SAFETY CULTURE AND PATIENT HARM EVENTS:
A CONTINGENCY THEORY PERSPECTIVE IN THE CONTEXT OF COMPLEX ADAPTIVE SYSTEMS

by

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A DISSERTATION

Submitted to the graduate faculty of The University of Alabama at Birmingham
in partial fulfillment of the requirements for the degree of
Doctor of Science-Health Services Administration

BIRMINGHAM, ALABAMA

2015
This study examines the correlation between a Culture of Patient Safety as measured by hospital staff surveys and actual patient harm attributed to hospital performance. It is generally accepted by health care management leaders that the presence of a strong culture of patient safety has become a critical component in reducing patient harm. However, little empirical evidence within multiple hospitals over time exists to support this belief. Healthcare managers can utilize this evidence in formulating patient safety improvement strategies within their organizations.

A theoretical framework consisting of Contingency Theory within the context of complex adaptive systems was utilized to develop and address the hypothesis. Data regarding Culture of Patient survey results, abstracted and externally reported patient harm events and internally reported patient harm events was collected from a study group of seven hospitals within a single health system clustered in one state over a four year period. A linear regression model with repeated measures was modified due to either low counts or lack of normal distribution. Bed size and difference in case mix was treated as a covariate and recorded as case mix adjusted patient days used to account for the differences in bed size and case mix complexity among the hospitals.

A Culture of Patient Safety was found to be correlated to broad measurements of patient harm but with respect to the low number of occurrences of certain hospital acquired conditions a Culture of Patient Safety was not found to have a significant correlation. However, the results can be viewed as suggesting that a Culture of Patient Safety is as essential as a structural
element to achieving zero harm as more commonly accepted structural elements such as training and equipment.

The results also suggest other differences between the hospitals beyond case mix and bed size have a significant effect. Such differences may lie in the actions and behaviors within the complex adaptive systems that make up each hospital microsystem and in the “fit” between patient safety with system strategy, resource allocation and management actions and behaviors.
DEDICATION

This dissertation is dedicated to my loving wife, Nancy Gatmaitan, who has provided unwavering encouragement and support to me throughout my career.

I also wish to dedicate this work to my father, Alejandro V. Gatmaitan, MD. Through a quiet, resolute and Christian valued life of service and sacrifice my late father instilled in me the value of education, service to others and the impact of just showing up every day to do good work.
ACKNOWLEDGEMENTS

I am sincerely grateful for the guidance provided by my chairman, Dr. S. Robert Hernandez, and committee: Dr. Stephen O’Connor, Dr. Nir Menachemi, and Dr. Bisakha Sen. They provided valuable insight throughout the process. Also, I am thankful for my classmates, who kept the journey enjoyable, informative and inspired me to cross the finish line.

There are many colleagues that provided assistance with my research that I wish to thank. I wish to acknowledge the quality office staff at each of the subject hospitals who fulfilled my numerous data requests in a supportive manner. In addition, the senior leadership of each hospital within my health system who as my colleagues work tirelessly every day in support of zero patient harm. To Diana Collins, Executive Assistant, who accounted for and arranged many details so that I may pursue the goal of completing this research while balancing my full time responsibilities.

Most especially I wish to thank Dan Evans, Steve Wantz and IU Health for their belief in me and the very significant support provided which enabled me to pursue and complete this journey. I am better prepared to provide the very best of evidence based decision making in service to IU Health and to share my learnings with all.
To my children--- Lindsay, Ally and Christian, my mother Hazel and most especially my wife Nancy---my deepest love and appreciation for their quiet patience and sweet encouragement.
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CHAPTER ONE
INTRODUCTION

One area of hospital performance that has drawn increased attention is patient safety as witnessed by the emphasis that The Centers for Medicare and Medicaid Services (CMS) has placed on Value Based Purchasing patient safety metrics. Measurement of reliability, safety and value by use of report cards, benchmarks and scorecards to measure hospital and health system performance is gaining relevance within health care organizations (Griffith, Alexander, & Warden, 2002; Hafner et al., 2011; Voelker, Rakich, & French, 2001). The extent of external, public reporting of comparative performance is unprecedented. Health care leaders are taking aim at achieving the published, external stakeholder performance targets of a given reporting period. Great pressure is being placed on healthcare leaders by the patient and related stakeholders to produce more “value” for the healthcare dollar. So much so that leaders may focus on a highly controlled, structured, and task oriented organization to achieve scorecard goals. Leadership incentive plans and other direct evaluations of success will increasingly reflect whether targets on these scorecards are achieved, only for the cycle to repeat itself in the next reporting period.

This is in addition to the fact that within the field it is increasingly clear that patient safety has become a discipline, complete with an integrated body of knowledge and expertise, and that it has the potential to revolutionize health care (Emanuel et al., 2008). In the 1990’s, the critical assumptions as to why people make errors that lead to adverse events shifted from a single cause, legalistic framework to a systems
engineering design framework, and in so doing, it changed forever the way people think about healthcare delivery (Emanuel et al., 2008). These critical assumptions are (Emanuel et al., 2008): Limiting Blame; Systems Thinking Transparency and Learning; Culture and Professionalism; Accountability for Delivering Effective and Safe Care; Health Care as an Industry; Rethinking Risk; and Emphasizing Teamwork as Well as Dyadic Relationships.

These assumptions directly or indirectly relate to the Culture of Safety within health care systems. Significant scholarly thought and empirical research has been devoted to the role that culture plays in organizational performance. A segment of that scholarship has been devoted to the creation of and the role of a strong culture within complex adaptive systems. The influence of culture is of interest because a strong and aligned culture is believed to influence groups and teams toward desired performance.

In this context, culture is comprised of rituals, symbols, traditions, inclusive actions and inquiry both positive and prosecutorial that leaders create and act upon which create operating principles and other guides for individuals and teams. Strong cultures are believed to be especially beneficial in guiding performance in areas that are gaining relevance for an organization such as patient safety.

Accountability: Influence vs. Tight Control

A singular emphasis on control aimed at achieving the current scorecard is not well suited for conditions of high task uncertainty (Sitkin, Sutcliffe, & Schroeder, 1994) which characterize modern hospitals and health systems. The problem is that leaders may not be appreciating the importance of safety culture in achieving performance
excellence within complex adaptive systems, especially a system with a high level of professional autonomy such as exists within hospitals. While short term performance measures may be achieved, sustained high reliability and safety is elusive without a supportive and inspiring culture to complement process improvement methodologies. Unintended consequences of tight control and lack of staff autonomy has, at times, led to decisions and actions by the members of the team that are counter to an organization’s mission.

The scandals associated with General Motors (GM) lack of action on a known fatal safety issue and the Veterans Administration (VA) health system’s leaders creating false records of patient wait times for appointments are just two recent examples of where leadership’s direct and indirect actions can be too focused on a targeted outcome resulting in the creation of a culture not consistent with the organization’s mission and values. In the case of GM, corporate leaders were proceeding with confidence that cars were safe and of high quality when an internal probe related to a faulty ignition switch found “a pattern of incompetence and neglect” throughout the company (“GM: Steps to a recall nightmare-CNNMoney,” 2014) and a 11 year delay before starting the safety recall. Deaths linked to GM’s faulty ignition switch rose to 30 with up to 1240 claims estimated to cost GM $400 million in settlements (edwards, 2014). Not surprising certain leaders acted slowly or failed to act due to what must have been overwhelming pressure to perform. The VA health system implemented measurable performance targets and associated incentive payments related to timely appointments as a result of complaints and whistle-blower findings of excessive delays.
Records released by the Phoenix VA Health Care System showed roughly $10 million paid out in management bonuses related to waiting time improvements over a three year period ("VA Hospital Scandal: 5 things to know," 2014). The focus on hitting those targets and receiving incentive pay by all levels of leadership created a pressure that resulted in an unintended consequence of leaders in as many as 93 facilities nationwide according to the Veterans Affair Inspector General Office being “pretty confident” scheduling or data manipulation of appointment wait times purposely taking place (Carney, 2014). As a result, Secretary of Veterans Affairs Eric Shinseki resigned amid allegations that as many as 40 veterans died while awaiting appointments in Phoenix VA facilities ("VA Hospital Scandal: 5 things to know," 2014). Both cases may be viewed as examples of how an organization, team or individual react to the overall culture and pressures in place sometimes counter to the organizations mission and values.

Likewise, in the health system and hospital field a significant and unprecedented financial impact is now in place related to patient safety harm event performance. Health system boards are increasingly placing measurement and performance on evaluation and incentive plans of leaders at all levels. Will such reaction by boards and leadership successfully result in dramatic improvement in the reduction of patient harm or will unintended consequences arise from a potentially overwhelming, unprecedented emphasis on “targets”? Strategic and operational plans, performance methodologies, tight controls, information systems and facilities plans are increasingly aimed at achieving annual safety targets. There remains a lack of a universally accepted defined measurement of patient harm.
Could hospital and health system leadership be vulnerable to inadvertently creating the conditions where members of the organization (micro systems) act in ways that are detrimental to patient safety and against the organization’s mission and values as a way to achieve highly visible annual performance targets? One area of hospital performance that has drawn increased attention is patient safety as witnessed by the emphasis that the Centers for Medicare and Medicaid Services (CMS) has placed on Value Based Purchasing (VBP). By publishing outcome and process results on patient safety and associating payment with such results, it is believed performance will improve. The culture created by leadership actions, behaviors and symbolism evidenced in this unprecedented period of accountability will have a major influence on whether the organization’s results will be sufficient and sustainable to achieve threshold and top levels of performance consistently. Will leadership be more effective if the focus is on intentionally creating a Culture of Safety rather than just the intended results and associated tasks? The aim of leadership should be the establishment of a strong culture of safety and staff engagement that is capable of sustained high performance as evidenced by routinely achieving performance metrics despite the ever changing conditions internal and external to the complex adaptive system which is a hospital or health system.

The Present Study

The Purpose of this study

This proposal outlines a study to examine the relationship between an organization’s Safety Culture, as defined and measured by the Culture of Safety Survey
tool developed by The Agency for Healthcare Research and Quality (AHRQ), and patient harm events measured as the United Hospital Consortium (UHC) Hospital Acquired Conditions (HACs) reported and internally reported significant patient harm events within a multi-hospital health system over a 4 year period.

The study will use the insights drawn from the theoretical framework of Contingency theory within a complex adaptive system that is the modern US hospital to examine the correlation of a Safety Culture to actual patient harm events.

Research Questions

The following research questions will guide the study:

1. Is there a relationship between a Safety Culture and internally reported patient harm incident reports?

2. Is there a relationship between a Safety Culture of a hospital and externally reported, abstracted hospital acquired conditions?

Contribution of the Study

The results of the proposed study will contribute to the literature in several ways. While the Culture of Safety survey tool has been examined frequently, a study of its relationship to actual reported harm events is unique, especially over time and across multiple hospitals with a single health system. The increased accountability placed on health system leaders to have their hospitals produce externally defined performance results is documented; however, this study shall contribute perspective as to the degree of focus these leaders should place on creating a culture of safety as a strategy to improve performance. A view of hospital and health system performance as a function
of complex adaptive systems within the Contingency Theory framework shall enhance the significance of hospitals and health system leaders to view their work as creating a positive Culture of Safety, less mechanistic and more emerging.

Attention will be drawn to the impact of Patient Safety Culture on performance within the context of complex adaptive systems calling into question the appropriate balance of control vs guiding leadership and influence also to be referenced as “structural elements” and structural exploration.”
Some years ago Peter Drucker observed that healthcare organizations are among the most difficult organizations to manage (Drucker, 2007, 2009). But the root cause of the difficulties facing healthcare management stem from the broader problems in the healthcare setting (Baker, 2001). The current system works poorly not just for managers, but also for professionals and staff, insurers and most of all patients.

Adding to the challenges in the current environment are the incipient technological forces that threaten to reorganize the industry in ways that few can anticipate (Baker, 2001). Revolutionary developments in pharmacogenomics, bioinformatics, and nanotechnology will alter the medical armamentarium, permitting more effective treatments tailored to the genetically determined needs of the patient with a greatly reduced potential for adverse reactions. Healthcare is thus faced with tremendous changes to the underlying technologies that augment the power to heal. Moreover, this technology is likely to increase, not diminish, the costs of care and pressures to increase access to services.

As healthcare organizations are referred to as systems such as a regional or local health system with missions to improve the health of the community it serves it is natural to view it as a “machine system” (Begun, Zimmerman, & Dooley, 2003). Such a
system is linear and to “fix” it is to replace the poor performing part. This mechanistic view of health care systems by health care managers has been ineffective in solving problems in patient safety and improving both cost and quality of health care.

