmental factors. Minimal attention is paid to the social determinants of health; the United States spend less on housing, unemployment, disability, family support, employment programs, while spending heavily on health care services. In addition, countries that tend to invest heavily in social services reaped the benefit in terms of positive health outcomes and results, while those that ignored such crucial areas tended to
struggle with negative health outcome as well as the skyrocketing cost of health care, as highlighted in the same study by Bradley, Taylor & Bradley (2015). The need and efforts to reduce patient harm and medical errors, and consequently enhancing patient safety, quality, and efficiency (HealthIT.Gov, 2018) all resulted in the introduction of the Health Information Technology for Economic and Clinical Health (HITECH Act of 2009 / Meaningful Use Act), which was part of the American Recovery and Reinvestment Act (ARRA). The American Recovery and Reinvestment Act (ARRA) was signed into law on February 17th, 2009, and allocated $19.2 Billion specifically to the Title XIII - the Health Information Technology for Economic and Clinical Health (HITECH) Act, in order to boost the use of Health Information Technology, like the Electronic Health Records (EHR) strategically to enhance the US healthcare services (HIMSS, 2018)

In an effort to improve healthcare effectiveness and efficiency, Meaningful Use evolved, as a step in the right direction, considering the obvious advantages. However, it will only go so far in reducing medical errors on a larger scale, unless heavy emphasis is placed on tackling such a challenge systematically. The true solution to enhancing the health system processes still lies in adopting a systems approach, as practiced in the industrial engineering, aerospace, and automotive manufacturing industries. Coincidentally, this particular viewpoint was already proposed about 80 years ago by the famous American, Henry Ford, as can be seen in his remarks: "The same kind of management which permits a factory to give the fullest service will permit a hospital to give the fullest service, and at a price so low as to be within the reach of everyone" (Ford, 1922).
Athenahealth (2016) inferred that the Meaningful Use initiative has been useful in reducing medical errors. According to Centers for Medicare and Medicaid Services, CMS (2018), Meaningful Use was designed to incorporate incentives and penalties, and having just EHR by itself does not suffice; the entity involved must clearly demonstrate that EHR is being used in ways that positively influence patients’ health.

There are 15 Core Objectives that every eligible professional must meet in order to receive EHR incentive payment, and all those objectives work together to support and promote clinical excellence. They include the following: CPOE (Computerized Provider Order Entry); Drug-drug and drug-allergy checks; maintain an up-to-date problem list of current and active diagnoses; e-Prescribing (eRx); maintain active medication list; maintain active medication allergy list; record demographics; record and chart changes in vital signs; record smoking status for patients 13 years or older; report ambulatory clinical quality measures to CMS/States; implement clinical decision support; provide patients with an electronic copy of their health information, upon request; provide clinical summaries for patients for each office visit; capability to exchange key clinical information; and protect electronic health information (CMS, 2018). All the above 15 objectives focus on reducing patient harm.

The causes of inefficiency, medical harm, and medical errors do not come from a single source alone, but due to multiple variables. In order to provide an effective solution, the healthcare industry must adopt the ‘systemic’ view of solving problems, as done in the industrial engineering, aerospace, and the military, respectively.
Medication Errors / Adverse Drug Events and the Need to Inculcate Patient Safety in Medical Curricula

Goldman & McGlynn (2005) indicated that 35% of preventable adverse drug events were known to occur during the time that drugs are administered, while a higher percentage (56%) were traced to the point when medications are ordered. Moreover, the curricula of most medical schools that train professionals, including pharmacists, incorporate relevant domains in the area of medication errors that will equip such professionals with the skills to effectively manage medication error challenges, thereby enhancing patient safety.

A study by Johnson, Latif & Gordon (2002) revealed that about 56% of pharmacy schools that were surveyed did not have some form of medication error instructions in their curricula. Only 15 out the 34 pharmacy schools that responded in the study indicated some form of medication error instructions in their entire course format. Karsh et al., (2005) stressed that: “A substantial number of the responding schools indicated that the following domains were not taught in their curriculum: human factors research (44 percent), medical errors (32 percent), root-cause analysis (62 percent), and failure mode and effects analysis (79 percent).” (p. 272).

The World Health Organization, WHO (2014) indicated that medication error is a major concern to patient safety, with an associated estimated annual cost of $42 billion, globally, without including healthcare cost, lost wages and productivity. Empirical evidence-based studies have confirmed that medication errors are preventable, not inevitable, and originate as a result of systemic problems, thereby clearly requiring a systemic approach (Nielsen, Merry, Schyve, & Bisognano, 2004). Although medication
errors are shown to be preventable (Crane & Crane 2006; WHO, Payne et al., 2016), the major causes are not human factors or negligence, but systemic failures (Migdail, 2000; Leape, Epstein, & Hamel, 2002).

**Human Factors**

A WHO study, stated that giving inadequate consideration to the 3 key human factor system designs: *cognitive element, physical / environmental element, and organizational element* may increase the likelihood for medical errors (WHO, Wetterneck, Holden, Beasley, Otles, 2016). Thus, it is important to consider Human Factor models and principles in the healthcare industry, especially in the management of medical errors. In all efforts to solve the problem of medical errors, focusing on a single element alone, like the EHR, and ignoring the rest of other factors will be counter-productive (WHO, Wetterneck, Holden, Beasley, Otles, 2016; Carayon et al., 2013).

