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Leadership safe practices snd their relationship with hospital deployment of the medication reconciliation innovation

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LEADERSHIP SAFE PRACTICES AND THEIR RELATIONSHIP WITH HOSPITAL DEPLOYMENT OF THE MEDICATION RECONCILIATION INNOVATION

by

Lance L. Roberts

An Abstract

Of a thesis submitted in partial fulfillment
of the requirements for the Doctor of
Philosophy degree in Health Services and Policy
in the Graduate College of
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Thesis Supervisor: Professor Marcia M. Ward

ABSTRACT

Within the last decade there has been considerable national attention focused upon hospital quality and patient safety performance. Improvements in performance have been realized, but the rate of improvement has been slow. There is an increasing consensus that new ideas and national strategies are needed to accelerate improvement efforts in addressing quality/safety issues. Currently, within the hospital setting more attention is being paid to the role of leadership starting with the board of trustees in addressing gaps in performance. Organization-wide awareness of critical gaps in performance, accountability structures, and organizational ability are considered critical facilitators of improvement efforts. The characteristics of awareness, accountability, ability, and action are components of a "4A" conceptual framework that is used most prominently by the National Quality Forum (NQF) in their Safe Practices for Better Healthcare toolkit to frame governance and leaderships' responsibilities in establishing leadership structures and systems to ensure the safety of patients and staff.

This study utilizes the National Quality Forum's version of the 4A model to frame an empirical examination of the relationship between leadership structure and system characteristics and hospitals' implementation of the medication reconciliation innovation. A Patient Safety, Culture, and Leadership survey was used to capture Iowa hospital CEO/Quality Leaders' perceptions of board and leadership awareness and accountability characteristics. And, on a quarterly basis since mid-2006 a separate web-based survey has captured Iowa hospital Quality Leaders' perceptions of medication reconciliation implementation.

Both cross-sectional and longitudinal analyses were conducted to examine the relationship between leadership structures and systems and hospital-wide deployment of the medication reconciliation initiative.

This study finds evidence that board-level awareness characteristics – the time the board spent in meetings on quality and safety issues, and the frequency of board receipt of a formal quality/safety report – were positively related to hospitals' early efforts to deploy the medication reconciliation initiative. Over time hospitals' financial ability was positively related to deployment of this initiative.

Further research should focus on how healthcare governance and leadership teams can use the elements of leadership structures and systems safe practices to effectively create and sustain a culture of safety.

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Thesis Supervisor

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CERTIFICATE OF APPROVAL

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PH.D. THESIS

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CHAPTER I. INTRODUCTION

Considerable evidence exists that the delivery of healthcare in the U.S. needs improvement in the areas of safety, timeliness, efficiency, effectiveness, equity, and patient-centeredness. In terms of patient safety, empirical research has documented the incidence of adverse events and complications in U.S. hospitals dating as far back as 45 years ago [1-4]. Within the last decade there has been considerable national attention focused upon addressing deficiencies associated with healthcare quality and patient safety performance in U.S. hospitals. But, the rate of improvement has been slow, substantial variation in quality and efficiency across the country remains, and there is an increasing consensus that new national strategies are needed to reduce this variation and the unacceptable amount of poor quality [5-20].

Healthcare is a complex, technical industry faced with significant external pressure to improve the quality, safety, and value of services provided. Although improvement is needed on many fronts, keeping people safe from harm should be the core competency and primary strategic focus of any healthcare organization. Only recently has there been a concerted national effort to build infrastructure and devise a national framework to efficiently prioritize, standardize, and incentivize value-based care. In the absence of an effective framework there have emerged myriad improvement innovations of varying complexity and value. Currently, within the hospital setting experts suggest that the quality of leadership starting with the board of trustees will determine whether or not hospitals will be able to adapt to increasingly stringent healthcare stakeholder expectations and ultimately survive. Board awareness of critical gaps in performance, accountability structures, organizational ability, and ultimately their actions will play a role in a hospital's ability to successfully navigate the current environment.

Unfortunately, empirical research examining the relationship between hospital board leadership characteristics and hospitals' implementation of safe practice initiatives is scarce. In addition, little research exists that sheds light on the potential cumulative effects of engaged boards, physicians, and organizational ability on hospitals' quality/safety initiative implementation efforts. Finally, because the adoption of innovations, best practices, and/or improvement efforts in healthcare is slow there is a need for more longitudinal studies of organizational leadership factors that may facilitate or impede the acceleration of organization-wide improvement efforts.

The goal of this research is to retrospectively examine the relationship of board awareness, board/physician accountability, and financial ability with hospital implementation of a salient clinical quality/safety improvement innovation - the Institute of Healthcare Improvement's (IHI) 100,000 (100K) Lives Campaign plank "Prevent Adverse Drug Events (ADEs) by implementing medication reconciliation" – near the end of the initial 100K Lives campaign and over time among Iowa hospitals. This study is primarily focused on specific board of director awareness and accountability characteristics; however, physician accountability and financial ability are included as these are also key factors in implementation initiatives.

The IHI is an independent not-for-profit organization that famously launched an ambitious national program to save 100,000 Lives in their "100,000 Lives Campaign" (100K Campaign) in 2004 [21]. The campaign was designed to align and equip hospitals with the information and tools necessary to positively impact the delivery of specific healthcare services. By design the program was kept simple. Because participation in the program was open to all U.S. hospitals free of charge, and the tools were designed for rapid adoption and "spread" of best practices throughout hospitals and their subunits, most hospitals took advantage of the low burden associated with the program and participated to some degree. The program focused on 6 "planks" of clinical topical areas and incorporated evidence-based practice toolkits, which if implemented nationally, had

the potential to avert 100,000 deaths. One of these 6 planks focused on the prevention of adverse drug events via the use of a new medication reconciliation "innovation". Through the Iowa Healthcare Collaborative (IHC) operating as the IHI "Node" organization in Iowa, all Iowa hospitals were engaged in the national program. The IHC engaged hospitals in reporting their "spread" of best practices throughout their organization on a quarterly basis starting in mid-2006, nearing the conclusion of the 100K Campaign which commenced in December, 2006. This measurement of diffusion became known as the "spread exercise" report and the "spread" data has been captured for all Iowa hospitals since mid-2006. Only some of the original 6 IHI planks were applicable to all hospitals. For example, some hospitals did not operate ventilators therefore one of the six original initiatives – prevent ventilator-associated pneumonia (VAP) – was not implemented by many hospitals. However, the medication reconciliation plank represented one clinical initiative that applied to all hospitals and targeted a common source of medical error – drug complications due to medications. Thus, the medication reconciliation improvement initiative was chosen as a response variable in this research as it is widely applicable to all hospitals, clinically important as a nationally-recognized patient safety innovation and initiative, and implementation data has been captured in Iowa hospitals since 2006.

The independent variables of interest in this research align with another important piece of national infrastructure – the National Quality Forum (NQF) Safe Practices. President Clinton's 1996 Advisory Commission on Consumer Protection and Quality in the Health Care Industry envisioned an entity that would be responsible for implementing a comprehensive plan for measurement and reporting, identifying core metrics for measurement and reporting, and promoting the development of the core measures. The NQF, which was established in May 1999 by a White House–convened planning committee facilitated by then-Vice President Albert Gore, represents the culmination of this vision [22]. Dr. Kenneth W. Kizer, NQF's first CEO and President, notes that NQF was

structured as a unique public–private collaborative organization with a mission to promote the delivery of high-quality health care.

Since NQF's inception, the Institute of Medicine (IOM), federal task forces, and major stakeholders have recommended that it be tasked with managing a set of standardized quality measurements. These core measures would provide a foundation for reporting systems that facilitate the capture of quality and patient safety practices critical to the prevention of medical errors, thereby supporting continuous improvement efforts throughout the United States [14, 23, 24].

In 2003, NQF utilized a formal consensus development process to identify and release a list of 30 nationally recommended, evidence-based "Safe Practices" from a pool of 220 candidate safe practices. These 30 Safe Practices were deemed to be universally applicable in clinical care settings to reduce the risk of harm to patients [25, 26]. It should be noted that a key characteristic of NQF's role in promoting safe practices is that the organization does not develop measures; rather, it is a neutral body that endorses measures. NQF continues to use a consensus-based review process to update the original 30 Safe Practices, based on the latest evidence for existing and proposed practices. Safe Practice updates were released in 2006, 2009, and 2010 [27-29].

The first NQF Safe Practice specifically targets the importance of top-level leadership in driving a culture of quality and safety. NQF Safe Practice #1 states "leadership structures and systems must be established to ensure that there is organization-wide awareness of patient safety performance, direct accountability of leaders for those gaps, adequate investment in performance improvement abilities, and that actions are taken to ensure safe care of every patient served" [28]. Furthermore, board of trustee, CEO, and physician leadership is the single most important factor in turning the barriers of awareness, accountability, ability, and action into accelerators of performance improvement. The "4A framework" of awareness, accountability, ability, and action used by the NQF to frame leadership responsibilities is used as a conceptual

framework in this study. Specifically, in this study board and physician awareness and accountability characteristics, along with organizational financial ability, are hypothesized to be important facilitators of hospital-wide implementation of an important patient safety initiative. And, collectively these characteristics may represent a "critical mass" that accelerates the adoption and implementation of this initiative.

Thus, there are several aims of this research. First, this study cross-sectionally estimates the degree to which key board characteristics, physician engagement, and financial resource ability were related to hospitals' implementation of the medication reconciliation patient safety initiative near the conclusion of the IHI 100K Lives Campaign. Second, this study estimates the degree to which initial levels of key board characteristics, physician engagement, and financial resource ability were related to hospitals' implementation of the medication reconciliation initiative over time. Third, this study examines the degree to which board characteristics, physician engagement, and financial resources were collectively related to hospitals' implementation of the medication reconciliation initiative cross-sectionally near the conclusion of the IHI 100K Lives Campaign and over time. The NQF's universally-applicable version of the 4A framework is used to map the characteristics of board-level leadership, physician engagement, financial ability, and patient safety initiative implementation into the four conceptual domains that the NQF deems to be critically important in assessing and addressing gaps in quality/safety performance – awareness, accountability, ability, and action.

This study adds value in a number of ways. First, increasing attention is being paid to the important role the hospital board plays in creating an organizational context that is conducive to any kind of change effort. The board of directors assumes the ultimate responsibility for the safety of care delivered in their organization. This study intends to shed light on the relationship between "top" board-level stewardship characteristics and the hospital-wide deployment of a nationally-important patient safety

initiative. Second, two perspectives of physician engagement with quality/safety efforts are examined – one that focuses on physicians' general engagement with quality/safety efforts, and another that is more strategic in that it involves board member interaction with physicians. Typically physicians are thought of as the quintessential stewards of safe care. However, boards may also play a role in ensuring the reliability of safe care by interacting with medical staff members to understand service delivery issues and ultimately taking action to help attenuate or remove organizational barriers to improvement. Third, the generalizability of the study is enhanced via the use of a conceptual framework, governance and leadership characteristics, and a nationally-salient patient safety initiative – medication reconciliation – that are all commonly bound within the overarching framework of the NQF Safe Practices. Because the NQF Safe Practices are applicable to a wide variety of health care organizations the results of this study may be informative to a broad spectrum of healthcare providers – including those settings outside the hospital domain. Although this study focuses on a specific patient safety initiative, the results may be generalizable to the implementation of similar, nationally important quality improvement efforts. Because a majority of US hospitals have been involved in similar national initiatives, and medication reconciliation is an initiative that is tightly linked with current national priorities and programs, the generalizability of results would be favorable. More locally, because all Iowa hospitals are engaged with all the IHI 100K and 5M initiatives, plus additional Iowa-specific initiatives through collaborative efforts spearheaded by the Iowa Hospital Association and Iowa Healthcare Collaborative Hospital Learning Community (HLC), these results will be informative to on-going and future implementation efforts. Fourth, this study examines hospitals' implementation of an important patient safety initiative using longitudinal data. Previous research states that this study design feature is lacking and is sorely needed to more fully examine the stages of organizational diffusion – from adoption, to implementation, to maintenance – of "evidence-based" practices.

Conceptual Framework

The first NQF Safe Practice specifically targets the importance of top-level leadership in driving a culture of quality and safety. NQF Safe Practice #1 states "leadership structures and systems must be established to ensure that there is organization-wide awareness of patient safety performance, direct accountability of leaders for those gaps, adequate investment in performance improvement abilities, and that actions are taken to ensure safe care of every patient served" [28]. Furthermore, board of trustee, CEO, and physician leadership is the single most important factor in turning the barriers of awareness, accountability, ability, and action into accelerators of performance improvement. The "4A framework" of awareness, accountability, ability, and action will be used as a conceptual model in this study.

The 4A framework has origins in the 4A Accelerator model that was developed and utilized by Dr. Charles Denham to assess an organization's progress relative to a performance gap along 4 dimensions: awareness, accountability, ability, and action [20]. This framework has been developed over a 20 year period and has been applied in sundry innovation implementation projects spanning many types of industries. Prominent, nationally-recognized healthcare organizations have adopted the use of this framework in driving quality and safety improvement efforts throughout the U.S. healthcare industry. Since 2004, the National Quality Forum and the Leapfrog Group adopted this model and have been using this model to frame the first NQF Safe Practice – Create and Sustain a Healthcare Culture of Safety [27-32]. The use of this framework and it's focus on leadership structures and systems is evidence of the increasing interest in how highly engaged leadership teams working with highly engaged boards can be a source of will for change throughout the entire organization [33].

In alignment with standardization and harmonization efforts within the healthcare industry, the NQF's application of the 4A framework is used as a conceptual guide for

this study. Figure 1 shows the conceptual relationships between the concepts and key variables used in this study.

Figure 1. Conceptual Framework

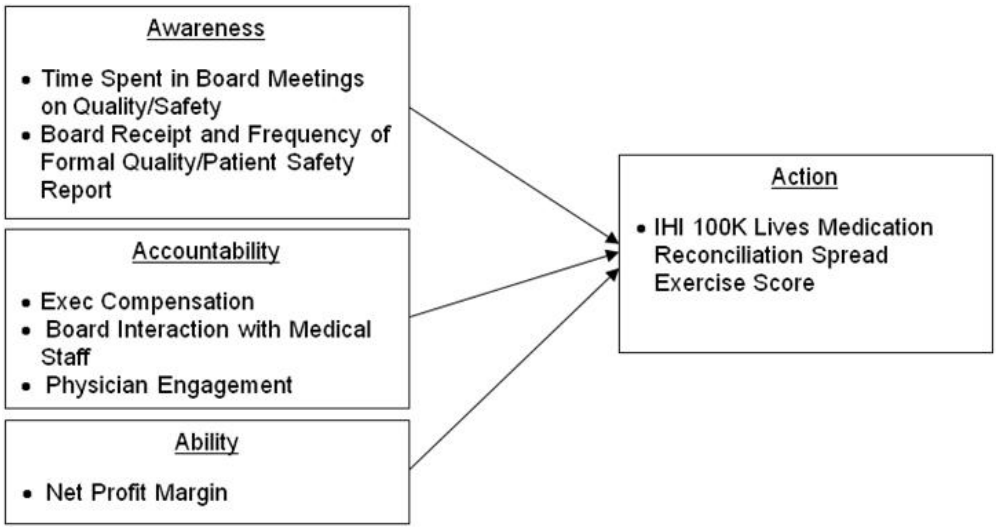


Table 1 shows both the conceptual and operational definitions of the key constructs used in this study.

As conceptualized, this study empirically examines the relationship between board-level management/leadership characteristics, medical staff engagement, and financial resource availability with the implementation of the medication reconciliation initiative, both cross-sectionally and over time.

Research Hypotheses

The cross-sectional and longitudinal-based research hypotheses related to the first two specific aims for this study are as follows:

Awareness Domain

Hypothesis H1a: More time spent by the board on quality/safety in board meetings is positively related to increased levels of medication reconciliation implementation near the conclusion of the 100K Lives campaign.

Hypothesis H1b: More time spent by the board on quality/safety in board meetings is positively related to increased levels of medication reconciliation implementation over time.

Hypothesis H2a: Greater frequency of formal quality/safety reports to the board is positively related to increased levels of medication reconciliation implementation near the conclusion of the 100K Lives campaign.

Hypothesis H2b: Greater frequency of formal quality/safety reports to the board is positively related to increased levels of medication reconciliation implementation over time.

Accountability Domain

Hypothesis H3a: Higher levels of board interaction with the medical staff are positively related to increased levels of medication reconciliation implementation near the conclusion of the 100K Lives campaign.

Hypothesis H3b: Higher levels of board interaction with the medical staff are positively related to increased levels of medication reconciliation implementation over time.

Hypothesis H4a: Executive compensation structures that include a portion of base salary or other merit/bonus incentive structures tied to quality/safety performance are positively related to increased levels of medication reconciliation implementation near the conclusion of the 100K Lives campaign.

Hypothesis H4b: Executive compensation structures that include a portion of base salary or other merit/bonus incentive structures tied to quality/safety performance

are positively related to increased levels of medication reconciliation implementation over time.

Hypothesis H5a: Higher levels of medical staff engagement in quality/safety improvement efforts are positively related to increased levels of medication reconciliation implementation near the conclusion of the 100K Lives campaign.

Hypothesis H5b: Higher levels of medical staff engagement in quality/safety improvement efforts are positively related to increased levels of medication reconciliation implementation over time.

Ability Domain

Hypothesis H6a: Greater financial resource availability is positively related to increased levels of medication reconciliation implementation near the conclusion of the 100K Lives campaign.

Hypothesis H6b: Greater financial resource availability is positively related to increased levels of medication reconciliation implementation over time.

Awareness-Accountability-Ability Composite Domain

The research hypotheses related to the third specific aim for this study are as follows:

Hypothesis H7a: Higher cumulative levels of board awareness and accountability, physician accountability, and financial ability are positively related to increased levels of medication reconciliation implementation near the conclusion of the 100K Lives campaign.

Hypothesis H7b: Higher cumulative levels of board awareness and accountability, physician accountability, and financial ability are positively related to increased levels of medication reconciliation implementation over time.

Table 1. Definitions of Key Framework Concepts

Conceptual Definition	Operational Definition
Awareness includes those structures and systems that are in place to provide a continuous flow of information to leaders [28]. Patient safety risks, hazards, and progress toward performance improvement objectives should be addressed at every board meeting.	Hospital CEO's and/or Quality Leaders indicate the extent to which their board engaged in key practices that are conducive to the receipt of sufficient and timely quality and safety information in 2006 – receipt and frequent review of formal quality/safety reports.
Accountability includes those structures and systems that are established to ensure that there is direct accountability of the governance board, senior/midlevel management, and physician leaders, and frontline caregivers to close certain performance gaps and to adopt certain patient safety practices [28]. The centers of gravity or leverage points in an organization exist with the leadership. In order to spur the adoption of needed innovations, leaders must be accountable for closing gaps. The personal accountability of leaders is a direct corollary to success [20].	Hospital CEO's and/or Quality Leaders indicate the extent to which senior executive compensation schemes were tied to quality/safety performance, the board was engaged with medical staff in quality/safety strategy setting, and physicians were viewed to be engaged with quality and safety improvement efforts in 2006.
Ability includes the capacity, resources, and competency that are critical to the ability of the organization to implement changes in their culture and in patient safety performance [28]. Financial resource availability is "that cushion of actual or potential resources which allows an organization to adapt successfully to internal pressures for adjustment or to external pressures for change in policy as well as to initiate change in strategy with respect to the external environment" [34, 35]. Financial resource availability may affect the organization's ability, strategically or tactically, to implement innovations.	The availability of financial resources in a given year will be measured using a rolling average of the Net Profit Margin percentage for the previous three year period.
Action include those structures and systems put in place to ensure that leaders take direct and specific actions [28]. These actions include performance improvement programs. To accelerate the adoption of innovative practices, leaders need to take explicit actions toward line-of-sight targets that close performance gaps and can be easily measured.	Hospital Quality Leaders' indication of their hospital's "Spread Exercise" scores measured their perception of the extent to which the IHI 100K Lives Campaign's medication reconciliation improvement initiative was deployed in their hospital over the time period spanning late 2006 through early 2010.

CHAPTER II. LITERATURE REVIEW AND CONCEPTUAL FRAMEWORK

Leadership and the Current Healthcare Environment

As some healthcare experts noted recently "the global financial meltdown, unknown impact of health care reform, and shrinking revenue per unit of care delivered have put most leadership teams into a crisis mode. Investment in most areas, and especially in patient safety, has been put on hold in many hospitals" [36]. However, in the new era of medical error awareness deemphasizing strategies aimed at improving quality and safety is untenable. Lucian Leape's 1994 JAMA article kick-started patient safety discussions within the healthcare field on a national level [37]. And, a mix of high-profile patient deaths along with national media coverage that ultimately led to the groundbreaking 1999 Institute of Medicine's To Err is Human report spawned an era in which traditional "outside" observers are demanding accountability for reportedly poor healthcare outcomes, especially in the hospital setting [14, 38, 39].

As improvement has been fragmented and frustratingly slow, the current healthcare environment may be caught in a "perfect storm". A governance expert states "health care is in crisis, challenging health care organizations to navigate a sea full of pressures and paradoxes" [40]. The "seas" of change are exerting considerable pressure on hospitals to elevate and sustain safety, timeliness, effectiveness, efficiency, equity, and patient-centeredness efforts while controlling costs at the behest of a dizzying array of stakeholders promoting programs of questionable efficacy. Many face dwindling resources needed to affect and maintain change efforts in terms of capital, personnel, and infrastructure; while the levels of outpatient care, bad debt, and charity care are increasing. It is notable that current federal policy is now dispatching a "flotilla" of new innovations designed to strategically steer hospitals and other healthcare stakeholders out of rough waters; in essence providing "rescue dingys" to assist healthcare providers that

are at risk of sinking at sea. Yet, the notes on these rescue boats will eventually come due, and many will need to prove their sea-worthiness quickly or risk losing key resources. A "tsunami" of value-based purchasing movements will help fund improvement efforts, but also threaten to sink those that are late adopters of structures and best practices designed to help keep them afloat [17, 20]. Thus, the "skies" are not necessarily clear on the horizon.

Organizational experts suggest that in this complex environment the traditional "three-legged stool" power configuration – of board, CEO, and medical staff – must work together more diligently in terms of quality performance; otherwise, drastic changes in organizational structures may be required [20, 41]. Strategically, given the complex nature of hospital operations strong leadership starting at the board of trustee level is needed to initiate, maintain, and support strategies designed to address organizational challenges. Too often a weak board is not involved in the strategic decision-making process; rather it is informed by leadership. Boards should understand the "big picture" of the hospital's future and be involved in creating a "bridge" of resources that link well with organizational tactics. Defects in the "bridge" between organizational strategies and the tactics carried out by operational leaders will be detrimental to performance [39]. Thus, board involvement in strategy setting and bridge construction is critical. Strategies and tactics are at risk for becoming misaligned potentially resulting in top-level leadership attending to more tactical issues rather than strategic planning and bridge building. To make matters worse, inadequate physician engagement has been reported as a real impediment to organizational progress as they have been reportedly less engaged in strategy setting or tactical issues. Again, without this important source of support even greater operational accountability has been assumed by governing boards and CEOs [41].

The domain of safety has a wide scope and hospital leaders do not lack for opportunities to engage in a variety of both regulatory and non-regulatory programs that aim to spur performance improvement in safety. In the past, governing boards and CEOs

have struggled to establish a clear business case for quality/safety activities, which to them seem like sunken costs of unknown value [41]. The "no margin – no mission" was a frequent response by organizational leaders when assessing requests for funding of quality/safety initiatives [20]. Given external pressures for transparency in cost, quality, and access and the looming tsunami of innovations designed to increase levels of quality, safety, and value the business case is becoming clearer. It is becoming increasingly important for hospital leaders to address safety as a fundamental, strategic priority.

The case for change is becoming increasingly evident with an expert stating "I'd argue that the most important force promoting hospital safety has been the creation of a business case for safety. Recently, boards and top executives have been subject to even more direct pressure. The IHI's 5 Million Lives campaign included a plank titled "Boards on Board", and a recent Joint Commission National Patient Safety Goal targets leadership engagement. As a result of these focused initiatives and more general pressures, many boards and leaders are increasingly involved in safety work" [16]. Another expert suggested CEO and governance members must realize that the financial success of our hospitals will pivot around our quality improvement efforts – and, that "it is time to get off our assets and put them to work" [42].

A greater congruence of thinking that promotes a "collective will", "united front", or "critical mass" among the board, CEO, and medical staff in hospital strategy inclusive of quality/safety improvement activities is essential [41, 43]. The board's ultimate responsibility for quality and patient safety strategy must be made clear. Physicians must step up their involvement in the quality dialogue. CEOs must understand they have the preeminent and central role in advancing improvement strategies in the hospital. Thus, they should work to ensure that quality improvement departments are structured appropriately and that these departments should be hospital-wide and multidisciplinary. A "will to action" is imperative to transform strategy from rhetoric to reality and

subsequently underpin continuous improvement efforts to achieve higher levels of performance [41].

However, there has been relatively little research conducted that examines the relationship between board-level leadership and organizational engagement with nationally-standardized quality/patient safety initiative implementation. In addition, there has been little research that studies the cumulative effects of board, physician leadership, and/or the availability of financial resources on organizational adoption and implementation of these initiatives. Furthermore, the pace of change is slow in healthcare – for example, it takes an average of 15-20 years for the results of clinical trials to become incorporated into standard practice [12, 44, 45]. In the field of patient safety the length of time until adoption and implementation can be longer [20]. Thus, researchers recognize the need for more longitudinal studies in this arena. In particular, longitudinal studies of nationally-recognized, evidence-based improvement innovations would enhance the internal validity of such studies while, perhaps more importantly, heighten the generalizability of results that could be useful in accelerating dissemination.

Past Board-level Research

Previous court rulings, some four decades old, have found that the board of trustees has the ultimate legal responsibility for hospital quality and safety – and this responsibility cannot be delegated [46-49]. In 2002, the Sarbanes-Oxley legislation declared that boards of directors have ultimate responsibility for the quality of care provided by a hospital [50]. Simple board oversight of quality/safety is not enough [51]. Healthcare experts have highlighted the importance of boards' will, execution, and constancy of purpose in establishing a continuous culture of quality and safety within hospitals [41, 47, 51-56]. Past research has focused on the association between specific board characteristics and/or actions with quality/safety performance.

