THE USE OF RED RULES IN PATIENT SAFETY CULTURE

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ABSTRACT

This study examines the use of Red Rules in patient safety culture. The presence of a strong culture of patient safety has become a critical component in reducing medical errors. Some hospitals are implementing Red Rules as a patient safety strategy with disciplinary consequences if not followed. The use of Red Rules and patient safety culture seem to be inconsistent.

The theoretical framework for control-based and commitment-based management was utilized to develop and address four hypotheses. The hypotheses address the impact of Red Rules on 1) staff perceptions of safety, 2) frequency of events reported, 3) number of events reported, and 4) staff perceptions of non-punitive response to errors. A survey was conducted among hospitals that have taken the Agency for Healthcare Research and Quality (AHRQ) Hospital Survey on Patient Safety Culture within the past five years. T-test, chi-square, and linear regression analyses were used to test the differences between hospitals using Red Rules and hospitals that do not use Red Rules. Key hospital characteristics (bed size, teaching status, ownership and control, geographic region) were treated as covariates and tested for significant differences.

The results showed no statistically significant differences between hospitals that use Red Rules and those that do not. Likewise, none of the key hospital characteristics revealed significant differences.
This is the first quantitative study on the effect of Red Rules in patient safety culture. Healthcare managers can utilize this evidence in formulating patient safety improvement strategies within their organizations.

Keywords: Red Rules, patient safety, just culture
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TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABSTRACT</td>
<td>iii</td>
</tr>
<tr>
<td>ACKNOWLEDGMENTS</td>
<td>v</td>
</tr>
<tr>
<td>LIST OF TABLES</td>
<td>viii</td>
</tr>
<tr>
<td>LIST OF FIGURES</td>
<td>ix</td>
</tr>
<tr>
<td>LIST OF ABBREVIATIONS</td>
<td>x</td>
</tr>
<tr>
<td>1. INTRODUCTION</td>
<td>1</td>
</tr>
<tr>
<td>Statement of the Problem</td>
<td>1</td>
</tr>
<tr>
<td>Purpose of the Study</td>
<td>6</td>
</tr>
<tr>
<td>Significance of the Study</td>
<td>7</td>
</tr>
<tr>
<td>2. LITERATURE REVIEW</td>
<td>9</td>
</tr>
<tr>
<td>The Evolution of Patient Safety Culture</td>
<td>9</td>
</tr>
<tr>
<td>Culture</td>
<td>9</td>
</tr>
<tr>
<td>Safety Culture</td>
<td>10</td>
</tr>
<tr>
<td>Patient Safety Culture</td>
<td>11</td>
</tr>
<tr>
<td>Red Rules</td>
<td>19</td>
</tr>
<tr>
<td>Theoretical Framework</td>
<td>23</td>
</tr>
<tr>
<td>3. METHODOLOGY</td>
<td>28</td>
</tr>
<tr>
<td>Study Design and Data Sources</td>
<td>28</td>
</tr>
<tr>
<td>Validity and Reliability of the AHRQ Survey</td>
<td>28</td>
</tr>
<tr>
<td>Selection of Hospitals</td>
<td>30</td>
</tr>
<tr>
<td>Data Collection</td>
<td>31</td>
</tr>
<tr>
<td>Human Subject Protection</td>
<td>31</td>
</tr>
<tr>
<td>Measures and Variables</td>
<td>32</td>
</tr>
<tr>
<td>Independent Variable</td>
<td>32</td>
</tr>
<tr>
<td>Dependent Variables</td>
<td>32</td>
</tr>
<tr>
<td>Covariates</td>
<td>35</td>
</tr>
</tbody>
</table>
Analysis ................................................................................................................37

4. RESULTS ...............................................................................................................39
   Descriptive Statistics ..........................................................................................39
   Statistical Analysis ...........................................................................................41

5. DISCUSSION .....................................................................................................48
   Review of Findings ..............................................................................................48
      Hypothesis #1 .............................................................................................49
      Hypothesis #2 .............................................................................................49
      Hypothesis #3 .............................................................................................50
      Hypothesis #4 .............................................................................................51
   Assessment of Findings .....................................................................................52
   Significance of Findings ......................................................................................53
   Limitations ..........................................................................................................53
   Recommendations for Management Practice ....................................................54
   Recommendations for Future Research/Analysis .............................................55
   Summary .............................................................................................................55

LIST OF REFERENCES ..............................................................................................57

APPENDICES

   A AHRQ HOSPITAL SURVEY ON PATIENT SAFETY .......................................66
   B EMAIL INVITATION .......................................................................................72
   C RED RULES SURVEY ..................................................................................74
   D IRB APPROVAL FORM ................................................................................80
## LIST OF TABLES

<table>
<thead>
<tr>
<th>Tables</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Descriptive Statistics for Completed and Partially Completed Surveys</td>
<td>39</td>
</tr>
<tr>
<td>2 Descriptive Statistics for Completed Surveys</td>
<td>41</td>
</tr>
<tr>
<td>3 Chi-square Test for Completed and Partially Completed Surveys</td>
<td>42</td>
</tr>
<tr>
<td>4 Chi-square and Fisher’s Exact Test for Completed Surveys</td>
<td>42</td>
</tr>
<tr>
<td>5 Linear Regression Analysis of Red Rules (Model 1) and Multivariable Regression Analysis of Red Rules and Ownership and Control (Model 2) on Staff Perceptions of Safety</td>
<td>44</td>
</tr>
<tr>
<td>6 Linear Regression Analysis of Red Rules (Model 1) and Multivariable Regression Analysis of Red Rules and Ownership and Control (Model 2) on Frequency of Events</td>
<td>44</td>
</tr>
<tr>
<td>7 Linear Regression Analysis of Red Rules (Model 1) and Multivariable Regression Analysis of Red Rules and Ownership and Control (Model 2) on Percentage of Events: No Events</td>
<td>45</td>
</tr>
<tr>
<td>8 Linear Regression Analysis of Red Rules (Model 1) and Multivariable Regression Analysis of Red Rules and Ownership and Control (Model 2) on Percentage of Events: 1 or More Events</td>
<td>45</td>
</tr>
<tr>
<td>9 Linear Regression Analysis of Red Rules (Model 1) and Multivariable Regression Analysis of Red Rules and Ownership and Control (Model 2) on Staff Perceptions of Nonpunitive Response</td>
<td>46</td>
</tr>
<tr>
<td>10 Independent Samples t-test for Completed Surveys</td>
<td>47</td>
</tr>
</tbody>
</table>


LIST OF FIGURES

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The Causal Chain from Management Approach to Clinical Outcomes ...............</td>
<td>25</td>
</tr>
<tr>
<td>2</td>
<td>Example of the Causal Chain from Management Approach to Clinical Outcomes</td>
<td>26</td>
</tr>
</tbody>
</table>
## LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
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<tr>
<td>HRO</td>
<td>High Reliability Organization</td>
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<tr>
<td>IHI</td>
<td>Institute for Healthcare Improvement</td>
</tr>
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<td>IOM</td>
<td>Institute of Medicine</td>
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<td>KHA</td>
<td>Kentucky Hospital Association</td>
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<td>NQF</td>
<td>National Quality Forum</td>
</tr>
<tr>
<td>OIG</td>
<td>Office of Inspector General</td>
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<td>VHA</td>
<td>Voluntary Hospitals of America (Changed in 1994 to VHA)</td>
</tr>
</tbody>
</table>
CHAPTER 1

INTRODUCTION

Statement of the Problem

Since the landmark report from The Institute of Medicine (IOM), *To Err is Human: Building a Safer Health System* (Kohn, Corrigan, & Donaldson, 1999), the concept of patient safety has been an emerging theme in the health care literature. Estimating that medical errors kill between 44,000 and 98,000 people in U.S. hospitals each year, the report captured the attention of providers and consumers of health services. Using the lower estimate of 44,000, the report revealed that fewer people die from highway accidents, breast cancer, or AIDS than from medical errors in a year (Kohn, et al., 1999). The fact that patients suffer from preventable injuries or illnesses in the absence of safe practices and patient safety interventions could no longer be ignored. Unlike a single disaster with many deaths and injuries, many episodes of single deaths had not gained much attention until the numbers were added up and reported. The IOM Committee recommended that healthcare organizations develop an atmosphere in which patient safety is a part of the culture and is identified as an organizational goal driven by leadership.

In spite of the widespread attention the IOM report received, progress to improve patient safety has been slow and difficult to measure (Leape & Berwick, 2005; Longo, Hewett, Ge, & Schubert, 2005). For example, the most recent patient safety report published by HealthGrades (Reed & May, 2011), reflects statistics which are
discouraging. Patient safety events cost the federal Medicare program nearly $7.3 billion and resulted in 79,670 potentially preventable deaths from 2007 through 2009. In a study conducted by the Office of Inspector General (OIG) in November 2010, it was estimated that every month 15,000 Medicare beneficiaries experience a potentially preventable medical error that contributes to their death (Levinson, 2010).

Many reasons for the slow improvement of patient safety have been cited in the literature and many interventions have been attempted. Kaissi (2006) posits that the patient safety movement has lagged due to an inappropriate focus on provider and patient-level factors rather than on the organizational factors that impact patient safety. A lack of attention to workforce issues such as employee competency, retention, and satisfaction is discussed as another crucial factor for improving patient safety (Gelinas & Loh, 2004). Other initiatives have been identified as being important to improving patient safety, including the adoption of electronic health records, the implementation of computerized physician order entry, team training, full disclosure to patients after harm events, and appointments of patient safety officers in healthcare organizations. However, the importance of culture remains a prominent and recurring theme in the literature. The patient safety follow-up report from the IOM identified the blame culture in health care as a major contributor toward medical errors (Institute of Medicine [IOM], 2001). Five years after the first IOM report, the National Quality Forum (NQF) identified 30 safe practices for better health care. Creating a culture of safety was listed as number 1 on the list (Agency for Healthcare Research and Quality [AHRQ], 2005). An updated report from the NQF four years later retained creating and sustaining a culture of safety as an ongoing priority (National Quality Forum [NQF], 2009).
As hospitals have begun work toward reducing mortality and improving patient safety, they have focused on shifting from a culture of blame to a culture of safety. The Agency for Healthcare Research and Quality (AHRQ) uses the definition from the Health and Safety Commission of Great Britain, which defines a culture of safety as the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures (Advisory Committee on the Safety of Nuclear Installations [ANSCI], 1993).

The AHRQ further describes key features of a culture of safety to include:

- acknowledgment of the high-risk nature of an organization's activities and the determination to achieve consistently safe operations;
- a blame-free environment where individuals are able to report errors or near misses without fear of reprimand or punishment;
- encouragement of collaboration across ranks and disciplines to seek solutions to patient safety problems;
- organizational commitment of resources to address safety concerns.

A culture of safety has been described as an atmosphere of mutual trust in which all staff members can talk freely about safety problems and how to solve them, without fear of blame or punishment. When an organization does not have this type of culture, staff members are often unwilling to report adverse events and unsafe conditions because they fear retribution or believe reporting won’t result in change.
Although the importance of having a culture of safety has been discussed in the literature for over a decade, there is evidence that much work needs to be accomplished. In its 2011 annual patient safety report, AHRQ reported that only 44% of hospitals’ staff feel that their organization has a nonpunitive response to errors and that mistakes would not be held against them or recorded in their personnel file. Additionally, 54% on average reported no events at their hospital during the past 12 months. Rather than indicating a decrease in actual medical errors, AHRQ’s interpretation of this survey finding is that most hospitals underreport events which “means potential patient safety problems may not be recognized or identified and therefore may not be addressed” (AHRQ, 2011).

