HIGH RELIABILITY IN MEDICATION ADMINISTRATION

by

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Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Business Administration

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Liberty University, School of Business

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Abstract

This research was designed to test the theory of Robust Process Improvement (RPI) as it has been applied to the problem of medication error at Navy medical treatment facilities (MTFs). Medication error is the greatest cause of patient injury in America. In an effort to duplicate the success of High Reliability Organizations (HROs), leaders of the Joint Commission advocated the application of Lean Six Sigma (LSS) as the key elements of RPI and the best way to increase safety and improve the quality of healthcare. The specific problem was that very little empirical evidence existed supporting the theory. The research question asked if the application of LSS could reduce medication error rates. To answer that question, the researcher used a quantitative pre-post design which measured the number of medication related Patient Safety Reports (PSRs) before and after the LSS studies performed at Navy MTFs. Navy Medicine was used as a test bed because it has developed a formidable LSS program. The researcher examined all Navy LSS studies that were directed toward reducing medication error. There were five studies conducted at three different MTFs. The research hypothesis $H1$ stated that the medication PSR rate prior to the LSS study would be greater than the PSR rate after the study. The five studies combined, showed a total reduction of PSRs from 462 to 407 but the reduction in PSR rate was not statistically significant. One of the LSS studies did show a statistically significant reduction of the PSR rate. Although the results did not give a decisive answer to the research question, it did provide credible evidence that LSS, if applied correctly, may reduce medication error. The findings also produced inquisitive insight into how the principles of HRO should be intertwined with the interventions of process improvement initiatives to create more long-term success.

Key words: Lean Six Sigma, High Reliability Organization, medication error

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<div align="center">**Section 1: Foundation of the Study**</div>

American healthcare organizations have never felt such urgency to increase the value of patient care. Financial, ethical, and safety issues have combined forces to compel leaders in the industry to develop new business models that will improve safety and the quality of care while creating an efficient delivery system (Kaplan, 2013).   One of the most prolific methodologies used in industry today is Lean Six Sigma (LSS). LSS is a data-driven quality management strategy used for solving problems, creating value and reducing defects (Özkan, 2017).   This dissertation is a study of the utility of interventions generated by LSS in their application to the reduction of medication errors at Naval Hospitals.

Background of the Problem

Almost 20 years ago, the Institute of Medicine (IOM) published two reports that shocked the public and sent the healthcare industry scrambling for solutions. The publication *To Err is Human: Building a Safer Health System* was released in 1999 (Kohn, Corrigan, & Donaldson, 2000). The authors conservatively estimated that 98,000 deaths annually were the result of medical errors and that these errors cost Americans over $30 Billion annually. The cost related to suffering and loss of trust is incalculable. Two years later, the IOM published *Crossing the Quality Chasm: A New Healthcare System for the 21st Century*. In this report, the committee gave broad recommendations for national priorities such as (1) creating better methods for applying knowledge to practice, (2) applying information technology to clinical care, (3) creating payment policies that encourage innovation and improvement, and (4) enhancing educational programs to strengthen the healthcare workforce. (Committee on Quality of Health Care in America, 2001). In subsequent studies, researchers, using updated data and new methodology for calculating deaths, estimated the count was closer to 210,000 deaths caused by medical error.

Some less-conservative researchers put the number as high as 400,000 (Pronovost, Cleeman, Wright, & Srinivasan, 2016).

Medication errors. The following four major conclusions came from the IOM reports: (1) medical errors are common and very costly, (2) systems cause errors, (3) errors can be prevented and safety can be improved, and (4) medication-related adverse events are the single leading cause of injury. In one epidemiological study, the researcher estimates that at least 1.5 million Americans are injured from medication errors every year. It was also estimated that every hospitalized patient is subject to at least one medication error every day (Yip & Farmer, 2015).

A medication error is defined as an "error in the prescription, dispensing, or administration of a medication with the result that the patient fails to receive the correct drug or the indicated proper drug dosage" (Merry & Anderson, 2011, p. 744). Children are particularly vulnerable to medication-related problems (MRPs) because of the immaturity of physiological systems and the risks involved in diluting medications (Merry & Anderson, 2011). Older people are susceptible to MRPs because they generally consume more medicines and their physical or cognitive deficiencies sometimes impair their communication with healthcare providers. MRPs most commonly occur when patients are transferred across different healthcare settings (Claeys, Nève, Tulkens, & Spinewine, 2012). Most preventable MRPs, that cross barriers to patients, occur in surgical units, intensive care units, and pediatric units (Nguyen et al., 2013).

High reliability organizations. Since the IOM reports were published at the turn of the last century, healthcare organizations have tried to emulate high reliability organizations (HROs) such as nuclear power, chemical processing, commercial aviation, and military operations (Carroll & Rudolph, 2006). These industries have proven themselves by successfully engaging

in high-risk activities, in dangerous environments, with very few adverse events (Claeys et al., 2012). In 2013, while representing the Joint Commission, Chassin and Loeb (2013) stated that establishing programs in LSS are the best way for healthcare organizations to improve safety and the quality of care. Their strategy for making healthcare an HRO rests on the following three pillars: (1) leadership engagement, (2) a culture of safety, and (3) robust process improvement (Chassin & Loeb, 2013).

Prioritization. During the last decade, The U.S. commercial aviation industry achieved reliability in passenger safety well above the sixth sigma (3.4 defects per million opportunities), causing only one death from air travel in over 100 million flights (Federal Aviation Administration, 2017). The aviation industry does not achieve Six Sigma level in everything it does. The aviation industry has focused great resources on achieving safe travel. They have not been as successful in getting luggage to the right place at the right time, avoiding delays, or garnering passenger satisfaction with in-flight meals. Because there is always a scarcity of resources, high reliability requires prioritization. Organizations must focus their resources on the most important aspect of the business.

When healthcare researchers and practitioners focus on singular problems, they have demonstrated great success in reducing errors. Two good examples are the case of central catheter-related blood stream infections and ventilator-associated pneumonia (Aboumatar et al., 2017). The challenge in healthcare is that healthcare delivery organizations want to be perfect in everything. The healthcare industry wants hospitals with zero infections and zero accidents. They want zero errors in surgical procedures, emergency treatment, medication delivery, and laboratory analysis, because they all involve the safety and well-being of human souls. Subsequently, healthcare professionals try to focus their resources on everything at the same

time and dilute their effectiveness.

   Lean Six Sigma. LSS gives an organization the tools to build teams that can focus

exclusively on the most perplexing problems in healthcare. LSS is process centric and

interventions are based on measurement and data analysis (Antony, Snee, & Hoerl, 2017). The

implementation of process changes includes a control plan to ensure continuity for the future. In

theory, a successful process improvement program, gives a healthcare organization the tools to

focus on each critical process, given enough time. If these improvements are sustained, an

organization can gradually mature toward high reliability with the goal of zero defects

(Yaduvanshi & Sharma, 2017). The other two pillars of HRO, culture of safety and leadership

engagement, enable process improvement by creating an environment free of fear where staff

members are focused on customer satisfaction and preoccupied with safety.

Problem Statement

   The general problem is medication errors are the single leading cause of injury in the

U.S. healthcare system. This problem was one of the findings from the landmark IOM reports

covered in the background section (Committee on Quality of Health Care in America, 2001;

Kohn et al., 2000). Since 2001, many researchers have confirmed this ongoing problem in peer

reviewed publications and books (Boytim & Ulrich, 2018; Frankel, Leonard, & Denham, 2006;

Merry & Anderson, 2011; Nguyen et al., 2013; Salima, Senior Instructor, & Midwifery, 2017;

Shi & Singh, 2017). In response to the general problem of medical error, The Joint Commission

advocates the application of the principles of HRO using the LSS methodology as a strategy for

reducing variation, error, and waste. Their recommendation is supported by significant evidence

of successful best practices in other industries (Anthony, Wiencek, Bauer, Daly, & Anthony,

2010; LeMahieu, Nordstrum, & Cudney, 2017; Özkan, 2017). However, LSS has not yet proven

its validity in healthcare. The effectiveness of LSS has not been studied extensively because it is

difficult to detect and measure errors in the health industry. As Pronovost et al. (2006) state, the

industry lacks empiric evidence to show the improvements in safety and quality of care.   The

fundamental method of measuring reliability using LSS in healthcare is recording defects that

can be measured as a rate. A valid rate requires a defined numerator (defects) and a denominator

(population at risk). Current, publicly reported metrics are insufficient because these measures

apply to less than 10% of the actual hospital discharges (Pronovost et al., 2006). Healthcare

lacks a strong framework to routinely measure problems and the magnitude of those problems. It

has been difficult to gauge the extent of problems because healthcare organizations all use

different measures for the same errors and provide little investment in measurement (Pronovost

et al., 2016).

The specific problem to be addressed is that very little research has been done to validate

the effectiveness of the LSS methodology in reducing medication error which is still the most

prolific cause of avoidable harm to patients (Trakulsunti & Antony, 2018; van de Plas et al.,

2017; Yip & Farmer, 2015).

Purpose Statement

The purpose of this quantitative, pre-post causal-comparative study is to determine the

effectiveness of LSS in reducing medication errors as it has been applied at Navy Medicine

hospitals. LSS has been adapted to many different functions in hospitals and clinics of the Navy

but only a portion of those projects apply directly to patient safety. This study will focus only on

the processes of medication delivery and how the Navy has applied these tools to reduce the

occurrence of error. The intent of this study is to discover any correlation between the

completion of an LSS study and an actual reduction of medication error and to make inferences

about the cause of those reductions in error. This study may contribute substantial evidence to

support a hypothesis about LSS and its application to medication administration. Evidence from

the results of this study may influence the way LSS projects are conducted at Naval hospitals in

the future.

Nature of the Study

      This research study will use a quantitative, non-experimental research method to test the

theory presented by Chassin and Loeb (2013) who stated that if Lean, and Six Sigma frameworks

were applied in healthcare, the industry would increase safety and the quality of care. This study

will focus on LSS projects chartered specifically to reduce medication errors in Navy Medicine.

The design of the study is causal comparative.

      Discussion of methods. Quantitative research is generally described as an examination

of the relationship among variables for the purpose of testing theories. By measuring variables,

the researcher can extract numerical data and use statistical procedures to make inferences about

the variables and how they relate to each other. Quantitative research tests theories deductively

using closed-ended questions. A quantitative report typically includes a review of literature, a

discussion of current theory, methods, and results. The results should explain how the researcher

protected against bias and should be in a format that other researchers can replicate (Creswell,

2014). The quantitative research method was selected because the nature of this study is best

suited for quantitative evaluation. The purpose of the study is to find empirical evidence

supported by statistical testing that LSS has been an effective tool in reducing medication error at

Navy hospitals. Since the variables are numerically measurable, statistical methods may be used

to establish correlation between variables and to make inferences about the cause-and-effect of

those variables. The researcher hopes that the study will be replicated and that the results

will contribute to the body of knowledge about the contribution of LSS to healthcare safety.

Qualitative research is a method of discovering the meaning that individuals or population demographics ascribe to human or social problems. Data is collected in the participant's setting and analysis is usually inductive, moving from the specific to the general. The research is driven by open ended questions and focuses on finding meaning in very complex settings (Creswell, 2014). Stake (2010) explained that qualitative research emphasizes human experience in described situations both personal and in organizational settings. It is interpretive but can also be experimental and empirical when evidence is well triangulated. It is almost always situational and what Stake described as personalistic. Stake interpreted the trend in social science as a movement away from the emphasis on cause and effect and toward personal interpretations. Qualitative studies help researchers understand what is happening, not how to improve what is happening (Stake, 2010). The qualitative research method was not selected for this very reason. The science of improving processes is, by its very nature, focused on how to improve the process that is under examination. To make effective interventions in healthcare, researchers need more data driven evidence of causality and less personal interpretation. Personal interpretation is often biased or distorted. Formal theory, based on quantitative research, is needed to develop interventions that will be effective (Davidoff, Dixon-Woods, Leviton, & Michie, 2015). Quality improvement studies are often very poor at describing the theoretical basis of the interventions. As a result, the outcomes are often not as good as expected (Dixon-Woods, Bosk, Aveling, Goeschel, & Pronovost, 2011). Quantitative data is critical in this process of developing quality improvement theory.

Mixed methods research is an approach that integrates the quantitative and qualitative methods. In some studies, a more comprehensive understanding of the research problem can be

attained if the researcher uses a combination of both quantitative and qualitative methods. Some

problems may require the involvement of philosophical assumptions and a theoretical framework

where a complete understanding may not otherwise be possible. The development of the

methodology was also driven by the concept that both qualitative and quantitative methods have

certain biases and weaknesses. By combining both methods, the weaknesses could be

neutralized (Creswell, 2014). According to Tashakkori and Creswell (2007) a successful mixed

methods study should demonstrate the following: (1) distinctly identifiable qualitative and

quantitative components, (2) identifiable conclusions based on qualitative and quantitative data

analyses, (3) the integration of qualitative and quantitative strands and reach conclusions that are

more meaningful than those of a qualitative or quantitative strand alone, and (4) a need for mixed

methods to answer questions that are clearly connected to both qualitative and quantitative

components. The mixed methods approach was rejected for this dissertation because the

researcher could not demonstrate all these requirements.

Discussion of design. This quantitative research will take the form of a pre-post causal

comparative design. The researcher will compare the error rates measured before and after an

LSS team has modified the independent variables. Creswell (2014) described causal-

comparative research as the comparison of two groups to make an inference about cause when

the independent variable has already been applied. In the Dictionary of Nursing Theory and

Research, causal-comparative studies are called correlational research where two or more groups

are compared. These groups may be compared prospectively or retrospectively (Powers, 2010).

Causal-comparative and correlation designs are very similar. They are both non-experimental

and are both used to find a relationship between dependent and independent variables. In

correlation studies, researchers are only concerned about the relationship between variables. If a

relationship exists, it may not be causal. A causal-comparative study, also called the ex-post-facto method, differs, in that the researcher tries to discover why and how a phenomenon occurs. It is similar to an experimental study, but it does not prove a cause and effect relationship between variables. Only a true experimental design can prove causation. In this regard, the name "causal" is a misnomer (Lenell & Boissoneau, 1996, p. 60).

The correlational design was not selected because correlation alone cannot contribute to the development of theory in the science of process improvement. The purpose of process improvement is to develop interventions that reduce error. Interventions in LSS studies should not be selected using correlation evidence alone. As Davidoff et al. (2015) explained, it is possible to achieve high quality interventions strictly based on intuition and experience, but it is rare, and it does not contribute to science. Using theory, based upon studies that can demonstrate causation, practitioners can greatly shorten the time needed to create successful interventions. The purpose of this study is to contribute statistical evidence supporting the theory that there is a correlation between LSS interventions and a reduction of medication error and to present evidence that certain interventions do cause a reduction of error.

A descriptive design is used to generalize facts about a population through sampling. This design is used when numeric data will be used to describe trends, opinions, or attributes. Creswell (2014) referred to this design as survey research. Descriptive design research is often used in healthcare to get data about the population's health condition, use of health services, and behaviors that may be correlated to illness (Fowler, 2009). The design can also be used to gather opinions such as the Solheim, Plathe, and Eide (2017) study of nurses in a medical education environment. Descriptive design was not selected for this research project because the data needed to demonstrate the effectiveness of an LSS study, is not available in any population. The

success of LSS interventions are determined by errors. The record of errors, in this case, is housed in a data base that can be extracted electronically.

In this research project, the LSS studies under examination will have already taken place. This is necessary to obtain longitudinal data after the LSS project is complete. The two independent groups under comparison, are longitudinal data bases of Patient Safety Reports (PSRs) before the LSS study and after. Longitudinal data is defined in this study as six months of continuous recording both before and after the LSS interventions. In this causal-comparative study, the researcher is seeking to determine if there is a statistically significant difference between the rate of medication errors recorded before and after the interventions of an LSS study. Appropriate inferential statistics will be used to determine the magnitude of the change between the two groups of dependent variables. Proportions tests will be used to determine if the post intervention group had a statistically significant reduction in the proportion of medication errors. (Lenell & Boissoneau, 1996). This study will measure the effect of LSS interventions on the dependent variable or the rate of subsequent medication errors. If there is a significant difference between the pre and post intervention data, the researcher will try to discover why and how these interventions prevented errors.

Summary of the nature of the study. The nature of this study follows a logical process to address the specific problem. Because the specific problem is the lack of empirical evidence supporting the theories of LSS application to the prevention of medication error, the method of the study is, by necessity, a quantitative study. The causal-comparative design is the most logical approach because of the barriers preventing a true experimental study. True experimentation would not be practical for this study because it would necessitate approval for the use of human subjects and the manipulation of variables in the administration of their

medications. The before-after causal-comparative study of LSS projects that have already taken

place, allows the researcher to examine the manipulations of variables that multiple LSS teams

have made independently. Using statistical tools, the researcher can make inferences about the

effectiveness of LSS projects in accomplishing their goals of improving the process of

medication administration. Comparing the medication error rates between pre and the post

intervention of an LSS project will directly answer the researcher's question: is LSS a viable tool

in reducing medication errors? This study could provide powerful evidence to support or reject

the theories of LSS application to healthcare.

Research Questions

The following general research question will provide a foundation for this study: Does

Chassin and Loeb's theory of LSS effectiveness in changing healthcare processes explain a

change in medication PSR rates after the intervention of an LSS study targeting medication

errors? If it is discovered that there is a correlation between the dependent and independent

variables, the researcher will explore the following question to make inferences about causation:

Can the differences in data groups be attributed to the interventions instigated by the LSS

studies?

Hypotheses

The research hypothesis, $H1$, for this project is stated as follows: The preintervention

PSR rate will be statistically larger than the postintervention PSR rate for medication errors. The

null Hypothesis H1o is stated as follows: There is no statistically significant difference between

the preintervention medication PSR rate and the post intervention PSR rate for medication errors.

This hypothesis attempts to directly answer the general research question by providing

evidence to support the supposition that LSS projects are correlated to a lower PSR rate when

applied to the process of medication administration. Due to the nature of the causal-comparative

design of this project, the research cannot prove causation. The researcher will attempt to show

correlation between LSS interventions and lower PSR rates. If the results are significant, the

researcher will attempt to link specific interventions to improvements and support a case for

causation.

Conceptual and Theoretical Framework

In quantitative inquiry, the researcher seeks to test theory, not to develop it. In the

postpositivist worldview, specific causes determine the effects or outcomes. The reductionistic

framework reduces ideas down into small discrete sets that can be tested (Creswell, 2014).

Using deductive reasoning, a theory should provide an explanation of why the dependent

variable *Y* would be influenced by the independent variable *X*. Theories emerge when

researchers test a predictor many times and receive consistent results (Creswell, 2014). Theory

presents a systematic view of the relations of variables that can explain and predict phenomena.

Theories often come in the form of definitions, concepts and interrelated constructs that support

this view (Kitchel & Ball, 2014).

Theory of Robust Process Improvement. The theory that explains the relationship

between the independent and dependent variables in this study is Robust Process Improvement

(RPI) which is the application of LSS and Change Management to healthcare. In the direct

application to medication administration, this theory suggests that if a hospital uses the LSS

methodology to modify the independent variables (steps of the medication process) they can

expect to see a reduction in the dependent variable (medication errors). Although an informal

theory, RPI has been the rationale and driving force for the application of LSS and change

management in healthcare.

The principles of high reliability were developed in the late 80s by Roberts and Rousseau (1989), professors at the University of California. They recognized that some industries operated in high-risk environments yet continued to maintain extremely high standards of safety. Some of these industries included nuclear power, commercial aviation, the chemical industry, and military operations. Roberts and Rousseau developed a list of characteristics that were common to all HROs. It was the principles of HRO that inspired researchers during the next decade to develop theory about how the healthcare industry could develop these characteristics. The characteristics will be explained in more detail in the literature review.

The theory of RPI is part of a more intricate concept called the three pillars of HRO. The first two pillars are Leadership and Culture of Safety. The third pillar, which is dependent on the first two pillars, is RPI. This theory was advanced by Mark Chassin in 1998 when he was Vice President of Excellence in Patient Care at Mount Sinai Medical Center (Chassin, 1998). He asked the question: is healthcare ready for Six Sigma? After comparing the sigma levels of HROs to the inexplicably dismal safety record of healthcare, he concluded that there will never be enough incentive to advance process improvement in healthcare until the public is aware of the magnitude of this problem. A year later, the IOM provided that public awareness with a report titled *To Err is Human: Building a Safer Health System* (Kohn et al., 2000).   Frankel et al. (2006) advanced the concept of high reliability in healthcare when they outlined the requirement of leadership to be engaged in the advancement of the tools of high reliability. Fei and Vlasses (2008) outlined the connection between the culture of safety and high reliability science. Three years later, Chassin and Loeb (2011) melded these three concepts together in what they called the three requirements of high reliability. Here, for the first time, they referred to the third pillar as Robust Process Improvement. In 2013, as leaders of the Joint Commission, Chassin and Loeb

(2013) further refined this theory in their historic paper, *High-reliability health care: Getting there from here*.

Historically, the healthcare industry has been slow to embrace LSS. Researchers are beginning to advanced RPI theory in healthcare. Although some research has been done, empirical evidence is still lacking, especially in the application of LSS to medication error (Langabeer, DelliFraine, Heineke, & Abbass, 2009). According to Chassin and Loeb (2013), RPI is based on the premise that the interventions from LSS projects in healthcare will have the same power to solve problems in healthcare as it has in manufacturing and other industries. In their conceptual framework for achieving high reliability in healthcare, Chassin and Loeb (2013) explain how they combined knowledge of health care organizations, literature from experts in high reliability industries, and studies from safety scholars outside healthcare. In their theory of RPI, the tools of LSS radically reduce the frequency of defective outcomes by markedly improving processes. When leadership is engaged in change management, an organization learns to systematically implement and sustain these process changes. These complementary tools, LSS and Change Management, are the best available methods for improving processes (Chassin & Loeb, 2013).

Lean Six Sigma. LSS reduces errors in medication delivery through the power of its methodology and organization. Teams redesign processes to produce less variation and fewer defects. LSS follows a prescribed scientific approach to problem solving referred to as DMAIC (define, measure, analyze, improve, and control). This methodology, when used to reduce errors, begins with a definition of the problem. By defining the problem and establishing a charter, the team focuses its resources on one specific process. The measurement phase ensures the team is using data-driven evidence to show where errors are occurring and to document the significance

of the errors. Armed with quantitative data, the team analyzes the root causes of the problem and maps the location of their occurrence through process mapping and value stream analysis. In the next phase, the team designs interventions to address the specific root causes defined in the analysis phase. Using the power of the organization, the team gathers the process owner, the champion (senior leader), and other process experts to implement the changes that will eliminate or reduce the occurrence of the defined problem. The team monitors the results during a validation period to ensure that the interventions (independent variables) have significantly reduced the occurrence of the error, known as the dependent variable. The final and ongoing phase is the control plan which is designed to sustain the improvements to the process. The team delivers the new process to the process owner with a plan to control and monitor the metrics. This control plan establishes trigger points that signal the process owner in the event of a relapse of the process (Liberatore, 2013; Pocha, 2010). Figure 1 illustrates the researcher's interpretation of the relationship between theory and variables in LSS methodology. LSS theory is process-centric. It is based on Deming's concepts that systems are to blame for human error (Deming, 2000). In LSS theory, process steps can be modified to improve proficiency and to reduce variation and defects by avoiding or negating the influence of the root causes of error. In most process improvement studies; teams analyze the current process (all the independent variables X) and determine the most significant causes of error. The team redesigns the process to reduce the probability that humans, machines, or material will fail (Kaushik & Kumar, 2017).

 Change Management. Based on the success of many other industries, Chassin and Loeb (2011) predicted that healthcare can receive the same benefits if healthcare organizations make RPI a common language throughout the organization. LSS should be applied to all process improvement work and every employee should be involved in LSS. They suggest that LSS

should be a part of every performance appraisal and should be a requirement for advancement in

the company. This total commitment to the LSS framework is the best way to reduce errors in

medicine and improve quality of patient care (Chassin & Loeb, 2013, p. 481). This concept was

also asserted by Aboumatar et al. (2017) who explained that high reliability cannot be achieved
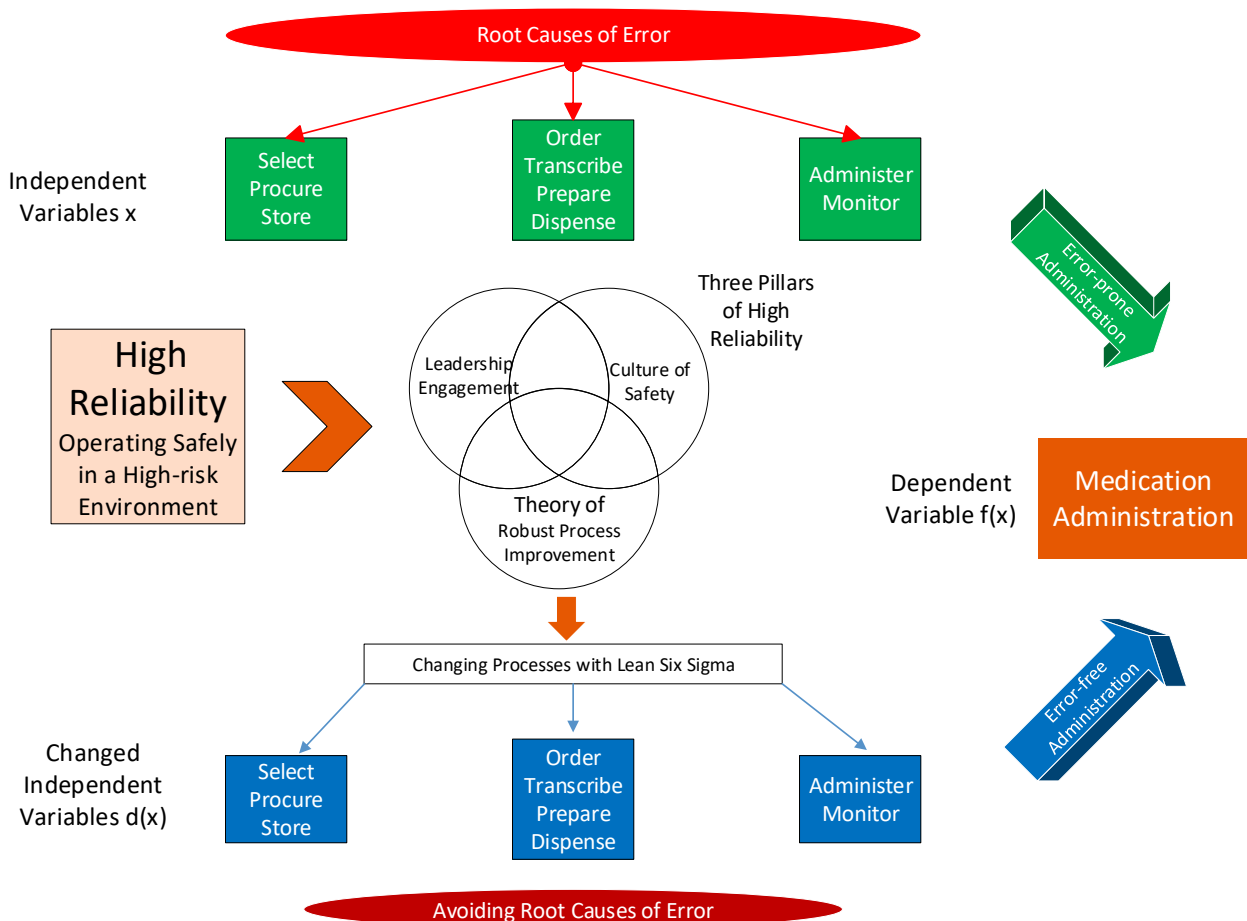
Figure 1. Relationships between theory and LSS variables. The steps of medication

administration (green) are vulnerable to many root causes of error. The concentric rings of high

reliability are intended to transform the process (blue) in a way that will protect it from these root

causes of error and create error-free administrations. The steps of the medication process are

independent variables that are modified during an LSS study. The dependent variable is the

actual administration of a medication.

without extremely high levels of engagement and performance from every member of an organization. Although very supportive of the concept, Aboumatar et al. (2017), interpret it somewhat differently. Where Chassin and Loeb suggest that Change Management means every staff member should be involved directly with process improvement, Aboumatar et al. (2017) were referring to individual competency. LSS is an important part of change management but not everyone in the hospital needs to be proficient in LSS. Each individual should be a high performer in their specialty.

        Summary of the conceptual framework. The theory of RPI, as presented by Chassin and Loeb (2013), will be used to explain the relationship between the dependent and independent variables as it is applied to the process of medication administration.   This theory suggests that LSS is the most effective way to improve safety and the quality of care because the methodology provides structure for redesigning processes to reduce variation and error. The principles of LSS, combined with effective Change Management, form the foundation of the theory upon which this research will be conducted. *Figure 1* is a graphic depiction of the interrelationship of HRO, RPI, and the variables of the medication administration process.

Definition of Terms

        A sigma level equates to 1 standard deviation. The standard deviation is a mathematical descriptive statistic of variation represented by the Greek letter "sigma" (LeMahieu et al., 2017, p. 91).

        The sigma shift refers to a phenomenon defined by Smith and Mikel during the development of LSS at Motorola. In the long term, a process will naturally shift 1.5 sigma levels (Harry, Schroeder, & Schroeder, 2000; Smith & Bellefeuille, 1993). The significance of this prediction is that an LSS practitioner must achieve a level of 6 sigma (2 defects per billion

opportunities) in the short term to maintain a sigma level of 4.5 (3.4 defects per million

opportunities) in the long term. This explains why practitioners usually refer to the 6th Sigma as

3.4 defective parts per million opportunities (DPMO) (Özkan, 2017).

Assumptions, Limitations, Delimitations

The following assumptions, limitations, and delimitations are recognized by the

researcher for this study. The primary metric for this study is the PSR. As stated earlier,

healthcare lacks a robust system for measuring the number of errors and their magnitude.

Although self-reported safety incidents are weak, they are still the best source of readily

available data highlighting safety events. PSRs are the main limitation of this study because of

the assumptions that must be made about reliability of the data.

Assumptions. Certain assumptions must be made about PSRs. First, that self-reported

data represent only 10% of actual errors (Pronovost et al., 2006). It is also assumed that the most

significant errors are reported at a much higher rate. As Chang and Mark (2009) explain, severe

errors are reported at a much higher rate, probably approaching 100%, because they are much

more difficult to ignore or hide. Non-severe errors are routinely ignored when staff members are

busy or do not think the error is significant enough to report.

Limitations. The primary limitation of this study is the use of PSR data. A much more

accurate collection of error rates would involve actual observations of medication administration

samples. The researcher, in this case, does not have the resources to train experts to conduct an

extensive collection plan. A sophisticated collection scheme requires extensive manpower and

may be disruptive to normal operations in a medical ward. This study will depend exclusively

on self-reported incidents.

Delimitations. This study is delimitated by the number of actual LSS studies performed

at Naval healthcare installations during the past ten years. Five LSS projects were identified as

meeting the criteria for this study. These five projects were performed at three different

hospitals. They all involved the reduction of inpatient medication error.

Significance of the Study

Because so little research has been done on the application of LSS to the reduction of

medication errors, this study will contribute significantly to the body of knowledge currently

available on this specialized topic. In a review of 140 articles on quality improvement in

healthcare and LSS, Langabeer et al. (2009) found that 75% of the studies were subjective or

articles of conceptual review. Very few employed any quantitative data. Twelve percent of the

articles used pre-post analysis of a single case, but no effort was made to control or moderate the

environment or confound the factors that might have influenced the changes. No equivalent

surveys have been conducted since 2009. In this study, the researcher will examine multiple

LSS studies conducted at different hospitals. By quantitatively studying the results of multiple

LSS studies targeting medication error, the researcher intends to add empirical evidence to the

body of knowledge about LSS and the reduction of medication errors.

Reduction of gaps. The gap is between what researchers think LSS can do in

healthcare, specifically for the reduction of medication errors, and what researchers have tested.

As more healthcare organizations embrace LSS, more researchers will have the opportunity to

study the effects of LSS projects on longitudinal error rates. Currently, there is significant

literature on the study of medication errors. Researchers know a lot about how when, and

where they occur. Because medication errors are the most prevalent risk to patients, it is also

the most studied phenomenon in healthcare. There are a moderate number of studies on LSS in

healthcare, but few demonstrate strong quantitative evidence supporting the connection

between LSS interventions and the long-term measurable dependent variables. There are only a few studies that specifically study LSS and medication errors. By conducting this study within Navy Medicine, with its multiple hospitals that have deeply embedded LSS programs, it is possible to test the theories of LSS in healthcare and close the knowledge gap between theory and evidence.

