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Correlating High Reliability Organization Practices With Preventable Harms Across Children’S Hospitals Participating In The Children’S Hospitals’ Solutions For Patient Safety Collaborative

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CORRELATING HIGH RELIABILITY ORGANIZATION PRACTICES WITH PREVENTABLE HARMS ACROSS CHILDREN'S HOSPITALS PARTICIPATING IN THE CHILDREN'S HOSPITALS' SOLUTIONS FOR PATIENT SAFETY COLLABORATIVE

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ABSTRACT

Background: Despite significant effort, focus, and resources dedicated to reducing patient safety risk, the healthcare system continues to have high error rates. Approaches and strategies implemented to decrease human error have been marginally successful in achieving sustainable reduction in patient harm.

Purpose: The purpose of this study was to examine the association between high reliability and patient safety outcomes by testing the following hypotheses: Organizations exhibiting more advanced high reliability practice will have fewer hospital acquired conditions (as defined by the Serious Harm Event Index (SHE) than organizations exhibiting less advanced high reliability practices; and organizations exhibiting more advanced high reliability practices will have fewer serious safety events (as defined by the Serious Safety Event Rate (SSE)) than organizations exhibiting less advanced high reliability practices.

Methods: High reliability practice data, as measured by the Chassin and Loeb (2013) framework, was obtained from 49 organizations participating in the Children's Hospital Solutions for Patient Safety collaborative. Ordinal logistic regression was utilized to test the association between high reliability practice scores and the SHE Index in 33 organizations and SSE Rate in 12 organizations.

Results: We were unable to demonstrate a significant relationship between overall high reliability practice as measured by the Chassin and Loeb (2013) framework and SHE Index or SSE Rate. The culture of safety component of high reliability practice was significantly and negatively associated to both SHE Index and SSEs. The leadership and robust process improvement components of high reliability practice were not associated with SHE Index or SSE Rate.

Conclusion: This study expands on findings from previous studies, which have shown an association between culture of safety and individual HACs and SSER. Safety culture scores were inversely associated with decreased patient harms, specifically hospital acquired conditions and serious safety events in this study. Organizational leadership and patient safety professionals can use the results of this study to inform and engage organizational leadership and the healthcare team on the application of high reliability principles to improve safety culture as an effective strategy to help eliminate preventable harm to patients.

Keywords: high reliability, patient harm, patient safety, hospital acquired condition,
Serious Safety Event Rate

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CHAPTER 1:

INTRODUCTION

Quality and safety are essential components of healthcare. Patients expect to enter the healthcare system to resolve a health problem and not have additional health problems created for them by the healthcare system. Nevertheless, healthcare is unsafe. As a result, many patients continue to experience serious preventable harm within the hospital setting (Kohn, Corrigan, & Donaldson, 2000). Developing theory and reported data from observed practice suggests that much of this harm is avoidable and preventable (James, 2013; Reason, 2000).

One such theory is high reliability organizational theory. High reliability organizations have been defined as organizations that “operate under very trying conditions all the time and yet manage to have fewer than their share of accidents” (Weick & Sutcliffe, 2011, p. 21). Application of high reliability principles has the potential to transform the healthcare industry into an industry that performs with a higher level of safety than is present today. Applying the principles of high reliability across an individual healthcare organization might facilitate the identification and correction of system and process failures as well as the prospective design of processes to eliminate or significantly decrease the risk of harm.

These attributes of high reliability guide the organization to effectively design or redesign processes making the wrong thing hard to do. Application of high reliability science to healthcare is in its early stages, but patient safety researchers hypothesize that the application of high reliability principles in healthcare settings can change organizations that deliver healthcare into safer environments for patients (Chassin & Loeb, 2013; Lyren, Brilli, Bird, Lashutka, & Muething, 2013; Weick & Sutcliffe, 2011). The purpose of this research was to articulate and test a conceptual framework for measuring the association between the implementation of high reliability principles in healthcare and patient safety outcomes.

Statement of Problem

The Institute of Medicine's (IOM) report *To Err Is Human, Building a Safer Health System* highlighted that human error contributes to harm in tens of thousands of patients hospitalized in the United States each year (Kohn et al., 2000). Despite significant effort, focus, and resources dedicated to reducing patient safety risk, progress has been slow. Recent literature suggests rates of harm from human error remain constant nearly 15 years after *To Err is Human, Building a Safer Health System* was published.

Based on this, and other similar publications, it appears that the approaches and strategies implemented to decrease human error have been only marginally successful in achieving sustainable reductions in patient harm over time at the national level (Agency for Healthcare Research and Quality, 2015; James, 2013; Landrigan et al., 2010; Leape & Berwick, 2005; Levinson & General, 2010).

While reducing events of human error and associated patient harms has not been reliably achieved in healthcare, several industries (i.e., commercial aviation, naval aviation, nuclear power) have had success with reducing human error and dramatically improving safety industry wide. As early as the 1980s researchers began evaluating conditions that allow these industries to achieve such reliably safe outcomes (Roberts, 1989; Weick & Sutcliffe, 2011). The concept of "high reliability" evolved from this work. Recently, these lessons have been applied to healthcare in order to evaluate whether the translation of these "high reliability" practices into healthcare could decrease the incidences of patient harms (Weick & Sutcliffe, 2011).

Although substantial speculation exists that translating the principles from high reliability industries into healthcare will be transformative, there is little evidence to date that these principles have resulted in sustainable improved patient safety outcomes when specifically applied to healthcare. Several researchers have attempted to translate high reliability principles into concrete behaviors and practices relevant to healthcare, yet no research to date has determined if these high reliability actions have directly impacted patient harms (Brilli et al., 2013; Chassin & Loeb, 2013; Lyren et al., 2013; Muething et al., 2012).

The ability to evaluate the association of high reliability practices and patient harms has recently advanced with the development of an assessment tool that measures the extent of compliance to these high reliability practices (Chassin & Loeb, 2013). While not formally validated, this tool at present is the only published tool that assesses a healthcare organization's commitment to high reliability practices in its healthcare operations. This tool offers an opportunity to assess the association of these practices with patient safety outcomes.

Statement of Purpose

The purpose of this research was to articulate and test a conceptual framework for measuring the association between the application of high reliability principles in healthcare and patient safety outcomes. This study is based on a series of activities undertaken by a pediatric hospital collaborative seeking to improve patient safety in the affiliated organizations. Because of the substantial effort required to implement high reliability principles, the adoption of high reliability practices occurs at different rates within different organizations, similar to the adoption of technology solutions to enhance operational practices. The progressive spread of solutions across an industry is well described in the innovation diffusion literature (Rogers & Shoemaker, 1971).

Many factors affect an organization's timing of technology adoption and of implementing innovative operational practices emerging in an industry. The participating children's hospitals are presumed to have different cultural characteristics and different approaches to managing patient safety that may affect selecting and implementing new operational approaches. This natural variation provides an opportunity to study the effects that these high reliability principles may have on patient safety outcomes in these organizations.

The goal of this study was to examine whether self-reported organizational compliance with high reliability practice was associated with patient safety outcomes as reported by these organizations. The results of this study have the potential to inform healthcare organizations regarding the importance and impact of high reliability principles and practices on the safety outcomes of hospitalized patients.

Background

Quality and safety are important components of healthcare; however, the healthcare system has higher error rates than other similarly complex systems. The IOM defines healthcare quality as consistently using current professional knowledge to increase the probability of achieving a desired outcome (Lohr & Schroeder, 1990). Patient safety, a component of healthcare quality, is defined by the IOM as freedom from accidental injury (Kohn et al., 2000). This definition has been explained by the National Research Council (Kohn et al., 2000) as providing patients with appropriate services, delivered by providers that are technically competent, have good communication skills, engage in shared decision making, and practice in ways that are sensitive to the patient's culture.

In 1999, the IOM released its report highlighting patient safety risk in hospitals within the United States. The initial report, *To Err is Human: Building a Safer Health System*, estimated that between 44,000 to 98,000 people die each year in hospitals as a result of preventable medical errors. This estimate placed hospital-based errors as the ninth leading cause of death in the United States, at an estimated industry cost associated with the deaths as between $8.5 and $17 billion annually. The IOM defined a medical error as "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim" (Kohn et al., 2000, p. 4).

The IOM report cited data from the Harvard Medical Practice Study (Brennan & Leape, 1991), in which researchers evaluated the incidence of adverse events occurring in more than 30,000 hospitalizations in the state of New York in 1984. The study found an incidence of adverse events resulting in an increased length of stay or disability in 3.7% of these hospitalizations. Among these adverse events, 58% were estimated to be preventable events and 27.6%, or 27,179 events, were thought to be a result of negligence, defined as "care that fell below the standard" (Brennan & Leape, 1991, p. 370). Approximately 73% of these adverse events were classified as resulting in "temporary harm", 7% as "serious permanent harm", 14% of the adverse events led to death, and in 6%, severity was unable to be determined (Brennan & Leape, 1991).

A follow-up to the initial IOM report, *Crossing the Quality Chasm: A New Health System for the 21st Century* was released in 2001. It outlined a strategy for improving the healthcare delivery system. This report asserted that "between the healthcare we have and the healthcare we could have lies not just a gap, but a chasm" (Institute of Medicine Committee on Quality of Health Care in America, 2001, p. 1). Within this report, the quality of healthcare was scrutinized.

The report cited failures to utilize resources efficiently, lack of safe systems, and overutilization of services. The authors concluded that the current healthcare system did not consistently provide high quality or safe care (Institute of Medicine Committee on Quality of Health Care in America, 2001). The report recommended six aims for improvement: healthcare should be safe, effective, patient-centered, timely, efficient, and equitable (Institute of Medicine Committee on Quality of Health Care in America, 2001).

Broad recommendations were made within these two IOM reports for improving the quality of healthcare (Institute of Medicine Committee on Quality of Health Care in America, 2001; Kohn et al., 2000). A significant contribution of the reports was raising public awareness and accelerating local organizational action regarding patient safety. These reports spurred individual healthcare providers and professional organizations to engage in collaborative safety improvement initiatives. In 2002, The Joint Commission established the first in a series of safety priorities known as the National Patient Safety Goals. These goals, recommended by a panel of experts in patient safety, were established to help organizations focus on and address specific issues designed to improve patient safety (The Joint Commission, 2015).

In December 2004, voluntary efforts to reduce preventable harms emerged at a national level when the Institute for Healthcare Improvement (IHI) launched the 100,000 Lives Campaign (Berwick, Calkins, McCannon, & Hackbarth, 2006). Hospitals across the United States were encouraged to voluntarily work together and with the IHI to improve safety outcomes to prevent an estimated 100,000 deaths that could be expected to occur as a result of patient care errors.

The IHI subsequently launched the 5 Million Lives Campaign (McCannon, Hackbarth, & Griffin, 2007) to expand efforts to decrease all harm whether preventable or not (McCannon et al., 2007). This definition of harm, known as "all cause harm", changed the safety discussion for hospitals from a focus on decreasing preventable harm to monitoring harm from a patient perspective, for whom harm is harm – preventable or not. Both campaigns advocated prescriptive interventions without providing specific instructions for establishing an organizational infrastructure (i.e., policies and training) to support sustainable improvements in patient safety.

In the late 2000s, the IHI continued to encourage national change by introducing the Triple Aim: better care for individuals, better health for populations, and lower per capita costs (Institute for Healthcare Improvement, n.d.). This initiative moved away from individual hospitals implementing specific interventions to a vision of transformation in the structure of the healthcare delivery system to meet the interdependent goals of the Triple Aim. A similar approach was called for in reports published by the National Research Council (Berwick, Nolan, & Whittington, 2008). However, there were many barriers to addressing the Triple Aim that were not easily overcome regardless of the individual or organizational desire to improve healthcare quality (Berwick et al., 2008).

Despite many initiatives to improve the safety of healthcare delivery systems, high rates of patient harms continued. For example, Kerr et al. (2004) reported that only 50% of adults receive the care recommended for their respective medical condition (Kerr, McGlynn, Adams, Keesey, & Asch, 2004; McGlynn et al., 2003). Five years after the IOM reports were released, there was little concrete evidence of improvement in patient safety at a national level (Leape & Berwick, 2005). Barriers to improvement described at this time included culture, lack of leadership for safety, and lack of comprehensive inclusive measures of harm (Leape & Berwick, 2005). Leape and Berwick (2005) hypothesized that in order for significant progress to occur, everyone within healthcare must be accountable for improving patient safety, not just the select few executives, administrators, and researchers focused specifically on the patient safety agenda.

Ten years after *To Err is Human*, Landrigan, Sharek, et al. (2010) concluded that rates of preventable harm remained high and unchanged over a 6-year time frame. In a study of 2,341 admissions between 2002 and 2007 in the state of North Carolina, rates of all cause harm were studied. The IHI Global Trigger Tool methodology, a tool utilizing triggers in a random retrospective review of patient records to identify potential adverse events, was used to identify and validate harms (Griffin & Resar, 2009).

Within the study, 585 incidences of patient harm were found, a rate of 25.1 per 100 admissions. No significant change in the rate of harm over time was found. The findings of the study implied a lack of improvement in safety despite increased attention and resources dedicated to patient safety improvement. The authors concluded that further research was needed to identify methods for transforming healthcare in a way that achieved sustainable improvements in patient safety (Landrigan et al., 2010).

In an Office of the Inspector General report to Congress in 2010, harm was reported to occur in 27% of a random sample of 780 discharged Medicare patients. These episodes of patient harm resulted in $324 million in costs to Medicare for the single month that constituted the study's sample (Levinson & General, 2010). A more recent estimate of harm derived from review of published literature asserted there are more healthcare safety issues than previously estimated, leading the authors to estimate that preventable harm is associated with between 210,000 and 440,000 deaths per year in United States hospitals (James, 2013).

The lack of clear evidence regarding improvement and the prevalence of harm have spurred discussions regarding patient safety problems. These discussions suggest culture as a barrier to improvement within hospitals (Leape & Berwick, 2005). For healthcare providers and consumers, there has been little progress in finding sustainable solutions to patient safety problems (Chassin & Loeb, 2011).

In 2010, the Patient Protection and Affordable Care Act, commonly referred to as the ACA, was signed into law to drive reform of the healthcare system. The ACA included strategies for improving the quality and safety of healthcare. To facilitate implementation of the ACA, the Centers for Medicare and Medicaid Innovation (CMMI) was established to evaluate new approaches to improve the quality, safety, and affordability of care (Centers for Medicare and Medicaid Services, 2016a). The CMMI established a mission with the following three central tenets, which are well aligned with the IHI's concept of the Triple Aim:

- Better healthcare: Improve individual patient experiences of care along the IOM's six domains of quality: Safety, Effectiveness, Patient-Centeredness, Timeliness, Efficiency, and Equity.
- Better health: Encourage better health for entire populations by addressing underlying causes of poor health, such as physical inactivity, behavioral risk factors, lack of preventive care and poor nutrition.
- Lower costs through improvement: Lower the total cost of care resulting in reduced monthly expenditures for each Medicare, Medicaid or Children's Health Insurance Program beneficiary by improving care.

(Centers for Medicare and Medicaid Services, 2016a)

To achieve these directives, the CMMI launched challenges and partnership initiatives encouraging individual organizations to move forward to improve healthcare safety. One such initiative, launched in 2011, was the Partnership for Patients, which created groups of organizations committed to working together in a safe and reliable manner to improve patient outcomes. The Partnership for Patients established the following two goals: (1) to decrease preventable hospital-acquired conditions (HACs) by 40% by the end of 2013 as compared to 2010, and (2) to reduce preventable complications during transitions from one care setting to another in order to decrease hospital readmissions by 20% by the end of 2013 as compared to rates for 2010 (Centers for Medicare and Medicaid Services, n.d.-b).