Another recent study conducted by researchers at Johns Hopkins found the most common reason among radiation oncologists for failing to use online error-reporting systems designed to improve patient safety and the quality of care was fear of getting into trouble and embarrassment (Harris, 2011). Although nearly all respondents viewed error reporting as their responsibility and had observed near-misses or errors in their clinical practice, most reported concerns about getting colleagues into trouble, liability, and embarrassment in front of colleagues as reasons for underreporting. The shift from a blaming culture is occurring at a slow pace in healthcare.

Even though there has been slow progress in safety within the healthcare field, there are examples of organizations that face challenges as complex as healthcare with low incident rates and a nearly total elimination of catastrophic events over recent years. For example, the areas of aviation and nuclear power are frequently cited for the work that has been accomplished in improving safety and reducing errors. More specifically, most improvements in aviation safety are a result of better coordination, communication,
and decision making (Pronovost et al., 2003). In aviation, individuals are encouraged to
discuss adverse events to learn from errors. Teamwork training is a formal mandate by
the United Nations for all international carriers (Pronovost et al., 2003).

It has been suggested that healthcare organizations learn from other industries
such as aviation and implement similar strategies. However, several concerns have been
expressed that the practices that have been effective in other industries will not work in
healthcare. First, humans are not machines designed and built by people that come with
an instruction manual. Second, unexpected outcomes can occur as a result of multiple
technologies being used together, especially in high-risk areas such as Emergency
Departments, Critical Care Units, and Operating Rooms. Third, healthcare organizations
are very complex, with many staff, departments, technologies, and computers being used
to care for patients (Kaissi, 2006). In spite of these observations, the IOM does not
support the claims that healthcare is unique and cannot use strategies from other
industries. The IOM also points out that these practices used by other industries have not
hindered innovation or resulted in the loss of a competitive edge (Kohn, et al., 1999).

One example of a significant patient safety improvement in healthcare has been in
anesthesia safety. Mortality from anesthesia has declined 10-fold in the past several
decades. This improvement has been a direct result of a focused effort in multiple areas:
equipment, supervision, training, and teamwork (Leape, Berwick, & Bates, 2002).

In an effort to increase patient safety, healthcare organizations are not only
focusing on a culture of safety, they are implementing new programs to develop and
implement safe practices and to train healthcare workers in patient safety (Leape et al.,
2009). Unfortunately, there has been a lack of consistency and agreement about which
practices will most improve safety (Leape, Berwick, & Bates, 2002). For example, an
error-reduction strategy borrowed from the aviation, manufacturing, and nuclear power industries, known as Red Rules, is now being tried in hospitals. AHRQ defines Red Rules in the following manner: “Rules that must be followed to the letter. In the language of non-health care industries, red rules ‘stop the line’. In other words, any deviation from a Red Rule will bring work to a halt until compliance is achieved. Red Rules, in addition to relating to important and risky processes, must also be simple and easy to remember” (Patient Safety Network Glossary [PSNet], 2011). Red Rules are rules that cannot be broken. They are standards that should be used every time a specific process is used except in rare or urgent situations. If broken, they can lead to serious disciplinary action.

There are many rules, regulations, standards, policies, and procedures in healthcare organizations. Unlike these, Red Rules are to always be supported by the entire organization. Therefore, if a staff member calls for work to cease for the sake of patient safety based on a Red Rule, management must be supportive. The goal is for Red Rules to foster a culture of patient safety.

However, there is little evidence that Red Rules lead to safer care for patients. Further, the use of Red Rules seems to be blaming and punitive, which is in conflict with the attributes of a patient safety culture, which are characterized by trust and transparency. The concept of a culture of patient safety and the use of Red Rules seem to be inconsistent.

Purpose of the Study

The purpose of this study is to explore the effects of Red Rules on staff perceptions of safety, frequency of events reported, number of events reported, and staff
perceptions of non-punitive response by hospital management. The theoretical framework for control-based and commitment-based management outcomes will be used to frame the hypotheses. The independent variable in this study is the implementation of Red Rules. The study compares a group of general, acute care hospitals who have implemented Red Rules with a similar group that have not implemented Red Rules. These hospitals will be evaluated using metrics from the AHRQ Hospital Survey on Patient Safety Culture.

This study is designed to answer the following questions:

1. Do staff perceptions of safety diminish following the implementation of Red Rules?
2. Does the frequency of events reported decrease following the implementation of Red Rules?
3. Does the number of events reported decrease following the implementation of Red Rules?
4. Do staff perceptions of non-punitive response diminish following the implementation of Red Rules?

Significance of the Study

For over a decade, health professionals have been aware of the urgent need to improve patient safety in hospitals. In spite of an upsurge of patient safety initiatives, progress has been slow and the results have been minimal. Many interventions are being tried in hospitals without the benefit of evidence-based proof of their effectiveness. It is important that healthcare professionals use evidence-based research to guide them in determining the most effective strategies for patient safety improvement. Since a culture
of safety has been determined to be a critical element in the improvement of patient safety, it is important that strategies that support a strong patient safety culture are implemented. Conversely, it is equally important that strategies that harm a culture of patient safety be avoided. There is very little quantitative evidence in the literature about the impact of Red Rules on patient safety culture. Determining whether the implementation of Red Rules is an effective strategy can inform health professionals who are working to improve patient safety, an important topic in healthcare research.

The next chapter will discuss the concept of culture and its impact on organizations. The subcomponents of safety culture and patient safety culture will be described, as well as the evolution from a “blaming culture” to a “blameless culture” to a “just culture”. The use of Red Rules as an intervention to improve patient safety will also be discussed, along with the theoretical framework utilized to formulate the hypotheses for the study.
CHAPTER 2

LITERATURE REVIEW

The Evolution of Patient Safety Culture

This chapter describes the evolution of patient safety culture in healthcare, beginning with a broad description of culture and the subcomponent, patient safety culture. Within the spectrum of patient safety culture, the pendulum swing from a blaming culture to a blameless culture to a just culture is described. A new strategy in patient safety, Red Rules, is then discussed, as well as the theoretical framework and resulting hypotheses.

Culture

The culture of an organization is an intangible concept that exhibits itself in tangible ways. Culture is defined in various ways, including:

- “The way we do things around here.” (Deal & Kennedy, 1982, 2000, p.4)
- The personality of an organization (Atchison & Carlson, 2009)
- A shared set of attitudes, beliefs, or norms.

A more formal definition is provided by Schein (2004, p. 18). He defines culture as “a pattern of shared basic assumptions that was learned by a group as it solved its problems of external adaptation and internal integration, that has worked well enough to
be considered valid and, therefore, to be taught to new members as the correct way to perceive, think, and feel in relation to those problems.” Culture within organizations is evident at three levels. The first level, known as artifacts, is within the visible structures and processes of the organization, including its architecture, technology, and products. It is also displayed in the dress code, myths and stories told about the organization, and through its rituals and ceremonies. The second level reflects an organization’s beliefs and values espoused in its stated mission, vision, values, goals, and strategies. The third level includes those unconscious beliefs, perceptions, thoughts, and feelings that drive the actions of a group (Schein, 2004). Since culture permeates organizations at every level, it is key to achieving patient safety in hospitals.

Since culture is defined by Schein (2004) as a learned behavior that is taught to others, it is possible for healthcare organizations to reshape their culture to a safety culture. As evidence mounts for the importance of improving patient safety through culture change, hospitals are implementing strategies to move toward a safety culture.

Safety Culture

Safety culture is a component of organizational culture (Vogus, Sutcliffe, & Weick, 2010). Originating outside health care, safety culture is a key feature of organizations that consistently minimize harm events while conducting complex and hazardous work. Known as high reliability organizations (HROs), they are committed to safety at all levels, from frontline workers to executives (PSNet, 2011). Safety culture is described as “more than a group of individuals enacting a set of safety guidelines--it is a group of individuals guided in their behavior by their joint belief in the importance of safety, and their shared understanding that every member willingly upholds the group’s
safety norms and will support other members to that common end” (Merritt & Helmreich, 1996, p. 2).

There are multiple sources of evidence pointing to the effectiveness of having a safety culture within an organization. This is especially important in industries with high-risk, error-prone activities. The fields of aviation and nuclear power have achieved successful safety outcomes by recognizing that most errors are due to problems with systems rather than people. When this concept was accepted by the healthcare industry, it was considered a welcome change from blaming individuals involved in medical errors (Walton, 2004).

**Patient Safety Culture**

Patient safety culture is a specialized component of safety culture within the healthcare industry. It is a relatively new concept in the healthcare industry. The culture within hospitals plays an important role in the effectiveness of patient safety initiatives. In *To Err is Human*, the IOM defined patient safety as the prevention of harm to patients, where harm can occur through errors of commission and omission. It further reported that “a strong culture of safety . . . is viewed by many in the safety field as being the most critical underlying feature of their accomplishments” (Kohn, et al., 1999, p. 160). A study published in 2005 concludes that senior leader support of a culture of learning and prevention, coupled with an organizational structure that supports collaboration, provides a culture of patient safety, as well as a positive financial return (Odwazny, Hasler, Abrams, & McNutt, 2005).

Although evidence for the importance of a patient safety culture has been established, hospitals have struggled to achieve it. Barriers to achieving a culture of
safety in health care have been examined in several studies. These barriers are broad in nature, ranging from technological advances to system complexity. However, most barriers are rooted in cultural traditions.

For example, as researchers look for evidence that safety in healthcare has improved over the past decade, they are finding that the risk for harmful events may be increasing (Chassin & Loeb, 2011). Advances in technology, new drugs, and procedural innovations are occurring at a rapid pace. These advances add layers of complexity to the delivery of care. Complexity increases the chances of errors. Patients are sicker, but lengths of stay are shorter. Treatments once provided on an inpatient basis are now performed in outpatient settings. The authors describe an intersection of two patient safety issues: highly vulnerable patients and complexity of care. Safety culture is seen as one of three key requirements for achieving high reliability (leadership and process improvement are the other requirements). Trust in the workforce is described as essential for problem identification, reporting, and improvement. Trust is a key component of culture.

Autonomy and individual accountability are pervasive characteristics of the professional culture of medicine. These attributes contribute to safety risks by 1) supporting a piecemeal approach to improvement in systems without addressing root causes and 2) approaching improvement in an incomplete, ineffective, and fragmented way due to the professional culture of medicine (Vogus, et al., 2010). The healthcare delivery system is affected by physicians’ efforts to retain control over their work, resulting in inconsistent patient care, which inhibits a patient safety culture. The lack of teamwork as a result of the established hierarchy in the field of medicine has been a long-standing barrier to patient safety culture. Embedded in these behaviors is also the
unwillingness to acknowledge human fallibility, contributing further to the lack of progress toward patient safety. The legal system and litigious society in the United States prohibit health providers from admitting errors, an important theme in patient safety culture. These behaviors and beliefs are deeply rooted through years of medical school training (Akins & Cole, 2005).

Although many barriers have been discovered and discussed in the literature, the use of punishment for errors has been acknowledged as the single greatest barrier to error prevention in healthcare (Leape, 1997). This action has been labeled a blaming culture.