      Implications for Biblical integration. The basis for the framework of Six Sigma is reducing variation to the point that humans can almost eliminate the probability of error. Mathematical formulas that represent distributions, suggest the attainment of perfection is impossible, but the goal in reaching the sixth standard deviation is recognized as a worthy goal and probably close to the best humans can expect to achieve in industry. Improving business processes has become essential, not just for advantage, but for survival. It is fitting that this basic creed of doing no harm, continuous improvement, and striving for perfection is also the basis of most biblical teachings. The primary difference is that Six Sigma focuses on improving the creations of men. God's focus, in biblical writings, is on the perfection of His creation—Man.

      The very design of this mortal world is one of imperfection. It is a world where disease, accidents, mutation, and infirmities are expected probabilities of existence. One might argue that the brilliance of this mortal creation is displayed by the ability of the earth and its living inhabitance to sustain life despite their imperfection. But this researcher supports the proposition that the imperfections of this mortal world are intentional and provide men an opportunity to improve their estate. The definition of estate in this case would be the character, capability, and capacity of men to do good. Jesus Christ taught his disciples to be better than the world, not to be superior, but to be effective servants and ministers. "Let your light so shine before men, that

they may see your good works, and glorify your Father which is in heaven" (Matthew 5:16, KJV). In the Acts of the apostles, Luke wrote, "For so hath the Lord commanded us saying, "I have set thee to be a light of the Gentiles, that thou shouldest be for salvation unto the ends of the earth" (Acts 13:47). In Paul's farewell to the Corinthians he wrote, "Be perfect" (2 Corinthians 13:11), and the Savior said, "Be ye therefore perfect…" (Matthew 5:48). This continuous striving to become better, is how men earn the privilege of leading and serving others in His ministry. The Savior told his followers to first, pull the beam out of your own eye, then help your brother remove the mote from his eye (Luke 6:41). Jesus Christ, being of perfect stature, is the perfect minister and healer. In healthcare, the providers of health services are continually striving to be worthy ministers of their patients. It is a commendable goal in medicine to seek perfection. Not until the providers of medicine can honestly declare that they "do no harm," can they ever become true healers of the sick.

Relationship to field of study. The Healthcare Management Cognate is an exploration of the challenges of healthcare. Most of the courses in the study of healthcare are related to the industry's efforts to provide safer, less expensive, and higher quality healthcare. In healthcare informatics, students learn about the new innovative information technology that helps reduce error by giving patients and providers more information (Nelson & Staggers, 2014). In healthcare administration, students learn about the burgeoning costs of healthcare in this country while the quality of care is still below most industrialized nations. Healthcare students also study legal and ethical issues in healthcare. One of the most significant factors in the rising cost of healthcare is the burden of insurance and malpractice lawsuits. The industry continues to struggle with negligence in the practice of medicine (Pozgar & Santucci, 2016). This study of process improvement, with a focus on medication errors, is at the heart of the

challenges in healthcare. Healthcare is on the edge of major advancements in the discipline of quality improvement. This study, and many that will follow, will pave the way for significant reduction in common errors in healthcare and bring the industry closer to high reliability.

Summary of the significance of the study. Very little empirical evidence is available to support the use of LSS in reducing medication errors in healthcare. The significance of this study is in its defined effort to reduce the gap between the theory of what LSS can do, and what has been proven. Closing this gap in healthcare is challenging because of the limitations of current safety measurement systems. By making certain assumptions about the reliability of PSR data, the researcher intends to show a statistically relevant improvement in the PSR rates after LSS interventions.

As a doctoral student at Liberty University, the researcher is obliged to demonstrate a connection between his work and biblical teachings. In this case, the connection is convincing. The Bible is God's training manual to improve and perfect the souls of men. Those that apply its principles become better people. LSS is a human framework designed to perfect the enterprises of men. Those organizations that use it, become progressively better. It might be too presumptuous to call LSS an extension of God's work. To be safe, the researcher simply claims a significant integration with biblical principles.

This study delves into the heart of the problems of healthcare business. The greatest challenges in healthcare stem from poor safety, low efficiency, and high costs (Shi & Singh, 2017). LSS is the champion upon which healthcare leaders are casting their hopes and their resources. This study is an effort to test their theory.

A Review of the Professional and Academic Literature

This literature review consolidates some of the most significant studies that relate to

the topic of LSS and medication error. The first section is an examination of theory in the

science of process improvement and an outline of RPI. The second section is a collection of

articles on the dependent variable--medication error. It begins with a general review of the

nature, the cause of medication error, and some proposed solutions. The third section contains

an overview of the general applications of LSS to the independent variables. The first subsection

is a review of LSS application to industry in general. It is a review of the development and

current state of LSS. The second subsection is a discussion of the connection between High

Reliability and LSS and how the medical industry is applying techniques from aviation to

improve safety and the quality of healthcare. The third subsection is a review of articles where

LSS was applied directly to healthcare.

The fourth section is a review of LSS studies that were designed specifically to modify

the independent variables in the process of medication administration. These are all studies

created to reduce medication error. This section is broken down into the three subsections of the

process: pharmacy, prescriptions, and nursing.

The fifth section contains a review of articles about existing strategies for reducing

medication errors using information technology.   This review will focus primarily on Six Sigma

and the reduction of variation and error, rather than Lean and the reduction of waste. This aligns

with the purpose of the study, to determine the effectiveness of LSS in reducing medication

errors. The sixth and final section is a summary where the researcher will present all the key

concepts from the review in an organized and condensed format.

Theory in Process Improvement. Formal theory is a difficult commodity to find in

the science of process improvement and more difficult to find in healthcare improvement. The

reason for this lack of theory is outlined in a brilliant article by Davidoff et al. (2015) called

Demystifying theory and its use in improvement. He and his colleagues explain that "many

professionals, including improvement practitioners, are unfortunately mystified and alienated by

theory, which discourages them from using it in their work" (p. 228). Many practitioners believe

theory is superfluous to process improvement. Davidoff made a case for the need for effective

formal theory in process improvement by claiming that formal and informal theory is already

woven into every process improvement endeavor. Although theory is always present,

practitioners are usually not aware of it and do not make it explicit in their studies. Theory is

essential to process improvement for the following three reasons: (1) personal intuition is often

distorted and biased, (2) formal theory maximizes learning and the accumulation of knowledge,

and (3) theory promotes the transfer of learning from one project to the next (Davidoff et al.,

2015). The authors suggest that process improvement practitioners and managers need theory to

help design the best interventions. However, where clinical researchers may follow rigorous and

fixed protocols in hypothesis testing studies, practitioners are more likely to rely on experiential

learning cycles of interventions and repeated adjustments.

A good example of a formal theory in healthcare process improvement comes from the

Michigan project by Dixon-Woods et al. (2011). The researchers used theory-oriented methods

to develop an ex post theory about a Michigan intensive care unit improvement project that

reduced the rate of central venous catheter bloodstream infections. Dixon-Woods et al. (2011)

employed three steps: (1) identified the initial theories of change, (2) added new information in

the form of theoretical contribution, and (3) synthesized the information to create an updated

theory (p.167). The article was an excellent outline of the approach, the interventions, and the

successes of the project. The outline of the original program theory is very clear. The authors

identify six steps, each with an associated hypothesis, in the conceptual framework. However,

the explanation of the development of new theory is lost in the dialog. The new theory is never

succinctly stated as with the original theory. This inability to formulate a cohesive new theory

probably lends more evidence to Davidoff's claim that most practitioners are mystified by

theory. The researchers stress the importance of understanding program theory when

interventions involve complex social interventions. The success of the Michigan project hinged

on the community-based model. Establishing community bonds led to strong peer monitoring

and allowed lessons to be shared.   Failure to understand the theoretical dynamics of this social

structure would likely have led to failure (Dixon-Woods et al., 2011).

The researcher found one LSS study based on formal theory that addressed medication

error. In this project, the researchers were attempting to reduce medication administration errors

by eliminating all interruptions. Nelms and Treiber (2011) based their approach on theory

established by Watson (2006) called the Carital Model. The model is based on the following

three precepts: (1) practice loving kindness, (2) authentically present oneself to patients, and (3)

develop and sustain a trusting relationship. The theory is based on evidence that practicing

kindness towards self, patients, families, and other staff will benefit nurses and their patients. An

important part of this concept is that nurses need to center themselves by stopping and reflecting

before moving from one patient to the next. Watson recommends that this self-centering take

place during hand washing in what she calls the Zen of handwashing. This is the time when a

nurse clears her/his mind of previous patients and cares, to be in a proper condition to move on

to the next patient. This centering helps nurses practice with calmness under stress. The final

element of this model is a systematic completion of the steps of a medication review such as

verifying medication orders, checking the seven rights, verifying allergies, verifying names etc.

This practice of centering and developing authentic presence has the potential to enhance the

critical elements of nursing (Nelms & Treiber, 2011). Although the article was very interesting and perhaps profound in its allegation of the power of a caring system, one might suspect that this article supports Davidoff's assertion that improvement practitioners are alienated by theory. The idea of Zen washing, authentic presence, and loving kindness might confound a very systems centric LSS Black Belt trying to re-engineer a process.

RPI was designed as a theory for practical application of process improvement in healthcare. The new approach of change management, Lean and Six Sigma, are more robust at solving persistent safety and quality problems than any other tool (Chassin & Loeb, 2013). Together, they were called Robust Process Improvement. If effectively applied in healthcare, organizations can avoid critical failure common in clinical care. The framework for this theory is grounded in high reliability science and considerable experience of experts applying principles of HRO in healthcare (Chassin & Loeb, 2013). The Agency for Healthcare Research and Quality (AHRQ) contributed significantly to the research supporting efforts to improve the quality and safety of healthcare and testing process improvement theory (Dixon & Shofer, 2006). Others who have contributed to the establishment of this theory are Fei and Vlasses (2008) who furthered work on reliability science and the culture of safety. Frankel et al. (2006) described the importance of leadership engagement in change management. May (2013) applied RPI to clinical work at the nursing level. The rest of this literature review is dedicated to exposing the problems in medication administration and finding researchers who have tested and enlarged the theory of RPI in its application to the administration of medications.

Medication error. The length and breadth of articles on medication errors is so large, it was difficult to know where to begin. Some studies were of a very general nature, targeting many sources of medication errors. Others focused on the pharmacy that prepared the drugs or

the nurses who administer them. Keers, Williams, Cooke, and Ashcroft (2013) completed a study

aimed to systematically review empirical evidence about the cause of all medication

administration errors (MAEs). They reviewed 54 unique studies and classified MAEs according

to Reason's model of accident causation. They determined that the most reported unsafe acts

were slips and lapses in judgement. The second most common mistakes were knowledge-based

errors and deliberate violations. A host of other violations included communication errors such

as in documentation or transcription. Pharmacies contributed errors through dispensing errors

and wards contributed with supply and storage issues. Nursing and patient issues were also an

important part of the study (Keers et al., 2013, p. 1045).

   Pharmacy errors. This article by Goldspiel et al. (2015) is a report from the American

Society of Health-Systems Pharmacy (ASHP). It is intended as a guide for pharmacy operations

in hospitals for the treatment of cancer patients with chemotherapy and biotherapy agents.

Although this list of best practices is directed to the prevention of errors in the use of these

cancer fighting agents, the authors explain that these practices can be broadly applied to the

entire medication administration system.   This comprehensive guide of best practices include

recommendations for (1) prescribing systems and prescribers, (2) medication preparation and

dispensing systems and the roles of pharmacists, (3) the role of nurses in the medication

administration system, (4) the importance of patient education, (5) manufacturers and regulatory

agencies, and (6) ways to identify and manage medication errors (Goldspiel et al., 2015, p. 7).

Under recommendations for medication preparation and dispensing systems, the authors explain

the importance of (1) medication labeling, (2) dosage calculation, (3) instructions to patients, (4)

route of medication administration, (5) instructions for administration including warning labels,

(6) expiration dates and cautions, and (7) storage specifications (Goldspiel et al., 2015, p. 26).

Under guidance on the role of the pharmacists, the authors explain that pharmacists are to ensure

medications are used safely and rationally. They are also commissioned to increase awareness

among hospital staff on potential medication errors. The guidelines are extensive and

comprehensive and are not detailed here. This article is an excellent reference for best practices

of medication administration. The article provides guidance on what should happen in correct

medication administration but does not contain any guidance on how to establish systems that

would ensure these best practices are used.

     As president of the Institute for Safe Medication Practices and author and co-author of

many articles on medication error, Cohen (2010), played a prominent role in the discussion. In

this article, he addressed weak medication labeling practices and how they contribute to

medication errors. He discussed hazard messages and warning labels and the best and worst of

both. He explains that effective medication warning labels should have three critical

components. The first is a signal word such as danger or deadly, that draw attention to the

warning and expresses the importance of the label. The second component is an explanation of

the consequences of deviating from the instructions such as, unsafe use can cause death. The

third component is an explicit hazard message that cannot be misinterpreted. This message tells

the user specifically what to do, not what to avoid. He encourages the FDA to adopt and

disseminate standard guidance on labeling pharmaceutical products (Cohen, 2010).

     Another study, conducted by Cochran and Haynatzki (2013), compares the medication

error rates of three different hospital categories.   The three hospital classes are based on size

(census), availability of a pharmacist, and bar-coding. The primary objective was to document

error rates between three classes of hospitals. The secondary objective was to identify predictors

of these errors. The study involved nine critical access hospitals (CAS) and included the

observation of 3,103 medication passes. Forty-four errors were identified of which 13 did not

reach the patient. Of the 31 errors that did reach the patient, some required monitoring but none

caused harm. Human factors and communications were the two most frequent causes of error in

all the systems. In smaller CAS hospitals, with daily census of five or less, only 48% had a

pharmacist available at the hospital for more than five hours per week.   Smaller hospitals also

lacked financial strength and were slower to adopt technology. Fewer small hospitals utilized

bedside bar-code systems. The researchers concluded that the higher usage hospitals had lower

error rates, with or without bar code systems. Hospitals with the lowest error rate had on-site

pharmacist support for more than 40 hours or more per week and utilized bar-code systems.

Hospitals with more than 40 hours per week of pharmacist support and no bar-coding system had

lower rates than hospitals without 40+ hours of pharmacy support. The researchers concluded

that that bar-coding was an important variable, but pharmacists played the most important role in

preventing medication errors. In all cases, fewer errors occurred when pharmacists dispensed

medications versus other healthcare professionals. Pharmacists can prevent errors by (1)

reviewing orders, (2) reconciliating medications, (3) managing the formulary, (4) designing

medication use policies and procedures, and (5) participating in quality-improvement projects

(Cochran & Haynatzki, 2013, p. 2222).

   Nursing. Because nurses are the primary administers of medication in the hospital

setting, they are the focus of many studies on medication errors. The following articles outline

many of the issues. Pauline Cook is the New Zealand Nursing Organization (NZNO)

Competency Advisor and writes many articles on the role of nurses and the administration of

medications. Cook (2014) stated that many medication errors occur when a nurse loses

concentration, becomes interrupted, or follows improper procedures. Some of the important

factors are stressors, staff levels, workloads, and workflow. A nurse who is in poor health, whether by fatigue, stress, or depression, may contribute to the cause of errors. Cook (2014) concludes that medications are more complex than ever before and require extreme exactness. Interruptions are one of the leading variables in medication administration error.

A review of literature on nurse interruptions during medication administration is a critical piece to solving the medication error puzzle. Eight years ago, Westbrook, Woods, Rob, Dunsmuir, and Day (2010) conducted a landmark study on the impact of interruptions on nurses preparing medications in a clinical setting. They were testing the hypothesis that interruptions can cause medication errors. They studied nurses preparing and administering medications at six wards in two major hospitals in Sydney Australia. The all-volunteer sample included 98 nurses preparing and administering 4271 medications. The researchers used 12 indicators of medical errors and divided them into procedural and clinical errors. The following were the results for procedural errors. Medication administrations with no interruptions had a procedural failure rate of 69.9%. With administrations that had three or more interruptions, the failure rate increased to 84.6%. The results for clinical errors were quite different. Twenty five percent of medication administrations had a least one clinical error. Those with zero interruptions had a clinical error rate of 25.3%. With three or more interruptions, the rate increase to 38.9%. Nurse experience did not change the outcome in clinical errors, but it was associated with a higher rate of procedural errors (Westbrook, Woods, et al., 2010). This corroborates the findings of Chang and Mark (2009) who found that more experienced nurses were associated with more non-severe errors. Many other studies followed that confirmed an association between interruptions and higher error rates in medication preparation and administration (Raban et al., 2015; Westbrook, 2014; Westbrook, Duffield, Li, & Creswick, 2011; Westbrook, Rob, Woods, & Parry, 2011).

One sharp dissenting voice came from Hopkinson and Jennings (2013). Their project

was a review of all the studies on nurse interruption during the previous 10 years. They

reviewed 791 articles and selected 31 that met the criteria to be included. In their review, they

suggested that the accepted beliefs about the connection between interruptions and errors were

more "conjecture than evidence-based" (Hopkinson & Jennings, 2013, p. 38). In comparing and

contrasting these studies, the researchers raise the question about whether all interruptions are

disruptive. They reasoned that it was not clear if minimizing all interruptions was beneficial or if

there were other unintended consequences from reducing interruptions. Some of the studies

suggested that certain interruptions produced positive outcomes. In their final analysis, they

conclude that the study of nursing interruptions is still at the "descriptive, exploratory level" and

that the definitions of interruptions and methodologies for research were too inconsistent

(Hopkinson & Jennings, 2013, p. 51). They complained that even with weak evidence, some

researchers have proceeded with interventions to minimize interruptions. Hopkinson and

Jennings (2013) were probably pointing the finger at Anthony et al. (2010) who had just

completed a study on the effectiveness of creating no-interruption zones in intensive care units.

Westbrook and Li (2013) wrote a postured response to the Hopkinson and Jennings (2013)

article stating that although they were in agreement about the need for more consistent

definitions of interruptions to compare studies and develop theory, they took exception to the

statement that the connection between interruptions and errors was just conjecture. They pointed

out that the Westbrook, Coiera, et al. (2010) study clearly showed a significant association

between interruptions and the risk of major errors. Westbrook and Li (2013) also stated that

Hopkinson and Jennings (2013) had incorrectly characterized data on interruptions and the

percentage of clinical errors and thereby ignoring the stated relationship between the severity of

errors and interruptions. Westbrook and Li (2013) conceded that the impact of interruptions on nurses' work was very complex and not fully understood but felt that Hopkinson and Jennings (2013) had downplayed the empirical evidence presented.

In her response to the response, Hopkinson reiterated that of all the studies reviewed on the subject, Westbrook, Woods, et al. (2010) was the only study offering any empirical evidence and this should only be considered beginning evidence (Westbrook & Li, 2013). Hopkinson and Jennings (2013) were primarily concerned that it was too early to start intervening against interruptions. Researchers need to better understand the nature of interruptions. Some interruptions are necessary to prevent errors and there may be unintended consequences of eliminating all interruptions. Reducing interruptions reduces communications and may create an environment where error is more pervasive. The challenge is to find, identify, and sustain interruption that are contributing to safety (Westbrook & Li, 2013). The rebuke from Hopkinson and Jennings did not deter Westbrook who completed a study in 2017 that tested bundled interventions to reduce interruptions during medication administrations. The project included a plan to have acute care nurses wear brightly labeled vests reminding patients, staff, and educators not to interrupt nurses while they were preparing or administrating medications. The vests were successful at lowering interruptions, but the nurses universally rejected the notion of putting on the bulky garment every time they were working with medications (Westbrook et al., 2017).

Chang and Mark (2009) conducted a study to find the antecedents of severe and non-severe medication errors to determine if they were different. This was a six-month longitudinal study using 279 nursing units at 146 randomly selected hospitals. The researchers studied the nurse's environment and collected data on the following factors: (1) work environment such as shifts and hours worked, (2) team interaction and communications, (3) personal factors like

education and experience, (4) patient factors such as age, health, and prior hospitalization, and (5) medical related support systems.

The results were interesting and significant for root cause analysis of medication errors in the nursing environment. None of the antecedents predicted both types of error. Some antecedents showed a negative correlation with one type error while showing a positive correlation with the other. The authors concluded that the severe and non-severe errors have different predictors. The most noteworthy results came from the personal factors. Nursing expertise had a negative correlation with non-severe medication errors. The greater the nurse experience, the fewer the number of non-severe errors. This difference was statistically significant. The relationship was the opposite for severe errors, although not statistically significant. In looking at education, the number of Bachelor of Science in Nursing (BSN) prepared nurses was negatively correlated to severe medication errors. As the proportion of BSN nurses increased, up to 54%, the number of severe medication errors decreased. This relationship was statistically significant. In contrast, nurse education level had a positive association with non-severe errors. As education level increased, so did the number of non-severe errors. This was a statistically significant relationship. Medication-related support services were positively correlated to non-severe errors. The higher the support level, the greater the number of non-severe errors. Although this relationship was statistically significant, there was no correlation with severe errors. None of the patient characteristics showed correlation to either type medication error (Chang & Mark, 2009, p. 74)

The first study to combine qualitative and quantitative methods to explore how nurses administer medications was an ethnographic study by McLeod, Barber, and Franklin (2015). The study contributed some important observations about nurse behavior and medication

delivery systems. The purpose of the study was to better understand nurse practices, workflow,

and interruptions and distractions. The study revealed how medication systems can hinder or

enhance safe medication administration. The researchers observed 43 nurses and 56 drug rounds.

The quantitative portion revealed an average 5.5 interruptions and 9.6 distractions per hour

during drug rounds. These findings were similar to an earlier study by Biron, Loiselle, and

Lavoie-Tremblay (2009) that measured an average 6.7 interruptions per drug-round hour. In

addition to interruptions and distractions, the McLeod study focused on systems configurations

and nurse behavior types. The study led to the following conclusions. Safe medication practices

were facilitated by the configuration of systems. Observers noted that nurses developed their

own workaround practices when system-based problems existed. To reduce MAEs, hospitals

needed to optimize ward-based medication systems for efficiency and safety. The researchers

noted that nurses require help in managing interruptions and distractions. Nurses must balance

their conflicting priorities and demands during drug rounds. Over-tasked nurses tended to

provide less patient-centered care. It is noteworthy that McLeod et al. (2015), like Hopkinson

and Jennings (2013), did not advocate completely eliminating interruptions and distractions

because many of them were beneficial to the patient. Rather, they advocated leaders direct their

effort to training nurses in managing interruptions and distractions.

Observations of nurse behavior during medication administration rounds led to some

unique conclusions. Researchers described two predominant behaviors types. The first was task

focused behavior where nurses administered drugs as efficiently as possible. The second

behavior type was patient-interaction focused where nurses interacted with patients in a positive

way. Although both behaviors helped to reduce errors, the patient-interaction behavior led to

more patient involvement and enabled patients to assist in finding and preventing errors

(McLeod et al., 2015).

  In an article by Durham, Suhayda, Normand, Jankiewicz, and Fogg (2016), researchers established a pilot program to increase registered nurse (RN) sensitivity to the risk of errors in medication administration. This was an observational study that used process improvement techniques to develop a human factors-based medication pilot program to reduce MAE. The results of their root cause analysis identified the following factors in MAEs: (1) time pressure, 2) poor human-system interface, (3) information overload, (4) misperception of risk, and (5) lack of system feedback (Durham et al., 2016, pp. 75-76).

  The research team developed a pilot that incorporated the following strategies for reducing the probability of MAEs. First, standardize and simplify processes by using checklists, providing accountability for practice, and by using simulation-based training. Second, develop a systems-based approach. It is much more effective than focusing on human behavior alone. Third, mindfulness is focusing on what is occurring at the moment. This practice is developed through meditation exercises. The final strategy was error interception. This was a preoccupation with failure that involved surveillance of the patient and environment and in knowing policies and procedures. It involved double checking medications and cross-checking patient information. The researchers noted that a supportive work environment was associated with good interception practice. Their results showed that RN error interception practices increased consistent behavior performance and reduced risk of MAEs. The researchers noted that electronic systems helped to reduce errors but contributed to a decline in RN situational awareness. A combination of both technology and RN situational awareness was the most effective way to enhance safety in medication administration (Durham et al., 2016).

  The Five Rights are procedural goals of medication administration. They include

right patient, right medication, right time, right dose, and right route. In subsequent iterations a

sixth right was added--correct documentation.   Medication administration is highly prone to

error because of multiple handoffs that depend on human verification. Unfortunately, there is

little established guidance on how to ensure the verification of the five rights. In an article

published in 2014 by the Hospital Quality Institute (HQI), the authors commented that the focus

on practitioner's failure does not usually consider mitigating circumstances such as poorly

designed infusion devices, ambiguous medication labels, poor lighting, insufficient manning, or

lack of mistake proofing systems (Institute, 2014). When practitioners commit an error in

medication delivery, they usually report having confirmed all five rights. Researchers in human

factors described this phenomenon as a misperception when products or instructions look alike.

Because humans develop a mental image of their environment, they try to recognize items

through mental comparison and often fail to see disconfirming evidence when two product labels

have similarities (Institute, 2014). In Table 1, Grissinger (2010) listed some of the root causes of

failure to successfully verify the five rights. To successfully navigate the five rights,

Table 1.

Contributing Factors to Failure to Verify the Five Rights (Grissinger, 2010, p. 542).

- Poor lighting. Inadequate staffing patterns.
- Poorly designed medical devices.
- Handwritten orders.
- Trailing zeros (e.g., 2.0 vs 2) or using a decimal point without a leading zero (e.g., .2 instead of 0.2). Misinterpretation of such an order can result in a 10-fold dosing error.
- Ambiguous drug labels.
- Lack of an effective independent double-check system for high-alert drugs.

practitioners need to read labels and request an independent double check if required. Nurses

should question medication orders that are illegible or appear incorrect. Functional bar-code

technology can be an effective part of a successful system. Grissinger (2010) concluded that

nurses and other practitioners should not be held accountable for successfully achieving the five

rights. They should be held accountable for following the processes and protocols set up by their

organizations for administering medicine. This perception is in line with the fundamental

concepts established by Deming in the early days of the Quality movement, that people fail

because their managers have not established processes that prevent them from failing (Deming,

2000). If nurses are going to be held accountable for verifying the five rights, then they should

be given authority to design a system that will ensure success. Hospital staff cannot be held

accountable for a process they cannot control. Improvement needs to be made to the system for

medication administration, not to individual behavior. Grissinger (2010) stated it most

succinctly, "The five rights are not a behavioral model for achieving medication safety; they are

goals for which organizations must accept responsibility and design fail-safe ways so that the

goals can be achieved" (p. 1).

Providers. Some medication errors occur at the very beginning of the process—the

provider's prescription. A study by Tully et al. (2009) provided very useful information about

variables that can cause a physician to make a medication error. The purpose of their project was

to identify studies that provided any evidence about the causes of prescription errors initiated by

both specialists and non-specialists. The researchers looked for potential ways of reducing

errors. This was a very comprehensive study that provided an enormous cache of information

about the relationship of the variables to the problem. Researchers selected 17 studies from a

search of 1,268 papers identified during the literature search. Causes of medication errors were

grouped according to Reason's model of accident causation which include (1) active failures, (2)

error-provoking conditions, and (3) latent conditions (Tully et al., 2009, p. 820). Active failures

were considered unsafe acts performed by prescribers in direct contact with patients. All

medication errors were the result of at least one active failure. Active failures included errors in judgment caused by inadequate knowledge of the patient, disease, or drug. This also included skills-based slips and lapses of memory. The most common error was in dose prescription. Many prescription errors were the result of rule-based errors or not understanding a patient's contraindication for a prescribed medication. Error provoking conditions did not directly cause error, but they are usually present in active failures. They are related to tasks being performed and the environment where it is performed. Typical error provoking conditions include lack of training or experience, fatigue, high workload, stress, or poor communication between healthcare professionals. Latent conditions were organizational processes that created environmental conditions where active failure was more likely. This included a culture where there was a reluctance to question senior physicians when procedures should be questioned. There was an absence of the characteristics found in the culture of safety such as effective conflict resolution. In this environment, some doctors held the attitude that prescribing medicine was not very important. Some lacked self-awareness about making errors because there was no system for feedback. A final characteristic was poor integration between clinical and pharmacy computer systems.

The researchers recommended that prescribers reduce active failure by improving their technical skills and better understanding medications and disease. They could also benefit from non-technical skills such as management of stress and improving inter-professional communication skills. The researchers concluded that the complexity of the prescription errors precludes any quick fixes. The study provided significant understanding of the causes of errors and interrelationships of variables (Tully et al., 2009).

In their 2010 study on the impact of interruptions of doctors completing clinical tasks,

Westbrook, Coiera, et al. (2010) concluded that interruptions were a significant threat to patient safety. The research team set out to measure the correlation between doctor's rates of interruption and their task completion time and rates of completion. They observed 40 doctors for 210 hours in an emergency department of a 400-bed hospital. Researchers found that 11% of all tasks were interrupted and doctors failed to return to 18.5% of those interrupted tasks. The average time-on-task (TOT) was 1:26 minutes. Interruptions correlated to higher TOTs in the raw data, but after corrections were made for length-biased sampling, TOTs were shorter after an interruption. This data led researchers to the conclusion that interrupted tasks were truncated to make up for lost-time and may increase the probability for error (Westbrook, Coiera, et al., 2010).

The most commonly mentioned problem associated with prescription error in this literature review was transcription errors. The main cause of transcription error was illegible physician handwriting. Transcription errors may be credited to nurses or pharmacists who usually put the blame on difficult-to-read prescriptions or a misunderstood verbal order. Transcription errors can also occur with erroneous entries in electronic order management systems (Benitez, Forrester, Hurst, & Turpin, 2007; Esimai, 2005; Maaskant et al., 2015). Details of these systems are outlined in other sections.

LSS applications. The intent of this section was to present literature on the background of how LSS started in industry and to make a connection between the LSS movement and HRO. The final section is a general summary of how LSS has been applied to the medical industry.

Industry. Bill Smith, an engineer, developed Six Sigma in the middle of the 1980s, as the Senior Quality Assurance Manager at Motorola Inc. His business improvement approach

was designed to find the cause of defects and eliminate them. Errors and mistakes were defined

by the needs and wants of the customer (Antony et al., 2017). As Smith described it, Motorola

wanted defect-free performance from all its products and services. A defect was defined as any

failure to meet customer satisfaction. Quality was measured by the total number of defects per

unit of work through the entire process of manufacturing and delivering products. The result was

fewer delivered defects and a reduction in early failures. The key to robust design was making a

product that could withstand the variation of use. Where most industries were designing

products to withstand variation up to three standard deviations from the mean, Motorola required

engineers to build with tolerance limits to six standard deviations, so their products could

withstand twice the normal variation. He used the example of a hand held radio that could be

repeatedly dropped four feet to a concrete floor and continue operating normally (Smith &

Bellefeuille, 1993).

Six Sigma is a process-oriented, data driven approach to eliminating defects by reducing

variation in products, processes, and transactions. Six Sigma involves a disciplined and highly

organized structure that includes certifications of expertise such as Yellow Belt, Green Belt,

Black Belt, Master Black Belt, and Project Champion (Montgomery & Woodall, 2008). Interest

in Six Sigma grew rapidly during the 1990s. Motorola established Motorola University

Consulting and Training Services to teach Six Sigma concepts. Companies spent large sums of

money to train their employees. General Electric, for example, spent over $50,000 per employee

(total $1.6 billion) to train and certify belts to operate their Six Sigma system. By 1999,

Motorola University had trained over 92,000 employees world-wide. Many of these companies

already had well established management systems such as Ford, 3M, and Honeywell. Initially, it

was just manufacturing firms that took an interest in the new system. Soon, financial firms

joined, then the service industries, and eventually healthcare. Some notable companies on that

list are Allied Signal, Citibank, JP Morgan Chase, American Express, Home Depot, Starwood

Hotels, and Kaiser Permanente. Today, most Fortune 500 companies have invested in Six Sigma

(LeMahieu et al., 2017; Özkan, 2017).

Lean Management is a management tool that was developed by Womack, Jones, and

Roos (1990) during the 1980s. The concept of lean management focused on increasing

efficiency and lowering costs by reducing waste. Although at one time it was a competing

strategy, the lean concepts are a natural complement to Six Sigma. The term Lean Six Sigma

was first introduced in 2003. Since that time, the two methodologies have become synonymous

(Antony et al., 2017).

The success of LSS in most industries is well documented. Researchers present

supporting quantitative evidence that LSS companies consistently outperform the market.