For example, a qualitative case study found that board involvement in quality and patient safety efforts varied widely and was mostly done in a post hoc manner [57]. Other qualitative research has determined that board characteristics and activities are now recognized by many researchers and quality experts to be essentially important to quality and patient safety efforts [40, 43, 52, 53, 55, 56, 58-71]. Quantitative research has been anemic.

Early empirical studies of governance and leadership factors that promote the adoption and implementation of quality improvement efforts were published in 1996-1997 by Weiner, Alexander, and Shortell [43]. The 1996 survey-based study focused on what role the board plays in organizational adoption of leading continuous quality improvement (CQI) and Total Quality Management (TQM) programs – both popular and widespread quality innovations for that time. Board leadership was measured as the number of quality-related reports received by the Board, and activity measured as the number of actions (requesting additional quality data to be collected, initiating a special quality study, taking corrective action on an identified problem) taken by the board over the past 12 months. CQI/TQM adoption was measured as a binary variable indicating whether a hospital was formally and behaviorally committed to CQI/TQM. The study found that formal management and CEO involvement in governance demonstrated little effect on CQI/TQM adoption, however physician involvement did play a significant role in adoption. In addition, in terms of control variables hospital size and multihospital system membership were significantly related with CQI/TQM adoption.

The second empirical study published by the same authors as above using some of the same sources of data focused on research questions related to leaderships' efforts in promoting clinical involvement in hospital QI efforts [68]. The premise for research was that high-level leadership may be especially critical in cultivating clinical involvement in CQI/TQM as healthcare managers often lack direct control over the incentives and work conditions that affect physician behavior. Leadership from the top may be crucial for breaking down departmental and professional barriers that impede the efforts of cross-

functional teams to address quality issues. Low clinical involvement (defined as an organizational-wide construct) in QI efforts seems to be due as much to management's reluctance to recruit physicians as to physician's reluctance to participate. Given the central role that clinical personnel play in resource allocation decisions, hospital leaders will have to devise strategies to increase clinical involvement in quality improvement if they wish to realize the full benefits of industrial quality improvement methods. In this study the authors found that board activity and quality monitoring characteristics were significantly related to clinical involvement in CQI/TQM implementation. Active staff physician engagement with governance was also related to greater involvement with CQI/TQM activities. Another interesting finding was that hospitals that had been involved with CQI/TQM activities over longer periods of time had significantly greater levels of clinical involvement in CQI/TQM activities.

The results from these two early, groundbreaking studies suggest that leadership from the "top" is a key success factor. Leaders can enhance the credibility and sustainability of the CQI/TQM effort by linking it to the organization's mission and strategic objectives. Leaders can support efforts by allocating sufficient resources for CQI/TQM, aligning compensation and performance appraisal systems to QI objectives, and by demonstrating personal, visible commitment to continuous improvement. Leaders can build physician participation in CQI/TQM by engaging with the medical staff in ways that drive QI efforts. Results suggest that leadership may issue from several sources – managers, boards, and physician leaders. Health service researchers may need to broaden the concept of leadership from the top. Strong board leadership may be crucial for creating a corporate culture for quality and for sustaining a "constancy of purpose". Although it was not addressed in these studies, nursing leadership may also play an important role in promoting clinical acceptance and involvement in CQI/TQM efforts. In terms of future studies the authors suggest that there is a need for longitudinal research that can specify the causal direction of statistical associations; for example, does

board quality monitoring promote clinical involvement in CQI/TQM, or does clinical involvement in CQI/TQM promote board quality monitoring [68]?

Hoff and colleagues' more recent (2004) systematic review examining linkages between organization factors and medical errors/ patient safety found that there were no articles that met their acceptance criteria for board involvement [72]. However, since 2004 there has been an increase in the number of studies that have focused on the roles boards play in driving a culture of safety.

In general, the most recent set of quantitative research has found better hospital performance associated with various board characteristics [50, 61, 66, 73-75]. The board-level characteristics associated with higher levels of quality/safety processes and outcomes are involvement in the development of a quality dashboard, longer use of quality dashboards, use of a dashboard for more than just informational purposes, higher frequency of board dashboard review, board engagement with medical staff in developing a quality strategy, engagement in quality, higher percentage of women on the board, CEO evaluation process effectiveness, formal self-assessment of board, formal and regular discussion of community benefit, effective board culture, "active" versus "passive" decision making, clinical members on board, higher amounts of board time spent on quality/safety, increased levels of board expertise/training, and board chair familiarity with Joint Commission or Hospital Quality Alliance (HQA) measures.

Although this recent research highlights the relationship between board characteristics with better process and outcome measures there still exists gaps in governance performance. For example, Jha and Epstein's recent research involved a sample of 722 not-for-profit U.S. hospital board chairs and found that fewer than half of the boards rated quality of care as one of their two top priorities [75]. Alarmingly, among clinically low-performing hospitals (bottom 10% on 19 HQA/CMS process measures) no board chair reported that their performance was worse or much worse than the typical U.S. hospital. Overall, the large differences in board activities between high-performing

and low-performing hospitals suggested that governing boards may be an important target for intervention for policymakers hoping to improve care in U.S. hospitals. Obviously, significant gaps remain between leaderships' perception of performance and reality.

Past Physician / Medical Staff Research

The "early" Weiner, Alexander, and Shortell studies from 1996-1997 focusing on CQI\TQM innovation implementation found that clinical staff physician representation on the board was significantly positively related to CQI\TQM adoption [43, 68]. Interestingly, this relationship was negative if this board representation was a physician-at-large [43]. Staff physician board representation was also related to physician participation in formal QI training, physician participation on QI teams, departments with QA/QI teams, and the use of clinical data by formal QA/QI teams [68]. The authors quote Don Berwick stating "barriers to physician involvement may turn out to be the most important single issue impeding the success of quality improvement in medical care". In discussion they suggest that leaders can build physician participation in CQI/TQM by engaging with the medical staff in ways that drive QI efforts. Also, the results suggest that leadership may originate from several sources – managers, boards, and physician leaders [68].

Similar to the 1965 Darling v Charleston Memorial Hospital case, case law solidifies the importance of medical staff engagement with patient safety. In the 1980 Johnson v Misericordia case the court found the hospital 80% liable for a surgical adverse event via a failure in credentialing activities conventionally undertaken by the medical staff and overseen by the governing board [47, 49, 53]. More recently, the father of patient safety, Dr. Lucian Leape, warned us about physician apathy and the lack of physician representation on boards [76, 77]. Studies suggest that a major barrier to improvement activities is a low level of support from the medical staff; and better outcomes have been

found in hospitals with higher levels of interaction between the board and the medical staff [62, 69, 74].

Weiner and colleagues' 2006 study found that increased levels of hospital staff, senior management, and hospital unit involvement in QI efforts were not significantly related to better patient safety outcomes [78]. The authors posit that a systematic "critical mass" approach to organizational QI efforts may actually dilute the focus, spread resources too thinly, fragment coordination, and therefore the efficacy of QI efforts may wane. However, higher levels of physician engagement in QI teams was significantly related to better hospital-level AHRQ Patient Safety Indicator (PSI) scores for rates of Postop Complications (i.e.- Postop Resp Failure, Postop Pulmonary Embolism or DVT, Postop Sepsis, Postop Physiologic or Metabolic Derangement) and rates of Technical Difficulty (i.e. - Postop Hem or Hematoma, Iatrogenic Pneumothorax, Accidental Puncture or Laceration). However, the estimates for physician engagement for Technical Adverse Events (Complications of Anesthesia, Decubitus Ulcer, Postop Hip Fractures) and Failure to Rescue were not statistically significant; although the relationship between these measures were in the hypothesized direction. The authors claimed the mixed results suggest that some patient safety problems are more "physician sensitive" than others [78]. This also suggests that some quality/safety problems are more sensitive to other resource issues, for example – nursing or non-nursing staff issues.

Overall, many other experts mirror Leape's view that physicians and medical staff should become more involved in organizational activities [20, 40, 62, 79-81]. While a few decades ago the prevalent paradigm might have been that physicians were solely responsible for the quality of care, were the individuals most qualified to judge the quality of care, and were the key influencers of quality improvement strategy, that mindset is quickly being revised. It is being replaced by an environment in which many types of healthcare professionals have an increasingly important role in establishing organizational strategies. However, physician engagement in leadership activities is still

recognized as a critically important piece of coalition building for change efforts within hospitals. The right physicians can serve as "boundary spanners" to champion quality initiatives. If physicians are able to shed traditional roles as quality ombudsmen to participate more actively in roles as quality/safety directors and advocates, hospital/physician collaborators, proponents for the community, champions for HIT, opinion leaders, overseers of reimbursement trends, and board members the ability of an organization to overcome barriers to change may be enhanced.

Leadership / Compensation Structure / Culture

Hearld et al.'s recent systematic review found that, in general, leadership was the most effective organizational characteristic associated with quality improvement outcomes and was studied predominantly at the hospital level [82]. Leadership studies most often focused on the effect of clinical opinion leaders or physician champions on quality improvement initiatives, but not on explicit leadership frameworks or "organization-wide" clinical leadership characteristics. The review also found that, in general, although many types of professional groups were represented in studies, clinical leadership demonstrated the most consistent results across studies.

CEO compensation has also been the focus of attention in driving higher quality and patient safety. Governance experts suggest that CEO compensation should be linked to specific quality/patient safety performance targets [40, 61, 65, 83]. In the Vaughn et al. study better clinical quality outcomes were associated with hospitals where the CEO/COO is identified as the person with the "greatest impact on QI" performance and where compensation of senior executives was based in part on QI performance [74]. Using the data collected in the Vaughn et al. study, unpublished analyses of the difference in quality scores between types of compensation shows that "Base Compensation", "Merit Increase", "Bonus Incentive", "Not at All" are related to decreasing quality scores respectively [84]. Hospitals with an executive compensation structure that linked

quality/safety performance with Base Compensation pay had significantly higher quality scores (M=104.27, SD = 5.8) than hospitals that did not utilize this structure (M=99.35, SD=6.58), $t(90) = -2.45$, $p < 0.05$, two-tailed. Another interesting finding is that there was a "huge" amount of variability in quality scores for the "Not at All" compensation type.

In contrast, a small survey-based study conducted by McDonagh suggests that CEO performance is not the prime driver of quality of care [85]. Rather, survey respondents viewed clinical expertise – especially doctors and nurses working in collaborative teams – as the most influential factor on quality of care. The social dynamics between CEOs and boards (working relationships, tolerance for ambiguity, appetite for organizational puzzles, engaged, quality of mind, commitment to team play) may be more important than structural characteristics (size, compensation, subcommittees) in providing valuable "governance as leadership" to the hospital which in turn underpins and promotes better performance. According to a 2004 Commonwealth Fund report, developing the right culture for quality to flourish and attracting/retaining the right people to promote quality are 2 of the 4 most important factors that underpin successful high-performing hospitals [86]. However, it should be noted that active leadership and personal involvement on the part of the board, CEO, and leadership team help drive a healthy organizational culture.

These findings align with Collins and colleagues' studies of "great" organizations that suggest that it is highly important to "get the right people on the bus" [87]. It is not "what" you do in terms of vision, strategy, organizational structure, tactics; rather it is "who" – the *right* people - performing organizational tasks that are the foundation for creating value for the organization. In essence, this theory suggests that by "getting the right people on the bus" the problems of motivating and tightly managing people to do the right thing through compensation or other organizational structures are eliminated. In fact, their study found no systematic patterns linking executive compensation (salary,

bonuses, stock, long-term compensation) to better organizational performance. Rather, executives that focused energies on carefully building great teams of self-disciplined people were associated with better performing organizations [87]. Other healthcare industry experts support Collins and colleagues' findings stating that the days of the 3 CEO "keeps" – keep the board happy, keep the doctors happy, and keep your job – are over [20]. The best CEOs are aggressively crafting coalitions across board members, physician leaders, and senior management teams to drive meaningful change – essentially getting the "right people on the bus". An integrated leadership team composed of high-quality individuals may drive those behaviors, values, and culture that are necessary to succeed in a complex environment.

These findings also align somewhat with a recent survey-based assessment of organizational culture and hospital safety performance. Singer, et al. analyzed responses from a Patient Safety Climate in Healthcare Organizations (PSCHO) survey along with hospitals' AHRQ PSI measure performance on Medicare beneficiaries [88]. The study found that hospitals with a better safety climate had lower relative incidence of PSIs. However, it was notable that frontline personnel's perceptions of better safety climate predicted lower risk of experiencing PSIs, but senior manager perceptions did not. Their findings suggest that executives may not be aware of the actual quality of the culture of safety that exists within their organization. Or, perhaps there was a spurious relationship between frontline personnel's perceptions of safety climate and rare patient safety outcomes.

Thus, given the current gaps in governance and leadership infrastructure and the importance of skilled leadership to drive and maintain safety efforts it is not surprising that the focus on boards' will, execution, and constancy of purpose has progressed quickly on a national scale. In 2004, Dr. Don Berwick, CEO of the Institute of Healthcare Improvement (IHI) challenged the industry to do better. IHI challenged the leadership of U.S. hospitals to prevent 100,000 deaths over an 18 month period via a

national campaign aimed at aligning and equipping hospitals to do better. The campaign was called the 100,000 Lives campaign which was followed by the 5 Million Lives campaign. Interestingly, the 5 Million Lives campaign recognized the importance of governance and leadership roles in creating the will to change and overseeing the execution of improvement announcing that one of the 5 Million Lives "planks" was getting the "Board on board" in regard to quality/patient safety [56, 70, 89-91].

IHI 100,000 Lives Campaign

IHI is an independent not-for-profit organization helping to lead the improvement of healthcare throughout the world. Founded in 1991 and based in Cambridge, Massachusetts, IHI works to accelerate improvement by building the will for change, cultivating promising concepts for improving patient care, and helping health care systems put those ideas into action [21]. The organization has been involved in 2 national hospital-based initiatives designed to align and equip hospitals with the information and tools necessary to positively impact the delivery of specific healthcare services. The initial IHI 100,000 Lives (100K Lives) campaign was a 1 ½ year project beginning December 14, 2004 focusing on 6 "planks" of performance that represented evidence-based practices, that if implemented nationally, had the potential to avert 100,000 deaths. Salient leadership groups like the American Medical Association, the American Nurses Association and the Joint Commission on Accreditation of Healthcare Organizations immediately signed on to the campaign. Several federal agencies, including the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, the Veterans Health Administration and the Agency for Healthcare Research and Quality pledged support as well [92].

The scale associated with the initial IHI 100K Lives campaign drew a lot of national attention, after all, the goal was to save 100,000 lives among all US hospitals. For operational purposes in the campaign, a "life saved" was defined as a patient

successfully discharged from a hospital who, absent the changes achieved during the campaign, would not have survived. Although the 6 original interventions are conceptually simple and feasible, implementing them can be complex, requiring cultural changes. The campaign calculated lives saved by tracking mortality rates, comparing a hospital's mortality data for each month of the campaign period (from January, 2005 to June, 2006) to its mortality data from that same month in 2004. Monthly "lives saved" data were collected from hospitals across the country and a national volume and case-mix adjustment was applied to account for the overall change in patient acuity and volume between 2004 and the campaign period. IHI reported publicly the number and names of participating hospitals, as well as the aggregate number of lives saved across all hospitals [93].

The outcomes associated with the initial campaign were also noteworthy on a national scale. Although it was anticipated that about 1,600 of 5,759 U.S. hospitals could be expected to participate, about twice the expected number – approximately 3,103 – of the nation's hospitals participated. The estimated number of lives saved was about 122,342 plus or minus about 2000 lives over the year and a half campaign timeframe [94, 95]. However, the campaign methodologies and thus the exact number of lives saved were disputed by some. For example, several potentially confounding factors were highlighted by prominent researchers: secular trends may have accounted for the decrease in deaths, the precipitous drop in deaths reported by IHI does not align with AHRQ's estimates of the decline in death rates over the same time period, hospitals self-reported mortality data, estimates of the extent of hospitals missing data ranged from 14%-27%, the potential that in some hospitals 15 months of data or less were extrapolated to produce 18-month estimates of effectiveness, several risk-adjustment strategies were used originating from several premier research organizations (CareScience, Solucient, Premier), hospitals' coding processes may have artificially improved death rates, data were not validated, and the potential for response bias [96, 97]. IHI's Dr. Berwick

recognized some of the limitations associated to a national campaign, corrected some misinterpretations, but also stated that a conservative estimate of lives saved would be about 114,400 assuming hospitals with no data had no lives saved [98].

Perhaps the most noteworthy achievement was that IHI succeeded in establishing and promoting a set of achievable goals for U.S. hospitals against the backdrop of a "crowded marketplace". IHI's use of a collaborative "just do it" philosophy, without too much epidemiological or statistical preparation, helped catapult the effort quickly and effectively throughout a large population of health care providers. This relatively short-term "quick win" on a national scale may have been a key driver of major change. The success of this initial innovative effort may have affected the nationwide dissemination of their second major campaign - the 5 Million Lives campaign. The initial 100K Lives campaign was followed by the 5 Million Lives (5M Lives) campaign – initiated on December 12, 2006 - that added 6 additional planks targeting key areas ripe for improvement efforts. Notably, this campaign included a plank that focused on boards' engagement with patient safety issues.

Nationally, the IHI quality improvement campaigns were innovative in that the campaign material was made available to all U.S. hospitals and nodes free of charge. Thus, evidence suggests that some hospitals chose to "opt out" of more resource-intensive initiatives; instead choosing to engage in less burdensome efforts in regard to data collection, reporting, and making improvements at a rate and depth that was appropriate for their hospital [99, 100].

In Iowa, the Iowa Healthcare Collaborative (IHC) has helped to promote the engagement of hospitals with the IHI campaigns serving as the Iowa "node" – the hospitals' focal point for engagement with the IHI campaigns. Each participating hospital or system of hospitals is expected to engage all stakeholders—boards, executives, managers, frontline providers, patients, families—in the campaign process, developing explicit targets, accountabilities, and campaign work plans, applying quality

improvement methods to drive change, and regularly reviewing the organization's performance [101]. IHC along with the Iowa Hospital Association has been collecting "Spread Exercise" data since March, 2006 which assesses hospitals' self-reported levels of hospital implementation for eleven of the twelve IHI "planks" of clinical performance. In Iowa, through IHC's collaborative work all 117 hospitals (100%) have reported engagement with these campaigns, and "spread exercise" scores have been reported by Iowa hospital quality leaders over the past four years.

IHI 100K Lives Initiative – Medication Reconciliation Process

This study focuses on Iowa hospitals' implementation of a specific initiative within the IHI 100K Lives Campaign relating to the prevention of adverse drug events (ADEs) – medication reconciliation. This particular initiative focused on one particular source of adverse drug events, those events related to medication errors that may arise because patients' medications are not reviewed *at all transitions in care* for potential harm. As noted previously, effective evidence-based healthcare practices may take a long time to be widely used in a standardized way. The essence of IHI's innovative approach was to effectively and efficiently "spread" the knowledge and tools needed by organizations to implement clinically-focused sets of best practices. Thus, the response variable used in this study is the "spread" score of hospitals' implementation of this best practice over time. The "spread" scores represent the degree to which the best practice is implemented throughout the organization.

As part of an IHI initiative, Jane Justesen, a nurse at Luther-Middelfort-Mayo Health System in Eau Claire, Wisconsin, pioneered the tools and forms needed to create, update, and reconcile a patient's medication record during hospitalization. Using these innovative tools IHI's goal was to "prevent adverse drug events (ADEs) by implementing medication reconciliation at all transitions in care – *at admission, transfer, and discharge*.

The important and innovative aspect of this initiative was to educate and reframe how clinicians view the "act" of medication reconciliation [102].

IHI specifically noted that the term "medication reconciliation" had been misinterpreted as a discrete *action* of obtaining a list of patients' medications instead of a systematic, three-step *process*. The three-step process involved verification (collection of the medical history), clarification (ensuring that medications and doses are appropriate), and reconciliation (documentation of changes in the orders) each time a patient moves from one setting to another. Hospitals had previously taken different approaches to complete this process [102, 103].

The original 100K Lives campaign aligned and equipped clinicians to use a model of improvement consisting of 2 parts: forming a multidisciplinary team to set clear aims, establish measures, and identify changes that are likely to lead to improvement; and testing small-scale changes using a Plan-Do-Study-Act (PDSA) cycle. Successful small-scale tests of change could then be implemented and subsequently "spread" to other parts of the organization [103]. IHI provides a suite of tools designed to help organizations accelerate improvement including evidence-based research, successful protocols, processes, order sets, forms, instructions, metrics, and guidelines for implementing key changes. Thus, the innovation was designed to educate, align, and equip organizations to apply a best practice organization-wide in a new, systematic way.

Background on the Importance of Medication Reconciliation

Drug-related complications are a common source of preventable harm; and alarmingly this has been known for quite some time. Schimmel's 1964 research found that well over 50% of the adverse events captured in a prospective study of the types and frequency of hospital complications were categorized as reactions to therapeutic drugs [1]. In addition, the research studies providing the foundation for the groundbreaking Institute

of Medicine's "To Error is Human" report found that drug complications are the most frequent source of non-operative adverse events [3, 4]. More recently, a systematic review found that errors in prescription medication histories occurred in up to 67% of cases [104]. In terms of reducing the incidence of medication-related adverse events, the sources of the research-based evidence that underpin the medication reconciliation initiative are part of the IHI toolset [102, 103]. Because the research shows that adverse drug events are a common outcome of medical error, and a large portion of patients are at risk of experiencing drug complications, this IHI 100K Lives initiative is universally applicable to all hospitals.

The Joint Commission highlighted the importance of addressing medication reconciliation processes. The accurate and complete reconciliation of medications across the continuum of care was added as a Joint Commission 2005 National Patient Safety Goal.

The National Quality Forum (NQF) also focused on medication error and medication reconciliation within many of their consensus-based national standards and endorsed safe practices. In 2002, the NQF identified a set of 27 serious adverse events that should be reported by all licensed healthcare facilities and form the basis for a national state-based reporting system that could lead to substantial improvements in healthcare. Updated in 2006, this set included patient death or disability associated to a medication error [105]. In 2003, the NQF released their 30 Safe Practices for Better Healthcare, simply called the NQF Safe Practices, which could be universally applied in healthcare settings to reduce the risk of harm to patients [106]. In 2006, the NQF updated their 2003 list of Safe Practices to include the safe practice that healthcare organizations should develop, reconcile, and communicate an accurate patient-specific medication list throughout care [27].

More recently the NQF convened national healthcare stakeholders and worked to collaboratively indentify a set of high-leverage areas that should be the focus of

improvement efforts on a national scale. These high-leverage areas are those with the most potential to result in substantial improvements in health and healthcare. The NQF-convened National Priorities Partnership identified a set of priorities and goals that collectively address four major challenges – eliminating harm, reducing disparities, reducing disease burden, and removing waste - that are important to every American. The priorities and goals are arranged within a list of six priority areas. The improving the safety and reliability of America's healthcare system priority area includes a goal that all healthcare organizations and their staff will strive to ensure a culture of safety while driving to lower the incidence of healthcare-induced harm. Certainly, boards and hospital leadership are responsible for establishing a culture of safety within their organizations. A separate priority area focuses on ensuring patients receive well-coordinated care within and across healthcare organizations, settings, and levels of care. Within this priority area healthcare organizations are challenged with the goal of clearly communicating medication information to patients, family members, and the next healthcare professional and/or organization responsible for care, and reconfirming medications each time a patient experiences a transition of care [107].

The importance of addressing medication errors was also underscored by the inclusion of medication-related patient safety events within the Patient Safety Organization (PSO) rules set in motion by the 2005 Patient Safety and Quality Improvement Act. Under federal rules released in 2008, hospitals and other providers have the ability to work with Patient Safety Organizations (PSOs) in a privileged and confidential way to collect and analyze information regarding the safety of care in any healthcare setting. The reporting and analysis of medication errors are included as one of the nine original patient safety domains initiated by this legislation.

More locally, the Iowa Hospital Association (IHA) has identified patient death or serious disability associated with a medication error as one of eight specific events included in IHA's guidelines for non-payment of serious adverse events.

Despite widespread and long-term focus on this source of potential harm to patients, the probability of harm due to gaps/lapses in medication reconciliation processes is still significant. For example, a more recent study found that over one-third of study patients (35.9%) experienced medication order errors at admission, and 85% of these errors originated in medication histories [108].

The Impact of Regulation – Joint Commission

Devers and colleagues identify three general mechanisms that stimulate improvement of quality and safety – professionalism, market forces, and regulation [109]. Their qualitative survey-based study conducted in twelve metropolitan areas found that a regulatory body, not market forces, has a stronger impact on hospitals' efforts to improve patient safety. In particular they found that a quasi-regulatory organization, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), has been the primary driver of hospitals' patient safety initiatives. Professional and market initiatives have facilitated improvement, but hospitals report that these forces have had less impact on patient safety initiatives than JCAHO accreditation efforts.

The essence of JCAHO's strengths in driving patient safety initiatives is derived from their quasi-regulatory position in hospitals' environments. Because hospitals must be accredited by JCAHO or undergo a regulatory review by CMS to participate in Medicare, and Medicare accounts for approximately 40% of hospitals' revenues, hospitals are incentivized to be JCAHO-accredited or at least adhere closely to their requirements to qualify for federal/state programs [109].

JCAHO has been an "early" driver of major patient safety policies including establishing a sentinel event policy (1996), patient safety standards (2001), and national patient safety goals (2003). The 2001 patient safety policies included an early focus on hospital leaderships' responsibilities for creating a culture of safety. The patient safety goals were rolled out in 2003 and have been continuously updated on an annual basis.

Many of these "early" JCAHO policies formed the content of the initial set of thirty national "safe practices" established by the National Quality Forum (NQF) in 2003. The systemic risks associated to medication use were addressed in many of these early JCAHO policies and subsequent NQF 30 Safe Practices and IHI improvement initiatives.

For example, the safe use of potentially hazardous "high-alert" medications (NQF Safe Practice #29) was a 2003 JCAHO patient safety goal that focused primarily on the identification of these drugs in an effort to reduce errors related to their potential misuse. The NQF Safe Practices also included limiting and standardizing the number of drug concentrations available in an organization (Safe Practices #28 and #30). And, later IHI included the prevention of harm from "high-alert" medications as a 5M Lives initiative during the 2006-2008 campaign.