Workloads, distractions, and several other environmental factors are known to play key contributory roles to some level to medication errors (WHO, Payne et al., 2016). Researchers from Texas A & M University concluded that there is a strong body of evidence supporting the fact that hospitals’ physical and environmental factors affect clinical outcome (Zimring, Joseph, & Choudhary, 2004), especially, medical errors, which included medication errors. Poor lighting, stress, auditory and visual distractions can lead to medication errors (Seki & Yamazaki, 2006; Karavasiliadou & Athanasakis, 2014; Zimring, Joseph, & Choudhary, 2004). This Texas A & M study showed that there is a shortage of registered nurses, which increases the stressful workloads, while the average age was more than 43 years. All these factors were shown to pose a significant
risk to patient safety (JCAHO, 2002; Zimring, Joseph, & Choudhary, 2004). In essence, balancing workloads to optimal levels, reducing distractions, and effectively managing stressors and the physical environment where medical services are provided may be useful in reducing medication errors.

**EHR, Impacts, their Intended and Un-Intended Consequences**

Although electronic prescribing has been shown to enhance patient safety (Lourenco, Bursua, & Groo, 2016; Kaushal, Kern, Barrón, Quaresimo & Abramson, 2010) by preventing some level of medication errors, it also has been known to lead to adverse outcomes that contribute to medication errors. Liao et al. (2017) demonstrated that although the Electronic Health Records (EHR) enhanced patient safety by significantly reducing prescription errors EHRs also contributed to a spike in wrong dose administration and medication omissions.

Electronic Health Records have a potential for generating medical errors (WHO, Wetterneck, Holden, Beasley, Otles, 2016). Bowman (2013) found that despite numerous clinical benefits the ehr was associated with several unintended consequences, which included but were not limited to the following: increase in medical / medication errors that adversely impact patient safety, increase in fraud and abuse, legal consequences, and many other clinical risks and concerns. Thus, despite the general consensus on the usefulness of the EHR, its overall effectiveness and/or safety are yet to be proven (McDonald, 2006; Brown, Shaw, Grimm, Muttitt, & Gebran, 2008).

The EHR is characterized with design flaws (AHIMA, 2017) and is very complex (Bowman, 2013), and such complexity contributed to the unintended consequences of
usability errors (Phillips & Fleming, 2009; Hoffman & Podgurski, 2008). Most of the EHR errors are traced to poor design, and not as a result of user/human errors. Such inherent design flaws make it easy for patients to miss medications, be given the wrong dosages and/or the wrong medications (Kannry, 2011) thereby leading to increase in medication error rates in various health facilities nationwide. For instance, according to Kaiser Health News, (2016), an EHR design error gave a faulty instruction that a child weighing 44 pounds be given a sedative 10 times the required dosage. The issue of misidentifying patients has become more prevalent during the digital era, in contrast with the pre-EHR era, where patient misidentification was very rare, as shown in the same study.

Trends from The Doctors Company indicated that EHR-related legal issues between 2007 and 2013 were relatively minimal (at about 1%) of all malpractice cases, but this rate doubled between late 2013 and early 2014 (Allen, 2015). A possible explanation for such a sharp increase is that it takes about 5 to 6 years to close malpractice cases that may have started after a facility or health system implemented EHR software.

Contrastingly, a recent study by Troxel (2015) indicated that user factors actually contributed more than system factors (64% vs 42%) of the overall EHR-related medical malpractice claims from January 2007 to June 2014. Troxel’s findings inferred that according to data from The Doctors Company, which is the largest United States’ physician-owned medical malpractice insurer, that there are eight System factors and seven User factors:

- Failure of system design
- Electronic systems/technology failure
- Lack of EHR alert/alarm/decision support
- System failure—electronic data routing
- Insufficient scope/area for documentation
- Fragmented EHR
- Lack of integration/incompatible systems
- Failure to ensure EHR security.

The seven User factors included the following:

- Incorrect information in the EHR
- Hybrid health records / EHR conversion
- Prepopulating/copy and paste
- EHR training/education
- EHR user error (other than data entry)
- EHR alert issues/fatigue

--EHR/CPOE workarounds

(Troxel, 2015).

It is very important to enhance relevant EHR-related processes as well as Clinical Decision Support Systems (CDSS), since their inherent risks cannot be eliminated completely. Such measures will also help to address most unintended consequences of EHRs, in addition to improving patient safety (Bowman, 2013; Coiera, Westbrook & Wyatt, 2006; Fox & Thomson, 2002).

Notably, pharmacies can still dispense 1.5% of electronically discontinued medications, despite their higher risk of adverse side effects, and this is a great concern
for patient safety, according to Harvard Vanguard Medical (Allen & Sequist, 2012). More recently, Lourenco, Bursua, & Groo (2016) indicated several instances of prescriptions discontinued in the local EMR failing to transmit stop orders to the pharmacy and resulting in patients receiving refills of discontinued medications that had adverse effects on their health.

**Summary**

The US healthcare industry has been struggling with the critical issue of reducing medical errors and enhancing patient safety for a very long time. Improvement efforts are still moving slowly, in terms of reducing preventable patient harm. Numerous empirical studies has demonstrated that despite the fact that the US spends a significant amount on healthcare, yet many Americans still lose their lives as a result of preventable medical errors (Donaldson, Corrigan, & Kohn, 2000; FDA, 2016; Goldman & McGlynn, 2005; Heavey, 2005; Schoen et al., 2005; James, 2013; Masters in Healthcare, 2018; Shahrokhi, Ebrahimpour & Ghodousi, 2013).

