The Response of the U.S. Health Care System to the Institute of Medicine's Report on Medical Errors

By

Rajkamal Gill

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This thesis has been accepted on behalf of the Department of Public Policy and Administration by their supervisory committee:

BJ Moore, Ph.D. — Date: 5/8/2019

Tony Pallitto, MSA-HCM — Date: 5/7/19

Brandie Vigil, MS-HCA — Date: 05/06/19

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Abstract

The emphasis on improvement of the quality of health care in the United States has been ongoing for decades. With the publication of the Institute of Medicine's report in 1999 on the high occurrence of medical errors, health care organizations realized the depth of the issue. The goal of this study was to analyze the overall response of the U.S. health care system to the report on medical errors and assess whether improvements in patient safety have been initiated. To achieve the goal, the researcher conducted a content analysis of textual materials. The paper introduces the Systems Theory and a quality improvement framework, FOCUS PDCA, and the findings are evaluated on how they relate to the theory and continuous quality improvement method. The textual materials concluded that improvements have been attempted throughout the country to help reduce the number of preventable deaths due to medical errors. The content analysis indicates gaps in how the issue is currently being handled and the necessity for efforts to continue to help resolve medical errors. Recommendations including standardization, quality analysis, and a mandatory reporting system to help decrease the prevalence of errors that impact many Americans.

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Chapter 1: Introduction

The Institute of Medicine (IOM) is a nonprofit organization intended to be a source for accessibility to ongoing research and other publications in health care, for medical organizations, doctors, leaders and managers (Institute for Healthcare, 2018). Utilizing previous studies, the IOM established a basis to report the excessive number of patient deaths occurring due to medical errors. One study used was the Harvard Medical Practice Study which provided the initial estimate of 3.7% of hospitalizations having adverse events (James, 2013). Of the estimate, 58% were preventable incidences occurring due to preventable medical errors (James, 2013). In addition, the Utah Colorado Study was analyzed by the IOM which found the rates of adverse events were lower (James, 2013). The IOM extrapolated the data from the two studies to determine the estimation of deaths from medical errors per year and the publication of the report was the first time the issue of "patient safety became a focal point for reform" (Baker, 2004, p.151). The report demonstrated the need for improvement in patient safety, and the necessity for a health care system focused on improving medical errors.

As defined by the IOM, medical errors are "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim" (Institute of Medicine, 1999, p.1). These mistakes are often preventable; however, specific steps must be taken by the health care system in order to improve and sustain an environment which ensures patient safety. There are different types of errors which lead to adverse events taking place. The IOM categorizes these errors into diagnostic, treatment, preventive, and other (Appendix A). Some examples of common problems include wrong-site surgery, improper transfusions, falls, burns, and incorrect patient identification (Institute of Medicine, 1999). The reporting of these errors is still not a common practice; therefore, the analysis of the causes of the problem continues to be

difficult, which further leads to undesirable outcomes, including preventable patient deaths.

According to the IOM report, *To Err is Human,* published in November 1999, between 44,000 to 98,000 individuals were dying in hospitals due to errors which were preventable (Institute of Medicine, 1999). The number has since increased and the current estimate of deaths due to medical errors is approximately 250,000 deaths a year, making medical errors the third leading cause of death in the United States (Johns Hopkins, 2016). The latest John's Hopkins study states that errors continue to be representative of "systemic problems, including poorly coordinated care, fragmented insurance networks, the absence or underuse of safety nets, and other protocols, in addition to unwarranted variation in physician practice patterns that lack accountability" (Johns Hopkins, 2016, para. 10).

These results have not varied much from the IOM report in 1999 which stated that medical errors "are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them" (Institute of Medicine, 1999, p.2). In a 2017 survey conducted by NORC at the University of Chicago, the researchers determined the number of individuals who had a personal experience with a medical error as 21%, and 31% of individuals were involved in caring for another individual who experienced medical error (Institute for Healthcare, 2017). It can be concluded from the statistics and similarities in causes that not much has changed since the original report outlined the flaws in health care. Improving patient safety continues to be a challenge for the health care system; therefore, the quality of health care must be improved to the level where patient safety is of the utmost concern.

Quality improvement is a necessity in health care and a specific goal of quality improvement is patient safety. "The compelling need to improve patient safety has placed increasing emphasis on quality improvement" (Lighter, 2013, p.13). In the IOM's report,

Crossing the Quality Chasm: A New Health System for the 21st Century, the need for health care quality to improve is illustrated. The institute "concluded that it is not acceptable for patients to be harmed by the health care system that is supposed to offer healing and comfort" (Institute of Medicine, 1999, p.2). In addition, the report claimed that the collaboration of multiple constituencies has to take place in order to advance the health care system and work towards improving patient safety (Institute of Medicine, 2001). To transform the system and improve the quality of care, six aims were outlined by the IOM that require health care to be safe, effective, patient-centered, timely, efficient, and equitable (Institute of Medicine, 2001). However, the recent study indicating the increase in preventable deaths suggests the health care system has not been transformed as anticipated.

Errors in health care are not uncommon; however, the high prevalence of mistakes that lead to the loss of life is suggestive of the inabilities of the health care system to transform towards a safer environment. As a recipient of health care, an individual has expectations to be provided with the best possible care but such errors may lead to the loss of trust in the system. Although the IOM has recommended ways for the health care system to improve, how hospitals have responded to these recommendations is still in question, especially in specific communities.

Problematic Issue

The IOM report has outlined numerous aims to allow health care organizations to work towards achieving goals of patient safety; however, the number of patient deaths due to medical errors is on the rise. Therefore, whether or not hospitals are in actuality working towards improving standards of patient safety is unclear.

Problem Statement

The problem being addressed in this study is the high prevalence of medical errors in the U.S. health care system.

Purpose of the Study

The purpose of the study is to analyze how the health care system of the United States has transformed to provide a safer environment for patients in regard to improving medical errors.

Usefulness of the Study

The study may allow the impact of the IOM's report to be analyzed. In addition, cases from which certain improvements have emerged in health care will also be analyzed. The analysis may provide an overview of the reactions of the health care system to adverse events involving patient safety, and may restore trust and refocus efforts of health care organizations to create a safer patient care system.

Chapter 2: Literature Review

The literature review will analyze how the health care system of the United States has responded to the high number of preventable deaths. The increase in the number of deaths due to medical errors is a continuing issue for health care organizations. Cases where preventable deaths have led to safety programs being implemented and the distinctive approaches taken by different agencies will be discussed. The status of medical errors in other countries will be examined for comparison to the United States. The Systems Theory and Motivation Theory will be introduced and explained and the relevance of each theory to patient safety will be discussed.

Patient Safety

In order to determine whether the necessary steps have been taken to improve the safety of patients, the definition of the term is of importance. Patient safety is defined by the National Quality Forum (NQF) as "the prevention and mitigation of harm caused by errors of omission or commission that are associated with healthcare, and involving the establishment of operational systems and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur" (National Quality Forum, 2009). However, there are various other definitions of the term; therefore, the categorization of an event which may fall under a patient safety indicator is challenging. For instance, patient safety is defined by the Institute of Medicine as 'freedom from accidental injury;' however, disagreements have hindered the complete definition of the term (Emanuel et al., 2008). As the Agency for Healthcare and Research Quality (AHRQ) states, the differences are what lead to the discrepancy in estimating the number of patients who undergo a preventable harmful event, "which ranges from about 12% among Medicare patients in the 2010 Office of the Inspector General study to nearly 33% in a 2011 study" (Agency for Healthcare, 2018, para.9). Not only is the definition of patient safety

important, but rather how different techniques are used to measure patient safety is of importance as well.

According to the AHRQ, there are numerous techniques which can possibly be utilized and the differences in the methods increase complexity in measuring patient safety (Agency for Healthcare, 2018). “There is no single validated method for measuring the overall safety of care provided in a given health care setting” (Agency for Healthcare, 2018, para.2). The differences were also prevalent when clinicians who were working on the studies used to formulate “*To Err is Human*” had disagreements over which error should be categorized as preventable and which should not (Agency for Healthcare, 2018). The AHRQ states that there are different purposes for measurement which includes: “to evaluate the effectiveness of safety interventions, identify new or emerging safety threats, compare safety across hospitals and clinics, or to determine whether patient safety is improving over time” and depending on the reasoning behind the measurement, the correct method should be utilized (Agency for Healthcare, 2018, para.5). The AHRQ has identified four different methods (Appendix B) which can be used to measure patient safety, including retrospective chart review, incident reporting systems, automated surveillance, and administrative/claims data (Agency for Healthcare, 2018).

The categorization of an adverse event also requires definition. An adverse event is “an event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patients” (National Quality Forum, 2009, p.2). The World Health Organization (WHO) has also described harm and the different levels of severity. The WHO has a classification system in which harm is based on the severity of the event (Cooper et al., 2018). The descriptions range from harm severity being *none* to *death.* In the *none* category, the detection of symptoms was not present and therefore treatment was not

required (Cooper et al., 2018). The next category is *mild,* which describes that the severity of the symptoms was mild and either there was no treatment or only the minimal amount of intervention necessary (Cooper et al., 2018). If the situation required more than minimal intervention and lead to a longer length of stay and/or there was the loss of function either long term or permanently, the event falls under *moderate* category (Cooper et al., 2018). If the severity is significantly high and leads to the necessity for an intervention required to save the life of the patient, and the life expectancy of the patient has decreased due to the event, the harm would be classified as *severe* (Cooper et al., 2018). The last classification in the system is when a patient's life is lost due to the incident and this is labeled as *death* (Cooper et al., 2018). The classification system allows for a universal definition of the severity of harm; however, the improvement of patient safety is necessary in order to avoid harm events.

There are 27 identified events which lead to a comprise in patient safety and these are considered to be adverse events (Appendix C). The identification of adverse events was established in 2002 by NQF, when the "federal government's Quality Interagency Coordination Committee concurred with the IOM's recommendation for greater health care error and adverse event reporting" (Kizer & Stegun, 2005, p.340). The NQF was created in 1999 when it was established by the Advisory Commission of the President that there was a need for an organization "to promote and ensure patient protections and healthcare quality through measurement and public reporting" (National Quality Forum, 2018, para.1). Organizations utilize approaches outlined by the NQF as they are based on evidence and performance measures endorsed by the NQF meet "rigorous criteria" (National Quality Forum, 2018, para.2). The NQF did not identify all possible events but rather there was the establishment of requirements to be on the list of *serious reportable events* (Kizer & Stegun, 2005). The only events that are listed by

the NQF are events that are “(1) clearly identifiable and measurable, and therefore feasible to include in a reporting system; (2) of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the health care facility; and (3) of concern to both health care providers and the public” (Kizer & Stegun, 2005, p.342).

In addition, there are requirements which have to be met for an event to qualify to be placed on the list. The event must be unambiguous, serious, usually preventable, serious, and one or more of the following: adverse, an event which indicates that there is a problem in the safety system of the facility, and/or that the event is essential for public credibility (Kizer & Stegun, 2005). Although the NQF has established a list of 27 adverse events, the events are first categorized into either surgical events, product or device events, patient protection events, care management events, environmental events, or criminal events (Kizer & Stegun, 2005). The establishment of the classification system attempts to move the nation one step closer to a safer patient care environment.