JCAHO added a "medication reconciliation" national patient safety goal in 2005. This goal became a national Safe Practice in NQF's 2006 Update of Safe Practices (Safe Practice #14). Apparently, this particular goal has been difficult to achieve. Recently JCAHO issued a statement regarding the continued high prevalence of medication errors, and noted in March, 2010 "since the Goal on medication reconciliation was instituted in 2005, many organizations have struggled to develop and implement effective and efficient processes to meet the intent of the Goal." Correspondingly, JCAHO has suspended the use of hospitals' performance results in accreditation scoring and is working with stakeholders to improve the usability of this goal's recommendations and requirements. JCAHO plans to release an update to this goal in January, 2011 [110]. To maintain a historic perspective and highlight the slow pace of change in relation to this innovation, IHI included the prevention of adverse drug events by implementing medication reconciliation as an initiative within the initial 100K Lives campaign which began in 2004.

In terms of the research related to JCAHO national patient safety goals and corollary NQF Safe Practices there is evidence of a relationship between hospitals' use of

these goals and practices and quality/safety improvement efforts. Ward and colleagues NQF survey-based study of Iowa hospitals found a relationship between JCAHO-accredited hospitals and higher scores on JCAHO-related NQF Safe Practice items [111]. Hospitals' progress on those NQF 30 Safe Practices that are directly related to JCAHO patient safety goals and recommendations, which had been promoted by JCAHO as "National Safe Practices" for some time (e.g. - wrong site surgery, hand washing), were higher than other safe practice scores. These results suggested that JCAHO's quasi-regulatory influences may have impacted which safe practices receive the most implementation or improvement action among hospitals. This influence may even affect small rural hospitals that may not be formally engaged in JCAHO's programs due to resource constraints, but tend to follow the certification recommendations as a guide in improvement efforts. A second NQF Safe Practice survey that was conducted by the Texas Medical Institute of Technology (TMIT) during the same time frame as the Ward et al. study also found that Iowa hospitals performed particularly well in areas of JCAHO focus [112]. Similarly, Wachter's survey found that hospitals thought that progress in patient safety in the post-'To Err Is Human' years was due to first - an "overall increased sensitivity to the patient safety issue" – and secondly, to "regulations (i.e.- JCAHO)" [9]. Because physicians remain highly individualistic, regulatory solutions may have been an important early step in spurring hospitals' safety improvement efforts . Longo and colleagues' survey also found that hospitals that were JCAHO-accredited showed statistically significant improvements in a variety of patient safety system implementations [113]. They also acknowledge the catalytic effect on hospitals' patient safety improvement efforts since 2003 when JCAHO strengthened their standards by tying national patient safety goals to accreditation. In contrast, Miller et al.'s nationally representative study found few relationships between hospitals' JCAHO accreditation scores and AHRQ patient safety or inpatient quality measures [114]. However, worse performance on a composite Patient Safety Indicator (PSI) factor analysis score

(predominantly postoperative issues) was associated with worse performance on JCAHO scores.

In part due to their public reporting program – www.qualitycheck.org on their Quality Check web site – JCAHO is thought to be a relatively strong facilitator in changing hospital behavior in regard to patient safety systems [113]. In contrast, others warn that JCAHO accreditation alone does not guarantee top-tier quality; rather it should be viewed as only one of the measures of true quality of care [65].

CHAPTER III. DESIGN AND METHODS

Patient Safety, Culture, and Leadership Survey

This research builds upon a previous survey-based project initiated by the Iowa Hospital Association (IHA) in 2004 that focused on assessing hospital leaderships' perceptions of hospital adoption and implementation of the NQF 30 Safe Practices. A total of 100 of 117 Iowa hospitals responded to the initial 2004 NQF Safe Practice survey. Our project team conducted analyses of this initial survey. This culminated in a published manuscript of Iowa hospital leaderships' perceptions of hospital engagement with the NQF 30 Safe Practices in the American Journal of Medical Quality [111].

Starting in November, 2006 the Iowa Healthcare Collaborative and the University of Iowa College of Public Health's Center for Health Policy and Research embarked on a project to conduct a follow-up survey on the NQF Safe Practices. In early 2007, NQF released a "2006 Update" to the original 30 NQF Safe Practices. These "updated" Safe Practices were included in the follow-up survey and the survey was expanded to include items assessing hospital culture and leadership attributes important to this project. This survey was called the Patient Safety, Culture, and Leadership (PSCL) Survey.

Several additional items were added to the PSCL survey that were designed to assess the degree to which Iowa hospitals are engaged in evidence-based governance and leadership practices with respect to board, physician, and medical staff engagement characteristics. Survey responses to these items were used as independent variables of interest in this study. These survey items were used by Dr. Vaughn and colleagues in previous research efforts, within their Executive QI Survey instrument, and permission was granted to use these items in this survey [74]. The purpose of their research was to identify structures and processes that are most likely to strengthen quality improvement activities within hospitals. We utilized the same or similar survey items relating to the amount of time that boards spend on quality issues, board receipt of a formal quality

measurement report, board interaction with medical staff, senior executive compensation, and physician engagement in quality/safety improvement efforts. Vaughn et al.'s research found higher levels of these organizational characteristics were related to better quality outcomes. It is also notable that Vaughn and colleagues' research is used as part of the evidence base in the "Get the Boards on Board" initiative promulgated by IHI in their 5 Million Lives Campaign [102].

The PSCL survey was introduced to the Iowa Healthcare Collaborative's Data Committee and approved for distribution to Iowa hospital CEOs/Quality Leaders in a reduced format to minimize burden upon survey respondents. This survey was approved for use by the University of Iowa's institutional review board (IRB). The survey items used in this study are shown in the Appendix.

A total of 4 waves of the PSCL survey were sent to Iowa hospital CEOs and Quality Directors throughout the Fall of 2007. A total of 104 out of 117 hospitals responded to the survey. The responses represent 89% of all Iowa's nonfederal, acute care hospitals.

Differences between 2007 PSCL survey responders versus non-responders were examined. These results are shown in Table 2. Responders were not significantly different from non-responders on a set of American Hospital Association (AHA) Annual Hospital Survey variables.

The dependent variable data used in this study were collected using a different method. A website-based data collection tool was used to capture hospital Quality Leaders' perception of their hospitals' deployment of IHI 100K/5M Lives Campaign implementations. These data have been captured by IHC/IHA since 2006. This study focuses on a single IHI 100K Lives initiative related to adverse events associated with drug complications – medication reconciliation.

Dependent Variable – IHI 100K Lives Medication Reconciliation

The dependent variable used in this study measures the extent to which the drug complication-related initiative "medication reconciliation" was implemented within the hospital. This variable is derived from hospital Quality Leaders' on-line quarterly "Spread Score" survey response data over time starting October, 2006 – January, 2010. These longitudinal data are called "spread scores".

Medication Reconciliation – This variable captured hospital Quality Leaders' response to IHI 100K Lives Campaign Reporting Tool survey item "Select the following option that best describes the status of the Prevent ADE's (Medication Reconciliation) intervention at your hospital". The data were captured using the following response categories:

No Adoption (0) – Hospital not in campaign and/or measure.

No activity (1) – There has been no activity to implement this intervention in the hospital.

Discussion Only (2) – Intervention has been discussed for possible implementation, but has not yet been implemented.

Incomplete (3) – Implementation has begun, but not all elements of the intervention are in place.

Selective (4) – Intervention has been fully implemented within some units/departments, but has not been implemented hospital-wide.

Hospital-wide (5) – The intervention has been fully implemented throughout the hospital.

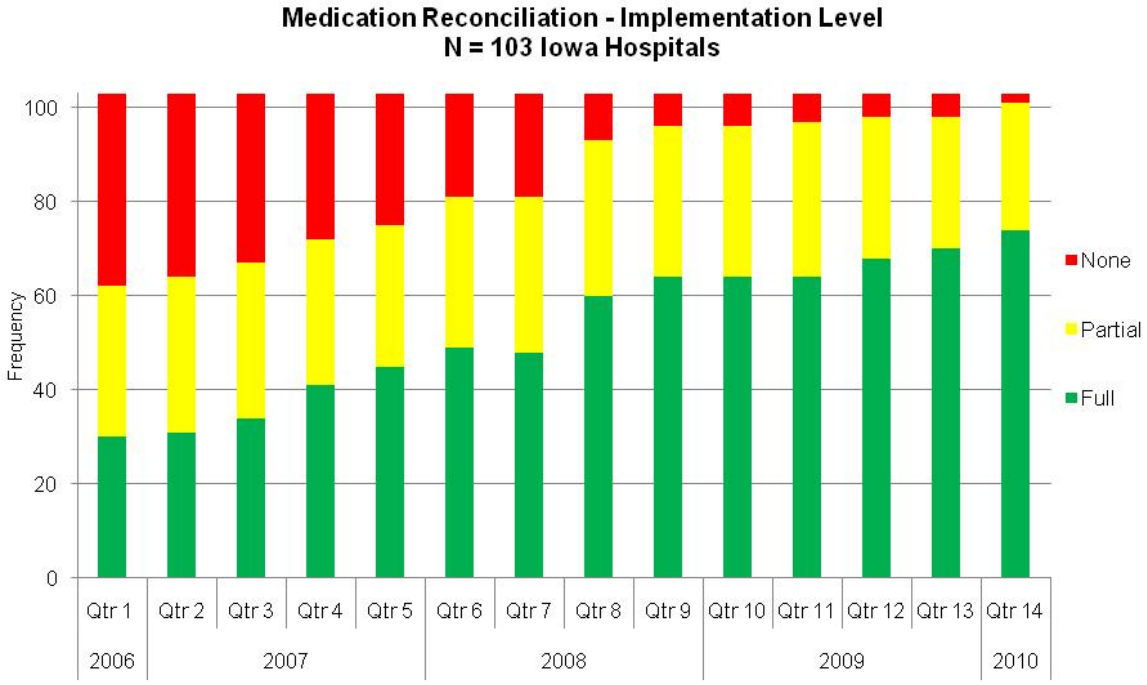
There were no missing data in any time period (over 14 quarters).

As a first step in examining the structure of the dependent measure, the trend in hospitals' IHI 100K medication reconciliation response pattern over time was examined. An "individual hospitals" plot showed variability in initial medication reconciliation

implementation and in response patterns over time. A population plot was used to examine the population of hospital responses over time. The distribution of the original 5-category response variable was reviewed in a longitudinal stacked bar plot. Based on the apparent skewness in these response category distributions, and the sample size limitations inherent to this study, the initial response categories were collapsed into three, more evenly distributed categories as shown in Table 3.

The resultant graphical plot of the recategorized dependent medication reconciliation implementation response variable over time is shown below in Figure 2.

Figure 2. Medication Reconciliation Initiative Implementation



Independent Variables

Awareness Domain

All of the data for the variables in this domain come from the 2007 PSCL survey. The survey items assessed hospital leaderships' perceptions of their organization's 2006 board-level engagement with quality and patient safety issues.

Board Time Spent on Quality/Safety – The data for this variable was captured via the PSCL survey item "On average during your hospital board meeting in 2006, what proportion of time was focused specifically on quality and safety of care issues?". The descriptive statistics for this survey item are shown in Table 4.

Frequency of Board Receipt of Formal Quality Report – The data for this variable was captured via the PSCL survey item "In 2006, did your board receive a formal quality and safety measurement report from your hospital, and if "yes", how often did the board receive this report in 2006?". The descriptive statistics for this survey item are shown in Table 5.

Accountability Domain

All of the data for the variables in this domain come from the 2007 PSCL survey. The survey items captured hospital leaderships' perceptions of their organization's 2006 board-level engagement with quality and patient safety issues.

Board Interaction with Medical Staff – The data for this variable was captured via the PSCL survey item "In 2006, to what extent did your board interact with medical staff (other than the CMO or President/Chief of Medical Staff) to establish quality and safety strategy?". The descriptive statistics for this survey item are shown in Table 6.

Executive Compensation – The data for this variable was captured via the PSCL survey item "In 2006, how was senior executive compensation tied to quality and safety performance?". The descriptive statistics for this survey item are shown in Table 7.

Physician Engagement – The data for this variable was captured via the PSCL survey item "In 2006, to what extent were physicians (medical staff) engaged in quality and safety improvement efforts?". The descriptive statistics for this survey item are shown in Table 8.

Ability Domain

The variable used in this domain comes from annual Iowa Hospital Association (IHA) Profiles reports published by the IHA (longitudinal data spans the years 2003-2009) [115-118].

Net Profit Margin – The raw data collected represent a longitudinal, continuous variable using a 3-year rolling average of Net Profit Margin percentage for the previous three year period. The algorithms used to calculate hospitals' net profit margin in a given year are shown below:

Net Profit Margin % = Total Revenue Margin / Total Revenue

Where: Total Revenue Margin = Total Revenue – Total Expenses

Total Revenue = Net Patient Revenue + Operating Revenue + Non-operating Revenue + Tax Appropriations

Total Expenses includes all payroll and non-payroll expenses (including bad debt) as well as any non-operating losses.

The descriptive statistics for hospitals' previous 3-year net profit margin data are shown in Table 9.

Control Variables

A set of control variables is also used in multivariate analyses. Within the Iowa hospital setting these variables captured potentially important influencers of improvement efforts. These include the impact of regulatory requirements and other potential sources of resource availability that may be related to the variability in medication reconciliation implementation.

Joint Commission on Accreditation of Healthcare Organizations (JCAHO) certification – Hospital JCAHO accreditation status is a dichotomous indicator of "yes" for accreditation or "no" if null. These longitudinal data come from the 2006 - 2009 AHA Annual Hospital Surveys [119-122].

Critical Access Hospital (CAH) – Hospital CAH status is a dichotomous indicator of "yes" for CAH or "no" if a non-CAH. Hospital class (CAH, rural PPS, rural referral, and urban) longitudinal data come from the Iowa Hospital Association's Profiles reports (spanning the years 2006-2009) [116-118].

System Affiliation – Hospital system membership is a dichotomous indicator of "yes" for system-affiliation or "no" if not affiliated to a system. System membership longitudinal data come from the 2006 - 2009 AHA Annual Hospital Surveys [119-122].

Hospital Size – Hospital size is a continuous variable indicating a hospital's size based on the number of acute beds. Hospital size longitudinal data come from the Iowa Hospital Association's Profiles reports (spanning the years 2006-2009) [116-118].

The descriptive statistics for the control variables used in this study are shown in Table 10.

Power Analyses

Preliminary power analyses utilizing Fitzmaurice and colleagues' projected sample size equation for longitudinal studies with a binary response were conducted using the following assumptions: Correlation between repeated responses = 0.50, 14 repeated measures over 3.5 years, alpha = 0.05, Beta = 0.2, and an effect size of a 40% difference in the probability of hospital "Full" implementation over the length of the study [123]. Results show a power of 80% is achieved with 9 hospitals per group. Sensitivity analyses showed that the study sample sizes to detect a difference in probability of 20% and 10% were 36 and 146 per group respectively.

Statistical Methods

The primary approach is to analyze the relationship of the independent variables with the IHI 100K Lives medication reconciliation implementation response variable cross-sectionally and over time. Fourteen quarters of ordered, multinomial data is used to model the multinomial logit response related to the independent variables. The variable "quarter" is used in the model to assist in the analysis of changes in the response variable over time.

A random effects model is specified to account for potentially significant within-hospital variability associated to differences in initial spread scores (intercept) and slope over time. In order to account for random effects associated to within-hospital variation, a generalized linear mixed effects model (GLMM) is used to model the cumulative logit response of longitudinal data over time. The data are analyzed using the SAS software PROC GLIMMIX procedure.

The SAS PROC GLIMMIX technique provides a relatively "new" and powerful way to model correlated outcomes with different types of distributions. The procedure extends many of the basic concepts and ideas of standard linear regression mixed effect analyses to settings where the response variable may be non-continuous and can no longer be assumed to possess a normal distribution. Thus, the PROC GLIMMIX procedure uniquely permits the specification of a non-continuous distribution similar to the multinomial distribution used in this study. The technique can be used to incorporate random effects into a model, which is an important feature in estimating and accounting for the variability in subject-specific response trajectories over time, yet it also allows for population-averaged (marginal) inferences. The use of this procedure is also suited to handling missing data assumed to be missing at random [123-125].

Using this generalized linear model, a suitable transformation of the mean response is achieved by the introduction of a "link-function". In this study a multinomial distribution is specified using the GLOGIT link function which enables the modeling of

multinomial responses. An attractive feature of the use of the GLOGIT link function is that it yields two odds ratio estimates encompassing comparisons among the three ordinal response categories. The two odds ratios allow for the comparison of independent variable log odds (of success) effects between the "Full" and "Partial" groups and the "None" implementation group. This allowed for examination of the independent variables' log odds (of success) in relation to achievement of partial and full implementation compared to a reference category of no implementation. And, this approach allowed examination of the difference in log odds of success between partial and full implementation.

The use of this technique has limitations. When the sample size is low or there are a small number of repeated measures, the convergence rate of GLIMMIX models can be very low [123, 125]. Taking into account the limitations due to the sample size and number of repeated measures used in this study, along with the potential computational limits of the GLIMMIX procedure, it was anticipated that a data reduction technique similar to those proposed by Harrell/Lee and Iezzoni, and used by other researchers, might be needed to build and fit a parsimonious multivariate model [126-131].

Model construction involving longitudinal data employed several model building and data reduction techniques. First, an important feature of binary or multinomial data is that there is usually not much information available about random effects beyond a random subject effect (random intercept) when the number of repeated measurements is small [123]. Although there are a considerable amount of repeated measures (14 total) available in this study, the random effect coefficients for both the intercept and slope (quarter) will be viewed for significant added value to the model. These random effects will be eliminated from the model based on a significance level of 0.05.

A two-staged data reduction technique to trim the number of predictor (independent) variables was used to guard against building models that are overspecified [126-131]. The total possible sample size is constrained in this research in significant ways -

the total number of non-specialty hospitals returning the PSCL survey (n = 103) may be further constrained by instances where hospitals did not respond to a particular survey item. Thus, given the constraint of this study in being able to support an effective sample size in the neighborhood of 96 – 103 hospitals, we anticipated a need to constrain the number of independent variables to approximately 2 (a ratio of 20 events per independent variable in the case of simple logistic regression models) in cross-sectional models and 4 to 5 at the maximum in longitudinal models [128].

Stage 1. Examination of "bivariate" relationships was conducted between each of the independent and control variables with the dependent variable utilizing a generalized linear model. Because an important feature of this study was the use of longitudinal data, the main effects of quarter (time), and the independent variable of interest, along with their interaction were included in the model. Each bivariate implementation equation can take the form of the following generalized linear mixed model (GLMM) equation:

For the ith hospital at the jth measurement occasion (j = 1,2,3, … 14):

$$Ln\ MedRec_{ij} = (B_1 + b_{1i}) + B_2Board_j + (B_{3+}b_{3i})Quarter_j + B_4Board*Quarter_{ij} + e_{ij}$$

The coefficients b_{1i} and b_{3i} represent the random effects of intercept and slope respectively. The B_2 coefficient yields a cross-sectional (intercept) log odds for class variables and a longitudinal log odds for continuous variables, while longitudinal log odds is captured by the B_3 and B_4 coefficients. An "unstructured" Cholesky parameterization of the covariance structure (TYPE = CHOL) related to random effect components of the model was used to allow an unstructured, positive definite variance covariance matrix to be established.

Independent variable or interaction terms that exhibit a significant log odds coefficient at the two-tailed, $p < 0.15$ level were retained. Main effect terms were not retained if the interaction term was significant. Multicollinearity between independent variables retained in this step was analyzed using appropriate statistical techniques.

Independent variables that were collinear were either combined in a composite metric (e.g. – in the case of conceptually related Awareness, Accountability domain variables) or comparatively analyzed for their relative strength in contributing to the overall model fit. Collinear control variables were also comparatively analyzed for their relative strength in contributing to the overall model fit. In total, this step allowed for a screen of those variables suitable for advancing to subsequent multivariable analyses.

Data were reduced further when there were several predictor variables within a particular domain - Awareness or Accountability – that met the bivariate significance criteria. An index of these variables was constructed by summing the independent variables' scores (or alternatively, the mean score if a particular independent variable had a significant amount of missing data) [127, 128]. A bivariate examination of this index score was also analyzed in the same manner as above.

Stage 2. First, a fully saturated multivariate generalized linear mixed model was be constructed using all significant stage 1 fixed effects, control variables, and random effects for intercept and slope. The potential existence of a non-linear model was examined by building a quadratic model utilizing squared time terms. The Wald Type III statistics were used to examine the significance of quadratic terms within a particular model. Multiple covariance patterns were tested within these saturated models to determine the "best" covariance pattern to use in the model. The covariance pattern that "best" reflected the correlation of repeated measures within hospitals were chosen from amongst 4 covariance patterns – unstructured (Cholesky), compound symmetry, toeplitz, and a first-order auto-regressive.

Second, the random effects were examined for significance using a covariance test (COVTEST). Random effects were eliminated from the model based on a Chi-Square test of the differences between models with and without random effects. This test is based on differences in -2 Log Likelihood test statistics. Non-significant results at the

$p > 0.05$ level resulted in the elimination from the model of the random effect being tested.

Third, Type III Wald tests of fixed effects were used to examine the significance of interaction and main effect terms. Non-significant terms were eliminated from the model at the $p > 0.15$ level and any reduced model terms not meeting the $p < 0.05$ level were eliminated from the final model.

Diagnostic tests of model assumptions were conducted using various graphical tools that are built into the GLIMMIX procedure. In general, the GLIMMIX procedure allows for graphical plotting of residuals by linear predictor to check homoscedasticity of the error term. In addition, the assumption of normal distribution of errors can be viewed via histogram, Q-Q, and box plots of the residuals. In particular, outliers as identified by residuals > |3| were examined for data coding accuracy. The impact on model fit of both the removal of outlier cases and/or outlier-associated hospital data were examined in sensitivity analyses.

The unit of analysis is the hospital. All statistical analyses were conducted using SAS software, version 9.2 (SAS, Cary, NC).

Sensitivity - Alternative Analyses

The multinomial nature of the response variable used in this study allows for alternative analyses using different categorizations of the responses. The five category response variable could be reconceptualized into different groupings. For example, the response variable could be condensed into a binomial distributed variable – "non-full" versus "full" implementation - allowing for a generalized linear mixed model to be constructed using the binomial logit link function. Similar sensitivity analyses might entail different categorizations of both dependent and independent variables.

Table 2. PSCL Survey Responder versus Non-Responder

Variable (2005 AHA Survey)	Responding Hospitals - 2007 PSCL Survey (N = 104)	Non - Responding Hospitals (N = 13)	p - value
Total Hospital Beds (HOSPBD)	91	108	0.852
General Medical and Surgical Beds (GENBD)	43.9	54.0	0.461
Medical/Surgical ICU Beds (MSICBD)	4.4	3.9	0.947
Total Facility Admissions per Year (ADMTOT)	3148	2946	0.640
Emergency Department Visits per Year (VEM)	9631	9707	0.972
Average Daily Census (ADC)	54.3	59.2	0.820
Full-time Equivalent Total Personnel (FTE)	481	436	0.259
Full-time Registered Nurses (FTRNTF)	86	75	0.509
Rural Hospitals (% CAH/Rural PPS)	77.9%	69.2%	0.494
Hospital Type (% State/ County/City)	51.5%	46.2%	0.719
Member of Health System (% Yes)	51.9%	61.5%	0.513
JCAHO Accredited (% Yes)	26.2%	23.1%	1.000
Hospital Self-assesses against Baldrige-like Criteria (% Yes)	60.2%	33.3%	0.075
Hospital Maintains Separate Nursing-home Type of Long-term Care Unit (% Yes)	34.0%	30.8%	1.000

Note: Tests utilized Mann-Whitney U and Chi-Square.

AHA = American Hospital Association, PPS = Prospective Payment System, JCAHO = Joint Commission on Accreditation of Healthcare Organizations.