The Institute of Medicine (IOM) (America, 2001) in its report, Crossing the Quality Chasm, provides a set of recommendations and a list of "simple rules" to reorient and restructure U.S. healthcare. It offers an appealing vision of a healthcare system focused on the patient, offering timely, safe, efficient, and effective services to all who need them.

The idea that a set of simple rules and a shared vision for healthcare will transform working relationships and engender more effective outcomes for patients and caregivers is a compelling one. The genesis of this idea stems from complex adaptive systems theory and fundamental work done in biology and physics, The application of complex adaptive systems thinking to human systems and organizations is a rapidly evolving field (Ruth A Anderson & McDaniel Jr, 2000; Axelrod, Axelrod, & Cohen, 2000; Begun et al., 2003).

Consistent with this approach, the IOM report authors note that creating a common purpose or shared goals and identifying a few simple rules to guide behaviors for those in the healthcare system will create a context for "a healthcare system capable of dramatic changes in quality." How many large integrated delivery systems are capable of the decentralization of decision making necessary to allow simple rules to influence behaviors? Most of these delivery systems have spent the last five to ten years
pursing integration strategies; assembling clinics, hospitals, and physician practices; and trying to create common identities among them. The increased complexity and size of these organizations has meant that many senior leaders have focused considerable effort grappling with the economic, legal, and organizational problems of creating these new organizations. The purpose of many of these mergers was to improve the coordination of care for patients across the continuum. Yet many delivery systems have stalled while trying to integrate their various parts and to create common human resources, information management, and planning activities (Shortell, Bennett, & Byck, 1998). The huge costs associated with mergers along with increasing competition on the price of care has also meant that many delivery systems have had to lay off staff and limit services to maintain viability. As a result, these organizations have increased, not diminished, their controls on local operating units, trying to standardize procedures and eliminate duplication in facilities and staff. Highly controlled operating units are now directed to achieve new performance targets based on external stakeholder interests such as CMS Value Based Purchasing (VBP). A linear, controlled leadership style does not often or clearly provide the “simple rules” and vision needed by the various micro systems to adjust appropriately so as to achieve sustained high performance relative to patient harm events over time.

Adequate fit between structures and processes, permitted through a safety culture and enhanced through learning, is an important path to be adopted by health care organizations to reduce medical errors (Kaissi, 2006). This is where culture plays an important role. As from a Contingency Theory perspective we suggest that health care
organizations in general, operate from a misfit between contingencies and structures (Kaissi, 2006).

Complex organizations such as hospitals and health systems are composed of a series of hierarchically organized subsystems resulting in huge complex networks of smaller microsystems (Vincent, 2010). These subsystems include equipment, individuals, teams, organizations and environments (Kaissi, 2006). It is important to appreciate the “nature” of patient safety which has a high degree of complexity as it has the traits of humanism and is technical in nature. The nature of patient safety has been described as trustworthiness; dependent on open learning; emerges from systems design; and is a property that is designed for the nature of illness (Emanuel et al., 2008).

The concept of organizational culture helps us understand the mysterious and seemingly irrational things that happen in these complex organizations. Organizations develop cultures that affect in many ways how the members feel, think, and act. It is suggested that the only thing of real importance that leaders do is to create and manage culture (Schein, 2006). Culture is a deep phenomenon that is complex and difficult to understand. It is a learned product of group experience. Thus, culture can be learned, but most importantly, it can be changed. According to Schein (1985), culture is defined as a “pattern of basic assumptions—invented, discovered or developed by a given group as it learns to cope with its problems of external adaptation and internal integration—that has worked well enough to be considered valid, and therefore to be taught to new members as the correct way to perceive, think, and feel in relation to these problems.” Three levels of culture are identified: (1) basic assumptions, which are not to be debated
or questioned, and unconscious realities that constitute the essence of culture; (2) values, which are the day-to-day principles that guide behavior; and (3) artifacts, which are the constructed physical and social events that are the observable manifestations of assumptions and values (Schein, 1985).

In relation to safety, there are, in general, 2 types of organizational culture: culture of blame and culture of safety. The culture of blame is highly influenced by the “person approach” to dealing with medical errors. The person approach is based on the premise that “bad things happen to bad people” and thus focuses on the unsafe acts of people at the “sharp end.” It advocates that unsafe acts are a result of aberrant mental processes. Contingency theory, organizational culture, and organizational learning each offer separate insights on the issue of patient safety and medical errors.

This view of a Conceptual Framework can be viewed in Figure 1.

Figure 1: Conceptual Framework

Contingency Theory and Culture: the best fit

In this section, we explain how these perspectives can be complementary in understanding the concept of culture of safety impact on harm events.
The first link that we will make is Contingency Theory and organizational culture. Health care organizations must be both centralized and decentralized if they are to cope with contextual contingencies and reduce their error rates. However, a system in which both centralization and decentralization occur is difficult to be designed. This stated by Weick, “before you can centralize you have first to decentralize so that people are socialized to use similar decision premises and assumptions so that when they operate their own units, those decentralized options are equivalent and coordinated.” (Weick, 1987). Culture can impose order and serve as a substitute for centralization. Culture creates a homogeneous set of assumptions and decision premises, which when invoked on a local and decentralized level, they allow coordination and centralization to be preserved (Weick, 1987). More importantly, compliance in this case occurs without the need for surveillance.

Another link is between organizational culture and organizational learning. As suggested before, organizational learning can be hampered by cultures of blame that pervade many health care organizations. A litigious society is also a contributing factor to a culture of blame. Rather than asking the questions about the root causes of the errors, it is easier to find culprits for errors and to point fingers at a single individual. Especially in organizations with strong competition for resources and power, organizational culture is a source of blame and a block to effective learning. Units or departments associated with an accident attempt to shift the blame to others, whereas hospitals in general have strong incentives such as fear of litigation to hide errors. Although in hospitals, cases of adverse occurrences are discussed at monthly morbidity
and mortality conferences, grand rounds, and peer review, these activities “all share the same shortcomings: a lack of human factors and thinking about systems, a narrow focus on individual performance to the exclusion of contributory team and larger social issues, hindsight bias, a tendency to search for errors as opposed to the myriad causes of error induction, and a lack of multidisciplinary integration into an organizational wide safety culture.” (Donaldson, 1999). These reviews are also held in strict confidence as protected peer review or under the heading of medical education. Another connection can also be made between culture and learning. In high-hazard industries such as health care, a major learning strategy, trial and error, is not possible because errors cannot be contained. However, reliable performance is difficult when trial and error are precluded. Thus, substitutes for trial and error should be developed in the system. An important aspect of these substitutes is an organizational culture of safety that values storytelling. As described by Weick, “a system that values stories and storytelling is potentially more reliable because people know more about their system, know more of the potential errors that might occur, and they are more confident that they can handle those errors that do occur because they know that other people have already handled similar errors.”

In brief, high reliability organizations are a prime example of the system approach. They design their structure in a flexible way that allows proper fit with the contextual contingencies; they rely on a strong culture of safety that manifests itself as an organization learning from its mistakes in order to improve. However, pressure felt
by hospital and health system Boards and leadership can often results in simple annual
targets, a culture of blame and tight process controls.

Contingency Theory

Contingency Theory, within the context of hospitals and health systems as complex adaptive systems, represents a comprehensive framework for understanding that key agents of the firm will self organize and behave in complex ways that are difficult for leaders to predict based on contingency factors such as uncertainty. Therefore, a leader is well served by creating a strong culture which guides and supports actions and behaviors within the group that are favored by leaders so as to achieve desired organizational performance

Contingency theory is common in the scholarly studies of organization behavior, design, performance, and planning and management strategy. The proposition is that an organization outcome is the consequence of a fit or match between two or more factors (Van de Ven & Drazin, 1984). Fit is the key concept in this proposition and a problem when not defined early in the work. There are three ways to define and test the fit: Selection, Interaction and Systems approaches (Van de Ven & Drazin, 1984). As it relates to hospitals and health systems taking aim at process and outcome targets, many set by external stakeholders and regularly changing, consideration should be given to the fit between the Principle and its Agents, the collective work force, systems in use and other resources available. The fit includes individual and collective self-interests and incentives aligned with the hospital and health system. Therefore, it is imperative that a priority be made as to the selection of agents (members of the medical staff and its
leadership), and all others in the workforce so that all have aligned self-interests, personal standards and incentives toward safety and quality. Due to the complexity inherent in hospitals and health systems and associated clinical micro systems the interactions among all should be facilitated or otherwise guided by leadership as such interaction is central to fit. The frequency, type and tone of interaction should all be influenced by intention in creating a safe culture. Finally, the systems in place such as an integrated and aligned improvement methodology and high functioning decision support system greatly enhance and reinforce the culture of safety and resulting outcomes.

Contingency Theory is an open system view of environmental impacts on internal organizational structures, processes and strategies, and a reaction to classical management theory and other closed system perspectives (Kaissi, 2006; Mintzberg, 1979). It is based on the general premise that there is no best way to organize and that any ways of organizing are not equally effective. Thus, the best way to organize is contingent on the environment (Galbraith, 1973). Accordingly, managers should strive to achieve a fit or alignment among the key elements of their organization’s operating environment and its internal design (Young, Parker, & Charns, 2001). Thus while contingency theory asserts that there is no one best way to organize universally, it does hypothesize that there is one best way given a certain type of operating environment. The theory also holds, “that an organization may have multiple and diverse operating environments across division or subunits and that its internal design will be differentiated accordingly to reflect this diversity.” (Hardy, 1983). The theory assumes
that organizations generally are capable of adapting to changing environments. Researchers consider uncertainty as an important contingency factor that could influence organizational design (Lawrence & Lorsch, 1986). Galbraith also proposed that information processing requirements as the central mediating mechanism between uncertainty and organizational design. In summary, higher levels of environmental uncertainty create greater information processing requirements for the organization (Galbraith, 1995).

The various contingencies include organizational size, technology (production, information), and environment (uncertainty, resource munificence, and degree of competition) and constitute the context within which the organization operates (Mintzberg, 1979). Structure is defined as both the officially prescribed formal organization and the de facto, unofficial formal organization (Donaldson, 1999). It includes formalization, differentiation, centralization, span of control, specialization, etc.

Relative to selection and interaction, a Contingency Theory of Socialization proposes that there are distinct stages of socialization and the personal and organizational contingencies that control an individual’s movement through the stages are impactful (Feldman, 1976). The outcomes of socialization seem to be directly related to eventual high performance and creation of a safe culture. Those outcomes are the degree of developed and aligned feelings of general satisfaction, mutual influence, internal work motivation and job involvement (Feldman, 1976).

High Reliability Organization Theory views that accidents can be prevented through good organizational design and management (Reason, 2000). The proper
organization of people, technology, and processes can handle complex and hazardous activities at the acceptable levels of performance. Thus, the concept of High Reliability Organizations (HROs) emerged. These are “systems operating in hazardous conditions that have fewer than their share of adverse events,” (Reason, 2000) have intrinsic safety and are able to withstand their operational dangers and still achieve their objectives. Examples of HROs include nuclear aircraft carriers, air traffic control systems, and nuclear power plants. High Reliability Organizations face many challenges such as managing complex demanding technology to avoid failures and maintaining the capacity for meeting periods of high-peak demand. They are complex, internally dynamic, and intermittently, intensely interactive, and they perform exacting tasks under considerable time pressure (Kaissi, 2006). The main distinguishing feature of HROs is their ability to carry out these demanding activities with low incident rates and an almost complete absence of catastrophic failures over several years (Kaissi, 2006).

Although the above-mentioned challenges and characteristics are highly similar to health care organizations, the outcomes vary substantially (IOM reports 45,000-98,000 deaths per year). Thus, it is suggested that there are lessons to be learnt on health care from these organizations. As suggested by the IOM, “claims that healthcare is unique and therefore not susceptible to a transfer of learning from other industries are not supportable.” (L. T. Kohn, Corrigan, & Donaldson, 2000). Moreover, the practices adopted by other industries have resulted neither in stifled innovation nor in loss of competitive benefit (L. Kohn, Corrigan, & Donaldson, 1999). From a Contingency Theory perspective, these organizations have managed to develop structures,
processes, and strategies that allow them to achieve fit with contingencies (complexity and tight coupling) and with other contingencies (interdependence and uncertainty) (Kaissi, 2006). For example, contingency in a nuclear aircraft carrier emanates from the potential for unexpected sequences, complex technologies, and indirect information sources.

Zayac et al. have suggested several conditions that lend themselves to a robust empirical test of contingency theory. The conditions are as follows:

- Changing environmental conditions suggesting the need for organizational change
- Differences in organizational attributes and in local environmental conditions
- Ambiguity around the appropriateness of change
- Specific identifiable factors likely to affect fit
- Both changes in organization and related changes in performance can be empirically observed

Many of these conditions are likely to be satisfied in the health care industry, within a large health care system, or within a single hospital within a system (Zajac, Kraatz, & Bresser, 2000).