However, pre and post studies of LSS performers in Fortune 500 firms did not show

overwhelming evidence that LSS companies outperform companies of equal size in their

industry. Using 14 ratios, LSS companies showed significant improvement in only five of those

ratios. The author suggested that the numbers may be skewed by so many weak businesses

introducing LSS simply as a tool to demonstrate to investors and customers their interest and

intent to improve quality and reduce costs. Non-quantifiable benefits from LSS were significant.

Literature showed that LSS practices used structured improvement methods that stimulated

better learning and knowledge transfer within organizations (Özkan, 2017).

In a review of published literature, Antony et al. (2017) assembled the following top

five benefits from large manufacturing companies using LSS: (1) increased financial savings,

(2) increased customer satisfaction, (3) reduced costs of poor quality i.e. scrap, rework, defects

etc., (4) reduced cycle time, and (5) reduced inventory. The top five motivation factors

implementing LSS were to (1) stay in competition within the global marketplace; (2) increase

customer satisfaction; (3) improve product quality and manufacturing operations; (4) enhance the

bottom line savings and top-line growth; and (5) reduce cost of poor quality (p. 1079).

Leadership is a critical component to successfully implementing LSS. Laureani and

Antony (2017) conducted a qualitative analysis using semi-structured interviews to explore the

relationship between leadership and LSS deployment. They also developed a model to

determine the relationship between the need for strong leadership and the size of a company and

industry sector. The authors listed 10 different leadership styles documented by various authors

during the last 15 years. Interestingly, one style is the Six Sigma Leader. This is a leader who

advocates a higher standard of effectiveness. This leadership was based on the foundational

principles of Six Sigma. Incidentally, a company leader can follow these principles even if the

company does not instigate an LSS organization (Pande, 2007). During their interviews with key

players in successful LSS programs, the following five themes emerged: (1) commitment, (2)

employee motivation, (3) leadership style, (4) program deployment, and (4) training.   Laureani

and Antony (2017) list the following essential leadership characteristics under leadership style:

(1) visible, (2) communicative, (3) inspirational, (4) consistent, (5) targeted, (6) leading by

example, (7) flexible, (8) perceive Lean Six Sigma as a philosophy, (9) clearly define roles and

responsibilities, and (10) able to build (p.405).   The authors also made some general conclusions

about the size of a company and their dependence on leadership and process in establishing a

new LSS program. Companies with fewer than 1000 employees depended more on leadership to

establish a new LSS program. In contrast, companies with more than 1000 employees depended

more on the correct processes to optimize an LSS roll-out (Laureani & Antony, 2017).

      HRO and aviation.   In a scathing rebuke of the healthcare system, the renowned pilot, Chesley Sullenberger, stated that if 200,000 people died in aircraft accidents every year, aviation would come to a screeching halt. There would be a presidential commission and congressional hearings. No aircraft would fly until the problem was solved. Yet, healthcare quietly continues while some speculate that deaths caused by medical error may be double that figure (Kapur, Parand, Soukup, Reader, & Sevdalis, 2015). In this section the researcher presents literature on high reliability and its application to the aviation industry. He also compares aviation and healthcare and their efforts to increase safety.

      Sutcliffe (2011) summarized the characteristics of highly reliable industries as (1) operating in an unforgiving social and political environment, (2) using risky technology with high potential for error, (3) operating in an environment where the severity of consequences from errors precludes learning through experimentation, and (4) using complex processes to manage complex technologies (p. 134). The concepts that came to define highly reliable organization were developed by researchers at the University of California Berkeley (Roberts & Rousseau, 1989; Weick, 1987). Aircraft carriers, the nuclear industry, and commercial aviation became the models for those theories. All these industries operate in high-risk environments yet continue to maintain extremely high standards of safety. HRO principles focus on social and organizational aspects of safety and accident prevention rather than on technology (Sutcliffe, 2011).

      LSS is connected to HRO through its methodology to reduce variation and error. Using the techniques defined by the American Society of Quality (ASQ), industries that measure a failure rate in their most critical operation, that falls outside the Sixth Sigma, or six standard deviations from the expected average of a normal distribution, are considered

highly reliable organizations. A Six Sigma rate, (accounting for a 1.5 sigma shift in the long-term), equates to an error rate of 3.4 defects per million opportunities (Yang, El-Haik, & NetLibrary, 2009).   In aviation, for example, LSS practitioners might count the number of Class A mishaps per million flights. A nuclear plant might measure the number of critical incidents per hours of operation.

Vogus and Sutcliffe (2007) classified the principles of HRO into five categories. These categories should form the basis for any approach to improving safety. The first category is developing a preoccupation with failure. The second is a reluctance to simplify interpretations of problems. The third is a sensitivity to operations, meaning that a company scrutinizes its most critical processes and constantly improves and refines them. The fourth is a commitment to resilience. Resilience is a company's agility in adjusting to failures, changes, and threats. The fifth category is deference to expertise, meaning that problems are addresses and decisions made by those with the most skill, not those who carry the most rank or prestige in the company.

Although some literature on this subject revealed resentment by medical professionals at the comparison between aviation and healthcare, Hunt and Callaghan (2008), it was a comparison that was hard to avoid. The entire premise for the theoretical application of LSS to healthcare was based on its success in other industries that have achieved high reliability in high-risk industries (Chassin & Loeb, 2011). Of all the industries that were recognized for their high reliability, aviation had the most in common with healthcare (Henriksen & Moss, 2004). Both industries employed some of the highest paid professionals (pilots and doctors) that performed the primary high-risk function of the industry, yet in most cases, did not participate in the management of the business. These professionals worked in small temporary teams consisting of experts in multiple disciplines. This comparison referred to flight crews, aircraft maintenance

teams, surgery teams, and specialty care units. All were temporarily thrown together on short

notice with little opportunity to form cohesive units. Both industries deal with a large volume of

customers that must be transported to different locations where each transfer involves risk.

Another similarity, and one that makes both industries unique, is that customers (travelers and

patients), were the entities that actually pass through the primary processes of the industry. In

contrast, customers of manufacturing and most service industries, simply purchased the end

product of the process. The significance of this difference was that healthcare and aviation

customers were subjected to the extraordinary risk of the industries' primary processes (Gerstle,

2018; Kapur et al., 2015; McGreevy, Otten, Poggi, & Robinson, 2006; Oliver, 2018). In Table 2,

Kapur et al. (2015) compared characteristics of healthcare and aviation. The researchers pointed

out that aviation generally had a much stronger culture of safety that owns up to its safety errors.

Healthcare delivery systems had many competing economic demands that created a reluctance to

share safety issues with the public. Another significant difference between healthcare and

aviation was training. Although both pilots and doctors went through rigorous training to

achieve qualification, aviators underwent regular proficiency checks, usually performed in

sophisticated simulators. Aviators also received behavioral analysis and training in leadership,

team interaction, situational awareness, managing stress, and coping with fatigue.   Researchers

made a case that healthcare providers were in greater need of team training than aviators.

Communication errors were even more likely in healthcare settings because the teams were

larger and healthcare settings had more distractions and interruptions, and more information in a

very dynamic environment (Kapur et al., 2015).

        In a research project by McGreevy et al. (2006), the authors sought the recommendations

of instructor pilots to improve safety in surgical operating rooms. The first suggestion was to

Table 2.

Contrasting Features of Aviation and Healthcare

Domain	AVIATION	HEALTHCARE
History	Hundred years	Hundreds of thousands of years
Key Raw Materials	Aircraft, usually less than 30 years old, serviced every few months	Human bodies, can live to around 100 years, check-up every 1-2 years or less frequently
Activities	• Pilots operate one or two types of aircraft • Episode usually lasts 1-10 hours, with same crew on board	• Health care professionals must deal with a wide variety of equipment, diseases and presentations • Duration of inpatient stay may be days or even years with numerous changeovers of staff
Equipment	• There is a degree of standardization of displays across aircraft • Most procedures are automated, with multiple back-up systems in place • Information such as weather conditions is automatically available	• There is relatively little standardization of design across medical equipment • Automation of procedures, and back-up systems are somewhat variable with much of healthcare being hands-on.
Service Users	• Passengers are healthy • Passengers usually have little knowledge of the crew or aircraft or airline. • Crew rarely know names of individual passengers and the captain will seldom console a passenger personally if things go wrong.	• Patients are sick, vulnerable, and injured • Patients will often come equipped with well-researched information about their condition, their doctors, and their hospital • Staff will know each patient well and may also become familiar with their families. A consultant will generally console a patient if things go wrong.
Service Delivery	• More homogenous • The same crew usually on board a flight • Pilots do not become acquainted with passengers or must console them if anything goes wrong • Comfort and luxuries rather than safety can be correlated with ability to pay • There are few subspecialties of pilots and crew	• More heterogeneous with a number of subspecialties involved • Health professionals get to know their patients and build up a rapport with them • Care is personal and patients are often involved in treatment decisions • Quality of care can be related to the ability to pay especially in developing countries • There are many subspecialties in healthcare
Safeguards	• Many safeguards are in place with a high degree of automation and computerized support • There are strictly enforceable rules to exclude adverse effects of fatigue or alcohol on pilot's performance	• Limited safeguards, hands-on work and a relative lack of automation and computerized support • Lack of strictly enforceable rules to exclude adverse effects of fatigue. Rules about alcohol are seldom made explicit or strictly enforced
Safety	• Equal for everyone on plane • Fatalities can be over 100 at a time and usually include the crew of the plane • The setting of targets is relatively infrequent and rarely conflicts with passenger safety	• Can correlate with ability to pay especially in developing countries • Fatalities generally involve one person. Staff fatalities directly associated with patient care are very rare • Targets may often be present and may on occasions conflict with patient safety
Adverse Events	• Major adverse events are always investigated by national body • Major adverse events are often featured in media • Pilot immunity is often part of the reporting culture • Adverse event investigation reports are always published	• Major adverse events are usually only investigated locally, though may occasionally be subject to wider investigation • Major adverse events only occasionally featured in the media • Immunity is not necessarily part of the reporting culture and disciplinary procedures are wide ranging • Adverse event investigation reports are seldom published

Note. This table is adapted from "Aviation and Healthcare: A Comparative Review with Implications for Patient Safety" by Kapur, N., Parand, A., Soukup, T., Reader, T., & Sevdalis, N. (2015). *JRSM Open, 7*(1), p. 2.

require crew resource management (CRM) training as part of hospital credentialing. In the early

days of aviation, research showed that the root cause of many accidents was poor communication

and too much arrogance in the cockpit. In a survey of hospital staff, researchers found that 50%

of doctors and nurses would not discuss error because of (1) personal reputation (76%), (2) threat

of malpractice (71%), and (3) the egos of other team members (60%) (McGreevy et al., 2006, p.

1083). The second recommendation was for team briefings prior to every operation. This is a

practice that is becoming common practice in operating rooms across America. These briefings

are often called huddles or time-outs. The third recommendation was for surgeons and

administrators to write standards for their organization. The fourth was to recognize age and

fatigue as factors in surgeon performance. The fifth was to start requiring surgery check rides as

part of hospital credentialing. The sixth was to establish a blameless culture in morbidity and

mortality (M&M) conferences like the culture found in aviation accident investigations. The

seventh, recommendation, was for random drug testing for all staff (McGreevy et al., 2006).

  Gerstle (2018) explained that the use of checklists was a distinguishing feature in aviation

that could be adapted to healthcare. In aviation, checklists are an integral part of all workflow.

Aircraft and ground crew use checklists for routine procedures, complex operations, and

emergencies. Most routine and complex operation checklists are accomplished as a do-verify

or a challenge-response. Emergency checklists are generally memorized. Some applications of

checklists in healthcare are starting to appear in surgery, infection control, and medical

diagnosis. Checklists could also be effective in key transition points such as patient hand-offs

between wards (Kapur et al., 2015). Oliver (2018) described some of the standards that

contribute to aviation's excellent safety record. Aviation strictly enforces standards of minimum

crew rest. Flights will even be delayed or cancelled if a crew member has not met the

requirements. An aircraft would never take off without a full complement of crewmembers. In

healthcare, acute care procedures often proceed without all the essential staff members or with

staff members who have worked extensive hours without proper rest.

In defense of healthcare, Oliver (2018) pointed out that modern aviation is inherently safe

today. Jennifer Riordan was the first aircraft related fixed-wing fatality in U.S. commercial

aviation in 15 years. By contrast, hospitals deal with people who may be extremely sick with life

threatening illness or injuries. Patients regularly die in hospitals for a myriad of ailments.

Procedures in hospitals are not inherently safe. Many procedures involve extreme risk to the

patient. Airlines have more control over their work environment. Airlines can cancel flights if

they involve high risk such as presented by weather or equipment failures. During the 911 crisis,

the entire industry was shutdown. In contrast, acute healthcare providers must accept all

patients, regardless of the risk involved. A vivid example was the treatment of COVID patients.

Many failures in both aviation and healthcare are traced back to non-homogeneous teams

comprised of independent members with no team structure that have no procedure for cross-

examination. CRM was the answer to these problems and proved to be extremely successful in

aviation (Powell & Hill, 2006).   Many authors have written about applying the principles of

aviation psychology to healthcare. Henriksen and Moss (2004) studied the application of these

human factors to facilitate better teamwork and communications across various clinical domains.

CRM was designed to promote safety by increasing team performance. The focus of CRM

training was on "communication, decision making, interpersonal relations, crew/team

coordination, and leadership" (Powell & Hill, 2006, p. 179). The authors also suggested that the

primary roadblock in the resistance to CRM in healthcare was doctors. Physicians tenaciously

defend their professional autonomy and programs like CRM were designed to break down

autonomy and spread the responsibility of safety to everyone on the team. Nurses generally

endorsed the concept for obvious reasons. Some of the features of CRM that should be applied

to healthcare are peer monitoring, briefings, defining operation procedures and standards,

recognizing fatigue, regular check rides, blame free reporting culture, checklists, and the sterile

cockpit concept (Kapur et al., 2015). Some physicians strongly supported CRM. McGreevy et

al. (2006) suggested that CRM training should be part of all physician credentialing.

Many of the principles of CRM that were developed in aviation have been incorporated

in healthcare's cultures of quality and safety that were fully endorsed by the Joint Commission

(TJC) (Chassin, 1998; Chassin & Loeb, 2011, 2013). The Joint Commission defined this culture

of safety as an ethos that enables trust. In this culture, hospital staff are empowered to speak up

when they see any risk to a patient. It is a culture where staff are not afraid to report errors and

near misses even if they are their own. The culture is a summary of knowledge, behaviors,

beliefs, and attitudes that all the staff share about the importance of safety and the wellbeing of

their patients (The Joint Commission, 2017).

General medical application. As President and chief executive officer of TJC, Mark

Chassin's writings were extremely influential to healthcare in general and key to this

dissertation. Chassin was the author and co-author of many articles on the application of LSS in

healthcare. His 2013 article with Jared Loeb, formed the theory and structure for the LSS

maturity model used in Navy Medicine today. His articles contributed significantly to this

research project (Chassin, 1998, 2012; Chassin & Loeb, 2011, 2013).

Interest in the application of LSS to healthcare has grown significantly in the last 15

years. da Silva, Filser, Juliani, and de Oliveira (2018) conducted a bibliometric analysis of LSS

literature to find the research trends and scientific gaps. They discovered that research into LSS

has grown exponentially since 2003. Figure 2 shows the growth in the number of research papers

on LSS since 2003. The authors discovered a significant growth in the interest in LSS and

healthcare.
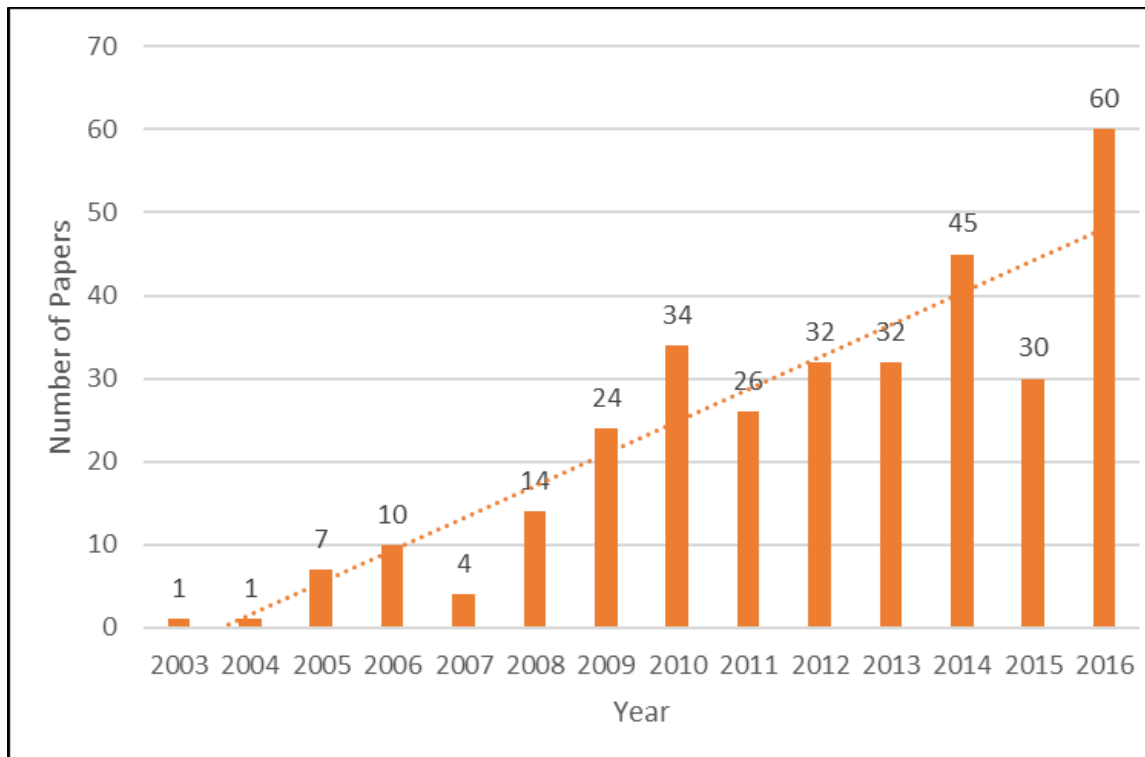
Figure 2. Publication on LSS literature up to 2016. Adapted from "Where to Direct Research in

Lean Six Sigma?" by da Silva, F. F., Filser, L. D., Juliani, F., & de Oliveira, O. J. (2018),

International Journal of Lean Six Sigma, 9(3), pp. 324-350.

The authors identified healthcare as one of the main research trends in LSS and suggested

that more research was needed. Two similar studies were conducted in 2016 that corroborated

these findings (Raja Sreedharan & Raju, 2016; Yadav & Desai, 2016). Figure 3 shows the ten

most researched areas of LSS in the same period. Subjects related to healthcare accounted for

112 of the 281 articles (da Silva et al., 2018, pp. 330-331).

Langabeer et al. (2009) produced a study giving an excellent overview of early
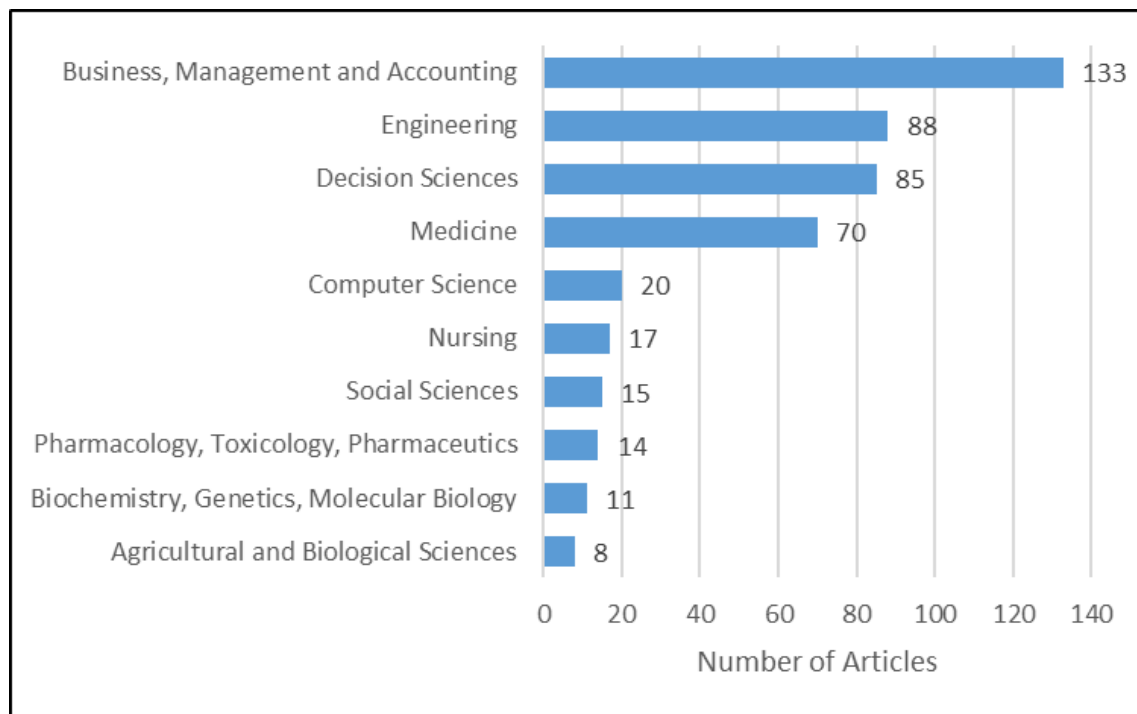
Figure 3. Ten most researched LSS subjects. Adapted from "Where to Direct Research in Lean

Six Sigma?" by da Silva, F. F., Filser, L. D., Juliani, F., & de Oliveira, O. J. (2018),

International Journal of Lean Six Sigma, 9(3), pp. 324-350.

applications of quality improvement in healthcare. The purpose of the study was to find out if

LSS was a good fit for the healthcare industry. The study used mixed research methods

employing surveys and semi-structured interviews that examined LSS integration. They

concluded that the healthcare industry would probably follow other industries in their application

of LSS but there were still many weaknesses. The authors expected to find a greater emphasis

 on reducing medical errors. Their surveys showed that reducing medical errors was the lowest

overall goal of LSS projects. Efficiency was the most common goal yet there was little evidence

that quality managers were defining measurable expectations. One of the biggest problems they

observed in the transition to LSS was physician resistance. In their final analysis, the researchers

recommended that quality managers focus on successful projects that achieve measurable

value. Each project needs to establish concrete goals to improve the probability of attaining

them. They suggested that LSS goals must not only improve efficiency but enhance the quality

of care (Langabeer et al., 2009).

Medical errors were often the result of poorly designed, complex systems. This article by

Buck (2001) was the documentation of a first attempt to use LSS to improve organizational

processes in medication administration and laboratory processing. The project took place at

Froedtert Hospital in Milwaukee. The conclusions did not provide quantitative evidence for

success, but the authors describe the methodology as extremely powerful. They also stated that

LSS required a profound organizational commitment and staff training.

A study by J. Liberatore (2013) was conducted as a very broad and comprehensive

review and assessment of all the current Six Sigma literature in healthcare. He identified 88

hospitals and healthcare providers that have implemented LSS. His research showed that in 42%

of the LSS projects, the primary metric was error rate. In 38% of the projects the primary metric

was reducing process time and 19% of the projects sought to increase productivity. This was in

stark contrast to the Langabeer et al. (2009) project from four years earlier that criticized

healthcare for failing to apply LSS to error reduction. Liberatore presented a dismal outlook for

LSS in healthcare. In his findings, 67% of the projects showed initial improvement in the

primary process metric but only 10% of those projects could sustain the improvement. He

concluded that LSS must be internalized by healthcare professionals to ensure long-term success.

More work needs to be done to shape LSS programs to implement changes that are not only

statistically significant but practical. Research also showed that many of the failures were the

result of improper implementation of the LSS structure (Liberatore, 2013).

Feng and Manuel (2008) investigated the broad status of LSS in the U.S. healthcare

system. Fifty-six healthcare organizations responded to the survey. Their findings presented information about LSS projects, costs, benefits, and barriers to implementation. They found that predominant categories for LSS studies were cycle time reduction, process flow improvement, and medical error reduction. The average LSS project lasted from four to seven months. LSS was not for the little guy. Successful programs had committed full-time black belts and companies with fewer than 400 employees could rarely justify the expense. This survey in 2006 showed that only 26% of the organizations that responded had implemented an LSS program. Only 11% of the respondents were considering LSS. Most of the programs were in operation less than four years indicating that in 2006, LSS was still in its infancy in healthcare (Feng & Manuel, 2008).

Today, studies can be found on just about every clinical and business aspect of healthcare. The following are two good examples. In a study to reduce the cesarean section rate, Chai et al. (2017) used the DMAIC methodology to develop interventions that "improved parturient women assessment system, strengthened pregnancy nutrition guidance, implementation of painless labor techniques, enhanced midwifery team building, and promotion of childbirth-assist skills" (p. 562). After a ten-month validation period, the results showed a decrease in the cesarean rate from 41.8% to 32%. In a study to improve an internal medicine residency program, Brateanu, Thomascik, Koncilja, Spencer, and Colbert (2017) used LSS to evaluate a graduate medical education assessment system. The project identified gaps and deficiencies in the system and helped administrators find ways to simplify and improve the system. Continuous process improvement methodologies helped the faculty fix entrenched systems that seemed unfixable (Brateanu et al., 2017).

Although LSS studies were found on a large breadth of subjects, there are still

relatively few peer reviewed articles on improving the medication administration system.

This finding was unusual given that medication errors are still the single largest source of patient

harm in healthcare (Yip & Farmer, 2015).

  LSS application to medication error. One of the most recent articles on LSS

application to medication administration was written by Trakulsunti and Antony (2018). In their

viewpoint paper, the authors reviewed four LSS studies designed to reduce medication errors.

The purpose of the study was to fill a gap in the literature. Current literature showing the success

of LSS in improving medication processes is very limited compared to other healthcare settings.

In this article, the authors reviewed four highly successful LSS projects that reduced medication

errors in different segments of the medication process (Trakulsunti & Antony, 2018, p. 426).

These four projects are outlined in the sections on LSS application to pharmacy and prescription.

The authors concluded from the review of these projects that LSS was a powerful tool for

reducing medication error. The tools of Lean improved the medication process by enhancing the

workplace environment and reducing excessive workloads. These benefits, in turn, reduced

incorrect dosage calculations and miscommunication. The Six Sigma tools reduced the mean

errors by reducing variation in the medication processes (Trakulsunti & Antony, 2018, p. 432).

In all of these cases, the most significant benefits from the application of LSS were (1) improved

patient safety, (2) improved internal and external customer satisfaction, (3) effective

communication, (4) improved team dynamics, (5) enhanced employee morale, and (6)

quantifiable cost savings (Trakulsunti & Antony, 2018, p. 431).

  Researchers from the Department of Industrial and Systems Engineering department at

Northern Illinois University, conducted a single LSS project on a complete medication delivery

system from prescribing to administering. Using the DMAIC structure, they completed all five

phases including the implementation of eight specific interventions. During the measurement

phase, the team concluded that the system was at a 3.38 sigma level. The study presented an

excellent value stream analysis, fishbone diagram (root cause analysis) and Failure Mode and

Effects chart. The analysis phase found that medication administration accounted for most of the

recorded errors. The eight interventions were (1) new physician order forms, (2) new medication

administration forms, (3) new refusal (PRN) form, (4) new inadvertent incident report form, (5)

organized and labeled the medication room, (6) labeled medication carts, (7) developed a non-

punishment approach and anonymous error reporting system, and (8) an education and training

program for error prevention. Unfortunately, they did not include a validation phase in this

study. The reader is left wondering if the interventions were effective (Polovina, Polovina,

Yenigella, & Chen, 2014).

Another application of LSS to the medication problem was presented by Nayar, Ojha,

Fetrick, and Nguyen (2016) in their study of dual-care veterans accepting medications from

inside and outside the system. The researchers applied LSS to one urban VA medical center

(VAMC) to solve organizational quality problems. By mapping the process, researchers found a

primary bottleneck in the introduction of non-VA healthcare records into the system that cause

confusion and discrepancies that slowed the system and contributed to medication errors. The

findings provided valuable information to help VA providers improve the quality of care to

veterans. The study also demonstrated the flexibility of LSS in addressing the wide array of

variables that influence medication administration.

LSS application to pharmacy. One of the earliest and most comprehensive LSS studies

of pharmacy processes was conducted by Chan (2004) in Taiwan. This study of outpatient

medication problems was designed to reduce pharmacist dispensing errors. The author began

collecting data on dispensing errors in 2000. The national error reporting system stated that

pharmacist dispensing errors were the second most common medical error in Taiwan. This study

showed the practical application of LSS to outpatient medication dispensing at an institution that

had never used LSS before. This article described the process. The primary intervention was

reducing the pharmacists' workload by installing an automatic dispensing unit. Part of the

interventions included training in the redesigned process and development of a standard

operating procedure (SOP). The results showed a reduction in errors from the current rate of

338.8 per million prescriptions to 230 per million (Chan, 2004, p. 130).

The Esimai (2005) project was designed to study the errors occurring in the medication

administration record (MAR) of a large hospital. Using the LSS DMAIC methodology the

researchers defined the MAR problems as (1) wrong dose, (2) wrong drug, (3) duplicate entries,

(4) incorrect frequency, (5) omissions, (6) discontinuations not carried out, (7) orders not

received, (8) patient profile incorrect, and (9) incorrect route (Esimai, 2005, p. 52). Because of

the way the study was designed, most of the interventions focused on pharmacy procedures. In

the current medication process, orders were faxed to the pharmacy where they were profiled in

the MAR. Nurses then reviewed the MAR and report the errors. The pharmacy tech recorded

the errors, including the type error and who made the error. Because the nurses could correct

their own errors in the MAR, most of the recorded errors were blamed on the pharmacy. This

data showed an unusually large number of errors coming from a few pharmacists. The root

cause analysis focused on why pharmacy staff were making so many errors. This analysis

revealed the following most common causes: (1) fax transmission problems, (2) legibility of

physician's handwriting and their use of abbreviations, (3) distractions and interruptions, (4)

non-reconciliation between nurses, physicians, and pharmacists, and (5) miscellaneous common

errors such as oversight (Esimai, 2005, p. 54). The chosen interventions included significant

instruction and supervision focused on educating pharmacy staff on medication guidelines and

on improving individual performance. The implementation plan also included (1) the installation

of a computerized physician ordering management system (CPOM) that eliminated the problem

of poor physician handwriting, (2) separating phone and fax lines, (3) standardized times for

medication administration between hospital nurses and pharmacists, (4) monthly meetings

between pharmacists, doctors, and nurses, and (5) designating a pharmacy employee to manage

all external calls (this was a major source of distraction and interruption). The results showed a

decrease in total error rate from .33% to .14% in five months. The project also reduced costs by

$1.32 Million annually (Esimai, 2005, p. 57).

    The Benitez et al. (2007) study was one of the four cases discussed by Trakulsunti and

Antony (2018). This LSS study, using the DMAIC format, had goals to reduce medication errors

and standardize the medication process throughout the hospital. Many of the root causes of

errors and the interventions were similar to the Benitez et al. (2007) study. Part of the

interventions addressed the problem of interruptions of pharmacy personnel during the

preparation of medications. The first intervention was to establish a protocol for all intravenous

fluid orders to be submitted before 0600 to provide early preparation. A second intervention

authorized a single pharmacy tech to receive all external calls by fax. If the issue could not be

handled by the tech, the pharmacist was given the request only after he or she completed the

current medication order. A third interventions included an education program to train

pharmacists on a consistent medication order entry format. A fourth intervention corrected the

problem of illegible physician orders by revising the order form. The team discovered that the

order form did not provide enough space for the physician to write the order. Doctors had to

write extremely small or spill their handwriting outside the lines. The new form added 10

more lines and darkened the margins.

The second goal of the project involved revisions to the medication process and are

explained in the next section because they apply specifically to nursing.

LSS application to nursing. It was difficult to find current literature on LSS projects that

directly addressed nursing errors in medication administration. This was surprising given the

abundance of literature describing the problems with medication administration. It was also

noteworthy that in The Joint Commission's 2018 hospital national patient safety goals, all three

goals listed under medication safety, addressed problems in the administration of medication and

relate to nursing and advanced practice nurse duties. These goals were better described as action

plans to accomplish an objective. The first of these action plans was to label all medications that

were not labeled. Much of the manual labeling took place in nursing wards and operating rooms

when medications were diluted or put into syringes. The second was a warning to use extra

caution with patients who took medications to thin their blood. The third outlined the method for

ensuring patients were receiving the correct medications, finding out what medication patients

were already taking, and making sure patients understood what medications they were supposed

to take after they got home (The Joint Commission).