HACs are defined as injuries to patients associated with the delivery of healthcare. The Centers for Medicare and Medicaid Services (CMS) estimate that more than half of the HACs that occur are preventable and result in approximately $4.5 billion in unnecessary healthcare spending per year (Centers for Medicare and Medicaid Services, n.d.-b). The nine specific HACs within the Partnership for Patients initiative included: Adverse Drug Events (ADE), Catheter Associated Bloodstream Infections (CLABSI), Catheter Associated Urinary Tract Infections (CAUTI), Falls, Obstetrical Adverse Events (OBAE), Pressure Ulcers (PU), Surgical Site Infections (SSI) for specific surgical procedures, Ventilator Associated Pneumonia (VAP), and Venous Thromboembolisms (VTE). It was estimated that if the goals of the Partnership for Patients initiative were achieved, 60,000 lives would be saved, preventable injuries and complications would be reduced by millions, and as a result, healthcare costs would be reduced by an estimated $35 million (Centers for Medicare and Medicaid Services, n.d.-b).

CMS expanded the Partnership for Patients initiative in 2011 by moving from individual hospital participation to networks. The agency established 26 hospital engagement networks (HENs), which received funding designated for innovation in quality and safety improvement. The HENs that were funded include state, regional, and national networks encompassing over 3,700 hospitals. CMS charged the 26 funded HENs to identify and spread successful and sustainable methods for reducing occurrences of the nine previously identified HACs and readmissions (Centers for Medicare and Medicaid Services, n.d.-b).

Beginning in October 2014, healthcare organizations experienced a new financial incentive to reduce HACS as the ACA implemented the HAC Reduction Program. This program implemented a financial penalty to applicable organizations performing in the bottom quartile of organizational performance with HACs (Centers for Medicare and Medicaid Services, 2016b).

Preliminary reports regarding the success of the Partnerships for Patients initiative were encouraging. Based on a 2014 U.S. Department of Health and Human Services report (2014), HACs reportedly declined 9% from 145 HACs per 1,000 discharges in 2010 to 132 HACs per 1,000 discharges in 2012 (U. S. Department of Health and Human Services, 2014). The Agency for Healthcare Research and Quality reported sustainment with no further improvement with 2015 HAC rates of 121 HACs per 1,000 discharges in both 2013 and 2014.

While these gains in patient safety are important, the Agency for Healthcare Research and Quality (2015) acknowledged that the reasons for HAC reduction are not fully understood. In order to fully understand and sustain improvement, the healthcare industry must adopt strategies that will transform healthcare into an industry that eliminates preventable harm to patients. To expand the success of the HENs, CMS released a Request for Proposal in February 2015 seeking projects to achieve further reduction in HACs (Centers for Medicare and Medicaid Services, n.d.-a).

In summary, the prevalence of patient harm events in healthcare organizations gained impetus as a public concern with the publication of the IOM report in 1999. Efforts to date have focused on improving patient safety outcomes. These efforts have produced some success; however, more information is needed to develop strategies to further improve and sustain these gains. Figure 1 summarizes selected voluntary and legislative initiatives to improve patient safety.

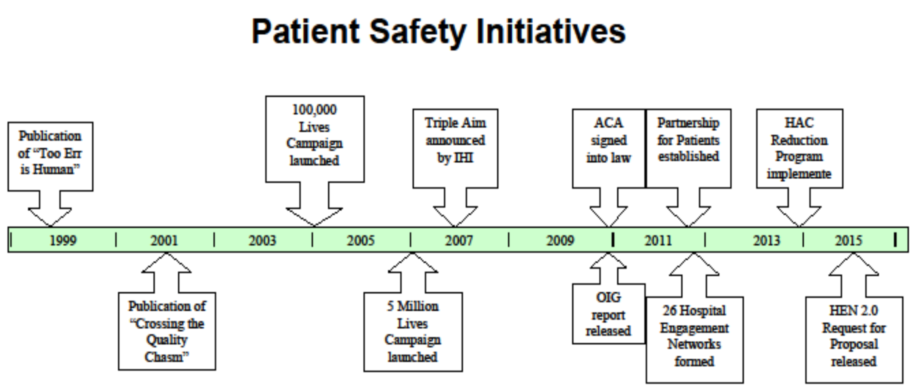

Figure 1. Milestones in the US Patient Safety Movement

CHAPTER 2:

LITERATURE REVIEW

High Reliability Organizations (HROs) achieve remarkable safety rates despite the complexity of the organizations and the inherent risks associated with the type of work they perform (Gatmaitan, 2015; Kaissi, 2006; Reason, 2000; Weick & Sutcliffe, 2011). Specific characteristics seem to make these organizations different from other complex organizations that experience high error rates.

Many forward-thinking healthcare organizations seek to emulate these characteristics in an effort to become highly reliable. It is generally believed that implementation of specific strategies that embody the characteristics of high reliability organizations may positively impact patient safety outcomes. To date, this impact has been measured only indirectly through quality improvement studies because tools to measure high reliability have been scarce and existing measures have been based on employee perception, rather than on specific organizational characteristics and behaviors.

High Reliability Organizations

After 15 years of intense efforts to improve patient safety, only marginal improvement has been demonstrated to date. Patient safety researchers now hypothesize that in order to transform healthcare organizations into reliably safe places for patients the root causes of patient safety risk must be identified and addressed with effective interventions that produce sustainable improvements (Chassin & Loeb, 2013; Gaba, 2000; Landrigan et al., 2010).

Many patient safety researchers further hypothesize that the principles of high reliability organizational theory can address these root causes. When effectively adopted within the healthcare setting, high reliability approaches may provide sustainable countermeasures that minimize preventable patient harms (Brilli et al., 2013; Chassin & Loeb, 2011; Lyren et al., 2013; Muething et al., 2012).

HROs have been defined as organizations that "operate under very trying conditions all the time and yet manage to have fewer than their share of accidents" (Weick & Sutcliffe, 2011, p. 21). The inability of other approaches to reliably and substantially improve patient safety outcomes has led to interest in evaluating the impact of HRO concepts on healthcare delivery. When the definition of a HRO is translated to healthcare, reliability is defined as "the capability of a process, procedure or health service to perform its intended function in the required time under existing conditions" (*High Reliability Error Prevention Training*, 2013).

Research into high reliability industries began at the University of California at Berkeley in the 1980s. Investigators studied organizations involved in high risk activities that demonstrated reliably safe performance (Roberts, 1989). This work described key characteristics of high reliability organizations such as deference to expertise and reluctance to simplify, and highlighted the importance of continuous training and redundancy in processes that when not present increases the risk of failure (Roberts, 1989, 1990; 2001).

Weick and Sutcliffe (2006; 2011) expanded on this work by describing five attributes of consistently highly reliable organizations. The authors conducted an extensive analysis of three disparate high reliability industries (naval aviation, nuclear power, and firefighting). Despite major differences between these industries, they all consistently adhered to the following five principles: (1) preoccupation with failure, (2) reluctance to simplify, (3) sensitivity to operations, (4) commitment to resilience, and (5) deference to expertise. These principles allowed organizations to anticipate potential failures and contain them in order to minimize harm. The connection between the tenets and principles of high reliability are described in Table 1.

TABLE 1

TENET AND RELATED PRINCIPLES OF HIGH RELIABILITY

Tenet of High Reliability	Principle of High Reliability
Anticipation	Preoccupation with Failure Reluctance to Simplify Sensitivity to Operations
Containment	Commitment to Resilience Deference to Expertise

Anticipation was described by Weick and Sutcliffe (2011) as foreseeing an unexpected outcome and preventing any progression of course of events that is unwanted. Anticipation is accomplished by paying attention to failures, fully understanding the details of situation. Preoccupation with failure, the first attribute of anticipation, describes the concept of organizations treating small failures as symptoms that something bigger is wrong within a system or process. HROs view small failures as problems that can create a chain reaction within the system and ultimately lead to catastrophe. To prevent catastrophic outcomes, HROs ensure that these small failures are appropriately diagnosed and quickly addressed. When detected as small failures, HROs make use of more options that exist for correction, whereas failures later in the process are often more complex and provide limited options for correction. HROs act with a sense of urgency and have a strong response for correction of even the smallest failures (Weick & Sutcliffe, 2011).

Sensitivity to operations, the second attribute of anticipation, means always paying close attention to the risks present within the work on the front lines. In the case of healthcare, this would mean work on the inpatient unit, in the clinic, in the radiology suite, or other points of patient care. If failures occur on the front line, these failures can continue to evolve or accelerate through the remaining steps of a process, potentially resulting in unacceptable outcomes. This principle reflects a belief that front line workers (e.g., nurses, respiratory therapists, pharmacists, or physicians) often know the most about failures that are occurring in their area and what steps within a process can be adjusted to eliminate these failures. HROs take advantage of this knowledge (Weick & Sutcliffe, 2011).

Reluctance to simplify, the third of the three attributes of anticipation, encourages diversity in information. HROs rely on diverse information that encompasses the expertise of a variety of individuals and sources, and provides a better understanding of work and options available in a given risky situation. For HROs, it is essential to embrace diversity, as diversity provides information, and greater skill in the detection of potential failures. Simplification often limits details through categorization approaches that condense information and results in a loss of details. HROs ensure important information is preserved and details are appropriately investigated when uncertainty arises (Weick & Sutcliffe, 2011).

Containment was described by Weick and Sutcliffe (2008) as preventing catastrophe after an unexpected or unwanted event, such as a failure within a system, occurs. Commitment to resilience, the first of the two attributes of containment, describes how HROs detect, contain and bounce back from events that do occur. All systems have a probability of failure; however, if failures are detected and mitigated early, the system can continue to function without compromising a good outcome. HROs acknowledge that failures can and will continue to occur within systems, so they focus on what can be done to absorb the failure and continue to operate safely (Weick & Sutcliffe, 2011).

Deference to expertise, the second attribute of containment, means that within HROs decisions can be made by the person or persons who have the most knowledge and expertise about the issue at hand. Decisions are deferred to the most knowledgeable person, regardless of rank or place in the organizational hierarchy. Multiple individuals may have important information to contribute and HROs consider all information to make the best decision for the system. At the same time, individuals within HROs recognize the limits of their knowledge and ask for help when needed (Weick & Sutcliffe, 2011).

High Reliability Organizational Theory

The concept of high reliability as applied in organizations is emerging as its own theoretical perspective and is commonly referred to as high reliability organizational theory (Gaba, 2000; Kaissi, 2006; Rijpma, 1997; Youngberg, 2004). The theory postulates that organizations can handle complex and hazardous activities at acceptable levels of performance with the proper management of people, technology, and processes (Kaissi, 2006; Reason, 2000; Youngberg, 2004). This is accomplished by being able to effectively anticipate, prevent or contain, and respond to failures.

High reliability has roots in contingency theory which indicates that the structure and processes within an organization should be contingent on the work being performed and the environment in which it is being performed (Cole & Scott, 2000; Kaissi, 2006). Organizations within certain industries such as healthcare must deal with a large amount of uncertainty on a daily basis. Consequently, they must be able to manage this uncertainty in order to achieve desired outcomes. Many contingencies, or uncertainties, within the environment impact organizational structures and processes. The general premise of contingency theory is that organizations must adapt their organizational structures and processes based on the contingencies they are facing (Gatmaitan, 2015; Kaissi, 2006).

Contingency theory emphasizes that information about the process is needed in order to deal with the uncertainties and unexpected events that unfold (Cole & Scott, 2000; Kaissi, 2006). This holds true when considering the quality and safety of care provided to hospitalized patients as well. Healthcare is a dynamic environment at the individual, organizational, and industry levels. Contingency theory is connected to patient safety by linking system failures to uncertainties.

Kaissi (2006) indicated that errors are the result of system failures that occur when an organization does not respond to contingencies or uncertainties. Contingency theory helps explain how healthcare managers effectively manage increasingly complex work and large amounts of information (Cole & Scott, 2000; Kaissi, 2006).

Within highly reliable organizations managers at all levels must be trained to manage the unexpected (Roberts, 1990; Roberts et al., 2001; Weick & Sutcliffe, 2011). Fluctuations or variation in performance must be monitored and controlled, and the organization must be flexible while holding individuals accountable to fix problems (Kaissi, 2006; Roberts, 1990; Schulman, 2004; Sutcliffe, 2006; Weick & Sutcliffe, 2011). Problems can be solved more quickly and effectively in uncertain or unexpected situations when managers are flexible and can (and are allowed to) adjust processes based on their analysis of the situation and lessons learned from past experiences (Kaissi, 2006; Sutcliffe, Sitkin, & Browning, 2000; Weick & Sutcliffe, 2011).

High reliability organizational theory is often compared and contrasted with Normal Accident Theory, a well-established theory in the safety literature (Kaissi, 2006; Rijpma, 1997, 2003; Tamuz & Harrison, 2006). Normal accident theory states that accidents and error are inevitable in systems that are complex, tightly coupled, technological systems (Kaissi, 2006; Rijpma, 1997). The more complex and tightly coupled the system, the higher the probability that an accident will occur.

Perrow (1981) depicted this inevitability with the accident of Three Mile Island stating that it was unpreventable and normal, as it is “not feasible to train, design, or build in such a way as to anticipate all the eventualities in complex systems where the parts are tightly coupled” (p. 19). Perrow further argued that accidents are inevitable as systems cannot respond and/or shut down to every alarm or signal of a potential failure and still be productive.

An example of a complex and tightly coupled system within healthcare is the use of a computerized provider order entry system. Utilization of a computerized provider order entry system allows for changes to a patient's plan of care to occur rapidly without personal interaction between healthcare providers. This reduces the number of opportunities for any error or system failures to be identified and corrected prior to reaching the patient.

While Normal Accident Theory and high reliability organizational theory overlap in many ways, the theories diverge substantially on the tenet of preventability of events. Researchers exploring high reliability found that highly reliable organizations can prevent accidents and/or mitigate their consequences even when they occur within complex and tightly coupled systems by applying the principles of high reliability (Kaissi, 2006; Reason, 2000; Weick, 1987). HROs require that humans who operate complex systems become more effective at risk identification and mitigation by making risk more visible. HROs provide individuals with the authority necessary to adapt processes to prevent or minimize the harm.

High reliability organizational theory, like Normal Accident Theory, indicates that errors will happen; however, it differs in the inevitability of events. If organizations are structured to recognize errors, contain them before they become larger catastrophic events, and recover effectively from the events, high reliability organizational theory suggests catastrophic outcomes can be avoided (Kaissi, 2012; Reason, 1990, 2000; Weick & Sutcliffe, 2011).

Some industries that have implemented strategies for becoming highly reliable, such as naval and commercial aviation, have achieved and sustained low safety event rates over long periods of time (Weick & Sutcliffe, 2011). Observation of these outcomes triggered the study of how these high-risk organizations achieved and maintained these outcomes. Studies of HROs in non-healthcare industries are based on qualitative recall data of events and factors leading to safety event, as well as preventative strategies, rather than quantitative measurement of principles of high reliability (Roberts, 1989, 1990; Roberts et al., 2001). Studies of HROs to date have focused on identifying the characteristics of such organizations (Roberts, 1990; Schulman, 2004; Weick & Sutcliffe, 2011).

High reliability has thus far been assessed in healthcare by qualitatively describing how healthcare exhibits characteristics inconsistent with HROs (Chassin & Loeb, 2013; Gaba, 2000). Gaba (2000) indicated that healthcare verbalizes safety as a priority; however, actions within healthcare do not support safety as the highest goal. Productivity and cost reduction are competing priorities for safety. While improvements in patient safety should reduce costs globally through reducing care needs after an error, actions implemented to explicitly lower costs, or provide more efficient care may actually increase errors by increasing complexity (Chassin & Loeb, 2013; Gaba, 2000).

This contention is supported by the lack of resolve in the differences between industries such as structure, training, and organizational learning, between healthcare and other high-risk industries. In order for improvements from safety initiatives to be sustained, the structure of healthcare organizations must be changed (Institute of Medicine Committee on Quality of Health Care in America, 2001). Organizational actions and behaviors must demonstrate that safety is pivotal to productivity and cost reduction, and a culture of high reliability and safety must be attained (Chassin & Loeb, 2013; Gaba, 2000).

Culture and safety attitudes have been identified as surrogate markers for measuring high reliability (Gaba, Singer, Sinaiko, Bowen, & Ciavarelli, 2003). An organization's safety culture can be defined as "the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management" (Agency for Healthcare Research and Quality, 2014, p. 1). In the most basic sense, the safety culture of an organization can be summarized as the way employees act when no one is looking (*High Reliability Error Prevention Training*, 2013).

