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The medication administration process is complex and frequently leads to errors. Medication errors have a global impact of over $42 billion annually, and in the US an impact of over $21 billion annually. Medication errors have been researched for over 20 years following the Institute of Medicine's landmark study, *To Err is Human*, but they continue to increase.

The purpose of this study was to evaluate contributing factors to late medication administrations (LMAs). Complexity theory guided the study design and data analysis, supporting the wide array of factors that have been shown, individually, to contribute to medication errors and the inter-reliant system structure of the medication administration process.

A six-hospital system was the setting for the study. Descriptive statistics and multilevel Negative Binomial regression modeling was performed to model relationships among variables. Three levels of nested predictor variables were tested in the modeling: shift characteristics were nested within nurse characteristics, which were nested within unit characteristics. Shift characteristics were time of shift (day or night) and presence of a permanent charge nurse. Nurse characteristics were years of experience, highest degree obtained, full-time equivalent status, and specialty certification. Unit characteristics were patient population, unit size, nurse manager years of experience, and nurse manager specialty certification.

Results showed that registered nurses working on units with intensive care unit (ICU) patient populations had higher average count of LMAs when compared to nurses working with patient populations on medical-surgical, stepdown or mixed units, after controlling for all other predictors in the model and nurse and unit clustering. Nurses who had earned an associate's degree were found to have higher average count of LMAs when compared to bachelor's prepared

nurses, controlling for all other predictors in the model and nurse and unit clustering. Shifts that had a permanent charge nurse had a higher average count of LMAs when compared to shifts that were staffed with a relief charge nurse and controlling for all other predictors in the model and nurse and unit clustering.

Both individual nurse and unit characteristics appear to influence the occurrence of LMAs on nursing units and the use of multilevel regression modeling mirrors the inter-reliant concept supported through complexity theory and nested structure frequently found in healthcare.

THE COMPLEXITY OF LATE MEDICATION ERRORS

by

Carey J. Estes

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Approved by

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DEDICATION

Dedicated to my husband Edward, without your love and support I would have never accomplished this.

APPROVAL PAGE

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CHAPTER I: THE COMPLEXITY OF MEDICATION ERRORS

Introduction

Medication errors are the leading cause of medical harm that impacts patients, families, nurses, and healthcare systems directly. Medication errors are now recognized as a global priority by the World Health Organization (WHO), with a global impact of over $42 billion annually (World Health Organization, 2016). In the United States (US), preventable medication errors affect more than 7 million patients across all care continuums and cost the US over $21 billion annually (Lahue et al., 2012).

Over 20 years ago the impact of errors in medicine was highlighted in the Institute of Medicine's landmark study, *To Err is Human* (2000). This report estimated that 44,000-98,000 patients died every year from a preventable medical error (Kohn et al., 2000). Although this report was released over two decades ago and much work has been done to address the problem of medical errors, little progress has been made to decrease patient harm (Pronovost et al., 2003; Zohr et al., 2017). Medical errors are now considered the third leading cause of death in the US with an estimated 250,000-400,000 people dying from a preventable medical error annually (Makary & Daniel, 2016). The largest portion of medical harm is medication errors that affect approximately 5% of hospitalized patients (AHRQ, 2018; Tariq & Scherbak, 2019). One type of medication errors that have been identified are late or omitted medications. Medication administration times, per the Centers for Medicaid and Medicare (CMS), must specifically address the timing of medication administration that includes administering medications outside of their scheduled due time (Department of Health and Human Serivices, 2014). Late medications have been identified with the establishment of the five rights of medication administration, however, until the implementation of the electronic health record and bar code

medication administration true timing of medication administration has been hard to track. Late medication administration errors are a different approach to medication error research as they are quantifiable through electronic data. Late medication errors account for about 25% of medication errors, are considered "preventable" and have led to serious harm (Loresto et al., 2019).

Nurses are disproportionately impacted by medication errors, as 57.4% of errors are attributed to nurses (Jember et al., 2018). In the US medication errors were identified as a national patient safety initiative over two decades ago and extensive research has been conducted to identify the multiple causes of medication errors. However, the rate and impact of medication errors continues to increase (Pop & Finocchi, 2016). A multitude of factors contributing to medication errors have been identified, including system, nurse, and environmental factors. All of these factors have been studied from a mechanistic viewpoint with little research that evaluates how the factors are interconnected in the complex healthcare environment.

History of Medication Errors

From the start of medicine and nursing, it has been acknowledged that errors and harm should be avoided. The foundations of medication safety were originally described over 2500 years ago in the *Oath of Hippocrates* (Hajar, 2017). Although it is not believed to be written by Hippocrates, the oath outlines an essential element for physicians to do no harm (Hajar, 2017). The oath physicians now take upon completion of medical school varies and language has been updated to reflect modern medicine, yet the premise that above all, no harm should be done to patients is still relevant.

Patient safety or preventing harm was also identified by Florence Nightingale, who identified that a hospital should do no harm to patients (Nightingale, 1863). The Nightingale Pledge was developed in the early 1900s and is based on the Hippocratic Oath (Jones, 1909).

This pledge reinforced the belief that a nurse has a moral duty to do no harm. Other versions of the Nightingale Pledge actually state the nurse shall give no drug in error (Nightingale, 1863). The Nightingale Pledge reaffirms nurses' unwavering obligation to protect their patients, not just from personal errors, but errors of other disciplines.

The first person to write about quality and safety in healthcare was Avedis Donabedian. Donabedian was a Turkish physician who sought to define and measure the quality of healthcare (Ayanian & Markel, 2016). His initial work, *Evaluating the Quality of Medical Care,* was published in 1966 and served as a model for improving safety and quality for the next 50 years (Ayanian & Markel, 2016).

Arguably the most famous and impactful work on medication errors in healthcare was the Institute of Medicine (IOM) report in 2000, *To Err is Human.* This landmark report brought errors and harm in healthcare to the forefront of America. *To Err is Human* was a compilation of results from the Harvard Medical Practice Study and the Utah and Colorado Medical Practice Study. This study highlighted overall harm in healthcare but had a particularly strong focus on medication errors and the potential impact of computerized provider order entry (CPOE) (AHRQ, 2018). Following release of this report, the proportion of articles on patient safety and harm increased by 178% in the following decade (Stelfox et al., 2006).

Impact of Medication Errors

The World Health Organization has reported that harm from medications is the largest portion of errors, and "wrong time medication administration errors are the second largest category of medication error reported worldwide" (Taufiq, 2015, p. 2). It is estimated that medication errors occur in 5% of patients who are hospitalized and 7,000-9,000 people die annually from a medication error in the United States (AHRQ, 2018; Tariq & Scherbak, 2019).

Patient harm has been addressed on both global and national levels. The World Health Organization recognizes medication errors as a leading cause of morbidity and mortality and has presented medication safety as the third global patient safety priority (Sheikh et al., 2019). The Joint Commission has a national patient safety goal to address the safety of medications, Goal 3 is to improve the safety of using medications (Catalano & Fickenscher, 2008). In addition to harm, medication errors have a costly impact. Recent data finds medication errors have an annual global cost of $42 billion (Machen et al., 2019).

Rates of medication errors vary dramatically in the literature, with reported rates between 4-20% of patients receiving at least one medication in error during their hospitalization (Choo et al., 2010; Hayes et al., 2015). The IOM has updated their findings and reports that every day a patient in the acute care setting receives a medication in error (Institute of Medicine, 2007) and 100,000 patients die from medical errors in hospitals alone (Rodziewicz & Hipskind, 2020).

Definition of Medication Errors

Medication errors are defined by the Food and Drug Administration (FDA) as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer" (Food and Drug Administration [FDA], 2019). They can occur at any point in the medication use process and range from procurement, prescribing, transcribing, dispensing and administration. Medication errors are commonly referred to as medication adverse events (MAEs). Building on the FDA's definition of a medication error, the most comprehensive definition is from the National Coordinating Council for Medication Error and Reporting and Prevention (NCC MERP). They define medication errors as:

A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use (NCC MERP, 2020).

Administration Errors

Administration errors are cited as the most common form of medication errors and range between 27-70% of all reported medication errors (Alshehri et al., 2017; Mansouri et al., 2013; Ramya & Vineetha, 2014). Administration errors are based on deviation from the "five rights" of a safe medication administration process. These rights include the right patient, the right drug, the right dose, the right route and the right time.

There are several factors that are unique to nursing that contribute to medication errors. A large percentage of nursing time is attributed to medication administration, studies find between 21% to 40% of a nurse's work time is dedicated to medication related tasks (Folkmann & Rankin, 2010; Hayes et al., 2015; Hughes & Blegen, 2008; Westbrook et al., 2011).

Patients in the hospital are exposed to increasing amounts of daily medications, with the average patient receiving 25 medications a day (Bates, 2014). One study that sought to define a safe medication administration approach identified 28 different behaviors required from the nurse for each medication administration, all of which were important to ensure the patient's safety just from the nursing perspective (Johnson et al., 2011).

Administration is arguably the most hazardous step of the medication use process, and the nurse is the last person to handle the medication prior to administering it to the patient (Alshehri et al., 2017; Xu et al., 2014). The majority of nurses have reported they have been involved with at least one medication error during their career, with some reports indicating every nurse has administered a medication in error at some point in their career (Choo et al., 2010; Treiber & Jones, 2010). More recent findings indicate 61.5% of nurses surveyed reported making a medication error in their career, and half of those who reported they made a medication error, reported they occur yearly (Aires et al., 2016). Medication errors are also the most frequent patient morbidity that is attributed to nursing (Nyide et al., 2019). Administration errors can have a devastating impact on patients, families, nurses, and healthcare organizations. Given the magnitude of their rate and impact, administration errors will be the focus of this research proposal.

Late Medications

Errors can fall into two categories, errors of commission or errors of omission. Errors of commission are when an error occurs because of an action that was taken, and errors of omission are the result of an action that was not taken (WHO, 2005). Errors of omission include both late medication administration and missed medication administration (Bragadottir & Kalisch, 2018). Nurses estimate medications are administered late almost 20% of the time (Welton et al., 2018) and wrong time medication administration occurrences, including late medications are the "second largest category of medication errors reported worldwide" (Taufiq, 2015, p. 2). Late or omitted medications have led to patient dead and serious harm (Taufiq, 2015). Rates of wrong time medication administration occurrences have been found to range from 0.5-35.7% of the time medications are administered (Taufiq, 2015).

The Centers for Medicare and Medicaid Services (CMS) was enacted over 50 years ago to oversee the national healthcare programs (Centers for Medicare and Medicaid [CMS], 2020). As part of this oversight CMS has created rules that define a safe medication pass, part of which defines a timely medication administration. CMS allows an organization to define time parameters for medications based on drug class and indication, and to outline time critical medications that must be administered within 30 minutes before or after the scheduled administration time (CMS, 2014). Multiple studies indicate late and omitted medications are the most frequent type of medication error and lead to increased lengths of stay, delayed recovery, severe harm and mortality in patients (Alomar et al., 2020; Coleman et al., 2013; Salami et al., 2019; Taufiq, 2015). Factors that impact missed care, which includes omitted medications, are environment and personal characteristics, nursing perceptions of staffing levels and degree of teamwork (Bragadottir et al., 2016). Missed care has also been linked with decreased job satisfaction, increased desire to leave the nursing profession and absenteeism from the workplace (Cleary-Holdforth, 2019).