Table 3. Medication Reconciliation Response Categories

Base Response Category	Recategorized Response
No Adoption (0) – Hospital not in campaign and/or measure	None (0) – No implementation
No activity (1) – There has been no activity to implement this intervention in the hospital.	
Discussion Only (2) – Intervention has been discussed for possible implementation, but has not yet been implemented.	
Incomplete (3) – Implementation has begun, but not all elements of the intervention are in place.	Partial (1) – Partial implementation
Selective (4) – Intervention has been fully implemented within some units/departments, but has not been implemented hospital-wide.	
Hospital-wide (5) – The intervention has been fully implemented throughout the hospital.	Full (2) – Full implementation

Table 4. Board Time - Descriptive Statistics

Board Time Spent on Quality / Safety Issues	Frequency	Percent	Categorical Group
missing	1	0.97	missing
0%	0	0	“Low”
1 - 10%	51	50.49	“Low”
11 - 25%	30	28.16	“Medium”
26 - 50%	18	17.48	“High”
> 50%	3	2.91	“High”

Table 5. Frequency of Report - Descriptive Statistics

Frequency Board Receives a Formal Quality / Safety Report per Year	Frequency	Percent	Categorical Group
missing	3	2.91	missing
Board Did Not Receive a Report	3	2.91	"Low"
Annually	5	4.85	"Low"
Twice per Year	4	3.88	"Low"
Quarterly	44	42.72	"Medium"
Every Other Month	8	7.77	"High"
Monthly	36	34.95	"High"

Table 6. Board Interaction - Descriptive Statistics

Extent of Board Interaction with Medical Staff to Establish Quality / Safety Strategy	Frequency	Percent	Categorical Group
missing	1	0.97	missing
Board Not Involved in Setting Strategy	16	15.53	"Low"
No Interaction	16	15.53	"Low"
Somewhat	58	56.31	"Medium"
A Great Amount	12	11.65	"High"

Table 7. Executive Compensation - Descriptive Statistics

Senior Executive Compensation Tied to Quality / Safety Performance	Frequency	Percent	Categorical Group
missing	7	6.8	missing
None	48	46.6	"Low"
Merit/Bonus/Incentive	35	33.98	"Medium"
Base Only	8	7.77	"High"
Base and Merit/Bonus/Incentive	5	4.85	"High"

Table 8. Physician Engagement - Descriptive Statistics

Extent of Physician Engagement in Quality / Safety Efforts	Frequency	Percent	Categorical Group
missing	2	1.94	missing
Not At All	0	0.00	"Low"
Some Extent	32	31.07	"Low"
Moderate Extent	48	46.6	"Medium"
Great Extent	21	20.39	"High"

Table 9. Net Profit Margin (Previous 3-Year) - Descriptive Statistics

	2006		2007		2008		2009	
	Mean (%)	Std Dev (%)	Mean (%)	Std Dev (%)	Mean (%)	Std Dev (%)	Mean (%)	Std Dev (%)
Net Profit Margin (Previous 3-Year)	4.5	3.7	4.78	3.8	5.57	4.2	5.07	4.2

Table 10. Control Variables - Descriptive Statistics

	2006		2007		2008		2009	
	Freq	Percent	Freq	Percent	Freq	Percent	Freq	Percent
Joint Commission on Accreditation of Healthcare Organizations (JCAHO)								
No	68	66.02	76	73.79	73	70.87	73	70.87
Yes	35	33.98	27	26.21	30	29.13	30	29.13
Critical Access Hospital (CAH) Status								
No	30	29.13	30	29.13	30	29.13	30	29.13
Yes	73	70.87	73	70.87	73	70.87	73	70.87
System Membership								
No	49	47.57	49	47.57	49	47.57	49	47.57
Yes	54	52.43	54	52.43	54	52.43	54	52.43
	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev
Hospital Size (Acute Beds)								
	71.27	110.94	72.12	111.44	72.01	113.23	70.87	111.16

CHAPTER IV. RESULTS

The overall statistical approach focused on identifying those awareness, accountability, and ability organizational characteristics that exhibit a relationship with the outcome of interest both cross-sectionally and over time. The approach utilized a relatively new generalized linear mixed model (GLMM) statistical technique on multinomial data. The SAS PROC GLIMMIX procedure used to model the data in this study fits statistical models to data with correlations, skewed data over time, nonconstant variability, and where the response variable is not necessarily normally distributed. Given the unique limitations of this particular statistical technique and procedure, coupled with a dataset comprised of a limited number of units of analysis and repeated measures, the utilization of a "staged" analytical approach was highly warranted. The SAS PROC GLIMMIX procedure exhibited limitations when working with multinomial response data. However, the analytical features available in the PROC GLIMMIX technique when working with binomial responses are not as limited. Therefore, both a multinomial and a binomial model were used to analyze the data. The results from both the multinomial and binomial GLMMs are presented. Limitations associated with the multinomial model are presented in the results.

Multinomial Model

Stage 1 Bivariate Cross-sectional and Longitudinal Model Building Results

Within stage 1, a bivariate GLMM model was progressively built and analyzed through a series of model-building stages for each variable of interest in an effort to construct a best model suitable for handling the unique characteristics of the data for which these models were designed. In general, the results of the preliminary model-

building stages for the bivariate analyses were quite similar; these results are briefly reviewed in the following paragraph.

The first step in the model-building process consisted of building a quadratic model in an effort to test the fit of a non-linear quadratic model as opposed to a linear model. These models incorporated the use of a time-squared main effect and interaction term. Very few of the quadratic models analyzed converged. Therefore, no solution was computed for these models. For those models that did converge on a solution none of the quadratic terms were significant at the $p < 0.15$ level using the Wald Type III statistic. Thus, all subsequent models were built as linear models.

The second step in the process tested the significance of each of the random effects – intercept and slope. None of the models converged with the random slope term incorporated in the model. Covariance parameter tests showed that the random intercept term was highly significant in all models at $p < 0.0001$. Thus, all subsequent models were built as generalized linear mixed models (GLMMs) that incorporated a hospital-specific random intercept.

Next, a series of covariance structure matrices – Cholesky, toeplitz, compound symmetry, first-order autoregressive, and heterogeneous autoregressive – were tested to identify a best covariance structure for repeated measures. The results of these tests showed that overall, the unstructured Cholesky covariance structure resulted in the construction of a positive definite structure that was no different in the lack of fit from all other covariance structures. Many of the other covariance structures, most notably the simpler compound symmetry and the first-order autoregressive structures, did not result in the establishment of a positive definite covariance structure. Because the Cholesky covariance structure established a positive definite structure, it was no different in the lack of fit as compared to other nested covariance structures, and SAS and other researchers recommend the use of the Cholesky parameterization as compared to other unstructured parameterizations, the Cholesky covariance structure was used in all models.

Finally, bivariate analyses were computed using the GLMM models as delineated above. The Wald Type III fixed effect results for each GLMM model are shown collectively within Table 11.

Several of the independent variables of interest and control variables were significant within their respective GLMM model. Instead of displaying the solution of fixed effects, which show the resultant regression parameters and need some interpretation in regards to the strength and direction of a variable's effect on the response variable, odds ratios were computed to facilitate this interpretation.

A simple logistic regression model was built to further assess cross-sectional effects at Quarter 1 in terms of the odds of "full" or "partial" medication reconciliation implementation. The results suggest that increased levels of time the board spends on quality/safety in board meetings is related to increased levels of medication reconciliation implementation near the conclusion of the 100K Lives campaign. In particular, Table 12 shows that the odds of reaching "full" medication reconciliation implementation were significantly greater for those hospitals that spent >=26% of their board meeting time on quality and safety compared to those that spent 0-10%. Also, the "medium" board time group shows greater odds of reaching "full" medication reconciliation near the end of 100K Lives campaign as compared to the "low" board time group.

The results show a significant interaction between the board time spent on quality and safety reports and time. A review of the odds ratio results from the GLMM analysis shown in Table 13 suggests that the odds of "full" implementation increased over time (on average with a 1 unit difference in time – comparing Quarter 8.5 to Quarter 7.5) for all groups. The odds ratio estimates suggest that both the "high" and "low" board time groups had better odds of reaching "full" medication reconciliation implementation over time. However, an inspection of the model's fixed effects solution found that the "low" Board Time group was significantly higher than the "medium" Board Time group within the "full" medication reconciliation response category ($p = 0.0008$).

The cross-sectional Quarter 1 results suggest that the frequency with which the board receives a formal quality and safety report is not related with increased odds of "full" or "partial" medication reconciliation implementation as shown in Table 14.

The results for the longitudinal analysis of the Frequency to Report require a little more interpretation in order to tease apart the underlying relationship. The GLMM model results from Table 11 above suggest that the interaction term of Frequency of Report interaction with Quarter (time) is a significant term within the model. Further inspection of the results in Table 15 show that all the response categories within this variable exhibit increased odds of "full" and "partial" implementation over time. The longitudinal comparison that is significant is between the "high" and "medium" frequency of report groups ($p = 0.0295$). The difference between these two groups was determined by running the model with recoded formatting for the response categories (formatting the "high" response category group as the reference group) and reviewing the solution for fixed effects. Contrary to the hypothesized expectation the "medium" frequency of report group was identified as having significantly higher odds of "full" implementation as compared to the "high" group.

In general however, the odds of "full" and "partial" implementation increase over time within all response categories, with the "medium" frequency of report group exhibiting slightly higher longitudinal average odds as compared to the other two frequency of report groups.

The results show that the Board Interaction main effect term met the inclusion criteria ($p < 0.15$) for advancement to a multivariate model (p-value = 0.0796). However, a closer inspection of the solution of fixed effects was needed to determine that there exists a significant difference in implementation odds between two of the groups within the Board Interaction variable. Boards that interact with the medical staff at a "high" amount were related to greater odds of "full" implementation than boards that interact

with medical staff at a "low" amount. The odds associated with this comparison are shown in Table 16.

The longitudinal results for the Board Interaction term also reached a significance level to allow advancement to a multivariate model ($p = 0.0782$). On average, all of the Board Interaction groups show significantly increased odds of both the "full" and "partial" medication reconciliation response categories over time as shown in Table 17. And, the fixed effects, along with an inspection of the odds ratios between Board Interaction categories, suggest that there was not a significant difference in the odds of "full" or "partial" implementation between any combination of the Board Interaction groups.

The Executive Compensation intercept term was not significant within the model. The odds ratio results from a simple logistic model are shown in Table 18. Thus, base pay as a component of executive compensation, nor a merit/bonus/incentive component of compensation, was related to higher levels of medication reconciliation implementation near the end of the 100K Lives Campaign.

The longitudinal results suggest that the Executive Compensation interaction term was not a significant term within the model. An inspection of the odd ratios shown in Table 19 show that all of the Executive Compensation groups are significantly related to both "full" and "partial" implementation over time. However, the solution of fixed effects, and an inspection of the odds ratios in Table 19, show that there are no significant differences in the odds of "full" or "partial" implementation between groups within the Executive Compensation variable. Thus, base pay as a component of executive compensation, nor a merit/bonus/incentive component of compensation, was related to higher levels of medication reconciliation implementation over time.

The Physician Engagement term is not related to "full" or "partial" implementation at quarter one. The cross-sectional odds ratio results for this term are shown in Table 20. Thus, the results suggest that increased levels of physician

engagement in quality and safety improvement efforts were not related to increased levels of medication reconciliation near the end of the 100K Lives Campaign.

The results suggest that physician engagement was related to higher levels of medication reconciliation implementation over time. The results in Table 21 show that all Physician Engagement groups were related to higher odds of implementation within both the "full" and "partial" implementation response categories. A review of the model's solution for fixed effects shows that the "medium" physician engagement group is significantly lower than the "low" group ($p = 0.0336$) in terms of reaching "full" implementation – contrary to hypothesized expectations. Similarly, the "low" physician engagement group had higher point estimates of the odds of "full" implementation compared to the "high" group, but this difference in odds ratios was not significant ($p = 0.0815$). An inspection of the odds ratio estimates mirror these relationships as the "low" group has an odds ratio of 3.35 compared to 2.42 and 2.44 in the "medium" and "high" groups respectively. There were no statistically significant differences between Physician Engagement groups within the "partial" medication reconciliation response category. Thus, we conclude that physician engagement was related to medication reconciliation over time, but in a direction opposite to the one hypothesized within the "full" response category. This direction reverses in the "partial" implementation response category, but the strength of the physician engagement effect is not significant.

The results suggest that there was not a significant relationship between 3-year rolling net profit levels and higher levels of medication reconciliation implementation near the conclusion of the 100K Lives campaign. The cross-sectional odds ratios are shown in Table 22.

However, the longitudinal results are different. A review of the odds ratios in Table 23 show that net profit was related to higher levels of implementation over time for both the "full" and "partial" response categories.

As shown previously in Table 11 the control variable interaction terms JCAHO accreditation and system membership interaction were not longitudinally significant. However, CAH membership, system membership, and hospital size interactions with time met the significance criteria ($p < 0.15$) for advancement into multivariate analyses. The bivariate odds ratios for the control variables at Quarter 1 are shown in Table 24 below. JCAHO accreditation, non-CAH, and larger-sized hospitals as measured by the number of acute beds are related to higher odds of "full" medication reconciliation. Hospital size was related to "partial" implementation, but rather marginally.

In total there were several variables that met the significance criteria (set at $p < 0.15$ in Stage 1) to move on to the next stage of analyses. Significant variables were tested for multicollinearity to determine if multiple variables should be collapsed into a composite variable, and tested for significance, before moving on to subsequent stages of analyses.

Stage 2 Multivariate Analyses

Multicollinearity Analyses and Creation of Composite Domain Variables

Simple chi-square tests within the Awareness and Accountability domains showed significant collinearity between the independent variables of interest. Within the Awareness domain the variables Board Time Spent on Quality/Safety and Frequency of Board Report were significantly associated ($p < 0.0001$). Similarly, the variables with the Accountability domain Board Interaction with Medical Staff and Physician Engagement were significantly associated ($p < 0.0001$). The variables within each domain were combined into a composite score by summing the scores of each variable for only those hospitals that had non-missing scores for each independent variable within the domain. This step allowed the creation of two composite variables for the Awareness and Accountability conceptual domains.

There was also significant collinearity within most of the control variables, but not all variables were collinear. Only the System Membership / CAH and System Membership / Hospital Size (acute bed) pairings were not collinear. The JCAHO variable exhibited significant association with the CAH, Hospital Size, and System Membership variables. Given that the bivariate analyses showed that the interaction between system membership and time was significantly related to increased odds of medication reconciliation implementation this interaction term was advanced to the next stage of analyses. Also, although several of the control variables were cross-sectionally significant only the JCAHO variable was advanced to subsequent stages as it was highly correlated with other control variables related to hospital size, and hospital engagement with accreditation activities is a much more "actionable" option for leadership in terms of addressing quality and safety issues.

In addition, the cross-sectionally significant Net Profit variable was converted from a continuous variable into a nominal variable composed of three equally-sized categories - "high", "medium", and "low" net profit categories. This was accomplished by establishing tertiary cutoff points within the distribution using a Microsoft Excel percentile function. Conceptually, this singular variable serves as the Ability conceptualization as denoted in the conceptual framework model. This 3-category arrangement also facilitated the construction of a super-composite variable composed of the non-missing hospital-level sum of the Awareness, Accountability, and Ability domains. The sum among the three domains ranged from 0 – 6, thus this composite variable was also recategorized into a 3-category nominal variable. Scores of 0 and 1 were recategorized as "low" (0), scores 2-4 were categorized as "medium" (1), and scores of 5 and 6 were categorized as "high" (2) within the Aware/Accountability/Ability (AAA) composite variable. This composite variable was used in subsequent stages of analyses to test the additive effects of hospital board/leadership awareness, accountability, and ability characteristics.

The composite variables for the Awareness, Accountability, Ability domains, along with the Aware/Accountability/ Ability variable, were tested in bivariate analyses using the same methods used in the individual independent and control variable analyses. The results of bivariate analyses involving composite variables are shown in Table 25.

The Awareness main effect along with the Accountability*Quarter, and Ability*Quarter interaction terms were retained for input into a multivariate model in subsequent stage 2 analyses. None of the terms from the bivariate analysis of the Awareness/Accountability/Ability composite variable reached a level of significance to meet the criteria for inclusion in subsequent multivariate models. Thus, the results suggest that there is not an additive effect of leadership awareness, accountability, and ability upon hospitals' medication reconciliation implementation – either cross-sectionally or over time.

Multivariate Results

Similar to the results found in stage 1 model building the tests for differences of fit between the Topelitz, Compound Symmetry, Auto-regressive, and Auto-regressive Heterogeneous were no better than the Cholesky covariance structure. Thus, the Cholesky covariance structure was used in multivariate models. Models built with time-squared quadratic effects did not converge on a solution. Thus, a linear model solution was used to analyze the study data. The tests for the significance of a random intercept were significant, thus the random intercept effect was retained in multivariate models.

The initial multivariate model included all the significant variables identified in stage 1 bivariate models. The fixed effect solution results for this multivariate model are shown in Table 26. The results show that the JCAHO accreditation main effect was significant. And, the Accountability, Ability, and hospital size interaction terms with time were significant.

A reduced multivariate model was constructed by eliminating the non-significant terms from the fully saturated multivariate model – the Awareness main effect and the System Membership*Quarter interaction terms. The fixed effect solution for the final reduced model is shown in Table 27.

The solutions for fixed effects and the associated odds ratios for this solution are shown in Tables 28 and 29 below. The fixed effect solution results suggest that JCAHO accreditation was significantly related to both "full" and "partial" medication reconciliation implementation. In addition, the "medium" group within the Accountability domain was significantly related to "partial" implementation compared to the "low" Accountability group after controlling for JCAHO accreditation and hospital size.

Further review of the between group comparisons within the odds ratio solutions show that on average the "medium" Accountability group was related to a higher odds of "partial" medication reconciliation as compared to the "low" Accountability group (OR = 4.14, 95% CI 1.03 – 16.66). On average over time (Quarter 8.5 compared to Quarter 7.5), the results show that all groups within the Accountability and Ability domains were related to higher odds of "full" and "partial" implementation after controlling for JCAHO accreditation and hospital size.

Binomial Model

A binomial model was constructed in order to simplify the interpretation of results, increase the power of the analysis, and to facilitate the examination of model fit via the use of residual diagnostics and fit statistics that are available for this type of model in the SAS PROC GLIMMIX procedure. This binomial model helps address some of the analytical issues encountered with the multinomial model.

In order to facilitate a multivariate cross-sectional analysis, the dependent variable was further collapsed into two mutually-exclusive categories – "full/partial (1)" and "<

partial (0)" medication reconciliation implementation. The "full/partial" categorization includes the "full" and "selective" response categories. Thus, the "full/partial" categorization increases the number of events available for a multivariate cross-sectional analysis. The binomial model construction followed the same staging methods as were used for the multinomial model.

Cross-Sectional Analyses

The cross-sectional analyses assessed the effects of the variables of interest on medication reconciliation implementation outcomes in Quarter 1 – near the conclusion of the IHI 100K Lives Campaign.

Stage 1 - Bivariate Cross-sectional Model

Simple logistic regression models were used to measure bivariate relationships between each independent and control variable with the dependent variable - medication reconciliation implementation. The bivariate results are shown collectively in Table 30.

The results show several variables of interest that met the significance criteria of $p < 0.15$ to move on to subsequent multivariate analyses. Conceptually, within the Awareness domain, only board time spent on quality/safety met the significance criteria to advance to a multivariate model. Within the Accountability domain only the variable board interaction with medical staff met the criteria. The Ability variable – Net Profit Margin – did not meet the criteria. And, the control variables JCAHO accreditation, CAH membership, and Hospital Size met the multivariate inclusion criteria. All of these variables moved on to the next step of analysis within Stage 1.

Several of the control variables exhibit multicollinearity. To address multicollinearity issues, and as part of the data reduction strategy, two saturated multivariate logistic regression models were built and compared to determine which of the two significant control variables – CAH Membership or Hospital Size - would move on to subsequent analyses. Comparison of model fit statistics for the CAH and Hospital

Size models showed Akaike Information Criterion (AIC) values of 130.13 and 131.04 respectively. Because of the lower AIC value the model including CAH Membership is a better fit than a model with Hospital Size. Therefore, CAH membership was included in subsequent multivariate analyses.

Stage 2 - Multivariate Cross-sectional Model

The results of the fully saturated model are shown in Table 31. The results show that the Board Interaction with Medical Staff variable and the CAH Membership variables did not meet the initial inclusion criteria ($p < 0.15$). These variables were removed from the model to create a reduced model.

Residual diagnostics were conducted to identify potential outliers. Per recommended practice, residual outliers with an absolute value greater than 3 were inspected for potential issues [132]. The results for the reduced model showed no residuals that met this criteria.

The final reduced model Type 3 fixed effects solution is shown in Table 32. No other variable was eliminated from this model. The results show that the variable Board Time Spent on Quality/Safety was significantly related to "full/partial" medication implementation near the conclusion of the IHI 100K Lives Campaign while controlling for JCAHO accreditation.

The final model regression parameter estimates are shown in Table 33 and the odds ratio results associated to this model are shown in Table 34.

Overall, the Quarter 1 cross-sectional results suggest that the board time spent on quality/safety issues was positively related to hospitals' "full/partial" medication reconciliation implementation near the conclusion of the 100K Lives Campaign. Within the Board Time variable "medium" levels of time spent on quality/safety issues was related to better odds of "full/partial" implementation compared to "low" levels.

However, the "medium" level of time spent was related to significantly higher odds of "full/partial" implementation compared to the "low" time group.

The cross-sectional results also suggest that a cumulative effect of awareness, accountability, and ability was not related to higher odds of "full/partial" medication reconciliation implementation near the conclusion of the 100K Lives Campaign. Finally, accreditation by the Joint Commission was positively related to "full/partial" implementation.

Cross-sectional Hypotheses Results

Within the Awareness domain, multivariate model results suggest that hypothesis H1a can be confirmed. Higher levels of time the board spent on quality/safety issues were related to higher levels of medication reconciliation near the conclusion of the IHI 100K Lives Campaign. The hypothesis H2a cannot be confirmed – the frequency with which the board receives a formal quality/safety measurement report was not related to higher levels of "partial/full" medication reconciliation near the conclusion of the IHI 100K Lives Campaign.

Within the Accountability domain, the results suggest that hypotheses H3a, H4a, and H5a cannot be confirmed. Although bivariate analyses suggest that boards' interaction with medical staff was the strongest board safe practice within this domain, multivariate analyses could not support the strength of this relationship.

Within the Ability domain, the results suggest that hypothesis H6a related to hospitals' net profit margin was not related to "full/partial" implementation near the conclusion of the IHI 100K Lives Campaign.

Finally, for the composite analysis regarding the cumulative effects of Awareness, Accountability, and Ability the results cannot confirm hypothesis H7a regarding the cumulative effects of these hospital leadership and ability characteristics on "full/partial" implementation near the conclusion of the IHI 100K Lives Campaign.

Longitudinal Analyses

In longitudinal analyses generalized linear mixed models (GLMM) were built using the SAS PROC GLIMMIX techniques. Because the power of these models are increased due to the addition of 14 time periods of measurement, the dependent variable was modeled as a binary variable with "full" medication reconciliation as the event of interest. This facilitates some comparison of binary and multinomial results. However, this contrasts with the cross-sectional model in which both the "full" and "partial" response categories were collapsed into a single category and compared against all lesser categories in a binary model. The model building process followed the same staged approach as used in previous analyses.

Stage 1- Bivariate Longitudinal Model

Individual generalized linear mixed models were used to measure bivariate relationships between each independent and control variable with the dependent variable. The bivariate results for these models are shown collectively in Table 35.

Those variables exhibiting statistical significance at the $p < 0.15$ level were included in subsequent analyses. The main effects of senior executive compensation and JCAHO accreditation were included in subsequent models. Because there were multiple significant variables within the Awareness and Accountability domains the data were reduced further by creating composite scores of these variables. This was accomplished by creating a sum score and categorizing the scores. The board time and frequency of report interaction variables were combined into a 3-category ("high", "medium", "low") Awareness interaction composite variable. The board interaction and physician engagement interaction variables were collapsed into a 3-category ("high", "medium", "low") Accountability composite variable. Because the net profit margin interaction term met the significance criteria this term was included in subsequent models and represented the "Ability" concept. Because there were significant interaction terms in all

three conceptual domains, a super composite variable – consisting of a sum of the Awareness, Accountability, and Ability composite scores – was created to test the hypothesis related to the cumulative effects of these characteristics on "full" medication reconciliation implementation. The Ability variable – represented by net profit margin – was converted from a continuous variable to a 3-category variable to facilitate the creation of the super-composite Awareness/Accountability/Ability variable. Finally, the control group interaction terms for CAH status, system membership, and hospital size were advanced to subsequent multivariate models.

Each of the composite variables was tested for evidence of a curvilinear relationship with the dependent variable. None of these tests showed the existence of a quadratic effect. In addition, models were tested to see if a random slope (time) was a significant term in the model. None of the models converged on a solution using a random slope term. However, all models with random intercept terms converged and the term was significant in all models ($p < 0.0001$). Thus, GLMMs using a random intercept term were used in subsequent analyses. In addition, the Cholesky parameterization was used in all models.

The composite variable bivariate relationships were tested to examine their interaction and main effect significance levels. This was used to determine if individual composite scores would be advanced to subsequent model-building stages. The composite score results shown in Table 36 below show that the Awareness main effect and the Accountability and Ability interactions with time were significant. These composite variables were retained for entry into a multivariate model.

Stage 2 – Multivariate Longitudinal Model

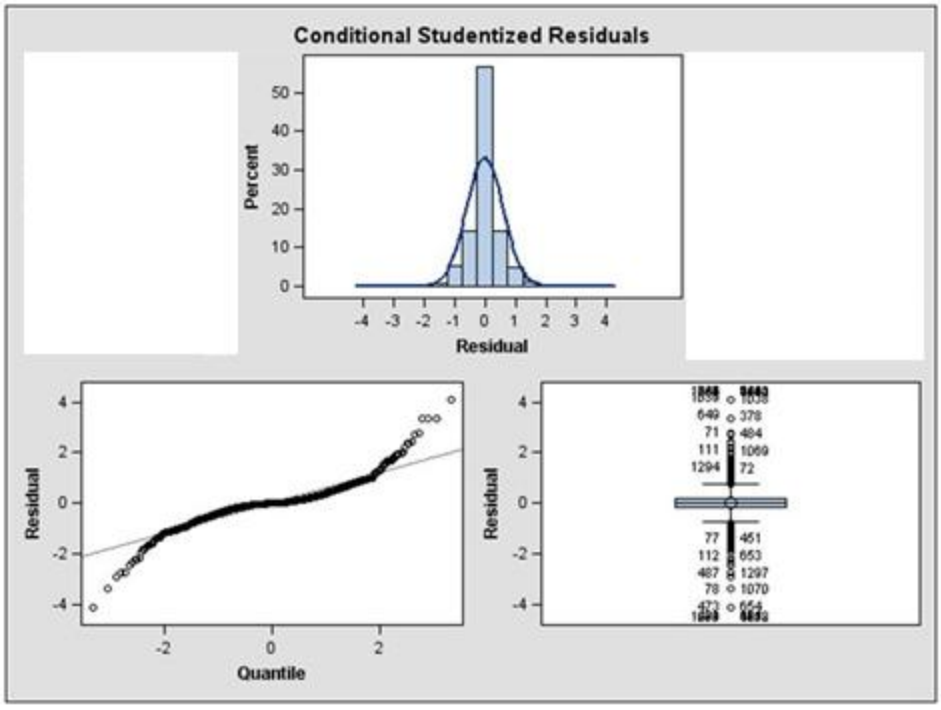
All significant variables from bivariate GLMM analyses were entered into a multivariate longitudinal model. The results from an initial multivariate model are shown in Table 37**.** The main effects of JCAHO accreditation and senior executive

compensation did not meet the inclusion criteria of $p < 0.15$ to advance to subsequent models. The Awareness main effect was retained. The interaction terms for system membership and hospital size also did not meet the inclusion criteria so these terms were not retained in subsequent models.

The results of a reduced longitudinal multivariate model are shown in Table 38. The Awareness main effect and interaction terms for Accountability, Ability, and CAH status were significant effects in a reduced model.

