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Human Factors Contributing to Preventable Adverse Drug Events in Healthcare: A Grounded Theory Approach Pilot Study

Thomas Ryan Hilgers

HUMAN FACTORS CONTRIBUTING TO PREVENTABLE ADVERSE DRUG EVENTS IN HEALTHCARE: A GROUNDED THEORY APPROACH PILOT STUDY

by

Thomas Ryan Hilgers

CLINT R. BALOG, Ph.D., Thesis Committee Chair

KATHERINE A. MORAN, Ed.D., Thesis Committee Member

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Abstract

The following thesis details a grounded theory methodology (GT) pilot study of preventable adverse drug events (pADEs) in healthcare. This research used the methodological approach to develop a categorical theory for the chief workplace contributors to intra-hospital intensive care unit (ICU) preventable adverse drug events. While this study represents only a foray into the use of GT to explain pADEs, the results implicate specific areas of concern that may be followed up on in future qualitative or quantitative research. Pursuant of a Straussian grounded theory methodology, this study leaned fundamentally on the interview of individuals with first-hand experience with the phenomenon of interest. A total of 10 participants, eight nurses and two physicians, with varying levels of experience and places of employment, were recruited for these interviews. The resultant data were analyzed, coded, and categorized by the researcher to develop a graphical representation of the emergent data categories. That graphical representation materialized in an axial coding paradigm in which four primary categories describe a core phenomenon. The core phenomenon identified in this study as a main cause of pADEs within ICUs was breakdowns in nursing care. The four overarching categories used to describe the core phenomenon were causal conditions (i.e. communication errors, fatigue, a nursing shortage), strategies (i.e. incident reporting, safety processes, staffing strategies), consequences (i.e. nurse burnout, disconnect with management, running out of time), and contextual conditions (i.e. standard practices, patient satisfaction surveys, time of day). These categories were informed by the data and through selective coding, a final theory was drawn. This study concluded that breakdowns in nursing care can be attributed to an incredible workload, which causes nurses to ignore safety processes.

Keywords: human factors, adverse drug events, human error, grounded theory

Dedication

To my grandmother, Beth E. Jaquinta.

You will always be in our hearts.

We miss you, Nana.

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To my father, Thomas F. Hilgers, and my mother, Jae E. Hilgers. You taught me what it means to be a lifelong learner and to always keep my head up. There is no obstacle too great. Thank you for always encouraging me.

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CHAPTER 1. INTRODUCTION

Introduction to the Problem

The safety-critical nature of medicinal patient care within hospital settings necessitates a constantly proactive and preventative approach to potential opportunities for error. While much research has been conducted around the incidence and typicality of medical error within the American healthcare system, it is not always clear where the propensities for error can creep in within these environments. This thesis research seeks to contribute to the large and well researched subject of human error in complex environments through investigation of a much more specific facet of the larger subject. Prescription and delivery of medication is, itself, a complex sub-system of the healthcare field. Further, it is a safety-critical sub-system, as errors within it have the potential to cause severe patient health complications.

In a 2013 webinar presented by Dr. Rollin J. Fairbanks, Associate Director of the MedStar Institute for Innovation (MI2), human components in complex healthcare environments were equated to the metallic components of a civil engineering bridge project. The civil engineer(s) in charge of the bridge are responsible for knowing the properties of the metal that may cause it to break under certain conditions. If the hypothetical bridge were to collapse due to exposure to these known conditions, no one would blame the metal. However, Dr. Fairbanks continued:

> But when we expose [healthcare professionals (HCPs)] to conditions which are conducive to human error, that facilitate error, we tend to blame [them] for that error, and we try to focus on changing the error rate within the [HCPs], rather than changing the environment[s] in which they're working. (2013)

In general, complex systems, of any type, are defined by the components they involve. Any component, be it an inanimate building material, technical software program, or sentient human being, has its own unique attributes. These individual attributes, when viewed from the perspective of the system, hold the key to the fallibility of the construct. It is therefore paramount that a system's engineer be wholly cognizant of the individual breaking points of the system's components. This is especially true for safety-critical systems.

Based on the notion that human beings are innately fallible and that this condition cannot be changed (Reason, 1990), the reactionary and punitive mentality of "name, blame, and train" within the medical field is largely misfocused (Croskerry & Cosby, 2009; Fairbanks, 2013). Unlike the human condition, the conditions under which human components work can be changed (Reason, 1990). Therefore, seeking to understand the limitations of human actors within a system and building an error-resistant safety culture around that is a more effective plan of action (Croskerry & Cosby, 2009; Fairbanks, 2013).

Background of the Problem

The subject of preventable medical errors is one that garners much attention. This is no surprise as its very nature is comprised of potentially painful events that never needed to occur. The commonly cited Institute of Medicine (IOM) report, *To Err is Human: Building a Safer Health System*, caught the attention of many by quantifying the staggering frequency of preventable errors in medicine (1999). Estimating between 44,000 and 98,000 yearly deaths due to medical error, the report called for a 50% reduction in error within the proceeding five years. Toward that goal, the report has spawned numerous other reports that estimate the frequency of and further categorize the different modalities of medical error, and, ultimately, the 50% reduction has been shown to be a much loftier goal than originally thought (Kaushal et al., 2010).

Around the same time frame, a study by Thomas et al. (2000), found that adverse events occurred in about 2.9% of 15,000 randomly sampled hospitalizations within a representative sample of hospitals from Utah and Colorado.

Comparatively, two more recent studies, Levinson & General (2010), and Classen et al. (2011) show an increase in adverse event incidents over the Thomas et al. study at 13.1% and 33.2%, respectively. However, one could argue that the driving force behind the discrepancy in figures is due to differences in study methodology, sampling, and measurement criteria (Classen et al., 2011). Regardless, while their methodologies are varied, these reports do not show a trend toward the reduction of preventable medical error (Fairbanks, 2013).

Unfortunately, specific figures for the prevalence of medical error, both in general and in specific sub-types, cannot be determined because there does not exist a uniform system for reporting or qualifying preventable medical errors (Classen et al., 2011). In fact, Classen et al. (2011) states that they found "at least ten times more confirmed, serious events" (p. 581) than other methods based on a comparison of three different methods for detecting adverse events commonly used.

In a 2008 meta-analysis of eight studies of adverse medical events, surgical- and drug-related mistakes were found to be the first and second most common types of adverse medical errors, respectively (de Vries, Ramrattan, Smorenburg, Gouma, & Boermeester, 2008). A primary difference between these two error modalities is the intrinsic risk of the environments in which they occur. Surgical errors, though they are the most common, may occur within already dire circumstances. Conversely, the use of drugs has become an integral part of many Americans' day-to-day routines and is extremely commonplace in hospital care as well. An

individual or HCP may not typically regard taking or administering medication as a risky action (Page, Linnebur, Bryant, & Ruscin, 2010).

The medical drug-use process is complicated and oftentimes lengthy. This process, specifically within the context of a hospital, at a minimum, consists of the prescribing of the medication, the approval of the medication by the facility's pharmacy, the delivery of the medication to the patient, and post-delivery monitoring of the patient. However, each of these steps can be further magnified to reveal many more potential steps (Page et al., 2010). For example, the medication delivery step can be broken into many sub-steps, which may differ depending on the drug's administration route (e.g. subcutaneous, oral, infused, etc.). Further, a variety of HCPs may be involved in the administration as well, and the HCPs involved may have also been involved in prior stages of the medical drug-use process.

Based on the patient outcomes observed in the post-delivery monitoring stage of the process, the doctor may decide to adjust the patient's medication; thus, making the entire process cyclical. Depending on the patient's need, and the complexity of their treatment, the length of the process in-turn creates opportunity for use-error to creep in (Page et al., 2010; Kanjanarat, Winterstein, Johns, Hatton, Gonzaler-Rothi, & Segal, 2003). Errors within the process can occur at any step and are not exclusively associated with any type of drug or treatment plan (Kanjanarat et al., 2003). Preventable adverse drug events (pADEs) can turn a relatively risk-free hospital stay into a potentially life-threatening experience.

This frightening reality is not exclusive to any group of patients. However, certain demographics of patients, most notably the elderly, are more likely to encounter pADEs due to the frequency at which they are prescribed medication as well as certain typical characteristics of the group (Page et al., 2010). Adults aged 65 years and older represent the largest per capita

consumers of prescription medications and account for over 35% of annual hospital admissions in the United States (Healthcare Cost and Utilization Project [HCUP], 2006; Qato et al., 2008; Page et al., 2010). Further, many of these patients are being prescribed concurrent medications. Based on more than three thousand interviews with senior living facility residents, Qato et al. (2008) found that that 29% used at least five prescription medications concurrently. Further, studies show that patients taking two drugs concurrently face a 13% risk of negative drug-drug interaction (Goldberg, Mabee, Chan, & Wong, 1996). These statistics rise to 38% if the patient is taking four medications, and 82% if the patient is taking seven or more concurrent medications (Goldberg et al., 1996). The risk of taking concurrent medications follows these individuals into the hospital when they are admitted and potentially prescribed new medications for their emergent situation.

Several other disadvantages to the elderly patient population present themselves. Physiological changes that make senior adults more vulnerable to the strong effects of medication, and the presence of multiple comorbidities put the elderly at an increased risk of pADEs (HCUP, 2006; Qato et al., 2008; Page et al., 2010). Comorbidities, or the presence of more than one chronic condition, is most pervasive within the hospital setting (Page et al., 2010). Depending on a patient's specific comorbidities, the prescription and delivery of medication can become a dangerous and potentially inconsistent practice. Patients experiencing age-related memory problems or extreme physical complications may need additional care and attention (Rice & Feldman, 1983).

Statement of the Problem

While, as previously stated, there is a healthy body of research around the subject area of preventable medication errors and risk mitigation strategies for avoiding this type of error

(*Medication Management Technologies* [*MMT*], 2015), if judged based on the continued prevalence of the problem, these strategies are failing, in some way, to fully solve the issue. Much of the current body of literature is aimed at measuring and defining the pADE problem, and/or evaluating strategies for mitigating pADE risk (HCUP, 2006; Qato et al., 2008; Keers et al., 2014; Page et al., 2010; Kanjanarat et al., 2003; *MMT*, 2015). This researcher believes that what is largely missing from this research is a "ground up" theory from the healthcare professional's (HCP's) perspective. Instead of approaching the problem from the quantitative end, this study interviewed HCPs involved in the process of interest and sought to qualitatively define the problem and its causes.

Though this unique approach to the problem, the research assumed a deterministic approach. If it is understood and accepted that human nature is innately fallible (Reason, 1990), it may therefore be the situations and environments in which the human works that are error prone (Reason, 1990; Fairbanks, 2013). While these errors are preventable in that changes must be made to prevent re-occurrence, given the above reasoning, faulty work environments make these errors all but inevitable. The researcher set out to determine, from the candid perspective of the HCP, where the systemic shortcomings are occurring, thereby allowing pADEs to occur.

Purpose and Significance of the Study

The purpose of this research was to develop a foundational descriptive understanding from which a theory of the causes of pADEs, within the intensive care units (ICUs) of American hospitals, from the perspective of the HCPs in the hospital setting could be derived. The researcher's belief is that such an understanding may add qualitative color to the already existing wealth of quantitative data around the topic.

While the study focused specifically on preventable medication errors within hospital intensive care patients, the insights gained may have a broader significance. As evidenced by the application of such aviation best practices as Crew Resource Management (CRM) within the healthcare field (Kasper & Jentsch, 2016), insights into the human performance component of any safety-critical system have the potential to be valuable as a solution in an unrelated or tangential field. Further, the theme of the overarching research problem, that systems and environments allow for the errors within themselves, ties this focused research to the much larger whole of human error within complex systems.

