SYSTEMIC AND HUMAN FACTORS THAT CONTRIBUTE TO MEDICAL ERROR:

A STUDY OF HIGHER RELIABILITY

A Doctoral Thesis Presented to the
Faculty of the College of Education
University of Houston

In Partial Fulfillment
of the Requirements for the Degree

Doctor of Education

by

LaTasha R. Burns

December 2017

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To each of you that read this piece, I encourage you to live life to the fullest, find inspiration from within, and always pay it forward.

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Abstract

Background: Despite a focus on improving patient safety and quality of care since the publication of the 2000 report, To Error is Human, there has not been much progress toward preventing adverse medical errors. Many health care organizations are beginning to apply high reliability principles, such as human factors engineering, to help address safety problems. A use of these methods and principles has proven successful in high-risk, complex industries, such as aviation. Like aviation, the health care industry is complex and error prone. Therefore, the experiences cultivated from highly reliable industries might be useful in improving work processes and systems in health care. **Purpose:** The purpose of this study was to explore the lessons learned from highly reliable industries, such as aviation, by investigating systemic and human factors that led to medical errors in one health care facility. Using the Human Factors Analysis and Classification System (HFACS) to analyze and categorize causal factors from 108 root cause analyses, the study site was able to determine if an association existed between systemic and human factors. Determining what causal factors were most problematic allowed leaders to precisely focus efforts to specific interventions that would alleviate reoccurrence of the errors. **Methods:** This quantitative exploratory study used descriptive statistics to organize the data alongside higher reliability principles in order to meaningfully evaluate the medical errors. **Results:** The data analysis resulted in seven major findings, which yielded two overall indicators of focus: (1) attention to efforts that realize zero harm and (2) managing processes that effectively reduce systemic issues. **Conclusion:** Leadership's attention to these major focus areas gives insight as to how patient care can be efficiently provided. Likewise, applying human factors engineering

principles to medical errors can help improve patient safety, provide empirical knowledge to health care professionals, and increase reliability in the health care industry.

Keywords: Human Factors Analysis and Classification System, HFACS, root cause analysis, medical error, adverse event, preventable adverse event, preventable medical error, patient safety, human factors in health care, high reliability, and reliability in health care

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Chapter 1

Introduction

On any given day in any hospital setting across the United States, preventable adverse medical errors occur that necessitate improvements in patient care. For example, the sponge inadvertently left inside the surgical patient, leaving behind obscure agonizing abdominal pain before infection sets in; the medication injected into a baby's intravenous line at a dose calculated for a 200-pound man; and the excruciating infection determined to be a result of contaminated equipment used at the bedside (Binder, 2013). These like many other errors are what led to the formation of the Institute of Medicine's (IOM) Committee on the Quality of Healthcare in 1998. The mission of the committee was to identify strategies to realize a substantial improvement in the quality of health care services provided to Americans (IOM, 2001). The first report produced by this committee in 2000 was *To Err is Human: Building a Safer Health System* which generated widespread interest in discussion and research about patient safety issues. The IOM stunned the health care industry estimating that from 44,000 to 98,000 people die annually due to medical errors in America (Kohn, Corrigan & Donaldson, 2000). Likewise, a 2003 RAND Corporation's Quality Assessment Tools system qualitative study magnified these estimates by claiming patients that are hospitalized are treated with the appropriate care regimens only 50 percent of the time, which may speak to poor outcome indicators regarding the health of the American public (McGlynn, Asch, Adams, Keesey, Hicks, DeCristofaro & Kerr, 2003). A more recent study by James (2013) reports that more than 210,000 deaths annually were associated with preventable patient harm in hospitals, causing one to suspect that the number of medical errors is continuing to grow

instead of decline. These damaging reports left health consumers uncertain about their confidence in the health care industry and generated a widespread call for the federal government and the health care industry to make improvements in patient care outcomes. According to Leape and Berwick (2005), apprehension regarding improvements in patient safety still persists. Although, some efforts to increase the number of quality and patient safety activities have been promising, a need for research in these areas still exists (National Patient Safety Foundation [NPSF], 2015).

The purpose of this quantitative descriptive exploratory study is to close the gap in the lack of empirical research by evaluating the systemic and human factors that led to medical errors from existing historical root cause analyses (RCAs) from four fiscal years. The historical RCAs were evaluated using the structured human factors method, Human Factors Analysis and Classification System (HFACS) to categorize the causal factors of the medical errors.

Statement of the Problem

The aviation industry, nuclear power plants, and space exploration agencies have all been recognized as highly reliable organizations due to their complex, highly socio-technical systems that are prone to catastrophic mishaps (Weick, Suttcliffe, & Obstfeld, 1999). Due to its large-scale, convoluted environment, with continuous moving parts, health care has been labeled as a complex organization, but has yet to successfully reach the status of high reliability. Health care is beginning to borrow engineering quality improvement concepts, such as human factors principles and root cause analyses methodology to evaluate and address safety concerns. Originally, human factors principles, such as the HFACS were designed for use with military aviation accidents

(Shappell & Wiegmann, 2000). Furthermore, the 2001 study conducted by Wiegmann and Shappell demonstrated that the HFACS could be applied successfully in other complex industries, such as health care. In fact, the HFACS along with root cause analysis is becoming a familiar resource to the health care sector because the method helps to identify and address many problems and solutions. In fact, the RCA method was used by the organization in this study to identify the causal factors in the 108 historical RCAs that were analyzed. Moreover, the RCA process is a method used for problem-solving and helps to identify the root causes to failures and errors. The literature shows that the RCA framework is worthwhile, as it examines three questions:

- what happened;
- why it happened; and
- what can be done to prevent it from reoccurring?

However, there are times when the process is not conducted appropriately. Instead, the process of blaming the individual, by asking "who did what?" is the outcome. By determining what systemic and human factors are associated with an error, instead of blaming an individual as the cause, a means to preventing the error is produced. Additionally, there is a fourth question that should be considered during the analysis: has the risk of recurrence been reduced or alleviated (Wu, Lipshutz, & Pronovost, 2008)? It would be beneficial to evaluate data from previous error investigations using the HFACS methodology to identify and classify the causes of medical errors and identify the systemic and human factors that prevail. Determining the factors that lead to medical errors provides a course of dialogue for executive and clinical health care leaders, such as quality officers and physicians. Likewise, focusing of what factors are associated with

medical errors may help to improve patient outcomes, build a culture of safety, prevent reoccurrence of errors, and advance steps in the right direction to becoming a highly reliable industry.

Purpose of the Study

The goal of this study is to evaluate systemic and human factors data and bring awareness to organizational health care leaders regarding the benefits of focusing on human factors that are identified when using the HFACS to analyze errors and their causes. The data from historical RCAs will be aggregated and trended using the HFACS codes to identify and categorize the causal factors associated with medical errors. The intent of the analysis is to identify factors that lead to medical errors in order to close the gap between systemic and individual human factors that lead to medical errors. The factors that are determined to be most prevalent in this study will be the focus areas for determining a framework for bridging the gap between systemic and human failures. Fully identifying and understanding systemic and human factors and the association with high reliability concepts allows for a focus on identifying trends in medical errors, and more awareness as to the benefits of focusing on human factors in health care.

Research Question

The problem to be addressed in this study is to identify the systemic and human factors related to causal factors from previously conducted RCAs so that medical errors may be understood. The following research question is intended to provide answers to the dilemma posed in the statement of the problem: What are the associations between systemic and human casual factors that contribute to medical errors?

Context of the Study

Retrospective archival data from 108 previously conducted RCAs will be analyzed using the HFACS methodology to identify the human and systemic causes of errors, as well as interventions which can be implemented in this academic health care facility assisting it in its approaches to achieving high reliability. The past four fiscal years, (2012-2015) of RCA data has been previously coded (using the HFACS) by a group of seven patient safety specialists (one being the author of this thesis) who have been trained in the HFACS methodology. These specialists work in a centralized patient safety department overseeing the investigation and completion of the organization's RCAs. The seven data extractors work in various, diverse health care professions, which include three registered nurses, one pharmacist, one respiratory therapist, and two medical technologists experienced in infection control and clinical microbiology. Collectively, the professionals have 37.75 years of cumulative patient safety experience and an average of 3.9 years of experience using the HFACS to code actions from RCAs (see Appendix A, Table 1.1 for complete demographic table). All of the staff members have been formally trained in assigning the HFACS Nano codes, which is a systematic alpha-numeric code given to each causal factor identified in the RCA data. The setting for the study is in an academic organization which is a cancer treatment and research center located in a medical complex, in the United States.

Significance of the Problem

Caldwell (2007) highlighted the importance of studying human behavior that strengthens system performance rather than a single emphasis on human error causation. Reason (1995) supports that it is best to consider multiple causes of an incident at

different operational levels, i.e., individual, supervisory, and organizational. This focus reduces the desire to solely blame the individual involved in the event, but instead contributes the cause of the error to the complex system in which the individual was placed. Instead of focusing on systems issues that enhance adverse-event recovery efforts, many organizations concentrate on short-term, superficial solutions that fail to solve the real (root) problems. The health care industry has traditionally concentrated on improving health care services instead of the design of the overall system (Rivera & Karsh, 2007). Thus a focus on identifying systemic and human factors that contribute to medical errors in the system can be of benefit, such as using a human factors engineering (HFE) model or high reliability concepts. High reliability specializes in achieving a system that performs with a low to no probability of error and injury and with a high probability of quality and safety (Rivera & Karsh, 2007), while HFE takes into account human strengths and limitations in the design of the system (see Chapter 2 for more discussion on HFE and high reliability).

Patient safety experts are beginning to explore additional avenues, such as high reliability and HFE, in an effort to prevent or reduce the recurrence of errors. Similarly, in nonmedical industries, successful organizations have improved safety by designing systems that protect against human fallibility by using HFE concepts, such as simplified standards, automation of technical functions through simulation, standardization of practices, and supporting teamwork (Henriksen & Battles, 2001). With this comprehensive process, improved outcomes and error reduction becomes normalized. Unlike health care, the aviation industry is known to have successfully embedded HFE

practices into its system to improve safety. Likewise, a focus on these system designs in health care through error-analysis may prove beneficial in reducing errors.

A breakthrough study by Leape, Lawthers, Brennan, and Johnson (1993), demonstrated that greater than two-thirds of the adverse events they studied were preventable and only 28% occurred because of the failure of a health care provider, while 42% were influenced by issues aside from neglect. In addition to these appalling statistics, the IOM (2001) reported that most mistakes that are made by individuals are caused by systems failures, not by individual carelessness or incompetence. The US Agency for Healthcare Research and Quality (AHRQ) reported in December 1999 that preventing medical errors has the potential to save approximately $8.8 billion per year (AHRQ, 1999; Meyer, Battles, Hart & Tang, 2003). These striking statistics make medical errors the eighth leading cause of death in the United States. The IOM (2001) also estimated that preventable errors cost the nation between $17 and $29 billion annually in direct and indirect costs.

A more recent study conducted in 2013 by James, proposes that between 210,000 and 440,000 deaths occur from preventable errors in hospitals each year. By these figures, health care errors are estimated to be the third leading cause of death in the United States, just under cancer and heart disease (Binder, 2013; James, 2013, Makary & Daniel, 2016). These differing statistics in deaths per year due to medical errors is probably due to James's use of the Global Trigger Tool (GTT) endorsed by the Institute for Healthcare Improvement (IHI) that finds specific clues or triggers during a systematic medical record review by trained nurses, pharmacists and physicians that suggest an adverse event has occurred. The estimates from the IOM's original study in 2000 are now

quite old and were based on randomly selected discharge records from one state (New York) in 1984, which did not use the GTT. The GTT provides a more comprehensive, evidence-based estimate of the number of preventable adverse events (PAEs), as compared to the IOM's study methods of general medical record reviews by medical professionals. James's estimates are reasonable taking into account the many unreported or undocumented incidents that occur in hospitals, the increased complexity of medical practice and hospital systems, and an aging population that is living longer and requiring more medical innovation in technology and clinical practice.

The American Society for Healthcare Risk Management (ASHRM, 2006) contends that "if medical errors can be reduced through adherence to sound processes in care, fewer health care dollars will be spent to settle claims, and therefore, potentially more money can be spent on patient care" (p. 117). One may argue whether this information is true or not, regardless, a reduction in errors is a definite benefit to patients, as well as health care providers. For this reason, health care leaders should focus on developing a culture of safety and a learning organization by stipulating and supporting "an overt and pervasive commitment to patient safety as a strategic goal" (ASHRM, 2006, p. 119). Fully understanding the relationship between human factors, patient safety, preventable adverse events, and improved care interventions allows for a focus on identifying trends in errors, and more awareness as to the benefits of identifying systemic and human factors that contribute to medical errors in health care. In addition, this may help to prevent costly, avoidable errors. If errors are not reviewed to adequately identify and address the occurrence and repeat of incidents, then the problem will continue to exist.

Definitions

The following listing includes the major conceptual definitions for this study with operational definition given.

1. Active errors/failures are the acts or conditions that precipitate an incident, which usually involve the front-line staff. The consequences are immediate and often can be prevented.
2. Latent errors/failures are error-prone problems hidden within the health care system that contribute to adverse events.
3. Institute of Medicine – (currently the National Academy of Medicine) is an American nonprofit, non-governmental organization which provides national and international advice on issues relating to biomedical science, medicine, and health, and serves as an adviser to improve health aims to provide unbiased, evidence-based, and authoritative information and advice concerning health and science policy to policy-makers, professionals, leaders in every sector of society, and the public at large. (www.nam.edu)
4. Human factors – Human factors refer to organizational/job factors, environmental, and individual characteristics which influence behavior at work in a way which can affect health and safety. Human factors cross three aspects: the job, the individual and the organization and how each impacts a person's health and safety-related behavior. (World Health Organization (WHO), 2009)
5. Ergonomics – Also known as systems engineering or human factors engineering is "the application of scientific information concerning humans to the design of objects, systems, and the environment for human use. It examines the

environmental, organizational and job factors of humans interacting with systems, as well as the physiological and psychological characteristics which influence behavior at work. (WHO, 2009)

6. The Joint Commission – An independent, not-for-profit organization, which accredits and certifies health care organizations and programs in the United States. Accreditation and certification by The Joint Commission is recognized as a symbol of quality that reflects an organization's commitment to maintaining exceptional performance standards and patient safety. Their mission and vision is to continuously improve health care for the public, by inspiring organizations to provide safe and effective care of the highest quality and value. At the time of the writing of this thesis Dr. Mark Chassin is president of The Joint Commission. (www.jointcommission.org)
7. High reliability organizations (HROs) –
    a. organizations that understand the performance of their systems, constantly search for system defects, rigorously pursue an understanding of system failures, and learn to prevent or mitigate errors. (Diller, Helmrich, Dunning, Cox, Buchanan and Shappell, 2014)
    b. Karl Weick describes HROs as an infrastructure grounded in processes of collective mindfulness which are indicated by a preoccupation with failure, reluctance to simplify interpretations, sensitivity to operations, commitment to resilience, and deference to expertise. In HROs are people are alert, aware and can detect subtle changes in which contexts vary and

call for contingent responding (i.e., collective mindfulness) (Weick, et al., 1999).

8. Culture of safety or safety culture – the concept of consistently minimizing adverse events despite carrying out intrinsically complex and hazardous work. Organizations are considered highly reliable organizations when they maintain a commitment to safety at all levels, from frontline providers to managers and executives. "This commitment establishes a 'culture of safety' that encompasses these key features:
    - acknowledgment of the high-risk nature of an organization's activities and the determination to achieve consistently safe operations
    - a blame-free environment where individuals are able to report errors or near misses without fear of reprimand or punishment
    - encouragement of collaboration across ranks and disciplines to seek solutions to patient safety problems
    - organizational commitment of resources to address safety concerns" (www.psnet.ahrq.gov)
9. Preventable adverse events (PAEs) – an injury to a person that resulted from a medical intervention rather than the underlying medical condition. It is unintentional harm to a person originating from any aspect of health care management. (for example, a retained foreign object or intravenous (IV) line connection error)
10. Medical error – failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim (www.ahrq.gov).

11. Patient safety – the prevention of harm to patients (IOM)
12. The RAND Corporation - a nonprofit, nonpartisan research organization that develops effective solutions to public policy challenges to help make communities throughout the world safer and more secure, healthier and more prosperous. (www.rand.org)
13. Just Culture - is a culture in which front-line operators and others are not punished for actions, omissions or decisions taken by them which are commensurate with their experience and training, but where accountability is the focus and gross negligence, willful violations and destructive acts are not tolerated. (www.outcome-eng.com)

Summary

As a result of basic systems flaws, the health care system is prone to errors, which can be detrimental to providing safe patient care. In order to fully understand human factors and the relationship between patient safety, preventable adverse events, and improved care interventions a focus on identifying trends in errors may help to prevent costly, unnecessary incidents. Health care stakeholders are charged with ensuring the safe delivery of care to patients without harm. Although quality patient care is a critical component of health care, providers face many challenges in today's complex health care environment in trying to keep patients safe.

Therefore, a focus on the safety of care being provided in the health care system is a priority. The health care industry must take measures to reduce preventable errors, recognize the need to expand and reform health care legislation, and reduce health care costs, not to mention the lives that can potentially be saved when attention is rendered to

these areas. This study will provide a forum that places attention on reducing health care errors through a focus on error reduction strategies, based on high reliability principles, to improve patient safety outcomes. Systemic and human factors from RCAs will be evaluated to determine what influences medical error-causation. Chapter 2 will discuss a review of the literature.

Chapter 2

A Review of the Literature

Introduction

A literature search was conducted from PubMed, CINAHL, Medline, and SCOPUS search engines. HFACS, root cause analysis (RCA), medical error, preventable adverse error, preventable medical error, and human factors in health care were keywords and key phrases used to conduct the search. A total of 91 articles and books were compiled from the initial search in which a total of 38 articles, two dissertations, and ten books were specific to this study of human factors and patient safety. Included in the 48 articles and books were five articles which were specific to human factors research in health care settings.

Human factors can be categorized in an organized manner by using the framework, HFACS. This classification system was originally used in other complex non-medical industries, such as the military and aviation, but is now finding a place in the medical field since the early 2000's. As a matter of fact, according to Gurses, Ozok and Pronovost (2012), a need exists for a systematic framework that formulates and organizes efficient interventions that may assist the health care industry to move toward improved patient safety outcomes and meaningful measures.

Since the early 1900's high risk organizations, such as the engineering (and aviation) industry, have adopted a systems approach, such as RCA methods to manage safety (Reason, 1995). The importance of a systems approach to error elimination is that this process recognizes human fallibility, organizational failures caused by poor decisions of leaders, and external factors, such as imposed policies and regulatory burdens, that

contribute to errors. According to Kohn, Corrigan and Donaldson (2000), human factors engineering (HFE) and its systems approach was also recognized as a critical component in assisting to ensure patient safety in health care settings. Health care professionals, governmental and organizational leaders need to utilize the concepts from HFE sciences in order to learn methods to redesign health care systems so that quality care can be produced along with improved patient safety processes (Gurses, Ozok & Pronovost, 2012; Leape, Berwick, & Bates., 2002; Pronovost et al., 2009). Although, there is little focus on awareness and training of health care professionals and leaders in the benefits of human factors error analysis, results from a quantitative study conducted by Azimi and Bahadori (2012) suggest that education has a positive effect on improving managers' attitudes toward developing a culture of safety. Moreover, a focus on human factors to prevent errors from occurring or reoccurring will prove valuable in shaping an organization's safety culture, improvement in patient safety and the patient's experience. Experts who specialize in human factors recognize individuals are integral components in health care systems and understand their skills and limitations must be considered when optimizing the performance in a system to produce safe care (Gurses, Ozok & Pronovost, 2012). Nonetheless, a focus on individual responsibility for errors is not likely to be effective as an error reduction strategy alone; the system should be considered as a focus to decreasing medical errors.

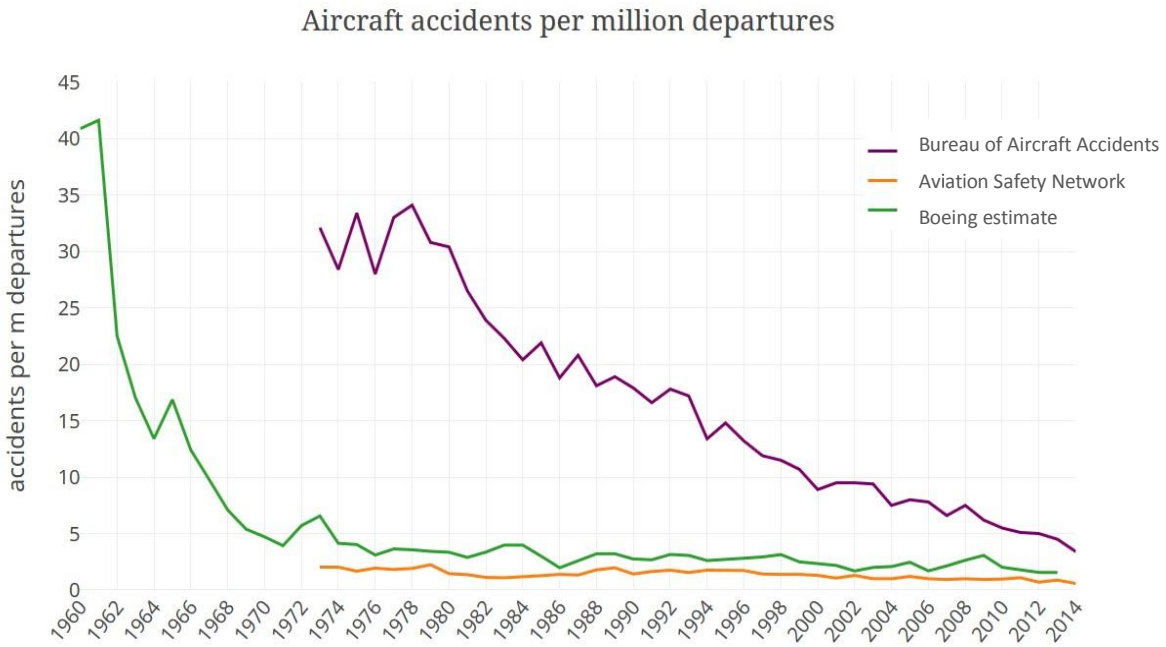
From Persons Approach to RCA: Systems Approach

In general, human error is viewed as a failed plan of action or the use of incorrect planning to achieve an aim (Kohn et al., 2000). Frequently errors made by humans in the environment of complex systems are interchangeable with preventable adverse events

(PAEs). In recent literature, human error is a repeated theme cited as a main contributing factor to many significant incidents (Wiegmann & Shappell, 2001) and this theme will continue as humans are inherently fallible. Likewise, Wiegmann and Shappell (2003) state that 70 to 80 percent of all aviation accidents can be partially attributed to a human error. In fact, as depicted in Figure 2.1, over the last fifty years in spite of a drastic decrease in aviation accidents (fifty accidents worldwide per year reduced to one or two per year today), the rate of human error factors has only been reduced by 50 percent (Wiegmann & Shappell, 2003).

Figure 2.1

Aircraft Accidents per Million Departures



Source: National Transportation Safety Board – www.ntsb.gov; excerpt from The Guardian

Convincingly, this is a significant reduction in accidents and can in part be attributed to the use of human factors investigative and analysis processes (e.g., HFACS). Nevertheless, the system must also be considered as a major factor for error causation.

Historically, human error has been defined as the "persons approach", but more recently the "systems approach" has surfaced in the literature (Reason, 2000). The "persons approach" prevalent in the 1990's, focused on the unreliable, error-prone individual who was blamed as the cause of errors in the organization and who was placed in a system that was considered free from hazards (Woods, Dekker, Cook, Johannesen & Sarter, 2010). In this approach, errors were thought to occur due to cognitive biases (psychological factors) in a person, including memory lapses, lack of motivation, inattentiveness, and complacency. Since the burden lies with the person involved, the recommendations for addressing these errors included education, better selection of staff, creation of detailed procedures, and the dismissal of the individual whose actions led to the incident. Nonetheless, these actions were found to be punitive and ineffective, as human error continued to persist (Wiegmann & Shappell, 2001). Even with putting these interventions in place, errors continued because the focus was on the fallible individual and there was no redesign of the system in which the person was placed.

More recently a transition to the "systems approach" is how human error is now viewed. With this method, human error is considered to be an indicator for latent failures buried in the organization's system, the blunt end, rather than the deficiency of an individual (Woods et al., 2010). Consequently, safety professionals investigate the system in order to unfold the latent organizational and technical factors, which created the conditions leading to the error committed by the individual (Reason, 1995). Representations of latent factors include:

- weak system design,
- manufacturing defects,

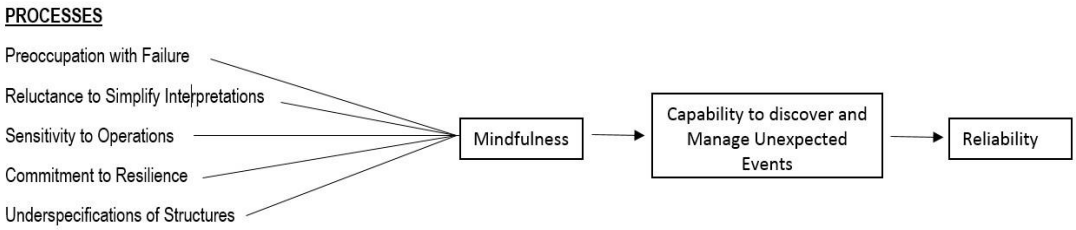
- inefficient technology,
- ineffective oversight and staff education,
- inadequately defined policies and procedures, and
- deficient materials and facilities.