True numbers of medication errors are hard to quantify. Studies commonly cite that reported medication errors are a small portion of true medication-related adverse events (Cavell & Oborne, 2001), with one recent study finding upwards of 60% of adverse events go unreported annually (Elden & Ismail, 2016). The gold standard for evaluation of medication errors is observation, however this is not without limitations (Palmero et al., 2019). Observation is resource intensive, time consuming, depends on human actions and can alter behaviors, namely through the Hawthorne effect. Observation can never identify all errors that are occurring on any given shift. Given the impact and prevalence, in the proposed study late medication administration will be used as a marker for medication errors because it is an objective marker

that can be identified from the patient chart and will allow for a more accurate error rate. Per CMS guidelines, organizations are required to define acceptable timeframes for medication administration. The study site has defined a late medication as a medication that is administered more than 60 minutes past the scheduled due time.

Study Purpose

The purpose of this study was to examine the multiple system inputs that impact medication errors to better understand the relationships between these complex factors and how they affect late medication administrations. It is widely accepted that errors are never the result of one single cause or factor (Mansour et al., 2012; Reason, 1990) and complexity has long been cited as a contributing factor to medication errors (Clancy et al., 2008). Specific factors that will be evaluated include unit level characteristics, nurse level characteristics and shift level characteristics. Specific research aims for this study are:

Specific Aim 1: Examine the relationships among nursing unit characteristics and amount of late medication administration occurrences per shift.

Specific Aim 2: Examine the relationships among registered nurse (RN) characteristics and amount of late medication administration occurrences per shift.

Specific Aim 3: Examine the relationships among nursing unit characteristics, registered nurse characteristics and the occurrence of late medication administration occurrences per shift.

Complexity Theory

The nature of the whole is always different from the sum of its parts

Frith of Capra, The Web of Life (Chafee & McNeill, 2007)

Identifying a theory to frame a research study is important for many reasons, it helps to guide development of the research question, aids in study design and furthers the understanding

of knowledge gained through the study. A theoretical framework can help to explain the how and why behind research questions rather than just describing the findings (Polit & Beck, 2017). Theory helps to structure research questions and helps to identify variables that affect the phenomena one is researching. Theory can also identify relationships that would not otherwise be apparent.

The framework that traditionally has been used to understand medication errors is a mechanistic view in which the system is viewed as a machine that needs to be broken down into individual parts to be studied and understood (Wheatley & Kellner-Rogers, 1995). Medication errors have been studied for decades and numerous factors and conditions have been identified that contribute to medication errors. Despite extensive research, error rates have continued to increase, and patient harm persists. Given the lack of progress with traditional theories, a different approach is suggested.

The theoretical framework that will guide this research study is complexity theory, also referred to as Complex Adaptive Systems (CASs). Complexity theory is a subset of systems theory (Warren et al., 1998) and builds on the concept that systems are built on humans and humans are "intelligent, creative, adaptive, and self-organizing" (Wheatley & Kellner-Rogers, 1995, p. 8). It is these attributes that affect medication administration processes and can both prevent and contribute to errors.

Healthcare has frequently been described as a complex system and the medication administration process, a subset of healthcare is also considered a complex system. The American Organization of Nurse Executives refers to complexity theory in their Guiding Principles for Future Healthcare Delivery (Clancy et al., 2008) and complexity was cited years ago in the IOM report as a key contributor to errors (Clancy et al., 2008). In complex systems,

variables are often difficult to measure (Hayles, 1999). Complex systems are marked by periods of rapid growth and change, with seemingly small variations leading to big changes (Warren et al., 1998). Complexity is defined along a continuum and the amount of complexity can vary within the system (Thompson & Clark, 2012). With complexity theory, change within a system is seen as constant, that the system is continually evolving and rarely stagnant (Warren et al., 1998). Nursing has been defined as the "quintessential complex intervention" (Thompson & Clark, 2012, p. 277). Contrary to a mechanistic view, complexity theory argues that once a system is broken down into parts, it is no longer a system (Clancy et al., 2008).

There are key features that define CAS, it is these features that will guide this research study to better understand the relationships with previously identified factors that contribute to medication errors. The key features of complexity theory that will be used to guide this research study include embeddedness, unpredictability, emergence, self-organization, feedback loops and relationships, strange attractors, and fuzzy boundaries.

Structural Embeddedness of Complex Systems

The term embedded can be translated as entrenched, surrounded, rooted or implanted. Moving this definition further, embeddedness which typically comes from business or science, refers to a network of interpersonal relationships that are typically complicated in nature (Dequech, 2003). Nursing and the medication administration process are both embedded systems and processes. Nurses are embedded within the organization, with other disciplines and patients and families. The process of medication administration is embedded within the nurse's day and the other care activities that need completed. Medication administration is also embedded with multiple disciplines. These range from the provider who orders the medication, pharmacist who

verifies and prepares the medication, nurse who physically administers the medication and patient and family who receive the medication.

Complexity theory recognizes that an organization or system is made up of multiple moving parts, the system can continue if any one of these parts are removed and will adapt to the new environment. In a hospital, a nurse is an example of this. If the nurse is removed, the system will continue to function and adapt (Warren et al., 1998). This is in contrast to Newtonian guided physics, which theorized that the best way to understand a system was to break it into the different parts; examining and studying each part would lead to knowing the system and its problems, and that viewing relationships within the system is not important (Benson, 2005; Forbes-Thompson et al., 2007; Karwowski, 2012; Rickles et al., 2007).

Embeddedness is particularly applicable with medication errors. With traditional science, errors have been broken apart and looked at in pieces, viewing the pieces as a machine and ignoring relationships. Root cause analyses have been conducted to determine the primary "root cause" in the belief that by fixing these one or two causes, future errors will be prevented (Benson, 2005). Much of safety science has used this approach and attempted to break down processes to understand where the error has occurred. While this theory has been useful, it fails to recognize that actions do not occur in a vacuum and are impacted by relationships and other activities or processes that are occurring simultaneously (Litaker et al., 2006). The lack of progress on reducing medication errors over the past 20 years further exemplifies the limitations resulting from this practice (Wilson, 2009). Embeddedness is central to the design of this study as shifts are nested within nurses, who are nested within units, which are nested within hospitals. Separating the levels will fragment a system and in research can lead to erroneous results.

Non-Linearity, Unpredictability

Traditional system theory postulated that systems would function in a linear fashion and results can be predicted (Benson, 2005; Phelps & Hase, 2002; Rickles et al., 2007). Complexity theory is framed with nonlinear thinking and complex adaptive systems are not constructed on cause and effect, instead they are dynamic (Forbes-Thompson et al., 2007; Hayles, 1999; Phelps & Hase, 2002). In addition, a linear system has no reaction; in contrast, with a nonlinear system the individual components have a reaction that forms something new. With complexity theory, changes do not follow a traditional linear slope and a small change can result in a dynamic, unpredictable and extreme outcome (Warren et al., 1998). The classic example of change in complexity science is the analogy developed by Edward Lorenz. Lorenz proposed a butterfly who flapped its wings in the Amazon could alter the path of a tornado in Texas (Warren et al., 1998). Complexity theory also postulates that inputs are not proportional to outputs and appreciates that small changes can have big effects and big effects can lead to small changes (Rickles et al., 2007). This is relevant with medication errors, seemingly the exact circumstances can produce a safe medication pass at one time and the next time lead to a catastrophic error. Errors in healthcare or medication administration are often considered random, however through the lens of complexity theory these events can be viewed as patterns to be explored and understood (Clancy et al., 2008; Long et al., 2018). In this study, the components of the medication administration process, nurse, unit and organization combine to result in either a safe medication administration process or an error.

Distributed Control and Self-Organization in Complex Systems

Complex systems possess disseminated control and will self-organize; spontaneously to adapt to a changing environment (Rickles et al., 2007). Complex adaptive systems are made up

of humans, humans are characteristically capricious and change behaviors to adapt to their needs (Forbes-Thompson et al., 2007). What may seem chaotic is their spontaneous attempts to bring control into their environment. Self-arrangement, configuration, and orderliness is central to complexity theory (Anderson et al., 2003). Self-organization is spontaneous, and the rate of organization depends on the tempo of communication or information exchange, relationships, and the mixture of intellectual representation (Anderson et al., 2003, p. 13). Complex systems are open and receptive to feedback. This feedback is then used to help the system evolve and change (Rickles et al., 2007). Self-organization is inherent, nonlinear and a result of multiple feedback loops (Anderson et al., 2004). Self-organization can be seen in how each unit is similar, but unique at the same time. No two nursing units are exactly the same and each nursing unit will perform differently based on the unique characteristics and staff that are working on any given shift.

Rules, Feedback Loops and Relationships of Complex Systems

Related to self-organization, complex systems are guided by simple rules that form the basis for their self-organization (Paley, 2007). Behaviors and outcomes in turn are guided by these rules (Paley, 2007). A complex system is defined as having multiple feedback loops, "recursive information flows" and all the variables are in communication with each other (Hayles, 1999, p. 6). It is through these feedback loops that information from output is processed back through the system in the form of inputs (Clancy et al., 2008). These cycles of information change behaviors. It is frequently stated that behavior cannot be predicted with CAS, but it can be observed and the rules that guide behavior studied and understood (Litaker et al., 2006; Paley, 2007). In humans, these rules are defined as "instincts, constructs and mental models" (Paley, 2007, p. 237). The rules can also be defined as what is important to the system and how

behaviors are reinforced. With medication safety, this can be seen in decisions nurses make in regard to timeliness versus safety. Decisions they make will be based on inputs and feedback from peers, culture and leadership.

Fundamental to complexity theory is the importance of relationships that exist within a system. Complexity theory ascertains that relationships are more important than the individual agents (Burns, 2001). These relationships can occur between humans, items or constructs. It is through examining these relationships, complexity theory can provide a richer picture that highlights relationships between constructs that could not be found using traditional linear thinking (Hayles, 1999; Litaker et al., 2006; Rickles et al., 2007). Complexity theory finds that the relationships appear to be random, but after careful review, patterns that guide this relationship can be identified. Out of these unique relationships, complexity theory recognizes that dynamic instability can be erroneously viewed as noise or an abnormality versus understanding this is part of a system's behavior and needs to be incorporated into findings (Karwowski, 2012; Litaker et al, 2006). Linear theories tend to ignore abnormalities as they do not fit with traditional thinking, instead complexity theory views anomalies as unique opportunities to gain a deeper understanding of the system and relationships within the system (Woodside et al., 2018). With complexity theory, stronger improvements are made by understanding the system, relationships and response to the environment (Forbes-Thompson et al., 2007). For this study, this concept most closely aligns with unit culture.

Strange Attractors

Contrary to most theories, complexity theory does not have traditional antecedents, rather the understanding is that systems are open and continually interacting with the environment (Woodside et al, 2018). Along these lines, since complexity theory does not assume that systems

function in a linear fashion and that for an increase in x there will always be a corresponding increase in y, the notion that something is required before a change is not necessary. In fact, complexity theory posits strong, balanced relationships between constructs is actually quite rare (Woodside et al., 2018).

Complexity theory finds CAS are governed by strange attractors. Strange attractors are an object, person or article that generates patterns of behavior in the system and can create dramatic changes in a system with very little energy (Benson, 2005). These attractors are called strange in that they can arise from anywhere, both inside a system and outside a system and are not always obvious (Vincenti & Jelavic, 2012). The role of the attractor is to help create order out of chaos (Thietart & Forgues, 1995). Strange attractors can be people, processes or "other variables" (Benson, 2005, p. 6). An example of a strange attractor can be seen in emergency rooms as the expertise and number of specialty providers attracts large numbers of patients arriving for treatment (Benson, 2005). Strange attractors in this study are the predictor variables as it is unknown if and how they might affect the occurrence of late medication administrations.