One of the core concepts of LSS stated that processes should be designed to meet the

customer's needs. In the Benitez et al. (2007) case, the researchers determined that the new

medication process would be designed around the needs of the primary internal customer—

nurses. The new process provided nurses (1) quick access to the medication order information,

(2) quick pharmacy turn-around-time, (3) access to a history of patient medications, (4) portable

and mobile access to medication information, (5) ability to double check information, and (6) an

order entry system that was trustworthy (Benitez et al., 2007, p. 41). During the measurement

phase of the study, a process map revealed that nurses were not checking the MAR against the

physician orders. In lieu of checking the MAR, nurses created a historical log of all medication

orders and used that to ensure the accuracy of the administration. After an investigation of the

practice, the team concluded that the historical chronology was not as accurate as the MAR. The

history was considered redundant and had to be eliminated. The change reduced workload by

seven minutes per day per patient and increased the accuracy of the MAR. The team proposed

three approaches to meeting the six stated requirements of the new process. The first proposal

was to maintain the medication list with the currently operational Patient Care Activity Record

(PCAR). The concept was to enhance that system rather than replace it. The second was to

deploy the Medication Administration Checking (MAC), a bar code system which would detect

discrepancies between medication orders at the bedside. The third option was to install an

optical character recognition (OCR), technology that converts handwritten orders to electronic

files (Benitez et al., 2007, pp. 41-44).   The Pugh chart displayed in Figure 4 shows the decision

matrix used to select the best alternative. The team voted to maintain and enhance the current

PCAR system. After the final validation of the new process, the team surpassed the 50% error

reduction goal. The results were verified by 30 chart audits per week. Medication errors rate fell

from .4 errors per bed to less than .04 errors per bed every month for four months after the

interventions (Benitez et al., 2007, p. 44).

A recent and well-documented study by Kieran, Cleary, De Brún, and Igoe (2017), was

a pre-post intervention project using LSS to improve the efficiency of oral drug rounds.

Although the project's primary goal was the reduction of cycle time, it did address some of the

 root causes of drug administration errors outlined earlier by Cook (2014). These root causes of

Key Criteria	Current process (chronology)	Existing patient care activity record	Medication administration checking system (MAR)	Optical character recognition
Concept Selection Legend Better + / Same S / Worse -				
Available immediately for printing		S	-	S
Less than three steps to access the document		S	S	S
Quick turnaround time		S	S	S
Facsimile of order available in real time		S	S	S
Able to see all medications for the entire patient stay	Datum (baseline)	-	-	-
Able to see medication start and stop dates		S	S	S
Nurse should not need to go back to station for document		S	S	-
Serve to double check all orders in MAR		S	S	+
Medications sort in the same way as in MAR		+	+	-
At least 95% accurate the first time		+	+	+
Consistency in order entry by all pharmacists		+	+	+
Sum of Positives		**3**	**3**	**3**
Sum of Negatives		**1**	**2**	**3**
Sum of Sames		**7**	**6**	**5**

Figure 4. Pugh Selection Matrix. This is a typical decision matrix used to evaluate the strength

of each option. Adapted from "Hospital Reduces Medication Errors Using DMAIC and QFD"

by Benitez, Y., Forrester, L., Hurst, C., & Turpin, D. (2007). *Milwaukee: American Society for*

Quality Control, Inc., 40(38), p. 43.

nursing errors in medication administration were interruptions, fatigue, and overtasking. This

was a full DMAIC project that reduced the oral drug rounds from an average of 125 minutes to

51 minutes. The most significant result was a 75% reduction in drug supply interruptions. Table

3 shows the team interventions. Note the visual triggers and signage used to promote isolation

of the trolley and reduce interruptions.

Table 3.

Detailed Intervention Overview (Kieran et al., 2017, p. 806)

Intervention type	Intervention description
Trolley and materials intervention	• **Assignment of staff to maintain trolley order**: A staff nurse was assigned the task of carrying out weekly trolley clear-outs at quieter ward periods during night shift or at weekends. **Visual Standard Operating procedure and standard work developed**: A visual checklist and standard operating procedure was developed in line with the hospital's policy on administration of medical preparations and was affixed to the inside of the trolley. All supply issues were agreed to be completed at the end of the round.
Supply intervention	• **Communications board**: A communications board was designed collaboratively with nursing and pharmacy staff to easily identify any medications required post-round to include the date and time of order, the destination location/trolley and denoted space to indicated when seen by the pharmacist, drug ordered, drug delivery time, drug received and trolley restocked. • **Visual triggers**: A system was developed using coloured sticky tabs (andons) to allow nursing staff to indicate when medications were running low on the trolley giving them a visual reminder to restock that medication at the end of the round. These were also used by nursing staff to identify any queries they had in relation to drugs charted for patients which could then be addressed at the end of the drug round in line with the new standard work process that had been developed.
Direct interruption intervention	• **Trolley signage**: Trolley 'Do not interrupt' signage was developed to act as a visual indicator when the nurse was conducting the round. Signage was considered from all angles so that it would be visible during the round. • **Communications campaign**: A communications campaign was developed highlighting the complex task of drug rounds and detailing the risk of medication error as a result of interruptions. Staff emails were disseminated and posters were put up in strategic locations on the ward to target potential sources of interruption. • **Nursing teamwork strategy**: Given the majority of direct interruptions were from patients, the nursing staff devised a team-based strategy where nominated nursing staff carried out the drug round after handover each morning. The nurses assigned to carry out the round advised patients using a standardized message that they were carrying out the drug round and to use their call bells for attention. Other nurses and healthcare assistants were then free to attend to patient calls.

Researchers in the van de Plas et al. (2017) study completed a controlled before-after study of a full DMAIC LSS project on parenteral medication administration. The structure of the project was useful as a template for the study of medication error at Naval Hospitals. Although not stated as a project directed to nurses and nursing procedures, all the interventions were centered on nursing operations. The project goal was to reduce medication administration errors by 50%. In the background paragraph, the researchers reviewed the historical approach to reducing medication error. The list included (1) nursing education, (2) drug round tabards—worn by nurses to reduce interruptions, (3) computerized physician order entering system (CPOE), (4) barcode verification, and (5) new protocol implementation including a two-nurse policy for medication verification (van de Plas et al., 2017, p. 1). In this project, errors were divided into seven categories including (1) wrong patient, (2) wrong drug, (3) wrong dose, (4)

wrong dose form, (5) wrong route, (6) wrong time $\geq$ 90 minutes, and (7) wrong duration. In gathering baseline data, researchers placed disguised, trained observers in the control ward and intervention ward of the internal medicine department at Maastricht UMC. Observers witnessed 32 parenteral medication administrations. Of the 19 observations in the control ward, 14 (74%) had one or more errors. Six of those errors had a significant risk of harm. Of the 13 observations in the intervention ward, six (46%) had at least one error and one presented significant risk of harm. Researchers discovered that bolus injections produced the highest potential for risk. In 57% of those administrations, the nurses injected the bolus too fast and put their patient at risk. In the analysis phase, the team used an Ishikawa diagram (fish bone Figure 5) to find root causes of the incorrect bolus injections (van de Plas et al., 2017).

In the improvement phase, the team developed the following interventions: (1) substitution of bolus injections with infusion, (2) education of nursing staff by the hospital pharmacist, (3) developed instructional leaflets, and (4) institutionalization of drug-round tabards (van de Plas et al., 2017, p. 3). In the post intervention phase, the team observed 100 parenteral medication administrations in the control ward and 59 administrations in the intervention ward. The most significant contribution of the study was the discovery and elimination of rapid bolus injections at the Maastricht hospital. Because of the small data set, results concerning the number of medication errors were inconclusive. The researchers endorsed the LSS strategy as a suitable approach to tailored improvements. This project illustrated the challenges in observing large sample sizes in the clinical setting. Observing in the medical setting can be intrusive and often requires weeks or months of observation to detect enough errors to reach an effective sample size.

The Red Rules Book is an interesting HRO concept from the nuclear industry that could
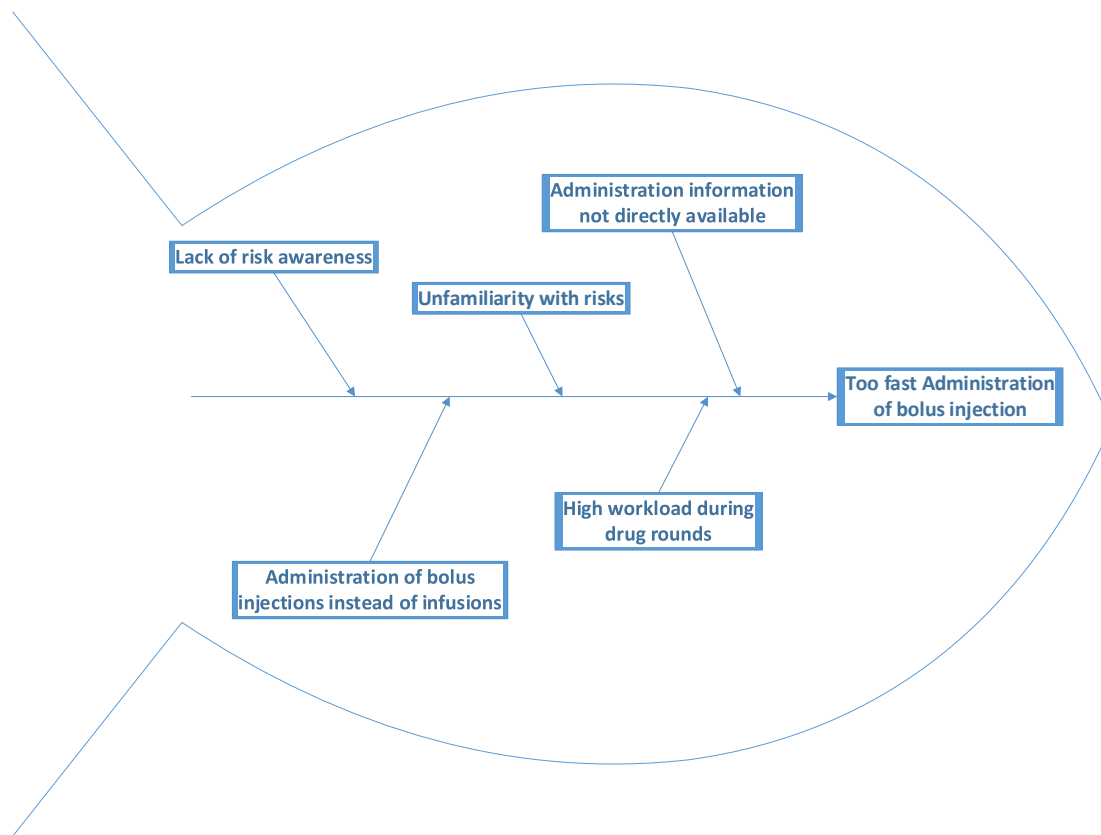
Figure 5. Root cause analysis of bolus injections. A simple root cause analysis using the fish

bone diagram; adapted from "Experiences with Lean Six Sigma as Improvement Strategy to

Reduce Parenteral Medication Administration Errors and Associated Potential Risk of Harm" by

van de Plas, A., Slikkerveer, M., Hoen, S., Schrijnemakers, R., Driessen, J., de Vries, F., &

Bemt, P. v. d. (2017). *BMJ Quality Improvement Reports, 6*(1), p. 4

be integrated with a medication LSS project designed to reduce nursing errors. This practice

was outlined by Karsten (2011) in her article directed to nursing leaders. Red rules are specific

rules that can never be broken. These are rules that must be followed to the letter of the law.

The purpose of these rules was to establish a protocol where anyone working at the front lines

can stop the work process, when one of the red rules has been violated, without fear of

retribution. As an example, Karsten (2011) suggested that rules in healthcare could be

established to mandate hand sanitation. Red Rule protocols for proper management of medications processes could help control medication processes after they have been improved. Appropriate disciplinarian procedures were suggested to effectively engage everyone (Karsten, 2011).

LSS application to prescription. No LSS studies were found that specifically address medication errors originating with providers in the prescription phase. There were, however, several studies that included interventions for the prescription phase. These studies were discussed in other sections of the literature review. The most prevalent error was from transcription due to illegible physician handwriting on manual order forms. The most common solution was the implementation of electronic systems such as CPOE and CPOM systems which required physicians to enter medication orders directly into an electronic data base (Cho, Park, Choi, Hwang, & Bates, 2014; Esimai, 2005; van de Plas et al., 2017). The Cho et al. (2014) study made it clear that although CPOM may eliminate transcription errors due to illegible handwriting, it does not prevent errors in the entry of prescriptions. No literature was discovered that confronted this specific problem except to depend on physicians and nurses to catch the errors.

The other approach to managing the physician handwriting was presented by Benitez et al. (2007). The LSS team in this study simply made the prescription order form bigger so that physicians did not have to write smaller or write outside the prescription lines.

Using technology to reduce medication error. The most ambitious initiatives to address the problems of medication error are electronic medication administration systems and bar-code technology. One of the most prolific researchers in this field is David W. Bates who has written over 600 peer-reviewed articles with over 105,296 citations from 1995 to the

present.   As a physician, biomedical informatician, and professor of medicine at Harvard

Medical School, he is recognized as the most cited author in the fields of patient safety and

biomedical informatics. Most of the articles used in this section are co-authored by Bates or

contain multiple citations from his works (Bates, 2018).

     Computerized prescription order entry. Some researchers have suggested that

technology and automation are the keys to preventing physician prescription errors. Focusing

just on the computerized physician order entry (CPOE) systems, Cho et al. (2014) conducted a

study to investigate potential errors introduced by the system in prescriptions, administration,

and documentation.   The team completed observations and chart reviews at two surgical

intensive care units (ICUs). They found a surprising large volume of errors in a very mature

CPOE system. Of 534 prescriptions issued, 53% had at least one error. Of the 306 drug

administrations observed, 19% had errors. Two thirds of the errors were originated as verbal

errors that were incorrectly entered in the system. In 248 correctly administered medications,

82% were documented incorrectly. One bright spot in the study was the finding that of all the

incorrect prescriptions, 93% of the errors were intercepted by nurses prior to administration. The

research team concluded that even with a mature CPOE system, medical errors were relatively

high. The biggest source of error was from erroneous prescription entry and transcription of

verbal orders. A better system is needed (Cho et al., 2014).

     Children are especially vulnerable to medication errors due to weight-based dose

miscalculations in the prescription phase. The greatest concern in pediatric intensive care units

(PICUs), is the large number of medications and the frequent incidents of renal and hepatic

failure that demand frequent dose adjustments. In one study, Kadmon, Pinchover, Weissbach,

Kogan Hazan, and Nahum (2017) wanted to determine if medication errors increased over time

after implementation of a CPOE system. In their study, the CPOE program also included a

clinical decision support system (CDSS), which was an indispensable part of the system. CPOEs

were introduced in the early 2000s and preliminary studies indicated high success in reducing

error rates. However, more recent studies have not been as positive. The Cochrane Studies in

2015 looked at seven pediatric centers and found no reduction in medication error rates or in the

incident of harm inflicted on patients as a result of CPOE introduction (Maaskant et al., 2015).

Kadmon et al. (2017) pointed out that the Cochrane Studies only included two PICUs and only

one of those used a CDSS integrated with the CPOE. Kadmon et al. (2017) had similar results in

their 2015 study, but follow-on studies in 2016, after they made interventions, showed a

significant decrease in error rates. In their 2015 study, prescription error rates increased from

1.4% in 2007 to 3.2% in 2015. A breakdown of these errors showed that 23 of 40 prescription

errors were caused by the CPOE system itself. Thirteen errors were due to unintentional repeat

medication boluses and 10 of the errors were cause by missing daily repeats. All 23 of the errors

were caused by incorrect prescription from defaults. The following year, after revisions to the

CPOE defaults, the medication error rate fell from 3.2% to 1%. The researchers concluded that

an essential part of using and depending on electronic support systems is a surveillance of

prescription errors accompanied by interventions to eliminate the root cause of those errors. By

repeatedly evaluating the CDSS, the research team moved the PICU to a gradual reduction of

the error rate (Kadmon et al., 2017).

   BCMA and eMAR. Although bar-code technology has been used for decades in the

retail and shipping industries, it was only recently introduced to medicine. Studies conducted in

2009 show that 24% of hospitals use bar-code medication administration (BCMA) while only

3.6% of hospitals use a fully closed-loop process that integrates physician-order entry systems to

maximize point-of-care safety processes (Bowers et al., 2015; Poon et al., 2010). Numerous

studies have been conducted during the last five years that present mixed results after

implementation of BCMA systems. Bowers et al. (2015) pointed out that most medication errors

took place at the patient bedside where the medicine was finally delivered to the patient.

BCMAs were designed to prevent medication errors by removing the human element when

identifying medications and matching them to the correct patient. The system guides the hospital

staff through the verification process and alerts the user of potential mistakes. Bowers et al.

(2015) completed a pre-post study of the implementation of BCMA at six pilot units. They

compared the use of variables related to safety in the medication administration process and the

effectiveness of reducing error. Specifically, they wanted to know if BCMA (1) increased point-

of-care medication administration documentation, (2) decreased medication errors, (3) increased

workstation on wheels (WOW) usage, and (4) increased medication workstation usage for

medication retrieval.   The results showed a statistically significant increase in documentation,

WOW usage, and workstation usage. There was no reduction in the number of medication

errors. Table 4 shows the results in types of medication errors both pre and post implementation

(Bowers et al., 2015)

Table 4

Types of Medication Administration Errors (Bowers et al., 2015, p. 507).

	Total (n = 70)	Postimplementation (n = 40)	Preimplementation (n = 30)	P
Type of medication event				.65
Wrong time	34 (48.6%)	20 (50.0%)	14 (46.7%)	
Wrong medication	6 (8.6%)	2 (5.0%)	4 (13.3%)	
Wrong dose	19 (27.1%)	11 (27.5%)	8 (26.7%)	
Wrong route	11 (15.7%)	7 (17.5%)	4 (13.3%)	

The authors concluded that although BCMA was a valuable tool to ensure the five rights

of medication administration are conducted, the technology did not replace the scrutiny of a

good nurse when it came to determining the advisability of a medication. Bowers et al. (2015) explained that overreliance on the technology has unintended consequences. When technology became a substitute for nursing judgment, the risk of medication error increased when the technology did not work or was bypassed.

In an on-going study at four Dutch hospitals, the researchers made similar observations about BCMA. Although the technology had the potential of reducing many common MAEs, the workarounds for this technology may be the root cause of other MAEs that are harmful to patients (van der Veen, van den Bemt, Bijlsma, de Gier, & Taxis, 2017). Table 5 is an extract from the Hospital Quality Institute that shows the typical reasons why a BCMA would be bypassed.

Table 5

M*ost Frequent Reasons Why Medications are not Scanned* (Institute, 2014, p. 2).

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1) No bar code on dose
    a) Split dose
    b) Liquid medication in syringe
    c) Bar code on outer box/wrapper discarded with first use (ointment, eye drops, inhalers)
    d) Patient's own medication; no bar code
2) Bar code damaged
    a) Bar code torn when unit dose peeled open
    b) Bar code on ointment "crimped" with successive administrations
3) Bar code hard to read with the scanner
4) To avoid system default to the next scheduled dose when the current dose is being administered beyond the acceptable time frame set in the bar-coding system
5) Patient off nursing unit; bar code administration system not available
6) Patient registration not complete; emergency medication needed

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Not all research on BCMA showed such pallid results. Some researchers documented significant success in reducing medication error after implementation of BCMA.   Poon et al. (2010) conducted a before-and-after study of bar-code implementation at a major medical

training center. Their results showed an overall decrease in error rate from 11.5% to 6.8% after

incorporating a bar-code verification with an electronic medication administration record

(eMAR). They concluded that the eMAR significantly reduced the rate of errors in transcription

and medication administration as well as preventing adverse drug events. The eMAR system

documents the administration of drugs at bedside. The bar-code scanning verifies patient and

drugs and prevents most transcript errors. One factor for the disparity in results may be the level

of sophistication in the Poon study. In their study, the researchers trained observers to evaluate

14,041 medication administrations and review 3082 transcriptions. This scrutiny of actual

administrations was much more thorough than depending on self-reported incidents that only

represent a fraction of the actual errors that take place.   The researchers classified errors into

three types: (1) timing, (2) non-timing administrative, and (3) potential adverse events. The

results showed a decrease in non-timing error from 11.5% to 6.8% with a 48.5% reduction of

adverse events. Timing errors were reduced from 16.7% to 12.2% with no reduction of adverse

events. The most striking statistic was the reduction of transcription errors from 6.1% to zero.

Of those transcription errors, 2.9% were potential adverse events (Poon et al., 2010, p. 1701).

In the final analysis, the authors estimated that because the hospital administers 5.9

million doses of medications per year, the eMAR and bar-code system could potentially prevent

95,000 adverse drug events every year (Poon et al., 2010, p. 1701).   The success of the study in

demonstrating such a drastic reduction in medication errors may be attributed to the

sophistication of the study and the methodology of observing medication error. The study may

also be overly optimistic because of its relatively short validation period (4 to 8 weeks) after the

interventions.

Another significant observation from the study referred to decision support software that

could be embedded in the physician-order entry system. This technology is still on the cutting

edge of medical science and may become a significant factor in reducing error in the future.

While the eMAR and bar-code systems prevent errors associated with lapses of memory or slips

in executing a medication therapy plan, decision support software could prevent errors that are

associated with poor judgment, insufficient knowledge, or incomplete clinical information (Poon

et al., 2010).

  Decision support software. Training a doctor to learn and memorize all the intricacies of

a healthcare specialty, including the types and proper use of medications, takes over 10,000

hours of training. It also takes 13-17 years to move scientific results to the clinic and often it is

out of date when it arrives. The concept of decision support software or CDSS, was to create a

simulator that can think like a doctor. This framework may be the best way to move information

to the clinic faster and equip the doctor with tools to make better decisions (Bennett & Hauser,

2013). With expanding use of electronic health records (EHR), the healthcare industry was ripe

to "uncover fundamental patterns that can be used to predict optimal treatments, minimize side

effects, reduce medical errors/costs, and better integrate research and practice" (Bennett &

Hauser, 2013, p. 10). Currently, patients receive the correct diagnosis and treatment on the first

pass less than 50% of the time. Bennett and Hauser (2013) hypothesized that an artificial

intelligence (AI) approach could surpass human decision-making performance. Bennett and

Hauser did not suggest that AI will replace doctors but that using AI and capable physician

evaluation together, may provide the most accurate diagnosis and the best treatment with the

correct medications.

  In an experimental study of EHR decision support systems, Horsky et al. (2016) observed

and analyzed the decision patterns of clinicians receiving drug interaction alerts. They

observed 32 clinicians using five different EHR systems in 171 different prescribing decisions. The results showed a surprising low response rate from the AI alerts. Clinicians actively reduced risk in 40% of the cases when responding to high-severity alerts. Clinicians reacted by increasing the patient monitoring and or changing the drug doses. By contrast, when receiving low-severity alerts, 71% of clinicians left prescriptions unchanged. In low-severity cases, clinicians expressed more confidence that patients could tolerate treatments and felt that the benefits were worth the risk. The research showed strong evidence that most drug-drug, and drug allergy alerts were disregarded. The study also suggested that EHR decision support systems might contribute to error by complicating the decision process with too much information displayed in ambiguous context. The researchers concluded that clinicians in this study believed alerts were just one factor to consider in a broad context of care and that alerts were not good at predicting potential harm to any specific patient (Horsky et al., 2016).

In a similar study, Nanji et al. (2018) reached surprisingly equivalent findings. In their study, 73% of all patient alerts involving drug-drug interactions and duplicate drugs were ignored. The study showed that 60% of the overrides were appropriate. The authors concluded that decision support systems need to be optimized to avoid alert fatigue (Nanji et al., 2018).

Variables in the study. The dependent variable for this study was defined as a medication administration. It changed from a success to a failure when any one of the following six errors occurred: (1) incorrect medicine, (2) incorrect patient, (3) incorrect dose, (4) incorrect timing, (5) incorrect route, or (6) incorrect documentation. Each failed administration can be counted as a single opportunity for failure or it can be assigned multiple opportunities for failure. In LSS methodology, the defective parts per million (DPPM) is computed by dividing the total errors by the total opportunities for error. This ratio is then multiplied by 1 million. The

instrument of measurement for this variable was the PSR. This report was produced by hospital staff when a deviation from correct medical procedures occurred which could potentially harm a patient. The PSR structure is similar in most hospitals.   The independent variables included all the components that contributed to the medication administration process including all humans, machines, and materials resources. All these resources interacted in defined process steps that created, and or moved the medication to its final destination--the patient. The independent variables in the medication administration process generally fell into the following categories: (1) selecting and procuring medication, (2) storing, (3) ordering and transcribing, (4) preparing and dispensing, (5) administering medication, and (6) monitoring effects (Esimai, 2005).

Every step in this process was prone to error because the root causes of these errors infected every variable in the system. During the analysis phase of an LSS project, the team attempted to find the root causes of the error. The team then changed the variables (process steps) to reduce or eliminate the influence of these root causes on the variables. An example of a root cause might be the human misreading of drug labels. A team might choose to modify the process by changing the method of identifying a drug from visual identification to bar-code scanning. By negating this root cause, the new process may reduce the probability of a drug being misidentifies and contributing to one of the six errors. Obviously, there may be other root causes such as damaged labels that may lead to barcode reading errors.

These interventions vary because each of these LSS studies was designed and conducted independently. Some studies may have targeted a specific part of the medication process, while others may have addressed the entire process. The structure of each study, and its team, should be considered mediating variables which stand between the independent and dependent variables (Creswell, 2014).

Summary of the literature review. At the conclusion of this literature review, an overarching theme clearly emerged. Medication errors are the result of systemic problems that require systematic change. The root causes of error are complex, and solutions are rarely simple. This is a summary of the key findings from each section.

The search for meaningful, formal theories, applicable to medication process improvement, did not prove to be very fruitful. Davidoff et al. (2015) claimed that improvement professionals are simply "mystified and alienated" by theory (p.228). The authors explained that more formal theory in the improvement science would contribute to the accumulation of knowledge and the transfer of learning. The RPI theory used for this study, is a very broad and informal theory that defines the relationship between the independent and dependent variables for this study.

The next section was an examination of literature that defined the dependent variable, or MAEs. The errors were approached from the functions of the three main players in medication administration: pharmacists, providers, and nurses. Most pharmacy errors were related to the following four causes: (1) medication labeling, (2) dosage calculations, (3) instruction to patients on such things as cautions, warnings, and route of medication and (4) storage, which is often related to expired medications (Goldspiel et al., 2015). Some of the common tools used to prevent these errors are (1) reviewing orders, (2) recalculating medications, (3) better management of the formulary, and (4) participation in quality improvement (Cochran & Haynatzki, 2013).

Nurses were the primary focus of MAEs because they have the responsibility of delivering the medication to the patient. They are the last hope of preventing error and ensuring the Six Rights of medication are successfully met. According to Cook (2014), nursing MAEs

were caused by loss of concentration, interruptions, or following incorrect procedures. Much of

the literature focuses on interruptions. Although most studies showed a reduction of non-critical

medication errors using interruption free zones, it was not conclusive that this isolation during

medication administration was the best policy for the overall quality of care. Many scholars

suggested that some interruptions were a critical part of the medication process and were

essential for the effective care of patients (Hopkinson & Jennings, 2013; Nelms & Treiber,

2011). A final point worth mentioning is Grissinger's dialog about good systems configuration

in medication administration. Rather than holding nurses liable for achieving an industry goal of

Six Rights, they should be held responsible for following the hospital's process for administering

medication. Hospital management is responsible for configuring effective medication

administration system that prevents their nurses from failing (Grissinger, 2010).

The provider initiates the medication process with a doctor's order. When a doctor or

nurse provider incorrectly prescribes a medication, it is called a prescription error. The root

causes of prescription errors were classified into three main categories: (1) action failure, (2)

error-provoking conditions, and (3) latent conditions (Tully et al., 2009). Action failures were

errors in judgment caused by a lack of knowledge of the patient, disease, or medication. Every

error was the result of at least one action failure. Error-provoking conditions may lead directly

to an action error. These include such things as lack of training, fatigue, high workload, stress,

or poor communication.   Latent conditions were poor organizational environments where failure

was more likely to occur. This might be described as a non-culture of safety where staff

members were afraid to expose problems or point out dangerous situations. Tully et al. (2009)

recommended continuous improvement in technical skills and more training for providers in

non-technical skills such as stress management and inter-professional communication skills. The

most common action error was in transcription, stemming from verbal orders and notoriously difficult-to-read physician handwriting. Improvement professionals took two approaches to solve the problem. The first was to integrate an electronic ordering system where the doctor enters the order directly into the system. The second was simply expanding the size and shape of the paper order so the doctor has more room to write (Benitez et al., 2007).

LSS is an extremely successful methodology used to make systematic change in industry by reducing waste and decreasing variation and error. LSS has been applied in most industries around the world and its recent application in healthcare has helped the industry focus its resources on the most significant problems (Antony et al., 2017; Özkan, 2017). The end objective of the application of RPI and its supporting concepts of leadership engagement and culture of safety, are to achieve HRO status. HROs are industries that operate in high risk environments while maintaining a superior record of safety. The characteristics of HROs include (1) preoccupation with failure, (2) reluctance to simplify, (3) sensitivity to operations, and (4) commitment to resilience (Vogus & Sutcliffe, 2007). Aviation is one of the premier HROs and offers several effective tools that are gradually infiltrating healthcare organizations. CRM is one of the most effective ways to increase the culture of safety. Some of the most prominent features of CRM are (1) peer monitoring, (2) briefings, (3) defining operation procedures and standards, (4) recognizing fatigue, (5) regular check rides, (6) blame free reporting culture, (7) checklists, and (8) the sterile cockpit concept (Kapur et al., 2015).

The third section was an exploration into the general application of LSS in healthcare. There have been great advances in the last 15 years in the number and diversity of studies published on LSS in healthcare (da Silva et al., 2018). This exponential growth in LSS has contributed to the quality of research, but as Liberatore (2013) points out, healthcare still

struggles with sustainment. In the projects he studied, 67% demonstrated improvement. Only 10% of those projects could sustain the same level of improvement. LSS in healthcare is still in its infancy. Most medical errors are the result of poorly designed processes in very complex systems. To prove themselves in healthcare, LSS practitioners need to demonstrate their ability to make significant improvement to clinical systems and maintain those changes after the projects are complete (Buck, 2001; Feng & Manuel, 2008).

In the fourth section, the researcher examined LSS projects conducted specifically in medication administration to find the most recent successful interventions in preventing errors in the process functions of pharmacists, physicians, and nurses. Although the most prolific problem in healthcare was medication error, LSS applications to medication error were very limited (Trakulsunti & Antony, 2018). In one successful LSS study by the Systems Engineering Department at Northern Illinois University, researchers reduced persistent medication problems with the following interventions: (1) revised four medication administration forms, (2) organized an isolated medication room for nurses, (3) labeled all medication carts, (4) strengthened the non-retribution error reporting system, and (5) developed a medication education program (Polovina et al., 2014).

In LSS application to pharmacy operations, Chan (2004) used LSS to study the dispensing error problem. Their interventions included the installation of automatic dispensing units. Rewriting all the SOPs, and training personnel. The LSS interventions from the Esimai (2005) project reduced transcription error by installing a CPOM system. They also addressed the problem of pharmacist interruption by hiring a full-time administrator to manage all incoming phone calls. Interventions also included the establishment of a regular meeting between physicians, nurses, and pharmacists. The project reduced administrative errors by 19%

(Esimai, 2005).

In the application of LSS to nurses' administration of medication, two LSS projects were worth reviewing. Benitez et al. (2007) completed an LSS study to restructure their medication administration system to provide nurses (1) quick access to the medication order information, (2) quick pharmacy turn-around-time, (3) access to a history of patient medications, (4) portable and mobile access to medication information, (5) ability to double check information, and (6) an order entry system that was trustworthy (p. 41). It was significant to note that the LSS team considered two new electronic systems that would have incurred significant expense. Using a Pugh decision matrix, the team chose to enhance their current system at a much lower cost. They were still able to reduce medication errors by 50%.