High Reliability

An important principle of continuous systems improvement is to learn from previous incidents so that similar ones are not repeated. In addition, ongoing improvement of systems has been a major focus of The Joint Commission (TJC) since its inception in 1951. Most recently TJC has set a lofty goal of assisting its accredited organizations with means to become high reliability organizations (HROs) by providing tools that aid them through the process along the high reliability journey (Chassin & Loeb, 2013). As defined by O'Connor and Cohn (2010), HROs are "those organizations that succeed in avoiding catastrophes in high-risk environments" (p. 1). Likewise, Weick and Sutcliffe support high reliability theory by building an infrastructure that is cognitively mindful of these five concepts: (1) focus on failures, rather than successes; (2) resistance to over simplify assumptions; (3) observation of operations and its effect on the system; (4) develop resilience to recognize and manage unexpected events; and (5) distributed deference by delegation of action to the frontline experts (Weick & Suttcliffe, 2006). (See Figure 2.2, A Mindful Infrastructure for High Reliability)

Figure 2.2

A Mindful Infrastructure for High Reliability



Weick and Suttcliffe's (2006) focus on mindfulness suggest that when frontline staff feel empowered and trusted to make educated decisions about work tasks, they are actively and psychologically in tune to potential hazards and mishaps. However, leadership must support and listen to the expertise of staff at the front-line, be alert to subtle changes, and continuously improve and learn. To this same point, Weick and Suttcliffe (2007) state in order to survive, organizations must develop resilience in high risk situations, and focus on small clues by remaining mindful and alert. Originally, high reliability theory focused on being error-free, but now the idea is to be harm-free (0% of defects) when errors occur (Hines, Luna, Lofthus, Marquardt, & Stelmokas, 2008; Weick et al., 1999). This idea takes into account the need to understand human error and the inevitable nature of humans' fallibility. In this study the facility evaluates both events of harm as well as those events that do not reach the patient (near misses), which attests to the high reliability principle of preoccupation with failures. Although this facility has not reached the status of becoming highly reliable, as no healthcare facility has, its efforts in conducting root cause analyses for non-sentinel events is noteworthy.

Due to the complexities of the practices, processes, and systems at many levels, the medical field has been deemed a high-risk, error-prone industry (Chassin & Loeb, 2013). Safety is a goal in any hazardous environment and for this reason, health care consumers

and the health care industry would like to see an elimination of harmful errors in these high-risk settings. Through an investigation and analysis of errors implemented in health care settings, along with embedding hazard-reduction interventions, these types of incidents can be greatly reduced, if not alleviated.

Human Factors Origination and Use

The study of human factors originated in the military, and has had successes in other high-risk industries, such as nuclear, aviation, and banking. In fact, Wiegmann and Shappell (2003) support that a use of human factors analyses has helped decrease the number of aviation accidents over the last half century. Most recently health care has found value in a focus on HFE methods. For example, Rogerson and Tremethick (2004) determined that a use of HFE to redesign a complex critical care hospital unit, instead of blaming individuals for reoccurring errors was useful in preventing errors. The authors suggest that the use of a science-based approach such as HFE to designing complex operations and systems is beneficial in reducing variation by standardizing processes, equipment design, communication structures, and system functionality. Although standardizing processes in some instances can prove beneficial, for example checklist have become a resilient process when used appropriately (Gawande, 2009), some authors caution on the use of standardization as it may produce more errors instead of improvements (Weick et al., 1999). This is a valid statement as the organization in which this study is occurring takes a strategic innovative approach, which is a borrowed business concept for change. The concept blends strategy development and creative exploration by ensuring practice guidelines and standards are not explored beyond safe boundaries in

order to discover future services and products. Taking a cautious, but thoughtful approach to safety is a resilient and shrewd process.

"Lapses in patient safety represent a significant global problem that results in preventable morbidity, mortality, and costs of care" (Pronovost, Goeschel, Marsteller, Sexton, Pham & Berenholtz, 2009, p. 330). Likewise, improvement efforts that advance patient safety has seen slow engagement. A potential reason for this lag is the inadequate integration of human factors principles and methods in these efforts, also known as, systems engineering in health care (Gurses, Ozok, & Pronovost, 2012). Furthermore, patient safety problems are complex and rarely caused by one factor or component of a work system, hence the importance of taking a systems approach to evaluating errors in health care.

The health care industry would benefit from utilizing human factors processes that systematically identify problems, prioritize them in an orderly manner, and develop sound, effective solutions (Gurses, Ozok, & Pronovost, 2012), such as the Human Factors Analysis and Classification System (HFACS) which will be explained in detail later. Although, health care has adopted the use of RCAs to systematically evaluate errors, patient safety events continue to occur. In fact, a study by Diller, Helmrich, Dunning, Cox, Buchanan and Shappell (2014) was the only study found that researched the use of the HFACS to categorize RCAs. According to Diller et al. (2014), many hospitals use the RCA method, which was adapted from the aviation, industrial psychology and HFE disciplines, as their investigative method. These authors determined that by categorizing 73 retrospective RCAs that did not follow a structured, systems approach during the analysis of the RCA data, the authors could not effectively use the HFACS as a

classification system for those RCAs. However, when the standardized approach of the HFACS was applied to an additional 105 RCAs prospectively, the authors found that the RCA data could be categorized into actionable systematic causes of error. This categorization helped the authors focus specific performance improvement efforts that ultimately could improve patient safety. Moreover, the authors suggest that testing the use of the HFACS in other health care organizations to ensure the efficacy of its application is warranted. Hence this study's archival data was investigated using the RCA process, thus there are drawbacks in that the mechanism is a retrospective review of an incident. Much rich and valid information can be lost if an investigation is not conducted in a timely manner. In addition, stakeholders many not freely speak up regarding the incident if they feel the process to be vindictive and punitive. To avoid some of these barriers a prospective approach using one-on-one interviews with the parties involved may prove useful. Also, adopting a non-punitive, systematic approach to incident investigation, such as Just Culture© may be beneficial.

Consequently, human error is now regarded as a latent aspect in the system instead of the main reason for an error. Human errors have been classified in ways to help recognize behaviors that jeopardize the safety of those involved. However, the lack of standard terminology and principles for coding the actions has restricted the capability to analyze data across organizations and industries. Hence the development of HFACS, one of many conceptual frameworks. This system includes an error reduction analysis method adapted from Reason's Swiss Cheese Model.

An Explanation of the Human Factors Analysis Classification System (HFACS)

The study of human and system error is not unique to the health care industry. One of the most prominent techniques, James Reason's Swiss Cheese Model (1990), is based on the idea of active and latent failures that occur at four levels or tiers in the model (see the HFACS Framework, Appendix C, Figure 2.4). Expanding on this idea, the HFACS was developed to associate contributing factors and errors. In 2001, Wiegmann and Shappell investigated 119 aircrew related accidents using the HFACS framework which validated HFACS's reliability and validity to identify the underlying systemic and human factors associated with aviation accidents. The article also suggests that the HFACS may be a useful tool for guiding future incident investigation systems in other complex industries, such as medicine. In fact, a meta-analysis conducted by Berry (2010) on seventeen complex multi-industry companies, ten of which were from aviation, developed HFACS benchmarks that could be used as comparative data across industries. Although it may be true that the HFACS has been frequently and successfully applied in the field of aviation, the health care industry has been slow to adapt possibly due to the complexity of the health care environment and the lack of attention to the pervasive safety issues found in diverse settings (NPSF, 2015). Nevertheless, the health care industry is beginning to find value in utilizing the HFACS framework to analyze errors. For instance, the 2014 Diller et al. study used the HFACS to categorize causal factors from 105 RCAs. They found that the top three human factors were ineffective communication, decision/skilled-based errors and routine violations. Likewise, a study was conducted utilizing structured interview questions derived from the causal categories within the HFACS to determine that inappropriate communication, a lack of teamwork,

and poorly planned supervision were the main influences leading to errors in the operating room suite (ElBardissi, Wiegmann, Dearani, Daly, & Sundt, 2007). ElBardissi et al.'s (2007) study made several suggestions, such as crew resource management training to improve the human factors discovered in each tier of the HFACS model.

James Reason's Swiss Cheese Model of Human Error

A well-researched and immensely valued error causation model is Reason's (1990) Swiss Cheese Model (SCM), which will be one of the theoretical framework to support this study. As a complement to Rasmussen's (1982) work, Reason (1990; 1995) conducted significant research on human error by associating human behavior as "unsafe acts" committed by an individual at the front line (sharp end) preceding a preventable event (Ergai, 2013). Knowing that humans are inclined to error he stresses that safety defenses be established to avert system failures. Reason's (1995) SCM acknowledges the concept that taking a systems approach is necessary when investigating human error. Accordingly, Reason (1990) hypothesized that most incidents can be traced to one or more of four failure domains:

1. Unsafe Acts,
2. Preconditions for Unsafe Acts,
3. Unsafe Supervision, or
4. Organizational Influences.

The SCM is displayed as a stack of slices of Swiss cheese, as illustrated in Appendix B, Figure 2.3 in the SCM, an organization's safeguards against system breakdowns are displayed as an array of barriers and protections, represented as slices of Swiss cheese. The holes in the slices represent system failures or deficiencies that vary in location

across the slices. A failure exists when holes in all slices temporarily line up allowing a hazard to pass through which leads to an error (Reason, 2000).

The SCM also includes both active and latent failures. During an investigation, an active failure, which is the act of the individual resulting in an immediate incident, is usually attributed as the cause of an incident. Conversely, latent errors are difficult to ascertain, as they typically exist at the supervisory and organizational levels and include related factors. Latent errors may lie dormant in the system for a prolonged period going undetected and possibly exist as a deeper root cause of the incident (Wiegmann & Shappell, 2003).

Correspondingly, a 2014 publication discovered significant differences in the responses of junior and senior staff in a surgical department based on their analysis of the subcategories of the HFACS: Unsafe Supervision, Organizational Influences, and Preconditions for Unsafe Acts (Konieczny, Seager, Scott, Colbert, Dale, & Brennan, 2014). Konieczny et al. (2014) suggest that deficiencies in organizational influences and supervisory failures can lead to further issues at the Unsafe Acts and Preconditions for Unsafe Acts levels of the HFACS (see the HFACS Framework, Appendix C, Figure 2.4). Therefore, it is important to understand and address the latent concerns so improvements in patient safety may be determined. Although the SCM is a useful framework in theory, Wiegmann and Shappell (2003) identified limitations with the SCM in practice, which included the lack of identification of error causation. For this reason, Wiegmann and Shappell adapted the SCM by developing the HFACS.

Human Factors Analysis and Classification System

The guiding theory for the HFACS is James Reason's SCM. Reason postulated that most incidents can be traced to one of the four failure domains: organizational influences, supervision, preconditions and specific unsafe acts (see the HFACS Framework, Appendix C, Figure 2.4). The HFACS system is a human error taxonomy created to provide an extensive structural framework used to identify and categorize causal factors of errors. Based on the comprehensively organized data, safety interventions can be subsequently suggested and their efficacy determined (Shappell & Wiegmann, 2000). The HFACS identifies the holes or failures in the model, hence, providing a measure to systematically classify the causes of errors and serving as a valuable resource for incident investigation (Wiegmann & Shappell, 2003). Comparable to Reason's SCM, the framework for the HFACS is hierarchical and grouped into nineteen causal factors across four tiers. Similar to the SCM, the four groupings are based on active and latent failures. The first level designates the active, human failures, Unsafe Acts, whereas the other three co-dependent levels include the latent failures: Preconditions for Unsafe Acts, Unsafe Supervision, and Organizational Influences (see the HFACS Framework, Appendix C, Figure 2.4). Co-dependency of the HFACS tiers is supported in the Li and Harris (2006) study in which 523 aircraft accidents in China occurring from 1978 through 2002 were analyzed utilizing the HFACS framework. The results of the study showed a key relationship between the active failures and latent conditions within the organization. The authors support Reason's theory and postulate fallible decisions by upper management levels created Preconditions for Unsafe Acts to occur that directly affected the performance of the pilots (Li & Harris, 2006).

HFACS Framework

Unsafe Acts. Unsafe Acts is the initial level of the HFACS which could advance to an individual performing an error. At this tier the responsibility for the error is placed on the individual, which is quite similar to the previously discussed persons approach. According to Shappell and Wiegmann (2000), 80% of all aviation accidents can be linked to unsafe acts. However, the underlying cause(s) must be determined to fully discover the reason(s) for the error. Errors and Violations are the two classifications for the Unsafe Acts. Errors are inadequacies made by the individual that flounder in fulfilling the desired actions and include three intrinsic error types: Skill-based, Decision-based, and Perceptual. Violations are the purposeful disregard of established rules by a person and are separated into two sub-categories, Routine and Exceptional. According to Shappell and Wiegmann (2003), who used the HFACS model in their study, determined that 60.5% of the 119 accidents in this aviation study were Skill-based errors found under the Unsafe Acts tier. By the same token, Shappell and Wiegmann's theory was supported in the 2014 study conducted by Diller et al. In this study, the HFACS Nano codes for Unsafe Acts were coded in 49.8% of the 105 RCA cases, with the Errors sub-category noted in 32.6% of those coded cases. These physical errors occur with little or no consciousness usually due to the fact that these events are familiar, highly automated tasks, which become redundant in nature. The redundancy of the task usually leads to an increased opportunity for error because the individual is working in an automated mode. For instance, a nurse preparing to administer a medication performs a check to ensure s/he is administering the correct medication. Yet, during the check, s/he becomes absorbed in the customary activities of preparing the medication, totally forgetting to

compare the medication against the physician order and administers the incorrect medication dose, hence, committing a Skill-based error. Generally, Skill-based errors are predominantly caused by a preliminary failure or lack of attention and frequently appear as disregard or mishaps in a process or sequence of events.

Decision errors are the second type of Unsafe Act. They are described as willful acts or honest mistakes of an individual that are carried out as planned, but the outcomes signify that they are insufficient or unsuitable for the situation. The three types of Decision errors include Rule-based, Knowledge-based, and Problem-solving (Wiegmann & Shappell, 2003). Rule-based errors, often denoted as procedural errors, arise when a condition goes undetected or is misdiagnosed, and the inappropriate procedure is performed (Rasmussen, 1982). Knowledge-based errors take place when an individual chooses an action that is found to be improper for the situation. Such errors are enhanced by factors such as inexperience, time constraints, and stress. In some instances, an individual is challenged to face a predicament that is not clearly understood or for which no explicit strategy abides requiring a creative resolution (Ergai, 2013). In such instances, the time necessary to embark upon a viable answer is hardly accessible.

Perceptual errors are the last type of decision-based error, which ensue when degradation of the senses occur, such as those inputs that are observed or heard. These errors are induced by the misjudgment of information which leads to a discrepancy between what an individual perceives as reality and what actually is real. Violations, which can be Routine or Exceptional, are performed when the individual deliberately disregards an established regulation or protocol (Wiegmann & Shappell, 2003). Routine Violations present as minor departures from directives which are condoned by

managerial staff, consequently becoming common practice. Conversely, Exceptional Violations are serious deviations from rules and regulations that are not tolerated by management. While a pharmacist bypassing a system alert when preparing to dispense a medication is an example of a routine violation, practicing as a pharmacist without a license is an example of an Exceptional Violation.

Precondition for Unsafe Acts. Preconditions for Unsafe Acts begin the second level of the HFACS and the first latent tier. Components of the level include Environmental Factors, Conditions of the Operator, and Personnel Factors. Environmental Factors are grouped into two categories: the Physical Environment and the Technological Environment. The Physical Environment describes both the operational (e.g., equipment or machinery) and ambient (e.g., environmental) conditions. The Technological Environment is concerned with the arrangement of machinery and equipment, the interface among workers and equipment and the detail of the displays, which is a considerable issue in human error due to human-technology interfaces (Wiegmann & Shappell, 2003). The second classification of the Preconditions for Unsafe Acts, the Conditions of Operators, is identified by three causal factors: Adverse Mental State, Adverse Physiological State, and Physical/Mental Limitations. According to Wiegmann and Shappell (2003), the Adverse Mental State of the individual deals with problems such as inattentiveness, exhaustion, task fixation, and loss of situational awareness, that can negatively influence the manner in which an individual performs. The Adverse Physiological State concerns conditions pertaining to medical illness and physiological or physical incapacitations. The Physical/Mental Limitations subcategory is associated with situations in which the skills of the individual are exceeded by the

requirements of the job, such as disparate aptitude or mismatched physical capability for safely accomplishing a task (Wiegmann & Shappell, 2003).

The Personnel Factors component is the final category of the Preconditions for Unsafe Acts. This tier is categorized into two causal factors: Communication and Coordination, and Fitness for Duty. Communication and Coordination between management and team members include instances such as a lack of clear team communication or the inadequacy of an individual to use all possible resources, leading to poor decision making (Wiegmann & Shappell, 2003). Wiegmann and Shappell (2003) state that 29.4% of aviation accidents were due to a lack of communication and teamwork. The Fitness for Duty category involves off-duty activities that affect the individual's personal readiness to operate as expected, including alcohol intoxication, overdose on medications, and infringement of respite specifications between work shifts. Diller et al.'s 2014 study noted the HFACS Nano codes (see Appendix D) of Preconditions for Unsafe Acts in 40.6% of the RCAs investigated; making this tier the second most cited HFACS category in their medical study, after Unsafe Acts. Likewise, according to Konieczny et al. (2014) distorted mental status, illness, increased fatigue and stress all increase the likelihood that an error will occur. Hence, the authors suggest that the medical industry should mimic the aviation safety model by recognizing that personal mental status can adversely affect a person's performance (Konieczny et al., 2014).

Unsafe Supervision. The third level, Unsafe Supervision, concerns actions and decisions of supervisors and managers that can affect the performance of frontline staff. It is categorized into four sections: Inadequate Supervision, Planned Inappropriate Operations, Failure to Correct a Known Problem, and Supervisory Violations. Inadequate

Supervision includes intervals when management either fails to grant or gives incorrect direction, management, and education. The Planned Inappropriate Operations section consists of those situations when supervisors fail to calculate the hazard associated with a task, thereby placing employees at an undesirable level of risk; these situations include inadequate staffing, performance of a task that is not in accordance with rules/regulations, and sparse opportunities for adequate employee rest (Wiegmann & Shappell, 2003). Instances in which unacceptable conditions persist such as with a lack of equipment, training or behaviors are identified, yet actions remain uncorrected are all situations in the Failure to Correct a Known Problem category.

According to Wiegmann and Shappell (2003), the Supervisory Violations category is the perverse disregard of the established rules and regulations and also can be recognized as flaunting authority by those in positions of leadership. Fortunately, Diller et al.'s (2014) study found very few (4%) Unsafe Supervisory HFACS categories and likewise only 5.6% Organizational Influences (the next and last HFACS tier). However, one could conclude that since both the Unsafe Acts and Preconditions for Unsafe Acts categories were extremely high the oversight of personnel may be lacking, influencing many of the errors.

Organizational Influences. The last level, and final latent tier, involves the organizational impacts where deficits and failures can be tracked to the uppermost levels of the organization. The three causal factors characterized in this tier are Resource/Acquisition Management, Organizational Climate, and Organizational Process. Wiegmann and Shappell (2003) described Resource/Acquisition Management as top management's decisions related to the misappropriation of resources, such as machinery,

finances, facilities, and people. The Organizational Climate captures variables, such as the organizational structure, culture, and policies, which affect job performance (Wiegmann & Shappell, 2003). Likewise, the Organizational Process category alludes to the decision-making that dictates the daily activities of a facility, such as operations, procedures, and oversight. Frequently latent conditions within the organizational level are overlooked during incident investigations, which could possibly be the case in the Diller et al. (2014) study as previously mentioned. Similarly, Wiegmann and Shappell (2003) found that 5% of aviation accidents resulted from inadequate supervision (as discussed in previous tier), while 8.4% of accidents were due to a breakdown in organizational processes. Equally, Berry (2010) summarized that collectively fewer organizational (and supervisory) factors were noted in her multi-industry human factors study. Although, percentage findings from the HFACS tend to be lower in this tier it still provides a means for scrutinizing such considerations in the investigative and analysis phases.

Summary

HFACS, a framework adapted from Reason's SCM (1990) for error analysis is an ideal methodology for use in the investigation of root cause analyses as the context provides a reliable, standardized structure for determining causal factors that identify systemic, human and behavioral influences. The HFACS structure bridges the gap between Reason's SCM of error causation and the practical application for the investigation of human and system error and incident causation. Drawing on Reason's theory, the HFACS describes failures within four levels of error causation: Unsafe Acts, Preconditions for Unsafe Acts, Unsafe Supervision, and Organizational Influences. Originally used to successfully investigate causation for military aviation accidents

(Wiegmann & Shappell, 2001), the HFACS has been adopted by various complex, high-risk non-aviation industries, such as mining, petroleum and gas, construction, and most recently the medical field (Diller et al., 2014; ElBardissi et al., 2007; Konieczny et al., 2014; Wiegmann & Shappell, 2001). The literature positively supports a use for the HFACS in the health care sector as denoted by the Diller et al. (2014) study; however, more research is needed in this field to gauge the potential realizations. Utilizing high reliability principles alongside human factors principles may suggest better ways in which leaders within healthcare facilities can more successfully obtain and sustain reliability in practices, processes and systems. Chapter 3 will focus on the methods this study will utilize to determine these approaches.

Chapter 3

Methodology

Introduction

This study utilized a descriptive method to analyze and categorize the causes of errors using the HFACS framework. A descriptive design was used as this method best summarized and described the archival data which was collected from previously conducted root cause analyses (RCAs). Chapter Three covers an explanation of the data source, procedures, and analysis, all of which were IRB-approved through the University of Houston and the organization in which the study was conducted.

Data Source

The data source was archival data made available through appropriate approvals from the study site. The academic health care facility is a renowned comprehensive cancer center in the southern region of the United States. The HFACS framework was used to categorize and analyze 108 RCAs associated with medical patient safety incidents that occurred during the 2012-2015 fiscal years (September 1st – August 31st of each year) in the facility in which the study was conducted. From September 1, 2011 to August 31, 2015 an electronic incident-reporting system captured a total of 44,021 voluntarily reported patient events (mean = 1,006 events per month) at this institution, which included events resulting in the 108 RCAs that were analyzed in this study. A vendored-software database was used to group the most recent year's RCAs' human factors to better identify the HFACS categories. It is important to note, this software system was purchased in the last fiscal year (2015) of this data analysis, but prior to this software system, a Microsoft Access system was used for analysis. It is expected that the

new software system will allow for better mapping to causes identified from the human factors. Delineating specific causal factors can better assist with establishing reasons for gaps in the system that lead to errors. The RCA data was grouped into specific identifiable focus areas so that the data could be analyzed to determine what systemic and human factors attributed to medical errors.

Procedures

Root Cause Analysis Selection. The root cause analyses were selected from reported patient safety events from the organization's internal incident reporting system. The criteria for RCA selection included sentinel events as defined by The Joint Commission; high harm events; low to no harm events that reached the patient; near misses which had a potential for risk; events high in risk, with a low probability of being performed routinely; or trended items derived from reported events. This is important information since The Joint Commission requires their accredited facilities to conduct an investigation of any sentinel event. The organization in this study is accredited by The Joint Commission, however conducted root cause analyses on events that caused serious harm to the patient, as well as potential harm or near misses (see Table 3.1 AHRQ Harm Score Description and Harm Levels). The organization uses the Agency for Healthcare Research and Quality (AHRQ) harm scale for hospitals version 2.1 in categorizing the harm levels for the RCAs (AHRQ, 2003).

Table 3.1

AHRQ Harm Score Descriptions and Levels

Description	Level of Patient Harm
Death	9
Permanent harm	8
Severe harm	7
Temporary harm	6
Significant harm	5
Minimal harm	4
No harm	3
Near miss	2
Unsafe Condition	1

A focus to investigate near miss incidents, as well as harmless events takes a proactive approach to safety which helps to identify and address unsafe conditions early. Comprehensive identification and understanding of adverse events can identify both active failures and latent conditions that lie dormant within an organization. Conducting proactive investigations, and not only for sentinel events, assists organizations in identifying weaknesses that can be remedied before they pose any significant risk to patients (Chassin & Loeb, 2013).

Root Cause Analysis Meeting. Once it was determined that an RCA was warranted, based on the criteria previously stated, the RCAs were scheduled for one and a half hours, which allows for ample discussion time. The meetings were conducted in a multidisciplinary, inter-professional fashion in which all team members that were involved in the incident, as well as appropriate administrative managers of the patient care areas were called to an assembly to discuss the incident in a non-punitive manner. The meeting was led by the patient safety team staff and prior to the meeting staff members may be questioned or interviewed to ascertain information in order to prepare a

process flow timeline of events leading up to the error. Discussion of the incident occurred using questions established from a mixture of Just Culture system thinking and the HFACS structure that were informally developed by the organization's patient safety department. During the RCA meeting discussion, the root causes that led to the error were determined by those involved in the incident and captured on a cause and effect fishbone diagram. During the discussion of the incident, root causes were collected in the fishbone diagram and action items were formulated based on the root causes. These root causes were later coded using the HFACS tool modified by this institution (see Appendix D) to determine the human casual factors that led to the event.

Human Factors Analysis. After the conclusion of the RCA meeting, the seven patient safety data extractors (see Appendix A, Table 1.1) met to code the causal factors from each RCA using the HFACS Nano codes (see Appendix D). Each of the predetermined root causes (that led to the error) were reviewed in the monthly HFACS coding meetings with these seven patient safety data extractors. To ensure the data extractors remain focused and alert the meetings lasted for 60-90 minutes in length. Any number of the 252 HFACS Nano codes (causal factors) were assigned to a root cause from the RCA during this meeting by physically reviewing the 19 HFACS categories from each of the four HFACS tiers (see Table 3.2). The 252 Nano codes are the list of error-contributing categories and subcategories that list the specific human behaviors (active errors) and system situations (latent conditions).