In order to contain adverse events from occurring as frequently, highly rated safety practices have been established for health care organizations to adopt for the improvement of patient safety. The NQF was also asked to take on the task of formulating the safety practices which can be applied universally in “applicable clinical care settings to reduce the risk of errors and harm to patients;” as a result, there were 30 evidence-based practices (Appendix D) which were established in 2003 (Kizer & Blum, 2005, p.23). The safe practices are divided into five categories which are: “(1) creates a culture of safety, (2) matches health care needs with service-delivery capabilities, (3) facilitates information transfer and clear communication, (4) adopts safe practices in specific clinical settings or for specific processes of care, and (5) increases safe medication use” (Kizer & Blum, 2005, p.27). The identification of the safe practices allows for a

universal system which health care facilities can adopt to ensure the improvement in patient safety, as adverse events in health care have unfavorable consequences.

Medical errors

Medical errors occur due to several different incidences that take place in the care of a patient. The incidences can be divided into either diagnosis or treatment errors (Cakmak, Demir, & Kidak, 2017). Misdiagnosis is an issue which arises when a physician is incapable of correctly diagnosing a disease or misinterprets a disease (Cakmak, Demir, & Kidak, 2017). A treatment error is when the necessary medical intervention is delayed and results in serious or fatal consequences (Cakmak, Demir, & Kidak, 2017). In addition, performing an intervention without the necessity is also a treatment error, along with instances of "forgetting foreign substances in the patient's body, choosing the wrong treatment method, not performing the necessary tests, wrong drug application, patient mixing, wrong side surgery and failure to comply with infection and hygiene rules" (Cakmak, Demir, & Kidak, 2017, p.443).

Adverse events can be quantified into five common categories of medical errors: "errors of commission, errors of omission, errors of communication, errors of context and diagnostic errors" (Boerner, 2016, p.30). The common medical errors have led to medical errors being the third leading cause of death in the United States (Cha, 2016). In addition, when a medical error takes place, there is an associated financial cost and the overall cost of medical errors in the United States is an estimated $19.5 billion (Allen, 2011). However, Mello and others argue that because there is a shift of the costs from the hospital to outside parties, including Medicare, the leaders of a hospital often do not have the financial incentive of working towards improving patient safety (Mello et al., 2007).

IOM recommendations

In order to address issues surrounding patient safety, in the report *To Err is Human*, the Institute of Medicine made several recommendations. The IOM report outlines a four-tiered approach which can be used to increase patient safety. The approach recommends the establishment of a single agency to ensure patient safety standards are set and achieved and that research, tools, and protocols are put in place to ensure that knowledge about safety is enhanced (Institute of Medicine, 1999).

Table 1

Four-tiered approach to a safer health care system

	Approach
a.	"Establishing a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety."
b.	"Identifying and learning from errors by developing a nationwide public mandatory reporting system and by encouraging health care organizations and practitioners to develop and participate in voluntary reporting systems."
c.	"Raising performance standards and expectations for improvements in safety through the actions of oversight organizations, professional groups, and group purchasers of health care."
d.	"Implementing safety systems in health care organizations to ensure safe practices at the delivery level."

Note. Adapted from Institute of Medicine. (1999). To err is human: Building a safer health system. Retrieved from http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf

In addition, the report recommends the development of a reporting system which should be mandatory, nationwide, and available to the public (Institute of Medicine, 1999). In this system, information pertaining to a patient death resulting from a serious medical event would be reported by every hospital in order to assign accountability to the organization (Institute of Medicine, 1999). Apart from the mandatory reporting, the IOM also recommends a voluntary reporting system (Institute of Medicine, 1999).

The development of performance standards is an additional recommendation in the report. The expectations for patient safety are formed through the standards, and the report mentions the necessity of healthcare leaders to incorporate training on patient safety (Institute of Medicine, 1999). The fourth recommendation made by the IOM is the development and integration of safety systems. Again, the report outlines how leadership should be involved in ensuring safety practices are ongoing throughout the organization (Institute of Medicine, 1999).

The report also mentions how medical errors can be prevented by improving processes in hospitals. For instance, drugs which are of full-strength are stocked in hospitals and the drugs have to be diluted in order to diminish the toxicity (Institute of Medicine, 1999). However, if an individual is unaware of the need to dilute the drug, a medical error occurs which results in unfavorable consequences (Institute of Medicine, 1999). Therefore, if safety measures were put in place, similar mistakes might be easily avoided.

Underreporting

The literature suggests that although the IOM recommended the establishment of a system of reporting medical errors, not every adverse event is recorded. Various reasons can lead to the underreporting of medical errors. For instance, the perception “that an error does not need to be reported if it does not seem to cause harm” is prevalent (Scott & Henneman, 2017, p.211).

In addition, the lack of a reporting system or the familiarity of staff with the existence of a reporting system can also lead to the discrepancy in the data (Scott & Henneman, 2017). There is also the fear of adverse consequences, including negative feedback from others in the organization, which contributes to the underreporting (Scott & Henneman, 2017). Although the IOM suggested "the concept of a culture of safety to encourage error reporting without fear of repercussion or blame," the issue of health care providers not reporting events that could harm patients, continues to exist (Scott & Henneman, 2017, p.211). "These concerns suggest use of an anonymous reporting system may increase the number of reported errors" (Scott & Henneman, 2017, p.211).

The reporting system is voluntary and has not been adopted by every state; therefore, the improvements in patient safety are steady. "Despite the existence of multiple avenues for reporting, underreporting of adverse events and medical errors is widely recognized. In essence, providers in the healthcare industry are less likely to voluntarily report adverse events due to the normalization of deviance from standards, fear of malpractice liability, and fear of injury to their professional reputations" (Forrest, 2016, p.481). The fear of blame should be eliminated in order for the health care system to work towards improving the safety of patients. Laws have been constructed since the IOM's report on medical errors, to improve reporting issues; however, the laws have not necessarily proven to significantly improve the situation.

Government Regulations

In response to the IOM's recommendations, Congress worked towards alleviating the notion and fear of blame by amending Title IX of the Public Health Service Act (Vemula, Assaf, & Al-Assaf, 2007). In 2005, Congress passed the Patient Safety and Quality Improvement Act of 2005 (PSQIA), in response to the IOM report and to increase patient safety. The act has multiple

objectives which are: “(1) to encourage a culture of safety and quality in the U.S. healthcare system by providing for a healthcare error reporting system that protects information and improves patient safety and quality of healthcare and (2) to ensure accountability by raising standards and expectations for continuous quality improvements in patient safety through the actions of the Secretary of Health and Human Services” (Vemula, Assaf, & Al-Assaf, 2007, p.6). Through the act, legal protection is provided to healthcare providers in order to create a safety culture by participating in a voluntary reporting system (Vemula, Assaf, & Al-Assaf, 2007).

PSQIA’s purpose is to create patient safety organizations, create patient safety databases and legal protection for reporting of adverse events which is to include protection for whistleblowers (Vemula, Assaf, & Al-Assaf, 2007). The Department of Defense also partakes in the reporting system by making it mandatory for health plans that fall under the TRICARE program to report an adverse event that takes place (Vemula, Assaf, & Al-Assaf, 2007). The act is the first time that the federal legislature has attempted to tackle the issue of patient safety and leads towards the development of a reporting system nationwide while allowing the opportunity to collect data (Motto, 2016). The aim of the act is to encourage reporting which can also help improve patient safety by allowing hospitals and other health care facilities to learn from adverse events.

In order to report an event under the act, an organization has to have membership in Patient Safety Organizations (PSO) which allows for protection of providers (Motto, 2016). PSOs are managed by the secretary of Health and Human Services (HHS), which certifies that an organization is compliant with § 924(d) of the PSQIA and each organization must also submit what the policies and procedures are so that the secretary is able to approve the policies (Motto, 2016). In addition, PSQIA is expected to conduct certain activities under the act which includes:

> Efforts to improve patient safety and the quality of health care delivery; the collection and analysis of patient safety work product; the development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices; the utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk; the maintenance of procedures to preserve confidentiality with respect to patient safety work product; the provision of appropriate security measures with respect to patient safety work product; the utilization of qualified staff; activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system (Agency for Healthcare, n.d.).

The PSQIA has allowed for the protection of providers during the disclosure of medical errors. Information that is disclosed is to remain confidential and cannot be shared with a third party (Motto, 2016). The protection is to allow for increased reporting of incidences while mitigating the fear of providers (Motto, 2016). However, due to the system being voluntary, there is no consistency in reporting adverse events (Motto, 2016). On the other hand, there are regulations in place for the reporting of an adverse event which occurs due to a device malfunction (Motto, 2016). The regulations are enforced by the Food and Drug Act (FDA) and organizations including hospitals, nursing homes, and surgery centers are required to report to the FDA and manufacturer, any type of death or severe injury that was caused by a device within ten business days (Motto, 2016).

Initiatives Emerging from Patient Stories

Laws have emerged from patient incidences which resulted in the loss of life. For instance, Niles Moss passed away in 2006 in a hospital in Orange County, California, due to a hospital acquired infection known as Methicillin-resistant Staphylococcus Aureus (MRSA), and in response, his mother launched a campaign to force hospitals to publish data on the percentage of patients who acquire hospital infections (Schoch, 2010). Nile's law was passed by the state in 2008 leading to increased publication of the data. In addition, hospitals in California have collaborated to work towards reducing infection rates. The partnership of the hospitals is known as the Hospital Quality Institute (HQI), and their objective is to provide coordination, support improvement, and harmonize measures for patient safety and quality improvement activities (Hospital Quality Institute, n.d.). The Institute has established programs and other tools and resources for organizations to work towards promoting a culture of patient safety.

A similar incidence has led to the possible adoption of a law which would eliminate unnecessary medical errors. In 2002, Leah Coufal was admitted to Cedars-Sinai Medical Center in California for a surgical procedure (Szczerba, 2013). After the procedure, Coufal was given pain medication without being on a monitor, and the medication ultimately lead to respiratory arrest (Szczerba, 2013). The incidence provoked the patient's mother to fight against preventable medical errors and push for the state to adopt Leah's Law. "The bill would mandate that all hospitals electronically monitor patients' breathing after surgery, especially when the patient has been given powerful painkillers known as opioids" (Szczerba, 2013, para.7).

Similarly, in 2000, at the Medical University of South Carolina, Lewis Blackman underwent elective surgery but died shortly afterwards due to a medical error (Patient Safety Movement, 2018a**).** Blackman was prescribed the adult course of the painkiller Toradol, which

was injected every six hours to help with his uncontrolled pain (Patient Safety Movement, 2018a**).** The high dosage of the painkiller affected the patient's breathing and although Blackman was facing difficulty, the hospital and resident providers did not seem to be concerned with the additional symptoms that were also arising (Patient Safety Movement, 2018a). Due to the symptoms going unnoticed, the patient passed away and the autopsy indicated the patient had passed from a perforated duodenal ulcer, which is a risk of the medication Toradol (Patient Safety Movement, 2018a**).** The hospital later responded to the incidence by ensuring safety protocols were in place for the future. The hospital's strategic plan now includes the creation of a safety culture (DerGurahian, 2009). In addition, a patient-safety law emerged from the case and the hospital now requires identification badges which allow for clear differentiation between the different providers (DerGurahian, 2009).

The Michael Skolnik Medical Transparency Act that was passed in Colorado also resulted from a patient incidence in which misdiagnosis by a neurosurgeon led to a preventable death. Michael Skolnik was admitted to a hospital due to a seizure which possibly resulted as a side effect of a medication the patient was taking (Patient Safety Movement, 2018b). During the hospitalization, a CT scan was conducted which showed a dot in the patient's brain and the neurosurgeon concluded the need for surgery as it seemed to be a cyst (Patient Safety Movement, 2018b). The patient was taken for surgery; however, the cyst was not removed or seen but rather the procedure led to consequences including deep vein thrombosis, DIC, sepsis, systemic infections, and pulmonary embolism. (Patient Safety Movement, 2018b). The complications eventually led to Skolnik's death. The family believed that not having information on who the neurosurgeon was what lead to an adverse event and, therefore, pushed for an act for transparency (State of Colorado, 2018). The act was passed in 2007 and has since expanded with

new state requirements for physicians, who fall under one of the 54 license types, to complete questionnaires in order to provide patients with resources to make the correct decision (State of Colorado, 2018).