In the study by van de Plas et al. (2017), researchers reviewed the most common LSS approaches to reducing medication errors. The list included (1) nursing education, (2) drug round tabards—worn by nurses to reduce interruptions, (3) computerized physician order entering system (CPOE), (4) barcode verification, and (5) new protocol implementation including a two-nurse policy for medication verification (van de Plas et al., 2017, p. 1). This project specifically addressed errors in parenteral medication administrations where bolus injections were administered too quickly. The team implemented the following interventions: (1) substitution of bolus injections with infusion, (2) education of nursing staff by the hospital pharmacist, (3) developed instructional leaflets, and (4) institutionalization of drug-round tabards. The results were inconclusive because of small population size (van de Plas et al., 2017, p. 3).

The fifth section was a review of the most common technological approaches to improving medication administration. The studies in this section provided mixed results. Some

studies showed the tools to be extremely effective while others showed little improvement. The most common theme from these studies was a warning that these electronic systems were excellent tools, but they were not a substitute for good judgement.

CPOE systems are designed to let providers enter prescriptions directly into an electronic database. The main purpose was to reduce transcription error. Cho et al. (2014) completed a comprehensive study of CPOE and concluded that even mature systems had high MAE rates primarily because of prescription entry errors and transcription mistakes from verbal orders. The Cochran studies from 2015 looked at pediatric centers and found no reduction of MAEs with the use of CPOE (Maaskant et al., 2015). The initial Kadmon et al. (2017) study showed similar results. However, in a follow-on study, the researchers found that the CPOE system itself was generating errors. After fixing the offending software, the MAE rate dropped from 3.2% to 1%. The key lesson was that electronic systems need regular surveillance and interventions. They cannot be installed and forgotten.

BCMA systems use bar code technology to reduce patient bed-side errors by removing the human element when identifying medications and matching them to the patient (Bowers et al., 2015). The researchers did not find statistically significant reductions in the MAEs after the implementation of BCMA. They concluded that an overreliance on the electronic system had unintended consequences. Technology became a substitute for judgment and when the technology failed, work-around procedures resulted in poor outcomes. Poon et al. (2010) discovered that BCMAs are much more successful when used with an electronic medication administration system (eMAR). Results of their study showed statistically significant reductions in timing, and non-timing errors. There was no reduction in potentially adverse events.

CDSSs are electronic simulators that help physicians make decisions about patient care.

Although still on the cutting edge of technology, they are becoming more common and more sophisticated. As the use of EHRs increases, CDSSs are beginning to acquire enough data to predict optimal treatments. The goals of these systems are to minimize error, reduce costs, and better integrate research and practice (Bennett & Hauser, 2013). In early trials of CDSSs, Horsky et al. (2016) observed that providers responded to CDSS inputs in 40% of the high alert cases. Only 29% of the providers responded in low severity alerts. Similar results were reached by (Nanji et al., 2018).

The last section was a review of variables. The dependent variable in this study was administrative medication error as defined by a failure of one of the Six Rights: (1) incorrect medicine, (2) incorrect patient, (3) incorrect dose, (4) incorrect timing, (5) incorrect route, or (6) incorrect documentation (Cook, 2014). Error rate was measured in LSS as defects per million opportunities. The independent variables were the components that were used in the administrating of medications. These components included human, mechanical, and material resources that were grouped together functionally to form processes. These processes performed the following functions: (1) selecting and procuring medication, (2) storing, (3) ordering and transcribing, (4) preparing and dispensing, (5) administering medication, and (6) monitoring effects (Esimai, 2005). LSS teams attempted to reduce medication error by improving these processes.

Transition and Summary of Section 1

This foundational section is designed to bring the reader from the problem to a purpose and from a purpose to a design for study with a theoretical framework. A literature review formed the background for understanding the problem, the variables, and how researchers have approached both in the past. This is a summary of this section.

The general problem of this study is that medication errors are the single leading cause of injury in the U.S. healthcare system. The Joint Commission advocated the application of LSS in solving this problem and many advances have been made. The specific problem is that very little research has been done to validate the effectiveness of this methodology in reducing medication error. The purpose of this study is to contribute to the body of knowledge about the effectiveness of LSS in solving medication administration problems. More specifically, the purpose of this study is to find out if LSS application in Navy Medicine hospitals is correlated to a reduction of medication error.

The method will be a non-experimental quantitative study and the design is a pre-post causal comparative design. The general research question asks: Does Chassin and Loeb's theory of LSS effectiveness in changing healthcare processes explain a change in medication PSR rates after the intervention of an LSS study targeting medication errors? The research hypothesis states: the preintervention PSR rate will be statistically larger than the postintervention PSR rate for the same medication errors. This study is based on the RPI theoretical framework from Chassin and Loeb (2013) which is an application of LSS and Change Management to healthcare. RPI is part of a three-pillar concept including leadership commitment and culture of safety, which are a framework for developing HROs. In this conceptual framework, high reliability is the ultimate objective of the healthcare industry.

This study has significance because so little research has been done to reduce the gap between what practitioners believe LSS can do in healthcare and what researchers have actually tested. This researcher intends to contribute to the body of knowledge about the application of LSS to the prevention of medication error. The research will specifically address the application of LSS at Navy Medicine.

Section 2: The Project

In this section, the researcher describes the details of this research project. It begins with subsections on the purpose of the study and the role of the researcher. Since this project involves the collection of archived data only, the section on the role of participants will focus on the individuals who will assist in obtaining this data. The methodology and research design within that methodology are critical to the success of the study and are justified and explained in more detail. The method will be a non-experimental quantitative study that is designed to add empirical evidence to support the theory of RPI in healthcare. The specific framework of the study is a pre-post causal comparative design. The general research question asks: Does Chassin and Loeb's theory of LSS effectiveness in changing healthcare processes explain a change in medication PSR rates after the intervention of an LSS study targeting medication errors? The research hypothesis states: the preintervention PSR rate will be statistically larger than the postintervention PSR rate for the same medication errors.

The population and sampling methods are also clearly established. Data collection methods are described including an outline of the instruments and the collection techniques. In the data analysis portion, the researcher describes the variables, data types, and how these variables relate to the problem, research question, and the hypothesis. The final portion of this section is a discussion of the reliability and validity of the instruments used in data collection and analysis.

Purpose Statement

The purpose of this quantitative, pre-post causal-comparative study is to determine the effectiveness of LSS in reducing medication errors as it has been applied at Navy Medicine hospitals. LSS has been adapted to many different functions in hospitals and clinics of the Navy

but only a portion of those projects apply directly to patient safety. This study will focus only on the processes of medication delivery and how the Navy has applied these tools to reduce the occurrence of error. The intent of this study is to discover any correlation between the completion of an LSS study and an actual reduction of medication error and to make inferences about the cause of those reductions in error. This study may contribute substantial evidence to support a hypothesis about LSS and its application to medication administration. Evidence from the results of this study may influence the way LSS projects are conducted at Naval hospitals in the future.

Role of the Researcher

The researcher's primary role in this study is planning, organizing, analyzing data, and preparing a final report. The researcher will depend on many other individuals for the collection of data.   As a doctoral candidate in business administration and healthcare, the researcher has been exploring applications where business principles can advance the effort to improve the quality and safety of healthcare in America. The researcher first developed an interest in the subject of medication error through his work as a business consultant in healthcare. In his current assignment as an LSS Master Black Belt with Navy Medicine, he has observed the challenges of an intricate medication administration system. Navy Medicine's LSS program has been very successful in improving many aspects of healthcare. Surprisingly, there has been very little application of the tools to reducing medication error. Although there have been some specialized projects relating to medication error, very few have focused on the primary processes of medication administration and no one in Navy Medicine has attempted to improve the entire medication process as a single system.   The researcher has made this his personal quest, to determine the current state of LSS application to medication administration and to contribute his

personal effort to make significant, measurable gains toward high reliability in medication administration.

In this study, the researcher is taking a broad look at the effectiveness of LSS application to medication administration by reaching outside the MTF where he works and examine LSS studies throughout the enterprise. The researcher hopes to gain a better understand of the tools that are currently applied to this problem and make some quantitative assessment of their effectiveness.

None of the academic elements of the study have been outsourced to any other person or entity. The researcher will require assistance in accessing data. The idea and basic concepts for this project are the sole responsibility of the researcher. It is expected of the researcher that he will collect accurate, unbiased data and that he will analyze and present it fairly.

Participants

Due to the nature of this study, no participants will be engaged except for administrative purposes. In this ex post facto study, the events have already taken place and the data has already been collected and archived in various places. The events are LSS studies in Navy Medicine that were designed to reduce medication error. The researcher will access these studies and their results through the Strategic Process Improvement Data Repository (SPIDR). Currently, the Department of Defense (DoD) is transitioning all military healthcare administration, including research oversight, from the individual services to the Defense Health Agency (DHA). Although their processes for research approval and data sharing are still under development, all applications for approval and data sharing will be made with DHA. The project will likely be reviewed by a military institutional review board (IRB) with scrutiny from the Human Resources Protection Program (HRPP). The researcher expects an exemption based on

the fourth exemption criteria which is: research with existing data or documents. The researcher

will also apply for a Data Sharing Agreement (DSA) with DHA to access PSR and pharmacy

information that is essential for the completion of this project. Once approved, the researcher

will approach the safety office and the pharmacy division to request specific data fields.

The pharmacy and safety data will not contain personally identifiable information (PII) or

personal health information (PHI). The researcher will strictly follow any de-identification

requirements outlined in the DSA. No text fields from PSRs will be requested or used in the

study or the report. The data is all aggregate data. Results from PSR and pharmacy data will

only be categorized and counted as discrete occurrences. The LSS project reports do not contain

any PII. To collect data from DoD, the researcher will require the assistance of a military officer

to act as the government sponsor. The government sponsor has been designated. His

responsibilities are outlined in the Data Sharing Agreement Application (DSAA).

Research Method and Design

The logic of employing the quantitative method in this research project is to examine the

relationship between the independent and the dependent variables of this study to evaluate a

hypothesis. If the statistical analysis can provide evidence to support or reject the hypothesis,

one will have evidence to support an answer to the research question. The causal-comparative

design was selected as the most appropriate approach to determine if a correlation exists between

the variables in this study and to make inferences about cause and effect. In this section, the

researcher expounds on the logic of his selection of method and design and summarizes the

argument for both.

Discussion of method. Quantitative research is generally described as an examination

of the relationship among variables for the purpose of testing theories. By measuring variables,

the researcher can extract numerical data and use statistical procedures to make inferences about the variables and how they relate to each other. Quantitative research tests theories deductively using closed-ended questions. The results should explain how the researcher protected against bias and should be in a format that other researchers can replicate (Creswell, 2014). The quantitative research method was selected because the nature of this study is best suited for quantitative evaluation. The purpose of the study is to find empirical evidence supported by statistical evidence that LSS has been an effective tool in reducing medication error at Navy hospitals. Since the variables are numerically measurable, statistical methods may be used to establish correlation between variables and to make inferences about the cause-and-effect of those variables.

     Discussion of design. The researcher has selected the causal-comparative design, also known as ex post facto research, to conduct a non-experimental examination of the variables. The purpose is not only to find out if the phenomenon occurs, but what causes it to occur. However, causal-comparative studies cannot prove a cause-and-effect relationship between variables. In this regard, the word causal is a misnomer (Lehmann & Mehrens, 1979). Only true experimental research can prove causation. In experimental research, the independent variables are tightly controlled through design and statistical analysis (Creswell, 2014). Yet, in many circumstances, where a quantitative analysis is desirable, the variables cannot be controlled or manipulated. Kerlinger (1973) described an ex post facto study as empirical research where the researcher does not have control over the independent variables because the events have already occurred. Empirical research is a secondary analysis of original research that tests a new hypothesis that has not been tested in other studies (American Psychological Association, 2010). The case might also exist where variables cannot be manipulated either because of ethical or

practical reasons. The most classic example is the case made against the tobacco industry. The

U.S. Surgeon General has determined that cigarette smoking causes lung cancer and other

ailments that are hazardous to human health. As the tobacco industry correctly points out, the

Surgeon General's conclusion is incorrect because that conclusion is based on causal-

comparative research of humans and experimental research on animals. There has not been any

true experimental research on humans. This does not diminish the powerful inferential data

linking tobacco to severe illness. There is enough evidence to render true experimental tobacco

research on humans completely unethical (Lenell & Boissoneau, 1996).

    This discussion on method and design has finally led to the key question: If causal-

comparative studies do not prove causation, then what is the difference between a correlation and

a causal-comparative study? According to some researchers, there is very little difference

(Creswell, 2014; Kerlinger, 1979; Powers, 2010). Correlation studies use correlation coefficients

to discover relationships between variables. Correlation research can also be used to predict the

strength of that prediction. A correlation between the movement of two variables may mean that

one variable is changed by the other. On the other hand, the correlation between those variables

may be completely by chance or may be driven by other variables that were not measured.

Correlation statistics cannot be used to predict cause-and-effect relationships (Lenell &

Boissoneau, 1996). However, inferences can be made about variables without direct

intervention by observing concomitant variation in the independent and dependent variables.

The primary difference is in how the independent variable is measured and analyzed. In causal-

comparative studies, normal data are analyzed using t tests, analysis of variance or covariance.

When data are not normally distributed, or they are binomial, the researcher may use

nonparametric tests such as Chi-square test, Mann-Whitney U test, or the Wilcoxon signed-rank

test. Correlation tools may be applied to predictive studies. Some of these techniques include the scatter gram, least squares method, and regression analysis (Lenell & Boissoneau, 1996).

Causal-comparative studies can be used to determine the effectiveness of a procedure or method. An example of this strategy is given by Smith and Glass (1977) who used this design to produce evidence that psychotherapy counseling was effective. The researchers used controlled evaluations of treated and untreated groups. This strategy is similar to the approach that will be used in this research project which is designed to determine the efficacy of using LSS to reduce medication error. The researcher will test the first group of patients that were treated prior to the application of LSS to the medication process. The research is not actually testing the patients but observing the rate of medication error among this group of patients as reflected by the rate of PSRs reported during a given period of time. To complete the analogy, the second group, or control group, are patients treated after the LSS project was applied to the medication process. The second group is tested the same way, by counting the number of PSRs relating to medication error that were recorded after the application of the LSS project. This second group has had the benefit of LSS treatment on their medication process. If the difference in error rates are statistically significant, the researcher will test the independent variables between the groups to determine if there is a correlation between specific interventions that were used and the outcome of the error rates.

Summary of research methods and design. The quantitative method of research was selected as the most appropriate method because of the problem and purpose statement statements in the introduction. The problem statement identifies the lack of empirical evidence to support the efficacy of LSS as a tool to reduce medication error.   Empirical studies, by nature, are quantitative. In the case of this study, the variables can be measured and analyzed

numerically. Empirical studies are also post de facto studies which are designed to find correlation between variables and make inferences about cause-and-effect using statistical analysis. The post de facto or causal-comparative design is used in place of experimental research when variables cannot be controlled or manipulated. In some cases, it may be unethical to perform controlled experiments, or it may just be impractical to manipulate the variables in a study.

In this study, the non-experimental approach is the most appropriate for two reasons. Firsts, a true experimental design would require the manipulation of the variables by the researcher during an LSS team event. This would defeat the purpose which is to discover the efficacy of an LSS project that was conducted in its natural environment. The second problem with experimental research, in this case, is timing. Where the researcher is interested in the longitudinal outcome of LSS intervention, the researcher would have to wait extensive time after each project to collect the required data. Using the ex post facto design, the researcher can combine the examination of multiple projects that were completed over several years. This broader sample will increase the leverage of the data and make it possible to complete the study in an acceptable window of time.

Population and Sampling

In the measurement phase of the DMAIC framework, an LSS team seeks to find the distribution of occurrences in a given population under study. Defining and measuring the population are essential steps to a successful research project. Establishing a benchmark of the current process is critical to understanding the extent of the problem and to establish a standard against which the team will measure its improvements. After an LSS team has analyzed the data and implemented changes to improve the process, a validation process begins. In this validation

process, the team measures the population again, in the exact same way, to determine if the

team's interventions have affected the occurrences by changing the shape of the distribution.

Since the researcher seeks to determine the effectiveness of LSS interventions, this study will

mirror the technique of measuring the population prior to interventions and after. This first step

in the analysis phase of this study is defining the population and establishing the rules of

engagement for sampling.

Discussion of population. The population under study in this research project is defined

as: all medication administrations for in-patients during the six months prior to the LSS

medication study and six months after the study at the MTF where the LSS study took place.

The researcher will examine five different LSS studies that were conducted at three different

MTFs.

LSS studies in healthcare that examine safety and quality of care, usually measure error

rate. A rate is a fraction where the numerator is defined as the number of defects, and the

denominator is usually defined as the opportunities for adverse occurrences among the

population at risk (Pronovost et al., 2006). A population at risk infers the number of patients at

risk but a population may be defined as specific encounters rather than the actual patient. A good

example is how catheter-related blood stream infections are measured in terms of the number of

infections per 1,000 catheter days. Patient falls are measured as the ratio of falls per 1,000 bed

days. (Jha, Li, Orav, & Epstein, 2005). Medication errors have no standard convention for

measuring error rate. Medication errors would ideally be measured as a ratio of errors over the

number of patients who received a medication. In a controlled, experimental study, a very

accurate count of errors could be collected as well as an accurate population of patients. For

an effective experiment, surveillance systems must be in place to monitor the numerator and

the denominator (Gordis, 2013).

In this non-experimental study, where the researcher is examining multiple studies and their outcome at various MTFs, measuring each member of the population, or even conducting accurate samplings of errors in each population is untenable. For a non-experimental study, a more practical approach is to obtain the patient census for the periods of time under study and use this as the population. Unfortunately, there would be many inaccuracies. One problem is that not all patients receive medications and the census does not indicate which patients received medication. A second problem is that most patients receive multiple medications and thus reflect multiple opportunities for error. This is data that could be collected but would require the examination of each individual patient record in the population or the sample population.

As a better technique, this researcher proposes to define the population as the number of medications dispensed during the given period. Each individual medication could be classified with multiple opportunities to be administered incorrectly. The number of opportunities for error would be multiplied by the number of medications dispensed to inpatient wards.

The researcher has intentionally omitted the study of outpatient errors. Although outpatient medications errors represent a significant portion of the total medication related PSRs, all the LSS projects under review targeted inpatient medication error only. The researcher found no LSS studies that targeted outpatient medication.

The number of medications dispensed to inpatient wards is the population, or denominator. The numerator is the number of medication errors as reflected by the count of PSRs. This method, although better than a patient count, is also subject to error. Not all medications dispensed to an inpatient ward are actually administered to a patient. Some medications, after being dispensed to the clinics, are wasted because of expiration, damage,

mislabeling, or simply unused. The author accepts these errors as a detriment to the validity of the ratio itself. It may not reflect the actual rate of error for the given period. These inaccuracies in population do not reflect the same detriment to the reliability of the ratio if measured exactly the same in every case. The primary purpose of the study is to examine the difference in the ratio before the LSS study and after the study. If the ratio is changed only by the number of errors, the proposed population could accurately answer the research question of how the error rate changed after the LSS interventions.

Discussion of sampling. No sampling techniques will be required for this research project. In this study, the entire population of medication administrations is measured for the five LSS studies under examination.

In many cases, populations under study in healthcare are too large to measure the entire population. Sampling methods are used to make inferences about the characteristics of a population or the distribution of events within that population. When measuring continuous data in a population such as time, temperature or speed, the statistician is interested in predicting the mean of a population and a confidence interval for that mean. Confidence intervals can be developed for populations where the standard deviation is known or unknown. Random sampling is the key to accurate prediction of a population and margin of error is determined by the size of the sample. The primary tool for hypothesis testing in normally distributed populations is the *t*-test, based on the *t*-distribution (Weiss & Weiss, 2012).

Making inference for populations with discrete data, also known as attribute data, is much different. Attribute data include nominal (names or labels), ordinal (scales: poor, good, excellent), and binomial data where the attribute is a pass or fail (George, Rowlands, Price, & Maxey, 2005). The data for the dependent variable (medication administrations) is binomial. For

each event (medication administration) it can be measured only as a success or a failure. With

attribute data, there is no significance to a mean or standard deviation of the mean. With

attribute data, the statistician is concerned with proportions. Proportion refers to the percentage

of the population that has the designated attribute. To make inferences about population

proportions, one uses z-tests, also known as proportions tests (Weiss & Weiss, 2012).

In this study, the researcher intends to make inferences about the population of

medication administrations in the U.S. Navy medical system. The study is designed to make

inferences about how LSS affected the population of medication administrations after an LSS

medication study was concluded at a designated MTF. Because this population is defined and

the population is not under strict surveillance, as in an experimental study, the entire population

can be measured in each case.

The number of medications dispensed to inpatient units is archived and can be retrieved

to represent the entire population of medications dispensed both before and after each LSS study.

The numerator, or PSRs in this ratio, are also available and do not require sampling. All PSRs

recorded during the population administration of medications are collected from electronic data

bases. This ratio of medication errors over medication administrations constitutes the dependent

variable and will provide the primary results of the study. At the conclusion of the study, if the

hypothesis is rejected, the researcher will make inferences about how LSS studies designed to

reduce medication error can elicit the same results or better results in the future.

Summary of population and sampling. In this non-experimental study, the population

is defined as: all medication administrations for in-patients during the six months prior to the

LSS medication study and six months after the study. Because of the nature of this study,

sampling techniques are unnecessary to make inferences about the population of medication

administrations or medication errors. The researcher intends to use the use the entire population

of errors and medications administered during the designated periods of time. The researcher

defines the population of errors as the total number of recorded PSRs during the designated

period of time. The researcher defines the population of medication administrations as the

number of medications dispensed to inpatient units.

Data Collection

In this section, the researcher explains how the data for this research project will be

collected, stored, and organized. The researcher will be gathering data from three primary

sources: (1) the pharmacy, (2) the PSR system, and (3) the SPIDR repository. After a brief

discussion of instruments, the researcher explained collection techniques which includes a

description of the PSR system and how information is gathered from the hospital staff. The final

segment outlines how the data from the three sources of data will be classified for analysis.

Instruments. No specialized instrument is required to collect the data for this research

project. The data for the population of medications dispensed is retrieved from reports produced

by the pharmacy division at DHA. PSR data is retrieved from the safety division at DHA. The

pharmacy and safety divisions will release data from the selected fields after the approval of a

DSA. The fields of interest from pharmacy are (1) inpatient medications dispensed, (2) date,

and (3) location (MTF). The PSR fields of interest are (1) the number of medication related

PSRs, (2) date, and (3) location (MTF). All data is discrete. No open fields will be requested.

Data collection techniques. No special technique is needed to collect data for this

project. Extensive permissions will be needed to access the data. Although the researcher is not

directly involved in the collection of the original data for the PSRs, it is worth mentioning how

this data is retrieved. The PSR system was established as a self-reporting survey, accessible by

all staff members. When staff members at the hospital observe events that could be considered a threat to a patient's safety, the member is expected to report it through the PSR system. Entries are normally made electronically but there is also an option for paper entries. The information is consolidated and maintained in a central data base at DHA. The submissions are anonymous and do not normally contain personal information unless the submitter choses to enter it in the open comments. Certain information is required to complete the submission, but the submitter may expound on an event with a few words or a discourse.   The following constitute patient safety issues that should be reported: (1) an event that could harm a patient, (2) an event that did harm a patient (3) a procedure or act performed contrary to instructions, standard operating procedures or best practices that could lead to harm of a patient.

Data for the pharmacy reports is electronically entered in a data base by the pharmacy staff every time a medication is dispensed. Every medication that leaves the pharmacy is meticulously recorded and categorized as to its destination. The researcher will be collecting the number of medications dispensed to all inpatient units.

Data from the actual LSS projects under study will be collected from the reports in SPIDR. Reports are entered in SPIDR by contracted LSS Black Belts that work for the MTF's commander where they are assigned. Each completed study has a charter, tollgate presentation, and a benefits workbook. The charter was used to define the problem and initiate the project. The presentation summarizes each phase of the DMAIC process and includes supporting documents. The Benefits Workbook quantifies the benefits of the project. Using the charter and the tollgate, the researcher will glean the critical elements of the project including the purpose of the study, expected benefits, and the specific interventions used to solve the problem. The interventions are central to the study because they are the catalyst to changing the independent

variables. These interventions will be classified and counted for each project.

Data organization techniques. Raw data will be stored on unclassified government computers. After the DSA is approved and data has been presented to the researcher, it will be stored on a designated government network with an approved Authority to Operate (ATO). The data will be organized and sorted by the researcher using Excel® spreadsheets. Pharmacy data will be organized as the number of medications dispensed to inpatient units per month by each MTF. PSR data will organized as the number of patient related PSRs per month by each MTF. Data from the LSS studies will be classified according to the type of intervention. Each intervention will be classified into one of five categories. Each LSS study may have more than one category of intervention. The five categories are (1) electronic interventions—includes CPOE, CDSS, BCMA, or pharmacy dispensing systems, (2) procedural interventions—includes changing SOPs, requiring staff to perform differently such as using new forms, checklists, two-person policies or other HRO techniques, (3) Systematic interventions—includes new systems (not electronic), changing the process including moving equipment, changing routes, or creating interruption free zones, (4) Training—includes formal training for pharmacists, providers, nurses, corpsmen, interns, or patients, and (5) culture modification—includes actions that are specifically designed to improve the culture of safety or culture of quality. Each intervention will be classified according to these five categories regardless of which area of the medication administration process it is applied. The researcher will not stratify the data according to the six areas of the process where the error takes place.

Summary of data collection. No special instruments are required to collect data for this project. All data are archived in three different data systems and will be extracted electronically. No special collection techniques are required to retrieve the data for this project. PSR data is

self- reported survey data. All staff members have access to input safety events. The output data can only be retrieved by authorized users.

Collected data will be organized in logical format for analysis. Dispensed medications are classified as inpatient medications dispensed per month at each MTF. Medication PSR data will be classified as number of events per month at each MTF. LSS intervention data will be classified into five areas identified as electronic, procedural, systematic, training, and culture of safety and quality.

Data analysis

How the data will be analyzed is fundamental to the success of this research project. It begins with a thorough description of the variables used in the study.   The previous section described how the data will be collected. The purpose of an analysis of the data is to determine if there is sufficient evidence to reject the null hypothesis. The goal of this section is to provide the reader with a roadmap of how the author will reach his conclusions and to provide the reader sufficient information to recreate the analysis.

Variables used in the study. The dependent variable for this study is the outcome of an encounter where a medication is administered to a patient. The measurement of this variable will take the form of discrete data, also called attribute data. Each medication administration has the attribute as either a success or a failure. This is a binomial measurement because each administration can only be classified as one or the other. The general problem described in section one, established that medication errors are the most prevalent cause of injury to patients in the U.S. healthcare system. The problem statement ties process improvement to the solution by explaining that TJC has endorsed LSS as the best way to improve safety and the quality of healthcare. The specific problem is that not enough research has been done to prove the efficacy

of LSS in reducing medication errors. The purpose of the study is to add evidence to the body of

knowledge about the strength of LSS in lowering the rate of medication error. The dependant

variable is the essential data that that could support the assertion of the research hypothesis

which states that the preintervention PSR rate will be statistically larger than the postintervention

PSR rate for the same medication errors. The rate of error is formed by the ratio of PSRs to

medications administered.

In this causal comparative study, the researcher is trying to find a connection between the

dependent variable and the independent variables. The independent variables are found among

the process steps in the administration of medication. Researchers have broken down these steps

into three primary areas: (1) prescribing, (2) dispensing, and (3) administering. Esimai (2005)

breaks these steps down further into the following six steps: (1) selecting and procuring

medication, (2) storing, (3) ordering and transcribing, (4) preparing and dispensing, (5)

administering medication, and (6) monitoring effects. Every step in these processes contain

independent variables that could affect the dependent variable.

In LSS, practitioners are concerned with specific interventions or changes to the

processes of medication prescription, distribution, and administration. If all other independent

variables are held constant, both before and after an LSS study, then the independent variables

that have been changed are those that the researcher would like to measure. In the literature

review, many different interventions were discussed. The researcher has classified the most

common interventions into five discrete attributes that will capture every type intervention found

in the LSS studies under examination. The five attributes of the dependent variables are (1)

electronic, (2) procedural, (3) systematic, (4) training, and (5) culture of safety and quality. How

the independent variables are measured and analyzed is instrumental to finding a correlation

between the interventions and the rate of errors. It is also necessary for making inferences about which interventions may cause more change than others. In order to infer causation, the researcher needs to test the independent variables to find commonality in LSS projects that cause the dependent variable to change. Table 6 lists the variables by classification.

Table 6.

Classification of Variables

Variable Type	Name	Classification	Data Type
Dependent	Medication Error	PSR relating to medication	Discrete/binomial
Independent	Interventions	(1) Electronic changes	Discrete/ordinal
Independent	Interventions	(2) Procedural changes	Discrete/ordinal
Independent	Interventions	(3) Systematic changes	Discrete/ordinal
Independent	Interventions	(4) Training changes	Discrete/ordinal
Independent	Interventions	(5) Culture changes	Discrete/ordinal

Hypotheses. In the research hypothesis, the researcher states that the preintervention PSR rate will be statistically larger than the postintervention PSR rate for medication errors. In the first stage of analysis, the researcher is looking for any change in the total error rate between groups. The researcher will create a ratio with total medication errors over total inpatient medications for the preintervention group and the postintervention group. The preintervention group will include medication errors six months prior to the start of the implementation phase of the study. The postintervention group will include medication errors six months after implementation of interventions. A proportions test will be calculated for each study using a .95 confidence level. The researcher is looking for a p value less than .05 to demonstrate a statistical significance. This test will determine if there is enough evidence to reject the null hypothesis which states that there is no difference between the preintervention medication PSR rate and the post intervention PSR rate for medication errors (Weiss & Weiss, 2012). The

test will be performed at the .95 confidence level. The results will also be displayed graphically.

If the researcher finds cases where the error rate in the preintervention group is greater than the postintervention group, the next stage will test the interactions between the independent variables and the dependent variables. Optimally, the researcher would use some form of regression analysis, but the study lacks independent variables that can be measured with continuous data. Using graphic analysis to demonstrate association, the researcher will compare each individual intervention with its associated output (the study's reduction in error) to determine if one intervention is associated with a higher reduction of errors. The results will be displayed using a bar graph. The results of this test will be used to make inference about the cause of any reductions in error (Statistics How To, 2019).

All statistical tests and graphical productions will be performed using data analysis features in EXCEL® and the statistical program Minitab®.

Summary of data analysis. The dependent variable for this study is the outcome of encounters where a medication is administered to a patient. The attribute of the variable is binomial. It is measured as a success or a failure. The dependent variable is the essential data used to test the hypothesis. If it can be shown that the medication error rate was statistically larger in the preintervention group versus the post intervention group, the researcher will reject the null hypothesis. The hypothesis will be tested using proportion tests. The variables will be tested at the .95 confidence level.

The independent variables are the specific interventions that were used to change the dependent variables in the LSS study. Testing the independent variables is essential to finding evidence to support a statement about a correlation between specific interventions and a reduction of medication errors. Graphic analysis will be used to demonstrate association

between each type intervention and the successful reduction of error.

Reliability and Validity

This section is an examination of the value of data in terms of reliability and validity. These two elements should be evaluated to determine the strength of the study. The researcher must find ways of evaluating reliability and validity and identify threats to their strength. Reliability generally refers to the consistency of test scores or responses across different constructs. Validity refers to the usefulness or applicability of inferences derived from instruments (Creswell, 2014). Reliability and validity are related to each other. Poor measurement reliability will affect the validity of the project and is a prerequisite for measuring validity. However, understanding reliability of data is not sufficient for measuring validity (Gliner, Morgan, & Harmon, 2001). As Harmon, Morgan, and Gliner (1999) noted, it is impossible for any research study to achieve the highest ratings in every dimension of research validity. In most cases, researchers must sacrifice strength in one aspect of the study to gain strength in another. Using the following suggestion by Harmon et al. (1999), the researcher will attempt to evaluate his data on a continuous scale from low to high in each applicable category.

Reliability. Reliability refers to consistency. In every sampling test, there is an observed score and a true population score. The researcher's challenge is to find the variation or error between the two. Harmon et al. (1999) refers to two types of reliability: (1) measurement, or test reliability, and (2) research, or study, reliability. Measurement reliability concerns the strength of the test and can be measured under the following four methods: (1) test-retest reliability, (2) equivalent forms of reliability, (3) internal consistency reliability, and (4) interrater reliability (Gliner et al., 2001). The primary instrument for collecting data for the dependent variable is the PSR system and it is difficult to test under any of these four constructs of measurability. Using

self-reported data is problematic for any research study because the researcher is depending on the hospital staff to observe errors and to formally document it. The researcher has no control over the survey or the respondents.