Table 3.2:

Notations of Numerical Nano codes for HFACS Categories

	HFACS Category Type	* HFACS Tier Level	# of Numerical Nano codes Assigned to this HFACS Category
1	Decision errors	1	16
2	Skill based errors	1	15
3	Perception errors	1	8
4	Routine violations	1	12
5	Exceptional violations	1	9
6	Environmental errors	2	15
7	Technological errors	2	10
8	Adverse Mental State	2	16
9	Adverse Physiological State	2	5
10	Physical / Mental Limitations	2	16
11	Coordination / Communication / Planning Factors	2	11
12	Fitness for Duty	2	6
13	Inadequate Supervision	3	20
14	Planned Inappropriate Operations	3	16
15	Failure to Correct a Known Problem	3	8
16	Supervisory Violations	3	11
17	Resource Acquisition Management	4	22
18	Organizational Climate	4	16
19	Organizational Processes	4	20
		Grand total:	**252**

*Legend (see also Appendices C and D):
Tier 1 = Unsafe Acts
Tier 2 = Preconditions to Unsafe Acts
Tier 3 = Unsafe Supervision
Tier 4 = Organizational Influences

Any of the seven data extractors could suggest a category or Nano code to assign to a root cause, however it must be agreed upon through consensus before it was assigned. Consensus was managed through an active deductive reasoning model during the meeting. Discussion was conducted in an open, round table manner by stating the root

causes that led to the error, actively reviewing the root causes of the event and reading through each Nano code in each HFACS category and tier, then deciding which Nano codes to assign to the root cause(s). This process has been termed "consensus coding", which is a method of team-based discussion and clarification (of assigned HFACS Nano codes) (Wiegmann, ElBardissi, Dearani, Daly, & Sundt, 2007). Likewise, expert verification checking was used as a method to increase the reliability of coding, as the seven data extractors are clinically trained in their respective professions, such as professional nursing, pharmacy, and allied health (i.e., respiratory therapy, infection control and laboratory medicine), as well as being trained in the analysis of the HFACS (see Data Extractors' Training section). Each staff member was assigned an incident event type based on their area of clinical profession. For example, the pharmacist reviews all medication events routinely, conducts necessary RCAs on medication errors, and his expertise was relied on during the HFACS coding of medication errors. These methods were used to gain the most agreement and reliability in coding the causal factors data.

Often there were several Nano codes and categories assigned to each root cause since typically there is more than one root cause that led to an error. When there is disagreement in the coding process or a lack of consensus, a code was assigned by majority voting and agreement from the team members by determining which code best fit the root cause. If there was a nonexistent code needed for a root cause, the team felt this was a great way to create emergent themes. This conflict analysis created an opportunity for innovation and the creation of future HFACS Nano codes due to external influences that were not presently available in the HFACS listings of categories, hence the idea of emergent themes. These items were placed in a collective listing for potential

consideration to be later added to the facility's healthcare Nano code list of HFACS categories. This listing created a schema of potentially new HFACS Nano codes that may be significant and unique to the healthcare industry.

Consequently, this research study allowed the team to determine if there were gaps in the HFACS framework and if it could be assumed that the HFACS could be used to investigate errors in the healthcare industry. When disagreement with coding or a lack of codes existed, the team determined there were additional Nano codes (see Appendix D) that evolved that related to the healthcare sector. Once the RCA data was categorized and grouped using the HFACS taxonomy, the HFACS Nano codes that resulted from the meeting were uploaded into a secure Microsoft software database for grouping and analysis from which a "Red-Green Map" or Stop Light Map" (see Chapter 5) was created. This study analyzed the Nano codes from the database by determining which human factor focus areas occurred most often. Based on the coded classifications, potential interventions or potential gaps in the HFACS framework were recommended based on the prioritized systemic and human factors.

Data Extractors' Training. The data extractors were previously described in Chapter 1, Context of the Study section of this thesis. However, to elaborate on their training in human factors analysis, each of them was provided a two day, 16-hour didactic course on the HFACS instructed by the creators of the HFACS. The training sessions included hands-on, face-to-face instruction with practice problems, in-depth descriptions of each HFACS tier, an overview of human error and human factors, and an associate certification by exam at the end of the two-day coursework.

Research Question

Descriptive research can yield important information about data that lead to valuable recommendations (Knupfer & McLellan, 2011). The following research question was answered by this quantitative descriptive exploratory study: What are the associations between systemic and human factors that contribute to medical errors?

Data Analysis

This study employed the use of descriptive statistics to classify and organize retrospective archival data from 108 previously conducted root cause analyses (RCAs) over four fiscal years. Likewise, chi square testing was used for statistical analysis of the RCAs to determine any association between them or predictable patterns in the data. The objectives of this quantitative descriptive study were to analyze and categorize the causes gathered from the RCAs using the HFACS methodology to identify the reasons these errors occur. Quantitative methods were used for examining the data from the RCAs and the HFACS. Descriptive statistics was used to provide the frequency of information on the most common HFACS categories, RCA event types, and numbers of RCAs, such as the following descriptive statistics:

- number of RCAs conducted by fiscal year,
- number of RCAs by event type,
- number of RCAs with repeated event type categories,
- causal factor categories by RCA,
- number of active and latent failures,

- number of contributing factors by classification type and subcategories (i.e., Unsafe Acts, Preconditions for Unsafe Acts, Unsafe Supervision, and Organizational Influences), and
- number of RCAs by service line and/or location

Upon completion of the quantitative analyses, recommendations for practice were made regarding how the analysis of the systemic and human factors could be used as focus areas for patient safety improvements. The hope was to suggest what gaps exist in the present HFACS framework that could be used as focus areas in assisting this organization in better developing a culture of safety on their journey to high reliability, as well as better describing how the HFACS framework can be used in healthcare.

Summary

A descriptive study method was used to organize the HFACS systemic and human factors data from 108 previously conducted RCAs. The HFACS data was analyzed using descriptive statistics in order to provide meaningful data that was evaluated. The aim of the quantitative analysis was to offer suggestions for improvement efforts to leaders within this academic health care facility by introducing high reliability principles along with human factors data. The desire was to recommend how this information could be used to make better patient safety decisions that would lead to improvements in patient safety along the journey to high reliability. The subsequent chapter will discuss the results of the HFACS analysis for the organization in this study.

Chapter 4

Results

Introduction

The previous chapter detailed the procedures used in collecting the data, as well as the methods used to analyze the data. Through a closer analysis of the Human Factors Analysis and Classification System (HFACS) four tiers: Unsafe Acts, Preconditions for Unsafe Acts, Supervisory and Organizational Influences, this exploratory study ascertained if system and human factors were associated with medical errors that occur within the organization in this study.

In the organization for this study, root cause analyses (RCAs) were conducted on events that cause harm to patients; reach patients, but cause no harm; as well as near misses, which do not reach the patient at all. The harm scores were derived from the Agency for Healthcare Research and Quality (AHRQ, 2017), which is a group that partners with the United States Department of Health and Human Services to help ensure evidence-based, safe, quality healthcare is rendered throughout the United States of America (USA). The harm scores are used widely in the USA as a common taxonomy to classify patient safety incidents. Similarly, the HFACS was the system used within this organization to categorize patient safety incidents to assist in event investigation. HFACS views human error as a symptom of a larger problem within the organization, not the cause of the incident. With the use of the HFACS, failures were classified, analyzed and trended to assist this organization in understanding the root causes of events, especially those that were repeated. By trending historical patient safety data, organizations can safeguard against risks and hazards to protect against future untoward incidents in care.

The intent of this study was to use the HFACS framework to determine what associations exist between system and human factors that can be addressed in order to better develop a culture of safety within the organization in this study. Descriptive statistics helped exam the event types and locations, harm levels by event category, and causal factors that are detailed in the study findings.

Finding 1: Events resulting in harm were the most frequently reported type of event by harm level, but was usually temporary harm

As denoted in Table 4.1, 60% (64) of the 108 RCAs resulted in harm (moderate to high) to a patient (cumulative harm levels 6-9), while 39% (44) resulted in minimal to no harm (cumulative harm levels 2-5). Lastly, only 1% (1) was reported as a near miss. The majority of harm events (42%) resulted in temporary harm to the patient, which is the lowest level of harm. The description of harm levels (see Table 4.1) with patients' outcomes are summarized as follows:

- Near misses: avoidance of error reaching the patient causing no harm or a safe guard worked effectively (levels 1 and 2)
- Reached the patient: the event reached the patient, but caused minor to no harm (levels 3-5)
- Harm to patient: event reached the patient and cause moderate to severe harm or death (levels 6-9)

Table 4.1

Distribution of harm levels for RCA (reported) events

*Outcome	*Description of Harm Levels	Level of Patient Harm	# of RCA events (cumulative fiscal years, 2012-2015)	% Harm Level
Harm to patient	Death	9	16	15%
	Severe permanent harm (e.g., significant dysfunction or quality of life)	8	3	3%
	Permanent harm (e.g., increased susceptibility to disease progression)	7	0	0%
	Temporary harm	6	45	42%
Reached the patient	Additional treatment (e.g., additional interventions during hospital admission or encounter or increased length of stay, but no other injury)	5	12	11%
	Emotional distress or inconvenience (e.g., mild anxiety, pain, or physical discomfort requiring monitoring, but no other intervention)	4	23	21%
	No harm	3	8	7%
Near miss	Near miss (e.g., fail-safe design, effective safeguard, or recovered error which was noticed and no harm reached the patient)	2	1	1%
	Unsafe condition (e.g., unsafe environment or care area)	1	0	0%

*Note: Based on ARHQ Common Format Taxonomy (AHRQ, 2003)

It is imperative to note that harm levels 6-9 are important, because at these levels the error has reached the patient and has caused some level of moderate to high harm to include death, severe permanent harm, or temporary harm. Harm levels 3-5 reached the

patient, but caused minimal to no harm, such as emotional distress. Lastly, levels 1 and 2 have not reached the patient at all and are good areas of focus to study when trying to build a culture of safety. Equally, one must consider the patient population when reviewing events within this organization. Oncology patients are an "at-risk" population, as many of these patients are immuno-compromised and physiologically depleted due to the nature of the disease processes and treatment regimes. This study did not analyze the type of events reported in direct relation to the patient population, but it is generally important to consider this fragile population in the context of the study in relationship to the magnitude of harm and hazards in patient care.

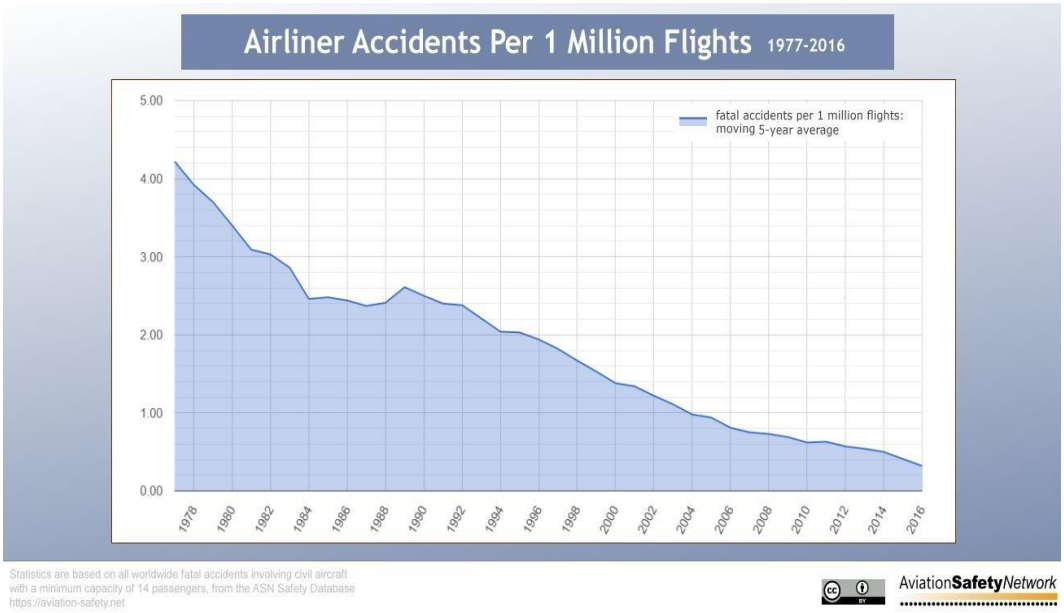
Finding 2: There is a 0.15% adverse defect (error) rate, which is low, but not low enough

The study reviewed RCA causal data from four consecutive fiscal years (2012-2015). In fiscal year 2012 there were 28 RCAs conducted, followed by 26 in fiscal year 2013 and 24 in 2014. Lastly, 30 RCAs were completed in fiscal year 2015. Fifty-three (49%; from 44,021 reported events) of the 108 RCA events across all years occurred in an inpatient care setting, while 25 (23%) occurred in an outpatient clinic setting. The remaining events (28%) occurred in either an operating room (13; 12%), diagnostic or interventional radiologic area (9; 8%), emergency room setting (7; 7%), or morgue (1; 1%). The rate of adverse events or defects (harm of 6-9 = 64) (based on the number of RCAs conducted from all reported events (44,021) over the four-year period) was estimated to be 1 in 688 (total reported events over four years (44,021) / total high harm event levels 6-9 = 64)) reported events during the four-year period.

Through this analysis, we found that the present rate of harmful defects for this organization is 0.15% (# of adverse events (64) / total reported events for all four fiscal years (44,021) x 100). The goal is 0% (0.0003% = Six Sigma). In the aviation and manufacturing industries, such as automobile and oil and gas, the quality control process called Six Sigma is utilized (Chassin, 1998; Hines, Luna, Lofthus, Marquardt, & Dana, 2008; Kohn, Corrigan, & Donaldson, 2000). A company which has Six-Sigma quality, experiences only 3.4 defects (errors) per million products or events, which is an error rate of 0.0003% (3.4 defects / 1 million events x 100) (Chassin, 1998). According to Chassin (1998), in health care, quality problems frequently occur at error rates of 20 to 50%, or 200,000 to 500,000 per million. A more recent study by Singh, Meyer & Thomas (2014), postulate an outpatient diagnostic error rate of 5.08% based on research estimates from three observational studies. Additionally, a 2005 study showed prescription error rates of 0.5%-3% for pharmacists based on varying workload (Marken, 2005). Lastly, the Shojania, Burton, McDonald, & Goldman (2003) study revealed major (missed diagnosis) autopsy error rates of 8.4%-24.4%, when 53 autopsies were evaluated. As one can decipher from these studies, the healthcare industry's varying range of error rates at 0.5%-50% has not yet reached Six Sigma (0.0003%), as compared to other industries. In contrast, according to International Air Transport Association (IATA, 2017) the commercial aviation industry reported in 2016 a major jet accident rate of 0.39% (from 2011-2015 rate = 0.36%), which was the equivalent of one major accident for every 2.56 million flights or error rate of 0.00004% (1 accident / 2.56 million flights x 100) (Figure 4.1, Airline Accidents per 1 Million Flights). This is a drastic difference as compared to the healthcare industry.

Figure 4.1

Airline Accidents per One Million Flights



Note: Source – Aviation Safety Network, Flight Safety Foundation, March 2017 www.flightsafety.org

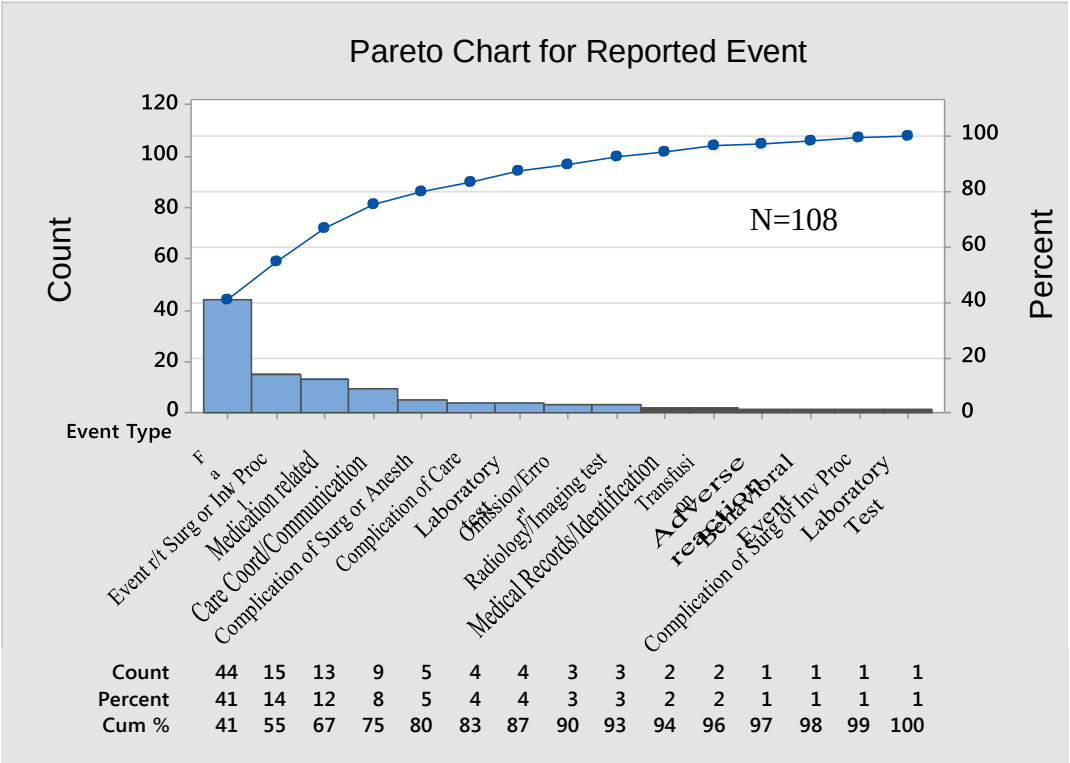
Finding 3: Five event types lead to 80% of the adverse events

Sub-finding A: Falls account for 41% of the adverse events

The distribution of events by type is depicted in Figure 4.2, Pareto Chart for Reported Event Types. There was a mean of 27 RCA events per fiscal year with variation from year-to-year (range 24-30). These events are distributed across both inpatient and outpatient settings.

Figure 4.2

Pareto Chart for Reported Event Types



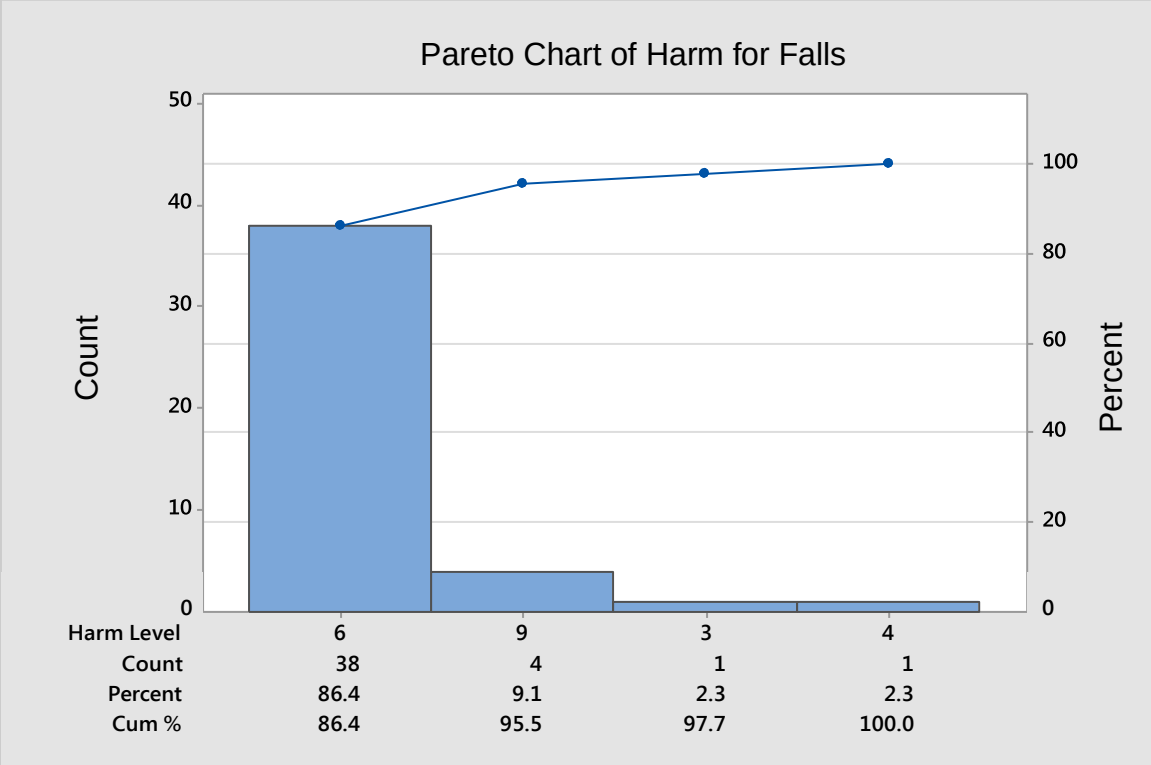
Across all four fiscal years, the most reported event type for which an RCA was conducted is patient falls (44) (see Figure 4.2 Pareto Chart for Reported Event Types and Appendix E, Table 4.2 Event Types by Harm levels and Location Types). Events related to Surgery or Invasive Procedures (n = 15) was the second most reported event type that required an RCA and include potential examples such as incorrect instrument counts, incorrect surgical procedure or retained foreign objects. Medication-related events (n = 13) include possible examples such as wrong medication, wrong timing or wrong patient and was the third reported event type in which an RCA was conducted. Care Coordination and Communication event type (n = 9) was the fourth reported group, which include communication issues and access to care problems. Finally, there were five events from the Complication of Surgery and Anesthesia event type.

Using concepts from the Pareto Principle that 80% of consequences stem from 20% of the causes (Dhand, 2014), one can conclude that 20% of harmful event types lead to 80% of the adverse events. If the Pareto Principle was applied to this organization, focusing on the top five reported event types (falls (41%), Events related to Surgery or Invasive Procedures (14%), Medication-related (12%), Care Coordination/ Communication issues (8%), and Complication of Surgery or Anesthesia (5%)) would alleviate 80% of the reported adverse events (see Figure 4.2 Pareto Chart for Reported Event Types).

Falls (44 events) account for the majority (41%) of the events types with a harm level of 6. Therefore, a focus on preventing falls would greatly reduce adverse events with harm. Unfortunately, there lack subcategories in the incident reporting system for falls, which makes it difficult to conduct a deeper analysis as to why falls occur or reoccur within this institution. Likewise, 86.6% of falls have a harm of 6, while 95.5% of falls have high harm levels of 6 and 9. (see Figure 4.3, Pareto Chart of Harm for Falls).

Figure 4.3

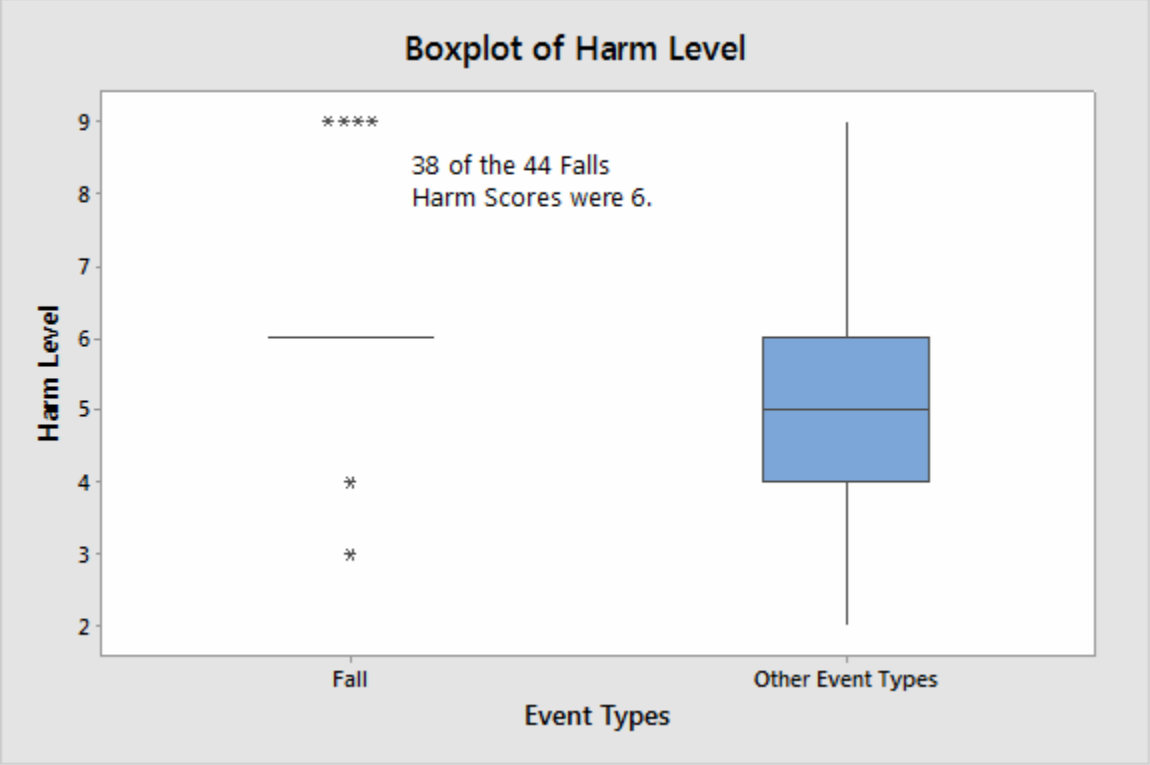
Pareto Chart of Harm for Falls



In comparison, all other event types (see Figure 4.2 Pareto Chart for Reported Event Types) have a lower harm level with a median harm level of 5 (additional treatment), while the median harm level for Falls is 6 (temporary harm) (*p-value*<0.000) (see Figure 4.4 Boxplot Comparing Harm Levels by Event Type). Meaning that if a fall were to occur within this organization as compared to other event types, the harm would result in a higher level, temporary harm of 6. However, if other event types occurred the harm level would likely be less than 6.

