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Monitoring Hospital Safety Climate Using Control Charts of Non-harm Events in Reporting Systems

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MONITORING HOSPITAL SAFETY CLIMATE USING CONTROL CHARTS OF
NON-HARM EVENTS IN REPORTING SYSTEMS

A Thesis
Presented to
the Graduate School of
Clemson University

In Partial Fulfillment
of the Requirements for the Degree
Master of Science
Industrial Engineering

by
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May 2014

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ABSTRACT

The primary aim of this thesis is to design an approach and demonstrate a methodology to supplement safety culture assessment efforts. The framework affords an enhanced understanding of hospital safety climate, specifically reporting culture, through the use of control charts to monitor non-harm patient safety events documented in reporting systems.

Assessing safety culture and climate remains difficult. One of the most common methods to assess safety culture is a self-report survey administered annually. Surveys assess safety climate, because they are a snapshot of the management's and front-line staff's perceptions of safety within their settings. One component of safety culture is reporting culture, which is assessed by survey questions targeting the total number and frequency of events reported by individuals.

Surveys use subjective data to measure outcome variables with regard to patient safety event reporting. Relying on subjective data when organizations also collect data on actual reporting rates may not be optimal. Additionally, the time lag limits management's ability to efficiently assess the need for, and the effect of improvements. Strategic interventions may result in effective change, but annual summary data may mask the effects. Additionally, there are advantages to focusing on non-harm events, and capturing non-harm event reporting rates may aid safety climate assessment.

Despite the limitations of reporting systems, incorporating actual data may allow organizations to gain a more accurate depiction of the safety climate and reporting culture. With the increased prevalence of reporting systems in healthcare organizations,

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the data can be used to track and trend reporting rates of the organization. Incorporating control charts can help identify expected non-harm event reporting rates, and can be used to monitor trends in reporting culture. Data in reporting systems are continuously updated allowing quicker assessment and feedback than annual surveys.

The methodology is meant to be prescriptive and uses data that hospitals typically collect. Hospitals can easily follow the summarized approach: check for underlying data assumptions, construct control charts, monitor and analyze those charts, and investigate special cause variation as it arises. The methodology is described and demonstrated using simulated data for a hospital and three of its departments.

DEDICATION

       I would like to dedicate my thesis those who have experienced harm as a result of preventable medical errors, as well as the countless others who have experienced patient safety events, but were fortunate to escape harm.

ACKNOWLEDGMENTS

I would like to extend my sincere appreciation to my masters' advisor, Dr. David Neyens for his constant support, guidance, and patience throughout this stage of my education. I would like to thank Dr. Ashley Kay Childers, Dr. Thomas Diller, and Dr. Scott Mason for serving as my thesis committee members and providing recommendations and support to the advancement and completion of my thesis. Finally, I would like to extend gratitude to my friends and family for their support throughout this thesis process and my graduate studies.

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CHAPTER ONE

INTRODUCTION

The primary aim of this thesis is to design an approach and demonstrate a methodology to supplement current safety culture assessment efforts. The framework affords an enhanced understanding of hospital safety climate, specifically reporting culture, by using control charts to monitor non-harm patient safety events documented in reporting systems. Control charts are a type of statistical process control tool used to translate data into meaningful information. They provide graphical illustrations of process behavior, which assist in recognizing, in real-time, if new information indicates the process may be changing (e.g., points falling beyond control limits warrant investigation).

Following studies that produced evidence supporting high rates of harm in healthcare settings, notably adverse events, efforts were established to promote a patient safety movement. As part of this undertaking, healthcare organizations were encouraged by national government organizations to develop and promote a culture of safety. Recommendations were also made to develop reporting systems to track patient safety events and errors, in order to learn from them and prevent their reoccurrence. One element of an organization's safety culture is reporting culture.

Current analyses of safety culture assessment and measurement rely heavily on the use of self-report questionnaires. Most of the surveys include questions directed at reporting culture; however, analysis of the data is aggregated at such a level that it may be hard to assess the effect of strategic interventions (e.g., training) within this time

period. Organizations track survey results over time, but incorporating data from other systems currently in use may provide a better assessment of patient safety efforts and subsequent safety culture.

There are several limitations of reporting systems; however, meaningful information in these systems may be underutilized. While the act of documenting events in reporting systems may be voluntary, there are certain patient safety events that require additional investigations, such as root cause analyses. Many healthcare organizations use reporting systems as a means to identify those patient safety events requiring additional action. Although healthcare organizations typically encourage their employees to report all types of events along a harm spectrum (i.e., from non-harm events, or near misses, to events that result in death), the actual reporting rates of these events vary.

Underreporting remains an issue for reporting systems for all types of events; however, it could be argued that the rates of documented reports for harm events may better reflect actual rates, compared to near misses and events that do not result in any harm. This is based on several assumptions: outside agencies require reporting of some types of harmful events making these events more of a requirement, errors involved in harm events are often more transparent compared to non-harm events, and organizations tend to effectively communicate their expectations surrounding reporting harm events as opposed to non-harm events.

Accident causation models that describe the relationship between non-harm and harm events suggest there are approximately 300 near misses, or accidents that do not cause harm, for each one patient safety event that results in a major injury (Heinrich,

1959). Also, the relationship often defines near misses as precursor events to harm. As a counterpoint, it could be argued that employees may be more inclined to report near misses, since events did not result in harm, and the fear of disciplinary action may be mitigated.

The nature of this thesis is meant to be prescriptive, as several assumptions are made in order to apply this methodology to preexisting healthcare data. The aim is to offer healthcare organizations an approach to analyze their reporting system data in a meaningful way so trends in reporting rates can be quickly identified. The methodology is meant to provide practitioners a simple means of illustrating data in order to evoke discussions surrounding improvement interventions and to gain a better understanding of the hospital's journey towards improving patient safety by enhancing safety culture and climate.

Chapter 2 presents background information and a literature review on a range of interconnected topics discussed in this thesis: patient safety, safety culture and safety climate, reporting systems, and control charts. Chapter 3 aims to connect the topics described in the literature review, discusses gaps in current assessment methods, and defines the thesis methodology and the application of control charts to data from reporting systems. It includes the framework for hospitals on how to utilize this methodology when conducting analysis at the hospital, as well as department, level. In chapter 4, the methodology is demonstrated using simulated data. Actual data from a regional healthcare network's reporting system were employed to simulate reporting rates at all harm levels. The simulated data does not characterize the actual reporting rates of

this healthcare network, but instead is meant to represent aggregate documented event reports based on a similar underlying distribution. The results chapter presents descriptive statistics and c-type (count) and u-type (rate) control charts for the simulated data at the hospital level as well as for three departments within the hospital. Chapter 5 describes how to interpret the control charts based on the simulated data results in terms of safety climate and reporting culture, accounting for the assumptions made for this thesis. Finally, general conclusions and future recommendations for the application of this methodology are discussed.

CHAPTER TWO

LITERATURE REVIEW

The work presented in this chapter provides background information and a
literature review of the overarching and interconnected topics discussed in this thesis.
Operational definitions of many wide-ranging terms are defined throughout the chapter.
Initially, a high-level overview of patient safety in healthcare, past and present, is
presented as a backdrop for many issues reviewed in this document. The concept of
safety culture and its counterpart safety climate are discussed subsequently, which is
followed by the presentation of reporting systems. Lastly, the chapter concludes with
background information on control charts and the benefits their application provides to
healthcare.

Patient Safety

Analogous to quality, patient safety is defined abstractly. The Institute of
Medicine (IOM) defines *patient safety* as "the prevention of harm to patients" (Aspden,
Corrigan, Wolcott, & Erickson, 2004). The Agency for Healthcare Research and Quality
(AHRQ) describes *patient safety* as both a discipline and also an attribute of healthcare
systems. Focusing on the latter, patient safety specifically aims to "minimize the
incidence and impact of and maximize recovery from adverse events" (Emanuel et al.,
2008). As opposed to a patient's disease or condition, unintended harm due to care, or an
adverse event, occurs by an act of commission (e.g., doing something wrong) or omission
(e.g., failing to do the right thing) (Aspden et al., 2004). Injury caused by medical care

does not necessarily imply negligence or poor quality care; rather an *adverse event* indicates an undesirable clinical outcome followed by some aspect of diagnosis or therapy rather than the underlying disease process (AHRQ, 2012e; Brennan, Leape, et al., 1991). Brennan et al. (1991) suggest that some adverse events are preventable while others may be unavoidable and unpredictable. *Medical errors* include both failures of a planned action to be completed as intended or the use of a wrong plan to achieve an aim (i.e., commission), or the failure of an unplanned action that should have been completed (i.e., omission) (AHRQ, 2012c; Aspden et al., 2004). However, not all medical errors lead to harm or adverse events. Adverse events and error, together embody the relevant terms used to describe patient safety events for the purpose of this thesis (Kerr, 2000; Thomas & Petersen, 2003).

Traditionally, healthcare professionals were believed to be infallible (Emanuel et al., 2008). Medical errors were related to incompetence and those that committed them deserved blame and punishment; thus there was a punitive culture (Emanuel et al., 2008). A hospital environment with this type of culture is perpetually hazardous to providers, patients, and the learning community. Under such circumstances providers are afraid to speak up, patients are harmed, and the lack of reporting makes learning from errors and adverse events nearly impossible (Emanuel et al., 2008). James Reason (1990) encourages looking at error in two ways: human or active errors, and system or latent errors. The former are committed by individuals making slips (skill-based errors) or mistakes (knowledge- or rule-based errors), while the latter are due to technical design or issues and decisions made by the organization. Based on systematic investigation of

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preventable complications, one author stated that, "faulty systems of care are responsible for error more often than individuals" (Chassin, 1998). By recognizing that the most competent healthcare professionals are susceptible to committing errors and by gaining an understanding that care delivery is only as reliable as its underlying systems and processes, affords a pathway to approaching a patient safety improvement movement. Accepting the systems thinking perspective, the healthcare industry has been able to realize many problems can be remedied by changing the system instead of placing blame on the individual when errors and harm occur.

The Reason Model (also known as the Swiss Cheese Model) of accident causation helps describe the overall system problem related to patient safety events and incidents (Reason, 1990). Defined by the AHRQ's Common Formats, *incidents* are events that reach the patient, regardless of whether or not harm was inflicted (AHRQ, *Common Formats*). *Patient safety event*s on the other hand may be caught before reaching the patient, but are discrete in time with clearly defined complications or with the possibility thereof (NQF, 2006, 2007; WHO, 2009a). Patient safety events defined for the purpose of this thesis include incidents as well as events that do not reach the patient (i.e., near misses). Reason's model hypothesizes that there are many levels of defense in any system, each wrought with holes known as latent conditions (e.g., poor design, lack of training, limited resources). When incidents occur they are the result of an active error and multiple hazards passing through latent conditions. While it may be easy or convenient to blame the individual at the active end of the error, patient safety events are inevitable until underlying upstream latent conditions are addressed (Carthey, 2013;

Emanuel et al., 2008).

Understanding that the nature of the problem was not the individual but the system, some healthcare organizations have turned to high-reliability organizations (HRO) (e.g., aviation and nuclear energy) to learn from their successes. HROs are those involved in complex, high-risk, and often-unpredictable environments, which deliver safe and consistently high quality service over time. Refer to the AHRQ's *Becoming a High Reliability Organization: Operational Advice for Hospital Leaders* for additional information on high reliability concepts and their implementation into healthcare (Hines, 2008). Pronovost et al. (2006) stated, "HROs have proven that the context in which care is delivered, called organization culture, also has important influences on patient safety." By studying their practices and embracing the three key components of HROs: leadership engagement, robust process improvement, and an organizational culture of safety, healthcare may see an improvement in patient safety.

Early foundational patient safety studies in the United States highlighted cause for public concern related to adverse events. In 1991, Brennan et al. set out to determine the incidence of adverse events, specifically those resulting from negligence or substandard care, partially due to increasing malpractice litigation (Brennan, Leape, et al., 1991). Using a large sample of randomly selected patient records from acute care hospitals in the state of New York from 1984, statewide adverse event incidence rates were approximately 3.7 percent for hospitalized patients, of which about one percent involved negligent care (Brennan, Leape, et al., 1991). Leape et al. (1991) expanded on these findings in order to learn about injuries resulting from adverse events and their causes.

This study found that many adverse events were neither preventable nor predictable, but the article goes on to state that, "preventing these 'unpreventable' adverse events will require advances in biomedical knowledge" (Leape et al., 1991). High rates of adverse events due to management errors identified in this study indicate the potential for immediate system changes. Rather than waiting for medical advances, changes in the short term, may prevent or reduce errors attributed to management issues. Studies of retrospective record review to assess adverse event rates were conducted around this time period in countries other than the United States; the rates of error in healthcare were common (Vincent, Neale, & Woloshynowych, 2001).

A study by Andrews et al. (1997) took a different approach to the discovery of adverse events, claiming previous reports underestimated error rates. The authors claimed that some events may never be discovered by the provider nor the patient; however, their observational study uncovered an adverse event in 480 of the 1,047 patients observed (Andrews et al., 1997). This rate of approximately 46 percent is much higher than the findings reported in Brennan et al. (1991). This difference demonstrates that the quantification of epidemiological rates of adverse events and errors is complex, and the choice of method used to determine these rates can lead to considerable variability.

Due to increased attention on these studies of the epidemiology of errors and adverse events, many government health agencies around the world sponsored influential reports (Flin, 2007). The renowned IOM report *To Err is Human: Building a Safer Health System* suggested hospitals may in fact not be safe places to receive healthcare based on estimates of the quantification of preventable medical errors resulting in death

within the United States (Kohn, Corrigan, & Donaldson, 2000). The United Kingdom's Department of Health published similar reports, which discussed organizational culture and reporting systems as areas of focus for valuable active learning (Stationery Office, 2000; Stationary Office, 2001).

Patient safety practices have been created to help manage and reduce the likelihood of harm and patient safety events; however, the journey is in its infancy. The AHRQ's report *Making Health Care Safer: A Critical Analysis of Patient Safety Practices* used an evidence-based approach to evaluate a wide range of specific practices in use (Shojania, Duncan, McDonald, Wachter, & Markowitz, 2001). A sequel to this report *Making Health Care Safer II: An Updated Critical Analysis of the Evidence of Patient Safety Practices* (2013) provides a comprehensive review of the practices and programs currently in place (e.g., interventions to improve hand hygiene compliance, rapid response teams, use of beta blockers to prevent perioperative cardiac events) (Shekelle, 2013). Notable recommendations from these reports relevant to patient safety, for this thesis focus on an organization's safety culture and reporting systems.

Pronovost et al. (2009) argue that despite numerous patient safety activities, there remains a lack of empirical support indicating patient safety improvement. Due to the conceptual nature of safety and variety of safety problems (e.g., misdiagnoses, falls, procedural complications, and medication errors) it is difficult to develop and quantify accurate and reliable patient safety measures. Reliable patient safety measures can help establish priorities, generate discussion for new ideas for improvement, and evaluate whether implemented efforts are effective (Classen et al., 2011). The AHRQ claims that

measurement of patient safety remains an area for development (Aspden et al., 2004). Healthcare quality uses the Donabedian Model for the measurement of quality of care. It focuses on structures, processes, and outcomes (Donabedian, 1966). Patient safety has struggled to use this approach, since valid rates are hard to calculate for several reasons. Pronovost et al. (2006) acknowledged the following difficulties which lead to biased rates: certain types of patient safety events are uncommon and rare (e.g., serious medication errors and wrong-site surgical procedures), the of lack standardized definitions, surveillance methods mainly rely on self-reporting, denominators are typically unknown (i.e., populations at risk), and the time periods for exposure are often unspecified. These issues are common throughout the industry, but by focusing on reducing these biases and accounting for limitations in measurement, the patient safety domain can create metrics to benchmark, monitor, and trend their improvement strategies and interventions.

To reiterate, the goal of patient safety in healthcare is to minimize the incidence of adverse events, and to learn from the patient safety events that do occur. In the AHRQ's recent report entitled *Monitoring Patient Safety Problems*, the methods used to uncover and monitor adverse events and errors were described as a specific patient safety practice (Shekelle, 2013). One of the chapter in the report is dedicated to discussing the following techniques: event reporting, direct observation, chart review, malpractice claims, patient complaints and reports to risk management, executive walk rounds, trigger-tools, patient interviews, morbidity and mortality conferences, autopsy, and clinical surveillance (Shekelle, 2013). This report serves as a current meta-analysis on the

approaches in use based on the findings of three patient safety assessment reviews. A detailed discussion of the benefits and limitations of each method can be found within those articles (Michel, 2003; Shojania, 2010; Thomas & Petersen, 2003). No single method proven superior since they aim to assess a range of healthcare issues with varying levels of resources. Additionally, many of these methods focus on capturing and quantifying errors and adverse events, but typically do not measure metrics on learning from these types of events. While a single measure of patient safety remains in debate, the use of a broad set of methods to uncover and monitor safety issues, errors, and adverse events provides a more comprehensive assessment of the level of safety within an organization.

Safety Culture & Safety Climate

Commonly discussed in patient safety literature is the theme of safety culture within an organization, its development as a key patient safety practice or strategy, and its value as a summary variable of patient safety (Pronovost, Miller, et al., 2006; Weaver et al., 2013). Nieva and Sorra (2003) explain that the foundation of the patient safety movement is the promotion of a culture of safety. One aspect of an organization's culture, *safety culture*, is something both an organization creates (e.g., structures, practices, controls, and policies) and encompasses (e.g., beliefs, attitudes, and values) regarding safety and its enhancement (Croll, Coburn, & Pearson, 2012; Flin, 2007; Robb, 2010; Weaver et al., 2013). Drawing from industries advanced in safety sciences, the most commonly accepted definition of safety culture, which can be easily adapted to the

healthcare domain, comes from the nuclear industry. "The *safety culture* of an organization is 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" (Health & Commission, 1993).

The AHRQ's interpretation, to paraphrase key features, of a culture of safety encompasses several activities. These include the acceptance of the high-risk nature of an organization's undertakings, a shared goal for the organization to achieve safe operations at all times with a commitment of resources to safety efforts, an environment that is blame-free where workers are able to report safety events without the fear of punishment, and collaboration between providers of all levels is encouraged in order to solve patient safety problems (AHRQ, 2012d).