Parallel Forms Reliability refers to the problem of pre-test influencing the participant's score on the post test. This construct is not applicable to the PSR instrument because the instrument is not a test. Internal consistency reliability is only applicable to tests where data from several items are combined to give one composite score. Interrater reliability is not applicable to this data because it refers to situations where the instrument is an outside observer who judges the score of the episode or behavior.

Test-retest reliability is the most applicable to this project and refers to the procedure of re-testing persons in a similar population to compare scores. The concern, in this case, is that different individuals in different hospitals may respond to the survey in different ways. Some individuals at different MTFs may choose to report more incidents than others. A difference in reporting rate could be responsible for a change in pre-post PSR rates rather than the instrument (LSS study). The coefficient of stability is often used to examine test-retest reliability. To be effective, this test must be accomplished when there is little happening that is related to the substance of the instrument. The test uses the correlation coefficient to compare PSR outputs between the three MTFs. Correlation output values are between -1 and +1. In a stable system, one would expect the score to be a high positive score. Although the PSR system could not be independently tested outside the actual environment, the researcher could measure correlation of PSR reports between the three hospitals outside the window of LSS medication studies. A score of zero would indicate low reliability. A score of +.5 would indicate moderate reliability. A score of +1 would indicate the highest reliability (Gliner et al., 2001). Another effective measure

of stability would be a control chart measuring the change of PSR rates over time or the time between events. In a stable reporting system, the time between PSR arrivals will remain below the upper control limit and above the lower control limit (+3 or -3 standard deviations). Reported points outside these limits indicate the influence of non-normal variation and would indicate a lack of control or consistency in the reporting system.

Research, or study reliability, is called replication. This refers to the reliability of the entire study, not just the instruments or measurements. If the study were repeated under similar circumstances, would the results be the same? To make a case for replication, the same study needs to be replicated with similar results. In attempting to include multiple LSS studies in this research project, the researcher is attempting to find common results between projects. However, the extensive differences in the chartered purpose of these studies are sufficiently unique that a case for replication will likely be poorly supported. This study will need to be performed again at different hospitals with similar LSS projects under similar conditions.

Validity. In their discourse on research reliability and validity, Campbell and Stanley (1966) broke down validity into two broad categories—internal and external. Internal validity refers to the strength or capability of the design. External validity is about generalizability. The researcher wants to know to what extent the results of his or her study can be applied to other variables, settings and populations. Their definition can be applied to both experimental and non-experimental designs. Cook and Campbell (1979) broke down internal validity into statistical conclusions and internal validity. They divided external validity into construct validity and external validity. Using these four categories, Harmon et al. (1999) developed a construct to evaluate studies that integrates these concepts and clarifies how research validity of the entire study depends on the special instruments used to take measurements. Figure 6 lists the three

grading criteria for internal validity. Figure 7 lists the grading criteria for external validity. The

researcher's self-grading of validity and reliability for this project is shown in Table 7.

MEASUREMENT RELIABILITY AND STATISTICS

Base rating on:
1) Reliability of instruments/ measures
2) Appropriateness of power
3) Appropriateness of statistical techniques
4) Appropriateness of interpretation of the analysis

LOW	MEDIUM	HIGH
Low on all of above	Mixed on above	High on all of above

INTERNAL VALIDITY

Equivalence of Groups on Participant Characteristics

Base rating on:
1) Equivalence of the groups on attributes other than the independent variable
2) Adequacy of attempts to equate participant characteristics (e.g., ANCOVA)

LOW	MEDIUM	HIGH
Groups very different No control of participant characteristics	Some attempts to equate groups	Random assignment to groups

Control of Experiences and Environment Variables

Base rating on:
1) Extent to which extraneous events could affect one group more than the others
2) Extent to which extraneous events could affect both groups and obscure true effect
3) Adequacy of attempts to reduce extraneous influences

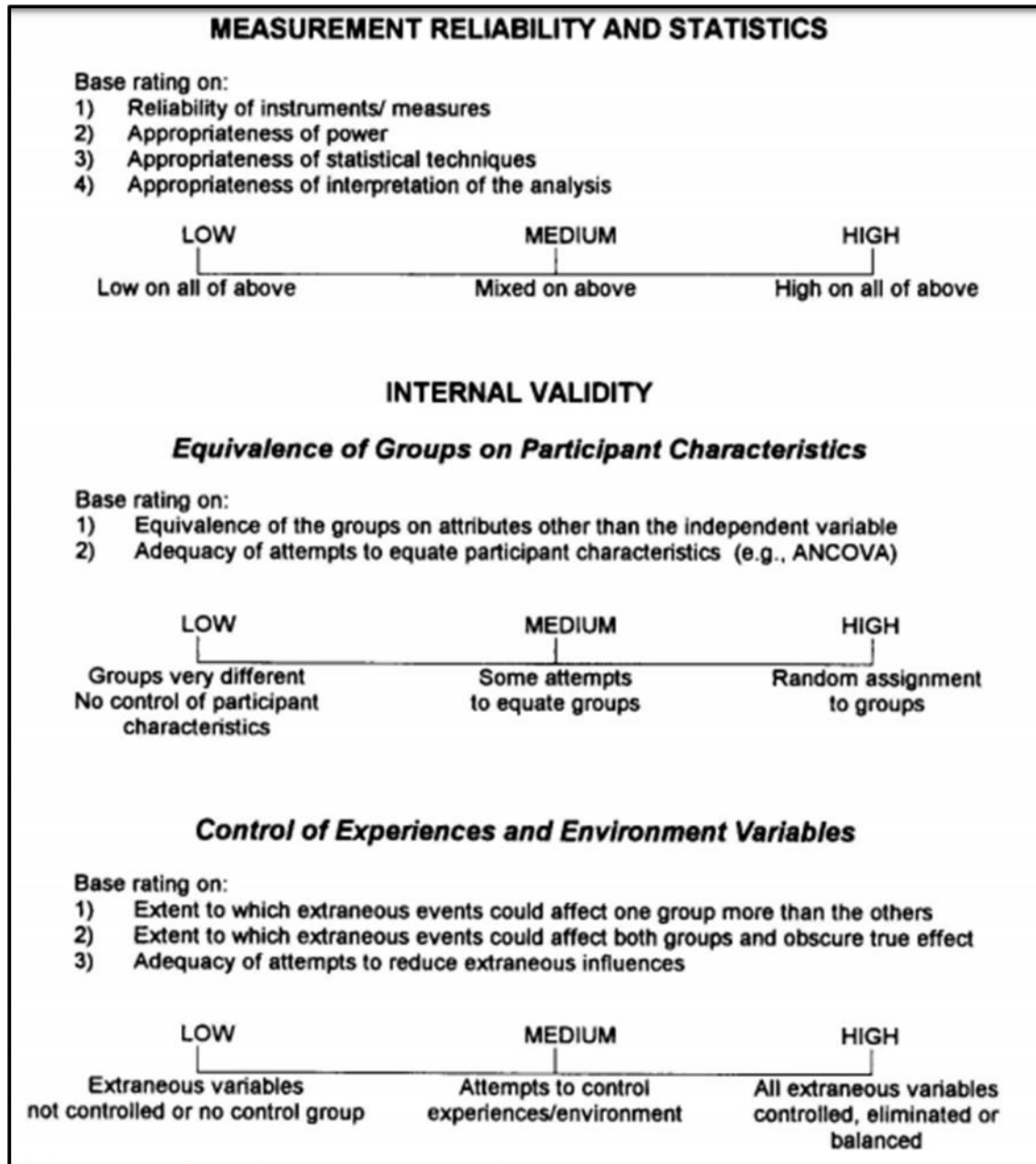| LOW	MEDIUM	HIGH
Extraneous variables not controlled or no control group	Attempts to control experiences/environment	All extraneous variables controlled, eliminated or balanced

Figure 6. Rating scale for internal validity (Harmon et al., 1999, p. 482)

More should be said about the nature of the PSR system and its validity as a survey

instrument for research. Pronovost et al. (2006) is very critical of the use of self-reported safety

MEASUREMENT VALIDITY AND GENERALIZABILITY OF THE CONSTRUCTS

Base rating on:
1) Appropriateness of operational definition of the treatment to the construct of interest
2) Validity and generalizability of the dependent variable measures

LOW	MEDIUM	HIGH
Treatments and measures not valid or generalizable	Some problems with validity or generalizability	Treatments and measures are valid and generalizable

EXTERNAL VALIDITY

Population

Base rating on:
1) Representativeness of accessible population vis-à-vis theoretical population
2) Adequacy of sampling method from accessible population
3) Adequacy response/return rate

LOW	MEDIUM	HIGH
Actual sample unrepresentative of the theoretical population	Some attempt to obtain good sample	Actual sample representative of theoretical population

Ecological

Base rating on:
1) Naturalness of setting/conditions
2) Adequacy of rapport with testers/observers.
3) Naturalness of procedures/tasks
4) Appropriateness of timing and length of treatment
5) Extent to which results are restricted to a specific time in history

LOW	MEDIUM	HIGH
Unnatural setting, tester, procedures and time	Somewhat artificial (e.g., questionnaire)	Natural setting, tester, procedures and time

Figure 7. Rating scale for external validity (Harmon et al., 1999, p. 483)

reports for two reasons. First, safety reports are difficult to report as a rate because there is no

clear denominator. Errors are not matched to specific patients so error rates could have

inaccuracies. Secondly, the error count is biased because it is unknown how many errors

actually took place. Notwithstanding, many researchers use PSR systems because they are the

most available and practical measure of hospital error. Tracking and measuring every patient

and medication administered requires large control groups with extensive test periods to collect

Table 7

Researcher's Self-Rating of Validity

Category	Rating	Comments
Measurement Reliability and Statistics	Medium	PSR reliability is not strongest type survey--statistical techniques could be stronger with continuous data
Internal Validity	Medium	Group attributes were not selected--groups formed without intervention--characteristics are similar
Control of Experiences and Environmental Variables	Low	No control over extraneous events that could affect both groups and obscure true effect
Measurement Validity and Generalizability of the Constructs	Medium	Dependent variable generalizable to other MTFs
External Validity	High	PSR sampling includes entire population of designated groups
Ecological	High	All LSS studies took place in their natural setting--results restricted to a specific time in history

enough errors to be statistically significant. Large controlled environments are expensive and very disruptive to normal hospital operations.

In their study of medication error, Chang and Mark (2009) pointed out that not all medication errors are reported equally (p.75). Severe errors were much harder to conceal and are reported at a much higher rate, even approaching 100 percent. This is likely the case at Navy MTFs. Although records are kept on the severity of harm for each PSR, the proportion of these cases will not be reported in this study because of de-identification requirements. All medication related PSRs reflect some type of error and will all be counted equally. The reporting of a PSR requires some effort on the part of staff member and are usually initiated only when a deviation has taken place which cannot be ignored or dismissed.

The actual error ratios in this study will not be 100 percent accurate and may not be a valid representation of how many errors actually took place. For the purpose of this study, the reliability, or consistency, of the data is more significant. The purpose is to measure a change in error rate between the pre and post groups. Consistently reported data will deliver the desired

results and provide high validity to the study.

Surveys of this nature that depend on self-reported incidents are not unique to medicine. Wildlife management departments have successfully used similar tactics when they perform fish counts. Fish and Game managers catch fish, tag them, and release them back into the wild. They depend on fishermen to voluntarily report the incident when they catch a tagged fish. Some of the captured fish with tags will not be reported. However, with proper background studies on response rates, experts can provide valid data for estimating fishing pressure, growth, exploitation rates, and species landed (Green, Matlock, and Ferguson, (2010).

Summary of reliability and validity. Evaluating reliability and validity of this project is critical to establishing the strength of the data. Reliability is the consistency of test scores for responses across different constructs. Reliability will be evaluated using the test-retest method by applying the correlation coefficient to PSR scores from each of the MTFs. These PSR scores will be measured during a period when the instrument (LSS study) is not a factor. The researcher is expecting a positive correlation score between 0 and 1 to indicate consistency in PSR surveying across the three locations (Gliner et al., 2001). The researcher will also create control charts showing time between PSR arrivals over an extended period of time to establish statistical control.

Validity is a measure of applicability of inferences derived from instruments. Internal validity refers to the strength or capability of the design. External validity is about generalizability, or how the results can be applied to other variables, settings, and populations. The researcher evaluated the validity of this project using eight measures that evaluate test validity and research validity (Harmon et al., 1999). The self-rated projected results were displayed in Table 7.

Transition and Summary of Section 2

In Section 2, the researcher completed the blueprint for this dissertation that will guide the field work and analysis in the final phase of this study. In this section, the researcher reviewed the purpose of the study and explained the role of the researcher. He described the participants, reviewed the method and design of the study, and outlined the population and sampling procedures. The researcher explained how the data will be collected and analyzed and provided a thorough evaluation of the reliability and validity of this data.

Through his unique position as an LSS consultant, the researcher has explored opportunities to apply certain business principles to increase safety and quality of healthcare. The purpose of this study is to determine the effectiveness of LSS in reducing medication errors as it has been applied at Navy Medicine hospitals. The researcher's primary role is in organizing the study, collecting data, analyzing the data, and preparing a final report.

In this ex post facto study, the primary participants in the study will be those individuals who will extract data needed for the analysis. The researcher is seeking permission from three divisions at DHA to access data on process improvement projects, safety reports, and pharmacy dispensing rates. The researcher will coordinate with HRPP officials at DHA to determine if a DHA IRB exemption is warranted. They will also help the researcher apply for and develop a DSA.

This study is based on quantitative research designed to provide evidence to support or reject a hypothesis. The causal comparative design, also known as ex post facto research, is secondary analysis of original research that tests a hypothesis that has not yet been tested. This non-experimental design will test groups of medication administrations before and after the interventions from five LSS studies. This study will not require sampling techniques because the

study will include the entire population of medication administrations from all five studies. Since the study will be comparing error rates between the before and after groups, the rate must be defined. The rate of error is defined as the proportion of medication PSRs to inpatient medications dispensed during the measured period. The population consists of all medications dispensed for inpatient use at each hospital during the time periods of six months before and six months after each intervention.

Data for the project will be collected from three sources. Pharmacy division will provide information on the number of inpatient medications dispensed. The Safety division will provide PSR data. Results of LSS studies will come from the SPIDR data base. No special data collection techniques will be employed. Each PSR will be classified as one medication error or a failed medication administration. Interventions will be classified into the following five categories: (1) electronic interventions, (2) procedural interventions, (3) systematic interventions, (4) training, or (5) culture modification.

The purpose of the data analysis is to determine if there is sufficient evidence to reject the null hypothesis. The null hypothesis is stated as follows: there is no statistically significant difference between the preintervention medication PSR rate and the post intervention PSR rate for medication errors. The dependent variable is the critical variable in this analysis. The dependent variable is defined as the encounter when a medication is administered to a patient. Each administration is classified as a success or a failure. The data is discrete and binomial. The researcher will test the hypothesis using proportions tests. If there is sufficient evidence to reject the null hypothesis, the researcher will analyze the interaction between the five independent variables (LSS interventions) and the dependent variable. Using graphic analysis, the researcher will compare each individual intervention with its associated output (the study's reduction in

error) to determine if one intervention is associated with a higher reduction of errors.

The final element in section 2 was an evaluation of reliability and validity of the data that will be used in this study. A thorough discussion of reliability and validity resulted in an evaluation of the validity of this project using a scale developed by Harmon et al. (1999). The researcher rated the project low in control of experiences and environmental variables. It was rated medium in measurement reliability and statistics, internal validity, and measurement validity and generalizability of the constructs. The study was rated high in external validity and ecological setting. In an evaluation of the PSR system as a dependent variability, the researcher concluded that although the PSR system has significant weakness, it is still the best available data for this ex post facto study where multiple studies are involved.

The field work for this research project will begin after all permissions for access to data have been granted by the respective DoD organizations and the Liberty University IRB has approved the study.

<center>**Section 3: Application to Professional Practice and Implications for Change**</center>

In this section the researcher presents the findings of the study and makes fundamental recommendations for professional practice based on quantitative results and logical conclusions. The first subsection is a condensed overview of the study, its purpose, research question, hypothesis, methodology, and the timeline leading to the obtaining of data. In the second subsection, the findings are presented in a logical order beginning with a general overview of the data retrieval process, its organization, and an overview of the findings. The statistical tests and quantitative results are explained in more detail under the section titled hypothesis. This section contains the results and analysis of each statistical test and critical observations that led to the research conclusions. The subjects of data reliability and causation were also revisited as part of

the analysis. The final segment of the analysis is a description of how the hypothesis addresses

the research question and a conclusion with a summary of findings.

In the third subsection, the researcher describes the logical application of these findings

to professional practice and outlines the unique challenges of applying LSS to medication

administration. This subsection contains a description of how this research is relevant to the

practice of medicine and discusses the implications of the findings in relation to the biblical

framework of this study. The fourth subsection lists recommendations for action based on the

conclusions of this study. The fifth subsection gives recommendations for further study and the

sixth subsection is a compilation of the researcher's reflections. The final subsection

summarizes the study and the researcher's conclusions.

Overview of the Study

The use of LSS methodology in healthcare to solve problems of patient harm and medical

error is intertwined with the development and application of HRO principles. As part of their

strategy to make the healthcare industry Highly Reliable, leaders of The Joint Commission

advocated the application of LSS to reduce error and increase the quality of healthcare. Chassin

and Loeb (2013) developed the theory of RPP as one of the three pillars of High Reliability.

They theorized that application of RPP, with the oversight of enlighten leaders who understand

process improvement and who developed a culture of safety and quality, could reduce error in

healthcare. The specific problem this research addresses is that very little research has been done

to test the effectiveness of LSS in reducing medication error. The research question is designed

to test this theory by asking if the application of LSS to medication error can reduce the

medication related PSR rate. The research hypothesis is directly related to the research question.

The research, or $H1$ hypothesis states that the preintervention PSR rate will be statistically larger

than the postintervention PSR rate for LSS studies designed to reduce medication error.

The purpose of this study is to add empirical evidence to the body of knowledge about the effectiveness of LSS in reducing medication error. The dependent variable of the study is medication error rate and will be measured as the number of medication related PSRs over the number of inpatient medications dispensed during the same period.

The researcher found five projects at Navy Medicine installations that were identified as LSS studies designed to reduce inpatient medication error. In this research project, the independent variables are identified as the steps of the medication administration process. The independent variables are manipulated by interventions of the LSS project for the purpose of influencing the dependent variable. The dependent variable is defined as the actual medication error that occurs when a medication is erroneously administered. In this project, the researcher will identify any correlation between the conducting of LSS projects and the reduction of the PSR error rate.

The researcher began making application for a data sharing agreement with the government immediately after Liberty University IRB issued conditional approval of the study on 26 April 2019. The approval was contingent upon the DoD approval of a data sharing agreement. Since the data is aggregated centrally, the researcher made request to DHA for pharmacy and safety reports. Upon application to DHA, the Data Sharing Board made it clear that they would not consider the application until a DoD agency had reviewed the protocol and made their own determination as to human research. An electronic IRB (eIRB) application was submitted in June 2019. The application was reviewed by the IRB at the Naval Medical Center in San Diego (NMCSD). In August 2019, The NMCSD IRB classified the study as EXEMPT which meant that the study was not considered human research and a full IRB study was not

required. During the next five months, the NMCSD IRB studied the proposal to determine if the

research should proceed. The commander signed the Determination Letter on 7 January 2020,

allowing the research team to submit the DSAA. The DSAA was submitted on 20 January 2020

and approved on 15 May 2020. The Liberty IRB gave full approval to conduct the study on 19

May 2020. After the dissertation committee completed their administrative review on 29 May,

the field work was initiated.

      The first and most impressionable finding from the data was how few studies were

conducted in pursuit of reducing medication error. In almost twelve years since Navy Medicine

embarked on its LSS odyssey, over 1,800 projects have been completed. Among those, the

researcher found only five projects that were chartered to reduce in-patient medication error.

The researcher found no studies that addressed outpatient medication error. This seems to reveal

a significant gap when considering that typically, more than one third of all PSRs are medication

related and almost one third of all medications PSRs are classified as outpatient. This

information may not suggest that hospitals are ignoring medication errors, but rather that they are

depending on other systems to address problems. The next section will show the analysis of the

findings to determine the effectiveness of those five studies in reducing medication errors.   The

significance of the findings show that Navy Medicine could better leverage its safety programs

by more fully engaging the methodology of LSS in supporting the three pillars of HRO.

Presentation of the Findings

      The final analysis of the data showed mixed results in a most unexpected way. In two of

the five LSS studies, the PSR rate decreased in the six-month period after the study. In one of

those two studies the decrease was statistically significant at a .95 confidence level.

Unexpectedly, the most sophisticated of the five LSS studies experienced a statistically

significant increase in the PSR rate after the study. The other two studies had almost no change

to the PSR rate. A thorough examination of all five LSS studies revealed that most of the studies

were planned with a very narrow scope which greatly reduced the probability of reducing the

overall hospital medication error rate. Scope, in this case refers to the areas described by

Goldspiel et al. (2015) who recommended researchers address potential for making medication

errors in the following six areas: (1) prescribing systems and prescribers, (2) medication

preparation and dispensing systems and the roles of pharmacists, (3) the role of nurses in the

medication administration system, (4) the importance of patient education, (5) manufacturers and

regulatory agencies, and (6) ways to identify and manage medication errors.

   After receiving the raw data files from the Pharmacy and Safety offices at DHA, the

researcher began associating the data with the five LSS studies under review. The Safety data

listed all PSRs classified as medication errors during a five-year period for the three medical

facilities where the five LSS studies were conducted. The count of inpatient errors was rolled up

into 10 six-month periods. Five of these six-month periods corresponded to the six months prior

to each of the five LSS studies under examination. The other five periods corresponded to the

six months after the conclusion of each study.

   The second phase of data analysis involved matching the number of inpatient doses with

the PSR counts to obtain error rates for each of the ten periods. Organizing the pharmacy data

became the greatest challenge of the study because the count of dispensed medications is not

aggregated centrally by DHA. Prior to receiving the DSA, the researcher understood that

individual doses were tracked centrally. The inpatient doses, defined as all individual and IV

doses, can be pulled at each MTF but only for the past year. The count of inpatient doses had to

be estimated by dividing the total cost of inpatient medications by the average cost per dose. The

DHA pharmacy office was able to access the cost of inpatient doses by subtracting the cost of

outpatient medication costs from total medication expenditures. The average cost per dose was

determined by dividing the annual inpatient medication cost by the annual count of inpatient

medication doses at one MTF. The inpatient medication cost for each of the ten periods was then

divided by the average cost-per-dose to derive an estimate of the count of inpatient doses for

each period. The PSR error rate was then computed by dividing the count of PSRs in each

period by the estimated count of doses given for the same period.

As described in Section 2, the researcher compared the PSR rates from the six-month

period prior to the studies to the six-month period after the conclusion of the study. An analysis

of the data revealed that in two of the five LSS projects under review, PSRs related to medication

errors were greater in the six months prior to the LSS study when compared to the six-month

period after the study. Using inferential statistics, the researcher determined that this reduction

in PSR rate was statistically significant in one of the two cases where the error rate was reduced.

Table 8 contains a breakdown of the data used for this research project. Each study was assigned

an alpha numeric identifier, A through E, to preclude geographic identification. The table lists

each project with a brief description of the problem and general goal of the study. This data

includes a breakdown of the scope and the independent variables or interventions used in each

study. Listed under dependent variables, the researcher has listed the before and after results of

the PSR count matched with the total inpatient doses for the same six-month period.

Hypotheses. The research hypothesis, $H1$, for this project is stated as follows: The

preintervention PSR rate will be statistically larger than the postintervention PSR rate for

medication errors. The null Hypothesis H1o is stated as follows: there is no statistically

significant difference between the preintervention medication PSR rate and the post intervention

Table 8

Study Data

High Reliability in Medication Administration					
	Study A	**Study B**	**Study C**	**Study D**	**Study E**
Project Type	OPI	RIE	DMAIC	RIE	RIE
Study Title	Reduce Medication Errors In Adult Inpatient Setting	Medication Errors	Inpatient Medication Errors	Reducing Peri-Operative IV Antibiotic Medication Errors	Decreasing Medication Errors in Intra-Op Patient Transfers
Problem	High rate of med error recorded for hospital	High med error rate with post-operative C-section patients	High PSR rate for hospital: Multiple med errors recorded	High number of IV antibiotic errors in transfer from OR to Wards	High med errors after patient hand-off from MOR to CCND PACU .
Goal	Reduce the number of medication errors hospital-wide	Decrease error rate associated with post-recovery C-section patients	Reduce entire hospital monthly PSR rate	Reducing number of Peri-Op IV Antibiotic Medication Errors	Decrease Qtr med error rate related to MOR PACU hand-off
Scope					
Prescribing		X		X	X
Pharmacy					
Nursing	X	X	X	X	X
Patient Education			X		
Manufacturing/Regulation					
ID/Manage Med errors		X	X	X	
Independent Variables Used					
Electronic Changes			X	X	
Procedural Changes		X	X	X	X
Systematic Changes					
Training Changes	X	X	X	X	X
Cultural Changes			X		
Dependent Variable					
Pre-Study Events (PSRs)	231	19	21	175	16
Possible Events (doses)	202058	31923	36503	276582	38416
% Defective	0.1143%	0.0595%	0.0575%	0.0633%	0.0416%
DPMO	1143	595	575	633	416
Sigma Level (no shift)	3.05	3.24	3.25	3.22	3.34
Post-Study Events (PSRs)	188	20	39	139	21
Possible Events (doses)	230141	31170	21734	234976	32410
% Defective	0.0817%	0.0642%	0.1794%	0.0592%	0.0648%
DPMO	817	642	1794	592	648
Sigma Level (no shift)	3.15	3.22	2.91	3.24	3.22

Note. DPMO=Defective Parts per Million Opportunities, RIE=Rapid Improvement Event,

OPI=Other Process Improvement, DMAIC=Define, Measure, Analyze, Improve, Control.

PSR rate for medication errors. Because the data is binomial (pass or fail), statisticians recommend the proportions test, or Z test for evaluating the hypothesis. Proportions tests are like Sample t-tests but are designed for proportions and percentages. Chi-square tests can also be used to evaluate proportions and percentages. Chi-square tests are similar to the ANOVA tests which are designed for continuous data (Weiss & Weiss, 2012).

The analysis began with a proportions test. The test is called a two-sample test that compares the error rates for the six-month period prior to the start of each study to the error rate of the six-month period after the conclusion of each LSS study. Each LSS study was tested individually. Note that the six-month time periods include the time prior to the start of the project and the six-month period after the conclusion of the study. The period during the execution of the study is ignored because in a typical LSS study, the dependent variable begins to change gradually as interventions may take some time to pilot, test and implement. The proportions test, also known as a Z test, is designed to compare proportions or percentages of different samples to determine if they are significantly different. In the two-sample Z test, the test statistic (Z) is computed using the following formula:

$$Z = \frac{\rho_1 - \rho_2}{\sqrt{\rho_p(1-\rho_P)}\sqrt{(1 \div N_1)+(1 \div N_2)}} \quad \text{where} \quad \rho_p = (x_1 + x_2) \div (N_1 + N_2).$$

Using a confidence level of .95, the researcher entered a Z chart to obtain the *Za* value of 1.6449. This is a right-tailed test because the *H*1 states that the PSR rate of the first sample (pre-study) will be greater than the second test group (post study). If the Z value is greater than the *Za,* the researcher rejects the H1o. Computing the P value is an alternate means of making that decision. The P value is the probability of the event occurring. If this probability falls outside the acceptable area of the normal distribution, as defined by the confidence level, the H1o is

rejected. In this case, if the P value is less than .05, the H1o will be rejected. The data from each LSS study were analyzed independently. The results of the comparisons showed that in two of the five cases, medication error rates decreased in the six-month period after the study. The results of the proportions test showed that the difference in that change was statistically significant in Study A at the .95 confidence level. The information is displayed in Table 9. In the case of Study A, the researcher rejected the null hypothesis and concluded that at the .95 confidence level, the PSR rate for medication errors was greater in the pre-study group than the post study group.

Table 9

Proportions Tests (Z Test) where Ha=P1>P2

	Study A	Study B	Study C	Study D	Study E	Total
Pre Events X1 =	231	19	21	175	16	462
Possible Events N1 =	202058	31923	36503	276582	38416	585482
Post Events X2 =	188	20	39	139	21	407
Possible Events N2 =	230141	31170	21734	234976	32410	550431
P1 =	0.001143	0.000595	0.000575	0.000633	0.000416	0.000789
P2 =	0.000817	0.000642	0.001794	0.000592	0.000648	0.000739
Pp =	0.000969	0.000618	0.001030	0.000614	0.000522	0.000765
Z =	3.439667	-0.234750	-4.435389	0.592536	-1.342996	0.956938
Confidence Level	0.050000	0.050000	0.050000	0.050000	0.050000	0.050000
Za =	1.6449	1.6449	1.6449	1.6449	1.6449	1.644854
P value =	0.0003	0.5928	1.0000	0.2767	0.9104	0.169299
Reject Ho?	YES	NO	NO	NO	NO	NO

Note. At 95% confidence level (.05), reject Ho if Z>Za or P value <.05.

In the second test, the Chi-square procedure compares all the studies together to determine if the change in PSR rates was statistically significant when comparing the before and after groups. It also shows which studies are contributing the most to that change. The Chi-square goodness-of-fit test uses the following formula to compute a test statistic (X^2):

$$X^2 = \sum (0 - E)^2 \div E.$$

This test statistic represents the combined difference between the actual observed PSR rate from the post-study group, and the expected PSR rate that was computed from the pre-group results. Because each of these studies were conducted at different places and different times, the expected outcome for each study was computed independently. The X^2 is calculated for each study, then, the results are added together to derive the total X^2 statistic. A hypothesis test using Chi-square distribution is always a right-tailed test. If the computed test statistic is greater than the statistic from the table, the researcher rejects the null hypothesis. The statistic derived from the table accounts for the four degrees of freedom at the .95 confidence level. The results revealed that the distribution of PSR rates for all the studies did change significantly between the pre-groups and the post-groups. Because of the nature of the Chi-square test, the X^2 variable negates the negative variable so the test does not distinguish between a positive and negative variance. The outcome of the test was influenced by a significant decrease in the PSR rate after study A but also a significant increase in the PSR rate after study C (see Table 10). Note the X^2 test statistics is larger than the table values for both Study A and Study C. Considering all five

Table 10

Chi-square Test.

	Study A	Study B	Study C	Study D	Study E	Total
Pre-Study Frequency	231	19	21	175	16	462
Pre-Study Possible Events	202058	31923	36503	276582	38416	585482
Pre-Study Relative Frequency	0.001143	0.000595	0.000575	0.000633	0.000416	
Post-Study Observed Events O =	188	20	39	139	21	407
Post-Study Possible Events	230141	31170	21734	234976	32410	550431
Expected Events E =	263	19	13	149	13	456
Test Statistic X^2 =	21.439446	0.113046	56.149741	0.629586	4.168737	82.500554
DF=(5-1)=	4					
Table VII X^2 at .05 =	9.488000					

Note. If the Test Statistic X^2 is greater than table value at .95 confidence level (.05), reject Ho.

studies, the number of errors was reduced from a total of 462 to 407 where the expected count

was 456. This was due to the high reduction of errors in Study A from 231 to 188 and the

reduction in Study D from 175 to 139. However, based on this test, the researcher cannot

conclude that the five studies together had a statistically higher PSR rate prior to the five studies.

