ADVERSE EVENTS IN HEALTHCARE AND THE ABILITY TO IMPROVE THE QUALITY AND SAFETY OF PATIENT CARE IN THE HOSPITAL

by

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A dissertation submitted to the faculty of
The University of North Carolina at Charlotte
in partial fulfillment of the requirements
for the degree of Doctor of Philosophy in
Public Policy

Charlotte

2015

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ABSTRACT

MAUREEN WALSH KORICKE. Adverse events in healthcare and the ability to improve the quality and safety of patient care in the hospital
(Under the direction of DR. TERESA L. SHEID)

This dissertation examines the influence of external and internal constraints on adverse event management in hospitals. Using a multilevel organizing framework, in three separate studies I explore the mechanisms of constraint that impact adverse event management and contribute to organizational processes designed to promote organizational learning and performance improvement initiatives to advance patient safety.

The first study, Chapter 2, examines state mandated adverse event reporting and the impact on patient safety. Mandated reporting of adverse events is an environmental level influence to coerce hospitals to improve patient safety through the mechanisms of identifying and addressing patient harm resulting from medical management. Analysis revealed no association between state mandated reporting of adverse events and patient safety. These findings suggest current environmental regulations in the form of mandated reporting have limited impact on patient safety. The reporting of adverse events may not be enough to prompt hospitals to focus on opportunities for improvement.

The next two studies, Chapters 3 and 4 employ an exploratory qualitative approach to examine organizational management of sentinel events, a subset of adverse events, in hospitals. In Chapter 3 I explore the sentinel event management structure and influences that impact the management structure within the constraints of internal influences. Hospitals exhibit significant coercive, normative, and mimetic influences

constraining the management of sentinel events that yields limitations in organizational learning and performance improvement initiatives to impact patient safety. These findings reveal multiple and varied constraints inform organizational design of sentinel event management programs. Sentinel event cases generate significant attention at high levels of hospital administration and provide the basis for organizational learning.

The third study, Chapter 4, explores sentinel event data collection and the application of a classification system using the principles of system safety and human factors to aggregate and analyze sentinel event data at the hospital level. Findings indicate the methodology developed for data collection and application of classification codes provides a mechanism for hospitals to manage sentinel event data in aggregate as a way to identify system-focused improvement initiatives.

The combination of mechanisms of constraint limits organizational learning thus restricting opportunities for performance improvement. The multiple constraints of hospital management of adverse events is impacting efforts to improve patient safety and these mechanisms must be recognized as challenges in the complex hospital environment.

DEDICATION

To my family

ACKNOWLEDGMENTS

I would like to acknowledge my committee for their tremendous kindness, support, and guidance throughout my doctoral studies and the dissertation process. My chair, Teresa Scheid, for her counsel, mentorship, and friendship. Teresa's help with my research has been invaluable as she has guided me along the theoretical exploration of adverse event management and qualitative data analysis. William Brandon for challenging me to view the health care delivery system through a different lens and strengthening my work; Jennifer Troyer for methodological guidance; and James Laditka for offering his insight into the health care system.

Many thanks to my friends and colleagues who offered encouragement and support throughout my studies and the dissertation process. I would like to thank my Center for Advancing Pediatric Excellence colleagues who shared their expertise and provided valuable feedback on my work. Stephany De Scisciolo Cavallo and Jeanne Leising, both dear friends and colleagues who have strengthened my work.

Ultimately my case study organization was not able to allow use of the information and sensitive data gathered for this study. However I would like to recognize the managers from the organization who contributed much of their time and expertise to the original case study.

Lastly, I would to like to thank my wonderful family for their unwavering love and support as I pursued my PhD: my husband Jonathan, daughters Caroline and Juliana, and my mother, Eleanor Walsh.

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LIST OF ABBREVIATIONS

ACA	Patient Protection and Affordable Care Act of 2010
AHRQ	Agency for Healthcare Research and Quality
ANCC	American Nurses Credentialing Center
CMS	Centers for Medicare & Medicaid Services
HHS	U.S. Department of Health and Human Services
IOM	Institute of Medicine
MedPAR	Medicare Provider Analysis and Review
NQF	National Quality Forum
OIG	Office of Inspector General
PSI	Patient Safety Indicator
PSO	Patient Safety Organization
USNWR	U.S News & World Report

CHAPTER 1: PATIENT SAFETY AND ADVERSE EVENTS

1.1 Introduction

Patient safety, adverse events, and patient harm resulting from medical management continue to vex the United States health care delivery system. A myriad of public and private initiatives has been introduced to coerce the health care delivery system to improve patient safety which include the reporting of adverse events, public reporting of performance indicators, and pay for performance initiatives. Many formal mandates require recognition, identification, and investigation of adverse events, yet these interventions have not yielded widespread shifts in care delivery. Research in patient safety and quality improvement points to the complexity of the U.S. health care system as a primary barrier to efforts that address dangerous patient situations. In addition, controversy exists over operational definitions for adverse events, quality and safety terminology, and measures that represent quality of care and patient safety.

The overall research objective of this dissertation is to examine how hospitals manage adverse events within the boundaries of external and internal constraints. The external environment imposes requirements through regulatory and accreditation requirements. Within the organization, professional norms and values also play an important part in the recognition and management of adverse events. Finally, hospitals impose constraints on other hospitals to perform in a certain way. These considerations impact how hospitals define and implement management structures. The organizationally

defined management structures then influence the analysis of adverse event data used to inform the performance improvement initiatives required to improve patient safety.

My dissertation research comprises three individual studies to develop a deeper understanding of adverse event management and improvement opportunities in the complex, high-risk, knowledge-driven hospital setting. My goal is to develop an understanding of the mechanism or mechanisms of constraint that influence the management of adverse events and patient safety in hospitals. Employing a multi-level organizing framework allows me to investigate the external environment and organizational structures that influence a hospital's management of adverse events.

In this introductory chapter, I review the patient safety and adverse event literature. I then discuss my conceptual framework that relates performance improvement principles to adverse event management. Following is an outline of institutional theory and the constraining impact on organizational management of adverse events, the dissertation's organizing framework and an overview of the three levels of my research. I conclude with a brief discussion of adverse event management, patient safety, and public policy.

1.2 Background

In spite of a myriad of public and private initiatives to improve patient safety in health care delivery, the industry has been slow to respond. Fourteen years after the publication of the Institute of Medicine (IOM) landmark report (Kohn, Corrigan, & Donaldson, 2000) which provided a framework to address the ills of the health care system, there has been little change in practice or even agreement on terminology or how to measure patient safety. Reports of patient harm persist in the popular press and

peer-reviewed journals, and many harm events continue to be unrecognized and unreported. Even when these events are recognized, limited learning from failure impedes targeted improvement initiatives to advance patient safety.

While the actual numbers of adverse events are unknown, the cost to patients and the economy is high. Estimates indicate patient harm resulting from medical management results in two to four million serious adverse events in the United States each year, with approximately 400,000 resulting in premature deaths (James, 2013). It is estimated that in 2008 medical errors cost over $17 billion (Van Den Bos, Rustagi, Gray, & Halford, 2011). In addition, over 34 percent of Americans believe they or a family member have suffered from a medical error (Kaiser Family Foundation, 2004).

The media reporting of several high-profile tragic adverse events has placed additional pressure on hospitals to improve patient safety. Betsy Lehman, a *Boston Globe* health reporter, died as a result of medication errors at the Dana Farber Cancer Institute, errors that were not recognized until a routine medical record audit months after Ms. Lehman's death (Altman, 1995); Jesica Santillan died in 2003, as a result of error at Duke University Hospital after receiving a heart and lung transplant with an incompatible blood type (Maugh II, 2003). The actor Dennis Quaid's newborn twins were victims of medication errors requiring additional medical treatment (*Fox News,* 2007), and the death of a 12 year old boy at New York University's Langone Medical Center resulted from a failure to followup on laboratory results and the ensuing treatment (Dwyer, 2012) All of these hospitals are well known and considered high-performing hospitals (*US News & World Report,* 2012).

These very public reports of fatal medical errors resulting from medical management impact the legitimacy of hospitals in providing safe patient care. Legitimacy, or the perception of legitimacy, is the "social acceptability and credibility" (Scott, Ruef, Mendel, & Caronna, 2000, p. 239) hospitals need if they are to appear as if they are doing everything they can to identify, understand, and prevent adverse events. Public reports of patient death caused by medical management erode legitimacy, internally and externally, both within the hospital in which the event occurred as well as within other hospitals. As a society, we are aware that patient harm from medical management can occur, but we assume that all hospitals work to minimize patient harm and that these occurrences are rare. However, when we learn that a catastrophic event has occurred at a well-known hospital, our confidence is shaken and questions arise as to what hospitals are doing to prevent these terrible occurrences and seemingly avoidable outcomes.

Various groups measure and publicize patient safety in U.S. hospitals, including the Centers for Medicare and Medicaid Services (CMS), *U.S. News & World Report* (USNWR), Leapfrog, Health Grades, and Consumer Reports. Public reporting can be considered a method to influence hospitals to focus on improving patient safety. The design of professional education that incorporates the concepts of patient safety and performance improvement also represents an external mechanism to address patient safety. Regulatory requirements and accreditation requirements imposed on hospitals are also mechanisms to pressure hospitals to address and improve patient safety.

The IOM's seminal report, *To Err is Human: Building a Safer Health System* (Kohn et al., 2000), summarizes U.S. policy and accreditation efforts to address patient

safety and improve the quality of care for patients. Many of the IOM recommendations are based on the aviation industry's design and enforcement of standards, accident investigation techniques, and incident reporting and performance improvement methods, all of which use the principles of system safety and human factors. A main focus of patient harm from medical management is to learn from errors and to prevent recurrence of these errors or adverse events through a formal reporting system. The IOM report supports a hybrid approach including mandatory and voluntary reporting. Mandatory reporting is recommended to promote accountability focusing on serious adverse events stemming from medical care or intervention, while voluntary reporting is recommended to promote improvement efforts focusing on errors that do not result in harm. The IOM framework attempts to prompt hospitals to identify adverse events and take action to ensure that these events do not recur. The focus on identification and reporting of adverse events forms the basis of many of the regulatory and accreditation requirements to force hospitals to address patient safety.

1.3 Institutional Theory

I applied the sociological concept of institutional conformity to my exploration and analysis of hospital management of adverse events and patient safety. Organizations conform, or become more "homogenized" or similar, by adopting common behaviors and structures (DiMaggio & Powell, 1983). Hospitals may become more similar in structure and function. However, efforts to make hospitals more similar do not represent improvement; rather, such efforts just means that hospitals are becoming more alike.

I investigate the mechanisms of conformity that are demonstrated in hospitals response to patient safety issues or adverse events. Formal and informal constraints guide

hospitals in the development of organizational management structures related to adverse events. Little is known about how hospitals address and interpret the constraints that drive organizational approaches to identification and management of adverse events. Ideally, the management of adverse events promotes learning for the organization which in turn provides the focus for performance improvement opportunities. Identification of the mechanisms of influence that are present in the management of adverse events in hospitals can guide policy and performance improvement discussions to further advances in patient safety.

DiMaggio and Powell (1983) identify three mechanisms that can lead to organizations becoming more similar: coercive constraints, normative constraints, and mimetic constraints. Coercive constraints involve constraints imposed by the external environment such as regulatory or accreditation requirements that may or may not involve sanctions if requirements are not met. Normative constraints are typically associated with professionalism (i.e. striving to "do the right thing") considering common values and ethics. Mimetic constraints involve organizations copying one another, particularly if an organization is thought to be successful. In such cases, other organizations mimic what the organization is doing or what they think the organization is doing. The three mechanisms for conformity can be present individually or two or more forces may influence hospitals simultaneously. In looking at hospital adverse event management programs, I expected to see evidence of coercive, normative, and mimetic constraints. I examined how these constraints of conformity manifest in patient safety outcomes and hospital design and management of adverse event programs, as well as the resultant adverse event data.

Hospitals will conform to various pressures in order to maintain legitimacy. Legitimacy, a loose concept in the literature, is socially constructed and is an assumption that the organization is acting in a desirable manner (Suchman, 1995) or "is doing what it is believed it ought to be doing" (Scheid & Greenley, 1997, p. 404). This idea of legitimacy suggests a path to conformity with organizations mimicking other organizations, leading to imitation of processes. Uncertainty has been identified as a primary driver of imitation (DiMaggio & Powell, 1983). It is easier to mimic the formal structure of organizations that can lead to legitimacy, such as policies but it is more difficult to mimic the informal constraints because they are typically poorly defined and the ways in which the policies are put into practice are unknown.

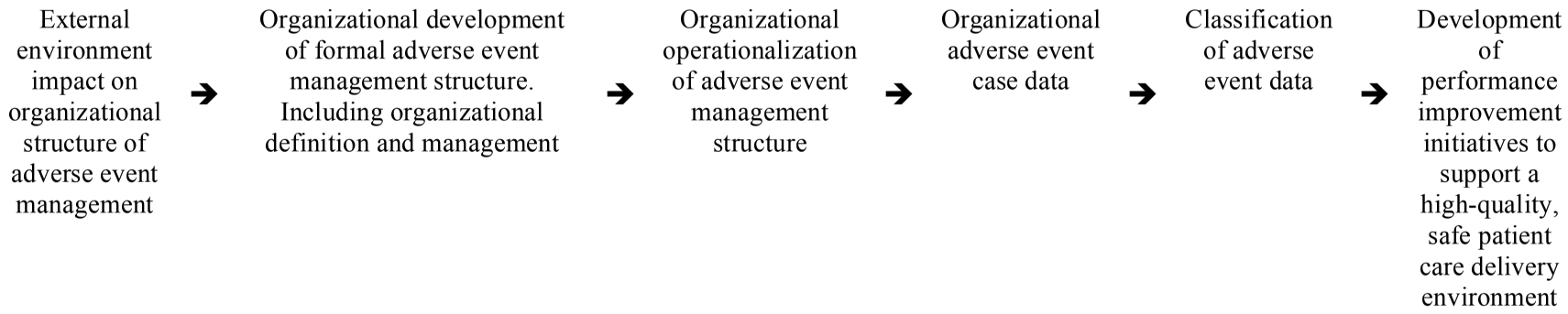
Early work indicates that the mimetic influence related to performance improvement initiatives has not resulted in improved patient outcomes (Dixon-Woods, Bosk, Aveling, Goeschel, & Pronovost, 2011; Chassin, 2013). Normative and mimetic influences were identified as both positive and negative influences in the implementation of infection control initiatives in the intensive care unit setting (Dixon-Woods et al., 2011). All three mechanisms of conformity - coercive, normative, and mimetic - have been linked to adoption of critical care practices in the hospital setting (Campion & Gadd, 2009). In addressing mimetic conformity, Chassin (2013) notes that "one size does not fit all" and suggests that not all improvement initiatives should be replicated. The findings of these studies support the need for further investigation into the manner in which hospitals' interpret various pressures to manage adverse events.

1.4 Conceptual Framework

Organizational structures should include performance improvement principles in the design of adverse event management programs. The cause of adverse events in hospitals is typically complex and can be addressed using a quality improvement framework (Brady, Redmond, Curtis, Fleming, Keenan, Malone, & Sheerin, 2009). Once an adverse event is identified and the case is investigated, the learning resulting from the case can define target areas for focused improvement efforts. Principles of performance improvement should be considerations within the formal and informal management constraints of adverse events (Vogus, Sutcliffe, & Weick, 2010), in order to improve patient safety. Incorporating performance improvement principles of leadership and team development into organizational structures focused on patient safety is a primary mechanism to facilitate change. Figure 1.1 illustrates my conceptual model which incorporates the principles of performance improvement, leadership, and team development.

My dissertation research focuses on the environment and organization levels to investigate the mechanism or mechanisms of influence on adverse event management and patient safety. The decision about what constitutes an adverse event and the identification of these events occurs in large part in the environment level, but the organization level determines how these adverse events are reviewed and managed. Policies developed by the hospitals may reflect external regulatory pressures, but such policies are designed and implemented within organizational constraints and are subject to normative and mimetic pressures.

Figure 1.1: Conceptual model for adverse event management



Performance improvement is a process by which performance can be advanced or enhanced (Juran, 1989) and has been universally adopted by health care providers and organizations to generate change and redesign care delivery (Batalden & Davidoff, 2007; Perla, Provost, & Parry, 2013). The quality improvement (QI) process consists of identified steps (Juran, 1989). First the organization must adopt a methodology or process for performance improvement.[1] Organizations then need to target initiatives for an improvement focus. Adverse events provide opportunities for improvement based on learning from the failures of workflow processes.

Senior leaders are responsible for long-term changes in the functioning of the health care system (Nelson, Batalden, & Godfrey, 2007). For change to occur, leaders must facilitate bringing meaning to the work, create the context of the whole, define possibilities and limitations, create supportive infrastructures for health information and human resources, stay connected, and drive out the fear of change (Nelson et al., 2007). In addition, it is the responsibility of senior leadership to foster positive relations between all levels of the organization, from top management to mid-level management, to frontline staff. It is imperative for senior leadership to support middle management in the implementation of improvement work to negate the impact "that the typical hospital professional bureaucracy structure can have on QI programs" (Balding, 2005, p. 285). The involvement of senior leadership in adverse event management can focus an organization's processes and staff on patient safety improvements.

Teams are a necessary component of the performance improvement process; they are integral to the design and implementation of the improvement initiative. These teams

[1] Common performance improvement methodologies in the health care delivery arena include Six Sigma, Lean, Model for Improvement, and Plan-Do-Study-Act (PDSA).

require training, resources, and motivation for successful improvement efforts (Juran, 1989). Successful performance improvement programs incorporate "a negotiation of working arrangements in the context of established authority relationships" (Finn, Learmonth, & Reedy, 2010, p. 1149) that can cross professional and organizational divisions.

Due to the complex nature of the performance improvement process in organizations it is imperative to look at the organization as a system, or sum of many moving parts. Any problems encountered in the organization ends up crossing multiple groups or divisions (Hackman & Wageman, 1995). Successful patient safety and improvement work requires adoption at multiple levels of the hospital and integration into the daily workflow of multidisciplinary teams.

1.5 Multilevel Research Organizing Framework

Four levels of change that have been identified with successful improvement work are the environment, organization, microsystem, and individual (Ferlie & Shortell, 2001). Assessment of all four levels is necessary to understand and improve the quality and safety of health care delivery and offers the greatest potential for change (Ferlie & Shortell, 2001). I employed a multilevel framework for my dissertation research to investigate the mechanisms of constraint that influence management of adverse events and patient safety in the hospital, including the interdependencies among the various levels. The interdependency between levels can identify responses to pressures and opportunities to promote improvements in patient care, inform policy discussions, and future research. The multilevel focus presents a more robust analysis of how hospitals improve patient safety based on identified adverse events and the motivators for this

work. Applying the multilevel framework to hospital adverse event management distinguishes between the system and the actors within the system (Geels, 2004) and can better identify the mechanisms of influence that affect organizational management of adverse events.

Figure 1.2 illustrates my organizing framework, which embodies the four levels of change model (Ferlie & Shortell, 2001). This graphic, modeled on the Reid, Compton, Grossman, and Fanjiang (2005) design, delineates the "nested" levels of the health care delivery system. The boundaries of each level are represented by a dashed line to reflect the dynamic and complex state of health care delivery. The levels are linked at the top to represent the interdependencies among the four levels.

The four-levels of the model represent the various influences impacting the delivery of patient care. The outermost level, the external environment, comprises all groups that impact the functioning of the organization. The external environment encompasses national bodies, accrediting and licensing agencies, public disclosure of information, payment policies, and the legal system (Ferlie & Shortell, 2001). Federal and state adverse event reporting regulations and The Joint Commission accreditation requirements provide examples of external pressures coercing hospitals to identify and manage adverse events.

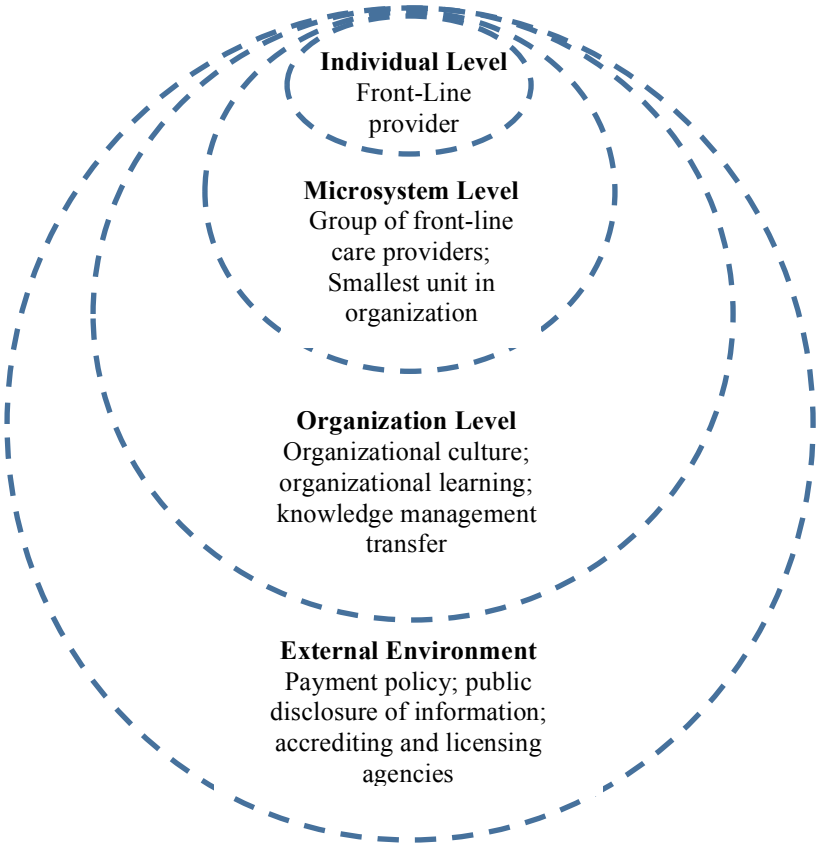


Figure 1.2: Graphic representation of four-levels of change model (Ferlie & Shortell, 2001)

The second level, the organization level, is where the hospital interprets and defines adverse events and designs management structures to address them. It is at the organizational level where formal implementation of a program to promote learning and develop strategies to improve care occurs. At this level the focus is organizational development, organizational culture, organizational learning, and knowledge management transfer (Ferlie & Shortell, 2001). In addition to adverse event management, hospitals design or adopt the framework for a performance improvement program. Organizational management decisions and processes indirectly impact front-line patient

care and resource allocation. The organization's management process for adverse event management provides the framework for leadership and team development.

The microsystem and individual levels are not part of this research study but it is important to recognize the impact of these levels on direct patient care. The microsystem level represents the smallest unit in an organization and includes the core team of health professionals who provide care to patients. The majority of the organizations work occurs at this level and it is the job of the microsystem to standardize care (Nelson et al., 2007; Ferlie & Shortell, 2001) and promote teamwork (Shekelle et al., 2011). Performance improvement work at the microsystem level includes team development; task redesign; clinical audits; and implementation of guidelines, protocols, and pathways (Ferlie & Shortell, 2001) that were designed at the organization level. The individual level represents the individual practitioner on the care delivery team. The focus at this level is to educate individuals; provide data feedback; and implement guidelines, protocols, and pathways (Ferlie & Shortell, 2001). Figure 1.3 represents my dissertation organizing framework including the environment and organization levels.

1.6 External Environment Level Research

The external environment has a tremendous impact on the structure of hospitals by constraining them to conform to regulatory pressures. The first stage of my dissertation research focuses on the external environment and examines adverse event state reporting policy and patient safety. In Chapter 2, I investigate the relationship between states with mandated adverse event reporting and patient safety outcomes.

Although the external environment plays a significant role in improvement efforts in the health care delivery industry, there is scant agreement on the impact of these

external pressures on hospital improvement efforts. Critics cite little pressure from external regulation or market forces to improve the quality of care delivery (Ferlie & Shortell, 2001) while proponents identify external regulation and pressure as driving factors in health care organizations' implementation of improvement efforts (Kaplan, Provost, Froehle, & Margolis, 2011; Devers, Pham, & Liu, 2004).

Mandated reporting of adverse events can be a mechanism to "coerce" hospitals to identify, evaluate, and ultimately improve the quality and safety of patient care. Legal mandates can result in coercive constraints (DiMaggio & Powell 1983) that may force or coerce hospitals to address patient adverse events, thereby impacting hospital operations and structure. However, hospitals are ultimately responsible for patient outcomes through their care delivery processes and management of the multidisciplinary care team (Huesch, 2011).

My research on the potential effects of the external environment examines the influence of state adverse event reporting and the effect on patient safety. In looking at the influence of state adverse event reporting on patient safety, my key objective was to develop a better understanding of institutional improvement efforts resulting from the coercive constraints of regulatory policy and their impact on patient safety. The hypothesis of this research is that state-mandated reporting by hospitals of adverse events has coerced organizations to implement improvement programs that result in higher levels of patient safety.