National organizations such as the Department of Health in the United Kingdom and the IOM in the United States have identified the development of safety culture as a key component for the improvement of safety in healthcare (Flin, 2007). The IOM however stated, "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" (Corrigan, 2005; Croll et al., 2012).

Efforts to create a positive safety culture are better prefaced by separating safety

culture into albeit overlapping elements, however there is no standardized breakdown. The following components often discussed in the literature are open culture, just culture, reporting culture, learning culture, informed culture, and flexible culture. Cultures that are *open* allow healthcare professionals to feel safe and comfortable discussing patient safety events and safety concerns with employees at all levels of the organization (Carthey, 2013). *Just culture* combats the traditional punitive nature of healthcare errors. Often cultures that are *just* describe the balance between environments that realize the systems approach to learning from errors, those that are outside the control of the individual, while maintaining accountability for reckless behavior (Marx, 2001). Safety cultures embracing open and just behaviors allow for enhanced *reporting cultures*. Typical barriers to reporting patient safety events can include: fear of blame and punishment, belief of added burden in terms of time and effort, failing to see the benefits, and lack of trust in effective change. A *learning culture* works to acquire lessons learned from reported events and uses that knowledge to develop systematic change (Reason & Hobbs, 2003). Taking the component learning culture one step further, an informed culture relies on a strong reporting culture. *Informed cultures* effectively learn from past experiences and actively spread "best practices" (Reason & Hobbs, 2003). Finally, a *flexible culture* illustrates that employees are able to adapt effectively to changes in terms of safety (Reason & Hobbs, 2003).

It may be unreasonable to suggest that efforts to improve the culture of an organization will lead directly to improved patient outcomes (Weaver et al., 2013). However, there is a general agreement that an improvement in the culture can contribute

to enhanced safety in healthcare; safety culture may be better described as a precondition for change rather than the agent itself (Foundation, 2013). Several studies suggest that there is a positive relationship between culture and safety outcomes (Croll et al., 2012; Hofmann & Mark, 2006; Singer, Lin, Falwell, Gaba, & Baker, 2009). Additionally, interest in the measurement of organizational culture which supports these findings has grown (Singla, Kitch, Weissman, & Campbell, 2006). The United Kingdom's industrial safety regulator recommends that "high-risk industry organizations measure their safety culture on a regular basis" ((HSE), 1999; Flin, 2007).

The terms climate and culture are often inadvertently used interchangeably despite their different meanings (Flin, 2007; Weaver et al., 2013). *Safety climate* can be summarized as the shared perceptions of an organization's safety culture, and it only provides a snapshot of these acuities at a given point in time. From the organizational literature, it has been suggested that climate "is only a surface manifestation of culture and that culture manifests itself in deeper levels of unconscious assumptions" (Flin, 2007; Schein, 1990).

Systematic reviews have been conducted to identify and assess intervention strategies for improving safety culture and climate (Morello et al., 2013; Shekelle, 2013; Weaver et al., 2013). Important to the development of the thesis methodology is the belief that culture is "local." The variability of safety culture between departments, within the same hospital, has been noted as greater than even between hospitals (Pronovost & Sexton, 2005). These findings indicate that culture assessments results are better aggregated to the unit or departmental level.

Assessing safety culture and climate remains difficult. One of the most common methods used to assess safety culture takes the form of self-report questionnaires or surveys, which by definition assess safety climate. Culture may only be measurable by qualitative methods (e.g., ethnographic studies, longitudinal observations), while quantitative methods (e.g. questionnaires, surveys) used to assess climate may not fully represent the overall safety culture (Flin, 2007; Weaver et al., 2013). Due to the vast resource commitment of qualitative means of measuring culture, assessments of culture are commonly conducted via safety climate measurement. Culture may be slow to change, but climate may have the ability to change more quickly with specific and targeted interventions (e.g., training on just culture, and clearly communicated prioritization of safety compared to other objectives by upper management), thus assessing change over time may be valuable.

Survey results aim to establish baseline and benchmarking measures, identify weaknesses in safety culture, help to evaluate and track changes of safety interventions, and often are completed to fulfill requirements for regulatory organizations (Nieva & Sorra, 2003). Multiple reviews of patient safety climate survey instruments have been conducted (Colla, Bracken, Kinney, & Weeks, 2005; Singla et al., 2006). Findings from these reviews highlight that surveys span several safety climate dimensions, which may not correspond to the previously defined elements of safety culture (e.g., open, just, reporting cultures) (Flin, 2007). No standard classification of the components of safety culture makes climate assessment that much more complex, and this can lead to variability in survey measures.

The AHRQ cited that organizations on average administer surveys every 16 months, and caution against administering within a six-month period (AHRQ, 2010). Colla et al. (2005) describe five common safety climate dimensions found in most surveys: leadership, policies and procedures, staffing, communication, and reporting. The Singla et al. (2006) review also mention most surveys aim to assess reporting infrastructure. Survey questions focusing on reporting provide knowledge of reporting culture, and data on reporting trends may provide insights into an organization's open, just, and reporting components of safety culture.

There are numerous surveys in use, and the two most often recommended, based on their psychometric evidence (valid and reliable methods for psychological and qualitative measurement), are Sexton's Safety Attitudes Questionnaire (SAQ) and the AHRQ's Hospital Survey on Patient Safety Culture (HSOPS) (Croll et al., 2012; Flin, 2007; Robb, 2010; Sexton et al., 2006; Sorra & Nieva, 2007; Weaver et al., 2013). The HSOPS, for example, assess two outcome variables related to reporting; the frequency of event reporting within a specific department and the number of events reported (Sorra & Nieva, 2007). The question on frequency of events reported is subjective, and is evaluated using a 5-point Likert scale of frequency (ranging from never to always). The question referring to the number of events reported asks participants to recall and quantify the number of events personally reported in the 12 months prior. Flin (2007) argues, "the extent to which the safety climate questionnaire scores related to the specified [outcomes] measures…should be based on objective data that are measured from a different source." Itoh et al. (2002) conducted a study and found no correlation

between survey responses of reporting compared to actual rates of adverse events reported. This may suggest that employee responses do not provide a valid or reliable measure for these outcome variables in terms of reporting culture. Incorporating findings from other data sources, such as reporting systems, may provide a clearer picture of the reporting culture component within safety culture, and thus a comprehensive assessment of hospital safety climate.

Reporting Systems

The adage that history has a tendency to repeat itself holds true in medicine as well, and striving to learn from mistakes has propelled the detection of errors in medical care. A variety of processes have been used to identify and record errors resulting from care in order to prevent their reoccurrence. Early methods revealed medical errors retrospectively through morbidity and mortality conferences and malpractice claims data (Shojania et al., 2001). Foundational studies by Brennan, Leape, Vincent, and Andrews mentioned previously used retrospective chart reviews to quantify adverse event rates (Andrews et al., 1997; Brennan, Leape, et al., 1991; Leape et al., 1991; Vincent et al., 2001). Along with their wide-ranging findings these methods are costly and labor intensive. They typically only detect adverse events, as opposed to identifying the hazards and causes of error; additionally, they tend to neglect events that do not lead to injury (Barach & Small, 2000). Recently, computerized surveillance systems have been implemented to capture certain types of errors (e.g., medication errors). However, this method requires advanced technologies (Whipple et al., 1994). Another active method of

surveillance, includes global trigger tools and direct observation (AHRQ, 2012a; Classen et al., 2011). While most error identification strategies are retrospective, some institutions utilize prospective methods, such as quality assurance audits and failure modes and effects analyses (FMEA) to assess issues and hazards before patient safety events occur (Boxwala et al., 2004; Commission, 2010; Shojania et al., 2001).

While there are currently numerous methods for discovering medical errors and adverse events, most hospitals utilize reporting systems, which differ from other methods because they rely on front-line personnel to collect information on patient safety events. The scope and specific aims of reporting systems vary greatly within healthcare, and the literature notes multiple titles for these systems (e.g., error reporting systems, incident reporting systems, patient safety reporting systems (PSRS)). Despite these differences the main purpose remains the same: collect qualitative data on patient safety events in order to learn from them (Michel, 2003). The key component of these systems compared to other patient safety methods is that front-line personnel, those directly involved in providing patient care, document patient safety events (AHRQ, 2012a). Some hospitals allow patients, their families, or patient advocates to submit event reports in their systems (WHO, 2005).

Currently, there remains no universal reporting system in the United States, but other countries have been able to successfully implement nation-wide systems (e.g., National Reporting and Learning System (NRLS) in the United Kingdom). Due to this lack of standardization, hospitals are often responsible for creating their own reporting systems, as well as methods of learning from reported events. Reports typically include:

time and day of the event occurrence, site of the event with location or department, roles of participants and those reporting (e.g., patient, staff, visitor), the type of event that occurred, some classification of severity and/or level of preventability, and a free-text section used to describe the event or state of the system (Boxwala et al., 2004). These reports result in some combination of structured and unstructured data.

The technique of reporting systems, taken from high-risk and complex industries, offers an adverse event and error detection strategy that is relatively inexpensive and less time consuming compared to formal studies (Michel, 2003; Shojania et al., 2001). Event reporting can provide benefits over other methods of error and adverse event detection because it can be integrated into staff's day-to-day operations, and the analysis of qualitative data can help identify latent errors and system level problems (Thomas & Petersen, 2003). One study looking to create their own reporting system conducted interviews and found reporting did not disrupt the workday nor interfere with patient care (Weingart, Callanan, Ship, & Aronson, 2001). A study conducted by O'Neil et al. (1993) discovered that physician reporting systems uncovered adverse events not found in a retrospective record review, and the events identified by physicians were thought to be preventable leading way to quality improvement efforts.

In the past, reports were typically paper based, but many healthcare organizations have switched to Web-based methods for data entry. The World Health Organization (WHO) also cites e-mail, fax, mail, and phone calls as other modes for submitting reports (WHO, 2005). Healthcare employees must be trained on the types of patient safety events to report as well as how the events should be documented. While the development and

assessment of training programs are critical to the success of generating data for this approach, they are outside the scope of this thesis. The lack of a universal reporting system has made learning from documented patient safety events that much more difficult ,due to the variability in the systems between institutions at all levels (e.g., local, national, international).

The World Alliance for Patient Safety, created by the WHO, summarized four core concepts of reporting systems. These concepts include: the system's fundamental role is to enhance learning from failures, the individuals who report should not be punished, the value of reporting lies in the organization's response to the collected reports (i.e., feedback and recommendations for change) not just for the sake of reporting, and resources should be dedicated to those responsible for analysis, learning, and dissemination of findings and recommendations (Organization, 2005). Supporting those standards, the AHRQ recommends that key components of effective systems include: a supportive environment where staff's privacy of those who report is protected, reports should come from a range of personnel, a summary of reported events should be distributed in a timely manner to staff, and there should be a structured approach for review and development of action plans (AHRQ, 2012a). The following list of characteristics for successful reporting systems was complied from many authors: nonpunitive, confidential, independent, expert analysis, timely, systems-oriented, and responsive (Cohen, 2000a, 2000b; Connell, 2000; Gaynes et al., 2001; Leape, 2002). Most importantly though, an environment that fosters an enhanced reporting culture, is a prerequisite to reporting system success (Barach & Small, 2000). An enhanced reporting

culture requires organizations to include open and just cultures.

The IOM's report *To Err is Human: Building a Safer Health System* stressed healthcare organizations and practitioners utilize voluntary reporting systems in addition to mandatory ones as part of their internal improvement strategies (Commission, 2013; Kohn et al., 2000). Reporting systems can assume both mandatory and voluntary objectives. Various issues involved with each system have been noted. Cohen suggested that with mandatory systems, staff are less likely to provide meaningful information that may be useful in terms of learning by others, because their primary focus is self-protection and compliance to regulation (Cohen, 2000b). Typically, the act of documenting patient safety events is voluntary; however, accreditation bodies, such as the Joint Commission (TJC), require reports of certain patient safety events (e.g., sentinel events). *Sentinel events* as defined by TJC are adverse events, "involving unexpected death or serious physical (e.g., loss of limb or function) or psychological injury, or the risk thereof (any process variation for which a recurrence would carry a significant chance of a serious adverse outcome)" (Commission, 2013).

The act of reporting itself is of little value without analyzing and learning from the information collected. Patient safety event reports have the potential to be aggregated at different levels (i.e., national, regional, hospital, unit) allowing for different types and levels of learning. The benefits of reporting are maximized if learning can occur at multiple levels (Pronovost et al., 2011). For example, analysis of a report at the unit level is specific and unique; at the hospital level, learning can reduce harm across units where similar hazards are present; and from the regional or national standpoint, learning at this

broader level reduces risks common throughout the entire healthcare system.

There are also differences in reporting systems which can be categorized into those used to address external objectives versus systems that focus on reporting for internal purposes. Some hospitals' reporting systems are solely created to fulfill accreditation requirements and report externally at a regional or national level, while others use systems that keep reports internal and completely confidential. There are tradeoffs between these systems, and many hospitals create reporting systems to address multiple aims. It is believed that at the national level, the following objectives could be realized: the identification of hazards and effectively targeting resources, the ability to capture more rare events allowing for earlier identification of unsuspected hazards, the aggregate analyses can identify common contributing factors for certain events, and successful system changes can be disseminated as "best practices" (Barach & Small, 2000; Flowers & Riley, 2001; Leape, 2002). Barach and Small (2000) noted "accountability, transparency, enhanced community relations, and sustaining trust and confidence in the healthcare system" as incentives for the society in support of reporting at the national level.

The following are examples of national level reporting systems used across the world. The Sentinel Event Database, maintained by TJC, is not entirely voluntary. This is because if the TJC learns that an accredited hospital fails to report sentinel events, then the hospital must provide evidence of their root causes analysis (RCA) or risk loss of accreditation (Leape, 2002; Shojania et al., 2001). The United Kingdom's National Health System (NHS) developed the National Reporting and Learning System (NRLS),

and was noted by the AHRQ's *Advances in Patient Safety: New Directions and Alternative Approaches* as, "perhaps the most mature, country-level PSRS [Patient Safety Reporting System] in existence" (Flowers & Riley, 2001). A final example that is the maintained by the Australian Patient Safety Foundation is the Australian Incident Monitoring System (AIMS) (Webb et al., 1993). The previously mentioned benefits are being achieved in some places, however in the United States the majority of reports are typically managed at the hospital level with some regional level learning through the use of Patient Safety Organizations (PSOs) and state level mandatory reporting systems (Pronovost et al., 2011). Regional or state level systems are also responsible for making sure hospitals are accountable for safe practices (Flowers & Riley, 2001; Kohn et al., 2000; Leape, 2002).

The focus of voluntary reporting systems is to identify and capture a broad set of events that led or could have led to patient harm in an effort to learn from them. Again, an event is defined as, "any type of error, mistake, incident, accident, or deviation, regardless of whether or not it results in patient harm" (AHRQ, 2012f). Based on the AHRQ's *Common Formats* definition, *incidents* include only events that reach the patient. While many systems are categorized as incident reporting system, they are actually intended to collect data on all types of events along the harm spectrum, thus falling outside the realm of the AHRQ definition. While patient safety events such as near misses may not reach the patient, they can help detect system hazards and weaknesses. *Near misses*, close calls, benign errors, or precursor events are patient safety events that do not produce harm, only because of chance, prevention, or mitigation

(AHRQ, 2012b; Aspden et al., 2004; Battles, Kaplan, Van der Schaaf, & Shea, 1998;

NQF, 2002, 2007). Learning from these types of events and implementing system

changes may prevent future sources of harm. The idea of a harm spectrum includes non-

harm near misses or individual hazards and errors on one end, and sentinel events on the

other. Between these two extremes are events that reach the patient but do not cause

harm, and other adverse events with varying degrees of harm (WHO, 2009b).

The literature discusses the difficulties of collecting data on patient safety events

using the reporting system method. Typically these issues are discussed as barriers to

reporting. Although the barriers overlap, they include psychological factors, factors

influenced by the organization and its culture, and barriers associated with the manner

and modes of data transcription.

There are psychological factors that can be seen to influence motivation to report.

Many of these revolve around peer or staff approval. Concerns regarding fear of

punishment, liability, and potential legal exposure, also described as medico-legal issues,

present challenges (Cohen, 2000a; Cullen et al., 1995; Leape, 2002; Mariner, 2001;

Shojania et al., 2001; Thomas & Petersen, 2003). These issues stem from skepticism

about confidentiality and anonymity. If employees do not perceive a benefit, do not

believe that follow-up efforts will be conducted, or believe in a lack of effectiveness in

the system, then they are less likely to report (Cullen et al., 1995; Leape, 2002). While

the above-mentioned barriers would be considered psychological factors on the level of

the individual, these attitudes can either be removed or heightened based on the culture of

the organization in which they work. Organizational culture can also influence

employees' perception of event reporting as extra work and a burden (Barach & Small, 2000; Billings, 1998). The safety climate is a major factor in either the success or failure of reporting efforts. Organizations with a positive safety culture will not see any reports as trivial, but will embrace all levels of harm detection. Also, there will be clearly defined roles as to who is responsible to report when events occur. Leape (2002) mentioned that mandatory reporting systems typically do not result in informative feedback, which from the standpoint of the hospital, reporting is regarded as "all risk and no gain" and can result in damage to reputations and loss of business. Lastly, there are limitations due to the manner and modes of data transcription. This type of barrier includes time pressures, employees being too busy, and the modes of reporting, such as forms, are too long (Evans et al., 2006; Leape, 2002; Thomas & Petersen, 2003).

Regulations have been passed to alleviate concerns of medico-legal issues, such as the Patient Safety and Quality Improvement Act of 2005, which encourages voluntary and confidential reporting, and it created Patient Safety Organizations (PSOs) to analyze patient safety data for learning purposes (AHRQ, December 2012). However, it is important to notice that many of these barriers are based on employees' attitudes and perceptions that can be addressed through training and positive safety climate efforts. Organizations that provide simplified reporting methods, clearer definitions of events and designation of staff responsibilities for reporting events, education on reporting, feedback and follow-up on reports, and reassurance of the nature and purpose of reporting system can mitigate many of the psychological barriers (Michel, 2003; Vincent et al., 2001).