Figure 4.4

Boxplot Comparing Harm Levels by Event Type



Sub-finding B: Four event categories result in a 74% repeat rate

Of the 108 RCAs, four event type categories (Events related to Surgery or Invasive Procedure; Medication related events; Laboratory Testing related events; and patient Falls) had repeated incidences. Of the 108 RCAs, five event subcategories were repeated for a total of fifty-seven incidences (54.6%) (see Table 4.3 Reoccurring Event Types). For this study recurrence is defined as three or more repeat events. Patient falls was the most repeated event type with 44 incidences (100% event repeat rate). (see Table 4.3 Reoccurring Event Types). A focus on human factors related to these repeated event categories, especially Falls, would be advantageous. Additionally, specific attention

should be given to the efficacy of the corrective actions that were identified from the RCAs, especially falls.

Table 4.3

Reoccurring event types over all fiscal years (2012-2015)

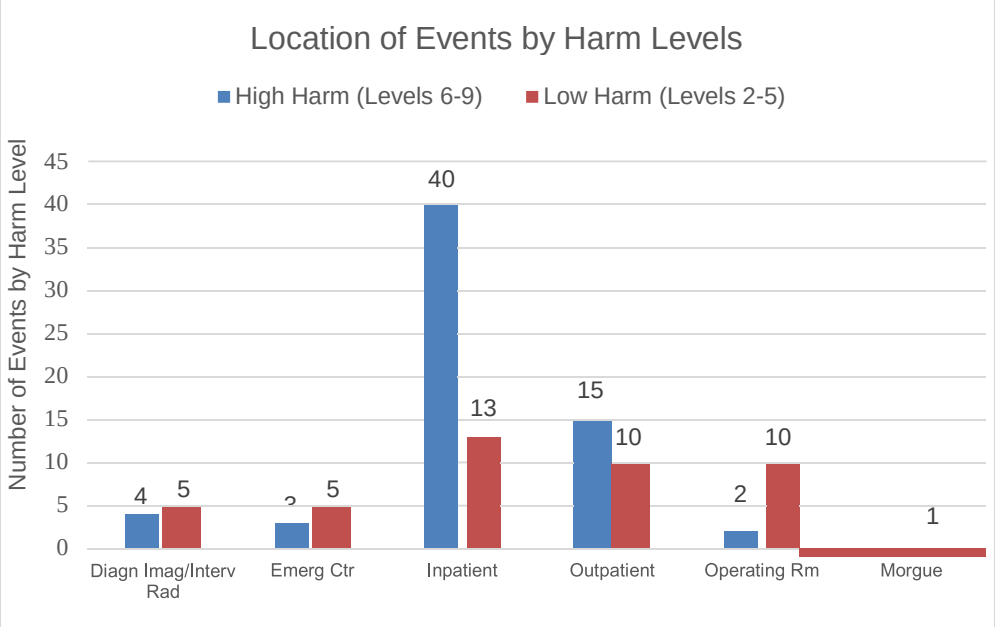
Event Category	Event Subcategory	# of Events Repeated of Total	% Repeat Rate for Category
Falls	Patient fall	44 of 44	100% (44 of 44)
Event related to surgery or invasive procedure	Foreign body accidentally left in patient	4 of 15	47% (7 of 15)
	Wrong side (L vs R) surgery/procedure	3 of 15	
Medication related	Medication Overdose	3 of 13	23% (3 of 13)
Laboratory testing related	Laboratory reporting result issue/report unavailable	3 of 5	60% (3 of 5)
	Overall totals	57	77 (74%)

Finding 4: 38% of high harm occurred in an inpatient area in relation to total harm for all RCA events

Locations of all events by harm level in which an RCA was conducted are depicted in Figure 4.5, Location of Events by Harm Levels.

Figure 4.5

Location of Events by Harm Levels



Pearson chi-square test was conducted and found that the operating room (OR) locations are performing differently, at a 95% confidence level (*p-value* = 0.002) as compared to the other patient care areas, i.e., inpatient units, outpatient centers, emergency centers, and diagnostic imaging areas. The event that occurred in the morgue was excluded from the sample analysis because there was no way to make meaningful use of the data in relation to harm levels. The OR areas have a lower incidence of high harm which suggests that practices in the OR are not associated with practices in other patient care areas. Consequently, it would be beneficial to look at why the operating room locations are performing differently and why the events reported in the OR have lower harm levels (harm levels of 2-5), as compared to other patient care environments. Of great importance, one should note that although the OR areas have a higher incidence of low harm, the event types tend to reoccur and are more hazardous prone.

The chi-square test revealed that inpatient patient care areas may also have a predictable pattern of behavior, however it is difficult to prove as additional data is warranted. Nonetheless, the *p-value*, 0.002 is small enough to cause suspicion that the inpatient setting is behaving differently as well, as compared to other locations. However, of importance to the inpatient setting is that 38% of high harm occurred in an inpatient area in relation to total harm for all RCAs. This is not to suggest that the inpatient areas are more hazardous, but it is more likely that if an event were to occur in an inpatient area, the harm would be higher. However, more data would provide the opportunity to determine if adverse events are truly more prone in the inpatient setting. Additionally, this data does not take into consideration the risk and environment of an inpatient setting, the frequency of harm, frequency of reporting from each location site, or chance of opportunity for an event.

Finding 5: There is variation in human factors identified across industries, however, study site identified more system factors, while comparative sites identified more individual factors.

As previously detailed in the literature review in Chapter 2 there are four levels in the HFACS which assist to investigate and identify active and latent failures in processes and systems. When analyzing root causes from the study site's RCAs, any of the 252 Nano codes from the HFACS are assigned to a causal factor to help investigate and identify why an incident occurred. In this particular exploratory study, the distribution of HFACS Nano codes was collected for the 108 previously conducted RCAs, which revealed 2,013 human factor Nano codes over a four-year period in one organization (see Table 4.4 Distribution of HFACS Casual Categories by Fiscal Year). In contrast, the

Diller et al (2014) study analyzed 1,711 Nano codes over a two-year period for 105 patient events. (see Table 4.5 Distribution of HFACS Causal Categories (Comparative Data for Study Site, Diller Study & Berry Study)

Table 4.4

Distribution of HFACS Casual Categories by Fiscal Year (Study Site)

Distribution of HFACS Causal Categories by Fiscal Year (Study Site)																				
	FY 2012 (28 RCAs conducted)				FY 2013 (26 RCAs conducted)				FY 2014 (24 RCAs conducted)				FY 2015 (30 RCAs conducted)				**Cumulative FYs (108 RCAs conducted)**			
Human Factord Analysis and Classification System (HFACS)	Total Nanocodes per Category	% of nanocodes per category	#ofRCA Cases witha nanocode fromthis category	% of cases witha nanocode fromthis	Total Nanocodes per Category	% of nanocodes per category	#ofRCA Cases witha nanocode fromthis category	% of cases witha nanocode fromthis category	Total Nanocodes per Category	% of nanocodes per category	#ofRCA Cases witha nanocode fromthis category	% of cases witha nanocode fromthis category	Total Nanocodes per Category	% of nanocodes per category	#ofRCA Cases witha nanocode fromthis category	% of cases with a nanocode fromthis	Total Nanocodes per Category	% of nanocodes per category	#ofRCA Cases witha nanocode from this category	% of cases with a nanocode from this category
Organizational Influences	101	23%			95	24%			80	24%			141	17%			**417**	**21%**		
Resource Management	28	6%	14	50	23	6%	12	46	14	4%	8	33	43	5%	19	63	**108**	**5%**	**53**	**49%**
Organizational Climate	29	7%	14	50	39	10%	20	77	27	8%	12	50	49	6%	19	63	**144**	**7%**	**65**	**60%**
Organizational Process	44	10%	19	68	33	8%	18	69	39	12%	15	63	49	6%	16	53	**165**	**8%**	**68**	**63%**
Unsafe Supervision	87	20%			51	13%			49	15%			142	17%			**329**	**16%**		
Inadequate Supervision	32	7%	15	54	16	4%	8	31	19	6%	11	46	47	6%	11	37	**114**	**6%**	**45**	**42%**
Planned Inappropriate Operations	23	5%	12	43	21	5%	12	46	20	6%	11	46	44	5%	15	50	**108**	**5%**	**50**	**46%**
Failure to Correct Known Problem	25	6%	17	61	11	3%	9	35	7	2%	6	25	38	5%	13	43	**81**	**4%**	**45**	**42%**
Supervisory Violation	7	2%	6	21	3	1%	3	12	3	1%	3	13	13	2%	4	13	**26**	**1%**	**16**	**15%**
Preconditions for Unsafe Acts	117	26%			110	28%			97	29%			329	39%			**653**	**32%**		
Environmental Factors																	**166**			
Physical Environment	5	1%	5	18	3	1%	3	12	4	1%	4	17	15	2%	7	23	**27**	**1%**	**19**	**18%**
Technological Environment	35	8%	17	61	21	5%	16	62	23	7%	9	38	60	7%	18	60	**139**	**7%**	**60**	**56%**
Condition of the Operator/Employee																	**211**			
Adverse Mental State	15	3%	9	32	30	8%	17	65	27	8%	12	50	101	12%	24	80	**173**	**9%**	**62**	**57%**
Physical/Mental Limitations	5	1%	4	14	0	0%	0	0%	3	1%	3	13	23	3%	10	33	**31**	**2%**	**17**	**16%**
Adverse Physiological State	0	0%	0	0%	6	2%	5	19	0	0%	0	0%	1	0%	1	3%	**7**	**0%**	**6**	**6%**
Personnel Factors																	**276**			
Communication and Coordination	57	13%	22	79	50	13%	22	85	39	12%	17	71	128	15%	24	80	**274**	**14%**	**85**	**79%**
Fitness for Duty	0	0%	0	0%	0	0%	0	0%	1	0%	1	4%	1	0%	1	3%	**2**	**0%**	**2**	**2%**
Unsafe Acts	141	32%			141	36%			106	32%			226	27%			**614**	**31%**		
Errors																	**492**			
Decision-making Errors	64	14%	25	89	47	12%	19	73	41	12%	19	79	68	8%	23	77	**220**	**11%**	**86**	**80%**
Skill-based Errors	40	9%	22	79	53	13%	21	81	44	13%	19	79	102	12%	26	87	**239**	**12%**	**88**	**82%**
Perceptual errors	12	3%	10	36	10	3%	6	23	7	2%	6	25	4	0%	4	13	**33**	**2%**	**26**	**24%**
Violations																	**122**			
Routine Violations	25	6%	16	57	29	7%	13	50	13	4%	8	33	49	6%	12	40	**116**	**6%**	**49**	
Exceptional Violations	0	0%	0	0%	2	1%	2	8%	1	0%	1	4%	3	0%	2	7%	**6**	**0%**	**5**	
	446				397				332				838				**2,013**	**100%**		

Table 4.5

Distribution of HFACS Causal Categories (Comparative Data for Study Site, Diller Study & Berry Study)

Distribution of HFACS Causal Categories (Comparative Data for Study Site, Diller Study and Berry Study)										
			Study Site Cumulative HFACS Data (108 RCAs) (health care)				**Diller Study Cumulative HFACS Data (105 RCAs) (health care)**				**Berry Study Cumulative (mean) HFACS Data (22,165 cases) (mixed; mostly aviation)**
Human Factord Analysis and Classification System (HFACS)			Total Nanocodes per Category	% of nanocodes per category	# of RCA Cases with a nanocode from this category	% of cases with a nanocode from this category	Total Nanocodes per Category	% of nanocodes per category	# of RCA Cases with a nanocode from this category	% of cases with a nanocode from this category	% of nanocodes per category
Organizational Influences			417	**21%**			96	**6%**			n.d.
	Resource Management		108	5%	53	49%	34	2%	11	11%	2%
	Organizational Climate		144	7%	65	60%	33	2%	24	23%	1%
	Organizational Process		165	8%	68	63%	29	2%	18	17%	12%
Unsafe Supervision			329	**16%**			69	**3%**			n.d.
	Inadequate Supervision		114	6%	45	42%	26	1%	19	18%	3%
	Planned Inappropriate Operations		108	5%	50	46%	9	0%	9	9%	5%
	Failure to Correct Known Problem		81	4%	45	42%	14	1%	13	12%	2%
	Supervisory Violation		26	1%	16	15%	20	1%	18	17%	2%
Preconditions for Unsafe Acts			653	**32%**			694	**41%**			n.d.
	Environmental Factors		166	8%	79		96	6%			
		Physical Environment	27	1%	19	18%	52	3%	33	31%	42%
		Technological Environment	139	7%	60	56%	44	3%	23	22%	17%
	Condition of the Operator/Employee		211	11%	85		146	9%			
		Adverse Mental State	173	9%	62	57%	130	8%	59	56%	5%
		Physical/Mental Limitations	31	2%	17	16%	1	0%	1	1%	12%
		Adverse Physiological State	7	0%	6	6%	15	1%	9	9%	2%
	Personnel Factors		276	14%	87		452	26%			
		Communication and Coordination	274	14%	85	79%	449	26%	90	86%	9%
		Fitness for Duty	2	0%	2	2%	3	0%	3	3%	2%
Unsafe Acts			614	**31%**			852	**50%**			n.d.
	Errors		492	25%	200		558	33%			
		Decision-making Errors	220	11%	86	80%	113	25%	99	54%	32%
		Skill-based Errors	239	12%	88	82%	426	7%	57	94%	46%
		Perceptual errors	33	2%	26	24%	19	1%	16	15%	5%
	Violations		122	6%	54		294	17%			
		Routine Violations	116	6%	49	45%	270	16%	84	80%	
		Exceptional Violations	6	0%	5	5%	24	1%	12	11%	5%
			2013	100%			1711	100%			

Decision-making errors and Skill-based errors are frequently cited most often in HFACS analyses as an active failure in errors and this was found to be true in this research. For instance, 614 (31%) Nano codes were categorized as Unsafe Acts with most of the errors relating to Decision-making (220 Nano codes; 11%) and Skill-based errors (239 Nano codes; 12%). (see Table 4.5A Comparative Unsafe Acts Tier)

Table 4.5A

Comparative Unsafe Acts Tier (study site and comparison sites)

Distribution of HFACS Causal Categories (Comparative Data for Study Site, Diller Study and Berry Study)												
				Study Site Cumulative HFACS Data (108 RCAs) (health care)				**Diller Study Cumulative HFACS Data (105 RCAs) (health care)**				**Berry Study Cumulative (mean) HFACS Data (22,165 cases) (mixed; mostly aviation)**
Human Factord Analysis and Classification System (HFACS)				Total Nanocodes per Category	% of nanocodes per category	# of RCA Cases with a nanocode from this category	% of cases with a nanocode from this category	Total Nanocodes per Category	% of nanocodes per category	# of RCA Cases with a nanocode from this category	% of cases with a nanocode from this category	% of nanocodes per category
Unsafe Acts				614	**31%**			852	**50%**			n.d.
	Errors			492	25%	200		558	33%	172		
		Decision-making Errors		220	11%	86	80	113	25%	99	54%	32%
		Skill-based Errors		239	12%	88	82	426	7%	57	94%	46%
		Perceptual errors		33	2%	26	24	19	1%	16	15%	5%
	Violations			122	6%	54		294	17%	96		
		Routine Violations		116	6%	49	45	270	16%	84	80%	
		Exceptional Violations		6	0%	5	5%	24	1%	12	11%	5%
				2013	100%			1711	100%			

In a 2014 study by Diller et al. 25% of errors resulted from decision making concerns, while 16% were routine violations. A meta-analysis by Berry (2010) completed across several industries which used the HFACS to investigate accident and near miss cases in aviation, rail, food, entertainment, and mining companies found that skill-based errors were found in 46% of the investigated cases, while decision-making errors occurred in 32% of the cases. It may be important to note, the total number of cases from the meta-analysis was 22,165 and varied in the number of cases reported from seventeen

companies (10 aviation, 2 mining, 3 maintenance, 1 food service, and 1 entertainment), none being healthcare facilities.

The top five Skill-based and Decision-making causal factors from analyzed RCAs are denoted in Figures 4.6A and 4.6B.

Figure 4.6A

Skill-based Errors Causal Factors (Top 5)

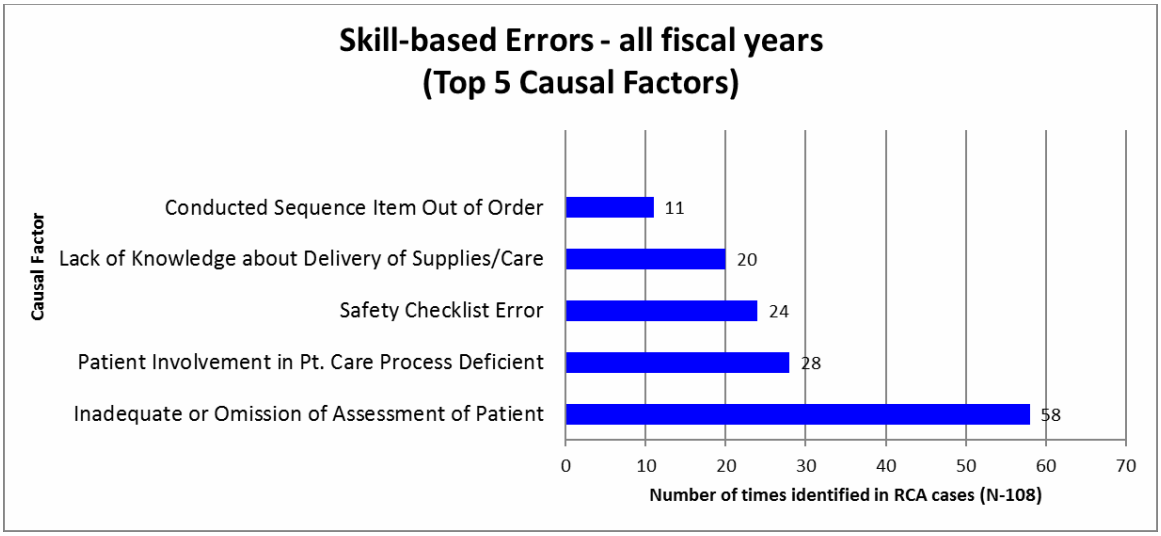
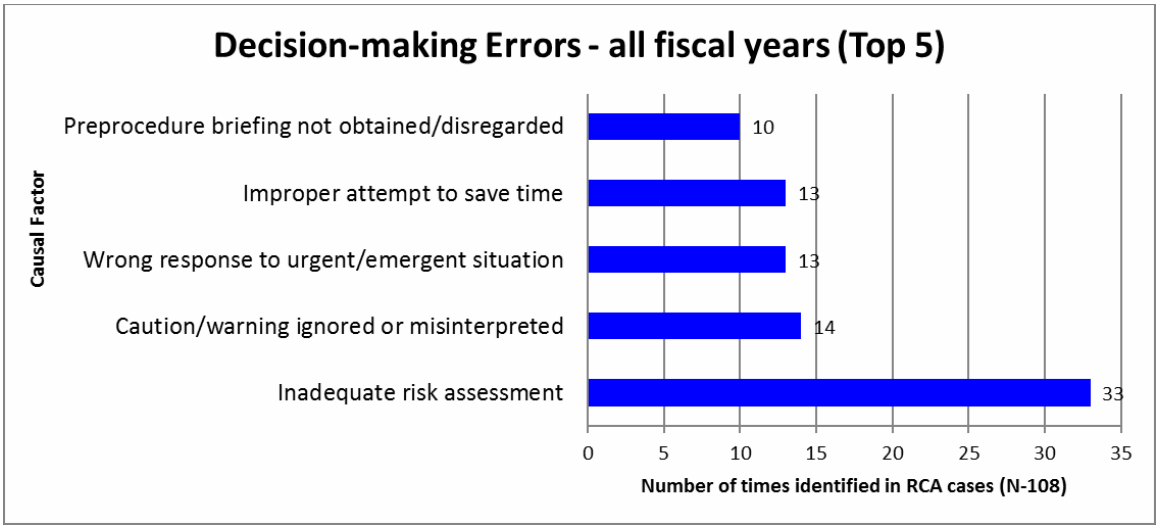


Figure 4.6B

Decision-making Errors Causal Factors (Top 5)



Under the Preconditions for Unsafe Acts tier for the study site, 653 (32%) Nano codes were identified. The most common identified subcategory was Communication and Coordination (274 Nano codes; 14%), followed by Adverse Mental State (173 Nano codes; 9%) and Technological Environment (139 Nano codes; 7%). (see Table 4.5B Comparative Preconditions for Unsafe Acts Tier)

Table 4.5B

Comparative Preconditions for Unsafe Acts Tier (study site and comparison sites)

Distribution of HFACS Causal Categories (Comparative Data for Study Site, Diller Study and Berry Study)											
			Study Site Cumulative HFACS Data (108 RCAs) (health care)				**Diller Study Cumulative HFACS Data (105 RCAs) (health care)**				**Berry Study Cumulative (mean) HFACS Data (22,165 cases) (mixed; mostly aviation)**
Human Factord Analysis and Classification System (HFACS)			Total Nanocodes per Category	% of nanocodes per category	# of RCA Cases with a nanocode from this category	% of cases with a nanocode from this category	Total Nanocodes per Category	% of nanocodes per category	# of RCA Cases with a nanocode from this category	% of cases with a nanocode from this category	% of nanocodes per category
Preconditions for Unsafe Acts			653	**32%**			694	**41%**			n.d.
	Environmental Factors		166	8%	79		96	6%	56		
		Physical Environment	27	1%	19	18%	52	3%	33	31%	42%
		Technological Environment	139	7%	60	56%	44	3%	23	22%	17%
	Condition of the Operator/Employee		211	11%	85		146	9%	69		
		Adverse Mental State	173	9%	62	57%	130	8%	59	56%	5%
		Physical/Mental Limitations	31	2%	17	16%	1	0%	1	1%	12%
		Adverse Physiological State	7	0%	6	6%	15	1%	9	9%	2%
	Personnel Factors		276	14%	87		452	26%	93		
		Communication and Coordination	274	14%	85	79%	449	26%	90	86%	9%
		Fitness for Duty	2	0%	2	2%	3	0%	3	3%	2%

The top five Communication and Coordination causal factors from analyzed RCAs are denoted in Figures 4.6C and the top five Adverse Mental Status causal factors are represented in Figure 4.6D.

Figure 4.6C

Communication and Coordination Error Causal Factors (Top 5)

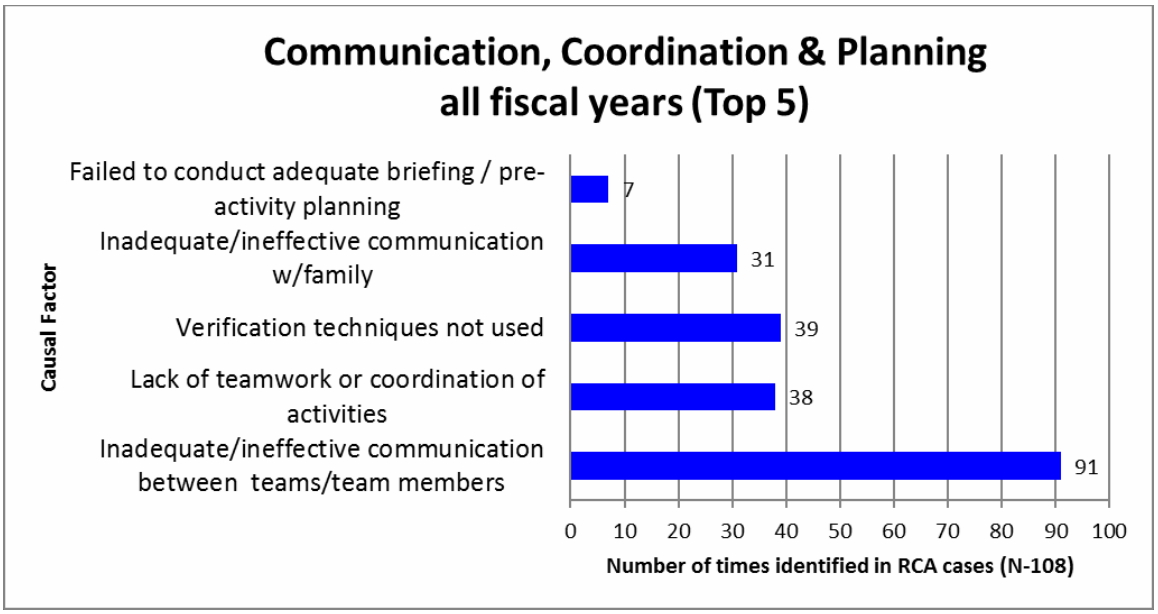
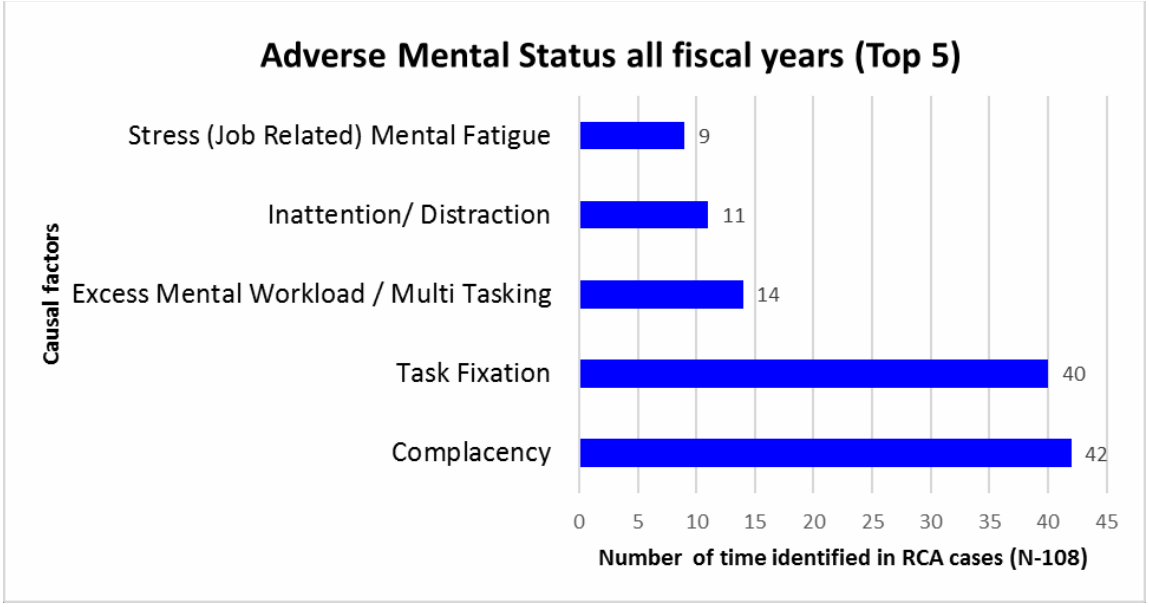


Figure 4.6D

Adverse Mental Status Error Causal Factors (Top 5)



Similarly, the Diller et al. (2014) study notes 694 (41%) Nano codes, with Communication and Coordination (449 Nano codes; 26%), Adverse Mental State (130 Nano codes; 8%), Physical Environment (52 Nano codes; 3%) leading this tier. Likewise, Berry (2010) discovered other industries that use the HFACS found 42% of the cases that were investigated had physical environment concerns, while 12% had physical and mental limitations. Nine percent of cases had crew resource management (team-work and communication) concerns and finally, 17% had technological concerns.