To work towards amending processes which lead to adverse events, hospitals are working towards investing funds to improve medical errors. Recently, Rhode Island Hospital was involved in incidents that occurred due to lack in patient and procedure identification (Rhode Island Medical Journal, 2018). The incidents include patients undergoing exams intended for a different patient and patients having surgery on the wrong site (Rhode Island Medical Journal, 2018). The hospital and the Rhode Island Department of Health (RIDOH), have outlined the necessary steps to combat the issues in a consent agreement and the hospital agreed to invest $1 million in improvement efforts (Rhode Island Medical Journal, 2018).

Additionally, the RIDOH has contracted with Kent Hospital in an agreement which involves the hospital committing $1.7 million to improve adverse events (Rhode Island Medical Journal, 2018). Kent Hospital had issues similar to Rhode Island Hospital in which patients underwent wrong site surgical procedures but also catheters which were used for certain procedures were never removed (Rhode Island Medical Journal, 2018). The Joint Commission has established a protocol to address the issues of wrong sites with three required steps before a procedure begins, including identification verification, operating site marking, and a *time-out* before the procedure begins (Lighter, 2013).

A medical error at Johns Hopkins Hospital initiated the involvement of the family to establish a program to help improve patient safety. In 2001, a toddler who had first and second-degree burns was seen and treated at the facility but a few days later, a preventable death took place due to dehydration (Kalb, 2006). Based on the stability of the vital signs of the patient, the

providers did not see an issue when the parents of Josie King vocalized their concerns (Kalb, 2006). However, the concerns were valid and the hospital did conclude that severe dehydration had led to the death (Kalb, 2006). To ensure that other parents do not have to undergo similar situations, the family worked with the hospital to establish the Josie King Patient Safety Program and the organization is now stringent on communication (Kalb, 2006).

Lawsuits

When medical errors occur, some patients and their families opt to utilize the court system, resulting in medical malpractice lawsuits. However, courts do not recognize all cases as being entitled to compensation; therefore, the number of paid malpractice claims has reduced over the years. Because the majority of the cases are determined to have no reason to be initially filed, over 60% of medical malpractice cases are dismissed (Sohn, 2013).

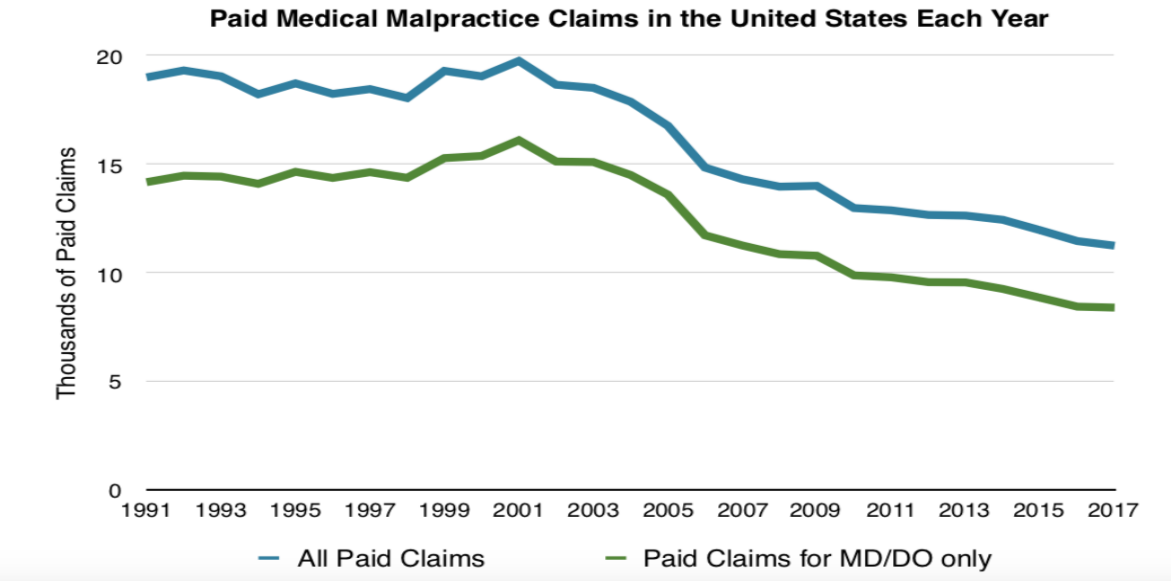

Figure 1. Number of paid claims (in thousands) by year, from 1991-2017. Adapted from http://truecostofhealthcare.org/wp-content/uploads/2018/08/United-States-Malpractice-1.pdf

The cost of medical malpractice claims leads to millions of dollars being paid. The decrease in the number of claims being paid indicates that the health care system may be moving

towards improvements in patient safety. However, the numbers continue to be significantly high, indicating that there is still room for improvement.

Country Comparison

In comparison to other countries, the U.S. has the highest rate of medical errors. According to 2016 data, 19% of patients reported experiencing medical, medication, or lab errors in the past two years (Sawyer & McDermott, 2019). Countries such as the France and Germany have the lowest rates of medical errors with 8% and 7%, respectively, of patients undergoing adverse events, respectively (Sawyer & McDermott, 2019). However, the data is indicative of other countries such as Canada (15%), Sweden, and Netherlands also having higher incidences of patient safety events (Sawyer & McDermott, 2019). The data illustrates that medical errors are a global issue; therefore, patient safety improvement must be initiated to work towards a safer health care environment.

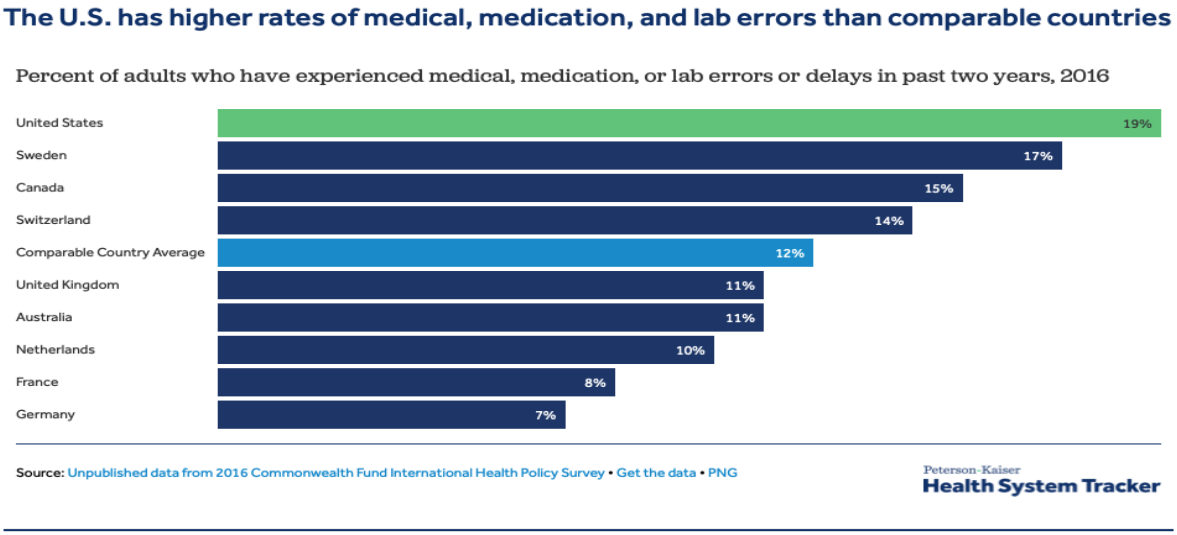

Figure 2. Comparison of countries on the rates of medical errors. Adapted from https://www.healthsystemtracker.org/chart-collection/quality-u-s-healthcare-system-compare-countries/#item-30-day-mortality-heart-attacks-ischemic-stroke-lower-u-s-comparable-countries

Improvement Programs

Affiliations of large organizations with quality improvement programs have emerged to work on the establishment of a patient safety culture. LifePoint Health (LP), collaborated with Duke University Health System to establish DLP Healthcare which works with community hospitals nationwide to improve patient safety (Frush et al., 2018). DLP has established methods to help towards enabling community hospitals to "continuously work to improve patient care, patient safety, and patient satisfaction-as reflected in the Institute of Medicine's six aims of quality" (Frush et al., 2018, p.389). Over 70 community hospitals are owned and operated by LP (Frush et al., 2018). The collaboration has demonstrated a decrease in harms and in 2014 there was over a 40% reduction in harms which was the standard goal of the Centers for Medicare & Medicaid Services (CMS), in addition to readmission rates being reduced by 12% (Frush et al., 2018).

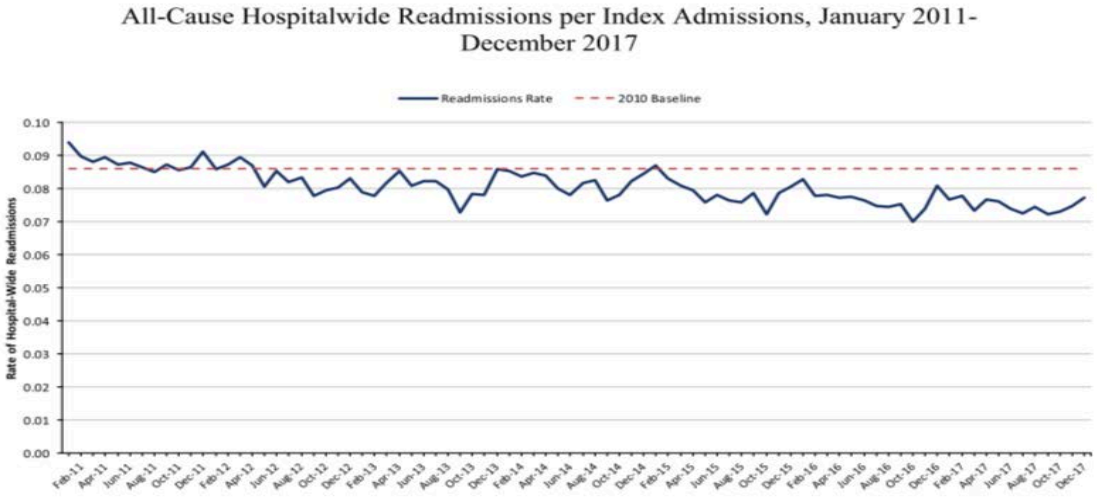

Figure 3. The reduction in readmission rates January 2011-December 2017. Adapted from https://www.jointcommissionjournal.com/article/S1553-7250(18)30216-2/pdf

The Office of the Inspector General (OIG) published a study in November 2010 to obtain the number of Medicare beneficiaries who faced adverse events, and concluded that

approximately 13.5% of adults with Medicare underwent an adverse event (Levinson, 2010). Of the estimated proportion, 1.5% experienced an adverse event which led to the patient's death, which translates to 15,000 patients per month (Levinson, 2010). To help combat the issue and make hospitals safer, an initiative begun which is known as Partnership for Patients. The program has over 8,000 partners which includes hospitals and other health care facilities (Centers for Medicare, n.d.). In addition, federal agencies have also joined the initiative (Centers for Medicare, n.d.).