Fuzzy Boundaries

Similar to embeddedness is the concept of fuzzy or porous boundaries. Complexity theory maintains that a system's borders are open and interact with the environment. The system is responsive to conditions, culture and atmosphere surrounding it; it adapts with and to the environment that surrounds the system (Johnson et al., 1964; Pina e Cunha & Vieira da Cunha, 2006). These interactions produce results (Johnson et al., 1964). In addition, the boundaries are porous and allow for energy to be gathered from the environment to prevent system death, they allow the system to evolve, grow and change (Pina e Cunha & Vieira da Cunha, 2006). Fuzzy boundaries within nursing can be seen with both patients and nursing staff. Both patients and

nurses can float through the various departments in the organization and there is a dedicated group of nurses who have no primary nursing unit they are assigned to, rather they float to the unit with the greatest need for any given shift. At the organizational level, some nurses float between hospitals in the healthcare system, especially in the Emergency Department.

The interactions between humans and machines are a second example of fuzzy boundaries in complex adaptive systems. The outcomes of the interaction between technology and humans cannot always be determined and is subject to volatility and varying outcomes (Clancy & Delaney, 2005; Karwowski, 2012). This is a key point when evaluating the impact of technology on medication errors and unintended outcomes with the implementation of new technology (Benson, 2005). The interactions between the multiple systems increases the complexity and leads to "unpredictable and unwanted behaviors," also defined as workarounds and errors (Karwowski, 2012, p. 985). To reduce medication errors through the lens of complexity theory, one needs to "accept unpredictability," "respect autonomy and creativity" and respond with flexibility (Karwowski, 2012). With medication safety this can be seen with workarounds to address technology or processes that are not efficient, do not fit within desired workflows or what the nurse finds best for the patient (Wilson, 2009). Given the ever-changing times because of the COVID-19 pandemic, healthcare has more fuzzy boundaries than at any other time. Fuzzy boundaries for this study are defined as the use of temporary travel staff, and the "flex" units that were created at various times to accommodate for influxes of COVID-19 patients.

Emergence

Complexity theory views systems as constantly changing or emerging as they react to their environments and the relationships that guide their behavior. Change is thought to be

natural and necessary (Phelps & Hase, 2002). Emergence results from change and is a result of self-organization; the results of emergence are fundamentally novel from previous system processes (Goldstein, 1999). Emergence removes the thought that innovation and change can only occur from external innovations versus internal results from the system (Essen & Lindblad, 2013). From a safety perspective, it is felt that errors emerge out of these interactions (Clancy & Delaney, 2005; Phelps & Hase, 2002). Workarounds are a primary example of emergence, as the system adapts to change and new technology (Phelps & Hase, 2002). These workarounds can lead to unintended consequences or outcomes including medication errors. For the definition of this study, emergence can be viewed as the outcome of late medication occurrences. Workarounds were also seen in discrepancies with bar code medication administration (BCMA) scanning compliance rates.

Further Research about Medication Errors

Complexity theory offers a conceptual framework to evaluate causes and relationships of medication errors. With complexity theory, the goal is not to control the research context, rather to look for patterns of behavior and outcomes (Long et al., 2018). With complexity theory the focus is the system, the outcome of a system is different than the sum of its parts (Litaker et al., 2006). By evaluating patterns and relationships that occur between agents and the environment and adopting a longer-term focus of understanding the "complex contextual factors" that affect outcomes a deeper understanding of causes of medication can occur (Long et al., 2018, p. 3). Closer analysis of seemingly erratic behavior can decrease missed opportunities to understand emergence (Litaker et al., 2006). Medication administration is a complex system indicated by the multiple different providers, technology, and steps in the process and the propensity for errors (Clancy et al., 2008). Framing research with complexity theory incorporates the additional

finding of relationships to previously identified individual factors, will add the interconnected and complex nature of healthcare. Research to date has not examined how the complex multilevel relationships between organizational, unit and nurse characteristics contribute to medication errors. Given this lack of understanding, there is limited development of new practices that alleviate medication errors and important findings might have been discarded as noise with traditional theories.

CAS is a conceptual model, meaning it is more difficult to use it to frame a research study, but history has demonstrated that traditional models have not provided the insight that will lead to improvements in nursing practice (Clancy et al., 2008). As mentioned, prior models have taken the Newtonian approach and broken down systems to analyze each part. However, with the lack of progress in reducing medication errors over the past twenty years, it is clear a new approach is warranted. Through the use of complexity theory, the unique relationships that are found in healthcare and the increasing use of technology can be more deeply explored in an effort to generate new knowledge that will lead to further reduction in medication errors.

CHAPTER II: REVIEW OF LITERATURE

Review of the Literature

To better understand the factors contributing to medication errors a literature review was conducted to explore contributing factors to medication errors, as it is well established that medication errors are the result of a complex mix of multiple factors. Contributing factors to medication errors will be reviewed with a focus on individual and organizational factors.

The literature search was completed using PubMed and CINAHL databases. The search was limited to the last 10 years. Search terms included medication errors, nursing and organizational behavior. To ensure all recent articles were identified a broad search under the search heading medication error in nursing was also conducted for the past 2 years. Lastly, given the specific focus of this study, late and omitted medication errors, an additional search was done including late medication errors. This generated no results, thus the review of literature includes what is known about the general factors that affect medication errors. Articles were limited to peer-reviewed, full text articles that were available in the English language. Medication safety is a global priority, therefore, studies conducted in any part of the world were included. Studies were further limited to acute care settings, focused on the nursing profession, and primarily addressing administration errors. To ensure transparency of the methodology and results, use of systematic review articles was limited and instead results were constrained to primary research articles whenever possible. Articles that addressed medication errors primarily attributed to other disciplines such as physicians or pharmacists were excluded. Medication safety has been researched for over 20 years and a rich body of research exists. Older articles focused on factors that have been addressed through the use of technology, including illegible handwriting were excluded in this review. Following review of the articles, they were hand searched for applicable

references. The final sample included 87 articles that discussed medication errors in nursing with a focus on organizational behavior. No articles were identified that only researched one type of medication errors and in specific, late medication errors.

Extensive research has been conducted to evaluate the multiple factors that contribute to medication errors. Factors that contribute to medication errors are vast and vary from personal factors, organizational factors and more recently the influx of technology use in health care (Frith, 2013; Hung et al., 2013). Many studies have looked at these individual factors with the goal of identifying causes of medication errors. However, complexity theory uses a different perspective, it argues these factors cannot be dissected and viewed individually. Rather the system must be evaluated in its entirety with a focus on the relationships among these factors. The key concepts of complexity theory were used to frame the results of the literature review, and include embeddedness, emergence, self-organization, strange attractors, rules, feedback loops and relationships, and fuzzy boundaries. Although these factors were broken apart to review the literature, they are all related and many topics could fall into multiple categories. For example, emergence is the outcome of self-organization which is dependent upon rules and feedback loops.

Embeddedness of Medication Administration

Complex adaptive systems all have components of embedded or nested-systems and findings from two studies about the medication administration process verify the embedded nature of medication administration. Medication administration is a complex process that involves many steps, coordination with other disciplines, and extensive pharmacological knowledge. Review of the medication process has identified 30-40 steps that need to be conducted by various disciplines to complete a medication administration (Sears et al., 2013).

Administration tasks are frequently intertwined with other work and disciplines (Hayes et al., 2015; Hughes & Blegen, 2008).

Emergence

Emergence is the natural changes that occur in a system which are neither forced nor accidental. Emergence has also been defined as disruption, dissonance, disturbance, a change in a system that is unsettling or unknown (Holman, 2018). Medication safety research shows that a number of factors contribute to emergence or changes in medication administration processes, and in turn contribute to medication errors. Emergence includes changes in the system that include mistakes and culture.

Mistakes

A mistake is defined as something that was not intended, a deviation from what was intended (Hansen, 2006). This can be the result of inattention, distractions or changes in the system. Emergence in a system is the change in outcome that is not planned or intentional. Historically there have been two ways of attributing error, a personal approach to medical error and a systems approach to medical error. The personal approach defines errors as a result of flaws in judgement, mental processes and carelessness (Reason, 2000). A system approach views errors as a byproduct of culture, environment and systems. Reason's model proposed that each layer in a system had inherent flaws, or latent failures and when circumstances allowed these holes to align, an error occurred. Complexity theory removes the breakdown of a system into layers or parts and instead views errors as the outcomes of relationships between agents, processes and the environment, also referred to as emergence.

In medication safety literature, nursing factors that contribute to mistakes include deviation from procedures, distractions and lack of knowledge (Brady et al., 2009). A systematic

review of the causes of error identified unsafe acts as the most common cause of medication errors (Keers et al., 2013). Personal factors related to these errors included "lack of concentration, complacency and carelessness" (Keers, et al., 2013, p. 1058). Common examples of errors include misidentification of either patients or medications and are tied to inattention, complacency and neglect (Keers et al., 2013; Vilela & Jerico, 2015). Using complexity theory, these personal factors are a byproduct of interaction with organizational factors such as too heavy a workload, fatigue, interruptions or distractions (Keers et al., 2013). They are the result of the system overtaxing human capabilities and leading to errors.

Culture

Culture is often defined as emergence as it is the result of shared beliefs and values (Clancy et al., 2008). Unit climate and culture are frequently cited as causes of medication errors (Drach-Zahavy et al., 2014; Gurses et al., 2009; Lawton et al., 2012; Managregada et al., 2018). Unit climate is reflected in the values, attitudes and behaviors that are displayed in the workplace; these behaviors can either have a positive effect on errors or a negative effect on workflows and outcomes (Drach-Zahavy et al., 2014; Lawton et al., 2012). It has been found that individuals will conform to unit culture when they join an organization; this impacts medication errors (Machen et al., 2019). A unit or organization with a strong safety culture will elevate the level of new individuals and a unit or organization with a weak safety culture will decrease this behavior in individuals. This can include if speed and efficiency are valued over safety (Lawton et al., 2012). Staff that receive positive reinforcement to expedite procedures or discharges, even at the sake of bypassing safety, will continue these behaviors. Another aspect of culture that has been found to mitigate medication errors is an open and trusting environment (Drach-Zahavy et al., 2014, Mierio et al., 2019; Pazokian et al., 2014).

Self-Organization

Complexity theory recognizes systems are living entities that will adapt and change to their environment. The changes are a byproduct of the shared rules, norms and values. Instead of developing from top down directives, self-organization occurs from self-governance within a system (Long et al., 2018). Studies of the factors contributing to medication errors that illustrate self-organization in the medication administration process include violations, multitasking behaviors, and interruptions and distractions.

Violations

Compared to mistakes that are accidents, violations are intentional deviations from policies. Violations in work procedures by nurses cause medication errors, although the violations are seldom malicious in nature, rather they are the result of poor workflow design or poor fit of technology with workflows (Brady et al., 2009; Keers et al., 2013). Through the lens of complexity theory violations are the outcome of self-organization. Violations are also the result of cultural norms, and can arise when organizational priorities compete with actual workload. They are the outcome of the relationship between the nurse, environment, processes and technology. For example, a nurse who does not use bar code medication scanning in order to expedite discharging patients, can receive praise for efficiency. If the organization values this throughput metric more than the safety of adhering to BCMA, the violation will be reinforced. This is a by-product of the unit self-organizing to meet organizational priorities.

Violations were more frequent in emergency situations or when workloads are high, indicating more complexity in the situation (Alper et al., 2012; Choo et al., 2010). Violations are defined as short-cuts, skipped steps or bypassing technology safeguards (Frith, 2013). One example is nurses administering medications to patients without verifying patient identity or

failing to use BCMA. Findings from a pediatric hospital study found nurses only reported verifying the patient identification (ID) via the wrist bracelet 39% of the time they administered medications and 20% reported they rarely or never verify patient ID with a wrist bracelet (Murphy & While, 2012). Lack of proper patient identification leads to errors. Lack of proper identification occurs more often on units with long-term patients, due to the familiarity between the nurse and patient, consistent patient identification is viewed as unimportant, redundant or insulting to the patient (Alper et al., 2012).