The Unsafe Supervision HFACS level had the least identified human factors, which is not an uncommon finding, with 329 (16%) Nano codes assigned. (see Table 4.5C Comparative Unsafe Supervision Tier)

Table 4.5C

Comparative Unsafe Supervision Tier (study site and comparison sites)

Distribution of HFACS Causal Categories (Comparative Data for Study Site, Diller Study and Berry Study)									
	Study Site Cumulative HFACS Data (108 RCAs) (health care)				**Diller Study Cumulative HFACS Data (105 RCAs) (health care)**				**Berry Study Cumulative (mean) HFACS Data (22,165 cases) (mixed; mostly aviation)**
Human Factord Analysis and Classification System(HFACS)	Total Nanocodes per Category	% of nanocodes per category	# of RCA Cases with a nanocode from this category	% of cases with a nanocode from this category	Total Nanocodes per Category	% of nanocodes per category	# of RCA Cases with a nanocode from this category	% of cases with a nanocode from this category	% of nanocodes per category
Unsafe Supervision	329	**16%**	156		69	**3%**	59		n.d.
Inadequate Supervision	114	6%	45	42%	26	1%	19	18%	3%
Planned Inappropriate Operations	108	5%	50	46%	9	0%	9	9%	5%
Failure to Correct Known Problem	81	4%	45	42%	14	1%	13	12%	2%
Supervisory Violation	26	1%	16	15%	20	1%	18	17%	2%

In comparison, the 2014 Diller et al. study coded only 3% (69) of their causal factors under the Unsafe Supervision tier. However, unlike the Diller et al. (2014) study, the two most cited subcategories in this tier were Inadequate Supervision (114 Nano codes; 6%)

and Planned Inappropriate Operations (108 Nano codes; 5%). Figures 4.6 E and 4.6 F denote the specific causal factors for each of these subcategories.

Figure 4.6E

Inadequate Supervision Error Causal Factors (Top 5)

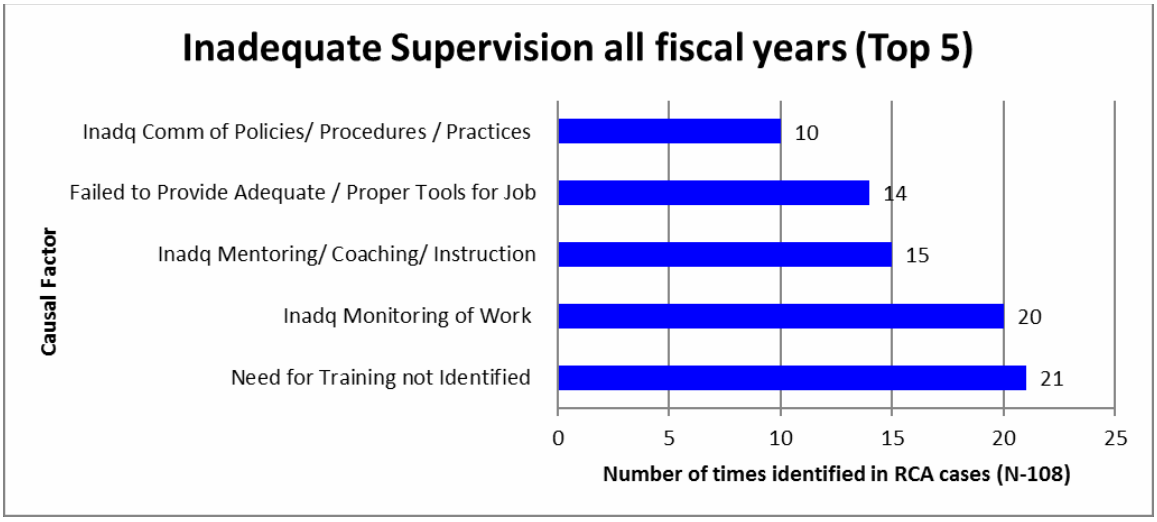
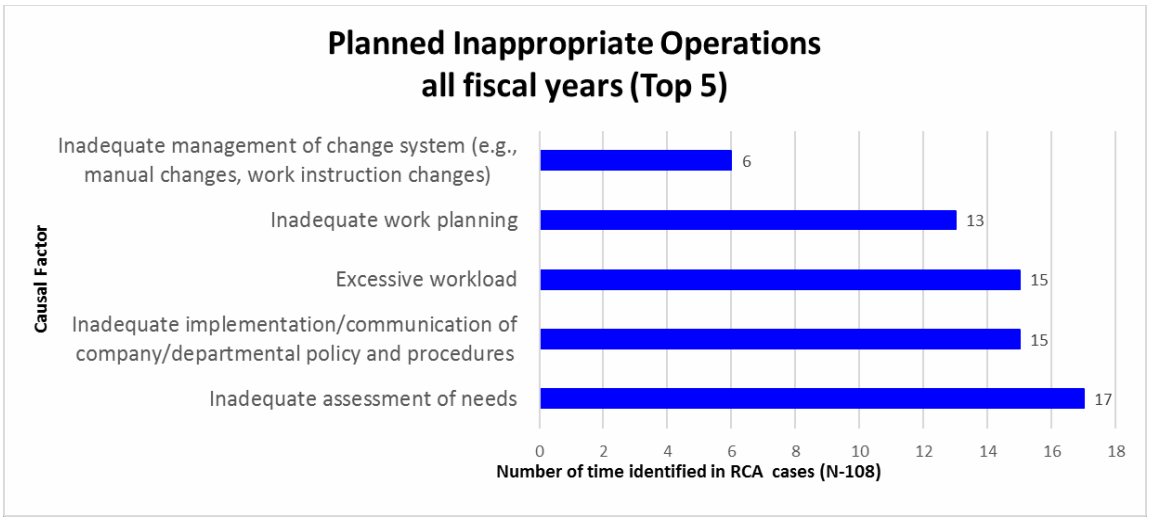


Figure 4.6F

Planned Inappropriate Operations Error Causal Factors (Top 5)



The Diller et al. (2014) study noted Inadequate Supervision (26 Nano codes; 1%) and Supervisory Violations (20 Nano codes; 1%) as the most frequently cited causal factors

under the Unsafe Supervision tier. Similarly, in the Berry (2010) meta-analysis Inadequate Supervision was reported in 3% of the cases, while Planned Inappropriate Operations was found in 5% of the cases.

Lastly, the Organizational Influences tier is where most latent conditions lie undetected and can lead to system issues within an organization. 417 (21%) total Nano codes were identified, with the three subcategories, Organizational Process, Organizational Climate, and Resource Management closely matching one another, at 165 Nano codes (8%), 144 (7%), and 108 (6%), respectively. (see Table 4.5D Comparative Organizational Influences Tier)

Table 4.5D

Comparative Organizational Influences Tier (study site and comparison sites)

Distribution of HFACS Causal Categories (Comparative Data for Study Site, Diller Study and Berry Study)										
		Study Site Cumulative HFACS Data (108 RCAs) (health care)				**Diller Study Cumulative HFACS Data (105 RCAs) (health care)**				**Berry Study Cumulative (mean) HFACS Data (22,165 cases) (mixed; mostly aviation)**
Human Factord Analysis and Classification System (HFACS)		Total Nanocodes per Category	% of nanocodes per category	# of RCA Cases with a nanocode from this category	% of cases with a nanocode from this category	Total Nanocodes per Category	% of nanocodes per category	# of RCA Cases with a nanocode from this category	% of cases with a nanocode from this category	% of nanocodes per category
Organizational Influences		417	**21%**	186		96	**6%**	53		n.d.
	Resource Management	108	5%	53	49%	34	2%	11	11%	2%
	Organizational Climate	144	7%	65	60%	33	2%	24	23%	1%
	Organizational Process	165	8%	68	63%	29	2%	18	17%	12%

The causal factors under the organizational subcategories at detailed in Figures 4.6G, 4.6H, and 4.6I.

Figure 4.6G

Organizational Processes Error Causal Factors (Top 5)

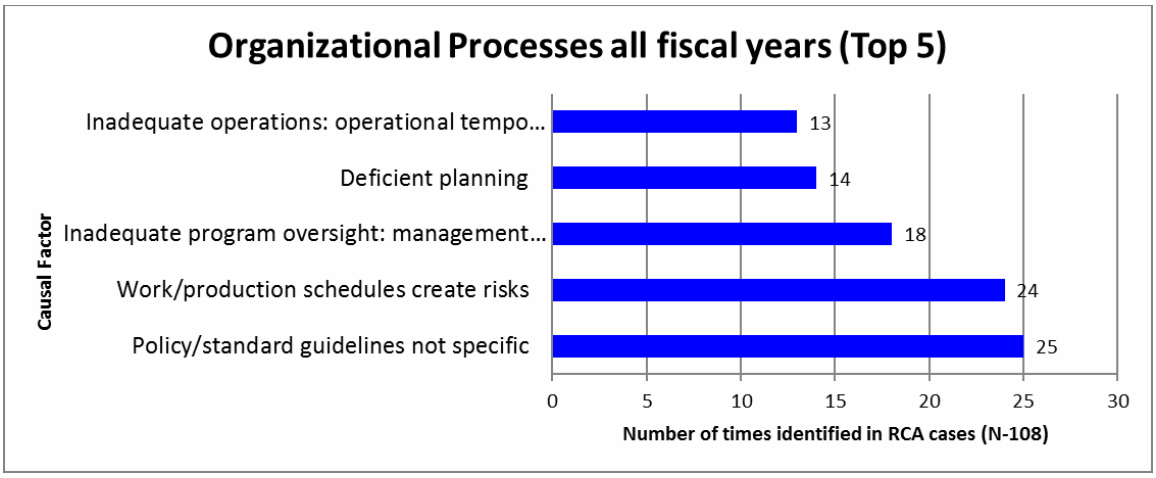


Figure 4.6H

Organizational Climate Error Causal Factors (Top 5)

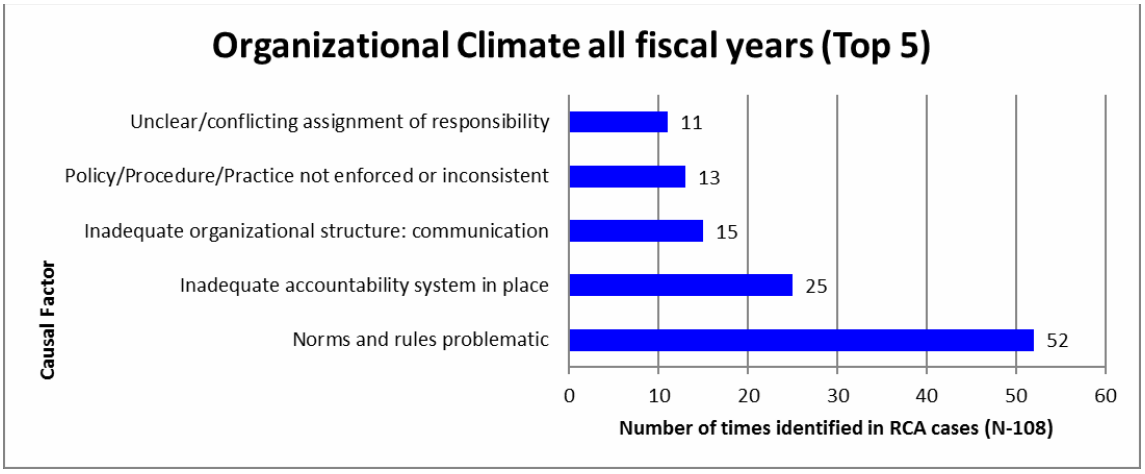
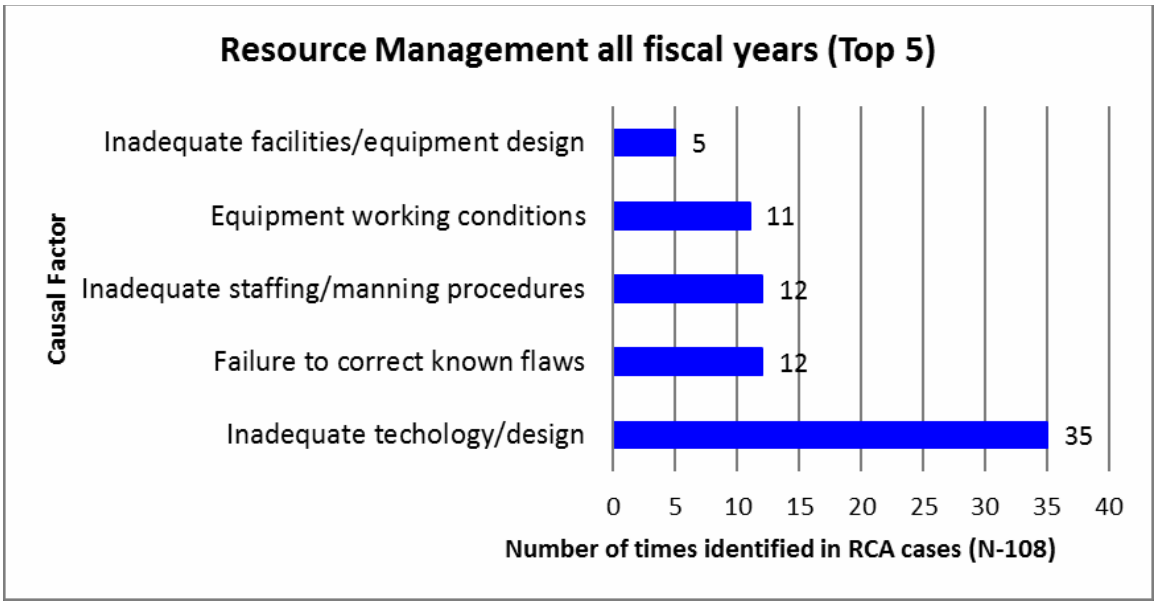


Figure 4.6I

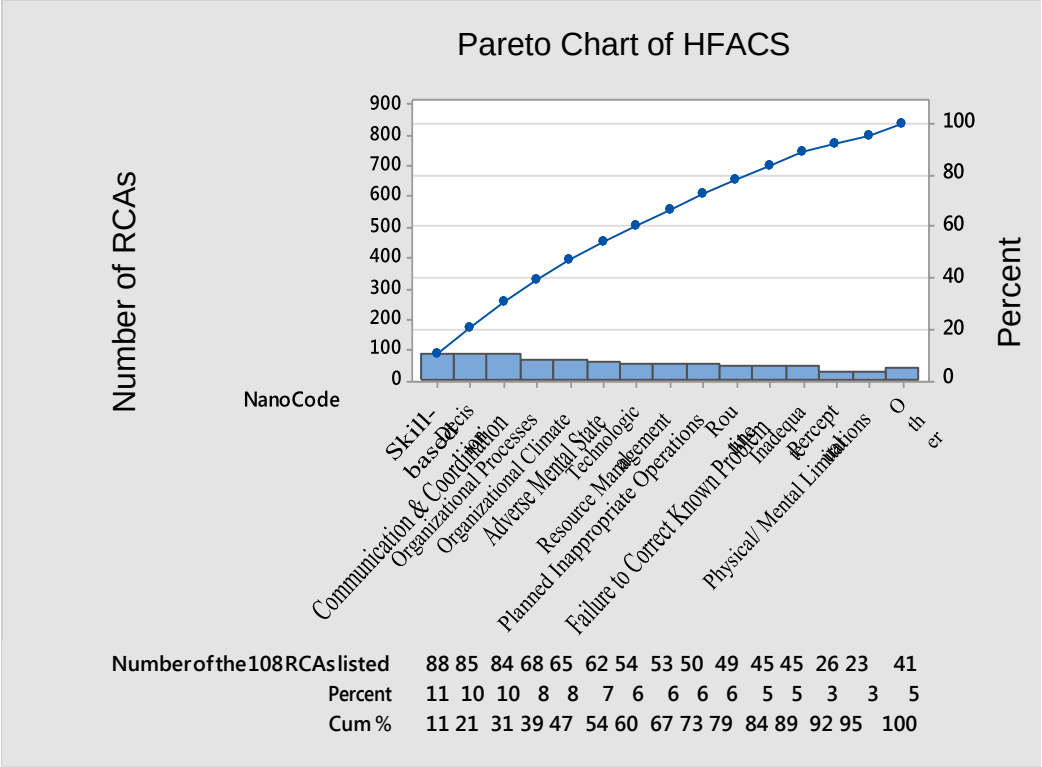
Resource Management Error Causal Factors (Top 5)



However, the Diller et al. (2014) study did not identify as many causal factors in this tier, as only 96 Nano codes (6%) were cited. Correspondingly, the subcategories in this tier noted equally smaller volumes of reported Nano codes: Organizational Process (29 Nano codes; 2%), Organizational Climate (33 Nano codes; 2%), and Resource Management (34 Nano codes; 2%). In comparison, the Berry (2010) meta-analysis ranged from 12% for Organizational Process, 1% for Organizational Climate, and 2% for Resource Management. Figure 4.7, Pareto Chart of HFACS Nano codes displays that cumulatively 21% of errors are derived from Skill-based and Decision-making errors. General Pareto principles support that a focus on these two human factors categories would alleviate 80% of the causal factors.

Figure 4.7

Pareto Chart of HFACS Nano codes



Finding 6: There is an association between systemic and human factors, as when a systemic issue is found, there is most likely a human component.

The presence or absence of each HFACS causal category was determined through the use of a binary method (the presence or absence of at least one systemic or human factor in a case) which allowed for the percentage of cases associated with each HFACS causal category to be determined. Using this method, it was found that HFACS causal categories at each HFACS tier are not mutually exclusive. For example, one case can include multiple skill-based and decision-making errors. With this understanding, 106 (98%) of the 108 RCAs had at least one human factor associated with the case. 95 (88%) of 108 RCAs had at least one systemic issues associated with it. With 98% of the cases

having a human factor and 88% having a systemic factor, it is statistically significant (p-value = 0.006) that the systemic and human factors are highly associated. In most cases, there were multiple human and systemic factors associated with the error. Of those 106 cases where there was at least one human factor error, 94 (86%) of them also had a system error of some kind, and 12 (11%) did not. There was only one case where there was a system error and not an identified human factor associated with it. Equally, there was one case that was not coded, resulting in having neither a human or systemic factor. Removing this one case from the analysis, changes the results to 99% of the cases having a human factor and 89% having a systemic factor. In short, it was found that there is usually always a human component of some kind (99%) and typically a system component of some kind (89%) with each case that was analyzed. Highly unlikely, but possible, a case can have human error without having a system error (1 (0.9%) of 106 cases in this study), but there is not much evidence to support being able to have a system error without there also being some kind of human error.

A review of the top reported event types revealed that of the 44 falls there were 42 human factors and 32 system factors identified as opposed to 108 total RCAs having 95 systems factors, while both Events related to Surgery or Invasive Procedure and Care Coordination/Communication categories had equal numbers of human and system factors, 15 and 9 respectively (see Table 4.6 Human vs. System Factors by Event Type).

Table 4.6

Human vs. System Factors by Event Type (top 4)

Event Type	Sum of at least 1 human factor	Sum of at least 1 system factor	# of RCAs
Fall	42	32	44
Event r/t Surgery or Invasive Procedure	15	15	15
Medication related	13	12	13
Care Coordination/Communication	9	9	9
Grand Total	**79**	**68**	**81**

Meaning, it is statically significant (*p-value* = 0.04) that 73% of falls were caused, in part, by systems errors, while 88% of all RCAs are caused, to some extent by system issues. Therefore, a focus on systems will not do as much to help falls as it would to help other event types; nonetheless a focus on system factors will benefit all event types. Equally, a focus on both system and human factors would be beneficial to all event types.

Finding 7: Patient/family contributing factors emerged as a theme that was not previously identified.

As data extractors were coding causal factors using the HFACS it was frequently found that patient and family member factors influenced errors or incidents. Routinely, the HFACS is focused on identifying and investigating human error from the worker's perspective and does not take into consideration patient and family member factors that may lead to a medical error or incident. Therefore, during the HFACS coding sessions, the data extractors began documenting patient and family factors that were influencers to incidents. Some examples of these patient/family influencers were:

- Noncompliance with care regimen

- Lack of communication with care team
- Refusal of care
- Not following instructions or completing interventions as recommended by care provider/team
- Type of footwear or clothing worn contributes to event or lack of safety, e.g. falls
- Presence of family members contributes to miscommunication, lack of communication or understanding,
- Co-morbidities contribute to errors or mishaps

As an example of a potential case, a patient may have been instructed to contact the nurse to assist them to the restroom, but instead of calling for the nurse the family member assists the patient to the restroom. Upon transport to the restroom the patient falls and hits their head causing a brain bleed (hematoma) or fractured bone. This injury prolongs the hospital stay, causes more pain and anguish to the patient, and potentially could have been circumvented. For this reason, it is important to capture these influencers because presently these are concerns that contribute to incidents, but may never be captured and addressed with the present HFACS framework.

Summary

In summary, descriptive statistics was used to complete an analysis of HFACS categorical data to determine if there were any associations between systemic and human factors. An analysis of harmful events was conducted suggesting possible improvements to systemic concerns, if harmful events are given attention. It can be postulated that there is an association between human and systemic factors as it relates to errors. Lastly, an

emergent theme was identified and discussed. In the final chapter, conclusions from the study will be made and future implications discussed.

Chapter 5

Discussion, Recommendations, and Conclusions

Summary of the Empirical Findings

This exploratory research study sought to analyze and categorize the causes of errors using the HFACS framework to determine their association. Descriptive statistics was used as this method best summarized and described the archival data from 108 previously conducted root cause analyses (RCAs). The gap the research addresses is the association between systemic and human factors as they relate to medical errors. This information is important because any reduction or prevention of errors in the healthcare industry could potentially save lives, improve patient satisfaction and the patient experience.

There were seven findings from the analysis of the data that are summarized in Table 5.1. The findings support there is an association between systemic and human factors. An additional finding that resulted was a need to focus on harmful events and the location of these events within the study site.

Table 5.1

Table of Findings

Theme	Findings	Description of Finding
Harm as an Indicator for High Reliability	Finding 1	Events resulting in harm were the most frequently reported type of event by harm level, but was usually temporary harm
	Finding 2	There is a 0.15% adverse defect (error) rate, which is low, but not low enough
	Finding 3	Five event types lead to 80% of the adverse events
		Sub-finding 3A: Falls account for 41% of the adverse events
		Sub-finding 3B: Four event categories result in a 74% repeat rate
	Finding 4	38% of high harm occurred in an inpatient area in relation to total harm for all RCA events
System Issues as an Indicator of Safety	Finding 5	There is variation in factors identified across industries, however, study site identified more system factors, while comparative sites identified more individual factors.
	Finding 6	There is an association between systemic and human factors, when a systemic issue is found, there is most likely a human component
Emergent Theme	Finding 7	Patient/family contributing factors emerged as a theme that was not previously identified.

One of the main findings is that 60% of the root cause analyses that were evaluated had a harm level of 6-9, however, most resulted in temporary patient harm. The setting for this harm was usually in an inpatient setting. The error rate for these events were 0.15%, but the goal is 0%. Another finding showed that 80% of the adverse events resulted from five event types, which repeated in some instances. The study site found more system factors in its analysis using the Human Factors Analysis and Classification (HFACS) in relation to the comparative sites. When a system factor was found, it was almost always associated with a human factor. Lastly, an emergent theme evolved related to patient and family influencers to errors. In summary, there were two overarching indicators found, harm and system issues, that the study site should consider monitoring and addressing.