In addition to the barriers of reporting systems, and despite their potential

benefits, there are several recognized limitations of patient safety event reporting systems. In this review the limitations can be summarized as the lack of epidemiological data about adverse events and error due to issues with underreporting, biases, inconsistent terminology related to its subjective nature, and finally the limitations imposed by multiple classification schema.

"The rate of adverse events is estimated to range between 2.9 and 16.6% of acute care hospital admissions" (Evans et al., 2006; Thomas et al., 2000; Wilson et al., 1995). However, the percent of documented adverse events is low, with one study estimating 1.5%, and the American College of Surgeons estimating that reporting systems only capture 5-30% of adverse events ("Patient safety manual," 1985; O'Neil et al., 1993; Shojania et al., 2001). "Underreporting of adverse events is estimated to range from 50-96% annually" (Barach & Small, 2000; Cullen et al., 1995; Kohn et al., 2000; Leape, 1994). Based on this quote, a review of the literature indicates there is no question that reporting systems collect only a fraction of events and cannot accurately collect epidemiological data. This is attributed to the fact that reported events are likely to underestimate the numerator needed to calculate a valid rate, and the denominator, or number of opportunities for event occurrence, is unknown. Therefore, event reports deliver a snapshot or instance of safety issues (AHRQ, 2012a; Cullen et al., 1995; Michel, 2003).

Due to the nature of reporting, there are inherent selection and reporting biases which affect underreporting and hinder reliable rates of incidence and prevalence. Selection bias refers to systematic error where the reports may not be representative of

the population. Studies also indicate that reporting rates of nurses are much higher than any other healthcare professional (AHRQ, 2012a). "Physicians have been reluctant partners in reporting" (Leape, 2002; Mariner, 2001). The AHRQ's recommendation for successful systems, mentioned reports should be representative of a range of personnel. A lack of reporting by a certain type of staff may also attribute to these biases. Events that actually get documented are also subject to reporting bias, which includes factors influencing the reporter to report. Examples of reporting bias that might influence the behaviors of the reporter are their understanding of what and how to document, or their beliefs surrounding expected follow-up or feedback efforts, or the lack thereof. Studies have shown that the visibility and identification of the event and/or its outcome, particularly by junior, less experienced staff, and the reporting culture of the unit will have an influence on whether events get reported. Also, if an event is unusual, interesting, or particularly dangerous it is more likely to get reported (Beckmann et al., 1996; Kohn et al., 2000; Pronovost et al., 2011; Vinen, 2000).

Another limitation of reporting systems, and patient safety efforts in general, is inconsistent terminology. The President of TJC stated, "It is no small irony that the progressively expanding national discussion on patient safety over the past several years are not based on a common language. This critical missing element has hindered our collective ability to collect patient safety data in a consistent fashion, analyze process failures, mine data (e.g., trends, pattern analysis), and disseminate new knowledge about patient safety" (Boxwala et al., 2004; *Testimony of Dennis S. O'Leary, President, The Joint Commission on Accrediation of Healthcare Organizations*, 2002). As mentioned

before, the range of data collected in reporting systems varies greatly. This could be due to the subjective nature of definitions and terminology since standardized terminologies are not in place.

This issue extends into the final limitation discussed in this review, the use of multiple classification schemas. In addition to the ways to classify events, reporting systems include harm severity rating scales of events that are subjective in nature. The overall lack of standardization in reporting systems is a major issue, especially when trying to learn from error and harm (Michel, 2003). Some examples of the multiple classification schemas for patient safety and levels of harm include, the HPI SEC & SSER Patient Safety Measurement System for Healthcare, TJC patient safety event taxonomy, and the WHO's International Classification of Patient Safety (ICPS) (Chang, Schyve, Croteau, O'Leary, & Loeb, 2005; Healthcare Performance Improvement, 2009; WHO, 2009b). Classification of patient safety events falls outside the scope of this review, but classifying harm severity remains relevant. Harm is categorized differently between institutions; however, there is a distinct differentiation between patient safety events that result in harm and those that do not. Non-harm events in this thesis are commonly referred to as near misses in the literature.

Major adverse and sentinel events tend to attract media attention, however near misses tend to occur more often based on theories and models of accident causation (Battles et al., 1998). Studies from other industries indicate that near miss safety events have similar characteristics to those found in serious events, leading to their title as precursor events (Battles et al., 1998; Nagel, 1988). A simply analogy goes as follows. A

risk factor is to error as a near miss is to an adverse event, thus by learning from near misses the hope is to prevent adverse events. Several authors have studied this idea and have created accident pyramids to summarize the relationship between accidents and near misses, and relative frequencies and seriousness (Radvanska, 2010). As early as 1931, Heinrich proposed that for each main injury, there were 29 minor injuries, and 300 unsafe acts or near misses (Heinrich, 1959). Later a study conducted by Bird et al. (1974) using accident reports from a broad set of companies suggested that for each fatal accident there were 10 serious accidents, 30 accidents, and 600 incidents resulting in no harm. The intent of these models is not to be representative of the ratios specific to a certain industry or group. Rather the models demonstrate that the more serious events are rare and they explain the amplified opportunities to learn from "lesser events" (Radvanska, 2010). Analyzing non-harm events offers the opportunity to implement system changes in order to prevent harm events from occurring.

"Focusing on data for near misses may add noticeably more value to quality improvement than a sole focus on adverse events" (Barach & Small, 2000). The limited number of reported serious harm events gives few cases for learning opportunities, and by focusing more heavily on the near misses, the approach becomes more proactive rather than reactive while waiting for serious harm to occur. One organization argues that if non-harm events do not encompass 70% of all events reported, then awareness of the benefits of reporting should be increased, because these events are essentially free learning lessons (Carthey, 2013). Near misses offer numerous benefits over adverse events. There are fewer psychological barriers to data collection of non-harm events.

Events that do not result in harm are subject to much less liability and medico-legal risk, and fear of punishment is reduced (Barach & Small, 2000; Shojania et al., 2001). In addition to potential for a greater frequency of events to be captured and later analyzed; analysis of non-harm events is less susceptible to hindsight bias (Barach & Small, 2000; Shojania et al., 2001).

The analysis of non-harm events is even less streamlined in the healthcare system. One study, which used time-trending reporting of incidents to focus on learning and event prevention, found there were 3.5 times as many near misses compared to actual errors (Arnold, Delaney, Cassapi, & Barton, 2010). Another study conducted in the United States, found there are approximately seven times as many near misses as adverse events (Bates et. al, 1995). In the healthcare domain, it is estimated that near misses occur 3-300 times more often than harm-events (Barach & Small, 2000). There remain few published articles on the analysis of near-miss reports, and none have been found which suggest using near miss reports as a measure for reporting culture or safety climate.

Control Charts

After identifying key metrics and collecting data, a common measurement issue remains – how to analyze and interpret the data? In quality and patient safety improvement it is important to assess whether interventions are leading to effective change. In the United States, during the 1920's, the basic theory of statistical process control (SPC) was developed by Walter A. Shewhart at the Bell Telephone Laboratories, and was later popularized worldwide by W. Edwards Deming (Deming, 1986; Shewhart,

1931). Montgomery (2013) describes SPC as a collection of seven problem-solving tools (i.e., histogram or stem-and-leaf plot, check sheet, pareto chart, cause-and-effect diagram, defect concentration diagram, scatter diagram, and control chart) used to achieve stability, improve capability through the reduction of variability, and monitor performance of processes. SPC has also been depicted as, "a branch of statistics that combines rigorous time series analysis methods with graphical presentation of data, often yielding insights into the data more quickly and in a way more understandable to lay decision makers" (Benneyan, Lloyd, & Plsek, 2003). Though the tools of SPC were created for the manufacturing domain, the methodologies have been used in many industries including healthcare, where they first took root in the laboratory setting (Thor et al., 2007).

Benneyan et al. (2003) discuss the use of SPC in healthcare to as a tool for communication between healthcare entities as they relate to improvement efforts. In order to see if one group is "significantly different" from another Benneyan et al. (2003) note tests of significance as the most common method for this claim. Although these methods have strong statistical power when based on large data sets, there is a delay in accumulating sufficient amounts of data necessary to conduct the tests (Benneyan et al., 2003). The paper explained that often this leaves healthcare practitioners resorting to simple bar charts, line graphs, or tables when presenting data, where only qualitative statements rather than statistical tests are used when discussing improvement (e.g., whether or not there "seems" to be an improvement). On the other hand, Benneyan et al. (2003) states that, "SPC methods combine the rigor of classical statistical methods with

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the time sensitivity of pragmatic improvement; by integrating the power of statistical significance tests with chronological analysis of graphs of summary data as they are produced, SPC is able to detect process changes and trends earlier."

A foundational part of the SPC strategy is based on Shewhart's theory of variability, which recognizing both origins of variation: common and special cause (Montgomery, 2013; Thor et al., 2007). Trying to determine if a process' performance has changed can be challenging for many reasons, one of which is natural or chance cause variation. These terms as well as noise and non-assignable cause refer to common cause variation. This type of variation is inherent to a process regardless of how well it is designed or maintained.

When a variable is measured repeatedly, such as a patient's body temperature, different values may result even if nothing has changed (i.e., they are not sick). One reading may indicate a body temperature slightly greater than 98.6° Fahrenheit, which might lead to the conclusion that the patient is fighting an infection. If the healthy patient does not in fact have a fever, this slight variation would be considered common cause, which may be expected due to the underlying statistical distribution and the range of acceptable healthy body temperatures. Conversely, if a patient's body temperature is measured at 103° Fahrenheit, this measurement is less likely to be due to common cause variation. This deviation would be considered special cause variation, also known as a signal or assignable cause.

Special causes result from, "variation due to events, changes, or circumstances that have not previously been typical or inherent in the regular process" (Benneyan et al.,

2003). Special causes can be due to external factors that may not be completely controllable, or they can results from methodical interventions. Both of these types of special causes have the potential to either become a part of the process (e.g., a sustained shift) or be temporary. A process that exhibits special causes is said to be out of control, and these instances require investigation.

An advantage of SPC is the ability to quickly detect assignable causes in order to conduct investigations of their source in a timely fashion. The primary and most technically sophisticated SPC tool to filter out common causes from potential special causes is the control chart (Wheeler, 2003). Also known as Shewhart control charts, they graphically display a series of measurements of a quality characteristic of interest versus chronological time, in order to monitor the behavior of a process (Sherman, 2012). In addition to the data of interest, a center line, which typically represents the average value of the measured characteristic, and upper and lower reference thresholds called control limits, which are typically set at three-sigma (standard deviations) from the mean, are plotted on the chart (Woodall, Adams, & Benneyan, 2012). The upper control limit (UCL) and lower control limit (LCL) are calculated using process data and are used to define inherent variation in the process. These limits illustrate the range data should almost always fall within if the process is in statistical control. The use of control charts in other industries is well established, and recently in healthcare the benefits have been realized in administrative and clinical processes (Benneyan, 2008). The Joint Commission has identified control charts as a helpful way to compare current performance with historical patterns, and as a means to assess process stability and

variability (Benneyan, 2008; Organizations, 1997). Their use in monitoring adverse events and other healthcare applications have been demonstrated in the literature (Benneyan, 2001; Noyez, 2009).

Control charts can be categorized as either for variables or for attributes. This differentiation is the first step in determining which type of control chart to construct. Variables are quality characteristics that can be measured on a numeric scale and can assume any value over some defined range (i.e., continuous data). Tennant et al. (2007) conducted a systematic review of the use of control charts in monitoring clinical variables (e.g., systolic blood pressure) in individual patients. Other examples for variable control charts in healthcare include patient wait times, the time between adverse events, or the number of cases between surgical site infections (Benneyan, 2001; Benneyan et al., 2003; Woodall et al., 2012). The most recognizable control charts for variable data are the Xbar and R (or s) charts. The Xbar control chart, or control chart for means, is used for controlling process average or mean quality level. Process variability can be monitored with either the control chart for the range, an R control chart, or the control chart for standard deviation, referred to as an s control chart for sample data. Usually in practice an Xbar and R chart are constructed for each variable quality characteristic, since both mean and variability are important to maintaining processes that are in control. Continuous variables are modeled by continuous probability distributions such as the Normal, Lognormal, Exponential, Gamma, and Weibull distributions (Montgomery, 2013; Woodall et al., 2012). The Xbar, R, and s control charts base calculations for control

limits on the normal distribution. Data that are skewed may need to be transformed before these control charts should be applied.

When quality characteristics cannot be represented numerically, but can only take on certain discrete values the data represents attributes. Attribute data as opposed to continuous data typically involves counts, proportions, or rates (Woodall et al., 2012). With attribute data each element is classified as either conforming (e.g., good, non-defective) or nonconforming (e.g., bad, defective) with respect to the specification(s) of the quality characteristic. Elements of the sample may be nonconforming as a whole, where the element does not satisfy one or more of the specifications (i.e., defective), or could consist of one or more nonconformities (i.e., defects). A nonconforming entity will consist of at least one nonconformity. But an entity with more than one nonconformity does not necessarily mean it is nonconforming; it depends on the specifications of the quality characteristic. When healthcare professionals attempt to diagnose patients with a particular disease there are often sets of criteria, of which if a patient is positive for some threshold they are said to have the disease. Thus, for example, a patient may not be diagnosed with a disease, but may be positive for multiple of its criteria. This is similar to the relationship of an entity conforming or nonconforming as a whole (e.g., defective), and that same entity consisting of one or more nonconformities (e.g., defects).

There are four common types of attribute data control charts (p, np, c, and u). Discrete variables are modeled by discrete probability distributions such as the Hypergeometric, Binomial, Poisson, and Negative binomial and Geometric distributions.

Binomial distributions describe processes that have a sequence of independent Bernoulli trials where each results in a success or failure. P-type and np-type control charts should be used for data that are distributed according to a Binomial distribution. The p-chart, or control chart for proportion defective, analyzes the proportion of nonconforming units in a sample, where the sample size may vary for each sample. Examples include the proportion of patients readmitted or the proportion of doctors who work more than 60 hours per week. The np-chart, or number of defectives control chart, assesses the number of nonconforming units in a sample, where the sample size is constant for each sample. Examples include the number of patients readmitted or the number of doctors who work more than 60 hours per week.

The Poisson process is a stochastic process, which counts the number of defects or nonconformities in a given time interval, or the number of defects per unit (i.e., rate) in a given time interval. Like the Binomial distribution, the Poisson process is also a model for counting successes, where the successes are relatively rare. The Poisson distribution is useful for situations where the event of interest has a low probability of occurrence, but many opportunities to occur. C-type and u-type control charts should be used for data that are distributed according to a Poisson distribution. The c-chart, or control chart for defects or nonconformities, monitors the total number of nonconformities per unit, where the sample size is fixed. The total number of nonconformities per unit can also be thought of as the total number of patient safety events occurring in a given unit of time, where there could be more than one event per patient. Other examples include the number of patient falls or the number of equipment failures. The u-chart, or control chart for defects

or nonconformities per unit, monitors the average number of nonconformities per unit in a sample. With this type of chart the sample size can vary. This "rate is adjusted to average per some common sampling denominator size" (Benneyan, 2008). The average number of nonconformities per unit can also be thought of as the total number of patient safety events per patient day occurring over some specified unit of time. Again, there can be more than one event per patient. Other examples include the number of patient falls per 1,000 patient days or the number of equipment failures per 100 equipment days.

The quality literature describes six structural components of control charts: x-axis, y-axis, center line, control limits, zones, and rational subgroups (Kubiak, 2009). The x-axis represents the time order of subgroups; in SPC terminology a subgroup is a sample. The y-axis corresponds to the measurement of the quality characteristic of interest. And, the centerline represents the process average that is calculated based on process data. Control limits indicate the expected amount of variation in a process, for those that are in statistical control.

Setting the boundaries, or sigma-levels, in order to detect meaningful change in the process is discretionary (Blumenthal, 1993). In the manufacturing industry control limits are set at $\pm$ 3 sigmas, or standard deviations from the mean, in order to detect special cause variation (Carey & Lloyd, 1995). When setting these limits practitioners must consider the combined total risk of Type I and Type II error. Type I error, or a false positive, would translate to mistaking special cause variation for actual common cause variation. This type of error would lead to unnecessary investigation and possible tampering; it increases as the sigma-level decreases. Conversely, increasing the sigma-

level (wider control limits) leads to an increase in Type II error, or false negatives. Type II errors result in "under controlling" where a data point does not lead to investigation when the point is actually the result of special cause variation. The combined total risk is minimized at the $\pm$ 3 sigma-level (Carey & Lloyd, 1995). Based on this setting, for every 1,000 data points, it would be expected that three points fall outside of the control limits that are actually due to common cause variation rather than special cause. In healthcare, Carey and Lloyd (1995) mention that a case could be made for the use of $\pm$ 2 sigma (i.e., warning limits) depending on the nature of the problem (e.g., processes that involve the well being of patients). As a rule of thumb, "when in doubt, avoid tampering with the process" (Kubiak, 2009). It is best to avoid tampering with a process until the causes of variation are understood, because often tampering leads to increased variability.

In addition to examining points falling outside the control limits, special causes variation tests can be applied to points falling within the limits to assess patterns and runs. One way to describe these rules or tests is by classifying zones that represent the distance between each standard deviation. In the Montgomery (2013) text, the Western Electric *Statistical Quality Control Handbook* (1956) decision rules for detecting nonrandom patterns are described. Zone C corresponds to $\pm$ 1 sigma, zone B is between $\pm$ 1 sigma and $\pm$ 2 sigma, and zone A is between $\pm$ 2 sigma and $\pm$ 3 sigma. Western Electric's rules suggest that the process is out of control if it satisfies one of the following: one point outside the $\pm$ 3 sigma limits "action limits," two out of three consecutive points plot beyond the $\pm$ 2 sigma "warning limits," four out of five consecutive points plot at a distance of one-sigma or beyond from the center limit, or

eight consecutive points fall on one side of the center line (Handbook, 1956; Montgomery, 2013). These rules apply to one side of the centerline at a time. Control charts are, "designed to detect large but transient shifts in the process mean" (Lim, 2003). These rules increase the power of control charts by allowing for detection of smaller process shifts (improvements or deteriorations) more quickly, at the cost of a minor increase in Type I error (Benneyan et al., 2003; Montgomery, 2013). Benneyan et al. (2003) includes two more decision criteria for nonrandom patterns: six successive points increasing or decreasing (a trend) or obvious cyclic behavior to the previous rules, and notes that investigating special cause patterns while waiting for more data to prove statistical significance is powerful psychologically as well as statistically.