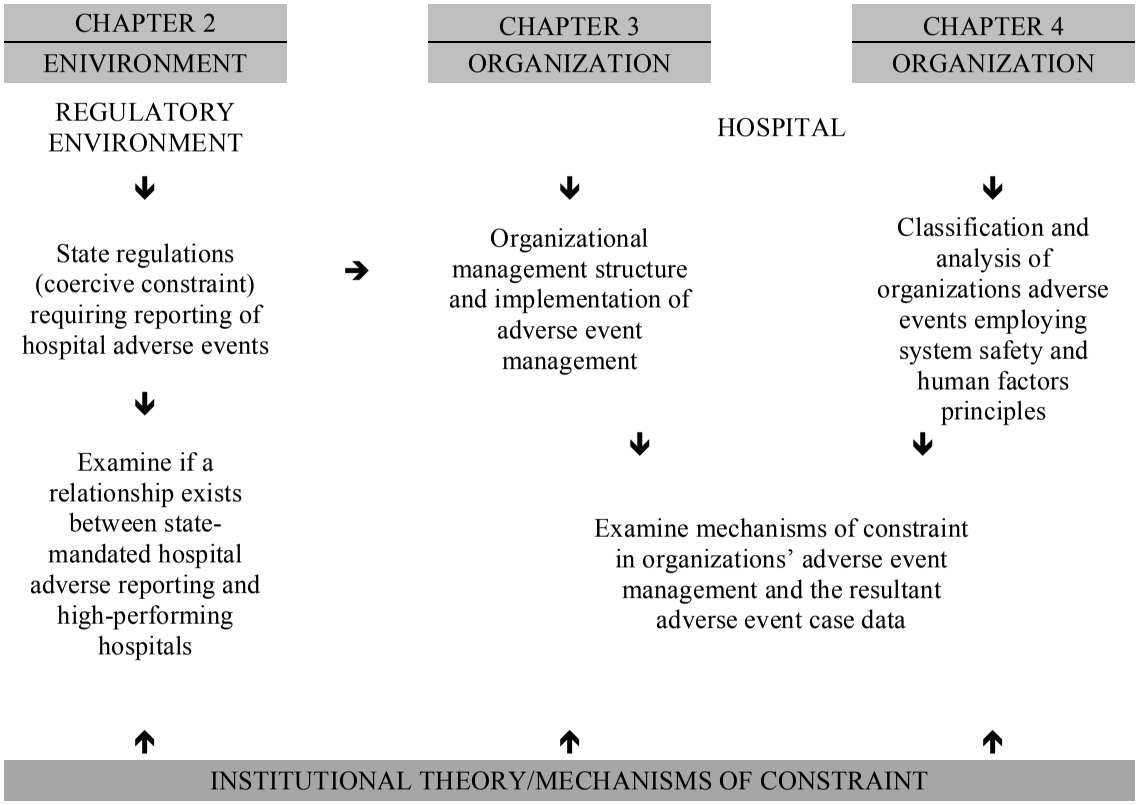


Figure 1.3: Dissertation organizing framework

I use a quasi-experimental, comparative posttest study design to examine the impact of state-mandated adverse event reporting on patient safety scores with hospitals as the unit of analysis. As of 2010, 27 states plus the District of Columbia required mandated reporting of hospital adverse events. The hospital data used for this analysis comes from the USNWR 2012-2013 Best Hospital Rankings. The data includes hospital-specific data for over 700 U.S. teaching hospitals from 49 states and the District of Columbia. The USNWR patient safety score is a composite measure of six indicators of patient safety during and after surgery. In an attempt to recognize internal hospital constraints that could impact the management of patient safety as it relates to the USNWR patient safety score, I include proxy measures to provide institutional context including Magnet accreditation status, surgical volume and percent of surgical admissions.

Magnet accreditation is a proxy for a potential organizational shift towards a multidisciplinary focus for the management of health care delivery. A positive work environment for nurses has been shown to result in improved patient outcomes (Lundstrom, Pugliese, Bartley, Cox, & Guither, 2002; Friese, Lake, Aiken, Silber, & Sochalski, 2008). Surgical volume and percent of surgical admissions are included because higher surgical volume could indicate a more intense focus on surgical processes, if hospitals perform more surgical procedures they should be better at performing the procedures and caring for the patients post-procedure. I expect a positive association between state-mandated event reporting, Magnet accreditation, surgical volume, and the percent of surgical admissions and the patient safety score. An ordered logistic regression is used to estimate factors that influence patient safety scores.

State mandated reporting requirements and the outcome of patient safety scores relate to how hospitals respond to coercive mechanisms, in the form of state regulation, to improve patient safety through adverse event reporting. What remains unknown is how hospitals design and implement programs to manage their patient safety programs. Exploring this phenomenon required investigation at the organization level.

1.7 Organization Level Research

The second stage of my research study focuses on the organization level. The overall research objective for the organization level study is to examine how hospitals manage adverse events within the boundaries of external and internal constraints. At the organization level, the focus is on organizational development, organizational culture, organizational learning, and knowledge management transfer (Ferlie & Shortell, 2001).

Much of the information available regarding adverse event reporting focuses on the reporting of adverse events to external agencies that analyze the data, detect trends, and develop improvement initiatives (Kohn et al., 2000). There has been little focus on how hospitals are managing adverse event programs internally and whether application of the principles of system safety and human factors are being applied at the organizational level. Additionally, if an organization does classify adverse events using the principles of system safety and human factors, do the classifications drive organizational patient safety improvement efforts? From a hospital management perspective there are five phases of patient safety (Kohn et al., 2000):

- identification of adverse events
- understanding of the event
- recommendations for improvement
- implementation of the improvement strategies
- monitoring to ensure sustainability of improvement strategies

My organization level research focuses on hospital adverse event (sentinel event) management structure for the identification and understanding of the sentinel events. I examine how hospitals interpret requirements, or external constraints, to improve patient safety and how this interpretation is implemented within the organizations amid internal constraints. Hospitals may have developed robust adverse event management systems that include performance improvement principles resulting in knowledge transfer, organizational learning, and data that can drive performance improvement initiatives to improve patient safety. Or hospitals may have developed an adverse event management program that is a "mixture of compliance and evasion" (Scheid & Suchman, 2001, p. 106) that focuses adverse event management on legitimacy more than performance.

1.7.1 Organization Research: Original Case Study

My original organization level research was completed at one U.S. hospital. Appendix B outlines the process to secure access to the data as well as approval to use the data through IRB and organizational data committee clearance. Throughout data collection and initial data analysis I was assigned to one representative in the case study organization as my contact. Prior to the defense of my dissertation I met with the organizational representative (different person due to staffing changes) to review the qualitative and quantitative data as well as my theoretical and methodological work and data analysis. The organizational representative cited concerns of anonymity of the organization, analysis of the organizational process, and the results of the taxonomy classifications. Prior to the defense of my dissertation the organization determined the information in Chapter 3 (policy and practice analysis) needed significant revisions with organizational leaders offering to guide me in this work. I declined this offer as my

dissertation committee was already guiding the scholarly work of the dissertation. The organization's leaders and legal counsel determined the sentinel event classification data were proprietary information and could not be publicly shared.

There is no data, quantitative or qualitative, from the original case study research included in this dissertation. The work presented in Chapter 3 and Chapter 4 are extensions of my theoretical and methodological work resulting from the case study. In both Chapter 3 and Chapter 4 I explain the original research methodology for data collection and analysis and extend this methodology to publicly available information in Chapter 3 and present the classification methodology in Chapter 4.

1.7.2 Adverse Event Management

The first study at the organization level of my dissertation research, Chapter 3, focuses on hospital adverse event management structure for sentinel events. The objective of this research is to explore how hospitals identify and understand sentinel events within the boundaries of external and internal constraints. I begin by focusing on organizational identification of sentinel events and the mechanisms of constraint that influence this decision. The following research questions (RQ) guide the inquiry of organizational identification of sentinel events:

- RQ1: What is the definition of sentinel events in each organization?
- RQ2: Who in the organization deems a patient safety occurrence a sentinel event?

I then explored how the organizations understand sentinel events through the formal sentinel event management structure, assessing for mechanisms of external and internal constraints. The following research questions focus on how hospitals understand sentinel events:

- RQ3: What are the hospital processes for sentinel event review?
- RQ4: Does the management of sentinel events include multidisciplinary teams?
- RQ5: Who are the leaders of the sentinel event process?

The data for this study comes from publicly available hospital sentinel event policies to define coercive constraints from the external environment and how they shape sentinel event management. My study is descriptive and explores how hospitals formally describe the process they want to see happen in response to a case of patient harm resulting from medical management.

1.7.3 Adverse Event Data

The second study at the organization level, Chapter 4, focuses on hospital sentinel event data and is an extension of my previous chapter. The objective of this research is to generate knowledge about identified sentinel events through classification and analysis. Analysis of adverse events employing human factors classification can delve into the reason for the error instead of focusing on the task or workflow failure itself (Mitchell, Williamson, Molesworth, & Chung, 2014). Mechanisms of constraint in adverse event data are derived from the organizational management structure of adverse events and impact the learning from these events and patient safety improvement initiatives.

I collected and classified sentinel event data using a patient safety taxonomy and analyzed the data to explore trends and mechanisms of influence constraining the classifications. The following research questions are relevant to this level of research:

- RQ1: Can The Joint Commission Patient Safety Taxonomy be applied to sentinel event case data?
- RQ2: What are the classifications of sentinel events?
    - RQ2A: What are the levels of patient harm of sentinel events?

  - RQ2B: What are the types of error contributing to sentinel events?
  - RQ2C: What is the most frequent setting of sentinel events?
  - RQ2D: What are the causes of sentinel events?

- RQ3: Are there influences of constraint detectable in sentinel event classifications?

The case study organization was unable to approve the use of the proprietary classified sentinel event data in my dissertation, hence I present the methodology used to develop my adapted taxonomy, sentinel event data collection and analysis methods.

1.8 Adverse Event Management, Patient Safety, and Public Policy

The purpose of this multilevel study is to build upon existing knowledge, as well as to generate new knowledge, regarding the constraints imposed on and by hospitals in regard to adverse events and patient safety. Hospitals may respond to constraints in such a way that adverse events are not addressed in a manner that improves the safety of the patient. Generating knowledge of hospital adverse event management within the boundaries of external and internal constraints can inform stakeholders and policy makers as to how hospitals might be responding to policy initiatives.

The external environment level of study focuses on state level public policy, but the findings can inform federal policy initiatives as well. It is important to consider the linkage between requirements for adverse event management and performance improvement requirements in policy considerations. The findings at the environment level may support more prescriptive policies in the definition or reporting of adverse events.

The findings from my organization level study can have state and federal level implications for public policy. Identification of the mechanisms of influence for adverse event management can inform policy considerations for regulation of adverse event

management and payment policy. Payment strategies can be considered that recognize hospitals for implementing comprehensive system level improvement efforts, based on findings from adverse event data. Professional licensure regulations can be updated to include successful completion and sustainability of performance improvement work related to patient safety. For states with mandated reporting requirements, classification of historical data can be analyzed to identify statewide improvement initiatives.

My dissertation research explores the impact of external and internal constraints of adverse event management with a focus on the pressures and mechanisms driving hospitals to conform to these constraints and the impact on patient safety. Investigating adverse event management within the social context of internal and external constraints can extend knowledge to recognize opportunities for improvement that will result in the delivery of higher quality, safer patient care in the hospital. Expanding the knowledge of organizational approaches to adverse event management may prompt further exploration and testing of regulatory requirements that can hasten the pace of improvement in patient safety.

CHAPTER 2: IMPACT OF STATE MANDATED ADVERSE EVENT REPORTING REQUIREMENTS ON HOSPITAL PATIENT SAFETY

2.1 Introduction

The external environment has a tremendous impact on the structure of hospitals and hospital culture. The external environment level encompasses all groups that impact the functioning of the organization. National bodies, accrediting and licensing agencies, public disclosure of information, payment policy, and the legal system all comprise the external environment (Ferlie & Shortell, 2001). Patient safety, quality improvement, and adverse events continue to be salient topics in the external environment. For the most part, the decision of what constitutes an adverse event and the directive to identify these events occurs in the external environment level. State adverse event reporting policy provides one form of external pressure on hospitals to identify and manage adverse events in their organization and offers an opportunity for hospitals to use this mandate as a driver of patient safety initiatives.

Mandated reporting of adverse events can be a mechanism to "coerce" hospitals to identify, evaluate, and ultimately improve the quality and safety of patient care. Legal mandates can result in coercive conformity (DiMaggio & Powell, 1983) that may force or influence hospitals to address patient adverse events and thereby impact hospital operations and structure. Hospitals are ultimately responsible for patient outcomes through their care delivery processes and management of the multidisciplinary care team (Huesch, 2011). Much of the focus for adverse event reporting has been on data

aggregation for trending purposes, particularly to identify trends in errors and develop evidence-based improvement initiatives. However this focus leaves unanswered the question of the impact of current mandated reporting efforts on patient outcomes. Adverse event identification and reporting mandates impact the organizational processes but it is unclear whether the identification of adverse events prompts improvement initiatives that result in improved patient safety.

This research on the potential effects of the external environment explores the impact of state adverse event reporting and its effect on patient safety. Using a quasi-experimental, comparative post-test study design, I assess hospital reporting of adverse events related to patient safety as a function of state policy regulation. My objective is to develop a better understanding of institutional improvement efforts resulting from regulatory policy and its impact on patient safety.

In this chapter, the first level of my multi-level dissertation study, I review the patient safety, adverse event, and performance improvement literature that led to my research question and hypothesis. Next, I present my study methodology and findings followed by a discussion of these findings, including their limitations, and conclusion.

2.2 Background

The external environment plays a significant role in improvement efforts in the health care delivery industry; however there is virtually no agreement on the impact of these external pressures on hospital improvement efforts. Critics cite little pressure from external regulation or market forces to improve the quality of care delivery (Ferlie & Shortell, 2001), while proponents identify external regulation and pressure as driving factors in the implementation of improvement efforts by health care organizations

(Kaplan et al., 2011; Devers et al., 2004). A possible explanation for this lack of agreement on the influence of external pressures is the dearth of studies to assess the impact of regulation on hospital quality of care (Mukamel, Haeder, & Weimer, 2014). I would expect hospitals in states with adverse event reporting policies to have highly engaged performance improvement programs resulting in better patient safety outcomes. Much of the focus for adverse event reporting is on the aggregation of data to generalize findings but we should still expect a higher level of performance from hospitals in states with regulatory pressures.

Little evidence suggests that environmental pressures from federal and state policy, along with accreditation agencies has had a positive impact on prompting change in hospitals (Wardhani, Utarini, van Dijk, Post, & Groothoff, 2009). The external environment can impose rules and regulations for the organization but it is the actors within the organization who direct implementation of the regulations (Scott et al., 2000). Due to significant accreditation requirements, almost every hospital in the United States has a performance improvement program and has adopted a quality improvement framework.[2]

Institutional theory offers a rich framework to examine adverse event identification and patient safety in hospitals. Institutions are the frameworks guiding interactions between humans and minimize uncertainty in day-to-day life (North, 2006). Institutions have been identified as both formal constraints (rules) and informal constraints (codes of behavior), both of which are the "constraints that human beings

[2] Beginning in the 1990's, The Joint Commission initiated performance improvement *concepts* as part of the accreditation process and in 1996 launched the Sentinel Event initiative**.** Medicare Conditions of Participation also require hospitals to maintain a performance improvement program to qualify for Medicare reimbursement.

impose on themselves" (North, 2006, p.5). Institutions impact the functioning of the organization and addressing adverse events includes both formal and informal constraints. Regulatory mandates require formal constraints but it is the informal constraints, or how the work gets done, that act on the regulation and have the ability to foster transformation within the system.

Institutionalization is the process by which these devised interactions become embedded in social thought and action (Meyer & Rowan, 1977). Colyvas and Jonsson (2011) extend this theory by identifying institutionalization as pertaining to "stickiness or how things become permanent" (p. 30), noting that things can spread without becoming institutionalized. In addition, these researchers note that, while concepts can be adopted, the actual function may not be implemented in a way in which the work was intended.

Since hospitals have formally institutionalized performance improvement programs in response to external requirements, one would expect a fairly high number of hospitals to provide high-quality, safe patient care. What remains unknown is how hospitals activate these improvement programs and how the improvement work gets done in response to patient safety events. To continue attracting patients, hospitals must be perceived to provide safe patient care. To address this perception or "social acceptability and credibility" (Scott et al., 2000, p. 239), hospitals need to appear as if they are doing everything they can to identify, understand, and prevent adverse events from happening. In other words, hospitals need legitimacy in their efforts to manage adverse events.

For hospitals, legitimacy constraints can include recognizing and reporting adverse events, in addition to adopting a framework of improvement, but not necessarily implementing improvement work as it is intended. When something is institutionalized, it

must be based on legitimacy and reproduction (Colyvas & Jonsson, 2011). Coercive measures, such as adverse event reporting, can be the first step to improving patient safety, but the practice needs to be implemented and reproduced throughout the organization. Hence, the organization must adopt strategies that ultimately will improve patient safety.

Identified theoretical markers for evaluating institutionalization include patterned activation and reproduction; actual integration into modes of reproduction; the depth and durability of the object that spreads; and feedback that features the higher and lower order links that become mutually reinforcing (Colyvas & Jonsson, 2011). Both formal and informal constraints require a variety of connections at multiple levels of the organization. This chapter aims to extend institutional theory to the regulatory environment by exploring the link between regulatory policy and patient outcomes.

Significant regulatory efforts are in place that attempt to impact care delivery at both the federal and state level. To date, federal patient safety policy initiatives continue to pursue the IOM recommendation to learn from errors and prevent recurrence of these errors through formal reporting systems (Kohn et al., 2000). The Patient Safety Organization Act of 2005 required the development of Patient Safety Organizations (PSOs) which would collect, aggregate, and analyze data related to patient safety and adverse occurrences. Today, there are 81 registered PSOs in 30 states and the District of Columbia (Agency for Healthcare Research and Quality (AHRQ), Patient Safety Organization Program, 2014) and PSOs are still being recruited. (U.S. Government Accountability Office, 2010). However, a mandate for health care organizations to submit their adverse event data to the PSOs does not exist.

While there have been no results of this federal policy initiative to date, AHRQ continues developing data collection and analytical tools (U.S. Government Accountability Office, 2010) and has developed the *Common Formats* to standardize data collection for reporting of adverse events including incidents, near misses, and unsafe conditions (AHRQ, Patient Safety Organization Program, 2014). Policy efforts continue to focus on the reporting and trending of adverse event data. Provisions in the 2010 Patient Protection and Affordable Care Act (ACA) require health insurance exchange plans to enter into contracts with hospitals that report adverse events to a PSO (Patient Protection and Affordable Care Act of 2010).

State health policy efforts also focus on reporting of adverse events in efforts to improve patient safety. As of 2010 27 states plus the District of Columbia require mandatory reporting of hospital adverse events (West, Eng, Lyda-McDonald, & McCall, 2011). The first states to require mandatory reporting of hospital adverse events were South Carolina in 1976 followed by Massachusetts in 1980 and New York in 1985 (U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), 2008). Figure 2.1. presents a graphic display of state adverse event reporting efforts. States with mandatory adverse event reporting are shaded.

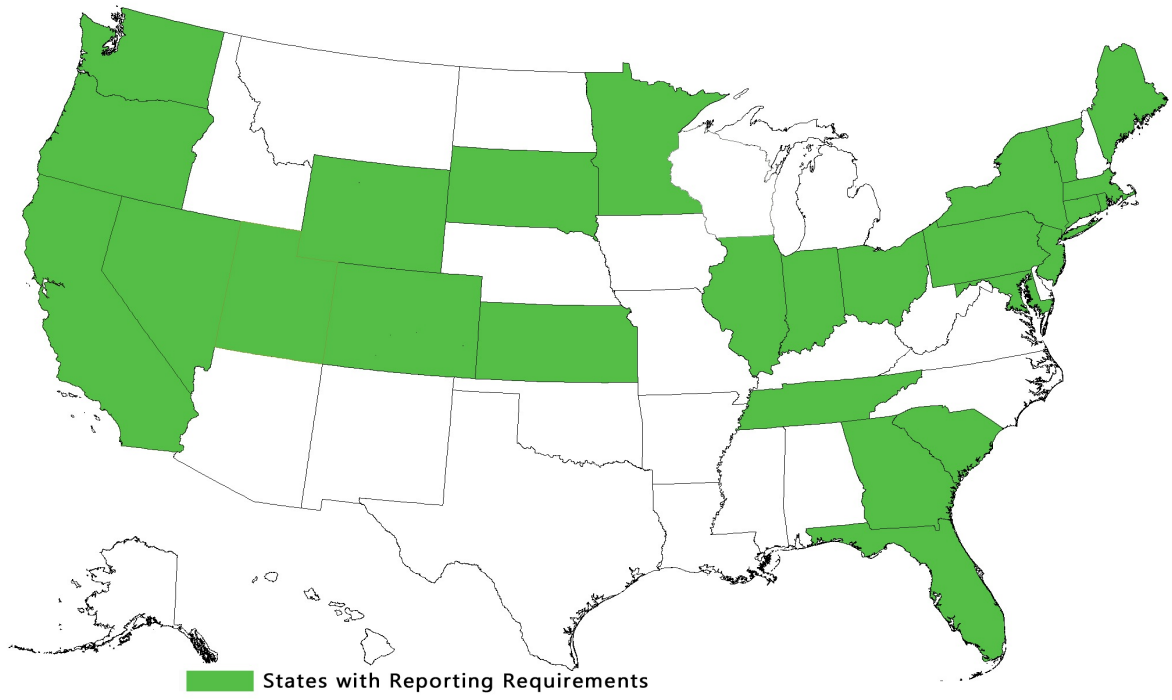


Figure 2.1: U.S. states and adverse event reporting requirements

Each state has implemented an individual reporting structure, with no standardization of reporting requirements. Significant discretion is left to the individual hospital to define the process by which adverse events are examined and decisions are made to report such an event. There is considerable variability between states as to what hospitals are required to report in terms of the event itself, patient name, results from any investigation, or corrective action plans (HHS, OIG, 2008). There is also significant variation in the number of adverse events reported by hospitals to state systems. In 2006 Pennsylvania received 200,000 reports, while South Dakota received 10 (Rosenthal & Takach, 2007). New York State reports receipt of 30,000 reports annually (Fox, Tiedemann, Davis, & Cantor, 2004). The variation in reporting and reporting requirements does not allow for aggregation and analysis of adverse events on a scale

large enough to provide information on patient safety trends and prompt evidence-based quality initiatives. In spite of the degree of variability in approach among state reporting requirements, I argue that the potential effects of mandates can "coerce" hospitals to identify and address known safety issues resulting in safer environments located in states with regulatory reporting requirements.

A lack of common operational definitions of adverse events continues to plague patient safety work and efforts to design adverse event reporting systems. Three states with mandated reporting use the National Quality Forum (NQF) (2006)[3] defined reportable events while 23 states developed their own reportable event list (HHS, OIG, 2008). There has been no advancement of patient safety resulting from state adverse event reporting due in part to the variation in reporting requirements (HHS, OIG, 2008). Other barriers, including the lack of operational definitions, state professional licensure requirements do not keep up with advances in quality and safety work, and lack of leadership by Medicaid as a major stakeholder, diminish mandated adverse event reporting efforts (Rosenthal & Booth, 2005). The lack of consistency in regulatory identification of quality and safety measure perpetuates slow moving patient safety improvement efforts. However, the potential exists for organizations to target patient safety initiatives resulting from regulatory pressure. Adverse event reporting requirements force an organizational focus on patient safety issues. While the measures

[3] The NQF is a not-for-profit organization founded in 1999 as part of recommendations from the *President's Advisory Commission on Consumer Protection and Quality* in the healthcare industry. NQF was established to focus on improving healthcare delivery through developing plans for defining and implementing measures, data collection, and reporting standards. Financial support for the NQF comes from a variety of funders including private sources and the Centers for Medicare & Medicaid Services (CMS) with 34 percent of funding derived from membership dues. NQF membership is comprised of Member Councils - consumer, health plan, provider organization, public/community health agency, purchaser, quality measurement research & improvement, supplier & industry, and health professionals. Only organizations are members of NQF (NQF, 2014).

are different for every state, reporting requirements offer an opportunity for hospitals to develop operations and structures that promote organizational learning and improvement within the hospital.

New York State has one of the most comprehensive and oldest state adverse event reporting systems. State reporting has been found to increase the awareness of adverse events and prompt hospitals to increase the allocation of resources to the task of adverse event identification and reporting. Unfortunately most hospitals are more interested in meeting the reporting requirement than improving care delivery (Fox et al., 2004). One major barrier in the New York state reporting system is the strong link between the adverse event reporting process and the New York Department of Health that manages professional oversight. Adverse events submitted to the state adverse event reporting system include the physician license number and reports submitted to the state can be sent to the New York State Office of Professional Medical Conduct for disciplinary action (Fox et al., 2004). This process perpetuates the view of the adverse event as an individual error and negates a system-focused approach; it also promotes a lack of transparency that can curtail reporting of adverse events. Thus, an organization may be reluctant to identify adverse events that could impact patient safety. The implementation of the regulatory requirement linking the adverse event to professional conduct constrains the hospital adverse event process as a response to state requirements it can also lead to professional sanctions against a physician. This scenario creates uncertainty and may influence hospitals to recognize fewer adverse events as reportable.

Recent work indicates the safety of patient care in the hospital is not affiliated with either political party, with no difference in patient safety when analyzing

congressional districts (Millenson & Morrow, 2014). Table 2.1 displays the top ten safest hospitals and Table 2.2 displays the least safe hospitals by rank, state, congressional district, political party affiliation of the current representative (Millenson & Morrow, 2014) and the state mandated adverse event reporting status. The presence or absence of state mandated reporting requirements does not appear to impact this measure of patient safety with 70 percent of the states with the safest congressional districts requiring reporting of adverse events and 80 percent of the states with the least safe congressional districts requiring reporting of adverse events.

Table 2.1: Safest Congressional Districts (Millenson & Morrow, 2014)

Rank	State	District	Party	State Mandated Adverse Event Reporting Requirements
1	NC	Congressional District 5	R	N
2	MD	Congressional District 3	D	Y
3	GA	Congressional District 6	R	Y
4	OH	Congressional District 1	R	Y
5	VT	Congressional District –At Large	D	Y
6	NC	Congressional District 3	R	N
7	MD	Congressional District 7	D	Y
8	OR	Congressional District 3	D	Y
9	FL	Congressional District 18	D	Y
10	TX	Congressional District 35	D	N

Table 2.2: Least Safe Congressional Districts (Millenson & Morrow, 2014)

Rank	State	District	Party	State Mandated Adverse Event Reporting Requirements
1	NY	Congressional District 5	D	Y
2	TX	Congressional District 27	R	N
3	NV	Congressional District 1	D	Y
4	IN	Congressional District 7	D	Y
5	CA	Congressional District 51	D	Y
6	MI	Congressional District 3	R	N
7	IL	Congressional District 4	D	Y
8	CA	Congressional District 26	D	Y
9	NY	Congressional District 8	D	Y
10	NY	Congressional District 27	R	Y

Ferlie and Shortell (2001) report the *core properties* are necessary for successful improvement work at the environment, organization, and microsystem levels. The complex external environment of health care grapples with distinct care delivery systems, wide-ranging state policies, "wide variability in leadership, culture clashes between cost-containment and QI mindsets as well as between professional groups," and the occasional focus on developing effective health care teams. (Ferlie & Shortell, 2001, p. 302). These challenges continue to pervade regulatory attempts to coerce hospitals to improve care delivery and ensure patient safety. Figure 2.2 illustrates the *core properties*. These core properties challenge the basic performance improvement work in hospitals impacting patient safety. The environment can impose limitations and pressure on organizations as well as the people who make up the organization. Pressures from the external environment can also motivate or provoke the organization and actors within the organization to change (Scott et al., 2000) with regulations that impact both the formal and informal constraints of hospitals.