Harm as an Indicator for High Reliability

Discussion of Results

The leaders at The Joint Commission have developed roadmaps and frameworks to assist health care organizations on its journey to high reliability (Chassin & Loeb, 2013). The aim of higher reliability organizations is to maintain safety or resilience if an event does occur. Although a lofty goal, zero patient harm is what these health care organizations strive toward and according to executive leaders at the study site this is their vision for the organization. As noted in Chapter 2 high reliability organizations focus on harm-prevention, awareness to minor indicators that may eventually lead to catastrophes, and leadership principles that are committed to empowering frontline staff in the promotion of safety (Chassin & Loeb, 2013; Weick & Sutcliffe, 2007). During the four-year study period, the organization in this study had an estimated rate of adverse events (defects) in 1 of 688 (0.15%) reported events. This finding advocates that a focus on high reliability or zero harm (defects) should be a goal for this organization. It is important for organizations to measure error rates, especially adverse error rates as this is a quantifiable metric that supports the journey to higher reliability. Coincidentally, the study site leadership has already vowed to work toward the high reliability journey. In order to reduce its error rate, the researcher suggests that this organization should focus on error-reduction/prevention strategies, such as utilizing HFACS to identify causal factors, developing interventions that alleviate issues and sustain safety, while maintaining a goal of zero harm (Chassin & Loeb, 2013).

A synthesis of the findings established that harm, the location of harmful events, and reoccurring event types should be evaluated further. During the HFACS data analysis for this study it was found that high harm levels 6-9 corresponded with these four top reported event types: Falls, Events related to Surgery or Invasive Procedures, Medication related, and Care Coordination/Communication events. Specifically, falls accounted for 41% of reported events for which an RCA was conducted and 96% of falls had some level of harm (levels 6-9). Likewise, falls had a 100% repeat rate. Meaning falls reoccurred after action items were put in place that should have prevented a reoccurrence. Therefore, this result suggests that a focus on reducing falls would dramatically reduce the events with high harm, as well as repeated events.

Two settings in which patient care was provided stood out regarding the outcome of harm during the analysis: operating room areas and inpatient care areas. After conducting a chi square analysis in Chapter 4, the operating room (OR) settings were found to perform differently as compared to the other patient care settings. Likewise, the inpatient care settings had a higher harm level for reported events, as compared to other patient care areas, but more data is warranted to suggest a predictable pattern. Regardless, 38% of high harm occurred in an inpatient setting in relation to total harm. However, this is not to suggest that the inpatient settings are more hazardous, but other factors that contribute to harm must be considered, such as the complexity of the care environment, the oncology patient population, and the opportunity for an event to occur.

Recommendations for Practice

Regarding fall events, a need for more sustainable and stronger action items that consider better technology, forced-functions, and the use of human factors engineering

would be beneficial. For example, it was frequently cited as a root cause that patients refuse to utilize the bed alarms due to personal preference and annoyance with the alarms because of the audible noise. The oncology patient population can have longer inpatient admissions which lend to more noncompliance to the rules and nurses tend to give these patients "passes" out of courtesy. Although this organization has a robust fall reduction program (Alexander, 2015), it might be beneficial to evaluate interventions that improve patient compliance with fall precautions by involving patients in the care processes.

A suggested intervention is to take a team-approach to fall reduction programs since of the 44 harmful falls, 42 had individual human factors associated with leading to the error. One example that the study site is presently implementing for improvements in its fall reduction program is to create a sense of mindfulness. A nurse-led awareness campaign using fall communication boards and team-based competition across an inpatient floor helped to decrease fall rate averages from 4.28 to 2.28 falls per month (Alexander, 2015). Some positive outcomes of this project included improvements in the staff members' awareness that falls are considered a "never event" for this patient population, which resulted in improvements for the team members' fall prevention assessment skills. Also of importance, patients and family members were included in the project which highlighted how safety could be enhanced with patient and family involvement, as well as improving the patient's care experience.

In addition, it is important to review actual and near miss safety data because there is value in analyzing events that do not reach the patient or cause harm to the patient. Any event that can be circumvented, is a step in the right direction toward the goal of a harm-free environment. Chassin and Loeb (2013) suggests that trending safety

data will help identify safety systems that need improvement. This study focused on determining what and where the most risk occurred so that more proactive assessments and approaches could be implemented to alleviate repetitive events and build a safer culture. However, the analysis process of RCAs is a responsive process, instead of a proactive process.

Knowing that near miss events do not reach the patient and thus does not cause any adversity, it would be prudent for the study site to focus on increasing the reporting and analysis of near miss events, since it is a proactive process and occurs before an event reaches a patient. Only one (1%) of 108 RCAs was reported with a harm level of 2 (near miss) and none (0%) were reported for unsafe conditions. Building a highly reliable safety culture requires decreasing the number of reported harmful events, therefore taking a proactive approach to safety by analyzing more near miss events and focusing on interventions that circumvent issues before an error reaches the patient could avoid the occurrence of future harmful events.

Organizations need a proactive approach to safety and quality by identifying and addressing unsafe conditions early, along with conducting risk assessments that lead to key safety elements. Taking this proactive approach may lead to becoming more highly reliable. Risk assessments, such as failure modes and affects analyses are useful tools that proactively look at what should be addressed to avoid unsafe conditions. Therefore, specific to this organization it is recommended to take a deeper analysis into the near miss incidents to determine if there are areas of focus that could be included in its patient safety plan.

A noteworthy action the study site has taken is to conduct daily safety briefings. During these 15-minute briefings, senior leaders, physicians, and middle managers across the organization meet (call-in option is available) to discuss harmful (harm level 6-9) events and significant events (harm levels 1-5). The goal of the briefing is to look at issues that occurred around safety in the past twenty-four hours to prepare for the next twenty-four hours. Information of importance that is also shared in these sessions include staffing needs and patterns, patient volumes, and operational concerns. Since the inception of the safety briefing (9 months), the researched noted that the organization has seen a 4% (at the time of this writing) increase in reported events (difference in percent increase of reported events between FY 2015 (28%) and FY 2016 (32%)). This increase lends to a culture of reporting and a culture of responsiveness to reported events.

Furthermore, an additional example of moving toward higher reliability is the hiring of a human factors engineer. This role was partly instituted to help the organization evaluate the HFACS data and develop system and human factors interventions that would sustain practices. This engineer works closely with the staff in the patient safety department which is a great partnership, as it increases the activities and focus toward building a safer culture.

Regarding the location of reported events, usually exploratory statistical analyses drive new questions. After a more in-depth analysis of the operating room (OR) environments in this study, several questions arose. For instance, why are the events that occur in this OR less prone to harm? Could it be the OR staff are better trained, have better reporting practices, have better technological equipment available, or could the OR environment be in tune to promoting a safety culture and catch events before they reach

the patient or cause harm to the patient? These ORs appear to be less prone to harming patients, as most of the adverse events did not cause harm to the patients (see Figure 4.4). Likewise, this research suggests that the use of safety checklists and check points, familiar practices in OR settings, make the OR environment more prone to safety. More data is warranted to study these questions, but one could postulate that while incidents may occur in this OR, patients are less likely to be harmed.

Nevertheless, the following is an example of how the HFACS helped focus improvement efforts in this organization. Across fiscal years 2013-2015 there were five cases in which a foreign object was retained unintentionally, but did not cause harm to the patient and was rectified prior to the patients' discharges. This practice was noted to be caused by a lack of policies for non-countable surgical items. With attention placed on the examination of the HFACS in these cases, specifically, Organizational Influences (processes and climate), Unsafe Supervision (failure to correct a known problem and planned inappropriate operations) and Unsafe Acts made by team members, policy changes were put in place for "non-countable" items, which has helped to greatly reduce (no reported RFO events at the time of this writing) this untoward practice and change the culture in the OR environment. When issues are addressed using a methodical, team-based approach, positive outcomes can be realized.

System Issues as an Indicator of Safety

Discussion of Results

Eighty-nine percent of the RCAs that were conducted had at least one systemic factor noted in the case. (see Table 4.6, Human vs. System Factors by Event Types). During the analysis of the HFACS Nano codes the two top tiers, Unsafe Supervision and

Organizational Influences were found in more cases than expected as compared to the aviation literature (Berry, 2010) and the health care facility in the Diller et al. (2014) study. The organization in this study, coded 16% of its cases with Nano codes from the Unsafe Supervision HFACS tier, while the Diller et al. (2014) study coded only 3% of its cases under this same category. Likewise, Organizational Influences was coded in 21% of the cases in the study site, but in only 6% of the 2014 Diller et al. study. The study site should focus efforts at the system level to determine what organizational and supervisory concerns exist. Likewise, the study site respectively coded 31% and 32% of RCAs cases with Unsafe Acts and Preconditions for Unsafe Acts Nano codes respectively (at the human level), as compared to 50% and 41% in the Diller et al (2014) study.

Since Skill-based and Decision-making errors make up 21% of the human causal factors (see Figure 4.6 Pareto Chart of HFACS Nano codes) a focus by leadership on these issues would be beneficial. Likewise, efforts to improve communication factors and coordination of care would be helpful.

Recommendations for Practice

Since latent conditions are usually found in the top two HFACS tiers and are typically considered to be recognized as systemic issues (Reason, 2000; Weigmann & Shappell, 2003), this may signify that latent conditions in the system are being identified more frequently in the study site during case investigations, which in turn could help with addressing systemic problems if addressed. Looking at the HFACS, the framework relates each tier as being inter-related as one action, or lack of action from a specific level can affect the outcome from another level (Weigmann & Shappell, 2003). Likewise, as mentioned in Chapter 2 of this study, Reason (1990) postulated that interactions exist

with active and latent failures in the Swiss Cheese model. When holes in the Swiss cheese align, an error results (see Appendix B, Figure 2.3, James Reason's Swiss Cheese Model). Similar to latent conditions and the Swiss Cheese Model, causes or contributing factors to incidents are not random, but repeat over time forming a complex interactive chain of causal factors (Berry, 2010). Berry (2010) identified "error pathways" which increase the chance of an error occurring from a failure at a different level within the HFACS framework. Berry proposed that by studying these relationships, failures could potentially be proactively identified and avoided.

This supports the research in this study, as it was found that at least one systemic and human factor existed for all root cause analysis (RCA) cases that were analyzed (except for one that had no codes assigned). This suggests that there is an association between systemic and human factors as it relates to contributing to an error. For example, a lack of staff training from a supervisor (Unsafe Supervision) can have a direct effect on an employee's skill-base (Unsafe Acts) leading to an error regarding a particular process. Or perhaps a lack of policy (Organizational Processes) may lead to an error of commission or omission at the front line (Unsafe Acts or Preconditions for Unsafe Acts). Konieczny et al (2014) supports this concept by stating that failures at the organizational and supervisory levels can influence failures at the Unsafe Acts and Preconditions for Unsafe Acts levels, therefore making improvements at the system level (organizational and supervisory) can influence improvements at the Unsafe and Preconditions (human) levels. With this being said, since human and systemic factors appear to be associated with error causation, and high harm events in this study have both a human and systemic

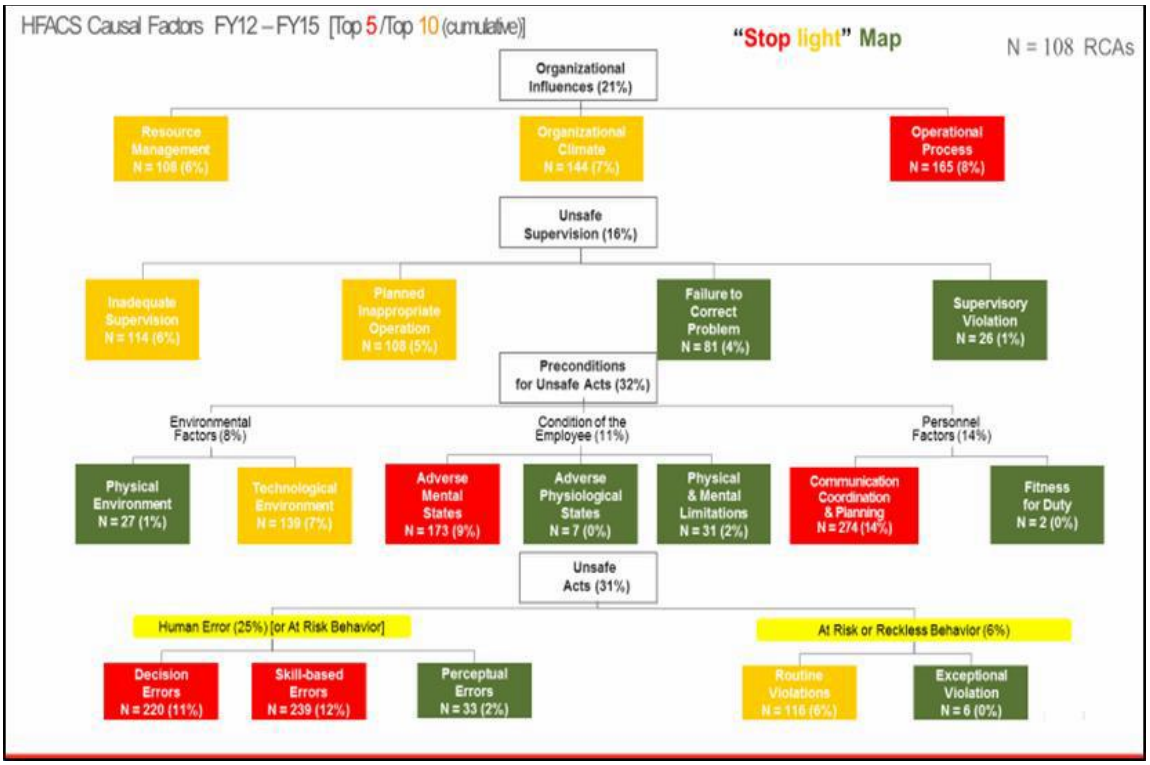
factor, taking a “systems approach” to safety and error-prevention can reduce high harm events, as well as repetitive events.

Reason (2000) and Wood et al. (2010) proposed that taking a “systems approach” to safety in lieu of blaming an individual (“persons approach”) solely, could be beneficial to building a safety reporting and empowered culture. Reason (2000) also postulated that human error is an indicator for latent failures buried in an organization’s system. With these concepts in mind, a “systems approach” supports the building of a non-punitive culture and encourages individuals to report unsafe conditions. Likewise, “systems approaches” to error-causation acknowledges that people can drift or become reckless in behavior, which can lead to harm. Therefore, taking a “just culture” (see definitions) approach to patient safety fosters a systemic organizational thought process. For this reason, individuals who feel supported will speak up when untoward events or near mishaps occur.

Another prudent intervention used at the study site was the development of a “Stop Light” metric from the HFACS (see Figure 5.1, "Stop Light” Map). The “stop light” helped the leaders within the study organization to determine focus areas and easily identify priorities for the patient safety plan (it was found the “stop light” process was frequently only used at the time of the annual report development). The “stop light” assists the study organization in identifying human and systemic factors by highlighting the areas of focus. HFACS Nano codes were calculated and aggregated. Those causal factors receiving the highest volume of Nano codes were considered to be the areas of prioritization and it would benefit the patient safety staff and leaders to use the “stop light” more frequently, for example when investigating individual RCAs.

Figure 5.1

"Stop Light Map": Distribution of HFACS Causal Categories



This sample "Stop Light" map details areas of focus in relationship to human and system factors from the 2,013 identified causal factors. Red areas are the top five focus areas and are the most coded HFACS for all 108 RCAs. These areas are where this organization should begin focusing its efforts in order to be most effective in improving safety. The red and yellow boxes combined are the top ten areas of focus and the green boxes are the least coded human and system factors. The green boxes are the least areas of focus, but still should be addressed.

Using the "Stop Light" map to determine focus areas the researcher has suggested strategies (suggestions) for addressing the systemic concerns in the Organizational Influences tier as detailed in Table 5.2 Strategies for Addressing Systemic Concerns. The mapping would be used in this fashion to identify strategies to address all priority areas.

The strategies are suggested based on the experiences of the researcher and theory of HFACS and human factors engineering.

Table 5.2

S*trategies for Addressing Systemic Concerns (Organizational Influences)*

HFACS Tier	Causal factor	Sample Strategy/Suggestion
Organizational Influences	Inadequate staffing procedures	Ensure staffing plans are developed and utilized based on departmental and patient needs.
	Inadequate technology/design	Use human factors engineers to assist with human-technology designs. Use "forced-functions" and simulation activities, when possible.
	Norms and rules problematic	Conduct a culture of safety survey and address deficiencies.
	Inadequate/Lack of accountability system	Create performance measures that link to workflows with accountability procedures.
	Policy/procedure/practices not enforced/written/understood	Develop clear policies with accountability systems.
	Inadequate organizational structure for communication	Develop various standardized processes for hierarchal and cross-sectional communication with means to ensure completed.

An additional useful tool that could be used proactively for RCAs is an investigative resource of predetermined interview questions based on the HFACS framework. This tool would assist patient safety professionals to better investigate cases by proactively asking questions that seek to identify human and system factors. As well this tool would be helpful in detecting the areas of biggest impact within the organization.

An Emergent Theme

Gaps in the association concept include the need to embrace that there are existing factors that relate to how the patient (and family) contributes to error causation, as well as

how the complex health care work environment can contribute to medical errors. As noted in Chapter 4, emergent themes evolved from the HFACS analyses that were conducted by the data extractors. For instance, lack of compliance by patients and family members to the treatment plan led to errors. For this reason, the patient (and family) should be considered as a factor of error causation within the complex, inter-related health care system.

As previously noted patient and family involvement is integral to successful patient experience, however, at times the patient unknowingly can contribute to an error. At times when the data extractors coded the data, event causal factors would not "fit" into a present HFACS category, such as the patient (and family) factors (influencers). Since HFACS is purposed to analyze events from the health care provider's perspective, a new category arose from the analysis, which were labeled Patient (and family) Influences (factors), similar to the top HFACS tier, Organizational Influences. In the future, this organization plans to continue to add to this list of patient factors (see finding 7 in Chapter 4) and create Nano codes for patient causal factors. The hope is to publish this information to contribute to the body of research after ascertaining validation of the data. The study site will continue to collect data on emergent themes, as well as additional Nano codes that do not "fit" into the present HFACS schema. Beginning with falls, the study will develop subcategories in this particular event category by analyzing the falls data to determine causes (themes) that are leading to the falls. From that analysis it can be further determined what subcategories of data that can be collected.

Conclusions

Conclusion 1. As health care organizations strive to become more highly reliable attention to the successes of other highly reliable industries should be considered. Weick and Sutcliffe (2006) have suggested five concepts that help senior leaders build a "mindful" organization. The researcher agrees with all five concepts, except to argue the focus on only failures and not successes (see High Reliability section in Chapter 2). From a patient safety perspective, the researcher believes it is equally important to focus on successes (what we are doing right), as well as failures. Studying what we get correct helps to develop more processes that have positive outcomes for patients. Likewise, near miss events that do not reach the patient and cause harm, as well as harmful patient events must be considered in order to progress toward the high reliability goal of zero harm.

Since it was noted from the data analysis that patients are a factor in error causation, the middle management and senior leaders within the study organization should consider working with patient groups by focusing on the top reported harmful events, more specifically falls on the inpatient setting as well as categories in which events are repeated. These focus groups could devise measures and interventions that are patient-centric. Fortunately, when patients are harmed within the study organization, usually it is temporary (harm level 6). The study site has a low error rate (0.15%), but has not yet reached zero. In the study site, harm levels could be improved by focusing on system issues and including patients in the improvement measures. Since no health care organization has yet reached high reliability, the main emphasis is to stay vigilant and resilient. Including patients in these efforts and using human factors engineering the

facility can continue to determine how systems and processes can be designed to support human limitations.

Conclusion 2. Highly reliable organizations should first focus on system factors in order to design error-proof infrastructures. If the system is not properly designed, errors are certain to occur. Poorly designed systems lead to individual work-arounds (causing errors) by staff that may be disguised as unsafe acts on the individual's part. It was determined through the use of the HFACS that there is an association between system and individual human factors. It is beginning to identify system issues at a rate higher than other comparative organizations (see Table 4.5) which will assist it to develop a foundation for a strong safety culture. Senior leaders should be trained in high reliability and human factors concepts as this helps to develop the necessary skills to build a safe culture. Likewise, measuring, monitoring and sustaining metrics is an important priority for an organization that is on its journey to high reliability. The researcher urges other health care organizations to use an investigative classification system, such as HFACS, as it will help to identify and prioritize improvement interventions. In this study HFACS was used to increase the identification of system factors (at the supervisory and organizational level), as this helped health care leaders and patient safety professionals take a "systems approach", in lieu of a punitive "persons" approach (Chapter 2). Likewise, developing an investigation tool that is mirrored after the HFACS framework will lead to discovering more human and system factors proactively that can be addressed.

Conclusion 3. A theme that emerged was patient and family involvement in care processes with the development of "patient and family influencers". This organization

found that patient and family members are a human component not considered in the investigative HFACS model, but contributes to error causation. It is understood that the HFACS has been adapted to the health care industry and for this reason, the study site captured factors not initially considered in the HFACS model. However, the study site considered it important to capture these contributing factors, as errors were caused by direct involvement of patients and family members beyond the control of staff members. Interventions that get patients more involved in their care advances the patient-centered model and is an important focus for this organization. Future research will involve the continual adaptation of the HFACS framework to the health care setting with the development of patient/family influencers.

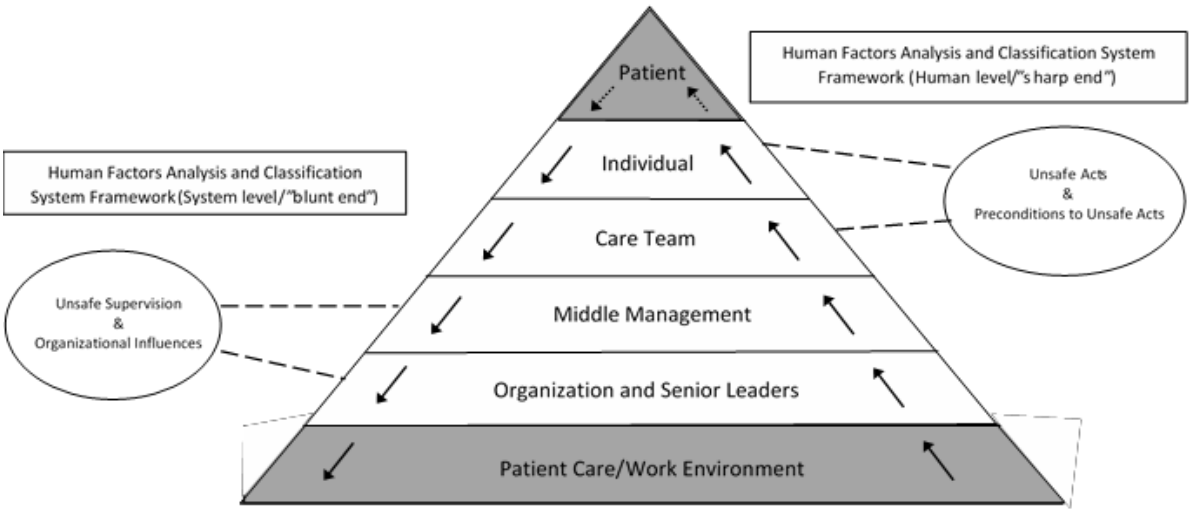
Recommendations for Theory

This inter-related health care system schema takes into consideration that the patient (and family) can be an important contributor to errors that occur within the patient care (health care) environment. In this model, the HFACS is displayed as the system and human factors that occur as care and services are provided at different levels among the staff members and leadership team. Unsafe Acts (individual factors) and Preconditions for Unsafe Acts (care team factors) reflect as the human components to the HFACS framework, while the Unsafe Supervision (middle management factors) and Organizational Influences (senior leadership factors and organizational processes) mirror the system level where decisions are made by senior leaders. The model is inter-related as human (“sharp end”) and system (“blunt end”) components are associated and co-dependent. The patient (human agency) is considered most important and therefore is at the top of the pyramid. Including the patient (family) and complexity of the health care

environment completes the model in regards to causal factors for medical errors and the context for them. Highly reliable organizations pay attention to systemic and human factors as they lead to failures. This practical model proposes to display the complexity of the error-prone health care environment, the human and system components working in tandem within the environment and the different levels of interactions in relation to the HFACS framework.

Figure 5.2

Multi-level Health Care System Schema with regards to HFACS



Recommendation for Future Inquiry and Research

More research is warranted regarding the location of events within this organization, as it would be interesting to study if similar operating rooms (ORs) and inpatient settings in other organizations function in the same manner as the study site. Research that considers the risky environment that an oncology inpatient setting or OR imposes on safety, as well as the oncology patient population in relationship to the frequency of harmful opportunities should be given attention.

It would be useful to conduct more comparative research with other health care oncology organizations that use human and system factor classifications systems, such as HFACS to determine if there are similar issues across the industry. As well, a national (international) incident reporting system that is viewable to the public would be beneficial to use for comparative benchmarks and transparency within the health care industry. These comparative databases would help further research, as national incident

reporting data would be readily available, just as aviation incident reporting databases are today. The ability to analyze patient safety events and compare harm across the healthcare industry in relation to causal factors would benefit the industry in getting closer to "zero harm" and higher reliability.

Since the use of human factors engineering principles is fairly new to the health care sector, more research surrounding the use of human factors analysis and implementation of human factors principles (borrowed from other industries) would be beneficial to patient safety science. Likewise, exploring the use of human factors engineering and concepts such as proactive risk assessments in patient safety is a beneficial approach to identify threats before an event occurs. This proactive approach to patient safety could lead to harm prevention.