The final component of control charts, rational subgrouping emphasizes that, "the variation within subgroups (or samples) should be as small as possible in order to easily detect subgroup-to-subgroup variation" (Kubiak, 2009). The equations below can be used to calculate the control chart parameters for attribute data (Montgomery, 2013):

Table 2.1 Attribute Data Control Chart Formulas

Control Chart Formulas	C-type	U-type
Upper Control Limit (UCL)	$\bar{c} + 3\sqrt{\bar{c}}$	$\bar{u} + 3\sqrt{\dfrac{\bar{u}}{n}}$
Center Line (CL)	$\bar{c}$	$\bar{u}$
Lower Control Limit (LCL)	$\bar{c} - 3\sqrt{\bar{c}}$	$\bar{u} - 3\sqrt{\dfrac{\bar{u}}{n}}$
Notes	$\bar{c} = count\ per\ subgroup$; n must be a constant	$\bar{u} = \dfrac{x}{n}$, $average\ count\ per\ subgroup$; If n varies, use $\bar{n}$ or individual n_i

It is possible that the lower control limit may be less than zero; in this case it is acceptable to set the LCL equal to zero.

Control charts provide information on deciding how to react to a process, in the present, based on the most recent information. They provide insights into things that need immediate attention as well as when not to intervene.

Control chart utilization is best described by its two-phase application. In retrospective, or Phase I use, observations are analyzed following data collection in order to calculate trial control limits. The purpose of the trial limits is to determine whether the process has been in statistical control during the time period data were collected. The goal of Phase I is to bring the process into statistical control by addressing any points falling outside of the trial control limits. When a process is stable, it is possible to predict with some level of certainty, what is likely to happen in the future. "It is highly desirable to collect 20-25 samples, or subgroups of size n, where n is typically between 3 and 5, to compute the trial control limits" (Montgomery, 2013). When control charts include points

falling outside the trial control limits or there is a specific pattern violating the trend rules, the special causes must be investigated. After the causes are identified, practitioners must determine whether these points should be removed from the data. Occasionally, Phase I will require several cycles of recalculating trial limits, but eventually the process will become stabilized. Phase II, the monitoring phase, can begin once the process is in control where each data point is compared to the process control limits. Once in this phase efforts to reduce the common-cause variation and overall process variability can be addressed, however this is outside the scope of this thesis.

In Montgomery's text (2013) effective use of control chart depends on periodic revision of the control limits and centerline since processes may shift out of control over time. Revising these limits after a certain time period is recommended, however that time varies depending on the process.

"The value of the control chart lies not in the novelty of the statistical principles underlying it, but in the ease and reliability with which it converts data into information" (Blumenthal, 1993). It is important that the charts are used correctly, but their application offers a simple means of assessing process behavior and system changes.

CHAPTER THREE

METHODOLOGY

Current assessment of hospital safety climate relies heavily on safety culture surveys administered on annually. Survey assessments use subjective data from employees to measure outcome variables with regard to patient safety event reporting. It may be hard for employees to recall the exact number of reports they made within the last year, making results less reliable and valid. There are known benefits of involving front-line staff in improvement efforts; however relying on subjective data when organizations typically collect data on actual reporting rates within the organization seems inefficient. Plus, this type of time lag does not provide management an efficient strategy to determine whether improvement efforts have a beneficial effect. Though most hospitals assess survey findings over time, the current method assess changes that make take up to a year before they are realized. Strategic interventions may result in effective change, but the yearly level of summary data may mask the effects. Furthermore, many surveys do not aim to capture information on the varying levels of harm for reported events. Based on the advantages of non-harm events it seems relevant to want to collect this type of data for safety climate assessment.

Despite the limitations of reporting systems, incorporating actual data may allow organizations to gain a more accurate depiction of the safety climate and specifically reporting culture. Since the use of reporting systems is becoming routine in healthcare organizations, data from these systems can be used to track and trend actual reporting rates of the organization. Currently, the sum of reported events is depicted in bar charts in

chronological time. But incorporating SPC tools, such as control charts, can help identify baseline measures for the expected number of non-harm events that get reported, and they can be used to monitor trends in reporting culture. Since data in reporting systems is continuously updated, rates can be calculated frequently allowing for much quicker feedback compared to yearly survey results. Although hospitals use different classification schemas of harm severity, most strategies differentiate between events that result in harm and those that do not. Documentation of non-harm patient safety events in reporting systems may indicate organizations with enhanced safety cultures, based on the notion that non-harm events are not as essential as harm events to report. Reporting of non-harm events may indicate practitioners are attempting to learn proactively by documenting non-harm events as opposed to responding reactively to harm. Assessment of safety climate may benefit from understanding the level of harm associated with the events front-line professionals are reporting.

Although reporting systems cannot produce epidemiological rates, rates of documented harm events may better reflect actual rates of harm events compared to the rates of documented non-harm events versus their actual rates. Again, this is based on the idea that harm events pose a bigger threat to the organization in terms of patient safety and accreditation; reporting is often required by outside agencies for the more serious harm events.

However, the debate surrounding the true meaning of high reporting rates remains. "High reporting rates may indicate an organizational culture committed to identifying and reducing errors and adverse events rather than a truly high rate"

(Edmondson, 1996; Thomas & Petersen, 2003). For the purpose of this thesis, an increase in reporting rates of patient safety events indicates a culture that embraces quality and patient safety improvement, as opposed to an environment that has decreasing safety levels.

Due to the lack of standardization within and between reporting systems, and the differences between classifications of harm severity, this methodology is not meant to be descriptive, but rather prescriptive and provide a framework for hospitals to modify based on their systems and data which are currently collected by the healthcare organization.

Objective

The primary aim of this thesis is to design an approach and demonstrate a methodology that aids in understanding hospital safety climate, using control charts as a method to monitor documented non-harm patient safety events in reporting systems over time and across multiple departments.

Approach

In order for hospitals to use this approach they must collect two types of data: reporting system data and some type of data to make units comparable. Hospitals should utilize reporting systems, where front-line staff document patient safety events. As part of their system, each event report should include the department where the event occurred and some associated level of harm severity (e.g., harm score). It will be necessary for each organization to determine a clear distinction between events that result in harm

verses those that should be considered non-harm. In addition to creating control charts based on data at the hospital level of analysis, control charts can be created for different departments within the hospital. Based on the literature, variability of safety culture between departments, in the same hospital, has been noted as greater than even between hospitals (Pronovost & Sexton, 2005). These findings indicate that culture assessment is best described locally or at the departmental level; and this methodology is enhanced when analyses are conducted at this level. For the most accurate analyses the hospital should maintain data to reduce biases and make departments comparable, such as census data to calculate patient days or staffing levels, for the entire hospital and for each department analysis.

The first step of the methodology is to check if the data from the reporting system follows a Poisson distribution. This check can be conducted on the harm events, non-harm events, as well as all events collectively; the approach will be described in terms of non-harm events. Also, the check can be conducted on the entire data set for the hospital or at the department level.

The initial check can be completed in several ways. The easiest of which is to construct a histogram of the frequency of non-harm events per some unit of time and visually check whether the data follows a Poisson distribution. Poisson distributions are skewed right but that skew becomes less pronounced as the mean increases, and may appear to be more 'bell' shaped. The unit of time is variable and will depend on the interest of the individual hospital. The methodology recommends the analysis be conducted at the week level. Based on current patient safety event reporting rates this

may be the lowest level of aggregate analysis that is meaningful. Surveys typically provide data at the yearly level, which can be improved upon, however analyses less than at the week level (e.g., daily) may include too much variability.

Another way to check this assumption would be to conduct a goodness of fit test on the data to assess whether a Poisson distribution can be assumed. The Poisson distribution is characterized by only one variable, lambda; and, the mean and variance are both equal to this parameter. In addition to this initial assumption, there are three basic assumptions for all Poisson distributions that are described here in terms of the non-harm event analysis. First, the opportunity for documented non-harm event occurrence is very large, arguably the opportunity for them may be infinite, but the average number per some unit of time is actually pretty small. The second assumption is that the occurrences of these types of events are independent; again it could be argued that non-harm events serve as precursor events to harmful ones, but here the thesis assumes each non-harm event is independent of the other. Lastly, there must be an equal likelihood of occurrence between samples where the conditions should be consistent from sample to sample.

Assuming the non-harm events follow a Poisson distribution, Shewhart control charts should then be created for the data. Using R Project, a software program for statistical computing, the Shewhart control charts can be constructed using the qcc function within the qcc library. Control charts can be created using other software, but R is recommended.

The discrete data can then be plotted in the form of either c-type (count) or u-type (rate) control charts. The c-type control chart represents the number of non-harm events

reported per some unit of time. Again, weeks are suggested as the subgroup or sample, in order to provide management with a method of early detection for special cause variation. This unit of analysis could be easily adapted depending on the needs of the organization (e.g., bi-weekly, monthly, quarterly). C-type control charts can be produced only with the underlying assumption that the sample size is fixed, or in this case that the opportunity for event reporting of non-harm events is infinite.

In order to compare departments and improve upon the c-type control chart a common denominator, such as patient days or staffing levels should be applied, to adjust for specific patient populations. Given data to create standardized denominators, the u-type control chart can be constructed, which represents the average number of non-harm events per some common sampling unit per unit of time (e.g., average number of non-harm events per 1,000 patient days per week). The methodology recommends a rate such as "per 1,000 patient days" because it is the standard method of recording and reporting census data for hospitals and departments.

The final step in the methodology is to analyze the control charts created using R. For both the c-type and u-type control charts, it is imperative to investigate data points that are not in statistical control. Points of interest are those highlighted in yellow and red on the control chart when using R. The yellow data points represent violations in control chart trend rules. The red data points highlight the points that fall outside of the 3-sigma control limits (i.e., special cause variation). Hospital management must investigate the points in red. Based on statistical evidence they are most likely not produced by the underlying distribution where results of such magnitude are unexpected. Investigating the

cause of the yellow data points may provide detection of small process shifts, but at the cost of an increased Type I error. It is recommended that the process be closely monitored when yellow data points appear.

As mentioned previously, special causes are often attributed to external factors that may not be completely controllable (e.g., computer servers may be down so reports can not be entered as they occur, but create a backlog), or they can result from methodical interventions (e.g., training). Both types of special causes have the potential to either become a part of the process (e.g., a sustained shift) or be temporary.

The purpose of this step is to ensure that the process is in statistical control. If all points fall within the 3-sigma level control limits then the process does not warrant investigation, but the charts should be continuously monitored. Updating the charts at the time unit of analysis (e.g., weekly) allows for detection of process shifts and changes, since each new point is plotted and compared to the control limits.

When special causes are investigated it may be determined that some points are extreme outliers, which for the purpose of calculating control limits should be excluded. Control limits are calculated using historical data, and including extreme outliers causes the limits to be wider than they should be, if it is determined that the point occurred because of extremely unordinary circumstances.

The value of this methodology is not solely in the construction of control charts, but the ease with which this tool converts data into information and the type of information it provides (Blumenthal, 1993). Control charts' ability to detect special cause

variation provides practitioners with a means to monitor reporting culture, and assess or validate whether interventions lead to changes that are statistically significant.

In order to demonstrate this methodology data from a regional healthcare network's reporting system was obtained. This healthcare network was chosen, because of its relatively advanced safety culture and preexisting use of patient safety reporting systems. At this regional healthcare network, upper management supports ongoing training of the benefits of safety culture (e.g., "just culture" training) and training on the processes of event reporting. This includes information and training on the types of events to include, how the information should be input, and how event should be classified including how to rate the level of harm.

The regional healthcare network currently uses the AHRQ's Hospital Survey on Patient Safety Culture as a means of determining hospital safety culture [climate]. In order to supplement these results, the thesis methodology is initially applied to one hospital in the network. Event reporting and survey results are currently analyzed at the hospital level. The control chart methodology was applied to three departments in addition to the hospital as a whole to better assess climate "locally."

Reports from the network's reporting system database were extracted into a spreadsheet, which excluded personal identifying information. The data extraction produced roughly 30,000 reports, each of which included an ID number, who was affected by the event (patient, visitor, staff or unsafe condition or improvement), event type (e.g., omission/errors in assessment, diagnosis, monitoring), event category (e.g., diagnosis issues), event subcategory (e.g., missed diagnosis), event occurrence date, harm

score, site name (e.g., hospital name within system), location/service name (e.g.,

department name), and the event description. The variables of importance for the

analyses are the ID number, event occurrence date, harm score, and location.

This network is a member of the University HealthSystem Consortium (UHC)

Patient Safety Net; and their a real-time, Web-based event reporting system, Safety

Intelligence Program powered by Datix, uses the AHRQ's *Common Formats Harm Score*

v.1.1 (UHC, 2014).

This harm scale classifies events on a 1 to 9 scale, see Table 3.1 (Guide, 2013):

Table 3.1 AHRQ Common Format Harm Score v.1.1 referenced in UHC Safety
Intelligence Powered by Datix

	HARM
9	**Death** "Dead at time of assessment."
8	**Severe permanent harm** "Severe lifelong bodily or psychological injury or disfigurement that interferes significantly with functional ability or quality of life. Prognosis at time of assessment."
7	**Permanent harm** "Lifelong bodily or psychological injury or increased susceptibility to disease. Prognosis at time of assessment."
6	**Temporary harm** "Bodily or psychological injury, but likely not permanent. Prognosis at time of assessment."
	REACHED THE PATIENT
5	**Additional treatment** "Injury limited to additional intervention during admission or encounter and/or increased length of stay, but no other injury. Treatment since discovery and/or expected in future as a direct results of event."
4	**Emotional distress or inconvenience** "Event reached patient; mild and transient anxiety or pain or physical discomfort, but without need for additional treatment other than monitoring (such as by observation; physical examination; laboratory testing, including phlebotomy; and/or imaging studies). Distress/inconvenience since discovery and/or expected in future as a direct result of event"
3	**No harm evident, physical or otherwise** "Event reached patient, but no harm was evident."
	NEAR MISS
2	**Near miss (requires selection of one of the following)** • "Fail-safe designed into the process and/or safeguard worked effectively • Practitioner or staff who made the error noticed and recovered from the error (avoiding any possibility of it reaching the patient), spontaneous action by a practitioner or staff member (other than person making the error) • Spontaneous action by a practitioner or staff member (other than person making the error) prevented the event from reaching the patient • Action by the patient or patient's family member prevented the event from reaching the patient • Other • Unknown"
1	**Unsafe condition**

In this schema, scores of 1 and 2 are considered "near misses," scores 3-5 are classified as "reached the patient," and 6-9 are identified as "harm." An event may reach the patient, but not result in harm. For example, the wrong dose of a drug may be administered to the patient, and the patient may not suffer from adverse effect. In the literature, this event would likely be defined as a near miss due to chance. However, at the regional healthcare network it receives a harm score of 3, which is classified as "reached the patient" instead of "near miss."

The methodology presented in this thesis requires differentiation between harm and non-harm events. Based on the classification schema used at this healthcare system, patient safety events documented with harm scores 1, 2, and 3 represent this thesis' operational definition of non-harm events. Harm scores 4-9 are considered harm events. Although harm scores of 3 reach the patient, they do no result in harm and are considered non-harm events in this analysis. Careful consideration should be taken when classifying events into the operational definitions of harm and non-harm.

In order to protect the confidentially of the data from the regional healthcare network, the actual data from the hospital of interest were not included as part of the analysis. However, the data were used as a basis to create data sets. Although the data in the analysis is simulated it is meant to be representative of hospital reporting systems. In order to simulate realistic data, the function used to produce the simulated data accounted for the fact that the hospital data contained twice the number of non-harm events as harm events.

After the dataset was simulated to represent one hospital in the healthcare network, the first step of the methodology was applied for the non-harm events aggregated at the week level. Prior to initial methodology, check bar plots for each level of analysis (e.g. hospital level and department level), were created to illustrate the total number of event reports by harm score. In order to determine whether the data for all non-harm patient safety events (i.e., events with harm scores 1, 2, and 3) follow a Poisson distribution, histograms were plotted at the hospital level, and then for each of the three departments. Assuming the data followed a Poisson distribution, c-type and u-type control charts using R were constructed using all the data. The healthcare network also provided census data. This allowed for quantification of a common denominator, 1,000 patient days, and the ability to create u-type control charts for the hospital and each department.

The final analysis step for the simulated data is explained in Chapter 5. In order to assist with this portion of this methodology c-type and u-type control charts for harm events are plotted beside their corresponding non-harm control charts. Chapters 4 and 5 each include a hospital level followed by a department level section.

CHAPTER FOUR

RESULTS

Patient safety event reports from the healthcare network included approximately

30,000 documented reports spanning about 2.5 years, for a total of 130 weeks. Analyzing

one hospital within the regional healthcare network produced a sample of about 13,000

reports. The actual ratio of non-harm to harm events equaled 2.09. After the simulated

data set was created, descriptive statistics were calculated based on the new data. Harm

scores 1, 2, and 3 operationally define non-harm events, whereas scores four through nine

are defined as harm events. An initial analysis is conducted at the hospital level, and then

similar analyses are conducted for three different departments.

Hospital Level

Table 4.1 displays the total number of events reported at each harm score.

Table 4.1 Simulated Event Reporting: Hospital Level

	Non-harm events			Harm events					
Harm Score	1	2	3	4	5	6	7	8	9
Number of events reported	2622	884	5872	2058	1308	766	136	180	165

The total number of simulated event reports was 13,991. The ratio of non-harm

(9378) to harm (4613) events equaled 2.03. Figure 4.1 illustrates a bar plot of the total

number of event reports by harm score. Patient safety event reports with a harm score of

three occurred most frequently, followed by events with a harm score of one. The

histogram in Figure 4.2 illustrates the frequency of non-harm events when analyzed at the

week level. The data passes the visual check of satisfying a Poisson distribution.

Applying the fitdistr function in the vcd package results in a calculated lambda of 72.1

non-harm event reports per week, with a standard error of 0.75. Figures 4.3 and 4.4

display the hospital level control charts for the c-type and u-type, respectively. Figure 4.5

illustrates the hospital level c-type control charts for both non-harm and harm events.