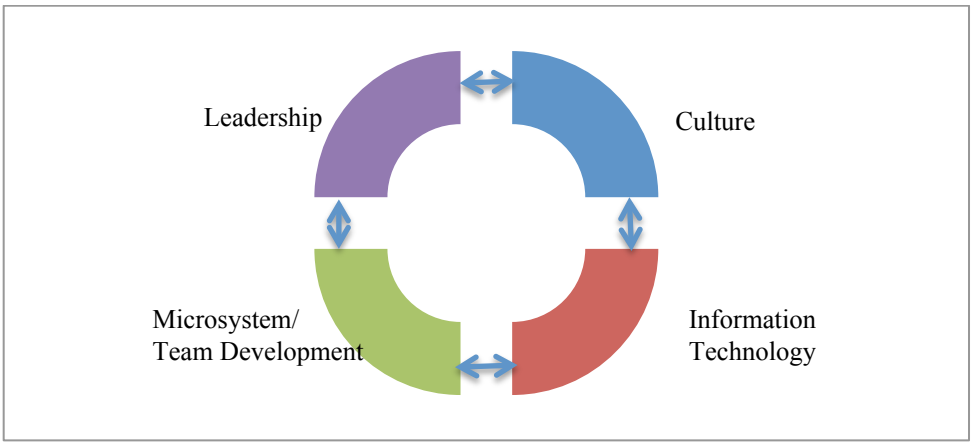


Figure 2.2: Graphic presentation of Ferlie & Shortell's (2001) *core properties*

Mandatory reporting of adverse events can compel hospitals to pursue an open dialogue about patient safety concerns. A performance improvement framework can prompt and support this dialogue as well as provide a framework for change (Brady et al., 2009). In hospitals, the increased reporting of adverse events has been linked to organizations providing safer care (Hutchinson et al., 2009). Identification and organizational learning resulting from adverse events can prompt hospitals to action and focus improvement initiatives to impact the quality and safety of care delivery.

The significant level of requirements for hospitals and performance improvement, coupled with mandated adverse event reporting requirements, should result in a safer patient environment. This study tests the hypothesis of a relationship between patient safety scores and performance improvement work. The hypothesis of this research is that state mandated reporting by hospitals of adverse events has coerced organizations to implement improvement programs that result in higher levels of patient safety.

2.3 Research Design

The following research question is posed for the external environment study: Is there a relationship between states with mandated adverse event reporting and patient safety scores? The objective of this level of research is to determine whether the coercion of mandated reporting impacts hospital patient safety scores. Demonstrating that hospitals in states with mandated reporting of adverse events have higher patient safety scores supports the idea that environmental coercion alters care delivery and improves the quality and safety of patient care in the hospital. Positive findings in relation to mandated reporting of adverse events and higher patient safety scores would support ongoing federal and state policy efforts to implement mandated adverse event reporting.

As mentioned above, I hypothesize that state mandated reporting by hospitals of adverse events has coerced organizations to implement improvement programs that result in higher levels of patient safety. To investigate this hypothesis for the external environment level of research, I use a quasi-experimental, comparative posttest study design with an ordered logistic regression to examine the impact of state mandated adverse event reporting on patient safety scores. Hospitals are the unit of analysis. The independent variables are the presence of state regulations requiring hospitals to report adverse events, Magnet accreditation, surgical volume and the percentage of inpatient surgical admissions. Figure 2.3 presents the comparative posttest design (Royse, Thyer, Padgett, & Logan, 2006) of my study.

$$X \_ \_ O_1$$

$$O_2$$

Figure 2.3: Comparative posttest research study design

The treatment of state mandated adverse event reporting is X, which is the intervention for group O_1, or states with mandated reporting requirements. O_2 is the comparison group, or states with no mandated adverse event reporting requirements. The broken line represents nonrandom assignment.

2.3.1 Data

Public reporting is another type of external pressure being applied to hospitals to coerce improved patient care. The annual USNWR hospital rankings and associated data are one type of public reporting of the quality and safety of patient care. USNWR is a privately owned business that publishes annual hospital rankings in print (for purchase) and online (for free) that are widely available to the public. The patient safety outcome measure I use for this study is the USNWR patient safety score. While the USNWR rankings identify some hospitals as being better than others, there is uncertainty as to whether these hospitals provide a safer environment for patients. Public reporting of quality and patient safety outcomes are important to encouraging the spread of safety practices, that must become routine in hospital care delivery (Leatherman, Hibbard, & McGlynn, 2003) and this observation holds true for improvement work as well.

The USNWR rankings are based on a mix of outcome and process measures, as well as physician reputation scoring. Research supports that hospital leaders, physicians (Rosenthal, Chren, Lasek, & Landefeld, 1996), and consumers value the USNWR hospital rankings (Pope, 2009). An early study of the USNWR hospital rankings found that leaders of ranked hospitals indicate that (1) the ranking information is accurate, (2) awareness of the rankings was high among administrative and physician leadership, and (3) a large number (86 percent) used the rankings in hospital advertising

(Rosenthal et al., 1996). The USNWR hospital rankings have been found to have a significant influence on patient choice of hospital for nonemergent care and have a positive impact on hospital volumes and revenue (Pope, 2009). It is estimated that patients based 15,000 hospital choice decisions on the USNWR rankings over 11 years, resulting in $750 million dollars in revenue for higher ranked hospitals (Pope, 2009). Until there is widespread agreement about measures of quality and patient safety, the USNWR hospital rankings are a valuable input to the dialogue about hospital quality and safety. The simple method of ranking hospitals is easy for people to interpret and understand (Pope, 2009). In addition, the USNWR rankings are widely available with hospital-specific measures available for free on the USNWR website.

The USNWR top-ranked hospitals were found to have lower mortality rates (Chen, Radford, Wang, Marciniak, & Krumholz, 1997; Mulvey et al., 2009) and higher compliance with rates for aspirin therapy and beta-blocker use, which suggests organizational use of treatment guidelines (Chen et al., 1997). The USNWR hospital rankings are limited to teaching hospitals and a greater use of evidence-based treatment is found in teaching hospitals (Allison et al., 2000). These various research findings further the use of USNWR rankings and data as a valid measure of hospital quality and patient safety. Although no studies have focused on the USNWR patient safety score, the validated history of findings related to the USNWR rankings offers strong support for the use of patient safety scores as a well-grounded patient outcome measure that reflects the workings of the organization.

The USNWR data are obtained with permission from the USNWR Best Hospital rankings magazine and online information from the 2012-2013 Best Hospitals Report

(USNWR, 2012) and USNWR Best Hospital Methodology. The hospitals included in this study are those ranked in the USNWR 2012-2013 annual best hospital rankings.

The USNWR Best Hospitals report identifies the top hospitals in the United States in 16 specialties. This hospital ranking is designed as a report card "to help consumers determine which hospitals provide the best care for the most serious or complicated medical conditions and procedures" (Murphy et al., 2012, p.1). Of the 16 specialties, 12 are data driven, with scoring on structure measures, process measures, and outcomes. Hospital reputation alone determines the rank of the remaining four categories of hospitals, with reputation assigned from physician survey responses.[4] This research will include rankings for the 12 specialty areas that are derived mainly from data and exclude the four reputation-only ranked specialties of ophthalmology, psychiatry, rehabilitation, and rheumatology.

The hospitals are graded on a scale of 0 to100, with the score comprised of four factors: reputation, patient survival, patient care, and patient safety. The four factors are weighted differently as follows:

- Survival score – 32.5% - outcome measure
- Reputation score – 32.5% - process measure
- Patient Care score – 30% - structure measure
- Patient Safety score – 5%

While I do not use the USNWR hospital ranking order in this study, I include the ranking information to provide an overview of the categorization of hospital rank. Table 2.1 is an example of the type of publicly available hospital data. There are three levels of rankings for hospitals: *honor roll*, *nationally ranked,* and *high performing*. In order to be named to the *honor roll*, a hospital must rank near the top in six or more specialties. In

[4] For a more detailed description of the USNWR ranking methodology see Appendix A.

the 2012-2013 ranking, 17 hospitals were named to the *honor roll*. Table 2.1 captures the *honor roll* (top-ranked) U.S. hospitals for 2012-2013 as an example of the type of hospital data available. Also included in Table 2.3 is the state adverse event reporting requirements and the patient safety score for each hospital. Of note, only one hospital (Cleveland Clinic) in this group of the top-ranked U.S. hospitals has the highest level patient safety score.

Table 2.3: USNWR 2012-2013 Honor roll hospitals

USNWR Rank	Hospital	State	State Reporting Requirement	USNWR Patient Safety Score Range 1 (lowest) 3 (highest)
1	Massachusetts General Hospital	MA	Yes	2
2	Johns Hopkins Hospital	MD	Yes	1
3	Mayo Clinic	MN	Yes	1
4	Cleveland Clinic	OH	Yes	3
5	Ronald Reagan UCLA Medical Center	CA	Yes	1
6	Barnes-Jewish Hospital/Washington University	MO	No	2
7	New York-Presbyterian University Hospital of Columbia and Cornell	NY	Yes	2
8	Duke University Medical Center	NC	No	2
9	Brigham and Women's Hospital	MA	Yes	2
10	UPMC-University of Pittsburgh Medical Center	PA	Yes	2
11	NYU Langone Medical Center	NY	Yes	2
12	Northwestern Memorial Hospital	IL	Yes	2
13	UCSF Medical Center, San Francisco	CA	Yes	2
14	Mount Sinai Medical Center	NY	Yes	2
15	Hospital of the University of Pennsylvania	PA	Yes	1
16	Indiana University Health, Indianapolis	IN	Yes	2
17	University of Michigan Hospitals and Health Center	MI	No	2

The top 50 hospitals are identified for each of the 16 specialties and are termed *nationally ranked* hospitals. In the 2012-2013 rankings, 148 hospitals met the criteria for inclusion in the *nationally ranked* category. The remaining recognized hospitals are noted to be *high performing* hospitals. In the 2012-2013 ranking, 585 hospitals were recognized as high performing hospitals with 49 states plus the District of Columbia represented. Wyoming is the only state that does not have a 2012-2013 USNWR ranked hospital.

The model for the external environment level study includes one dependent variable - the ranked USNWR patient safety score - that represents the adjusted percentile ranking of the hospital for the number of expected adverse events. The data for the patient safety scores are from the MedPAR[5] files from 2008, 2009, and 2010.

The MedPAR data (administrative claims data) is information extracted from insurance claims data instead of pulled directly from the patient medical record. There is some debate regarding the validity of using administrative claims data for determining quality of care outcomes. Considered limitations are the lack of information on patient risk factors, the inability to identify higher risk patients, and the inclusion of only Medicare patients (Hannan, Racz, Jollis, & Peterson, 1997). Inconsistent operational definitions for postoperative complications have been noted as a cause of discrepancies between administrative claims and clinical documentation (Koch, Li, Hixson, Tang, Philips, & Henderson, 2012). While there are limits, administrative claims data offer a valid yet conservative estimate of hospital quality of care problems (Normand, Wang, & Krumholz, 2007). Furthermore, MedPAR data have been used in multiple research

[5] The Medicare Provider Analysis and Review (MedPAR) File contains data from claims for services provided to beneficiaries admitted to Medicare-certified hospitals. In addition, the records contain detailed accommodation and departmental charge data as well as days of care. The MedPAR File allows researchers to track inpatient history and patterns/outcomes of care over time. Data of death information is appended up to three years after date of discharge.

studies (for example, Ross et al., 2010). Currently, administrative claims data offer a reasonable opportunity to assess patient care because the data include 100 percent of inpatient hospital stays for Medicare beneficiaries and are publicly available.

The USNWR patient safety score is the Patient Safety Indicator (PSI) index code for each hospital. This index is developed for the USNWR hospital rankings and is a composite measure taking a value of 1, 2, or 3.[6] This composite measure is constructed using five of 11 AHRQ PSIs. According to the AHRQ the PSIs are a group of measures that will generate evidence related to adverse events for surgeries and procedures (AHRQ, 2014). The following six PSIs are included in this composite measure (Murphy et al., 2012), along with their definitions (U.S. News & World Report, 2012):

PSI 04: Death among surgical patients with serious treatable complications

PSI 06: Iatrogenic pneumothorax (collapsed lung)

PSI 09: Postoperative hemorrhage or hematoma (major bleeding or bruising after surgery)

PSI 11: Postoperative respiratory failure (breathing trouble or failure after surgery)

PSI 14: Postoperative wound dehiscence (surgical wounds opening unexpectedly after surgery)

PSI 15: Accidental puncture or laceration (unintended injury or harm during surgery)

The USNWR patient safety score provides a useful dependent variable for an analysis of the impact of state policy related to adverse events and patient injury. Patient

[6] The PSI score for each hospital is not available only the ranked scores are available. USNWR uses two adjustments to the data. The first corrects for random variation and the second adjusts for case mix across hospitals. The adjustments are proprietary and not available. (A. Comorrow, personal communication, October 9, 2013).

safety scores offer a measure of effectiveness of overall improvement efforts. The identification of an adverse event should prompt hospitals to investigate the event and develop an improvement plan

The primary independent variable for the external environment level is state mandated reporting of hospital adverse events. Three independent variables are included in the model as control variables that provide context for hospitals: Magnet accreditation status, surgical volume, and the percent of surgical admissions. The Magnet Recognition Program awards accreditation to organizations that promote nursing professionalism. While Magnet accreditation, surgical volume and percentage of surgical procedures does not directly impact surgical PSI, they may be indicators of organizational context related to improvement efforts.

Magnet accreditation is included as a control variable because it may signal a change in organizational culture. The Magnet accreditation variable is a proxy for an organizational shift towards a multidisciplinary focus for the management of health care delivery. A positive work environment for nurses has been shown to result in improved patient outcomes (Lundstrom, Pugliese, Bartley, Cox, & Guither, 2008; Friese et al., 2008). In addition, Magnet accreditation has significantly improved the hospital working environment for nurses and improved the quality of patient care (Aiken, Buchan, Ball, & Rafferty, 2008). The American Nurses Credentialing Center (ANCC) Magnet Recognition Program awards accreditation to organizations that promote nursing professionalism and improve patient outcomes based on patient and nurse-sensitive indicators, such as pressure ulcers and catheter-related infections. (ANCC, 2014). If the promotion of nursing professionalism is formally (accreditation) and informally

(implementation) institutionalized, one would expect a direct positive impact on patient outcomes. I expect a positive relationship between the patient safety scores and Magnet accreditation.

The five PSIs included in the USNWR rankings focus on surgery-related events. Hospitals with a higher number of admissions are associated with lower rates of death for patients with acute myocardial infarction, heart failure, and pneumonia (Ross et al., 2010). This finding suggests that the more experience or volume a hospital has with a certain population the higher the level of quality of care provided. I use two variables to investigate the impact of volume on patient safety: surgical volume and the percent of surgical admissions. Surgical volume is the number of surgical inpatient admissions. The percent of inpatient surgical admissions variable is constructed using the ratio of inpatient surgical admissions and total inpatient admissions. Hospitals with a higher number of surgeries and a larger proportion of inpatient surgical admissions are expected to provide a higher level of safe patient care. I expect a positive relationship between the patient safety scores and the volume and percentage of surgical admissions.

2.3.2 Methods

An ordered logistic regression model is used to analyze the external environment level data using the USNWR rank-ordered patient safety score as the dependent variable. The ordered logistic model allows for prediction of the likelihood that a state without mandated reporting of adverse events belongs to the group with the highest patient safety scores. Ordered logistic regression is used to estimate factors that influence patient safety scores. Analysis was conducted using Stata 13 software (StataCorp., 2013). Table 2.4 summarizes the study variables and coding.

Table 2.4: Summary of research study variables and coding

Dependent Variable	Independent Variable	Control Variables
USNWR Patient Safety Score: 1 = <25th percentile (lowest quality) 2 = 25th-74th percentile (mid-level) 3 = >75th percentile (highest quality)	*State Mandated Reporting of Hospital Adverse Events:* 1 = State Reporting Requirement 0 = No State Reporting Requirement	*Magnet Accreditation:* 1 = Hospital Awarded Magnet Accreditation Status 0 = No Magnet Accreditation *Model I: Inpatient Surgical Admissions:* Ratio of inpatient surgical admissions and total inpatient admissions *Model II: Surgical Volume*: Number of inpatient surgical admissions

The dependent variable for the external environment level of study is patient safety scores. Using the patient safety score as the dependent variable allows an analysis of the impact of state policy related to adverse events and patient injury. The USNWR patient safety score is a composite score of PSI index code for each hospital, which is coded into three groups:

- 1 = <25th percentile (lowest quality); greater number than expected adverse events
- 2 = 25th-74th percentile; expected number of adverse events
- 3 = >75th percentile (highest quality); less than expected number of adverse events.

The major independent variable for the environment level study, state mandated reporting of adverse events, is a binary variable. The independent variable provides the assignment into comparison groups. Hospitals in states with mandated adverse event reporting are assigned a value of 1, while hospitals in states without adverse event reporting are assigned a value of 0.

The Magnet accreditation control variable is also a binary variable providing the assignment into comparison groups. Hospitals with Magnet accreditation are assigned a value of 1, while hospitals without Magnet accreditation are assigned a value of 0.

Two logistic regression models were used to examine surgical volume. In Model I, the percent of inpatient surgical admissions is a continuous variable. This variable is constructed using a ratio of inpatient surgical admissions and the total inpatient admissions per hospital. In Model II, the surgical volume control variable is the number of inpatient surgical admissions to each hospital and is a continuous variable.

2.4 Findings

Of the 712 hospitals in the database meeting inclusion criteria, 670 hospitals had complete data and are included in the analyses. The patient safety score, a range of one through three, has a mean of 2.05. Almost two-thirds of the hospitals included in the analyses (65.5 percent) are located in states with regulatory requirements mandating the reporting of adverse events. Hospitals that achieved Magnet accreditation account for an average of 36 percent of the hospitals. The average hospital inpatient surgical volume is 6,817 cases ranging from 491 to 50,918 cases. The average inpatient surgical admission rate is 31.6 percent for hospitals included in this study. Table 2.5 presents the descriptive statistics for the dataset.

Table 2.5: Descriptive statistics of variables

Variable	# Hospitals	Mean (SD)	Min	Max
Patient Safety	670	2.053 (.679)	1	3
State Mandated Adverse Event Reporting	670	.655 (.476)	0	1
Magnet	670	.360 (.480)	0	1
Accreditation				
Inpatient Surgical Volume	670	6789.02 (5071.37)	491	50918
Percent Surgical Admissions	670	.316 (.132)	.024	1

The patient safety score is a range of one (lowest score) to three (best score) with a mean score of two. Approximately 54 percent of hospitals have a patient safety score of two and experience the expected number of adverse events. Hospitals with the lowest patient safety score account for 20.4 percent of cases, while 26 percent of hospitals have the best patient safety score and experience less than the expected number of adverse events. Table 2.6 presents the distributions of patient safety scores among hospitals.

Table 2.6: Distribution of Patient Safety Score

Patient Safety Score	# Hospitals	% of Hospitals
Low (1)	137	20.4
Mid (2)	360	53.7
High (3)	173	25.8

Two ordered logistic regression analyses were conducted to predict patient safety scores for hospitals using state regulatory requirements for adverse event reporting and

Magnet accreditation, volume of inpatient surgical admissions, and percent of inpatient surgical admissions as predictors. Table 2.7 presents the regression results. The table displays log odds with standard errors in parentheses.

Table 2.7: Ordered logistic regression results

	I. Percent Surgical Admission	II. Surgical Volume
Mandated Reporting	.116	.098
	(.156)	(.157)
Magnet	-.817***	-.660***
	(.162)	(.165)
Percent Surgical Admission	-1.35*	
	(.607)	
Surgical Volume		-.000091***
		(.0000168)
Observations	670	670
Prob >chi^2	0.0000	0.000
Pseudo R^2	0.028	0.048

***p<0.0001
*p<0.05

In Model I, I examined the log odds that hospitals with state mandated adverse event reporting requirements with Magnet accreditation and the association of the percentage of surgical inpatient admissions with the hospital patient safety score. In Model II, I examined the log odds that hospitals with state mandated adverse event reporting requirements with Magnet accreditation and the association of surgical volume and the hospital patient safety score.[7]

Model I was significant (p<0.0001), with two of the three variables significantly related to the patient safety score. Hospitals with Magnet accreditation would expect a

[7] I performed the Brant test on both models to test the proportional odds assumption. Model I did not violate the assumption. Model II was significant and did violate the parallel regression assumption. The surgical volume variable contained one-outlier hospital with 50,918 surgical cases, I reran Model II excluding this outlier and obtained similar results to the original Model II. Based on this finding and the similar regression results for Model I and Model II, I include Model I for discussion.

.817 ($p<0.0001$) decrease in the log odds of having a higher patient safety score. While holding other factors constant there is a significant increase in the probability that a hospital with Magnet accreditation will have a lower patient safety score. Hospitals with a one-unit (100 percentage points) increase in inpatient surgical admissions would expect a 1.35 ($p<0.05$) decrease in the log odds of having a higher patient safety score. There is no association between state mandated adverse event reporting and the patient safety score.

Model II was also significant ($p<0.0001$), with two of the three variables significantly associated with the patient safety score. Hospitals with Magnet accreditation would expect a 0.660 ($p<0.0001$) decrease in the log odds of having a higher patient safety score. While holding other factors constant there is a significant increase in the probability that a hospital with Magnet accreditation will have a lower patient safety score. A higher surgical volume is associated with a .000091 ($p<0.0001$) decrease in the log odds of having a higher patient safety score given that all other variables in the model remain constant. While the relationship is significant, there is little effect. There is no association between state mandated adverse event reporting and patient safety.

Further analyses are undertaken with predicted probabilities[8] using mean percent of inpatient surgical admission rates of 31.6 percent, 10 percent, and 50 percent.[9] Table 2.8 presents these results. The probabilities of this model reveal little variation in the probability of having higher patient safety scores. Hospitals are most likely to have a mid-level patient safety score regardless of adverse event reporting requirements, Magnet

[8]Stata's "prvalue" command is used to calculate the predicted probabilities.
[9] The predicted probabilities were run for both Model I and Model II. Only Model I results are presented; there was little difference between the two models.

accreditation status, and surgical volume or percent of inpatient surgical admission rate. Overall, the predicted probabilities do not show much difference from the original distribution of the patient safety score (see Table 2.6).

Table 2.8: Predicted probabilities for patient safety scores and surgical admission rate

	Average Surgical Admit Rate (31.6%)			10% Surgical Admit Rate			50% Surgical Admit Rate		
	Patient Safety Score			Patient Safety Score			Patient Safety Score		
Hospital Environment	Low	Mid	High	Low	Mid	High	Low	Mid	High
Mandated Adverse Event Reporting with Magnet accreditation	.28	.55	.17	.23	.56	.21	.33	.53	.14
Mandated Adverse Event Reporting with no Magnet accreditation	.15	.54	.32	.11	.50	.38	.18	.55	.26
No mandated adverse event reporting with Magnet accreditation	.31	.54	.15	.25	.56	.20	.36	.52	.12
No mandated adverse event reporting with no Magnet accreditation	.16	.55	.29	.13	.52	.35	.20	.56	.24

Hospitals in states with or without mandated adverse events reporting requirements, an average percent of inpatient surgical admission rate, and with or without Magnet accreditation have a 55 and 54 percent probability of having a mid-range patient safety score which demonstrates no difference when compared to the original distribution of patient safety scores. Hospitals in states with mandated reporting requirements, an average percentage in inpatient surgical admissions, and no Magnet accreditation have a probability of 32 percent for having the highest patient safety scores. This is a greater percentage than the original patient safety score distribution of 25.8 percent of hospitals

with the highest patient safety score. Hospitals in states with mandated reporting requirements plus Magnet accreditation, and an average inpatient surgical admission rate have a probability of 15 percent for having a low patient safety score which is less than the 20.4 percent reported in the original distribution.

As with states with reporting requirements, hospitals in states with no reporting requirements and an average inpatient surgical admission rate have the probability to perform with mid-range scores with (54 percent) or without (55 percent) Magnet accreditation, which is no different than the original distribution of patient safety scores. The predicted probabilities indicate that states with no reporting requirements fare slightly worse in terms of patient safety scores.

Similar to hospitals with the average inpatient surgical admission rate, hospitals with only a 10 percent admission rate in states with mandated adverse events reporting requirements, and with or without Magnet accreditation, have a 50-56 percent probability of having a mid-range patient safety score. Hospitals with a 10 percent inpatient surgical admission rate offer the highest probability of the best patient safety scores. Hospitals in states with mandated reporting requirements, a 10 percent inpatient surgical admission rate, and no Magnet accreditation have a probability of 38 percent for having the highest patient safety scores. This is a greater percentage than the original patient safety score distribution of 25.8 percent of hospitals with the highest patient safety score.

Hospitals with a 50 percent inpatient surgical admission have a probability of the lowest patient safety scores. Consistent with my other findings, hospitals with Magnet accreditation have a probability for having lower patient safety scores even with a higher percentage of inpatient surgical admissions. When compared to the original patient safety

score distribution, hospitals with a 50 percent inpatient surgical admission rate have a higher probability of low patient safety scores when compared to a 10 percent and average inpatient surgical admission rate as well as the original patient safety score distribution. Hospitals with Magnet accreditation in states with and without reporting requirements have a probability of 33 percent and 36 percent respectively, of low patient safety scores. This is also a higher percentage of low scores when compared to the original distribution of 20.4 percent of hospitals with a low patient safety score.

2.5 Discussion

In this chapter, I explore the external environment for the impact of state regulatory policy on publicly reported patient safety scores. I find no relationship between state mandated adverse event reporting and better patient safety scores. Achieving Magnet accreditation status and having a higher volume and higher ratio of inpatient surgical admissions decreases the likelihood of having a higher patient safety score. The results of this study do not support my hypothesis that external pressure in the form of state adverse event reporting policy leads to a higher level of patient safety (as measured by patient safety score) suggesting that regulatory policy to identify and report certain adverse events does not prompt performance improvement efforts that enhance patient safety outcomes.