Medication errors has remained a major obstacle to improving patient safety in the US, considering that there is high prevalent of medication use in the American society (Kaufman, Kelly, Rosenberg, Anderson, & Mitchell, 2002), which includes both prescribed and over-the-counter drug uses. There is an inconsistent agreement on the universal definition of the term medication errors, according to a 2016 WHO study (Payne et al., 2016). Although the emergence of EHR helped to resolve some types of clinical errors, several empirical studies highlighted that the introduction and implementation of EHR also came with numerous unintended consequences that pose
significant threat to patient safety. The systems put in place for tracking medical errors are also shown to be flawed (Classen, et al, 2011). The current literatures reviewed in this study establishes the context for creating the new knowledge as to whether the adoption and implementation of the EHR / HITECH Act contributed to an increase, decrease or had no impact on the US medical errors. This is the gap addressed in this study.

The purpose of this research is to look in-depth into the use of EHR, to measure and determine its impact on medical errors, by the use of relevant research data, empirical studies, data analysis, and interpretation. The inferences to be drawn from this study will show if the use of EHR actually contributed to an increase, decrease or had no effect on medication errors.
CHAPTER III
METHODOLOGY

Study Design and Hypotheses

A descriptive, retrospective, quantitative study approach using hospital medical records and ICD-9 codes was applied to the problem of medication errors within the stipulated overall timeframes of 2007 to 2014 which incorporated the pre- and post–EHR / Meaningful Use periods utilized for the research. Data from the Healthcare Cost and Utilization Project (HCUP) database were utilized to determine the overall counts of specific medication errors in the aforementioned Pre- and Post EHR eras.

The dependent variables of interest were the total counts of the medical errors per year, per hospital and combined. Independent variables would include whether it is Pre or Post EHR time, the average size of the contributing hospital as measured by number of beds, and the region of the hospital. The hospital is the unit of analysis.

The medication error was measured in relation to the overall percentage of medical errors that are non-medication related, and it is represented as \( \text{Rxper OE} \), (percent that Medication errors as a % of the non-medication medical errors for the month). \( \text{Rxper OE} \) variable shows the percentage of monthly medication errors as a percentage of all other medical errors that are not caused by medications. The \( \text{Rxper OE} \) was recorded monthly, from January 2007 to December 2014. The \( \text{Rxper OE} \) data was analyzed to make an inference as to whether the volumes of medication errors increased, decreased, or stayed the same between the years 2007 to 2014.
Graphs were plotted using the Rxper OE and the months and the trends observed was utilized in determining the impact of the Electronic Health Records (EHR) on medication errors between 2007 and 2014, that included both Pre- and Post- (EHR) periods.

From the remaining records, we extracted all admissions with an E-code of interest. Admissions with secondary diagnosis codes for an adverse event were retained. We coded medication errors separately from other adverse events to test the hypothesis that these types of errors declined more than other medical adverse events after implementation of the HITECH Act because medication order entry is usually the first meaningful use improvement implemented in a hospital. The coding used for the data extraction is provided below.

**Hypotheses**

The Null Hypothesis was as follows: there is no difference in the volume or counts or the trends of the medication errors between 2007 and 2014 as indicated in the presence of ICD 9 CM Codes that identify medication errors) between the Pre- and Post- EHR eras). The alternate is that there is a difference in the volume or counts or pattern of the medication errors (those ICD 9 CM Codes used for identifying medication errors).
## Definition of Variables

### Study Variables / Description of Research Data Elements

Source: [https://www.hcup-us.ahrq.gov/db/nation/nis/nisdde.jsp](https://www.hcup-us.ahrq.gov/db/nation/nis/nisdde.jsp)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
<th>Value</th>
<th>Value Description / Date</th>
<th>General Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGE</td>
<td>Age in years at admission</td>
<td>0-124</td>
<td>Age in years</td>
<td>Missing</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Missing</td>
<td>Invalid</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Unavailable from source (coded in 1988-1997 data only)</td>
<td>Inconsistent: beginning with 1998 data, EAGE02, EAGE03, EAGE04, EAGE05; in 1988-1997 data, ED021, ED3nm, ED4nn, ED5nn</td>
</tr>
<tr>
<td>CM_VALVE</td>
<td>AHRQ comorbidity measure for ICD-9-CM codes: valvular disease</td>
<td>0</td>
<td>Comorbidity is not present</td>
<td>Comorbidity is present</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>Comorbidity is present</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>A</td>
<td>Invalid</td>
<td></td>
</tr>
</tbody>
</table>
Data Sources

The study utilized secondary data from the Healthcare Cost and Utilization Project (HCUP). The data set utilized was the National (Nationwide) Inpatient Sample, NIS, (NIS Database, 2007 – 2014). The collected data set was analyzed and utilized in making inferences regarding the study. The NIS data set is a very reliable research data source and has been widely used and referenced in numerous policy, clinical, and non-clinical studies in the US (Schoenman, Sutton, Kintala, Love, & Maw, 2005).

Study Population and Data Extraction

All patient admissions in the NIS sample for the years 2007-2014 were included. Admissions with a DRG of 449, 450, and 451 were excluded to avoid capturing admissions were medication poisoning was the reason for the hospital admission. The collected data set were analyzed with descriptive statistics.