Violations are frequently seen with the five rights of medication administration. The five rights were developed years ago as the gold standard to provide a safe medication administration process (Sullivan, 1991). As stated by the Institute of Same Medication Practices (ISMP), the "five rights" are the goal of a safe medication pass, but are not directions on how to accomplish each step. In a survey regarding medication practices with high alert medications, almost a third of participants, 32.7%, stated the "fives" have become so "routine" they are not cognizant of each step, 27.7% stated they are not able to complete the five rights due to interruptions and 27% stated they were not able to complete the five rights due to workload (Engles & Ciarkowski, 2015). Over 80% of physicians stated they were not aware of what the five rights of medication administration are, highlighting persistent issues in viewing the five rights as the primary mechanism to prevent medication errors (Engles & Ciarkowski, 2015).

Violations of policies and protocols from personal neglect have been frequently cited as contributing to medication errors (Brady et al., 2009; Sears et al., 2013). Violations of policies and protocols are frequently the result of the environment or culture. In one study nurses reported they were forced to decide between following a policy or doing what they felt was best for the patient (Davis et al., 2009). This highlights the dilemma between poorly developed policies or

policies that are too rigid and do not factor into the complex healthcare environment or patient needs. Complexity theory emphasizes the importance of the relationship between policies and work tasks. These relationships have not been studied in medication safety research leaving deficits in understanding.

Interruptions and Distractions

Interruptions and distractions are frequently cited in the literature as contributing to medication errors (Alomari et al., 2015; Brady et al., 2009; Bucknall et al., 2019; Choo et al., 2010; Davis et al., 2009; Esque et al., 2016; Gurses et al., 2009; Hayes et al., 2015; Johnson et al., 2019; Otaibi et al., 2018; Sears et al., 2013). Interruptions have been found in relationship to interdisciplinary communication and technology (Hayes, et al., 2015). Interruptions are frequently self-initiated, meaning nurses initiate the interruption in their workflow, and are dangerous in that they lead to loss of concentration and errors of omission (Hayes et al., 2015). Distractions are commonly cited by nurses as a cause of medication errors. One study reported that 65.9% of respondents felt distractions directly contributed to medication errors. Rates of interruption with medication passes vary between 18-33% of all medication passes (Hall et al., 2010; Junior de Freitas et al., 2019). Distractions and interruptions can arise from the environment, technology, patients, and other disciplines. Given the pervasive conditions, the relationship between these factors needs to be understood.

Multitasking

Multitasking has been linked to medication errors and can also be tied to interruptions and decreased performance (Brady et al., 2009; Choo et al., 2010; Hayes et al., 2015). Unfortunately multitasking is frequently considered an expected part of the nursing workflow. Multitasking has been described as the nature of nursing work and experienced nurses value their

perceived abilities to multitask (Yen et al., 2018). It has also been found that increased use of technology, such as smartphones, alerts and computerized charting has only boosted the amount of multitasking that is performed by nurses (Yen et al., 2018). This constant switching between multiple subjects, topics and workflows leads to increased rates of medication errors and fatigue (Brady et al., 2009; Choo et al., 2010; Yen et al., 2018). Complexity theory views this as emergence. Another form of multitasking is precepting a new graduate or employee. This additional task requirements and responsibilities have been found to increase the rate of medication errors (Sears & Goodman, 2012). This could be attributed to an increase in workload, but also patient teaching distracts the nurse from medication administration as they are discussing the process and fielding questions.

Human limitations have also been found to contribute to medication errors. This is seen when the task demands outweigh the human capabilities (Choo et al., 2010). Inappropriate task demand is most frequently seen with poorly designed or implanted technology (Choo et al., 2010). Other human limitations include attempting to process too much information, multitasking, labeling and packaging issues with medications, and the environment nurses work in (Drach-Zahavy et al., 2014)

Strange Attractors

Strange attractors can be viewed as antecedents to events or a catalyst that contributes to change. In medication safety research, strange attractors can be viewed as contributing factors to both medication errors and factors that mitigate medication errors. Strange attractors can be factors associated with the system or factors outside of the system. These attractors vary from the experience and knowledge of the nurses who are employed by the organization to hospital size.

Findings from studies addressing nursing personal factors and attributes can be linked to this complexity science concept.

Knowledge and Education

Training, experience and pharmaceutical knowledge have all been linked to medication errors (Choo et al., 2010; Keers et al., 2013; Keers et al., 2014; Wondimeneh et al., 2020). Insufficient training, especially for a specialty area or one with many high alert medications has been found to increase error rates (Sears & Goodman, 2012). In one study that evaluated knowledge regarding high alert medications, only 28% of nurses surveyed reported they learned about high alert medications and the risks associated with them in school (Engles & Ciarkowski, 2015). Several articles found knowledge and rule-based mistakes were a contributing factor to medication errors (Chedoe et al., 2012; Choo et al., 2010; Dilles et al., 2009; Keers et al., 2013). Formal education has also been looked at in relationship to medication errors with varying results. One study found nurses holding bachelor's degrees were more likely to identify adverse effects from medication administration compared to diploma-prepared nurses (Dilles et al., 2009). This same study found that diploma-prepared nurses were more inclined to strictly follow policy and protocols on medication administration compared to bachelor's-prepared nurses, who were more likely to deviate from a scripted process based on patient conditions and needs (Brady et al., 2009; Dilles et al., 2009). This highlights the complexity of the system and how nurses react differently based on personal factors such as knowledge, education and experience to best meet the needs of their patients.

Another area of knowledge that has not been well studied, but has been linked to medication errors is computer literacy. Younger nurses have reported higher computer literacy skill levels than older nurses, but are not always able to find needed information (Davis et al.,

2009). Lack of pharmaceutical knowledge and math skills in nursing has also been linked to medication errors (Brady et al., 2009). Frequently younger, less experienced nurses are found to have lower levels of pharmaceutical knowledge and mathematical skills (Otaibi et al., 2018). One study that evaluated math skills of nursing students found only 35% of the students scored 70% or higher on a math test (Cleary-Holdforth & Leufer, 2013).

Experience

Both lack of experience and being an expert have been found to contribute to medication errors (Brady et al., 2009; Keers et al., 2013; Wondimeneh et al., 2020). Lack of experience has been tied to lower levels of confidence, lack of pharmaceutical knowledge and deferring to experts who are not always correct (Alomari et al., 2015; Keers et al., 2013; Treiber & Jones, 2010; Otaibi et al., 2018). One study found nurses' behaviors related to medication administration and adherence with policies was influenced by "familiarity" with other staff members, popularity of other staff members and overall relationship with others (Davis et al., 2009). Younger staff were more inclined to defer to more experienced staff and were more likely to deviate from medication policies based on unit norms (Davis et al., 2009; Murphy & While, 2012). At the other end of the spectrum, expert nurses have been found to spend more time critically assessing patients and intervening, this decreases the amount of time spent on medication related tasks and contributes to medication errors (Chang & Mark, 2011). One study that evaluated severe medication errors found experienced nurses were more likely to practice outside of their scope of practice, which leads to medication errors (Bjorksten et al.,2016). Contrasting results can be found as well to support the idea that experienced nurses make fewer medication errors (Wang et al., 2015).

Staffing Level and Mix

Staffing has long been identified as a factor that contributes to medication errors. Staffing levels or staffing "intensity" is defined as the number of nursing hours worked per patient day and has a direct impact on medication errors (Dubois et al., 2013; Otaibi et al, 2018). Staffing mix is defined as the ratio of bachelor-prepared nurses to associate degree-prepared nurses, diploma-prepared nurses or nursing aides. Units that are staffed with more registered nurses have been found to have decreased error rates, but only to a saturation point, after that level is reached, medication errors have been found to increase (Chang & Mark, 2011; Drach-Zahavy et al., 2014; Dubois et al., 2013). Professional models of nursing that support increased proportion of bachelor's-prepared nurses and nurses participating in professional governance models have also been linked with decreased rates of medication errors (Dubois et al., 2013).

Unit Size and Autonomy

Another unit factor that has been linked to medication errors is unit size (Hung et al., 2013; Lawton et al., 2012; Mark et al., 2008). Larger units, including physical size and number of patient beds, that have a higher ratio of nurses to supervisors have increased error rates (Drach-Zahavy et al., 2014). Direct oversight of nurses is closely tied to the amount of autonomy a nurse practices with. Autonomy is a complex subject that has been studied in numerous research studies with differing outcomes. Studies have found nurses with increased rates of autonomy, typically due to less supervision and oversight, have increased rates of medication errors (Hung et al., 2013; Hung et al., 2015). It is important to point out that nurses with high degrees of professional autonomy tend to have increased levels of psychological safety and might be more likely to report errors with less fear of retaliation (Hung et al., 2015). In another study, low levels of autonomy lead to emotional fatigue, increased job dissatisfaction and

increased rates of medication errors (Ko et al., 2018). Autonomy is frequently considered a mitigating factor for medication errors (Ko et al., 2018). The discrepancies in these findings warrant further research.

Hospital Characteristics

Hospital size is another area that has been evaluated in relationship to medication errors. Hospital size was first examined by the IOM in 2006 when they found dramatically different rates of errors in different organizations (IOM, 2006). Geographic region and rural location have also been identified as a factor that contributes to medication errors (Mark et al., 2008). Mark et al. found urban hospitals are staffed with a higher number of bachelor-prepared registered nurses compared to rural hospitals. Changes in supplemental staff such as Licensed Practical Nurses (LPNs) and nursing aides have been found to impact medication errors in hospitals (Mark et al., 2008). Overall work conditions and support services have been found to be better in urban hospitals compared to rural organizations (Mark et al., 2008). It has been found that having fewer support services available increases the workload of Registered Nurses (RNs). Other organizational differences that have been identified include if the hospital is a teaching institution and the number of medical residents they are staffed with. Teaching hospitals with lower numbers of residents have poorer patient outcomes when compared to more aggressively staffed teaching hospitals (Mark et al., 2008).

Day Characteristics

The day of the week affects medication errors rates as well. There are conflicting results regarding error rates on night shift compared to day shift, but multiple studies have found increased rates of harm that occur to patients on the weekend compared to weekdays, so much that a term called the “weekend effect” has been coined (Miller et al., 2010; Sumant, 2017).

Many factors previously identified affect medication errors on a day-to-day basis. Weekend shifts have fewer support departments in place and nurse administrators are typically not working on site; this leads to greater nurse autonomy with decreased oversight.

Rules, Feedback Loops and Relationships

All complex systems are governed by norms, rules and feedback loops that guide behaviors. In the body of research about medication safety this construct is somewhat harder to define, but includes interactions with the system, policies and procedures, organizational factors and unit characteristics.

Policies

Organizations where the majority of decisions are made at high levels in the hierarchy with little input from individuals who actively complete the work have been found to have increased rates of medication errors (Hung et al., 2015). Likewise, the importance of clear medication administration policies was highlighted in several studies and deviation from policies has also been found to contribute to medication errors (Bjorksten et al., 2016; Davis et al., 2009; Sears et al., 2013). Units with poorly defined policies and procedures have been found to have increased rates of medication errors (Alomari et al., 2015; Metsala & Vaherkoski, 2013). Having clearly defined policies and procedures is not enough to address medication errors because organizations need structural support for their policies and procedures (Alomari et al., 2015; Oshikoya et al., 2013). In addition, nurses' perceptions of the policies have an effect on medication errors. Organizations with policies that are viewed favorably by nursing staff, have lower rates of medication errors (Ko et al., 2018). Age has also been found to be a factor relating to policies and procedures. One study found younger nurses were less inclined to follow medication administration policies (Otaibi et al., 2018). Overall knowledge and adherence to

policies has been found to be low (Oshikoya et al., 2013). With complexity theory this can also be defined as self-organization.