The program has two goals which are: (1) making care safer, and (2) improving care transitions (Centers for Medicare, n.d.). There are 11 key areas the initiative focuses on including: adverse drug events, central line-associated blood stream infections, catheter-associated urinary tract infections, *Clostridium difficile* bacterial infections, pressure ulcers, injuries that result from patient falls, sepsis, surgical site infections, venous thromboembolism, ventilator-associated events, and readmissions (Centers for Medicare, n.d.). The initiative is joined by large hospitals around the nation including Dignity Health, Minnesota Hospital Association and others (McKinney, 2014). The program has impacted national rates of harm which is demonstrated with the improvement in readmissions and reduction of other inpatient harm rates (Fornango et al., 2015). The results reported from 2011 to 2013 demonstrate the reduction rates with "over 5,000 fewer venous thromboembolism (VTE) events, over 50,000 fewer falls, over 118,000 fewer OB-EEDs, and 45,000 fewer surgical site infections" (Fornango et al., 2015, p.6). To help eliminate medical errors, CMS also initiated programs which would reserve payment for hospital acquired conditions (Boerner, 2016). The Hospital Readmissions Reduction Program fines hospitals for patient readmission due to conditions which are common, including hospital-acquired infections and medical errors (Boerner, 2016). In 2008, CMS

announced what would be done to help reduce *never events,* and improve the quality of patient care (Centers for Medicare, 2008). The laws established are requirements for CMS to withhold payment to a hospital which does not report quality measures, as the reporting of quality data was expanded in 2008 (Centers for Medicare, 2008). The expansion of data allows the public to compare hospitals on quality measures and determine where an individual would like to seek care (Centers for Medicare, 2008). Overall, the initiative works towards increasing transparency in the data and improving quality of care.

Similar to the CMS' initiative, a national nonprofit organization, The Leapfrog Group, was founded in 2000 to address the necessity for transparency in the data. In addition, the group works towards the improvement in quality and patient safety (The Leapfrog, n.d.c). Hospital performance is collected through the Leapfrog Hospital Survey and data is reported to the public for assistance in decision making (The Leapfrog, n.d.c). In addition, Leapfrog "assigns letter grades to hospitals based on their record of patient safety," further allowing patients to make decisions based on the hospitals data on errors, injuries, and infections (The Leapfrog, n.d.c, para.1). The group currently has affiliations with approximately 2,000 hospitals around the nation in 36 states (The Leapfrog, n.d.c).

One of the major movements of the Leapfrog Group is to reduce the number of early elective deliveries. The group reported the "rates of early elective deliveries by hospital" in 2010 for the first time and it was determined that the average rate, nationally, was 17% (The Leapfrog, n.d.a). With continuous reporting through Leapfrog, in six years, the national rate decreased to 1.9%, indicating the progress of the program (The Leapfrog, n.d.a). In addition, the group has influenced hospitals to develop their own programs to help reduce the number of early elective

deliveries and one hospital is the Midwest Business Group on Health in Illinois, where the organization's rate decreased by 20% in a period of five years (The Leapfrog, n.d.a).

Another initiative has emerged, inspired by patient stories, known as the Patient Safety Movement. The founder, Joe Kiani, utilized the IOM's report on the high number of preventable deaths, and questioned what possibilities were present to address the issue at hand (Patient Safety Movement, 2018c). Throughout the years, the problem of preventable deaths was not eradicated and with the publication of a report by the Office of Inspector General in 2010 which stated that a high number of Medicare beneficiaries were facing adverse events, Kiani become intrigued to find a solution. In order to help move the nation towards a health care system where no patient passed away due to a medical error, Kiani formed the Patient Safety Movement Foundation (Patient Safety Movement, 2018c).

The Patient Safety Movement foundation has saved over 81,533 lives as of February 2018, through partnership with hospitals across 44 countries, which illustrates the successful efforts of the movement (Patient Safety Movement, 2018c). The Patient Safety Movement works in conjunction with the Masimo Foundation. The foundation established the necessity to address medical errors and preventable deaths and together the two organizations work towards reducing the rate of preventable deaths to the point of zero deaths from medical errors by 2020 (The Clinton Foundation, n.d.).

High Reliability Organizations

As a step towards improving patient safety, the concept of high reliability organizations (HROs) has emerged in health care. The idea of HROs is relatively new in health care but not in other industries including aircraft carriers and other industries (Christianson, Sutcliffe, Miller, & Iwashyna, 2011). An organization which is considered a HRO establishes the highest level of

commitment to safety (Christianson, Sutcliffe, Miller, & Iwashyna, 2011). Behind an HRO are certain principles that allow an organization to concentrate on issues and implement solutions utilizing the correct resources (Christianson, Sutcliffe, Miller, & Iwashyna, 2011). The goal of HROs is not to cover the mistakes that take place, but rather to use the mistakes to be prepared for unexpected events in the future, with the correct methods of managing similar situations (Christianson, Sutcliffe, Miller, & Iwashyna, 2011). High reliability organizations have "five key principles that facilitate both problem detection and problem management" (Christianson, Sutcliffe, Miller, & Iwashyna, 2011, p.2). The principles are: "preoccupation with failure", "reluctance to simplify", "sensitivity to operations", "resilience, and deference to expertise" (Christianson, Sutcliffe, Miller, & Iwashyna, 2011, p.4). The utilization of the principles allows HROs to work towards a system of patient safety.

Health systems around the nation have begun to work towards being HROs where there is zero harm to the patient. An example is the Memorial Hermann Health System. The organization launched a program known as "Breakthroughs in Patient Safety," in 2006, where experts from other HRO industries were brought to help train employees "to perform tasks in a safe, highly reliable manner" (Memorial Hermann, n.d., p.5). The implementation of the program has led to the increase in better outcomes and safer, coordinated care (Memorial Hermann, n.d.). In the steps towards becoming an HRO, Memorial Hermann has also implemented a program known as MEDSAFE to ensure that patient identification is accurate and that the administration of medicine is done in a safe manner (Memorial Hermann, n.d.).

Health care organizations that strive to be high reliability organizations also utilize other health systems as a source. One organization is the South Carolina Hospital Association, that has partnered with The Joint Commission Center for Healthcare Transformation, and other health

care facilities to help each other towards becoming a high reliability organization (South Carolina Hospital, n.d.). The goal of the organization is to be harm free and deliver care that is safe for every patient, every time (South Carolina Hospital, n.d.). In addition, the organization has a separate program to recognize hospitals in the state that are progressing towards a safe environment for patients in certain areas, including post-surgery infections (South Carolina Hospital, n.d.). With the improvements made, across the state, hospitals have been harm-free for 12, 18, 24, and some for even 45 months (South Carolina Hospital, n.d.). Recently, the organization is working towards launching a blueprint, adapted from the American College of Healthcare Executives and the IHI/NPSF Lucian Leape Institute, which would promote leaders to focus on achieving high reliability (South Carolina Hospital, n.d.).

Additionally, Cincinnati Children's Hospital Medical Center is also working towards becoming an HRO. The organization uses the principle of an HRO improving methods and processes by recognizing current problems (Cincinnati Children's Hospital, 2018). The main focus in becoming an HRO relies on the improvement in reliability based on process, establishment of a reliability culture, and "leveraging human factors by creating intuitive designs" (Cincinnati Children's Hospital, 2018, para.1). In addition, the organization focuses on several additional principles which includes "improving situational awareness", "managing by prediction," and "looking at human factors" (Cincinnati Children's Hospital, 2018, para.2). Organizations have different methods but share the goal of being a zero-harm facility, and other health care systems can utilize applicable principles and procedures to join the organizations towards improving patient safety. Organizations can change processes through the utilization of theories that can help determine where quality improvement is necessary.

Theory

Systems Theory. Theories are used to explain, predict, control, and make meaning of certain phenomenon. A theory used to describe an organization which is dependent on its different divisions to function as a whole is known as the Systems Theory. The theory was first introduced in the 1920s by an Austrian biologist, Karl Ludwig von Bertalanffy, and later described as General Systems Theory in 1969 (Anderson, 2016). Bertalanffy developed the theory to illustrate that principles which are known universally can be applied to a system in general, and that a general theory can be applied to the system independent of the system's elements (Cordon, 2013).

In order for a system to function, the theory explains that individual parts must be correlated with each other (Anderson, 2016). The application of systems theory to medical errors "lumps adverse events together across types, and allows us to detect patterns and system failures" (Anderson, 2016, p.594). The use of the systems theory allows for health care organizations to address issues and help postulate solutions for the entire system to improve patient safety (Cordon, 2013). The WHO describes a health care system as a system that "consists of all organizations, people and actions whose primary interest is to promote, restore or maintain health" (World Health Organization, 2007, p.2). In order to improve patient safety, the systems theory is useful to describe how health care organizations need to coordinate with various existing systems in order to achieve the goal of reducing the number of preventable deaths.

Health care organizations have to continue undergoing change in order to keep up with the overall health care system of the nation. Hospitals are an open system because of their interaction with the external environment, which impacts how change has to be implemented by

keeping the different parts of the organization in mind (Zakus & Bhattacharyya, 2007). One component of the systems theory is the chaos theory, based on the priniciple that different parts of a system are interrelated and that order emerges out of chaos (Cordon, 2013). When a system responds to change, at first the situation may seem chaotic; however, when closley examined, there is indication of the system being within preset boundaries (Cordon, 2013). “Without the partnering of these two great forces [order and chaos], no change or progress is possible” (Cordon, 2013, p.17). In addition, the systems theory utilizes the input-process-outcome mechanism to explain how a system/organization operates, indicating how a health care organization depends on the surrounding environment and processes to achieve desired goals (Figure 4).

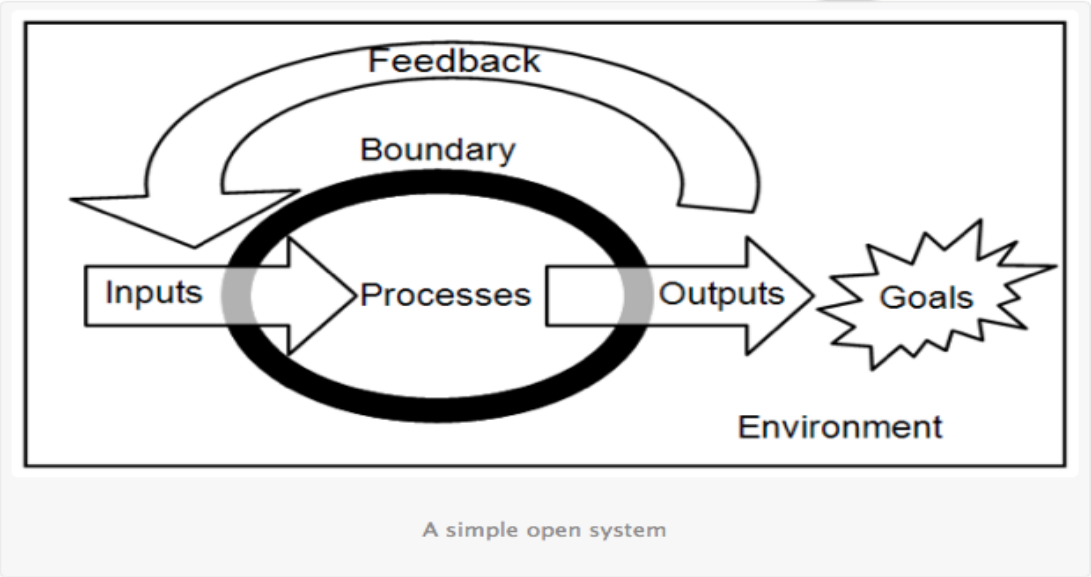

Figure 4. Open system framework. Adapted from https://careersintheory.wordpress.com/2011/05/19/a-simpler-system/

Continuous Quality Improvement. To improve the quality of care in a health care facility, the care providers must have the motivation to work towards achieving the organizational goals. To strengthen an organization’s performance, administrators have to focus

on “continually finding new opportunities for improvement” (Lighter, 2013, p.177). Often an organizational change has to occur in order to improve the quality of care. In order to bring change, the organization has to utilize strategic decision-making strategies and one strategy/tool is FOCUS PDCA.