Blaming culture. In the past, the traditional response to medical errors in healthcare has been to identify and blame an individual when an error occurs. Frequently referred to as the “name, blame and shame” approach, those most directly involved in the event are singled out for punishment. This response leads to fear of punishment which inhibits reporting. This results in a cycle in which more errors result because the organization is not aware of errors and does not have the opportunity to learn from its errors. Another outcome of blaming and the fear it generates is a loss of innovation and creative problem-solving. Workers that are fearful do not take risks, which are a key component of innovation. Without innovation, problems aren’t solved and errors continue (Paul, 1997). Blaming individuals is a short-term fix for a long-term systems solution. Without a permanent solution, additional quick fixes (blaming) are used (Paul, 1997). This type of approach is counterproductive to a culture of improving patient safety.

A prominent characteristic of a blaming culture is the expectation of perfection from individuals (Whittington & Cohen, 2004). In this setting, workers are to never make mistakes. If a mistake is made, it is the worker’s fault and he or she is blamed and
shamed for the error. This culture is based on unrealistic expectations of perfection, particularly at a time when healthcare has grown to be so complex. Additionally, healthcare professionals are educated to assume personal responsibility for the care of patients. For example, physicians are taught that they are the “captain of the ship” in the operating room. This is reinforced by medical and nursing curricula, as well as the U.S. legal system which holds individuals accountable for malpractice (Wachter, 2004). This type of individualistic thinking, rather than one of teamwork and systems thinking, supports a blaming culture.

Another characteristic of a blaming culture is the use of a commonly used tool in hospitals, the incident report. This form is used to track events individually. Incident reports focus on a specific event and the individuals involved rather than the circumstances and systems surrounding the event. Opportunities for learning to prevent future events are frequently lost to this reporting system (Morath & Leary, 2004). Traditional incident reporting systems are routinely linked to the human resources disciplinary action function. Often, disciplinary action is taken against the individuals involved because the incident is reported as, and interpreted as, human error. Because human resource disciplinary actions are considered confidential to protect the individuals involved, an atmosphere of secrecy is created around the incident. If there is potential legal involvement, another layer of secrecy is created. This results in little opportunity for learning and prevention of similar future incidents.

An awareness of errors within an organization is key to improving patient safety. This awareness is not possible if workers are punished for unintentional mistakes. A blaming culture that punishes workers rather than improving systems incentivizes workers to hide rather than to report errors. In landmark testimony to a Congressional
Committee, Leape (1997) asserted that workers only report errors that they cannot hide. Within highly punitive organizations, he estimated that 95% of errors are not reported. Additionally, this prevents organizations from receiving information needed to identify unsafe systems and create safer ones. Leape (1997) also testified that organizations that have moved from a blaming culture and made reporting safe for workers have experienced large increases in reporting.

Another national leader in patient safety, James P. Bagian, M.D, and former astronaut and investigator for the National Aeronautics and Space Administration, also testified before a Senate subcommittee. He contends that a blaming culture is a major stumbling block to safety improvement, discouraging the identification of problems and providing disincentives for reporting (Bagian, 2003).

The IOM declared that “the biggest challenge to moving toward a safer health system is changing the culture from one of blaming individuals for errors to one in which errors are treated not as personal failures, but as opportunities to improve the system and prevent harm (IOM, 2001, p. 79). With the growing evidence to correct the atmosphere of a blaming culture, many hospitals moved to a blameless culture to promote reporting of errors in order to improve patient safety. The goal was a transparent culture, with open communication between providers and patients to identify, manage, mitigate, or eliminate errors and near misses (Frankel, Gandi, & Bates, 2003).

Blameless culture. In an effort to move from a blaming culture, hospitals strived to implement a blameless or blame free culture. The blameless culture acknowledged that a large proportion of unsafe acts were honest errors, recognized as slips, lapses and mistakes that even the best people can make. These acts were not considered to be
blameworthy. It was also believed that there was little remedial or preventative benefit to punishing individuals who committed the errors. The goal of this move was to create a culture of trust and transparency where errors could be reported and reviewed without fear of punishment or shame (Pizzi, Goldfarb, & Nash, 2001). By creating a safe environment for reporting errors, the examination and correction of errors could prevent future events. Using the aviation industry as a model, some hospitals established anonymous report mechanisms for reporting of errors and near misses. This approach has been successful in aviation, resulting in improved safety for the industry.

Unfortunately, hospitals began to realize that the concept of a blameless culture had two serious weaknesses. First, it did not address instances in which individuals willfully and/or repeatedly engaged in dangerous behaviors that others would recognize as being likely to increase the risk of an adverse outcome. Second, it did not distinguish between culpable and non-culpable unsafe acts. Although the blameless culture supported workers in reporting errors, it did not include warranted punishment (GAIN Working Group E, 2004).

Evidence of these flaws in a blameless culture was reflected in a survey conducted by the Institute for Safe Medication Practices (ISMP, 2001). Hospital workers interpreted the swing from a blaming culture to a blameless culture with concerns in this survey of 1,255 participants. About 15% of those responding believed that a blameless culture excuses poor performance and absolves staff of responsibility for patient safety. Twenty-six percent of nurses feared increased carelessness if workers know they will not be punished for mistakes. The inability to terminate problem employees was another concern raised by 19% of nurses in this survey. Issues with evaluating competency in a blameless culture were also expressed. Twenty-two percent of frontline staff believed
that a blameless culture may be detrimental to an organization (ISMP, 2001). The study exposed the limitations of a blameless culture and the need for hospitals to find a place between a blaming culture and a blameless culture to address patient safety. A middle ground is needed that includes accountability. The middle ground is a just culture.

*Just culture.* The need for personal accountability has been identified as a necessary component of a well-rounded patient safety culture. In the literature, this emerging theme is being called a “just culture” (Marx, 2001). A just culture has been defined by AHRQ as a culture that “recognizes that individual practitioners should not be held accountable for system failings over which they have no control. A just culture also recognizes many individual or active errors represent predictable interactions between human operators and the systems in which they work. However, in contrast to a culture that touts ‘no blame’ as its governing principle, a just culture does not tolerate conscious disregard of clear risks to patients or gross misconduct (e.g., falsifying a record, performing professional duties while intoxicated). In summary, a just culture recognizes that competent professionals make mistakes and acknowledges that even competent professionals will develop unhealthy norms (shortcuts, “routine rule violations”), but has zero tolerance for reckless behavior” (PSNet, 2011).

Several authors have written about the need to balance a culture of patient safety with a just culture, citing the importance of combining openness that is not punitive with personal accountability (Conner et al., 2007; Frankel, Leonard, & Denham, 2006; Gorzeman, 2008; Wachter & Pronovost, 2009; Walton, 2004). Several models for implementation of a just culture have recently emerged in the literature. For example, the Institute for Healthcare Improvement (IHI) endorses the concept of a fair and just culture.
supported by appropriate policies and procedures and accountability at the individual and organizational levels (Conway, Federico, Stewart, & Campbell, 2010). Physician-specific accountability strategies have been discussed as well (Goldmann, 2006; Leape & Fromson, 2006). Goldman (2006) posits that consequences should be in place for repeated failures to follow clear rules when well-functioning systems are in place. More specific recommendations are suggested by Leape & Fromson (2006), with a four-step model system: 1) adopting standards, 2) requiring compliance, 3) monitoring performance, and 4) responding to deficiencies. They call on involvement at the national level to implement this model.

However, the model receiving the most attention is James Reason’s Unsafe Acts Algorithm (Reason, 1997). Healthcare organizations are beginning to use this model to determine how system issues and human factors contribute to events (Wachter & Pronovost, 2009). The model provides a decision tree for determining responsibility for unsafe acts when analyzing an error or adverse event. Questions included in the algorithm help the user determine the range of responsibility on a 9-point scale, ranging from egregious, intentional acts involving sabotage or substance abuse to system-induced or blameless errors (Reason, 1997).

The just culture’s goal is to determine the consequences of an unsafe act fairly based on an individual’s accountability and responsibilities within the context of the environment. Four key categories of fault in a just culture are:

1. Human error: Unintentional slips, lapses, and mistakes;
2. Negligent conduct: Failure to exercise care expected of a prudent worker;
3. Reckless conduct: Conscious disregard for a known risk;
Additionally, the following key questions are used to determine accountability of an individual’s actions:

1. Were the actions intended?
2. Was the individual under the influence of unauthorized substances?
3. Did the person knowingly violate existing policies, procedures, or expectations?
4. Would another individual in the same situation perform in the same manner?
5. Does the individual have a history of unsafe acts (Reason, 1997)?

There are many benefits of a just culture. First, a just culture can lead to increased reporting of events and near misses, providing opportunities to prevent similar events from happening in the future. Second, a just culture builds trust throughout the organization by establishing clear boundaries for acceptable and unacceptable behavior. It also sends a message to front line workers that safety is more important than assigning blame. Third, a just culture improves operational management by establishing clear expectations for job performance and consequences for deviating from those expectations (GAIN Working Group E, 2004).

Red Rules

In the search for finding a balance between a blaming culture and a blameless culture, some hospitals have implemented Red Rules. Although used in other industries such as aviation and nuclear power, Red Rules are new in healthcare. The healthcare field is governed by many rules and regulations from various sources: government, payers, and accrediting bodies. However, Red Rules differ from these types of rules in
several ways. Developed by E.C. Simpson, a retired executive from the nuclear industry, Red Rules are used to reduce the probability of harm to patients (Bisognano, Lloyd, & Schummers, 2007). Red Rules should be associated with acts that have the highest level of risk to patient or employee safety if not performed exactly each and every time (Clapper, 2011). The most frequently cited attributes of Red Rules are:

1. They are few in number;
2. They are clear and obvious;
3. They are firm in identifying the consequences for noncompliance;
4. They focus on decision-based rather than skill-based activities (Bisognano, et al., 2007).

Several examples of Red Rules are found in the literature. The most commonly discussed Red Rules are:

1. Timeouts shall be performed prior to all procedures.
2. Two forms of identification shall be used to identify patients before taking action with a patient or patient information.
3. All specimens shall be labeled at the patient’s bedside.

Other examples include not only organizational but department-specific Red Rules. For example, use of standard lifts is a Red Rule in one hospital’s Rehabilitation Department. In some Respiratory Departments, there is a Red Rule that ventilators shall be plugged into red emergency outlets (Bisognano, et al., 2007).

The early literature on Red Rules contains some qualitative studies describing the Red Rule implementation process within organizations. For example, a case study describing the process at Sentara Norfolk General Hospital describes the use of behavior based expectations balanced with Red Rules, with the effectiveness described as “staff
has generally perceived that the process is fair” (Yates, Hochman, Sayles, & Stockmeier, 2004, p. 537). Another article about Sentara’s program describes Red Rules as “among the most important elements of the culture of safety” (Sipkoff, 2005, p.1). Failure to observe the Red Rules results in written reprimands and counseling to achieve 100% compliance. In a later publication about the same organization, strategies are discussed to avoid the perception that Red Rules are punitive. The authors advise that introducing Red Rules without a culture that supports disclosure and questions could be counterproductive (Hines, Luna, & Lofthus, 2008). A different hospital describes the implementation of Red Rules into a safety culture as a difficult process. However, it does not include a discussion on outcomes (Sharf, 2007).