The SAS PROC GLIMMIX procedure does allow for residual diagnostics to be conducted in binomial models. Therefore, a residual analysis was conducted on reduced binomial model results. A student standardized residual panel is shown in Figure 3.

Figure 3. Binomial Model - Residual Diagnostic Panel



An examination of the residual diagnostic output found that, in general, the residuals were normally distributed near the middle of the distribution, but exhibited some divergence near the tails of the distribution. There were 6 outlier cases (> |3|) that were examined in more detail. The results show that these 6 outlier cases were related to three hospitals. An examination of the raw data related to these outlier cases did not expose data entry errors, rather their outlier status was likely due to changing medication reconciliation scores near the time periods associated with the outlier cases. These cases were likely related to hospitals changing their implementation scores from "non-full" to "full" near the outlier case in question, or had changed their scores several times over the course of the measurement period. One hospital had changed their implementation score from "full" to "non-full" over time.

Several additional sensitivity analyses were conducted to analyze the effect of using a difference variance structure, removal of outlier cases, and removal of outlier hospitals on model fit. First, a different variance function was used within the SAS Proc GLIMMIX model that entails removing the binomial distribution link function and the intercept random effect, then substituting an automatic variance function that considers the distribution of the data as unknown [133]. The results of this model showed a worse fit with exacerbated residual issues. One model examined the impact in model solutions associated to the removal of the 6 outlier cases (removal of 6 cases with residuals > |3|). An additional model examined the impact associated to the removal of the three hospitals containing outlier residuals.

The removal of individual outliers did not result in a model that was free from outlier cases or exhibit a better fit. Fit statistics indicate a slightly better fit in the original model as the reduced model with removed residual cases had a slightly lower generalized Chi-Square/df statistic (0.39 vs. 0.36). The removal of hospitals associated to outlier cases resulted in a model that was similar in regards to the residual panel plot, but the model fit statistics were even lower than the original model (0.39 vs. 0.31). Therefore,

because the original data associated to the 6 outlier cases were verified as accurate data and subsequent models did not seem to improve model fit the original model's solution was retained.

Table 39 shows the fixed effect solutions for the final multivariate model and the odds ratio results for this model are shown in Table 40.

An inspection of the odds ratios yields more evaluable information regarding where signification associations with "full" medication reconciliation implementation exist. The Awareness main effect term in this model represents an adjustment to the population intercept term at Quarter 1. A review of the results for the Awareness main effect suggests that the odds of "full" implementation was significantly higher in the "high" and "medium" board awareness groups compared to the "low" board awareness group in Quarter 1. Additional analyses conducted with the "medium" group set up as the comparison group found that the odds of "full" implementation for the "high" board awareness group compared to the "medium" board awareness group were not significantly different.

A review of the interaction term odds ratio results show that all groups' odds of "full" implementation were significantly improving over time. The odds ratio table shows the average cross-sectional odds, represented at a mid-point in time at Quarter equal to 7.5. Between group differences are obtained by reviewing the fixed effects results above. Within the Accountability domain, the "low" group's odds of "full" implementation (1.991, 95% CI 1.751-2.264) were significantly higher than the odds of "full" implementation for the "high" group (1.376, 95% CI 1.236-1.533). Similarly, additional analyses conducted with the "medium" group set up as the comparison group found that the "medium" group's odds of "full" implementation (1.958, 95% CI 1.71-2.241) were significantly higher than the "high" group's odds. However, the "low" and "medium" groups' odds were not significantly different. Within the Ability domain, both the "high" and "medium" groups' odds of "full" implementation were significantly

higher than the "low" group's odds. However, the "high" and "medium" groups were not significantly different. These results are controlled by CAH status. The results suggest that the CAH hospital status had significantly lower odds of "full" implementation (1.398, 95% CI 1.309 – 1.493) compared to the non-CAH hospitals (2.192, 95% CI 1.846 – 2.603) over time.

Longitudinal Hypotheses Results

Within the Awareness domain, the stage 1 bivariate analyses suggest that both the board time spent on quality/safety issues and the frequency of the board's receipt of a formal quality/safety report were significantly related to "full" medication reconciliation over time. However, when these two variables were combined in a composite Awareness domain variable and entered into the stage 2 multivariate analyses board awareness was not related to "full" implementation over time. The Awareness composite variable main effect was a significant intercept term in the longitudinal model reconfirming the results found in previous cross-sectional analyses regarding the statistically significant relationship between board time spent on quality/safety issues and "full" implementation near the conclusion of the 100K Lives Campaign. Therefore, multivariate analyses do not support hypotheses H1b and H2b.

Within the Accountability domain, the bivariate stage 1 analyses suggest that senior executive compensation tied to quality/safety performance was not related to "full" medication reconciliation implementation over time. Thus, there is no support for hypothesis H4b. In contrast, the stage 1 bivariate results suggest that board interaction with medical staff and physician engagement characteristics are significantly related to "full" implementation over time. When these two variables were combined into a composite Accountability domain variable the results again found a significant relationship between board and physician engagement accountability characteristics and "full" implementation over time. However, an inspection of the differences between

groups within the Accountability variables found that the "low" and "medium" groups were increasing their probability of "full" implementation at a faster rate in comparison to the "high" group. Thus, there is no support for hypotheses H3b and H5b.

Within the Ability domain, hospitals' net profit margin was related to "full" medication reconciliation implementation over time. Furthermore, both the "high" and "medium" net profit margin groups exhibit increasing levels of "full" implementation over time as compared to the "low" net profit margin group. Thus, the results support hypothesis H6b.

The results also suggest that a cumulative effect of awareness, accountability, and ability characteristics was not related to "full" medication reconciliation implementation over time. Therefore, there is no support for hypothesis H7b.

Sensitivity Analyses – Missing Data

Although there were no missing data for the dependent variable or control variables used in this study, several of the independent variables of interest in this study were missing data. The independent variables Board Time Spent on Quality/Safety Issues, Frequency of Board Report, Board Interaction with Medical Staff, Senior Executive Compensation, and Physician Engagement had some level of missing data; however, the extent of missing data was limited for most of these variables. Sensitivity analyses were conducted to examine the potential impact of changing missing data to non-missing data on modeling decisions. To accomplish this task a "single imputation" approach was used in two different ways [128]. First, all missing data values within a variable were recoded from missing to the highest possible value. Second, missing data within a variable were recoded from missing to the lowest possible value. Bivariate statistics were regenerated and examined for their potential impact on modeling decisions.

In the cross-sectional binomial model the significance level for the variable Board Interaction with Medical Staff changed from $p = 0.1228$ to $p = 0.1592$ when missing data were recoded with the lowest possible value. This change would have resulted in excluding this variable from a subsequent multivariable model. Because this variable was excluded from a subsequent multivariate model because it did not meet the significance criteria for inclusion, the impact of the recoding change would have had no effect on results. For all other variables, changes to missing values had no impact on modeling decisions.

In the longitudinal binomial model none of the changes to missing values would have resulted in a modeling decision change.

Table 11. Multinomial Bivariate Models - Fixed Effects Test Results

Type III Tests of Fixed Effects				
Effect	Num df	Den dF	F Value	Pr > F
Time Spent in Board Meetings on Quality/Safety				
BoardTime	4	174.4	3.73	0.0062
Quarter	2	1416	94.05	< 0.0001
BoardTime*Quarter	4	1416	8.22	< 0.0001
Frequency of Board Receipt of Formal Quality/Safety Report				
Freq Report	4	132.5	2.03	0.0935
Quarter	2	1388	100.35	< 0.0001
FreqReport*Quarter	4	1388	3.38	0.0092
Board Interaction with Medical Staff to Establish Quality/Safety Strategy				
BoardInteract	4	173.8	2.13	0.0796
Quarter	2	1416	57.73	< 0.0001
BoardInteract*Quarter	4	1416	2.1	0.0782
Senior Executive Compensation Tied to Quality/Safety				
Sen Ex Comp	4	135.2	1.68	0.1578
Quarter	2	1332	89.3	< 0.0001
Sen Ex Comp*Quarter	4	1332	1.12	0.3459
Extent of Physician Engagement with Quality				
Phys Engage	4	122.4	2.18	0.075
Quarter	2	1402	108.5	< 0.0001
Phys Engage*Quarter	4	1402	5.44	0.0002
Financial Resources				
Net Profit	2	1434	0.28	0.7579
Quarter	2	1434	41.52	< 0.0001
Net Profit*Quarter	2	1434	4.4	0.0125
Joint Commission on Accreditation of Healthcare Organizations (JCAHO)				
JCAHO	2	1434	2.99	0.0506
Quarter	2	1434	64.21	< 0.0001
JCAHO*Quarter	2	1434	0.99	0.3709
Critical Access Hospital (CAH)				
CAH	2	209.4	2.71	0.0688
Quarter	2	1434	73.58	< 0.0001
CAH*Quarter	2	1434	5.86	0.0029

Table 11. Continued

System Membership				
System Member	2	147.2	2.15	0.1203
Quarter	2	1434	132.14	< 0.0001
System Member*Quarter	2	1434	2.02	0.1332
Hospital Size – Bed Size				
Size (Categorical Bed Size_)	4	537	1.85	0.118
Quarter	2	1430	50.62	< 0.0001
Size*Quarter	4	1430	2.42	0.0463

Table 12. Board Time - Quarter 1 Odds Ratios

Med Rec Implem	Board Time Spent on Quality/Safety Comparisons	OR	95% C I	
Full	High >=26% vs Med 11-25%	1.54	0.36	6.60
Partial	High >=26% vs Med 11-25%	1.56	0.33	7.36
Full	High >=26% vs Low 0-10%	10.00	2.41	41.58
Partial	High >=26% vs Low 0-10%	3.06	0.78	12.09
Full	Med 11-25% vs Low 0-10%	6.50	1.94	21.77
Partial	Med 11-25% vs Low 0-10%	1.97	0.63	6.12

Table 13. Board Time - Longitudinal Odds Ratios

Odds Ratio Estimates					
Med Rec Implem	Board Time	Qtr Comparison	OR	DF	95% C I
Full	High >=26%	8.5 - 7.5	3.07	1416	2.2 - 4.286
Partial	High >=26%	8.5 – 7.5	1.81	1416	1.35 - 2.42
Full	Med 11-25%	8.5 – 7.5	1.86	1416	1.55 - 2.24
Partial	Med 11-25%	8.5 – 7.5	1.65	1416	1.38 - 1.97
Full	Low 0-10%	8.5 – 7.5	2.83	1416	2.41 - 3.31
Partial	Low 0-10%	8.5 – 7.5	1.79	1416	1.57 - 2.04

Table 14. Frequency of Report - Quarter 1 Odds Ratios

Med Rec Implem	Frequency of Report Comparisons	OR	95% C I	
Full	High >=Bimonthly vs Med Quarterly	2.24	0.79	6.39
Partial	High >=Bimonthly vs Med Quarterly	0.53	0.19	1.52
Full	High >=Bimonthly vs Low No Report - <Quarterly	3.56	0.63	20.16
Partial	High >=Bimonthly vs Low No Report - <Quarterly	0.84	0.19	3.80
Full	Med Quarterly vs Low No Report - <Quarterly	1.59	0.26	9.54
Partial	Med Quarterly vs Low No Report - <Quarterly	1.59	0.38	6.63

Table 15. Frequency of Report - Longitudinal Odds Ratios

Odds Ratio Estimates					
Med Rec Implem	Freq Report	Qtr Comparison	OR	DF	95% C I
Full	High - >=Bimonthly	8.5 - 7.5	2.08	1388	1.77 - 2.44
Partial	High - >=Bimonthly	8.5 - 7.5	1.75	1388	1.50 - 2.03
Full	Med - Quarterly	8.5 - 7.5	2.70	1388	2.28 - 3.20
Partial	Med - Quarterly	8.5 - 7.5	1.75	1388	1.51 - 2.03
Full	Low - No Report - <Quarterly	8.5 - 7.5	2.18	1388	1.66 - 2.85
Partial	Low - No Report - <Quarterly	8.5 - 7.5	1.68	1388	1.30 - 2.12

Table 16. Board Interaction - Quarter 1 Odds Ratios

Med Rec Implem	Board Interaction with Medical Staff Comparisons	OR	95% C I	
Full	High Great Amount vs Med Somewhat	2.75	0.61	12.29
Partial	High Great Amount vs Med Somewhat	0.64	0.10	4.21
Full	High Great Amount vs Low Not at All	6.61	1.28	34.14
Partial	High Great Amount vs Low Not at All	1.26	0.18	8.97
Full	Med Somewhat vs Low Not at All	2.41	0.78	7.48
Partial	Med Somewhat vs Low Not at All	1.98	0.72	5.47

Table 17. Board Interaction - Longitudinal Odds Ratios

Odds Ratio Estimates					
Med Rec Implem	Board Interact	Qtr Comparison	OR	DF	95% C I
Full	High Great Amount	8.5 - 7.5	2.72	1416	1.62 - 4.58
Partial	High Great Amount	8.5 - 7.5	2.41	1416	1.44 - 4.03
Full	Med Somewhat	8.5 - 7.5	2.29	1416	2.00 - 2.63
Partial	Med Somewhat	8.5 - 7.5	1.62	1416	1.44 - 1.84
Full	Low Not at All	8.5 - 7.5	2.52	1416	2.09 - 3.03
Partial	Low Not at All	8.5 - 7.5	1.82	1416	1.55 - 2.14

Table 18. Executive Compensation - Quarter 1 Odds Ratios

Med Rec Implem	Executive Compensation Structure Comparisons	OR	95% C I	
Full	High Base or Base&Merit/Bonus/Incent vs Med Merit/Bonus/Incent	0.31	0.05	1.94
Partial	High Base or Base&Merit/Bonus/Incent vs Med Merit/Bonus/Incent	1.32	0.31	5.70
Full	High Base or Base&Merit/Bonus/Incent vs Low None	0.80	0.13	4.80
Partial	High Base or Base&Merit/Bonus/Incent vs Low None	1.76	0.45	6.83
Full	Med Merit/Bonus/Incent vs Low None	2.55	0.87	7.43
Partial	Med Merit/Bonus/Incent vs Low None	1.33	0.45	3.92

Table 19. Executive Compensation - Longitudinal Odds Ratios

Odds Ratio Estimates					
Med Rec Implem	Executive Compensation	Qtr Comparison	OR	DF	95% C I
Full	High - Base or Base&Merit/Bonus/Incent	8.5 - 7.5	2.70	1332	1.96 - 3.73
Partial	High - Base or Base&Merit/Bonus/Incent	8.5 - 7.5	1.67	1332	1.267 - 2.21
Full	Med - Merit/Bonus/Incent	8.5 - 7.5	2.34	1332	1.91 - 2.88
Partial	Med - Merit/Bonus/Incent	8.5 - 7.5	1.71	1332	1.42 - 2.06
Full	Low - None	8.5 - 7.5	2.30	1332	2.00 - 2.65
Partial	Low - None	8.5 - 7.5	1.77	1332	1.56 - 2.01

Table 20. Physician Engagement - Quarter 1 Odds Ratios

Med Rec Implem	Physician Engagement Comparisons	OR	95% C I	
Full	High Great Extent vs Med Moderate Extent	0.59	0.16	2.18
Partial	High Great Extent vs Med Moderate Extent	1.07	0.32	3.57
Full	High Great Extent vs Low Some Extent	1.17	0.29	4.79
Partial	High Great Extent vs Low Some Extent	1.67	0.46	6.01
Full	Med Moderate Extent vs Low Some Extent	1.99	0.67	5.96
Partial	Med Moderate Extent vs Low Some Extent	1.56	0.53	4.63

Table 21. Physician Engagement - Longitudinal Odds Ratios

Odds Ratio Estimates					
Med Rec Implem	Physician Engage	Qtr Comparison	OR	DF	95% C I
Full	High - Great Extent	8.5 - 7.5	2.44	1402	1.87 - 3.18
Partial	High - Great Extent	8.5 - 7.5	1.95	1402	1.51 - 2.51
Full	Med - Moderate Extent	8.5 - 7.5	2.42	1402	2.01 - 2.90
Partial	Med - Moderate Extent	8.5 - 7.5	1.87	1402	1.57 - 2.22
Full	Low - Some Extent	8.5 - 7.5	3.35	1200	2.64 - 4.25
Partial	Low - Some Extent	8.5 - 7.5	1.58	1402	1.36 - 1.82

Table 22. Net Profit Margin - Quarter 1 Odds Ratios

Med Rec Implem	Net Profit Comparisons	OR	95% C I	
Full	Net Profit	1.024	0.90	1.16
Partial	Net Profit	0.988	0.87	1.12

Table 23. Net Profit Margin - Longitudinal Odds Ratios

Odds Ratio Estimates					
Med Rec Implem	Net Profit	Qtr Comparison	OR	DF	95% C I
Full	5.09%	8.5 - 7.5	2.36	1434	2.12 - 2.63
Partial	5.09%	8.5 - 7.5	1.70	1434	1.55 - 1.87

Table 24. Control Variables - Quarter 1 Odds Ratios

Med Rec Implem	Control Variables	OR	95% C I	
JCAHO Accreditation				
Full	Yes vs No	10.08	3.22	31.53
Partial	Yes vs No	2.65	0.84	8.32
Critical Access Hospital (CAH)				
Full	Yes vs No	0.12	0.04	.40
Partial	Yes vs No	0.36	0.11	1.19
System Membership				
Full	Yes vs No	2.21	0.84	5.79
Partial	Yes vs No	1.45	0.57	3.66
Hospital Size - Bed Size				
Full	Number of Acute Beds	1.017	1.004	1.031
Partial	Number of Acute Beds	1.015	1.001	1.028

Table 25. Composite Variables - Bivariate Results

Effect	Num df	Den dF	F Value	Pr > F
Awareness Composite				
Awareness	4	167.1	1.76	0.1396
Quarter	2	1388	56.9	< 0.0001
Awareness*Quarter	4	1388	1.31	0.2659
Accountability Composite				
Accountability	4	145.7	0.94	0.44
Quarter	2	1402	45.6	<0.0001
Accountability*Quarter	4	1402	1.99	0.093
Ability Composite				
Ability	4	1430	1.64	0.1615
Quarter	2	1430	127.77	<.0001
Ability*Quarter	4	1430	1.82	0.1231
Awareness/Accountability/Ability (AAA) Composite				
AAA	4	893.8	0.27	0.8988
Quarter	2	1374	42.24	<.0001
AAA*Quarter	4	1374	1.02	0.3967

Table 26. Multivariate Model - Fully Saturated

Type III Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Awareness	4	95.91	1.17	0.3301
JCAHO	2	1073	3.1	0.0457
Accountability*Quarter	4	1043	3.73	0.0051
Ability*Quarter	4	1362	5.25	0.0003
System Member*Quarter	2	1094	0.19	0.8292
Size*Quarter	4	1362	3.93	0.0035

Table 27. Multivariate Model - Reduced

Type III Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
JCAHO	2	1158	3.8	0.0225
Accountability*Quarter	4	989.3	3.69	0.0055
Ability*Quarter	4	1396	5.31	0.0003
Size*Quarter	4	1396	4.22	0.0021

Table 28. Multivariate Model - Reduced Model Fixed Effects Solution

Solutions for Fixed Effects							
Effect	Med Rec Implem	Group	Estimate	Std Err	DF	t Value	Pr > |t|
Intercept	Full		-4.4593	0.6691	136.5	-6.66	<.0001
Intercept	Partial		-2.3775	0.498	147.1	-4.77	<.0001
Joint Commission on Accreditation of Healthcare Organizations (JCAHO)							
JCAHO	Full	Yes	2.3439	0.854	949	2.74	0.0062
JCAHO	Partial	Yes	1.726	0.8213	585	2.1	0.036
JCAHO	Full	No	0	.	.	.	.
JCAHO	Partial	No	0	.	.	.	.
Time (Quarter)							
Quarter	Full		0.8323	0.09614	1356	8.66	<.0001
Quarter	Partial		0.5518	0.08657	1185	6.37	<.0001
Accountability							
Accountability*Qtr	Full	High	-0.1954	0.2866	716.6	-0.68	0.4956
Accountability*Qtr	Partial	High	0.2869	0.2399	800.2	1.2	0.2322
Accountability*Qtr	Full	Med	-0.01423	0.1046	622.8	-0.14	0.8919
Accountability*Qtr	Partial	Med	0.1893	0.09457	511.5	2	0.0458
Accountability*Qtr	Full	Low	0	.	.	.	.
Accountability*Qtr	Partial	Low	0	.	.	.	.
Ability							
Ability*Qtr	Full	High	0.1623	0.1018	1174	1.59	0.1113
Ability*Qtr	Partial	High	-0.1143	0.09088	1009	-1.26	0.209
Ability*Qtr	Full	Med	0.01389	0.09154	1396	0.15	0.8794
Ability*Qtr	Partial	Med	-0.0835	0.08523	1396	-0.98	0.3274
Ability*Qtr	Full	Low	0	.	.	.	.
Ability*Qtr	Partial	Low	0	.	.	.	.
Hospital Size (Categorical Bed Size)							
Size*Qtr	Full	Large	0.4406	0.1845	1330	2.39	0.0171
Size*Qtr	Partial	Large	-0.00922	0.1616	1396	-0.06	0.9545
Size*Qtr	Full	Med	0.07802	0.1759	1396	0.44	0.6574
Size*Qtr	Partial	Med	0.001913	0.1651	1396	0.01	0.9908
Size*Qtr	Full	Small	0	.	.	.	.
Size*Qtr	Partial	Small	0	.	.	.	.

Table 29. Multivariate Model - Odds Ratios

Odds Ratio Estimates							
Med Rec Impl	Group	Comparison Group	Qtr	Comparison Qtr	OR	DF	95% CI
Joint Commission on Accreditation of Healthcare Organizations (JCAHO)							
Full	Yes	No	7.5	7.5	10.421	949	1.95 - 55.691
Partial	Yes	No	7.5	7.5	5.618	585	1.12 - 28.193
Accountability							
Full	High	Low	7.5	7.5	0.231	716.6	0.003 - 15.718
Partial	High	Low	7.5	7.5	8.599	800.2	0.251 - 294.12
Full	Med	Low	7.5	7.5	0.899	622.8	0.192 - 4.197
Partial	Med	Low	7.5	7.5	4.136	511.5	1.027 - 16.664
Full	High	High	8.5	7.5	2.383	782.8	1.407 - 4.036
Partial	High	High	8.5	7.5	2.16	842.6	1.374 - 3.397
Full	Med	Med	8.5	7.5	2.856	1396	2.282 - 3.575
Partial	Med	Med	8.5	7.5	1.96	1148	1.582 - 2.428
Full	Low	Low	8.5	7.5	2.897	1396	2.348 - 3.575
Partial	Low	Low	8.5	7.5	1.622	1396	1.347 - 1.952
Ability							
Full	High	Low	7.5	7.5	3.377	1174	0.755 - 15.104
Partial	High	Low	7.5	7.5	0.424	1009	0.111 - 1.617
Full	Med	Low	7.5	7.5	1.11	1396	0.289 - 4.267
Partial	Med	Low	7.5	7.5	0.535	1396	0.153 - 1.873
Full	High	High	8.5	7.5	2.997	1396	2.381 - 3.771
Partial	High	High	8.5	7.5	1.811	1396	1.478 - 2.219
Full	Med	Med	8.5	7.5	2.583	1396	1.999 - 3.339
Partial	Med	Med	8.5	7.5	1.867	1396	1.473 - 2.367
Full	Low	Low	8.5	7.5	2.548	1349	1.984 - 3.272
Partial	Low	Low	8.5	7.5	2.03	1249	1.615 - 2.553

Table 29. Continued

Hospital Size (Categorical Bed Size)							
Full	Large	Small	7.5	7.5	27.226	1330	1.802 - 411.30
Partial	Large	Small	7.5	7.5	0.933	1396	0.087 - 10.052
Full	Med	Small	7.5	7.5	1.795	1396	0.135 - 23.871
Partial	Med	Small	7.5	7.5	1.014	1396	0.089 - 11.52
Full	Large	Large	8.5	7.5	3.531	1396	2.525 - 4.939
Partial	Large	Large	8.5	7.5	1.888	1396	1.398 - 2.549
Full	Med	Med	8.5	7.5	2.457	1396	1.683 - 3.588
Partial	Med	Med	8.5	7.5	1.909	1396	1.35 - 2.699
Full	Small	Small	8.5	7.5	2.273	1105	1.832 - 2.819
Partial	Small	Small	8.5	7.5	1.905	1203	1.581 - 2.296

Table 30. Binomial Model - Bivariate Results

Type 3 Analysis of Effects			
Variable	df	Wald Chi-Square	p - value
Independent Variables			
Board Time Spent on Quality/Safety	2	11.125	0.004
Frequency of Board Review of Formal Quality/Safety Report	2	1.423	0.491
Board Interaction with Medical Staff	2	4.195	0.123
Executive Compensation Tied to Quality/Safety Performance	2	2.318	0.314
Extent Physicians Engaged with Quality/Safety	2	1.429	0.489
Net Profit (Previous 3-Year Rolling Avg)	1	1.472	0.225
Control Variables			
JCAHO accreditation	1	14.514	0.0001
CAH Hospital	1	10.117	0.0015
System Member	1	1.898	0.168
Size - (Categorical)	1	10.734	0.0047

Table 31. Binomial Model - Fully Saturated Model Results

Type 3 Analysis of Effects			
Effect	DF	Wald Chi-Square	Pr > ChiSq
BoardTime	2	4.8144	0.0901
BoardInteract	2	0.3281	0.8487
JCAHO Accreditation	1	3.8918	0.0485
CAH Member	1	0.8688	0.3513

Table 32. Binomial Model - Reduced Model Results

Type 3 Analysis of Effects			
Effect	DF	Wald Chi-Square	Pr > ChiSq
BoardTime	2	6.1131	0.0470
JCAHO Accreditation	1	9.2206	0.0024

Table 33. Binomial Model - Reduced Model Parameter Estimate Results

Analysis of Maximum Likelihood Estimates						
Parameter	Group	DF	Estimate	Std Err	Wald Chi-Square	Pr > ChiSq
Intercept		1	-1.4061	0.3582	15.4073	<.0001
BoardTime	High	1	0.7037	0.6113	1.3253	0.2496
BoardTime	Med	1	1.2757	0.5188	6.0459	0.0139
BoardTime	Low	0	0	.	.	.
JCAHO Accreditation	Yes	1	1.5096	0.4971	9.2206	0.0024
JCAHO Accreditation	No	0	0	.	.	.