Safety culture has been hypothesized to be an important predictor of safety outcomes and successful implementation of safety strategies (Cameron & Barnett, 2000; Singer et al., 2003). In an effort to compare safety culture in a high reliability industry to the safety culture in healthcare, one researcher evaluated differences in safety climate survey responses from naval aviators and healthcare workers (Gaba et al., 2003). The study found a statistically significant difference in responses considered problematic between naval aviators and all healthcare workers and between naval aviators and healthcare workers in high hazard areas such as the emergency department and operating room (Gaba et al., 2003). These findings suggest that there is an opportunity to improve safety culture scores, which represent employee behaviors in healthcare with the implementation of high reliability principles.

One of the few studies assessing the status of healthcare across the high reliability continuum used culture of safety as a surrogate marker of high reliability status (Singer et al., 2003). To date, culture of safety survey results are the best way to measure where organizations are along the HRO continuum; however, this approach to measuring HRO "status" looks at safety culture alone, which is only one component of achieving high reliability.

High Reliability and Patient Safety Outcomes

Application of high reliability principles can improve targeted patient safety issues by informing deliberate process design. The Institute for Healthcare Improvement (IHI) indicates that strategically designing for high reliability is a key factor of success (Resar, Griffin, Haraden, & Nolan, 2004). Hospitals were able to significantly decrease poor outcomes in care for heart failure patients, patients admitted with pneumonia, surgical site infections, and return to smoking after acute myocardial infarction through such an approach (Resar et al., 2004).

Utilizing the high reliability principles of sensitivity to operations and reluctance to simplify, the IHI continued recommendations for improvement by applying care bundles to decrease the occurrence of specific HACs. A care bundle is defined as a collection of best practices that, when reliably followed, can prevent an adverse event (Resar, Griffin, Haraden, & Nolan, 2012). Critical thinking and teamwork are encouraged through the use of the care bundles because reliably adhering to the care bundle requires collaboration and coordination of the entire team (Resar et al., 2012).

The care bundle is descriptive yet allows adaptation to the patient's clinical situation within defined parameters. For example, a care bundle to prevent CLABSI includes a set of best practices such as of daily discussion of necessity, functionality, and utilization of the central line by the bedside and medical care team and standardization of central line access procedures (Children's Hospitals' Solutions for Patient Safety, n.d.-b). Bundles of best practices to prevent various HACs have been developed over time, and several studies have demonstrated a reduction in the rates of harms such as CLABSI and VAP when organizations reliably comply with these bundles (DePalo et al., 2010; Jacobsen, 2008; Lin et al., 2012; Miller et al., 2010; Pronovost et al., 2006; Pronovost et al., 2010; Pronovost, Watson, Goeschel, Hyzy, & Berenholtz, 2015; Resar et al., 2005). These studies are early “proofs of concept” that the application of certain HRO principles in healthcare can indeed result in decreases in errors and patient harms.

In order to measure the overall impact of these efforts, some organizations have adopted a composite measure of HACs, referred to as the Serious Harm Event (SHE) Index or the Preventable Harm Index (Brilli et al., 2013; Lyren et al., 2013). This composite measure aggregates data from multiple patient harms providing a more comprehensive measurement of patient safety (Brilli et al., 2013; Children's Hospitals' Solutions for Patient Safety, 2015; Lyren et al., 2013).

In addition to decreasing the occurrence of specific HACs, application of high reliability principles can be employed in healthcare to reduce other types of safety events. While there is currently no standard method used by all healthcare organizations for measuring preventable harms, many organizations have adopted the Serious Safety Event Classification system developed by Healthcare Performance Improvement, LLC. to standardize the approach to measuring harm (Throop & Stockmeier, 2009).

This classification of harm takes into account deviations from the standard of care as well as failure to recognize, mitigate, or treat known complications of care when classifying serious safety events (SSE). The adoption of this classification allows for the calculation of a standardized composite measurement of SSEs using the Serious Safety Event Rate (SSER), which is a volume adjusted measure (Throop & Stockmeier, 2009).

Interventions consistent with the principles of high reliability have been developed and implemented in healthcare to reduce patient harms. These interventions include leadership methods such as safety governance, leadership walk rounds and daily organizational safety huddles, error prevention behavioral training, causes analysis programs, and lessons learned programs. Table 2 describes the link between these interventions and the five principles of high reliability. Organizations that have adopted and implemented high reliability interventions have seen improvement in patient safety outcomes; some of which are summarized in Table 3.

TABLE 2

LINK BETWEEN INTERVENTIONS AND HIGH RELIABILITY PRINCIPLES

Principle of High Reliability	High Reliability Intervention
Preoccupation with Failure	Safety Governance Leadership Walk Rounds Organizational Safety Huddles Error Prevention Behavioral Training Cause Analysis Lessons Learned
Sensitivity to Operations	Safety Governance Leadership Walk Rounds Organizational Safety Huddles Error Prevention Behavioral Training Cause Analysis Lessons Learned
Reluctance to Simplify	Error Prevention Behavioral Training Cause Analysis
Deference to Expertise	Safety Governance Leadership Walk Rounds Organizational Safety Huddles Lessons Learned
Commitment to Resilience	Safety Governance Leadership Walk Rounds Organizational Safety Huddles Cause Analysis Lessons Learned

TABLE 3

NOTABLE ACCOMPLISHMENTS IN SAFETY IMPROVEMENT

Organization	Initiatives Implemented	Improvement Achieved	Time Frame of Study	Author Citation
Sentara Healthcare	Safety as Core Value, Behavior-Based Expectations, Root Cause Analysis Program, Focus and Simplify Work Processes and Procedure Documentation	40% reduction in Serious Safety Event Rate	2 years	(Yates et al., 2005)
Children's National Medical Center	Safety Transformation Initiative: Safety Governance, Employee Accountability, Error Prevention Strategies, Reporting and Cause Analysis, Situational Awareness and Engagement	70% reduction in Serious Safety Event Rate, Estimated savings of $35 million	3 years	(Hilliard et al., 2012)
Nationwide Children's Hospital	Error Prevention Training, Leadership Methods Training, QI Program Enhancement Multidisciplinary Microsystem-based teams	83% reduction in preventable harm, significant increase in safety culture scores	2 years	(Brilli et al., 2013)
Helen DeVos Children's Hospital	Safety Based Training, Root Cause Analysis, Failure Mode Classification of Events and Safety Behavior, Safety Governance, Transparency	68% reduction in Serious Safety Events	2 years	(Peterson, Teman, & Connors, 2012)

Organization	Initiatives Implemented	Improvement Achieved	Time Frame of Study	Author Citation
Cincinnati Children’s Hospital Medical Center	Safety Governance, Error Prevention, Root Cause Analysis and Common Cause Analysis, Lessons Learned Program	Significant decrease in Serious Safety Events, Significant increase in days between Serious Safety Events, Significant improvement in patient safety culture outcomes	2 years	(Muething et al., 2012)
Ohio Children’s Hospital Association	Safety Governance, Leadership Methods, Error Prevention Behavioral Training, Cause Analysis Programming, Lessons Learned Program	55% decrease in serious safety events (estimated 70 less), 40% reduction in Serious Harm Events, including HACs (estimated 18 less)	2 years	(Lyren et al., 2013)

Measuring High Reliability

Tools for measuring how highly reliable an organization is have been scarce and largely based on the perceptions of employees within the organization. Youngberg (2004) presented an instrument to measure characteristics of high reliability based on the domains of leadership, reporting culture, trust and transparency, safety as a top priority, flexibility in hierarchy, existence of standards and processes to support reliability, and training and development.

Weick and Sutcliffe (2011) included audits for assessing how the organization performs in relation to its described principles of high reliability in their book *Managing the Unexpected, Resilient Performance in an Age of Uncertainty (*2011). These tools are perception based, thus should be administered to multiple people within an organization in order to gain an adequate assessment of the organization as a whole. Only one audit tool developed by Weick and Sutcliffe (2011), the Safety Organizing Scale, has undergone validation testing (Vogus & Sutcliffe, 2007).

Chassin and Loeb (2013) recognized a need to be able to measure high reliability practice within healthcare using a framework that is not based on employee perception, but rather on concrete organizational structures and behaviors they believe are increasingly present as the organization becomes more highly reliable. To begin this process, Chassin and Loeb analyzed how highly reliable organizations function using Weick and Sutcliff's (2011) five principles of high reliability as a foundation. These findings were then compared to current characteristics and performance of various healthcare organizations, which reflected marked differences when compared to highly reliable organizations within each of the five principles of high reliability (Chassin & Loeb, 2013). The authors integrated these analyses into a framework incorporating the five principles of high reliability by assessing the domains of leadership, safety culture, and robust process improvement (Chassin & Loeb, 2011) as shown in Figure 2.

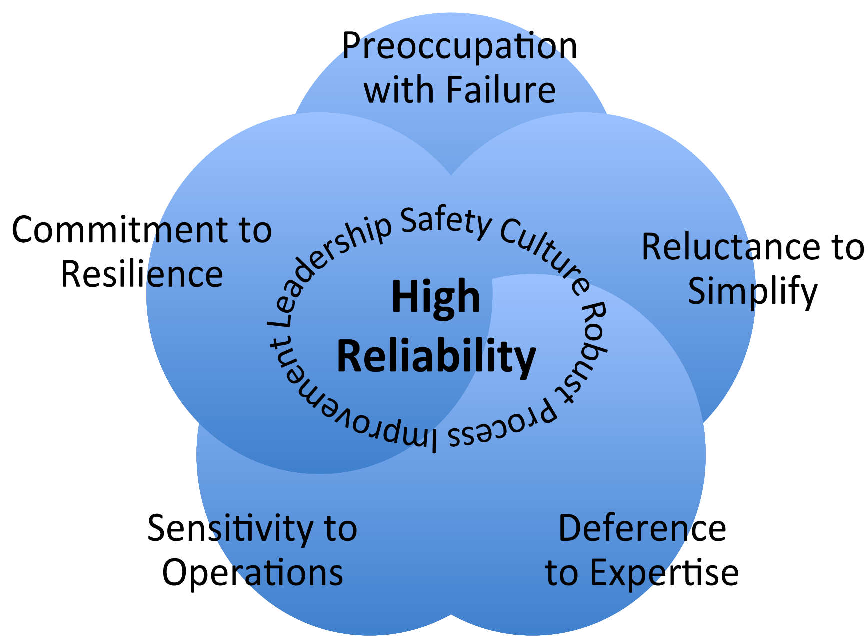

Figure 2. Model of High Reliability

The Chassin and Loeb (2013) framework provides an assessment tool which is clear and concise with objective behavioral questions that measure high reliability.

Chassin and Loeb (2013) pilot tested the framework with individual hospital leaders and then hospital leadership teams. Modifications were made based on feedback from the qualitative assessment of the framework as well as experiences leadership teams provided from assessing their own hospital (Chassin & Loeb, 2013).

Within the Chassin and Loeb (2013) framework, there are four stages of maturity for hospitals on the journey to high reliability. Within the first stage of the framework (the earliest stage of high reliability), the organization displays early characteristics of high reliability. In this beginning stage, the leadership focuses on regulatory compliance. Leadership does not acknowledge the importance of process improvement and does not include process improvement within the strategic plan for the organization.

Within safety culture, there is no program for assessing the safety culture, and investigations only occur on the most serious of events. Organizations in this stage have limited personnel trained in quality improvement, and there is not a defined and standard approach to quality improvement (Chassin & Loeb, 2013).

The second stage of the framework of the high reliability continuum describes organizations that are developing the characteristics of high reliability. In this stage, the leadership of the organization recognizes the need for quality improvement and delegates, rather than assumes, personal responsibility and advocacy for the development of a plan. Quality is only one of many priorities, it is not part of the organizational reward system, and few staff and physicians are engaged in the work. Within safety culture, investigations begin to demonstrate common causes of safety events and some functional areas of the organization begin to move away from a culture of blaming individuals when errors occur. The quality improvement program begins training staff on the robust quality improvement tools that the organization has adopted and pilots projects using these tools from the training (Chassin & Loeb, 2013).

In the third stage of the framework of the high reliability continuum, organizations demonstrate characteristics that are advancing towards high reliability. The leadership is involved in developing the quality agenda, which has been made one of the top priorities of the organization. Quality measures are included in the organization's reward systems and physicians often lead quality improvement efforts, as their leadership is vital for success. Safety culture is recognized as a high priority by all levels of the organization and safety concerns are more frequently reported. The quality improvement program has a wide reach through the adoption of robust process improvement tools with plans to train staff throughout the organization in these methods (Chassin & Loeb, 2013).

In the fourth and final stage of the framework, organizations demonstrate characteristics that are consistent with high reliability. The leadership is committed to patient safety and communicates patient safety as the highest institutional priority. Patient safety measures are directly tied to the organization's reward systems and physicians regularly lead quality activities. Safety culture is strong in this stage. Staff recognizes accountability for safety and frequently reports safety concerns for review and countermeasure implementation. The quality program is fully implemented throughout the organization and process redesign focuses on making it hard to do the wrong thing (Chassin & Loeb, 2013).

Chassin and Loeb's (2013) framework is the first to provide a rubric which attempts to operationalize the five principles of high reliability into concrete organizational behaviors in the areas of leadership, safety culture, and robust process improvement that is not based on the perception of employees responding to a survey. Their framework links the five principles of high reliability to the three domains delineated within the framework.

While the domains within this framework have not been quantitatively linked to the five principles of high reliability, Chassin and Loeb (2013) argued that the organizational behaviors within the three domains embody the characteristics within each of the five principles. Furthermore, the authors suggested that high reliability cannot be achieved without commitment of leadership, a widespread focus on safety, and the creation of a learning organization through robust process improvement. Despite the imperfections of the framework, the areas of leadership, safety culture, and robust process improvement are three domains that healthcare can leverage to continually progress towards high reliability.

CONCEPTUAL FRAMEWORK

Reductions in patient safety risk and improvements in safety outcomes have been accomplished by embedding the principles of high reliability into all levels of the organization by constantly focusing on patient safety. Implementation of strategies within the areas of leadership, safety culture, and robust process improvement facilitate daily communication for anticipating, correcting, mitigating, and learning from safety outcomes. These strategies operationalize the concepts within the five principles of high reliability.

Within the area of leadership, a commitment to safety can be demonstrated through interventions such as establishing safety governance and implementing leadership walk rounds (Hilliard et al., 2012; Lyren et al., 2013; Muething et al., 2012). Safety culture can be improved through deployment of error prevention behavioral techniques, transparency initiatives, and reliable implementation of care bundles (Brilli et al., 2013; Hilliard et al., 2012; Muething et al., 2012). Robust process improvement encompasses vigorous cause analysis and lessons learned programs and supports organizational quality improvement training programs (Brilli et al., 2013; Hilliard et al., 2012; Lyren et al., 2013; Muething et al., 2012). Figure 3 visually depicts how these interventions are related to the model of high reliability.

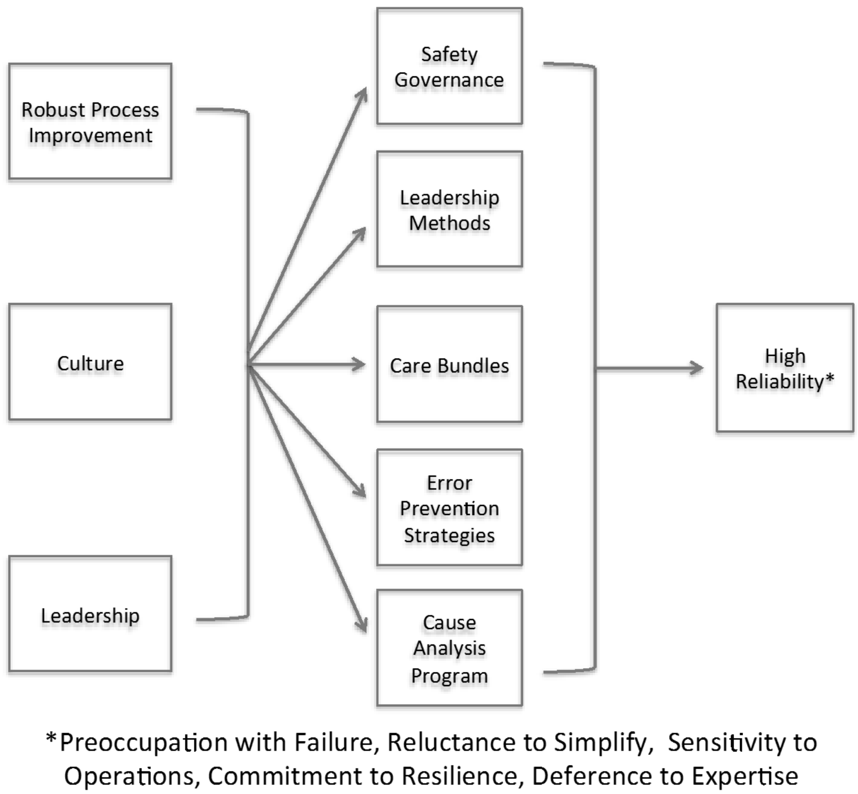

Figure 3. Relationship of safety improvement interventions and high reliability

High reliability is a dynamic state, as organizations try to remain continuously focused on safety as the highest priority, and implementation of strategies designed to facilitate progression towards high reliability take time. Figure 4 depicts the progression of organizations through the beginning, developing, advancing, and approaching stages of high reliability as they implement strategies to address leadership, safety culture, and robust process improvement.