Limitations of these research findings must be considered. This external environment level research is conducted using only one year of data giving a single point in time perspective of patient safety scores rather than a time series analysis that could reveal improvements in patient safety scores over time. Given the lengthy history of

improvement work in hospitals, I expected a larger number of hospitals to have a better patient safety score.

The USNWR composite patient safety score renders a limited analysis, with a large number of hospitals in the mid-range or performing as expected. Individual hospital scores would offer a more concise analysis using a continuous variable, thus allowing a more robust comparison of scores. Finally, no standardized reporting of adverse events or corrective action plans exists across states. Due to differences in operationalization and implementation of mandated adverse event reporting among states, the precise intervention is unknown. This limitation is true for the states with no mandated reporting requirements as well, allowing hospitals to manage adverse events differently. The lack of precise knowledge as to how hospitals in various states manage adverse events limits the generalizability of the findings of the external environment level research.

In spite of these limitations, this study adds to the literature of regulatory policy impact on performance improvement work and patient safety. Much of the current literature is identified as "anecdotal narrative" (Leatherman et al., 2003). This quantitative analysis of patient outcome measures extends knowledge of the impact of regulatory policy on patient safety outcomes.

The negative relationship of the control variables, Magnet accreditation, inpatient surgical volume, and percentage of inpatient surgical admission rates is surprising. The finding related to Magnet accreditation may be consistent with hospital attempts at legitimization (Scott et al., 2000). In my study, Magnet accreditation provided a proxy for organizational context as the recognition promotes a positive work environment for nurses that have resulted in improved patient outcomes (Lundstrom et al., 2002; Friese et

al., 2008). The negative association of Magnet accreditation and patient safety may implicate the lack of institutionalization of Magnet components. Hospitals may pursue Magnet accreditation in an attempt to look comparable to other hospitals; that is, to look as if they are doing what is required to provide a safe patient environment, which is a sign of mimetic conformity. However Magnet accreditation may be achieved formally without changing the informal constraints of the nursing profession within the organization, thus negating the positive impact on patient safety.

The patient safety outcome score is a composite measure of post-surgical care. Using surgical volume and the percentage of surgical admissions provided the variables focused on surgical and postoperative complications. Surgical care is an appropriate context in the identification and successful management of complications since it is grounded in hospital systems and teamwork (Ghaferi, Birkmeyer, & Dimick, 2009). Intuitively a higher volume or percentage of surgical cases could indicate a higher level of competency and safety due to the frequency of surgical procedures. While early research indicated a relationship between volume and patient outcomes, recent research findings suggest that the "modest rigor" of earlier studies triggers questions concerning the true magnitude and meaning of hospital volume and quality relationships (Halm, Lee, & Chassin, 2002). The negative relationship of surgical volume and the percentage of surgical admissions found in my study supports Auerbach, Landefeld, & Shojania's (2007) findings that suggest surgical volume showed no consistent association with patient death or hospital readmission. While a higher surgical volume and percent of surgical admissions suggests a more intense level of managerial focus, including adverse

event management, my findings do not support this conclusion. Instead, the findings support the need for further research on the impact of volume on patient safety outcomes.

Most hospitals are predicted to have the *expected* number of adverse events. This finding could signal mimetic conformity (DiMaggio & Powell, 1983), with few hospitals having a higher patient safety score. For hospitals to have the expected number of adverse events may be a measure of conformity. Hospitals are performing to the level of other hospitals, no better, no worse, but equal with their peers. There may be no perception of need to move to a better patient safety score. The organization may not be willing to expend the efforts or be able to identify how to decrease the number of adverse event occurrences and there is no incentive to compete with other hospitals. This may be evidence that, once a hospital reaches patient safety levels comparable to the majority of other hospitals (mid-range or as expected), there is minimal effort to attain a higher level of patient safety.

Previous research has shown that hospitals with high baseline CMS Hospital Compare scores continued to perform at the same level over time while low-performing hospitals made the greatest progress in improving outcomes, possibly due to implementation of structural changes that improve scores (e.g., health information technology) and which have a greater impact on outcome measures than taking a QI approach targeting specific patient care measures (Werner & Bradlow, 2010). Hospitals may have taken generalized steps to improve patient safety that conformed to the institution and due to the informal constraints and lack of external pressures, not pursued further improvement in patient safety, thus yielding expected levels of patient safety rather than improved levels.

The impact of regulatory policy on patient safety is consistent with institutional theory that recognizes both formal and informal structures - the rules and the behavior. State regulatory policy requires hospitals to develop formal processes to recognize and report specified adverse events which forces accountability. However, the formal processes may not be implemented in a way that results in an organizational impact on performance improvement work. These findings may indicate that performance improvement as a concept has been institutionalized with formal rules and policies, but is not operationalized in the organization.

Mandated reporting of adverse events may not be enough to trigger all of the theoretical markers of institutionalization (Colyvas & Jonsson, 2011) thus limiting an organization's improvement efforts resulting from identified adverse events. The managerial component of reporting adverse events to state regulatory agencies may allow hospitals to look as if they are doing what is required to protect patients. But the activation and reproduction of actual improvement opportunities as defined by the adverse event process (if any) does not seem to be occurring when looking at patient safety scores. Hospitals may have adopted mechanisms to deal with the formal constraints of adverse event reporting without changing any of the informal rules that drive the day-to-day work and interaction of the health care delivery team. Adverse event management may be viewed as a managerial duty necessary to address the reporting task without addressing the far more difficult task of changing the health care delivery system.

Another consideration is that hospitals may see adverse event reporting as a somewhat ambiguous mandate. Adverse events are defined differently by various accreditation and regulatory agencies and require reporting and/or varied interventions.

Multiple, inconsistent regulatory directives may result in rules that are less clear and lead to "less structuration of activities" (Geels, 2004, p. 913). Organizations may have developed complex, high-level activities to determine *if* patient safety events meet the criteria for reporting (MacPhail, 2010). If this construct is true, managerial attention may be shifted to the reporting decision rather than the improvement process.

Directions for further research are identified from this external environment analysis. Effects of regulatory policy should examine various patient outcome measures because the ultimate goal of adverse event regulation is to improve patient safety. Institutions, both formal and informal, need further study to generate knowledge of improvement work resulting from regulation. In the following chapter of my multi-level dissertation study, I investigate how organizations define and manage identified adverse events.

2.6 Conclusion

Regulatory efforts to improve patient safety can have limited effects. State regulatory mandates requiring hospitals to report adverse events are not associated with higher patient safety scores. Magnet accreditation is highly associated with lower patient safety scores. The volume of surgical cases and the percent of inpatient surgical admissions are negatively associated with patient safety.

This research aims to develop a better understanding of institutional change resulting from regulatory policy and the impact of such change on patient safety. This work includes two forms of external pressure, publicly reported data and regulatory requirements, to coerce hospitals to deliver high-quality, safe patient care. Early adoption of performance improvement work by hospitals may have been motivated by a desire to

improve patient safety but 30 years later these efforts may focus solely on reporting and documenting adverse events rather than using these events to drive safety initiatives. Little is known about how hospitals develop programs to identify and understand adverse events. The next chapter of this dissertation moves to the organizational level and examines how organizations manage adverse events thus offering an opportunity to examine how organization identify and understand adverse event management and the link to improvement work.

CHAPTER 3: ORGANIZATIONAL ADVERSE EVENT MANAGEMENT

3.1. Introduction

Hospitals formally implement programs to improve patient safety and define and develop mechanisms to identify and understand adverse events. Consequently, hospitals represent the organization level in the multilevel organizing framework described by Ferlie and Shortell (2001, Figure 1.2 in Chapter 1).To prompt organizational learning and the transfer of knowledge, the organization defines the framework and mechanisms to identify and understand adverse events. The organization policy for managing adverse events frames the organizational process and prompts the actors in the organization to put the *process* into *practice* to investigate and understand patient harm resulting from medical management and identify opportunities for improvement to enhance patient safety.

The external environment provides a framework in which hospitals must function in relation to adverse events, including federal and state regulations, accrediting bodies, and pressures from similar organizations to perform or act in a certain way. It is within the confines of the structure of the external environment that the organization interprets its own rules and guidelines to identify and understand adverse events. Organizations have significant discretion in how to identify and manage adverse events and little is known about how hospitals formally design programs to manage patient

safety. Hospitals are responsible for patient outcomes through their care delivery processes and management of the multidisciplinary care team (Huesch, 2011) and research continues to indicate that the pace of improvement is slow with limited impact on patient safety (see previous chapter; Barach & Small, 2000). Studies have consistently found little improvement in hospital adverse event rates (Wang et al., 2014) perhaps because there is minimal evidence that defines the best practices for adverse event management. In other words, it is not that hospitals are resistant to efforts to improve, rather they may not know exactly what to do, or how best to limit adverse events. In this chapter, I examine the process of sentinel event management, a subset of adverse events in five hospital policies.

Theoretically, the structure of a hospital adverse event management program prompts action within the organization to learn from past failures and initiate efforts to improve patient safety. However, rather than learning, processes can also be designed in ways that support existing structures and methods that sustain poor performance (Weick & Sutcliffe, 2003). A policy describes how the adverse event review process should work; the practice is how the work really gets done. I am interested in both the process and practice of adverse event management and the mechanisms that influence them.

This chapter explores how five hospitals define and understand its most serious adverse events, sentinel events. My original research study which forms the basis for this work used an exploratory case study research design. The extension of the case study work, captured in this chapter, is applied to several hospitals' sentinel event processes or organizational policies. I assess the opportunity for organizational learning stemming from the management of serious adverse events. My objective is to develop an

understanding of how hospital's identify and understand serious adverse event management and provide empirical evidence of the management structure.

Following the theoretical arguments raised in the previous chapter, one would expect that hospitals would respond to both external pressures arising from legislation or accrediting agencies, as well as internal pressures from both professionals and administrators within the hospital. One would expect that professional groups within the hospitals would have their own expectations and normative beliefs about what constitutes quality care and the "proper" handling of adverse events. External and internal pressures may be aligned, or they may be in conflict. In addition, conflict may exist between professional groups (such as administrators, nurses, and physicians) about the proper way in which to address patient care events resulting from medical management. However no one has examined how hospitals define and develop programs for the management of serious adverse events. This exploratory research offers insight into the *black box* of serious adverse event management at five U.S. hospitals.

In this chapter, which conveys the findings of the second stage of my multi-level dissertation study, I first review the patient safety, performance improvement, and organizational learning literature and discuss the institutional theory that provides the framework for my exploratory research. I then present my study methodology including the original case study research and the current work that extends knowledge gained from the original study. This is followed by the findings and a discussion including limitations and conclusions.

3.2 Background

Adverse events represent a failure or breakdown of processes at some level of the

organization that result in medical mismanagement. Reason (1997), in his Swiss Cheese model, describes the successive "holes" in the work flow process, with an error or mistake passing through the perfectly aligned holes to impact the patient. Figure 3.1 provides a graphic representation of the Swiss Cheese model (Reason, 2000). There are likely multiple patient care scenarios that hit one wall or another in which harm does not reach the patient. Adverse events can arise from complex interactions in the health care delivery system and are the result of many different organizational factors (Reason, 1997), such as multiple caregivers, a variety of workflow processes in one area, and multiple handoffs. To prevent recurrence of these adverse events, it is necessary to investigate and analyze the event to determine and understand the cause.

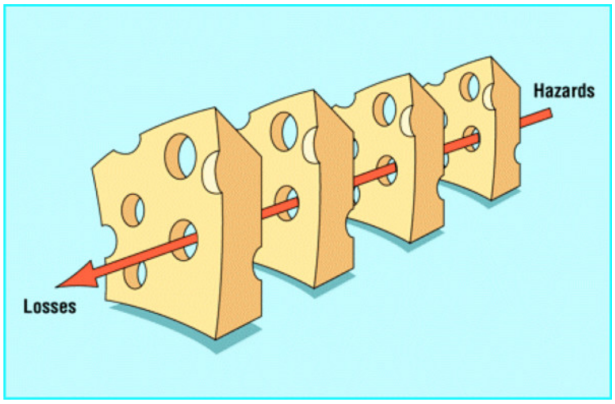


Figure 3.1: "Swiss cheese" model of errors (Source: Reason, J. 2000. Human Errors: Model and management. BMJ, 320, p. 769)

Error management theory recognizes that errors result from both active failures and latent conditions. Active failures are carried out by front-line staff who are in direct contact with the patient. Latent conditions are organizational processes, as well as organizational culture, that can lead to weaknesses in the system that may result in errors

(Reason, 2000). Adverse event management focuses on active failures that have resulted in harm or near-harm to the patient and require retrospective examination. The process of identifying and understanding adverse events can be designed to expose latent conditions in the organization and prompt the performance improvement work required to eradicate or temper such conditions.

Human error is a constant consideration in health care delivery as human variability can result in error and adverse events. Safety science considers both a person-focused and system-focused approach to manage these errors (Reason, 2000). The person-focused approach, typically seen in health care, focuses on individual behavior and unsafe acts with corrective measures targeted at reducing variability in individual practice (Reason, 2000). A system-focused approach views errors as consequences of "recurrent error traps in the workplace and organizational processes that give rise to them" with corrective measures targeted at organizational issues that are the cause of errors (Reason, 2000, p. 768). A system-focused approach is more consistent with the idea that organizations are open systems with interrelationships rather than linear cause and effect chains (Senge, 2006). The focus of the medical profession on individual performance has been found to be a significant barrier to group work (Singer et al., 2009) and can be an obstacle to a system-focused approach to adverse event management. The slow pace of improvements in patient safety work may indicate that hospitals are managing adverse events with a continued focus on individual behavior rather than on the system as a whole. As change is difficult for organizations (North, 1990), both process and practice would need to embrace a system-focused approach to understanding adverse

events that would then inform organizational learning to facilitate performance improvement that would ultimately lead to better patient safety.

Organizational learning is a change in the organization resulting from experience, with the experience happening over time, and is affected by the organization's external environment (Argote & Miron-Spektor, 2011). The basic premises of organizational learning are (1) the tension that arises between assimilating *new* learning (exploration) and applying the learning (exploitation) and (2) intuiting, interpreting, integrating, and institutionalizing which are related to the feed-forward and feedback[10] processes that cross all levels of the organization (Crossan, Lane, & White, 1999). Intuiting is related to personal experience; interpreting is the explanation of insights to others; integrating is the development of shared understanding and coordinated action; and institutionalization is the formalization of processes (e.g. organizational policies) (Crossan et al., 1999).

The basic assumptions of organizational learning are especially relevant to hospital adverse event management in that they allow assessment of knowledge management in the complex hospital organization. Much of the patient safety and health care quality literature identifies and encourages the need for organizational learning (for example see Goh, Chan, & Kuziemsky, 2013), but the literature lacks a discussion of ways in which to impact organizational learning in the hospital setting.

While organizational learning is imperative for improving patient safety and the quality of care, organizational learning is not intuitive (Carroll & Edmondson, 2002). An organizations process can be designed in a way to maximize learning from the experience

[10] Feed-forward and feedback are concurrent processes. Feed-forward is the flow of new ideas and actions from the individual to the organization and feedback is the flow of what has already been learned from the organization to groups and individuals (Crossan et al., 1999).

of adverse events. Organizational learning encompasses the levels of organization, microsystem, and individual (Crossan et al., 1999; Argote & Miron-Spekter, 2011) to ensure formalization of a change in practice resulting in higher quality of care and improved patient safety.

From a hospital management perspective, the first two phases of patient safety work are to identify and understand adverse events (Kohn et al., 2000). For many organizations, this phase is captured in policies that outline the standardized process for management of these events. One of the first considerations in improving patient safety is the organization's structure or formal program for adverse event management. This structure provides the framework for the management of the adverse event process, which implicitly defines the adverse event data and impacts analysis of the organization's adverse events. This includes the organizational definition of what constitutes an adverse event, how, and by whom they are identified, and who in the organization reviews the events and defines the corrective action plans. Not only do organizational structures define what staff is involved, but they also define the level of authority each role can have (Scott et al, 2000). These organizational processes will theoretically influence the organizational learning that will foster change to improve safety.

At the same time, organizational processes are not always positive. The process of adverse event management may be practiced in such a way that it has a negative impact on organizational learning. Weick and Sutcliffe's (2003) study of the organizational management of adverse events at one hospital highlighted the organizational structures that not only allowed continued poor performance but also justified the poor performance both internally and externally. The research identifies these justifications which make it

difficult to learn from adverse events and stop the justified action and easier to confirm the validity of the hazardous actions, thereby allowing unsafe patient care practices to continue.

Hospitals are typically identified as hierarchical or bureaucratic organizations. Hierarchical organizations are associated with predictable operations that are governed by structures and policies. Hierarchical organizations have also been identified as organizations with a lower safety climate (Singer et al., 2009), which can account for limited advances in patient safety. Further, hierarchical organizations have been found to have limited communication and information flow (Singer et al., 2009). Organizations that focus on teamwork and participation (i.e., a group-oriented organization) are found to have better safety climates (Singer et al., 2009). An organization that includes teamwork in the formal process of adverse event management as well as practice can have a positive impact on patient safety.

To explore the organizational management process of identifying and understanding adverse events I employ institutional theory to direct my investigation. Institutions are the frameworks guiding interactions between humans and minimizing uncertainty in day-to-day life (North, 1990). Institutions have been identified as both formal constraints (rules) and informal constraints (codes of behavior), both are "constraints that human beings impose on themselves" (North, 1990, p.5). Institutions impact the functioning of the organization, and their approach to addressing adverse events includes both formal and informal constraints. Such constraints can also be external or internal or both. Policies designed (formal constraints) to promote a structure

for hospital adverse event management can prompt interactions among staff and influence informal constraints within the organization.

3.2.1 Multidisciplinary Teams

Developing effective teams is crucial to patient safety (Leape & Berwick, 2005) and multidisciplinary teams are essential to adverse event management as any problem encountered in the organization will ultimately cross multiple groups or divisions (Hackman & Wageman, 1995). The limited use and general lack of multidisciplinary teams has contributed to the slow pace of improvements in patient safety (Barach & Small, 2000). In the clinical arena the collaborative work required of groups of health care professionals has been cited as the "thin culture of team work" (Wachter & Shojania, 2004, p. 215), which means that individual professionals working with the same patient are not always functioning as a coordinated team. Knowing that challenges to effective teamwork are present in health care, it is especially important to identify barriers to collaboration when developing teams to work together for organizational learning.

It is within multidisciplinary teams that integrating occurs, which is the shared understanding that leads to collective action (Crossan et al., 1999). Shared understanding is imperative for organizational adverse event management. Various professionals and members of the health care delivery team working together allows conversations to take place that capture not only the process of the work but the practice of how the work actually gets done. It is this integration that can prompt a system-focused approach to organizational learning associated with patient harm resulting from medical management. By system-focus, I refer to the organization with all of its complexities and interrelationships. Due to the complex nature of the performance improvement process in

organizations, one must look at the organization as a system, or a sum of many moving parts. Successful patient safety and improvement work requires open discussion among team members and integration into the workflow of multidisciplinary teams.

While multidisciplinary teams are important in a system-focused approach to adverse event management, the composition of the teams may pose challenges for organizational learning. Senge (2006) identifies the need for teams to tap into the insight of all team members to address complex issues. However, it is important to recognize the low status of front line staff in the hospital hierarchy and how this difference in power (Tucker & Edmondson, 2003) can inhibit sharing among the professions, which is required for organizational learning (Carroll & Edmondson, 2002). For multidisciplinary teams to be successful, leaders must understand the dynamic interdependencies of teams within the organization (Carroll & Edmondson, 2002). The combination of effective multidisciplinary teams and enlightened leadership is an important component of adverse event management and organizational learning.

3.2.2 Leadership

Fear of change can be a barrier during the process of understanding adverse events, but leadership can provide the guidance and support teams need to attain organizational learning. Successful organizational learning includes not only senior administrators, but also mid-level managers as well as informal or network leadership (Carroll & Edmondson, 2002). Informal leaders are individuals in the organization that do not have a managerial or leadership title but who exert influence within their network.

Senior leaders are responsible for long-term changes in the functioning of the health care system (Nelson et al., 2007). Senior leadership can streamline initiatives, and

connect all activities to a single purpose. In addition, it is the responsibility of senior leadership to foster positive relations among all levels of the organization, from top management to mid-level management to front line staff. The role of leaders is important in engaging nurses and other staff in improvement work (Draper, Felland, Liebhaber, & Melichar, 2008). It is imperative for senior leadership to support midlevel management in the implementation of improvement work, to negate the impact "that the typical hospital professional bureaucracy structure can have on QI programs" (Balding, 2005, p. 285).

Physician leadership is an important consideration in hospital adverse event management as physicians continue to be in a position of symbolic power (Freidson, 2001) and are increasingly moving into the management of health care systems (Light, 1997). Physicians are often leaders of hospital teams since they maintain significant power in the hospital hierarchy. Within the complexity of today's health care delivery, much of the patient care work or physician driven work is carried out by others (Timmermans & Berg, 2003), such as nurses and pharmacists. If others are more familiar with work that is considered physician work, the front line staff may be experts on the work and the work flow process. This scenario would require physicians to be exemplary leaders and team facilitators to prompt teams to improve patient care.

Nurse leaders are also identified as important to organizational leadership because they have direct impact on patient safety (Armstrong & Laschinger, 2006). Nurses are involved in all levels of care delivery in the hospital, and it is important that they not only be included in adverse event management teams, but also act as team leaders. The importance of nursing leadership has been recognized in improvement work with nurses acting as project managers in the intensive care unit for infection control improvement

initiatives (Dixon-Woods et al., 2011). Bureaucratic organizations need leadership that is able to facilitate groups of professionals working together and help to remove barriers for the team.

There have been indications of problems with improvement work in hospitals that impacts the opportunities for improving patient safety. Multidisciplinary teams and the leadership of these teams are important, but change is difficult in organizations and problematic behaviors may continue (Hackman & Wageman, 1995). Quality improvement programs are not being implemented in a robust fashion and the more difficult yet pivotal components of improvement work are being ignored (Hackman & Wageman, 1995). Leape et al. (2009) cite the bureaucratic hospital structure as the cause of the slow pace of improvement, with its lack of teamwork and inability to develop structures to address patient safety issues in a system-focused framework. Adverse event management processes direct who participates in the adverse event process, potentially setting the stage for teamwork and organizational learning. Adverse event management can be an opportunity for hospitals to integrate performance improvement principles into the workflow to promote learning and improve patient care.

3.2.3 Mechanisms of Influence

Adverse event management in hospitals is constrained or influenced by multiple factors, yet little is known about the organizational interpretation of these influences or constraints on adverse event management. DiMaggio and Powell (1983) identify three mechanisms that can influence organizations: coercive constraints, normative constraints, and mimetic constraints. Coercive constraints involve constraints or rules imposed by the external environment, such as regulatory or accreditation requirements, that may or may

not involve sanctions if requirements are not met. A hospital located in a state with adverse event reporting requirements must consider these requirements in identifying adverse events. The Joint Commission accreditation requirements can impact adverse event management as well. The Joint Commission is recognized as being the most influential force for patient safety programs in hospitals (Small & Barach, 2000; Devers, Pham, & Liu, 2004). Many of The Joint Commission standards focus on leadership in hospitals to create a safety culture and promote change within the organization (Small & Barach, 2002). A focus on leadership from external regulators can create the tension within organizations to drive changes to improve patient safety. Coercive influences are meant to prompt hospitals to improve patient safety. However, some hospitals may interpret coercive regulations in a way that does not promote improvements. The process of adverse event management could appear to address patient safety but be set up in such a way as to continue current practice, thus effecting little to no change in behaviors, as Wiener (2004) states, the goal is to "demonstrate that a system to examine error is in place should the inspectors ask to see it" (p. 87).

Normative constraints are typically associated with professionalism striving to "do the right thing" considering common values and ethics. Normative influences are focused on informal and symbolic measures that hold value within the organization (Scheid & Suchman, 2001). In adverse event management normative influences may dictate who is assigned leadership roles and who in the organization works on adverse events.

Mimetic constraints involve organizations copying one another, particularly if an organization wants to be thought of as being successful. In such cases, other

organizations mimic what a successful organization is doing or what they think it is doing. Within hospitals, major divisions between clinical and managerial operations make implementing improvement efforts difficult (Ferlie & Shortell, 2001), and this clash between professional groups over organizational goals can lead to copying other hospitals to avoid the need to engage in the disruptive process of analyzing competing goals. This "copying" is referred to as mimetic conformity (DiMaggio & Powell, 1983). Normative and mimetic influences can have a positive impact on hospital work and were identified as having a successful effect on the implementation of infection control initiatives in the intensive care unit setting (Dixon-Woods et al., 2011). I expect to see coercive, normative, and mimetic influences present in hospital sentinel event management programs. I will examine how these influences manifest in the hospital process of sentinel event management and explore if one type of influence appears more powerful that the others.

3.3 Research Objectives

3.3.1 Original Research Objective

In the original organization level study, I used an exploratory case study research design to examine how one hospital identifies and understands adverse events. The hospital and the University of North Carolina at Charlotte provided institutional research approval for the original case study.

In my original research I used a combination of qualitative and quantitative information to allow for an in-depth analysis of the organizational process and practice of sentinel event management in one hospital. To capture both the process and practice of sentinel event management, I reviewed organization documents to identify the process of

sentinel event management as outlined in policies and reviewed retrospective sentinel event case data to assess the practice of sentinel event management. I conducted staff interviews to obtain a full understanding of how sentinel event management policies were put into practice and why certain practices occurred.

Using a single case study design allowed for a comprehensive analysis of how the organization interpreted various influences to identify and understand sentinel events. This study design afforded the opportunity to delve into the complex social phenomena (Yin, 2014) of the mechanisms of influence that impact sentinel event management in the high risk, knowledge-driven hospital setting.

The focus of patient safety events caused by medical management in the case study was a subset of adverse events, sentinel events. A sentinel event, as defined by The Joint Commission (The Joint Commission, Sentinel Event Policy, 2014) is:

> … any unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injuries specifically include a loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of serious adverse outcome.

Sentinel events are identified by a large number of hospitals as The Joint Commission accredits approximately 77 percent of U.S. hospitals (The Joint Commission, 2014). Any hospital that is accredited by The Joint Commission must identify sentinel events and perform a root cause analysis for each case. The Joint Commission does not require mandatory reporting of sentinel events but does request that accredited hospitals voluntarily report sentinel events. While The Joint Commission reporting of sentinel events is not mandatory, the accrediting organization continues to put pressure on hospitals to investigate and react to sentinel events.