Table 34. Binomial Model - Reduced Model Odds Ratios

Effect	Group Comparison	OR	95% C I
BoardTime	High vs Low	2.021	0.610 – 6.697
BoardTime	Med vs Low	3.581	1.295 – 9.900
JCAHO Accreditation	Yes vs No	4.525	1.708 – 11.989

Table 35. Binomial Model - Fixed Effects Results

Type III Tests of Fixed Effects				
Effect	Num df	Den dF	F Value	Pr > F
Time Spent in Board Meetings on Quality/Safety				
BoardTime	2	1323	7.53	0.0006
Quarter	1	1323	137.74	<.0001
BoardTime*Quarter	2	1323	17.24	<.0001
Frequency of Board Receipt of Formal Quality/Safety Report				
Freq Report	2	1297	4.82	0.0082
Quarter	1	1297	141.68	<.0001
FreqReport*Quarter	2	1297	3.82	0.0221
Board Interaction with Medical Staff to Establish Quality/Safety Strategy				
BoardInteract	2	1323	4.96	0.0071
Quarter	1	1323	104.76	<.0001
BoardInteract*Quarter	2	1323	3.84	0.0218
Senior Executive Compensation Tied to Quality/Safety				
Sen Ex Comp	2	1245	3.05	0.0479
Quarter	1	1245	127.61	<.0001
Sen Ex Comp*Quarter	2	1245	1.39	0.2489
Extent of Physician Engagement with Quality				
Phys Engage	2	1310	4.9	0.0076
Quarter	1	1310	155.15	<.0001
Phys Engage*Quarter	2	1310	10.84	<.0001
Financial Resources				
Net Profit	1	1336	0.11	0.7424
Quarter	1	1336	41.13	<.0001
Net Profit*Quarter	1	1336	7.23	0.0072
Joint Commission on Accreditation of Healthcare Organizations (JCAHO)				
JCAHO	1	1336	6.35	0.0119
Quarter	1	1336	123.28	<.0001
JCAHO*Quarter	1	1336	0.01	0.9152
Critical Access Hospital (CAH)				
CAH	1	1337	6.57	0.0105
Quarter	1	1337	118.54	<.0001
CAH*Quarter	1	1337	6.84	0.009

Table 35. Continued

System Membership				
System Member	1	1337	5.4	0.0203
Quarter	1	1337	181.45	<.0001
System Member*Quarter	1	1337	5.09	0.0242
Hospital Size – Bed Size				
Size (Categorical Bed Size)	2	1334	3.18	0.042
Quarter	1	1334	82.97	<.0001
Size*Quarter	2	1334	2.92	0.0542

Table 36. Binomial Model - Composite Fixed Effects Test Results

Type III Tests of Fixed Effects				
Effect	Num df	Den dF	F Value	Pr > F
Awareness				
Awareness	2	1297	5.21	0.0056
Quarter	1	1297	70.69	<.0001
Awareness*Quarter	2	1297	1.53	0.2159
Accountability				
Accountability	2	1310	4.96	0.0071
Quarter	1	1310	169.64	<.0001
Accountability*Quarter	2	1310	11.53	<.0001
Ability				
Ability	2	1334	1.91	0.1486
Quarter	1	1334	179.45	<.0001
Ability*Quarter	2	1334	3.2	0.041
Awareness/Accountability/Ability (AAA) Composite				
AAA	2	1282	1.28	0.2792
Quarter	1	1282	84.34	<.0001
AAA*Quarter	2	1282	0.67	0.5101

Table 37. Binomial Model - Fully Saturated Model Results

Type III Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Awareness	2	59.11	3.31	0.0435
JCAHO Accreditation	1	1005	0.34	0.5574
Senior Exec Compensation	2	53.51	0.81	0.4523
Accountability*Quarter	2	503.5	18.97	<.0001
Ability*Quarter	2	1288	6.7	0.0013
CAH*Quarter	1	838.1	3.5	0.0619
System Memb*Quarter	1	930.8	0.54	0.4621
Size*Quarter	2	1288	0.29	0.7462

Table 38. Binomial Model - Reduced Model Results

Type III Tests of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Awareness	2	70.36	4.43	0.0155
Accountability*Quarter	2	1048	17.3	<.0001
Ability*Quarter	2	1377	7.81	0.0004
CAH*Quarter	1	651.7	25	<.0001

Table 39. Binomial Model - Fixed Effects Results

Solutions for Fixed Effects						
Effect	Group	Estimate	Std Err	DF	t Value	Pr > |t|
Intercept		-4.8758	0.788	80.2	-6.19	<.0001
Awareness	High	4.4037	1.625	78.7	2.71	0.0083
Awareness	Med	2.0164	0.958	62.2	2.11	0.0393
Awareness	Low	0	.	.	.	.
Accountability*Quarter	High	-0.3693	0.069	1377	-5.36	<.0001
Accountability*Quarter	Med	-0.0169	0.07	665	-0.24	0.8098
Accountability*Quarter	Low	0	.	.	.	.
Ability*Quarter	High	0.2199	0.056	1377	3.95	<.0001
Ability*Quarter	Med	0.08414	0.044	1377	1.91	0.0564
Ability*Quarter	Low	0	.	.	.	.
CAH*Quarter	Yes	-0.4498	0.09	652	-5	<.0001
CAH*Quarter	No	0	.	.	.	.

Table 40. Binomial Model - Odds Ratio Results

Odds Ratio Estimates						
Category	Qtr	Comparison Category	Comparison Qtr	df	OR	95% C I
Awareness						
High	1	Low	1	78.74	12.75	3.216 – 25.336
High	1	Med	1	78.65	10.883	0.479 - 22.408
Med	1	Low	1	62.17	7.512	1.107 - 20.957
Accountability*Quarter						
High	7.5	High	7.5	1377	1.376	1.236 - 1.533
Med	7.5	Med	7.5	1106	1.958	1.71 - 2.241
Low	7.5	Low	7.5	1109	1.991	1.751 - 2.264
Ability*Quarter						
High	7.5	High	7.5	1208	1.971	1.75 - 2.219
Med	7.5	Med	7.5	1377	1.721	1.541 - 1.922
Low	7.5	Low	7.5	1377	1.582	1.425 - 1.756
CAH Status*Quarter						
Yes	7.5	Yes	7.5	1377	1.398	1.309 - 1.493
No	7.5	No	7.5	806.2	2.192	1.846 - 2.603

CHAPTER V. DISCUSSION

To our knowledge this is the first longitudinal study to be conducted utilizing the 4A Accelerator Model as a framework for examining the relationship between leadership structures and hospital-wide deployment of a specific, nationally prominent, and important patient safety initiative. The 4A framework was designed to assess an organization's progress relative to gaps in performance within four domains: awareness, accountability, ability, and action. This framework is becoming increasingly recognized as a tool that can be applied within the healthcare industry – an industry that has been slow to address patient safety as a priority [28]. In healthcare, the Leapfrog Group challenged the Texas Medical Institute of Technology (TMIT) and national experts to incorporate the principles of the framework into a survey that would allow healthcare organizations to assess their performance in adopting and implementing the National Quality Forum's Safe Practices and help them to create a roadmap for change efforts [20]. Since then this framework has been included in the original Safe Practice #1 – Create and Sustain a Culture of Safety – and included in the Leapfrog Group's own "Leapfrog Hospital Survey" [17, 20, 28, 32].

It was only recently, in 2009, that the NQF increased the transparency of the "best-practice" elements subsumed within Safe Practice #1 by promoting these elements to Safe Practices. The four elements are now the first four NQF Safe Practices – Leadership Structures and Systems; Culture Measurement, Feedback, and Intervention; Teamwork Training and Skill Building, and Identification and Mitigation of Risks and Hazards. The reorganization of these safe practices highlights the ethical, fiduciary, and legal responsibilities of governance, in concert with top leadership, in creating and sustaining a culture of safety. In addition, healthcare leaders are increasingly being called upon to transform the delivery system in ways that make it financially sustainable. Healthcare stakeholders are looking for better results. The National Quality Forum calls

upon governance, administrative, and clinical leaders to act independently and collectively on teams in their local communities to drive prioritized transformation efforts. The first four Safe Practices may increase leaderships' ability to effectively lead transformation efforts by providing a "checklist" of governance best practices. Many of the leadership structures and best practices are included in this study; many of which have not been examined in other studies in a theoretically-cohesive or empirical manner [72].

In Iowa, two simplified versions of a National Quality Forum Safe Practice survey have been fielded among all Iowa non-federal acute care hospitals since 2004. The last survey fielded among all Iowa hospitals was the PSCL survey in 2007. The scope of the 2007 PSCL survey was widened beyond the NQF Safe Practices and included items that correspond with the leadership structures and systems concepts within the 4A framework. Hospital leaderships' perceptions of their progress on a few key leadership structure and system concepts were collected using the PSCL survey. At the same time two additional national improvement programs were being launched by the Institute of Healthcare Improvement.

These two major quality and patient safety programs were being deployed among hospitals across the United States during the same time that the NQF Safe Practices were being introduced to the healthcare community. The IHI 100,000 Lives and 5 Million Lives campaigns spanned the years 2004 through 2008. The medication reconciliation innovation was a part of both of these campaigns. All Iowa hospitals voluntarily took part in both campaigns, reported their progress on implementation efforts, and continue to engage in data collection, assessment, and improvement efforts on all the original IHI campaign innovation planks.

In general, Iowa hospitals leaderships' self-reported perceptions of medication reconciliation implementation suggest that Iowa hospitals have made great strides in implementing this important safe practice over time. The trend in higher levels of

implementation is clearly evident in a review of simple run charts. However, identifying the most salient governance, leadership, and organizational factors related to their achievements is a difficult task.

The primary purpose of this study was to empirically analyze the relationship of hospital board, leadership, and resource characteristics with higher implementation levels of an important safe practice innovation that was developed to prevent common medical errors - medication reconciliation. The results of this study suggest that there were some awareness and ability characteristics that were associated to hospitals' implementation of this safe practice, but the results are mixed. For example, both cross-sectional and longitudinal model results suggested that hospitals whose boards were spending higher amounts of time in board meetings on quality/safety issues were related to higher initial levels of achievement in implementing medication reconciliation. Over time hospital ability – in the form of increasing levels of available financial resources – was related to increased levels of "full" hospital-wide deployment of the medication reconciliation safe practice.

From an analytical standpoint the initial approach used in this study utilized a multinomial model to analyze the hospital-wide implementation of the medication reconciliation innovation across three response categories – "none", "partial", and "full". Given the inherent limitations in these models an alternative binomial model approach was employed in an effort to increase the sensitivity to detect the outcomes of "partial" or "full" implementation of the medication reconciliation safe practice in cross-sectional analyses, and "full" implementation in longitudinal analyses. The analysis of the study data using a binomial model was conducted in response to a number of factors. The multinomial model exhibited considerable variability in the results likely due to the number of independent and dependent variable response categories being modeled within a dataset with a limited sample size. The multinomial model also did not allow the researcher to review traditional residual analyses to identify potential issues with model

fit. The multinomial model results are also somewhat difficult to produce using the SAS PROC GLIMMIX technique and the interpretation of results are more difficult when there are three or more response categories.

The binomial and multinomial model analyses results exhibited some similarities and differences. In quarter 1, near the conclusion of the IHI 100K Lives Campaign, both models' results suggested that JCAHO accreditation was significantly related to higher levels of medication reconciliation. However, the binomial model also found that the time spent by boards in reviewing quality/safety issues was also significantly related to higher levels of medication reconciliation implementation. The longitudinal results of both models suggest that higher levels of financial resource availability were related to higher levels of medication reconciliation implementation over time. And, greater hospital size – as measured by the number of acute beds in the multinomial model and indicated by non-CAH status in the binomial model - was related to higher levels of implementation over time.

The rest of the discussion below focuses on the binomial model results as these analyses more effectively zero in on "partial/full" implementation results in cross-sectional analyses and "full" implementation in longitudinal analyses.

Cross-sectional Results Discussion

Cross-sectional analyses focused on determining if awareness, accountability, and ability characteristics were related to hospitals' actions in implementing a salient safe practice – medication reconciliation - near the conclusion of the 100K Lives Campaign. Several individual board-related awareness and accountability characteristics were significantly associated with "partial/full" medication reconciliation.

Within the Awareness conceptual domain the results found a strong relationship between the time a board spends on quality and safety issues and "partial/full" implementation. In general, higher levels of board time spent on quality/safety issues

were related to "partial/full" implementation. However, only the "medium" category was significantly higher than the "low" category. These findings suggest that this board characteristic may have played a contributory role in hospitals' achievement of medication reconciliation implementation during this time period. These findings are supportive of IHI's 5 Million Lives Campaign "Board on Board" initiative, and it's associated toolkit that urges "at a minimum, boards should start by spending at least 25% of their meeting time on quality and safety issues" [33]. However, these cross-sectional results suggested that the strongest effect was for those boards that spent at least 11% or more of their time on quality and safety. The findings also align with the NQF awareness structures and systems specification that states "governance boards and senior administrative leaders should be regularly and thoroughly briefed" on performance gaps [28]. These results also have face value as leaderships' "awareness" of gaps in organization performance was likely increased during 2006 as one national IHI Campaign drew to a close, another IHI Campaign was kicked-off, the National Quality Forum's efforts were gaining focus and acceptance, CMS' national pay-for-reporting programs were gaining speed, and JCAHO was active in both the development of nationally-recognized safe practices and hospital accreditation.

It is also notable that JCAHO accreditation was also significantly related to implementation efforts. The confluence of board awareness and JCAHO accreditation activities might suggest that hospitals that were involved in JCAHO accreditation programs were more aware of gaps in performance and through their accreditation activities had taken early action to resolve these gaps. Medication reconciliation implementation was one focus area that JCAHO would have been monitoring in accreditation programs during this time period. As JCAHO accreditation was a particularly strong predictor in this model, the results suggest that this organizational characteristic may have been a highly important driver of change. It may also suggest that an efficacious governance and leadership "action" might be the engagement of the

organization in JCAHO-like regulation-oriented activities. As mentioned in the introduction, this study's results regarding the strength of quasi-regulatory effects align with the expert opinions and research that supports this notion [65, 109, 111-114]. In addition, in Iowa JCAHO accreditation is associated with larger non-CAH hospitals and hospitals that are members of hospital systems. These associations are likely similar across the country. In rural areas this may be cause for concern. Recent health reform legislative mandates will affect CAH hospitals. In the past, CAH hospitals have largely been exempt from prominent national reimbursement schemes designed to impact quality/safety performance issues. In particular, the Health Information Technology for Economic and Clinical Health (HITECH) Act will soon require hospitals to adopt and meaningfully use technologies designed to address national quality and patient safety goals. Financial penalties will be associated to non-adoption over time. Small rural hospital governance and leadership teams across the nation face immediate pressure to become aware of, and take action on, the adoption and implementation of information technology. The abilities of these organizations to adopt, implement, and harmonize both quality/safety improvement programs and new technologies will be tested. Due to the already complex and technical nature of the delivery of healthcare services the potential for unintended consequences to develop as the result of the integration of additional technological infrastructure is certainly going to increase.

Within the Accountability domain the board interaction with medical staff exhibited the strongest relationship with medication reconciliation. Senior executive compensation and physician engagement exhibited weak relationships with medication reconciliation implementation. This might suggest there exist additional opportunities for some hospitals to engage more fully in these safe practices. The NQF accountability structures and systems specifications state that "performance should be documented using methods such as performance reviews and/or compensation incentives"[28] . Additionally, the Joint Commission has suggested that senior leadership "make the organization's

overall safety performance a key, measureable part of the evaluation of the CEO and all leadership" [134]. Interestingly, physician engagement was not associated to "partial/full" implementation within the cross-sectional analysis. However, this characteristic was significant over time. Perhaps the engagement of physician leadership was not as strong in 2006 and, through increased national attention placed on the importance of physician leadership development, this characteristic has become stronger over the past few years. The results also suggest there was a difference in the "type" or mode of physician engagement. The board interaction with medical staff on quality/safety strategy is a different construct than the extent to which physicians were engaged in quality/safety improvement efforts. Thus, the relative strength of the board interaction with medical staff finding in this study mirrors the results from the early Weiner, Alexander, and Shortell studies in that leadership from the "top" may strengthen physicians' engagement with improvement efforts [43, 68]. This finding may underscore the saliency of top leadership, at the board of director level, in that boards that engage in a strategy-setting coalition with the medical staff more effectively create a "constancy of purpose" for complex organization-wide improvement efforts compared to more decentralized physician-led approaches.

Within the Ability domain, hospitals' previous 3-year average net profit margin was not significantly related to implementation efforts. These results may not be too inordinate given the relative economic conditions prevalent in 2006 in comparison to the conditions that exist now. Interestingly, financial ability was highly significant over time suggesting that organizational financial stability may have become more important during the 2006 – 2010 time period. The linkage between financial ability and patient safety initiative deployment assumes that some amount of capital is being invested in some manner – whether that be on equipment, personnel, or other systems-driving resources – that increases the ability of an organization to effectively undertake quality improvement efforts. The NQF Safe Practices specify that governance boards and senior leadership

should, on a regular and periodic basis, ensure that financial allocations for patient safety systems be assessed and adequately funded [28]. And, IHI has recently recognized the importance of the addition of the hospital's Chief Financial Officer (CFO) as part of the governance and leadership team when assessing and addressing gaps in quality/safety performance [135]. The CFO can assist organizational leadership in understanding the linkages between cost and quality. This will become especially important in the eminent era of value-based purchasing. Changes in the payment environment at the national level already explicitly penalize hospitals for defects in care. For example, CMS currently withholds reimbursement for ten hospital-acquired conditions (HACs), that also align with NQF's list of serious reportable events that should never happen ("never events"), when such conditions are not present on admission and thus presumed to be an outcome of hospital care.

Longitudinal Results Discussion

The GLMM bivariate models found that all of the independent variables of interest except senior executive compensation were significantly related to "full" medication reconciliation over time. The senior executive compensation term did meet the initial significant criterion to be advanced to subsequent multivariate models as a main effect intercept term, but it failed to remain a significant term in the final model. The other variables of interest were collapsed into composite domain variables – Awareness, Accountability, and Ability – and a "super "composite variable was created to capture the cumulative effects of all of these characteristics. The super-composite variable – Awareness/Accountability/Ability (AAA) – was not significantly related to "full" implementation, either longitudinally or cross-sectionally. Thus, we cannot confirm within this study the existence of a cumulative effect of board and leadership awareness, accountability, and ability characteristics upon hospital-wide deployment of medication reconciliation implementation. The collapsing of several categorical

variables may have attenuated the results for this variable and for several of the other domain variables. The model results for the other domain variables suggested that the Awareness domain was only significant as a main effect intercept term while the Accountability and Ability terms were significant interaction terms.

The final results suggested that the Awareness domain characteristic was a stronger intercept term than the JCAHO term. This might suggest that "high" board-level awareness characteristics might have served as a high platform for increased levels of "full" medication reconciliation over time, thus within a sample size-constricted dataset served as a better fit as an intercept term in the model. However, the odds ratio confidence intervals for the Awareness domain were very wide suggesting low cell sample sizes in the analysis. Larger studies would be needed to address the inherent sample size issues associated to this study – especially in regards to cross-sectional studies. Interestingly, JCAHO accreditation was not a significant interaction term. Therefore, these results suggest that over time JCAHO accreditation was not a significant factor in "full" implementation. Temporally, we must take into consideration that the practice of medication reconciliation became a "new" JCAHO National Patient Safety Goal in 2005, and subsequently this patient safety goal was adopted by the NQF as Safe Practice #14 in 2006 – "healthcare facility must develop, reconcile, and communicate an accurate medication list throughout the continuum of care". Hospital engagement with this quasi-regulatory body's quality/safety improvement processes, NQF's adoption of JCAHO's national patient safety goal, and the IHI 100K Lives focus on medication reconciliation as a centerpiece for preventing adverse drug events in their first national campaign, likely heightened hospitals' awareness and accountability to implement this safe practice. Later in 2009 JCAHO dropped its inclusion of medication reconciliation performance for accreditation purposes. In historical context, the variability in the emphasis JCAHO placed upon medication reconciliation over time may explain why

JCAHO accreditation was significantly related to hospitals' "partial/full" implementation in 2006, but then this relationship waned in subsequent years.

Both the Accountability and Ability domains were significantly related to "full" implementation over time. However, within the Accountability domain the odds of "full" implementation were higher in the lower accountability groups. A post hoc review of the proportion of hospitals achieving "full" implementation over time, within the board interaction with medical staff and physician engagement variables that made up the Accountability composite, show that this effect may be due to the variability in physician engagement performance. A review of snapshots in "full" medication reconciliation performance across time - in Quarter 1, Quarter 7, and Quarter 14 – show that the "medium" physician engagement groups were associated with higher levels of "full" implementation status in all three quarters. In contrast, there was a linear dose-response relationship between the board interaction with medical staff variable and "full" implementation. In total, the mixed results within the Accountability domain are likely attributable to physician engagement variability. Physician engagement also exhibited lackluster results in the cross-sectional analyses. The evidence suggests that physician engagement may not have been a key facilitator of improvement efforts. In regards to hospitals' financial ability, the final multivariate model results suggest that there exists a linear dose-response relationship between 3-year net profit margin levels and "full" implementation. Although this variable was not a significant predictor in cross-sectional analyses, this may have become a more important factor over time. Perhaps financial health was an even more important barrier in 2009 as economic pressures became increasingly harsh.

Economic and financial pressures may have increasingly become a barrier to small, non-system hospitals' ability to engage in quality/safety improvement efforts. Interestingly, the results suggest that CAH status was related to lower odds of "full" implementation compared to non-CAH hospitals. Both the cross-sectional and

longitudinal analyses suggest that CAH hospitals may have found it difficult to implement important quality/safety programs at a rate equal to that of other hospitals. CAH hospitals may benefit from policies that recognize the significant barriers faced by these hospitals. However, post hoc t-tests show CAH hospitals lagged larger hospitals in 3-year rolling net profit margins during 2006-2008, but not in 2009. Perhaps other barriers to awareness and accountability structures and systems impeded their progress over time. A large majority did not participate in JCAHO accreditation activities, but just over half were members of a hospital system. In terms of the leadership structures included in this study 61% had boards that spent <= 10% of their time in board meetings on quality/safety issues, 36% had boards that did not interact at all with the medical staff, and 37% had "low" levels of physician engagement. Leadership's ability to address awareness, accountability, and ability barriers may be especially important moving forward as current health reform efforts place more time-sensitive and stringent quality/safety performance requirements upon CAH hospitals. In fact, as the results for this study were being written rural hospital representatives were meeting with Department of Health and Human Services officials to discuss their progress, as well as their needs and concerns regarding the "meaningful use" requirements for the HITECH Act electronic health record incentive payments, such as limited access to capital, tight timelines, and workforce shortages. Hospital CEOs representing small U.S. hospitals were meeting with National Coordinator for Health Information Technology David Blumenthal, M.D., and representatives from the Centers for Medicare & Medicaid Services and Health Resources and Services Administration to identify issues and think through possible policy and program solutions to ensure that the meaningful use requirements work for all communities.

Study Limitations

This study utilizes multiple surveys that assess leaderships' perceptions of hospital characteristics and hospital engagement with a nationally-recognized quality/safety improvement program. These surveys were designed to be of low burden to responders, therefore a singular leadership person was directed to provide a response on behalf of their organization. Thus, there are likely sources of response bias inherent to this study and the inaccuracy of singular measurements for organizational characteristics is a significant threat to the internal validity of the study.

In addition, many of the governance and leadership characteristics were only measured at one point in time. An assumption is made that these top-level leadership characteristics remained constant over the course of the study timeframe from late 2006 through the first quarter of 2010. Other researchers have suggested that board characteristics do not change much over time, thus studies that incorporate singular measures of these characteristics are not adversely affected by threats to the internal validity of research design such as historical, maturation, or mortality [43]. These researchers offer other references to support this statement [136-138]. However, in an environment characterized by an increased pace of change, coupled with the fact that increasing attention is being paid to governance accountability, one might question the applicability of this premise in future studies that focus on these topics. More frequent and longitudinal measures of governance and leadership characteristics would bolster the internal validity of studies conducted in this line of research.

The primary analytical approach using multinomial data proved to be challenging. In some ways the challenges were not anticipated going into the study. The mixed effect, multinomial model showed evidence of an inability to provide solutions for a number of statistical computations. This is likely due to several unique and limiting properties of the data and the types of analyses used in this study – incorporation of random effects, longitudinally-correlated data, potentially skewed multinomial distributions, and low

power due to low unit-of-analysis sample size. In addition, it was recognized that another limiting factor of GLMM multinomial models was an inability to provide model statistics that could be used to compare the fit between similar, yet different models. This is because the GLMM uses "pseudo" likelihood methods to derive the log likelihood of the data. Consequently, obtaining traditional likelihood-based tests and statistics that can be used to compare the fit between similar marginal models, and between different covariance pattern structures, is not tractable. Moreover, because of the multinomial nature of the data residual diagnostic tools are not available for multinomial models. Taken together, the results of multinomial-based analyses may be subject to threats to statistical conclusion validity. However, the binomial model capabilities likely strengthened statistical conclusion validity.