Data Extraction Coding

If DRG24 in (449, 450, 451) then delete; *delete admissions with primary diagnoses of medication poisoning to avoid counting present on admission;

array Ecode{4}; *array all dx variables for accidents;

do i=1 to 4;

if substr(Ecode{i},1,1) in ('E851', 'E852', 'E853', 'E854', 'E855', 'E856', 'E857', 'E858') then MedAE=1;

if substr(Ecode{i},1,5) in ('E8736', 'E8738') then MedAE=1;

end;
array Dx{15}; *array all dx variables for complications/comorbidities;

do i=2 to 15;

if substr(Dx{i},1,4) in ('5192', '5121', '9975', '9982', '9980', '9983', '9991','9964') then OtherAE=1;

if substr(Dx{i},1,5) in ('99731') then OtherAE=1;

if substr(Dx{i},1,3) in ('960', '961', '962', '963', '964', '965', '966','967', '968', '969', '970', 
'971', '972', '973', '974', '975', '976', '977', '978') then MedAE3=1;

end;

If MedAE=1 or MedAE3=1 or OtherAE=1;

RxAE=0;

If MedAE=1 or MedAE3=1 then RxAE=1;

Rationale for Utilizing Pre and Post EHR Era Data

The investigators used the Pre - and Post - HITECH Act / EHR implementation data was to be able to effectively determine the trends in the medication errors data, as well as empirically revealing its true impact on the U.S. healthcare system.

It is essential to recognize the possible constraint that some hospitals in the NIS database may have experienced at various stages of EHR implementation, which typically occurs in phases. According to Kazley et al (2014):
“EHR use is measured using stages based on individual applications reported in the hospitals. These include stage 0 (no automation), stage 1 (automation of ancillary services including a clinical data repository, and pharmacy, laboratory, and radiology information systems), stage 2 (stage 1 + automation of nursing work flow with electronic nursing documentation, and medication administration records), and stage 3 (advanced EHR including: stages 1 and 2 + CPOE and clinical decision support).

Data Analysis (Statistical)

The Pre - and Post - EHR / Meaningful Use Act study data were extracted, and a binary variable with a value of 0 was assigned to data from the years 2007-2010 to indicate the pre-HITECH period. The post adoption period 2011-2014 were assigned a value of 1 to indicate the post-HITECH Act period.

A time series analysis was used to assess the effect of regulation implementation. The assumptions were that medical error should be decreasing steadily at the same rate between the pre- and post-HITECH Act eras and that medication errors would improve faster after the regulatory change. Another assumption was that EHR introduction contributed to any change we observed in the volume or rate of medication errors. Regression analysis was used to predict the total number of hospital medication errors. The traditional level of alpha=0.05 or the 5% level was used to determine statistical significance.

According to (Kirkendall, et., al, 2012), the International Classification of Diseases, ICD Codes has been widely used in the past studies for measuring hospital medical /
medication errors in the billing data. Additionally, Houglad, et. al (2008) highlighted
that the International Classification of Diseases, 9th Revision, Clinical Modifications
(ICD-9-CM) Codes, serves as one of the most effective tools for detecting and tracking
Adverse Events (AEs), like medication errors. Thus, the researcher utilized selected
ICD-9-CM Codes to designate medication errors.

The following ICD-9-CM Codes were used to designate medication errors, because
these types of errors could reasonably be expected to be prevented by use of a direct
order entry system for hospital medications:

(E873.6) Non-administration of necessary drug or medicinal substance

(E873.8) Other specified failure in dosage

The E-codes: (E873.9) Unspecified failure in dosage; (E875.1) Contaminated
substance injected or used for vaccination; and (E875.2) Contaminated drug or
biological substance administered by other means were not included as medication errors
because these types of adverse events would not be expected to be good indicators for the
effects of EHR use on medications errors.
CHAPTER IV
RESULTS

The study focused on answering the research question: What is the impact of
Electronic Health Records (EHR) on patient safety, as measured by medication errors,
following the HITECH Act?

a. Was there an increase or decrease in the number of in-hospital medication errors
from 2007 to 2010, and after the implementation of The Meaningful Use Act /
Electronic Health Records (EHR) from 2011 to 2014?
b. Were the changes observed between the pre- and post- Electronic Health Records
(EHR) era statistically significant?
c. Did the medication errors change as a percent of all adverse events/medical errors
after the implementation of the HITECH Act, controlling for patient
characteristics and time trends?

Initial Analysis and Baseline Characteristics

All hospital admissions in the NIS data sets for the years 2007 through 2014 were
examined. A total of 674 hospitals had an identification number in the 2007 dataset.
However, 28.1% of admissions were missing a hospital designation, so this is not a
perfect indicator of the number of hospitals included in this analysis. This data set was so
large that it required analysis approaches specific for “big data” that could only be
performed on one of the large CEDAR workstations. The table below provides
illustrative descriptive data for the year 2007. The NIS is a weighted 20% sample of all
admissions to acute care hospitals from all states that are part of the AHRQ HCUP data repository. Hospitals are sampled at a rate of approximately 20%, and once weighted; they are representative of all US hospital admissions for the year. The weighted versus unweighted rates were examined for one year, and there was no meaningful differences in the adverse event rate. Thus, because we are interested in measuring changes over time in the risk of recorded medical errors, and specifically in the recorded medication errors as a percent of all medical errors, as compared to absolute counts of errors for the US, we did not use the sampling weight in our analysis. The 2007 data set were examined to assess the odds ratio for risk of medication errors per quarter for the year. However, the logistic regression model could not be estimated because the measures of association between the observed and predicted values were not calculated and because the predicted probabilities are indistinguishable when they are classified into intervals of length 0.002. Consequently, the approach of using logistic regression for this “big data” analysis was abandoned. Instead, the percent change in medication errors as a proportion of all medical errors in a time period (Rxper OE) was used. The characteristics of the population in the first year of data used in the study are provided below (Table 1)