**Complex Adaptive Systems**

Michael Niemeier, MD, Chief Quality Officer, of IU Health Methodist, a consistent top US News & World Report and UHC hospital, once stated that quality is why patients and their families turn to us and safety is why they leave their loved one in our care. The distinctive work processes required for teams and individuals to be both
high quality and safe are at the core of a hospital’s essence as a complex adaptive system.

Health care systems are considered complex adaptive systems (America, 2001; Ruth A Anderson, Crabtree, Steele, & McDaniel, 2005; Hamel, 2004; Litaker, Tomolo, Liberatore, Stange, & Aron, 2006). A complex system is one that is adaptive in its local environment, is composed of other complex clinical micro systems (for example, a surgical ICU unit) and behaves in a non-linear fashion (change in outcome not proportional to change in input) (Shiell, Hawe, & Gold, 2008). “Most important is the understanding that attention to relationships and interdependence is critical for developing effective management strategies.” (McDaniel, Driebe, & Lanham, 2013).

In some respects, this is obvious as one need only be a patient or observer for 24 hours in a typical nursing unit to notice the differences or adaptations that exist between one clinical team and the other or from day shift to night shift to weekend shift. Multi-hospital systems are particularly challenged by the complex adaptive systems represented by each hospital when implementing a standard protocol. A leader simply cannot announce an outcome goal derived from an external stakeholder, exhort the team to carry on, provide incentives and tight controls within processes and equipment then expect highly reliable and safe care. As such the introduction of any change does not have a direct path or impact on system performance. So the introduction of public scorecards and performance targets based on national process and outcome measures such as the CMS VBP or various pay for performance (P4P) measures may not directly result in hospital performance improvement.
“When the principle characteristics of complex adaptive systems - agents interconnected in self-organizing, emergent and coevolving systems - are considered, a major insight is that the behaviors of these systems are fundamentally unknowable” (Suchman, Sluyter, & Williamson, 2011). Evolution of complex organizations often is accompanied by feedback effects, nonlinearity and other conditions that add to the complexity and unpredictability of healthcare organizations (Begun et al., 2003). The introduction of management change such as the introduction of greater leadership accountability through the use of scorecards and leadership incentives to achieve targets, within a complex adaptive system such as a hospital or health system is intended to have a significant positive impact on targeted outcomes. However, when such change is introduced in a linear fashion it is “unknowable” how exactly the complex adaptive system will perform. The performance may be greatly mediated by the culture of safety within the numerous micro systems. Achievement of process outcomes related to patient safety and clinical outcomes such as adverse events with injury requires a collaborative effort within and among clinical micro systems that share a strong safety culture based on actions, beliefs and self-interests. Anderson suggests, “...managers who address seemingly intractable problems in healthcare such as patient safety will be required to view health care organizations as complex adaptive systems and include patients as full participants in co-producing their health care.” (Ruth A. Anderson, 2013)

The concept of structural “exploration” is when hospitals provide employees access to key information and empower them to adapt their processes to environmental
changes so as to optimize quality methods (Douglas & Judge, 2001). Likewise, hospitals that place a strong emphasis on structural “control” of procedures, operations and work activities (standard work) also can optimize quality methods (Douglas & Judge, 2001). Quality methods integrated into job descriptions, performance reviews, incentive plans, rounding and other admin practices are examples of structural “control”.

**Clinical Microsystems**

The clinical microsystem provides a conceptual and practical framework for approaching organizational learning and delivery of care. Healthcare organizations are in some sense conglomerates of smaller systems, not coherent monolithic organizations. The microsystem unit allows organizational leaders to embed quality and safety into a microsystem’s developmental journey. Leaders can set the stage for making safety a priority for the organization while allowing individual microsystems to create innovative strategies for improvement. Tensions exist between the conceptual theory and the daily practical applications of providing safe and effective care within healthcare systems (Mohr, Batalden, & Barach, 2004). Healthcare institutions continue to face challenges in providing safe patient care in increasingly complex organizational and regulatory environments while striving to maintain financial viability. Healthcare organizations are often complex, disorganized, and opaque systems to their users and their patients. This disorganization may lead to patient discomfort and harm as well as much waste.

A clinical microsystem is a group of clinicians and staff working together with a shared clinical purpose to provide care for a population of patients (Mohr et al., 2004;
Nelson, Batalden, Mohr, & Plume, 1997). The clinical purpose and its setting defines the essential components of the microsystem. These include the clinician and support staff, information and technology, the specific care processes, and the behaviors that are required to provide care to its patients. Microsystems evolve over time, responding to the needs of their patients, providers, and external pressures (Mohr et al., 2004). They coexist with other microsystems within a larger (macro) organization. Examples of clinical microsystems include a cardiovascular surgical care team, a community based outpatient care center, or a neonatal intensive care unit. Each example has in common core elements: a focused type of care, clinicians and staff with the skills and training needed to engage in the required care processes, a defined patient population, and a certain level of information and technology to support their work. The core elements are consistent across these examples.

Safety Culture

There is a critical need to enhance health system capacity, so that all patients will receive care that is safe and effective. (O’Kane et al., 2008). To that end patient safety has emerged as a discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of healthcare delivery (Emanuel et al., 2008). Despite the emergence of patient safety as a discipline, with associated methods and policies, increased transparency of results through CMS Hospital Compare and growing financial payment contingencies, for example, there is still much improvement needed and great variation noted within and between hospitals and health systems. The following stories suggest that perhaps the culture of safety is a
prominent variable to be nurtured by leadership which can bring about less variation and significant reduction in patient harm events.

The CEO frequently and publicly represents to the newly assigned staff of a completely new, modern hospital that the aim is to be a medication error free hospital. Within just one week of its opening a near fatal IV administration error occurs despite the presence of state-of-the-art safety features within the IV pump and medication administration processes. Following the completion of a root cause analysis the CEO takes steps to reinforce a culture of safety by ensuring that the story surrounding the error is shared with all clinical staff with the message that the aim to be error free is still valid as this incident is evidence more work is needed. While it was found that the nurse activated override features to the safety “guardrails” on the pump designed to prevent such an error, further investigation found nurses frequently doing so because of the settings on the “guardrails”. A sound safety culture is one where the knowledge of safety features being frequently in override would trigger a response by management to make adjustments so the “guardrails” would be more effective. By looking deeper into the process, the nurse was excused from blame and, in fact, praised by agreeing to allow her story to be shared with all clinical staff. The leadership response to this event made a lasting impression on the culture of safety. The hospital, while still not yet medication error free, has performed at the top of its multi-hospital system in terms of fewest harm events and Culture of Safety scores.

In another hospital within the same health system an early career nurse self-reported his error in inadvertently reusing an Epi pen in the treatment of diabetes on a
second patient. A violation of safety policy. Leadership was aware of the risk of this occurring as part of its investigation of similar previous errors. Rather than being punished the nurse was praised by the Senior Quality Officer for self-reporting. The nurse later expressed to colleagues the importance to him of being supported by leadership instead of punished, “I was already beating myself up for the avoidable error. Experiencing a non-punitive culture firsthand allowed me to forgive myself and rededicate myself to safe practice.”

In the same hospital leadership conducts Daily Safety Awareness Huddles (DASH), a national best practice. Each department verbally shares a brief safety awareness report for the purpose of building situational awareness organization wide of conditions that could lead to error or of near misses since the last report. In one such DASH a report was shared of a patient fall without injury when the patient was trying to get out of bed without assistance despite prior restrictions. Immediate investigation revealed none of the fall prevention protocols were in place. The senior executive could have let the verbal report stand with a “let’s be more careful next time” message. Instead, the executive immediately met with nursing, clinical engineering and supply chain stating the expectation that countermeasures be immediately in place to prevent a repeat occurrence until final measures are implemented. The attention by the senior leader to not let this event be treated as “routine” was important to the entire leadership in reinforcing a culture of safety.

In each of these cases leadership actions and behaviors were intentional in regards to creating and reinforcing a culture of safety within the hospital. Does it
matter? Or, can strong safety performance be achieved simply through Process, Structure and Outcomes (Donabedian, 1988) combined with tight management controls aimed at finding the person to blame if errors exist?

However, to effect patient safety it is necessary to find the right fit of structure, process and outcomes so as to be relevant and useful to the micro systems active within the complex adaptive system of a hospital or health system. Charles Vincent (Vincent, 2011) identified seven elements that influence safety which provides important insight as to how to find the right fit it. They are as follows:

1. Organization and management factors
2. Work environment factors
3. Team factors
4. Task factors
5. Individual factors
6. Patient characteristics
7. External environment factors

The practices, decisions and symbols around these elements that comprise the daily life of a health care organization and associated micro systems can be considered its Patient Safety Culture.

It is increasingly clear that patient safety has become a discipline, complete with an integrated body of knowledge and expertise and that it has the potential to revolutionize health care (Emanuel et al., 2008). In the 1990’s the critical assumptions as to why people make errors that lead to adverse events shifted from a single cause,
legalistic framework to a systems engineering design framework, and in so doing, it changed forever the way people think about healthcare delivery (Emanuel et al., 2008). These critical assumptions are (Emanuel et al., 2008):

Limiting Blame; Systems Thinking; Transparency and Learning; Culture and Professionalism; Accountability for Delivering Effective and Safe Care; Health Care as an Industry; Rethinking Risk; and Emphasizing Teamwork as Well as Dyadic Relationships.

Organizational culture is a concept often used to describe shared corporate values that affect and influence members’ attitudes and behaviors (Cooper, 2000). Safety culture is a sub-facet of organizational culture. The myriad of definitions of “organizational culture” and “safety culture” that abound in both the management and safety literature suggests the concepts to business-specific cultures is not clear cut. However, it is important, “Ambitious corporate sustainability activities and strategies have to be embedded in the organization’s culture in order to be successful.” (Baumgartner, 2009).

The patient safety culture is rooted in the 1970’s and 1980’s, when medical malpractice claims were great in number and severity (Wilson & Hatlie, 2001). Publication of these errors, including those cases in the 1990’s, led to intense public scrutiny of health care practices. The movement was strengthen by several initiatives, including the recognition of health care risk management as a profession, adoption of continuous quality improvement principles, and the advancement of the role of the pharmacist (Wilson & Hatlie, 2001).
The Institute of Medicine Reports in 1999 and 2001 (To Err Is Human and Crossing the Quality Chasm) and the adoption of patient safety goals by The Joint Commission have created an atmosphere of urgency about this issue in hospitals.

The concept of safety culture arose in the aftermath of the Chernobyl disaster. In health care it has been highlighted as a necessary element in achieving high reliable and safe organizations (America, 2001). It is argued that safety culture represents a new way of conceptualizing processes of risk handling and management in organizational and other contexts (Pidgeon, 1991). Culture can be conceptualized as primarily an ideational system of meanings, and safety culture as one concerned with the norms, beliefs, roles and practices for handling risk. “Possible elements of “good” safety culture are elaborated under the three headings: norms and rules for dealing with risk, safety attitudes and reflexivity on safety practices” (Pidgeon, 1991).

Great importance has been attached to a culture of safe practice in healthcare organizations, but it has proved difficult to engage frontline staff with this complex concept (Kirk, Parker, Claridge, Esmail, & Marshall, 2007). The resulting framework conceptualizes patient safety culture as multidimensional and dynamic. The framework moves the agenda on from rhetoric about the importance of safety culture to a way of understanding why and how the shared values of staff working within a healthcare organization may be operationalized to create a safe environment for patient care with communication based on mutual trust and openness.

Aspects of a positive safety culture framework include (Kirk et al., 2007):

- Shared perceptions of the importance of safety
- Confidence in the efficacy of preventive safety measures
- Organizational learning
- Committed leadership and executive responsibility
- A “no blame”, non-punitive approach to incident reporting and analysis

Dimensions of patient safety (Kirk et al., 2007) include: Overall commitment to quality; Priority given to patient safety; Perceptions of the causes of patient safety; Investigating patient safety incidents; Organizational learning following a patient safety event; Communication about safety issues; Personnel management and safety issues; and Team working around safety issues.

Professional peer modeling behaviors and individuals’ beliefs about the value of those behaviors in improving patient safety are important predictors of the health care workers’ patient safety behavior (Wakefield, McLaws, Whitby, & Patton, 2010). Findings from studies like these may help explain the limitations of current knowledge-based approaches to patient safety reform. Total Quality Management (TQM) was an earlier effort to achieve high reliability and safety. The singular emphasis on control that characterized traditional approaches to total quality management implementation are not well suited to conditions of high task uncertainty (Sitkin et al., 1994). Although fundamental precepts advocated by founders of TQM can accommodate uncertainty the way basic TQM has been articulated and implemented has not reflected the distinct, learning oriented requirements associated with high levels of uncertainty (Sitkin et al., 1994). TQM practice and organizational performance is significant. Some categories were particularly strong indicators: leadership, management of people, and customer
focus as opposed to TQM tools and techniques such as process improvement, benchmarking and information analysis (Samson & Terziovski, 1999). Leadership approached TQM in a linear, control fashion believing a tight implementation of process improvement tools and published results would yield sustained and improved performance.