Research Design

The most effective and interesting pursuit of the research question was determined by the researcher to be through a grounded theory methodology. The belief that the grounded theory methodology is acutely suitable for this research question was based on the methodology's efficacy for the construction of theory based in study data. Grounded theory methodology has several major schools of thought and each share many commonalities. While this research leaned heavily on the systematic Straussian procedure for grounded theory methodology set forth by Corbin and Strauss (2015), in which categories, codes, and a constant comparative method of data analysis are used to develop emerging theories (Corbin & Strauss, 2015; Creswell & Poth, 2017).

Grounded theory research typically focuses on processes or actions that have specific steps or phases that occur over time (Creswell & Poth, 2017). For this study, grounded theory methodology was applied to the intra-hospital drug-use process described previously. The study's data not only helped form a descriptive understanding of this process and the specific steps within, but also served as a basis for the development of an explanation (theory) for errors

caused in this process. Further, this study collected its data through the interview of HCPs in the hospital setting. Interviews are the chief data gathering method used in the grounded theory methodology (Creswell & Poth, 2017). Though this study's participants were HCPs working within the ICUs of their hospitals, the emergent theory indicated that the human factors issues identified may also contribute the HCP error elsewhere in the hospital. Additionally, because the study's focus was exclusively on intra-hospital adverse drug events, patient culpability was not considered in this study as a (Page et al., 2011).

The interviews conducted for this research were guided but not scripted. A more detailed description of data collection methods to be used can be found in the Chapter 3. Additionally, the methodology used to organize and analyze the study data will be explained in more detail there as well.

Research Question

This research study asks, through qualitative inquiry, the following research question: "*What are the human factors contributing to preventable adverse drug events in hospital settings?*". However, the path towards the theoretical answer to this research question was largely indirect, and cumulative. As stated in the introduction to this topic, clinical culpability is a sensitive subject (Croskerry & Cosby, 2009; Fairbanks, 2013). To answer the research question, the researcher used an open interview in which a broad picture of the HCP's day-to-day experiences and difficulties was explored and through which specific concepts and common experiences were coded and categorized (Corbin & Strauss, 2015). Through probing questions, the interviews took their focus on pADEs in a hospital environment. This question set the foundation for the research and served as a basis for the methodology selection. The open-ended

nature of the question allowed the researcher to form the study direction and interpretation around the data as it was gathered (Corbin & Strauss, 2015; Creswell & Poth, 2017).

Barriers of the Study

Several barriers existed to this study that needed to be addressed, either in the study's design or noted in the study's limitations, to ensure that data were gathered and that those data were gathered in a proper, transparent way. The first barrier was gaining access to hospitals and being allowed to interview the nurses and doctors. The researcher does not work at, or has ever previously conducted research at, any such facilities, and thus that relationship needed to be built from the ground up or circumvented entirely. An additional barrier that compounded the first was the sensitivity of the medical industry to privacy. For good reason, healthcare facilities are very careful about the privacy of their patients. For the conduct of this study, the researcher did not have the time or opportunity to build a research relationship with any of the major hospitals in his area. Therefore, to circumvent this barrier, HCPs were recruited directly for the study through a third-party recruitment agency. Strict confidentiality measures were put in place to protect the HCPs, their patients, their employing healthcare facilities, and the researcher himself, from any legal recourse.

Limitations and Delimitations of the Study

Limitations

Several limitations exist that restrained the scope of the project. The primary result of these factors was the limit of the study to a pilot of the chosen methodological application. Given these limitations, the research may still contribute to the field by creating opportunities for further research and raising questions in need of answers. One substantial limit to this project was time. The completion of this research was bounded by two nine-week terms as part of

Embry-Riddle Aeronautical University's (ERAU's) Master of Science in Human Factors degree. The first term encompassed the construction of the research proposal, and the submission for institutional review board (IRB) approval. The second term consisted of the research and data analysis (Ison, Vincenzi, Anderson, & Balog, 2015). Further, the researcher aimed to conduct this research while concurrently working full time. While this certainly magnified the time constraint on the research, several benefits did come from this limitation as well. The researcher is employed with a medical device design consultancy and thus had a solid background of qualitative contextual inquiry in the healthcare field. Though the nature of this research (i.e. the methodology chosen) was new to the researcher, his previous training in interviewing study participants was valuable for the conduct of the study.

Another limit to this research was the sensitivity of the topics being broached. It was the researcher's hope that all accounts given by the interviewed HCPs would be truthful, but it was a distinct possibility that a fear of perceived negative repercussions may motivate biased response. Therefore, it was even more important for the researcher to lean on his experience as a moderator for confidential studies and clearly outline and explain the confidentiality measures being taken. Through a careful understanding that their name would not be associated with any of their input to the study, HCPs should have felt comfortable to give their open and honest perspective.

Additionally, the research did not have a formal budget and any expenses, apart from the recruitment of participants, were paid by the researcher himself. Because of this, a limitation to the study was in the ability to afford the continuous sampling of study participants. Grounded theory methodology typically pulls from larger samples of participants as the research continues until conceptual saturation has been determined by the researcher (Creswell & Poth, 2017). This research was limited in that it had a set budget for sampling and no additional participants could

be gathered to follow new lines of inquiry or continue theoretically sampling. Though this limited this study's ability to form a conclusive theory, leading it to be run as a pilot study, it also permits the discussion of potential courses of continuing research.

Delimitations

Several delimitations were also present in this research. The researcher's specific skillset and level of experience offered both positive and negative effects for the study. His familiarity with the medical field from the perspective of human factors and usability engineering lends itself to defining the problems facing HCPs in the workplace. However, the researcher is not, himself, clinically trained. The clinical experiences of the HCPs being studied needed to be consolidated into general insights for both the researcher's and reader's benefit.

Further, as is the case with any qualitative methods study, the subjectivity of the data gathered relies heavily on the researcher's own abilities to derive insight and assign meaning (Yin, 1994; Corbin & Strauss, 2015). Because the researcher himself is not well versed in grounded theory methodology, expert review of the proposed research study will be used throughout the process to mitigate any individual weaknesses arising from this inexperience. Towards the completion of this thesis project, a committee of proven researchers were assembled to help guide the researcher through the process.

Finally, the nature of the relationship between the research topic and the participants gives way to potential challenges to the validity of testimony collected. Because preventable errors in healthcare were being studied, HCPs had a reasonable motivation to minimize their own perceived fault. This risk to data credibility was mitigated through a thorough participant informed consent process but should be noted in the consideration of the data. By properly

informing the participant of their rights to confidentiality and that the subject of the research is not HCP error but instead the underlying causes of error in the workplace.

Definition of Terms

Several terms to be used throughout the conduct of the proposed research that should be defined upfront are as follows:

1. Healthcare professional
2. Hospital Setting
3. Intensive Care Unit
4. Adverse drug event

Healthcare professional (HCP) will be defined as any employee of a hospital that plays a role in the medication process (from prescription to delivery). Depending on the amount of staff interviewed, roles and titles may also be included in the study report. However, this information will not be included if is shown to have the potential to identify study participants.

Hospital setting will be defined for this study as those healthcare institutions which have both outpatient and inpatient capabilities, an intensive care unit (ICU), and an internal pharmacy. Outside of this study, "hospital setting" may be used to describe a much wider range of facilities that deal in the health and recovery of patients.

Intensive Care Units (ICUs) are department(s) within the hospital that cater to patients with severe and life-threatening illnesses and injuries. ICUs can be further identified by the specific types of illnesses or injuries they specialize in (e.g. neurological ICU, cardiovascular ICU, and medical ICU).

Adverse drug event (ADE) is defined by Kanjanarat et al. (2003) as "adverse patient outcomes associated with unsafe use of drug therapy, ineffective drug therapy, or inadequate

access to drug therapy" (p. 1751). The research will refer to ADEs as preventable adverse drug events (pADEs) as the study's focus is to generate a theory for their cause and, by extension, possibilities for their prevention.

CHAPTER 2. LITERATURE REVIEW

Introduction

The factors existing within clinical environments that contribute, either directly or indirectly, to preventable adverse drug events were the focus of this study. To properly understand the weight of the data to be collected, one must contextualize the focus within its larger field of study. In the most forthright terms, this study's interview asked its participants to point to the factors within their work environment that most contribute to medication error. It is through an understanding of the legitimate human factors and systems theory behind these errors that the data was to be viewed. This literature review provides a basis for that contextual understanding of the subject by reviewing related fields of study that encompass preventable adverse drug events (pADEs) from most broad to most specific.

Theoretical Orientation

The chosen methodological approach to the proposed research is that of grounded theory methodology. Therefore, as a theory was constructed over the course of the study as data was gathered to inform it, no specific theoretical orientation was selected for the research. This was consistent with the selected methodology and allowed the study approach to continually evolve to better suit the research needs of the grounded theory in development (Creswell & Poth, 2017). While the researcher himself was familiar with the medical field through working tangentially to it (in medical device design and testing), the researcher was also distinctly aware that the personal accounts and self-perceived difficulties of HCPs may be unexpected to him. The flexibility of not assuming a theoretical framework allowed for the open interview data collection method to be shaped by the data as it was gathered. To this end, it was important that

study participants were adequately assured of the confidentiality of the study to support and encourage their candid honesty throughout the interview.

Review of Topical Research Literature

Complex Systems Theory

Throughout time there has been a constant, though not consistent, progression towards more and more complex technology (Minai, Braha, & Bar-Yam, 2006). This progression does not simply see an increase in technological complexity, but also an increase in the complexity of the natural and urban environments in which it exists (Minai et al., 2006; Ogilvy, 2013).

Systems theory, in general, is used to describe a system in which components, or actors, work together to produce or accomplish some task that would be impossible using any one of the components on its own (Svítek, 2015). As systems grow in complexity, and involve more actors, those systems can achieve even greater results. However, along with the more ambitious goals of these systems, complex systems are also much harder to define. That is, it can be difficult or potentially impossible to list and understand every actor within a complex system as many of those actors may be, themselves, subsystems (Ogilvy, 2013). The complex system of concern may only be a piece of a larger, even more complex parent-system. The more variables and actors within the systems, the more unpredictable that system may be. But prediction, or at least estimation, is important for large, potentially safety critical complex systems.

Towards defining complex systems, such that one can make predictions and/or extrapolations based on them, there are two primary schools of thought: arrogant, and humble systems thinking (Ogilvy, 2013). Arrogant systems thinking holds that the pursuit of a systems understanding can yield total control of a system through the adjustment of key variables. Conversely, humble systems theory looks at the immense effort required to acquire that level of

systems understanding and deems the pursuit not just impossible to complete, but dangerous to pursue (Ogilvy, 2013). It is considered dangerous in that by attempting to understand and manage a complex system, one may ultimately change the system for the worse. Further, to achieve an understanding of a complex system, one must pursue a potentially unlimited string of sub-systems on one end, parent-systems on the other, and the entanglements between them all (Ogilvy, 2013; Svítek, 2015). As with many polar dichotomies (e.g. the nature vs. nurture argument), the truth of the matter cannot be proven and is likely a more moderate compromise. Both arrogant and humble systems thinking stem from the "shared recognition of the inter-connectedness of all things" (Ogilvy, 2013, p. 337). In summary, while arrogant systems thinking follows that inter-connectedness to the conclusion that you cannot fix one thing without fixing everything, humble systems theory concludes that because all things are inter-connected one may never be able to isolate the direct causes for complex effects within the system. Between these two modes of thinking: one may seek to influence, if not control, a complex system though the educated modification of its variables.