<table>
<thead>
<tr>
<th>Variable Description</th>
<th>Mean (SD) or N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>47.1 (28.2)</td>
</tr>
<tr>
<td>Number of Diagnoses</td>
<td>6.7 (4.4)</td>
</tr>
<tr>
<td>Length of Stay</td>
<td>4.6 (6.9)</td>
</tr>
<tr>
<td>Female Sex</td>
<td>4,694,503 (58.94%)</td>
</tr>
</tbody>
</table>
The variable of interest in the study was medication errors identified by ICD-9 Codes present in the discharge data. The overall rate of medication errors recorded was 0.19% in the data set. We calculated the medication error rate for the hospital with hospital identifiers and observed a mean rate of 0.21% and a range in rates from 0.00% to 5.85%, with a median value of 0.12% and an inter-quartile range of 0.4% to 0.23%.

### Fluctuations in Observed Patterns of Medication Errors

The trend in medical errors showed fluctuations at various degrees throughout the years used in the study (2007-2014). The observed trends and medication error fluctuations are another area for future research, because they may help to clarify why those trends occurred during those years, and what happened, as well as help in designing appropriate predictive models that will boost future positive health outcomes in the
United States. Medication error (Rxper OE) as shown in the data was initially at 6% in January 2007. It increased gradually during the 2007-2010 periods before a spike to 8.3% in January 2011. January 2011 represents the beginning of the Post-EHR period.

**Figure 1: Monthly Prescription Errors as a Percent of All Medical Errors**

Quarterly comparisons of the medical errors between the pre- and post EHR periods (2007-2010) versus (2011-2014) showed that medication errors occurred more frequently during the 2011 – 2014 period. There was an initial significant medication error spike in 2011, which coincided with the beginning months of the Post-EHR implementation stage.
The overall volume of medication errors increased gradually over the years from the pre–EHR period to the post-EHR era. The average Rxper OE obtained from 2007-2010 was 6.78%, while that from the 2011 – 2014 was 7.98%. This represents a 1.2% higher proportion of medication errors in the post-EHR period versus the pre-EHR era.

However, when the trend of increase in medication errors as a proportion of all errors using multivariable regression was further examined, it showed a mean increase of 0.24% per year over the observed time period (p=0.0048). This percent increased by 0.06% each year after 2010, but this increase was not statistically significant (p=0.6397). Thus, the change observed in the “raw” percentages is the result of a longer time trend and is not clearly associated with the implementation of the HITECH Act.

By comparing the two eras monthly, quarterly, bi-annually, and annually, it was found that medication errors consistently increased after the EHR was implemented.
during the 2011-2014 post era. The trend also showed that the volume of medication errors was lower prior to the implementation of the HITECH Act, but spiked sometime after the EHR was implemented.

Figure 3: Bi-annual Rates of Medication Errors

![Figure 3](image-url)

**Rxper OE Comparison Using the Averages of the Pre- and Post- EHR Medication Errors Percentages**

Total medication error percent averages were calculated for both the 2007 – 2010 and the 2011 – 2014 periods: The total for the post-EHR era indicated a higher number of medication errors (7.98%) versus the pre-EHR era, which was at (6.78%).

By using the 3-monthly (quarterly) averages of the medication errors from 2007 to 2014, found that the first quarter of 2007 (January-March) had the lowest number of
medication errors (5.97%). The highest observed quarterly average was in 2014 (April-June), at 8.77%.

The study findings do not support the hypothesis that there was a change in the volume or levels of in-hospital medication errors between the Pre-and Post-Electronic Health Records (EHR) timeframe. Medication errors increased during the post-EHR period (2011-2014). However, those results appear to indicate a worsening of medication errors over time, which was unexpected and requires further investigation.

**Medication Errors Controlling for Patient Demographics**

The following research question was examined: Did the medication errors decrease as a percent of all adverse events/medical errors after the implementation of the HITECH Act, controlling for changes in the type of patients seen?

We found that medication errors increased as a proportion of all medical errors after the implementation of the HITECH Act. That increase, however, was due to a decrease in other types of medical errors, while the rate of medication errors overall remained stable. This finding requires further exploration. We decided that this finding required further study and performed an exploratory analysis of the trends in the “raw” and the nationally weighted data for all medical errors, medication errors and other types of medical errors. The results from these additional analyses are provided below.
Additional Exploratory Analysis of the Trends in Observed Medical Errors in NIS Data

The unexpected findings to the research questions that was posed to the NIS led to the exploring the trends in observed numbers of hospital admissions with any medical error, medication error and non-medication medical errors over time. The counts in admissions over time were examined. Since the counts were normally distributed, a simple ordinary least squares regression model was used in this analysis. The number of admissions was aggregated by the Month giving us a total of 108 observational time periods. Additionally, a new variable was constructed by multiplying the observed number of events in the NIS data set by the NIH sampling weight to reflect the number estimated nationally for each month. We did this transformation to neutralize any differences in the sampling of hospitals included in the NIS over the observation time from 2007 through 2014. The result proved to be illustrative of why we failed to find an effect in our original study questions. The results of the observed and weighted trends are shown in the Table 2 below.