**Safety Climate**

Safety Climate as part of organization culture might be considered an alternative safety performance indicator (Guldenmund, 2000). Three levels at which organization safety culture can be studied—basis assumptions, espoused values and artifacts (Schein, 2006). At the level of espoused values we find attitudes, which are equated with safety climate. The basic assumptions, however, form the core of culture. Most important is the assessment of the organization’s basic assumptions, since these are assumed to be explanatory to its attitudes (Schein, 2006). Schein mentions particular dimensions around which basic assumptions form:

1. *The nature of what is reality and truth*—this assumption generally defines what is safe and what is not.
2. *The nature of time*.
3. *The nature of space*. The workplace and their hazards as related to efforts to prep and clean.
4. *The nature of human nature*—are they accident prone, little focus.
5. *The nature of human activity*—what is work? To what extent does one take initiative? Is production and bottom line the essence of the organization which
may lead to compromise as to safety? Closely related to assumption one where some level of error is acceptable may be acceptable if production targets are met.

6. *The nature of human relationships*—whether it is acceptable or expected to correct another’s safety behavior. The authority gradient may dictate one follow formal and informal leaders even if less safe.

Applying Schein’s model to the concept of a culture of safety yields the following:

(Kaissi, 2006).

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<td><strong>Artifacts</strong></td>
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Medical errors is a severe problem.

Beliefs and Assumptions

Safety comes first. Errors are due to situational factors.

No illusion of free will.

Causes of errors are relatively banal in themselves.

Measuring Culture of Safety

When in dialogue with hospital and health system staff and their perceptions of patient safety within the organization, the variety of definitions and measurement systems can be a problem. In its Culture of Safety Survey tool, The Agency for Healthcare Research and Quality (AHRQ) defines patient safety as “the avoidance and prevention of patient injuries or adverse events resulting from the process of health care delivery”.

The Safety Culture among health care professionals in hospital units is believed to influence safety performance (Smits et al., 2012). One study of the mediation effect of safety culture among hospital professionals in the relationship between specialty and safety could not give support for that claim (Smits et al., 2012). The Health Foundation (2011) published a research scan that included approximately 15000 articles on safety and safety culture between 2000 and 2010. Only 100 addressed the connection between safety culture and performance with just 50 as empirical studies. The studies were of single hospitals and at one point in time with results mixed as to a correlation between a Culture of Safety and outcomes.
In an effort to facilitate the measurement of a culture of safety AHRQ researched and developed a Culture of Safety Survey which measures twelve dimensions of patient safety including “overall perceptions of patient safety”. See Attachment B or go to the AHRQ link:


Hospitals that use the survey can compare results year over year internally as well as to national average and 90th percentile scores.

The twelve dimensions of patient safety culture measured by the survey are as follows:

- Teamwork within units
- Supervisor/manager expectations and actions promoting patient safety
- Organizational learning – continuous improvement
- Management support for patient safety
- Overall perception of patient safety
- Feedback and communications about error
- Communication openness
- Frequency of events reported
- Teamwork across units
- Staffing
- Handoffs and transitions
- Nonpunitive response to errors.
Contributing to Culture

Patient Safety practices, actions and signage can constitute cultural setting practices, rituals and symbols that together comprise what an organization does to shape and reinforce its culture are numerous. Both AHRQ and Institute for HealthCare Improvement (IHI) advocate many such practices (AHRQ, 2013). These practices, actions and behaviors include:

- **Teamwork within units**: daily huddles, warm handoffs between shifts, safety contests.

- **Supervisor/manager expectations and actions promoting patient safety**: stoplight reports indicating staff safety concerns and ideas for improvement and the manager’s status in addressing; management audits on checklist and other routines

- **Management support for patient safety**: timely action including expense approval and/or capital investment in safety tools such as bedside bar coding and bed alarms; senior leader safety rounding; holding the line on performance of checklists even with high profile physicians

- **Org. learning-CI**: a formal methodology in place for capturing incidents especially near misses and methods for investigation such as root cause analysis and improvement such as LEAN business systems

- **Overall Perception of Patient Safety**: intentional measurement of staff perceptions of the culture of safety and resulting action; Board standing agenda item on patient safety.
• Feedback and Communications about Error: humanize safety error by including the name and personality to all serious injury reports, wide distribution of safety event information.

• Communication Openness: discussion about safety events is frequent and at all levels.

• Frequency of Events Reported: reward units with most events reported with emphasis on near miss. Completion of event reports part of annual competency assessments

• Teamwork Across Units: Active daily briefings with all departments to promote situational awareness led by senior leader

• Staffing: priority on flexible staffing and pay plans; treat incidents of low staffing as “never” events.

• Handoffs and transitions: “warm” handoffs in place between department and shift change; team patient rounding including physician and nurse

• Nonpunitive Response to Error: “Just Culture” algorithm core of admin policy regarding response to error.

Additionally hospital leadership teams have utilized symbols and rituals to articulate and reinforce its Safety Culture. A “seal” has been used by some hospitals to represent its culture. Figures 2 and 3 illustrate two examples that note “Pursues Perfection” and “Safety” as core principles depicted with the organization’s seal which is placed in prominent locations or embedded within presentations.
Figure 2. Pursues Perfection Seal

Figure 3. Safety Seal
The seal has even been affixed to the executive suite and Board room coasters as depicted in Figures 4 and 5.

Figure 4. Seal Imprint

Figure 5. Seal Display
To summarize, Contingency Theory suggests finding the right “fit” of leadership, control and influence is dependent on the inputs, structure and complexity of the organization. Information processing requirements as the central mediating mechanism between uncertainty and organizational design. Within Hospitals as Complex Adaptive Systems it is unknowable as to the final outcome of a decision or set of rules at the microsystem level such as an inpatient unit. Leaders aiming for a desired outcome may be best served by creating a Culture of Safety consisting of a vision, reinforcing behaviors and simple rules then allow the microsystem to adjust or find the right fit contingent upon numerous factors and limiting direct control. A Culture of Safety matters in modern health systems which are complex adaptive systems. Relative to its performance, the health system’s performance is highly dependent on the numerous micro systems that are dynamic in nature. That is, dynamic in terms of members, circumstances and resources. To be highly reliable in an unprecedented environment of accountability and transparency leaders must balance efforts to control processes and actions with influence. Tighter control within micro systems may at times lead to unintended outcomes. Leaders may be better served by significantly influencing the micro systems by creating a positive and strong Culture of Safety balanced with tight structural controls.

Defining and Reporting Harm Events

In recent years, due to the Institute of Medicine (IOM) report which suggested as many as 90,000 patients died in US Hospitals per year due to preventable harm (L. Kohn et al., 1999), there has been increased attention on incidents of Harm and Adverse
Events in hospital settings. However, in 2014 there is still not one “source of truth” adopted by accrediting bodies, government entities and health care organizations which defines, measures and documents adverse events and their severity.

The Joint Commission and the Health Facility Accreditation Program (HFAP) hospital accrediting bodies have different standards as to Adverse Events. HFAP Adverse Event standard 12.00.23 states, “Adverse events are injuries resulting from medical care, as opposed to adverse outcomes arising from underlying disease.” HFAP, like more and more health care organizations and state legislative public reporting statutes, has adopted the CMS’s Hospital-Acquired Conditions (HAC) and the National Quality Forum’s “Serious Reportable Events (SRE) lists as guidance in reporting adverse events.

The JCAHO and leading health systems have elected to utilize an index which captures all patient care incidents and classifies such based on circumstances and severity as opposed to adopting just one or two defined adverse event lists such as those adopted by HFAP. A commonly used system is the National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP) Medication Error Index that can both record but also stratify/scale each event. More information can be found at http://www.nccmerp.org/medErrorCatIndex.html. The Institute for Safe Medication Practice (ISMP) has also implemented this index for use in its database. Attachment A is an algorithm which illustrates the decision and classification system that indicates adverse events classified as E or above. Typically those health care organizations using this system will use Level E or above as a trigger for intense root cause analysis and countermeasures to be in place.
CMS sponsored Partnership for Patients is a national collaborative aimed at reducing patient harm through formation of a Hospital Engagement Network (HEN). In this effort definitions of harm developed by the Health Research and Educational Trust (HRET) are offered as an option for hospitals. A Harm Improvement Calculator is part of the measurements which is designed for use by hospitals in measuring a “Harm across the Board” rate. Again, the Partnership for Patients and suggested measurements are all optional at this time.

There is yet another emerging approach to adverse events and reporting as evidenced by The HPI SEC & SER Patient Safety Measurement System for Healthcare published by Healthcare Performance Improvement (Throop & Stockmeier, 2009). In addition to determining whether harm occurred, this tool measures if there was a deviation from generally accepted practice standards and if the deviation resulted in harm. The concept is to more closely link harm measurement to the presence of and deviation from standard work processes.

In response to concerns about the quality of care in US Hospitals, acute care hospitals have been participating in the federal Inpatient Quality Reporting (IQR) program mandated by the Medicare Prescription Drug, Improvement and Modernization Act of 2003. In the first year of this pay-for-reporting program, hospitals submitted performance data on 10 specific measures of health care quality, often referred to as the “core measures.” The CMS paid hospitals that submitted these data the full Medicare payment, adjusted annually for inflation. This program has continued to develop, in both the number of quality measures required and the amounts of money
tied to these measures. By October 2013, the program had grown to encompass 55 health care quality measures. If a hospital doesn’t submit these data in a timely and accurate way each quarter, the hospital is penalized 2% of the total annual Medicare payment. It is unknown whether these process outcomes are related to hospital-level outcomes. One study that did attempt to correlate found Hospital Compare process measures predicted small differences in risk-adjusted mortality rates (Werner & Bradlow, 2006). Another study of the current Pay for Performance (P4P) initiative quality measures on Orthopedic surgery found high process scores on P4P not associated with lower rates of complications or mortality (Bhattacharyya, Freiberg, Mehta, Katz, & Ferris, 2009). This was due to the observation that the quality measures have limited validity because of poor discrimination, lack of measure balance, and lack of correlation with important clinical outcomes. Public reporting and pay for performance are intended to accelerate improvements in hospital care, yet little is known about the benefits of these methods of improving care. One study found only a modest 2% to 4% improvement over two years between hospitals under pay for performance and those not (Lindenauer et al., 2007).

Value Based Purchasing

In an unprecedented manner, patient safety as part of Value Based Purchasing is impacting hospital reimbursements. The CMS has implemented three key pay-for-performance programs to drive QI in hospitals, known as the Hospital Value-Based Purchasing (HVBP) program, the Hospital Readmissions Reduction Program (HRRP), and the Hospital-Acquired Conditions (HAC) reduction program. The quality measures
included in these programs are a subset of the (currently 55) measures required by the IQR pay-for-reporting program (Brooks, 2014). Quality improvement (QI) and patient safety initiatives are further described under Title III of the legislation: “Improving the Quality and Efficiency of Health Care” (see www.hhs.gov/healthcare/rights/law).

The HAC program conditions and results have been published on the CMS compare website since 2010. When the presence of an assignment of a HAC to an MS-DRG is associated with a higher payment as a secondary diagnosis the hospital does not receive the higher payment (Medicaid, 2012).

Eleven conditions have been published on the CMS website. Those conditions are as follows:

1. Foreign object retained after surgery
2. Air embolism
3. Blood incompatibility
4. Stage III and Stage IV pressure ulcers
5. Falls and trauma
6. Catheter-associated urinary tract infection (UTI)
7. Manifestations of Poor Glycemic Control
8. Vascular catheter-associated infection
9. Surgical Site Infections
10. Deep Vein Thrombosis (DVT)
11. Iatrogenic Pneumothorax with Venous Catheterization
The HVBP program is designed to reward hospitals that perform well on a set of quality measures, compared with all other reporting hospitals, and that improve over time, compared with their own baseline data. Because the program is “budget neutral,” no Medicare funds beyond those already budgeted are spent. Hospitals that don’t meet the CMS national benchmark (being equal to the mean of the top decile for each measure) or that don’t improve over time are penalized. In fiscal year 2013, the first year of the program, 1% of base payments were withheld; in fiscal year 2014, 1.25% was withheld. The withheld amount increases by 0.25% each year until it reaches a maximum of 2% in 2017. Each year, new measures may be added to the HVBP program and others deleted.