Articles containing quantitative outcomes for the use of Red Rules are minimal; however, those that exist focus on reductions in reported errors and near-misses. In one health system, reports of errors and near-misses almost tripled the first year after implementing a patient safety program; however that number dropped in half the following year (Weinstock, 2007). Leaders in the organization are certain that errors haven’t dropped that steeply. Rather, they believe that staff are less vigilant in reporting incidents (Weinstock, 2007). Another health system reported a 57% decline in sentinel events and near misses following the implementation of a patient safety program and an 89% decrease in preventable sentinel events (Carlton, 2004). A sentinel event is an adverse event which is neither expected nor acceptable, in which a patient experiences death or serious harm. The word sentinel reflects the egregiousness of the event and the likelihood that investigation will reveal serious problems in current policies or procedures (PSNet, 2011). Events are called sentinel because they reflect the need for immediate investigation and response.
A two-tier study reporting the effectiveness of Red Rule education reflected low recall of educational efforts within a hospital (O'Neil, Speroni, Dugan, & Daniel, 2010). The first tier of the study measured the effectiveness of education within 13 hospital departments. Of 128 participants, 61% provided a correct or partially correct definition for Red Rule 1 and 12% for Red Rule 2. The first Red Rule required the use of two patient identifiers prior to an action or procedure. The second Red Rule made it mandatory to confirm the correct action or procedure prior to beginning. The second tier of the study quantified factors that contributed to safety events within the hospital. Thirteen nurses violated a Red Rule and were asked to identify the contributing factors. The frequency of factors was interruptions (77%), rushing (69%), inadequate staffing (39%), fatigue (31%), and poor communication (38%). None of the thirteen respondents reported an awareness of committing an error at the time of the event. The authors conclude that there is a need to educate health care providers about error reporting. They also discuss the importance of leadership communication to ensure providers that they will be protected if they report errors. Finally, they state that organizations must create nonpunitive environments where employees feel supported.

The use of Red Rules seems to have taken a similar journey as that of patient safety culture. The early literature indicates a more punitive approach. In one example, Red Rules, if broken, result in disciplinary actions including censure and possible termination of employment (Frankel et al., 2006). In a later example, Red Rules are described as inviolate in nature with no excuses for violations accepted (Strong red rules, 2011). However, the most recent literature describes Red Rules as a nonpunitive communication tool and a method of support for front-line staff. There is emphasis on the use of thorough communication throughout an organization when implementing Red
Rules. The purpose and intent must be thoroughly explained and understood for Red Rules to have the intended results. They are used to support front line workers to stop the line when a Red Rule is being violated. Red Rules are not described as a punishment program or disciplinary process but a safety improvement tool (Grissinger, 2012).

In summary, patient safety culture has been evolving since the IOM’s report on errors in healthcare (IOM, 1999). Grounded on a tradition of a blaming culture, when faced with the reality that a blaming culture inhibits patient safety, hospitals worked to shift to a blameless culture. When flaws with a blameless culture became apparent, hospitals moved to a more balanced position by implementing the concept of a just culture. A tool used in other high risk industries, Red Rules, is being tried by hospitals to improve safety through accountability. However, the evidence of the effectiveness of Red Rules is lacking in the literature. The existing literature describes steps for implementation; however, quantitative studies describing the impact of Red Rules are limited to the impact on number of errors reported and the effectiveness of education about Red Rules.

Theoretical Framework

Since the concept of culture is closely linked to patient safety, models used to examine culture were considered for this study. The most commonly cited was the Competing Values Framework (Quinn & Rohrbough, 1983). This has been used in many studies to examine the relationship between culture and organizational effectiveness, such as patient safety (Davies, Mannion, Jacobs, Powell, & Marshall, 2007; Singer et al., 2009). The framework reflects two axes: one indicates whether an organization is focused internally or externally; the other axis reflects dimensions between flexibility and
control. Of significance to this study is the dimension of hierarchical culture which emphasizes control and formal decision-making, with enforcement of rules and regulations. This seems to be consistent with the implementation of Red Rules. Opposite the hierarchical culture is the group culture which values human relations, informal communication, and decentralized decision-making; this dimension is consistent with a patient safety culture. However, the other two dimensions of the model (Developmental and Rational) do not seem to address the variables of patient safety and Red Rules. A recent study describes this as a limitation of the Competing Values Framework within the context of patient safety (Khatri, Brown, & Hicks, 2009). This study suggests that a model comparing the characteristics of the two dimensions, Hierarchical and Group, be used instead. This model, which is based on McGregor’s Theory X and Theory Y management theories (McGregor, 1985), was first introduced by Khatri in 2006. It proposes linkages between management philosophy and clinical outcomes by comparing control-based management outcomes with commitment-based management outcomes (Khatri, Baveja, Boren, & Mammo, 2006). Control-based management assumes that people are incapable of self-discipline and can’t be trusted. Therefore, they must be monitored and controlled to ensure that they behave. The consequences of this type of management include low morale, a climate of mistrust, employee turnover and absenteeism, and a sense of indifference toward work. This approach affects clinical outcomes by decreasing the detection and reporting of errors and by reducing the motivation and effort of employees. The authors describe a cycle in which errors lead to more control and monitoring of employees, which increases a blame culture, resulting in punishment, which leads to hiding of errors and lack of learning from mistakes, resulting in more errors (Khatri, et al., 2006).
The opposite approach, commitment-based management, assumes that people work best when they are fully committed to the organization, are trusted, and are allowed to work autonomously. The results are actively engaged employees who go beyond the call of duty and seek additional responsibility. A different cycle is described in which staff report errors and learn from mistakes in an open and trusting environment, resulting in a highly motivated and self-directed staff (Khatri, et al., 2006).

A later study tested this model and found the control-based management approach to be associated with a culture of blame. In contrast, the commitment-based approach was associated with a culture of learning from mistakes, camaraderie, and motivation (Khatri, Halbesleben, Petroski, & Meyer, 2007). The framework of control-based and commitment-based management is viewed as respectively overlaying the culture of blame and culture of safety in the most recent study by Khatri (2009). The model also describes the link from management approach to clinical outcomes (Khatri, et al., 2006).

<table>
<thead>
<tr>
<th>Management Approach</th>
<th>HR Management Practices</th>
<th>Employee Behaviors</th>
<th>Clinical Outcomes</th>
</tr>
</thead>
</table>

Figure 1. The Causal Chain from Management Approach to Clinical Outcomes.

Note: Adapted from “Medical Errors and Quality of Care: From Control to Commitment” by N. Khatri, A. Baveja, S. Boren, and A. Mammo, 2006, California Management Review, 38(3), p. 122-123. Copyright 2006 by The Regents of the University of California. Reprinted by permission of the University of California Press.

Applying Khatri’s model to this study, the management approach is represented by the implementation of Red Rules. In response to this, the human resource management practice of the disciplinary process, including suspension and termination, is
enforced. From this practice, employees react with behaviors that are counter-productive to a patient safety culture. These behaviors include hiding errors and overlooking unsafe conditions. The final step in the chain is clinical outcomes. In this scenario, clinical outcomes will worsen as a result of hidden errors and unaddressed, unsafe conditions, resulting in increased morbidity and mortality.

<table>
<thead>
<tr>
<th>Management Approach</th>
<th>HR Management Practices</th>
<th>Employee Behaviors</th>
<th>Clinical Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red Rules</td>
<td>Disciplinary Process</td>
<td>Hiding/Overlooking Errors</td>
<td>Increased Morbidity/Mortality</td>
</tr>
</tbody>
</table>

Figure 2. Example of the Causal Chain from Management Approach to Clinical Outcomes

Using the theoretical framework for control-based and commitment-based management outcomes, it seems that Red Rules will be viewed as punitive and perceived as a form of control-based management. As a result of creating a punitive environment with the establishment of Red Rules, the frequency and number of reported errors will decrease because staff will fear the consequences of reporting errors. Finally, staff will perceive that the organization’s response to errors is punitive, rather than non-punitive.

The study will test the following hypotheses:

1. Staff perceptions of safety will diminish following the implementation of Red Rules;
2. The frequency of events reported will decrease following the implementation of Red Rules;

3. The number of events reported will decrease following the implementation of Red Rules;

4. Staff perceptions of non-punitive response will diminish following the implementation of Red Rules.
CHAPTER 3

METHODOLOGY

Study Design and Data Sources

This study compared four measures of patient safety culture among two groups of hospitals that use the AHRQ Hospital Survey on Patient Safety Culture. The two groups consisted of a study group of hospitals that have implemented Red Rules as a patient safety strategy; the comparison group was comprised of hospitals that have not implemented Red Rules. The four measures used from the AHRQ survey are:

- Staff perceptions of safety;
- Frequency of events reported;
- Number of events reported;
- Staff perceptions of nonpunitive response.

Validity and Reliability of the AHRQ Survey

The AHRQ survey is sponsored by the Quality Interagency Coordination Task Force and is funded by AHRQ (See Appendix A). The assessment tool was developed using three sources of information: 1) scientific literature on safety, errors, accidents, and error reporting, 2) interviews with hospital employees and managers to identify key patient safety and error reporting issues, and 3) other published and unpublished safety culture assessment tools (Sorra & Nieva, 2004). The reliability and validity of the survey was established through a psychometric analysis consisting of numerous techniques,
including item analysis, content analysis, exploratory and confirmatory factor analyses, reliability analysis, composite score construction, correlational analysis, and analysis of variance. The survey pilot data was gathered from 1,437 hospital staff in 21 hospitals in the United States. Based on the analyses, the resulting 12 dimensions and 42 items were shown to have acceptable levels of reliability (Sorra & Nieva, 2004).

The survey was first released in November 2004 to assess hospital staff opinions on patient safety issues, medical errors, and event reporting. The tool has 42 items that measure 12 areas of patient safety culture. These areas are:

1. Communication openness.
2. Feedback and communication about error.
3. Frequency of events reported.
4. Handoffs and transitions.
5. Management support for patient safety.
7. Organizational learning—continuous improvement.
8. Overall perceptions of patient safety.
10. Supervisor/manager expectations and actions promoting safety.
11. Teamwork across units.
12. Teamwork within units.

Two additional questions are included in the survey. One asks respondents to provide an overall grade on patient safety for their work area/unit. The other asks for the number of events reported over the past 12 months (Sorra & Nieva, 2004).
Selection of Hospitals

This study was designed for hospitals that have taken the AHRQ Hospital Survey on Patient Safety Culture within the past five years (2007 through 2011). The study group consisted of hospitals that have implemented Red Rules as a patient safety strategy and the comparison group consisted of hospitals that have not implemented Red Rules. Since hospitals that have implemented Red Rules are limited and difficult to identify, hospitals involved in structured patient safety initiatives likely to use strategies such as Red Rules were targeted for participation. The invitations (Appendix B) were distributed via e-mail with a link to the web-based Red Rules survey (Appendix C), to the VHA Central Target Zero Patient Safety Collaborative, Kentucky Hospital Association (KHA) Accreditation, and IHI Patient Safety Executive listserves. These groups were initially selected for inclusion due to their high level of patient safety initiatives and their willingness to distribute the survey. The e-mails were addressed to individuals responsible for patient safety activities within acute, general care hospitals involved with patient safety initiatives.

To increase the number of hospitals in the sample, snowball sampling was also conducted among colleagues. This method is useful when the studied characteristic, in this study—Red Rules, is rare or new. Colleagues working in hospitals that are using Red Rules were asked to identify other hospitals that use Red Rules for potential participation in the study.

A reminder e-mail was sent two weeks after the original invitation was distributed. Due to a low response rate, the survey deadline was extended and the survey was also sent to patient safety officers identified through state patient safety
organizations. In addition, participants were offered a token of appreciation (a 4 GB USB flash drive) and a chance to win a Visa gift card for completing the survey.