Table 2: Multivariable Models Testing Time Trends in Observed Counts of Medical Errors for Years Before and After the HITECH Act

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>All NIS Medical Errors (p Value) Model 1</th>
<th>All NIS Medical Errors (p Value) Model 2</th>
<th>All NIS Medical Errors (p Value) Model 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>218,790 (&lt;.0001)</td>
<td>224,622 (&lt;.0001)</td>
<td>65,572 (.1849)</td>
</tr>
<tr>
<td>Year</td>
<td>-106 (&lt;.0001)</td>
<td>-109 (&lt;.0001)</td>
<td>-30 (.2239)</td>
</tr>
<tr>
<td>Post HITECH (Post=1)</td>
<td></td>
<td>17 (.8827)</td>
<td>477,881 (&lt;.0001)</td>
</tr>
<tr>
<td>Year-Post Interaction</td>
<td></td>
<td>-238 (&lt;.0001)</td>
<td></td>
</tr>
<tr>
<td>Model R-square</td>
<td>0.4551</td>
<td>0.4552</td>
<td>0.5817</td>
</tr>
</tbody>
</table>
The univariate model (Model 1) clearly showed that the total number of admissions with medical errors decreased by 106 per year. However, the number of admissions with medication errors did not significantly decrease (p=.8827) for the time period after the HITECH Acts implantation (Model 2). However, Model 3 shows that the number of admissions with medical errors decrease by 238 per year (p value for slope < .0001) for the post HITECH years. Thus the HITECH act was associated with an acceleration of the time trend observed for improvement in the number of admissions with medical errors observed in the NIS data over time.

The weighted NIS data for medication and non-medication errors reflect the error patterns that we would expect to observe for all US hospitals over the years before and after the HITCH Act. The data are shown in Figure 4.
The data from Figure 4 was used to estimate multivariable models reflecting the patterns observed in data. Table 3 below shows the two models (Model 4, 5) for the estimated US numbers of medical errors using the weighted number for admissions with medication errors and admissions with non-medication errors.
Table 3: Multivariable Models Testing Time Trends in Weighted National Estimates of Trends by Type of Medical Error for Years Before and After the HITECH Act

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Medication Errors (p Value) Model 5</th>
<th>Non-medication Errors (p Value) Model 6</th>
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<td>Intercept</td>
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<td>349,855 (.0916)</td>
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<td>49 (.0002)</td>
<td>-162 (.1160)</td>
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<td>Post HITECH</td>
<td>75 (.0922)</td>
<td>933,980 (.0101)</td>
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<tr>
<td>Year-Post Interaction</td>
<td>-37 (.0923)</td>
<td>-465 (.0101)</td>
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<tr>
<td>Model R-square</td>
<td>0.4004</td>
<td>0.4314</td>
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</table>

The results of the multivariable estimate of trends in weighted medication errors over time (Model 5) shows an increase of 49 admissions with medication errors per year, with statistical trends of higher numbers (75 p=.0922) with a slight decrease in rate (-37 p=0.923) after the HITECH Act’s implantation. However, the model estimates reflect the nearly flat data trend observed in Figure 4.

However, the trend for non-medication errors is substantially different. We observed a non-significant decrease over time (-162 p=.1160) with a major, statistically significant change in intercept at the time that the HITECH Act was implemented (Post HITECH=933,980 p=.0101), and a substantial annual decrease of 465 (p=.0101) for slope for the years after the HITECH Act was implemented. The model clearly reflects the trends observed in these data as shown in Figure 4 above, and indicates that a substantial improvement in admissions with non-medication errors was associated with the time of implementation of the HITECH Act.
Discussion of Results

Reviewed literatures indicated that the Electronic Health Records have a potential for generating medical errors (WHO, Wetterneck, Holden, Beasley, Otles, 2016). Evidence by Bowman (2013) also showed that despite numerous clinical benefits, the EHR was associated with several unintended consequences. By comparing the rates of medication errors before and after implementation of the Meaningful Use Act and EHR adoption, the study addresses the extent to which EHRs have impacted rates of medical errors, if at all.

Medical errors have serious negative impacts and are a major stressor for patients, families, and the U.S. healthcare and legal systems. It is imperative to reduce this issue to a manageable level. A most useful step in handling the present issues with medical error will be universal acknowledgment that medical errors do actually occur at alarming rates, and that this issue demands urgent attention.

Organizations that have committed such errors are ethically obligated to be honest about their mistakes, regardless of the consequences – legal, financial, or otherwise. They should own up to their responsibility and focus their energy on how to continuously make improvements and implement effective countermeasures that will address medical errors.
Absence, partial or complete lack of transparency related to medical error reporting is and will be one of the greatest concerns and threat to this and future similar studies relevant to patient safety, unless appropriate measures are taken to guard against such. Organizations must encourage reporting all data that will be useful in reducing the levels of medical errors in the U.S., as well as globally, including the ‘near misses.’ Reason (2016) stressed the importance of having a well-coordinated, transparent reporting culture of all medical errors, including near misses to manage the risks of organizational accidents. Absence or lack of such a culture can undermine efforts to address patient safety issues, nationally and globally, as well as sabotage efforts to implement effective counter measures (Reason, 2000). This lack may also lead to a greater future healthcare catastrophe. In his book: ‘The truth about Chernobyl’ Medvedev (1991), the researcher highlighted that the Chernobyl nuclear disaster was mainly due to the complete absence of clear and transparent reporting culture in the Soviet Union system.