A deeper dive or subcategories for falls in needed. This may assist to determine focused interventions to help alleviate falls. Presently, the AHRQ Common Format (2003) is used to describe event types in the study site's incident reporting system, however, specifically for falls there are no subcategories that exist to further explain the reason for the fall. It would be useful if AHRQ could further research with health care facilities in order to develop subcategories specific to falls. This would provide more meaningful data regarding falls, reasons they occur, and potential interventions of focus.

More research, analysis and training is needed to ask, "what happens when we get things right (instead of wrong)." Meaning we should focus on analyzing more near misses and deeper analysis for efficient processes, such as positive outcomes that result in patient care activities. For example, analyze processes in the operating room that result in no retained foreign object after a surgical procedure is completed. What went well and

worked as expected for the team and how or why did the results end positively or as expected? Perhaps the use of simulation centers and virtual environments will prove beneficial in enhancing productivity, measuring human performance, and operational effectiveness (O'Connor & Cohn, 2010). In health care, virtual environments and simulations enable training in costly, dangerous, risky or otherwise impossible to train practices by allowing errors to be simulated and automated through computers without causing harm to a patient and reducing the time it takes to conduct research. Due to the physiological and physical factors related to an actual patient safety event, it is not always feasible to reenact an error, however, using technology to enhance patient safety science could prove beneficial. Such as simulating positive outcomes in contrast to untoward outcomes. The comparison is an opportunity to learn and anticipate what should be expected and what should not be expected as an outcome in a situation.

Lastly more research is warranted for studies that combine cognitive, behavioral, and human factors sciences. The blended approach could inquiry as to "how people are empowered to practice safely," or ask "how management styles influence behavior in relation to systemic and human factors," or study "how bureaucracy effects patient safety." How can falls be approached using a patient-centered model that involves patients? Likewise, many questions arose specifically from this study and are areas of future inquiry:

- Does this organization receive more reported events from staff in its inpatient setting; if so, why?
- Which patient care areas are resulting in the most harmful events and why?

- How to increase reporting and how to capture what is not reported?
- What are the differences between what senior leaders, middle management and staff members think are the human and system factors that lead to errors and specific interventions to address them?
- What are the specific skill-based and decision-making errors and how to address them?
- What are the specific organizational and supervisory factors and how to address them?
- Analyze the type of events reported and magnitude of harm and hazards that contribute to errors in the oncology patient population/setting.

A deeper analysis of the event reports, the people that report, organizational leaders, patients, as well as those who do not report or find barriers to reporting are all potential areas of focus in answering these questions. In turn, improved interventions can be formulated that may potentially alleviate an event from occurring or reoccurring.

Limitations

This study has relevant findings beneficial to many health care leaders and educators in the health sciences; however, it has certain limitations. First, the study utilized archival data of RCAs that were retrospectively conducted from a self-reported event system. Therefore, the number of events reported may not be representative of the actual errors that are occurring in the system. However, the culture of reporting in this organization is good (44,021 events reported during the four-year period; mean reported events = 1006/month), therefore the sample of data that was analyzed is a starting point for error prevention. Nevertheless, a prospective approach to investigations might be

useful in better determining more systemic and human factors. The study used data from fiscal years (FY) 2012-2015, as this study progressed HFACS and RCA data from FY 2016 and part of FY 2017 became available. The use of this data could provide an update to the systemic and human factors, as well as provide more recent case studies and analyses. For example, during FY 2016 a robust electronic health record was acquired by the study site. Consequently, many technological human factors at the Preconditions HFACS tier may have been eliminated.

Another limitation of this study is the context of where the study took place. The study was conducted in one organization which specifically treats an oncologic patient population, however, it was intended to be an exploratory study lending its research to the study of human and systemic factors in health care which lead to medical errors. Since not much research exists in this area for healthcare this one organization and study lends to furthering research. A study on a greater scale using more human factors and investigative data may provide more robust findings.

Perspective of the Author

The researcher's own perspective and experience of the issues aided in the analysis of the data that was collected and in the conclusions that were made. The researcher is a patient safety professional as well as one of the data extractors working within the study facility. It became prudent for the researcher to maintain awareness and identify ways of keeping bias out of the data analysis. Methods such as peer review and debriefing were essential to the success of this study. Peer review was completed by requesting that doctoral prepared colleagues read this thesis and provide feedback as to the writing techniques used. As well, debriefing meetings were scheduled along the

journey of completing this written work with doctoral and masters prepared colleagues to ascertain if my voice was reflected as being biased in this writing. This process helped influence my writing because at times I became engulfed in the work along the way.

Additionally, the thesis committee members were strategically chosen based on their experience with human factors and human behavior. In particular, Dr. Scott Shappell is one of the developers of the HFACS and has conducted widespread research in several diverse and highly reliable industries using the HFACS framework. Likewise, Dr. Robert Hausmann has conducted extensive research in leadership and organizational behavior in highly reliable contexts. The combination of their experience and knowledge aided my research tremendously.

Summary

The main findings of this study are that a focus on systems issues and harmful patient events helps improve patient safety, while building a culture of safety. This is important as the organization in this study is on the journey to high reliability. Highly reliable organizations work toward a goal of zero harm (0% error rate). While this organization is close, its error rate is still 0.15%.

Another finding was the need to address patient influences that lead to errors as the HFACS framework was meant to address aviation incidents, but has been adapted for use in the healthcare industry. Although the present HFACS framework is targeted at the workforce, this study's analysis found that patients (and family members) can contribute to incidents that occur, for example when there is lack of compliance to care regimens. This is an area of opportunity that may assist in creating a better culture of patient safety and an improved patient experience.

Culture change is not easy to accomplish, but leadership commitment is the first step. It has taken the aviation industry over forty years to change its culture, but a steady focus by leaders in this industry is helping accomplish the change (Chassin & Loeb, 2013). Likewise, leadership commitment to culture change in the health care industry can be accomplished by vigilantly learning from previous mishaps and taking a proactive team-approach to safety.

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Appendix A

Table 1.1

Data extractors' demographics and professional work experience (years)

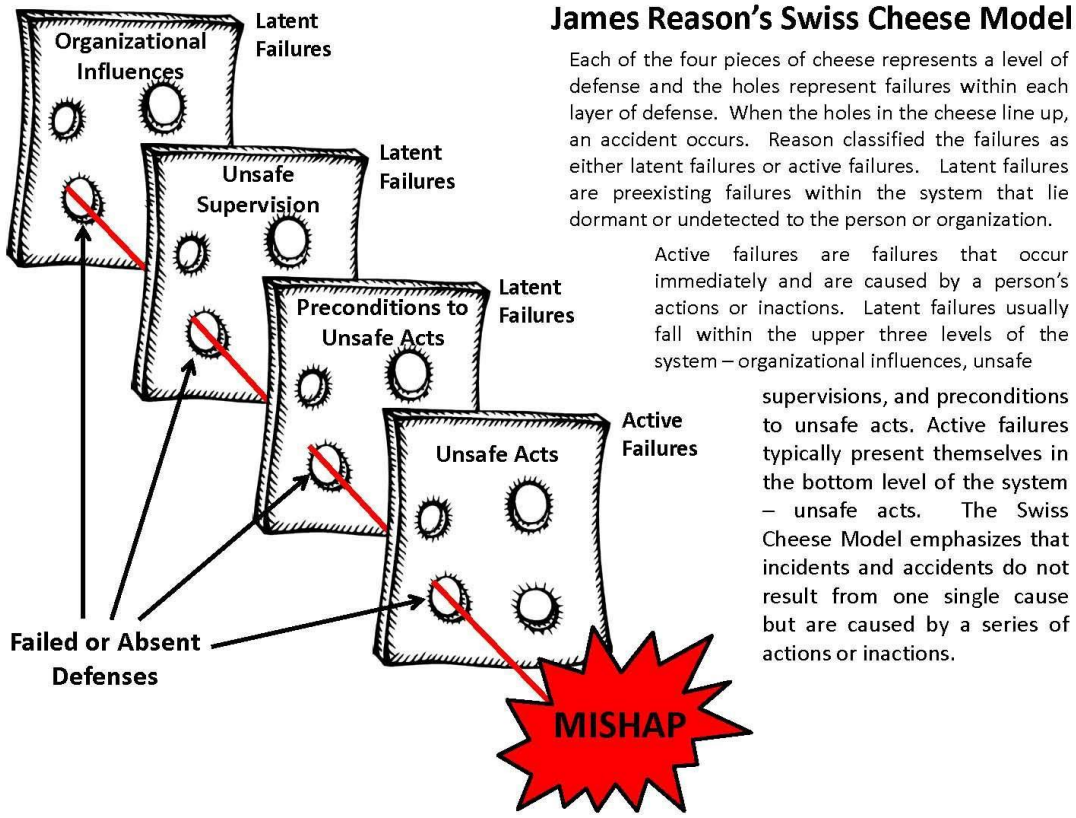
	Total years worked in Quality/Patient Safety	Total years worked in Patient Safety at this organization	Total years scoring HFACS data	Total years of formal training in scoring HFACS data	Total years served in professional clinical role
Extractor 1: Registered Nurse	12	3	3	2.5	24
Extractor 2: Registered Nurse	3	3.25	2	1	17
Extractor 3: Registered Nurse	1.5	1.5	1	1	11
Extractor 4: Pharmacist	7	7	4	5	19

Extractor 5: Respiratory Therapist	8	8	4	5	26
Extractor 6: Medical Technologist (Infection Control)	8	8	5	5	11
Extractor 7: Medical Technologist (Clinical Biology)	28	8	8	5	30
Cumulative years totaled	67.50	37.75	27	24.50	138
Average years totaled	9.64	5.39	3.86	3.50	19.71

Appendix B

Figure 2.3

James Reason's Swiss Cheese Model (SCM) (1990)

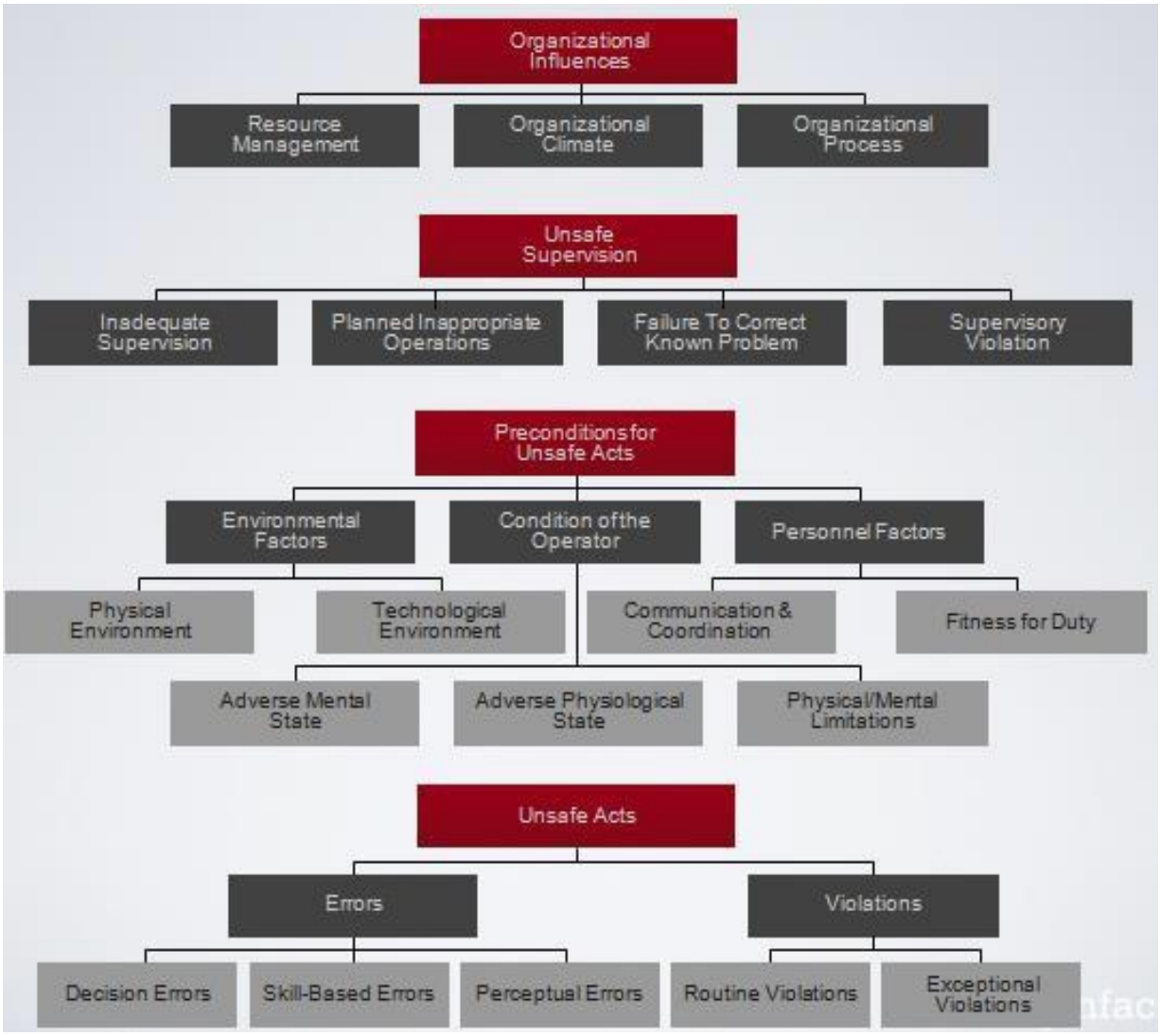


Source: www.pixshark.com

Appendix C

Figure 2.4

The Human Factors Analysis and Classification System (HFACS)



Source: www.hfacs.com

Appendix D

The Human Factors Analysis and Classification System (HFACS) Nano codes (used at healthcare facility study site)

"What happened?" (Unsafe Acts)

DECISION-MAKING ERRORS: Errors that occur when an individual proceeds as he intended, yet the plan proves inadequate or inappropriate for the situation (i.e., "an honest mistake").

- ☐ Caution/warning/information ignored or misinterpreted (e.g., clinical alarms) DE001
- ☐ Exceeded ability (i.e., competency) DE002
- ☐ Failure to prioritize task DE003
- ☐ Improper attempt to save time DE004
- ☐ Improper procedure performed DE006
- ☐ Improper remedial action DE007
- ☐ Improper placement/use of instrument/tools, equipment, PPE, and/or materials DE008
- ☐ Inadequate maintenance of equipment/supplies DE009
- ☐ Inadequate report provided DE010
- ☐ Inadequate risk assessment DE011
- ☐ Inadequate work pre-planning DE012
- ☐ Pre-procedure briefing not obtained/disregarded DE016
- ☐ Selected incorrect procedure DE017
- ☐ Use of defective instrument, equipment PPE, and/or materials DE018
- ☐ Wrong response to situation (e.g., failure to recognize, critical thinking failure) DE020
- ☐ Wrong tool/software application for the job DE021

SKILL-BASED ERRORS: Errors that occur during an individual's performance of a routine, highly practiced task that are considered "ingrained" skills.

- ☐ Conducted sequence item out of order/ reversed/omitted steps in procedure SBE001
- ☐ Data entry/cross check error (i.e. double check) SBE002
- ☐ Forgetting to inform team SBE003
- ☐ Habit transference (e.g., seen with the introduction of new equipment or procedure) SBE004
- ☐ Improper lifting/position for task SBE005
- ☐ Lapse of memory/recall for all or part of a procedure SBE008

- Misreading/misinterpreting paperwork or display/instrument SBE010
- Poor coordination or timing of action SBE011
- Poor technique (e.g., intubation, central line insertion, IV administration) SBE012
- Patient involvement in patient care process deficient SBE013
- Safety checklist error (e.g., universal protocol, WHO surgery checklist, double checks, medication reconciliation) SBE015
- Timing errors (i.e., performed task at the wrong time) SBE016
- Work or motion at improper speed (i.e., too fast or too slow) SBE017
- Lack of knowledge about delivery of supplies/care (delayed specimens, wrong care given, wrong location) SBE019
- Inadequate or omission of assessment of patient SBE020

PERCEPTION ERRORS: Unique skill-based and decision-based errors that occur as a result of an individual's inappropriate response to his degraded or "unusual" sensory inputs (such as sight, hearing, or balance illusions).

- Failure to hear/understand communications (e.g., due to noise) PE001
- Failure to identify risk/hazard PE002
- Misinterpreted/misread equipment PE003
- Misjudged the texture of a surface (e.g., slippery floor) PE004
- Misperceived patient factors (e.g., weight, strength, weight-bearing ability) PE005
- Misread displays/paperwork/text PE006
- Tactile distortion PE007
- Visual distortion PE008

VIOLATIONS: Are factors in an event when the operator intentionally breaks the rules and instructions. Violations are deliberate.

ROUTINE VIOLATIONS:

- Delivery of care beyond the scope of practice Disabled RV001
- guards, warning systems, or safety devices Distracting RV002
- behavior RV003
- Exceeding duty times RV004
- Failed to secure equipment or materials properly (e.g., not putting sharps in proper container) RV005
- Failure to follow orders RV006
- Inadequate/untimely documentation/communication (i.e., waiting until the end of the shift to document) RV007
- Operation with known deficiency in equipment performed RV008
- Risk taking RV010
- Taking shortcuts (not otherwise specified) - i.e., work-arounds RV011

- ☐ Use of equipment/instruments/PPE/material improperly RV012
- ☐ Violation of written policy/procedures/standard of care/ training (e.g., provider not available) RV013

EXCEPTIONAL VIOLATIONS:

- ☐ Delivery of care without license/qualification/privileges EV001
- ☐ Disabled guards, warning systems, or safety devices EV002
- ☐ Disruptive behavior EV003
- ☐ Excessive risk taking EV004
- ☐ Failed to secure equipment or materials properly (e.g., not putting sharps in proper container) EV005
- ☐ Failure to follow orders EV006
- ☐ Inadequate/purposeful untimely documentation/communication EV008
- ☐ Use of equipment/instruments/PPE/material improperly EV011
- ☐ Violation of policy/procedures/standard of care/training (e.g., re-consenting, provider not available) EV012

"Why did they do it?" (Preconditions for Unsafe Acts)

ENVIRONMENTAL FACTORS

PHYSICAL ENVIRONMENT: Are factors when the environment such as weather, climate, brownout (dust or sand storm) or whiteout (snow storm) or the design of the workspace (e.g., nurse's station, patient room) affect the actions of individual.

- ☐ Clutter, debris or slippery surfaces PhyE001
- ☐ Energized electrical systems PhyE002
- ☐ Fires or explosions PhyE003
- ☐ Hazardous material leak/release PhyE004
- ☐ Inadequate maintenance of humidity PhyE006
- ☐ Inadequate temperature regulation (too hot or cold) PhyE007
- ☐ Inadequate ventilation/air quality PhyE008
- ☐ Inadequate/improper workspace design (congestion or restriction) PhyE009
- ☐ Mechanical hazards (e.g., energized and non-energized, pump, battery) PhyE010
- ☐ Noise interference (e.g., alarm overload, desensitization) PhyE011
- ☐ Radiation (Ionizing & Non-Ionizing) PhyE012
- ☐ Restricted visibility/Inadequate lighting PhyE013
- ☐ Natural disasters (e.g., inclement weather, such as hurricanes, tornados, or floods) PhyE014

- Inadequate ergonomic design/awkward position (e.g. equipment or display location) PhyE015
- Inadequate workplace design: control systems/displays; electrical; mechanical; structural (i.e., visibility restrictions, overhangs, unprotected corners PhyE016

TECHNOLOGICAL ENVIRONMENT: Are factors in an event when automation or electronics affects the actions of an individual.

- Electronic double-check process lacking effectiveness TechE001
- Failures of information technology (software and hardware issues TechE002
- Inadequate technological design or user-interface (e.g., manuals, checklists, instruments; automation; displays) – may lead to a workaround TechE004
- Unclear or confusing labels/warning signs (e.g., overrides, electronic triggers, alert fatigue) TechE009
- Inadequate/defective/poorly designed equipment, material, PPE, or instruments TechE010
- Inadequate/defective warnings/alarms TechE011
- Incomplete/incorrect/not current/inaccessible standard procedures TechE012
- No CPOE TechE013
- Order set inadequate for procedure or lacks critical "red flags" TechE014
- Unclear/outdated policies/procedures/checklists TechE016

CONDITIONS OF INDIVIDUALS

ADVERSE MENTAL STATES: Attention management, awareness failures, or workload factors that affect the perception or performance of individuals.

- Boredom AMS002
- Complacency AMS004
- Confusion AMS005
- Excess mental workload/multi-tasking/task saturation/task overload AMS009
- Frustration AMS012
- Inappropriate peer pressure AMS013
- Inattention/Distraction AMS014
- Lack of confidence AMS015
- Mindset /preconceived idea/expectancy AMS017
- Misplaced motivation/inappropriate task prioritization AMS018
- Overaggressive/Anger AMS019
- Overconfidence AMS020
- Perceived haste/pressure to complete task AMS021
- Stress (job related) / mental fatigue AMS025
- Stress (personal) AMS026
- Task fixation/ tunnel vision / channelized attention AMS027

ADVERSE PHYSIOLOGICAL STATES: Medical or physiological conditions that can result in unsafe situations

- ☐ Impairment due to drugs or alcohol APS006
- ☐ Influences of medication APS008
- ☐ Medical Illness / conditions (cardiac, diabetes, visual illusions, hyperventilation) APS010
- ☐ Physical fatigue APS013
- ☐ Drowsiness APS018

PHYSICAL/MENTAL LIMITATIONS: Limitations in physical or mental capabilities that decrease the ability to cope with a situation, including not being qualified.

- ☐ Body shape (incompatible height, weight, size, strength, reach, etc.) PML001
- ☐ Inability to sustain body positions (include repetitive movement or range) PML002
- ☐ Inadequate or limited experience/proficiency/practice PML003
- ☐ Incompatible intelligence/aptitude PML004
- ☐ Incompatible / temporary physical capability PML005
- ☐ Lacking technical procedural knowledge PML006
- ☐ Language barriers PML007
- ☐ Learning/memory ability limitations PML008
- ☐ Limitation due to previous injury or illness PML009
- ☐ Misunderstanding training instructions PML010
- ☐ Motor skill, coordination or timing deficiency PML011
- ☐ Not current/qualified (i.e. expired license, expired certification, lack of competency) PML013
- ☐ Not familiar with job, equipment, or environment PML014
- ☐ Pre-existing psychological/personality problems PML016
- ☐ Sensory deficiency (visual, hearing, touch, taste, smell, balance) PML018
- ☐ Substance sensitivities or allergies PML019

PERSONNEL FACTORS

COORDINATION/COMMUNICATION/PLANNING FACTORS: Refer to interactions among individuals, crews, and teams involved with the preparation and execution of a mission that resulted in human error or an unsafe situation.

- Confusing/conflicting directions/demands by team member Failed CC001
- to conduct adequate briefing / pre-activity planning Failure of CC002
- "lead" to take charge (i.e. Code Blue, Time-outs) Failure to warn / CC003
- disclose critical information Inadequate/ineffective CC004
- communication between teams/team members CC005
- Inadequate/ineffective communication between shifts/job handoff CC006
- Inadequate/ineffective communication of hazards (e.g., lack of plan of care or discharge planning) CC007
- Lack of teamwork or coordination of activities CC008
- Standard terminology not used or understood (i.e. lettering, abbreviations) CC009
- Verification techniques not used CC010
- Inadequate Communication between team and patient/family CC011

FITNESS FOR DUTY (SELF-IMPOSED STRESS): Operator demonstrates disregard for rules and instructions that govern the individual's readiness to perform.

- Commuting irregularities (unanticipated or self-induced) PR001
- Inadequate rest/lack of sleep PR004
- Physical and mental limitations due to hang-over PR009
- Self-Medicating while off duty PR010
- Unreported disqualifying medical condition PR011
- Use of illicit drugs and alcohol that impact fitness for duty PR012

"What errors did the manager make?" (Unsafe Supervision)

INADEQUATE SUPERVISION: Is a factor in an event when department-level or manager-level supervision proves inappropriate or improper and/or fails to identify hazards, recognize and control risk, provide guidance, training and/or oversight and results in human error or an unsafe situation.

☐ Change introduced without training or adequate training	IS001
☐ Failed to provide adequate/proper tools for the job Failure to	IS002
☐ track job qualifications/skills	IS003
☐ Improper or insufficient delegation	IS004
☐ Inadequate coaching/on the job training of skills	IS005
☐ Inadequate communication of policy, procedure, practices or guidelines	IS006
☐ Inadequate design of training program	IS007
☐ Inadequate event reporting/investigation (e.g. lack of detail)	IS008
☐ Inadequate leadership job knowledge	IS009
☐ Inadequate monitoring of work (e.g. oversight of shift)	IS010
☐ Inadequate new hire training	IS011
☐ Inadequate or lack of safety meetings	IS012
☐ Inadequate performance measurement, evaluation, and/or feedback	IS013
☐ Inadequate recurrent training provided	IS014
☐ Inadequate safety walk-throughs or inspections	IS015
☐ Need for training not identified	IS017
☐ No measurement of training effectiveness	IS018
☐ Personality conflict between supervisor/manager and employee	IS019
☐ Training not reinforced on the job	IS020
☐ Training records incorrect	IS021

PLANNED INAPPROPRIATE OPERATIONS: Are factors in an event when supervision fails to adequately plan or assess the hazards associated with an operation and allows for unnecessary risk.