Fatigue

Fatigue and working the night shift also contribute to medication errors (Choo et al., 2010; Davis et al., 2009; Frith, 2013; Otaibi et al., 2018). Nurses who are fatigued, work multiple shifts in a row, work overtime or are on the night shift have been found to have increased rates of medication errors (Agyemang & While, 2010; Choo et al., 2010; Salami et al., 2019). A psychology study to measure the effects of fatigue found participants who were fatigued had decreased reaction times, decreased mental clarity, increased difficulty remembering things and increased mental fatigue (Kato et al., 2009). Given these effects, it is easy to see why fatigue leads to an increase in medication errors. Increased rates of medication errors while working night shift were found in both observational studies and evaluation of self-reported medication errors (Baghaei et al., 2015; Zaree et al., 2018). However, other studies have found conflicting results with no difference in rates of medication errors between day shift and night shift nurses (Pelliciotti & Kimura, 2010). Working overtimes on a routine or mandatory basis, and working more than 50 hours in a week has been strongly associated with medication errors compared to voluntary amounts of overtime (Otaibi et al., 2018). Overtime that has been found to increase medication errors is both working over 40 hours a week and shifts longer than 12 hours in length (Brady et al., 2009; Sears & Goodman, 2012)

Employee Performance

Employee performance, an output of organization culture, has a direct effect on medication errors (Hung et al., 2013; Hung et al., 2015). Communication, teamwork and trust are related to medication error rates; an open and trusting culture has a mitigating effect on these

rates (Chang & Mark, 2011; Choo et al., 2010; Gurses et al., 2009; Hung et al., 2015; Metsala & Vaherkoski, 2013). Nursing satisfaction has also been linked to medication errors, with lower levels of satisfaction leading to disengagement and increased rates of medication errors (Hung et al., 2015). Employee engagement, which is defined as a vested engagement and commitment to high performance work ethics, has been linked to a reduction in medication errors, therefore low levels of employee engagement have been linked to increased medication error rates (Mark et al., 2008). Increased amounts of job stress are linked to increased rates of medication errors (Ko et al., 2018).

Communication

Ineffective communication between healthcare team members has been found to contribute to medication errors (Aires et al., 2016; Gurses et al., 2009; Hung et al., 2013; Lawton et al., 2012; Otaibi et al., 2018; Sears et al., 2013). In contrast, good communication between members of the healthcare team, and effective working relationships have been found to mitigate medication errors (Gurses et al., 2009). Communication can occur between providers and nurses, during handoffs and between nurses and patients or families. Poor communication or a failure in communication has been identified as the third highest root cause of sentinel events (Joint Commission, 2020). A sentinel event is defined as an event that results in death, permanent harm or severe temporary harm (Joint Commission, 2020). It is not surprising that units with better communication have been found to have decreased rates of errors (Chang & Mark, 2011).

Unspoken Rules and Norms of Organizations

Unspoken rules and unit norms have a direct effect on medication errors. They are similar to culture, but more subtle and can vary dramatically from stated organizational culture. These unit norms have impact if procedures are followed and if workarounds are identified and

addressed (Lawton et al., 2012). Similar to this are feedback loops. If repeated attempts to address system issues are ignored, the feedback loop conveyed to staff is that reporting is not valued or addressed. This will translate to unit norms, where issues are not reported or addressed, rather they are just dealt with. This correlates with an organizations' attitudes about the importance of safety climate. Organizations that value safety climate, work toward patient safety and implement resources to promote patient safety have improved outcomes and decreased rates of errors (Lawton et al., 2012). When safety culture is valued, medication errors are mitigated (Managregada et al., 2018).

Nurse Manager Characteristics

Leadership is essential to guide unit culture, norms and day-to-day interactions. When evaluating the culture of a unit, the leadership characteristics of the nurse manager are essential to lay the foundation for the team. Leadership has also been identified as a contributing factor to medication errors (Lawton et al., 2012). Leadership affects how staff perform their jobs and provide safe patient care (Lawton et al., 2012). Leadership affects overall safety that affects how staff adhere to policies and procedures. Studies have also found that strong leadership has a direct impact on decreasing violations of medication administration policies and errors (Perry et al., 2015).

Safety is related to job satisfaction, organization commitment and stress, again, all factors that have an impact on medication errors (Perry et al., 2015). It has been found that as complexity of the environment or task increases, the importance of safety climate increases (Hoffman & Mark, 2006). Leadership has been identified as a key component of a good work environment, which ties back to nursing satisfaction and increased performance (Li et al., 2018). This stable environment can decrease stress, which has been linked to poor clinical judgement

and overreliance on heuristics (Kremer et al., 2002). Longevity of management has been found to be a factor related to quality and safety. Turnover of nurse managers and presence of an interim nurse manager have both been linked with decreased quality outcomes and fewer patient safety events (Warshawsky et al., 2013).

Fuzzy Boundaries

Complex systems have fuzzy (or porous) boundaries between the system and its external environment, and among its internal environment, people and technology. Open boundaries allow for interaction and energy exchange. They allow for energy to be gathered from other systems and keep a system alive. However, not all outcomes of porous boundaries are positive, they also allow for unintended consequences to occur with technology.

Workload

Workload is frequently linked to medication errors (Lawton et al., 2012; Murphy & While, 2012; Pazokian et al., 2014; Sears et al., 2013). When the patient-nurse ratio is too high, cognitive demands on the individual nurse are high, and medication error rates are also high (Alomari et al., 2015; Lawton et al., 2012). Striving solely for efficiency without consideration to safety culture has been linked to medication errors (Treiber & Jones, 2010). Other factors found to impact workload are infrastructure, lack of materials, lack of personal protective equipment, and lack of continuing education (Aires et al., 2016). Additional factors that increase workload include inadequate staffing, overtime, fatigue and off-service patients (Brady et al., 2009; Sears et al., 2013). One study that evaluated not just the rate of medication errors, but severity of medication errors found lack of training, precepting, overtime and off-service patients all increased the potential severity of the medication error (Sears & Goodman, 2012).

Environment and Patient Characteristics

Patient care environments are complex, noisy and frequently changing. Evaluation of the work environment and patient characteristics is a newer area of research. The work environment has been found to have a direct impact on medication errors (Gurses et al., 2009; Lawton et al., 2012). One new finding that relates to medication errors is patient complexity. Patients who have care needs that exceed the complexity of the unit have been found to increase the rate of medication errors (Aires et al., 2016). This can be seen when patients are too quickly moved out of the intensive care unit to make room for emergencies or patients with increasingly complex needs that are bedding on medical floors. Differences in patient populations have also been linked to medication errors. One study found the rate of medication errors on surgical units was double that of error rates on medical units (Wang et al., 2015).

The number of medications a patient is on increases the number of medication errors. Not only are there more opportunities for an error, but this also increases the patient complexity (Aires et al., 2016). Patient complexity is also increased by the number of procedures that are required during a hospitalization (Aires et al., 2016). These procedures can range from dialysis to imaging studies to surgery.

Distractions and interruptions have been linked to increased rates of medication errors in multiple studies and were mentioned earlier under personal factors (Bucknall et al., 2019; Davis et al., 2009; Esque et al., 2016; Johnson et al., 2019; Oshikoya et al., 2013; Otaibi et al., 2018; Sears et al., 2013). However, distractions and interruptions can also arise from the environment, technology, patients, and other disciplines, making them an organization factor as well (Hall et al., 2010). Distractions are commonly cited by nurses as a cause of medication errors. One study reported that 65.9% of respondents felt distractions directly contributed to medication errors and

found 18% of medication administrations were found to have interruptions (Hall et al., 2010). Another study found that 33% of medication passes were interrupted (Junior de Freitas et al., 2019).

Workplace Design

Other aspects of the environment include lighting levels, noise levels, and physical design of the unit (Frith, 2013; Gurses et al., 2009; Lawton et al., 2012). Both poor lighting and high noise have been identified as unit factors that increase medication errors (Kaboodmehri et al., 2019; Mahood et al., 2011;). Medication rooms that are a long distance from patient care areas have also been linked to increased rates of medication errors (Lawton et al., 2012).

Nurses evaluating work design frequently found inefficiencies and discrepancies between what they considered ideal work conditions and actual work conditions. Structure and process were judged at about 60% of what they would be in an ideal work setting (Lima et al., 2017). Adherence with medication administration was scored less than 50% of ideal and encouragement of reporting what was only 60% of ideal (Aires et al., 2016).

Unit Instability

Bed management, frequent moving of patients or inappropriate patient placement has been linked to medication errors (Lawton et al., 2012). Another term that describes this is unit instability. Unit instability refers to admissions, discharges, patients being transported off the floor for procedures and transfers to higher levels of care, typically intensive care units (Duffield et al., 2014). This constant change increases stress, workload and multitasking and is linked to increased medication errors. Further, increased moves lead to increased patient complexity, which was previously cited as a factor contributing to medication errors (Aires et al., 2016).

Medication Administration Technology

Medication administration technology (MAT) has been developed with the intention of standardizing processes, eliminating failures due to human performance and assisting with clinical decision making (Wulff et al., 2011). Although the medication administration process is primarily performed by nursing professionals, it is unclear the extent that nursing input has been considered in the creation, implementation and maintenance of this technology. Some researchers have asserted MAT should not be implemented until there is proof that it reduces medication errors and adverse events (Wulff et al., 2011). Technology that has been implemented in health care to address medication errors includes Computerized Provider Order Entry (CPOE), automated dispensing cabinets (ADC), barcode medication administration (BCMA), smart infusion pumps, radio frequency identification (RFID), and electronic medication administration records (eMARs) (Costa et al., 2017).

Problems with Technology

Overreliance on technology has been found to contribute to medication errors (Treiber & Jones, 2010). This is when the nurse puts more faith into what technology is reporting, without critically thinking through the medication administration process. Broken equipment is another issue with technology that has been found to increase rates of medication errors (Ledbetter et al., 2017). Broken equipment is the most frequently cited reason for system downtime and leads to frustration, poor compliance and workarounds (Ledbetter et al., 2017).

Outcomes from a systematic review of MATs found most nurses felt positive about the effects of the technology, but outcome data was ambivalent (Wulff et al., 2011). Another study that reviewed new graduate nurses' use of technology, found younger nurses were more inclined to have positive views regarding technology, but frequent workarounds and non-compliance with

technology was modeled by experienced nurses working on the unit (Orbaek et al., 2015). The study also found that warning systems could prevent error, but too frequent and inappropriate use of warnings led to automatic dismissal of alerts (Orbaek et al., 2015). Another study that investigated staff perceptions of a recently implemented electronic medication management system found that although the majority of end-users felt the system improved medication safety, over half also felt it contributed to new categories of errors (Van de Vreede et al., 2018). This study also found that success of implementation is based on sufficient training, ongoing staff feedback, use of human factors research to better understand human limitations and characteristics, and accurate identification of workflows and workarounds that are subsequently created (Orbaek et al., 2015). Additional factors included organizational climate, positive workplace culture and timely adjustments to systems once issues were identified (Orbaek et al., 2015). Additional findings are that many of the technology interventions fail to address the working climate and culture of the unit and organization (Alomari et al., 2015).

Balance of Technology

Lastly, the degree of technology has been linked to medication errors (Hung et al., 2013). Units that have increased use of technology, especially technology that has a poor fit to the work environment or lack of training, have increased medication error rates (Hung et al., 2013). However, not enough technology that increases human processes has also been found to increase nursing workload through increased mental and physical demands, leading to increased rates of medication errors (Salam et al., 2019). Technology literacy is another important factor that contributes to use and error rates. This means the nurse must understand how the technology works, but also understand the why behind creation of it (Orbaek et al., 2015).