**Study Limitations**

One limitation that may have impacted the research findings is related to human behaviors. In particular, there is a likelihood that leadership may try to suppress potential medical error-related reporting information that may trigger legal actions that could adversely impact shareholders’ earnings or even attract fines and penalties from the government and associated enforcement agencies. These factors are beyond the control of the researcher and are a major limitation for this research.

Another limitation was that there may also be some situations in the study or the literatures reviewed where the use and application of the strict definitions of EHR and
EMR were not adhered to. This results in EHR and EMR being used loosely and interchangeably.

A third limitation relates to time, as the research covered two different periods – Pre- and Post EHR. Some of the reported data and inferences from the earlier period may not represent the current picture of the present system. Later improvements may not have been reflected in some of the older referenced studies. Referenced studies utilized suitable timelines that accommodated the Pre- and Post EHR periods.

**Insights, Viewpoints, and Future Studies**

It is of the opinion of the researcher that the health care industry is designed for individuals and organizations that “truly care” for people. In essence, where is the “care” factor if health service organizations are focused deeply on hiding relevant data that will help address medical errors while millions of patients are dying in large numbers?

Using a systemic approach that includes root cause analysis, problem solving, mandatory governmental audits and verifiable corrective actions will help to reduce all medical errors, especially the medication errors. Such an approach would likely be successful since it ensures to reduce (rather eliminate) the root causes of medical errors, follows corrective measures, and places enormous emphasis on checks and balances to fix patient safety flaws.

Future studies should use the results of this research in designing causal studies that seek a better understanding of why medication errors increased after the implementation of the EHR. Also, future studies should continue to explore whether
widespread implementation of EHRs and other associated factors contributed to the increase in errors. The observed trends and medication error fluctuations should be further explored in future studies since they may reveal relevant information for designing better predictive models that will enhance patient safety in the United States. Also, there is the need to craft future policies and measures in a way that may deter health service organizations from hiding and / or under reporting medical errors as well as the near-misses.

**Seven Recommendations for Addressing Medical / Medication Error Issues in the United States Healthcare System**

First, it is important to note that using technology like the EHR alone cannot completely eliminate medical errors. The elimination of medical errors in the US healthcare system will require broader measures and efforts that go beyond the use of Health Information Technology like the EHR. Such measures may include providing appropriate training for healthcare employees, use of Quality Assurance (QA) and Quality Control (QC) initiatives, developing a systemic approach, implementing appropriate policies, or establishing cross-functional teams, engagement and collaborative efforts of all stakeholders.

The following ideas are recommended for addressing the issue of medication errors in the United States (and may also be beneficial to other types of medical errors as well):

1. Since medical errors are one of the leading causes of death in the United States (CDC, 2017), an effective policy is necessary to further enhance patient safety. Indeed, the present state of medical errors will not enhance patient safety without
envisioning and implementing effective changes. Imposing heavy penalties to organizations that commit medical errors may slightly reduce medical errors, but will not eliminate the problem altogether since the root causes will not be addressed. Penalties will encourage overtreatment or the practice of defensive medicine, which increases the cost of medical care (Manner, 2007).

2. Health Care Organizations should first acknowledge there are medical errors instead of hiding or denying them in order to evade possible punitive measures against their organizations. Acknowledging errors is a crucial step in providing the solution to an issue like these medical errors which has been plaguing the US healthcare industry for more than three decades. Organizations cannot effectively solve any problem unless it is acknowledged as a problem since it is usually the starting point of an effective problem solving model.

3. Extensive training of hospital personnel can help prevent and possibly reduce future, fatal errors, especially medication errors. The US government should provide medical error reduction training program vouchers to hospitals in order to train healthcare professionals and leadership teams in patient safety. Training curricula and seminars should be designed to include Empathy, Emotional Intelligence, and the viewpoint that the healthcare industry is for those that truly “care” for their patients. Knowledge gaps (if any) between the older generation of health care professionals and the newer generations in the areas of IT should be reviewed and balanced appropriately.

4. Medical care providers should become more patient-centered; primary care providers should be encouraged to balance their time between computers and in-
person interactions. Occasional internal and external audits should be conducted which may reveal the need to increase their time spent with their patients.

5. Reduction of medical error requires a broader and more diverse group of health professionals that can help assist with superior patient outcomes. The healthcare industry should hire employees from diverse disciplines, especially the industrial sectors, quality assurance, psychology, manufacturing, and many others in reducing medical errors. Knowledge of quality assurance and quality control principles should be employed in reducing variations.

6. All identified medical errors including near misses must be documented, entered into a database designed for recording the lesson learned, for future referencing, as well as having effective preventive measures in place against further occurrence.

7. Health Care Organizations should be proactive in preventing medical errors and mistakes, versus being reactive. Proactive measures should be implemented to prevent future errors as well as eliminating repeat occurrences of preventable medical errors.

Conclusions

Based on the research findings and literature review, there is a need to reduce medication errors in the United States of America, as well as globally. Empirical studies found that medical error is the third leading cause of death in the United States per Johns Hopkins research (Daniel & Makary, 2016).
A main finding in this study is that the implementation of the HITECH Act / EHR was followed by an increase in medication errors (as a proportion of all other errors) in the United States. In (2007-2010), the average Rxper was 6.78%, while that from the (2011-2014) was 7.98%. This difference represents a 1.2% higher proportion of medication errors in the post-EHR period, due to a decrease in non-medication / other types of medical errors. This increase in medical errors shown may also be as a result of improved reporting or detection from EHR, and not an actual increase in errors. However, this trend was further explored using Multivariable Regression, by reviewing the Rxper of medication error trend increases as a percentage of all errors. It was found to only increase by 6%/year after 2011, with a p-value of (p=0.6397), which is not statistically significant.