Studying current processes and finding methods of improvement to increase quality is what FOCUS PDCA allows for an organization to accomplish (Stoltz, 1996, p. 223). FOCUS PDCA provides organizations with the ability to study what process needs to be improved and what changes will bring about significant improvements (Stoltz, 1996). The method has two phases with the first being the steps of FOCUS and the second the steps of PDCA (Figure 5).

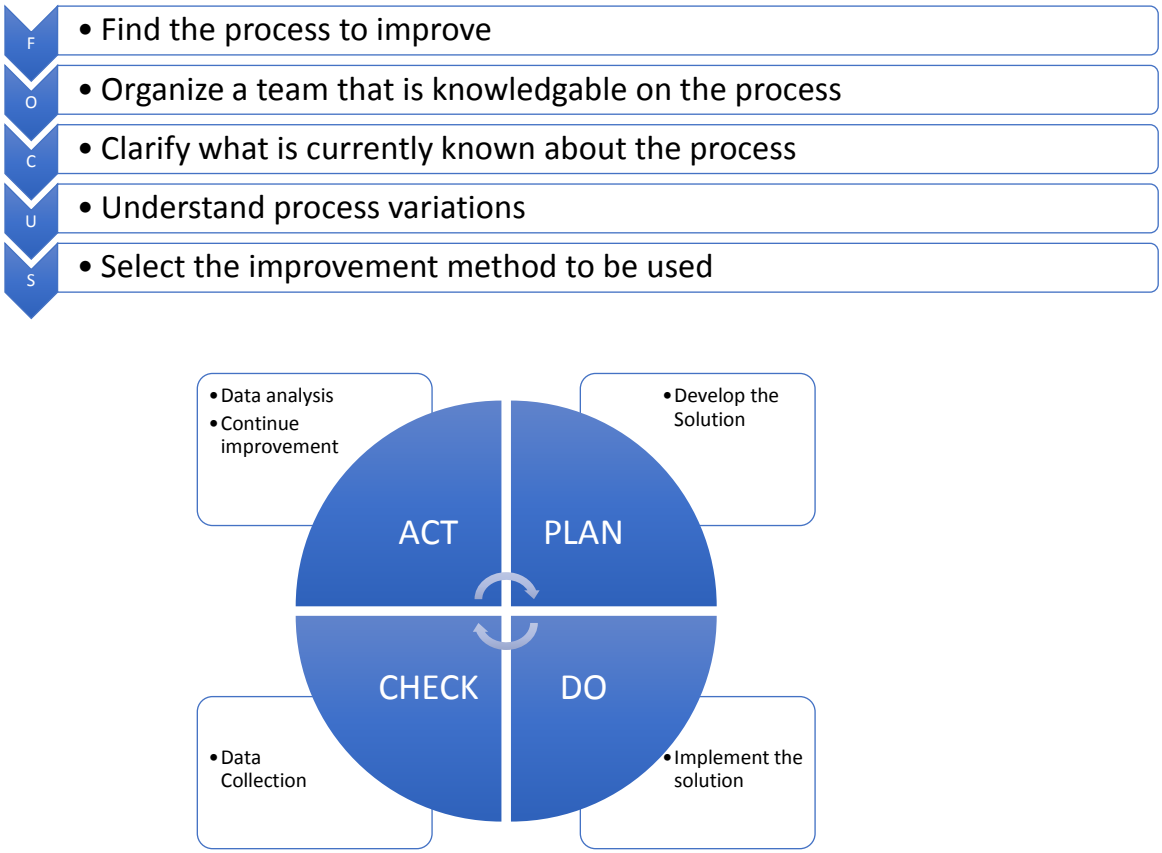

Figure 5. FOCUS PDCA.

The acronym FOCUS involves: finding the process to improve, organization of a team that is familiar with the process, clarification of what is currently known about the process, understanding the variations in the process, and selecting the method of improvement (Stoltz, 1996). The framework then moves onto the second phase which is the Plan-Do-Check-Act phase. First there is the planning of a solution to the issue, then the solution is implemented over a period of time, followed by measuring what the effectiveness of the implementation is, and then it is determined if the intervention was successful, and if so, control mechanisms are put in place to continue the new process (Lighter, 2013).

The FOCUS PDCA framework is one which can be continuously used by organizations so that different quality issues can be resolved. Through an analysis of the organization's current processes and the development of a possible solution, a health care facility can identify needs and change the manner in which its operations are conducted and thus improve the quality of care that is provided.

Literature Summary

The current quality of health care in the United States indicates the necessity for improvements. Initiatives are being worked upon by different agencies in order to combat the issue, with everyone from patients to hospitals and government agencies being involved. Literature that introduced how improvements have been made after the report by the IOM was presented in this chapter. The improvements were categorized into state laws, cases involving medical malpractice, and initiative programs. The variables will be used in the study to understand how hospitals in the U.S have begun improving the quality of care. The systems theory and a continuous quality improvement method were introduced and concluded the chapter

by indicating how the theories can be utilized by health care organizations to work on quality improvement initiatives.

Chapter 3: Methods

The purpose of chapter three is to describe the research design for the study, identify the sample frame and sample size, demonstrate how data was collected and analyzed, and to define the methodological rigor, protection of human subjects, and any limitations of the research. The aim of the research was to analyze the response of the health care system to the increasing number of deaths due to medical errors and recommend future steps that can be initiated to mitigate the issue.

Research Design

The purpose of the research was to understand what the response of the United States health care system has been to the increasing number of preventable deaths due to medical errors. The design approach for the research was non-experimental and the analysis was qualitative. Hermeneutics was utilized as the approach for the study. Hermeneutics is the approach "used by management scholars in a relatively more precise fashion to refer to research that engages in interpreting texts" (Prasad, 2002, p.13).

Sample Frame

The study was conducted using existing textual materials that pertain to the topic of medical errors and preventable deaths in the United States. The sample frame included online journals, newspaper articles, and other peer-reviewed sources. Information available on any laws that have been initiated, improvement programs which have been established, and other initiatives that have begun were also a part of the sample.

Sample Size

In order to meet the rigor challenges and fulfill the purpose of the study, the sample size was determined once there was saturation of textual material on the subject. When the analysis

no longer provides any new information, the sample size is determined as there is saturation of information (Morse, 2005). As Morse states, “when ongoing analysis reveals no new information appearing and no new categories emerging, sampling may cease” (Morse, 2005, p. 535).

Data Collection

For the study, textual materials were the data. The California State University, Bakersfield library search was used to find articles, along with Google Scholar, Centers for Medicare and Medicaid Services, Institute for Healthcare Improvement, The Joint Commission Journal on Quality and Patient Safety, Agency for Healthcare Research and Quality, and others. The terms that were used to find articles relating to the topic were: preventable deaths, medical errors, patient safety, Institute of Medicine, To Err is Human, and others.

Data Analysis

To analyze the collected data, the researcher used content analysis. The aim of content analysis is to organize “large amounts of text into an efficient number of categories that represent similar meanings” (Hsieh & Shannon, 2005, p. 1278). Content analysis organizes the categories that are found in the texts and then identifies the relationship amongst the categories (Hsieh & Shannon, 2005). “The goal of content analysis is ‘to provide knowledge and understanding of the phenomenon under study.” (Hsieh & Shannon, 2005, p.1278).

Methodological Rigor

The design of the study was qualitative; therefore, certain challenges were addressed. Some challenges that were addressed were the credibility, dependability, and transferability of the study, and the researcher attempted to address the integrity of the analysis.

IRB Approval

The researcher completed the Human Subjects Protection Training through the Collaborative Institutional Training Initiative, to meet the Institutional Review Board (IRB) requirement (Appendix E). The researcher signed up for CAYUSE and completed “Is My Project Human Subjects Research?” Due to the study not involving human subjects, the researcher was given approval from the IRB to continue the study and received the approval letter from IRB (Appendix F).

Limitations

The quality and the effectiveness of the research was impacted due to the time constraint for finishing the study.

Chapter 4: Results

Despite the numerous efforts initiated by health care organizations, issues surrounding patient safety due to medical errors remain to be resolved. In this chapter, efforts to improve medical errors were researched in order to analyze the response of the health care system to the initial publication of the severity of the issue. The chapter will focus on the discussion of how improvements have been made to help patient care be safer and analyzing what the improvement efforts mean in terms of improving the overall quality of the health care system. The research was completed using search terms including *improving medical errors*, *communication errors*, and *government and medical errors*. Of the approximate 75 articles reviewed, the results were obtained from 27 textual materials.

Findings

The health care system of the U.S. has initiated a response to the number of preventable deaths, which is indicated through different efforts to improve patient safety. The content analysis highlighted themes (Table 2) including improvement programs, health care organizations moving towards a patient-centered culture, and the transparency in reporting.

Table 2

Themes Emerging in Data Analysis

Themes		
Improvement Programs	Patient-Centered Culture	Transparency
Government policies and laws	Patient safety	Reporting of medical errors
Hospital reimbursement reduction program	Improving safety through communication	Accountability
Checklists	Reinforcing continuous quality improvement	
Campaigns and training programs		
Hospital accreditation and grading		
Electronic records and barcodes		
Drug labeling		

Improvement Programs

Governmental policies and laws. The U.S. government attempts to improve patient safety and the quality of health care through mandates and policies. The Patient Safety and Quality Improvement Act of 2005 (PSQIA) was signed into law on July 29, 2005 as a response to concerns surrounding patient safety (Agency for Healthcare, 2014). The act urges voluntary and confidential reporting of adverse events that affect patient safety (Agency for Healthcare, 2014). The fear of blame leads to providers being wary of reporting patient harm events; therefore, the act provides "Federal legal privilege and confidentiality protections" to any information providing a report (Agency for Healthcare, 2014, para. 3). In addition, liability and malpractice fears are addressed by the PSQIA by limiting the reported information being used in proceedings (Agency for Healthcare, 2014). Involvement of government entities allows legal attempts to be introduced to help improve patient safety.

Hospital reimbursement reduction program. The Center for Medicare and Medicaid Services (CMS) has initiated programs including the Hospital Readmissions Reduction Program and the Hospital Value-Based Purchasing (VBP) Program. Under the Affordable Care Act, as of October 1, 2012, Medicare is permitted to reduce payment to hospitals with readmissions for patients with "high-cost or high-volume conditions and procedures" (Medicare.gov, n.d., para. 3). Hospital readmissions are encouraged to be reduced through the program and as a result, the quality of care is expected to improve (Medicare.gov, n.d.).

The Hospital VBP Program is also established through the Affordable Care Act and enforced in 2013 (Medicare.gov, n.d.). Under the VBP program, inpatient stay payment is impacted, as the program "implements a pay-for-performance approach to the payment system" (Medicare.gov, n.d. para. 5). At the beginning of the fiscal year, Medicare adjusts payments

based on how hospitals perform on measures set by CMS, or based on how much improvement is indicated in the hospital's performance in comparison to the prior year (Medicare.gov, n.d.). The VBP program is initiated to help improve patient experience during inpatient stays and promote organizations to work towards improving clinical outcomes (Medicare.gov, n.d.). Health care organizations have also begun improving processes to ensure patient harm is reduced.