The Joint Commission has targeted specific sentinel events that it defines as "reviewable," which means that it can evaluate the sentinel event case file if and when it becomes aware of the event or through the routine accreditation process. Examples of "reviewable" sentinel events include unanticipated death or permanent loss of function, suicide, unanticipated death of a full-term infant, surgery on wrong patient, and unintended retention of a foreign object after surgery (The Joint Commission, Sentinel Event Policy, 2014).

If The Joint Commission becomes aware of a "reviewable" sentinel event via the media or family or employee complaint, it may review the management of such an event, and all regulatory requirements need to be met in order for the hospital to maintain The Joint Commission accreditation status. As part of the routine accreditation process, The Joint Commission could ask to review the organization's sentinel event policy, as well as sentinel event case files, to assess compliance with regulatory requirements necessary for accreditation. In response to these accreditation guidelines, hospitals have developed and implemented formal management procedures for sentinel events.

Once a sentinel event is identified within an organization, The Joint Commission "expects" the organization to investigate the sentinel event using a root cause analysis and to develop a corrective action plan within 45 days of the event followed by implementation and monitoring of the action plan to ensure improvement (The Joint Commission, Sentinel Event Policy, 2014). A root cause analysis, a quality improvement tool, is an investigative method to uncover "the fundamental, underlying reason for a problem" (Tague, 2005). A root cause analysis allows the identification of potential causes of the occurrence, the roles and departments involved, and can be performed with

a system-focused approach. Findings from the root cause analysis should drive the performance improvement initiatives.

3.3.2 Extension of Original Research

Being unable to present the original research findings, I applied the theoretical and methodological framework that I developed from the case study to publicly available hospital sentinel event policies. In this phase of the organization level study I use an exploratory research design to examine how hospitals identify and understand sentinel events. I examined the publicly available sentinel event policies of five hospitals. In this chapter I use qualitative information to allow analysis of organizational processes in management of sentinel event identification and understanding. To capture the process of sentinel event management, I reviewed hospital documents to identify the management process as outlined in organizational policies. Applying institutional theory to this exploratory work provides the framework for my research questions then guides the exploration of links and interrelationships in sentinel event management process.

The objective of this research study is to examine how hospitals identify and understand sentinel events. I investigate hospital policies for sentinel event management while exploring the influence of coercive, normative, and mimetic constraints. Policies are hospital documents developed to create "official representations of their activities" (Murphy & Dingwall, 2003, p. 53).

The first focus is on organizational identification of sentinel events. I focus on sentinel events, a subset of adverse events, as they are important organizational events that may include high level administrative involvement. As it is unclear how hospitals manage various adverse events I focus on sentinel events and explore the definition

adopted by hospitals and how sentinel events are managed internally. The review of policies is not to assess compliance with regulations but rather to assess how hospitals map out how they expect to respond to and manage sentinel events. This focus allows me to examine coercive constraints from the external environment that shape hospitals sentinel event management.

Next, I investigate who in the organization has the power to designate adverse events into the category of sentinel event. The roles of decision makers are defined within the internal constraints of the organization and may exhibit normative and mimetic influences. Understanding whom in the organization maintains the authority to elevate an adverse event to a sentinel event may indicate normative constraints within the typically bureaucratic hospital structure.

To capture how the hospitals understand sentinel events, I explore the hospitals management of the sentinel event cases focusing on the process as a prompt to organizational learning and performance improvement. Multidisciplinary teams and how they learn are important factors for performance improvement and should be part of sentinel event management. An organization that structures the management process to include multidisciplinary teams as a function of understanding sentinel events is prompting organizational learning from these occurrences. How these teams are structured is an important consideration as leadership at all levels is important to successful improvement work.

The research questions (RQ) for this organization level of research are presented in two categories: questions that address the identification of the sentinel events and

questions that address the understanding of sentinel events. The first two research questions focus on the how hospitals identify sentinel events;

RQ1: What is the definition of sentinel event in each organization?

RQ2: Who in the organizations deems a patient safety occurrence a sentinel event?

The following research questions focus on the how the hospitals understand sentinel events.

RQ3: What are the hospital processes for sentinel event review?

RQ4: Does the management and analysis of sentinel events include multidisciplinary teams?

RQ5: Who are the leaders of the sentinel event process?

3.4 Research Methods

3.4.1 Original Research: Research Site and Data Collection

My original research study was conducted at one hospital. For a summary of how I obtained permission and access to the original case study site and data, please see Appendix B. To initiate my research study, I conducted three interviews with a representative of the risk management department lasting 30 minutes, 45 minutes, and 60 minutes, respectively. Several interviews were conducted to identify the classification of adverse events that I was interested in studying. This decision proved to be difficult as the organization had a complex adverse event management program. I was referred to organization documents outlining various adverse event management systems within the hospital. I reviewed hospital policies to analyze the formal process for management of adverse events and focused my study on sentinel events. Data were collected from the individual event case files stored in the hospitals' confidential filing system.

Qualitative information for the hospital's sentinel event process and practices were collected from in-depth interviews. I conducted six interviews with the manager responsible for sentinel event management for an average of 50 minutes, with times ranging from 45 to 90 minutes. The interviews were conducted between June 2013 and July 2014. The interviews focused on the processes and practices surrounding identification and understanding of events in the hospital as well as sentinel event case data management. Interviews with the manager were essential in identifying formal and informal practices associated with sentinel event management that are not captured in the hospital documents and policies.

Initially I reviewed the hospital's policy for sentinel event management to analyze the steps involved in the formal process for managing a sentinel event. I then reviewed the sentinel event case files that were stored in the organization's confidential sentinel event filing system to determine whether organizational practice was consistent with organizational process.

3.4.2 Analysis of Publicly Available Sentinel Event Policies

As I am unable to share the findings of my case study research I extend the theoretical and methodological findings developed through my original research to publicly available documents. In order to obtain publicly available hospital sentinel event policies I performed a search of the Internet. Using the "Google" search engine I queried the phrase *hospital sentinel event policies*. The search returned 3,010,000 results. The sample of policies included in this study included five policies that focused on sentinel events and had a hospital name. I then performed another Internet search to verify the hospitals were actual hospitals and located a website for each hospital.

3.5 Findings

3.5.1 Sentinel Events as Defined within the Organizations

I first explored the hospitals definitions of sentinel events. The Joint Commission has defined sentinel events, but notes that this is a basic definition that allows organizations to add to or adapt the definition to the local context. The five policies contain definitions of sentinel events with most adopting The Joint Commission's exact definition of sentinel events as its own.

All of the policies heavily mimic The Joint Commission sentinel event definition. One policy takes The Joint Commission definition and clarifies that events may impact not only patients, but visitors and employees as well. Another policy closely follows The Joint Commission definition and includes consideration of an event as long as it is not a result of the natural cause of illness or underlying medical condition. While policies may not use the exact The Joint Commission definition, the message is consistent, focusing on understanding variance in care delivery that results in serious patient harm, or the potential for serious patient harm. In order to comply with accrediting requirements, all of the hospital policies include adverse events considered by The Joint Commission to be sentinel events. This adherence to accreditation requirements for defining serious events is evidence of coercive influences.

The definition of a sentinel event focuses on patient safety events that result in catastrophic harm to the patient or the recognition that an act could result in catastrophic harm. This definition constrains the organizations to examine only what could be the most devastating patient events should they occur. Events without catastrophic results may not be considered a sentinel event and thus receive less attention within the

organizations. The reliance on identifying and defining sentinel events in accordance with regulatory requirements represents the impact of coercive influences with The Joint Commission definitions driving organizational processes. The five hospital policies conform to accreditation regulations by identifying and defining the most serious patient safety events within the organization in concordance with coercive influences

3.5.2 Designating an Occurrence as a Sentinel Event

The next step I explore is to identify who in the organization is responsible for categorizing a patient safety event as a sentinel event. All of the hospitals have a process in place to identify occurrences that could be considered a sentinel event. Four of the five hospitals require the suspected sentinel event be reported to administration indicating a high level of administrative review within the organization. Table 3.1 presents the processes to designate an occurrence as a sentinel event by hospital.

Each of the sentinel event policies (100 percent) indicates a team of two people within the organization work together to assign the designation of sentinel event status to a patient safety occurrence. The decision to designate a sentinel event occurs at a high level within the leadership of the organization in all of the hospitals. Rooting potential sentinel events to higher levels of administrative review provides legitimacy by demonstrating that the hospitals believe these cases are significant and important for senior leaders to be aware of and address. Table 3.2 presents the roles within the organization that determines if an adverse event is designated as a sentinel event.

Table 3.1: Hospital process to designate occurrences as sentinel events

Hospital A	Hospital B	Hospital C	Hospital D	Hospital E
Suspected Sentinel Event	Suspected Sentinel Event	Suspected Sentinel Event	Suspected Sentinel Event	Suspected Sentinel Event
↓	↓	↓	↓	↓
Report to Administration	Report to Physician and Risk Management	Report to Administration	Report to Administration, Quality Management, Risk Management	Report to Administration and Physician
↓	↓	↓	↓	↓
Administration and Quality Management determine if sentinel event	Physician and Risk Management determine if sentinel event	Administration and Physician determine if sentinel event	Administration and Physician determine if sentinel event	Administration and Physician determine if sentinel event

Table 3.2: Organizational roles responsible for designating sentinel events

Hospital A	Hospital B	Hospital C	Hospital D	Hospital E
Administration	Physician	Administration	Administration	Administration
Quality Management	Risk Management	Physician	Physician	Physician

Hospital administrators and physician leaders are the most consistent roles in sentinel event designation with 80 percent of the policies including an administrator on the team and 80 percent of the policies including a physician leader on the team. I categorized as physicians any titles that included physician, medical director, chair, or chief.

The most common team combination identified in the hospital polices to designate a sentinel event pairs an administrator with a physician leader (60 percent). Representatives from Quality Management (20 percent) and Risk Management (20 percent) are included in one policy each. I categorized as Quality Management any titles that include the word quality (excluding physicians). I categorized Risk Management any titles that included risk management or legal counsel. The Quality Management representative is paired with an administrator in one policy and Risk Management is paired with a physician leader at another hospital. The pairing of physicians and administrators may indicate health care organizations are moving towards more collegial relationships between the business side and the clinical side of health care. This pairing could indicate both normative and mimetic influences in sentinel event management. Table 3.3 presents a descriptive summary of hospital teams designating sentinel events.

Table 3.3: Hospital teams assigning sentinel event status within hospitals

Hospital Teams Include:	# Teams	% Teams
Hospital Administrator	4/5	80
Hospital Administrator plus Physician leader	3/5	60
Quality Management	1/5	20
Risk Management	1/5	20

3.5.3 Organizational processes for sentinel event review

Next I explored the review process of sentinel event management as outlined in the hospital policies. Once an occurrence is deemed a sentinel event, a team is convened to complete the root cause analysis and corrective action plan at all five hospitals. All of the hospital policies require a root cause analysis to be completed for every sentinel event. However none of the policies indicates use of a specific root cause analysis document. The Joint Commission has created a document titled the "root cause analysis and action plan framework template" which is publicly available on their website for organizations to download and use. Providing a document to guide organizations root cause analysis process is a coercive mechanism to influence hospitals to investigate sentinel events using a standardized framework and guideline to determine system-focused causes of the events.

Sentinel events are reviewed at several levels within the organizations by different teams. The first group designates the occurrence a sentinel event. A second group, the root cause analysis team investigates the event and develops a corrective action plan. In two hospitals, a third team assesses the sentinel event review and corrective action plan and approves or changes the work done by the second team. In two of the hospitals committees can accept, modify, or decline the work done by the root cause analysis team.

In most of the policies it is not identified who is the hospital administration representative in the sentinel event management process. Only one of the policies indicate nursing leadership may be involved in the high-level decision making or management of sentinel events. The policies as written indicate responsibility for sentinel events and the reporting structure is influenced by normative constraints. In most of these organizations, physicians are assuming responsibility for patient safety events that are typically the result of problems within the system and are not just related to physician treatment. The processes do not indicate that nursing executives take a senior leadership role, even though nurses provide the majority of care to patients in the hospital (Needleman & Hassmiller, 2009) and direct physicians in the management of patients (Smith, Pope, Goodwin, & Mort, 2008). Normative constraints influence physician leadership as well as nursing non-leadership roles. Physician and administrative involvement at these organizations can also suggest mimetic conformity in addition to normative conformity, with physicians taking responsibility for managing sentinel events due to signals that are interpreted as indications most other hospitals manage their most serious patient safety issues in the same way. Table 3.4 presents the hospital processes for sentinel event management.

Table 3.4: Organizational processes for sentinel event management

Hospital A	Hospital B	Hospital C	Hospital D	Hospital E
Suspected Sentinel Event	Suspected Sentinel Event	Suspected Sentinel Event	Suspected Sentinel Event	Suspected Sentinel Event
↓	↓	↓	↓	↓
Report to Administration	Report to Physician and Risk Management	Report to Administration	Report to Administration, Quality Management, Risk Management	Report to Administration and Physician
↓	↓	↓	↓	↓
Administration and Quality Management determine if sentinel event	Physician and Risk Management determine if sentinel event	Administration and Physician determine if sentinel event	Administration and Physician determine if sentinel event	Administration and Physician determine if sentinel event
↓	↓	↓	↓	↓
Team conducts root cause analysis with corrective action plan	Team conducts root cause analysis with corrective action plan	Quality Management coordinates root cause analysis	Team conducts a root cause analysis with corrective action plan	Team conducts root cause analysis with corrective action plan
↓	↓	↓	↓	↓
Follow up and corrective actions continue until team satisfied there is resolution	Root cause analysis team assigns responsibilities for action plan steps & timeline for completion	Completed root cause analysis presented to Administration	Administration reviews and can accept or modify the action plan or request further review	Root cause assigns recommendations for responsibility for implementation of changes, ongoing monitoring, & timeline
	↓			↓
	Root cause analysis team evaluates effectiveness of the completed action plan			Recommendations presented to physician group
	↓			↓
	Root cause analysis documents & plan reviewed by Risk Management, Physician			Physician group can accept or decline findings and action plan

Normative constraints are apparent in the administrative review process practiced by the organizations with physicians involved in all stages of the sentinel event management processes. Mimetic influences could impact the decision to review sentinel event cases at high levels of administration, as the organizations may understand that sentinel event cases should be recognized as important and believes that this is what other hospitals are doing. Routing sentinel events to higher levels of administrative review provides legitimacy by demonstrating that the hospital believes these cases to be significant and appropriate for senior leader review.

There are several considerations for the two hospital policies that have a third team approve the work of the root cause analysis team. If the review team is a higher-level administrative team it may limit the empowerment of the lower ranking team and allow senior administrators to have the highest level of decision-making. Allowing a higher rank team to change the work of a lower level group indicates normative influences and a hierarchical authority structure. While it is unknown if this process is ever practiced, inclusion in organizational policy may lead the root cause analysis teams to limit action plans and recommendations given the potential of the decision to be modified by another group. This interpretation could present an interesting clash between normative influences, with the lower ranking team identifying fewer opportunities for performance improvement and the higher-ranking team identifying fewer cases in an attempt to maintain legitimacy or vice versa.

3.5.4. Multidisciplinary Teams

All five hospitals identify at least two teams to work on sentinel events within the organization. Two hospitals have a third team analyzing the root cause analysis findings

and corrective action plans. Team membership varies across the hospitals. The first team or group to become involved in management of a sentinel event is the team that designates an occurrence as a sentinel event. It appears that a unique root cause analysis team is assigned for each sentinel event and is convened to analyze the sentinel event and develop a corrective action plan. The third team, evident in varying degrees across two of the five hospitals, involved in sentinel event management is the group that reviews the work, including the findings and action plans, as identified by the root cause analysis team. In these two hospitals, the reviewing team can modify decisions or require further work or changes to the corrective action plan. Table 3.5 summarizes the teams involved in sentinel event management by hospital.

Table 3.5: Hospital teams involved in sentinel event management

	Hospital A	Hospital B	Hospital C	Hospital D	Hospital E
Team #1	Administration and Quality Management determine if sentinel event	Physician and Risk Management determine if sentinel event	Administration and Physician determine if sentinel event	Administration and Physician determine if sentinel event	Administration and Physician determine if sentinel event
	↓	↓	↓	↓	↓
Team #2	Team conducts root cause analysis with corrective action plan	Team conducts root cause analysis with corrective action plan	Quality Management coordinates root cause analysis	Team conducts root cause analysis with corrective action plan	Team conducts root cause analysis with corrective action plan
				↓	↓
Team #3				Administration reviews and can accept or modify the action plan or request further review	Physician group can accept or decline findings and action plan

I have previously outlined the team members and function of the first team that designates patient safety occurrences as sentinel events. The second team, the root cause analysis team, is brought together to investigate the sentinel event, complete the root cause analysis, and develop the corrective action plan. The level of importance of this team is significant because the group discussion regarding the sentinel event provides the opportunity for organizational learning and identification of performance improvement initiatives. Table 3.6 presents the representative roles that are considered for root cause analysis team by hospital with a "+" indicating this role is represented on the team.

3.6: Root cause analysis team members, by hospital

	Hospital A	Hospital B	Hospital C	Hospital D
Physicians	+	+		+
Senior Leadership	+		+	+
Midlevel Management	+	+	+	
Staff	+ Involved, Not Involved	+ Involved	+ Involved departments	+
Risk Management		+		+
Quality Management		+		+

Of the five sentinel event policies, four (80 percent) identify the roles that may participate in the root cause analysis. Of the four policies that outline root cause analysis team membership, all four (100 percent) identify multidisciplinary representation. Four of the policies (100 percent) include management representation with three policies (75

percent) including senior leaders and three policies (75 percent) including mid-level managers. I defined senior-level administration as a high-ranking leadership role in the hospital, such as administrators. I categorized mid-level management to include directors or managers. Physicians are included in three (75 percent) of the policies. Table 3.7 presents the descriptive summary of root cause analysis team membership.

Table 3.7: Descriptive summary of root cause analysis participants

Participants	# Participants	% Participants
Management Representatives	4/4	100
Hospital staff	4/4	100
Physicians	3/4	75
Risk Management	2/4	50
Quality Management	2/4	50

All four policies (100 percent) include staff members involved from departments where the sentinel event occurred. For example, if a surgical adverse event involved a nurse and a surgical technician, a nurse and surgical technician could be assigned to the root cause analysis team. Two of the policies (50 percent) specify that staff involved in the sentinel event is involved in the root cause analysis team. One policy (25 percent) notes staff from the involved department participates and one policy (25 percent) includes relevant staff. Both risk management and quality management representatives are included in the root cause analysis teams according to two policies (50 percent).

The use of a multidisciplinary team to understand sentinel events is important to organizational learning. All four hospital's processes incorporate multidisciplinary teams into every sentinel event review. This team design offers opportunities for different professional groups to interact, including front-line and administrative staff. Integrating is

the process of developing shared understanding among individuals and taking coordinated action through mutual adjustment followed by routinization of the action (Crossan et al., 1999). Review of sentinel events, if conducted using a system-focused approach, can allow the root cause analysis team to discuss and examine system issues that contributed to the specific case of medical mismanagement. Integration may be supported if team members are chosen based on their reputation as "team players" (Bunderson & Reagans, 2011), i.e., there may be fewer barriers to *integrating* within a multidisciplinary health care team.

The hierarchical structure of healthcare can significantly impact the integration and interpretation required for managing sentinel events because the "powerful status differences" between professions and individuals can be a barrier to open dialogue and innovation or investigation that promotes organizational learning (Carroll & Edmondson, 2002). It is unknown whether the structures of the root cause analysis teams allow team members to question assumptions about how things are and if there is enough organizational support to examine familiar work routines, both of which are needed for organizational learning. Normative constraints may influence how and whether team members participate in the discussions. If front-line staff is perceived by others, or by themselves, as lower ranking, their input will not receive consideration. The leadership of this working group can provide support and facilitate discussions among team members.

The process of engaging a multidisciplinary team to understand an organization's sentinel events may signal normative and mimetic influences. The process of sentinel event management is supported with empirical data that indicates multidisciplinary teams are convened to review sentinel event cases. Normative influences from the patient safety

pand quality improvement programs may influence the process and practice of multidisciplinary membership on the teams. These hospitals may also be copying the efforts of other hospitals in response to patient safety concerns. If so, this would suggest the presence of mimetic influences.

3.5.5 Leadership

Leadership of the multidisciplinary team is an important consideration for organizational learning. Two of the policies do not indicate who functions as leader of the root cause analysis team. One policy clearly denotes Risk Management as Chair and a physician as Co-Chair of the root cause analysis team. A second policy indicates Quality Management is to coordinate the root cause analysis process, although it is unclear if coordinating is comparable to leading.

Almost all of the teams included high-ranking administrators or powerful actors in the organizations with 75 percent of the teams including a physician, 75 percent of the team including a senior leader, and 75 percent of the teams including a mid-level manager. As previously noted, I defined senior-level administration as a high-ranking leadership role in the hospital, which includes administration and vice presidents. I categorized mid-level management to include managers and department directors. Table 3.8 presents the descriptive summary of organization leadership included on the root cause analysis teams.

Table 3.8: Management participants on root cause analysis teams

Management Participants	# Participants	% Participants
Senior Leader	3/4	75
Mid-level Management	3/4	75
Physicians	3/4	75

There are considerations for the presence of leadership on the root cause analysis teams. Senior leaders could be included on the team or lead the team. Senior leaders may be present to support mid-level managers (Balding, 2005). Normative pressures can influence the decision to include a senior level leader as there may be professional issues that a higher ranking leader needs to manage, or there may be perceived barriers within the team or barriers to designing the corrective action plan that could require intervention by a higher ranking leader

Mid-level managers would not be as high in power status as physicians and senior leaders; however they may be the direct managers of front-line staff. The presence of mid-level managers may deter staff involvement in teams as the perspectives of higher-ranking team members are given greater consideration than the perspective of lower ranking members (Bunderson & Reagans, 2011).

Physician involvement in the root cause analysis process signals a normative influence in the organizations for physicians to act as leaders of clinical issues. A question to consider is if physicians function as leaders in the root cause analysis process or clinical content experts. Since the root cause analysis teams are critical to organizational learning, concerns exist as to whether physician leadership will be able to facilitate open discussions and prompt innovative thinking or alternative explanations. Leadership of the team meetings may be left to a facilitator, but he or she would need

power within the organization and team to facilitate open discussions and prompt innovative thinking or alternative explanations.

Research suggests obstacles with physician leadership and may signal a problem with the functioning of the team. Physicians acting in administrative roles are reticent to use management tools as these challenge professional autonomy (Dixon-Wood et al., 2011). In addition, physicians in leadership roles have been found to circumscribe consideration of alternative practices and limit discussions by restricting agendas (Lawrence, Mauws, Dyck, & Kleysen, 2005). These physician actions may be a mechanism that allows physicians to place professional learning ahead of organizational learning (Waring 2007) or minimize the learning of a process that does not directly impact the physician workflow process. The normative constraints that lead an organization to promote physician leadership of this group can have a negative impact on identifying areas for improvement.

All three mechanisms of influence – coercive, normative, and mimetic - are evident in hospital sentinel event policies and are similar to what I found in my case study. Sentinel event management exhibits significant coercive influences in identifying, managing, and understanding patient harm that results in serious injury. Organizations are consistent in defining serious patient harm events as sentinel events and the need for a root cause analysis in accordance with accreditation requirements. Hospital policies indicate significant normative influences in the identification and understanding of sentinel events. Leadership presence on the sentinel event management teams, primarily physicians and administrators, signal normative and possibly mimetic influences.

Multidisciplinary teams are involved in several levels of the organizations and who is on the team represents both normative and mimetic influences.

3.6. Limitations

The primary limitation of my organization level research is inherent in the exploratory research design, which limits generalizability. However, the additional work extending the original case study supports the generalizability of my theoretical framework. In addition, the analysis of processes that hospitals design to identify and understand sentinel events and the theoretical framing of the methodology bolsters the strength of the research. Review of publicly available documents yields several limitations. Hospital documents available via a public search engine such as Google may not be current or the final documents adopted or in use at the hospitals. The research did not include contextual information for the hospitals such as organizational structure or the level of patient safety provided, leaving the impact of the process of sentinel event management on patient safety unknown for the specific hospitals. The focus on the process or sentinel event policies may not reflect the *practice* of sentinel event management in the various hospitals, the work of sentinel events may differ or vary from the formal policy.

3.7. Discussion

In this chapter, I explore sentinel event management in five hospital policies, focusing on the mechanisms of influence impacting the sentinel event management structure. Sentinel event management is a requirement of The Joint Commission accreditation and is representative of coercive pressures to identify and address severe patient safety occurrences. Categorizing an occurrence as a sentinel event reveals

normative pressures in a hierarchical setting, with the majority of hospitals identifying administration as having the authority to identify if an occurrence is defined as a sentinel event. Examining multidisciplinary groups in sentinel event management, I find strong indications of normative and mimetic influences on how sentinel event management is practiced within hospitals. Organizational policies require that multidisciplinary teams be convened to investigate and analyze each individual sentinel event, with physicians having a significant role in sentinel event work groups. Overall, all three mechanisms of influence - coercive, normative, and mimetic - are evident in hospital management of sentinel events.

This research provides empirical evidence of mechanisms of influence that constrain organizational response to sentinel events. For improvements to occur in the delivery of high quality, safe patient care, it is imperative for organizational learning to occur from the management of sentinel events. Organizations must develop formal constraints for the management of sentinel events to prompt organizational learning to deliver safer patient care.

There are several implications to consider from my research. The potential to report sentinel event cases to an external agency is the principal influence in managing serious adverse events. This finding supports previous research that found that external adverse event reporting requirements constrained hospital management processes of adverse events (MacPhail, 2010). Coercive constraints in the form of accreditation requirements are interpreted as significant constraints by the organizations in identifying and understanding adverse events. Little knowledge is available as to how organizations interpret coercive measures within the context of the organizations' process and practice

of adverse event management. Examining the influences that impact a hospital's definition of sentinel events offers an opportunity to understand how organizations translate coercive measures into action.

Accrediting defined requirements and the potential for external review of sentinel events significantly influences the identification and understanding of sentinel events. My findings suggest that hospitals are focusing on adverse events resulting in catastrophic patient outcomes based on accreditation requirements. This may limit the ability to look at near misses or potential adverse events as organizations expend a significant amount of resources to meet regulatory requirements. It remains unclear whether the current processes have actually improved patient safety.