The HRRP retroactively evaluates and compares hospitals using three years of data on 30-day all-cause readmissions in three disease processes: acute myocardial infarction, heart failure, and pneumonia. In fiscal year 2013, the penalty was 1% of base operating DRG payments (as in the HVBP program); the penalty will increase to 2% in fiscal year 2014 and to a maximum of 3% in 2015 and beyond. As part of the proposed regulations for 2014, additional disease processes or diagnoses will be added to this list in 2015, including chronic obstructive pulmonary disease, elective total hip arthroplasty, and elective total knee arthroplasty.

The HAC reduction program will begin in 2015. Hospitals that score in the top quartile of hospital-acquired conditions will be penalized 1% of their base operating DRG payments. This penalty will be applied after adjustments are made for the HVBP program and the HRRP; in fiscal year 2015 (beginning Oct 1, 2014), a hospital that
performs poorly according to the criteria of all three programs could be penalized as much as 5.5% of total Medicare payments. The proposed evaluation method includes two medical complication domains that will be combined for a total score. Domain 1 includes the AHRQ’s Patient Safety Indicators 90, a composite of the rates of eight patient safety indicators: pressure ulcers, central venous catheter–related bloodstream infections, hip fractures, postoperative pulmonary embolism/deep vein thrombosis, sepsis, wound dehiscence, accidental puncture during surgery, and iatrogenic pneumothorax. Domain 2 includes the CDC’s National Healthcare Safety Network measures for central line–associated bloodstream infection and catheter-associated urinary tract infection. These are reported as standardized infection ratios. It has also been proposed that more hospital-acquired conditions be added to Domain 2 in 2016 and 2017. This penalty has been capped at 1%. The percentage of decreased reimbursements for each of the three pay-for-performance programs increases from 2% in 2013 to 6% in 2017. Commercial payers are increasingly developing their own P4P measures or adopting the CMS initiatives which places even more payments to hospitals and health systems at risk.
CHAPTER THREE

Design and Research Methods

Introduction and Hypothesis

The study is a longitudinal, exploratory study of the relationship between the Culture of Safety within hospitals and their associated performance relative to patient harm events. The Hypothesis is that:

1. The number of actual harm events is inversely related to the Overall Perception of Safety as perceived by staff.

Method of Analysis

The dependent variables consist of two harm measures; UHC Hospital Acquired Conditions (HAC) reported to CMS using CMS definitions and protocols by each hospital and internally reported harm incident reports within each hospital unit rated Level E or higher using the National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP) Medication Error Index (Level E Harm). The independent variable is the one dimension noted as Overall Perception of Patient Safety measured by staff surveys taken at each hospital for four years (CoPS). Observations are measured at the hospital year level. Covariates include case mix adjusted patient days (Adjusted Pt. Days), the year and the hospital.

While there are ten dimensions to a Culture of Patient Safety measured by the survey tool due to the smaller number of hospitals studied the design will only include
one dimension, the Overall Perception of Safety. It is not advisable to have a large number of variables in relation to the number of observations because the estimates of the parameters are unreliable.

The research design is a quantitative study that explores the correlation between harm events and the culture of safety survey results along with the covariates noted by use of a multivariate regression analysis with repeated measures. This is preferred due to the response variables being comprised of continuous measures as opposed to binary in nature. Repeated measures takes into account that there are multiple measurements of the same hospital over time which are likely to be correlated.

The equation to analyze the available data is a multiple linear regression with repeated measures model. The equation is as follows:

\[
\text{Harm events} = \beta_0 + \beta_1 \text{overall safety perception} + \beta_2 \text{year} + \beta_3 \text{Hospital} + \beta_4 \text{case mix adjusted patient days} + \Sigma
\]

Or otherwise expressed as \( Y_{ij} = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \beta_4 X_4 + \Sigma \)

Whereby \( i = \text{Hospital} \) \( j = \text{year} \)

\( Y_{1ij} = \text{UHC reported Hospital Acquired Conditions} \)

\( Y_{2ij} = \text{Level E and above adverse events} \quad X_1 = \text{Overall Culture of Patient Safety} \)

\( X_2 = \text{year} \quad X_3i = \text{Hospital} \quad X_4 = \text{adjusted patient days} \)

Prior to completing the correlation analysis it is important to better understand the data so a set of descriptive statistics is required to determine distribution and other relevant characteristics to ensure the correlation analysis as
described will be valid. SPSS statistical package was utilized to complete the determination for the following:

1. Mean, Min, Max and Range for each Hospital and individual unit CoPS, Level E harm, and Adjusted Patient Days by Hospital.

2. Calculate the standard deviation of the above variables.

   It is important to save the residual values and subsequently conduct or analyze for normal distribution by conducting a normal probability plot with tests for Level E harm events as dependent variable. A Shapiro-Wilk p-value > .05 suggests no evidence of lack of normality. A Shapiro-Wilk p-value < .05 indicates a normal distribution does not exit. In that event, relevant data for the analysis will be transformed by natural log calculations. Once transformed the multiple linear regression is to be performed as opposed a multiple linear regression with repeated measures.

   The reported number of UHC reported HACs by hospital is a low number (0 to 10) per year. The Poisson Regression Model is indicated as the count is a positive integer only and not normally distributed. However, a frequency distribution indicating mean and standard deviation of HAC per hospital per year will be completed. If there is an issue with the inequality of the mean and variance (standard deviation squared) then a negative binomial generalized regression model is more appropriate. If the coefficient for the independent variable (overall safety survey) has a p-value < .10 there is evidence that Safety Culture correlates with Harm Events. A p-value < .10 is appropriate given the exploratory nature of the study and the low number of observations.

Data Sources
Culture of Safety Survey results are to be collected from the corporate quality office of a single health system comprised of seven hospitals for each of the four annual periods from 2011 to 2014. The Office of Quality at the system corporate office will also be utilized in collecting files on Level E harm event reports and UHC reported hospital acquired conditions or HACs. UHC HACs are conditions abstracted from claims data using the CMS definitions and protocols assigned to the CMS HAC reporting program.

System corporate finance office to provide case mix adjusted patient days total per year per hospital for the same reporting period.

Data management and analysis were performed using SPSS statistical software version 21 (IBM SPSS for Windows).

Human Subject Protection

The Institutional Review Board of the University of Alabama at Birmingham reviewed and approved the research (See Attachment D). This study employs the analysis of anonymous survey responses and blinded incident report data; therefore, it does not involve risk to human participants.
CHAPTER 4

RESULTS

Descriptive Statistics

Data were collected for seven hospitals within the same health system for each of the years between 2011 and 2014. Four data points per hospital per year with a maximum total of 16 observations per hospital. The data points were number of HAC, number of Level E harm reports, CoPS survey results and Adjusted Patient Days. A total of 113 observations were collected. See Tables 1 and 2.

Table 1.
Descriptive Measures by Hospital: HAC  2011-2014

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Mean</th>
<th>Range</th>
<th>Maximum</th>
<th>Minimum</th>
<th>STD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital 1</td>
<td>10.66</td>
<td>6</td>
<td>13</td>
<td>7</td>
<td>3.2</td>
</tr>
<tr>
<td>Hospital 2</td>
<td>5.25</td>
<td>4</td>
<td>7</td>
<td>3</td>
<td>1.7</td>
</tr>
<tr>
<td>Hospital 3</td>
<td>5.75</td>
<td>6.0</td>
<td>9</td>
<td>3</td>
<td>2.5</td>
</tr>
<tr>
<td>Hospital 4</td>
<td>32.5</td>
<td>34</td>
<td>48</td>
<td>14</td>
<td>15</td>
</tr>
<tr>
<td>Hospital 5</td>
<td>8.5</td>
<td>14</td>
<td>16</td>
<td>2</td>
<td>5.8</td>
</tr>
<tr>
<td>Hospital 6</td>
<td>30.5</td>
<td>41</td>
<td>48</td>
<td>7</td>
<td>17.89</td>
</tr>
<tr>
<td>Hospital 7</td>
<td>4.5</td>
<td>9</td>
<td>9</td>
<td>0</td>
<td>3.87</td>
</tr>
</tbody>
</table>
Table 2.

Descriptive Measures by Hospital: Level E harm 2011-2014

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Mean</th>
<th>Range</th>
<th>Maximum</th>
<th>Minimum</th>
<th>STD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital 1</td>
<td>189</td>
<td>196</td>
<td>295</td>
<td>99</td>
<td>81.87</td>
</tr>
<tr>
<td>Hospital 2</td>
<td>620</td>
<td>288</td>
<td>739</td>
<td>451</td>
<td>127</td>
</tr>
<tr>
<td>Hospital 3</td>
<td>2289</td>
<td>2457</td>
<td>3275</td>
<td>818</td>
<td>1080</td>
</tr>
<tr>
<td>Hospital 4</td>
<td>682</td>
<td>621</td>
<td>1077</td>
<td>456</td>
<td>275</td>
</tr>
<tr>
<td>Hospital 5</td>
<td>153</td>
<td>89</td>
<td>189</td>
<td>100</td>
<td>43</td>
</tr>
<tr>
<td>Hospital 6</td>
<td>523</td>
<td>337</td>
<td>690</td>
<td>353</td>
<td>149</td>
</tr>
<tr>
<td>Hospital 7</td>
<td>55</td>
<td>48</td>
<td>75</td>
<td>27</td>
<td>21</td>
</tr>
</tbody>
</table>

Interesting to note that data was not available in the system corporate quality office. As a result each hospital quality reporting office was contacted for data.

Hospitals 4 and 6 had a much higher Mean and Range of HAC events reported which is consistent with the fact that they also have a significantly higher number of Adjusted Pt. Days.

Hospital 3 reported a much higher number of Level E harm when adjusting for Adjusted Pt. Days than expected. It is likely the data is subject to inconsistency in reporting Level E harm due to the fact that Hospital 3 was a late entry into the hospital system and had not yet fully applied all system standards and definitions. This concept is supported by the significant drop (more than a 50% reduction from the mean) in reported Level E harm in the most recent reporting year compared to previous reporting periods. It has been reported that for the most recent reporting year the classification system was correctly applied.
The box plot illustrates the wide range relative to Level E harm reports by hospital.

Plot 1: Level E harm per hospital

An unexpected finding was that Hospital 3 had a much greater mean of reported Level E harm incidents relative to Adjusted Patient Days. All things being equal the mean of Level E harm incidents should rank order according to activity level of each hospital.

Hospital 4 has by far the most activity measured by Adjusted Patient Days however the data shows Hospital 3 with many more Level E harm incidents each year.

The next box plot depicts the mean and range of HAC per hospital. In this case the rank or order by highest mean reported does match with the activity level of each hospital as measured by Adjusted Patient Day.
A frequency distribution including mean and standard deviation within HAC data was conducted and results were a Mean of 15.48 and Variance of 227.10 indicating a negative binomial generalized regression model is more appropriate.

Other Results

It is informative to note that the CoPS results for Hospital 3 include an apparent outlier. The most recent reported CoPS result was significantly lower than previous year and represents a degree of change unlike any other year or for any other hospital. It has been reported that for that year the hospital completed a full EMR conversion to the system standard. During such times staff will express uncertainty as to duties and accuracy of work due to the lack of familiarity with the system that may translate into a perception of less safety.
Given the two outlier results associated with the same hospital (Level E harm incident reports and CoPS results) conducting the statistical analysis both with and without this hospital seems prudent and indicated.

An unexpected finding was in the descriptive statistics. HACs and Level E harm events were not found to be correlated. The correlation coefficient between HAC and Level E harm events was calculated as -.112.

Statistical Analysis

**Question:** Is there a correlation between HAC and Culture of Patient Safety?

A negative binomial generalized regression was conducted due to the low number of observations per year. See Table 3.

Table 3

<table>
<thead>
<tr>
<th>Year</th>
<th>Hospital 3 Omitted</th>
<th>With Hospital 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Coefficients</td>
<td>Sig.</td>
</tr>
<tr>
<td>Year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>COPS</td>
<td>.066</td>
<td>.705</td>
</tr>
<tr>
<td>Adjusted Pt. Day</td>
<td>-.040</td>
<td>.234</td>
</tr>
<tr>
<td>Adjusted Pt. Day</td>
<td>4.839E-6</td>
<td>.062</td>
</tr>
</tbody>
</table>

a. Dependent variable – HAC
b. Predictors: case mix, year, culture

Not unexpected is the significant correlation between HAC and activity level as measured by case mix adjusted patient days with Hospital 3 data omitted (p-value = .062) when considering a p-value < .10 as significant. There was no significant correlation between HAC and independent variable Year.
There does not appear to be a significant correlation between CoPS and HAC (p-value=.234) with Hospital 3 data omitted. This greatly exceeds the threshold for significance of p-value=.10.