It is important to re-acknowledge at this point that many Iowa hospitals achieved "full" hospital-wide medication reconciliation implementation by the end of this study as perceived by Iowa hospitals' quality leaders. The overall improvement in Iowa hospitals' implementation was quite notable. In late 2006, only 29.1% of the hospitals included in this study had reported their hospital had reached "full" implementation status. By the first quarter of 2010, 71.8% had reached "full" implementation status. During this timeframe Iowa hospitals periodically received feedback regarding their implementation performance on all the IHI 100K and 5 Million Lives initiatives through the Iowa Healthcare Collaborative – an external, local regional collaborative that engages hospitals in raising the standard of care. The use of external organizations in data collection, measurement, and reporting activities is recognized as a good practice by prominent opinion leaders, safety theory experts, and by the NQF in their Safe Practice Leadership Structures and Systems [14, 20, 28, 139]. The use of external collaborative partners in performance measurement activities enhances the transparency of individual hospital performance. Thus, an intended side effect of measurement and reporting schemes is the creation of a Hawthorne Effect. As organizational leaders participate in measurement

activities and review the results of their hospital's performance in comparison to others, this may spur intra-organizational efforts to increase their performance in those areas being measured. Leaderships' awareness and knowledge of performance gaps spurs the change pathway to improvement [140]. National public reporting schemes specifically point to the creation of the Hawthorne Effect as an intended strategy to raise the standard of care [20]. Although hospital-specific performance levels were never reported in Iowa using the data included in this study, statewide results were shared with the hospital community during the course of the study's time frame. The threats to the internal validity of this study that may have been introduced by the effects of private and public reporting activities are certainly a limitation to this study. But, in general the effect would have been experienced by all Iowa hospitals in a consistent manner. Of course, hospitals' engagement with other reporting and measurement programs may have had an effect on medication reconciliation implementation efforts. Public reports of hospital performance are certainly becoming more ubiquitous, thus the effects of public reporting efforts will likely remain a key limitation in studies of organizational and quality/safety performance.

The results of this study do have some limitations in terms of generalizability. Hospitals within the state of Iowa are all non-profit and comprised of a high percentage of rural hospitals (82 of 117 are critical access hospitals). In addition, many Iowa hospitals are publicly owned and do not allow physicians to be part of the board – a feature that is generally touted as good practice as long as particular physicians are not practicing within the facility for which they also serve on the board [141, 142].

In terms of the existing governance and leadership literature there are a multitude of board structures, practices, cultures, and other sources of leadership that are not examined in this study [62, 66, 71, 83]. Individual leadership characteristics may also play a role in establishing an organizational culture of quality/safety and agility needed to produce change. Leaders must be trustworthy, energetic, passionate about their work, respectful, results-focused, inspirational, and embody the core values of the organization.

These individual characteristics likely play a role in how people and systems work together to produce change. Structurally, board composition, size, well-organized committee structures, and diversity are not measured. Additionally, many experts suggest that an array of other clinical leaders will need to play an increasing role in healthcare operations. Besides physicians, the leadership skills of nurses, pharmacists, and direct care givers will need to be developed and integrated into myriad leadership/governance activities. Best practices of board self-evaluation, allowing CEOs to be a voting member of the board, robustly evaluating CEO performance, approval of definitions for committee responsibilities, developing well-devised organizational mission/vision/values that provide a complementary foundation for sound policies/practices/just cultures and subsequent behaviors, and evaluating community benefit were not examined in this study.

Additionally, within the context of this study there are several awareness, accountability, ability, and action specifications delineated by the National Quality Forum within the first four Safe Practices that focus on governance and leadership characteristics that were not included in this study. These specifications cover a wide range of structures and processes that are arranged within the 4A model framework. The Awareness domain includes the identification of risks and hazards, patient input, and culture assessments. The Accountability domain includes the establishment of a patient safety program, appointment or employment of a patient safety officer, the establishment of an interdisciplinary patient safety committee, and the engagement and use of external reporting activities. The Ability domain includes patient safety budgets, people systems, quality systems, and technology systems. Finally, the Action domain includes performance improvement programs, confirmation of values, teamwork training (both board and senior administrative leadership), board competency (related to awareness), time commitment to patient safety for a variety of activities (e.g. – staff/patient walk-

rounds), culture measurement, entire leadership structure engagement with Safe Practice #1 specifications, and medical staff input into patient safety programs.

There are also other conceptual models of complex innovation implementation that provide insight into other organizational features that may be important to quality/safety implementation efforts, but were not included in this study. The Klein and Sorra (1996) integrative model of the determinants and consequences of implementation effectiveness, and the subsequent adaptation of this model to the healthcare setting made by Helfrich et al. (2007), is one such model that provides a conceptual framework of interest to this field of work [35, 143]. The original Klein and Sorra model focused on the quality and consistency of targeted organizational use of an adopted innovation. Innovation implementation effectiveness was modeled to be dependent upon organizational climate and the "fit" of a given innovation with organizational values. A subsequent application added the important domains of management support – deemed in the original research to be the "primary antecedent of an organization's climate for implementation" [144]. Others have adapted this model for other research purposes [145, 146].

The subsequent adaptation of the Klein and Sorra model by Helfrich et al. addresses the determinants of implementation of "complex" innovations within healthcare [35]. An important distinguishing definition used in the Helfrich et al. framework was that innovations require the coordinated use by organizational members. However, adoption occurs at the organization level, and subsequently multiple individual users within the organization then determine whether they will embrace, comply with, or resist innovation use [35, 147]. Similar to the precursor Klein and Sorra models, the Helfrich et al. framework posits that innovation implementation effectiveness is related to management support. In contrast to the Helfrich et al. conceptualization, this study included board-level and physician-level leadership characteristics as part of the management support construct. In terms of the Helfrich framework this study did not attempt to measure how management communicates a rationale and priority for

innovation implementation. The study did not measure the extent to which formalized policies and practices are created by management to ensure facilitative actions are carried out and barriers are attenuated or removed. The perceived "fit" between these innovations and professional or organizational values, competencies, and mission are not assessed for their impact on the implementation climate. Moreover, the implementation climate is not examined in regard to how the innovation is perceived as an organizational priority. Finally, the study does not attempt to measure implementation effectiveness in terms of the quality of the innovation implementation, or the innovation effectiveness in terms of perceived or actual benefits to the organization as described in the Helfrich et al. model. Because we do not measure what really is happening at the bedside this study does not address the quality of the processes used to carry out medication reconciliation. Moreover, the study does not evaluate how the actual care at the bedside affects patient outcomes.

Frontline staff play a key role in sustaining a culture of safety as they are the individuals within the organization that are most likely to be aware of the problematic conditions, processes, and systems that may exist at the point of care [148]. A punitive work environment and/or a non-group oriented culture may discourage organizational learning and growth opportunities as staff may be fearful of reporting near misses, error-prone equipment and processes, and system-related errors [148, 149]. A just culture that embraces transparent error disclosure processes, while maintaining professional accountability, is an important first step for patient safety to become a reality. Variations in how top leadership effectively link organizational mission, values, strategies, practices and policies may affect how well a just culture is established within the organization. Variations in the culture are reflected as differences in the values that are shared among organizational members about what is important, their beliefs about how things operate in the organization, and the interaction of these with work unit and organizational structure and systems, which together produce the behavioral norms in the organization that

promote safety [88]. This in turn may affect how quality improvement initiatives are effectively carried out within an organization. This study did not examine the relationship between quality/safety leadership characteristics and the establishment of a just culture that may impact quality improvement efforts.

In terms of organizational characteristics, this study does not completely examine the "adaptive reserve" or "change readiness" of the organization [150, 151]. Although these characteristics are related to the ability domain within the 4A framework this study would benefit from a much deeper assessment of organizational capacity for change. These characteristics may impact organizational adoption and diffusion rates of innovations.

There may have been other quality/safety improvement initiatives, strategies, or tactics that hospitals were engaged in and were not studied; and these may have affected the adoption and diffusion rate of the medication reconciliation innovation. For example, active implementation strategies have been used to motivate change such as traditional and non-traditional continuing medical education (CME) methods, community-based strategies such as academic detailing, presence of opinion leaders, patient-mediated strategies, feedback/reminder systems, administrative interventions, implementation coordinators, pay-for-performance schemes, public reporting, risk and safety management systems, and use of financial incentives [150, 152].

The determination of the direction of causality is also a limitation. Although many previous studies have focused on clinical processes and outcomes, this study is similarly limited in its ability to determine whether engaged boards, physicians, and/or financial resource availability lead to higher levels of safe practice initiative implementation, or whether organizations that successfully implement safe practice initiatives to a higher degree sought out board, physician, and top-leadership personnel that "fit" the existing strategic mission, vision, and values of the organization [75]. Future studies would benefit from the capture of board awareness, accountability, awareness, and action structural characteristics over time. This would allow researchers to more

effectively utilize longitudinal methods to assess the relationships of these characteristics with quality/safety structures, processes, and outcomes.

Future Research

The evidence base for governance and leadership best practices is growing. Recent quantitative studies have shed light on the efficacy of good governance and leadership practices [50, 61, 66, 73-75]. Other research has presented us with a startling picture regarding some boards' lackadaisical focus on quality/safety issues and misperceptions of actual hospital performance on nationally-recognized quality and safety metrics [57, 75]. Given the current state of research in this area, more research is needed to strengthen the business case for the current set of governance and leadership "best practices". Given the complex and technical nature of the industry, along with increasing public scrutiny and regulatory constraints being placed on the organization, finance, and delivery of healthcare, there will likely be a burgeoning need to empirically examine the effects of a myriad of governance and leadership practices on the structures, processes, and outcomes of healthcare delivery systems. Governance and leadership issues intersect with a vast variety of healthcare issues. Furthermore, the wide variety of healthcare settings, micro-systems within those settings, and clinical applications suggest that the amount of research that could be conducted is deep and wide.

Hoff et al.'s systematic review of the literature examining linkages between organizational factors, medical errors, and patient safety provides good background and recommendations for future research in this area [72]. The AHRQ-funded review found that there were no articles that met their acceptance criteria for board involvement. Only 42 studies (<2% of all studies reviewed) met inclusion criteria of being empirical and employing a specific operationalization of error reduction, prevention, or enhanced patient safety as the dependent variable. Most of the studies reviewed (>60%) used little theoretical framework to underpin the study. And, only 20% of the studies appeared to

give enough confidence of a causal relationship between the organizational variable of interest and the dependent variable. They concluded that there is little evidence for asserting the importance of any individual, group, or structural variable in error prevention or enhanced patient safety. And, they concluded that there exists great variety in how organizational variables, when used as independent variables, are defined and operationalized across different settings. However, in regards to the types of dependent variables used in these studies a substantial number focused on medication errors, adverse drug events, medication complications, and proper drug therapy. A total of 42.8% of the studies looked at medication errors and adverse drug events. In their conclusion, the authors discussed several areas for future research.

The Hoff et al. systematic review authors noted that the health care field should not be studied as a "mechanical" system framework, rather it should be studied from the viewpoint of Complex Adaptive Theory – an adaptive system, which includes human beings that have the potential to respond differently and unpredictably at a given point in time [72]. They highlighted three related theoretical models that would be relevant to organizational factor research – normal accident theory, high reliability theory, and human factors theory – and discussed how each applies to the study of organization factors and medical error.

First, human factors theory borrows from the industrial engineering and psychology fields and was applied extensively in the aviation industry [14, 72]. The key premise in this theory posits that "latent" mistakes combine within a system to cause error. The interrelationships between humans, the tools they use, and the environments in which they operate are important to understand in assessing and mitigating risk. Although not all errors are related to human factors (for example, design of machine's control features), increased group-level interactions, multidisciplinary teams (teamwork), rapid response capability, feedback loops, system redundancies, decentralized decision making, and information systems are approaches that might be used to minimize the

potential impact of latent sources of error. Within NQF's use of the 4A model framework there exist leadership specifications for the use of teamwork training, team interventions, error feedback loops from frontline personnel to management personnel, engagement of medical leaders in the provision of direct input to patient safety programs, and the use of information technologies that all align with the study of human factors theory [28].

Charles Perrow's normal accident theory posits that errors in complex systems are unavoidable (accidents in risky systems are "normal" or a "system" accident). Inherent characteristics of interactively complex and tightly coupled systems make large accidents inevitable. Unexpected interactions of failures may occur in such a way that safety systems are defeated and sufficiently tightly coupled to allow a cascade of increasingly serious failures to occur. Organizational structural factors help shape the probability of error. The level of coupling between tasks and complexity of interactions determines level of risk. Perrow suggested several key organizational factors that could be used to reduce the probability of error – reduce the amount of hazardous materials, redesign the system to be less complex and tightly coupled, abandon the system, control personnel more closely, increase the proximity of elites to operating systems, centralization, use of "buffers" between steps in the process, increase the amount of feedback around errors, and increase feedback and the amount of information that is exchanged around critical phases in processes. Within the healthcare context the study of such practices as the engagement of boards with patients, staff, and clinical leadership; elimination of "high-alert" medications; use of nurses, pharmacists, doctors, and patients as part of the medication review process; and the use of technology in the form of computerized physician order entry (CPOE) and clinical decision support systems (CDSS) are all examples of factors that could be better studied along the lines of Perrow's theory. Especially, for those factors that have the innate potential to tighten the coupling of system processes such as the use of CPOE and CDSS.

Perrow also discussed "inelegant and robust" design features [72]. A robust design starts as one with the premise of fallibility on all parts – especially the designer. Inelegant design minimizes dual purpose components (reduces common-mode failures), utilizes off-the-shelf components (heighten familiarity, well-tested parts, low maintenance), components may be well cluttered or space wasting in order to allow easy maintenance and replacement, will have signals for component failures (automatic out-of-control warning systems), and will allow bypassing and reverse flows in emergencies. The study's authors noted that cheap "add-on" safety features are often added to complex systems. They believe that these types of redundancies and "add-on" safety systems are the biggest source of catastrophic failure in complex, tightly-coupled systems [72]. In healthcare, the impending increased use of health information technology will need to be carefully studied for "inelegant and robust" design features that decrease the probability of errors associated to tightly-coupled complex systems.

Perrow suggests that organizational structure should not be lean, too centralized, and the positions in it too specialized [72]. Crew resource management systems aboard ships and planes are examples of the inelegant design, in contrast to the elegant structure of the captain with the single-skilled subordinates, or the messy matrix structure versus the clean centralized one. Inelegant designs are more supportive of constant feedback about errors and a system-wide sharing of near misses. This is much better than naïve calls for "more training" and better than calls for a culture where top management is supposed to put security or safety first, which, like fantasy documents are sincere, but still fantasies. The disadvantage of these designs is that decentralized systems are slow to respond to widespread, multiple failures because the units cannot be instantly and unquestionably controlled from the top where often there is a superior view. In healthcare, the NQF Safe Practices specify that leadership should remain aware, hold themselves accountable, and take appropriate actions to identify risks and hazards and mitigate the potential for harm. Leaderships' activities should include direct patient input

and establishing a "just" culture where frontline personnel feel comfortable disclosing errors – including their own – while maintaining professional accountability [28]. One healthcare expert noted recently in a national webinar that some of the best ideas and innovations – the ones that generate the most enthusiasm and are implemented hospital-wide quickly likely as a byproduct of the "fit" of the innovation with employee and organizational values – do not come from national campaigns or organizational top leadership, rather they originate from frontline leaders [153]. Somewhere in the middle exists common ground where top leadership provides appropriate levels of organizational direction and resources needed by others to carry out strategies, yet also supports a culture that embraces subordinates' ideas and creates an environment where knowledge flows quickly and freely throughout the organization.

Perrow notes that large organizations are especially susceptible to "normal accidents" [72]. The larger the organization the more energy is available for release (for example, AIG concentration of world-wide financial flows, GM, Enron). While large organizations may have more "slack resources" – those not needed for production – they may be able to invest in safety systems, but resource expenditure will also need more coordination and control. Slack resources may also be absorbed in large organizations by the inevitable development of group interests, wherein personnel invest in relationships, routines, and procedures that will make their work easier or more pleasant. Although as likely in small organizations, prosaic organizational failures can be more catastrophic in large companies (for example, BP, Challenger, Exxon Valdez, AIG). Two combinations limit the possibility of failure-free organizations – designers cannot predict the total number of combinations of ways in which errors could occur, thus they are not able to "design out" system weakness points. And, combinations of two or more failures can interact in tightly-coupled, complex systems and can cascade and bring a system down (for example, Three Mile Island, ConEd and AT&T power outage). The expenditure of "slack resources" is enveloped as part of NQF's Safe Practice Leadership Structures and

Systems within the ability domain of the 4A framework [28]. Adequate funding of patient safety goals is a tenet of this safe practice. The degree to which this safe practice can be effectively carried out will be a salient area of research study, especially as healthcare costs and expenditures continue to rise at unsustainable rates, and health reform efforts will likely impart stress on the budgets of many organizations.

In addition, the NQF acknowledges the limitations of resource unavailability faced in many rural healthcare settings. As Perrow suggests, errors are just as likely in "small" organizations. The NQF suggests that the leadership of rural healthcare organizations may benefit by participating in national safety and quality collaborative initiatives of similar organizations [28]. Alliances among these organizations in noncompetitive service areas provide opportunities to share resources and information. Small rural hospitals may benefit from resource-efficient programs that have been used by larger organizations such as those offered by the NQF, IHI, QIOs, and local regional collaboratives [154]. As echoed by the ability domain within the NQF 4A Safe Practice framework, hospital leadership should monitor the ability of their organization to effectively engage in quality/safety improvement initiatives and match their capabilities to quality/safety program complexity [28]. Research conducted in Minnesota hospitals suggests that a hospitals' ability to successfully adopt improvement programs is a function of its capabilities [155]. Research that focuses on these settings, and their differential approaches to obtaining necessary resources for quality/safety improvement efforts as compared to other settings, will surely be valuable going forward.

James T. Reason extended Perrow's normal accident theory into the realm of high reliability. The key idea within high reliability theory is that complex organizational processes can be designed and managed for reliable performance [14, 72, 156]. However, creating and sustaining a culture of safety is also an important organizational characteristic and feature of high reliability organizations. Hoff et al. state that the development of a "culture of reliability", placing high organizational value on safety

training and education, and getting workers to buy into the importance of routine and redundancy are intertwined with the development of shared norms and values that emphasize safety [72]. The key organizational factors implied by the theory to reduce error include a "culture" of reliability and safety, system redundancies, training and education, decentralized decision-making, clear goals, measurement and feedback, and the use of routines. Teamwork and "collective mindfulness" are also viewed as important characteristics that are essential components of high-reliability organizations [157, 158].

In total, experts note that there are many similarities within these theories and that elements of all these theories may be applied in healthcare research depending on the nature of the situation being studied [72, 159]. Although several of these theories used to be viewed as competing theories, the current thought is that they complement one another [159]. In addition, many of these theories and frameworks can be applied to a number of settings [14]. The 4A framework used within NQF Safe Practice #1 includes leadership structures and systems that dovetail well with these theories. Future research might apply the use of the 4A model as an overarching framework with elements of normal accident, high reliability, and human factors research woven into the fabric of the 4A framework where it is best suited for integration.

There still exist several significant hurdles in overcoming the piecemeal and fragmented nature of our national quality measurement and reporting system. However, several recent healthcare developments are noteworthy in regards to infrastructure development that hold high promise for kick-starting additional research in areas that are related to this study.

The research conducted for this study was constrained by the piecemeal and fragmented nature of our national quality measurement and reporting system. In her individually-authored contribution to the National Academy of Engineering (NAE) and IOM's *Building a Better Delivery System: A New Engineering/Healthcare Partnership* Dr. Janet Corrigan - current President and CEO of the National Quality Forum – stated

that one of the systemic problems with the current U.S. healthcare system is that there are no standardized performance measures that enable cross-institutional comparisons [15]. She stated that this creates two problems: we do not know where the best performers are, and secondly, the best performers are not rewarded for their excellent work. This also hampers research efforts. A majority of the measures used in this study could be characterized as un-standardized measures of organizational characteristics and performance which were collected and entered into computerized systems manually using a variety of informational sources. Some primary sources of the measures used in this study would not provide these critical data for use in this research. For example, requests for Iowa hospital accreditation data sent to JCAHO using their data request forms were unanswered. On the other hand, some organizations were facilitators of research data collection. For example, the collection of the much of the independent variable data, and all of the dependent variable data, was facilitated by a localized external stakeholder (IHC) that also collaborated with a professional organization (IHA) to collect and transfer that data. However, it should be noted that all of this data relied heavily on manual data collection efforts. A much more robust national quality measurement and reporting system is needed to facilitate the efficient collection and transfer of the data needed for research efforts.

However, the landscape of quality measurement and reporting is changing in the United States as multiple national stakeholder groups are affecting change. For example, the NQF is now operating as a consensus-based body that is (1) implementing a comprehensive plan for measurement and reporting, (2) identifying core measures for measurement and reporting, and (3) promoting the development of the core measures [22]. NQF recognizes that the quality, "harmony", and "alignment" of metrics emanating from the growing pool of measure developers will be important characteristics that help bridge the gap between quality measurement/reporting and effective improvement. Although much work needs to be done, over time Dr. Corrigan envisions that better aligned and

harmonized metrics - that can "roll up and down" among physicians, teams, and hospitals; and that are NQF-endorsed™ utilizing a more time-efficient consensus process - will help NQF to achieve their goal of becoming the nationally-recognized facilitator of research efforts and the continuous quality improvement of American healthcare quality [160, 161].

The NQF Safe Practices themselves are good targets for future research. All of the independent and dependent variables of interest used in this study align with the NQF Safe Practices. This study is the first known research that uses the 4A framework to conceptually frame the connections between the original Safe Practice #1 – Create and Sustain a Culture of Safety with Safe Practice # 17 Medication Reconciliation. This research incorporated only two of thirty-four current Safe Practices and only scratches the surface as far as the depth of research that could be conducted just within these practices. Much more research could be conducted within the realm of the NQF Safe Practices.

Research that focuses on how the NQF Safe Practices are applied across healthcare settings is scare. Past hospital-based research shows that some Safe Practices do not pose a significant barrier to their implementation; and features of the Safe Practice measures themselves such as their low level of complexity or alignment with other salient patient safety programs – for example, JCAHO accreditation measurement, IHI, Leapfrog programs and initiatives – may promote adoption regardless of hospitals' geographic location, size, or other structural characteristics [99, 111, 162, 163]. However, researchers have also found that some of the original 30 Safe Practices are not applicable in many hospitals due to resource barriers. Lower Safe Practice adoption rates are recognized for resource-dependent practices such as implementing a computerized prescriber order entry system, ICU intensivist staffing, comprehensive pharmacist involvement in medication management, and referral of patients to high-volume hospitals. The barriers to adoption for these Safe Practices seem to be related to small size, rural location, staffing shortages, and the lack of financial resources that may be ameliorated by economies of scale or

health system management/ownership. However, some of the barriers to adoption of some of these Safe Practices are being addressed at the federal level. The quality and quantity of data may increase substantially over the next several years. Furthermore, the quality and quantity of research may improve and increase as research funding has expanded and is focused on national priorities and comparative effectiveness. These national efforts may open the doors for many more research opportunities.

Several important pieces of national infrastructure are being built that should underpin many research efforts. Some of this infrastructure aligns directly with the focus of this research. An important first step is contracting of the National Quality Forum as a national consensus-making body. The National Quality Forum convened the National Priorities Partnership – a collection of highly influential national healthcare organizations – to develop national priorities and goals [164]. Two of the national priorities are directly relevant to continued medication reconciliation research – improving the safety and reliability of America's healthcare system; and ensuring patients receive well-coordinated care within and across all healthcare organizations, settings, and levels of care. The former priority includes the goal that "all healthcare organizations and their staff will strive to ensure a culture of safety … they will focus relentlessly on continually reducing and seeking to eliminate all healthcare-associated infections (HAIs) and serious adverse events". Adverse events are inclusive of the set of NQF Serious Reportable Events, of which adverse drug events is a member. The latter priority includes the goal that "medication information will be clearly communicated to patients, family members, and the next healthcare professional and/or organization of care, and medications will be reconfirmed each time a patient experiences a transition in care". As highlighted earlier, the NQF is providing an additional service that aligns with the production of national priorities and goals. NQF is the national body that is endorsing metrics that are of sufficient quality to be used in performance assessment and quality improvement efforts. The problem in regards to medication safety is that in the absence of a set of nationally-

recognized and utilized data collection and measurement tools, it has been difficult to assess the performance of organizations in carrying out medication-related best practices on a national level and in a standardized way. However, that is changing also on a national level. And, change will likely bring about many opportunities for research and improvement efforts.

First, the Patient Safety and Quality Improvement Act of 2005 initiated the establishment of Patient Safety Organizations (PSOs) across the U.S. whose initial mission will be to collect data and act upon a set of nine specific patient safety events. One of the initial nine events focuses upon medication errors. The importance of the Patient Safety Act to the research community has not yet been realized. The Patient Safety Act requires all PSOs to collect event data on standardized patient safety event forms and forward that data to the Agency for Healthcare Research and Quality (AHRQ) for analysis and inclusion into the National Healthcare Quality Report. Thus, the goal is that healthcare stakeholders will have comparative metrics and knowledge that can be used as a basis for national learning and growth opportunities for "rare", system and non-system related, and "sensitive" adverse events. Nationally-representative measures that shed light upon the prevalence and severity of medication errors will be available to all Americans. These data should be especially useful in targeting and prioritizing potential research projects focused in this area.

Secondly, the American Recovery and Reinvestment Act of 2009 (ARRA) included an important piece of legislation that is designed to diffuse the adoption and implementation of a critical piece of national infrastructure that is largely absent in American hospitals and physicians' offices. The ARRA legislation includes Title XIII – called the Health Information Technology for Economic and Clinical Health Act, or "HITECH Act" – that will incentivize the adoption of electronic medical record technology across the nation. This single piece of legislation is incredibly important to

researchers, and to the study of medication-related quality/patient safety issues, for a number of reasons.

The ultimate goal of the HITECH act is the diffusion of "qualified" and "standardized" information technologies within U.S. doctors' offices and hospitals (including CAH hospitals) and the clinically meaningful use of these technologies in ways that support national priorities and goals. The program spans several years and plans are to implement the requirements of the HITECH Act over the next 5-6 years in three stages.

A prime area of focus for the HITECH Act is addressing medication errors. Stage 1 "core" objectives require doctors and hospitals to use computerized prescriber order entry (CPOE) for the medication ordering stage (hospital emergency department and inpatients), implement at least one clinical decision support system (CDSS) rule, generate and transmit prescriptions electronically (doctors only), keep an active medication and medication allergy list, and electronically exchange key clinical info (e.g., – medication list/allergies, test results within the hospital setting). In addition, notable Stage 1 "menu" objectives include the implementation of drug formulary checks, incorporation of lab-test results into electronic medical records, and performing medication reconciliation (initially, for the receiving doctor or hospital only). Interestingly, the HITECH Act backed off on using a "drugs to be avoided in the elderly" metric as a "core" clinical measure requirement for participation in the EHR incentive program. Although no medication safety-related clinical measures were included in the Stage 1 requirements, there will likely be medication safety-related measures added in later stages. Hospital leadership can anticipate future demands by becoming more aware of the changing environment and assessing their ability to initiate improvement efforts.