Lastly, coercive measures may provide the framework for mimetic influences on sentinel event management. Hospitals believe that other hospitals are assigning sentinel events to the highest level of review and allocating the greatest resources to them by adopting The Joint Commission sentinel event rules. Hospitals may assume that other hospitals are doing this with great success and therefore adopt these regulations as the events that receive the most attention in the organization.

The five policies I reviewed focus on The Joint Commission accrediting regulations and I found support for previous research that The Joint Commission is an influential force for patient safety programs in hospitals (Small & Barach, 2002; Devers et al., 2004). Even without mandated reporting requirements, The Joint Commission accreditation requirements coerce hospitals to identify significant events and to follow prescribed standards and rules. Hospitals in states with regulations requiring adverse event reporting, could add a different set of constraining influences on the identification

of adverse events for hospitals subject to state mandated reporting requirements. This investigation demonstrates that external accreditation regulation directly impacts how hospitals develop processes for managing serious adverse events. To have a positive impact on patient safety it is important for hospitals to be able to integrate coercive measures that promote organizational learning. Coercive measures may need to focus on normative influences in relation to patient safety work with professional (physician, nursing, management, etc.) training including multidisciplinary work and leadership training.

Patient safety and performance improvement should not be addressed as separate endeavors. Hospitals need to incorporate the principles of performance improvement into process and practice to improve the quality of care delivery to patients. As these policies indicate, regulatory and accrediting bodies can have a significant impact on the organizational approach to patient safety and resultant improvement initiatives.

My findings, both in my case study and in the review of five hospital policies, reveal that multidisciplinary teams are initiated to work on every identified sentinel event. Even though multidisciplinary teamwork appears important in the organizations, in two hospitals, the work of the root cause analysis team requires approval from what appears to be higher ranking teams, which can change or cancel any of the work done by the root cause analysis team. The threat of someone higher looking at the work and having the ability to change the group's decisions can imply that the frontline staff's input is not important and can be altered. This may have a constraining effect on the work done by lower ranking groups, especially for innovative work. Maintaining the

hierarchical structure within each hospital can inhibit organizational learning and have a detrimental impact on patient safety.

If this disparity were to occur, the higher-ranked actors, such as physicians and administrators, would drive much of the learning that takes place, negating the value of other team members. Since the frontline staff is in direct contact with the patient and other frontline caregivers, they can provide important contributions to the learning process. However, if they do not have an equal voice at meetings, their knowledge or experience does not become part of the organizational learning process. If the non-physician and non-managerial team members do not participate in team discussions, the potential to alter frontline work flow processes is limited because the more powerful decision makers, who are not intimately familiar with the frontline work, are making decisions based on incomplete information. This could result in teams defining formal constraints (process) that do not become the way the work is done (practice) thus limiting improvement opportunities.

Leadership of the root cause analysis teams must be considered. While few of the hospital policies indicate who leads the root cause analysis teams or review teams, leadership must be considered. Constraints on leadership roles in sentinel event management and patient safety may reveal normative influences for physicians to act as leaders of the process and practice. Within these hospitals, physicians are appointed leadership roles with the ability to control the decision to categorize an occurrence as a sentinel event, and modify other groups' work in relation to sentinel events. Limiting senior leadership review to physicians can impede a system-focused approach to evaluating or understanding patient safety issues and allows a single lens interpretation of

sentinel events to be shared with senior leaders of the organization, limiting learning at the highest level of the organization. A single lens view, rather than multiple viewpoints, that include nursing and administrative perspectives, limits organizational opportunities for understanding and change. If other hospitals confine the responsibility for sentinel event management to one professional line, this may be a factor in the limited advances in patient safety and quality of care. This practice limits the exposure of senior leaders to patient safety issues within the organization which can then impact resource allocation for patient safety and improvement initiatives.

If hospitals empower a single professional group to maintain control of sentinel events, this can limit the learning that can be gained from the experience of other groups. Analysis of hospital sentinel event management indicates leadership for clinical patient care is dominated by physicians. Allowing only physician leadership to focus on sentinel events may influence the organization to focus on individual responsibility for medical mismanagement rather than embracing a system-focused approach. This limits input from other groups, which may curtail discussions and innovations that could promote organizational learning and improve patient safety.

While normative pressures influence physician leadership, it is as important, if not more pressing to analyze the normative influences that constrain nursing leadership to an extremely limited role in patient safety management related to sentinel events. Every hospital has a senior nursing leader as part of the administrative leadership team. It is possible the hospital's nursing leaders exert influence on decisions regarding sentinel events, but further investigation is needed. None of the sentinel event policies examined as part of this study indicate that the hospital's nursing leader is involved in the sentinel

event management process. If senior leaders are responsible for the long-range vision and planning for the organization, input from high-ranking nurse leaders can impact organizational level initiatives to improve care, as well as the allocation of staff and money to focus on system-level improvements. If hospital leadership creates support for improvement work within the organization, it is imperative for the highest ranking nurse leader to be involved in sentinel event management to engage in learning at the administrative level and to promote action and learning to others in the organization. A consideration for further investigation is the clash between normative expectations to lead by physicians and not to lead by nurses and the impact on patient safety.

Another consideration of the impact of physician leadership on root cause analysis teams is that the leadership role may allow physicians to put professional learning ahead of organizational learning (Waring, 2007). It may also minimize the learning of a process that does not directly impact physician work. The normative constraint of physician leadership maintains the medical dominance over clinical issues in the hospital in lieu of other professionals and administrators. The organizational culture may dictate that physician leadership is necessary but it may benefit the organizations to expand leadership opportunities for sentinel event management to promote an integrated organizational learning environment that allows different conversations to occur. If the physician leader is not engaging all multidisciplinary team members and does not employ methods of facilitation, the team may not engage in open discussions and questioning of processes and practices. The work of the root cause analysis team can be constrained by normative pressures to recognize the authority of the physician, whether or not he or she is capable of facilitating teamwork. If the process to

identify and understand sentinel events does not include nursing or other clinical disciplines, this can limit the hospitals understanding of sentinel events. Organizations need to consider the development of processes or policies as vehicles for organizational learning to address the complexities involved in sentinel event occurrences.

3.8. Future Research

The inability to share the findings of my original case study underscores the tremendous opportunities available to improve the quality and safety of patient care. There are significant barriers to learning from patient harm resulting from medical management if no one wants to openly discuss the issues. This research highlights the reticence to share findings externally but may be indicative of how adverse and sentinel events are managed within hospitals with limited discussions leading to narrow learning resulting in minimal changes in care delivery. It is important to consider the mechanisms of influence related to limited transparency and the impact on organizational learning, external influences can impact mimetic influences to encourage transparency.

Further research is needed to confirm the influence of normative constraints on hospital management of sentinel events. As additional knowledge is developed, indicators of effective sentinel and adverse event management can be identified to improve patient safety. Future research should include ethnographic studies of the various levels of teams involved in hospital sentinel and adverse event management. The findings of such research could reveal nuances of the normative and mimetic influences that constrain team activities and limit improvements in patient safety. Finally, the process of organizational sentinel event management yields the data that drive patient safety

initiatives. My next research study (Chapter 4) explores methods to categorize sentinel event data using a systems safety and human factors classification taxonomy.

3.9. Conclusion

Hospital sentinel event management structures are essential to prompting organizational learning and performance improvement initiatives, but there is limited knowledge available as to how hospitals design and implement these management structures. This chapter explores sentinel event management in five hospitals to provide a greater understanding of how the occurrences are defined and understood by hospitals and the theoretical influences that guide the process of the management structure. For the sentinel event review process to promote organizational learning, open discussions that include questioning of current processes and practices and the opportunity to test innovative ideas need to occur to improve patient safety.

Coercive, normative, and mimetic influences on sentinel event management in these hospital policies have a significant impact on how the organizations define and identify patient safety occurrences for review and action. The constraining influences directly impact organizational learning and performance improvement and may limit organizational learning. To improve patient safety will require changes in the normative pressure of professionals that will allow a more system-focused approach to patient safety to encourage multidisciplinary learning. As the normative influences shift, hospitals can promote leadership opportunities for other members of the multidisciplinary team. As normative influences expand to include nursing and other care providers, mimetic influences will likely shift to be more inclusive of multidisciplinary input and leadership. This research study contributes to the literature on organizational management of sentinel

events by exploring the constraining influences organizations respond to in the process of sentinel event management

CHAPTER 4: ORGANIZATIONAL SENTINEL EVENT DATA CLASSIFICATION USING A SYSTEM SAFETY AND HUMAN FACTORS TAXONOMY

4.1 Introduction

From a hospital management perspective there are five phases of patient safety: identification of sentinel events, understanding of the event, recommendations for improvement, implementation of the improvement strategies, and monitoring to ensure sustainability of improvement strategies (Kohn et al., 2000). The previous chapter explored the identification and understanding of sentinel events; this chapter explores sentinel event data as a prompt for performance improvement recommendations. The organizational management structure frames the interpretation, expectations, and learning (Weick & Sutcliffe, 2003) from identified failures within the hospital. The sentinel event management structure should not be designed to "justify inadequate performance" (Weick & Sutcliffe, 2003, p. 82) but to advance improvements in the quality of care delivery and patient safety. Sentinel event data, or documented observations, are the information gathered as a function of understanding sentinel events and are important for organizations to attain "knowledge through inquiry, analysis, or summarization" (Provost & Murray, 2011, p. 25) and advance organizational learning and performance improvement work. Alignment of patient safety work and performance improvement work is critical to advance the quality and safety of patient care in the hospital.

This research study focuses on aggregation of sentinel event data at the organization level. The previous chapter exposed the design of the formal management structure of

hospital sentinel event management structure through organizational policies. At this next level of organization study I methodologically explore classification and analysis of sentinel event data to provide direction for performance improvement initiatives.

Opportunities for improved patient safety are strongly associated with the management of serious adverse events or sentinel events. Developing an understanding of an organization's sentinel events comes from reviewing and analyzing the adverse or sentinel event case data. The recommendations for patient safety improvement work depend on how sentinel events are managed within the organization and how they are identified and understood. Analysis of the classification of sentinel event data can prompt a system-focused perspective, which recognizes an open system with multiple interactions and can support improvement of organizational causes for failures rather than focusing on the individual(s) involved in the adverse event. A system-focused approach to improvement efforts offers a more long-range, proactive strategy to improve the quality and safety of patient care and helps streamline improvement efforts in the midst of competing priorities.

Much of the information available regarding adverse events focuses on reporting adverse events to external agencies who plan to analyze the data, detect trends, and develop improvement initiatives (Kohn et al., 2000). Little focus has been given to how hospitals are managing adverse event programs internally and whether application of the principles of system safety and human factors are being applied at the organizational level. Additionally, if an organization did apply classifications of adverse events using the principles of system safety and human factors, it is unknown whether the classifications can drive organizational patient safety improvement efforts.

For my original case study I used an exploratory case study research design, I classified one organization's sentinel events to identify trends and patterns in the data and mechanisms of influence constraining the data. My objective was to develop an understanding of and generate knowledge about organizationally identified sentinel events after classification. Analysis of sentinel events employing human factors classification can uncover the sources of the error instead of focusing on the task or workflow failure itself (Mitchell et al., 2014). Mechanisms of constraint - coercive, normative, and mimetic - apparent in sentinel event data are derived from the organizational management structure of sentinel events and impact the learning from these events as well as the recommendations for patient safety improvement initiatives. In this chapter, an extension of the original case study research, I present the methodology to explore whether the classification of sentinel events can offer a more system-focused approach to organizational learning by aggregating individual case data which can then prompt a more proactive approach to performance initiatives to improve patient safety.

I begin this chapter, the third stage of my multi-level dissertation study, with a review of the adverse event, sentinel event, adverse event classification, and organizational learning literature that provides the framework for my exploratory research. I then present my exploratory methodology and findings for classification and analysis of sentinel event data, followed by a discussion of study limitations and conclusions.

4.2 Background

Little is known about the number or type of adverse events in hospitals, particularly hospitals without state regulatory reporting requirements. One consideration

for the slow pace of improvement in patient safety is hospitals may not be harnessing learning opportunities from their failures such as sentinel events. Learning can occur from these failures by providing a view of actual work processes (Senge, 2006) and can target opportunities for improvement in the complex care delivery system. It is recognized that, to make health care delivery safer for patients, the working environment of frontline staff must be modified to prevent adverse events (Leape, 1997; Reason 2000). Sentinel event data target problem areas in the organization and can prompt changes that impact front-line care delivery.

While the actual number of adverse events is unknown, estimates indicate medical management results in two to four million serious adverse events in the United States each year (James, 2013). Among these, approximately 400,000 result in premature deaths (James, 2013). Many times, adverse events are not recognized or reported as patient safety issues, with hospitals missing up to 90 percent of adverse events (for example see Classen et al., 2011). When identified, medical management in hospitals has been found to result in adverse events in 3.7 percent of admissions (Brennan et al., 1991) to 7.5 percent of admissions (Baker et al., 2004), with half of the adverse events related to surgical procedures (Brennan et al., 1991; Baker et al., 2004). Almost 14 percent of adverse events are fatal (Brennan et al., 1991), and 36.9 percent of adverse events were found to be highly preventable (Baker et al., 2004). Hospital adverse events are most likely to occur in the operating room, patient room, and the emergency department (Leape et al., 1991).

The causes of adverse events, if identified, can be the basis for recommendations for improvement initiatives. The failure to carry out treatment and error in the application

of treatment has been identified as a primary cause of hospital adverse events (Baker et al., 2004). Failure to perform the intended treatment was found to be the cause of 20 percent of adverse events in an intensive care unit (Rothschild et al., 2005). Communication failures in the operating room have been linked to patient safety due to the increase in cognitive load, interruptions in routines, and increased tension during surgical procedures (Lingard et al., 2004). Adverse events continue to be recognized as a salient topic in the clinical and policy literature and the methods by which organizations manage adverse event data can leverage organizational learning to drive improvement efforts. While all hospitals experience adverse events, little meaningful knowledge is available as to how to manage adverse event data to impact organizational learning and reduce the frequency or recurrence of patient harm resulting from medical management.

4.2.1 Sentinel Events

Sentinel events are a type of adverse event and are defined by The Joint Commission as any unexpected occurrence involving death or serious injury or the risk thereof. Serious injuries specifically include a loss or loss of function of a limb (The Joint Commission, Sentinel Event Policy, 2014). The findings in the previous chapter revealed the significance of The Joint Commission's sentinel event requirements in managing sentinel events. The Joint Commission represents an influential force on patient safety programs in hospitals (Small & Barach, 2002; Devers et al., 2004). Sentinel events may be a starting place for organizations to classify events using a system safety and human factor taxonomy. Any hospital that pursues The Joint Commission accreditation must identify and manage sentinel events including a root cause analysis with action plan (The Joint Commission, 2014). If hospitals function in a manner similar to processes outlined

in policies in the previous chapter, there will be a comprehensive multi-level review and approval of the sentinel event designation, indicating an organizational commitment to acknowledging patient safety events resulting from medical management. Collecting and analyzing sentinel event data can allow organizations to capture patterns and trends of care delivery that have resulted in patient harm.

While near misses, errors that did not result in patient harm but represents vulnerability in the system (Kohn et al., 2000), are important to study, there are barriers to collecting near-miss data. As Dixon-Woods (2010) observed, frontline staff are accustomed to "organizational turbulence" and are commonly "engaged in retrieving and rescuing situations that had gone wrong" (p. 12). In an environment that operates in a constant state of response and reaction to daily work flow processes, it is difficult to identify near misses that result in no harm to the patient. On the other hand, coercive influences in the form of The Joint Commission accreditation requirements encourage hospitals to maintain information on sentinel events that can be used as a first step to generating data that drive recommendations for performance improvement initiatives.

Sentinel event reporting is not mandatory, but The Joint Commission aggregates and analyzes the voluntarily submitted sentinel event case data. Since 2012, the most frequent sentinel events reviewed by The Joint Commission are delay in treatment and the surgically related unintended retention of a foreign body and wrong-patient, wrong-site, and wrong-procedure errors (The Joint Commission, 2014). The Joint Commission has identified the top three root causes of sentinel events since 2012 as human factors, leadership, and communication (The Joint Commission, 2014). The Joint Commission

defines human factors to include staffing levels; staffing mix; staff supervision; medical staff credentialing; and rushing, fatigue, and complacency (The Joint Commission, 2014).

Since The Joint Commission is able to aggregate, analyze, and classify sentinel event data from the voluntary information available to them, hospitals can also harness their own information to form the basis for recommendations for system-focused improvement initiatives. Sentinel event data represent the information gathered as a function of understanding sentinel events and is important for organizations to attain "knowledge through inquiry, analysis, or summarization" (Provost & Murray, 2011, p. 25). Sentinel event case information is captured in root cause analysis documents that allow sentinel event data to be aggregated, classified, and analyzed. Sentinel events are a grouping of one type of adverse events primarily those that result in or have a high likelihood of resulting in serious patient harm. Hospitals can aggregate and classify their own data to provide a comprehensive analysis of sentinel events that can inform organizational learning and improvement work.

4.2.2 Classification of Events

A human factors approach, which incorporates error classification based on the models of human performance work, includes three categories: skill-based errors, rule-based mistakes, and knowledge-based mistakes (Rasmussen, 1983). These categories of errors have been widely applied in the analysis of failed outcomes in the high-risk fields of aviation, nuclear power, and railway operations (Reason, 1997), as well as health care delivery (Chang, Schyve, Crouteau, O'Leary, & Loeb, 2005; Rothschild et al., 2005). The delivery of complex health care includes three additional risks related to human errors, the disease process, treatment decisions, and treatment implementation

(Amalberti, Auroy, Berwick, & Barach, 2005). Classification of error types - skill, rule, and knowledge - is especially important to hospital patient safety as it can identify levels of risk and uncover a variety of latent conditions in the organization that can inform recommendations for performance improvement initiatives.

Classification of adverse events allows grouping of the type of event, location of event, involved staff, level of patient harm, and the type and cause of the error. Qualitative systematic analysis of incidents using human factors performance has been applied to the fields of aviation and anesthesia in health care (Barach & Small, 2000). Using a classification system of adverse events can support a more standardized approach to the analysis of adverse event data. The Joint Commission Patient Safety Event Taxonomy[11] is an example of a classification scheme that was developed to collect and organize patient safety data. This system was constructed using several years of sentinel event data voluntarily reported to The Joint Commission (Chang et al., 2005).

The aggregation and classification of data from hospital sentinel events may expose the latent conditions that continue to operate in hospitals and limit improvements in the quality and safety of patient care. The number of hospitals or hospital systems, if any, that classify sentinel events is unknown. Classification of sentinel events can provide a comprehensive, integrated assessment of factors in the organizational environment that are driving patient harm and prompt data driven local improvement efforts and organizational learning to prevent future sentinel events, thus improving patient safety.

[11] The original title of Chang et al.'s 2005 taxonomy was The JCAHO Patient Safety Event Taxonomy. In 2007 The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) changed its name to The Joint Commission (The Joint Commission, 2013). Hereafter I refer to The JCAHO Patient Safety Event Taxonomy as The Joint Commission Patient Safety Event Taxonomy

Classification of adverse events may allow examination of what Senge (2006) identified as organizational interrelationships instead of the assumed cause and effect sequence. Results of the sentinel event classification may prompt a different kind of discussion than simply talking about the individual case with a clinical focus because errors and mistakes can happen during the multiple interactions that occur during routine patient care.

4.2.3 Cause and Types of Errors

The cause and types of errors resulting from medical management and adverse events are important components of organizational learning and analysis of the data must incorporate both a person-focused and system-focused approach (Reason, 2000). The person-focused approach looks at individual behavior with a focus on decreasing the variability in individual behavior. A system-focused approach considers errors as consequences of the system or "recurrent error traps in the workplace and organizational processes that give rise to them" (Reason, 2000, p. 768). A system-focused approach is more consistent with the idea that organizations are open systems with interrelationships rather than linear cause and effect chains (Senge, 2006). The focus of the medical profession on individual performance has been found to be a significant barrier to group work (Singer et al., 2009) and can be an obstacle to a system-focused approach to adverse event management, organizational learning, and performance improvement.

The identification and understanding of adverse events within an organization can highlight both active failures and the contributory latent conditions. Active failures are easier to identify because typically there is an immediate effect or an immediate awareness that something has been done incorrectly or has gone wrong with patient

management. Almost all sentinel events will have an identified active failure. Latent conditions can cause active failures by "promoting errors and violations" (Reason, 1997, p. 11). For example, communication failures have been noted to occur because of poor coordination among the health care delivery team (Tucker, Singer, Hayes, & Falwell, 2008), which is a latent failure that could lead to an active failure. If an organization's process and practice of understanding adverse events is not comprehensive, latent conditions may not be identified.

It is the combination of latent conditions or weaknesses that result in active failures, allowing an adverse event to occur. If the latent conditions are not corrected they will continue to cause patient safety events and patient harm. Aggregating and further identifying the types and causes of adverse events can identify latent conditions in the system that can then be addressed through performance improvement initiatives.

Skill-based errors, also referred to as slips, lapses, or trips, occur during routine tasks that are automated or typically recurrent actions (Reason, 2000). These routine tasks have expected outcomes but in a failure situation, the expected outcome and the actual outcome differ. In the hospital setting, a routine task that is completed incorrectly and results in patient harm, is considered an adverse event. While skill-based errors highlight the individual error, the organizational context of the specific work and work environment must be considered in any adverse event analysis. Research based in a hospital intensive care unit found that 91 percent of adverse events occur during routine care, with 53 percent of the events due to skill-based errors (Rothschild et al., 2005). If over half of the adverse events result from failures in routine tasks, it is imperative to assess the environment in which these tasks occur to examine not only the active failure

but also the latent conditions that can be the cause of the skill-based errors. If hospitals focus only on individual skill-based errors, any multidisciplinary discussion of the event and contributing factors (including latent conditions) that led to the error is limited.

Rule-based mistakes are failures resulting from a familiar situation; that is something that is not typically encountered, but for which there are rules or policies to follow. The mistake is in the application of the rules - either a failure to apply the correct rule or a failure to apply the rule correctly – that results in an adverse event (Reason, 2000). Knowledge-based mistakes are a higher-level error classification and can be impacted by the training and knowledge of the frontline staff. Knowledge-based mistakes occur during times when scenarios unfold, the typical protocols or policies are insufficient, and immediate action is required (Reason, 2000). These can occur during emergent situations when the frontline staff is required to make an immediate decision, possibly based on incorrect or incomplete knowledge and the result is not the intended outcome. Research based in a hospital intensive care unit found that 29 percent of adverse events are due to rule- and knowledge-based mistakes (Rothschild et al., 2005). The rule-based and knowledge-based mistake categories are potentially valuable classifications to consider because they offer the opportunity to identify latent conditions within the organization by looking beyond the frontline staff to the organizational structure or management of a variety of scenarios.

Aggregating and classifying sentinel event data may lead to a better understanding of multidisciplinary interactions by capturing both the active and latent failures. Little empirical information is available to guide patient safety and quality improvement work related to sentinel events. There is even less empirical information

available related to the classification of sentinel events. The original research was designed to fill that gap and provide both theoretical and empirical evidence of sentinel event management in the hospital setting with the methodology presented in this chapter.

4.2.4 Mechanisms of Influence

DiMaggio and Powell (1983) identify three mechanisms that can influence how organizations respond to various influences to improve performance: coercive, normative, and mimetic. Coercive influences involve constraints imposed by the external environment such as regulatory or accreditation requirements. Normative constraints are typically associated with professionalism (i.e. striving to "do the right thing" considering common values and ethics). Mimetic constraints involve organizations copying one another particularly if an organization is thought to be successful. In such cases, other organizations mimic what a successful organization is doing or what they think it is doing. The three mechanisms for conformity can be present individually or several forces may be influencing hospitals at the same time. Consistent with my findings related to the study of organizational identification and understanding of sentinel events (Chapter 3), I expect to see coercive, normative, and mimetic constraints present in hospital sentinel event data. The sentinel event data are a direct outcome of the process and practice of understanding sentinel events, revealing the coercive, normative, and mimetic influences of an organization's sentinel event management structure. I further explore any additional mechanisms of influence apparent in the classification of sentinel event data.

4.3 Research Objective

The objective of my original case study research was to explore one organization's sentinel event data. This work was an extension of the original case study

discussed in the previous chapter, which explored organizational management of identifying and understanding sentinel events. My original analysis focused on aggregated sentinel event data at the organizational level. The hospital and the University of North Carolina at Charlotte provided institutional research approval for the original case study.

Classifying hospital sentinel events offers the opportunity to examine the issues that are important to a hospital's organizational learning. To explore identified sentinel events, I used descriptive, qualitative information to construct an original dataset of sentinel event data. I collected the descriptive data from retrospective sentinel event case files. Interviews were conducted with the manager responsible for sentinel event management to verify accurate interpretation of the sentinel event case file data and to explore practices related to sentinel event case file documents.

Using a case study design allowed for an exploratory inquiry into the hospital's sentinel events. I used a patient safety taxonomy to classify the sentinel events and allow analysis of the findings. Sentinel event classification will generate knowledge of the impact of the mechanisms of influence on the process and practice of understanding sentinel events and sentinel event data. Further understanding of the management of sentinel events can impact the recommendations for performance improvement opportunities.

The objective of this research study is to generate knowledge about organizationally identified sentinel events through classification and analysis. The exploratory research for this second stage of organization level study is twofold. First, I collect and classify sentinel event data using The Joint Commission Patient Safety

Taxonomy (Chang et al., 2005). Second, I analyze the classified sentinel event data to explore patterns and trends in the data and mechanisms of influence constraining the classifications. Standardization of sentinel event documentation can provide a reliable source for data extraction. Mechanisms of influence - coercive, normative, and mimetic - in sentinel event data are derived from the organizational management structure of sentinel events and impact the learning from these events and patient safety improvement initiatives. I investigate whether aggregating and classifying sentinel event data can offer a more system-focused approach to organizational learning. The research questions (RQs) for this organizational level of research are:

- RQ1: Can The Joint Commission Patient Safety Taxonomy be applied to sentinel event case data?

- RQ2: What are the classifications of sentinel events?
    - RQ2A: What are the levels of patient harm of sentinel events?
    - RQ2B: What are the types of error contributing to sentinel events?
    - RQ2C: What is the most frequent setting of sentinel events?
    - RQ2D: What are the causes of sentinel events?