Checklists. A method utilized by organizations to improve safety is the use of checklists. Surgery checklists have been established to help hospitals reduce the number of sentinel events that occur due to errors in surgery. The Joint Commission has established the Universal Protocol (UP) to reduce wrong-site, wrong-procedure, and wrong-person surgeries (The Joint Commission, n.d.b). The UP includes a surgery checklist available for health care organizations to utilize. The checklist involves conducting a pre-procedure verification process, marking the procedure site, and performing a time-out before the procedure begins (The Joint Commission, n.d.b). The implementation of the checklist is voluntary and organizations are not penalized for not using the checklist (The Joint Commission, 2012). In addition to checklists, other methods of improvement have been started by different organizations focusing to improve the high incidence of medical errors and patient harm.

Campaigns and training programs. Improvement programs have been established by different agencies to help achieve better patient safety. For instance, the National Quality Program, a collision between the Duke University Health System and LifePoint Health, improved patient safety by 62.5% in six years (Frush et al., 2018). Health systems across the country have established patient safety programs to help improve the prevalence of adverse events (Table 3). From the textual analysis, six major organizations have begun improvement

programs, in which many hospitals have opted to be involved in order to improve patient safety processes.

Table 3

Major Improvement Programs

Improvement Program	**Number of Hospitals Involved**
National Quality Program	70
Partnership for Patients	4000
The Leapfrog Group	1800
Patient Safety Movement	4710
National Center for Patient Safety	168 VA medical centers
100,000 Lives Campaign	3100

Note. Data for National Quality Program from (Frush et al., 2018), for Partnership for Patients from CMS.gov (n.d.), for Leapfrog Group from The Leapfrog Group (n.d.b), for Patient Safety Movement from Patient Safety Movement (2019), for National Center for Patient Safety from U.S. Department of Veterans Affairs (2018b), and for 100,000 Lives Campaign from Institute for Healthcare Improvement (2019a).

The Memorial Hermann Health System in Texas established a system to achieve zero patient harm and became a high reliability organization (Memorial Hermann, n.d.). The health system aims to achieve a culture of patient safety with improved and effective treatments, through the collaboration with physicians (Memorial Hermann, n.d.). Memorial Hermann involves leadership in the efforts as well. In monthly meetings, leaders and executives have the opportunity to provide input on the processes of changing the methods of health care delivery and ensuring that the outcomes are meeting the goals (Memorial Hermann, n.d.). Another improvement initiative is the Partnership for Patients, in which over 3700 hospitals voluntarily partake. The U.S. Department of Health and Human Services (HHS), initiated the program to

help reduce the number of hospital acquired conditions and preventable readmissions (McKinney, 2014). In addition, other government agencies are also becoming involved to help with the quality of health care.

Hospital accreditation and grading. The Joint Commission is an organization that evaluates health care facilities on the basis of quality and safety and is involved in the accreditation of health care organizations. The standards established by the Joint Commission are used by over 19,000 health care organizations to help continuous performance improvement (The Joint Commission, n.d.a) “Approximately 82 percent of the nation’s hospitals (including critical access hospitals) are currently accredited by The Joint Commission” (The Joint Commission, n.d.a, para. 9). In addition, The Joint Commission has initiated efforts to improve patient safety events. The Joint Commission implemented the Sentinel Event Policy in 1996, but revised the policy in 2014 to include concepts of patient safety (The Joint Commission, 2017). Any time a sentinel event transpires, health care organizations are expected to analyze the situation and improve faults in order to reduce the risks to patients (The Joint Commission, 2017). Hospitals accredited through the Joint Commission are “strongly encouraged, but not required, to report sentinel events,” and information obtained by the Joint Commission regarding patient safety events is used by the accredited organizations to help improve the quality of services provided (The Joint Commission, 2017, para.3).

Over the years, there has been a focus on allowing hospital performance to be transparent for patients through accreditations and grading. The Leapfrog Group reports data on over 2,000 hospitals in 36 states and utilizes a grade system to evaluate how well the organizations are doing to keep patients safe (The Leapfrog Group, n.d.b). In addition, the organization has voluntary surveys for hospitals to report on the quality of services provided (The Leapfrog Group, n.d.b).

Through the use of the programs, the organizations aim to help consumers of health care services to be well informed on the performance of the hospital they choose to receive care from. The availability of hospital information relies on the utilization of technological systems to ensure patients can access performance grades before they choose the health care organization to receive care from.

Electronic records and barcodes. The use of technology has been incorporated in the health care system to help reduce errors. As of 2016, 99.1% of hospitals in the U.S. are using a form of electronic health record (EHR), and of the 99.1%, 43.3% have fully adopted an EHR system, with only 1.0% hospitals having no EHR and using paper records (Pedersen, Schneider, & Schecklehoff, 2017). In addition, computerized physician order entry (CPOE) is being utilized by hospitals around the nation. From 2.7% of hospitals in 2003, to 95.6% of hospitals in 2016, the use of CPOE has drastically increased to help reduce physician order errors (Pedersen, Schneider, & Schecklehoff, 2017). Other methods of health care technology are also emerging to help improve patient safety.

Identification technology such as the use of barcodes with patient information have been introduced to health care settings to help reduce errors. Bar code medication administration (BCMA) systems are used to reduce medication errors that may occur due to improper patient identification or improper administration of the medication (Shah et al., 2016). The BCMA system verifies that the patient, the dose, the drug, the time, and the route are correct (Shah et al., 2016). When a nurse is ready to administer the medication, he or she scans the patient's wristband and the bar code on the medication, and the information is documented into the electronic medication record (Shah et al., 2016). The use of BCMA has increased from 1.5% of hospitals having the system in 2002, to 92.6% using the system in 2016 (Pedersen, Schneider, &

Schecklehoff, 2017). However, the cost of implementing the BCMA system continues to be a barrier for all organizations to utilize the technology (Shah et al., 2016). Medication errors are one of the main categories highlighted when medical errors are discussed; therefore, the use of systems such as BCMA may improve to be helpful if it is implemented by every health care organization.

Drug labeling. Medication errors affect many Americans per year, and accounts for the majority of medical error events overall. The U.S. Food and Drug Administration (FDA) aims to improve the number of medication errors to help deliver the right medication to the right patient and reduce other medication dispensing errors. The FDA reviews over 100,000 reports each year pertaining to possible medication errors and works on determining causes of the errors and methods of improvement (U.S. Food and Drug, 2018). Medication error prevention is attempted by the FDA through the review of labeling, naming, and packaging of drugs and the review of product design (U.S. Food and Drug, 2018). In addition, the FDA requires bar codes on drug label to allow scanning of the medication to eliminate wrong administration of the drug (U.S. Food and Drug, 2018). Patient safety is a concern in every aspect of health care delivery and has to be addressed by all those involved in providing patient care.

The use of technology and the initiation of CPOE orders has led to reductions in prescribing errors, leading to an overall decrease in the number of medication errors. The Agency for Healthcare Research and Quality mentions a meta-analysis from 2013 which determined a reduction of 48% in errors while prescribing with the use of CPOE, when compared to paper orders (Agency for Healthcare, 2019a). The results indicate that over 17 million medications errors were avoided in the United States (Agency for Healthcare, 2019a).

The decrease in such errors is helping reduce the number of adverse events, save financial costs associated with the errors, and improving patient safety.

Patient-Centered Culture

Patient safety. Creating a patient-safety culture is an aim of the health care system, and one method of establishing a safe culture is working towards becoming a high-reliability organization. The AHRQ describes the characteristics of a high reliability organization (HRO), which include: preoccupation with failure, reluctance to simplify, sensitivity to operations, deference to expertise, and commitment to resilience (Agency for Healthcare, 2019b). The goal of an HRO is to prepare for similar events in the future rather than cover current mistakes (Christianson, Sutcliffe, Miller, & Iwashyna, 2011). Health care organizations including the Memorial Hermann Health System, the South Carolina Hospital Association, and Cincinnati Children's Hospital Medical Center, began working towards becoming a HRO to improve the current methods and processes that could possibly be affecting the quality of care patients receive. However, the notion of becoming a high-reliability organization is not openly accepted by all health care organizations, and that may be due to the unwillingness to change the organizational culture (National Academy of Sciences, 2009). The reliability of patients on the health care system to provide safe care puts responsibility on professionals to improve methods of care, and different aspects must be addressed to ensure that the care provided is safe.

Improving safety through communication. Patients rely on the clinicians to thoroughly communicate the plan of care, or other information pertaining to the patient's care; however, communication errors lead to the majority of medical errors. Based on 2014-2015 data, the Joint Commission has identified communication errors as the main reason behind medical errors (Mackles, 2017). Over 1700 deaths in the U.S. have been linked to communication errors

(Bailey, 2016). Therefore, the focus on improving communication is key for organizations to improve patient safety.

A method of improving communication is the Situation-Background-Assessment-Recommendation (SBAR) technique. The health care team's communication with the patient is expected to improve with the use of SBAR. The technique follows the four steps as a framework for communication which begins with assessing the situation and formulating "a concise statement of the problem," knowing the background and having "pertinent and brief information related to the situation," articulating an assessment with "analysis and considerations of options," and preparing a recommendation with the "action requested/recommended" (Institute for Healthcare Improvement, 2019b, para. 1). The main focus of the technique is to help clinicians improve methods of communication with the patient as a means to improve patient safety. Methods to improve the quality of health care have to be incorporated by health care organizations to help improve errors and patient safety.

Reinforcing continuous quality improvement. The use of continuous quality improvement methods is involved in working towards reducing medical errors. A well-established example of utilizing a quality improvement method is the U.S. Department of Veterans Affairs (VA) and the use of root cause analysis. The VA uses root cause analysis to examine occurrences of adverse events (U.S. Department of Veterans Affairs, 2018a). "The goal of the RCA process is to find out what happened, why it happened, and how to prevent it from happening again" (U.S. Department of Veterans Affairs, 2018a, para. 2). The culture of the department is such that it focuses on preventing patient harm rather than punishing those involved (U.S. Department of Veterans Affairs, 2018a). The RCA is a viewed as a tool to compose strategies to prevent errors and build a culture of patient safety.

Root cause analysis is also utilized by the Joint Commission to help organizations improve processes. The Sentinel Event Policy of the Joint Commission is an initiative to "help organizations reduce variation, reduce risk, and improve quality" (The Joint Commission, 2019, para.1). Three documents including: The Patient Safety Systems, The Sentinel Event Policy, and The RCA2, are provided to help organizations determine the root causes of sentinel events and provide methods and techniques to effectively learn about why the event occurred and how it can be prevented in the future (The Joint Commission, 2019). Electronic access is provided to health care providers to help individuals learn about events, the root causes, and improvement recommendations, in order to help improve efforts to provide safer care.

Improvements in patient safety involve other quality improvement methods of Six Sigma. One tool utilized by health care organizations is the define-measure-analyze-improve-control (DMAIC) method. Errors in medication administration have improved in hospitals utilizing the DMAIC model. In 2007, Alton Memorial Hospital improved the incidences of adverse drug events through the use of a multidisciplinary team that utilized DMAIC (Benitez, Forrester, Hurst, & Turpin, 2007). Results of the intervention displayed a 90% improvement in order entry errors, reducing the overall number of errors "to less than 0.04 errors per bed every month for four months" (Benitez, Forrester, Hurst, & Turpin, 2007, p.45). The use of quality improvement methods may decrease incidences of patient harm and allow for evidence-based solutions to be available for the organization.