Figure 4.6 illustrates the hospital level u-type control charts for both non-harm and harm
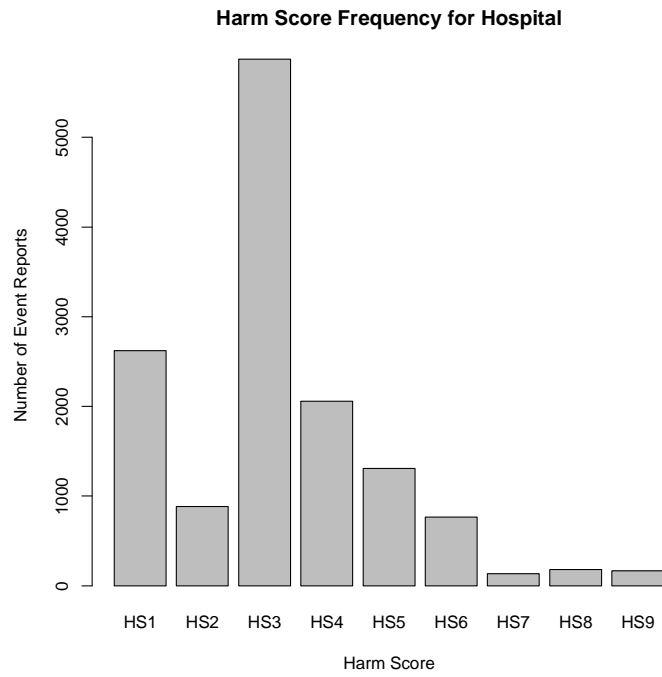
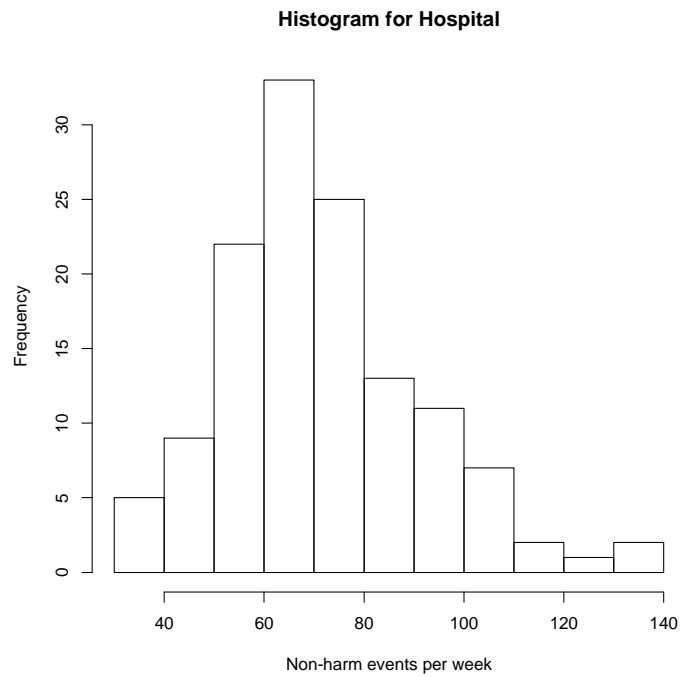events.

Figure 4.1 Bar Plot: Hospital Level

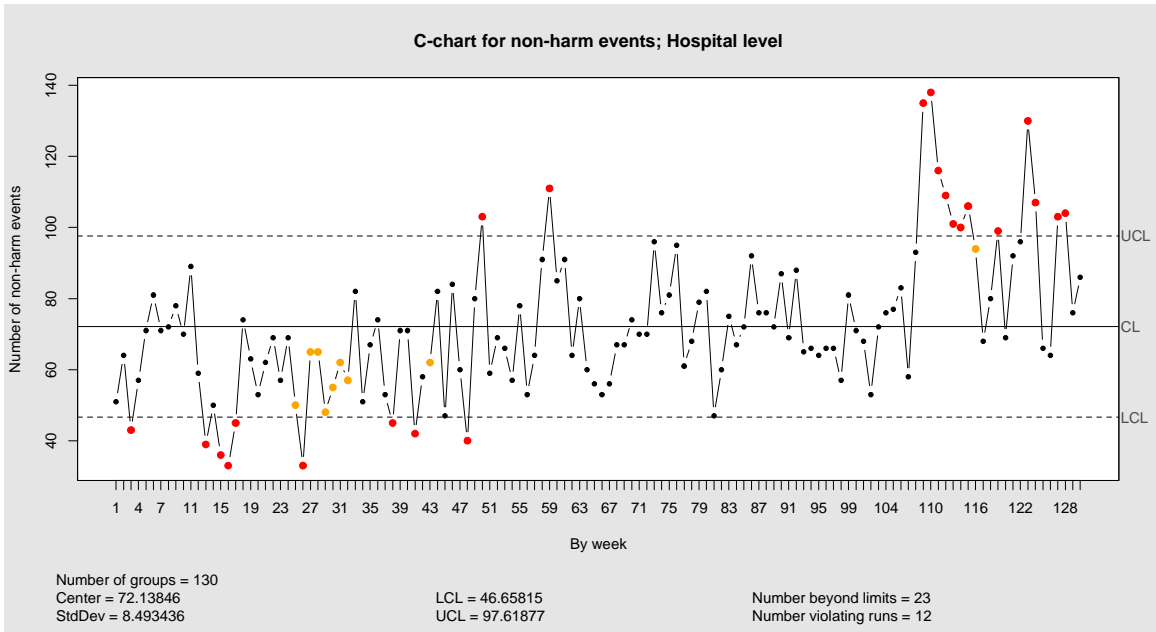Figure 4.2 Histogram: Hospital Level, by week
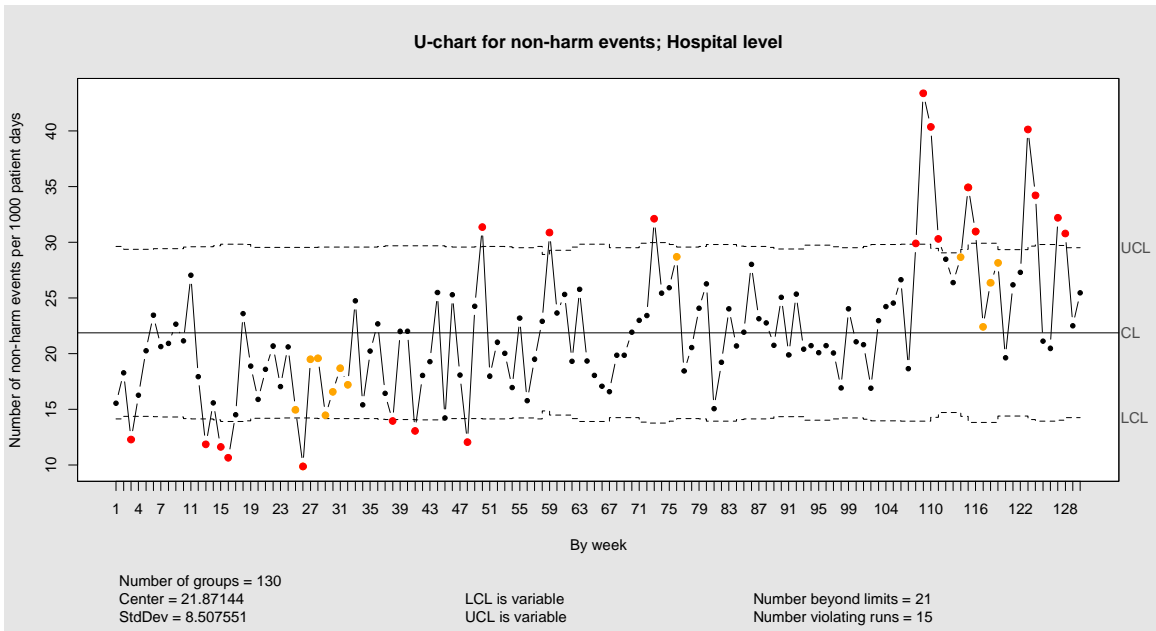
Figure 4.3 C-chart for non-harm events: Hospital level
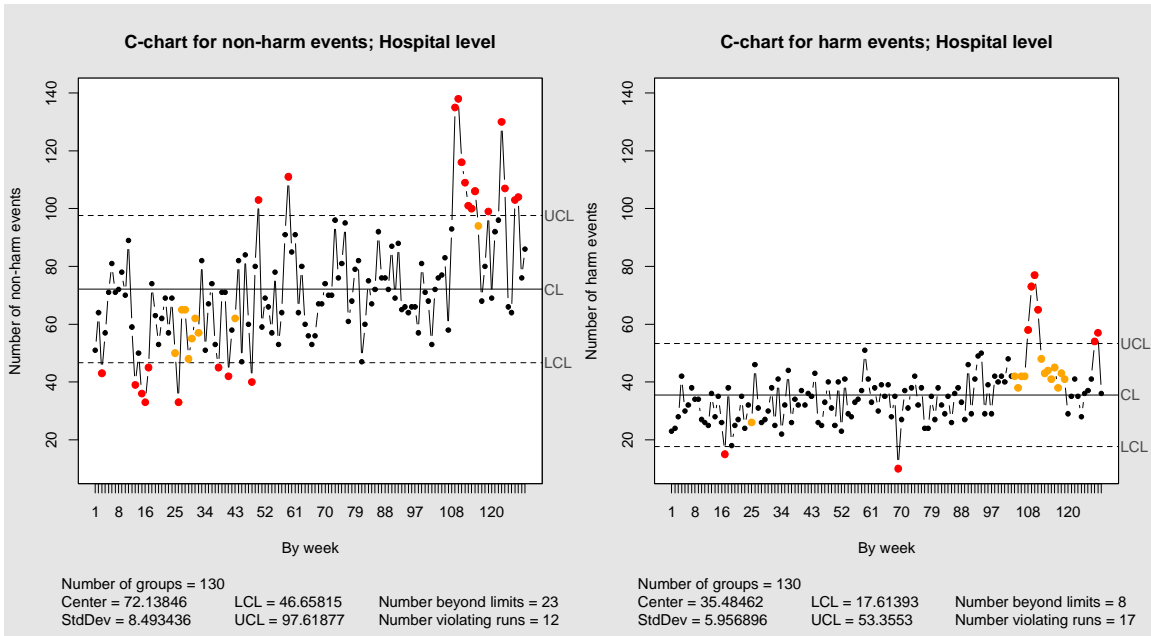

Figure 4.4 U-chart for non-harm events: Hospital level

C-chart for non-harm events; Hospital level

Number of non-harm events

UCL
CL
LCL

By week

1 8 16 25 34 43 52 61 70 79 88 97 108 120

Number of groups = 130
Center = 72.13846   LCL = 46.65815   Number beyond limits = 23
StdDev = 8.493436   UCL = 97.61877   Number violating runs = 12

C-chart for harm events; Hospital level

Number of harm events

UCL
CL
LCL

By week

1 8 16 25 34 43 52 61 70 79 88 97 108 120

Number of groups = 130
Center = 35.48462   LCL = 17.61393   Number beyond limits = 8
StdDev = 5.956896   UCL = 53.3553   Number violating runs = 17

Figure 4.5 C-chart for non-harm & harm events: Hospital level

U-chart for non-harm events; Hospital level

Number of non-harm events per 1000 patient days

UCL
CL
LCL

By week

1 8 16 25 34 43 52 61 70 79 88 97 108 120

Number of groups = 130
Center = 21.87144   LCL is variable   Number beyond limits = 21
StdDev = 8.507551   UCL is variable   Number violating runs = 15

U-chart for harm events; Hospital level

Number of harm events per 1000 patient days

UCL
CL
LCL

By week

1 8 16 25 34 43 52 61 70 79 88 97 108 120

Number of groups = 130
Center = 10.75847   LCL is variable   Number beyond limits = 7
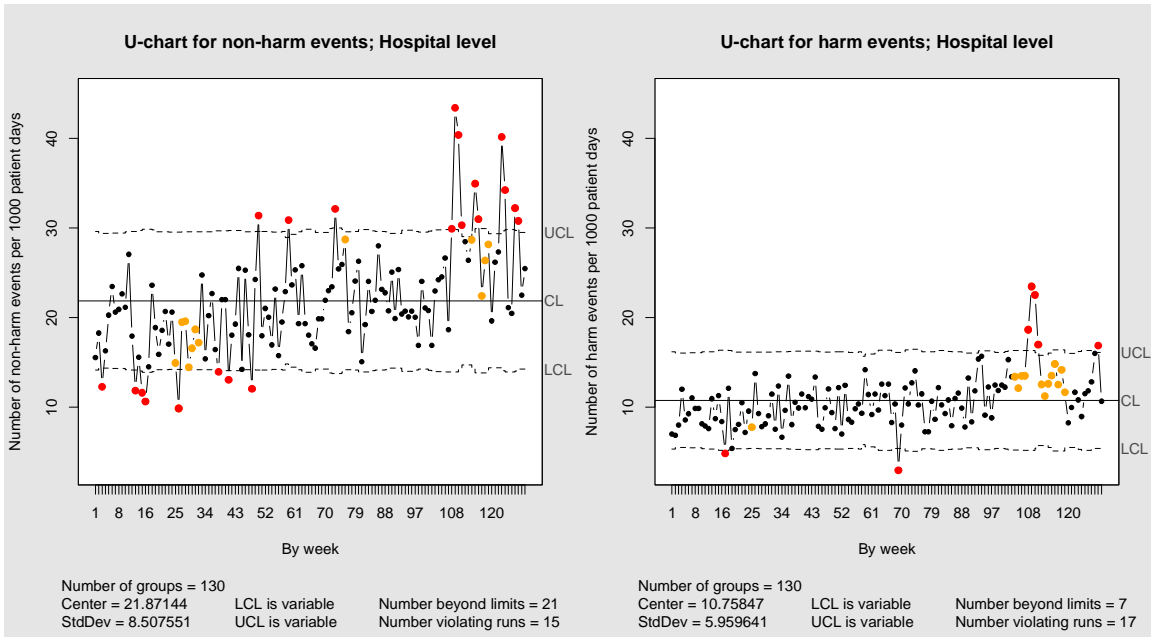StdDev = 5.959641   UCL is variable   Number violating runs = 17

Figure 4.6 U-chart for non-harm & harm events: Hospital level

Department Level

Department 1

Table 4.2 displays the total number of events reported at each harm score for Department 1. The total number of simulated event reports was 882. The ratio of non-harm (480) to harm (402) events equaled 1.19. Figure 4.7 is a bar plot of the total number of event reports by harm score. Patient safety event reports with a harm score of three occurred most frequently, followed by events with a harm score of one. The histogram in Figure 4.8 illustrates the frequency of non-harm events when analyzed at the week level. The data roughly passes the visual check of satisfying a Poisson distribution. Applying the fitdistr function in the vcd package results in a calculated lambda of 3.7 non-harm event reports per week, with a standard error of 0.17. Figures 4.9 and 4.10 display the hospital level control charts for the c-type and u-type, respectively. Figure 4.11 illustrates the hospital level c-type control charts for both non-harm and harm events. Figure 4.12 illustrates the hospital level u-type control charts for both non-harm and harm events.

Table 4.2 Simulated Event Reporting: Department 1

	Non-harm events			Harm events					
Harm Score	1	2	3	4	5	6	7	8	9
Number of events reported	152	124	204	150	136	75	11	11	19

Harm Score Frequency for Department 1

Figure 4.7 Bar Plot: Department 1

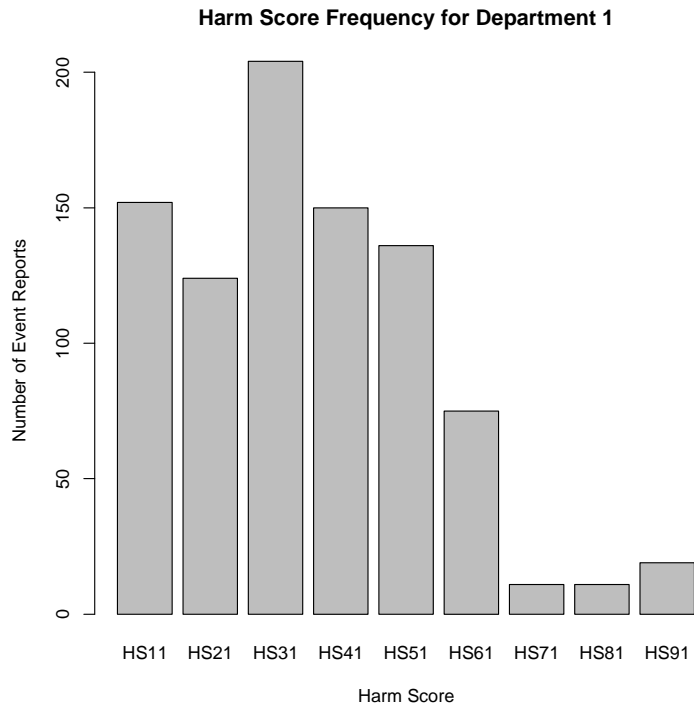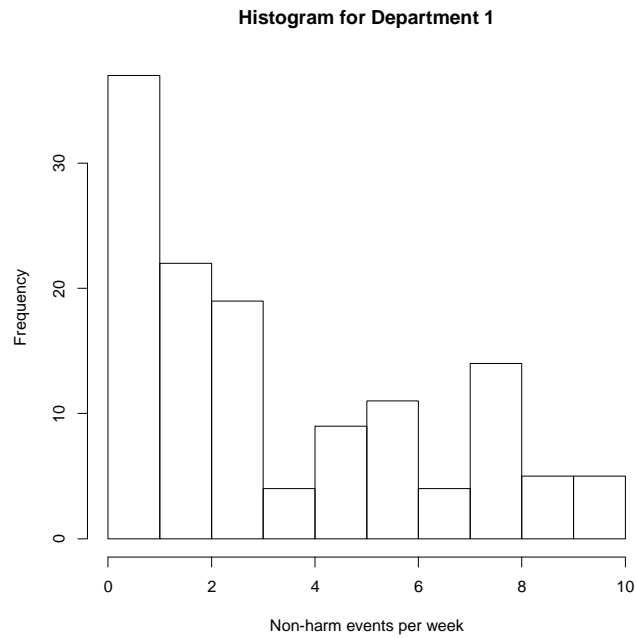**Histogram for Department 1**