Data Collection

From the responses received, hospitals were grouped into those that have implemented Red Rules and those that have not. Within the group of hospitals that has implemented Red Rules, AHRQ survey results from six months to two years after implementing Red Rules were used for the study. Hospitals that implemented Red Rules less than six months, or longer than two years, after completing the AHRQ survey were not included in the study. This was done to eliminate time frames that may be too short or too long to capture the effect of Red Rules. Since hospitals do not necessarily administer the survey every year, the survey which falls within the established time frame (6 months to two years after implementing Red Rules) was used for the study. This was possible since the survey questions have not changed over the years. For hospitals that have not implemented Red Rules, the most current survey was used in the study.

The data were downloaded from Zoomerang into Excel. From Excel, the data were imported into SPSS Statistics 17.0.

Human Subject Protection

The Institutional Review Board of the University of Alabama at Birmingham reviewed and approved the research (Appendix D). This study employs the analysis of anonymous survey responses; therefore, it does not involve risk to human participants.
Measures and Variables

Independent variable

The independent variable is a dichotomous measure identifying whether Red Rules are used, or not used, by a hospital. This was obtained through the web-based survey.

Dependent variables

The dependent variables in this study were measured by four questions from the AHRQ Hospital Survey on Patient Safety Culture. They are:

- Staff perceptions of safety. AHRQ defines this as the extent to which procedures and systems are good at preventing errors and there is a lack of patient safety problems. Participants are asked to respond to these statements using a 5-point Likert scale ranging from Strongly Disagree (1) to Strongly Agree (5). This variable is calculated by averaging the percentage of positive responses to each item measuring perceptions of patient safety. Percent positive is the percentage of positive responses (e.g., Agree, Strongly agree) to positively worded items (e.g., “Patient safety is never sacrificed to get more work done”) or negative responses (e.g., Disagree, Strongly disagree) to negatively worded items (e.g., “We have safety problems in this unit”). The statements comprising the composite question for staff perceptions of safety are:

  1. Patient safety is never sacrificed to get more work done;
2. Our procedures and systems are good at preventing errors from happening;
3. It is just by chance that more serious mistakes don’t happen around here (reverse worded); and
4. We have patient safety problems in this unit (reverse worded).

- Frequency of events reported. This is defined by AHRQ as the extent to which mistakes of the following types are reported: (1) mistakes caught and corrected before affecting the patient, (2) mistakes with no potential to harm the patient, and (3) mistakes that could harm the patient but do not. Respondents are asked to respond to these items using a 5-point Likert scale ranging from Never (1) to Always (5). A composite score is calculated by averaging the percentage of positive responses to the three questions making up the composite of Frequency of Events Reported. Percent positive is the percentage of positive responses (e.g., Most of the time, Always) to the following questions:
  1. When a mistake is made, but is **caught and corrected again before affecting the patient**, how often is this reported?
  2. When a mistake is made, but has **no potential to harm the patient**, how often is this reported?
  3. When a mistake is made that **could harm the patient**, but does not, how often is this reported?

- Number of events reported. Respondents are asked to indicate the number of events they have reported over the past 12 months. Response choices are:
1. No events
2. 1 to 2 events
3. 3 to 5 events
4. 6 to 10 events
5. 11 to 20 events
6. 21 events or more

The respondents answered this question based on how their AHRQ survey vendor provided the data. Some responded with answers as percentages; others with raw numbers. To provide an accurate description of responses, the variable was adjusted to reflect two responses: 1) No events or 2) One or more events. When the raw number was reported for the response “No events”, a percentage was calculated by dividing the raw number into the total number of responses. For example, if a hospital had 924 responses to the question on Number of events reported, and 515 of the responses were No Events, 515 was divided into 924 to reach 56% response for No Events.

A percentage was also calculated for the response “One or more events” by adding the responses in categories 2-6 (1 to 2 events through 21 events or more) then dividing that number by the total number of responses for the question. For example, if the same hospital with a total of 924 responses reported 301 responses for 1-2 events, 74 responses for 3-5 events, 21 responses for 6-10 events, 4 responses for 11-20 events, and 9 responses for 20 or more events, the responses were added together (301+74+21+4+9 = 409). The total number (409) was divided into the total responses (924) to reach 44% for the variable “One or more events”. The percentages of the two responses, No events
(56%) and One or more events (44%), equaled 100% for each hospital after the conversion was completed.

- Staff perceptions of nonpunitive response. AHRQ’s definition of this variable is the extent to which staff feel that their mistakes are not kept in their personnel file. All three survey items are reverse worded and use responses on a 5-point Likert scale from Strongly Disagree (1) to Strongly Agree (5). For this variable, positive responses are Strongly Disagree and Disagree. A composite score is derived by averaging the percentage of positive responses to the following three statements.
  1. Staff feel like their mistakes are held against them.
  2. When an event is reported, it feels like the person is being written up, not the problem.
  3. Staff worry that mistakes they make are kept in their personnel file.

Covariates

The following characteristics of the participating hospitals in both groups were tested for significant differences.

2. Teaching status
3. Ownership and control
4. Geographic region
Two of the characteristics were modified from the AHA categories. The AHA classifies bed size within eight categories:

1. 6-24 beds
2. 25-49 beds
3. 50-99 beds
4. 100-199 beds
5. 200-299 beds
6. 300-399 beds
7. 400-499 beds
8. 500 or more beds

For this study, the eight categories were collapsed into the following four categories:

1. 6-99 beds
2. 100-299 beds
3. 300-499 beds
4. 500 or more beds

Geographic region is also classified within eight categories by the AHA. The eight categories are:

1. Mid-Atlantic/New England
2. South Atlantic/Associated Territories
3. East North Central
4. East South Central
5. West North Central
6. West South Central
7. Mountain
8. Pacific/Associated Territories

These eight categories were collapsed into the following four categories for this study:

1. Mid-Atlantic/New England/South Atlantic/Associated Territories
2. East North Central/East South Central
3. West North Central/West South Central
4. Mountain/Pacific/Associated Territories

Analysis

Survey data were cleaned of out-of-range values, missing variables, and other data anomalies.

Descriptive characteristics, including frequencies and percentages, of the total respondents (including partially completed surveys), the study group, and the comparison group were computed and analyzed. Pearson chi-square tests of association were conducted to assess differences in completed and partially completed surveys. Chi-square tests were also used to assess differences in hospital characteristics for completed surveys. Frequencies, means, and standard deviations were computed for the two study groups. The primary outcomes were treated as continuous variables. Each dependent variable was tested separately using independent samples t-tests to compare the two study groups. A linear regression model was used to account for any imbalanced
characteristics or confounders affecting the outcomes under investigation. Hospital characteristics of \( p < 0.10 \) were considered as covariates. The model below reflects an undefined number of covariates that may affect the outcome (Y).
CHAPTER 4

RESULTS

Descriptive Statistics

There were 478 visits to the survey, with 213 surveys either partially or totally completed. Of the 213 surveys, 149 (70%) were partially completed and 64 (30%) were totally completed. The incomplete surveys lacked responses to the four questions from the AHRQ survey. Descriptive statistics for completed and partially completed surveys are presented in Table 1. Overall, the majority of hospitals were non-teaching (67.6%) and nongovernment (89.1%). The geographic region with the most responses was the Mid and South Atlantic/New England area with 45.5% overall. Bed size responses were mixed.

Table 1

Descriptive Statistics for Completed and Partially Completed Surveys

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall</th>
<th>Partial responses</th>
<th>Complete responses</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bed size</strong></td>
<td>213 (100.0)</td>
<td>149 (70.0)</td>
<td>64 (30.0)</td>
<td>0.10</td>
</tr>
<tr>
<td>6-99</td>
<td>60 (28.2)</td>
<td>43 (28.9)</td>
<td>17 (26.6)</td>
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</tr>
<tr>
<td>100-299</td>
<td>67 (31.5)</td>
<td>51 (34.2)</td>
<td>16 (25.0)</td>
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</tr>
<tr>
<td>300-499</td>
<td>50 (23.5)</td>
<td>28 (18.8)</td>
<td>22 (34.4)</td>
<td></td>
</tr>
<tr>
<td>500+</td>
<td>36 (16.9)</td>
<td>27 (18.1)</td>
<td>9 (14.1)</td>
<td></td>
</tr>
<tr>
<td><strong>Teaching status</strong></td>
<td>213 (100.0)</td>
<td>149 (70.0)</td>
<td>64 (30.0)</td>
<td>0.17</td>
</tr>
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<td>Teaching</td>
<td>69 (32.4)</td>
<td>44 (29.5)</td>
<td>25 (39.1)</td>
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</tr>
<tr>
<td>Non-teaching</td>
<td>144 (67.6)</td>
<td>105 (70.5)</td>
<td>39 (60.9)</td>
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<td><strong>Ownership and control</strong></td>
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<td>138 (68.3)</td>
<td>64 (31.7)</td>
<td>0.34</td>
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<tr>
<td>Government</td>
<td>22 (10.9)</td>
<td>17 (12.3)</td>
<td>5 (7.8)</td>
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<tr>
<td>Nongovernment</td>
<td>180 (89.1)</td>
<td>121 (87.7)</td>
<td>59 (92.2)</td>
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</tr>
<tr>
<td><strong>Geographic region</strong></td>
<td>*202 (100.0)</td>
<td>138 (68.3)</td>
<td>64 (31.7)</td>
<td>0.17</td>
</tr>
<tr>
<td>Mid &amp; South Atlantic/New England</td>
<td>92 (45.5)</td>
<td>59 (42.8)</td>
<td>33 (51.6)</td>
<td></td>
</tr>
<tr>
<td>East North &amp; South Central</td>
<td>55 (27.2)</td>
<td>35 (25.4)</td>
<td>20 (31.3)</td>
<td></td>
</tr>
<tr>
<td>West North &amp; South Central</td>
<td>24 (11.9)</td>
<td>20 (14.5)</td>
<td>4 (6.3)</td>
<td></td>
</tr>
<tr>
<td>Mountain/Pacific/Assoc. Territories</td>
<td>31 (15.3)</td>
<td>24 (17.4)</td>
<td>7 (10.9)</td>
<td></td>
</tr>
</tbody>
</table>

*Eleven respondents did not answer.
Descriptive statistics for the completed surveys are presented in Table 2. Of the 64 completed surveys, twenty-nine hospitals were in the study group (Red Rules) and thirty-five hospitals were in the comparison group (Non-Red Rules). Within the completed surveys, the largest number of hospitals (22) was in the bed size category for 300-499 beds, with 11 of those hospitals in each group (Red Rules and Non-Red Rules). The smallest number (9) was in the 500 or more beds category, with 3 using Red Rules and 6 not using Red Rules. Also within the completed surveys, 39.1% of the responses were from teaching hospitals; 60.9% were from nonteaching hospitals. The responses for ownership and control within the completed surveys were 7.8% for government owned and 92.2% for nongovernment owned. Only five hospitals were government owned and none of those five use Red Rules. Slightly over half (51.6%) of the completed surveys were from hospitals in the Mid and South Atlantic/New England region.

The total number of respondents taking the AHRQ survey in the 64 hospitals was 66,095. The AHRQ Hospital Survey on Patient Safety Culture 2012 User Comparative Database Report reports that 90% of hospitals administer the survey to all staff. Otherwise, it is administered to a sample of staff in all departments within the hospital (Sorra et al., 2012). The majority (76%) of respondents reported that they had direct interaction with patients, with thirty-five percent in a nursing role (registered nurse or licensed practical nurse). AHRQ reports that the characteristics of the hospitals in the database are consistent with those of hospitals in the American Hospital Association (Sorra et. Al, 2012). Similar characteristics were found in this study.

The primary method of hospital selection for participation in the present study was by invitation through listserves that support hospital-based patient safety initiatives...
and through snowball sampling. The survey response rate is unknown since the number of hospital contacts on every listserv is unknown.