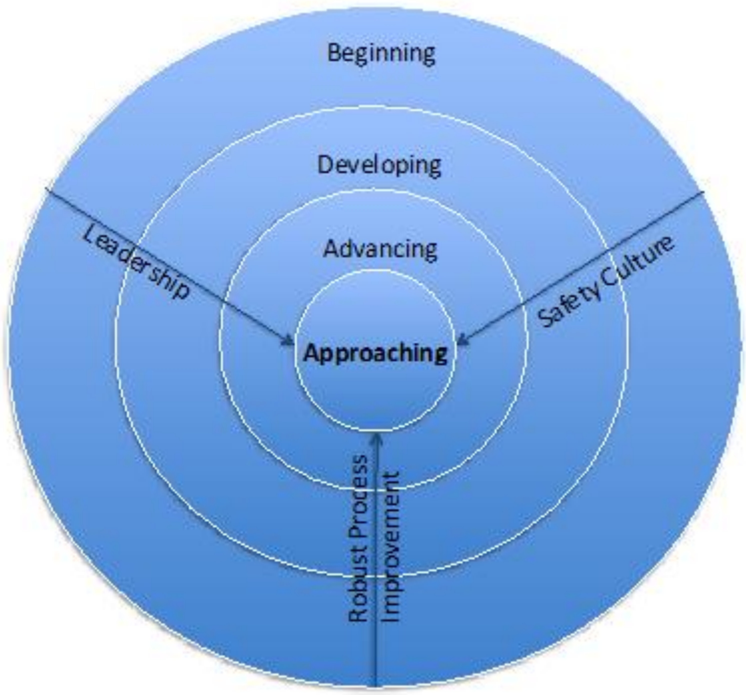

Figure 4. Components and stages of high reliability

This focus of this study was to determine if there is an association between high reliability practice as established by the Chassin and Loeb framework (2013) and patient safety outcomes. Specifically, this study tested the following hypotheses:

Hypothesis #1: Organizations exhibiting more advanced high reliability practice will have fewer hospital acquired conditions (as defined by the Serious Harm Event (SHE) Index) than organizations exhibiting less advanced high reliability practice.

Hypothesis #2: Organizations exhibiting more advanced high reliability practice will have fewer serious safety events (as defined by the Serious Safety Event Rate (SSER) than organizations exhibiting less advanced high reliability practice.

The gap in the current literature is the limited evidence explaining the relationship between high reliability and patient safety outcomes. Such evidence is needed to evaluate the effectiveness of translating high reliability principles into healthcare with a resulting improvement in patient safety outcomes. Given the lack of tools for assessing and measuring high reliability, the literature assessing the value of HRO principle integration into healthcare is limited to quality improvement studies utilizing time series data surrounding implementation of interventions consistent with high reliability organizational theory.

The Chassin and Loeb (2013) framework, however, attempts to operationalize the principles of high reliability in a way that can be measured. The tool may enable researchers to study the relationship between high reliability and patient safety outcomes. This study seeks to be the first study in healthcare to identify the association between HRO principle integration and patient safety outcomes. The results of this study should provide a significant contribution to the patient safety literature as the first effort to quantify the applicability of HRO principles to preventing patient harms.

CHAPTER 3:

METHODS

Study Design

In this study, a non-experimental research design was used to assess if high reliability practice is associated with patient safety outcomes, specifically preventable harms defined as HACs and SSEs.

Study Setting

The Children's Hospitals' Solutions for Patient Safety (CHSPS) network was originally formed as a Hospital Engagement Network (HEN) under contract with the Centers for Medicare and Medicaid Services (CMS) to reduce preventable harm. On January 1, 2015, the CHSPS was comprised of 95 United States-based pediatric hospitals. The stated mission of CHSPS is "working together to eliminate serious harm across all children's hospitals in the United States" (Children's Hospitals' Solutions for Patient Safety, n.d.-a). This mission translates into specific CHSPS goals, which are consistent with the CMS Partnership for Patients initiative to reduce preventable harm, including a targeted 40% reduction in a defined set of HACs. The CHSPS set an additional goal of a 25% reduction in SSEs.

The CHSPS network has adopted a two-prong approach for achieving these goals, and requires participating organizations to work on: (1) tactical quality improvement work by establishing and reliably performing care bundles to prevent HACs, and (2) improving safety culture through the application of high reliability principles and practices to prevent SSEs.

To improve safety culture, five cultural domains (safety governance, high reliability error prevention behaviors, high reliability leadership behaviors, cause analysis, and high performance microsystems) have been designated within the CHSPS network. These domains embody the principles of high reliability for implementation at the organizational level to improve patient safety outcomes. Organizations participating in CHSPS reported performance at different stages of application/implementation of these cultural interventions.

Study Sample

The population for this study was the 95 pediatric hospitals participating in the CHSPS network. The CHSPS accounts for more than 50% of all pediatric admissions to hospitals in the United States (S. Muething, Personal Communication, July 12, 2015). The organizations participating in the CHSPS were compared to hospitals that reported in the American Hospital Association Annual (AHA) Survey of Hospitals (2012) primarily restricting admissions to children. There were no statistically significant differences among the two groups in Registered Nurse (RN) hours per patient day, medical staff hours per patient day, employed physicians, or membership in a healthcare system.

Organizations participating in CHSPS had statistically significantly less Licensed Practical Nurse (LPN) hours per patient day. There were statistically significant differences among organizational ownership with the majority of organizations participating in CHSPS being not for profit, while organizations in the comparison group were distributed among government, not for profit, and investor owned. Bed size was also significantly different between the two groups. CHSPS organizations were varied in size while all the organizations in the comparison group reported less than 250 beds.

Of the 95 pediatric organizations participating in the CHSPS network, 49 (52%) responded to the high reliability survey. A total of 33 organizations were included in the analytical sample for the HAC portion of this study after exclusions were made as a result of missing data. A total of 12 organizations submitted data for inclusion in the SSER portion of this study.

Data

Secondary Data Sources

Two secondary data sources were utilized for this study. The CHSPS provided data used to calculate the dependent variable, the SHE Index. A requirement of participation in the CHSPS is monthly submission of data on each of the HACs. The CHSPS database holds data from participating hospitals beginning in 2011, the baseline 12 month period for the initial 33 participating hospitals. As hospitals joined the CHSPS, retrospective monthly data were submitted for a baseline period of 12 months prior to participation in CHSPS. The CHSPS provided monthly data from January 2011 through September 2015 for each participating hospital.

The CHSPS also provided the data for the dependent variable SSER. The CHSPS is contracted with a Patient Safety Organization to measure the overall SSER for CHSPS participating organizations that are members of the Patient Safety Organization. The Patient Safety Organization provides this aggregate data to the CHSPS. As a result of regulations governing the Patient Safety Organization, organizations responding to the survey were asked by the CHSPS to submit their organizational SSER as of August 2015 for use in this study.

An additional source of data was the AHA Annual Survey of Hospitals, which has been collected since 1946 (American Hospital Association, 2012). For this study, the 2012 AHA Annual Survey of Hospital database provided cross sectional data for organizational descriptive and staffing variables.

Survey Measurement Data

The Chassin and Loeb (2013) framework was transformed into a cross-sectional survey delivered in an online format utilizing Survey Monkey**® (**Appendix A). The survey tool was pilot tested with one participating organization, which provided feedback on instructions to be provided to those individuals gathering information for the organization’s response. Instructions were edited based on feedback from the pilot study to specify the job titles of individuals who should collaborate to generate an organizational response to the survey.

The survey was then sent via electronic mail to the organizational project managers and quality leaders for each of the 95 participating organizations. To maximize response rate, the survey was sent by the CHSPS clinical steering committee with a request for the project manager and/or quality leader to coordinate the response and submission of the survey. The communication provided instructions for completing the survey, clarified that all results would be blinded to the researcher, and reinforced that all results would be used by the CHSPS clinical steering committee to develop education to expedite improved performance across the entire collaborative.

The survey was accessed online through the hyperlink provided in the electronic mail. The survey remained open for response for 12 weeks. At the conclusion of weeks two and five, a follow up notification was sent by electronic mail to those organizations that had not submitted a response. At the end of week eight, the project managers of organizations that had not responded received a personal electronic mail from a member of the CHSPS Research Steering Committee to encourage participation. During weeks nine through 12, the project managers and quality leaders of organizations that had not responded received additional personal communications from members of the CHSPS Research Steering Committee to encourage participation. One response from each organization was submitted to the CHSPS via the online survey tool through Survey Monkey®.

The CHSPS staff linked the survey data to respective organizational outcomes, as well as hospital characteristic data from the 2012 AHA Annual Survey of Hospitals. This file was then de-identified and delivered to the researcher for analysis. The hospital identification codes were securely maintained by the CHSPS and were not shared with the researcher at any time.

The Institution Review Board (IRB) governing the CHSPS organization, Cincinnati Children's Medical Center (Appendix B), as well the IRB governing the researcher, the University of Alabama at Birmingham IRB (Appendix C), approved this study. All organizations within the CHSPS network signed a data disclosure agreement permitting the sharing of data for learning and research purposes as approved by the CHSPS Research Steering committee, which approved this study.

Variables

The purpose of this study was to assess the relationship between high reliability organizational characteristics and preventable harm. The dependent variables were preventable harm, defined as the Serious Harm Event Index (SHE), a composite measure of HACs, and Serious Safety Event Rate (SSER), a composite measure of serious safety events (SSE). The independent variables in this study were measures of high reliability, including the composite score of high reliability, and the scores for the leadership, safety culture, and robust process improvement domains. Various organizational descriptive variables were used to control for differences between organizations, thus allowing us to determine any association between the measure of high reliability and preventable harms.

Dependent Variables

The dependent variables in this study were two measures of preventable harms: the SHE index and the SSER. These variables were each composed of preventable individual events that result in significant harm or death to patients.

Serious harm event index (SHE Index)

The SHE index is a composite measure of preventable harm. Similar inpatient composite measures for preventable harms have been used in prior studies (Brilli et al., 2013; Lyren et al., 2013; Muething et al., 2012). For the purposes of this study, we defined the SHE index as the sum of events occurring between September 2014 and August 2015 for each of the HACs as specified in following calculation:

> SHE = Absolute numbers of CLABSI + CAUTI + OB AE + VAP + SSI for specified surgical procedures + ADE severity F-I + Falls with Moderate injury or higher + Pressure Ulcers stage III, IV, and Unstageable.
>
> *CLABSI: Catheter Associated Blood Stream Infection, CAUTI: Catheter Associated Urinary Tract Infection, OB AE: Obstetrical Adverse Event, VAP: Ventilator Associated Pneumonia, SSI: Surgical Site Infection, ADE: Adverse Drug Event

The SHE Index was measured as a whole number variable (Children's Hospitals' Solutions for Patient Safety, 2015). Data for the SHE Index did not meet the assumptions for linear regression as it was non-normally distributed. In order to perform regression analysis, the variable was transformed into a categorical variable for purposes of this study by dividing the outcome into quartiles.

Hospital acquired conditions (HACs)

The eight HACs are forms of preventable harms and have rigorous clinical and operational definitions established by HAC-specific expert panels through the CHSPS. The expert panels utilized current published definitions to establish the operational definitions, shown in Table 4.

TABLE 4

OPERATIONAL DEFINITIONS OF HOSPITAL ACQUIRED CONDITIONS

HAC	Defining Agency	Patient Population	How Measured
Central Line Associated Bloodstream Infection (CLABSI)	National Healthcare Safety Network (NHSN)	Patients of inpatient or observation status with a central line.	Absolute number of CLABSI
Catheter Associated Urinary Tract Infection (CAUTI)	NHSN	Patients of inpatient or observation status with an indwelling urinary catheter, excluding patient in the Neonatal Intensive Care Unit	Absolute number of CAUTI
Obstetrical Adverse Event (OB AE)	CHSPS Defined	Expectant mothers admitted for delivery of the infant	Absolute number of OB AE
Falls	National Database of Nursing Quality Indicators (NDNQI)	All patients of inpatient or observation status	Absolute number of falls with moderate injury or above
Ventilator Associated Pneumonia (VAP)	NHSN	All patients of inpatient or observation status who experienced mechanical ventilation	Absolute number of VAP
Adverse Drug Event (ADE)	National Coordinating Council for Medication Error Reporting and Prevention's Index for Categorizing Medication Errors (NCC-MERP)	All patients of inpatient or observation status	Absolute number of ADE

HAC	Defining Agency	Patient Population	How Measured
Surgical Site Infection (SSI)	NHSN	Patients who underwent a Spinal Fusion, Ventricular Shunt Placement or Revision, or Cardiothoracic Surgery	Absolute number of SSI in Patients who underwent a Spinal Fusion, Absolute number of SSI in Patients who underwent a Ventricular Shunt Placement or Revision, Absolute number of SSI in Patients who underwent a Cardiothoracic Surgery
Pressure Ulcer (PU)	NDNQI	All patients of inpatient or observation status	Absolute number of Serious PU (Stage III, IV, Unstageable, Deep Tissue Injury)

(Children's Hospitals' Solutions for Patient Safety, 2015)

Serious Safety Event Rate (SSER)

The CHSPS adopted Healthcare Performance Improvement, Inc.'s definition of a SSE as an event of harm resulting from a deviation from generally accepted performance standard that results in moderate to severe harm or death (Throop & Stockmeier, 2009). For example, a patient who undergoes an amputation of the incorrect leg would meet the definition of a SSE because the procedure was performed on the wrong site and resulted in significant permanent harm. All patients of inpatient observation, outpatient, surgical, and short stay status were included in the patient population for this measure (Children's Hospitals' Solutions for Patient Safety, 2015).

Hospitals reported the absolute number of SSEs per month stratified by SSE severity, as well as the number of adjusted patient days (Children's Hospitals' Solutions for Patient Safety, 2015). The monthly SSER, a volume adjusted measure of serious safety events (Throop & Stockmeier, 2009), is the sum of SSEs divided by total adjusted patients days multiplied by 10,000. The data for the SSER did not meet the assumptions for linear regression as it was non-normally distributed. In order to perform a regression analysis, the variable was transformed into a categorical variable for purposes of this study by dividing the outcome into quartiles.

Independent Variable

The Chassin and Loeb (2013) framework was utilized to quantify high reliability characteristics. The survey (2013) utilized 4-point numerical measurement scale by assigning numerical value to each stage on the continuum of beginning (1), developing

(2), advancing (3), and approaching (4). The stages represented operationally defined levels of maturity of high reliability in incremental stages along a continuum.

Performance was assessed through administration of the high reliability survey for each of the requirements for a high reliability organization: leadership, safety culture, and robust process improvement. High reliability was measured with an "overall" composite score of high reliability practice and then stratified by the high reliability domains of leadership, safety culture, and robust process improvement. An organization advances through the stages of high reliability as the overall composite score of high reliability increases. The score for each domain was calculated by adding the numerical value assigned for each component of the domain.