**Question:** Is there a significant correlation between Level E harm internal incident reports and CoPS?

A Linear Regression normalized using natural log Level E harm events analysis was completed. See Table 4.

**Table 4**

Linear Regression with dummy variables: natlog Level E harm

<table>
<thead>
<tr>
<th>Year</th>
<th>Hospital 3 Omitted</th>
<th>With Hospital 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adjusted R²</td>
<td>Adjusted R²</td>
</tr>
<tr>
<td></td>
<td>.924</td>
<td>.916</td>
</tr>
<tr>
<td>CoPS</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Coefficients</td>
<td>Coefficients</td>
</tr>
<tr>
<td></td>
<td>Sig.</td>
<td>Sig.</td>
</tr>
<tr>
<td></td>
<td>.079</td>
<td>.068</td>
</tr>
<tr>
<td></td>
<td>.023</td>
<td>.020</td>
</tr>
<tr>
<td></td>
<td>-1.734E-6</td>
<td>.027</td>
</tr>
<tr>
<td>Adjusted Pt. Day</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>-1.646E-6</td>
<td>.056</td>
</tr>
</tbody>
</table>

a. Dependent variable – Incidents

Adjusted R² was found to equal .924 indicating a relatively large amount of the variation is captured when accounting for differences between hospitals.

A Shapiro Wilkes value of .336 was calculated indicating a normal distribution as it is greater than the threshold value of <.05.

A significant correlation to Adjusted Pt Days is expected as incidents would increase with activity or number of patients treated, all things being equal.
CoPS was found to have a p-value equal to .020 when Hospital 3 data is omitted which can be considered as supporting a finding of significant correlation.

A significant, positive coefficient was found between Level E harm incidents and CoPS. A positive coefficient suggests that for every point increase in culture of safety score there is a .023 increase in the number of natural log reported Level E harm incidents.

Study Design and Methods Limitations

There is a limitation in the ability to generalize the correlation of one academic health center in a population of 7 hospitals. It would not be possible to conclude that in general the culture of safety of academic centers is significantly correlated to safety performance. It would also not be advisable to generalize the results to other health systems. However, since the research design is exploratory the value may be in identifying a possible generalization that would be worth exploring further in other health systems.

Selection bias is also a limitation deserving caution. Selection bias occurs when comparing two groups that were not randomly selected. When not randomly assigned the two groups may vary based on observed and unobserved differences. In the case of the hospital inpatient units, unobserved differences may include tenure of the unit leader or staff. Typical of regression models involving large dynamic organizations and nonrandomized data, at most what will be indicated is an association between Culture of Safety survey results and reported harm events but not causation. A finding of significant or insignificant association will still have importance to leaders.
The survey instrument measures and reports on ten dimensions that comprise the organization’s Culture of Safety. Each dimension is given equal weight in importance. However a limitation exists in that the number of observations are relatively low in number compared to the number of variables. To provide an opportunity to control for or avoid a false positive result only one dimension, the Overall Perception of Safety, will be used.

In order to reject the null hypothesis, the effect which is measured by coefficient needs to be relatively large, while the standard error of the coefficient should be relatively small. The number of observations does have a direct effect on standard error. Due to the smaller number of observations associated with the seven hospitals studied, the equation is less powerful and may not be able to detect true effects. Once again, since this research is exploratory in nature and that the equation may be of low power, if a correlation is detected between Culture of Safety and reported patient harm then there would be evidence to suggest repeating the study with more observations.

Another limitation is the possible presence of other covariates not accounted for in the equation such as tenure of the executive team, stability of the workforce at each hospital, time of each hospital within the health system. These potential unaccounted for covariates may have less of an effect due to the fact all of the hospitals are within the same system where one can assume a level of consistency with policy, procedure, training and resources available.
CHAPTER FIVE

DISCUSSION

Review of findings

Patient safety has received significant scrutiny in recent years with the emphasis that CMS has placed on Value based Purchasing and related measures designed to reduce unwanted hospital events from occurring. Numerous studies cited earlier suggest that a Culture of Patient Safety is correlated to a safe hospital environment. It is important to recall that research suggests that the “nature” of patient safety has a high degree of complexity as it has the traits of humanism and is technical in nature. The nature of patient safety has been described as trustworthiness; dependent on open learning; emerges from systems design; and is a property that is designed for the nature of illness (Emanuel et al., 2008). However, there was no empirical evidence to suggest that within a multi-hospital system over time that Culture of Patient Safety is in fact significantly correlated to a safe hospital environment.

This study was an attempt to determine if there was a relationship between a culture of patient safety as perceived by hospital personnel and patient harm events in a hospital system. The results suggest that there is no relationship between a high Culture of Patient Safety and patient harm events as recorded by hospital records externally examined by CMS. However, there was a significant positive relationship between a high Culture of Patient Safety and internally reported harm events reported
by hospital staff. Interestingly, no relationship was found between harm events as recorded by hospital records and internally reported harm events.

Management Implications

One possible explanation for the positive relationship between a high Culture of Patient Safety and internally reported harm events is that hospital personnel who are more sensitive to patient safety issues are more likely to actively identify and report real and potential events which result in harm to patients. This might suggest that a strong safety culture may result in more reported events in the short-run but hopefully improved systems and processes to improve safety in the long-run.

Alternatively, these results might suggest that to achieve the lower rates of CMS externally documented events requires a more “hardwired” application of stringent “structural elements” as a form of control. Standard work and LEAN processes coupled with Six Sigma analysis and application may be needed rather than a moderate approach which relies on a positive culture of patient safety.

What leaders may wish to consider given the research and scholarly thought which attributes importance to a Culture of Patient Safety and the correlation found in this study between that culture and internally reported events is that “structural exploration” or open and frequent transfer of information is a required, foundational element without which an organization could not advance to high reliability regardless of the degree of “structural elements” (i.e. standard work/LEAN and Six Sigma processes) in place. What leaders should be careful is not to consider patient safety
culture alone when trying to effect the incident of CMS externally documented events since there was no relationship found between culture and those events. Instead, an approach supported by the evidence is to view a positive CoPS and the associated “structural exploration” or “information processing requirement” as a foundational element within the set of “structural elements” needed to achieve high reliability which is necessary to reduce CMS externally documented events.

It is important to note that there was found to be a significant effect attributed to the differences between hospitals. The difference between degree of complexity and hospital size represented by case mix adjusted patient days (Adjusted Patient Days) between the seven hospitals was clearly noted in the descriptive statistics but it was also accounted for in the model. In addition, the hospitals in the study group were all part of one health system located in the same state suggesting a level of standardization regarding such things as equipment and technology utilized, EMR systems, staff training, policy and procedures. One can even suggest staffing ratios would be standardized across the system.

As cited earlier, a singular emphasis on control aimed at achieving a performance scorecard target is not well suited for conditions of high task uncertainty which characterize modern hospitals and health systems. If one where the senior leadership team responsible for the reduction of patient harm events the standardization or standard work, otherwise referred to as structural “control” relative to policy and procedures, staff training, equipment and other resources would be the first order of business. The analysis suggests a significant effect on patient harm results due to other
differences between the hospitals. A management emphasis on structural “exploration” or providing employees access to key information and empower them to adapt their processes to environmental changes so as to optimize quality, is also required to influence and account for these other differences between the hospitals. Those other differences may not be captured or explained within the dimensions measured by a Culture of Patient Safety survey but also those characteristics that exist within complex adaptive systems and the “fit” between strategy, measurement and action.

Consideration of hospitals as complex adaptive systems may imply that each hospital is a distinct microsystem acting and reacting upon a host of variables within its environment. In the study group an assumption is that equipment and other technology such as information systems, staff training, and hospital policies and procedures are standardized to some degree.

However, the study results suggests a strong effect attributed to the differences between the hospitals. Management may be well served when working to reduce or eliminate patient harm events to explore a better understanding of complex adaptive systems and what are effective actions and behaviors within such systems that can lead to less patient harm. The level and frequency of communication of information regardless of the authority gradient, the power of storytelling to impart information contributing to a greater self-awareness of patient safety, a high degree of transparency regarding actual performance and perceptions of the workplace by staff and the presence of a robust process improvement methodology.
Contingency Theory may help to explain the possible differences between hospitals and overall results of a lack of correlation between safety culture and actual patient harm. Contingency Theory proposes the degree of fit between an organization’s strategy, planning, resource allocations, leadership style and experience with its safety performance should be considered. In other words, some of the differences between the hospitals studied may be the degree of fit that exists among these factors. Perhaps the health system has a significant management strategy to reduce costs but is quiet on the issue of patient harm which would have an effect on the Culture of Patient Safety and actual performance related to patient harm. Appreciation of Contingency Theory would suggest management closely assess the fit between strategy, planning, budgeting and decision making as it relates to desired patient harm performance as a lack of fit may override efforts to cultivate a strong Culture of Patient Safety. A practical example is the more common use of corporate dashboards by hospitals and systems indicating top priority performance metrics. Evidence of “fit” would be presence of the Culture of Patient Safety survey result on the corporate dashboard.

An interesting finding for management consideration is the unexpected positive correlation found between the safety culture results and number of internally reported events when the outlier data was omitted. While previous research suggests self-reported internal harm events or incident reports are grossly under-reported it is worth noting that such underreporting may even include events of actual patient harm. A hospital safety effort would be severely handicapped if actual patient harm events were undetected due to low levels of reporting. The finding of a positive correlation between
a Culture of Patient Safety can provide reason for hospital management to continue to work to create a positive Culture of Patient Safety.

An additional management implication is reflective of the fact that the system corporate quality office was not a central repository of Culture of Patient Data, external HAC reports or internal incident reports and that neither the corporate quality office nor any of the hospital quality offices were collecting data for the purpose of study and evidence based decision making. This may suggest that the lack of evidence based decision making in this hospital and health system is not due to lack of data but rather the lack of intent upfront to collect data for the purpose of study, learning and reflection.

Research Implications

The question as to the significant correlation and direction of that correlation between a Culture of Patient Safety and patient harm events is an important one. Numerous stakeholders such as payers, patients, hospital leaders and direct patient caregivers have a strong interest and real incentives to eliminate patient harm events. The results of this study suggest that there may not be such a correlation as most expect, and whatever correlation does exist is due to complex factors. A longitudinal study with more observations is warranted in order to arrive at a definitive finding as to the correlation between a Culture of Patient Safety and patient harm events.

The lack of such a study in the past, despite the significant published research and writings on the connection between culture and patient safety may be attributed to two phenomenon. The most direct being the concern hospitals have had about
confidential patient harm event information. Much of such information is classified as some form of “peer review” status protected by state and or federal legislation, ironically to create conditions where patient care improvement can flourish. However, such legal status has had the effect of hospitals not sharing internal patient harm events even among hospitals within its own health system. The second possible explanation for lack of such a study is that health system leadership has not relied on empirical research to the degree clinical fields of study have. Evidence based decision making within the senior leadership teams of hospitals is only now beginning to receive attention due to the lack of appreciation for its value and the “belief” that empirical research requires more time and study than is available if timely decisions are to be made.

This study demonstrates a valid empirical methodology to model the correlation in a timely fashion with a modest amount of observations as well as demonstrates how patient and hospital identifying information can be protected. Health service researchers could approach a state hospital association and individual patient safety champions within hospital management about repeating a similar study with data from each hospital in the state.

The research provides an opportunity to study the relationship between HACs, which are externally reported patient safety incidents abstracted with strict protocols from independently coded claims data, and internally reported incidents based on staff reports. Is there a relationship between these two patient harm measures? The unexpected finding of no correlation warrants further study as it matters to those developing patient harm reduction strategies to understand definitively if the strategies
to patient harm, measured broadly, need to be different when trying to achieve zero
event rates for those strictly defined harm measures.

Another future research interest lies in the other eleven dimensions measured
by the Culture of Patient Safety survey and correlation of each to patient harm events.
Would each dimension have the same evidence and direction of correlation with actual
patient harm events?
References


APPENDIX A

NCC MERP INDEX FOR CATEGORIZING MEDICATION ERRORS
NCC MERP Index for Categorizing Medication Errors Algorithm

Harm
Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring
To observe or record relevant physiological or psychological signs.

Intervention
May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life
Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

*An error of omission does not reach the patient.


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Hospital Survey on Patient Safety

Instructions

This survey asks for your opinions about patient safety issues, medical error, and event reporting in your hospital and will take about 10 to 15 minutes to complete.

If you do not wish to answer a question, or if a question does not apply to you, you may leave your answer blank.

- An “event” is defined as any type of error, mistake, incident, accident, or deviation, regardless of whether or not it results in patient harm.
- “Patient safety” is defined as the avoidance and prevention of patient injuries or adverse events resulting from the processes of health care delivery.