Human Limitation

Humans, themselves complex systems within systems, have their own complexities that human factors professionals must keep in mind when designing complex systems in which there will be a human component. "Human factors dominate the risks to complex installations" (Reason, 1990, p. 201). When considering complex systems in which the human component is integral, human limitation must be at the forefront of the discussion around system errors. Reason (1990) hypothesized that most accidents occur because of a failure in one or more of four domains: organizational influences, supervision, preconditions, and specific acts. Building on Reason's framework, commonly known as the "Swiss Cheese model", Shappell and Wiegmann

(2001), towards their Human Factors Analysis and Classification System (HFACS), break those four domains into five: preconditions for unsafe acts, substandard conditions of operators, substandard practices of operators, unsafe supervision, and organizational influences. The primary difference between these two sets of domains is the division of "specific acts" into "substandard conditions of operators" and "substandard practices of operators". This distinction adds to Shappell and Wiegmann's domains a belief stated elsewhere in Reason's work: that "the capacities for being stressed, failing to perceive hazards, being imperfectly aware of the system, and having less than ideal motivation are brought by each person into the workplace" (Reason, 1990, p. 206). This assertion of the human condition is especially troubling in safety critical fields such as aviation and healthcare (Shappell & Wiegmann, 2001; Fairbanks, 2013). A design focus on the human component is important for human reliability within complex systems (Boring et al., 2009).

However, if human error is to be viewed as an inextricable part of the human condition, one must turn attention to the whole of human cognition to see exactly in what ways human error may affect the performance of an operator. Cognitive psychology studies the underlying psychological and physiological processes that allow human beings to perceive, learn, remember, and think about information (Sternberg & Sternberg, 2011). While there are many factors that may push human cognition to its limits, and beyond, cognitive overload is one of the most prevalent, especially within stressful environments (Sternberg & Sternberg, 2011; Sweller, Ayres, & Kalyuga, 2011)

Cognitive Overload. Human cognition is the unique way that each human being perceives sensory information as it is relayed by neurocognitive structures in the brain using the metaphoric lens of all their past sociocultural experiences (de Waal & Ferrari, 2010; Han &

Northoff, 2008; Sternberg & Sternberg, 2011). Cognitive variance among human beings paired with the variability of complex systems contributes to the overall complexity of using humans as system components. Of course, human cognition is not immune to human limitation. Cognitive overload is a combination, typically of large quantity, of sensory information and mental processing that exceed one's current capabilities for effectively managing (Sweller, Ayres, & Kalyuga, 2011). This overloading could be the result of an influx of sensory information, a limitation of the working memory, faulty referential information, or a combination of a number of factors. Further, the limit to the amount of stress one's cognitive faculties can endure is not static and may be determined at any given moment. Depending on a myriad of psychological and physiological variables within the human actor, their cognitive potential may fluctuate significantly (Sweller, Ayres, & Kalyuga, 2011; Plass, Moreno, & Brünken, 2010; Wingfield, Stine, Lahar, & Aberdeen, 1988). To echo Reason's position on the human condition, through one's capacity for feeling stressed, inattentive, or demotivated, it is also a part of the human condition to be susceptible to cognitive overload (Reason, 1990).

Murphy and Wright (1984) studied the effect that task experience had on cognitive load. They found that higher levels of expertise in a task gave way to lower levels of cognitive load, and therefore lessened the chance for overload. It follows that an individual who is trying a task for the first time may experience elevated cognitive load. Biernat, Kobrynowicz, and Weber (2003) found that one possible effect of heavy cognitive load was an increased tendency to rely on mental stereotyping. Mental stereotyping can be useful in repetitive tasks in which the same method must be used frequently, but can be detrimental to new tasks. In fact, within safety critical systems, attempting to apply old mental rules to a new task may be dangerous. When

human performance falters in healthcare it opens the door for the introduction of preventable medical errors.

Preventable Medical Errors

A true cornerstone of research on preventable medical error in the United States of America was the Institute of Medicine's (IOM's) 1999 report, *To Err is Human*. However, this report sparked response through research and dissertation. Many studies with similar methods that followed sought to either localize the type of data presented in the IOM report to their own healthcare system or to modify the criteria by which the data was evaluated (Thomas et al., 2000; de Vries, Ramrattan, Smorenburg, Gouma, & Boermeester, 2008; Levinson & General, 2010; Classen et al., 2011). Because of the differences between each study on preventable medical errors, there is essentially no agreement on the exact incidence of this problem in American healthcare. Therefore, it is impossible to know for sure the trajectory of the continuing trend of incidence either, though it does not appear that the problem is being significantly remediated (Fairbanks, 2013).

One argument against this large body of research on preventable medical errors is that the sizable numbers presented by the papers are the result of extensive extrapolation (Institute of Medicine, 1999; Brennan, 2000; Dvorchik et al., 2000). These dissenters posit that the data from a sample of hospitals cannot adequately represent the diversity of medical culture across the country. Organizational culture influences not just the safety culture of a hospital but also the rate of reporting of adverse events (Brennan, 2000; Dvorchik et al., 2000). Dr. Troyen Brennan, one of the authors of the IOM report, stated in an editorial that "the [IOM] report and the accounts of it in the media give the impression that doctors and hospitals are doing very little about the problem of injuries caused by medical care. Yet the data that the report cites give a

different impression" (Dvorchik et al., 2000, p. 1076). Though the extent to which the problem exists is debated, it is generally accepted that any trend of medical error is one in need of attention (Institute of Medicine, 1999; Dvorchik et al., 2000). Studies around this topic provide a statistical blueprint for areas in healthcare that need improvement.

Preventable Adverse Drug Events (pADEs)

According to these studies, one of the leading modalities of medical error is medication related (Thomas et al., 2000; de Vries et al., 2008; Levinson & General, 2010; Classen et al., 2011). The pharmaceutical industry in the United States is growing due to the extensive use of medication both within hospital settings and at home (Levinson & General, 2010; Kanjanarat et al., 2003). Within the scope of pADEs, there exists still more specific causes, and plenty of opportunity for human error to creep into the medication process (Page et al., 2010).

The medication process, by design, incorporates several to many different participants. A prescribing doctor must issue the prescription, that prescription must then be filled accurately at a pharmacy, and finally the medication must be delivered to the patient (Page et al., 2010). This process may look very different depending on the type of medication, the type of ailment being treated, and the environment in which the patient is being treated (Kaushal et al., 2001; Page et al., 2010). Depending on at what point in this process the medication error occurs, it may take different forms and possess different potentials for severity.

An error on the prescriber's part may result in an incorrect medication, or a correct medication that reacts adversely to the patient's other medications (Page et al., 2010; Goldberg, Mabee, Chan, & Wong, 1996). An error on the pharmacy's part is the least common but may result in the incorrect filling of a medication (Keers et al., 2014). Finally, an error on the dispenser's part is typically most likely, though this role is not always played by a healthcare

professional. If the patient is sent home with a prescription from a doctor, they become the dispenser. It is at this level that we see the most difficulty. Healthcare professionals such as nurses who are dispensing the medication may need to attend to many patients at once, and manage a myriad of complex bed-side devices, stand the most at-risk for cognitive overloading (Page et al., 2010; Fairbanks, 2013). Conversely, patients sent home with medication, especially elderly patients, may forget or refrain from taking their medication, may take an incorrect dose, or may be receiving medications from multiple sources (Barber, Safdar, & Franklin, 2005; Qato et al., 2008; Fusco et al., 2009). For this study, only intra-hospital ICU medication difficulties will be studied.

Summary

The proposed research is founded on Reason's (1990) contention that a proclivity for error is inextricable from the human condition and that, therefore, the onus for risk reduction within safety-critical systems falls to the system's designer. The piloted use of a grounded theory methodology, as described in the proceeding chapter, allowed for the construction of a theory suggesting contributing factors related to human error within the complex system of healthcare. Specifically, the complex sub-system of the patient-drug use process will be the focus of the study.

The ever-more specific topics described above set the context in which the proposed research will address Reason's contention. First, and most generally, complex systems theory describes the variability of large and interconnected systems, such as patient-medicinal care, in which there are many components and actors. These components and actors may themselves also introduce to the system a degree of complexity depending on their own traits and limitations. The most complex system component is the human being.

Second, human limitation was discussed as it is the foremost effector of system error (Barber et al., 2005; Boring et al., 2009; Fairbanks, 2013). While any system component has its limitations, no component contains the sheer variability of limitation as the human actor(s) within a system. In fact, one's limitations can be viewed as a defining aspect of their identity. Further, a specific type of human limitation (cognitive overload) was discussed as the researcher believes it to be a likely contributor to preventable medical errors. A belief that was supported by the results of the research.

Ultimately, several studies on medical error were used to convey to the reader the breath and importance of the issue the research plans to address. The problem of medical error in the United States is pervasive and, while not uniformly defined, requires continued research and innovation. The specific vein of medical error to be addressed in the proposed research, preventable adverse drug events, incorporates to a broad range of human actors in the conduction of potentially complex, and cognitively heavy, tasks.

This literature review of complex systems theory, human limitation, and preventable medical error shall set the context in which the proposed study will examine human factors contributing to preventable adverse drug events in healthcare and construct a foundation for the construction of a grounded theory.

CHAPTER 3. METHODOLOGY

Purpose of the Study

The primary purpose of this study was to advance beyond a description of the problem of preventable adverse drug events in healthcare and to instead begin to develop a "unified theoretical explanation" (Corbin & Strauss, 2007, p. 107) for why this problem may occur (Creswell & Poth, 2017). To do so, this study relied on a grounded theory methodology to build the theory from the ground up.

Medical error, specifically medicinal error, is a complex problem that receives a relatively large amount of attention and study (Berwick & Shojania, 2015; Classen et al., 2011). Rightly so, medical practice is not only extremely commonplace, but can also be incredibly safety critical, and error within that practice may affect anyone indiscriminately (Kanjanarat et al., 2003; Page et al., 2010). However, given some of the disagreement around the specific attributes of the problem (Fairbanks, 2013), especially in relation to the dissonance of criterion between the studies (Classen et al., 2011), a fresh approach to the problem may be warranted.

That fresh approach had its genesis in the grounded theory qualitative methodology. Grounded theory is uniquely suited for forming new, unbiased perspectives as the essence of the approach is that the study's theory does not come "off the shelf" but rather is constructed or 'grounded' in data from participants who have experienced the process" (Creswell & Poth, 2017, p. 82).

Using the grounded theory methodology, this study begins to develop a descriptive understanding, from the HCP's perspective, of the human factors contributing to errors within hospital settings. Within that understanding, the researcher sought to identify and describe the factors contributing to HCP error, specifically preventable adverse drug events (pADEs), in

clinical environments. Finally, a theory was constructed that explains the interrelationships of the identified factors. Based on the presented theory, potential mitigations and implications are discussed that may contribute to the reduction of pADE incidence.

Research Design

Flick (2014) describes qualitative research as the exploring of phenomena 'from the interior' by using the perspectives of research participants as the starting point. Qualitative research attempts to interpret those phenomena within the context of the meanings that involved parties assign to them (Denzin & Lincoln, 2011). Further, a qualitative approach to research carries with it the recognition of the studied phenomena's complexity as results cannot be simply explained through numerical representation, but instead "events are the result of multiple factors coming together and interacting in complex and often unanticipated ways" (Corbin & Strauss, 2007, p. 8). Grounded theory research is equipped to capture the complexity of a phenomena's natural complexity as it builds itself around a multitude of participant perspectives (Creswell & Poth, 2017; Corbin & Strauss, 2007).