Future Direction

Although there has been extensive research conducted on the factors and causes of medication errors, substantial progress to reduce harm has not been made. Review of medication safety literature found no studies that focused on specific types of medication errors, one type being late or omitted medication errors. These specific types of medication errors can provide insight into workload and nursing judgment. For example, some medications might be intentionally administered late due to patient conidiation or independent factors such as meal delivery that is important to coordinate with insulin administration. Late medication administration errors are also unique in they can be mined through the electronic record, eliminating many of the challenges with error identification.

Very few of the research studies used a theoretical basis to guide the research, this leaves tremendous gaps in literature and limits solutions to mitigate errors (Wulff et al., 2011). As stated earlier, theory can help to provide deeper understanding to findings and highlight relationships between factors. Complexity theory recognizes that systems are an integrated web of factors, people and processes; it is these relationships between variables that change outcomes. Using complexity theory as a framework, known factors are important, but the relationships between these factors provides more insight into how they operate. The limited use of theory can be seen as only one study highlighted the fact that a learning climate was able to mitigate other factors such as low levels of bachelor's-prepared nurses and higher patient to nurse ratios (Drach-Zahavy et al., 2014). Another example is experienced or expert nurses have been found to respond to unique needs and changes to patient conditions but have higher medication error rates. Further research is needed to understand this complex relationship.

Autonomy is also linked to increased error rates but has been found to mitigate error rates on units (Hung et al., 2015). Supportive environments that allow nurses to function at the top of their skill set is linked to increased satisfaction and improved patient outcomes, but also linked to increased error rates (Hung et al., 2015). The intersection of different organizational levels is another area that requires further research. One study identified different levels of organizations and that each level contributes to medication errors in a distinctly different way but did not explore how the levels are related and impact each other (Hung et al., 2013).

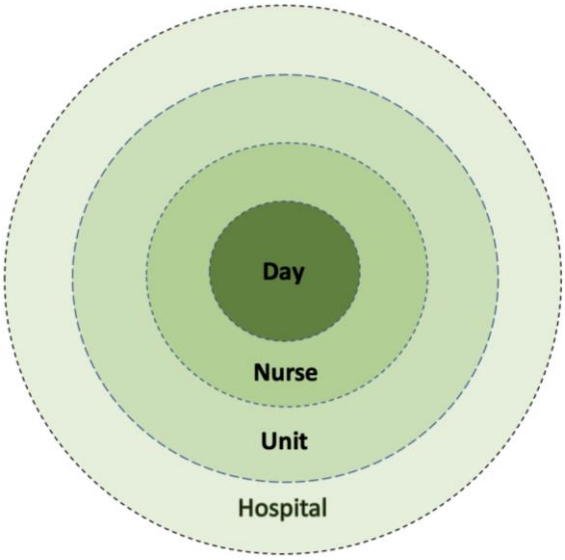
The majority of studies are based on reported medication errors, but literature supports that only 5-20% of medication errors are reported, this implores the question if these studies are accurately identifying all the factors related to medication errors and if interventions that have been identified are targeting true causes (Choo et al., 2010). Observation has been found to be the gold standard to identify medication errors, but studies highlight limitations with this method due to the Hawthorne effect. Given this limitation, alternative methods to accurately identify medication error rates should be explored. Education and training were found to decrease error rates, but human factors research highlights that education and training are the least effective methods for error reduction and that system improvements are better focused on forcing functions that actively prevent users from taking the wrong action (Eggerston, 2014; Keers et al., 2013).

CHAPTER III: RESEARCH DESIGN

Design

An associational research design was used with a four-level hierarchical data structure and repeated measures of the same nurse working multiple shifts during the study period. Individual shifts were nested within nurses, who were nested within units, which were then nested within hospitals (see Figure 1). Late medication administration (LMA) data were collected for a 3-month period of January through March 2021.

Figure 1.A. Nested Design of Late Medication Administrations (LMAs)



Setting and Sample

Data were collected from a six-hospital system: an 815-bed tertiary care center and five other hospitals split between critical access and a rural community. Critical access hospitals are designated as smaller facilities that are located in rural areas that receive additional funding from the government to support the financial vulnerability of these organizations and improve access to care (Center for Medicare and Medicaid Services, 2019).

Thirty-four adult, inpatient units were included in the study; 26 units from the tertiary care center and 8 from the smaller hospitals. This included 12 medical-surgical, 10 intensive care, 7 stepdown, and 5 mixed units (combined stepdown and medical-surgical beds). The study sample included all RNs who worked on these units and had administered a medication that was 60 minutes or more past the due time (late medication administrations (LMAs). For identification, each hospital was labeled with a letter. The main hospital was hospital A, the second largest with 30 beds, was hospital B. The remaining hospitals were hospitals C-F.

The patient population for the study was drawn from four types of patient care units. Intensive care units are designed for patients who require comprehensive management and either have or are at "risk of developing acute, life-threatening organ dysfunction" (Marshall et al., 2017, p. 271). Stepdown beds have been defined as an intermediate level of care for patients who are reasonably stable, require intermittent nursing attention and have a high possibility of deteriorating (Prin & Wunsch, 2014). Medical-surgical units provide care for a broad range of patients who are preparing for or recovering from surgical procedures or have a wide range of medical conditions (Academy of Medical-Surgical Nurses, 2020). Mixed units care for a combination of stepdown and medical-surgical patients for an identified disease group or procedure, for example, neurology or trauma surgery. To aid in data analysis through a more homogenous sample, only adult units were considered. Unit types that were excluded were labor and delivery, mother/baby, pediatrics, pediatric intensive care, neonatal intensive care, and specialty departments including the emergency department, procedural departments and behavioral health departments.

Initially I anticipated that 31 units would be studied. However, evaluation of the late medication administration occurrence data revealed a total of 34 different units. The additional

adult units were developed to accommodate the COVID-19 pandemic. As the number of patients testing positive for COVID-19 increased during the study period, flexible units were created. The type and number of units for the six hospitals are defined in Table 1.

Table 1. Hospital Unit Summary

	Hospital					
Type of Unit	A	B	C	D	E	F
Intensive Care	6	1	1	1	1	0
Stepdown	6	1	0	0	0	0
Mixed	4	0	0	0	0	0
Medical-Surgical	8	1	1	1	1	1

Numerous studies on medication error rates have found variations between pediatric floors, emergency departments, and intensive care units (McLeod et al., 2013; Miller et al., 2007; Poole & Carleton, 2008; Vazin et al., 2014; Weant et al., 2014). To aid comparison of findings, only adult units were included in the study. Pediatric populations are at higher risk for medication errors due to their physical size and vulnerability to medications, but typically have lower rates of errors (McLeod et al., 2013; Miller et al., 2007; Poole & Carleton, 2008). Emergency departments have been found to have the highest medication error rates, but the majority of the errors do not lead to patient harm (Vazin et al., 2014; Weant et al., 2014).

Based on the number of LMAs from a pilot study that was conducted in the summer of 2019, the projected number of LMAs were outlined in Table 2.

Table 2. Projected Number of RNs and Late Medication Administrations (LMA) During 3-Month Period

Hospital	Number of RNs Currently Employed	Average Number Daily LMA	Estimated Total LMA
A	876	1271	116,932
B	31	30	2760
C	29	34	3128
D	26	11	2010
E	23	22	2010
F	14	4.5	414

Operational Definition of Variables

Variables included characteristics from the three levels identified in the study - shift characteristics, nurse characteristics and unit characteristics. Operational definitions of these variables are outlined in Table 3.

Table 3. Operational Definitions of Predictor Variables

Variable	Definition
Shift Characteristics	
Shift	Day shift 0700 a.m. – 0659 p.m. Night shift 0700 p.m. – 0659 a.m.
Permanent charge nurse	Registered nurse who holds a permanent leadership position on the unit and has direct reports that was present on a given shift.
Registered Nurse Characteristics	
Years of experience	Length of time RN has worked for the organization in years.
Specialty certification	RN holds a current certification from a nationally recognized credentialing organization.
Degree	Highest nursing degree earned
Full time equivalent status	Full time - 36 hours or greater per week, part time - less than 36 hours a week, per diem - no confirmed hours per week.
Nursing unit characteristics	
Tenure of nurse manager	Years of experience at the organization.
Nurse manager degree	Highest degree earned, nursing or other.
Nurse manager certification	Nurse manager holds a current certification from a nationally recognized credentialing organization.
Unit Size	Number of hospital beds.
Patient Population	
Intensive care unit	Unit provides intensive and specialized care to critically ill patients (Marshall et al., 2017).
Stepdown unit	Unit provides care for intermediate acuity patients, between an ICU and general medical unit (Prin & Wunsch, 2014).
Mixed unit	Unit provides care for both stepdown and general medical-surgical patients.
Medical-surgical (MS) unit	Unit provides care for a broad range of medical patients and/or patients that are preparing or recovering from surgery (AMSN, 2021).

The outcome variable, late medication administration (LMAs) was defined as medications that are administered more than 60 minutes past their due time.

Nurse manager characteristics were included under unit characteristics because leadership is fundamental for setting the tone on a unit in an organization and nurse managers have an intricate role in safety culture and outcomes for their units (Warshawsky, Lake et al.,

2013). Studies also have found that strong leadership has a direct impact on decreasing administration violations and errors (Perry et al., 2015). Given this important relationship, the characteristics of nurse managers were used to define unit characteristics. To quantify nurse autonomy, unit size and presence of a permanent charge nurse were identified as both of these characteristics are a reflection of autonomy through daily oversight.

Process measures – process measures was defined as the electronic patient verification through scanning of the patient's identification wristband and electronic verification of medication through the use of bar code medication administration (BCMA).

Data Collection

Late medication data were collected retrospectively for a 3-month time period. Initially the time period was defined as the months of July through September 2020. This period was selected as it was 6 months past the initial start of the COVID-19 pandemic, which caused major disruptions in patient care and dramatically affected the hospitals' census. However, this time frame had to be changed to accommodate a delay in the availability of an updated report on nurses' education and certification status. Consequently, the time period for data collection on late medication administrations was January through March 2021. Although data were still collected during the COVID-19 pandemic, elective surgeries had resumed and hospital occupancy and length of stay were comparable to the 12-month period September 2020 through August 2021 at the tertiary care facility. The average monthly census for those 12 months was 689.67 patients, comparable to the census in January (715 patients/day), February (675 patients/day) and March (665 patients/day) of 2021. The average length of stay for the entire 12 months was 5.5 days, compared to the average length of stay for January (6 days), February (5.6 days) and March (5.2 days) of 2021.

Data were collected from five sources: Magnet® Active Employee with Education report, Magnet® Active Employee with Certification report, Kronos specific daily staffing data, the daily Late Medication Administration report, and Nursing Operations department report of bed number and capacity of all units. Nurse and nurse manager characteristics were collected from the Magnet® Active Employee with Education report and Magnet® Active Employee with Certification report. These reports are maintained by the Center for Nursing Excellence and information contain in these reports included length of time at the organization, highest degree obtained, FTE status and if the RN held a specialty certification. Employees that do not possess specialty certification were not on the Magnet® Active Employee with Certification report. Bedside care RNs were also identified from the Magnet® database reports as per organizational policy, all nurses that hold a nursing position titled as clinical RN, provide direct patient care for more than 50% of their scheduled hours. Both reports were updated in 2021.