Table 2

Descriptive Statistics for Completed Surveys

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall (n=64, % = 100)</th>
<th>Red Rules (n=29, % = 45)</th>
<th>Non-Red Rules (n=35, % = 55)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bed size</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-99</td>
<td>17 (26.6)</td>
<td>10 (51.5)</td>
<td>7 (26.6)</td>
<td>0.36</td>
</tr>
<tr>
<td>100-299</td>
<td>16 (25.0)</td>
<td>5 (17.2)</td>
<td>11 (31.4)</td>
<td></td>
</tr>
<tr>
<td>300-499</td>
<td>22 (34.4)</td>
<td>11 (37.9)</td>
<td>11 (31.4)</td>
<td></td>
</tr>
<tr>
<td>500+</td>
<td>9 (14.1)</td>
<td>3 (10.3)</td>
<td>6 (17.1)</td>
<td></td>
</tr>
<tr>
<td>Teaching status</td>
<td></td>
<td></td>
<td></td>
<td>&gt;0.99</td>
</tr>
<tr>
<td>Teaching</td>
<td>25 (39.1)</td>
<td>18 (62.1)</td>
<td>21 (39.1)</td>
<td></td>
</tr>
<tr>
<td>Non-teaching</td>
<td>39 (60.9)</td>
<td>11 (37.9)</td>
<td>14 (60.9)</td>
<td></td>
</tr>
<tr>
<td>Ownership and control</td>
<td></td>
<td></td>
<td></td>
<td>0.06</td>
</tr>
<tr>
<td>Government</td>
<td>5 (7.8)</td>
<td>0 (0)</td>
<td>5 (7.8)</td>
<td></td>
</tr>
<tr>
<td>Nongovernment</td>
<td>59 (92.2)</td>
<td>29 (45.3)</td>
<td>30 (53.8)</td>
<td></td>
</tr>
<tr>
<td>Geographic region</td>
<td></td>
<td></td>
<td></td>
<td>0.84</td>
</tr>
<tr>
<td>Mid &amp; South Atlantic/New England</td>
<td>33 (51.6)</td>
<td>15 (45.5)</td>
<td>18 (51.6)</td>
<td></td>
</tr>
<tr>
<td>East North &amp; South Central</td>
<td>20 (31.3)</td>
<td>10 (31.3)</td>
<td>10 (28.6)</td>
<td></td>
</tr>
<tr>
<td>West North &amp; South Central</td>
<td>4 (6.3)</td>
<td>1 (3.3)</td>
<td>3 (8.6)</td>
<td></td>
</tr>
<tr>
<td>Mountain/Pacific/Assoc. Territories</td>
<td>7 (10.9)</td>
<td>3 (9.7)</td>
<td>4 (11.4)</td>
<td></td>
</tr>
</tbody>
</table>

Statistical Analysis

Due to the variation in completed and partially completed surveys, a chi-square test was first conducted to assess differences in the respondents that completed the survey and those that did not complete the survey by the four hospital characteristics (bed size, teaching status, ownership and control, geographic region). The results of the chi-square tests were not significant (Tables 1 and 3), indicating that these particular variables did not explain the completion, or lack of completion, of the surveys.
Using the 64 completed surveys, statistical analysis was performed to assess differences in the two study groups. To ascertain differences in hospital characteristics (bed size, teaching status, ownership and control, geographic region) between hospitals that use Red Rules and those that do not, a chi-square test was conducted (Tables 2 and 4).
Of the four characteristics, only ownership and control had a $p$ value approaching significance, $x^2(1, N=64) = 4.494, p = 0.06$ (Table 2). To rule out any masking effects of ownership and control, a linear regression was conducted for each of the four outcome variables (staff perceptions of safety, frequency of events reported, percentage of events reported, and staff perceptions of non-punitive response) using ownership and control as a covariate with the formula:
Table 5

Linear Regression Analysis of Red Rules (Model 1) and Multivariable Regression Analysis of Red Rules and Ownership and Control (Model 2) on Staff Perceptions of Safety

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model 1</th>
<th>Model 2</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff perceptions of safety</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant</td>
<td>66.76</td>
<td>62.08</td>
<td>[39.27, 84.90]</td>
</tr>
<tr>
<td>Red Rules</td>
<td>-1.99</td>
<td>-2.35</td>
<td>[-8.86, 4.16]</td>
</tr>
<tr>
<td>Ownership &amp; control</td>
<td></td>
<td>2.52</td>
<td>[-9.56, 14.59]</td>
</tr>
<tr>
<td>$R^2$</td>
<td>0.007</td>
<td>0.009</td>
<td></td>
</tr>
<tr>
<td>$F$</td>
<td>0.408</td>
<td>0.288</td>
<td></td>
</tr>
<tr>
<td>$\Delta R^2$</td>
<td></td>
<td>0.003</td>
<td></td>
</tr>
<tr>
<td>$\Delta F$</td>
<td></td>
<td>0.174</td>
<td></td>
</tr>
</tbody>
</table>

*Note. N = 64. CI = confidence interval.*

Table 6

Linear Regression Analysis of Red Rules (Model 1) and Multivariable Regression Analysis of Red Rules and Ownership and Control (Model 2) on Frequency of Events

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model 1</th>
<th>Model 2</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency of events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant</td>
<td>62.91</td>
<td>57.03</td>
<td>[29.91, 84.16]</td>
</tr>
<tr>
<td>Red Rules</td>
<td>0.33</td>
<td>-0.13</td>
<td>[-7.86, 7.61]</td>
</tr>
<tr>
<td>Ownership &amp; control</td>
<td></td>
<td>3.17</td>
<td>[-11.19, 17.52]</td>
</tr>
<tr>
<td>$R^2$</td>
<td>&lt;0.001</td>
<td>0.003</td>
<td></td>
</tr>
<tr>
<td>$F$</td>
<td>0.008</td>
<td>0.101</td>
<td></td>
</tr>
<tr>
<td>$\Delta R^2$</td>
<td></td>
<td>0.003</td>
<td></td>
</tr>
<tr>
<td>$\Delta F$</td>
<td></td>
<td>0.195</td>
<td></td>
</tr>
</tbody>
</table>

*Note. N = 64. CI = confidence interval.*
Table 7

*Linear Regression Analysis of Red Rules (Model 1) and Multivariable Regression Analysis of Red Rules and Ownership and Control (Model 2) on Percentage of Events: No events*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model 1</th>
<th>Model 2</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant</td>
<td>50.53</td>
<td>53.31</td>
<td>[26.36, 80.25]</td>
</tr>
<tr>
<td>Red Rules</td>
<td>4.28</td>
<td>4.52</td>
<td>[-3.50, 12.53]</td>
</tr>
<tr>
<td>Ownership &amp; control</td>
<td>-1.51</td>
<td></td>
<td>[-15.85, 12.83]</td>
</tr>
<tr>
<td>$R^2$</td>
<td>0.022</td>
<td>0.022</td>
<td></td>
</tr>
<tr>
<td>$F$</td>
<td>1.26</td>
<td>0.642</td>
<td></td>
</tr>
<tr>
<td>$\Delta R^2$</td>
<td></td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>$\Delta F$</td>
<td></td>
<td>0.044</td>
<td></td>
</tr>
</tbody>
</table>

*Note. N = 59. CI = confidence interval.*

Table 8

*Linear Regression Analysis of Red Rules (Model 1) and Multivariable Regression Analysis of Red Rules and Ownership and Control (Model 2) on Percentage of Events: 1 or More Events*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model 1</th>
<th>Model 2</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant</td>
<td>49.47</td>
<td>46.69</td>
<td>[19.75, 73.64]</td>
</tr>
<tr>
<td>Red Rules</td>
<td>-4.28</td>
<td>-4.51</td>
<td>[-12.53, 3.50]</td>
</tr>
<tr>
<td>Ownership &amp; control</td>
<td>1.51</td>
<td></td>
<td>[-12.83, 15.85]</td>
</tr>
<tr>
<td>$R^2$</td>
<td>0.022</td>
<td>0.022</td>
<td></td>
</tr>
<tr>
<td>$F$</td>
<td>1.26</td>
<td>0.642</td>
<td></td>
</tr>
<tr>
<td>$\Delta R^2$</td>
<td></td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>$\Delta F$</td>
<td></td>
<td>0.044</td>
<td></td>
</tr>
</tbody>
</table>

*Note. N = 59. CI = confidence interval.*
Table 9

**Linear Regression Analysis of Red Rules (Model 1) and Multivariable Regression Analysis of Red Rules and Ownership and Control (Model 2) on Staff Perceptions of Nonpunitive Response**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model 1</th>
<th>Model 2</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff perceptions of nonpunitive response</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant</td>
<td>44.88</td>
<td>38.62</td>
<td>[13.73, 63.51]</td>
</tr>
<tr>
<td>Red Rules</td>
<td>-0.19</td>
<td>-0.69</td>
<td>[-7.85, 6.47]</td>
</tr>
<tr>
<td>Ownership &amp; control</td>
<td></td>
<td>3.38</td>
<td>[-9.81, 16.57]</td>
</tr>
<tr>
<td>$R^2$</td>
<td>&lt;0.001</td>
<td>0.004</td>
<td></td>
</tr>
<tr>
<td>$F$</td>
<td>0.003</td>
<td>0.133</td>
<td></td>
</tr>
<tr>
<td>$\Delta R^2$</td>
<td></td>
<td>0.004</td>
<td></td>
</tr>
<tr>
<td>$\Delta F$</td>
<td></td>
<td>0.263</td>
<td></td>
</tr>
</tbody>
</table>

*Note. N = 63. CI = confidence interval.*

Independent samples t-tests were conducted on the outcome variables (staff perceptions of safety, frequency of events reported, percentage of events reported, and staff perceptions of non-punitive response) to determine differences between hospitals that use Red Rules and those that do not use Red Rules. The independent samples t-test did not reveal statistically significant differences in the four outcome variables (Table 10).
Table 10

*Independent Samples t-test for Completed Surveys*

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Overall Mean</th>
<th>Red Rules Mean</th>
<th>Non-Red Rules Mean</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff perceptions of safety (n=64)</td>
<td>65.9±12.4</td>
<td>64.8±10.3</td>
<td>66.8±13.0</td>
<td>0.53</td>
</tr>
<tr>
<td>Frequency of events reported (n=64)</td>
<td>63.1±14.6</td>
<td>63.2±16.3</td>
<td>62.9±13.3</td>
<td>0.93</td>
</tr>
<tr>
<td>Percentage of events reported (n=59)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No events</td>
<td>52.5±14.6</td>
<td>54.8±15.3</td>
<td>50.5±14.0</td>
<td>0.27</td>
</tr>
<tr>
<td>1 or more events</td>
<td>47.5±14.6</td>
<td>45.2±15.3</td>
<td>49.5±14.0</td>
<td>0.27</td>
</tr>
<tr>
<td>Staff perceptions of non-punitive response (n=64)</td>
<td>44.8±13.4</td>
<td>44.7±12.6</td>
<td>44.9±14.3</td>
<td>0.96</td>
</tr>
</tbody>
</table>

This chapter presented the results of statistical testing for research conducted on the use of Red Rules from 64 hospitals representing responses from 66,095 hospital workers. The next chapter provides the discussion, conclusions, and recommendations.
CHAPTER 5
DISCUSSION

The purpose of this study was to explore the effects of Red Rules on staff perceptions of safety, frequency of events reported, number of events reported, and staff perceptions of non-punitive response by hospital management. The theoretical framework for control-based and commitment-based management outcomes was used to frame four hypotheses:

1. Staff perceptions of safety will diminish following the implementation of Red Rules;
2. The frequency of events reported will decrease following the implementation of Red Rules;
3. The number of events reported will decrease following the implementation of Red Rules;
4. Staff perceptions of non-punitive response will diminish following the implementation of Red Rules.