The overall composite score of high reliability was the independent variable, which was calculated as the sum of the individual question scores in each domain of high reliability. Each of the three domains thus had a single score. The range for the leadership component was 6-24, safety culture 5-20, robust process improvement 3-12, and overall high reliability 14-56. The high reliability survey tool is included in Appendix A.

Internal consistency of the high reliability survey and each domain of high reliability were evaluated using Cronbach's alpha. The resulting score for the survey (0.87) as well as the resulting score the safety culture domain (0.78), and robust process improvement (0.81) had adequate internal consistency reliability. The resulting score for the leadership domain approached adequate internal consistency (0.70) with a Cronbach's alpha of 0.66.

Control Variables

Additional questions were asked to gather descriptive information regarding individuals who participated in completing the survey and any major organizational changes within the last two years. The question regarding major organizational changes was asked specifically because the 2012 AHA Annual Survey of Hospitals data was the latest published data at the time of this study creating a two-year lag. Data for these questions were collected in categorical fashion and defined as having occurred during 2013 or 2014.

The 2012 AHA Annual Survey of Hospitals data were used to describe the hospitals participating in the CHSPS. These variables were also utilized as control variables within the analysis to hold characteristics constant in order to more accurately assess any relationship between the independent and dependent variables. Hospital bed size represents organizational descriptive characteristics of the hospital. Nursing hours per patient day, both RN and LPN, medical staff hours per patient day and employment of physicians represent levels of clinical staffing. All study variables are defined in Table 5.

Table 5

2012 American Hospital Association Annual Survey of Hospitals variables

Name	Data Type	Description
Hospital Bed Size	Continuous	Total Facility Beds Set Up and Staffed
Registered Nursing Hours Per Patient Day	Continuous	RN Full Time Equivalent * 2080 / Total Adjusted Patient Days
LPN or Vocational Nursing Hours Per Patient Day	Continuous	LPN Full Time Equivalent * 2080 / Total Adjusted Patient Days
Medical Staff Hours	Continuous	FTE Physicians and Dentists *

Per Patient Day		2080 / Total Adjusted Patient Days
Employed Physicians	Dichotomous	Yes No

Analysis

Nonresponse bias was tested by using independent samples t-test and Chi-square analyses to test for any difference in organizational descriptive and clinical staffing variables between survey responders and non-responders. Data were then analyzed using ordinal logistic regression techniques to determine if there was an association between high reliability practice and frequency of preventable harms as defined by the SHE Index and the SSER. Ordinal logistic regression was the technique selected as there was a single dependent interval variable with a potential relationship to one or more continuous and dichotomous independent variables (Hair, Black, Babin, Anderson, & Tatham, 2006).

High reliability was measured with an “overall” composite score of high reliability practice and then stratified by the high reliability domains of leadership, safety culture, and robust process improvement to determine if there was a differential relationship between specific high reliability component domains and SHE Index and SSER (Figure 5).

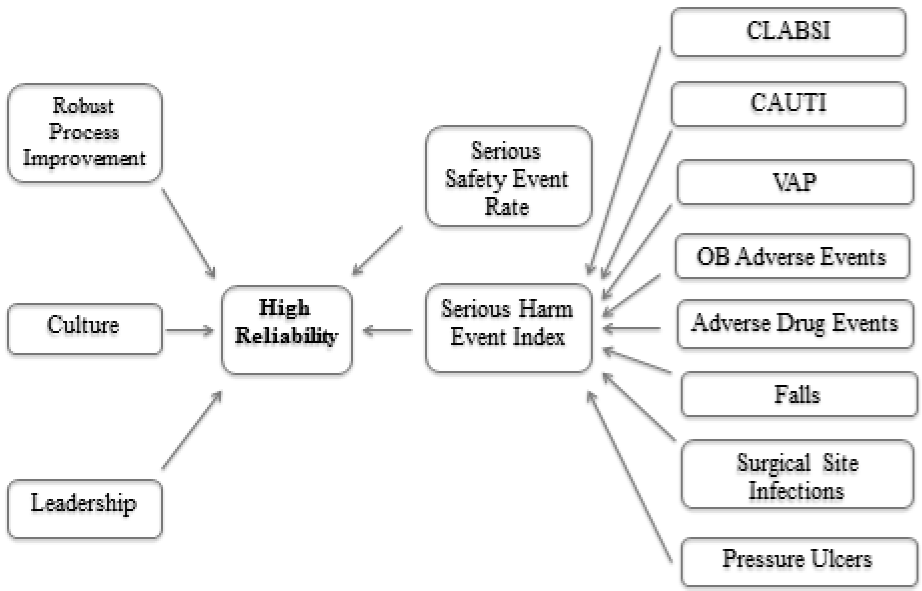

Figure 5. Relationship Between Independent and Dependent Variables

SHE Index

All data were reviewed for missing and outlier data. Descriptive statistics including total sample (n), minimum, maximum, mean, and standard deviation were reviewed for each continuous variable. For dichotomous and ordinal variables, descriptive statistics including total sample (n) and frequency were reviewed. The dependent variable SHE Index was transformed into a categorical variable by dividing the outcome into quartiles.

The first ordinal logistic regression model tested the association between the dependent variable, SHE Index, and the independent variable overall high reliability practice. Ordinal logistic regressions were then run to test the association between each component domain of high reliability (leadership, safety culture, and robust process improvement) and SHE Index.

As a second step, ordinal logistic regression models were run which were inclusive of organizational descriptive and clinical staffing control variables. These models tested the association between the dependent variable SHE Index and the independent variable overall high reliability practice while controlling for the various organizational descriptive and clinical staffing variables. Ordinal logistic regressions were then run to test the association between each component domain of high reliability (leadership, safety culture, and robust process improvement) and SHE Index while controlling for the various organizational descriptive and clinical staffing variables.

Within the 2012 AHA Annual Survey of Hospitals dataset, not all of the children's hospitals participating in the CHSPS collaborative had data reported that were specific to the children's hospital. In other words, some children's hospitals that are part of a larger system reported their data as part of the larger system. As a result, additional ordinal logistic regression models were run to test the association between the dependent variable SHE Index and the independent variable overall high reliability practice in only the 25 children's hospitals that reported children's hospital specific data. Ordinal logistic regressions were then run to test the association between each component domain of high reliability (leadership, safety culture, and robust process improvement) and SHE Index.

Next, ordinal logistic regression models were run to further test the association between the dependent variable SHE Index and the independent variable overall high reliability practice which controlling for the organizational descriptive and clinical staffing variables in the 25 children's hospitals that reported children's hospital-specific data. Ordinal logistic regressions were then run to test the association between each component domain of high reliability (leadership, safety culture, and robust process improvement) and SHE Index while controlling for the various organizational descriptive and clinical staffing variables.

SSER

Nonresponse bias was tested by using independent samples t-test to test for any difference in survey response between those organizations that submitted SSER data and those that did not. All responses were reviewed for missing and outlier data. Descriptive statistics including total sample (n), minimum, maximum, mean, and standard deviation were reviewed for each continuous variable. For the dichotomous and ordinal variables, descriptive statistics including total sample (n) and frequency were reviewed. The dependent variable SSER was transformed into a categorical variable by dividing the outcome into quartiles.

The first ordinal logistic regression model tested the association between the dependent variable, SSER, and the independent variable, overall high reliability practice. Ordinal logistic regressions were then run to test the association between each component domain of high reliability (leadership, safety culture, and robust process improvement) and SSER.

As a second step, ordinal logistic regression models were run which were inclusive of the organizational descriptive variable bed size. These models tested the association between the dependent variable, SSER, and the independent variable, overall high reliability practice, while controlling for the organizational descriptive variable bed size. Ordinal logistic regressions were then run to test the association between each component domain of high reliability (leadership, safety culture, and robust process improvement) and SSER.

Within these models, the organizational descriptive variable “free-standing” was removed due to low variability. The clinical staffing variables RN hours per patient day, LPN hours per patient day, medical staff hours per patient day, and employed physicians, were not included in these models due to concerns regarding multicollinearity given a relative high correlation among the clinical staffing variables and SSER. This is particularly an issue given the small sample size (n=12) in the analysis.

CHAPTER 4:

RESULTS

A total of 49 organizations responded to the survey for a 52% response rate. There were no significant differences identified in organizational descriptive and clinical staffing variables between survey responders and non-responders. Characteristics of the survey respondents are summarized in Table 6. The majority of organizations responding to the survey were free-standing children's hospitals (69.7%). The primary respondents to the survey were largely quality/safety/risk leaders within the organization (60.6%) or Chief Quality/Patient Safety Officers (33.3%). The majority of the primary respondents reported the length of time worked within the position was between one and five years (48.5%) while the length of time worked within the organization for the primary respondents was fairly evenly distributed.

The reported discipline of the primary respondent was largely physicians (33.3%) and RNs (27.3%). To complete the survey, participating organizations reported consulting primarily with risk and quality leaders (48.5%). No organizations reported consulting with the Governing Board to complete the survey. Of note, the majority of sites reported substantial organizational changes over the prior two years.

TABLE 6

CHARACTERISTICS OF SURVEY RESPONSDENTS (NON-EXCLUDED HOSPITALS; N=49)

Characteristic	Result (n (%))
Response Rate, %	49 (52%)
Type of Hospital (n=33)	
Free-Standing	23 (69.7%)
Hospital within a Hospital	3 (9.1%)
Hospital within a System	6 (18.2%)
Other	1 (3.0%)
Position within Hospital (primary respondent)	
Chief Medical Officer	2 (6.1%)
Chief Quality/Patient Safety Officer	11 (33.3%)
Other Quality/Safety/Risk Leader	20 (60.6%)
Length Worked in Position (primary respondent)	
< 1 year	4 (12.1%)
1-5 years	16 (48.5%)
6-10 years	7 (21.2%)
11-15 years	2 (6.1%)
16-20 years	1 (3.0%)
21 years or more	1 (3.0%)
Length Worked in Hospital (primary respondent)	
< 1 year	2 (6.1%)
1-5 years	5 (15.2%)
6-10 years	9 (27.3%)
11-15 years	6 (18.2%)
16-20 years	5 (15.2%)
21 years or more	6 (18.2%)

Discipline (primary respondent)	
Administration / Management	5 (15.2%)
Nurse Practitioner / Physician Assistant	1 (3.0%)
Other (please specify)	7 (21.2%)
Physician	11 (33.3%)
Registered Nurse	9 (27.3%)
Consultations during Survey Completion	
Board	0 (0%)
Chief Executive Officer	5 (15.2%)
Chief Operating Officer	2 (6.1%)
Chief Medical Officer	9 (27.3%)
Chief Quality/Patient Safety Officer	12 (36.4%)
Other Quality/Safety/Risk Leader	16 (48.5%)
Other	4 (12.1%)
Major Organization Change	
Merger/Acquisition	7 (21.2%)
Service Line Addition	10 (30.3%)
Significant Leadership Transition	24 (72.7%)
New Building/Expansion	16 (48.5%)
Significant EMR Change	13 (39.4%)
Other	6 (18.2%)
None	5 (15.2%)

SHE Index

Of the 49 responding organizations, 33 were included in the SHE Index study analysis and 16 were excluded (13 with more than 10% missing HAC data, two without adequate organizational identification, and one without any survey answers provided). To address missing survey data in the included sites, mean substitution was utilized. Mean substitution was also utilized to address any missing HAC data for included sites, and the SHE Index was subsequently calculated.

All variables were evaluated to identify potential outlier data, or data that exceeded 2.5 standard deviations, given the small sample size of the study (Hair et al., 2006). Three outliers were identified in the clinical staffing variable medical staff hours per patient day. All outlier values remained in the analysis, as there was no way to determine if the data were truly not representative of the population (Hair et al., 2006).

The SHE Index (harms per month) was initially measured as a continuous variable with a mean of 68.2, a standard deviation of 41.8, a minimum of nine, and a maximum of 162. The data for the SHE Index did not meet the assumptions for linear regression as it was non-normally distributed. In order to perform regression analysis, this variable was transformed into a categorical variable by dividing the outcome into quartiles. The SHE Index 25^{th} percentile was 38.8, the 50^{th} percentile was 58.1, and the 75^{th} percentile was 86.0.

High reliability practice was determined for each component measured in the high reliability survey as well as an overall high reliability practice composite. The maximum score obtainable for the overall high reliability composite was 56. The maximum score obtainable for the leadership component was 24, for the safety culture component, 20; and for robust process improvement, 12.

Table 7 summarizes the results of high reliability practice for the sample. The average score for overall high reliability practice was 43.1. The average score for the leadership component of high reliability practice was 19.0, the safety culture component of high reliability practice was 15.2, and the robust process improvement component of high reliability practice was 8.9.

TABLE 7

HIGH RELIABILITY PRACTICE: SERIOUS HARM INDEX

	N	Mean	SD	Minimum	Maximum
Overall Composite (of 56)	33	43.14	5.94	28	53
Leadership Composite (of 24)	33	18.98	2.78	11	23
Safety Culture Composite (of 20)	33	15.23	2.37	10	20
Robust Process Improvement Composite (of 12)	33	8.94	1.71	5	12

Organizational descriptive and clinical staffing variable descriptive statistics for the sample are summarized in Table 8. The majority of the sample consisted of free-standing children's hospitals (69.7%). The percentage of organizations that employed any physicians was 51.5%. The average organizational bed size was 464.5 beds. Within the clinical staffing variables, the average RN hours per patient day were 14.0, the average LPN hours per patient day were 0.4, and the average medical staff hours per patient day were 1.7.

TABLE 8

ORGANIZATIONAL DESCRIPTIVE AND CLINICAL STAFFING DESCRIPTIVE STATISTICS (N=33)

	N	Frequency (n (%))	Mean	SD	Minimum	Maximum
Free-Standing	33					
Yes		23 (69.7%)				
No		10 (30.3%)				
Bed Size	33		464.52	282.97	73	1,371
RN Hours per Patient Day	33		14.00	4.46	5.54	23.76
LPN Hours per Patient Day	33		0.44	0.42	0	1.38
Medical Staff Hours per Patient Day	33		1.66	2.67	0	9.41
Employed Physicians	33					
No		17 (51.5%)				
Yes		16 (48.5%)				

Table 9 shows the results for ordinal logistic regression on the relationships between high reliability practice (composite and components) and the SHE Index with no control variables. The hypothesis that organizations exhibiting more advanced high reliability practice will have fewer hospital acquired conditions (as defined by the SHE Index) than organizations exhibiting less advanced high reliability practice was not supported. The composite scores of overall high reliability practice, leadership, safety culture, and robust process improvement demonstrated no significant association with the unadjusted SHE Index.

TABLE 9

ORDINAL LOGISTIC REGRESSION RESULTS ON THE RELATIONSHIP BETWEEN HIGH RELIABILITY PRACTICE (COMPOSITE AND COMPONENTS) AND SERIOUS HARM EVENT INDEX (N= 33)

	Odds Ratio	Significance (p-value)	Lower Confidence	Upper Confidence
High Reliability Composite	1.02	0.69	0.92	1.13
Leadership Composite	1.10	0.41	0.88	1.38
Safety Culture Composite	0.91	0.50	0.70	1.19
Robust Process Improvement Composite	1.23	0.27	0.85	1.78

Table 10 shows results for the ordinal logistic regression results on the relationships between high reliability practice (composite and components) and the SHE Index with control variables. When organizational descriptive and clinical staffing variables were controlled for, the composite scores for overall high reliability practice, leadership, safety culture, and robust process improvement continued to demonstrate no relationship with organization SHE.

The organizational descriptive variable bed size was significantly and positively related to the SHE Index in the safety culture component models. Within these models, the odds of being in a higher SHE Index quartile increased slightly for each additional bed. The organizational descriptive variable bed size was not related to the SHE Index in the overall, leadership, or robust process improvement models. The organizational clinical staffing variable of RN hours per patient day was significantly and positively related to the SHE Index in the overall, leadership, safety culture, and robust process improvement component models. Within these models, organizations with higher RN hours per patient day had greater odds of being in a higher SHE Index quartile.