The grounded theory qualitative method, developed by Barney Glaser and Anselm Strauss and published in 1967, has since split into several distinct approaches because of disagreements about the meaning and procedures of grounded theory (Creswell & Poth, 2017). Grounded theory, in general, holds that theories should be situated (or "grounded") directly within data collected from the field. In this way, grounded theory provides for the construction of a theory of categories, consisting of the actions, interactions, and processes of individuals (Creswell & Poth, 2017). Currently, the two primary types of the grounded theory methodology are the systematic procedures of Corbin and Strauss (2015) and the constructivist approach of Charmaz (Bryant & Charmaz, 2010).

In Straussian grounded theory, the researcher seeks to employ systematic, analytical procedures to develop a theory that explains a process, action, or interaction, known as the research's core phenomenon, primarily by conducting interviews. These interview data are coded and categorized, and the research continues until the categories are saturated; that is, no new avenues of questioning are being revealed (Creswell & Poth, 2017; Corbin & Strauss, 2015). Conversely, the constructivist approach of Charmaz is typified by an emphasis on the researcher's view and discovery of hidden relationships and hierarchies of power, communication, and opportunity and does not focus on a single process or core phenomenon (Creswell & Poth, 2017; Bryant & Charmaz, 2010).

Because this research focuses on preventable adverse drug events within a hospital setting and the associated human factors, the Straussian approach to grounded theory is more applicable for its emphasis on a core phenomenon (Corbin & Strauss, 2015). Within the grounded theory methodology, no rigid organization exists as the research is meant to continually evolve to best fit the data being gathered. Data collection and analysis happen interchangeably throughout the study (Corbin & Strauss, 2015). Creswell and Poth (2017) describe this constant exchange as a "zigzag" process in which the researcher ventures out into the field to gather data and back into the office to analyze the data and adjust their collection method for the next visit to the field. In this, the constant comparative, method of data analysis, the interview method and treatment of participants can develop theoretically to better and more efficiently saturate the identified categories (Corbin & Strauss, 2015).

Though no universal order of methodological phases exists for the grounded theory methodology, there are several tasks that commonly take place sequentially: open coding, axial coding, categorization, and selective coding (Creswell & Poth, 2017; Corbin & Strauss, 2015). In

open coding, the researcher examines the collected data for any emerging categories. From these categories, the researcher employs axial coding to identify the core phenomenon of the research and then revisits the data to assign categorical meaning around the core phenomenon. These core phenomenon-centric categories are described by Corbin and Strauss (2015) as causal conditions, strategies, and consequences. In line with the qualitative importance of framing the research's subject within its own complexity, these categories answer the questions: what caused the phenomenon, what was done in response to the phenomenon, and what were the consequences of that strategic response (Creswell & Poth, 2017).

Target Population and Participant Selection

Grounded theory's constructivist properties necessitated the sampling of participants with first-hand experience with the study's focus so that a relevant theory could be created (Creswell & Poth, 2017; Corbin & Strauss, 2015). While it could not be guaranteed that every HCP within a hospital has experienced an adverse drug event with one of their patients, this study's sampling specifically sought out those HCPs who are regularly involved in the patient drug-use process. Specifically, HCPs who work in the Intensive Care Unit (ICU) of a hospital were of most interest to this study as their chief concern is the treatment and monitoring of critically unwell patients (Kanjanarat et al., 2003). Further, patients being treated in the ICU are most likely to be prescribed life-saving medicines putting them most at risk for adverse drug events (Kanjanarat et al., 2003; Kaushal et al., 2001). The HCPs involved in this process are typically doctors (MDs) and nurses (RNs) and may perform any combination of a myriad of tasks associated with patient drug-use (Page et al., 2011).

In order to gather a sample for this study, the researcher employed the use of a market research firm, which had a database of local HCPs. Based on a prepared screener that indicated

that participants must have current employment in a hospital ICU, the market research firm issued an open invitation in the form of an email. HCPs interested in participating in the study then filled out an online screener and received a call from the recruiter if they met all requirements for participation. Recruiting continued until the quotas of eight RNs and two MDs were met.

The deciding factor for these quotas was a financial one. As discussed previously, one of the limitations to this study was its budget, and that limitation primarily affected the recruitment of participants. Participants received an honorarium for their participation in the study that was relative to their professional qualifications. The specific compensation amounts for participants were based on industry standard and the recommendations of the employed market research firm.

While both RNs and MDs deal with the patient drug-use process within the ICU, their exact perspectives are very different from each other. In an ideal ICU, a bedside RN would be assigned to one or two patients (depending on patient acuity) whereas an MD may be expected to round all the patients in the unit (and potentially a few other units depending on the MD's position). To simplify, MDs may be seen as prescribers of medication while RNs are typically the administrators of said medicine. For that reason, it would be important to include both participant groups in the construction of a grounded theory. However, because a considerably larger honorarium was needed to recruit MDs, only two of that participant group could be sourced if the study was to maintain a minimum sample size of ten while also representing the unique perspectives of both RNs and MDs.

Procedures

Data Collection and Protection

The sole source of data used in this study was the guided interviews of the participants. Because of the sensitive nature of the subject matter of this study, it was important for the researcher to instill confidence in the participants' honest perspective through the assurance of strict confidentiality measures and care data protection. To follow through on his promises of diligence, the researcher took specific steps to ensure that neither the data nor the identities of the study's participants were compromised.

To record the interviews, audio recording devices were used. To protect against technical difficulties, audio from the interviews was digitally recorded in duplicate. The researcher reviewed the audio after the interview sessions and transcribed key portions or quotes. By alleviating the responsibility of taking constant notes during the interview, the researcher was allowed greater freedom to maintain the casual tempo of the interview while making small notes. Further, through transcription of the audio into text form, the researcher also gained a studied familiarity with the collected data, which aided in data congression and analysis. Any study data collected for a participant was labeled with a randomized participant number.

Data security. All physical data (interview protocols, note sheets, and consent forms) were scanned into PDF form and shredded immediately following each study interview. All electronic study data (audio, PDF, and text files) were stored on the ERAU provided OneDrive for Business online storage drive when not being actively reviewed. This method of storage allowed the researcher to increase data security by alleviating all physical copies of the data which could be misplaced or stolen, and password protecting the encrypted storage volume. Additionally, by using cloud storage, the researcher was able to access the data from anywhere

with internet. Use of the university provided OneDrive for Business was recommended by the IRB for this study and is consistent with the university's Cloud Security Policy. ERAU's IRB is registered with the Department of Health & Human Services and has been assigned the number IRB00005186. This research received the approval number #18-050 on December 11, 2017.

Interview Protocol

While no interview rubric was used for this study, an outline was used to aid the researcher in his investigational path (Stake, 1994). That outline evolved between participants as data from the previous participant revealed potential lines of questioning that would better reveal the emerging trends and categories of the data. The grounded theory methodology is constantly pursuant of categorical saturation in which additional interviews do not reveal any new categories (Creswell & Poth, 2017). To adequately investigate emergent categories, the interview outline needed to develop with the study, in ways that could not be predicted from its onset. Further, during each interview, categorical investigation was also served by departures from the outline. These egresses were at the researcher's discretion (Yin, 2006). The initial interviews were more general whereas later interviews maintained the broad questions while also delving into specific threads of questioning revealed from previous data. All interviews gathered demographic data on the HCPs such that their perspective may be contextualized.

Typically, grounded theory methodology employs continual sampling until the identified data categories become saturated and no new categories are emerging; that is, grounded theory does not typically follow-up with previous participants to explore new categories. While the first participants' interviews were more general than the final interviews, they also served a purpose that the final interviews did not: to set a foundation for the researcher to begin the theory's construction. However, because this study was unable to continually sample, participants were

given the option to be contacted regarding any further questioning that may help the researcher to explore emergent trends. Ultimately it was determined that follow-up was not necessary for the research.

Initial Interview Outline

1. Where are you currently employed?
2. What part of the hospital do you work in?
3. What is your current professional role? (or job title)
4. How long have you been in that role?
5. What degrees and/or certifications do you have?
6. How would you describe your interaction with patients on a day-to-day basis?
    a. What is your role in the ICU?
    b. How would you describe your interaction with patient's medications?
7. Who or what groups within the hospital would you identify as participating in the patient / prescription process?
    a. What would you say their individual roles are?
    b. What is communication between these different roles like?
8. How common are medication errors?
    a. Which role do you think is most likely to contribute to a medication error?
9. Have you ever been involved with an adverse drug event with a patient? (In the prescription or delivery of the drug? Or in the response to the event?)
    a. Can you tell me about that / those event(s)?
    b. What stood out to you as the cause(s) of that / those event(s)?
10. When / if a medication error occurs, what is the typical outcome?

   a. What is the hospital's reaction?
   b. Do you think that outcome is appropriate?
   c. How do you think that outcome effects future medication use?

11. Are there different types of medication errors? Different causes? Different outcomes?
12. In your opinion, what are the most effective ways to prevent medication errors?
13. How would you describe your familiarity with the medications your patients receive?
   a. How often do you run into a medication you've never heard of?
   b. Do you think that can lead to medication errors?
14. How would you describe the impact of medical devices on the medication process?
   a. How often do you work with a device you've never used before? Or a device that you may not be experienced with?
   b. To what extent do you believe medication delivering devices (like infusion pumps) can contribute to a medication error?
   c. Have you ever had difficulties with one of these medical devices?
15. Is it common for healthcare professionals to feel tired or exhausted at work?
   a. Do you think tiredness ever contributes to medication errors?
16. If you had to name one cause as the biggest cause for medication errors within the hospital, what would you say?
   a. Any runners-up?

Instruments

The primary instrument used in this research was the researcher himself. As the study's chief instrument, the researcher was both an instrument for data collection and analysis. In the vein of data collection, the researcher was experienced in the interviewing of HCPs as he is

regularly employed in the testing of medical devices through simulated use testing. In these studies, the researcher must moderate the session while being careful not to lead or bias the participants. Further, the researcher's ability to leverage constant comparative analysis was paramount to the study's aim of continually tightening the developing theoretical focus.

Beyond the researcher's own expertise, several other materials were present during the research for several purposes. First, an interview outline acted as a guide for the discussion, though strict adherence to the protocol was not necessary. The guide was meant to serve as a basis for the data being collected, not as a script to be read verbatim. The researcher leaned on his training in study moderation to create the natural, conversational tone that is necessary to set the participant at ease and allow for a free and honest discussion.

Data Analysis and Presentation

Data analysis happened in parallel to data collection in this study, as was necessary for the grounded theory methodology chosen. This analysis consisted of the coding and organization of data into emerging categories. Analysis of data throughout the study allowed for the efficient evolution of new interview focuses and the eventual construction of a theory. Theories produced by this type of study typically take one of several forms: "a narrative statement, a visual picture, or a series of hypotheses or propositions" (Creswell & Poth, 2017, p. 85). The researcher was the sole interview practitioner and data analyst. In this way, treatment of both the participants and the data remained consistent throughout the conduction of the study.

The chosen data presentation for this study relies on the graphical representation of the emergent categories around the core phenomenon. Through this type of presentation, the researcher is able to make connections between categories to form possible theories for the core phenomenon.

Researcher Expectations

The researcher chose a grounded theory methodology for his research question to pursue a unique theoretical explanation to the problem. Because that theory was meant to develop organically from the data collected and not from previous knowledge or hypothesis, the researcher had no explicit expectations for the results of the study.