Unit size and patient population were collected from the Nursing Operations department that tracks number of beds and capacity of all units. The presence of a permanent charge nurse was collected from the Kronos specific daily staffing data. This report is also managed by the Nursing Operations department and includes schedules of all employees and specific shifts they worked. Permanent charge nurses are identified through a different job code and their schedules reviewed and correlated to the study database.

The number of late medications for all nursing units was collected from an electronic report, the Late Medication Administration report, that is generated daily by the corporate information technology department (IT). It is managed by the pharmacy department and retrospective data was pulled from this database by the division director of pharmacy and shared with the primary investigator. This report contained all scheduled medications that were

administered more than 60 minutes late and included time critical medications that were considered late if administered more than 30 minutes past the scheduled due time. Additional information that was obtained from this report included the unit the medication was administered on, drug name, scheduled frequency, time medication was due, time medication was administered, nurse documenting administration of the medication and if bar code medication scanning was used to identify the patient and medication. Given this report was generated from the corporate IT department that included data from all six hospitals in the study.

Data Management

Data from these reports were merged into a comprehensive database for statistical analysis. The database included a unique ID number for each nurse in the study and the required information. Determination of shift worked was gathered from the late medication administration reports and is defined in Table 3. There could be instances of nurses appearing to administer medications on both shifts, for example, if a night shift nurse works over into day shift or administers medications late after 0700 a.m., however it was felt this would be a rare occurrence. Therefore, medications were attributed to the shift that correlated to the timeframe in which they were administered.

To assess the impact of missing data, some statistical guidelines report less than 5% will have a negligible impact on the results (McCoy, 2018), however this study had significantly higher rates of missing data. Two variables did not converge in the study based on the amount of missing data: nurse manager degree and nurse manager years of experience. As a result, these two predictor variables were removed from the final model.

Data Analysis

Analyses were completed using the Statistical Package for the Social Science (SPSS) version 17.0 (SPSS, Chicago) and Stata 17 SE (StataCorp, LLC, College Station, TX). Preliminary data analysis included frequencies and descriptive statistics of LMAs, unit, nurse and shift characteristics. Multilevel count regression (Negative Binomial) was used to model relationships and answer the study aims. To account for the nested effect of individual nurses (Level 2) and units (Level 3), Stata was used for multilevel regression with the cluster command.

An initial multilevel model for all three aims was preformed that included only random effects without any predictor variable as fixed effects (Bell et al., 2013). Model fit was determined by comparison of Akaike's Information Criterion (AIC) and Bayesian Information Criterion (BIC) values for each model, with a smaller value indicating better fit (Bell et al., 2013). Given only six hospitals, hospital-level predictors were not modeled, but the clustering effect of hospitals was accounted for in the multilevel modeling. The use of multilevel modeling was important to account for the nested effects and prevent inflated type 1 error rates (Bell et al., 2013). Based on variance inflation factors multicollinearity was not a concern (*VIF = 1.06 to 1.83*). A two-sided *p*-value <.05 was considered statistically significant.

Specific Aim 1: Examine the relationship between unit characteristics, and late medication administration was analyzed by evaluating descriptive statistics and count regression.

Specific Aim 2: Examine the relationship between nurse characteristics and late medication administration was analyzed by descriptive statistics and count regression.

Specific Aim 3: Examine the relationship among nursing unit characteristics, registered nurse characteristics and the occurrence of late medication administration. Multilevel count

regression was used to compare the defined unit characteristics, and the unique nurse characteristics in relationship to late medication administration.

Power of the study depended on the Aim with the largest sample size demanding statistical analysis, which was Specific Aim #3 that uses multilevel modeling. A Structural Equation Modeling (SEM) sample size guideline from Jackson (2003) applied here, and is based on the N:q hypothesis with a minimum of 10:1 ratio guideline where for q predictor variables, a sample size of N observations per predictor were needed. Given the large number of nurses (942) and LMA occurrences (2611) over the 3-month study period (see Table 2), the study was well powered (≥80%) to detect associations with up to three unit-level characteristics jointly using Jackson's N:q sample size guidelines.

Human Subjects

For protection of human subjects, IRB approval was obtained from the University of North Carolina at Greensboro. Hospital approval was obtained from the study site where the data were collected. For protection of nurse managers and bedside RNs all names were replaced with a unique identifier. This identification number was then used to replace the nurse's name on the daily Late Medication Administration report. Prior to saving, data that was collected from the Magnet® Active Employee with Certification report, the Magnet® Active Employee Education report and the Kronos timekeeping report also was replaced with the same unique nurse identifier. The late medication administration data does not contain any patient specific information and there is no concern for patient data exposure. All data were stored on a secure, password protected server and was only accessed by the primary investigator, research advisor and statistician. Data will be saved for a minimum of five years following completion of the study.

CHAPTER IV: MANUSCRIPT 1, USING COMPLEXITY TO FRAME MEDICATION SAFETY RESEARCH

Abstract

The aim of this discussion paper is to explore the use of complexity theory to frame medication safety research. This paper is based on the first author's experience as Quality Manager for Medication Safety and relevant literature and theory and has several implications for nursing. Medication errors have been researched for decades without significant reduction in errors. Mechanistic research methodologies, the approach typically used when studying errors, do not take into consideration the multifaceted and interconnected structure and process that define the medication administration process. As an alternative, complexity theory seeks to understand the interconnected, nested structure of systems and discern the patterns that guide behaviors. Complexity theory can bring a holistic view to design medication safety research, generate findings reflective of actual clinical practice, and lead to new insights for reducing medication errors. This article provides an overview of complexity theory and the advantages it has as a framework for medication error research.

Introduction

The purpose of this paper is to offer an analysis of complexity theory as a framework for research about medication safety. Complexity theory offers a different lens compared to theories that have been historically used to guide medication safety research. The majority of research has been considered through a mechanistic lens, asserting the best method to understand factors contributing to errors is by breaking systems into individual parts and pieces. This historic approach has ignored the inter-reliant and complex character of healthcare. This mechanistic approach to error reduction was adopted following its success in the fields of manufacturing and

aviation; it is based on the theory of constraints and performance measurement research (Lockmany & Spencer, 1998). This approach identifies the most rate limiting step of any process and seeks to address its limitations.

Healthcare can be compared to other complex, high-risk industries such as aviation and nuclear power, but differs through the integral and unpredictability of human interactions. Complexity theory maintains that a system dismantled into subparts is no longer a system, that the most important aspect of a system are the relationships among components. Complexity theory offers an inclusive assessment of the multitude of factors that contribute to medication errors and does not force our discovery to be narrowed to one specific factor or identifying what is believed to be the most important factor that contributes to errors. Complexity theory understands each situation as unique and not predictable and recognizes that variations that are commonly discarded as noise, or outliers, can be integral factors.

This paper provides an overview of complexity theory, highlight shortcomings of previously identified theories to evaluate errors and finish by exploring the contributions complexity theory can provide to improve medication error research.

Complexity Theory

Background and Introduction to Complexity Theory

The roots of complexity theory are founded in mathematics and physics. In its simplest form complexity theory seeks to find order in chaos through the simplest rules possible (Nunn, 2007). Complexity theory is created around understanding behaviors with complex systems and defines complex systems as non-linear, continually adapting, and exhibit self-emergent behaviors (Benson, 2005; Rickles et al., 2007). The roots of complexity theory stemmed from meteorologist, Edward Lorenz. In his work on weather patterns, Lorenz discovered that systems

can behave in ways opposed to traditional linear systems. Lorenz found that change is not always predictive and very small modifications can produce dramatic changes and altered outcomes (Lorenz, 1993). Complex systems are responsive to original circumstances, meaning very similar conditions can lead to divergent paths, and are the biproduct of history (Nunn, 2007). Complexity theory is built on several premises that differ from other systems theories and traditional ways of thinking. The main tenants of complexity theory include structural embeddedness, non-linear, distributed control and self-organization, rules and feedback loops, strange attractors, fuzzy boundaries, and emergence.

Structural Embeddedness of Complex Systems

Complexity theory recognizes that an organization or system is made up of multiple nested parts. This embeddedness is one of the key factors that differentiate it from other theories. This is significant when comparing it to traditional mechanistic theories that seek to understand systems by breaking them apart. Complexity theory also argues that if a system is broken down into its individual components, it is no longer a system. With structural embeddedness, parts of the system interact and are symbiotic, however, the system can continue if any one of these parts are removed. If change is significant, the system will adapt and evolve to the new environment as opposed to withering and dying. To understand medication errors, this view would stress it is not the individual contributing factors that are important, but the relationships among these factors that need to be studied. It would prevent too narrow a focus that could lead to inadequate analysis of the complex environment of the medication administration process.

Non-Linear and Unpredictable

Complexity theory views systems as nonlinear and dynamic (Forbes-Thompson et al., 2007; Hayles, 1999; Phelps & Hase, 2002). Change does not follow a traditional linear slope,

rather it is unpredictable (Warren et al., 1998). With complexity theory, inputs and outputs vary, small changes can have big effects and big effects can lead to small changes (Rickles et al., 2007). Although complex systems are random and do not follow cause and effect relationships, they do have patterns that can be identified and studied (Benson, 2005). Identifying and understanding these patterns can lead to deeper insight. Although outcomes are not predictable, patterns can identify trends, risks and weaknesses. This is important to realize when evaluating interventions as significant results in one system might not produce similar results in other systems.

Distributed Control and Self-Organization in Complex Systems

Complex systems possess distributed control and will self-organize to adapt to a changing environment, the rate of self-organization is dependent upon attractors in the system (Rickles et al., 2007). Humans are the core of complex adaptive systems; true to their nature, humans are capricious individuals and will change behaviors to meet their needs (Forbes-Thompson et al., 2007). What may seem chaotic and unstructured is actually an attempt to bring control into their environment. Self-arrangement, organization and regulation are central to complexity theory (Anderson et al., 2003). With complex systems, the rate of organizational change depends on the cadence of information exchange and relationships in the system (Anderson et al., 2003). Complex systems are open and receptive to feedback. This feedback is then used to help the system evolve and change further (Rickles et al., 2007). Self-organization of systems is valuable in understanding medication errors as any change that is implemented in a system can lead to self-organization that might result in different outcomes than expected.

Rules, Feedback Loops and Relationships of Complex Systems

Complex systems are guided by rules that affect behaviors, self-organization and outcomes (Paley, 2007). Complex systems have multiple feedback loops, with all the variables interacting with each other and recursive communication (Hayles, 1999). Outputs are reprocessed through the system as inputs (Clancy et al., 2008). These cycles of information are consistent and change behaviors.

Fundamental to complexity theory are the relationships that exist within a system, these relationships are viewed as more important than the individual agents (Burns, 2001). Relationships can occur between humans, items or constructs. Out of these unique relationships, complexity theory recognizes that dynamic instability can be erroneously viewed as noise or an abnormality versus understanding this is part of a system's behavior and needs to be incorporated into findings (Karwowski, 2012; Litaker et al., 2006). With complexity theory, stronger improvements are made by understanding the system, relationships and response to the environment (Forbes-Thompson et al., 2007). In fact, complexity theory suggests strong, balanced relationships between constructs is actually quite rare (Woodside et al., 2018).

When evaluating medication error research using complexity theory, one would realize that results are only valid for that point in time. Repeating the research might lead to different outcomes. What is more important than the outcomes or results would be the communication patterns identified within the system with the recognition that it is on-going, ever-changing and evolving.