TABLE 10

ORDINAL LOGISTIC REGRESSION RESULTS ON THE RELATIONSHIP BETWEEN HIGH RELIABILITY PRACTICE (COMPOSITE AND COMPONENTS) AND SERIOUS HARM EVENT INDEX WITH CONTROL VARIABLES (N= 33)

	Odds Ratio	Significance (p-value)	Lower Confidence	Upper Confidence
High Reliability Composite	0.99	0.99	0.89	1.12
Medical Staff Hours per Patient Day	0.88	0.36	0.66	1.16
Employed Physicians	3.85	0.20	0.89	1.67
LPN Hours per Patient Day	1.29	0.76	0.22	7.44
RN Hours per Patient Day	**1.38**	**0.002**	**1.12**	**1.70**
Bed Size	1.00	0.13	1.00	1.01
Leadership Composite	1.14	0.29	0.89	1.47
Medical Staff Hours per Patient Day	0.85	0.27	0.64	1.13
Employed Physicians	0.45	0.27	0.11	1.875
LPN Hours per Patient Day	1.72	0.55	0.29	10.27
RN Hours per Patient Day	**1.41**	**0.00**	**1.14**	**1.75**
Bed Size	1.02	0.1	1.00	1.01
Safety Culture Composite	0.79	0.13	0.58	1.08
Medical Staff Hours per Patient Day	0.86	0.25	0.64	1.14
Employed Physicians	0.27	0.09	0.61	1.23
LPN Hours per Patient Day	1.14	0.88	0.20	6.52
RN Hours per Patient Day	**1.41**	**0.00**	**1.15**	**1.74**
Bed Size	**1.00**	**0.05**	**1.00**	**1.01**
Robust Process Improvement Composite	1.01	0.74	0.70	1.66
Medical Staff Hours per Patient Day	0.88	0.37	0.66	1.17
Employed Physicians	0.41	0.24	0.94	1.80
LPN Hours per Patient Day	1.34	0.75	0.23	7.69
RN Hours per Patient Day	**1.38**	**0.02**	**1.12**	**1.69**
Bed Size	1.00	0.19	1.00	1.01

Results were similar across the 25 hospitals that reported pediatric-specific data to the AHA Annual Survey of Hospitals database. All variables were evaluated to identify potential outlier data, or data that exceeded 2.5 standard deviations given the small sample size of the study (Hair et al., 2006). Two outliers were identified in the variable medical staff hours per patient day. The outlier values remained in the analysis, as there was no way to determine if the data were truly not representative of the population (Hair et al., 2006).

The SHE Index for this subset of 25 hospitals, was initially measured as a continuous variable with a mean of 75.3, a standard deviation of 42.8, a minimum of nine, and a maximum of 162. Similar to the full sample of 33 organizations, the SHE Index did not meet the assumptions for linear regression as it was non-normally distributed. In order to perform regression analysis, the variable was transformed into a categorical variable by dividing the outcome into quartiles. The SHE Index 25th percentile was 48.0, the 50th percentile was 62.6, and the 75th percentile was 91.5.

A high reliability practice score was calculated for each component of high reliability as well as an overall high reliability composite for these 25 hospitals. The highest high reliability composite score identified in this study was 53. The maximum score of high reliability practice identified for the leadership component was 23; for the safety culture component, 20; and for robust process improvement, 12.

Table 11 summarizes the results of high reliability practice for the 25 sites that submitted pediatric-specific data to the AHA Annual Survey of Hospitals database. The average score for overall high reliability practice was 43.2. The average score for the leadership component of high reliability practice was 19, the safety culture component of high reliability practice was 15.1, and for the robust process improvement component of high reliability practice was 8.9.

TABLE 11

HIGH RELIABILITY PRACTICE PEDIATRIC SPECIFIC ANALYSIS (SITES SUBMITTING DATA TO THE AMERICAN HOSPITAL ASSOCIATION; N=25)

	N	Mean	SD	Minimum	Maximum
Overall Composite (of 56)	25	43.15	6.49	28	53
Leadership Composite (of 24)	25	19.17	2.94	11	23
Safety Culture Composite (of 20)	25	15.10	2.56	10	20
Robust Process Improvement Composite (of 12)	25	8.88	1.81	5	12

Organizational descriptive and clinical staffing descriptive statistics for the 25 sites submitting data to the AHA Annual Survey of Hospitals database are summarized in Table 12. The percentage of organizations that employed any physicians was 40%; the percentage of organizations that did not employ any physicians was 60%. The average organizational bed size was 335.5 beds. With the clinical staffing variables, the average RN hours per patient day were 15.1, the average LPN hours per patient day were 0.5, and the average medical staff hours per patient day was 1.5.

TABLE 12

ORGANIZATIONAL DESCRIPTIVE AND CLINICAL STAFFING DESCRIPTIVE STATISTICS FOR THE PEDIATRIC SPECIFIC ANALYSIS, N=25

	N	Frequency (n (%))	Mean	SD	Minimum	Maximum
Bed Size	25		335.48	122.06	73	595
RN Hours per Patient Day	25		15.12	4.300	6.34	23.76
LPN Hours per Patient Day	25		0.45	0.37	0	1.23
Medical Staff Hours per Patient Day	25		1.55	2.55	0	9.41
Employed Physicians	25					
No		15 (60%)				
Yes		10 (40%)				

Table 13 shows the unadjusted associations between high reliability practice (composite and components) and the SHE Index for organizations that reported pediatric-specific data to the AHA Annual Survey of Hospitals database. The hypothesis that organizations exhibiting more advanced high reliability practice will have fewer hospital acquired conditions (as defined by the SHE Index) than organizations exhibiting less advanced high reliability practice was not supported. The overall composite of high reliability practice, leadership, safety culture, and robust process improvement was not related to the SHE Index.

TABLE 13

ORDINAL LOGISTIC REGRESSION RESULTS ON THE RELATIONSHIP BETWEEN HIGH RELIABILITY PRACTICE (COMPOSITE AND COMPONENTS) AND SERIOUS HARM EVENT INDEX FOR HOSPITALS REPORTING PEDIATRIC SPECIFIC DATA TO THE AMERICAN HOSPITAL ASSOCIATION (N= 25)

	Odds Ratio	Significance (p-value)	Lower Confidence	Upper Confidence
High Reliability Composite	1.03	0.66	0.92	1.15
Leadership Composite	1.13	0.35	0.88	1.45
Safety Culture Composite	0.93	0.61	0.70	1.23
Robust Process Improvement Composite	1.22	0.34	0.81	1.83

Table 14 shows the results for ordinal logistic regression results on the relationships between high reliability practice (composite and components) and the SHE Index, with control variables. When organizational descriptive and clinical staffing variables were controlled, there was no association between overall high reliability practice, leadership, or robust process improvement. However, when controlled for organizational descriptive and clinical staffing variables, the safety culture component of high reliability practice demonstrated a significant and negative relationship to organization SHE Index (0.63, $p = 0.03$), meaning organizations had 37% lower odds of being in a higher SHE Index quartile for each point increase in the safety culture component of high reliability practice score.

The organizational descriptive variable bed size was significantly and positively related to the SHE Index in the overall, leadership, safety culture, and robust process improvement component models. Organizations had slightly greater odds of being in a higher SHE Index quartile for each additional bed.

The organizational clinical staffing variable of RN hours per patient day was significantly and positively related to the SHE Index in the overall, leadership, safety culture, and robust process improvement component models. Within these models, organizations with higher RN hours per patient day had greater odds of being in a higher SHE Index quartile.

The organizational clinical staffing variable of employed physicians was significantly and negatively related to the SHE Index in the safety culture component model (0.07, $p = 0.03$). Within this model, organizations with employed physicians had 99% lower odds of being in a higher SHE Index quartile than organizations with no employed physicians. The organizational clinical staffing variable ‘employed physicians’ was not related to the SHE Index in the overall high reliability, leadership, and robust process improvement component models.

TABLE 14

ORDINAL LOGISTIC REGRESSION RESULTS ON THE RELATIONSHIP BETWEEN HIGH RELIABILITY PRACTICE (COMPOSITE AND COMPONENTS) AND SERIOUS HARM EVENT INDEX FOR HOSPITALS REPORTING PEDIATRIC SPECIFIC DATA TO THE AMERICAN HOSPITAL ASSOCIATION (N= 25)

	Odds Ratio	Significance (p-value)	Lower Confidence	Upper Confidence
High Reliability Composite	0.91	0.19	0.78	1.05
Medical Staff Hours per Patient Day	0.75	0.16	0.50	1.12
Employed Physicians	0.14	0.08	0.16	1.26
LPN Hours per Patient Day	5.33	0.20	0.41	69.95
RN Hours per Patient Day	**1.34**	**0.03**	**1.04**	**1.73**
Bed Size	**1.02**	**0.01**	**1.01**	**1.04**
Leadership Composite	0.97	0.84	0.70	1.33
Medical Staff Hours per Patient Day	0.76	0.17	0.51	1.13
Employed Physicians	0.24	0.17	0.32	1.82
LPN Hours per Patient Day	4.92	0.23	0.34	66.28
RN Hours per Patient Day	**1.30**	**0.03**	**1.02**	**1.66**
Bed Size	**1.02**	**0.00**	**1.01**	**1.03**
Safety Culture Composite	**0.63**	**0.03**	**0.42**	**0.95**
Medical Staff Hours per Patient Day	0.71	0.13	0.45	1.11
Employed Physicians	**0.07**	**0.03**	**0.00**	**0.75**
LPN Hours per Patient Day	12.03	0.08	0.71	204.03
RN Hours per Patient Day	**1.43**	**0.01**	**1.08**	**1.91**
Bed Size	**1.03**	**0.00**	**1.01**	**1.04**
Robust Process Improvement Composite	0.73	0.26	0.41	1.28
Medical Staff Hours per Patient Day	0.73	0.13	0.48	1.10
Employed Physicians	0.14	0.09	0.02	1.41
LPN Hours per Patient Day	7.61	0.15	0.48	119.56
RN Hours per Patient Day	**1.37**	**0.03**	**1.04**	**1.81**
Bed Size	**1.02**	**0.01**	**1.01**	**1.04**

SSER

Twelve organizations contributed SSER data to this study. There were no statistically significant differences in overall high reliability practice nor the leadership, safety culture, and robust process improvement components of high reliability between those organizations that submitted SSER data and those that did not. The dependent variable SSER and independent variables were evaluated to identify potential outlier data, or data that exceeded 2.5 standard deviations given the small sample size of the study (Hair et al., 2006). One outlier was identified in the variable bed size. The outlier value remained in the analysis, as there was no way to determine if the data were truly not representative of the population (Hair et al., 2006). The organizational descriptive variable bed size had a mean of 441.5, standard deviation of 305.6, minimum of 258, and maximum 1,371.

SSER was initially measured as a continuous variable with a mean of 1.3, a standard deviation of 1.7, a minimum of 0.12, and a maximum of 6.5. Data for the SSER did not meet the assumptions for linear regression as it was non-normally distributed. In order to perform regression analysis, the variable was transformed into a categorical variable by dividing the outcome into quartiles. The SSER 25^{th} percentile was 0.4, the 50^{th} percentile was 1.1, and the 75^{th} percentile was 1.5.

A high reliability practice score was obtained for each component of high reliability as well as an overall high reliability composite. The maximum score of high reliability practice identified for the overall high reliability composite for these 12 organizations was 53. The maximum score of high reliability practice identified for the leadership component was 21, for the safety culture component, 20, and for robust process improvement, 12. Table15 summarizes the results of high reliability practice.

The average score of overall high reliability practice was 42.9. The average score of the leadership component of high reliability practice was 18.8, the average score of the safety culture component of high reliability practice was 15.2, and the average score of the robust process improvement component was 9.

TABLE 15

HIGH RELIABILITY PRACTICE: SERIOUS SAFETY EVENT RATE

	N	Mean	SD	Minimum	Maximum
Overall Composite (of 56)	12	42.92	5.02	35	53
Leadership Composite (of 24)	12	18.75	2.30	13	21
Safety Culture Composite (of 20)	12	15.17	2.13	13	20
Robust Process Improvement Composite (of 12)	12	9.00	1.71	6	12

Table 16 shows the results for ordinal logistic regression results on the relationships between high reliability practice (composite and components) and the SSER with no control variables. The hypothesis that organizations exhibiting more advanced high reliability practice will have fewer serious safety events (as defined by the SSER) than organizations exhibiting less advanced high reliability practice was not supported; however, the model was approaching a significant and negative relationship with SSER (0.78, $p = 0.07$), meaning that organizations exhibiting more advanced high reliability practice had 22% lower odds of being in a higher SHE Index quartile. The leadership and robust process improvement components of high reliability practice were not related to SSER. The safety culture component of high reliability was the only component of high reliability practice that demonstrated a significant and negative relationship with SSER (0.45, p = 0.04). Within this model, organizations that exhibited more advanced high reliability practice within the safety culture component had 55% lower odds of being in a higher SHE Index quartile.

TABLE 16

ORDINAL LOGISTIC REGRESSION RESULTS ON THE RELATIONSHIP BETWEEN HIGH RELIABILITY PRACTICE (COMPOSITE AND COMPONENTS) AND SERIOUS SAFETY EVENT RATE (N= 12)

	Odds Ratio	Significance (p-value)	Lower Confidence	Upper Confidence
High Reliability Composite	0.78	0.07	0.60	1.02
Leadership Composite	0.77	0.30	0.47	1.26
Safety Culture Composite	**0.45**	**0.04**	**0.21**	**0.96**
Robust Process Improvement Composite	0.62	0.17	0.31	1.23

Table 17 shows the results for ordinal logistic regression results on the relationships between high reliability practice (composite and components) and the SSER with control variables. When the organizational descriptive variable bed size was controlled for, there was no statistically significant relationship between high reliability practice and SSER (0.79, p = 0.08). The leadership and robust process improvement components of high reliability also demonstrated no association with SSER. The safety culture component of high reliability practice was the only model that demonstrated a significant and negative relationship to organization SSER (0.46, p = 0.04). Organizations that exhibited more advanced high reliability practice within the safety culture component had 54% lower odds of being in a higher SHE Index quartile. The organizational descriptive variable bed size was not associated with SSER in the overall, leadership, safety culture, and robust process improvement component models.

TABLE 17

ORDINAL LOGISTIC REGRESSION RESULTS ON THE RELATIONSHIP BETWEEN HIGH RELIABILITY PRACTICE (COMPOSITE AND COMPONENTS) AND SERIOUS SAFETY EVENT RATE WITH CONTROL VARIABLES (N= 12)

	Odds Ratio	Significance (p=value)	Lower Confidence	Upper Confidence
High Reliability Composite	0.79	0.08	0.61	1.03
Bed Size	1.00	0.82	1.00	1.00
Leadership Composite	0.76	0.28	0.45	1.26
Bed Size	1.00	0.49	1.00	1.00
Safety Culture Composite	**0.46**	**0.04**	**0.21**	**0.98**
Bed Size	1.00	0.93	1.00	1.00
Robust Process Improvement Composite	0.62	0.21	0.30	1.30
Bed Size	1.00	0.21	1.00	1.00

CHAPTER 5:

DISCUSSION, IMPLICATIONS, AND FUTURE RESEARCH

This non-experimental research study sought to assess the association of high reliability practice and patient safety outcomes, specifically preventable harms defined as HACs and SSEs in 33 pediatric organizations. Two hypotheses were tested: Hypothesis #1: Organizations exhibiting more advanced high reliability practice will have fewer hospital acquired conditions (as defined by the Serious Harm Event [SHE] Index) than organizations exhibiting less advanced high reliability practice; and Hypothesis #2: Organizations exhibiting more advanced high reliability practice will have fewer serious safety events (as defined by the Serious Safety Event Rate [SSER]) than organizations exhibiting less advanced high reliability practice. To our knowledge, this is the first study that tests the association between high reliability practice as operationalized by Chassin and Loeb (2013) and patient safety outcomes.

Review of Findings

Hypothesis 1: Organizational Serious Harm Event Index

The first hypothesis that organizations exhibiting more advanced high reliability practice will have fewer HACs (as defined by the SHE Index) than organizations exhibiting less advanced high reliability practice was not supported. There was no association between high reliability practice and the SHE Index. There could be multiple explanations for this finding. First, the results could be related to the small sample size of

33 organizations. Due to the small sample size there may not have been enough statistical power to determine any association between high reliability practice and the SHE Index.