CHAPTER 4. RESULTS

The Study and the Researcher

The purpose of Chapter 4 is to explain to the reader what data was collected, how it was analyzed, and present that data in an understandable manner. Given that this research used a grounded theory methodology, the sequential manner by which the data were treated was through open coding, axial coding, categorization, and selective coding. In this chapter, the primary emergent categories are introduced using an axial coding paradigm. From this data the researcher used selective coding to draw theoretical conclusions. Chapter 5 then discusses the implications of those conclusions.

Before delving into the results of this study, it is important to reiterate that this study represents a pilot endeavor into the use of grounded theory methodology to draw understanding of the complex issues facing healthcare professionals (HCPs) in the workplace today. Through the conduct of the study's 10 interviews, the researcher identified many potential categories; however, the researcher was not able to achieve data saturation in any of these categories. Therefore, while all categories will be listed for the reader to consider, only those with the most supporting data will be incorporated into the axial coding paradigm and selectively coded.

The researcher's professional background was the source of inspiration for this research. Currently employed full-time as a human factors engineer at a firm that regularly conducts studies on HCPs and healthcare technology, the researcher is continuously involved in the analysis of risk mitigation in the healthcare field through the design, development, and testing of cutting-edge technology. The pursuit of the degree of Master of Science in Human Factors was a logical step towards the development of an expert understanding of human experience within complex environments such as the intensive care units of American hospitals. The academic

requirements for this degree necessitated the researcher work individually on the study's planning and conduction, as well as the data collection and analysis.

Description of the Sample

Demographics of the Sample

Grounded theory research, regardless of the specific type, is typified by theoretical sampling. That's is, the continual sampling of participants driven by the data being collected and the categories that are emerging. However, grounded theory research does not naturally begin with any theoretical orientation. Therefore, as a pilot study, this research took the typical first step towards theoretical sampling which was purposive sampling. Purposive sampling is a sampling technique that relies on the best judgement of the researcher (Tongco, 2007). In this case the researcher chose to limit his scope to one specific type of hospital environment, the ICU, and to recruit RNs and MDs because they have frequent direct interaction with patients. If this research were to move beyond a pilot study and continually sample, the researcher may pursue certain participant demographics indicated, by the data already collected, as important stakeholders in the patient drug-administration process.

A demographic summary of the final sample population and details about their places of work is as follows:

- Department
    - Three RNs were employed in the Medical ICU (MedICU) of their hospital.
    - Two RNs were employed in the Neurointensive Care Unit (NeuroICU) of their hospital.
    - One RN was employed in the Cardiovascular ICU (CVICU) of their hospital.

  - One RN was employed in Mobile Pool team of their hospital and switches between contracts in any ICU in the network of hospitals.
  - One RN was employed at a hospital where they could "float" between ICUs as needed.
  - Both MDs round in several types of intensive care units at their hospitals.
- Professional Role
  - Five RNs were bedside nurses.
  - One RN was a charge nurse.
  - One RN was a nurse manager.
  - One RN was a shift supervisor.
  - One MD was employed as a Staff Hospitalist at their hospital.
  - One MD was employed as the Staff Attending Physician at their hospital.
- Experience and Education
  - RN experience ranged from 3 to 23 years.
  - Seven RNs had a bachelor's degree in nursing.
  - One RN had an associate degree in nursing.
  - Two RNs were actively pursuing a master's degree in nursing part-time.
- Five participants worked day shift.
- Four participants worked night shift.
- One participant worked both day and night shifts because they were in the process of switching professional roles.
- Six participants worked at the same hospital system.

- The recorded interviews lasted between 58 and 98 minutes, with an average time of 70 minutes.

Research Methodology Applied to Data Analysis

A detailed description of the research methodology chosen for this research can be found in Chapter 3 of this report. As described there, this study utilized a constant comparative data collection and analysis method. The researcher did not wait until the collection of all the data before beginning to conduct analysis. However, the type and thoroughness of the analysis did change depending on the stage of the research. Specific data analysis procedures employed in this study are summarized below.

During the active data collection phase:

- Before each interview was conducted, the researcher would review and finalize the interview outline to be used. This review included a study of the previous participant's notes (if applicable) to determine if any outline revision was necessary.
- During each interview, the researcher wrote shorthand notes on a scratch piece of paper to aid in the recall of insights during later data review.
- After each interview, the researcher listened to the audio recording of the interview and took more detailed notes, capturing insights and quotes where applicable. These were the notes used to shape any changes to the subsequent interview foci.

After all interviews were completed:

- The researcher initially evaluated each participant's notes for any observations directly relating to medication errors, specifically noting causes, strategies, and consequences associated with the pADEs. As the researcher collected and coded these data into common threads, he amassed a collection of broad and specific categories to describe the

totality of the problem as it was recorded in the interviews. This stage of analysis helped to solidify the researcher's understanding of what was happening in the data.

- From that general coded data, the researcher determined the apparent core phenomenon. The category to which most of the causes, strategies, and consequences all related.
- Following that determination, the researcher employed axial coding to construct a paradigm in which the core phenomenon is described by its causal conditions (the factors that caused it), its strategies (the actions taken in response to it), its contextual and intervening conditions (the broad and specific factors that influence it), and its consequences (the outcomes from using the strategies) (Creswell & Poth, 2017). These prescriptive overarching categories are consistent with the grounded theory methodology of Strauss and Corbin (1990). During this stage of focused coding, significance and frequency of codes were primarily considered.
- Finally, in selective coding, the researcher drew hypotheses through the connection of the categories presented in the paradigm.

Axial Coding Paradigm

Corbin and Strauss describe the coding and categorization process at the heart of grounded theory methodology as "doing analysis and denoting concepts to stand for data" (2015, p. 216). As data was gathered, trends were uncovered and classified by the selection of certain conceptual terms that would catch large collections of data points. The more data that fell under a conceptual term (e.g. communication errors) the more supported that term, or category, became. However, as this methodology also relies on the researcher as its chief instrument, a primary category may be only supported by a few data points if the researcher determines them to be significant within the context of the study.

> Medication problems are the biggest concern within any of the units … by virtue of the fact that each patient is on so many different medications, there is a potential for incorrect dosage, incorrect route of administration, drug interaction, or drug allergy. (Participant 96, personal communication, January 2, 2018)

This study focused on the problem of pADEs within American ICUs and their potential causes. Additionally, for this study, this research also took the general perspective that the environments in which HCPs work, not the HCPs themselves, are primarily at fault for these pADEs. Certainly, there is a range of HCP professionalism and diligence within the healthcare system, as is the case with any system involving human actors, but this notion is supported by the Participant 16's remark, "these are good people, they come into work to do good things, not to make mistakes" (personal communication, December 16, 2017).

According to Straussian grounded theory, it is typical for the researcher to identify an open coding category to focus on and create additional categories around that *core phenomenon* (Strauss & Corbin, 1990). Further, Strauss and Corbin prescribe those categories around the core phenomenon as causal conditions, strategies, consequences, and contextual and intervening conditions. The core phenomenon must connect to the overarching question or problem of the study, while the underlying categories must explain the core phenomenon.

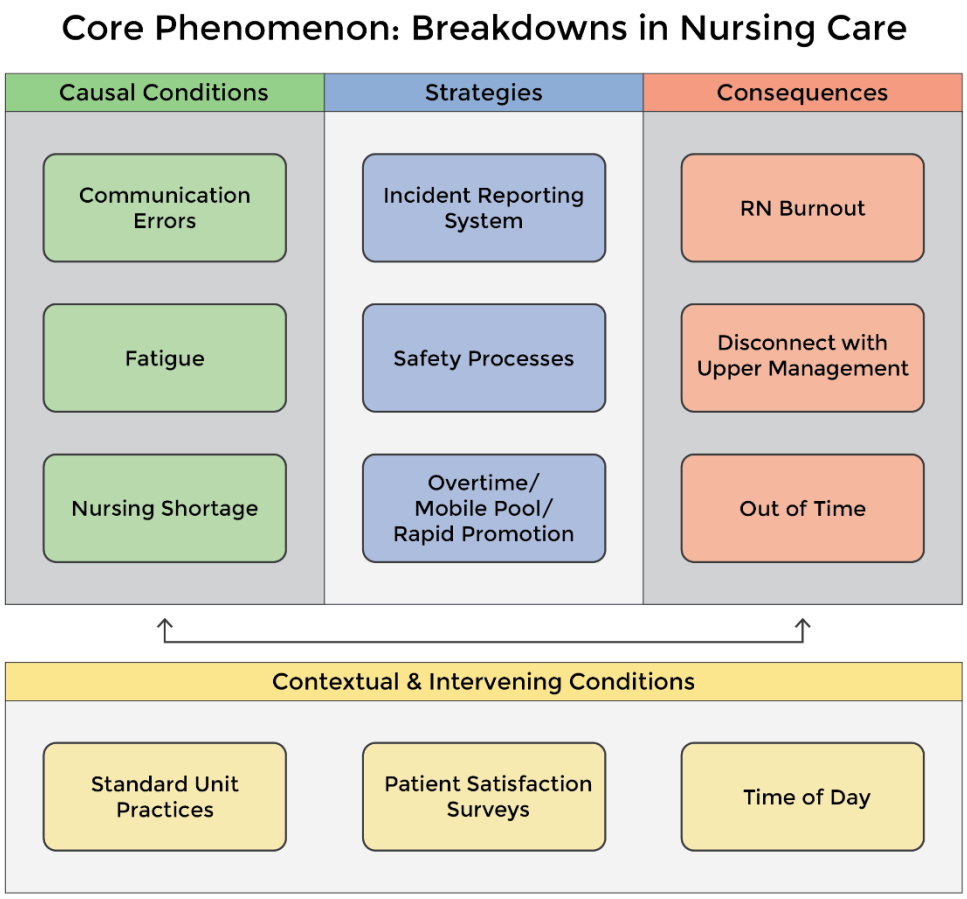

Figure 1. The Axial Coding Paradigm. Emergent data categories are organized by the specific roles they play in the core phenomenon. Arrows illustrate that many of the causal conditions could be considered consequences and vice versa.

Core Phenomenon

The data gathered in this study indicates that breakdowns in nursing care are the primary cause for pADEs in ICU patient care. These break downs include mistakes, lapses, and slips, and are due to a myriad of environmental and institutional factors.

"So much has been put on the nursing plate that they can't keep up, so they're tasking as fast as they can" (Participant 9, personal communication, December 17, 2017).

"Everyone has their days, we call them the night from hell when everything breaks loose" (Participant 69, personal communication, January 6, 2018).

From the interviews conducted, it was unambiguously apparent that the nursing profession, specifically within ICUs, is at a grave disadvantage to its surrounding conditions. “[Nurses] are the front line” (Participant 86, personal communication, December 21, 2017) and as such are oftentimes the last gate keeper between an adverse drug and a patient. Even if a mistake happened earlier in the patient drug-use process, it will almost always come down to the administering RN to catch the mistake. "It's like a game of telephone, the more hands something goes though, the better chance it will get messed up" (Participant 89, personal communication, December 19, 2017).

Several participants stated that their hospital practices evidence-based medicine. Evidence-based medicine is the integrating of individual patient care with the best available external clinical evidence from systematic research (Sackett, 1997). As the RNs are not prescribing or making the same patient plan decisions that the MDs would be, this evidence-based medicine is primarily seen in the many safety procedures set in place to aid the RN in the mitigation of potential patient risks, including pADEs. An example of these safeguards that came up frequently in the study’s interviews is the electronic scanning of almost every aspect of patient care into the patient’s medical record via a computer on wheels (COW). Before a patient is given any medicine, the patient’s wrist band must be scanned, and the medication must be scanned as well. Then, if the medication is to be hung as a drip, the RN must scan the IV pump and select/confirm the pump’s settings. If “it's when they deviate from the process that's in place, that's when the errors happen” (Participant 16, personal communication, December 16, 2017),

the fact that errors continue to occur suggests that HCPs are deviating from the established safety processes.