Transparency

Reporting of medical errors. Although underreporting remains an issue, there has been an increase in reporting of medical errors. Reporting systems have been mandated by some states while in others they are voluntary. In addition, the systems allow for professionals to report

errors anonymously, encouraging incidences to be reported on a regular basis. State-by-state regulations and requirements have been adapted to report adverse events and 29 states are currently listed as participating in the state-based reporting system (Jones, 2012). The National Academy for State Health Policy (NASHP) tracks the requirements for reporting and provides important information for each state including laws and regulations, to help with compliance (Jones, 2012).

In addition to state regulations, health care organizations focus on reporting events described as near misses. The publication of the IOM's report led to health care organizations focusing on establishing a culture of improving safety; therefore, the reporting of near-miss (Level 1) errors has been persistent (Journal of Oncology Practice, 2007). Confidentiality is a main component in reporting systems across the nation to ensure that errors are frequently reported.

Accountability. Government programs have been established to encourage health care providers to report a patient safety event. The fear of blame and loss of jobs led to health care professionals not reporting errors and also covering for each others' mistakes. The focus has however shifted from the culture of blame; therefore, anonymous reporting systems have been made available. The presence of the anonymous system allows for professionals to have accountability for their actions without fearing the adverse consequences.

In addition, organizational changes in culture have arisen to drift away from the culture of blame to address patient safety. The culture of organizations has also changed to increase the involvement of leadership is essential to ensure that clinicians do not fear being blamed when an error is reported. In addition, leadership can be involved to ensure that the organization provides a culture of learning, and that the overall organizational culture learns from mistakes and uses

performance improvement to improve the delivery of care (Sammer et al., 2010). “A learning culture creates safety awareness among employees and medical staff and promotes an environment of learning” (Sammer et al., 2010, p.162). An organizational culture that allows for physicians and nurses to be transparent about mistakes and encourages learning from mistakes rather than having a culture of blame, promotes efforts towards improving medical errors.

Analysis

Focusing on patient safety, multiple efforts to reduce medical errors have been initiated by different organizations. The IOM’s 1999 report on the number of preventable deaths caused a stir in the health care industry to take the concern seriously and thus improvements have been made to make patient care safer including changes in organizational cultures, grading of health care facilities, and the implementation of quality improvement initiatives, amongst other process enhancements. The success of improvement efforts is indicated through the decrease in malpractice lawsuits, decrease in medication errors, decreases in infection rates and patient falls in various hospitals across the country, and increased event reporting. The involvement of individuals and organizations have led to improvements and the subject of preventable deaths continues to be tackled throughout the nation.

In addition, preventative efforts have been brought about due to the financial incentive of improved patient safety. Because of the possibility of reduction in reimbursements, health care professionals have increased testing and work towards preventative care to be safe of adverse consequences in the future. In addition, increased attention to medical errors allows the health care system to save or reduce the annual financial costs associated with medical errors, indicating the financial motivation of improving the situation. However, despite of continuing efforts, not all areas of concern are addressed effectively. The content analysis indicates that

reporting of medical errors has improved; however, it is not to the point that every event where an error occurs is reported, indicating the areas that lack sufficient improvement.

The analysis indicates that the health care system has improved patient safety and continues to work towards becoming a system with no patient harm; however, the issue remains to be fully resolved. Reports of the increases in preventable deaths are questionable as the data analysis suggests improvement efforts are in actuality working towards leading the system to decrease medical errors. However, continued deaths due to errors are persistent in the health care system without a concrete solution or improvement. The data also indicates that root causes of adverse events must first be discovered to formulate a solution to the problem. The formulation of the causes is lacking and therefore a viable solution is not possible. Despite of the efforts to reduce patient harm, deaths due to medical errors continue to occur, which indicates that patient safety has not improved to the extent that it should have in the years since the IOM's publication of the data.

The emphasis of improvement efforts has to be refocused to determine underlying causes of medical errors. However, data suggests that there is currently too much variation in the definition of whether or not an error was preventable and therefore there is the lack of a standardized measurement strategy of patient safety. Due to no standardized definition, preventable deaths may be underestimated by some and overestimated by others. In addition, every organization has an individualistic approach to improving patient safety, but there is no nationwide collaboration focusing on improving the issues surrounding medical error prevalence. Also, there is no solid method of data collection for the number of medical errors that do occur, and therefore the complexity of the problem is not completely understood. Currently, data is extrapolated to establish a figure that may highlight the prevalence of medical errors and CDC

does not list medical errors as cause of death. The lack of standardization of measurements and standardized approaches towards improvements allow for medical errors to continue to occur and prevent research efforts to be focused on the elimination of causes of the errors.

Overall, the various efforts of health care organizations around the nation are indicative of the desire to improve patient safety. Campaigns, and other improvement initiatives such as policies and regulations are all in place to help the U.S. health care system be free of preventable harm to those who seek care. The content analysis of the research indicates that medical errors are of concern to all individuals involved in providing care, which has led to improvement efforts, and is not an area which is simply overlooked. Medical errors consist of different concepts and therefore many initiatives have been formed to help address the parts that formulate the problem as a whole. However, there continue to be flaws in the nation's health care system that remain to be sufficiently addressed in order to ensure the safety of patients is not hindered.

Theory Application

Systems Theory allows health care organizations to address issues and formulate solutions that can be applied to the system as a whole. Hospitals operate with an open systems framework and have to evaluate different components in order to effectively implement change. The research analysis indicates the necessity of health care organizations to assess the inputs, processes, and outputs, and the external environment in order to improve areas of concern in patient safety. In the health care system, organizations have to ensure that all systems are working properly because without the synchronization of the different parts, organizations are not able to achieve the best quality of health care. In addition, organizations have the ability to analyze and learn from successful interventions of other facilities and apply the methods to resolve the issues within.

The ability of an organization to change impacts its success and continuous quality improvement is a necessity in health care. To accomplish improvements in areas relating to medical errors, a method that can be utilized by health care organizations is the FOCUS PDCA framework. The results of the analysis indicate that continued organizational changes are necessary to improve the quality of care and address the ongoing issue of medical errors. In addition, because medical errors do not simply occur due to one reason, the utilization of FOCUS PDCA can help organizations continuously improve different processes that may be hindering safe patient care. With the help of ongoing improvement efforts, health care organizations can adopt methods that would help achieve the goal of delivering quality care while ensuring patient safety is at the center of every decision.

Chapter 5: Conclusion and Recommendations

The number of preventable deaths due to medical errors is alarming and continues to be an area of concern for the U.S. health care system. The IOM outlined six aims to improve the quality of health care, including the need for patient care to be safe, effective, patient-centered, timely, efficient, and equitable. Although health care organizations have attempted to increase the quality of care, the number of medical errors may be on the rise. The statistics are illustrative of the necessity for health care to continue to improve patient safety and reduce harm; however, differences in the understanding of medical errors and the inability of health care providers to agree upon what is preventable or not, do not allow for a concrete solution to be formed.

Recommendation One: Standardization

Due to the health care providers being unable to reach a consensus on the definition of what a preventable death is, there is not a single solution that every organization is able to adopt. Across the country, health care organizations have independently begun reforming processes involving patient safety. However, the number of organizations involved in improvement programs is not 100%, and every approach is restricted for the use of the organization initiating the improvement process. Therefore, first the establishment of a standard definition of preventable must be determined and there must be a governed improvement approach that is available for all health care facilities to utilize. In addition, a single agency must be appointed to account for all reporting of adverse events, to ensure that the depth of the issue is properly understood, and therefore allowing for the establishment of standard procedures to follow when adverse events occur.

Recommendation Two: Quality Analysis

To improve patient safety, a health care organization must first analyze faulty systems and then develop methods of improvement. An internal analysis of the organization should be conducted to gather data regarding where the overall system is lacking in terms of ensuring patient safety. In addition, health care organizations should conduct analyses of how the organization compares to others in patient safety, and take examples of successful interventions from one another and implement improvement methods accordingly. Utilizing methods such as root cause analysis would allow for the organization to identify why the adverse event took place, and offer a potential solution to improve upon the faults. In addition, training on how to improve quality and patient safety should be provided to all employees so that every care provider is involved in improving the overall delivery of health services.

Recommendation Three: Mandatory Reporting System

Majority of the existing reporting systems are voluntary and therefore, the number of incidences that are reported are not illustrating the entire impact of the issue of medical errors. The federal government should require every health care facility to report events concerning patient safety. There should be a federal mandate to report every patient harm event, regardless of whether a death occurred or not. In addition to mandatory reporting to the government, organizations must also be mandated to disclose errors to patients and family members. The disclosure of errors would allow for the maintenance of trust between health care providers and seekers. In addition, the providers would become accustomed to disclosure without the fear of blame and litigation. The adaptation of a mandatory reporting system would help improve the overall quality of health care in the nation. With the utilization of improvement methods, the health care system would become closer to being safe for all those involved.

Conclusion

The research and data analysis highlighted the gaps in resolving the issue of medical errors. The researcher will provide the collected information to be available to others through the California State University, Bakersfield library, as a resource for individuals to use for future reference. Overall, the data indicates that different methods and techniques have to be adopted by the health care system in order to focus on the high prevalence of errors. In addition, continued research has to be in place, to determine how to effectively solve problems that lead to medical errors. Health care organizations have to continue working towards becoming safe for patients and providing services efficiently.

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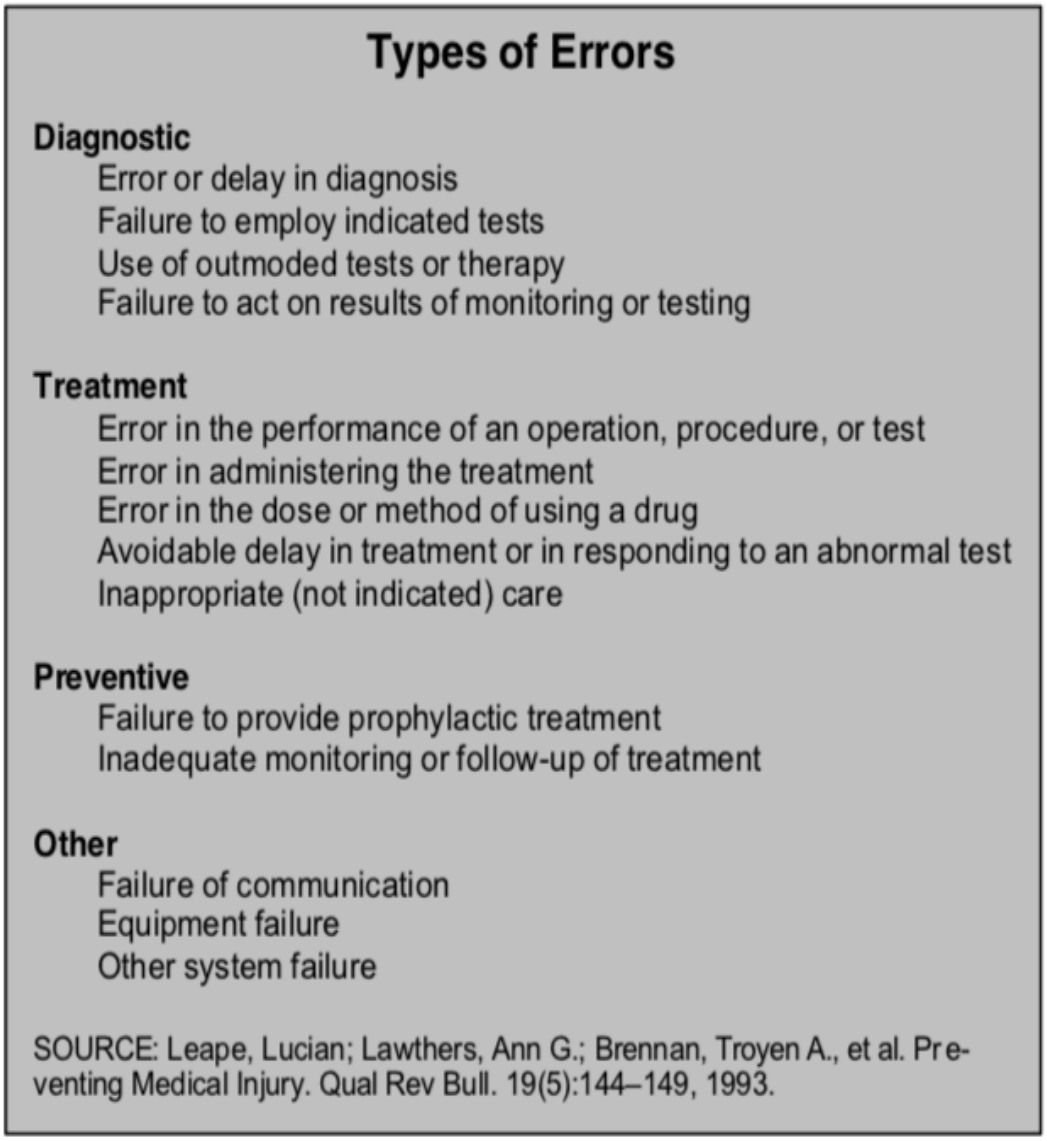
Appendix A