- RQ3: Are there influences of constraint detectable in the sentinel event classifications?

The case study organization was unable to approve the use of the proprietary classified sentinel event data in my dissertation, hence I present the methodology used to develop my adapted taxonomy, sentinel event data collection, and analysis methods. I include template tables for organizations to graphically illustrate the descriptive data resulting from sentinel event data classification.

4.4 Research Methods

4.4.1 Sentinel Event Data

The original case study was conducted at a hospital that offered extensive services offering an opportunity to explore sentinel events. To explore the hospital's sentinel events, I reviewed its sentinel event case data. This retrospective data are stored in the hospital's secure record keeping system. I collected data on 100 percent of the sentinel events that occurred between January 2012 and December 2013. Every sentinel event case file contained, at a minimum, a completed root cause analysis document including the corrective action plan. A root cause analysis is an investigative method to uncover "the fundamental, underlying reason for a problem" (Tague, 2005, p. 42).

I developed a data collection tool to capture the sentinel event case identifier, the level of harm to the patient, type of error, location in hospital of event, cause of the error, and free text summary of every sentinel event case. Using the sentinel event data collected from the hospital's data filing system, I developed an original sentinel event database. Initially I devised a coding system for each sentinel event. This was done to protect the anonymity of the patients and hospital and to ensure that I would be able to identify an individual case in the database during my research study. The data collection tool served as a guide for data collection to ensure consistency in the data.

I reviewed every sentinel event case file and extracted for each sentinel event, a case summary of the event, including information to determine level of patient harm, type of error, setting where event occurred, and the cause of the error. To gather the information for each case, I reviewed the entire case file to develop a summary of the case. This was necessary to better understand the clinical status of the patient and the sequence of events.

4.4.2 Sentinel Event Classification

From the case summary, I classified the sentinel event case data using an adaptation of The Joint Commission Patient Safety Taxonomy (Chang et al., 2005). The Joint Commission Taxonomy required significant adaptation for my research study as it was complex and included categories and characterizations that were not available in the sentinel event case data that I reviewed. My adapted taxonomy includes classifications for the level of harm to the patient, type of error, location in hospital of the sentinel event, and the cause of the sentinel event. These are data fields typically found in root cause analysis forms (Boxwala et al., 2004). Table 4.1 displays the classification and coding scheme for my adapted version of The Joint Commission Patient Safety Taxonomy.

The level of patient harm resulting from sentinel events is classified as a range of no harm or no detectable harm (level 1) to death of the patient (level 5). I categorize levels two, three, and four, as minimal harm, moderate harm, and severe harm, respectively. A patient with minimal harm (level 2) required little or no intervention resulting from the sentinel event. Patients with moderate harm (level 3) required additional intervention but not prolonged hospitalization. Patients classified with severe harm (level 4) required intervention necessary to sustain life with prolonged hospitalization, long-term care, or hospice.

Types of errors are coded using The Joint Commission Patient Safety Taxonomy classifications for types of error (Chang et al., 2005) and include the major categories of communication, patient management, and clinical performance. The patient management category focuses on management of patient care including incorrect delegation of care responsibilities, inadequate tracking or follow up of patient management, or inappropriate use of resources.

Table 4.1: Classification and coding scheme for sentinel event data

Classification Category	Code	Definition	
Level of Harm to Patient	1	No Harm/No detectable harm-insufficient or unable to determine any harm	
	2	Minimal Harm – Requires no intervention or little intervention	
	3	Moderate Harm – Requires intervention but not prolonged hospitalization	
	4	Severe Harm – Requires intervention necessary to sustain life with prolonged hospitalization long-term care, or hospice	
	5	Death	
Type of Error			
Communication	1	Inaccurate & incomplete information	
	2	Questionable advice or interpretation	
	3	Questionable consent process	
	4	Questionable disclosure process	
	5	Questionable documentation	
Patient Management	1	Questionable delegation	
	2	Questionable tracking or follow-up	
	3	Questionable referral or consultation	
	4	Questionable use of resources	
Clinical Performance			
Pre-Intervention	1	Correct diagnosis, questionable intervention	
	2	Inaccurate diagnosis	
	3	Incomplete diagnosis	
	4	Questionable diagnosis	
Intervention	1	Correct procedure with complication	
	2	Correct procedure, incorrectly performed	
	3	Correct procedure, but untimely	
	4	Omission of essential procedure	
	5	Procedure contraindicated	
	6	Procedure not indicated	
	7	Wrong patient	
Post-Intervention	1	Correct prognosis	
	2	Inaccurate prognosis	
	3	Incomplete prognosis	
	4	Questionable prognosis	
Hospital Location	1	Emergency Department	8 Rehabilitation
	2	Ambulatory Care	9 Pharmacy
	3	Skilled Nursing Facility	10 Hospice
	4	Operating Room	11Interrventional Radiology
	5	Clinical Laboratory	12 Cath. Lab
	6	Diagnostic Procedures	13 Outpatient Behavioral Health
	7	Psychiatric Unit	14 Patient Care Unit
			15 Other
Cause of Sentinel Event	1	Skill-based error	
	2	Rule-based mistake	
	3	Knowledge-based mistake	

Clinical performance is a type of error that can lead to patient harm and is further defined by the pre-intervention, intervention, and post-intervention phases of care. Table 4.1 includes the list of clinical performance categories and sub categories. The pre-intervention phase targets diagnosis – the diagnosis was correct but the wrong intervention was implemented, or the diagnosis was inaccurate, incomplete, or questionable. The intervention phase focuses on the direct contact with the patient in the hospital setting and includes the correct procedure with a complication; the correct procedure incorrectly performed or performed in an untimely manner; omission of an essential procedure; performance of a procedure that was contraindicated or not indicated at all; and an intervention performed on the wrong patient. The post-intervention category focuses on prognosis - was the prognosis inaccurate, incomplete, or questionable. In the clinical performance category, I expect to see more types of errors attributed to the intervention phase as patients typically enter the hospital for an invasive procedure or intense medical therapy requiring procedures performed by multiple caregivers.

I used hospital location categories from The Joint Commission Patient Safety Taxonomy (Chang et al., 2005), which includes 14 hospital locations such as the emergency department, operating room, and areas in which diagnostic procedures are performed (i.e., the cath lab). The one change I made to this category was to assign number 14 as "Patient Care Unit" and add number 15 as the "Other" category. The category "Other" was used to capture locations not identified in the list. Table 4.1 includes the entire list of hospital locations with the corresponding code.

The final category is the cause of the sentinel event. Event causes were coded as either a skill-, rule-, or knowledge-based error which is briefly defined by Chang et al.

(2005). Chang et al. (2005, p. 100) define human errors as (1) skill-based, which result in failure in execution of "preprogrammed" and stored instructions or routine tasks, (2) rule-based which result in failure in retrieval and usage of stored instructions or in performing familiar tasks, and (3) knowledge-based, which result in failure due to resource limitations (i.e., insufficient time) and incorrect or incomplete knowledge. To clearly define the error categories for classification purposes, I employed Reason's (2000) error definitions. A skill-based error (also termed slips, lapses, trips, or fumbles) is a routine task that does not go as planned, Rule-based mistakes occur during situations for which health care providers are trained or during a situation that is covered in a policy. A rule-based mistake typically involves failure to apply a rule or an incorrect application of a rule. Knowledge-based mistakes can involve a rare event in which standard protocols or policies are insufficient to address the unfolding scenario and the frontline staff needs to devise a solution on the spot - typically an emergent situation. I used these definitions to operationalize the cause of errors involved in sentinel events. Consistent with qualitative research methods I assigned a cause of error and type of error code inductively through several rounds of data review, refining my coding scheme to ensure consistent assignment of classifications (Murphy & Dingwall, 2003).

Management of sentinel events on an individual case basis limits the ability to address latent conditions. Looking at sentinel event cases individually, the medical mismanagement "represents latent failures coming together in unexpected ways", and the errors "appear to be unique in retrospect" (Kohn et al., 2000, p. 56), but aggregation of the data can lead to a system-focused perspective that can identify latent failures within the organization. The individual case review that is captured in hospital sentinel event

policies (see Chapter 3) does not support development of a proactive system-wide performance improvement strategy to protect patient safety.

As part of interpreting the qualitative root cause analysis data into descriptive quantitative data and data display I developed tables to present the aggregated classification data. I used the tables with the original case study and they worked well with the actual data. The tables correlate with the taxonomy fields and display the classification, number, and percentage for each field in the taxonomy. The tables provided a means to identify areas for improvement and disseminate the findings. I include templates for the tables as part of the methodology for analysis of sentinel event classifications.

4.5. Analysis of Sentinel Event Classification

I compiled a case summary for every sentinel event. To compose the case summary, I reviewed all of the documents in the case file, including free text notes on the root cause analysis and action plan, as well as any additional documents in the file. From the case summary, I was able to identify the level of patient harm, setting, type of error and the cause of the error. For most cases, I was unable to clearly understand the trajectory of events from reading only The Joint Commission root cause analysis and action plan framework. In many cases, the action plans addressed issues that I was not able to identify in review of the case files or did not correlate with information in the case files, leading me to conclude that the sentinel event case file documents did not capture all of the information discussed as part of the investigation. In order to capture these findings I included information from the action plans in my classification determination.

In return to surgery cases, I was unable to determine consequent outcomes related specifically to the retained foreign body and return to surgery. After several rounds of coding the data, if the patient did not die, I classified sentinel events of return to surgery for removal of unintentional foreign body as a severe level (level 4) of harm, defined as requiring intervention necessary to sustain life with prolonged hospitalization, long-term care, or hospice. I assigned a level 4 based on potential harm to the patient and Encinosa and Hellinger's (2008) finding that the inability to capture the long-range impacts of surgical adverse events underestimates the level of harm by 20 to 30 percent. Assignment to the severe level of harm seems most appropriate since all of the return to surgery sentinel events involved the patient being subjected to an unplanned surgical procedure requiring general anesthesia, thus exposing the patient to all of the potential complications of a surgical procedure and anesthesia.

For every sentinel event I reviewed the entire case file including the action plan. Initially I wrote a free text case summary in order to capture a basic understanding of the event such as what lead to the event, the location of the patient, and the surrounding circumstances. I assigned classifications first for the setting, followed by staff involved, level of patient harm, type(s) of errors, and finally the cause(s) of errors. Table 4.2 provides an example of data collection for one hypothetical sentinel event. The example used is not based on an actual case but could be representative of an unintended retention of a foreign body, a type of sentinel event reviewed by The Joint Commission (The Joint Commission, 2014). I include this example to exhibit/display the methods I used for collecting and analyzing the data. This example also exhibits the potential for identification of multiple types of errors and causes of errors.

Table 4.2: Example of sentinel event case and classification (classification in italics)

Case Summary: Setting	Level of Patient Harm	Type of Error	Type of Error	Cause of Error
Return to surgery for retained foreign body. *Setting: Operating Room*	Return to Surgery. *Severe harm- Requires intervention to sustain life. Level 4.*	Counts incorrect, team not notified immediately. *Clinical Performance: Inaccurate & Incomplete Information.*	Incision closed prior to verification of correct counts. *Clinical Performance: Intervention Category: Omission of essential procedure.*	Incision closed prior to verification of counts. *Skill-based error:* Counts not correct. *Rule-based mistake*: Counts not verified prior to closure of incision

The case involved an unintentional retained foreign body requiring a return to surgery. In the case summary I classified the location as the operating room. For the level of patient harm, I assigned level 4, (severe harm) because the patient would be returned to surgery for removal of the retained foreign body. I identified two types of errors in this sentinel event. The first type of error is classified as a communication error: the surgical team was not aware that surgical counts were incorrect. I also assigned a clinical performance type of error due to omission of essential procedures: the surgeon did not verify that counts were complete before closing the incision. This case was classified as both a skill-based error and a rule-based mistake. I assigned a skill-based error because counts were not correct. Surgical counts can be considered a routine task with typically recurrent actions. In this case, a difference would have occurred between the expected outcome (correct counts) and the actual outcome (incorrect counts). I also classified the case as a rule-based mistake: the incision was closed prior to completion of counts. A

normal process would have counts verified as correct prior to the incision being closed; this did not occur. This hypothetical case offers a glimpse into the complexity of hospital work. The classifications of the type and cause of errors in this sentinel event allows a more comprehensive examination of the care delivered. In this case, which has a clear active failure of incorrect counts, classification of the types and causes of errors allows a more nuanced review of the steps of the case, identifying latent failures. Without classification, this case could have been viewed as a rare event with the one individual responsible for counts held accountable for its occurrence perpetuating a person-focused rather than a system-focused approach. Classification revealed two causes of errors and two types of errors.

The types and causes of errors in this hypothetical sentinel event capture the potential for communication issues, particularly in the operating room. Lingard et al. (2004) found that communication failures in the operating room typically involve vocalizing a concern or question early enough to prevent a problem and that the information shared is incomplete and inaccurate, the entire team is not included in the conversation and situations are not addressed until they become an emergency.

4.5.1 Number of Sentinel Events

The first step in the quantitative analysis of the sentinel events is to count the number of events. As hospitals will have historic data for sentinel events, retrospective data can be compared by year. The number of sentinel events at a hospital prompts several considerations. The number of cases deemed sentinel events is a product of hospital's identification process that is constrained by coercive and normative influences (see Chapter 3). If estimates of the number of adverse events (James, 2013) and the poor

rate of identifying adverse events (Classen et al., 2011) are correct, the number of sentinel events for hospitals will be fairly low. A high number of sentinel events or an increasing of number of sentinel events requires scrutiny to determine if there are indeed more errors or the organization is identifying more errors.

4.5.2 Level of Harm to the Patient

One would expect a high percentage of sentinel events to result in some level of harm to the patient. A high rate of death from sentinel events would be consistent with the definition of sentinel events, the coercive The Joint Commission definition of sentinel events that focuses on serious injury and any unexpected occurrence involving death or serious physical injury (The Joint Commission, Sentinel Event Policy, 2014). The level of harm to assign for classification will be constrained by the information stored in the sentinel event case file. That information may underestimate the level of harm experienced by the patient and has been identified as a limitation in other adverse event studies (Ginsburg et al., 2009). Adverse event research has found that the impact of surgical adverse events can continue after hospital discharge with indications that the inability to capture the long-range impacts of adverse events underestimates the level of harm by 20 to 30 percent (Encinosa & Hellinger, 2008).

There may be sentinel events that resulted in no harm to the patient. The identification and categorization of those events that resulted in no harm could signify normative influences. This normative influence may reveal positive indications that the hospital is identifying near misses for a proactive approach to managing patient safety. Table 4.3 presents the template for presentation of the descriptive analysis of patient harm level resulting from sentinel events.

Table 4.3: Presentation Template - Level of patient harm resulting from sentinel events

Level of Patient Harm	# Events	% Events
Death		
Severe Harm		
Moderate Harm		
Minimal Harm		
No Harm/No Detectable Harm		

4.5.3 Type of Error

Classification of the type of error of sentinel events categorizes the "implied or visible processes that were faulty or failed" (Chang et al., 2005, p. 97) and included three levels of error: communication, patient management, and clinical performance. One could expect the type of errors to be distributed fairly evenly among the three categories. Each sentinel event likely includes more than one type of error or mistake. Table 4.4 presents the template for presentation of the descriptive analysis of the classification of types of errors found in sentinel event cases.

Table 4.4: Presentation Template -Types of errors of sentinel events

Types of Errors	# Errors*	% Errors
Communication		
Patient Management		
Clinical Performance		

*The number of errors may exceed the total number of sentinel events because events may involve more than one type of error.

4.5.4 Communication as Type of Error

The types of errors were further delineated into sub categories for each classification (Chang et al., 2005). The communication classification targets problems between various members of the health care delivery team and the patient. Issues with

communication have been identified as serious concerns in hospitals. Failures in communication can indicate poor coordination among the health care delivery team (Tucker et al., 2008) and can result in significant patient harm or near harm. One could expect a large number of the errors would be related to inaccurate and incomplete information. The consent process, disclosure process, and questionable documentation may prompt errors or near misses, but not be involved in, or be difficult to identify in sentinel event cases. Table 4.5 presents the template for presentation of the descriptive analysis of the sub classification of types of communication errors.

Table 4.5: Presentation Template - Sub classifications of communication errors

Communication Errors	# Communication Errors	% Communication Errors
Inaccurate/incomplete information		
Questionable advice/interpretation		
Questionable consent process		
Questionable disclosure process		
Questionable documentation		

4.5.5 Patient Management as Type of Error

One would expect patient management errors to be likely related to questionable tracking or follow-up as tracking or follow-up of patient status, condition, and care is of primary importance in the acute care hospital setting. Patients requiring acute care hospitalization typically have complex needs that require monitoring, analyses, and action by multidisciplinary caregivers. Questionable tracking and follow-up can be related to cross-discipline or single-discipline communication.

It is difficult to imagine sentinel events that would be caused by a questionable referral or questionable use of resources. While these issues may arise in sentinel event

cases, the questionable use of resources may not be evident or identified. Table 4.6 presents the template for presentation of the descriptive analysis of the sub classification of the types of patient management errors.

Table 4.6: Presentation Template - Sub classifications of patient management errors

Patient Management Errors	# Patient Management Errors	% Patient Management Errors
Questionable delegation		
Questionable tracking or follow-up		
Questionable referral or consultation		
Questionable use of resources		

4.5.6 Clinical Performance as Type of Error

The clinical performance classification targets failures that could lead to medical errors during the stages of pre-intervention, intervention, and post-intervention patient care (Chang et al., 2005).

One would expect the majority of hospital sentinel events in the intervention classification as hospitalized patients are typically receiving active treatment. Patient care in the hospital includes multiple caregivers and procedures including multidisciplinary group interaction. The pre-intervention category focuses on diagnoses related errors and may be difficult to identify in conjunction with a hospital sentinel event. The post- intervention categories focus on prognosis, and it is highly unlikely a prognosis could lead to a sentinel event in the hospital setting. Tables 4.7, 4.8, 4.9, and 4.10 present the templates for presentation of the descriptive analysis of the sub classification summary of clinical performance errors, clinical performance errors for pre-intervention

phase, clinical errors for intervention phase, and the clinical errors for post-intervention phase respectively.

Table 4.7: Presentation Template -Sub classifications of clinical performance errors

Clinical Performance Errors	# Clinical Performance Errors	% Clinical Performance Errors
Pre-Intervention		
Intervention		
Post-Intervention		

Table 4.8: Presentation Template - Sub classifications of clinical performance errors for pre-intervention phase

Clinical Performance Errors/ Pre-Intervention	# Clinical Performance Errors/Pre-Intervention	% Clinical Performance Errors/ Pre-Intervention
Correct Diagnosis, questionable intervention		
Inaccurate diagnosis		
Incomplete diagnosis		
Questionable diagnosis		

Table 4.9: Presentation Template - Sub classifications of clinical performance errors for intervention phase

Clinical Performance Errors/ Intervention	# Clinical Performance Errors/Intervention	% Clinical Performance Errors/ Intervention
Correct procedure with complication		
Correct procedure, incorrectly performed		
Correct procedure, but untimely		
Omission of essential procedure		
Procedure contraindicated		
Procedure not indicated		
Wrong patient		

Table 4.10: Presentation Template - Sub classifications of clinical performance errors for post-intervention phase

Clinical Performance Errors/ Post-Intervention	# Clinical Performance Errors/Post-Intervention	% Clinical Performance Errors/ Post-Intervention
Correct prognosis		
Inaccurate prognosis		
Incomplete prognosis		
Questionable prognosis		

4.5.7 Hospital Location of Errors

One could expect a high number of sentinel events to occur in the operating room, emergency department, diagnostic procedures, and patient care units. Previous studies (Leape et al., 1991; Baker et al., 2004) found the largest numbers of adverse events were surgically related. The operating room is the site of various professionals carrying out specific, interrelated duties coupled with high-technology procedures. Other likely sites for sentinel events could be the emergency department, diagnostic procedures, and patient care units, all places that provide highly technical services and are consistent with other research findings (Leape et al., 1991). Table 4.11 presents the template for presentation of the descriptive analysis of the frequency of sentinel events by location.

Table 4.11: Presentation Template - Frequency of sentinel events by location

Hospital Location of Sentinel Event Occurrence	# Sentinel Events	% Sentinel Events
Operating Room		
Emergency Department		
Diagnostic Procedures		
Patient Care Unit		
Other		

4.5.8 Cause of Sentinel Events

Skill-based errors, also known as slips or lapses, have been related to a larger number of sentinel events in the intensive care unit (Rothschild et al., 2005). One would expect the greatest cause of sentinel events to be skill-based errors. If a large number of sentinel events result in patient harm, the majority of cases would involve some type of active failure, where there is an immediate effect or awareness that something has gone wrong. It is important to include assessments beyond the skill-based errors that can reveal the rule- and knowledge-based mistakes distal to the active failure.

Rule-based mistakes, the failure to apply the correct rule or an incorrect application of a rule, and knowledge-based mistakes occur when scenarios unfold in which typical protocols or policies are insufficient and immediate action is required, are likely to be seen in many adverse events. Sentinel events associated with mistakes beyond the slips and lapses of skill-based errors offers the opportunity expose organizational interrelationships that contribute to latent failures.

4.6 Limitations

The limitations of this work must be considered. Using an exploratory case study research design allowed a detailed analysis of one organization's sentinel events, but these findings may not generalize to other hospitals or to adverse events other than sentinel events. The application of the adapted The Joint Commission Patient Safety Taxonomy presents several limitations to consider, as well. In testing The Joint Commission Patient Safety Taxonomy (Chang et al., 2005), I made significant changes to the original, complex classification scheme. I adapted the coding to align with the information included in the sentinel event case files of the original case study. To

demonstrate reliability, I coded iterative rounds, refining the coding scheme each time. As the sole researcher of this study, I did not examine inter-rater reliability of the adapted classification scheme due to limitations of my access to the data. Finally, I extracted the sentinel event data from the case study organization's investigation files, rather than directly from the medical record. The data used to provide the basis of classifications may contain bias that excludes pertinent information. The organizational categorization of the case as a sentinel event and the data collected as part of the investigation can impact the accuracy of the classification.

4.7 Discussion

In this chapter, I explore and classify sentinel event data and was able to apply an adapted version of The Joint Commission Patient Safety Taxonomy, based on the principles of system safety and human factors. Sentinel event case data, at a minimum, should include a root cause analysis with action plan. Hospitals may be using additional tools to understand sentinel events that can improve the accuracy of classification. Examining the classifications of sentinel events will reveal organization's integration of coercive influences stemming from accreditation requirements in the identification and understanding of sentinel events. Organizations may identify a small number of sentinel events, indicating normative influences to support the idea that hospitals provide safe care to patients. To identify a large number of sentinel events could imply that hospitals harm a large number of patients and is not adequately protecting its patients; this suggestion is not consistent with what hospitals or health care professionals should be doing. Due to the definition of sentinel events, there is a strong expectation that a large number of sentinel events result in death, a result of the coercive influence of focusing on

high harm sentinel events due to accreditation requirements. Normative constraints can also be apparent in the identification of sentinel events that do not harm the patient, indicating a proactive approach to patient safety within the organization. Classification of both the type and cause of medical management provides information that offers explanations of the events that capture the complexity of the care delivery system and the interrelationships of the care providers. With a variety of external pressures related to quality of care and patient safety, coupled with internal pressures from professionals and administration, this exploratory research offers a preliminary look into the *black box* of hospital of adverse events.

Organizations that respond to accreditation and/or regulatory requirements to identify and address adverse events or sentinel events have some type of data collection system in place. This presents an opportunity for organizations to aggregate and analyze information to support data-driven performance improvement recommendations to enhance patient safety.

There are two main indications of my research. The first is the aggregation of data related to the sentinel event cases. Sentinel events by definition include high patient harm or the potential of high patient harm events. The coercive influence of The Joint Commission constrains the way hospitals identify and understand sentinel events. Variation in the number of sentinel events between hospitals may suggest that there could be differences in how individual hospitals designate events of patient harm resulting from medical management as sentinel events.

It is questionable whether the number of identified sentinel events is an accurate representation of the number of events that occur in hospitals and may, in fact, represent

far less than the actual number of sentinel events. Rothschild et al. (2005) identified over 164 serious adverse events in two intensive care units in one year alone. A small number of sentinel events would provide support for research findings that indicate hospitals have a poor rate of capturing events (Classen et al., 2011). Normative pressures influence hospitals to keep the number of sentinel events low so as to appear legitimate in the provision of safe patient care. Mimetic influences may also be a driver in a small number of sentinel events; hospitals may feel it necessary to keep the number of sentinel events low so as to stay consistent with the number of such events that occur in other well-regarded hospitals, even though this number is unknown. A high number of sentinel events could indicate an organization dedicated to understanding events that impact patient safety particularly if there are cases with no patient harm.

The coercive influence of the definition of sentinel events impacts the level of patient harm assigned. The largest single category of patient harm resulting from sentinel events would likely be patient death. This reflects the accreditation agency's definition of sentinel events that only captures cases that focus on serious patient injury. In many sentinel event cases it may be difficult to discern the exact level of harm to the patient. A retrospective analysis of sentinel event case files will capture closed cases where immediate corrective actions should have been taken. The case files may not include required additional therapies or treatments while in the hospital, or after discharge from the hospital. Similarly, there is no indication of the impact of the sentinel event on the patients' economic status or quality of life. It is likely hospitals process of sentinel event management concludes with the immediate resolution of the event, leaving unanswered questions as to patient outcome. This may lead to an underestimation of the level of

patient harm, as noted by previous researchers (Encinosa & Hellinger, 2008). This would impact the level of harm for sentinel events that do not end in death. Thus not capturing the ultimate health outcome to the patient, such as prolonged hospitalization, or economic impact.

Normative influences are may also be present, if there are identified sentinel events that caused no harm to the patient. Staff and leadership within the organization may recognize the potential serious outcome of an event or near miss and elevated the case to receive high-level review. Protecting patients by preventing future recurrence of a dangerous situation reveals normative influences within the organization and supports the idea that organizations act in the best interest of patients to keep them safe from harm.

My findings reveal that information from The Joint Commission root cause analysis and action plan framework template did not provide sufficient information to apply a patient safety classification. This is an important consideration for regulatory and accreditation reporting of sentinel or adverse events. In order to apply classifications to sentinel event data, the root cause analysis form alone, including the action plan did not provide sufficient information.