Causal Conditions

Towards the definition of the core phenomenon, breakdowns in nursing care, several key categories emerged as causal conditions.

Communication errors. Communication errors were commonly described by participants as breakdowns in communication between themselves and other members of the patient medication process (i.e. MDs, pharmacy, other nurses). The focus of this issue appeared to be around the order of medications. While it is hospital policy for MDs to be the ones to place medication orders, verbal orders, though discouraged, do still happen. Participants indicated that a physician's percentage of verbal orders to manually entered orders is tracked by the hospital, but that that information is not available to the public. Ideally, verbal orders are given only when an MD is not able to access a computer (e.g. an RN calls them during night shift), however participants indicated that some MDs, specifically older MDs, were resistant to using the computer system themselves. Verbal orders present an opportunity for breakdowns in nursing care through increased responsibility and pressure on the position.

"There are some doctors you don't want to take a verbal order from because they would later claim 'that's not what I said'" (Participant 86, personal communication, December 21, 2017).

"It's like you're caught in the middle of this firestorm all the time" (Participant 9, personal communication, December 17, 2017).

Fatigue and exhaustion. Another causal condition apparent from the data was that of fatigue and exhaustion playing a role in the breakdown of nursing care in the ICU. Patients are in

constant need of nurses. While other professions may be able to take the night or weekend off, nursing and healthcare in general must keep going ad infinitum. Because of this need to provide healthcare 24 hours a day, seven days a week, the healthcare industry work shift norm is 12 hours (Geiger-Brown et al., 2012). Further, these are not easy shifts: “There are days where you don't get a break at all … you're not supposed to eat at the desk, so you end up throwing food in your mouth while you’re running. Days where you don’t go to the bathroom for 10 hours” (Participant 86, personal communication, December 21, 2017).

Night shift presents a unique proclivity for exhaustion in that many nurses shift their sleep schedules back to a regular schedule on their days off. Participant 69 indicated that they have worked night shifts for about 17 years so that they could be there for their children (personal communication, January 6, 2018). By working night shifts, Participant 69 was able to drive their children to and from school during the day and then work at night. However, Participant 69 also indicated that at times they were so tired driving from work after their shift that they felt unsafe.

Compounding the aforementioned issues contributing to fatigue in nursing care, the study’s interviews suggest that there is typically a large amount of overtime opportunity. “You sign up [for overtime] because you know that if somebody doesn't sign up on those days, everybody is going to be tripled. Or you might end up with someone in the unit who's not really trained properly, you'll get floats or someone like that because you need a body” (Participant 86, personal communication, December 21, 2017).

“Fatigue predisposes to medical errors” (Participant 96, personal communication, January 2, 2018).

Nursing shortage. Perhaps one of the reasons there is such a high amount of overtime available to nurses is because of a nursing shortage. This causal condition manifests itself in several negative ways that contribute to breakdowns in nursing care. “I think all of the hospitals are collectively just trying to get proper staff. I think that's a goal of any hospital, just to be adequately staffed. For safety and for retention of the nurses” (Participant 56, personal communication, January 7, 2018). Several participants indicated that there are high rates of nurse “burnout” due too high workloads placed on the profession. “You see a lot of turnover or you see a lot of nurses go the traveling route which you make 2 to 3 times the amount of money and you can work at more functional hospitals” (Participant 53, personal communication, January 4, 2018). However, it would seem that this high level of nursing staff turnover is primarily affecting new nurses who are entering the field. Participant 34 indicated that new nurses will cycle out whereas experienced nurses who have been around for some time will keep working (personal communication, January 10, 2018). This dynamic suggests that there is a perpetual level of inexperience being locked in these ICUs as new nurses are trained only to leave and be replaced by more new nurses.

"[As nurses] we're supposed to know what procedures are appropriate, what medications are appropriate, but when you're new, and we have a lot more new nurses now, 80% new nurses, things don't come easy and quickly" (Participant 9, personal communication, December 17, 2017).

Strategies

Strategies are actions taken in response to the core phenomenon (Creswell & Poth, 2017). These strategies may be protocols within the hospital for dealing with incidents resulting from a

breakdown in nursing care, or they may be attempts at the mitigation of the breakdowns in the first place.

Incident reporting. One category that was unanimously touched on in the study's interviews was that of the hospitals' incident reporting systems. While most participants indicated an understanding for the necessity of such a system, many voiced opinions around issues with the system. The two primary issues raised with incident reporting were that the systems had a very negative connotation and that nurses were not always sure that the reporting system worked or was worthwhile.

"We put the reports in, and we don't know where they go" (Participant 16, personal communication, December 16, 2017).

"If a nurse is likable, people will not report their mistakes as much" (Participant 9, personal communication, December 17, 2017).

"They're so long a tedious, at the end of the day it's the last thing you want to do so a lot of times you just skip over them" (Participant 53, personal communication, January 4, 2018).

Safety processes. In a safety critical system such as ICU healthcare, there are many safety processes in place to protect that patients and the HCPs. Many of this study's participants expressed faith in the fact that these processes do effectively prevent medical error, however these participants also indicated that processes are not always able to be followed for various reasons. For instance, causal conditions may negate the intention of these safety processes by preventing RNs from following them (e.g. a fatigued nurse may forget to do a process). Whether it be ignorance of the processes because there are frequently inexperienced nurses working in the ICU, or just not enough time to go through the "cumbersome" safety steps (Participant 16, personal communication, December 16, 2017).

"I don't care, I'm just going to grab it, I'll fix the discrepancy later" (Participant 9, personal communication, December 17, 2017).

Methods for mitigating nursing shortage. As discussed in the Causal Conditions section, the nursing shortage is affecting breakdowns in nursing care through the increased stress it puts on the nurses remaining in the workforce and the constant turnover it incites. In the conduct of this study's interviews, several strategies have been identified as responses to this problem. Though, some of these strategies may themselves be somewhat causal conditions as well. In fact, the first response to a shortage of nursing staff is the increase of overtime opportunities which has already been mentioned as a causal condition for fatigue in the workforce.

The nursing shortage has also lead institutions to develop "mobile pool" programs in which a nurse may not be tied to any one department or unit but may move semi-freely between units as needed. Participants indicate that many new nurses "go where the money is" and join the mobile pool (Participant 69, personal communication, January 6, 2018). A downside to this strategy is that nurses in mobile pool may need to learn the specifics of a new department much more frequently.

"There's always some kind of learning curve" (Participant 56, personal communication, January 7, 2018).

"As soon as I was off training, after a couple months they start you on night shift, and after only a couple of months of being on night shift they were trying to throw me into a charge nurse role" (Participant 53, personal communication, January 4, 2018).

Consequences

In Straussian coding, the consequences are typically the results of using the strategies. As seen in a few instances above, some of the codes selected from this study's data may cross over into several categories. For instance, overtime opportunities have already been discussed both as strategy responding to the nursing shortage but also as a potential causal condition for nurse fatigue in the workplace. There is even more overlap between the consequences category and the causal conditions category. An overlap of these two categories indicates a cyclical system such that a problematic RN work environment will continue to breed more of the same issues.

RN burnout. An example of this, high nurse turnover rates, may be the result (consequence) of excessive workload or fatigue but may also be a causal condition for other types of nursing breakdown factors (e.g. the presence of many inexperienced RNs in the workforce).

"The older nurses that put all the time into training the younger nurses are just done because they are tired of training and then training a new one, and it's that same feeling of uneasiness. Not trusting or being able to leave somebody without worrying" (Participant 53, personal communication, January 4, 2018).

"It's kind of hard, nurses come in, they get their experience and then they leave for greener pastures, or what they think is going to be a better opportunity" (Participant 56, personal communication, January 7, 2018).

Disconnect with Upper Management. This study also indicated, in some interviews, a dissatisfaction with the upper management in the hospital. While there is typically a hierarchy of HCPs on the unit (bedside nurse, charge nurse, etc.), incident reports and hospital policy are dealt with and dictated by hospital management. This management, as indicated by Participant

34, can cycle through the hospital relatively quickly, enacting “sweeping changes” and then moving on to different opportunities (personal communication, January 10, 2018). Management was also described by participants as very budget focused. This budgetary focus may itself feed into the cycle as a causal factor if it is responsible for the hiring or scheduling of less nurses.

Out of Time. Time is a large factor in nursing care and of the consequence categories identified in this research it is the one most likely to be both a consequence and a causal condition. "Nursing is always a time factor. We work 12-hour shifts, there's so much to do in that timeframe" (Participant 16, personal communication, December 16, 2017). Many participants indicated that the breakdown in nursing most likely to cause a pADE would be cutting corners or ignoring safety procedures. It is also supported that these corners are cut for two primary reasons, emergent and non-emergent. During an emergency, typical safety procedures take a back seat to primary patient care. “I think we decide that we're going to save lives before we're going to do 'computer stuff'. It's definitely a conscious choice” (Participant 16, personal communication, December 16, 2017). As time is critical in these situations and there is an increased amount of HCPs present, most of this study’s participants indicated that they believed skipping these “cumbersome” processes was the safer choice. “I don’t even think I would think twice about scanning the medication … I think it would be unsafe [to do the process]” (Participant 53, personal communication, January 4, 2018).

“[In an emergency,] you don't always get [the medication] from where you're supposed to get it” (Participant 86, personal communication, December 21, 2017).

Even in non-emergent situations it can feel like “you're managing a crisis here, and then turning around and managing another crisis” (Participant 9, personal communication, December 17, 2017). Some of the participants in this study indicated that a drive for efficiency and time

management could result in cutting corners on safety processes. “I'm so busy right now, this is faster” (Participant 89, personal communication, December 19, 2017). This time crunch may also be exacerbated by a shortage of ICU staffing as RNs would have to take on additional patients. “I have heard stories of other hospitals...I couldn't imagine taking care of more than two critical care patients” (Participant 69, personal communication, January 6, 2017).

“Disorganization can make a stressful schedule dangerous” (Participant 86, personal communication, December 21, 2017).

Contextual and Intervening Conditions

Several contextual and intervening conditions were categorized from the data collected. While some of these conditions could be viewed through the lens of a causal condition, a strategy, or a consequence, the researcher determined that these categories primarily act to modify the effect of the strategies used. These categories should explain the context in which the core phenomenon occurs (Creswell & Poth, 2017).

Standard ICU practices. “It almost becomes routine, a lot of the stuff we use” (Participant 16, personal communication, December 16, 2017). “All types of units have distinct types of complicated … each unit has its own unique worst-case scenarios” (Participant 96, personal communication, January 2, 2017). The regularity of HCP practice within different ICUs (MedICU, NeuroICU, CVICU, etc.) can be a support to patient care in that experienced RNs can become very familiar with certain patient conditions they may see on a regular basis and enact more proactive patient care. “You need to know what's going on with your patients … does the medication make sense” (Participant 16, personal communication, December 16, 2017). On the other side of the spectrum, the specialized nature of many ICUs may create a barrier for entry for new nurses or nurses that transfer from a different work environment. The data shows this is

particularly an issue with RNs who move from unit to unit regularly. These RNs must become capable at everything while becoming an expert at anything is more difficult.