☐ Excessive workload	PIO001
☐ Failure to provide adequate work/break schedule	PIO002
☐ Improper/insufficient delegation of authority	PIO003
☐ Inadequate assessment of needs	PIO004
☐ Inadequate equipment/safety records	PIO005
☐ Inadequate hazard assessment	PIO006
☐ Inadequate implementation/communication of company/ departmental policy and procedures	PIO007
☐ Inadequate initiating of safety review	PIO008

- Inadequate maintenance planning/scheduling PIO009
- Inadequate management of change system (e.g., manual changes, work instruction changes) PIO010
- Inadequate safety/hazard inspection system PIO011
- Inadequate work turnover process (e.g., asking another healthcare professional to perform task) PIO013
- Job beyond capability of employee PIO014
- Leadership implied haste PIO015
- Poor matching/pairing of employees PIO016
- Requested employee to perform undocumented procedure PIO017

FAILURE TO CORRECT KNOWN PROBLEM: This is a factor in an event when supervision fails to correct known deficiencies in documents, processes or procedures, or fails to correct inappropriate or unsafe actions of individuals, and this lack of supervisory action creates an unsafe situation.

- Failure to correct inappropriate behavior/identify risky behavior FCP001
- Failure to correct known reported problem FCP002
- Failure to place appropriate priority on needed repairs FCP003
- Failure to update/revise/enforce operating guidelines, and/or policies and procedures FCP004
- Improper performance is rewarded or tolerated or condoned FCP005
- Inadequate enforcement of Safe operations (i.e. hand washing, PPE, time-outs) FCP006
- Inadequate health hazard evaluation (OSHA) FCP007
- Inadequate identification of work place hazards FCP008

SUPERVISORY VIOLATIONS: Are factors in an event when supervisors willfully disregard instructions or policies, that creating the unsafe situation.

- Authorized unnecessary hazard SV001
- Authorized unqualified healthcare professional to perform task SV002
- Enabling excessive risk taking SV003
- Failure to enforce rules and regulations SV004
- Fraudulent documentation SV005
- Inadequate documentation SV006
- Inadequate inspection SV007
- Knowingly set priority of schedule over safety requirement SV008
- Leader encourages bending of the rules SV009
- Violation of operating guidelines, policy and procedures by a leader(s) SV010
- Willful disregard for authority by leader(s) SV011

"Did organizational errors influence the outcome?" (Organizational Influences)

RESOURCE/ACQUISITION MANAGEMENT: Resource management is a factor when processes or policies influence system safety, result in inadequate error management or create an unsafe situation.

- ☐ Equipment working conditions (use of damaged or outdated supplies/materials, or the unavailability of the right tools or manuals) RM001
- ☐ Excessive cost cutting RM002
- ☐ Improper handling/storage/transport of supplies/materials RM005
- ☐ Improper salvage and/or waste disposal RM006
- ☐ Improper selection/substitution/use of supplies/materials RM007
- ☐ Improper/lack of training protocol (i.e., not developed) RM008
- ☐ Inadequate contract/vendor approval process/selection/ inadequate specifications to contract/vendor RM010
- ☐ Inadequate facilities/equipment design RM012
- ☐ Inadequate identification of hazardous materials RM013
- ☐ Inadequate matching of qualifications for job RM014
- ☐ Inadequate material packaging/container RM015
- ☐ Inadequate monitoring of construction RM016
- ☐ Inadequate receiving inspection and acceptance RM017
- ☐ Inadequate staffing/manning procedures RM020
- ☐ Ineffective attrition/retention policies RM022
- ☐ Lack of financial reimbursement for procedure/process RM023
- ☐ Lack of funding RM024
- ☐ Lack of logistical support RM025
- ☐ No contractor/vendor pre-qualification/ use of non-approved contract RM026
- ☐ Personal protective equipment not made available RM027
- ☐ Purchasing unsuitable equipment/parts RM029
- ☐ Inadequate technology/design RM031

ORGANIZATIONAL CLIMATE: Is a factor in an event where the working atmosphere within the organization influences individual actions resulting in human error. (e.g., leadership structure, policies, and working environment).

- ☐ Employee behavior problematic Policy/practices/procedures OC001
- ☐ not practiced, enforced or consistent OC002
- ☐ Improper/ insufficient delegation of authority OC003
- ☐ Inadequate accessibility/visibility of leadership OC004

- ☐ Inadequate/lack of accountability system in place (e.g., SOPs, policies & procedures) OC005
- ☐ Inadequate drug and alcohol policies OC006
- ☐ Inadequate evaluation/promotion/upgrade OC007
- ☐ Inadequate hiring, firing, promotion, retention OC008
- ☐ Inadequate event reporting, investigation and corrective action policy and practice OC009
- ☐ Inadequate organizational values/culture not clearly defined/ communicated OC010
- ☐ Inadequate organizational customs/justice OC011
- ☐ Inadequate organizational structure: chain of command OC013
- ☐ Inadequate organizational structure: communication OC014
- ☐ Inadequate response to employee feedback OC015
- ☐ Norms and rules problematic/values, beliefs, attitudes OC017
- ☐ Unclear/conflicting assignment of responsibility/ reporting relationships OC018

ORGANIZATIONAL PROCESSES: Organizational processes are factors in an event if these processes negatively influence performance and result in an unsafe situation.

- ☐ Deficient planning OP001
- ☐ Environmental Management process not adequately implemented/ maintained OP002
- ☐ Failure to document change OP003
- ☐ Inadequate event reporting/investigation OP004
- ☐ Inadequate job safety analysis performed OP005
- ☐ Inadequate operations: operational tempo creates risk OP006
- ☐ Inadequate or incorrect performance feedback OP007
- ☐ Inadequate organizational training: not well defined or available OP009
- ☐ Inadequate performance measures/standards OP011
- ☐ Inadequate program oversight: management failed to monitor resources, climate, and processes to ensure a safe work environment OP016
- ☐ Inadequate strategic risk assessment OP017
- ☐ Lack of/inadequate established safety & quality programs/ risk management programs OP019
- ☐ Lack of job safety analysis conducted OP020
- ☐ Lack of/inadequate Standard Operating Procedures (e.g., inconsistent with work processes) OP021
- ☐ On time performance demands/time pressures OP023
- ☐ Outdated Standard Operating Procedures/no revision schedule OP024
- ☐ Policy/standard guidelines not specific/not written OP025

- Unclear definition of corrective action OP034
- Unclear definition of objectives OP035
- Work/production schedules create risks OP036

Appendix E

Table 4.2

List of Reported Event Types by Harm Level and Location Type

Event Type by Harm Level						
Fiscal Year	**RCA #**	**Event Type**	**Event Categor**	**Event Subcategory**	**Harm Level**	**Type of Location**
FY 2012	1	Event r/t Surgery or Invasive Procedure	Unintended blockage, obstruction or ligation	n/a	6	OP
FY 2012	2	Care Coordination/ Communication	Access to Care Problem	Delay in transfer	5	OP
FY 2012	3	Laboratory test	Reporting results/report unavailable	n/a	3	OR
FY 2012	4	Omission/Errors in Assessment, Diagnosis, Monitoring	Assessment issue	Delayed	4	EC
FY 2012	5	Medication related	Wrong timing	Too late	3	EC
FY 2012	6	Medication related	Wrong timing	Too late	4	EC
FY 2012	7	Fall	n/a	n/a	6	IP
FY 2012	8	Fall	n/a	n/a	9	EC
FY 2012	9	Fall	n/a	n/a	9	IP
FY 2012	10	Fall	n/a	n/a	6	IP
FY 2012	11	Fall	n/a	n/a	6	IP
FY 2012	12	Fall	n/a	n/a	4	IP
FY 2012	13	Fall	n/a	n/a	9	IP

FY 2012	14	Fall	n/a	n/a	6	IP
FY 2012	15	Fall	n/a	n/a	6	OP
FY 2012	16	Fall	n/a	n/a	6	IP
FY 2012	17	Omission/Errors in Assessment, Diagnosis, Monitoring	Diagnosis	Incorrect diagnosis	6	OP
FY 2012	18	Event r/t Surgery or Invasive Procedure	incorrect surgical or invasive procedure	Wrong implant by mistake	5	OP
FY 2012	19	Complication of Care	Unexpected death	n/a	9	IP
FY 2012	20	Medication related	Wrong dose	Overdose	4	IP
FY 2012	21	Event r/t Surgery or Invasive Procedure	Incorrect surgical or invasive procedure	Wrong side (L vs R)	4	OP
FY 2012	22	Complication of Surgery or Anesthesia	Respiratory failure requiring unplanned support <24 after procedure	Unplanned/ emergent intubation following procedure/treatment/test	5	IP
FY 2012	23	Care Coordination/ Communication	Access to Care Problem	Access to care	4	IP
FY 2012	24	Complication of Surgery or Anesthesia	Hemorrhage requiring unexpected transfusion or return to OR	n/a	8	IP
FY 2012	25	Laboratory test	Reporting results/report unavailable	n/a	9	OP

FY 2012	26	Care Coordination/ Communication	Communication inadequate	with other providers within patient care area	9	IP
FY 2012	27	Complication of Surgery or Anesthesia	Central nervous system event	Unexpected loss of consciousness	5	IP
FY 2012	28	Medication related	Missed dose	n/a	4	IP
FY 2013	29	Event r/t Surgery or Invasive Procedure	Foreign body accidentally left in patient	Guidewire	5	OR
FY 2013	30	Fall	n/a	n/a	6	IP
FY 2013	31	Fall	n/a	n/a	6	OP
FY 2013	32	Transfusion	Sample for compatibility testing	Mismatch from historical record	3	DI/IR
FY 2013	33	Medication related	Wrong dose	Overdose	2	OP
FY 2013	34	Care Coordination/ Communication	Message handling/resp onse problem	n/a	6	IP
FY 2013	35	Laboratory Test	Reporting results/report unavailable	n/a	6	OP
FY 2013	36	Radiology/ Imaging test	Wrong procedure	n/a	4	DI/IR
FY 2013	37	Fall	n/a	n/a	6	OP
FY 2013	38	Event r/t Surgery or Invasive Procedure	Incorrect surgical or invasive procedure	Wrong side (L vs R)	6	DI/IR
FY 2013	39	Fall	n/a	n/a	9	IP

FY 2013	40	Care Coordination/ Communication	Access to care problem	Inappropriate level of care	8	OP
FY 2013	41	Care Coordination/ Communication	Referral/consult problem	Other (referral/consult problem)	4	EC
FY 2013	42	Complication of Care	Other catheter or tube problem	Line or tube damaged/broken	4	IP
FY 2013	43	Fall	n/a	n/a	6	OP
FY 2013	44	Medical Records/Patient Identification	Other (medical records)	n/a	3	Morgue
FY 2013	45	Event r/t Surgery or Invasive Procedure	Other	n/a	4	OR
FY 2013	46	Laboratory test	Transport of specimen	n/a	4	DI/IR
FY 2013	47	Complication of Care	Unexpected change in patient status	Unplanned transfer to ICU	9	OR
FY 2013	48	Fall	n/a	n/a	6	IP
FY 2013	49	Event r/t Surgery or Invasive Procedure	Incorrect surgical or invasive procedure	Wrong implant by mistake	6	OR
FY 2013	50	Complication of Surgery or Anesthesia	Hemorrhage requiring unexpected transfusion or return to OR	n/a	9	IP
FY 2013	51	Fall	n/a	n/a	6	IP
FY 2013	52	Fall	n/a	n/a	6	IP
FY 2013	53	Fall	n/a	n/a	6	IP

FY 2013	54	Fall	n/a	n/a	6	IP
FY 2014	55	Fall	n/a	n/a	6	OP
FY 2014	56	Care Coordination/ Communication	Communication inadequate	with other providers within patient care area	3	IP
FY 2014	57	Fall	n/a	n/a	6	IP
FY 2014	58	Radiology/ Imaging test	Wrong site	n/a	5	DI/IR
FY 2014	59	Fall	n/a	n/a	6	DI/IR
FY 2014	60	Medication related	Known drug interaction	Drug-drug	4	IP
FY 2014	61	Care Coordination/ Communication	Access to care problem	Inappropriate level of care	5	IP
FY 2014	62	Medication related	Known allergy	Documented in record but missed	5	OP
FY 2014	63	Fall	n/a	n/a	6	IP
FY 2014	64	Fall	n/a	n/a	6	IP
FY 2014	65	Complication of Surgery or Anesthesia	Death	n/a	9	IP
FY 2014	66	Event r/t Surgery or Invasive Procedure	Foreign body accidentally left in patient	Instrument fragment	4	OR
FY 2014	67	Fall	n/a	n/a	6	IP
FY 2014	68	Medication related	Wrong patient	n/a	4	DI/IR
FY 2014	69	Laboratory test	Specimen collection	n/a	3	OR
FY 2014	70	Medication related	Wrong rate (IV)	Too quickly	4	OP

FY 2014	71	Fall	n/a	n/a	6	OP
FY 2014	72	Medical Records/Patient Identification	patient identification issues	n/a	3	OP
FY 2014	73	Fall	n/a	n/a	6	IP
FY 2014	74	Fall	n/a	n/a	6	IP
FY 2014	75	Fall	n/a	n/a	6	OP
FY 2014	76	Behavioral Event	Suicide or suicide attempt	n/a	9	OP
FY 2014	77	Fall	n/a	n/a	3	OP
FY 2014	78	Fall	n/a	n/a	6	IP
FY 2015	79	Event r/t Surgery or Invasive Procedure	Other	n/a	4	OR
FY 2015	80	Complication of Surgery or Invasive Procedure	Dehiscence, wound/flap/graft failure or disruption	n/a	6	IP
FY 2015	81	Event r/t Surgery or Invasive Procedure	Incorrect surgical or invasive procedure	Wrong side (L vs R)	5	OR
FY 2015	82	Fall	n/a	n/a	6	IP
FY 2015	83	Transfusion	Suspected transfusion reaction	n/a	4	IP
FY 2015	84	Event r/t Surgery or Invasive Procedure	Foreign body accidentally left in patient	Instrument fragment	4	OR

FY 2015	85	Fall	n/a	n/a	6	IP
FY 2015	86	Fall	n/a	n/a	6	IP
FY 2015	87	Fall	n/a	n/a	6	IP
FY 2015	88	Medication related	Wrong rate (IV)	Too quickly	5	EC
FY 2015	89	Event r/t Surgery or Invasive Procedure	Incorrect surgical or invasive procedure	Wrong patient	6	IP
FY 2015	90	Fall	n/a	n/a	6	OP
FY 2015	91	Complication of Care	Respiratory Complication	Other (respiratory complication)	9	IP
FY 2015	92	Fall	n/a	n/a	6	IP
FY 2015	93	Fall	n/a	n/a	6	IP
FY 2015	94	Fall	n/a	n/a	6	IP
FY 2015	95	Event r/t Surgery or Invasive Procedure	Foreign body accidentally left in patient	Sponge	4	OR
FY 2015	96	Medication related	Monitoring event	Clinical (lab value, vital signs)	9	EC
FY 2015	97	Fall	n/a	n/a	6	DI/IR
FY 2015	98	Care Coordination/ Communication	Access to care problem	Delay in treatment	5	IP
FY 2015	99	Adverse reaction	Adverse drug reaction	n/a	9	IP
FY 2015	100	Event r/t Surgery or Invasive Procedure	Foreign body accidentally left in patient	Other (foreign body)	4	OR

FY 2015	101	Fall	n/a	n/a	6	DI/IR
FY 2015	102	Fall	n/a	n/a	6	IP
FY 2015	103	Event r/t Surgery or Invasive Procedure	Unintended laceration or puncture	n/a	9	OR
FY 2015	104	Omission/Errors in Assessment, Diagnosis, Monitoring	Diagnosis issues	Delayed diagnosis	8	OP
FY 2015	105	Medication related	Monitoring event	Other monitoring event	5	OP
FY 2015	106	Radiology/ Imaging test	Incorrect isotope or amount administered	n/a	4	OP
FY 2015	107	Fall	n/a	n/a	6	IP
FY 2015	108	Medication related	Wrong dose	Overdose	4	IP

Legend:
IP = inpatient unit
OP = outpatient center
EC = emergency center
OR = operating room
DI/IR = diagnostic imaging / interventional radiology area

Appendix F

Table 4.4

Distribution of HFACS Casual Categories by Fiscal Year (Study Site)

Distribution of HFACS Causal Categories by Fiscal Year

Human Factord Analysis and Classification System (HFACS)	FY 2012 (28 RCAs conducted)				FY 2013 (26 RCAs conducted)				FY 2014 (24 RCAs conducted)				FY 2015 (30 RCAs conducted)				**Cumulative FYs (108 RCAs conducted)**			
	Total Nanocodes per Category	% of nanocodes per category	# of RCA Cases with a nanocode from this category	% of cases with a nanocode from this	Total Nanocodes per Category	% of nanocodes per category	# of RCA Cases with a nanocode from this category	% of cases with a nanocode from this	Total Nanocodes per Category	% of nanocodes per category	# of RCA Cases with a nanocode from this category	% of cases with a nanocode from this	Total Nanocodes per Category	% of nanocodes per category	# of RCA Cases with a nanocode from this category	% of cases with a nanocode from this	Total Nanocodes per Category	% of nanocodes per category	# of RCA Cases with a nanocode from this category	% of cases with a nanocode from this category
Organizational Influences	101	23%			95	24%			80	24%			141	17%			**417**	**20.7%**		
Resource Management	28	6%	14	50	23	6%	12	46	14	4%	8	33	43	5%	19	63	**108**	**5%**	**53**	**49%**
Organizational Climate	29	7%	14	50	39	10%	20	77	27	8%	12	50	49	6%	19	63	**144**	**7%**	**65**	**60%**
Organizational Process	44	10%	19	68	33	8%	18	69	39	12%	15	63	49	6%	16	53	**165**	**8%**	**68**	**63%**
Unsafe Supervision	87	20%			51	13%			49	15%			142	17%			**329**	**16.3%**		
Inadequate Supervision	32	7%	15	54	16	4%	8	31	19	6%	11	46	47	6%	11	37	**114**	**6%**	**45**	**42%**
Planned Inappropriate Operations	23	5%	12	43	21	5%	12	46	20	6%	11	46	44	5%	15	50	**108**	**5%**	**50**	**46%**
Failure to Correct Known Problem	25	6%	17	61	11	3%	9	35	7	2%	6	25	38	5%	13	43	**81**	**4%**	**45**	**42%**
Supervisory Violation	7	2%	6	21	3	1%	3	12	3	1%	3	13	13	2%	4	13	**26**	**1%**	**16**	**15%**
Preconditions for Unsafe Acts	117	26%			110	28%			97	29%			329	39%			**653**	**32.4%**		
Environmental Factors																	**166**			
Physical Environment	5	1%	5	18	3	1%	3	12	4	1%	4	17	15	2%	7	23	**27**	**1%**	**19**	**18%**
Technological Environment	35	8%	17	61	21	5%	16	62	23	7%	9	38	60	7%	18	60	**139**	**7%**	**60**	**56%**
Condition of the Operator/Employee																	**211**			
Adverse Mental State	15	3%	9	32	30	8%	17	65	27	8%	12	50	101	12%	24	80	**173**	**9%**	**62**	**57%**
Physical/Mental Limitations	5	1%	4	14	0	0%	0	0%	3	1%	3	13	23	3%	10	33	**31**	**2%**	**17**	**16%**
Adverse Physiological State	0	0%	0	0%	6	2%	5	19	0	0%	0	0%	1	0%	1	3%	**7**	**0%**	**6**	**6%**
Personnel Factors																	**276**			
Communication and Coordination	57	13%	22	79	50	13%	22	85	39	12%	17	71	128	15%	24	80	**274**	**14%**	**85**	**79%**
Fitness for Duty	0	0%	0	0%	0	0%	0	0%	1	0%	1	4%	1	0%	1	3%	**2**	**0%**	**2**	**2%**
Unsafe Acts	141	32%			141	36%			106	32%			226	27%			**614**	**30.5%**		
Errors																	**492**			
Decision-making Errors	64	14%	25	89	47	12%	19	73	41	12%	19	79	68	8%	23	77	**220**	**11%**	**86**	**80%**
Skill-based Errors	40	9%	22	79	53	13%	21	81	44	13%	19	79	102	12%	26	87	**239**	**12%**	**88**	**82%**
Perceptual errors	12	3%	10	36	10	3%	6	23	7	2%	6	25	4	0%	4	13	**33**	**2%**	**26**	**24%**
Violations																	**122**			
Routine Violations	25	6%	16	57	29	7%	13	50	13	4%	8	33	49	6%	12	40	**116**	**6%**	**49**	
Exceptional Violations	0	0%	0	0%	2	1%	2	8%	1	0%	1	4%	3	0%	2	7%	**6**	**0%**	**5**	
	446				397				332				838				**2,013**	**100%**		

Appendix G

Table 4.5

Distribution of HFACS Causal Categories (Comparative Data for Study Site, Diller Study & Berry Study)

Distribution of HFACS Causal Categories (Comparative Data for Study Site, Diller Study and Berry Study)										
			Study Site Cumulative HFACS Data (108 RCAs) (health care)				**Diller Study Cumulative HFACS Data (105 RCAs) (health care)**				**Berry Study Cumulative (mean) HFACS Data (22,165 cases) (mixed; mostly aviation)**
Human Factord Analysis and Classification System (HFACS)			Total Nanocodes per Category	% of nanocodes per category	# of RCA Cases with a nanocode from this category	% of cases with a nanocode from this category	Total Nanocodes per Category	% of nanocodes per category	# of RCA Cases with a nanocode from this category	% of cases with a nanocode from this category	% of nanocodes per category
Organizational Influences			417	**21%**			96	**6%**			n.d.
	Resource Management		108	5%	53	49%	34	2%	11	11%	2%
	Organizational Climate		144	7%	65	60%	33	2%	24	23%	1%
	Organizational Process		165	8%	68	63%	29	2%	18	17%	12%
Unsafe Supervision			329	**16%**			69	**3%**			n.d.
	Inadequate Supervision		114	6%	45	42%	26	1%	19	18%	3%
	Planned Inappropriate Operations		108	5%	50	46%	9	0%	9	9%	5%
	Failure to Correct Known Problem		81	4%	45	42%	14	1%	13	12%	2%
	Supervisory Violation		26	1%	16	15%	20	1%	18	17%	2%
Preconditions for Unsafe Acts			653	**32%**			694	**41%**			n.d.
	Environmental Factors		166	8%	79		96	6%			
		Physical Environment	27	1%	19	18%	52	3%	33	31%	42%
		Technological Environment	139	7%	60	56%	44	3%	23	22%	17%
	Condition of the Operator/Employee		211	11%	85		146	9%			
		Adverse Mental State	173	9%	62	57%	130	8%	59	56%	5%
		Physical/Mental Limitations	31	2%	17	16%	1	0%	1	1%	12%
		Adverse Physiological State	7	0%	6	6%	15	1%	9	9%	2%
	Personnel Factors		276	14%	87		452	26%			
		Communication and Coordination	274	14%	85	79%	449	26%	90	86%	9%
		Fitness for Duty	2	0%	2	2%	3	0%	3	3%	2%
Unsafe Acts			614	**31%**			852	**50%**			n.d.
	Errors		492	25%	200		558	33%			
		Decision-making Errors	220	11%	86	80%	113	25%	99	54%	32%
		Skill-based Errors	239	12%	88	82%	426	7%	57	94%	46%
		Perceptual errors	33	2%	26	24%	19	1%	16	15%	5%
	Violations		122	6%	54		294	17%			
		Routine Violations	116	6%	49	45%	270	16%	84	80%	
		Exceptional Violations	6	0%	5	5%	24	1%	12	11%	5%
			2013	100%			1711	100%			

The University of Houston IRB Approval Letter

UNIVERSITY of HOUSTON

DIVISION OF RESEARCH

October 3, 2016

Latasha Burns
c/o Dr. Sara G. McNeil
Curriculum and Instruction

Dear Latasha Burns,

Based upon your request for exempt status, an administrative review of your research proposal entitled "ANALYZING HUMAN FACTORS DATA TO GUIDE HEALTHCARE LEADERS' QUALITY IMPROVEMENT DECISIONS" was conducted on August 19, 2016.

At that time, your request for exemption under **Category 4** was approved pending modification of your proposed procedures/documents.

The changes you have made adequately respond to the identified contingencies. As long as you continue using procedures described in this project, you do not have to reapply for review. * Any modification of this approved protocol will require review and further approval. Please contact me to ascertain the appropriate mechanism.

If you have any questions, please contact Alicia Vargas at (713) 743-9215.

Sincerely yours,

Kirstin Rochford, MPH, CIP, CPIA
Director, Research Compliance

*Approvals for exempt protocols will be valid for 5 years beyond the approval date. Approval for this project will expire **October 2, 2021**. If the project is completed prior to this date, a final report should be filed to close the protocol. If the project will continue after this date, you will need to reapply for approval if you wish to avoid an interruption of your data collection.

Protocol Number: 16573-EX

Study Site Quality Improvement Assessment Board (QIAB) Approval Letter

To: Burns,LaTasha;

Cc: Project Database;

Subject: Your project has been approved and an entry created in Project Database for Project: Analyzing Systemic and Human Factors Data to Guide Healthcare Leaders" Quality Improvement Decisions

Date: Tuesday, September 13, 2016 3:58:18 PM

Project Name: Analyzing Systemic and Human Factors Data to Guide Healthcare Leaders' Quality Improvement Decisions

Quality Improvement Assessment Board (QIAB) Approval Letter Tracking

Number: 10431

Passcode: 15581717

Your project has been approved by the Quality Improvement Assessment Board (QIAB). Your project is now part of the institution's Project Database. You will use the database to track your project and record the results of your work. The information will also be used to update your manager and the cancer center's leaders about quality improvement projects at the institution.