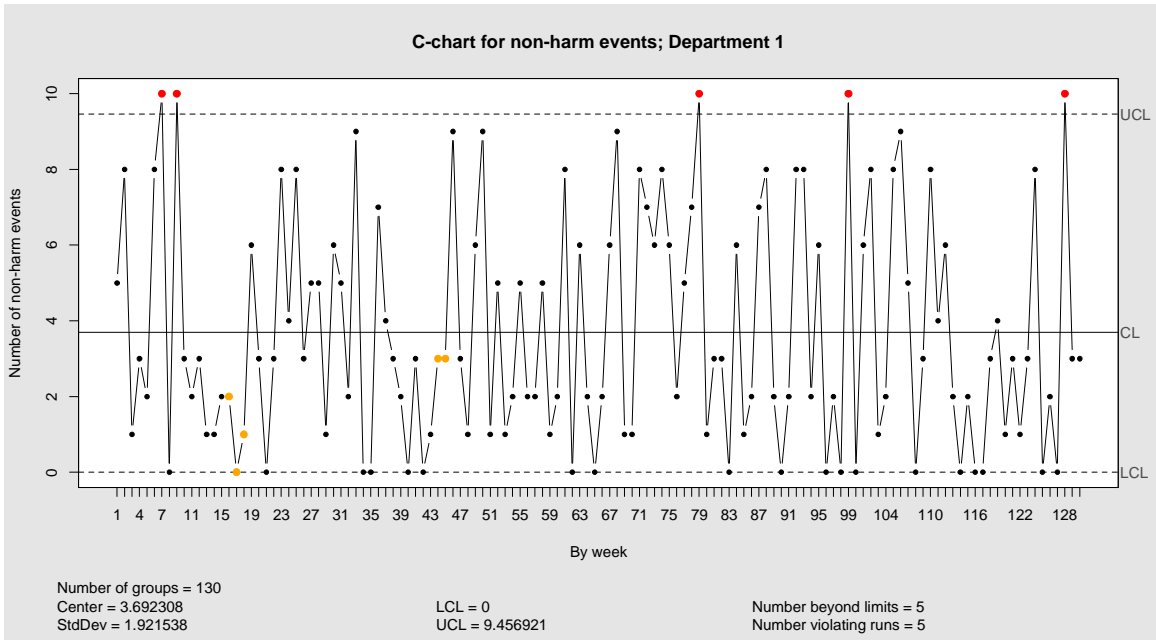Figure 4.8 Histogram: Department 1, by week

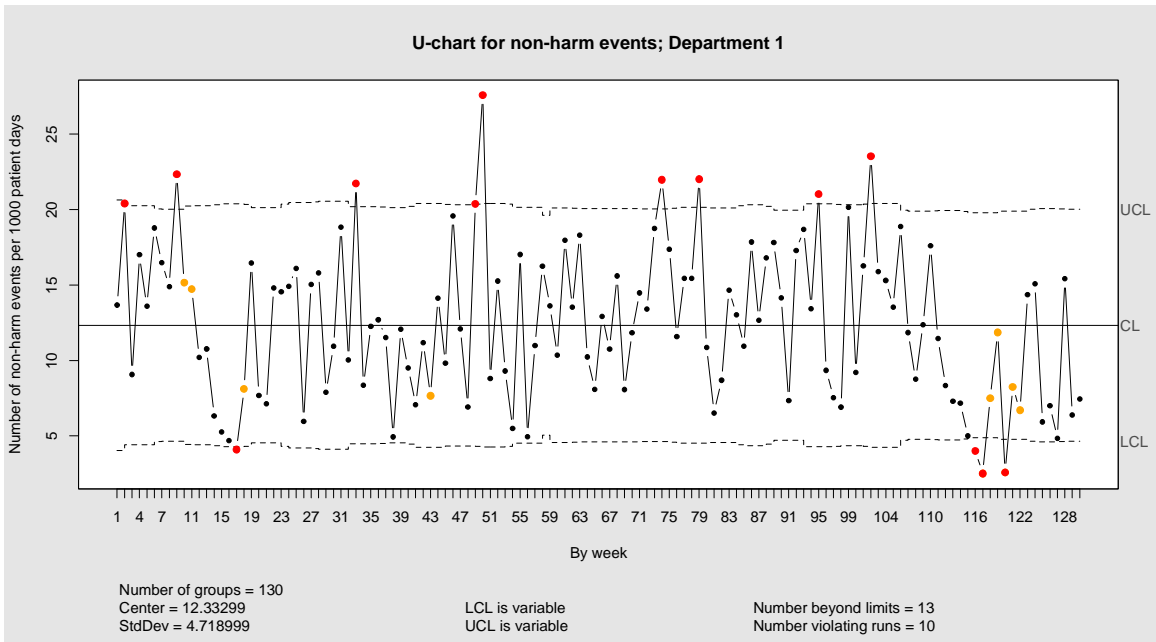Figure 4.9 C-chart for non-harm events: Department 1

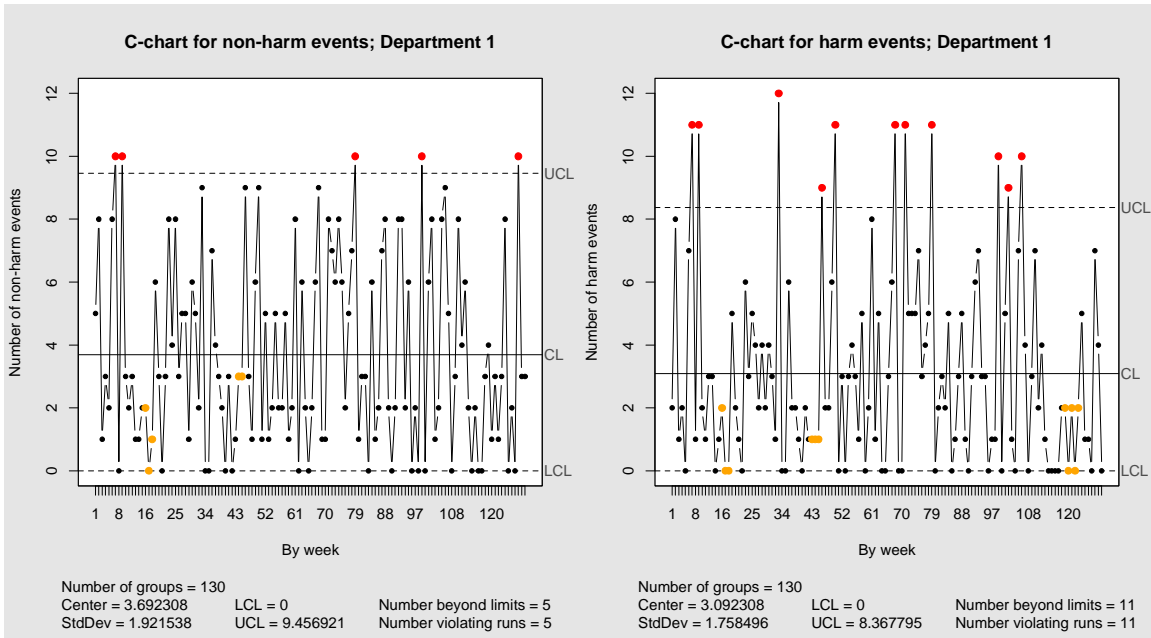

Figure 4.10 U-chart for non-harm events: Department 1

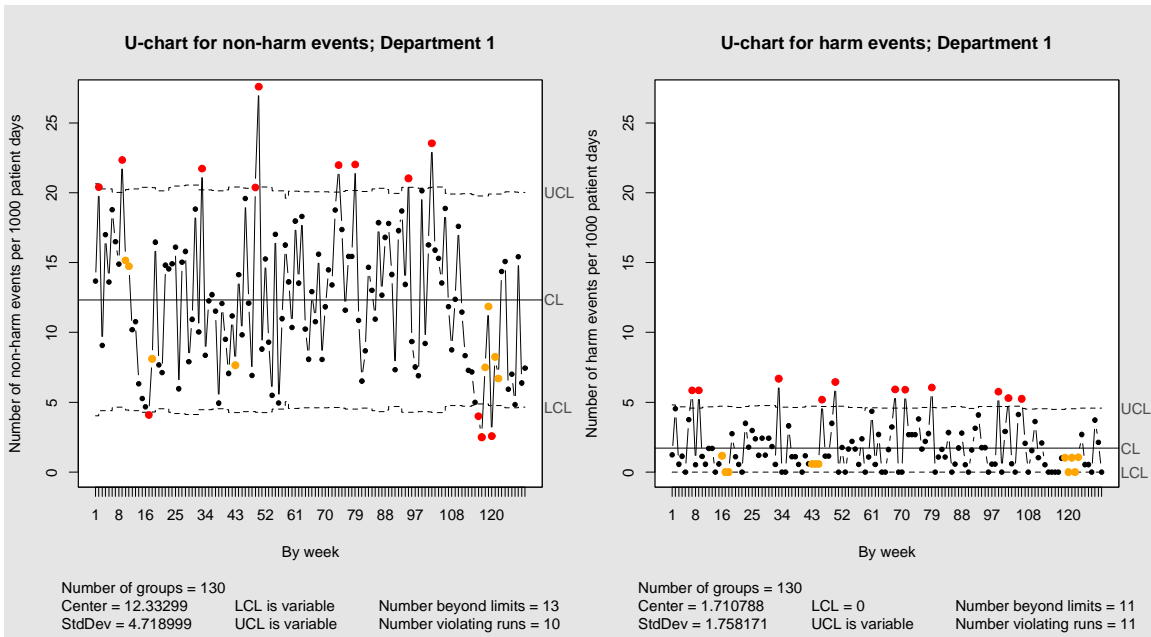Figure 4.11 C-charts for non-harm & harm events: Department 1

Figure 4.12 U-charts for non-harm & harm events: Department 1

Department 2

Table 4.3 displays the total number of events reported at each harm score for Department 2. The total number of simulated event reports was 749. The ratio of non-harm (429) to harm (320) events equaled 1.34. Figure 4.13 is a bar plot of the total number of event reports by harm score. Patient safety event reports with a harm score of three occurred most frequently, followed by events with a harm score of one. The histogram in Figure 4.14 illustrates the frequency of non-harm events when analyzed at the week level. The data roughly passes the visual check of satisfying a Poisson distribution. Applying the fitdistr function in the vcd package results in a calculated lambda of 3.3 non-harm event reports per week, with a standard error of 0.16. Figures 4.5 and 4.16 display the hospital level control charts for the c-type and u-type, respectively. Figure 4.17 illustrates the hospital level c-type control charts for both non-harm and harm events. Figure 4.18 illustrates the hospital level u-type control charts for both non-harm and harm events.

Table 4.3 Simulated Event Reporting: Department 2

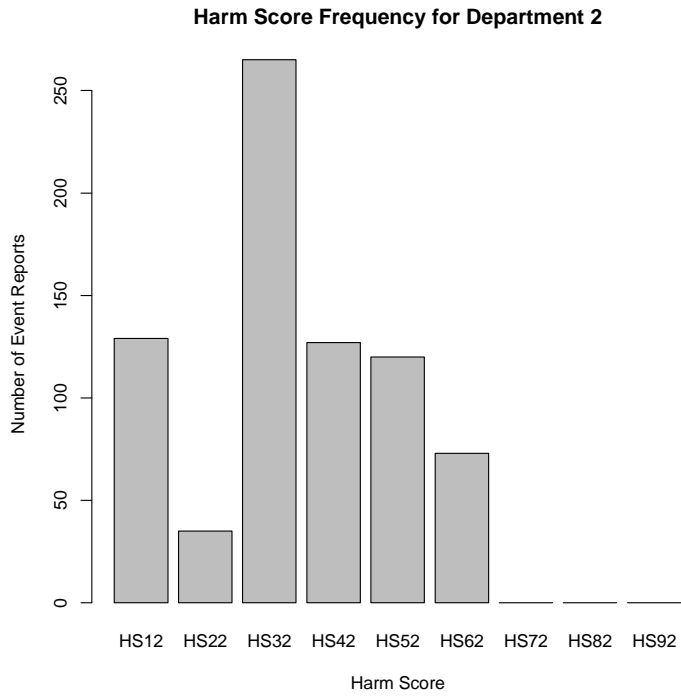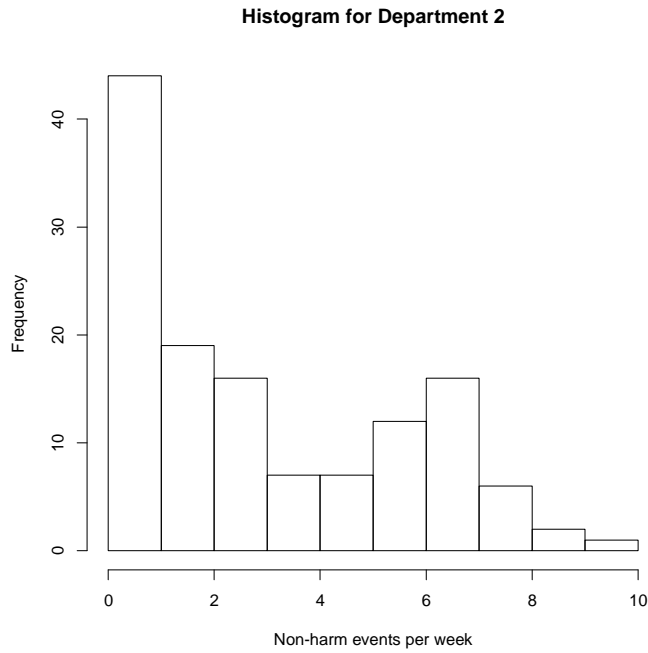|	Non-harm events			Harm events					
Harm Score	1	2	3	4	5	6	7	8	9
Number of events reported	129	35	265	127	120	73	0	0	0

Figure 4.13 Bar Plot: Department 2

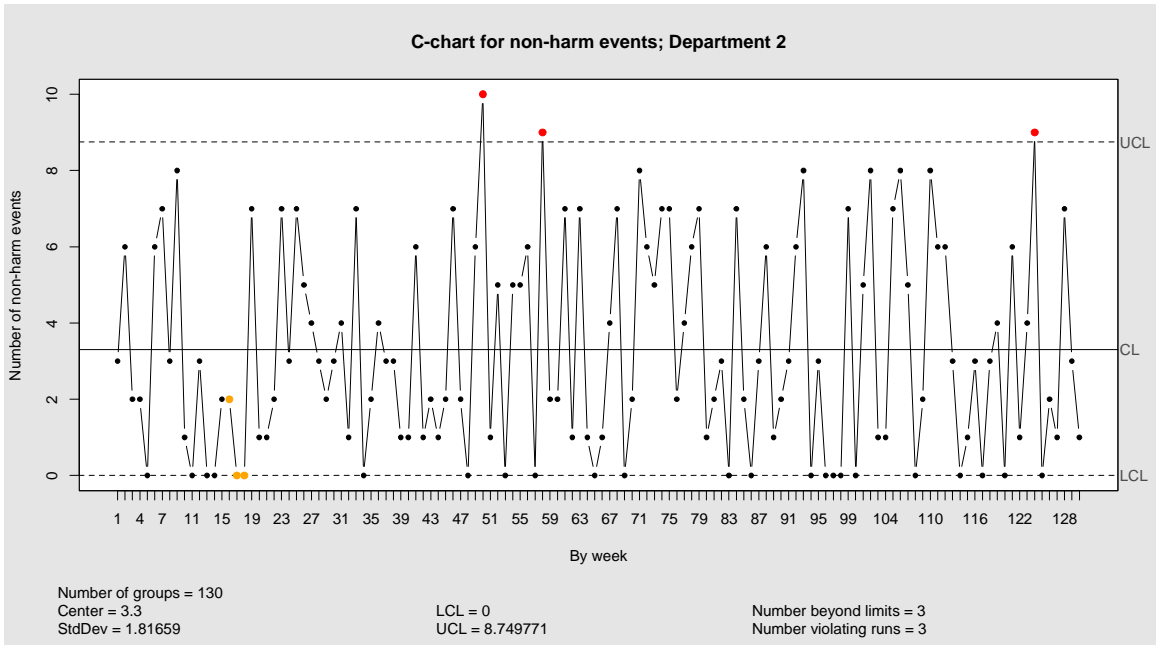Figure 4.14 Histogram: Department 2, by week