Patient satisfaction surveys. "You're managing a patient who is extremely ill, you're trying to emotionally support their family, and explain to them in a way they can understand, and [so] they still leave liking you" (Participant 9, personal communication, December 17, 2017). In 2002, through the efforts of Medicare and the Hospital Quality Alliance, Hospital Compare was created (Centers for Medicare & Medicaid Services [CMS], 2016). Hospital Compare is a website for the American public to access quantitative and qualitative information on how well hospitals in their area are performing. Data for this website is driven by both statistics and patient/family surveys (CMS, 2016). This study's participants had mixed opinions of the net result of these surveys on the level and type of care that HCPs provide to patients. It was brought up several times that what's best for the patient may not always be what the patient wants to do in the moment but because of the risk of a patient leaving a poor review, RNs may be less likely to push the patient towards their own recovery. "I'm not going to force [a medication] down someone's throat who doesn't want it" (Participant 34, personal communication, January 10, 2018). Conversely, patients or families may want what is not good for them (e.g. pain medications) and "instead of explaining why not, [RNs will] just say 'okay, sure', because they want them to like them" (Participant 9, personal communication, December 17, 2017).

"If a patient complains, they could 100% manipulate the nursing staff" (Participant 56, personal communication, January 7, 2018).

Time of day. A major contextual factor to RN care is simply the time at which the care is taking place. Depending on what shift and on what day of the week an RN is working, that RN may have access to a significantly distinct set of resources. Between the three main pillars of the

intra-hospital drug use process (MD, RN, and Pharmacy), the RNs' responsibilities appear to be the least effected by the time of day. Both the pharmacy and MD staffs are greatly reduced during night shift. Instead of potentially having a pharmacist on every unit, during nights and weekends pharmacy may be reduced to the hospital's central pharmacy. So too does the MD staff change during the night. Participants indicated that if a patient needed a med ordered in the night the RN would need to call the patient's physician. Not only might the MDs not always be reachable, but this increases the frequency of verbal orders being given.

Theoretical Selective Coding

In selective coding the researcher is tasked with drawing meaning, or a proposition from the axial coding paradigm to answer the study's research question (Creswell & Poth, 2017). This thesis research was designed to answer the question: "*What are the human factors contributing to preventable adverse drug events in hospital settings?*"

What become most apparent in the analysis of data, codes, and categories is how interconnected the complete system of medicinal patient care in a hospital environment really is. This interconnection is consistent complex systems theory as a change in one part of the system is likely to produce a result that is not always entirely predictable (Ogilvy, 2013). Truly, it is impossible to separate any of the categories identified from the entire context of the system. The stand-out categories presented above represent some of the most commonly touched upon as well as some of the most significant data collections that the researcher identified. However, this dataset was not saturated. If the researcher were to draw a theory from the paradigm, despite the research being a pilot of the grounded theory methodology, it would be that preventable adverse drug events in the hospital setting, specifically the ICU, are caused by breakdowns in nursing care, and that these breakdowns can be attributed to an incredible workload that causes RNs to

ignore safety processes. Finally, the result of these breakdowns further exacerbates their own causal conditions through RN burnout.

CHAPTER 5. DISCUSSION

This chapter's purpose is the discussion and framing of the data presented in Chapter 4. Because the research presented represents a pilot study of a unique methodological application, a primary aspect of this discussion is around the efficacy of the grounded theory mythology for this application, limitations of the research due to its short pilot status, and potential routes for future research.

Discussion of Results and Methodology

In summary, the objectives of this research were three-fold: to take a detailed look at preventable adverse drug events (pADEs) in healthcare as they really occur, to pilot the use of grounded theory methodology in the study of these events, and to develop a theory of the causes of pADEs within the intensive care units of American hospitals. The researcher believes that he was successful in the accomplishment of all three.

To obtain a detailed look at preventable adverse drug events in healthcare as they really occur, the researcher had to look beyond the quantified data amassed around the issue and instead listen to detailed, personal accounts of the lived experiences of HCPs, from HCPs. To the researcher, these interviews gave a very real sense of the frustration, the hard work, the pride, and the many other emotions HCPs might feel in the conduct of their work. Through the use of direct participant quotes, this research's categorical paradigm was given a sense of the gravity of some of the issues facing the healthcare industry's nurses today.

As a pilot of the use of grounded theory methodology to study the workplace causes for pADEs within ICUs, this research succeeded in proving that the methodology could be used to effectively reveal trends and open pathways for future research. The most effective aspect of the chosen methodology was the fact that it did not start with any predisposed theoretical framework

or hypothesis. RNs and MDs could speak freely about their broad experience as an HCP and the researcher was allowed to pursue new routes of questioning as they became apparent. This supported the success of the first objective in that it allowed for the collection of a more complete picture of the participants' lived experience and perspective.

In developing a theory of the causes of pADEs, within the intensive care units (ICUs) of American hospitals, this research also succeeded. To develop and inform a theoretical stance based on the data gathered, to *ground* a *theory* in the data, was a goal consistent with the application of grounded theory methodology.

Practical Implications of the Research

The regularly cited work, *To Err is Human: Building a Safer Health System* grabbed the attention of so many because of the staggering frequency of medical errors that were reported. Additionally, within their 1990 report, the Institute of Medicine issued a call for the 50 percent reduction in medical error over the proceeding five years. Following the IOM report others have attempted to analyze the same problem but with different measurement methods and locations of study. Though these differences in research may arguably prevent the direct comparison of the studies, it is apparent that the problem of medical error has not gone away (IOM, 1999; Thomas et al., 2000; Levinson & General, 2010; Classen et al., 2011). This study, specifically focused on a type of medical error, pADEs, suggests the same.

Another practical implication of the research is that the problems noted will continue as they are a product of themselves. Seen clearly in the demonstrated axial coding paradigm, the emergent categories are not disconnected from one another. Instead, they are vastly interconnected. Consequences may themselves be causal conditions and vice versa. The cyclical

nature of this system of codes and categories suggests that the difficulties and dangers to patients will continue until change is enacted on the system.

Theoretical Implications of the Research

Though this study did not take a theoretical framework, one primary assumption shaped the focus of the research. This study assumed that healthcare errors were the product of human limitation, not of HCP disregard or negligence. Reason (1990) states that "the capacities for being stressed, failing to perceive hazards, being imperfectly aware of the system, and having less than ideal motivation are brought by each person into the workplace" (Reason, 1990, p. 206). These "capacities" are a part of the "human condition", as Reason calls it, and cannot be separated from a human's performance within a complex system or workplace. This research supports the validity of the assumption. Participant 16 was quoted as saying, "these are good people, they come into work to do good things, not to make mistakes" (personal communication, December 16, 2017). The data collected suggests a sentiment in tune with this quote: that HCPs work hard to help their patients, not to cause harm. Therefore, the fact that harm still occurs, and mistakes are still made, implicates human limitation and flaws in systemic resiliency as the culprits.

Methodological Discussion

Though the use of grounded theory methodology in the study of healthcare practice, specifically nursing practice, is not new or unique, use of the methodology to help explain preventable adverse drug events (pADEs) was a largely novel use. The discussion around pADEs is a principally quantitative one with counts and statistics around locations and incidence (IOM, 1999; Thomas et al., 2000; Levinson & General, 2010; Classen et al., 2011). The researcher

chose grounded theory methodology in the hopes that a qualitative approach to the problem would bring informative color to the already established quantitative issue.

It is the researcher's belief that this study was a success because the pilot of the methodology proved effective in its application which suggests that it would be valid for future, larger applications. The categories identified in this pilot study could certainly be further explored in additional grounded theory studies. What was an analytic difficulty for the researcher, the sheer amount of data collected over the 10 open interviews, equates to an assortment of academic possibilities for future, potentially more specific, research endeavors.

The reason this pilot generated so much insight and research leads was largely due to the unique benefits of the chosen methodology. Because the methodology does not initiate with any specific theoretical orientation or hypotheses to be tested, the methodology remained open to following wherever the data may lead.

Limitations

Five limitations were present in the conduct of this research, some of which were mentioned earlier in Chapter 1. There was also a delimitation to this study that should be considered. Despite these limitations, the researcher achieved what he set out to achieve, but it is important to note any factors that may influence the reader's confidence in or interpretation of the data. As discussed in Chapter 1, the limitations on this study, specifically the time and economic constraints, drove it to be carried out as a pilot study.

The first limitation to this study that should be discussed is the incomplete sampling of participants. In a typical grounded theory research study, theoretical sampling must continue until categorical saturation is achieved, that is, no new categories are emerging from the data (Creswell & Poth, 2017). This study was limited to the sampling of 10 HCPs and relied solely on

purposive, not theoretical, sampling. Had the study been able to continue, emergent data trends from these first 10 participants would have informed the continued sampling of further participants (i.e. theoretical sampling).

Tied to the first limitation, the second is in the research's ultimately broad focus. Because the research was not able to continue sampling new participants and building its data set towards categorical saturation, the result was left somewhat less focused and more suggestive than ideally desired. However, given that this was a known limitation of the study, the research is still valuable to its field through that exact suggestive quality. With open ends, and unsaturated data, there are plentiful opportunities to build on the research.

A third limitation that became apparent to the researcher during the conduct of the study was in the variance of hospital policy and procedures between institutions. Differences in the policies of participants' hospitals ranged from simple differences in employee engagement programs to foundational discrepancies in emergency response protocols. Because this variance can possibly be magnified exponentially in the scope of the whole of American healthcare, the study may have been able to produce more tailored results had all the participants come from the same institution.

Another limitation was in the exclusive use of interviews as the data collection method in this study. "The use of interviews as the only means of data collection in grounded theory studies can result in researchers concentrating on the lived experience of participants instead of focusing on the social processes that take place through time" (McCann & Clark, 2003, p. 20). Glaser (1992) suggests that for proper grounded theory study to take place, it is vital to have observational data as well as interviews to discover the meanings of the participants. However, as previously discussed, there are several schools of thought in grounded theory academia and

other researchers do not hold Glaser's same views on the necessity of observational data. Straussian grounded theory, the school of thought followed by this research, is commonly not augmented by observational data (Strauss & Corbin, 1990; Creswell & Poth, 2017). This study's time constraints and the fact that the researcher does not have academic access to any healthcare facilities prevented the collection of observational data for this study.

A delimitation to this study presents itself in the decision to run the research as a paid research study. This decision was born out of necessity as the researcher did not otherwise have access to a healthcare facility or a group of healthcare professionals willing to be sampled. Additionally, in his professional career, the researcher commonly designs and runs medical device research studies in which the participants are paid for their time and participation. However, for this research, the paid status of the participants must be discussed as it could theoretically lead to participant bias. This bias could come in the form of answers that participants believed the researcher most wanted to receive. To mitigate this potential bias, the researcher assured all participants that they would be compensated regardless of their responses, regardless of their level of openness, and regardless even of the duration of the interview they stayed for. All participants were informed that they could discontinue their participation at any point, for any reason, without forfeiting their compensation. No bias was noted by the researcher. While participants were very forthcoming with information, the researcher attributes this to the same sentiment that Participant 16 remarked on: "these are good people, they come into work to do good things, not to make mistakes" (personal communication, December 16, 2017). As such, the researcher's impression is that the recruited HCPs were as open as they were about medical error because they honestly wanted to see educational advancement.

CHAPTER 6. RECOMMENDATIONS AND CONCLUSION

Recommendations for Further Research

Tied to this research's primary objective, to pilot the use of grounded theory methodology to address pADEs in intensive critical care units, is the understanding that this research was also meant to produce actionable recommendations for further research. The researcher has defined several potential avenues for subsequent investigation.

Future research could apply grounded theory methodology to the study of pADEs within a specific hospital or hospital system where safety protocols are uniform. This would allow the researcher to focus on a specific action or process without needing to account for potentially wide variance from hospital to hospital.