Review of Findings

The study sample was narrowed to 64 hospitals from 213 surveys due to missing responses from the AHRQ Hospital Survey on Patient Safety Culture. Several respondents began the survey but indicated that they could not complete it because they either 1) had not completed the AHRQ Hospital Survey on Patient Safety Culture, 2) had
completed a patient safety survey other than the AHRQ survey, 3) lived outside the United States, or 4) worked in a medical office practice or long-term care facility.

To determine differences other than missing responses for the four AHRQ survey questions, a chi-square test was conducted using the four hospital characteristics (bed size, teaching status, ownership and control, and geographic region). This did not reveal other differences between the respondents that completed the survey and those that did not complete the survey.

Hypothesis #1

The overall mean for staff perceptions of safety was 65.9 out of a possible 100, suggesting room for improving this outcome in the participating hospitals. Although the independent samples t-test did not show statistical significance between the study group and the comparison group (p = 0.53), the mean for hospitals using Red Rules was lower at 64.8, compared with 66.8 in hospitals that do not use Red Rules. This finding suggests the potential for decreased perceptions of safety among the study group (Red Rules), depending on the presence of other conditions discussed in the literature, such as a blaming culture rather than a just culture.

Hypothesis #2

The frequency of events reported had an overall mean of 63.1, with Red Rules hospitals having a slightly higher mean of 63.2 than hospitals that do not use Red Rules at 62.9. The comparison did not show significance (p = 0.93).

This outcome may reflect the effect of hospital campaigns to increase staff reporting of errors used in conjunction with the implementation of Red Rules. One
hospital in the Midwest has communicated the importance of transparency and open communication to support the development of a just culture. Although the organization uses Red Rules, which can result in disciplinary action, including dismissal, the structure supports the concept of good citizenship to improve patient safety (Frankel, et al., 2006). This reinforces the use of a multi-faceted approach to improving patient safety and implementing Red Rules with other patient safety initiatives.

A recent study on error disclosure found that staff who receive error disclosure training reported significantly higher levels of error disclosure culture and error disclosure trust culture. This study points to the positive impact of staff training in reporting errors to allow organizations to understand needed improvements resulting in fewer medical errors (Etchegaray, Gallagher, Bell, Dunlap, & Thomas, 2012). It is likely that hospitals that have implemented Red Rules and other patient safety strategies have conducted staff training on event reporting, resulting in no significant difference in the hospital groups in this study.

**Hypothesis #3**

The percentage of events reported was assessed using two variables: 1) no events reported or 2) one or more events reported. Both variables had means lower than the overall mean for frequency of events (63.1). The mean for no events was 52.5; the mean for one or more events was 47.5. This suggests that although staff responded that they identify and report errors, when asked the number of events actually reported, the majority did not report any events. Respondents from hospitals using Red Rules had the higher mean for reporting no events at 54.8; the mean was 50.5 in non-Red Rules hospitals. However, this was not a significant finding (p = 0.27). Conversely, when
reporting one or more events, respondents in non-Red Rules hospitals had a higher mean of 49.5 compared with a mean of 45.2 in Red Rules hospitals.

The low mean scores for frequency of events reported and percentage of events reported in this study are consistent with a recent report from the Office of Inspector General (Levinson, 2012). The report found that in 189 hospitals surveyed, hospital staff did not report 86% of events experienced by Medicare beneficiaries discharged in October 2008. Hospital administrators attributed the lack of reporting to staff misperceptions about what constitutes harm and what constitutes a reportable event. However, among the reasons given for events not being reported, fear of a punitive response was not listed. It is unclear from the report whether hospital administrators were provided a list of reasons to choose from or whether their responses were provided through an open-ended response format. In either case, fear of nonpunitive response is not represented as a reason given for not reporting patient safety events. This is not consistent with the latest report from AHRQ, described in detail in the following section.

Hypothesis #4

Staff perceptions of non-punitive response had a low overall mean of 44.8 out of 100 with almost no difference between the two groups (p = 0.96). This variable had the lowest mean score of the four outcome variables. This finding is consistent with the most recent AHRQ data released which reported 44% positive response among 567,703 hospital staff respondents from 1,128 hospitals (Sorra, J., Famolaro, T., Dyer, N., Nelson, D., Smith, S., 2012). Non-punitive response to error has shown little improvement since the first AHRQ Patient Safety Culture report in 2007 (American Medical Association,
2012). Approximately 20% of hospitals have improved their scores in this category over the past 5 years, while 16% have experienced lower scores.

Assessment of Findings

Contrary to expectations, this study did not find a significant difference between the study group (Red Rules) and the comparison group (Non-Red Rules). One possible explanation for this result lies in the level of awareness and effort in improving patient safety among the hospitals that participated in the study. In order to participate, hospitals were required to have completed the AHRQ Hospital Survey on Patient Safety Culture. This activity can be an indicator of a higher level of awareness and interventions regarding patient safety. Hospitals that have assessed their patient safety culture possibly possess a higher “mindfulness” for patient safety, resulting in strategies to reduce errors, and are advancing toward being a high reliability organization. A single tool such as Red Rules would more than likely not have an effect on patient safety culture, if used with other initiatives within a just culture.

Another explanation could lie in the timing of the implementation of Red Rules among the study group. As discussed in the literature review section, hospitals are evolving from a blaming culture to a just culture environment. The literature on Red Rules has also evolved from a tool associated with the disciplinary process to a tool used to support communication on critical safety issues. Within the study group of hospitals using Red Rules, the implementation year with the largest number of hospitals was 2007 with 11 (37.9%) hospitals. This could indicate that in the absence of evidence-based effectiveness, hospitals have hesitated to implement Red Rules. Those that have implemented Red Rules in more recent years are likely to have used a more commitment-
based approach than a control-based approach, using Red Rules as a communication tool rather than a disciplinary tool.

**Significance of findings**

This is the first quantitative study on the use of Red Rules in patient safety culture. This study adds to the emerging literature on patient safety initiatives and just culture. Hospitals that have avoided using Red Rules, fearing them as a punitive strategy, now have information not available before to help guide their decision about whether or not to use them.

**Limitations**

Although the sample size was adequate for this study, a larger sample might have provided a broader range of hospitals with varying levels of involvement in patient safety initiatives. In order to identify and include hospitals that use Red Rules for the study, hospitals involved in patient safety organizations were invited to participate. Using this group of hospitals may have skewed the results due to a higher level of patient safety awareness and sophistication.

The sample size also impacted the ability to detect a significant difference in the primary outcome variables. Given the observed sample size and standard deviation, the following power estimates were derived to detect a difference of five:

- Staff perceptions of safety – 47% power
- Frequency of events reported – 31% power
- Percentage of no events reported – 28% power
- Percentage of 1 or more events reported – 28% power
Staff perceptions of non-punitive response – 34% power

Analysis revealed that in order to detect a difference of five points in the two groups for each outcome variable, a much larger sample size would be required to have sufficient power to detect a difference of this magnitude.

This study was limited to hospitals that used the AHRQ Hospital Survey on Patient Safety Culture. Even though other hospitals were willing to participate, they could not answer the questions related to the outcome variables and were excluded from the study.

The implementation method for Red Rules was not examined in this study. The literature included descriptions of the process of implementing Red Rules, with varying timelines; however, this study did not capture data to investigate the effects of implementation methods for Red Rules.

Lastly, this study did not examine the differences between early and late adopters of Red Rules due to the sample size.

Recommendations for management practice

In the absence of evidence on the use of Red Rules, some hospital leaders have elected not to use them, assuming that they are inconsistent with a just culture and with improving patient safety. This study does not provide support for this belief. Used within a commitment-based management style as a communication tool to support staff in following safety rules rather than as a disciplinary tool in a control-based environment, Red Rules can be part of a comprehensive strategy to improve patient safety. To be consistent with a commitment-based management style, management might consider changing the name of Red Rules, which sounds controlling and threatening, to a name
reflecting a commitment-based approach, such as “Safety Stops”. The name of a tool can be an indication to staff of empowerment and support or discipline and blame. Red Rules are one of many tools that can be utilized to improve patient safety, which is the ultimate goal.

Recommendations for future research/analysis

Future research is needed to explore the effects of Red Rules in hospitals that may not have a comprehensive patient safety program. Used alone, without supportive and complimentary strategies, Red Rules may have the potential to be detrimental, rather than supportive, in achieving a culture of patient safety.

Another potential area for future research is to examine implementation methods and timelines for Red Rules. Exploration could include whether hospitals implemented Red Rules as a stand-alone strategy or as part of a multi-faceted approach. Additionally, short timelines could be compared with lengthy timelines to determine differences in outcomes.

A different, but interesting, measure could be the change in number of disciplinary actions for employees before and after Red Rules are implemented.

Summary

Patient safety is a critical component of healthcare management. Effective strategies to reduce medical errors and improve patient safety are of great importance to both givers and receivers of healthcare. Without evidence, healthcare managers are unable to make informed decisions about effective strategies to reduce harm. As
resources become more limited, implementation of evidence-based strategies becomes more important.

This study sought to determine the effect of Red Rules on patient safety culture. It is the first quantitative study on the use of Red Rules. The research did not show significant differences between hospitals that use Red Rules and those that do not. Healthcare managers can use this evidence in forming decisions to eliminate medical errors and improve patient safety. More studies quantifying the effectiveness of strategies are needed to make the best use of the dwindling resources in healthcare. This study serves as a practical tool to inform healthcare managers of the use of one emerging strategy in the fight for patient safety.
LIST OF REFERENCES


Leape, L. *Testimony to United States Congress House Committee on Veterans' Affairs.*
Washington, DC. (October 12, 1997)

Leape, L., & Berwick, D. (2005). Five years after to err is human: What have we learned?
*Journal of the American Medical Association, 293*(19), 238490.


*Annals of Internal Medicine, 144*(2), 107-115.


APPENDIX A

AHRQ HOSPITAL SURVEY ON PATIENT SAFETY
Hospital Survey on Patient Safety

Instructions

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

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

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

SECTION A: Your Work Area/Unit

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

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

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

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

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

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. We are actively doing things to improve patient safety</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. We use more agency/temporary staff than is best for patient care</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
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<td></td>
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<tr>
<td>8. Staff feel like their mistakes are held against them</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Mistakes have led to positive changes here</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. It is just by chance that more serious mistakes don’t happen around here</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. When one area in this unit gets really busy, others help out</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. When an event is reported, it feels like the person is being written up, not the problem</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>13. After we make changes to improve patient safety, we evaluate their effectiveness</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
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</tr>
<tr>
<td>14. We work in &quot;crisis mode&quot; trying to do too much, too quickly</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Patient safety is never sacrificed to get more work done</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Staff worry that mistakes they make are kept in their personnel file</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. We have patient safety problems in this unit</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. Our procedures and systems are good at preventing errors from happening</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### SECTION B: Your Supervisor/Manager

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

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>2. My supervisor/manager seriously considers staff suggestions for improving patient safety</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. My supervisor/manager overlooks patient safety problems that happen over and over</td>
<td>□ 1 □ 2 □ 3 □ 4 □ 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SECTION C: Communications
How often do the following things happen in your work area/unit? 

Think about your hospital work area/unit...