Second, there was limited variability within the organizational survey responses. Specifically, the range of high reliability practice scores was small. There was only one organization with a high reliability practice score below 28 (developing stage of high reliability). Thirty-two of the 33 organizations were in the top two stages of high reliability, resulting in a skewed distribution that minimized the ability of the model to detect any association between high reliability practice and the SHE Index.

Third, the hypothesis may not have been supported due to the amount of disruption reported within participating organizations. Only five of 33, or 15.2% of responding organizations, reported having experienced no major organizational changes within the last two years. Disruption was reported in the form of significant leadership transitions, new or expansion of facilities, significant electronic medical record changes, additions of service lines, and mergers and acquisitions. These types of disruptions can be associated with an increase in preventable harms including hospital-acquired conditions and serious safety events.

Such changes can introduce factors into the organization such as new order sets within the computerized provider order entry system, non-standardized practices as result of mergers and acquisitions, and high-risk situations as the result of introduction of new services. These factors of disruption affect an organization’s culture in ways that are not quantified by the tool used to measure safety culture. While reduction of harm can be the highest priority and focus of leadership, setting expectations and goals alongside strategic planning may not be able to overcome the impact of significant disruption.

Finally, the lack of association between overall high reliability practice and the SHE Index could be due to how high reliability practice was measured. Although the survey tool used to assess high reliability is presently perceived as the best available, there have been no studies to validate this survey tool. Since such survey characteristics as inter-rater reliability and reproducibility of this survey instrument have not yet been studied, the reliability of the tool is unclear. This could have biased the results in an unknown direction.

Within the components of high reliability practice, the safety culture component of the model was statistically significantly and negatively related to the SHE Index in the model limited to the organizations reporting pediatric-specific data to the AHA. The safety culture component of high reliability practice assessed trust, accountability, identification of unsafe conditions, strengthening systems, and assessment of the culture of safety (Chassin & Loeb, 2013). The higher the safety culture component score, the lower the quartile of the SHE Index. This finding is supportive of the application of high reliability principles within healthcare, as organizations with a culture of safety routinely recognize and report errors and unsafe conditions.

According to organizational theory, transparency allows organizations to develop and implement prevention strategies. Within these organizations there is a sense of ownership in this culture which allows staff to hold each other accountable to full adoption and adherence to prevention strategies. This approach requires a proactive culture consistently focused on identifying and correcting potential and actual safety issues before catastrophe, or patient harm due to a HAC occurs. Identified correction strategies are then communicated and disseminated broadly.

The CHSPS focused on tactical quality improvement work by establishing care bundles to prevent HACs (Children's Hospitals' Solutions for Patient Safety, n.d.-b). In order to increase high reliability, participating organizations not only implemented the care bundles, but also measure ongoing reliability to the care bundle. This allows the participating organizations to engage front line staff and physicians in obtaining adoption, adherence, and accountability to the care bundles. These behaviors are consistent with examples of the most advanced level of high reliability practice within the safety culture component (Chassin & Loeb, 2013).

This study expands on previous work exploring the relationship between the structured implementation of care bundles and specific HACs (Jacobsen, 2008; Miller et al., 2010; Pronovost et al., 2006; Pronovost et al., 2010; Resar et al., 2005). This study adopted a broader view by evaluating the impact of high reliability on an aggregate measure of HACs, the SHE Index. Implementation of care bundles using strategies that support high reliability principles, such as measuring reliability, allows the root causes of patient safety risk to be identified and corrected in a timely fashion producing a safer care environment for patients.

Organizational Descriptive and Clinical Staffing Variables

The descriptive variable bed size was statistically significant and positively related to the SHE Index in the safety culture component model tested with all 33 organizations as well as in all four models tested in the subset of organizations reporting pediatric-specific data to the AHA Annual Survey of Hospitals database. As bed size increases, organizations have slightly greater odds of being in a higher quartile of the SHE Index. This finding is reasonable and predictable; more beds equates to more patients, which results in greater opportunities for patients to develop hospital-acquired conditions. Since the SHE Index is not a rate, patient volumes are not corrected for in the index.

The clinical staffing variable RN hours per patient day was significantly and positively related to the SHE Index in the overall high reliability, leadership, safety culture component, and the robust process improvement models tested for all 33 organizations. The variable was also significant in all four models tested in just the organizations reporting pediatric-specific data to the AHA Annual Survey of Hospitals database. In all models, higher RN hours per patient day were associated with greater odds of being in a higher quartile of the SHE Index.

The literature presents varying findings regarding the association between nurse staffing and hospital acquired conditions including a positive association with various patient safety outcomes. (Ausserhofer et al., 2013; Blegen & Vaughn, 1998; Cho, Ketefian, Barkauskas, & Smith, 2003; Dunton, Gajewski, Taunton, & Moore, 2004; Frith et al., 2010; Kahlert Eng, 2015; Lang, Hodge, Olson, Romano, & Kravitz, 2004). One study reported RN hours per patient day were associated with higher HACs but only before the analysis controlled for severity of illness and length of stay (Kahlert Eng, 2015). The change in significance of the variable when controlled suggests that higher RN hours may be indicative of caring for sicker patients who may be at higher risk for developing a HAC. The severity of illness may be a relevant factor in this study, as the analysis did not control for patient acuity in any way.

The literature suggests that pressure ulcers may be one specific HAC that is positively associated with higher nursing staffing. Increased detection of pressure ulcers as a result of increased surveillance by nurses has been presented as one possible explanation for the positive association between pressure ulcers and nurse staffing (Cho et al., 2003; Choi, Bergquist‐Beringer, & Staggs, 2013; Dunton, Gajewski, Klaus, & Pierson, 2007; Kahlert Eng, 2015; Moates, 2014). Alternatively, it has been hypothesized that increased education of nurses to identify pressure ulcers that are present on admission in order to prevent financial penalties for HACs may impact overall reporting of pressure ulcers (Moates, 2014).

As a result of the focus of the CHSPS collaborative on HACs, it is reasonable to hypothesize that the positive association between RN hours per patient day and the SHE Index in this study was a result of increases in both detection and reporting. Nurses are the primary care provider for hospitalized patients. Higher RN hours per patient day allow nurses more time at the bedside to perform comprehensive versus focused assessments. Comprehensive assessments, which can involve gathering the patient's medical history, assessing the patient's general appearance and vital signs, and performing a physical exam afford the nurse the opportunity to identify any clinical element that is not within normal parameters or is potentially indicative of a hospital acquired condition. For example, the performance of a comprehensive skin assessment might reveal a pressure ulcer on the back, a HAC that would then be reported. A focused skin assessment, on the other hand, performed if a nurse has less time per patient, might not include examination of the patient's back.

Nurses often perform active surveillance for HACs because the majority of hospital-acquired conditions are related to nursing care (i.e., maintenance of lines/catheters, skin care). Active surveillance is time consuming and can be very difficult to perform when caring for patients at the bedside due to competing priorities. Higher RN hours per patient day could enable nurses to spend more time performing active surveillance to detect hospital-acquired conditions, which might increase the detection of patient harm.

In addition, higher RN hours per patient day could allow more time for nurses to report events. As organizations become more complex, additional responsibilities are added to nursing, requiring nurses to prioritize tasks to be completed prior to the end of the shift. Incident reporting systems can be cumbersome and time consuming (Uribe, Schweikhart, Pathak, Marsh, & Fraley, 2002). If a nurse is forced to prioritize tasks that will be completed prior to the end of the shift as a result of competing priorities, including direct patient care and documentation of patient care, incident reporting might be less likely to be completed as a lower priority than patient care.

The clinical staffing variable ‘employed physicians’ was significantly and negatively associated with the SHE Index in the safety culture component model tested in the subset of organizations reporting pediatric specific data to the AHA Annual Survey of Hospitals database. Organizations that have employed physicians have lower odds of being in a higher quartile of the SHE Index than organizations that do not have employed physicians.

One explanation for this finding may be that organizations that employ physicians have more ways of influencing physician practice and to connect physicians to work related to reducing patient harms. This relationship might encourage employed physicians to become more involved in the identification and documentation of HACs, thus increasing potential for detection of HACs. Furthermore, this arrangement might facilitate physicians' ability to evaluate physician practice issues that potentially contribute to the development of hospital-acquired conditions so that prevention and/or correction strategies can be implemented. Influence can then be exercised by the organization through directly incentivizing physicians to participate in work related to HAC prevention or encouraging physicians to be compliant with best practice through discipline for noncompliance.

Clinical staffing is an important contributor to patient safety (Cho et al., 2003; Choi et al., 2013; Dunton et al., 2007; Kahlert Eng, 2015; Moates, 2014). Preventable patient harms, specifically HACs, might not be easily detected if sensitive detection methods, such as active surveillance, are not employed. Organizations invested in patient safety emphasize the importance of safety culture and transparency; events must be known to be occurring in order to develop and implement effective prevention and correction strategies. These organizations have a culture of safety that fully embraces high reliability principles and routinely recognizes and reports errors and unsafe conditions. In order to do this, organizations invested in high reliability appear to staff at a level more likely to find HACs through surveillance, increased reporting of events, and increased transparency.

Hypothesis 2: Organization Serious Safety Event Rate

The second hypothesis that organizations exhibiting more advanced high reliability practice will have fewer serious safety events (as defined by the Serious Safety Event Rate [SSER]) than organizations exhibiting less advanced high reliability practice was not supported. There was no statistically significant association between high reliability practice and SSER ($p=0.07$).

There are several potential reasons that the hypothesis was not supported. First, there may have been insufficient power given the small sample size for the SSER portion of this study. Only 12 organizations reported SSER data. The other 12 organizations presently reporting SSER data to the Patient Safety Organizations associated with the CHSPS chose not to supply their SSER data for this portion of the study based on confidentiality concerns.

A second potential reason that no association between high reliability practice and SSER was observed could be the limited variability of high reliability practice scores within the organizational survey response. Of the 12 organizations that were included in the SSER analysis, no organizations had a high reliability practice score of less than 28, meaning that no organizations were classified in the beginning or developing stage of high reliability.

The majority of organizations had a high reliability practice score of 43 or greater, meaning that the majority of organizations were classified in the highest level of high reliability practice. This classification could reflect a biased view by respondents of their organizations. The lack of distribution across all possible high reliability practice scores limits the model from having the range of scores necessary to detect any association between high reliability practice and SSER.

A third potential reason that no association between high reliability practice and SSER was observed is that organizations participating in the CHSPS collaborative began membership at different points in time. As a result, the SSER may not have reflected current safety performance because the SSER measures across a rolling 12 months.

Current performance may have been skewed negatively, as older data utilized in the SSER may not have rolled off during the measurement period.

Similar to the association between the safety culture and the SHE Index, the safety culture component was statistically significantly and negatively related to SSER. This finding is supportive of the application of high reliability principles within healthcare. Organizations with a culture of safety routinely recognize and report errors, near misses, and unsafe conditions. There is a sense of ownership in this culture and among staff to demonstrate full accountability for consistent adherence to generally accepted performance standards.

Staff within organizations exhibiting the most advanced level high reliability practice trust each other fully and hold each other accountable. Within these organizations there is a proactive culture that consistently focuses on identifying and correcting potential and actual safety issues before catastrophe, or a serious safety event, occurs. These identified correction strategies, which facilitate easier adherence to generally accepted performance standards, are then communicated broadly to strengthen weaknesses identified (Chassin & Loeb, 2013).

Even though the sample for this portion of the study was smaller (n=12), there were no statistically significant differences in survey results within overall high reliability practice nor amid the leadership, safety culture, and robust process improvement components of high reliability when compared to the 21 organizations that responded to the high reliability survey but either were not eligible or did not submit SSER data for this study. The negative relationship between the culture of safety component of high reliability and SSER translates to better patient safety outcomes for those organizations that are more advanced within the culture of safety component of high reliability. This finding validates the concept that implementation of interventions supportive of promoting a culture of safety, such as leadership methods, error prevention behavioral training, and cause analysis are associated with decreased SSEs.

Organizational Descriptive and Clinical Staffing Variables

There was no association detected with the organizational descriptive variable bed size. SSER is a rate-based measure so bed size is adjusted for patient days. In addition, serious safety events are infrequent events that may not be connected to any specific process or condition. Rather, they are events that occur because a deviation from generally accepted performance standards occurred, which resulted in significant harm or death to the patient (Throop & Stockmeier, 2009). These types of events result from deviations caused by system failures. We speculate, therefore, one would not expect them to be affected by organization size, but by the staff's acceptance, adherence, and accountability to generally accepted performance standards and processes.

Implications for Practice

In this study, safety culture scores were inversely associated with patient harm, as measured by HACs and SSEs. Previous studies demonstrating a reduction in HACs largely focused on single HACs within specific units (i.e., intensive care units), within either single organizations, or among organizations coordinated through a statewide initiative or quality improvement collaborative (DePalo et al., 2010; Jacobsen, 2008; Lin et al., 2012; Miller et al., 2010; Pronovost et al., 2006; Pronovost et al., 2010; Pronovost et al., 2015; Resar et al., 2005).

Previous studies demonstrating a reduction in SSER were also based on data from single sites (Brilli et al., 2013; Burke, LeFever, & Sayles, 2009; Hilliard et al., 2012; Muething et al., 2012; Peterson et al., 2012). There was one statewide collaborative consisting of eight hospitals in Ohio that demonstrated a reduction in SSER (Lyren et al., 2013).

Data from our study expand on these studies, by suggesting an association between culture of safety survey results and individual HACs and SSER. This study demonstrates that the implementation of high reliability practices to improve safety culture is associated with rates of patient harms in the forms of HACs, as measured by the composite measure SHE Index and SSER. This study suggests an association between safety culture and patient harms.

Regulatory agencies require that organizations evaluate the culture of safety regularly but allow organizations to choose the evaluation strategy and frequency. Many organizational leaders and patient safety professionals within the CHSPS report building the culture of safety measurement into the patient safety program along with mechanisms to remove barriers that undermine a culture of safety (P. Sharek, Personal Communication, October 28, 2016). Organization leaders generally might consider these data to inform strategic plans for continuous improvement, including strategies for detection of patient harm, implementation of high reliability practices, measurement, and accountability. These data also support evaluation by regulatory agencies of the effectiveness of organizational leadership to continuously improve safety culture.

Clinical staffing, specifically RN hours per patient day, was associated with higher odds of being in a higher quartile of the SHE Index. HACs are not obvious conditions, and method of detection is important. HACs can be identified through clinical documentation and coding, incident reporting systems, and active surveillance, each with differing levels of sensitivity. Measuring and understanding patient harms that occur is an intensive undertaking. An organization must have an accurate depiction of patient harms, possibly in the forms of HACs, in order to implement the high reliability behaviors and practices to mitigate, correct, and, over time prevent these harms from occurring.

While there have been industry-wide efforts to increase transparency of quality and safety data, this study demonstrates (via 12 of 24 eligible sites declining to submit SSER data for fear of loss of confidentiality) that there continue to be significant issues limiting transparent sharing of quality and safety data across organizations. Transparency of quality and safety data is important to support a culture of safety and learning across the healthcare industry. Sharing successful strategies to improve the safety of care provided to patients through implementation of prevention strategies and advancement in the culture of safety has the potential to expedite improvement within the healthcare industry.

The Patient Safety and Quality Improvement Act of 2005 was intended to encourage organizations to work together on safety, but organizational legal departments, specifically within the CHSPS collaborative, continue to fear discovery of safety data and often prohibit the sharing of safety data (Sharek, October 28, 2016). The limited number of organizations participating in the SSER analysis of this study suggests that the Patient Safety and Quality Improvement Act of 2005 may not be working as intended. If organizations and collaboratives are unable to share results and evidence through publication in the literature of SSER reduction strategies, systematic progress may be impeded towards reducing preventable harm to patients and spending of unnecessary resources.

Limitations of the Study

There were several limitations of this study. The first limitation is related to the high reliability survey. The high reliability framework has not been previously validated as a tool to assess high reliability. In addition, the tool we used has not been validated. We used this tool because of its face validity The framework was not modified in any way when transformed into a survey in order to remain consistent to the framework. Some individuals participating in preparation of the organizational survey response provided feedback to the researcher that there was some difficulty differentiating between survey answer choices, which made it difficult to choose a response for those specific elements. Future work should focus on establishing the reliability and validity of this instrument.