Additionally, research studies could apply grounded theory methodology to the study of pADEs within a specific work shift. Data gathered in this study suggests that the resources available to HCPs change drastically from day shift to night shift. It may be valuable for future studies to evaluate and identify which resources are most vital and therefore should be constantly available and consistent.

Future researchers might also select an emergent category from this study's data and use it as the focus for an additional grounded theory study. If the researcher were to build upon this research himself, he would run a new grounded theory study but focus specifically on the issue of RNs skipping safety processes. Grounded theory could be used to build a theory from the ground up that explains the reasons and organizational culture behind those actions.

A final, non-grounded theory approach, to future research endeavors could be evaluate what human factors systems and solutions have been applied outside of the healthcare field that could be used to address the issues (categories) identified in this study. Specifically, there has

been notable success in the application of aviation best practices in the medical field. This is exemplified by the application of crew resource management, which was originally developed for aircraft cockpit management, within hospital departments such as operating rooms (Kasper & Jentsch, 2016). The aviation industry has also already researched pilot fatigue and implemented national guidelines to prevent this fatigue from resulting in danger. As one of the emergent causal conditions introduced in this study was that of fatigue in nursing practice, aviation human factors may again be applicable and a stimulating subject of future research.

Conclusion

Data from HCPs working within the ICUs of local hospitals was used to construct a theory for the cause of pADEs. To achieve this, the research piloted a novel methodological application using grounded theory that yielded a significant amount of data about the causal conditions, responsive strategies, consequences, and contextual conditions defining the problem. From these major categories, the researcher identified and explained several sub-categories which represent specific potential issues with ICU safe-practice. While this study was a pilot study, it was ultimately valuable in pointing the way forward for future research of the topic.

REFERENCES

Barber, N., Safdar, A., & Franklin, B. D. (2005). Can human error theory explain non-adherence?. *Pharmacy world & science*, *27*(4), 300-304.

Berwick, D. M., & Shojania, K. G. (2015). Free from Harm: Accelerating Patient Safety Improvement Fifteen Years after To Err Is Human. *Boston, MA National Patient Safety Foundation*.

Biernat, M., Kobrynowicz, D., & Weber, D. L. (2003). Stereotypes and shifting standards: Some paradoxical effects of cognitive load. *Journal of Applied Social Psychology*, *33*(10), 2060-2079.

Boring, R. L., Roth, E., Straeter, O., Laumann, K., Blackman, H. S., Oxstrand, J., & Persensky, J. J. (2009, October). Is human reliability relevant to human factors?. In *Proceedings of the Human Factors and Ergonomics Society Annual Meeting* (Vol. 53, No. 10, pp. 610-614). Sage CA: Los Angeles, CA: Sage Publications.

Brennan, T. A. (2000). The Institute of Medicine report on medical errors—could it do harm?. *New England Journal of Medicine, 342*, 1123-1125.

Bryant, A., & Charmaz, K. (2010). Grounded theory in historical perspective: An epistemological account. *Handbook of grounded theory*, 31-57.

Centers for Medicare & Medicaid Services (U.S.). (2016). Hospital compare: A quality tool for adults, including people with Medicare. Washington, D.C: United States, Dept. of Health & Human Services.

Classen, D. C., Resar, R., Griffin, F., Federico, F., Frankel, T., Kimmel, N., Whittington, J. C., Frankel, A., Seger, A., & James, B. C. (2011). 'Global trigger tool'shows that adverse

events in hospitals may be ten times greater than previously measured. *Health affairs, 30*(4), 581-589.

Corbin, J., & Strauss, A. (2007). *Basics of qualitative research: Techniques and procedures for developing grounded theory* (3rd ed.). Thousand Oaks, CA: Sage.

Corbin, J., & Strauss, A. (2015). *Basics of qualitative research: Techniques and procedures for developing grounded theory* (4th ed.). Thousand Oaks, CA: Sage.

Creswell, J. W., & Poth, C. N. (2017). *Qualitative inquiry and research design: Choosing among five approaches* (4th ed.). Sage publications.

Croskerry, P., & Cosby, K. S. (Eds.). (2009). *Patient safety in emergency medicine*. Lippincott Williams & Wilkins.

Denzin, N. K., & Lincoln, Y. S. (Eds.). (2011). *The Sage handbook of qualitative research*. Sage.

de Vries, E. N., Ramrattan, M. A., Smorenburg, S. M., Gouma, D. J., & Boermeester, M. A. (2008). The incidence and nature of in-hospital adverse events: a systematic review. *Quality and safety in health care, 17*(3), 216-223.

de Waal, F. B. M., & Ferrari, P. F. (2010). Towards a bottom-up perspective on animal and human cognition. *Trends in Cognitive Sciences, 14*(5), 201-207. doi:10.1016/j.tics.2010.03.003

Dvorchik, B. H., Gaynes, B. I., Hubbard, J. W., Kirk, J. K., Kobayashi, K., Sokol, G. H. (2000). American College of Clinical Pharmacology response to the Institute of Medicine report "To err is human: building a safer health system". *J Clin Pharmacol, 40*, 1075-1078.

Fairbanks, R. J. (2013, Jan 27). *Resilience Engineering Webinar (UIDP)- Part 1*. [Video File]. Retrieved from https://youtu.be/ymBodYHBvaQ

Flick, U. (2014). *An introduction to qualitative research*. Sage.

Fusco, D., Lattanzio, F., Tosato, M., Corsonello, A., Cherubini, A., Volpato, S., Maraldi, C., Ruggiero, C., & Onder, G. (2009). Development of criteria to assess appropriate medication use among elderly complex patients (CRIME) project. *Drugs & aging, 26*(1), 3-13.

Geiger-Brown, J., Rogers, V. E., Trinkoff, A. M., Kane, R. L., Bausell, R. B., & Scharf, S. M. (2012). Sleep, sleepiness, fatigue, and performance of 12-hour-shift nurses. *Chronobiology International, 29*(2), 211-219.

Glaser, B. G. (1992). *Basics of grounded theory analysis: Emergence vs forcing*. Sociology press.

Goldberg, R. M., Mabee, J., Chan, L., & Wong, S. (1996). Drug-drug and drug-disease interactions in the ED: analysis of a high-risk population. *The American journal of emergency medicine*, *14*(5), 447-450.

Han, S., & Northoff, G. (2008). Culture-sensitive neural substrates of human cognition: A transcultural neuroimaging approach. *Nature Reviews Neuroscience, 9*(8), 646-654. doi:10.1038/nrn2456

Healthcare Cost and Utilization Project (HCUP). (2006). Statistics on hospital-based care in the United States. *Rockville, MD: Agency for Healthcare Research and Quality*.

Institute of Medicine. (1999). *To err is human: Building a safer health system*. National Academies Press.

Ison, D. C., Vincenzi, D. A., Anderson, K., Balog, C. R., (Eds.). (2015). *Guide to the master of science in human factors (MSHF) thesis*.

Janiszewski Goodin, H. (2003). The nursing shortage in the United States of America: an integrative review of the literature. *Journal of advanced nursing, 43*(4), 335-343.

Kanjanarat, P., Winterstein, A. G., Johns, T. E., Hatton, R. C., Gonzaler-Rothi, R., & Segal, R. (2003). Nature of preventable adverse drug events in hospitals: A literature review. *American Journal of Health-System Pharmacy, 60*(17).

Kasper, K., & Jentsch, F. G. (2016). *Transitioning crew resource management into healthcare*.

Kaushal, R., Bates, D. W., Landrigan, C., McKenna, K. J., Clapp, M. D., Federico, F., & Goldmann, D. A. (2001). Medication errors and adverse drug events in pediatric inpatients. *Jama*, *285*(16), 2114-2120.

Keers, R. N., Williams, S. D., Cooke, J., Walsh, T., & Ashcroft, D. M. (2014). Impact of interventions designed to reduce medication administration errors in hospitals: a systematic review. *Drug safety, 37*(5), 317-332.

Leape, L. L., & Berwick, D. M. (2005). Five years after To Err Is Human: what have we learned? [Abstract]. *Jama, 293*(19), 2384-2390.

Levinson, D. R., & General, I. (2010). Adverse events in hospitals: national incidence among Medicare beneficiaries. *Department of Health and Human Services Office of the Inspector General*.

Medication Management Technologies: Provider Case Studies. (2015). *Medication management technologies: Provider case studies*. LeadingAge Center for Aging Services Technologies.

McCann, T. V., & Clark, E. (2003). Grounded theory in nursing research: Part 2--critique. *Nurse Researcher, 11*(2), 19.

Minai, A., Braha, D., & Bar-Yam, Y. (eds.) (2006). *Complex engineered systems science meets technology*. NY: Springer.

Murphy, G. L., & Wright, J. C. (1984). Changes in conceptual structure with expertise: Differences between real-world experts and novices. *Journal of Experimental Psychology: Learning, Memory, and Cognition, 10*(1), 144.

Ogilvy, J. (2013). Systems theory, arrogant and humble. *World Futures*, *69*(4-6), 332-344.

Page, R. L., II, S. A. L., Bryant, L. L., & Ruscin, J. M. (2010). Inappropriate prescribing in the hospitalized elderly patient: defining the problem, evaluation tools, and possible solutions. *Clinical interventions in aging, 5*, 75.

Plass, J. L., Moreno, R., & Brünken, R. (Eds.). (2010). *Cognitive load theory*. Cambridge University Press.

Qato, D. M., Alexander, G. C., Conti, R. M., Johnson, M., Schumm, P., & Lindau, S. T. (2008). Use of prescription and over-the-counter medications and dietary supplements among older adults in the United States. *Jama, 300*(24), 2867-2878.

Reason, J. (1990). *Human error*. Cambridge university press.

Rice, D. P., & Feldman, J. J. (1983). Living longer in the United States: Demographic changes and health needs of the elderly. *The Milbank Memorial Fund Quarterly. Health and Society*, 362-396.

Sackett, D. L. (1997, February). Evidence-based medicine. In *Seminars in perinatology* (Vol. 21, No. 1, pp. 3-5). WB Saunders.

Shappell, S. A., & Wiegmann, D. A. (2001). Applying reason: The human factors analysis and classification system (HFACS). *Human Factors and Aerospace Safety*.

Stake, R. E. (1994). Case Studies. In N. K. Denzin & Y. S. Lincoln (Eds.), *Handbook of Qualitative Research* (pp. 236-247). Thousand Oaks, CA: Sage Publications.

Sternberg, R. J., & Sternberg, K. (2011). *Cognitive psychology*. 6th edition. Nelson Education.

Strauss, A., & Corbin, J. M. (1990). *Basics of qualitative research: Grounded theory procedures and techniques*. Sage Publications, Inc.

Sweller, J., Ayres, P., & Kalyuga, S. (2011). *Cognitive load theory* (Vol. 1). Springer Science & Business Media.

Thomas, E. J., Studdert, D. M., Burstin, H. R., Orav, E. J., Zeena, T., Williams, E. J., ... & Brennan, T. A. (2000). Incidence and types of adverse events and negligent care in Utah and Colorado. *Medical care*, *38*(3), 261-271.

Tongco, M. D. C. (2007). Purposive sampling as a tool for informant selection. *Ethnobotany Research and applications, 5*, 147-158.

Wingfield, A., Stine, E. A., Lahar, C. J., & Aberdeen, J. S. (1988). Does the capacity of working memory change with age?. *Experimental aging research*, *14*(2), 103-107.

Yin, R. K. (1994). *Case study research: Design and methods*. Sage publications.

Yin, R. K. (2006). Case Study Methods. In J. L. Green, G. Camilli, & P. B. Elmore (Eds.), *Handbook of complementary methods in education research* (pp. 111-122). Mahwah, NJ: Lawrence Erlbaum Associates.