SECTION A: Your Work Area/Unit

In this survey, think of your “unit” as the work area, department, or clinical area of the hospital where you spend most of your work time or provide most of your clinical services.

What is your primary work area or unit in this hospital? Select ONE answer.

- a. Many different hospital units/No specific unit
- b. Medicine (non-surgical)
- c. Surgery
- d. Obstetrics
- e. Pediatrics
- f. Emergency department
- g. Intensive care unit (any type)
- h. Psychiatric/mental health
- i. Rehabilitation
- j. Pharmacy
- k. Laboratory
- l. Radiology
- m. Anesthesiology

Other, please specify: __________________________

Please indicate your agreement or disagreement with the following statements about your work area/unit.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. People support one another in this unit</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>2. We have enough staff to handle the workload</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>3. When a lot of work needs to be done quickly, we work together as a team to get the work done</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>4. In this unit, people treat each other with respect</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>5. Staff in this unit work longer hours than is best for patient care</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
</tbody>
</table>
### SECTION A: Your Work Area/Unit (continued)

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. We are actively doing things to improve patient safety</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. We use more agency/temporary staff than is best for patient care</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Staff feel like their mistakes are held against them</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Mistakes have led to positive changes here</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. It is just by chance that more serious mistakes don’t happen around</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>here</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. When one area in this unit gets really busy, others help out</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. When an event is reported, it feels like the person is being written</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>up, not the problem</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. After we make changes to improve patient safety, we evaluate their</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>effectiveness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. We work in “crisis mode” trying to do too much, too quickly</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Patient safety is never sacrificed to get more work done</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Staff worry that mistakes they make are kept in their personnel file</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. We have patient safety problems in this unit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. Our procedures and systems are good at preventing errors from</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>happening</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### SECTION B: Your Supervisor/Manager

Please indicate your agreement or disagreement with the following statements about your immediate supervisor/manager or person to whom you directly report.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. My supervisor/manager says a good word when he/she sees a job done</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>according to established patient safety procedures</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. My supervisor/manager seriously considers staff suggestions for</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>improving patient safety</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Whenever pressure builds up, my supervisor/manager wants us to work</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>faster, even if it means taking shortcuts</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. My supervisor/manager overlooks patient safety problems that happen</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>over and over</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SECTION C: Communications

How often do the following things happen in your work area/unit?

Think about your hospital work area/unit...

1. We are given feedback about changes put into place based on event reports ................................................................. □ 1 □ 2 □ 3 □ 4 □ 5

2. Staff will freely speak up if they see something that may negatively affect patient care ........................................................... □ 1 □ 2 □ 3 □ 4 □ 5

3. We are informed about errors that happen in this unit .............................................. □ 1 □ 2 □ 3 □ 4 □ 5

4. Staff feel free to question the decisions or actions of those with more authority .................................................................. □ 1 □ 2 □ 3 □ 4 □ 5

5. In this unit, we discuss ways to prevent errors from happening again........ □ 1 □ 2 □ 3 □ 4 □ 5

6. Staff are afraid to ask questions when something does not seem right .... □ 1 □ 2 □ 3 □ 4 □ 5

SECTION D: Frequency of Events Reported

In your hospital work area/unit, when the following mistakes happen, how often are they reported?

1. When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported? .......................................................... □ 1 □ 2 □ 3 □ 4 □ 5

2. When a mistake is made, but has no potential to harm the patient, how often is this reported? .......................................................... □ 1 □ 2 □ 3 □ 4 □ 5

3. When a mistake is made that could harm the patient, but does not, how often is this reported? .......................................................... □ 1 □ 2 □ 3 □ 4 □ 5

SECTION E: Patient Safety Grade

Please give your work area/unit in this hospital an overall grade on patient safety.

A: Excellent   B: Very Good   C: Acceptable   D: Poor   E: Failing

SECTION F: Your Hospital

Please indicate your agreement or disagreement with the following statements about your hospital.

Think about your hospital...

1. Hospital management provides a work climate that promotes patient safety ................................................................. □ 1 □ 2 □ 3 □ 4 □ 5

2. Hospital units do not coordinate well with each other .............................................. □ 1 □ 2 □ 3 □ 4 □ 5

3. Things ‘fall between the cracks’ when transferring patients from one unit to another .................................................................. □ 1 □ 2 □ 3 □ 4 □ 5

4. There is good cooperation among hospital units that need to work together .................................................................. □ 1 □ 2 □ 3 □ 4 □ 5
SECTION F: Your Hospital (continued)

Think about your hospital...

5. Important patient care information is often lost during shift changes ........
   □ 1 □ 2 □ 3 □ 4 □ 5

6. It is often unpleasant to work with staff from other hospital units ............
   □ 1 □ 2 □ 3 □ 4 □ 5

7. Problems often occur in the exchange of information across hospital units.
   □ 1 □ 2 □ 3 □ 4 □ 5

8. The actions of hospital management show that patient safety is a top priority.
   □ 1 □ 2 □ 3 □ 4 □ 5

9. Hospital management seems interested in patient safety only after an adverse event happens.
   □ 1 □ 2 □ 3 □ 4 □ 5

10. Hospital units work well together to provide the best care for patients ....
    □ 1 □ 2 □ 3 □ 4 □ 5

11. Shift changes are problematic for patients in this hospital ....................
    □ 1 □ 2 □ 3 □ 4 □ 5

SECTION G: Number of Events Reported

In the past 12 months, how many event reports have you filled out and submitted?

 □ a. No event reports   □ d. 6 to 10 event reports
 □ b. 1 to 2 event reports □ e. 11 to 20 event reports
 □ c. 3 to 5 event reports □ f. 21 event reports or more

SECTION H: Background Information

This information will help in the analysis of the survey results.

1. How long have you worked in this hospital?
   □ a. Less than 1 year    □ d. 11 to 15 years
   □ b. 1 to 5 years       □ e. 16 to 20 years
   □ c. 6 to 10 years      □ f. 21 years or more

2. How long have you worked in your current hospital work area/unit?
   □ a. Less than 1 year    □ d. 11 to 15 years
   □ b. 1 to 5 years       □ e. 16 to 20 years
   □ c. 6 to 10 years      □ f. 21 years or more

3. Typically, how many hours per week do you work in this hospital?
   □ a. Less than 20 hours per week   □ d. 60 to 79 hours per week
   □ b. 20 to 39 hours per week      □ e. 80 to 99 hours per week
   □ c. 40 to 59 hours per week      □ f. 100 hours per week or more
SECTION H: Background Information (continued)

4. What is your staff position in this hospital? Select ONE answer that best describes your staff position.
   - [ ] a. Registered Nurse
   - [ ] b. Physician Assistant/Nurse Practitioner
   - [ ] c. LVN/LPN
   - [ ] d. Patient Care Asst/Hospital Aide/Care Partner
   - [ ] e. Attending/Staff Physician
   - [ ] f. Resident Physician/Physician in Training
   - [ ] g. Pharmacist
   - [ ] h. Dietician
   - [ ] i. Unit Assistant/Clerk/Secretary
   - [ ] j. Respiratory Therapist
   - [ ] k. Physical, Occupational, or Speech Therapist
   - [ ] l. Technician (e.g., EKG, Lab, Radiology)
   - [ ] m. Administration/Management
   - [ ] n. Other, please specify

5. In your staff position, do you typically have direct interaction or contact with patients?
   - [ ] a. YES, I typically have direct interaction or contact with patients.
   - [ ] b. NO, I typically do NOT have direct interaction or contact with patients.

6. How long have you worked in your current specialty or profession?
   - [ ] a. Less than 1 year
   - [ ] b. 1 to 5 years
   - [ ] c. 6 to 10 years
   - [ ] d. 11 to 15 years
   - [ ] e. 16 to 20 years
   - [ ] f. 21 years or more

SECTION I: Your Comments

Please feel free to write any comments about patient safety, error, or event reporting in your hospital.

THANK YOU FOR COMPLETING THIS SURVEY.
<table>
<thead>
<tr>
<th>Hospital</th>
<th>Year</th>
<th>HAC</th>
<th>Level E harm</th>
<th>CoPS</th>
<th>Adj. Pt. Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2011</td>
<td>1</td>
<td>99</td>
<td>66</td>
<td>14668</td>
</tr>
<tr>
<td>1</td>
<td>2012</td>
<td>12</td>
<td>163</td>
<td>64</td>
<td>59324</td>
</tr>
<tr>
<td>1</td>
<td>2013</td>
<td>13</td>
<td>295</td>
<td></td>
<td>58631</td>
</tr>
<tr>
<td>1</td>
<td>2014</td>
<td>7</td>
<td>199</td>
<td>61</td>
<td>58804</td>
</tr>
<tr>
<td>2</td>
<td>2011</td>
<td>3</td>
<td>692</td>
<td>63</td>
<td>25333</td>
</tr>
<tr>
<td>2</td>
<td>2012</td>
<td>5</td>
<td>599</td>
<td>74</td>
<td>104721</td>
</tr>
<tr>
<td>2</td>
<td>2013</td>
<td>7</td>
<td>739</td>
<td>68</td>
<td>113991</td>
</tr>
<tr>
<td>2</td>
<td>2014</td>
<td>6</td>
<td>451</td>
<td></td>
<td>113473</td>
</tr>
<tr>
<td>3</td>
<td>2011</td>
<td>6</td>
<td>2183</td>
<td></td>
<td>17364</td>
</tr>
<tr>
<td>3</td>
<td>2012</td>
<td>9</td>
<td>2882</td>
<td>57.9</td>
<td>68949</td>
</tr>
<tr>
<td>3</td>
<td>2013</td>
<td>5</td>
<td>3275</td>
<td></td>
<td>69053</td>
</tr>
<tr>
<td>3</td>
<td>2014</td>
<td>3</td>
<td>818</td>
<td>45</td>
<td>71144</td>
</tr>
<tr>
<td>4</td>
<td>2011</td>
<td>14</td>
<td>1077</td>
<td>60</td>
<td>83752</td>
</tr>
<tr>
<td>4</td>
<td>2012</td>
<td>27</td>
<td>652</td>
<td>61</td>
<td>323219</td>
</tr>
<tr>
<td>4</td>
<td>2013</td>
<td>48</td>
<td>544</td>
<td></td>
<td>312573</td>
</tr>
<tr>
<td>4</td>
<td>2014</td>
<td>40</td>
<td>456</td>
<td>53</td>
<td>322481</td>
</tr>
<tr>
<td>5</td>
<td>2011</td>
<td>2</td>
<td>137</td>
<td>81</td>
<td>10848</td>
</tr>
<tr>
<td>5</td>
<td>2012</td>
<td>9</td>
<td>189</td>
<td>79</td>
<td>41656</td>
</tr>
<tr>
<td>5</td>
<td>2013</td>
<td>7</td>
<td>186</td>
<td>81.6</td>
<td>37554</td>
</tr>
<tr>
<td>5</td>
<td>2014</td>
<td>16</td>
<td>100</td>
<td>67</td>
<td>38347</td>
</tr>
<tr>
<td>6</td>
<td>2011</td>
<td>7</td>
<td>690</td>
<td>60</td>
<td>52585</td>
</tr>
<tr>
<td>6</td>
<td>2012</td>
<td>27</td>
<td>595</td>
<td>65</td>
<td>201139</td>
</tr>
<tr>
<td>6</td>
<td>2013</td>
<td>48</td>
<td>455</td>
<td></td>
<td>185247</td>
</tr>
<tr>
<td>6</td>
<td>2014</td>
<td>40</td>
<td>353</td>
<td>53</td>
<td>182405</td>
</tr>
<tr>
<td>7</td>
<td>2011</td>
<td>0</td>
<td>75</td>
<td></td>
<td>8207</td>
</tr>
<tr>
<td>7</td>
<td>2012</td>
<td>6</td>
<td>27</td>
<td>67.5</td>
<td>35816</td>
</tr>
<tr>
<td>7</td>
<td>2013</td>
<td>9</td>
<td>50</td>
<td></td>
<td>39760</td>
</tr>
<tr>
<td>7</td>
<td>2014</td>
<td>3</td>
<td>68</td>
<td>71.5</td>
<td>37857</td>
</tr>
</tbody>
</table>
APPENDIX D

HOSPITAL-ACQUIRED CONDITIONS and PRESENT ON ADMISSION
INDICATOR REPORTING PROVISION
Hospital-Acquired Conditions and Present on Admission Indicator Reporting Provision

Please note: The information in this publication applies only to the Medicare Fee-For-Service Program (also known as Original Medicare).

This publication provides the following information on the Hospital-Acquired Conditions (HACs) and Present on Admission (POA) Indicator Reporting provision in Acute Inpatient Prospective Payment System (IPPS) hospitals:

- Background;
- HACs;
- POA indicator;
- Exempt hospitals; and
- Resources.