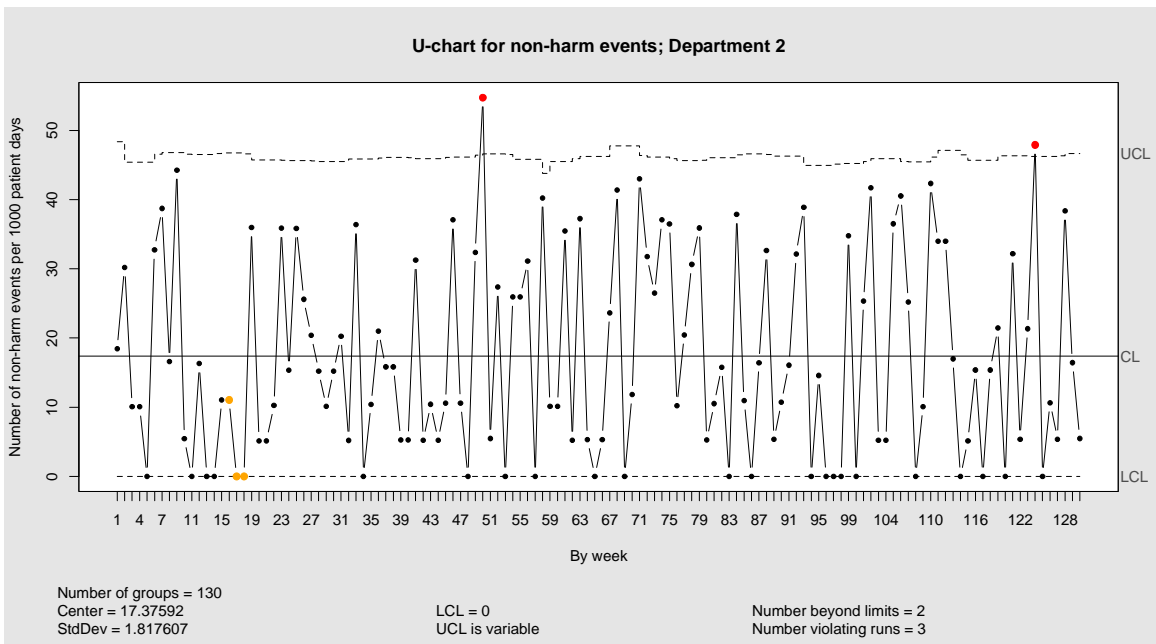Figure 4.15 C-chart for non-harm events: Department 2
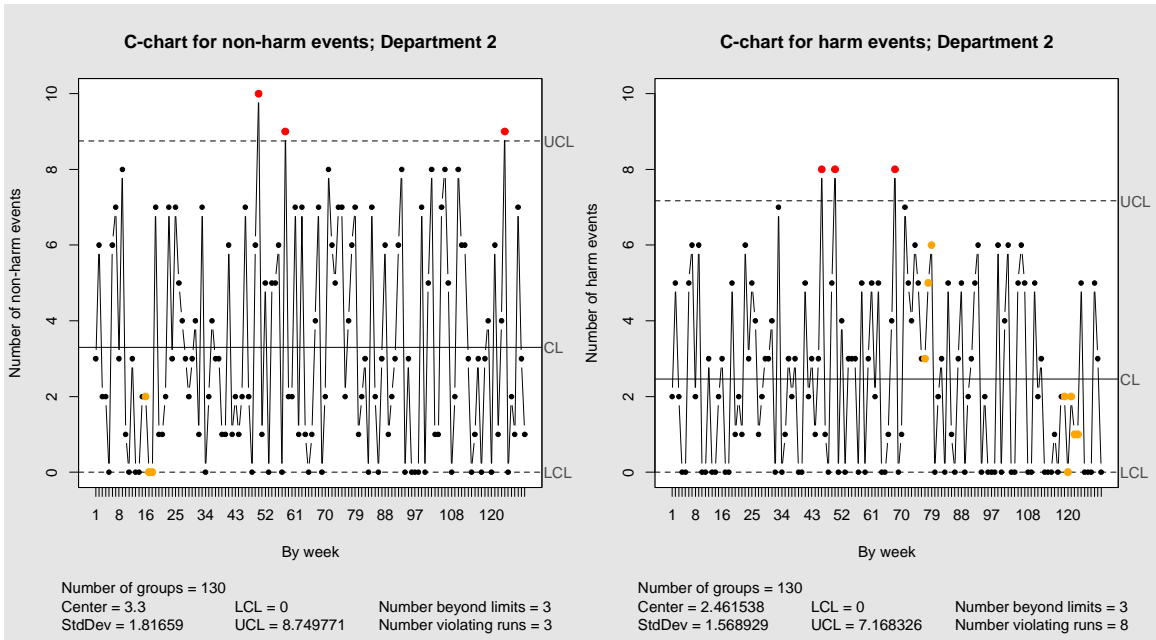

Figure 4.16 U-chart for non-harm events: Department 2

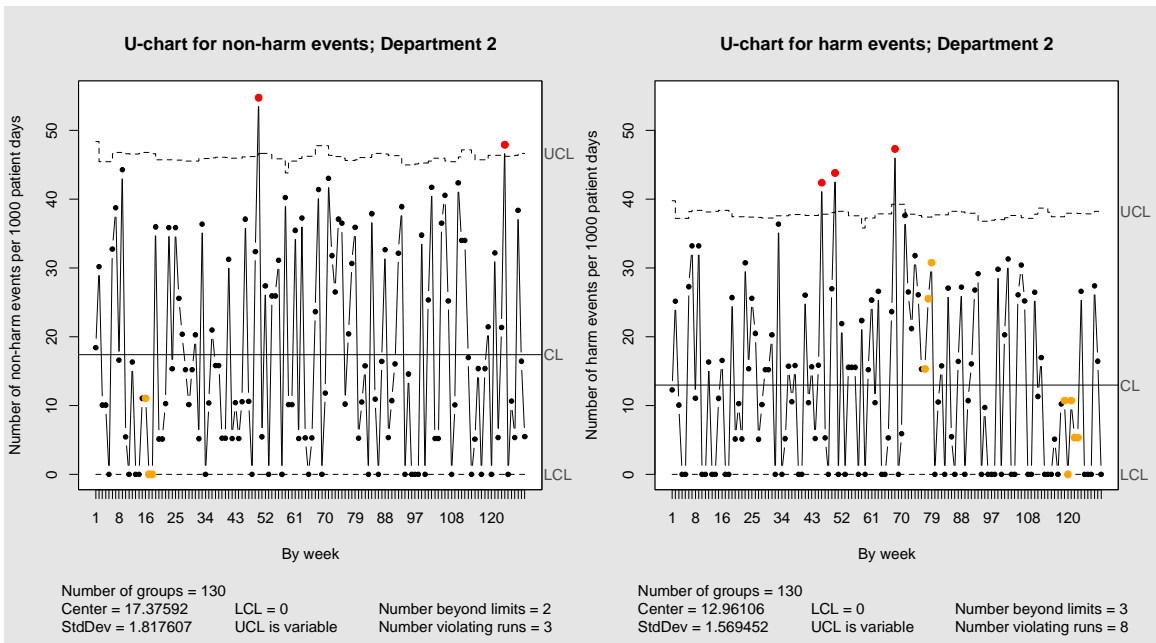Figure 4.17 C-charts for non-harm & harm events: Department 2

Figure 4.18 U-charts for non-harm & harm events: Department 2

Department 3

Table 4.4 displays the total number of events reported at each harm score for Department 3. The total number of simulated event reports was 876. The ratio of non-harm (609) to harm (267) events equaled 2.28. Figure 4.19 is a bar plot of the total number of event reports by harm score. Patient safety event reports with a harm score of three occurred most frequently, followed by events with a harm score of four. The histogram in Figure 4.20 illustrates the frequency of non-harm events when analyzed at the week level. The data passes the visual check of satisfying a Poisson distribution. Applying the fitdistr function in the vcd package results in a calculated lambda of 4.7 non-harm event reports per week, with a standard error of 0.19. Figures 4.21 and 4.22 display the hospital level control charts for the c-type and u-type, respectively. Figure 4.23 illustrates the hospital level c-type control charts for both non-harm and harm events. Figure 4.24 illustrates the hospital level u-type control charts for both non-harm and harm events.

Table 4.4 Simulated Event Reporting: Department 3

	Non-harm events			Harm events					
Harm Score	1	2	3	4	5	6	7	8	9
Number of events reported	130	40	439	132	85	49	0	0	1

Harm Score Frequency for Department 3

Figure 4.19 Bar Plot: Department 3

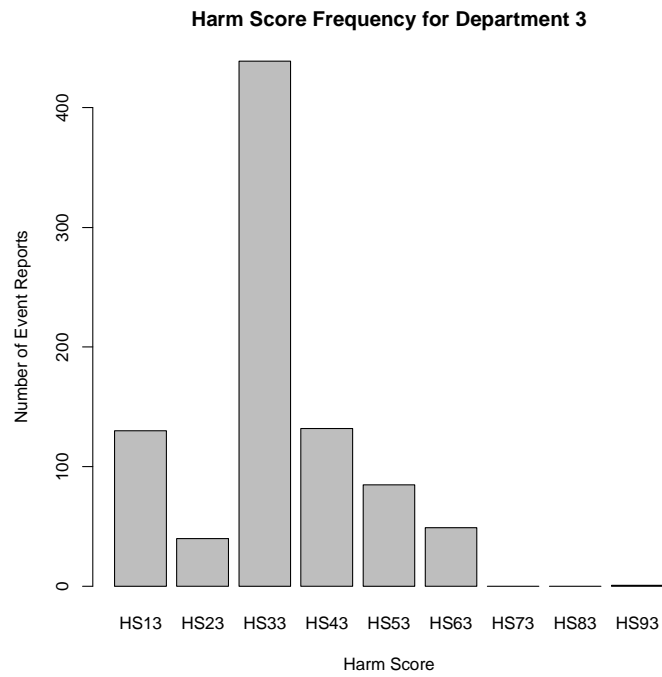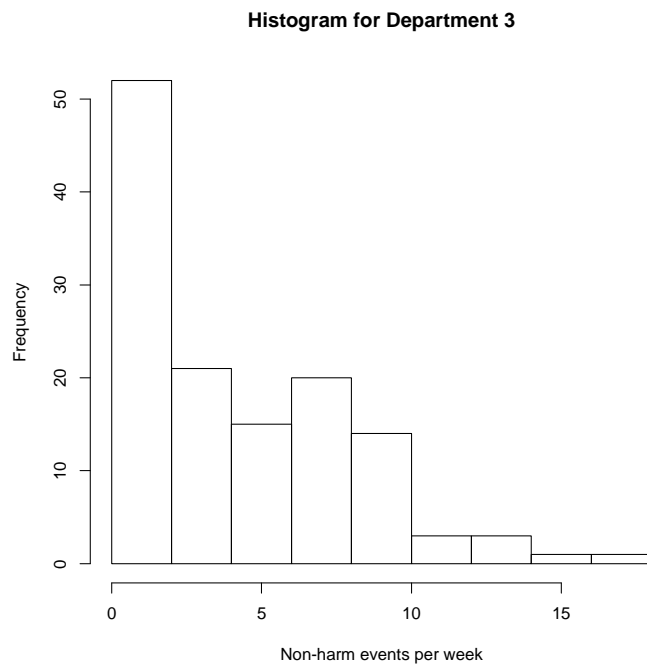**Histogram for Department 3**

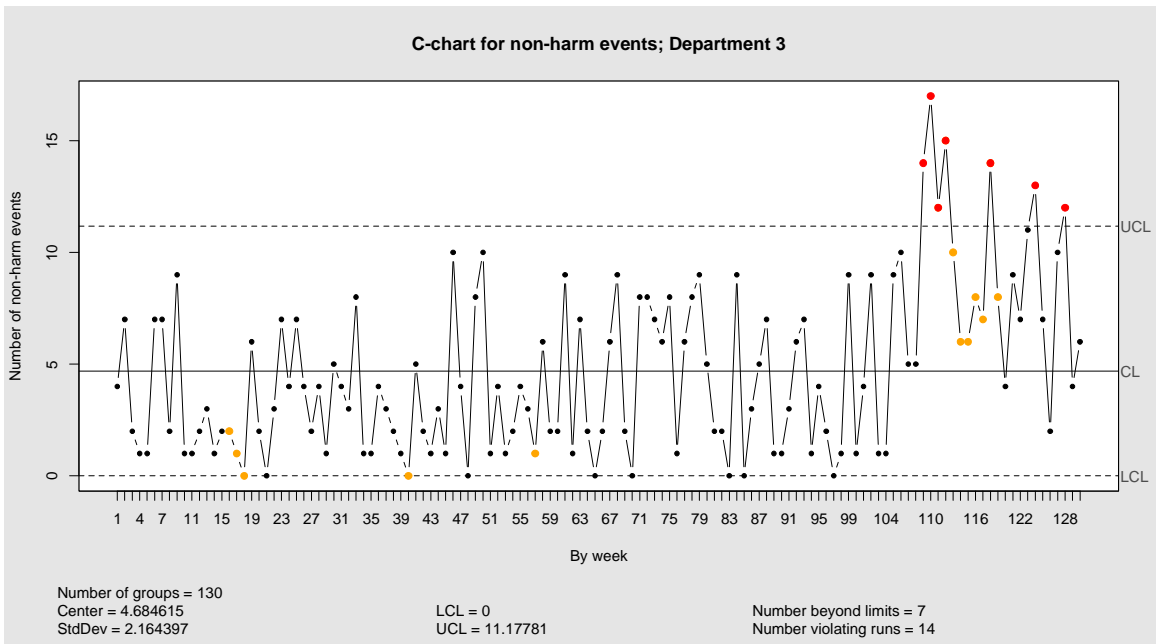Figure 4.20 Histogram: Department 3, by week

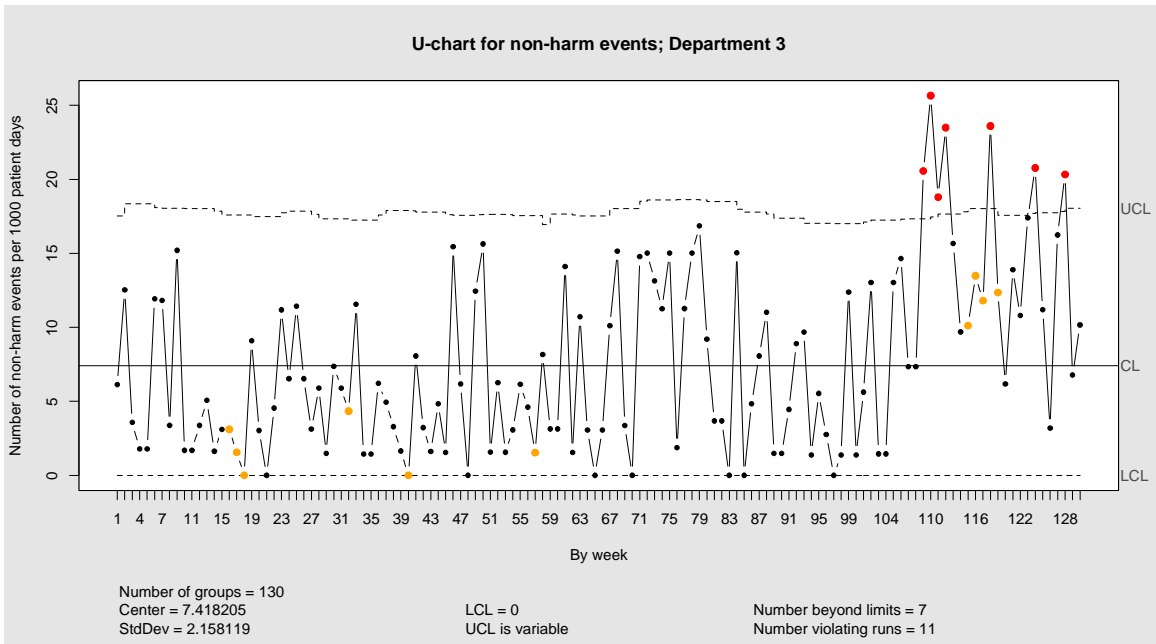Figure 4.21 C-chart for non-harm events: Department 3

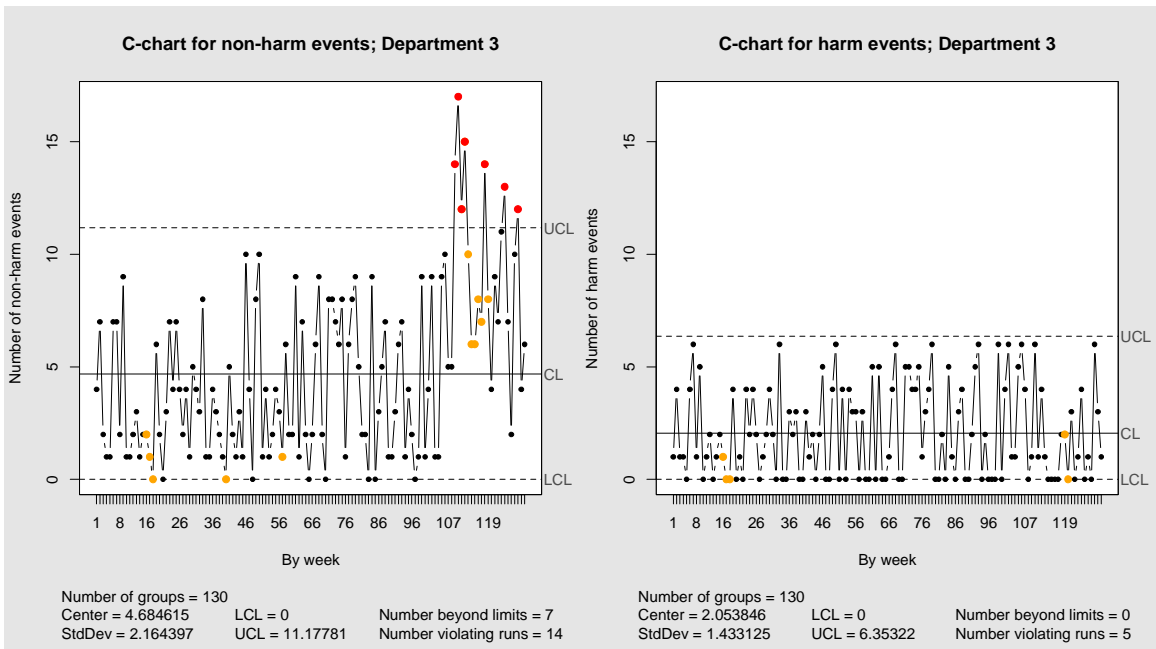Figure 4.22 U-chart for non-harm events: Department 3

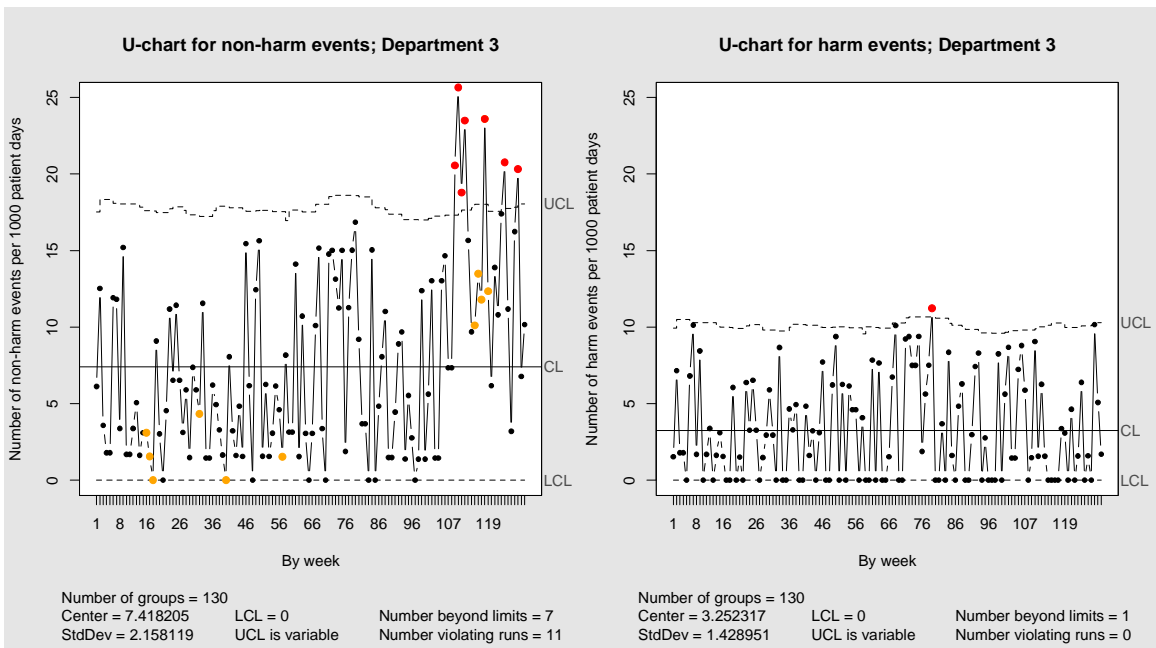Figure 4.23 C-charts for non-harm & harm events: Department 3

Figure 4.24 U-charts for non-harm & harm events: Department 3

CHAPTER FIVE

DISCUSSION AND CONCLUSIONS

Alarming rates of adverse events published by several studies motivated a patient safety movement. Advancement of these efforts required healthcare professionals to develop a systems thinking approach to harm causation. Medical errors committed to patients seeking care are often system design issues, as opposed to errors made my individuals. The healthcare industries began to understand this perspective, but there is still work to be done in this area. Recommendations were made by several government agencies around the globe to advance the safety of healthcare systems. The development of a culture of safety and patient safety event reporting systems are two patient safety strategies endorsed for this purpose.