From this test, the researcher can only conclude that the PSR rates were statistically different

when comparing the before and after groups. A useful graph is derived from the Chi-square test

showing the difference between the PSR outcomes of the post study period and the expected

outcomes based on the pre-study PSR rate for all five studies (see Figure 8).
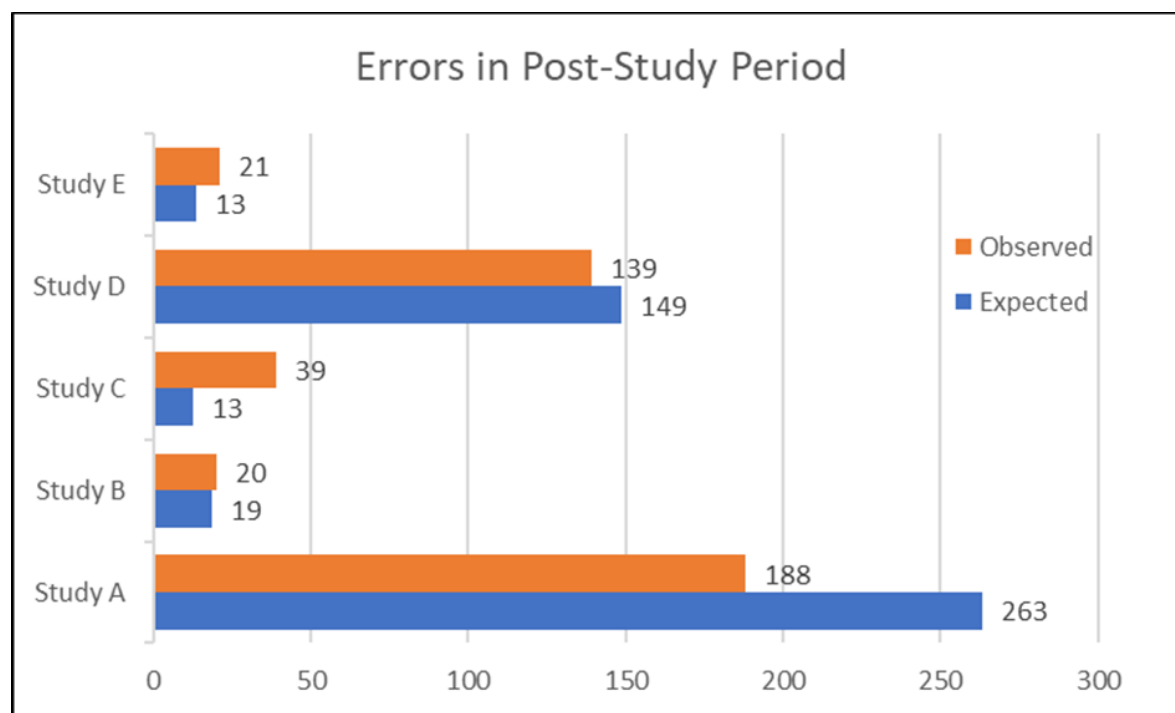

Figure 8. Errors in the post-study period. Using the Chi-square results, this graph shows the

difference between the observed errors from the post study period and the expected errors

based on the pre study results.

As a secondary test, the researcher performed a Z test using the combined data from all

 five studies (see far right column of Table 9). Where *P*=.169, the researcher failed to reject the

null hypothesis and concluded that the higher PSR rate of the pre-study groups, when compared to the post-study groups, was not statistically significant at the .95 confidence level.

Observations. Four critical observations of the application of LSS to medication error drove the conclusions of this study. The first observation is that the most successful study in this research project, Study A, was the one study that focused exclusively on the proficiency and education of new nurses assigned to the hospital. The primary intervention from this study was a nurse shadowing program for new nurses joining the team. The shadowing program had, as its primary goal, the training and mentoring of newly assigned nurses for the reduction of medication error. This approach is congruent with an entire body of literature that emphasizes the primacy of nursing in the medication administration process.

Although the curriculum for this training was not available to the researcher, significant studies on this topic suggest that many of the most important variables for successfully reducing medication errors can be taught through education or mentoring programs. Many studies correlate medication errors to the lack of concentration, frequent interruptions, or when nurses fail to follow procedures (Cook, 2014; Westbrook, Coiera, et al., 2010; Westbrook & Li, 2013). A study by Chang and Mark (2009) concluded that nurse experience and education have a significant correlation to the reduction of medication error. Another study by Durham et al. (2016), describes how good error interception practices can be taught through development of good patient surveillance and awareness of the patient environment. McLeod et al. (2015) described two types of behavior in nurses, task focused, and patient-interaction focused, both of which helped to decrease medication error. Being task focused helped nurses intercept errors before they reached the patient. Being patient-interaction focused helped patients learn how to assist in finding and preventing errors. Grissinger (2010) also described the importance of

double-checking medication orders when they are illegible or appear to be incorrect. Newly

arriving nurses at a hospital may be overwhelmed by the new environment, new people, and

perhaps different procedures. Nurses need help balancing conflicting priorities and demands

during their drug rounds. Where many researchers have advocated the elimination of all

interruptions during drug rounds, McLeod et al. (2015), advocated using training programs to

teach nurses how to manage interruptions and distractions. A predominant body of literature

support the view that nurses are the most critical link in the medication administration process

because they administer most of the medications to patients and they are the last opportunity for

quality inspection before the medication reaches the patient. Many areas of nurse proficiency

can be taught through training. Shadow programs are an effective way to integrate education and

mentoring. The outcome of this research suggests that the nurse shadow program was an

effective intervention and the best predictor for success.

     The second observation is that Navy Medicine has not applied LSS as a primary tool for

the reduction of medication error. Although one third to half of all patient safety reports are

typically medication related, less than .3% of all LSS studies addressed the problem. All Navy

hospitals have a challenge with medication error, yet only three of 112 installations in the Navy

have conducted at least one LSS study to address this problem. A logical explanation for this

deficit is that Navy hospitals already have a process for addressing medication errors. Every

Navy hospital has a Safety Office that follows strict protocol in addressing medical events.

These protocols usually preclude the chartering of a separate LSS study to investigate the same

problem. These safety directives and protocols often employ the same tools used by LSS such as

Root Cause Analysis (RCA) and Failure Modes and Effects Analysis (FMEA), yet their

interventions rarely involve the depth of discovery, analysis, interventions, and long-term

controls employed by a comprehensive DMAIC project. Patient Safety programs usually direct

actions to solve the problem that caused one particular event. Because there are so many events

during the year, these solutions must be implemented quickly and cannot possibly address the

entire system or the myriad of possible root causes of medication errors.

The third observation concerns the organization of the LSS program at Navy hospitals.

At the time of this study, there was very little direction from senior leadership in the process of

selecting the subject and scope of LSS projects. More commonly, LSS projects were started by

clinicians trying to solve specific problems in their scope of work.   These studies lacked depth

and rarely crossed functional boundaries.   Of the five LSS studies addressing medication error,

three were projects very narrowly focused on a limited portion of the medication administration

process. Although these studies were successful in reducing errors within their scope, they were

not likely to have an impact on the entire hospital's medication error rate.

The medication administration process is one of the most lengthy and complex processes

in the hospital system. Medications are conveyed across multiple functions including

manufacturers, transporters, pharmacists, providers, and nurses before they make their final entry

into the patient. In addition to the transportation and storage of medications, often these

compounds must be mixed or diluted manually before they can be administered. Because so

many medications are dispensed every year, the process is fraught with the potential for

mistakes. In an LSS system where there is little top-down direction, there is no incentive for a

company grade officer to voluntary take on a project of that magnitude. This is described by

Anthony (2017) who concluded from his research that leadership was the critical component in a

successful LSS program. Even in cases where senior leaders are directive in what problems to

confront, they may be reluctant to tie up their human resources in large complicated projects. As

a result, most of these projects were shallow and did not attempt to change the entire process. Leadership involvement is a critical factor in the success of an LSS program. This concept is supported by a body of literature on the application of LSS to medicine (Aboumatar et al., 2017; Antony et al., 2017; Durham et al., 2016; Laureani & Antony, 2017; Pande, 2007). Leadership engagement is described by Chassin and Loeb (2013) as one of the three pillars of HRO and an essential conduit for the successful conduct of RPI.

The fourth observation involves the application of HRO concepts in the intervention phase of the LSS projects. Very few of the LSS studies that were reviewed during this research project developed interventions that adhered to the principles of High Reliability. Although the teams from Studies B and C did attempt to introduce some of the common tools of HOR in their improvement phase, the final control plans lacked the discipline and rigor required to change and maintain these interventions over a long term. The Study C improvement team established a six-rights medication administration checklist that was posted at strategic locations throughout the hospital where medications were prepared or administrated. Study B team also created a modified 10 rights checklist adapted for the post-op cesarean recovery ward. However, no procedures were instigated to ensure they were used. No challenge and response procedures were instigated in conjunction with those checklists. There was no requirement to have all drug administrations checked by two individuals. Current policy only requires double checking with high-risk medications. In Study C, the new process was admirably crafted in a new SOP, but there were no follow-up tests to see if anyone had read the document or understood the new process. Tests were established to monitor the dependent variable but there were no follow-up inspections or audits to determine if the new procedures were followed. The importance of integrating HRO principles to improve safety is essential and is supported by a significant area of

research on high reliability (Carroll & Rudolph, 2006; Roberts & Rousseau, 1989; Vogus & Sutcliffe, 2007; Weick, 1987). For Chassin and Loeb (2013), the intertwining of HRO principles with LSS is what makes process improvement robust.

   Data reliability.   To examine the reliability of the data, the researcher performed correlation tests between the three studies and created control charts as outlined in the Validity and Reliability portion of Section 2.   The time series chart in Figure 9 shows the number of PSRs in each of 9 six-month consecutive periods for all three MTFs. The graphic display shows a downward trend in PSRs at MTF 1 and an upward trend in PSRs at both MTF 2 and MTF 3. MTF 1 has a much larger PSR rate because it is a much larger facility and serves a
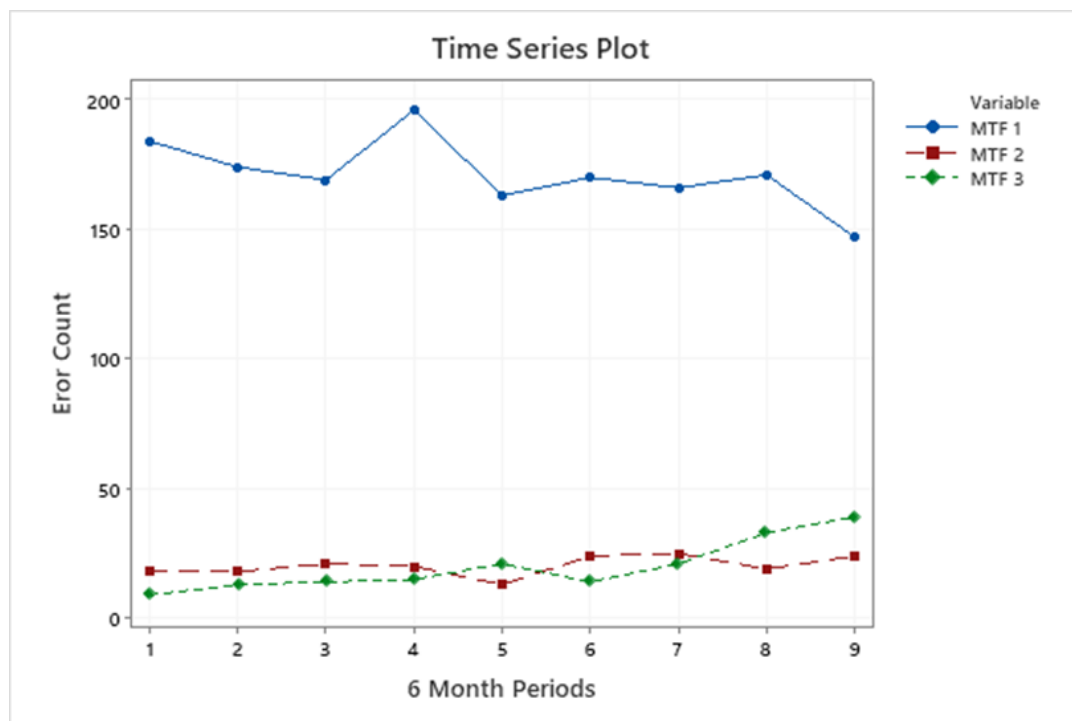

Figure 9. Time series plot of medication related PSR counts.

proportionately larger population. A noteworthy observation is the unusual rise of PSR count for 3 consecutive six-month periods at MTF 3. This is where Study C took place. This may suggest that some type of unusual event or influence is taking place.

Correlation is used to describe a relationship between two variables. The Pearson correlation coefficient is a statistical procedure that quantifies the strength of that relationship. The R coefficient is an output between 1 and -1. A zero indicates no correlation where a positive 1 indicates perfect correlation. The negative R indicates a negative correlation. A positive coefficient between the error rates of the three MTFs would indicate a stable system and contribute evidence to the reliability of the data (Gliner et al., 2001). These tests were conducted using the program Minitab®. The following formula is used to derive the R coefficient for correlation:

$$R = \frac{S_{xy}}{\sqrt{S_{xx}S_{yy}}} \qquad \text{where} \qquad S_{yy} = \Sigma(y - \bar{y})^2 \qquad S_{xx} = \Sigma x^2 - (\Sigma x)^2 / n$$

$$S_{xy} = \Sigma xy - (\Sigma x)(\Sigma y) / n.$$

The three graphs in Figure 10 show the results of those tests. Some positive correlation exists
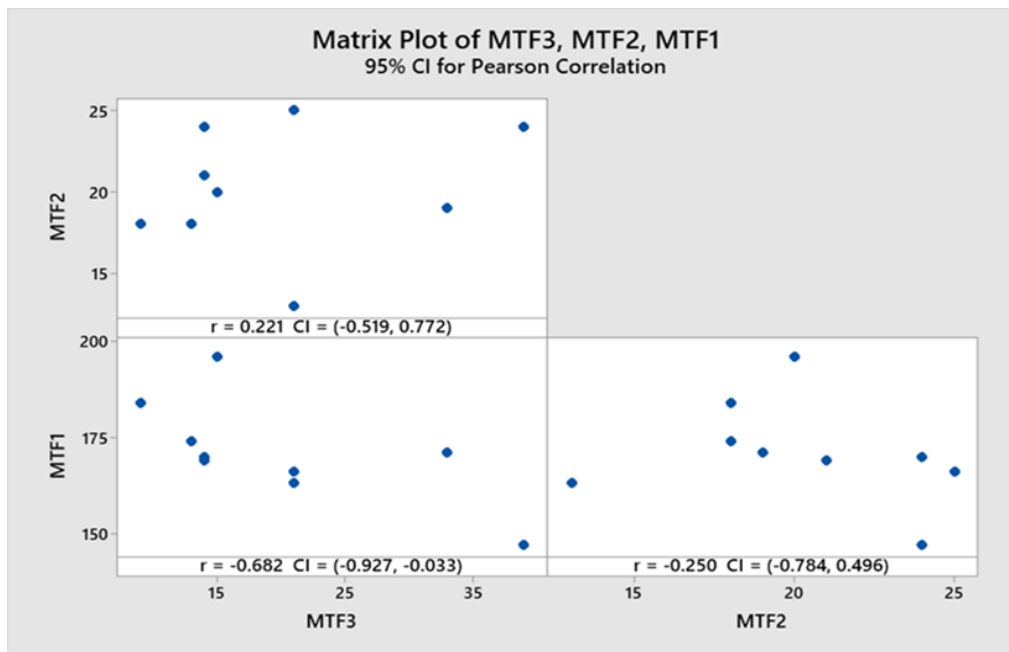

Figure 10. Pearson correlation coefficients.

between the smaller MTFs 2 and 3 with a 2.2 coefficient. Both smaller installations showed a

negative correlation when compared with MTF 1.

The control charts revealed even more about the instability of the PSR arrival rate. Using the recommendation of George et al., (2005), the researcher converted the error rate (binomial data) to continuous data by computing the time between errors so that it could be displayed on an Individual, Moving Range (ImR) chart. The Individual chart displays the time, in days, between each of the errors. The Range chart displays the variation between each error and the previous error. These graphs and the computed control limits (3 standard deviations) were produced using the program Minitab®. The charts demonstrate graphically that the PSR arrival processes at all three MTFs are not in control. Note the numerous data points that fall outside the upper control limit at MTF 1 (see Figure 11). MTF 1 is a much larger hospital and experiences a much larger
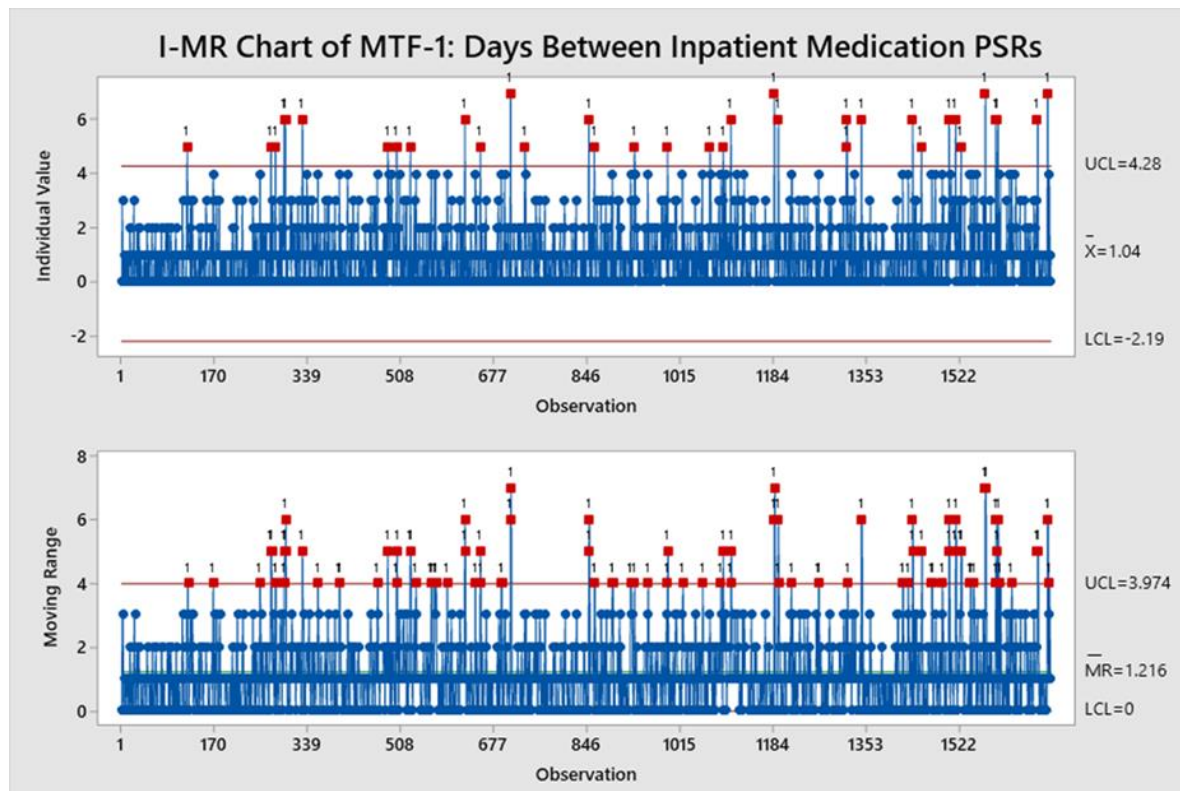

Figure 11. Individual, moving range chart for MTF1. The Individual chart displays the time between each PSR event. The Moving Range chart displays the variation between points.

error rate. The upper control on the Individual chart is only 4.28 days.   MTF 2, on the other

hand, is a much smaller installation and has an upper control limit for the Individual chart of 37.3

days (see Figure 12). The most interesting observation is the sudden and dramatic change in
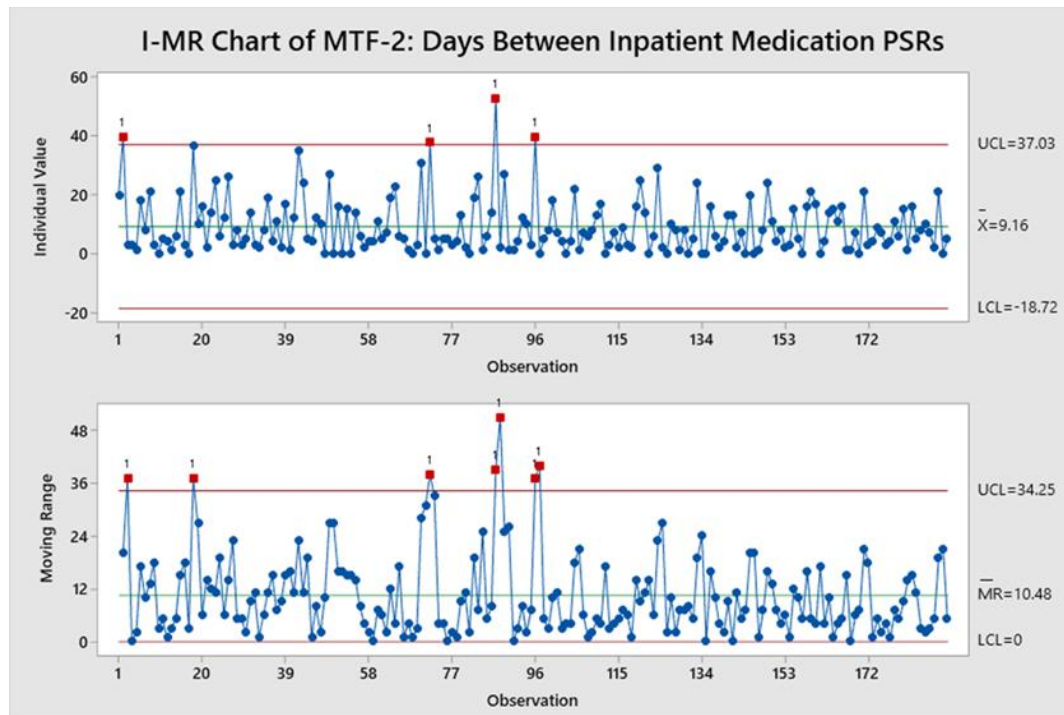

Figure 12. Individual, moving range chart for MTF 2.

stability of data at MTF 3 (see Figure 13). At data point 100, the system suddenly becomes very

stable. The average time between PSRs drops and the reports are arriving at very regular

intervals. This of course, also correlates with a sharply rising PSR rate. The same phenomenon

is occurring at MTF 2 but not as pronounced. This aberration indicates some type of special

cause variation where the data has been influenced by a unique and significant change or

manipulation, not by natural occurrence. The correlation tests and the control charts indicate that

the PSR system is not a stable process. These tests indicate low data reliability which

significantly reduces confidence in the statistical inferences made using the PSR output from the
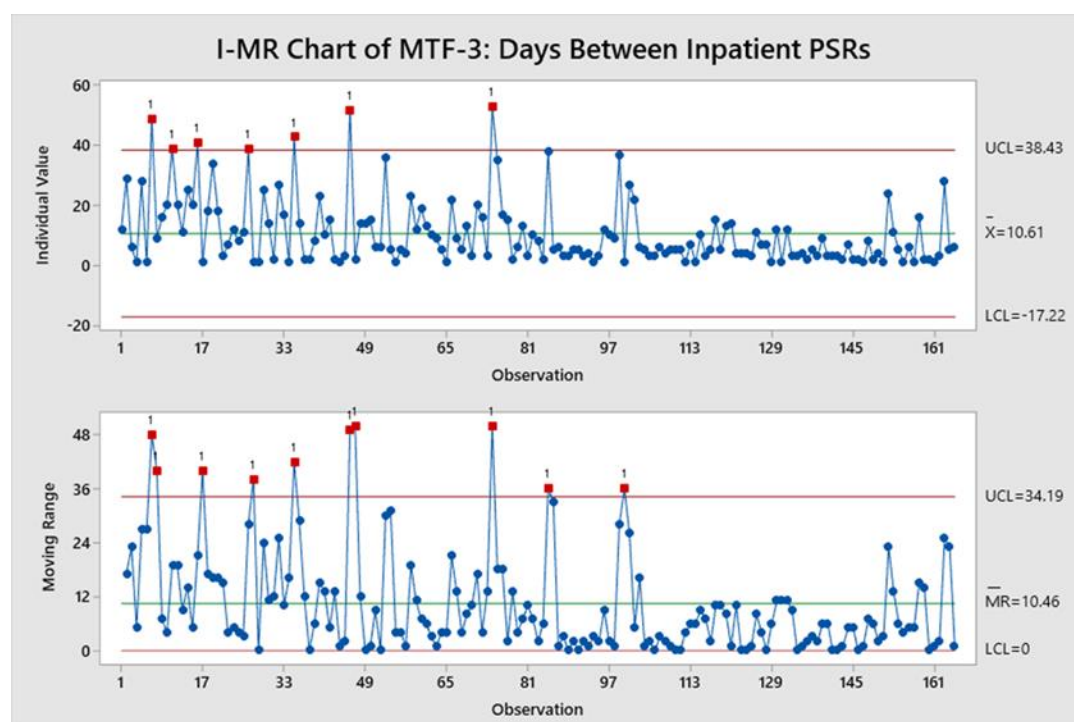
the system.

Figure 13. Individual, moving range chart for MTF 3.

Discussion of causation. A discussion of causation can only center on the two projects that demonstrated a statistically significant change in the PSR rate after the study. Study A was correlated to a decrease in PSR rate while Study C was correlated to an increase in PSR rate. Although it is understood that a non-experimental study cannot prove causation, the discussion is designed to lend evidence to support the theory of RPI by providing a link between certain interventions and the actual change of PSR rates. In this study, the researcher tested a hypothesis that has had little testing before. This research can only be considered preliminary in the effort to provide causational inferences to support RPI.

The analysis of Study A adds some inferential evidence to support the theory that an LSS study on medication error can reduce the PSR rate. Study C contributed evidence that by manipulating the independent variables, some of those variables may have contributed to an increase in the PSR rate by stimulating the voluntary documentation of medication errors.

Upon further investigation into the nature of studies B, D, and E, the results were not surprising. These three studies were very narrowly focused on a specific medication problem in a specialized area of the hospital. These three studies also addressed nurse education but only within the confines of one specific function or a specific medication. Because of their narrow scope, the results were not likely to significantly change the error rate in the entire hospital and they did not. Study B addressed the problem of medication errors that take place in post-op care after a cesarean surgery. Interventions included (1) training on patient turn-over, (2) changing of physician order sets, (3) refining the process with improved communication, and (4) implementing a 10-rights medication checklist. Study D focused on antibiotic medication error in wards where nurses receive patients from the main operating room (MOR). Interventions included (1) integrating the EMR to collects information from three data bases, (2) eliminating all paper charting in MOR, (3) changing physician order sets, and 4) educating nurses on intra-op procedures. Study E addressed medication errors in the patient hand-off between the MOR and the ICU. Some of the interventions included (1) development of a new hand-off report, (2) establishment a two-nurse hand-off policy, and (3) training for nurses and anesthesia providers.

Study A was distinguished from the others because it was designed to reduce the overall hospital medication error rate by influencing the capability of the entire cadre of nurses in a very large hospital. A nurse shadowing program was designed to help new nurses become acclimated to a new environment by paring them with a more experienced nurse and teaching a specified curriculum of medication error prevention. The positive results are encouraging for the LSS community.

Study C is the enigma of this research. Of the five LSS studies under examination, only Study C was a full DMAIC study that targeted the reduction of medication errors for the entire

hospital by applying analysis and interventions to more than one hospital function. Study C also applied interventions in four of the five intervention areas as shown in Table 8. Surprisingly, Study C was the only project that experienced a statistically significant increase in the error rate after the completion of the study. Study C was different from the other studies because of its broad multi-functional approach to reducing medication errors. Study C made electronic, procedural, and training interventions in all inpatient wards of the hospital. The training included all nurses who were involved with administering medications. The study scope included nursing, patient education, and development of a system to identify and manage medication errors. It did not address errors in manufacturing or regulatory agencies nor pharmacists and dispensing systems.

At the onset of this dissertation, the researcher intended to establish a relationship between the robustness of both the scope and breath of interventions and the change of the dependent variable. It would defy logic to believe that one could perfect the process of medication administration in one function, say within the pharmacy, and expect to eliminate, or significantly reduce overall medication error, if significant problems still exist in the prescription phase or patient interaction phase. It was the researcher's intention to lend credence to the theory of RPP by demonstrating that an LSS study that applies a broader range of interventions to reduce medication error, will increase the probability of yielding more success. The results from this research did not support that inference. In Figure 14, a graph compares the results of the Z test for each of the projects. The higher Z score indicates the higher statistical evidence that the PSR rate was changed after the intervention of the study. Those studies that show a negative Z, had an increase in PSR rate after implementation of their interventions. Although Project C utilized interventions in four of the five categories of independent variables, and had

the broadest scope of the LSS studies, it showed the poorest results.

Some of the most significant interventions in Study C included (1) installing monitors

and computers at all bedsides so that nurses do not have to print out medication paperwork or try

to remember orders, (2) instigating rapid log-in sequence, giving nurses instant access to all

medication orders, (3) creating preprinted labels for emergency and common medications, (4)

initiating a 6 rights campaign to encourage nurses to use the checklist, and (5) adding

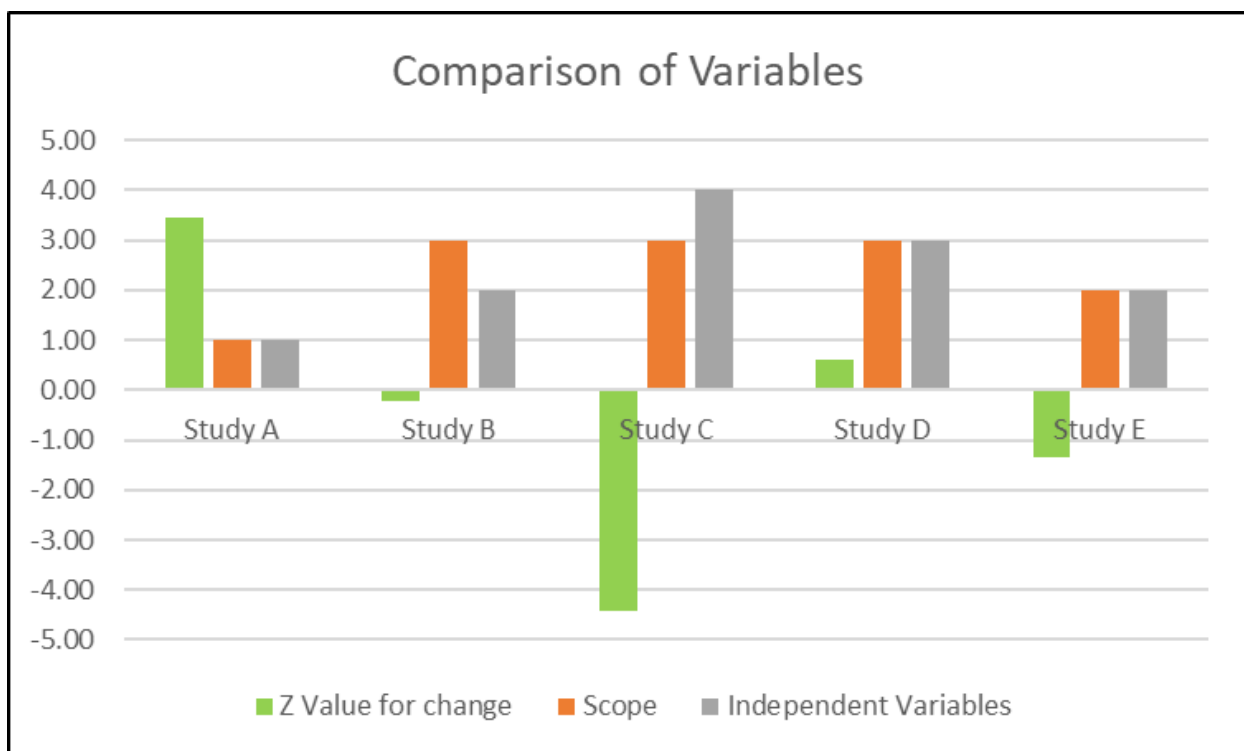medication administration procedures to the command nursing orientation program.

Figure 14. Comparing the effects of variables on the PSR rate. -Z=increase in PSR rate,

+Z=decrease in PSR rate.

One of the components of Study C's nurse training program that may have had the

greatest effect on the PSR rate, was an effort to educate nurses on how to use the PSR system.

This was a concerted effort to help nurses recognize medication errors and to teach them how to

submit PSRs. This focus on the importance of PSRs was coupled with an emphasis on non-

retribution for making errors. This represents a significant culture change by developing an environment free of fear. Nurses were encouraged to recognize and document their mistakes to help everyone learn from their error. This is a very enlightened approach and highly encouraged in the HRO culture. Although this effort was commendable, it did not contribute to the success of this research. In this case, the LSS study may have unintentionally increased the PSR rate even though the actual error rate may not have changed. Other possible causes for the unusual hike in PSR rates after Study C, include a combination of other variables such as the influx of newly graduated nurses and providers or the independent actions of the Safety Office. MTF 2, where Study B took place, showed a similar pattern of rising and a sudden controlled PSR rate. However, it is not likely that Study B was the culprit. Study B focused only on post cesarean medication error that occur in patient handoff between multiple providers.

The first inference about causation is that the most successful LSS project in this research, Study A, took a singular approach to the problem of medication errors by initiating a nurse shadowing program. The outcome suggests that it may not be as important how many different interventions are used in an LSS study but rather how singularly the team prioritizes its efforts and focuses on the most important variables.