Quality improvement tools may be an opportunity not only to investigate sentinel events but also guide the resultant improvement process towards a system-focused perspective. Potential tools to consider are a fishbone diagram and a process flow map. A fishbone diagram is a cause and effect diagram that identifies various causes for a problem (Tague, 2005) in different areas such as equipment, people, environment, and methods. A process flow map contains detailed information, and would include exact time and patient condition, at every step of the event and provides a visualization of how

systems and processes link together (Provost & Murray, 2011), thereby furthering an understanding of how an event happens (Tague, 2005).

The use of quality improvement tools can help identify what the expected process should look like and what happened in the case of the sentinel event. The use of these additional tools can prompt a deeper discussion among the multidisciplinary team members as they work together to understand the sentinel events by mapping out the workflow process of multiple team members to identify possible flaws in the system and formulate recommendations for improvement opportunities. The added materials can provide more comprehensive knowledge to inform the classification of the event.

The completion of a root cause analysis is an accreditation requirement of The Joint Commission; however, findings of this study suggest that requiring additional documents must be considered for future patient safety classification work. Hospitals may typically use The Joint Commission root cause analysis tool, indicating mimetic influences. Further testing and revisions of The Joint Commission root cause analysis tool should be considered before mandating requirements of data collection related to sentinel events.

The second step of this research study explored application of The Joint Commission Patient Safety Taxonomy to hospital sentinel events and the analysis of the classifications. Previous work has focused on classifying large numbers of events for trending purposes (Mitchell et al., 2014) with little work focusing on individual organization's use of classified data to inform performance improvement work. There are limited findings in the literature regarding classifications of sentinel events and little is known about organizational use of classification systems. Application of classification

typology to one organization's sentinel events generates new knowledge regarding what is needed from taxonomies to summarize and categorize findings from patient safety events on a broader scale.

To use The Joint Commission Patient Safety Taxonomy required significant adaptation to apply to hospital sentinel events. The Joint Commission Patient Safety Taxonomy domains are complex with multiple fields that included information not present in the hospital sentinel event case files. Data extracted from The Joint Commission root cause analysis and action plan framework template did not supply enough information to apply the original taxonomy classifications. If hospitals use only The Joint Commission root cause analysis and action plan framework template, they may not have enough case information to apply system safety and human factors classification to the retrospective sentinel event data.

Classifying hospital adverse events offers the opportunity to examine the issues that are important to hospitals organizational learning. Classification aggregates the system-focused performance issues and allows a system-focused view rather than a person-focused approach. It is unknown if or how many hospitals or hospital systems classify sentinel or adverse events.

This system-focused approach to improvement efforts offers a more long-range, proactive strategy to improve the quality and safety of patient care and can help streamline improvement efforts in the midst of competing priorities. To manage sentinel events hospitals system may need to continue the root cause analysis process and add the classification of event case data.

The classifications of the type of errors and the cause of errors are an especially important influence on the direction of organizational performance improvement initiatives. When organizations review adverse or sentinel events as individual cases, it is difficult to find commonality among the various cases. Application of classifications for the type and cause of errors allows systematic organization of factors involved in the cases. Classification of the cause of errors to skill-based errors, such as slips or lapses, and rule- and knowledge-based mistakes can further enhance organizational learning. Incorporating this information with the type of error classifications allows a different and more robust understanding of what is happening in the system to cause errors that result in harm to patients.

While classification of types of errors are spread across the three domains of communication, patient management, and clinical performance, the further sub classifications of these three domains are indicative of the significant interrelationships of care providers and highlight the importance of the team work that is required to ensure patient safety. The sub classifications will identify sentinel events that are related to inaccurate or incomplete information, questionable tracking or follow-up, and omissions of essential procedures. All of these causes are impacted by communication both within professional groups (e.g., doctor to doctor, nurse to nurse) or among multidisciplinary groups (e.g., nurse to doctor). Communication is a well-noted problem in care delivery (Lingard et al., 2004; Tucker et al., 2008) and continues to impact patient safety. Findings related to communication can support organization wide strategic initiatives to improve communication among team members. For hospitals

affiliated with medical and or nursing schools there is tremendous opportunity to develop teamwork and communication in professional education.

My findings reveal that classification of sentinel events can offer organizations an opportunity to analyze their sentinel event data in a meaningful way to inform data driven performance improvement initiatives to enhance patient safety. Seeing the system through the different lens of classification provides the opportunity to change the system (Senge 2006). It is also important to recognize the coercive, normative, and mimetic influences that shape organizations identification and understanding of sentinel events and ultimately impact the sentinel event data. The findings of this research study can add to the knowledge of hospital identification and classification of sentinel events. Additionally this research study can inform managerial use of sentinel event classifications and the impact of classification on organizational learning.

Finally, an important consideration of hospital sentinel event work is the impact of the catastrophic event on the patient, patient family, staff, and organization. Currently there is little information available that indicates patients and families are included in the sentinel event understanding or root cause analysis process. Looking at sentinel events aggregated as classifications can offer more of an opportunity to reflect on the system rather than the individual staff member and patient at the point of failure. Aggregated, classified sentinel event data may offer an opportunity to involve a patient representative on improvement teams related to patient safety.

4.8 Future Research

As noted in the previous chapter, the inability to share the findings and results of my original case study highlights opportunities to improve the quality and safety of

patient care. Classification of sentinel events and descriptive summaries may be interpreted as a threat to legitimacy as sentinel events are high harm events by definition. Further research is needed to determine if hospitals are classifying events and even if they are not, are hospitals sharing the findings of sentinel events internally to foster organizational learning. It is important to consider the mechanisms of influence related to limited transparency and the impact on organizational learning.

This initial descriptive research of the classification of sentinel event data supports future research for both the application of the taxonomy and the classification of sentinel events. In order to be able to use The Joint Commission Patient Safety Taxonomy and apply it to The Joint Commission required root cause analysis framework and corrective action plan, I needed to make significant changes to the original taxonomy to match the data available in the root cause analysis form. Further testing of the adapted taxonomy is needed to assess its validity and reliability and inter-rater reliability for classification of sentinel events. General research is needed on refining taxonomies for patient safety. Development of The Joint Commission Patient Safety Taxonomy included input from "medical specialty societies, business groups, government, health care agencies, and health care organizations" (Chang et al. 2005, p. 96) but did not include nurses and patients. Further adverse and sentinel event taxonomy development must include representatives from multidisciplinary frontline caregivers as well as patient safety and quality improvement specialists. Classifications should be designed to capture information already held by organizations so as to yield timely meaningful data.

4.9 Conclusion

Data collection and analysis of sentinel events is crucial to understanding the impact of the organizational environment on patient care and developing recommendations for performance improvement initiatives to enhance patient safety. However, knowledge of managing and classifying sentinel event data in health care settings is limited. The constraining influences that define sentinel event management influence the data available that is used to prompt performance improvement initiatives. Classification of sentinel event data using a system safety and human factors classification scheme is a mechanism that allows a system-focused approach, including consideration of latent conditions, to performance improvement, rather than the current person-focused performance approach. Aligning mechanisms of influence for hospital management of sentinel events and a focus on data driven performance improvement initiatives will advance improvements in the quality of care delivery and patient safety

CHAPTER 5: POLICY IMPLICATIONS TO INFLUENCE THE SAFETY AND QUALITY OF CARE DELIVERY

5.1 Introduction

Patient safety and the quality of health care delivery remain a salient public policy issue at both the federal and state levels. My research findings extend theory and generate new knowledge regarding the constraints imposed on and by hospitals relative to adverse events and patient safety. The three mechanisms of influence - coercive, normative, and mimetic - constrain hospital management of adverse events and sentinel events that have resulted in limited improvements in patient safety. The findings of this research can inform stakeholders and policy makers how hospitals are responding to current regulatory action, thus informing policy considerations. Future regulatory action related to adverse events should be designed to enable hospitals to focus on and improve organizational learning resulting from cases of medical mismanagement.

Hospitals must respond to external regulatory and accreditation requirements and implement regulations within the context of the internal, normative, organizational influences dictated by professional groups and administrators. External regulations for identification and reporting of certain adverse events and sentinel events can force hospitals to focus on cases of medical mismanagement. However, hospitals can respond in different ways that strive only to meet reporting requirements, or adapt the response as a starting point to improve the quality and safety of patient care. There are significant constraints influencing the delivery of safe patient care. The slow pace of improvements

implies hospitals need more guidance to impact organizational learning and performance improvement work rather than merely reporting for external data analysis. Regulatory, accreditation, and professional requirements should work to shift from a focus of trying to appear legitimate in the delivery of safe patient care, to a focus on the work of improving care.

5.2 Coercive Influences

Hospitals in states with mandated adverse event reporting do not provide safer patient care in comparison to hospitals in states with no regulatory reporting requirements. This indicates mandated adverse event reporting has limited impact on patient safety in the hospital setting. With over half of the states requiring reporting of adverse events and federal initiatives moving to reporting events to PSOs it is important to consider the lack of improvement resulting from current initiatives. There is little indication that requiring hospitals to report adverse events have successfully changed organizational practice to transform health care delivery.

Policies should be designed to move away from a focus on reporting events to focus on promoting organizational learning to prompt the process of understanding and improving care delivery. A more efficient mechanism would be to require hospitals to manage their own adverse or sentinel event data in a prescribed way to influence system-focused performance improvement initiatives. My research findings indicate promise in applying a patient safety taxonomy classification to hospital sentinel event data, data that many hospitals already collect in accordance with accreditation requirements. Adverse event reporting focused on aggregated classifications may prompt higher rates of case identification and mitigate concerns of sharing patient harm case data.

Policy efforts, both coercive and those that impact normative influences should prompt hospitals to focus on data at hand. Any organization that attains The Joint Commission accreditation status must identify and manage information from sentinel event cases. Hospitals in states with mandated reporting requirements must identify and manage information from state defined cases of medical management resulting in patient harm. Reporting requirements can focus on adverse or sentinel events as a starting point. Policy can be designed to prompt hospitals to use the data they are required to collect for reporting and accreditation purposes as a basis for performance improvement initiatives. While near miss cases resulting from medical management are important for learning, the slow pace of the identification and understanding of these cases poses barriers to data collection and organizational learning.

For states with mandated reporting requirements, classification of historical data can be analyzed to identify statewide improvement initiatives. Many states have at least several years' worth of hospital data. Taking the administrative burden of data collection and management into consideration, policy can influence states and organizations to use the adverse event data already collected to meet regulatory and accreditation requirements to formulate data driven performance improvement initiatives. Requiring states and organizations to apply empirically tested classification schemes to their own adverse or sentinel event data would shift the focus to using data internally to improve quality. Moving to system-focused data and away from individual-focused case data may motivate hospitals to identify more adverse or sentinel event cases.

Future policy efforts related to adverse event reporting need to consider the case information needed to assign a simple classification scheme. My study indicates

information captured in The Joint Commission root cause analysis and action plan framework is not enough to assign patient safety taxonomy classifications. Any intentions to aggregate and analyze adverse event data needs to incorporate documentation that is robust enough to classify but also reasonable for hospitals to manage. The process of collecting and analyzing data should not be solely for regulatory requirements but for hospitals to improve care. The findings need to be meaningful to the organization and coercive influences can hasten organizations use of data driven performance initiatives.

The use of multiple documents should be considered for further reporting requirements for adverse event data aggregation purposes. Additional improvement tools and requirements related to corrective action plans can be added to regulatory requirements to coerce organizational learning and speed up the pace of improvement efforts. Currently there is limited research related to event reporting and the use of system safety and human factor taxonomies. Funding for research to improve the safety and quality of patient care can have a significant influence in transforming health care delivery in the hospital setting.

Hospitals may need two methods to address patient safety, one for external reporting purposes and a second for internal investigation and performance improvement initiatives. Competing priorities including different regulatory and accreditation definitions and reporting requirements of events, as well as varying professional and organizational quality improvement initiatives, are proving to be a significant burden for hospitals to manage. The internal working data should be more robust and could include a higher number of cases than the external reporting data. If hospitals do not have to externally report their internal working data, the focus would be on improvement

opportunities rather than legitimacy. Even with voluntary reporting requirements, the consideration that an outside agency such as The Joint Commission can review sentinel event case data leads hospitals to identify sentinel event cases and manage the cases according to accreditation requirements amid concerns of legitimacy or looking like they provide a safe patient environment. External reporting requirements would still hold hospitals publicly accountable to identify and report errors to foster transparency related to medical management that results in patient harm.

5.3 Normative Influences

Any attempts to coerce hospitals to address patient safety and the quality of care must address the interrelationships of the care delivery team and the power and status differences (Bunderson & Reagans, 2011) that are present among health care providers. Communication between members of care delivery teams is essential. In fact, the lack of communication between care providers may be normal practice in health care delivery and goes unnoticed (Lingard et al., 2004). Effects of errors caused by communication failures can signal what is happening in the environment and is associated with patient harm. A primary area to target to impact patient safety in the hospital is to enhance team work. While it is not feasible to legislate mandatory teamwork, there is opportunity to influence health professions education.

To address the issue of multidisciplinary teamwork in healthcare delivery systems, policies must target educational opportunities that foster collaboration and academic programs should offer more interdisciplinary learning opportunities. One target population is academic medical centers that include both a medical school and nursing school. A coordinated effort of regulatory and accreditation requirements can be pursued

to enable academic medical centers to integrate comprehensive interdisciplinary systems-focused patient safety and performance improvement learning into curriculums. Educational accrediting bodies can also facilitate interdisciplinary learning in academic medical centers.

My research findings indicate it may take more than regulatory and accreditation mandates to improve patient safety and quality of care. Providing implementation strategies to hospitals for improvement initiatives is valued by hospital staff (Leape et al., 2006) and can quicken the pace of improvement work. Prescriptive implementation strategies and reporting requirements may help hospitals navigate complex organizational structures to initiate change resulting in improvements in patient care. The different ways hospitals respond to coercive influences needs to be a prominent consideration of adverse event management programs. The current method of identifying patient safety goals without providing direction and support on how to make this happen may be one of the reasons hospitals are not able to improve the safety of their patients (Leape 2006). There may be too many improvement and safety goals and hospitals have not developed the infrastructure to manage improvement efforts. In states with reporting mandates, hospitals may be able to manage the reporting requirements but not the improvement work.

Legislative action can be a positive catalyst to promote change in health care as is evident from the Washington State shared-decision making demonstration project (King & Moulton, 2013). The Washington state experiment can provide practical knowledge for future legislative action to coerce hospitals to improve patient safety. A demonstration project can provide information for future legislative provisions to foster successful

implementation of performance improvement initiatives related to patient safety work with front-line staff involvement, field-testing, and rapid implementation. This can promote performance improvement using management strategy and clearly defined set of techniques (Westphal, Gulati, & Shortell, 1997) for hospitals to use, resulting in higher levels of patient safety.

5.4 Mimetic Influences

The slow pace of improvement in patient safety is impacted by mimetic influences. There are strong tendencies to conduct patient safety events and work in a restricted or confidential manner. Transparency is a mimetic influence that can be fostered through normative and mimetic influences. The lack of transparency related to sentinel events and the investigative findings of the sentinel event identification and understanding process severely hampers advances in patient safety. Leading hospitals that move to transparency and facilitate open discussion can shift mimetic influences to disclosure and discussion impacting organizational learning and learning to promote a different appreciation of legitimacy in patient safety and quality improvement work.

5.5 Conclusion

Management of adverse events are strongly influenced by coercive measures defined by accreditation agencies and can offer opportunities to influence organizations to address failures in care delivery. However it is important to couple coercive influences with normative influences to impact health care delivery. The combination of regulatory requirements and shifting of normative influences to become more team oriented will foster mimetic influences. As multidisciplinary teams work successfully to improve the

safety of care delivery, hospitals will copy these actions. Ultimately, it is important to link adverse events with performance improvement.

In my dissertation, every level of research explores an important aspect of hospital adverse event management and patient safety. The role of public policy is critical to the quality and safety of health care delivery. These findings of hospital adverse event management supports future research opportunities and further informs exploration of polices to influence implementation and sustainability of improvement efforts to enhance patient safety and the quality of care delivery. Knowing that all three influences – coercive, normative, and mimetic – impact how organizations identify and understand adverse events, it is imperative to consider these influences in addressing both patient safety and quality improvement. Policies, both state and federal, and accreditation requirements can be designed in a way to enable health care organizations to enhance the organizational learning from adverse events. Normative pressures should focus on experiential education including multidisciplinary teamwork including health professionals and students. The combination of coercive and normative influences can impact mimetic influences resulting in widespread adoption of adverse event management processes and practices that work to improve patient care.

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APPENDIX A: U.S. NEWS & WORLD REPORT BEST HOSPITALS 2012-2013 RANKING METHODOLOGY

The U.S. News & World Report Best Hospitals report identifies the top hospitals in the United States in 16 specialties. This hospital ranking is designed as a report card "to help consumers determine which hospitals provide the best care for the most serious or complicated medical conditions and procedures" (U.S. News & Report Methodology, 2012, p.1). Of the 16 specialties, 12 are data driven with scoring based on structure measures, process measures, and outcomes. Hospital reputation alone determines the rank of the remaining four hospitals with reputation assigned from physician survey responses.

Ranked Specialties:

Cancer	Neurology & Neurosurgery
Cardiology & Heart Surgery	Ophthalmology*
Diabetes & Endocrinology	Orthopedics
Ear, Nose, & Throat	Pulmonology
Gastroenterology	Psychiatry*
Geriatrics	Rehabilitation*
Gynecology	Rheumatology*
Nephrology	Urology

*Reputation only rankings

All hospitals[12] responding to the American Hospital Association (AHA) 2010 hospital survey are included in the initial sample for the 2012-2013 US News & World Report hospital rankings. The ranking process for the top-ranked hospitals, according to US News & World Report, has several stages. There were 4,793 hospitals responding to the 2010 AHA survey that met criteria for inclusion in the rankings.

Hospitals included in the *first stage eligibility* phase of Best Hospital Rankings must met at least one of the following criteria:

- Membership in the Council of Teaching Hospitals (COTH)
- Medical school affiliation – American Medical Association or American Osteopathic Association
- At least 200 beds in use and staffed
- At least four important technologies available – diagnostic radioisotope services, full-field digital mammography, image-guided radiation therapy, multislice spiral CT, PET/CT scanner, robotic surgery, single-photon-emission CT, stereotactic radiosurgery.

After the first stage eligibility phase 2,224 hospitals met the criteria for inclusion.

[12] Excluded from initial eligibility are military installations, federal institutions, rehabilitation and acute long-term care facilities, and institutional hospital units such as prison hospitals and college infirmaries.

To progress to *second stage eligibility* hospitals met volume criteria in defined specialty diagnoses. These data were collected from 2008, 2009, and 2010 Medicare billing submissions. Hospitals that did not meet the volume criteria are still eligible for inclusion with a reputation score of 1 percent or greater. A total of 1,860 hospitals met volume criteria at this stage with an additional eight hospitals included because of reputation scores, for a total of 1,868 hospitals. These 1,868 hospitals were eligible to advance to the next round of ranking which is based on U.S. News & World Report composite measures related to structure, process, and outcomes.

A.1 Structure

To explain the methodology for the structure measure, I have included each indicator with an explanation of the indicator and data source.

Technology – The technologies included are derived from the AHA survey and include those from the eligibility requirement as well as and including such services as cardiac intensive care unit and computer-assisted orthopedic surgery. Credit is earned if the hospital provides one of these technologies. The hospital can deliver this service at the hospital or through a health system, local community network, contractual arrangement, or joint venture with another hospital.

Volume – This measure includes specialty specific discharges submitted for CMS reimbursement in 2008, 2009, and 2010. The volumes are adjusted using a weighted average of the hospital's volume and the volume for all hospitals at or above the 25th percentile. Data are obtained from the Centers for Medicare & Medicaid (CMS) billing submissions[13]

Nurse Staffing – This measure is intended to reflect the level of care required by the patient population. This includes both inpatient and outpatient care and includes the number of full-time registered nurses/the adjusted average daily census of patients, with higher weight being given to inpatient care. This measure is a composite of data from the 2010 AHA Survey

Trauma Center – This structure measure is included for Ear, Nose, & Throat, gastroenterology, cardiology & heart surgery, nephrology, neurology & neurosurgery, orthopedics, pulmonology, and urology. Points are given for the presence of a state-certified trauma center, with another point given if the trauma center is a designated Level 1 or Level 2 trauma center. Data are obtained from the 2010 AHA Survey.
Patient Services – This measure refers to services offered by the hospital that are a convenience for the patient such as translation services, cardiac rehab, or genetic testing and counseling. Data are obtained from the 2010 AHA survey.

[13] CMS billing data is obtained from the combined 2008, 2009, 2010 MedPAR data files and include hospital length of stay and discharge status. The data are aggregated using coding to account for severity of illness, risk of death, and hospital resources used. Low-intensity cases and cases not typically associated with the Medicare elderly population are excluded.

Intensivist – Hospitals have on staff at least one full-time critical care board certified physician who works in an intensive care unit. Data are obtained from the 2010 AHA survey.

External Organizations – Points are awarded if the hospital has obtained accreditation from any of the following agencies: *National Cancer Institute Cancer Center* (i.e., the hospital is an NCI clinical or comprehensive cancer center; Nurse Magnet; Epilepsy Center; NIA Alzheimer's Center; and/or FACT Accreditation (bone marrow transplant).

A.2 Outcomes

The outcome measure is defined as the *survival score.* The *survival score* is operationalized as the public measure of outcomes or mortality. The mortality ratio is presented as a score that represents the survival of patients 30 days after admission to the hospital. The survival score calculation is the weighted observed versus expected mortality rate for all specialties in each hospital. Hospitals with a higher survival score have the best mortality ratio. Data obtained from 2008, 2009, 2010 MedPar data files and the 2008, 2009, and 2010 AHRQ Healthcare Cost & Utilization Project (HCUP) and HCUP National Inpatient Sample data sets.

A. 3 Process Measures

The only process measure used in the hospital rankings is physician-determined reputation. U.S. News & World Report cites the lack of nationally accepted hospital process measures and states "an appropriately qualified physician who identifies a hospital as among the "best" is, in essence, endorsing the process choices made at that hospital and that nomination of hospitals by board-certified specialists is, therefore, a reasonable process measure" (U.S. News & World Report Methodology 2012, p. 26).

U.S. News & World Report surveyed a sample of 3,200 board-certified physicians from the AMA Physician Masterfile stratified by region and specialty and obtained a 41 percent response rate.

A.4 Patient Safety Score

This index is developed for the U.S. News & World Report rankings and is a composite measure. This composite measure is constructed using 5 of the 11 AHRQ PSIs which are endorsed by the National Quality Forum (NQF).

The six PSIs included in this composite measure are as follows (U.S. News & World Report Methodology, 2012):

- PSI 04 - Death among surgical patients with serious treatable complications
- PSI 06 - Iatrogenic pneumothorax
- PSI 09 - Postoperative hemorrhage or hematoma

- PSI 11 - Postoperative respiratory failure
- PSI 14 - Postoperative wound dehiscence
- PSI 15 - Accidental puncture or laceration

As part of the patient safety score each of the PSI scores is weighted equally. This ranking includes two weights. First, each PSI is weighted at 16.7 percent. Next, each individual PSI is weighted by the population at risk for each indicator. The 2012-2013 rankings are the first to employ the equal weighting methodology. Each of the six PSIs is given an identical weight equal of 16.7 percent equal to the reciprocal number of PSIs in the index. In addition, each PSI is adjusted based on the observation rate (specifically the standard error of the mean) in the PSI within each hospital. Further adjustment of the PSI value is equal "to a weighted average of the hospital's own value and that of the population" (p. 35). For hospitals with lower volume, the methodology weights more toward the population.

Case mix is included in the PSI score as a control variable. The case mix provides an understanding of the level of complexity of patient cases. This variable is included to control the difference among patient populations at hospitals.

APPENDIX B: PROCESS TO OBTAIN CASE STUDY DATA ACCESS

Access to hospital adverse event data is typically limited and difficult to obtain. Sharing information related to adverse events is very restricted in health care organizations. Accessing hospital adverse event data for my original case study was a lengthy, complex process and it took one full year to secure access.

My first clearance to hospital adverse event data was obtained from a senior leader of the hospital based on several discussions about my research objectives and research questions. The senior leader expressed interest in furthering the already significant patient safety work that had been done within the organization, as well as promoting patient safety and performance improvement research. Adverse event data had never been shared with an outside researcher and it was unclear what processes would be required to first permit me to access the data and then how to actually obtain the data. At my last meeting with the senior leader granting me access, I was referred to the organization's legal counsel. Legal counsel investigated who in the hospital was required to grant *permission* to access the adverse event data. Within one week, legal counsel had referred me to the director of the hospital's institutional review board (IRB), who provided explicit directions on IRB requirements and referred me to the organization's risk management and data access committee. The data access committee did not respond to my inquiries at this time.

Almost one month later, I exchanged several communications with a representative of the risk management department to define the adverse events for which I was requesting access. Since there is not a common terminology for patient safety events or adverse events, we had several exchanges to review the hospital's processes for

managing adverse events to identify exactly what type of adverse events I was interested in studying. Due to our inability to come upon a common terminology and identification of the adverse events that were part of my study, I met with the risk management department representative and a leader of the risk management department. It was determined at this point that another department managed the adverse event data I was pursuing and I was referred to the department manager.

Three months after initial clearance was granted, I had connected with the organization representative who managed the serious adverse event data. The next four months were spent identifying case files for review, negotiating access to the data, and determining how to achieve access to the case files. At this time, the organization did not want to allow any further permissions or clearance to data until organizational IRB approval was obtained. After review and approval by the department manager, I submitted the hospital IRB application. One month later, I received approval from the hospital's IRB and was then able to pursue university IRB approval for my research study.

I spent the following three months working with the hospital's legal counsel and department manager to develop a contract to protect the confidentiality of the patient data as well as the organization. This document, requiring my signature as well as organizational leadership signatures, was necessary prior to final *permission* to access the adverse event data. After signatures were obtained on the confidentiality agreement, organizational leadership determined that prior to *access* to the data, my research study needed clearance by the organization's data access committee. Approval was granted by the committee the following month. The final hurdle to accessing the data involved the

information technology (IT) department granting me access to the secured files. After almost 12 months, I had secured both *permission* and *access* to the hospital's adverse event data and could begin my data collection.