For example, one Iowa hospital is getting a jump start on measuring medication-related outcomes. Using the IHI initiative "Get Boards on Board" as a top-level leadership platform to drive improvement efforts, the hospital's team members have

begun to address medication-related issues and are using the metrics percent of patients with medication reconciliation tools, percent of patients with reconciled medications, and medication errors to assess their performance [165]. Similar metrics will surely be targeted for inclusion in national programs and will likely be the focus of much research.

The requirements of the HITECH Act will clearly create a need to monitor the effects of the use of technology in clinical work processes. The marriage of technology with human work processes may help address gaps in performance in some areas, but it may also bring about unintended consequences. For example, a related area of research is the use of pharmacists, nurse-led processes, and patients themselves in the medication ordering process. The Agency for Healthcare Research and Quality recently noted that while the importance of medication reconciliation is universally recognized, there is no consensus on the best method of carrying out the process of reconciling medications [166].

AHRQ claims a variety of methods have been studied, including having pharmacists perform the entire process, linking medication reconciliation to existing computerized provider order entry systems, and integrating medication reconciliation within the electronic medical record system [166]. Another avenue being explored is involving patients in reconciling their own medications [166, 167]. AHRQ claims that the evidence supporting patient benefits from reconciling medications is relatively scanty [166]. Interventions led by pharmacists or utilizing information technology have reduced actual and potential medication errors, but as yet, no system has resulted in an improvement in clinical outcomes. AHRQ also suggests that the effect of electronic systems and nurse-led processes has yet to be determined. The opportunities to conduct additional research within all these areas are likely to increase.

The outpatient setting is also an area that would benefit from additional research. A researcher reports that a search of AHRQ's Patient Safety Network site showed that since 2005 only about 10% of patient-safety studies have been performed in outpatient settings. The amount of research being conducted in this setting is out-of-balance

considering that there are approximately 902 million visits to U.S. physician offices each year compared to about 35 million hospital discharges [168]. Researchers note that the safety issues in ambulatory settings may differ from those in the inpatient setting [167]. For example, the outpatient settings may lack the organizational structures that enable them to address quality and safety improvement. The authors comment that "perhaps the greatest immediate challenge in addressing these safety issues is that of creating a culture of safety in the outpatient setting, which is so often fragmented and disorganized and lacking in clear leadership. In contrast, many hospitals have made large investments in patient safety teams, safety walk rounds, safety reporting systems, root-cause analysis, and culture survey. Ambulatory practices need some version of these investments – but few have made them yet" [167]. In addition, a review of AHRQ's 2008 and 2009 National Healthcare Quality Reports shows that the rate of improvement on safety is lagging in the outpatient setting. In 2008 and 2009, outpatient care improved by 1.1% and 1.4% compared to the inpatient setting's improvement rate of 2.8% and 5.8% respectively [19, 169]. Clearly there is a need for additional organizational and patient safety-related research in the outpatient setting.

In terms of medication safety in the outpatient setting a prospective cohort study showed that adverse drug events occurred in 25% of primary care patients, 13% of these events were serious, and 11% of these were preventable [170]. Similar to the inpatient setting, the causes for preventable adverse events in the outpatient setting were associated to errors at the ordering (prescribing) stage of the medication process.

It is important to understand where preventable and potential ADEs occur. Guided by theories that focus on studying system defects, researchers found that the most serious adverse drug event errors occur at the ordering stage (49%), compared to the administration (26%), dispensing (14%), and transcription stages (11%) [171]. It should not be surprising then, given that the ordering stage is a major source for error, that many studies support the view that an estimated 28% - 64% of adverse drug events are

considered preventable [172-177]. These data support the recommendations of key ADE prevention stakeholders including the American Society of Health System Pharmacists, American Nurse Association, United States Pharmacopeia, and the American Medical Association. These organizations recommend that hospitals establish a process in which nurses obtain and enter current height, weight, allergies, and home medications; prescribers enter medication orders directly into computer systems; pharmacists work in direct collaboration with prescribers; medication reconciliation is completed; medication orders are routinely reviewed and verified by a pharmacist before first doses are administered; and prescribers, pharmacists, nurses, and other workers seek resolution whenever there is any question of safety with respect to medication use [171, 178-180].

We recently conducted a study within a Midwestern health system that examined the impact of the introduction of a commercially-available HIT system on clinicians' work processes in the drug ordering stage. The study found a significant increase in the number of potential adverse drug event alerts that affected clinicians' workflow and responsibilities. Pharmacists played a key role in the disposition of these alerts. On average an additional 336 potential adverse drug event alerts per month per hospital (or approximately 10 potential alerts per day per hospital) were reviewed. From a systems standpoint, pharmacists' processes were important in identifying "true positive" potential adverse drug event alerts from among the increased number of potential adverse drug event alerts printed out by the HIT tools for review. Pharmacists effectively dispositioned approximately 94% of adverse drug event alerts as "false positive" alerts [181]. Thus, not only is the use of computerized technology a critical component of high quality care, there is an inherent process of medication error detection and prevention involving a team of healthcare professionals, conducted at the ordering stage, that is especially important in systematically reducing or eliminating adverse drug events and their outcomes.

The requirements of the HITECH Act are designed to increase the adoption and implementation of electronic-based technologies that have great potential of easing the burden of data collection upon healthcare providers. In the past, a variety of manual methods have been used to collect and study drug-related errors including chart review, self-reports, and direct observation. However, these techniques may be costly, inefficient, resource intensive, underestimate the frequency of adverse events, and be too retrospective in nature to prevent harm to patients on a real-time basis [182-186]. The HITECH Act requires adopters of technology to use "qualified" EHRs that will be able to transmit data in standardized formats. Thus, the problems of EHRs and other information systems' information exchange incompatibilities are addressed by the Act as providers will purchase and use commercially available EHR systems that have standardized core functionalities. While commercial vendors currently supply the vast majority of HIT systems being implemented in the U.S., much of the research has focused on the effectiveness of "homegrown" HIT applications developed in-house by technology champions in academic or large institutional settings. Systematic reviews highlight this gap and suggest the need for more research focused on commercial HIT applications [187-189]. For example, Chaudhry and colleagues' review of 257 HIT studies found only 9 studies that evaluated multifunctional, commercially developed HIT systems, and only 2 of these addressed medication errors directly. Both of these studies were conducted in separate departments within hospitals belonging to the same academic medical center system [187].

Potentially, the flow of standardized, high-quality data to be used for research and quality improvement purposes could be increased. As echoed by other researchers, the pace of change is slow in healthcare and the lack of longitudinal studies is problematic. The use of technology may facilitate the capture of data, consistently over long periods of time, potentially allowing more longitudinal research to be conducted. The availability of

longitudinal data would be especially attractive for use in organizational research or in research involving coordination of care that may span longer periods of time.

In total, the development of a more robust national quality measurement and reporting system as envisioned by the original members of the NQF Strategic Framework Board, the use of NQF-endorsed metrics prioritized by the NQF-endorsed national priorities, and widespread adoption and implementation of "qualified" healthcare information technologies could turn the barriers to research into accelerators. Additionally, the HITECH Act's initial requirement that technologies are used in a meaningful way to address medication safety-related issues, perhaps along with PSO baseline measurements of mediation-related patient safety events, may open the door to many more research opportunities that focus on the patient-centeredness, safety, efficiency, effectiveness, equity, and timeliness of medication delivery systems.

Given the backdrop of increasingly stringent federal requirements affecting many different types of healthcare providers there will likely be a need to study the capability of organizations, groups, and individuals to adopt and diffuse new technologies within clinical practice. Will smaller hospitals and physician groups with constrained resources be able to keep pace with regulatory requirements? Will small, rural hospitals' and physicians' lack of quality measurement and reporting experience – e.g. reporting CMS' Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) or Physician Quality Reporting Initiative (PQRI) data and measures - hinder the implementation of new regulatory requirements? Will the quality and safety of healthcare delivery improve over time? If "yes" which structures and processes of healthcare delivery systems are related to better performance? Some suggest that if small and resource-constrained providers find it difficult to survive in a rapidly changing environment there may be a contraction and/or consolidation of providers. In addition, the quasi-regulatory landscape appears to be changing as JCAHO faces increasing pressure from other organizations operating in the regulatory marketplace. JCAHO has been a primary driver of many

quality/safety initiatives for many years – what will be the effect of changes in the quasi-regulatory landscape upon quality/safety structures, processes, and outcomes?

The impending intersection of technology with leadership and clinical practice will be an interesting area to conduct research. I had the opportunity to ask Dr. Charles Denham a question related to the research conducted in this study during a nationwide Texas Medical Institute of Technology (TMIT) webinar that focused on the rollout of a leadership toolbox. I asked Dr. Denham to "comment on the usefulness and future applicability/enhancement of the 4A Model that frames the original NQF Safe Practice #1 - Create and Sustain a Culture of Safety as a "checklist" for governance/leadership"? Dr. Denham echoed the current importance of the 4A Model as a fundamental framework that focuses on board member and leadership awareness, accountability, and ability to impact "line of sight" actions [153]. He stated "it all starts with leaders". Dr. Denham highlighted Jha and Epstein's recent research that found that every board chair thought their hospital's quality safety performance was "average" or "above average" despite the reality that their hospital's performance on a key set of clinical quality members was in the bottom decile [75]. An expert on the webinar panel noted that this finding was a "staggering and sobering" comment on the state of healthcare governance. He thought a number of things contributed to the current state in which there seems to be a fundamental lack of awareness of the state of operations. For example, board members may be naïve about quality/safety measurement and how measurement can be used by leadership to identify and focus improvement initiatives. "Easy fixes", he mentioned, might include actions as simple as putting quality and safety on the agenda of every board meeting and getting board members engaged with patients and staff – two key variables studied in this research.

In terms of future enhancement and applicability, their plans include the crosswalk of the 4A framework onto the three "systems" of care that were highlighted in the TMIT webinar by both the actor Dennis Quaid and Dr. Denham - leadership, safe

practices, and technology [153]. These three systems represent core areas that provide a foundation for quality care and represent prime areas of focus for research.

In relation to the awareness and accountability domains within the 4A Model, TMIT's plans include the development of a fellowship program for young healthcare professionals that would target leadership development. The development of leadership training programs is likely a much needed piece of infrastructure given firsthand accounts of educational gaps that suggest that some of our nation's young healthcare professionals are not aware of some of the most fundamental quality and leadership safe practices. For example, during the TMIT webinar 4th year med student Daniel Henderson shared the results of a small survey he and his fellow students had conducted [153]. They found that 40% of fellow medical students had not heard of the NQF Safe Practices. This is alarming given the fundamental nature of the NQF Safe Practices, and that the doctors of the future aren't aware of these fundamental quality/safety best practices. What is the probability that future board members and senior leadership will be aware of leadership "best practices" given those professionals operating at the sharp end of care are not aware of these best practices? One expert member of the TMIT panel noted that as a former board member he was "aware" of the NQF Safe Practices, but from a board perspective was not aware of the applicability of the Safe Practices to governance and leadership activities. He also noted that board members have traditionally been members of the community that were more adept at raising money than understanding and taking action on clinical issues. Thus, many board members are not experienced in the quality and safety issues that are typically encountered in clinical settings. Obviously, board and leaderships' awareness of quality and safety fundamentals must increase. Research aimed at education initiatives and the efficacy of those initiatives will be of high importance.

In terms of safe practices – awareness is a key, fundamental concept in terms of the ability for governance and leadership to stay abreast of changes in the evidence base

regarding the best ways to deliver quality healthcare [153]. Changes in the evidence base will likely go beyond the clinical realm of the practice of medicine, but also include best practices for governance and leadership.

In terms of technology systems – governance and leadership will need to be aware of the ability of an organization to affect change [153]. As the healthcare industry adopts the use of technology – some of which has been slow to diffuse in the industry and for which adoption and diffusion is now being incentivized by the federal government - Dr. Denham hinted at the pitfalls associated to blindly adopting technology as a means to an end for quality, safety, operational issues. Rather, more importance should be placed on the establishment of engaged leaders and reliably safe processes before applying technology within systems. Governance and leadership should be aware of the ability of their organizations to execute the safe and effective adoption and implementation of technologies while avoiding unintended consequences that may arise when marrying technology with human work processes.

The introduction of more high technology into healthcare systems will need to be studied to shed light on how to effectively optimize the use of technology in the industry. As a research framework we can turn once again to the NQF Safe Practices. Within the Ability domain, the Safe Practice states that governance boards and senior administrative leaders should assess their organization's structures and systems-driving ability [28]. The technology systems sub-practice within this domain states that budgets for technologies should be regularly evaluated to ensure that patient safety impact can be optimized.

Structures and systems-driving ability also necessitates that governance and leadership regularly assess people systems [28]. The people systems sub-practice states that human resource issues should be addressed with input from assessments of other NQF Safe Practices that focus on people system capacity and competency. For example, skill mix, nurse and direct-caregiver staffing levels, intensive care unit staffing levels,

orientation, education, training, and competency are all human resource areas in which governance and leadership should be kept well-informed.

CHAPTER VI. CONCLUSION

Even ten years after the groundbreaking "To Err Is Human" report, ensuring the delivery of consistently safe care is considered a top national priority. As more robust national quality measurement, reporting, and analytical methods are being utilized to assess gaps in performance an increasingly clearer picture of quality and safety is being rendered. It is apparent that the rate of improvement is still slow. For the past two years AHRQ has determined that hospital patient safety is "lagging" and "merits urgent attention" [19, 169]. In 2008, AHRQ reported that hospital safety declined by a median annual rate of 0.9% per year over the previous 6 year period [169]. One year later AHRQ reported that 16 of 33 hospital safety measures showed worse or no change in performance [19]. It should not be surprising then that patient safety is one of the six current national core priority areas for improvement as promulgated by the National Priorities Partnership.

In an era of a multitude of financial, quality, and public safety mishaps there has been a general movement towards more regulation and oversight of the operations of many types of organizations. The Sarbanes-Oxley Act of 2002 was implemented as a regulatory approach to counter lapses in corporate integrity and governance oversight [141]. The legislation focused on stemming financial fraud in publicly held institutions. The financial corruption and resultant bankruptcy of Enron in 2001 is one of the most well-known examples of corporate lapses in management and oversight in U.S. history and was a precipitator of regulatory oversight legislation. Recent safety-related events - such as the BP oil spill disaster, mine collapses, salmonella contamination of eggs – remind us that there still exists significant variability in the awareness, accountability, ability, and actions of organizations to acquire and maintain highly reliable systems capable of preventing catastrophic safety-related events. This variability pervades even those organizations supposedly put in place to monitor or assist other organizations in carrying

out oversight activities. As Perrow and Reason suggested, in complex, technical systems there exists an inherent vulnerability that a combination of several factors may combine in such a way that accidents or harm occurs with little or no warning [139, 156, 190]. From a systems viewpoint it is important to be cognizant of the array of potential causes – emanating from both human and non-human sources – for error in systems. Leaders are responsible for managing these systems. The need to be aware of the issues they face and hold themselves and others accountable for establishing high reliability in these systems. Leadership must deploy appropriate sets of design features, structures, and processes and provide sufficient resources to ensure essential elements of quality and safety infrastructure are put in place. Leaderships' actions should ensure the detection and/or prevention of quality and safety defects that may lead to "normal" accidents. In healthcare, the complex and technical nature of the industry make it inherently vulnerable to "normal" accidents. Furthermore, the organization, delivery, and finance of healthcare services will likely increase in complexity. The quality of leaders themselves will increasingly be put to the test.

There has not been a lack of ideas to improve care systems – especially in the hospital domain. Rather, it seems as if there has been an abundance of evidence-based practices and improvement innovations that have been recognized as having sufficient face or empirically-tested value for immediate quality/safety improvement implementation. So, why aren't these ideas and known best practices being quickly diffused and implemented across care settings? The reasons are many. Within the hospital setting the delivery of care is quite complex, technical, and involves a wide variety of professionals to deliver good care. There are workforce shortages in many of the healthcare professions. Current reimbursement systems are not necessarily aligned with the production of healthy people and the benefits of improvement efforts may accrue to other actors within the healthcare system thus, the business case for improvement efforts is not immediately clear. Many in our populace are uninsured or underinsured

exacerbating revenue issues. Therefore, many organizations have difficulty in obtaining the necessary resources to initiate and sustain improvement efforts. Fortunately, some of the systemic flaws and gaps in fundamental infrastructure are being addressed. However, fully addressing these flaws and putting in place this infrastructure will take time. Unfortunately, for the individuals engaged in hospital governance and leadership the expectation for action and results is becoming more intense regardless of any real or anticipated lack of resources.

There is an increasing expectation that hospital governance and leadership be aware of the current environment and the gaps in their organizational structures and performance. They will be held accountable to hold themselves and others within their organization accountable for results. Leaders will need to accurately assess the ability of their organization to maintain current healthcare delivery services and to improve those operations that need improvement. Finally, immediate and focused action is needed to accelerate performance in targeted areas in need of improvement. In this current environment the actions of leaders are increasingly being placed under a magnifying glass as payers, purchasers, and patients scrutinize how well they address – not just quality and its subcomponent patient safety – but also the value, speed, and cost of the production of health.

It is against the backdrop of the public's knowledge of gaps in leadership performance that the quality of governance and leadership in U.S. hospitals is being increasingly scrutinized. Evidence regarding the variability in governance and leadership practices and the impact this variability has on processes and outcomes is coming to light. The simple lack of governance and leaderships' awareness of gaps in organizational performance has shocked some healthcare experts. Although government regulation may not be the best way to ensure, or enhance, a specified level of quality and safety in the healthcare industry there are those that suggest this may be inevitable [141]. Some say Sarbanes-Oxley for quality is around the corner. For example, one governance expert

recently stated that there are currently 13 states that mandate quality/safety educational requirements for board of trustee members [142]. And, eleven of these thirteen states require that board members attend programs (conferences, programs that offer continuing education credits) that focus on quality of safety.

As mentioned previously, Perrow suggested several practices and design features that could be used to address organizational aspects of reducing infrastructure vulnerabilities associated to system failures or "normal" accidents [14, 139]. Among these practices and features he noted "while one needs some, but not all redundancies, warning bells, whistles, and should try to instill safety cultures and continue to preach security vigilance – one should not let up for a moment on these – there is something else that can help, immensely: cultivation of, and openness to, the network of interested organizations and groups out there. Society should not seal organizations off from it, adversarial as they may be. Invite them in, give these stakeholders a role. Then, one is far more likely to have 'high reliability' organizations"[139]. Perhaps as a suggestion learned from Perrow, the IOM in their seminal work "To Err is Human" also suggested the use of voluntary reporting mechanisms as part of a reporting system that could be used to heighten accountability and improvement efforts [14]. It is interesting that the National Quality Forum echoes the advice of Perrow and the IOM in its current Safe Practices [28]. Within the Accountability domain of Safe Practice #1 - Leadership Structures and Systems – organizations should report adverse events to the appropriate external mandatory programs and voluntary programs as well as encourage voluntary practitioner reporting. And, organizations should publicly disclose compliance with all National Quality Forum-endorsed safe practices for pubic reporting that are applicable to the facility [14, 28].

Federal stakeholders are definitely ratcheting up hospital accountability requirements as CMS continues to add to the list of regulated structure, process, and outcomes measures that will be publicly reported. Within Iowa, hospitals have engaged in a mix of voluntary data collection and external reporting efforts. Notably, Iowa

hospitals have responded favorably to reporting a variety of quality and safety data to the Iowa Healthcare Collaborative and many of these data are reported publicly. In regards to the NQF Safe Practices a large majority of Iowa hospitals have responded to two NQF Safe Practice surveys in 2004 and 2007. The results of these surveys have been reported privately to hospitals highlighting their "perceptions" of progress on safe practices and providing comparisons to Iowa averages. A recent effort to field another NQF Safe Practice survey was met with resistance as the value of such a survey was questioned. Time will tell if the knowledge of hospital performance regarding safe practice implementation will be a valuable resource to hospital leadership.

The Iowa Healthcare Collaborative (IHC) is unique in that it fills the external stakeholder role for hospitals as recommended by Perrow, IOM, and the NQF. The IHC, in collaboration with the Iowa Hospital Association, Iowa hospitals, and a multitude of healthcare stakeholders from across the state continue to track hospital leaders' perceived progress on implementing the original 12 Institute for Healthcare Improvement (IHI) 100,000 Lives and 5 Million Lives campaign initiatives. This includes the initiative focusing on the medication reconciliation implementation to prevent adverse drug events, and also the "boards on board" initiative which targets those governance/leadership structures and processes that promote a culture of continuous improvement in quality, safety, and value.

Most recently a new project has begun that directly extends the applicability of the research presented in this study. A new "Spread Report Dashboard" has been designed to feedback to hospitals' CEO, Chief Nursing Officer, and the Quality Leader their hospitals' self-reported perception of the extent to which their hospital has deployed each of the twelve original IHI initiatives. The dashboard is designed to convey performance information over time along with comparison data that summarizes the performance of all Iowa hospitals, hospitals similar to them – in terms of hospital type (CAH, rural, rural referral, urban) – and hospitals within their geographic district. The

reporting of these performance data aligns with and enhances the current 74 process and outcome measures reported publicly by the IHC. More importantly, this "scorecard" is intended to raise leaderships' awareness of hospital performance in implementing salient, nationally important, quality improvement initiatives. The dashboard includes instructions that encourage these senior leaders to share this information with their board of trustees and other members of leadership, and encourages the leadership team to compare their "perception" of implementation performance to the "reality" of their current implementation levels. As noted by the Jha et al. study that highlighted the incongruency between hospital boards' perceptions of performance and the reality of their hospital's performance, heightening governance and leaderships' awareness of potential and actual gaps in performance may be especially valuable to these leaders as they formulate strategies and plans for improvement [75].

For those low-performing hospitals in the Jha et al. study, the lack of awareness may have been a fundamental barrier to the pursuit of excellence. Without an awareness of current performance, and the gaps associated to that performance, it would be especially fortuitous that leadership would be able to accurately assess organizational abilities, assign accountability, and act on improvement opportunities in a way that proved to be efficacious. As the results of this study suggest, governance practices that increase leaderships' awareness of current patient quality/safety issues may increase the ability of organizations to effectively execute the implementation of improvement initiatives designed to address gaps in performance.

In essence, the IHC "Spread Exercise Dashboard" program in Iowa is an example of a way in which an external stakeholder can assist organizations in spurring organizational awareness of the current environment. In addition, the provision of readily available knowledge and tools may effectively knock down the ability-related barriers to improvement efforts. A longer term goal, and the aim of applied research, will be to assist hospital leadership in the assessment of how well hospitals' perception of the

robustness of innovation implementation matches reality. Preliminary discussions and plans have detailed how the Spread Report Dashboard might evolve into a scorecard that marries specific improvement plank perception measures with existing structural, process, and outcome measures. Some of the relationships between IHI planks and actual clinical measures have already been identified and mapped out. Empirical analyses of the relationship between the "perception" of clinical performance with "real" structure, process, and outcome measures may assist governance and leadership in being aware of performance, holding stakeholders accountable for making improvements, and bolstering the ability of the organization to take action on targeted quality improvement projects.

As mentioned previously we can expect that as the U.S. quality measurement and reporting infrastructure is built and becomes more robust over the next few years there will be many more high-quality measures that are evidence-based and aligned with national priorities. Certainly, a large variety of healthcare stakeholders will be utilizing these measures to gauge the performance of healthcare delivery organizations. Healthcare organizations will be increasingly held accountable for both clinical and economic improvements in the delivery system. The increasingly complex and technical nature of healthcare operations necessitates that trustees, administrators, physicians, nurses, human resource staff, and other personnel across all departments and service lines form an effective coalition of leaders. Leadership will need to be aware of gaps in performance. They will need to be able to quickly and accurately assess organizational ability to implement changes in culture and performance. They will need to institute and manage accountability structures that are supportive of the improvement efforts. And, leadership will need to facilitate direct and specific actions that are effective in accelerating improvement.

Much of the focus on the healthcare delivery system is placed upon improvement. All stakeholders in the production of health and the delivery of healthcare should not forget that an important piece of improvement efforts is sustainability. The ongoing

control of gains is often an afterthought of improvement efforts. The sustainability of gains in improvement should yield a system that reliably delivers expected results. Governance and leadership would be wise to adopt and utilize a governance/leadership "checklist" of safe practices that can be used to accelerate the closure of gaps in performance and maintain achievements. This checklist may be an essential tool within the governance and leadership toolbox that helps them create and sustain a culture of safety throughout their organization. An evidence-based, standardized checklist like the one embodied by the National Quality Forum's first four Safe Practices could be used by healthcare leaders to ensure that the American healthcare system delivers care that is reliably safe, timely, effective, efficient, equitable, and patient-centered.

APPENDIX

Patient Safety, Culture, and Leadership Survey – Survey Items

34. On average during your hospital board meetings in 2006, what proportion of time was focused specifically on quality and safety of care issues? (Please mark one box)

0% □ 1-10% □ 11-25% □ 26-50% □ > 50% □

35. In 2006, did your board receive a formal quality and safety measurement report from your hospital? (Please mark one box)

No □ Yes □

If "Yes", how often did the board receive this report in 2006? (Please mark one box)

□ <= Monthly □ Bimonthly □ Quarterly □ Biannually □ Annually

36. In 2006, to what extent did your board interact with medical staff (other than CMO or President/Chief of Medical Staff) to establish quality and safety strategy? (Please mark one box)

Board not involved in setting quality strategy □ Not at all □ Somewhat □ A great amount □

37. In 2006, how was senior executive compensation tied to quality and safety performance? (Please mark all that apply)

Not at all □ Base compensation □ Merit increase □ Bonus or Incentive □

38. In 2006, who at your hospital had the greatest impact on quality and safety improvement efforts? (Please mark one box)

Board of Directors □ CEO/President □ COO □

CMO/Chief of Medical Staff □ CNO □ QI/QA Dir/Dept/Exec □

Physicians/Phys Champion □ Team Effort □ None □ Other □

39. In 2006, to what extent were physicians (medical staff) engaged in quality and safety improvement efforts? (Please mark one box)

Not at all □ To some extent □ To a moderate extent □ To a great extent □

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