When “your” is used in this publication, we are referring to Medicare Fee-For-Service health care providers.

ICN 901046  September 2014

BACKGROUND

As required by the Deficit Reduction Act of 2005 (DRA), the HAC-POA Indicator Reporting provision requires a quality adjustment in Medicare Severity-Diagnosis Related Group (MS-DRG) payments for certain HACs. IPPS hospitals must submit POA information on the principal and all secondary diagnoses for inpatient discharges on or after October 1, 2007. The HAC-POA payment provision under the DRA is distinct from the HAC Reduction Program described in Section 3008 of the Affordable Care Act of 2010, which authorizes the Centers for Medicare & Medicaid Services (CMS) to make payment adjustments to applicable hospitals based on risk-adjustment quality measures.

HOSPITAL-ACQUIRED CONDITIONS (HACs)

As required by Section 5001(c) of the DRA, by October 1, 2007, the Secretary of the United States Department of Health & Human Services was required to identify at least two conditions that:

- Are high cost or high volume or both;
- Result in the assignment of a case to an MS-DRG that has a higher payment when present as a secondary diagnosis; and
- Could reasonably have been prevented through the application of evidence-based guidelines.

For discharges occurring on or after October 1, 2007, IPPS hospitals do not receive the higher payment for cases when one of the selected conditions is acquired during hospitalization (that is, the condition was not present on admission). The case is paid as though the secondary diagnosis is not present.

The chart below provides the categories and corresponding complication or comorbidity (CC) or major complication or comorbidity (MCC) International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) codes included in the HAC payment provision for fiscal years (FY) 2014 and 2015.

<table>
<thead>
<tr>
<th>HAC Category</th>
<th>CC/MCC (ICD-9-CM Codes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreign Object Retained After Surgery</td>
<td>998.4 (CC)</td>
</tr>
<tr>
<td></td>
<td>998.7 (CC)</td>
</tr>
<tr>
<td>Air Embolism</td>
<td>999.1 (MCC)</td>
</tr>
<tr>
<td>HAC Category</td>
<td>CC/MCC (ICD-9-CM Codes)</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Blood Incompatibility</td>
<td>999.00 (CC)</td>
</tr>
<tr>
<td></td>
<td>999.51 (CC)</td>
</tr>
<tr>
<td></td>
<td>999.62 (CC)</td>
</tr>
<tr>
<td></td>
<td>999.63 (CC)</td>
</tr>
<tr>
<td></td>
<td>999.69 (CC)</td>
</tr>
<tr>
<td>Pressure Ulcer Stages III &amp; IV</td>
<td>707.23 (MCC)</td>
</tr>
<tr>
<td></td>
<td>707.24 (MCC)</td>
</tr>
<tr>
<td>Falls and Trauma</td>
<td>Codes within these ranges on the CC/MCC list:</td>
</tr>
<tr>
<td>• Fracture</td>
<td>800-829</td>
</tr>
<tr>
<td>• Dislocation</td>
<td>830-839</td>
</tr>
<tr>
<td>• Intracranial Injury</td>
<td>850-854</td>
</tr>
<tr>
<td>• Crushing Injury</td>
<td>925-929</td>
</tr>
<tr>
<td>• Burn</td>
<td>940-949</td>
</tr>
<tr>
<td>• Other Injuries</td>
<td>991-994</td>
</tr>
<tr>
<td>Catheter-Associated Urinary Tract Infection (UTI)</td>
<td>998.64 (CC)</td>
</tr>
<tr>
<td></td>
<td>Also excludes the following from acting as a CC/MCC:</td>
</tr>
<tr>
<td></td>
<td>112.2 (CC)</td>
</tr>
<tr>
<td></td>
<td>590.01 (CC)</td>
</tr>
<tr>
<td></td>
<td>590.11 (MCC)</td>
</tr>
<tr>
<td></td>
<td>590.2 (MCC)</td>
</tr>
<tr>
<td></td>
<td>590.3 (CC)</td>
</tr>
<tr>
<td></td>
<td>590.80 (CC)</td>
</tr>
<tr>
<td></td>
<td>590.81 (CC)</td>
</tr>
<tr>
<td></td>
<td>590.90 (CC)</td>
</tr>
<tr>
<td></td>
<td>597.0 (CC)</td>
</tr>
<tr>
<td></td>
<td>599.0 (CC)</td>
</tr>
<tr>
<td>Surgical Site Infection Following Cardiac Implantable Electronic Device (CIED)</td>
<td>996.61 (CC)</td>
</tr>
<tr>
<td></td>
<td>996.59 (CC)</td>
</tr>
<tr>
<td></td>
<td>And one of the following procedure codes:</td>
</tr>
<tr>
<td></td>
<td>00.50, 00.51, 00.52, 00.53, 00.54, 37.80, 37.81, 37.82, 37.83, 37.85, 37.86, 37.87, 37.88, 37.89, 37.90, 37.92, 37.93, 37.94, 37.95, 37.96, 37.97, 37.98, 37.99, or 37.99</td>
</tr>
<tr>
<td>Deep Vein Thrombosis and Pulmonary Embolism Following Certain Orthopedic Procedures:</td>
<td>415.11 (MCC)</td>
</tr>
<tr>
<td>• Total Knee Replacement</td>
<td>415.13 (MCC)</td>
</tr>
<tr>
<td>• Hip Replacement</td>
<td>415.19 (MCC)</td>
</tr>
<tr>
<td></td>
<td>And one of the following procedure codes:</td>
</tr>
<tr>
<td></td>
<td>00.85-00.87, 81.51-81.52, or 81.54</td>
</tr>
<tr>
<td>Iatrogenic Pneumothorax with Venous Catheterization</td>
<td>512.1 (CC)</td>
</tr>
<tr>
<td></td>
<td>And the following procedure code:</td>
</tr>
<tr>
<td></td>
<td>38.93</td>
</tr>
</tbody>
</table>

Note: As specified by statute, CMS may revise the list of conditions from time to time, as long as the list contains at least two conditions.
# Present on Admission (POA) Indicator

The chart below provides POA indicator, description, and payment information for FY 2015.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Description</th>
<th>Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>Diagnosis was present at time of inpatient admission.</td>
<td>Payment is made for condition when a HAC is present.</td>
</tr>
<tr>
<td>N</td>
<td>Diagnosis was not present at time of inpatient admission.</td>
<td>No payment is made for condition when a HAC is present.</td>
</tr>
<tr>
<td>U</td>
<td>Documentation insufficient to determine if condition was present at the time of inpatient admission.</td>
<td>No payment is made for condition when a HAC is present.</td>
</tr>
<tr>
<td>W</td>
<td>Clinically undetermined. Provider unable to clinically determine whether the condition was present at the time of inpatient admission.</td>
<td>Payment is made for condition when a HAC is present.</td>
</tr>
</tbody>
</table>


## General Reporting Requirements

The following list provides some POA general reporting requirements:

- You must include the POA indicator on all claims that involve Medicare inpatient admissions to general IPPS acute care hospitals or other facilities, and you are subject to a law or regulation that mandates the collection of POA indicator information;
- POA is defined as being present at the time the order for inpatient admission occurs. Conditions that develop during an outpatient encounter (including emergency department, observation, or outpatient surgery) are considered POA;
- The POA indicator is assigned to the principal and all secondary diagnoses as defined in Section II of the "Official Guidelines";
- You must resolve issues related to inconsistent, missing, conflicting, or unclear documentation;
- You should not report the POA indicator if a condition is not coded and reported based on Uniform Hospital Discharge Data Set definitions and current "Official Guidelines"; and
- CMS does not require a POA indicator for the external cause of injury code unless you are reporting it as an "other diagnosis."

## Coding

- The "UB-04 Data Specifications Manual" and "Official Guidelines" can help you assign the POA indicator for each "principal" diagnosis and "other" ICD-9-CM diagnosis codes reported on the UB-04 (paper claims) and ASC X12N 837 Institutional (837I) (electronic transmissions). For more information about the "UB-04 Data Specifications Manual," visit [http://www.nubc.org/subscriber](http://www.nubc.org/subscriber) on the National Uniform Billing Committee website;
- This publication is not intended to replace any guidelines in the main body of the "Official Guidelines" or provide guidance on when to report a condition. Rather, it provides information on how to apply the POA indicator to the final set of ICD-9-CM diagnosis codes assigned in accordance with Sections I, II, and III of the "Official Guidelines." The POA indicator should be assigned to those conditions for which an ICD-9-CM diagnosis code has been assigned; and
- As stated in the Introduction to the "Official Guidelines," a joint effort between the health care provider and the coder is essential to achieve complete and accurate documentation, code assignment, and reporting diagnoses and procedures.

## Documentation

The importance of consistent, complete documentation in the medical record cannot be overemphasized. Medical record documentation from any provider involved in the care and treatment of the patient may be used to determine whether a condition is POA. In the context of the "Official Guidelines," a "provider" is a physician or any qualified health care practitioner who is legally accountable for establishing the patient's diagnosis.

**Note:** Providers, their billing offices, third-party billing agents, and others involved in the transmission of this data must ensure that any resequencing of ICD-9-CM diagnosis codes prior to their transmission to CMS also includes a resequencing of POA indicators.
Billing

**Paper Claims**

On the UB-04, the POA indicator is the eighth digit of Field Locator (FL) 67, Principal Diagnosis and the eighth digit of each of the Secondary Diagnosis fields, FL 67 A–Q. You should report the applicable POA indicator (Y, N, U, or W) for the principal diagnosis and any secondary diagnoses as the eighth digit. Enter 1 if the diagnosis is exempt from POA reporting.

**Electronic Claims**

You should submit the POA indicator on the 837I in the appropriate Health Care Information Codes segment as directed by the "UB-04 Data Specifications Manual."

---

**EXEMPT HOSPITALS**

Because the HAC-POA payment provision applies only to IPPS hospitals, the following hospitals are exempt from the provision:

- Critical Access Hospitals;
- Long Term Care Hospitals;
- Maryland Waiver Hospitals,*
- Cancer Hospitals;
- Children’s Inpatient Facilities;
- Religious Non-Medical Health Care Institutions;
- Inpatient Psychiatric Hospitals;
- Inpatient Rehabilitation Facilities; and
- Veterans Administration/Department of Defense Hospitals.

* Maryland Waiver Hospitals must report the POA indicator on all claims.

---

**RESOURCES**

The chart below provides POA reporting by acute IPPS hospitals resource information.

<table>
<thead>
<tr>
<th>For More Information About…</th>
<th>Resource</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital-Acquired Conditions (Present on Admission Indicator)</td>
<td><a href="http://www.cms.gov/HospitalAcqCond">http://www.cms.gov/HospitalAcqCond</a> on the CMS website</td>
</tr>
<tr>
<td>All Available Medicare Learning Network® (MLN) Products</td>
<td>&quot;MLN Catalog&quot; located at <a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts</a>/Downloads/MLNCatalog.pdf on the CMS website or scan the Quick Response (QR) code on the right</td>
</tr>
<tr>
<td>Medicare Information for Patients</td>
<td><a href="http://www.medicare.gov">http://www.medicare.gov</a> on the CMS website</td>
</tr>
</tbody>
</table>
This fact sheet was current at the time it was published or uploaded onto the web. Medicare policy changes frequently so links to the source documents have been provided within the document for your reference.

This fact sheet was prepared as a service to the public and is not intended to grant rights or impose obligations. This fact sheet may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

Your feedback is important to us and we use your suggestions to help us improve our educational products, services and activities and to develop products, services and activities that better meet your educational needs. To evaluate Medicare Learning Network® (MLN) products, services and activities you have participated in, received, or downloaded, please go to http://go.cms.gov/MLNProducts and in the left-hand menu click on the link called 'MLN Opinion Page' and follow the instructions. Please send your suggestions related to MLN product topics or formats to MLN@cms.hhs.gov.

The Medicare Learning Network® (MLN), a registered trademark of CMS, is the brand name for official information health care professionals can trust. For additional information, visit the MLN’s web page at http://go.cms.gov/MLNGenInfo on the CMS website.

Check out CMS on:
APPENDIX E

INSTITUTIONAL REVIEW BOARD APPROVAL FORM
Form 4: IRB Approval Form
Identification and Certification of Research
Projects Involving Human Subjects

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

Principal Investigator: GATMAITAN, ALFONSO W
Co-Investigator(s):
Protocol Number: E141222007

The above project was reviewed on 2/16/15. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This project qualifies as an exemption as defined in 45CF 46.101, paragraph 47.

This project received EXEMPT review.
IRB Approval Date: 2/16/15
Date IRB Approval Issued: 2/16/15

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

Investigators please note:

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

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

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