Types of Errors

Diagnostic

- Error or delay in diagnosis
- Failure to employ indicated tests
- Use of outmoded tests or therapy
- Failure to act on results of monitoring or testing

Treatment

- Error in the performance of an operation, procedure, or test
- Error in administering the treatment
- Error in the dose or method of using a drug
- Avoidable delay in treatment or in responding to an abnormal test
- Inappropriate (not indicated) care

Preventive

- Failure to provide prophylactic treatment
- Inadequate monitoring or follow-up of treatment

Other

- Failure of communication
- Equipment failure
- Other system failure

SOURCE: Leape, Lucian; Lawthers, Ann G.; Brennan, Troyen A., et al. Preventing Medical Injury. Qual Rev Bull. 19(5):144–149, 1993.

Appendix B

Table. Strategies for Measuring Patient Safety. (Go to table citation in the text)

Measurement Strategies	Advantages	Disadvantages
Retrospective Chart Review	Considered the "gold standard," contains rich detailed clinical information	Costly, labor-intensive, data quality variable due to incomplete clinical information, retrospective review only
Incident Reporting Systems	Useful for internal quality improvement and case-finding, highlights adverse events that providers perceive as important	Capture small fraction of adverse events that occur, retrospective review only based on provider self-reports, no standardization or uniformity of adverse events reported
Automated Surveillance	Can be used retrospectively or prospectively, helpful in screening patients who may be at high risk for adverse events using standardized protocols	Need electronic data to run automated surveillance, high proportion of "triggered" cases are false positives
Administrative/Claims Data	Low-cost, readily available data, useful for tracking events over time across large populations, can identify "potential" adverse events	Lack detailed clinical data, concerns over variability and inaccuracy of ICD-9-CM codes across and within systems, may detect high proportion of false positives

Appendix C

Table 1 List of serious reportable events

Event	Additional specifications
1. Surgical events	
A. Surgery performed on the wrong body part	Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient.
	Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.
B. Surgery performed on the wrong patient	Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.
C. Wrong surgical procedure performed on a patient	Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient.
	Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.
	Surgery includes endoscopies and other invasive procedures.
D. Retention of a foreign object in a patient after surgery or other procedure	Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.
E. Intraoperative or immediately post-operative death in an ASA Class I patient	Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately post-operative means within 24 hours after induction of anesthesia (if surgery not completed), surgery, or other invasive procedure was completed.
2. Product or device events	
A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility	Includes generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.
B. Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used for functions other than as intended	Includes, but is not limited to, catheters, drains and other specialized tubes, infusion pumps, and ventilators.
C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facility	Excludes deaths associated with neurosurgical procedures known to be a high risk of intravascular air embolism.
3. Patient protection events	
A. Infant discharged to the wrong person	
B. Patient death or serious disability associated with patient elopement (disappearance) for more than four hours	Excludes events involving competent adults.
C. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a health care facility	Defined as events that result from patient actions after admission to a health care facility.
	Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the health care facility.

4. Care management events	
A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)	Excludes reasonable differences in clinical judgment on drug selection and dose.
B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products	
C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility	Includes events that occur within 42 days post-delivery.
	Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy.
D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a health care facility	
E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinimia in neonates	Hyperbilirubinimia is defined as bilirubin levels >30 mg/dl.
	Neonates refers to the first 28 days of life.
F. Stage 3 or 4 pressure ulcers acquired after admission to a health care facility	Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.
G. Patient death or serious disability due to spinal manipulative therapy	

5. Environmental events	
A. Patient death or serious disability associated with an electric shock while being cared for in a health care facility	Excludes events involving planned treatments such as electric countershock.
B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances	
C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a health care facility	
D. Patient death associated with a fall while being cared for in a health care facility	
E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility	
6. Criminal events	
A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider	
B. Abduction of a patient of any age	
C. Sexual assault on a patient within or on the grounds of the health care facility	
D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the health care facility	

Appendix D

Table 1 NQF-endorsed Safe Practices*

1.	Create a health care culture of safety.
2.	For designated high-risk, elective surgical procedures or other specified care, patients should be clearly informed of the likely reduced risk of an adverse outcome at treatment facilities that have demonstrated superior outcomes and should be referred to such facilities in accordance with the patient's stated preference.
3.	Specify an explicit protocol to be used to ensure an adequate level of nursing based on the institution's usual patient mix and the experience and training of its nursing staff.
4.	All patients in general intensive care units (both adult and pediatric) should be managed by physicians having specific training and certification in critical care medicine ("critical care certified").
5.	Pharmacists should actively participate in the medication-use process, including—at a minimum—being available for consultation with prescribers on medication ordering, interpretation and review of medication orders, preparation of medications, dispensing of medications, and administration and monitoring of medications.
6.	Verbal orders should be recorded whenever possible and immediately read back to the prescriber—i.e., a health care provider receiving a verbal order should read or repeat back the information that the prescriber conveys in order to verify the accuracy of what was heard.
7.	Use only standardized abbreviations and dose designations.
8.	Patient care summaries or other similar records should be prepared with all source documents immediately at hand (i.e., they should not be prepared from memory).
9.	Ensure that care information, especially changes in orders and new diagnostic information, is transmitted in a timely and clearly understandable form to all of the patient's current health care providers who need that information to provide care.
10.	Ask each patient or legal surrogate to recount what he or she has been told during the informed consent discussion.
11.	Ensure that written documentation of the patient's preference for life-sustaining treatment is prominently displayed in his or her chart.
12.	Implement a computerized physician order entry system.
13.	Implement a standardized protocol to prevent the mislabeling of radiographs.
14.	Implement standardized protocols to prevent the occurrence of wrong-site procedures or wrong-patient procedures.
15.	Evaluate each patient undergoing elective surgery for his or her risk of an acute ischemic cardiac event during surgery, and provide prophylactic treatment of high-risk patients with beta blockers.
16.	Evaluate each patient upon admission, and regularly thereafter, for his or her risk of developing pressure ulcers. This evaluation should be repeated at regular intervals during care. Clinically appropriate preventive methods should be implemented consequent to the evaluation.
17.	Evaluate each patient upon admission, and periodically thereafter, for the risk of developing deep vein thrombosis (DVT)/venous thromboembolism (VTE). Use clinically appropriate methods to prevent DVT/VTE.
18.	Use dedicated antithrombotic (anticoagulation) services that facilitate coordinated care management.
19.	Upon admission, and periodically thereafter, evaluate each patient for the risk of aspiration.
20.	Adhere to effective methods of preventing central venous catheter-associated blood stream infections.
21.	Evaluate each pre-operative patient in light of his or her planned surgical procedure for his or her risk of surgical site infection (SSI), and implement appropriate antibiotic prophylaxis and other preventive measures based on that evaluation.
22.	Use validated protocols to evaluate patients who are at risk for contrast media-induced renal failure, and use a clinically appropriate method for reducing risk of renal injury based on the patient's kidney function evaluation.
23.	Evaluate each patient upon admission, and periodically thereafter, for his or her risk of malnutrition. Employ clinically appropriate strategies to prevent malnutrition.
24.	Whenever a pneumatic tourniquet is used, evaluate the patient for his or her risk of an ischemic and/or thrombotic complication, and use appropriate prophylactic measures.
25.	Decontaminate hands with either a hygienic hand rub or by washing with a disinfectant soap prior to and after direct contact with the patient or objects immediately around the patient.
26.	Vaccinate health care workers against influenza to protect both them and patients from influenza.
27.	Keep workspaces where medications are prepared clean, orderly, well lit, and free of clutter, distraction, and noise.
28.	Standardize the methods for labeling, packaging, and storing medications.
29.	Identify all "high alert" drugs (e.g., intravenous adrenergic agonists and antagonists, chemotherapy agents, anticoagulants and antithrombotics, concentrated parenteral electrolytes, general anesthetics, neuromuscular blockers, insulin and oral hypoglycemics, narcotics and opiates).
30.	Dispense medications in unit-dose or, when appropriate, unit-of-use form, whenever possible.

Appendix E

CITI PROGRAM

Completion Date 06-Sep-2017
Expiration Date 05-Sep-2021
Record ID 24391587

This is to certify that:

RAJKAMAL GILL

Has completed the following CITI Program course:

Social, Behavioral, and Education Sciences Responsible Conduct of Research (Curriculum Group)
Social, Behavioral, and Education Sciences (RCR) (Course Learner Group)
1 - RCR (Stage)

Under requirements set by:

California State University, Bakersfield

CITI
Collaborative Institutional Training Initiative

CITI PROGRAM

Completion Date 06-Sep-2017
Expiration Date 05-Sep-2021
Record ID 24391586

This is to certify that:

RAJKAMAL GILL

Has completed the following CITI Program course:

Social & Behavioral Research - Basic/Refresher (Curriculum Group)
Human Subjects Protection Training - PI/Researchers (SBE) (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

California State University, Bakersfield

CITI
Collaborative Institutional Training Initiative

Appendix F

California State University, Bakersfield
Human Subjects Institutional Review Board
FWA00013908

Date: February 18, 2019

To: Rajkamal Gill, Department of Public Administration
BJ Moore, Department of Public Administration
cc: Chandra Commuri, IRB Chair
From: Isabel Sumaya, University Research Ethics Review Coordinator

Subject: Master's Thesis Project 19-62: Not Regulated Research Status

Thank you for bringing your Master's Thesis Project, "Analysis of the Response of the U.S. Health Care System to the Institute of Medicine's 1999 Report on Medical Errors", to the attention of the HSIRB.

On the submission form you indicated the following:

I want to interview, survey, systematically observe, or collect other data from human subjects, for example, students in the educational setting. **NO**

I want to access data about specific persons that have already been collected by others (such as test scores or demographic information). **NO**

Those data can be linked to specific persons (regardless of whether I will link data and persons in my research or reveal anyone's identities). **NO**

Given this, your proposed project will not constitute human subjects research. Therefore, it does not fall within the purview of the CSUB HSIRB.

If you have any questions, or there are any changes that might bring these activities within the purview of the HSIRB, please notify me immediately at (661) 654-2381.

Good luck with your project.

Thank you.

Isabel Sumaya, Ph.D.
University Research Ethics Review Coordinator
California State University, Bakersfield