These two techniques are primarily linked by a subcomponent of safety culture called reporting culture. Hospitals that embody open and just cultures support reporting culture success. There are specific approaches for enhancing overall safety culture, however assessment of culture and the analysis of patient safety interventions have proven to be complex issues. This is likely due to the complexity of culture, and lack of a gold standard to assess causality in patient safety interventions. This thesis methodology provides hospitals with a framework for reporting culture assessment, and a method to evaluate targeted inventions.

Most studies, in the literature, focus on serious harm events; however, there is much that can be learned about a hospital or department by investigating reporting rates of non-harm events. Harm events are less likely to go unreported compared to non-harm

events based on organizational workplace safety standards, staffs' comprehension of expectations for reporting, and ease of harm identification. A focus on non-harm events illustrates a proactive approach to learning about harm, as opposed to reacting to harm after its occurrence (e.g., conducting retrospective reviews). Therefore, organizations that devote efforts and resources to capturing data for non-harm patient safety events represent more positive safety cultures. Reporting of non-harm events compared to harm events reduces barriers of reporting. This is based on the notion that the fear of punishment is reduced and the perceptions about legal issues may be mitigated.

As a supplement to safety culture surveys, this methodology proposes that control charts can identify baseline measures for expected reporting rates, and can be used to monitor trends in reporting culture. The methodology is meant to be prescriptive and uses data hospitals typically collect as part of normal business. Hospitals with the required data can easily follow the summarized methodology: checking for underlying data assumptions, constructing control charts, monitoring and analyzing those charts, and investigating special cause variation as they arise. The methodology was described generally and was demonstrated using simulated data that was meant to represent patient safety event reporting rates for a hospital.

The regional healthcare network was chosen for its advanced efforts in patient safety improvement, and their efforts towards continuous improvement of safety culture are strong. A large set of reports was reduced to focus on a sample from one hospital within their network. Harm scores 1, 2, and 3 on the hospital's harm severity scale were considered non-harm events and was the focus of our analysis. Data were aggregated at

the week level in order to detect systems changes quickly. Data from the network were used to simulate a data set that is meant to be representative of typical hospital reporting rates. The simulated data set included a total of 13,991 reports. Descriptive statistics were run on the simulated data. Hospitals currently analyze data in their reporting systems by plotting bar charts of the frequency of each harm score, which was included in the results as well.

In order to create c-type and u-type control charts data must follow a Poisson distribution. There are three main assumptions of Poisson processes. The opportunity for occurrence of an event of interest must be large, while the average number of events that occur per some unit of time is small. Occurrences of events must be independent. The probability of an event within a time interval (e.g., each week) is independent of the probability of an event in any other non-overlapping interval. Non-harm events are often described as precursor events to harm events. However, for the purpose of this thesis, it is assumed that the non-harm events are independent. The last assumption requires that the data is stationary, where the probability of an event occuring does not change between time intervals.

In order to check for Poisson distributions histograms of the simulated data were created. From there c-type and u-type charts were created for non-harm events. U-charts are preferred because they provide the ability to compare departments based on a common denominator, and they more accurate based on the number of opportunities for occurrence. For example, comparison of a large department that has many patients to a smaller department with fewer patients requires a common unit, for example, patient

days. Census data from the regional healthcare network was provided in order to calculate rates per 1,000 patient days.

Using R, values for the UCL, CL, and LCL were calculated based on the entire data set. Points in red illustrate out of control points or special cause variation, warranting investigation. Points in yellow violate control chart rules for detecting nonrandom patterns. These points provide detection of smaller process shifts, but are not as significant as those in red.

The interpretation of these control charts may be debated. It is hard to distinguish whether the amount of events reported is suggestive of an environment where there is more harm (or the possibility of more harm), versus an increase in the reporting culture. "Increased incident reporting rates may not be indicative of an unsafe organization, but may reflect a shift in organizational culture toward increased acceptance of quality improvement and other organizational changes" (Battles et al., 1998).

For this thesis the following assumption is made: an increase in the number of events reported is indicative of an improvement in the reporting culture. This perception is supported by others and is affirmed through the following, "high reporting rates may indicate an organizational culture committed to identifying and reducing errors and adverse events rather than a truly high rate" (Edmondson, 1996; Thomas & Petersen, 2003). Additionally, an AHRQ report states, "increased incident reporting rates may not be suggestive of an unsafe organization, but may reflect a shift in organizational culture to increased acceptance of quality improvement and other organizational changes" (Shojania et al., 2001).

Assuming that the number of opportunities for improvement is infinite, documentation of non-harm events would indicate a culture that understands the benefits of learning from near misses, and one that is not regarded as punitive in nature. Alternatively, Pham et al. (2010) suggests that changes in event reporting do not indicate true changes in safety, but are rather linked to variation in reporting thresholds and the subjects who report the events. Recognizing that arguments against this assumption may exist, this remains as a limitation to our methodology.

Thus as points exceed the UCL, this methodology supports the notion that there is an improvements in the reporting culture. Conversely, points that fall below the LCL may indicate a decline in the reporting culture. Regardless of whether special cause variation represents good or bad results, investigations of the causes of out of control points should be conducted as soon as possible, because points falling outside the limits are not produced by the underlying distribution. "As time between the out-of-control event and the beginning of the investigation increases, the likelihood of determining root causes diminished greatly" (Kubiak, 2009). This method of early detection provides an advantage over survey data, since results are typically only analyzed about once a year.

As part of the investigation prompted by points falling outside of the control limits for non-harm events, it may be meaningful to plot similar control charts for harm events in order to get a comprehensive idea of reporting rates for the entire reporting system, and its associated reporting culture. Control charts of harm events may represent changing levels of harm if points fall outside of control limits. Assuming that it is more imperative to report events causing harm and that the reporting rates of harm may better

reflect actual rates, compared to non-harm, it may be suggested that harm event reporting

may be indicative of actual safety levels. Based on these assumptions the following table

illustrates the nine possible scenarios when events are classified as either non-harm or

harm and are plotted on control charts, see Table 5.1. This table is meant to aid the

hospital in interpreting control charts.

Table 5.1 Interpreting Non-harm and Harm Control Charts Simultaneously

Scenario	Non-harm	Harm	Interpretation
1	↑	↓	Investigate, ↑safety climate, ↓harm level
2	↑	−	Investigate, ↑safety climate
3	↑	↑	Investigate, ↑safety climate, ↑harm level
4	↓	↓	Investigate, ↓safety climate, ↓harm level
5	↓	−	Investigate, ↓safety climate
6	↓	↑	Investigate, ↓safety climate, ↑harm level
7	−	↓	↓Harm level
8	−	−	
9	−	↑	↑Harm level

This methodology calls for investigation when non-harm control charts illustrate

points falling above or below the control limits, as is shown in scenarios 1-6. Dashes

indicate the process remains in statistical control. Arrows in the non-harm and harm

columns correspond to instances where points fall above the UCL with up arrows, and instances where points fall below the LCL with down arrows. Based on our assumption, rows where non-harm control charts include an up arrow (i.e., scenarios 1-3) indicate an increase in safety climate, and those with down arrows (i.e., scenarios 4-6) indicate a decrease in safety climate. Assuming that harm event reporting rates may represent changing levels of harm if points fall outside of control limits, then rows where harm control charts include an up arrow indicates an increase in harm level where points fall above the UCL (i.e., scenarios 3, 6, 9), and those with down arrows indicate a decrease in the harm levels where points fall below the LCL (i.e., scenarios 1, 4, 7).

For example, scenario 1 would be an ideal situation. Here the non-harm control chart shows points falling above UCL, which would prompt an investigation, and may indicate an increase in safety climate. The harm control chart has points below its LCL, which may be representative of a decreasing level of harm.

A limitation of this methodology, since the focus is on non-harm, is illustrated in the last scenario. Since the non-harm control chart is in statistical control, management would not be prompted by this methodology alone to investigate, and it may not be determined that the harm level may actually be increasing. However, the methodology described in this thesis focuses on monitoring safety climate and its relationship to non-harm event reporting, not the level of harm within the organization.

Hospital Level

For analysis at the hospital level, the visual check of the histogram illustrates the data follows a Poisson distribution. The c-chart illustrates the number of non-harm events reported per week. The CL is equal to the parameter lambda; 72.1 non-harm events would be expected per week, and this value represents a baseline. Since the data is simulated and does not correspond to any one institution, there is no way to investigate the underlying causes of points falling outside the control limits. However, it appears that starting around week 108 the data falls above the UCL for a consecutive period of time, which should prompt investigation by management. A targeted intervention, such as training on "just culture," may have taken place the week prior to the beginning of this trend. This type of chart may help determine whether that training had an impact. Additionally, by continuing to plot points each week, management can determine if this shift in climate is lasting and becomes a part of the process, or if it is intermittent and reporting rates return to their previous levels.

The u-chart illustrates the average number of non-harm events reported per 1,000 patient days per week. The CL equals 21.9, where this value represents the expected number of non-harm events reported per 1,000 patient days per week. The findings are similar to those found in the c-chart.

In order to aid investigation it may be helpful to see harm event reporting rates for the same time period. Figure 4.5 illustrates c-type charts for non-harm and harm events plotted simultaneously; Figure 4.6 displays the same information using u-type control charts. Both figures illustrate that for the majority of time harm rates are staying in

control while non-harm events may be steadily increasing, corresponding to scenario 2 in Table 5.1. Except for during the few weeks around week 108, an interpretation of the control charts plotted together indicates that investigation should be prompted for special cause variation, there is an increase in safety climate, and levels of harm for the hospitals are remaining steady and are in statistical control.

Department Level

Based on the literature culture assessment is best described locally or at the departmental level (Pronovost & Sexton, 2005). The methodology is enhanced when analyses are conducted at this unit of analysis. Analyzing control charts by department provides a more accurate depiction of safety climate. It is important to make sure reports aggregated at the department level correspond to the census data for that department. Three departments were chosen from the simulated hospital sample and are discussed separately in the following sections.

Department 1

A visual check of the histogram for department 1 illustrates the data roughly follows a Poisson distribution. The c-chart illustrates the number of non-harm events reported per week. The CL is equal to the parameter lambda; 3.7 non-harm events would be expected per week, and this value represents a baseline. The c-chart has a standard deviation of 1.9, where the LCL is set equal to 0. This chart shows five points falling above the UCL that require investigation.

The u-chart illustrates the average number of non-harm events reported per 1,000 patient days per week. The CL equals 13.3, where this value represents the expected number of non-harm events reported per 1,000 patient days per week. The control limits of the u-chart do not require the LCL to be set equal to 0. This chart includes 13 points that fall outside the control limits, 9 above the UCL and 4 below the LCL. This chart provides more information since weeks are adjusted for 1,000 patient days.

As done with the analysis at the hospital level to aid investigation methods the following figures were constructed for department 1. Figure 4.8 illustrates the c-type charts for non-harm and harm events plotted simultaneously; Figure 4.9 displays the same information using u-type control charts. One scenario in Table 5.1 cannot define the overall situation for the entire time period for department 1, but the table can be referenced when each special cause variation is investigated based on findings of the non-harm control charts.

Department 2

A visual check of the histogram for department 2 illustrates the data follows a Poisson distribution. The c-chart illustrates the number of non-harm events reported per week. The CL is equal to the parameter lambda; 3.3 non-harm events would be expected per week, and this value represents a baseline. The c-chart has a standard deviation of 1.8, where the LCL is set equal to 0. This chart shows three points falling above the UCL that require investigation.

The u-chart illustrates the average number of non-harm events reported per 1,000 patient days per week. The CL equals 17.4, where this value represents the expected number of non-harm events reported per 1,000 patient days per week. This chart includes two points that fall above the UCL. This chart provides more information since weeks are adjusted for 1,000 patient days. One point attributed to special cause variation based on the c-chart was no longer considered out of control following this common denominator adjustment.

As done with the analysis at the hospital level to aid investigation methods the following figures were constructed for department 2. Figure 4.15 illustrates the c-type charts for non-harm and harm events plotted simultaneously; Figure 4.16 displays the same information using u-type control charts. For department 2 both non-harm and harm control charts remain in statistical control, which only a couple of exceptions. Again Table 5.1 can be referenced when each special cause variation is investigated based on findings of the non-harm control charts.

Department 3

A visual check of the histogram for department 3 illustrates the data follows a Poisson distribution. The c-chart illustrates the number of non-harm events reported per week. The CL is equal to the parameter lambda; 4.7 non-harm events would be expected per week, and this value represents a baseline. The c-chart has a standard deviation of 2.2, where the LCL is set equal to 0. This chart shows seven points falling above the UCL that require investigation.

The u-chart illustrates the average number of non-harm events reported per 1,000 patient days per week. The CL equals 7.1, where this value represents the expected number of non-harm events reported per 1,000 patient days per week. This chart as with the c-chart identifies seven points that fall above the UCL all occurring at the tail end of the data set. Both the c-type and u-type control charts indicate that there may be a process shift. This type of information would be very meaningful to management if this were the result of some type of specific intervention. By updating these charts on a weekly basis, feedback from interventions can be analyzed much more quickly than having to rely on surveys for these types of results.

In order to determine whether this increase is not due to increased levels of actual harm, the following figures should be analyzed. Figure 4.20 illustrates the c-type charts for non-harm and harm events plotted simultaneously; Figure 4.21 displays the same information using u-type control charts. Both figures illustrate that for the majority of time harm rates are staying in control while non-harm events may be steadily increasing, corresponding to scenario 2 in Table 5.1.

Currently management captures safety climate data on a yearly basis, but the control chart methodology provides a more current time-based description of reporting culture and analysis can be conducted in a much more timely fashion. For example, if an organization implements a certain intervention (e.g., training), currently management must wait a year to see if this intervention led to improvement without being able to prove causation. With this method of continuous monitoring, control charts can help to validate interventions within a much shorter time frame. Points falling outside the control

limits indicate that the data are not all produced by the same underlying process. As time between the out-of-control event and the beginning of the investigation increases, the likelihood of determining root causes diminishes greatly (Kubiak, 2009). As discussed previously, while waiting for more data to confirm statistical significance, control charts use rules to assess whether points falling inside the control limits are due to special cause.

As demonstrated using simulated data, control charts can serve as narrative about reporting culture, they can identify baseline measures for expected reporting rates, and they can monitor trends in the reporting culture over time and across departments. Updating the charts regularly prompts leadership to investigate unusual findings much more quickly compared to current survey assessment of safety culture. An increasing trend in reporting rates of non-harm events indicates that departments are working proactively to identify harm, rather than just reacting and documenting when harm events occur. In addition to serving as a reporting culture assessment and supplement to current safety culture assessment, this control chart methodology provides management with a way to evaluate targeted interventions. With that said, if points fall out of control following strategic interventions, investigations must still be conducted to make sure changes were due to that specific intervention and not other factors.

Limitations

For this thesis, non-harm events are assumed to be independent in order to construct attribute control charts, although they are often described as precursor events to patient safety events that result in harm. The data used to present the methodology was

simulated based on a random set of variables that were applied to actual data from a regional healthcare network. This may have implications when interpreting the data as it relates to realistic findings. It could be argued that the data should not be discussed the way it is currently done in this section, because obvious process changes or shifts in the data should prompt recalculation of the control limits. This may be true, but since data were simulated there is no way to use phase I control charts to bring the process into statistical control. Thus the control limits for the data in the results could be described as trial control limits. Lastly, this methodology assumes that an increase in reporting rates is due to an improved reporting culture and does not necessarily represent environments with increased levels of harm.

Conclusions & Future Work

This methodology establishes baseline non-harm event reporting statistics through the construction of control charts. Control charts illustrate a simple method to transform data from reporting systems into useful information and control charts can be used to monitor reporting system processes. A current limitation in measurement of statistical significance for interventions methods is remedied using this control chart approach. This methodology provides quicker feedback on interventions compared to current survey methods used to assess safety climate. Also, a clear distinction between harm and non-harm events does not have the issues found with other harm classification systems when trying to compare units and hospitals. Compared to surveys that collect outcome measures on reporting subjectively, this approach uses quantitative data, which is

commonly already collected in healthcare organization, to describe process changes in reporting culture and safety climate.

There is a need for future research to investigate how training affects safety climate and reporting culture, and how lasting those effects may be in certain hospitals or units specifically. Future research can also assess whether the interpretation of the control charts used in this methodology translates to findings of survey data.

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