1. We are given feedback about changes put into place based on event reports ..........................................................□ □ □ □ □
2. Staff are free to speak up if they see something that may negatively affect patient care ..........................................................□ □ □ □ □
3. We are informed about errors that happen in this unit ..................................□ □ □ □ □
4. Staff feel free to question the decisions or actions of those with more authority ..........................................................................................................................□ □ □ □ □
5. In this unit, we discuss ways to prevent errors from happening again .... □ □ □ □ □
6. Staff are afraid to ask questions when something does not seem right .... □ □ □ □ □

SECTION D: Frequency of Events Reported
In your hospital work area/unit, when the following mistakes happen, how often are they reported?

1. When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported? ..........................................................□ □ □ □ □
2. When a mistake is made, but has no potential to harm the patient, how often is this reported? ..........................................................□ □ □ □ □
3. When a mistake is made that could harm the patient, but does not, how often is this reported? ..........................................................□ □ □ □ □

SECTION E: Patient Safety Grade
Please give your work area/unit in this hospital an overall grade on patient safety.

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

SECTION F: Your Hospital
Please indicate your agreement or disagreement with the following statements about your hospital.

Think about your hospital...

1. Hospital management provides a work climate that promotes patient safety ..........................................................□ □ □ □ □
2. Hospital units do not coordinate well with each other ..........................................................................................................................□ □ □ □ □
3. Things “fall between the cracks” when transferring patients from one unit to another ..........................................................□ □ □ □ □
4. There is good cooperation among hospital units that need to work together ..........................................................................................................................□ □ □ □ □
SECTION F: Your Hospital (continued)

Think about your hospital…

5. Important patient care information is often lost during shift changes ……… □ 1 □ 2 □ 3 □ 4 □ 5
6. It is often unpleasant to work with staff from other hospital units .......... □ 1 □ 2 □ 3 □ 4 □ 5
7. Problems often occur in the exchange of information across hospital units .......................................................... □ 1 □ 2 □ 3 □ 4 □ 5
8. The actions of hospital management show that patient safety is a top priority .......................................................................................................................... □ 1 □ 2 □ 3 □ 4 □ 5
9. Hospital management seems interested in patient safety only after an adverse event happens ........................................................................................................ □ 1 □ 2 □ 3 □ 4 □ 5
10. Hospital units work well together to provide the best care for patients .... □ 1 □ 2 □ 3 □ 4 □ 5
11. Shift changes are problematic for patients in this hospital ................. □ 1 □ 2 □ 3 □ 4 □ 5

SECTION G: Number of Events Reported

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

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

SECTION H: Background Information

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

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

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

3. Typically, how many hours per week do you work in this hospital?
   □ a. Less than 20 hours per week □ d. 50 to 79 hours per week
   □ b. 20 to 39 hours per week □ e. 80 to 99 hours per week
   □ c. 40 to 59 hours per week □ f. 100 hours per week or more
SECTION H: Background Information (continued)

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

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

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

SECTION I: Your Comments

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

THANK YOU FOR COMPLETING THIS SURVEY.
APPENDIX B

EMAIL INVITATION
Dear Patient Safety Officer:

You are being contacted because you are responsible for patient safety within your organization. You were identified through your association with VHA, the Institute for Healthcare Improvement, the National Patient Safety Foundation, or the Kentucky Hospital Association as a potential participant in a study. The name of this research is "The Use of Red Rules in Patient Safety Culture, Protocol E 11223001," and this study is part of the requirements for completion of my doctoral degree from the University of Alabama at Birmingham. I am conducting research and writing a dissertation on the effects of Red Rules on patient safety culture in hospitals. The study will examine the relationship between the implementation of Red Rules and overall perceptions of safety, frequency of events reported, number of events reported, and non-punitive response to errors.

If you are employed by an acute, general care hospital that has taken the Agency for Healthcare Research and Quality (AHRQ) Hospital Survey on Patient Safety Culture within the past five years, you are eligible to participate in the research. Your participation is voluntary. It is my hope that a quantitative study can help organizations make an evidence-based decision about the use of Red Rules as a strategy to improve patient safety. If your organization agrees to participate, your data will be kept completely confidential and summary reports of the study's findings will be provided to you. The estimated time of participation is less than ten minutes to complete the attached survey. You will need your hospital's AHRQ Hospital Survey on Patient Safety Culture survey results in order to complete the survey. If you agree to participate, please click on the link below and complete the survey no later than March 2, 2012.

If you have questions regarding the research, please contact me using the following information:

Lisa Jones
Owensboro Medical Health System
811 E. Parrish Avenue
Owensboro, KY 42304-0007
lisa.jones@omhs.org
270-691-8282

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the Office of the Institutional Review Board for Human Use (IRB) at the University of Alabama at Birmingham (UAB) at (205) 934-3789 or 1-800-822-3816. If calling the toll-free number, press the option for "all other calls" or for an operator/attendant and ask for extension 4-3789. Regular hours for the Office of the IRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Thank you very much for your assistance with this research.

Best regards,

Lisa Jones

http://www.zoomerang.com/Survey/WEB22EQZXA8T3Y
APPENDIX C

RED RULES SURVEY
Red Rules

The Agency for Healthcare Research and Quality (AHRQ) defines Red Rules as: "Rules that must be followed to the letter. In the language of non-health care industries, red rules 'stop the line.' In other words, any deviation from a red rule will bring work to a halt until compliance is achieved." Red rules are more stringent than standard operating policies and procedures. An example of a red rule in health care might be the following: No hospitalized patient can undergo a test of any kind, receive a medication or blood product, or undergo a procedure if they are not wearing an identification bracelet. The implication of designating this as a red rule is that the moment a patient is identified as not meeting this condition, all activity must cease in order to verify the patient's identity and supply an identification band. Has your hospital implemented Red Rules as a strategy to improve patient safety?

- YES [Skip to 2]
- NO [Skip to 6]

What year did you implement Red Rules?

- 2007
- 2008
- 2009
- 2010
- 2011

Please provide the answers to the following questions from your hospital's AHRQ Hospital Survey on Patient Safety survey results for the survey taken from SIX MONTHS TO TWO YEARS after implementing Red Rules. Hospital Characteristics - Bed Size:

- 6-24 Beds
- 25-49 Beds
- 50-99 Beds
- 100-199 Beds
- 200-299 Beds
- 300-399 Beds
- 400-499 Beds
- 500 or more Beds
Teaching Status:
- Teaching
- Non-teaching

Ownership and Control:
- Government (Federal or non-Federal)
- Nongovernment (voluntary/nonprofit or proprietary/investor owned)

Geographic Region:
- Mid-Atlantic/New England (NJ, NY, PA, CT, ME, MA, NH, RI, VT)
- South Atlantic/Associated Territories (DC, DE, KY, MD, NC, VA, WV)
- East North Central (IL, IN, MI, OH, WI)
- East South Central (AL, FL, GA, MS, SC, TN, PR)
- West North Central (IA, KS, MN, MO, NE, ND, SD)
- West South Central (AR, LA, OK, TX)
- Mountain (AZ, CO, ID, MT, NM, UT, WY)
- Pacific/Associated Territories (AK, CA, HI, NV, OR, WA)

Please provide the answers to the following questions from your hospital's AHRQ Hospital Survey on Patient Safety survey results for the survey taken from SIX MONTHS TO TWO YEARS after implementing Red Rules. Number of responses to the survey:

Please enter your hospital's composite score (% positive) for: Overall Perceptions of Patient Safety:

Please enter your hospital's composite score (% positive) for: Frequency of Events Reported:
Please enter your hospital’s composite score (% positive) for: Nonpunitive Response to Error:

---

Please enter the number of events respondents reported on the survey in each of the categories listed below. Number of events reported:

- No events
- 1 to 2 events
- 3 to 5 events
- 6 to 10 events
- 11 to 20 events
- 20 events or more

[Skip Unconditionally to 10]

Please provide the answers to the following questions from your hospital’s MOST RECENT AHRQ Hospital Survey on Patient Safety Culture survey. What year was your Survey?

- 2007
- 2008
- 2009
- 2010
- 2011

[Skip Unconditionally to 7]

Please provide the answers to the following questions from your hospital’s MOST RECENT AHRQ Hospital Survey on Patient Safety Culture survey. Hospital Characteristics. Bed Size:

- 6-24 Beds
- 25-49 Beds
- 50-99 Beds
- 100-199 Beds
- 200-299 Beds
- 300-399 Beds
- 400-499 Beds
- 500 or more Beds
Page 7 - Question 14 - Choice - One Answer (Butler)

Teaching Status:

- Teaching
- Non-teaching

[Skip Unconditionally to 8]

Page 8 - Question 15 - Choice - One Answer (Butler)

Ownership and Control:

- Government (Federal or non-Federal)
- Non-government (voluntary/nonprofit or proprietary/investor owned)

Page 8 - Question 16 - Choice - One Answer (Butler)

Geographic Region:

- Mid-Atlantic/New England (NJ, NY, PA, CT, ME, MA, NH, RI, VT)
- South Atlantic/Associated Territories (DC, DE, KY, MO, NC, VA, WV)
- East North Central (IL, IN, MI, OH, WI)
- East South Central (AL, FL, GA, MS, MO, NE, ND, SD)
- West North Central (IA, KS, MN, MO, NE, ND, SD)
- West South Central (AR, LA, OK, TX)
- Mountain (AZ, CO, ID, MT, NM, UT, WY)
- Pacific/Associated Territories (AK, CA, HI, NV, OR, WA)

[Skip Unconditionally to 9]

Page 9 - Question 17 - Open Ended - Comments Box

Please provide the answers to the following questions from your hospital’s MOST RECENT AHRQ Hospital Survey on Patient Safety Culture survey. Number of responses to the survey:

Page 9 - Question 18 - Open Ended - Comments Box

Please enter your hospital’s composite score (% positive) for: Overall Perceptions of Patient Safety:

Page 9 - Question 19 - Open Ended - Comments Box

Please enter your hospital’s composite score (% positive) for: Frequency of Events Reported:
Page 9 - Question 20 - Open Ended - Comments Box

Please enter your hospital's composite score (% positive) for: Nonpunitive Response to Error:

Page 9 - Question 21 - Open Ended - One or More Lines with Prompt

Please enter the number of events respondents reported on the survey in each of the categories listed below. Number of events reported:

- No events
- 1 to 2 events
- 3 to 5 events
- 6 to 10 events
- 11 to 20 events
- 20 events or more

[Skip Unconditionally to 10]

Page 10 - Question 22 - Name and Address (2.5)

If you would like to receive the results of the survey please fill in your name and email address below.

- Name
- Email Address

Unconditional Skip to End

Thank You Page

Lisa Jones, VP Clinical Services
Owenboro Medical Health System
811 East Parrish Avenue
Owenboro, KY 42301
lisa.jones@omhs.org

Screen Out Page

Over Quota Page

Standard

Survey Closed Page
APPENDIX D

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

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The Assurance number is FWA00005960 and it expires on August 29, 2016. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56.

Principal Investigator: JONES, LISA K
Co-Investigator(s):
Protocol Number: E111223001
Protocol Title: The Use of Red Rules in Patient Safety Culture

The above project was reviewed on 1-6-12. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This project qualifies as an exemption as defined in 45CFR46.101, paragraph 4.

This project received EXEMPT review.
IRB Approval Date: 1-6-12
Date IRB Approval Issued: 1-6-12

Marilyn Doss, M.A.
Vice Chair of the Institutional Review Board for Human Use (IRB)

Investigators please note:

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

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

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