The second inference about causation is that the self-reported PSR system is very closely connected to the independent variables of nurse education. When conducting LSS studies that involve PSR system training, the interventions may cause an increase in the PSR rate.

Relationship of hypothesis to research question. In the introduction of this study**,** the following general research question was asked: Does Chassin and Loeb's theory of LSS effectiveness in changing healthcare processes explain a change in medication PSR rates after the intervention of an LSS study targeting medication errors? In Chassin and Loeb's theory of

Robust Process Improvement, LSS methodology is the key to the process improvement pillar. The research hypothesis of this study was designed to show that a series of LSS studies conducted at Navy hospitals over a decade, could lend empirical evidence to answer the research question by showing a statistically significant change in the medication error rate after the completion of these studies. The results of the hypothesis test did not provide a definitive answer to the question. Using the proportions test (Z test), the researcher failed to reject the null hypothesis in four of the five cases which states that there is no difference between the PSR error rates of the pre-study groups and the post-study groups. However, the results of study A leave sufficient evidence that an LSS study that prioritizes efforts on the most important variables may influence medication error rates.

Summary of findings. The findings of this quantitative study lend credible evidence to answer the research question by demonstrating that the application of LSS at Navy Medicine treatment facilities has made an impact on the reduction of medication errors as measured by the PSR system. The results did not answer the research question in a definitive way, but they do present preliminary evidence supporting the theory of RPI. Of the five LSS studies that were examined, Studies A and D had a reduction in PSR rate in the six-month period after the study was concluded. Together, the five LSS studies showed a total reduction of PSR count from 462 to 407. Because of the lower computed inpatient dose rate in the post-study groups, the overall PSR rate reduction was not statistically significant. Two statistical procedures were used to test the hypothesis. Based on the results of both the Proportions tests and the Chi-square test, the researcher rejected the H1o hypothesis, in the case of Study A, and concluded that the reduction of PSR rate was statistically significant at the 95% confidence level. The five LSS studies were also tested together. Based on the results of the Proportions test, the researcher failed to reject

the H1o and concluded that the overall decrease in the PSR rate was not statistically significant at the 95% confidence level.

Both Studies B and E displayed a slight increase in the PSR rate in the post-study period. Study C experienced a dramatic increase in PSR rate in the post-study period which was statistically significant. This result played a major role in the failure of the entire study group to reduce the PSR rate to a statistically significant level. The unusual results of this study brought into question the reliability of the self-reported PSR data. Results of the correlation tests showed very little positive correlation between the arrival rate of PSRs at the three MTFs tested which might indicate a lack of stability in the system. Analysis of the control charts showed a lack of statistical control in the arrival of PSRs at all three MTFs. The graphs suggest the influence of special cause variation in the PSR system. A rapid change in process control indicate the manipulation of the system either intentionally or by some unusual event. These results lower the confidence level in the use of the PSR system as an instrument to measure true error reduction.

Based on the results of the tests and observations of the Navy's application of LSS at medical installations, the researcher developed five major conclusions. Study A, which demonstrated the most successful outcome under the structure of this research, was a project that focused singularly on nurse education through the entire installation. The most successful LSS team focused its effort on the most important step in the medication administration system. The first conclusion of this research is that manipulation of the variable classified as nurse training proved to be best predictor of success.

The second conclusion is that Navy Medicine has not applied LSS as its primary tool to reduce medication error. Although medication error accounts for the highest percentage group of

PSRs, only five of over 1,800 studies during the last 10 years have addressed the problem of medication error. Although the LSS program has been very successful in supporting other strategic goals, the Navy has depended on other means to address medication error. To make long-term systematic changes that would test the theory of RPI, leaders need to direct their efforts toward solving safety issues using the LSS program.

The third conclusion is that Navy leaders will have to become more engaged in the LSS system before it will be capable of solving complicated safety issues. Medication administration is a complicated process that moves across multiple functions of the hospital. To create a team with the skills and endurance to study the entire process, the project would need to be orchestrated by the most senior leaders in the organization. Senior leaders at both the headquarters and the treatment facilities must become more engaged in the LSS program before it will be capable of solving the problems associated with medication administration.

The fourth conclusion concerns the application of HRO principles in conjunction with LSS. In Chassin and Loeb's theory of RPI, the HRO principles were the catalyst that would make process improvement robust. Navy Medicine could increase reliability by following HRO principles. An HRO system is preoccupied with failure and reluctant to simplify problems. An effective HRO-driven LSS program should constantly scrutinize the most critical processes and constantly improve them. In this study, the researcher has shown a body of literature supporting the concept of commonality between the airline industry and medicine. Many of the successful tools such as checklists, two-person policy, CRM, and check rides, have made commercial aviation a Six-Sigma industry, and could be incorporated in the control mechanisms of LSS projects in medicine. Navy Medicine needs HRO to create robust, enduring processes and to overcome the inertia behind the "way it has always been done."

The final conclusion pertains to the use of the PSR system as the dependent variable in medication research. The pros and cons of using self-reported errors have been thoroughly discussed earlier in this report. The results of this study buttress the concerns of Pronovost et al. (2006) who felt that self-reported safety reports were unreliable because 1) safety reports are difficult to report as a rate when there is no clear denominator, 2) errors are not matched to specific patients so error rates could have inaccuracies, and 3) the error count is biased because it is unknown how many errors really took place. The results of correlation tests and graphic evidence from control charts confirm that there is likely significant manipulation of PSR counts from special cause variation. In future studies of the medication administration system, researchers would do well to turn to more reliable measures of error. This path involves human research and the observation of actual errors which inevitability leads to higher costs, longer studies, and more risk.

Applications to Professional Practice

Considering the wide-spread application of process improvement methodologies in almost every industry today, the case for application of this study to professional practice is an easy task. What is not easy is explaining why in the healthcare industry, which has embraced the concepts of process improvement and HRO, is still struggling to control the process that harms the greatest number of patients. The application of process improvement to business is becoming a strategic obsession. There is a growing acceptance in the healthcare industry, and particularly military healthcare, that the best way to improve safety and the quality of care is through LSS. However, when considering the study of medication error, the application to business becomes an insurmountable task of chasing down endless opportunities for failure.

This challenge is most eloquently stated by Diamond (1999), "We tend to seek easy,

single-factor explanations of success. For the most important things, though, success actually requires avoiding many separate possible causes of failure" (p. 151). Diamond was referring to the application of the Anna Karenina principle in his best-selling book on human history. The principle stems from the classic novel, *Anna Karenina,* where Tolstoy opens his book with the sentence, "Happy families are all alike; every unhappy family is unhappy in its own way." The principle is that a happy family must have all the elements of success e.g., financial stability, affection, health, security. The absence of any one of the essential ingredients of success will lead to unhappiness. Although stemming from an unusual source, the principle has practical application to science and it aptly describes the business application of this study to professional practice. In their article *The Anna Karenina principle: A concept for the explanation of success in science*, Bornmann and Marx (2012) explain the diverse scientific applications of the principle. Complex undertakings always depend on many factors, and in some cases, each of them is essential for success. If one single element is missing, the event will fail. This is precisely the challenge with the administration of medication. Nothing can go wrong.

In a paper by Shugan and Mitra (2009), the authors apply the Anna Karenina principle to statistics. In adverse environments, where one expects predominantly unfavorable outcomes, favorable outcomes, although rare, provide more information. Conversely, in a propitious environment, such as in healthcare, were one expects predominantly favorable outcomes, unfavorable outcomes provide more information because one expects that all favorable outcomes to be the same. This principle has been applied to other fields of science, such as ecology and even plate tectonics, but it has never been applied to the science of process improvement in business. In this realm, the Anna Karenina principle has probably found its most compatible application.

The application of this study to healthcare business is the study of unfavorable outcomes. The reason why the application of LSS to medication error has not displayed more success is because it is an extremely complex problem to solve. Medication administrations take place in a black hole, filled with endless opportunities for error. Everything, in a long string of events, must happen correctly to produce a successful medication administration. It is difficult to find commonality in errors. Most unsuccessful medication administrations have a unique failure. Every medication that enters a patient at the incorrect time, or with the wrong dose, or the wrong ingredient, is a failed event. Every medication that enters the wrong patient or does not enter the patient, when it should, is a failed event. The root cause of that one failure may have been a distracted nurse or an administrative error. Every incorrectly diluted medication will have a different cause, perhaps a mathematical miscalculation or an incorrect or confusing label. An incorrect prescription could be caused by an exhausted physician or a misinformed provider. The different types of errors multiplied by the number of root causes in all the multiple process steps create an exponential number of opportunities for failure.

The Anna Karenina principle illustrates the challenge of researching medication administration problems. A researcher must study medication failures because only errors reveal root causes of problems. Successful administrations reveal little about the potential problems in the process. Even though hospital administrators always consider error rates too high, when compared with the number of medications administered in a year, they are comparatively low. Since each error is unique, eliminating one root cause of one error may provide little hope of preventing a different error. Studies of the medication systems must continue for months, if not years, to consolidate enough data to be useful. Because the diversity of error is so great, extensive data must be collected to find some commonality in errors that would lead to process

interventions that will prevent more than just a single error. It is unknown if the healthcare

system is even capable of creating or managing a perfect medication administration process.

One has never existed. There are simply too many things that can go wrong. The challenge,

however, should inspire improvement scientists and health practitioners to do better.

       The application of this study to biblical principles is also an easy task because what every

religion attempts to do for man is the same thing men are trying to do for business—improve it!

Every religion has, at its foundation, the improvement of humans, whether their efforts are

misguided or not, their intent is to make what they perceive as a better eternal soul. One might

conclude that the Judeo-Christian tradition in biblical teachings even takes that to an extreme.

From Moses' declaration "Thou shalt be perfect with the Lord" (Deut 18:13) to Jesus'

commandment, "Be ye therefore perfect, even as your Father, which is in heaven, is perfect."

(Matt. 5:48), the goal seems a bit lofty. Alternatively, had the Lord commanded achievement

that was something less than perfection, how low would He have set the bar in a world of men

and women with their diversity of commitment and capability? It seems unreasonable that God

would ask men to achieve something less than the best. The commandment to be perfect was not

given without instructions. The Ten Commandments are a basic foundation of that goal. These

were the minimum requirements to advance the human condition from their fallen state. When

Jesus Christ delivered the Sermon on the Mount, he took the process to the next level. In those

pages of the 5th chapter of Matthew, He describes exactly how the perfect man or woman would

act. Each admonition so simple and easy, yet the magnificence of them all together, so difficult.

       The ambition to create a medication administration process that does no harm seems to be

as elusive as the Biblical pronouncement that men should eschew all evil. After six thousand

years of Judeo-Christian teachings there is little evidence that another perfect man, besides the

Savior, has roamed the earth. Perfection of the human soul is the greatest of all ambitions of

man, and evidently the most difficult. The difficulty, and seemingly impossibility of the human

project, should not be a reason for despair but rather a source of inspiration. Look at what great

heights of human character and compassion have been achieved by men and women striving

for perfection. At the heart of the Savior's teaching is the process of repentance. This is an

ongoing process where the sinner focuses on one specific mistake he or she has made. The

first step is recognizing the error and feeling the discomfort of knowing one has made a mistake.

In the next step, the individual is expected to restore what he has taken or lost in the misdeed.

The final step is the penitent making a commitment to God that he or she will never make that

same mistake again. The process starts again when the individual makes a different mistake.

This continual upward spiral of eliminating error from one's life is the road to perfection. If an

individual fails to discipline him or herself and breaks that promise by committing the same sin

again, he or she has not progressed. There are so many ways that one can sin, perfection in this

life may never be possible, but this is how good men and women become great men and women

　　　　This process for perfecting men is uncannily similar to the LSS DMAIC process for

improving business. The DMAIC process is a study of error for the purpose of eliminating

failure. It starts with defining and recognition the problem, then, measuring it to understand the

extent of the damage. In the analysis and improvement phases the team determines the best way

to change the process so the same failure never occurs again. The last phase is called control.

This represents the phase of discipline where the process owner maintains the process. In the

control phase, the team measures the results to determine if the same failures are occurring and

to act, if necessary. After a predetermined time, if the process has reduced the level of errors, the

process owner moves to the next step by defining new errors that are occurring.

In healthcare, a hospital may never be able to prevent every conceivable error in the medication administration process but a system under constant surveillance and correction, can continually get better until it reaches those thresholds of 4, 5, or 6 Sigma. By continually reducing error through consistent application of HOR principles, using a proven methodology like LSS, hospitals can seal up those opportunities for error and eventually achieve that illusive threshold of 3.4 errors per million opportunities, considered by many in the business world to be as close to perfection as humanly possible.

The results of this study should impact all clinical managers and hospital leaders who are concerned with the safety of military hospital patients. The results give encouragement that LSS is still a viable methodology for reducing medication error and outlines the difficult challenges that have thwarted past efforts to perfect medication administration. The results of this study are particularly applicable to the improvement scientists who have been hired to assist DHA with this enormous responsibility. The results of this study will be made available to everyone through publication. The researcher intends to present the results of this research through various government healthcare forums.

Recommendations for Action

To accomplish this evolution in the application of RPP, leaders in healthcare should address the major conclusions of this study by taking the following dynamic initiatives: (1) establish medication error as a clinical priority, (2) make the LSS program the champion of safety issues as recommended by The Joint Commission, (3) develop stronger centralized control over the LSS program, and (4) integrate more fully, the discipline of HRO in the conduct of improvement studies.

DHA should first establish medication error as a clinical priority. The healthcare

community has proven that it can create high reliability in medical processes when it prioritizes and focuses its resources on singular problems. Examples cited earlier in this report include the case of central catheter-related blood stream infections and ventilator-associated pneumonia (Aboumatar et al., 2017, p. 663). Evidence from the IOC reports *To Err is Human: Building a Safer Health System* and *Crossing the Quality Chasm: A New Healthcare System for the 21st Century*, support the assertion that medication administration should be a priority. Medication-related adverse events are the single leading cause of injury in medicine (Kohn et al., 2000). It was estimated by Yip and Farmer (2015) that every hospitalized patient is subject to at least one medication error every day.

At the time of this study, the military health care system was in transition. Soon, all military health care facilities will fall under the jurisdiction of the Defense Health Agency. Strategic priorities for all military facilities will be established by the DHA Director. Health groups will no longer be stratified by the military services, but by their geographic market. The current DHA strategy is encompassed by the Quadruple Aim Performance Process (QPP). The four elements are: Readiness, Better Health, Better Care, and Lower Cost. Clinical safety issues are addressed under Better Care. DHA's Medical Affairs (MA) organization directs policy for clinical operations and quality management. MA has established a Clinical Quality Improvement Program that establishes priorities for all the MTFs. This is the organization that should focus on doing enterprise level LSS studies to develop the foundation for an effective medication administration process that prevents the most common errors while maintaining efficiency. DHA should elevate medication error to a first-tier priority and dedicate the resources necessary to solve this challenging problem.

The second recommended action is to establish LSS as the primary methodology for

solving medication administration challenges. If leaders of healthcare organizations want to

follow TJC guidelines for increasing safety in the medication administration system, they need to

commit to using the LSS methodology as their primary tool for solving these problems. This

study has not become a referendum on the efficacy of LSS but in how it has been applied at

Navy Medicine. This is a strategic issue that must be established by leadership at the highest

level of the organization. If LSS is to play a major role in making hospitals safer, then the

impetus for initiating these projects must be the safety metrics. The proportion of studies

conducted to address safety issues should match the proportion of measured safety problems. In

the past, the primary application of LSS at Naval Hospitals has been efficiency and improving

the effectiveness of auxiliary processes with the focus on military readiness. This may be similar

to many non-military hospitals. In a 2009 survey of hospitals using LSS, the researcher

concluded that efficiency was the most common goal while reducing medical errors was the

lowest (Langabeer et al., 2009). Four years later, a similar survey of 88 hospitals using LSS

showed that in 42% of the studies error rate was the primary metric. In 38% of the studies

reducing process time was the primary metric while 19% focused on increased productivity. The

trend seems to be a movement toward more emphasis on medical error. Figure 15 shows

previous strategic goals under Navy Medicine administration and the proportion of studies that

support each individual goal. There was no specific goal for hospital safety. Safety studies

would most likely be counted in the health or human capital category. Although the Navy's LSS

program has not focused primarily on safety issues, this does not diminish its success.   The

Navy LSS program has been extremely effective at improving process efficiency. Some of

benefits that have been tracked over the last eight years include financial benefits of $18 million

in cost savings and $37 million in cost avoidance. Under mission benefits, the Navy LSS

program reduced cycle time by 203,544 days and reduced waiting time by 742,584 days

(Strategic Performance Improvement Repository). What has not been shown, is a prioritization

in the use of LSS to solve the most pernicious problem in medicine today--medication error.
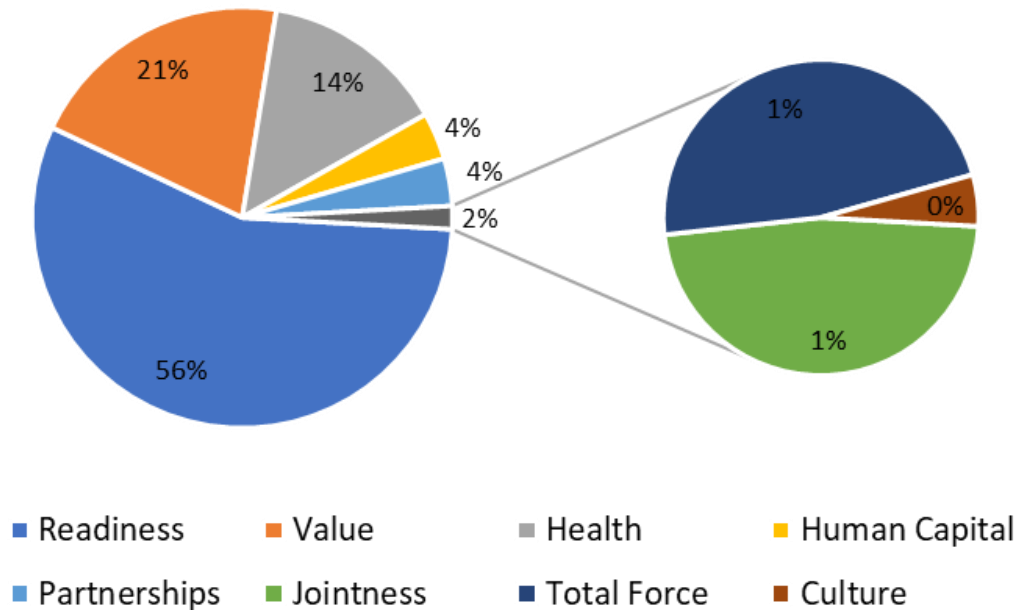

Figure 15. Goals support by LSS in the Navy program. This information was retrieved from the

Strategic Performance Improvement Data Repository (SPIDR).

The third recommendation is to develop stronger centralized control over the LSS

program. DHA has already make great advancements in that arena by directing the selection of

enterprise-wide process improvement projects at the headquarters. At the Strategy Planning and

Integration Branch (J-5), process improvement scientists assist each organization at both the

headquarters and the MTFs in developing improvement projects that support the QPP strategy.

This has become a regimented system where organizations at every level hold executive

planning sessions to select priorities and to submit their proposed and ongoing projects each year

to compete for allocation of resources. There is also a DHA office under J-5 called Enterprise

Solutions that conducts studies to improve processes that are common to all MTFs.

In conjunction with the headquarters' attempt to perfect the processes for military hospitals, administrators and clinicians at the medical facilities need to be fully engaged in monitoring their own processes. Leaders and administrators at the MTFs have actual control of the medication administration process and they must lead the fight to establish capable medication administration processes. Local leaders should direct the selection of LSS projects and guide the effort to assemble teams that have the capacity and commission to manage large-scale projects that scrutinize every step in the medication administration process.

The fourth recommendation is to more fully integrate HRO principles into LSS interventions. For improvement studies to be effective at reducing medication error in the long term, LSS practitioners need to incorporate the principles of HRO in their methodology. The primary tenants of HRO include (1) preoccupation with failure, (2) reluctance to simplify problems, (3) constant scrutiny of the most critical processes and constantly improving them, (4) commitment to resilience, meaning agility in adjusting to failure, changes, and threats, and (5) deference to expertise (Vogus & Sutcliffe, 2007).

In their theory of RPI, Chassin and Loeb believed that LSS should be the tool driving the implementation of HRO principles because it was the best way to improve safety and the quality of patient care. These LSS teams need to be empowered to instigate a robust and disciplined medication administration process that everyone should be expected to follow. After the process has been established and endorsed by senior leadership, it needs to be enforced. In LSS theory, practitioners rarely blame mistakes on individual workers but rather the process. If a process allows wide scale problems, this is leadership's failing. If leaders provide a successful process that prevents injury, then healthcare workers should be held accountable to use it. Some of the

most operative advice in this regard comes from Grissinger (2010) who stated that nurses should

not be held accountable for achieving a successful medication administration, they should be

held accountable for following processes and protocols set up by the organization. Hospital

managers need to design fail-safe ways to achieve their goals of successful medication

administration. Enforcement of an effective process can be accomplished with regular and

disciplined monitoring of the process through inspections, observation, and testing. Some of the

most common recommendations for the application of HRO principles to healthcare are

presented by Durham et al. (2016) who advocated use of checklists, accountability for practice,

simulator based training, and a system-based approach versus human based behavior. They

supported the HRO principle of pre-occupation with failure by surveillance of patients and the

environment. Some of these practices are still difficult to adopt in medicine where providers and

nurses consider themselves to be independent professionals, like lawyers or accountants.

Requiring the use of verbal response checklists or having someone double check work or

requiring two-man policy for critical procedures or having to submit to no-notice inspections still

seem offensive to many medical professionals. In other industries, such as aviation, and nuclear

power, checklists, two person policies and no-notice inspections are commonly expected

practices that are part of professional competency. These practices are essential to building a

culture of quality. Medical professionals should understand that professionals in HRO industries

are judged by error-free results. To sacrifice some independence is a small price to get there.

Recommendations for Further Study

This study can only be considered preliminary in the effort to quantify the success of

process improvement methodologies in reducing medication error. The theory of RPI must

receive much more rigorous testing in many ways before researchers can make a credible claim

of causation between the interventions produced in an LSS study and the positive outcomes of

reducing medication error. Studies should be conducted by organizations both in the military

and in civilian hospitals. More comparative studies should be done contrasting the medication

process outcomes of organizations that have applied LSS methodology to those that have not.

The key component to adding empirical evidence supporting the theory of RPI will be finding

organizations that have focused their efforts of process improvement on medication error. If an

organization has prioritized its effort on the reduction of medication error, researchers can better

evaluate the success of their interventions and isolate those interventions that have been most

effective. One of the greatest challenges of this effort will be finding ways to measure

medication errors without depending on self-reported metrics. The results of this study have

clearly demonstrated that PSR rates can be unstable. Researchers who can find effective and

unobtrusive ways of measuring actual errors will be more effective at correlating variables with

outcomes.

Experimental research is the most powerful quantitative research and needs to be

included in the testing of the RPI theory. Unfortunately, experimental research with medication

administration requires extensive preparation and is plagued with risks. One of the problems

with experimental studies in hospitals, is that the process must be observed for long periods of

time to extract enough data to make it useful. Experimental research requires extremely close

monitoring of both the numerator and denominator of the dependent variable to derive accurate

error rates. Even more challenging, is the manipulation of variables in a process that affects the

health of patients. This can be very disruptive to normal operations.

This researcher recommends a laboratory type experiment where a simulated medication

process is used to recreate the typical errors encountered in the real process.   In a simulated

medication process, one could enhance the degree of difficulty in each step to ensure higher error

rates in a short period of time. The researcher could experiment with various interventions and

use comparative groups to determine which interventions were more effective. Part of these

experiments should include the principles of HRO to see how more rigorous enforcement of

interventions affects the outcomes. The results of these experiments could establish successful

interventions that could be tested in real medication administration systems and measured over

long periods of time.

Reflections

For the researcher, the last four years have been a journey of discovery. The last year of

navigating a completely unfamiliar path for gaining access to healthcare data was particularly

enlightening. It was often a very lonely path trying to unravel the government approval process

through a web of protective barriers. The entire process required a good dose of patience and

persistence. It also required the assistance of key members of the military to whom the

researcher will be eternally grateful.

It would not be completely forthcoming if the researcher were to say that bias was

altogether absent from this research. As an LSS Master Black Belt and improvement scientists,

the researcher expects LSS studies to be successful. When they are not, the response is to find

out why LSS failed rather than to recommend a new methodology. Such is the case with this

study.   Over the years, the researcher has concluded that the DMAIC methodology is the most

scientific approach to solving problems because it is the culmination of an evolutionary process

that started 50 years ago. It is understood that the LSS methodology is just a tool for solving

problems. There have been many successful tools in the past and there is currently a myriad of

successful methodologies used in the market today. When there is failure in any effort to

improve a process, the reason is almost inevitable not because the tool was bad, but because of a weakness in the way it was applied. What seems clear is that any industry that intends to reduce defect rates above the third sigma, must apply the principles of HRO, if they want it to be successful.

There were weaknesses of this study that have been described in the findings. This study was non-experimental, and it used a dependent variable that had questionable reliability. The reliability of the dependent variable was reduced by the unexpected need to estimate the medication doses for each MTF.   A more pernicious problem was the possible interference of the PSR rate by the independent variables in an unexpected way.   The study interventions may have affected the PSR submission rates without affecting the true error rate.   Regardless of the weaknesses in this research, those five Navy process improvement teams each made a magnanimous effort to solve real problems with the best resources they had. All of the LSS projects made powerful interventions and showed improvement in the particular metrics they were measuring for the scope of their study.

The researcher had expected more success from the studies that had a broader scope and more sophisticated interventions. Notwithstanding the results of this study, the researcher is still convinced that the best approach to reducing a hospital medication error rate is to broaden the scope of the study to include all the steps of the medication process simultaneously. This effort will require an enterprise level effort that will inevitably involve intricate systematic change. The dedicated application of HRO will be essential to maintain the integrity of the new system.

Much has been written over the last 20 years about medical mistakes and the sorrow it has caused. It should not overshadow great success of healthcare around the world. The motto of "doing no harm" seems like a superfluous statement for an industry designed to nurture the

sick and the injured, but it is an honest admission of the challenges in medicine. Reducing error is the first step in making hospitals true centers of healing. The theme of nurturing the sick and injured is a continuous theme of the Bible and runs parallel with the objectives of healthcare. It is fitting that the medical industry still lifts the serpent on the staff, not as a symbol of injury but of healing, just as the ancient Israelites were told to look to the serpent and live.

Summary and Study Conclusions

This dissertation was a study of the effectiveness of Navy Medicine's application of LSS to the reduction of medication error at Naval Hospitals. It began with a review of the landmark IOC studies at the turn of the 21st century that describes how 98 thousand Americans die every year as a result of medical errors with a costs to the public of over $30 billion (Committee on Quality of Health Care in America, 2001; Kohn et al., 2000). These studies concluded that most errors were systematic and could be prevented. They also determined that medication errors were the single leading cause of injury. The general problem of this study is that medication error continues to be the most prolific cause of injury in medicine today. During the next 15 years, after the IOC reports, TJC leaders developed theory for how to make the medical industry a highly reliable organization. Their theory centered around three pillars: (1) leadership engagement, (2) culture of safety, and (3) robust process improvement (RPI). For 10 years Navy Medicine has embraced the theory by educating leaders, changing the culture, and developing RPI using the LSS methodology. The specific problem for this study was that very little research has been done to validate the effectiveness of the LSS methodology in reducing medication error. The purpose of this study was to determine if the Navy transformation has had an effect on the medication error rate where error rate is measured by PSRs. The research question asks: Does Chassin and Loeb's theory of LSS effectiveness in changing healthcare processes explain a

change in medication PSR rates after the intervention of an LSS study targeting medication

errors? The research hypothesis $H1$ states that the preintervention PSR rate will be statistically

larger than the postintervention PSR rate for medication errors.

This study was quantitative non-experimental research using a pre-post causal-

comparative design. The dependent variable was medication error and was represented by the

PSR rate. PSR rate was computed by dividing the number of PSRs for each six-month period by

the average number of inpatient doses administered during the same period. The independent

variables were the team interventions developed by the LSS study teams. These interventions

were designed to change the dependent variable. Five Navy Medicine sponsored LSS studies

were found that addressed medication error during the last ten years. The researcher compared

the six-month average PSR rate before each study to the six-month average PSR rate after

completion of the study.

The findings showed that the PSR rate was reduced in two of the five studies. The

reduction was statistically significant in one of the two studies. A comparison of the total

number of PSR in the before group to the after group, showed a reduction of PSRs from 462 to

407. The total reduction in PSR rate was not statistically significant for all five studies combined.

The researcher concluded that the findings of this quantitative study do lend credible evidence to

answer the research question by demonstrating that the application of LSS at Navy Medicine

treatment facilities has made an impact on the reduction of medication errors as measured by the

PSR system. The results did not answer the research question in a definitive way, but they have

helped close the gap in literature by providing some empiric evidence that an effective LSS study

can reduce medication PSR rates.

Based on observations of the study, the researcher developed the following five

additional conclusions: (1) the independent variable classified as nurse training proved to be best predictor of success, (2) Navy Medicine has not engaged LSS as the primary tool for reducing medication error, (3) military leaders need to become more engaged in the LSS system before it will be capable of solving complicated safety issues such as medication error, (4) the tools of HOR were not effectively applied in the control plans which lacked the discipline to maintain interventions over time, and (5) the PSR system is not a highly accurate system to determine error rates for research.

Based on the average PSR rates using all five LSS studies, the average Sigma level was 3.2. This means that 99.93 percent of all medication administrations were successful (without error). This hardly seems cause for alarm unless one considers that a large hospital administering one million medications a year would experience 687 failed doses. This is similar to Sigma levels measured at other hospitals (Langabeer et al., 2009; Polovina et al., 2014). This is a Sigma level that would never be acceptable in the aviation industry. Another more sobering realization is that experts estimate that self-reported errors only capture about 10 percent of actual errors (Pronovost et al., 2006). Three Sigma is considered the industry standard in manufacturing. The question is: Will medical leaders continue to accept the standard of quality required to manufacture light bulbs and toaster ovens, or demand a higher level of safety for their patients? Military medical systems have invested their hopes and treasure in the theory of RPI and have achieved some success. Leaders in medicine should look to other organizations that have reduced errors beyond the Sixth Sigma and follow their lead by prioritizing efforts on the most important aspect of their business—safety. By applying the dynamic principles of HRO, hospitals can continue that upward spiral toward a perfect medication administration system.

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Appendix: Glossary of Acronyms

AHRQ	Agency for Healthcare Research and Quality
AI	Artificial Intelligence
ASHP	American Society of Health Systems Pharmacy
ASQ	American Society of Quality
ATO	Authority to Operate
BCMA	Bar-Code Medication Administration
BSN	Bachelor of Science in Nursing
CAS	Critical Access Hospital
CDSS	Clinical Decision Support System
CDSS	Concept of Decision Support Software
CPOE	Computerized Physician Order Entering System
CPOM	Computerized Physician Ordering Management System
CRM	Crew Resource Management
DHA	Defense Health Agency
DMAIC	Define, Measure, Analyze, Improve, Control
DoD	Department of Defense
DPMO	Defective Parts per Million Opportunities
DPPM	Defective Parts per Million
DSA	Data Sharing Agreement
EHR	Electronic Health Record
eIRB	Electronic IRB
eMAR	Electronic Medication Administration Record
FMEA	Failure Modes and Effects Analysis
HQI	Hospital Quality Institute
HRO	Highly Reliable Organization
HRPP	Human Resource Protection Program
ICU	Intensive Care Unit
ImR	Individual, Moving Range
IOM	Institute of Medicine
IRB	Institutional Review Board
LSS	Lean Six Sigma
MAC	Medication Administration Checking
MAE	Medication Administration Errors
MAR	Medication Administration Record
M&M	Morbidity and Mortality Conference
MOR	Main Operating Room
MRP	Medication Related Problem
NMCSD	Navy Medical Center San Diego

NZNO	New Zealand Nursing Organization
OCR	Optical Character Recognition
PCAR	Patient Care Activity Record
PHI	Personal Health Information
PICU	Pediatric Intensive Care Unit
PII	Personally Identifiable Information
QPP	Quadruple Air Performance Process
PRN	Physician Referral Network
PSR	Patient Safety Report
RCA	Root Cause Analysis
RPI	Robust Process Improvement
SOP	Standard Operating Procedure
SPIDR	Strategic Process Improvement Data Repository
TJC	The Joint Commission
TOT	Time on Task
WOW	Workstation on Wheels