The study findings do not support the hypothesis that there was a change in the volume or levels of in-hospital medication errors between the Pre-and Post-Electronic Health Records (EHR) timeframe.
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## Appendices

### Appendix 1: Number of Medication, Non-Medication Errors and Rxper OE

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<th>YEAR</th>
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<th>OAEW</th>
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</table>

MedsW = number of admissions with a medication error (weighted to reflect all US admissions)

OAEW = number of admissions with a non-medication medical error (weighted to reflect all US admissions)

NIS Number = Month = actual count in the data set (unweighted)

Rxper OE = percent that Medication errors as a % of the non-medication medical errors for the month

<table>
<thead>
<tr>
<th>EHR System Factors: Technology, Design, and Security Issues</th>
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<tbody>
<tr>
<td>10% Failure of system design.</td>
</tr>
<tr>
<td>9% Electronic systems/technology failure.</td>
</tr>
<tr>
<td>7% Lack of EHR alert/alarm/decision support.</td>
</tr>
<tr>
<td>6% System failure—electronic data routing.</td>
</tr>
<tr>
<td>4% Insufficient scope/area for documentation.</td>
</tr>
<tr>
<td>3% Fragmented EHR.</td>
</tr>
<tr>
<td>0% Lack of integration/incompatible systems.</td>
</tr>
<tr>
<td>0% Failure to ensure EHR security.</td>
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</table>

Source: TheDoctors.Com
http://www.thedoctors.com/KnowledgeCenter/Publications/TheDoctorsAdvocate/CON_ID_006908

Appendix 3: EHR User Factors: EHR-Related Issues Attributable To Users

<table>
<thead>
<tr>
<th>EHR User Factors: EHR-Related Issues Attributable to Users</th>
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<tbody>
<tr>
<td>16% Incorrect information in the EHR.</td>
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<tr>
<td>15% Hybrid health records/EHR conversion.</td>
</tr>
<tr>
<td>13% Prepopulating/copy and paste.</td>
</tr>
<tr>
<td>7% EHR training/education.</td>
</tr>
<tr>
<td>7% EHR user error (other than data entry).</td>
</tr>
<tr>
<td>3% EHR alert issues/fatigue.</td>
</tr>
<tr>
<td>1% EHR/CPOE workarounds.</td>
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Source: TheDoctors.Com
http://www.thedoctors.com/KnowledgeCenter/Publications/TheDoctorsAdvocate/CON_ID_006908

Appendix 4: Locations Where EHR Claim Events Occurred
Locations Where EHR Claim Events Occurred

<table>
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<tr>
<th>Location</th>
<th>Percentage</th>
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<tbody>
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<td>Hospital Clinic/Doctor’s Office</td>
<td>43%</td>
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<tr>
<td>Ambulatory/Day Surgery</td>
<td>12%</td>
</tr>
<tr>
<td>Patient’s Room</td>
<td>10%</td>
</tr>
<tr>
<td>Operating Room</td>
<td>9%</td>
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<tr>
<td>Emergency Room</td>
<td>7%</td>
</tr>
<tr>
<td>Labor and Delivery</td>
<td>5%</td>
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<tr>
<td>Radiology/Imaging</td>
<td>4%</td>
</tr>
<tr>
<td>Dentistry/Oral Surgery</td>
<td>2%</td>
</tr>
<tr>
<td>Pathology, ICU, Neonatal ICU, Radiation Therapy, and Special Procedures</td>
<td>1% each</td>
</tr>
</tbody>
</table>

Source: TheDoctors.Com
http://www.thedoctors.com/KnowledgeCenter/Publications/TheDoctorsAdvocate/CON_ID_006908

Appendix 5: EHR Claim Events by Specialty

EHR Claim Events by Specialty

<table>
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<th>Specialty</th>
<th>Percentage</th>
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<tr>
<td>Primary Care—Family/Internal Medicine</td>
<td>16%</td>
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<tr>
<td>Obstetrics/Gynecology</td>
<td>15%</td>
</tr>
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<td>Surgical Specialties (other than cardiac surgery)</td>
<td>14%</td>
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<td>Nursing</td>
<td>7%</td>
</tr>
<tr>
<td>Radiology</td>
<td>5%</td>
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<tr>
<td>Anesthesiology and General Surgery</td>
<td>4% each</td>
</tr>
<tr>
<td>Pediatrics, Emergency Medicine, Psychiatry, and Orthopedics</td>
<td>2% each</td>
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<tr>
<td>Pathology</td>
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</table>

Source: TheDoctors.Com
http://www.thedoctors.com/KnowledgeCenter/Publications/TheDoctorsAdvocate/CON_ID_006908

Appendix 6: Top Allegations in EHR Claims

Top Allegations in EHR Claims

<table>
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<tr>
<th>Allegation</th>
<th>Percentage</th>
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<tr>
<td>Medication-Related:</td>
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<tr>
<td>Ordering wrong medication</td>
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</tr>
<tr>
<td>Ordering wrong dose</td>
<td>5%</td>
</tr>
<tr>
<td>Improper medication management</td>
<td>7%</td>
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