Another limitation is potential bias within the organizational survey response. Despite the instructions provided regarding how to craft the organizational response to the survey, there was not a way to validate that all organizations completed the survey as instructed. It appears that some organizations did not seek feedback from all members of the healthcare leadership team as suggested within the instructions. Limited involvement from different positions of the leadership team limits the perspectives represented within the response, thus potentially impacting the results of the survey.

There were also methodological limitations of the study. The sample size for the SHE Index portion of this study was reduced from 49 participating organizations to 33 participating organizations due to missing HAC data. Organizations joined the CHSPS collaborative at different points in time, some well into the timeframe of this study, resulting in missing monthly HAC data during the study timeframe. These missing data did not allow the researcher to calculate an accurate SHE Index for these organizations. More than 10% of monthly HAC data was missing, so these organizations were excluded from the analytic sample. The sample size for the SSER portion of the study was reduced to 12 due to organizations not reporting SSER data for inclusion in the study.

Within the SHE Index portion of the study, there was no way to control for how organizations detected HACs. The CHSPS encourages organizations to utilize active surveillance to detect HACs in addition to voluntary reporting through incident reporting systems; however, there is no mandate that specific detection methods be utilized. Active surveillance reveals more events than voluntary reporting through incident reporting systems; however, not all organizations have the resources available to conduct active surveillance. Utilization of different detection methods may have had a significant impact on the SHE Index.

Recommendations for Future Research/Analysis

Future research is needed to validate the Chassin and Loeb (2013) instrument or other tools for measurement of high reliability practice, potentially utilizing factor analysis. Validated tools can be used to further evaluate the association between high reliability practice and patient safety outcomes. Future research is also needed in the form of a longitudinal study testing the association between change in high reliability practice and change in patient safety outcomes within a single organization. It will be important to understand if high reliability practice among organizations reduces the frequency of hospital-acquired conditions and serious safety events over time.

Another area for future research is to examine the impact of disruption, specifically mergers and acquisitions, on patient safety culture and patient safety outcomes. The healthcare environment is a dynamic one; organizations must understand the impact of disruption in order to implement strategies to protect their patients from preventable harms.

Further studies replicating this study among a broader sample of organizations are needed. While the findings of this study demonstrated associations between a component of high reliability and patient harms, the results should be interpreted with caution. There were differences found between the organizations participating in the CHSPS and non-participating organizations that restrict admissions to children according to the AHA Annual Survey of Hospitals. In addition, this study was limited to organizations providing care to children and the results cannot necessarily be applied to care for the adult population.

CONCLUSION

In conclusion, this study sought to determine the association between high reliability practice and patient safety outcomes as operationalized by the SHE Index and SSER. This is the first known study to test this association. No statistically significant association between overall high reliability practice and patient safety outcomes was identified. Nevertheless, this research study provides a significant contribution to our current understanding by identifying some variables and relationships that merit further study.

There was an association between the safety culture component of high reliability and the SHE Index in the subset of organizations reporting pediatric-specific data to the

AHA Annual Survey of Hospitals database. There was also an association between the safety culture component of the high reliability tool and SSER. In both cases, the safety culture component of high reliability was inversely related to the SHE Index and SSER. These findings are supportive of the hypothesis that application of high reliability principles might improve safety culture and reduce patient harms.

Among the descriptive and clinical staffing variables included in the study, organizational bed size was associated with slightly higher odds of being in a higher quartile of the SHE Index. RN hours per patient day were positively related to the SHE Index. A reasonable hypothesis is that larger institutions have more opportunities to generate harm, and those with more nurses have greater ability to detect and report harm. Employment of physicians was associated with lower odds of being in a higher quartile of the SHE Index in a single model. Having more tools to influence physicians may lead to more physician engagement in high reliability efforts, with concomitant decrease in harm. These associations should be explored in future studies.

More studies are needed to further validate approaches to high reliability measurement we utilized in this study and to investigate the association between high reliability practices and patient safety outcomes. Despite the preliminary nature of the study findings, they provide some support for the validation of high reliability principles as advocated by organizational leaders and patient safety professionals.

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APPENDIX A

HIGH RELIABILITY SURVEY

Research Project Survey

Welcome!

Hello, and thank you for agreeing to complete this survey.

Please complete the BRIEF survey on the following pages, and submit ONE response per organization. Responses will help us learn where the Network is in the high reliability continuum. It is recommended that the survey be completed via the following method:

1. Director of Patient Safety complete the survey on paper,
2. Director of Patient Safety disseminates the DRAFT results to the CEO, COO, CNO, CMO, and Chief Patient Safety Officer to determine if they agree,
3. Any discrepancies in scorings should be discussed, and ONE final consensus response should be submitted via the survey link.

When completing the survey, read each answer choice completely beginning with the first listed. If at any choice, you cannot say the organization meets EVERY aspect of the answer, choose the previous selection as the answer best representing the organization.

The questions on this survey will be separated into four sections:

1. Participant Information
2. Leadership
3. Safety Culture
4. Robust Process Improvement & High Reliability

Next

Research Project Survey

Participant Information

Please answer the below questions regarding your hospital, your position, and the position(s) of anyone helping you to complete this survey.

1. What is the official name of your hospital?

2. What type of hospital is this?

- Free Standing Children's Hospital
- Hospital within a Hospital
- Hospital within a Health System
- Other (please specify)

3. What is your position within the hospital?

- Chief Executive Officer (CEO)
- Chief Operating Officer (COO)
- Chief Medical Officer (CMO)
- Chief Quality / Patient Safety Officer
- Other Quality / Safety / Risk Leader
- Other (please specify)

4. How long have you been in your current position?

- <1 year
- 1-5 years
- 6-10 years
- 11-15 years
- 16-20 years
- 21 years or more

5. How long have you worked in the hospital?

- <1 year
- 1-5 years
- 6-10 years
- 11-15 years
- 16-20 years
- 21 years or more

6. What is your discipline?

- Registered Nurse
- Nurse Practitioner / Physician Assistant
- Physician
- Administration / Management
- Other (please specify)

7. With whom did you consult while completing this survey? Please check all that apply.

- Board of Trustees member
- Chief Executive Officer (CEO)
- Chief Operating Officer (COO)
- Chief Medical Officer (CMO)
- Chief Quality / Patient Safety Officer
- Other Quality / Safety / Risk Leader
- Other (please specify)

8. Please select any major organization changes that have occurred in the last 2 years. Check all that apply.

- Merger / Acquisition
- Service Line Addition
- Significant Leadership Transition
- New / expansion building with significant change in patient volume and/or acuity
- Significant or substantial change in Electronic Medical Record (EMR)
- None
- Other (please specify)

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Research Project Survey

Leadership

For each of the categories below, please rate where your organization best fits. Read through all options and choose the statement that *best* describes your organization's leadership.

1. Board:

- Board's quality focus is nearly exclusively on regulatory compliance.
- Full board's involvement in quality is limited to hearing reports from its quality committee.
- Full board is engaged in the development of quality goals and approval of the quality plan, and regularly reviews adverse events and progress on quality goals.
- Board commits to the goal of high reliability (i.e., zero patient harm) for all clinical services.

2. CEO / Management:

- ◯ CEO / management's quality focus is nearly exclusively on regulatory compliance.
- ◯ CEO acknowledges need for plan to improve quality and delegates the development and implementation of a plan to a subordinate.
- ◯ CEO leads the development and implementation of a proactive quality agenda.
- ◯ Management aims for zero patient harm for all vital clinical processes; some demonstrate zero or near-zero rates of harm.

3. Physicians:

- ◯ Physicians rarely lead quality improvement activities; overall participation by physicians in these activities is low.
- ◯ Physicians champion some quality improvement activities; physicians participate in these activities in some areas, but not widely.
- ◯ Physicians often lead quality improvement activities; physicians participate in these activities in most areas, but some important gaps remain.
- ◯ Physicians routinely lead clinical quality improvement activities and accept the leadership of other appropriate clinicians; physicians' participation in these activities is uniform throughout the organization.

4. Quality Strategy:

- ◯ Quality is not identified as a central strategic imperative.
- ◯ Quality is one of many competing strategic priorities.
- ◯ Quality is one of the organization's top three or four strategic priorities.
- ◯ Quality is the organization's highest priority strategic goal.

5. Quality Measures:

- ◯ Quality measures are not prominently displayed or reported internally or publicly; the only measures used are those required by outside entities and are not part of reward systems.
- ◯ Few quality measures are reported internally; few or none are reported publicly and are not part of reward systems.
- ◯ Routine internal reporting of quality measures begins, with the first measures reported publicly and the first quality metrics introduced into staff reward systems.
- ◯ Key quality measures are routinely displayed internally and reported publicly; reward systems for staff prominently reflect the accomplishment of quality goals.

6. Information Technology (IT):

- ◯ IT provides little or no support for quality improvement.
- ◯ IT supports some improvement activities, but principles of safe adoption are not often followed.
- ◯ IT solutions support many quality initiatives; the organization commits to principles and the practices of safe adoption.
- ◯ Safely adopted IT solutions are integral to sustaining improved quality.

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Research Project Survey

Safety Culture

For each of the categories below, please rate where your organization best fits. Read through all options and choose the statement that best describes your organization's safety culture.

1. Trust:

- ◯ Trust or intimidating behavior is not assessed.
- ◯ First codes of behavior are adopted in some clinical departments.
- ◯ CEO and clinical leaders establish a trusting environment for all staff by modeling appropriate behaviors and championing efforts to eradicate intimidating behaviors.
- ◯ High levels of (measured) trust exist in all clinical areas; self-policing of codes of behavior is in place.

2. Accountability:

- ◯ Emphasis is on blame; discipline is not applied equitably or with transparent standards; no process exists for distinguishing "blameless" from "blameworthy" acts.
- ◯ The importance of equitable disciplinary procedures is recognized, and some clinical departments adopt these procedures.
- ◯ Managers at all levels accord high priority to establishing all elements of safety culture; adoption of uniform equitable and transparent disciplinary procedures begins across the organization.
- ◯ All staff recognize and act on their personal accountability for maintaining a culture of safety; equitable and transparent disciplinary procedures are fully adopted across the organization.

3. Identifying Unsafe Conditions:

- Root cause analysis is limited to adverse events; close calls ("early warnings") are not recognized or evaluated.
- Pilot "close call" reporting programs begin in few areas; some examples of early intervention to prevent harm can be found.
- Staff in many areas begin to recognize and report unsafe conditions and practices before they harm patients.
- Close calls and unsafe conditions are routinely reported, leading to early problem resolution before patients are harmed; results are routinely communicated.

4. Strengthening Systems:

- Limited or no efforts exist to assess system defenses against quality failures and to remedy weaknesses.
- Root Cause Analyses (RCAs) begin to identify the same weaknesses in system defenses in many clinical areas, but systematic efforts to strengthen them are lacking.
- System weaknesses are cataloged and prioritized for improvement.
- System defenses are proactively assessed, and weaknesses are proactively repaired.

5. Assessment:

- No measures of safety culture exist.
- Some measures of safety culture are undertaken but are not widespread; little if any attempt is made to strengthen safety culture.
- Measures of safety culture are adopted and deployed across the organization; efforts to improve safety culture are beginning.
- Safety culture measures are part of the strategic metrics reported to the board; systematic improvement initiatives are under way to achieve a fully functioning safety culture.

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Research Project Survey

Robust Process Improvement and High Reliability

For each of the categories below, please rate where your organization best fits. Read through all options and choose the statement that best describes your organization with regard to Robust Process Improvement. *Robust Process Improvement is defined as adoption of a single approach or any combination of approaches to process improvement (PDSA, Lean, Six Sigma, IHI Model for Improvement, etc).*

1. Methods:

- Organization has not adopted a formal approach to quality management.
- Exploration of modern process improvement tools begins.
- Organization commits to adopt the full suite of Robust Process Improvement (RPI) tools.
- Adoption of RPI tools is accepted fully throughout the organization.

2. Training:

- Training is limited to compliance personnel or to the quality department.
- Training in performance improvement tools outside the quality department is recognized as critical to success.
- Training of selected staff in RPI is under way and a plan is in place to broaden training.
- Training in RPI is mandatory for all staff, as appropriate to their jobs.

3. Spread:

- No commitment to widespread adoption of improvement methods exists.
- Pilot projects using some new tools are conducted in a few areas.
- RPI is used in many areas to improve business processes as well as clinical quality and safety; a positive ROI is achieved.
- RPI tools are used throughout the organization for all improvement work; patients are engaged in redesigning care processes, and RPI proficiency is required for career advancement.

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Research Project Survey

Thank You!

Thank you for completing this survey.

If you have any questions please contact...

Prev Done

APPENDIX B

CINCINNATI CHILDREN'S MEDICAL CENTER INSTITUTIONAL REVIEW BOARD APPROVAL

Institutional Review Board - Federalwide Assurance #00002988

Cincinnati Childrens Hospital Med Ctr

Date: 2/23/2015

From: CCHMC IRB

To: Principal Investigator: Kathleen Walsh
Anderson Ctr Health Sys Excell

Re: Study ID: 2015-0430
Study Title: Correlating High Reliability Organization practices with process compliance and harm across children's hospitals in the Solutions for Patient Safety collaborative

The Institutional Review Board (IRB) acknowledges receipt of the above referenced proposal. It was determined that this proposal does not meet the regulatory criteria for research involving human subjects (see below). Ongoing IRB oversight is not required.

Please note the following requirements:

Statement regarding International conference on Harmonization and Good clinical Practices. The Institutional Review Board is duly constituted (fulfilling FDA requirements for diversity), has written procedures for initial and continuing review of clinical trials: prepares written minutes of convened meetings and retains records pertaining to the review and approval process; all in compliance with requirements defined in 21 CFR Parts 50, 56 and 312 Code of Federal Regulations. This institution is in compliance with the ICH GCP as adopted by FDA/DHHS.

Thank you for your cooperation during the review process.

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45 CRF § 46.102(d): Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

45 CRF § 46.102(f): Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. data through intervention or interaction with the individual, or
2. identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

FDA regulations apply whenever an individual is or becomes a participant in research, either as a recipient of a FDA-regulated product or as a control, and as directed by a research protocol and not by medical practice. FDA-regulated activities involve individuals, specimens, or data, as patients or healthy controls, in any of the following:

a. any use of a drug or biologic, other than the use of an approved drug or biologic in the course of medical practice
b. any use of a device (medical or other devices, approved or investigational) to test the safety or effectiveness of the device
c. any use of dietary supplements to cure, treat, or prevent a disease or bear a nutrient content claim or other health claim
d. the collection of data or other results from individuals that will be submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit (including foods, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.)
e. activities where specimens (of any type) from individuals, regardless of whether specimens are identifiable, are used to test the safety or effectiveness of any device (medical or other devices, approved or investigational) and the information is being submitted to, or held for inspection by, the FDA.

See Research Policy R-03: Research That Must be Reviewed by the IRB for

the complete definition of Human Subject Research for further information.

APPENDIX C

UNIVERSITY OF ALABAMA AT BIRMINGHAM INSTITUTIONAL REVIEW

BOARD APPROVAL

THE UNIVERSITY OF
ALABAMA AT BIRMINGHAM

Institutional Review Board for Human Use

Form 4: IRB Approval Form
Identification and Certification of Research
Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The Assurance number is FWA00005960 and it expires on January 24, 2017. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56.

Principal Investigator:	RANDALL, KELLY
Co-Investigator(s):	
Protocol Number:	**E150310003**
Protocol Title:	*Correlating High Reliability Organization Practices with Process compliance and Harm Across Children's Hospitals in the Solutions for Patient Safety Collaborative.*

The above project was reviewed on 5/27/15. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This project qualifies as an exemption as defined in 45CF46.101, paragraph 2.

This project received EXEMPT review.

IRB Approval Date: 5/27/15

Date IRB Approval Issued: 5/27/15

Cari Oliver
Assistant Director, Office of the
Institutional Review Board for Human Use
(IRB)

Investigators please note:

IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approval to the IRB prior to implementation.

Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.

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