Strange Attractors

Complexity theory finds complex adaptive systems (CAS) are governed by strange attractors. Strange attractors are an object, person or article that creates patterns of behavior in

the system and can create dramatic changes with very little energy (Benson, 2005). These attractors are called strange in that they can arise from anywhere, both inside and outside a system, and are not always obvious (Vincenti & Jelavic, 2012). The role of the attractor is to help create order out of chaos (Thietart & Forgues, 1995). Strange attractors can be people, processes or elements (Benson, 2005). A strange attractor for medication errors is technology. Multiple different technologies have been implemented in the past 20 years to provider a safer medication administration process and include computerized provider order entry (CPOE), automatic dispensing cabinets (ACD) and bar code medication administration (BCMA). However, each of these technologies has produced unintended consequences and new behaviors. Technology is frequently associated with distractions, interruptions and works-arounds and can lead to increased workload, cognitive demands and errors (Wang et al., 2019). Strange attractors are an integral point when investigating medication errors through the lens of complexity theory and could lead to more substantial understanding. With complexity theory, unintended consequences that recognized and mitigated through understanding the strange attractors of a system.

Fuzzy Boundaries

Complexity theory maintains that a system's borders are open and interact with its environment, these boundaries are described as fuzzy indicating an open and porous system. These boundaries allow for feedback loops and change. The system responds to changes in conditions, culture, and environment that surround the system (Johnson et al., 1964; Pina e Cunha & Vieira da Cunha, 2006). These interactions produce outcomes and allow for energy to be gathered from the environment to prevent system death; interactions allow the system to evolve, grow and change (Johnson et al., 1964; Pina e Cunha & Vieira da Cunha, 2006). Human interactions with technology are often understood to be volatile, dynamic and unpredictable

(Clancy et al., 2008; Karwowski, 2012). As interactions between multiple systems increase, the complexity of the process also increases (Karwowski, 2012).

This porous environment could lead to greater understanding of medication error research that is framed by complexity theory. Any intervention, department or contributing factor can and will interact with the system around it. Technology is a key example of this, for technology implemented in one area will affect other areas and the system. Recent technology interventions include the use of smart phones by nurses. While these phones make communication easier on one level, they cause disruption on others, such as distractions or interruptions in critical processes such as medication administration.

Emergence

Emergence is the creation of new, often more complex behavior that evolves from the system. As mentioned earlier, complexity theory views systems as constantly changing or emerging as they react to their environments and the relationships that guide their behavior. Change is thought to be natural and necessary (Phelps & Hase, 2002). Emergence results from change and is a result of self-organization; the results of emergence are fundamentally novel from previous system processes (Goldstein, 1999). Emergence contradicts the belief that innovation and change can only occur from external innovations and not be an internal result from the system (Essen & Lindblad, 2013). These emergent behaviors are not predictable and often are unexpected (Karwowski, 2012). The risk with traditional theories is that emergence is typically viewed as artifact or noise and can be confused with errors (Karwowski, 2012). Viewing medication errors with emergence in mind can help plan for increased complexity with new technology or use of independent double checks that can affect the outcomes of work and even result in errors.

Why and How Complexity Theory is Different from Historical Research

Historically safety research has been guided by linear, structured mechanistic theories. Common examples of these theories include normal accident theory, high reliability theory, the System Engineering Initiative for Patient Safety (SEIPS) model and organizational behavior theories, with Kanter's theory being one of the most common. Comparing each of these to complexity theory highlights how these linear theories that fragment systems have limited the improvement that can be made in the field of medication safety research.

Normal Accident Theory

Normal accident theory (NAT) was developed following evaluation of the Three Mile Island disaster and contends that organizational factors contribute to accidents and disasters (Cooke, 2009). NAT recognizes two key types of accidents, normal and systems accidents. Organizational processes are defined as either tightly coupled or loosely coupled. Tightly coupled is defined as processes can only be accomplished in one way, delays are not possible and there is little slack in the system. In contrast, loose coupling allows for delays, variations and alternative methods in processes. Systems are defined as either complex or linear. Complex systems are defined as interconnected, having multiple feedback loops, are difficult to dissect and operators are siloed with limited views of the entire system. On the other hand, linear systems are simpler with limited interdependence and feedback loops.

Normal accidents occur in tightly coupled, complex systems and are inevitable. To reduce the risk of accidents, systems should loosen coupling and simplify, making them more linear. Normal accident theory takes into consideration that systems are affected by political, economic, and human factors. Normal accident theory acknowledges that organizations are "pretty sloppy, are chaotic garbage cans and riddled with interests" (Perrow, 1984, p. 219).

Although NAT agrees with safety culture, warning alarms and vigilance, it stresses these alone are not enough to prevent accidents and public oversight of systems in imperative.

The difficulty in using normal accident theory to frame medication safety research is the limitation that to improve processes they must be simplified and made linear. In theory this is sound, but in the reality of researching the multiple factors, human components and technology that make up the medication use process, this is not an obtainable goal. Linear systems do not allow for the reactions that occur between agents and results in the creation of something new. Normal accident theory identifies organizational factors as essential to accidents or errors, but ignores the human elements (Grant et al., 2018). The last major weakness in normal accident theory is it implies that accidents are the result of failures, however some accidents or harm can be the result of normally functioning systems that fail to understand the environment correctly, human limitations or normal deviance (Leveson et al., 2009).

High Reliability Theory

High reliability theory (HRT) emerged as an argument against NAT. NAT was deemed the pessimistic view and high reliability theory as the optimistic view of accidents and errors (Ruchlin et al., 2004). The premise with HRT was that accidents could be prevented as opposed to being inevitable. HRT uses the work of James Reason, in that humans are fallible and will make mistakes, however if enough safeguards (checks and balances) are created, errors can be caught and prevented. Safety is at the center of everything. Systems and processes are designed with flexibility to respond to hazards, and anyone can and should halt a process that is unsafe. HRT promotes tools such as mindfulness and continually learning from mistakes. Processes are built in redundancies used as a mechanism to prevent errors. HRT was used to frame the findings in the 1999 IOM report, *To Err is Human*. Mechanisms to improve safety of systems include a

robust reporting system, open and just culture, ensuring lessons are learned and effective changes are implemented, and utilizing a systems approach to errors. In contrast to NAT, HRT underestimates the impact of political factors. Medication error prevention studies that have highlighted the importance of a just culture, open and robust reporting system and learning from errors typically stem from HRT (Ruchlin et al., 2004).

HRT places importance on redundancies. An example of redundancies in medication safety is the use of independent double checks for high alert medications. However, redundancy decreases linearity and can lead to overconfidence in the safety of systems (Leveson et al., 2009). This factor is one that led to the Challenger Space Shuttle disaster when overreliance on redundancy lead to incorrect decision making (Leveson et al., 2009). Another weakness in the majority of HRT theories is they are created by engineers. Engineers create systems while scientists observe systems (Leveson et al., 2009). Using a theory created by professionals who design systems leaves tremendous gaps when it is compared to reality. HRT also lacks clear definitions of constructs. Without these it is hard to replicate a study and have a clear understanding of how it was applied to the research. One major weakness is the difference between reliability and safety. Reliability implies consistency and accuracy whereas safety means free from harm, risk or injury (Leveson et al., 2009). However, HRT uses these terms interchangeably and implies that a reliable system is a safe system. The last area that limits HRT as a theory to investigate medication safety is the premise that highly reliable organizations have stable processes with limited technology introduction (Leveson et al., 2009). Healthcare is changing at an exponential rate with ever increasing amounts of technology, therefore limiting the usefulness of this theory for on-going research.

The Systems Engineering Initiative for Patient Safety

The SEIPS model is one of the most broadly used system theories to frame safety science and has foundations in human factors and ergonomics (Holden et al., 2013). The creation of the SEIPS model was originally funded by the Agency for Healthcare Research and Quality (Carayon et al., 2006). The stimulus for development was the interdependence of healthcare systems and understanding that errors do not occur from a solitary event. In contrast, errors are a result of the multifaceted interactions between numerous systems, people and technology (Carayon et al., 2014). Similar to high reliability theory, the SEIPS model also moves beyond individual blame (Gobsee, 2002). The SEIPS model recognizes processes and outcomes that have an impact on the work system and emphasizes the interactions with person, task and environment (Steege & Rainbow, 2017; Steele et al., 2018).

In contrast with other theories, the SEIPS model was designed specifically to address health care quality and safety and has been used extensively to guide work in this area. It has been used in less frequently, however, for research specific to medication safety. Further limitations to the SEIPS model include that it is a descriptive model and all elements are weighted the same without the ability to recognize critical elements (Carayon et al., 2006). The SEIPS model is extensive and complex which can make implementation difficult and time consuming. Although the SEIPS model recognizes feedback loops and incorporates relationships, it is not to the extent they are stressed in complexity theory. Finally, system redesign utilizing the SEIPS model has not always led to a reduction in patient harm (Karsh et al., 2006).

Organizational Behavior

Kanter's theory of structural power is another systems theory that has been used for medication safety research. Different from the prior theories discussed, Kanter's theory moves from looking at organizational and system factors to looking at employee performance in relation to an organization (Shoemaker et al., 2010). Kanter's theory states that employee behaviors are an output of the organization and theorizes that systems and power, both formal and informal, influence a person's access to opportunities, power, resources and structure (Laschinger, 1996). Organizational factors affect the employee through behaviors such as increased self-efficacy, motivation, organizational commitment, decreased burnout, increased perceived autonomy, increased participation in management and job satisfaction (Laschinger, 1996). Ultimately this improves their effectiveness through achievement and success, respect and cooperation with the organization and satisfaction. While Kanter's model has been used to understand the effects of culture to reduce patient harm and medication errors the sole focus on human performance leaves tremendous gaps (Ko et al., 2018). While organizational behavior has been used extensively to understand how people behave in an organization and how to predict and improve outcomes, it lacks the fundamental importance of a more comprehensive model to address the multitude of factors that contribute to medication errors.

Implications for Research

Nursing Studies

Complexity theory has been used in relatively few nursing research studies. Thompson et al. (2016) completed a scoping review to assess how complexity theory had been utilized in nursing and health services research and identified only 44 studies. Out of these studies, the majority (27) were qualitative and focused on the concepts of relationships and interaction

(Thompson et al., 2016). Only one study was directly related to safety and error prevention, although several articles were related to quality improvement initiatives and improving outcomes. Complexity theory was not reviewed during an analysis of risk and safety theories and their application to nursing (Cooke, 2009). However, complexity theory can add depth, insight, and a more comprehensive model that cannot be found in research conducted using traditional frameworks. Given the limited use, it could provide insight into research that has previously been missing.

Research

For the past two decades extensive research has been conducted to reduce harm from medication errors; however, there has not been a significant reduction in medical harm (Benson, 2005; Billstein-Leber et al., 2018; Kohn et al., 2000). Research is important to build science and using theory to frame research allows for improved application to clinical practice, the ability to link research studies more clearly and produce evidence (Lor et al., 2017). Healthcare researchers do not always apply theory to research and often fail to link the research directly to the theoretical framework (Lor et al., 2017). Theory is important to explain how and why variables are related (Mark et al., 2004). The use of complexity theory to frame research will add the focus on relationships and patterns of behavior bringing additional insight into research. Data can illustrate, but not justify relationships which severely limits the learning that can occur (Mark et al., 2004).

The majority of work that has been done to reduce medication errors is based on mechanistic views which has broken down each step of the process to identify causative factors. Root cause analysis through QI efforts are based on the Newtonian view and have identified local patterns and helped people solve local problems due to those patterns. But this same

approach does not work for research. Safety science argues that errors have root causes, through eliminating the root causes, errors can be eliminated. This has worked for individual problems or errors but cannot be broadly applied. Research conducted based on mechanistic theories has identified the variables (structure and processes) contributing to medication errors, however the relationships between these variables have not been identified and a significant reduction in medication errors has not occurred. In contrast, complexity theory seeks to understand the dynamics between the micro and macro level of systems and helps to clarify multilevel relationships.

Complexity theory does not seek to define traditional cause and effect relationships and argues that outcomes cannot be predicted. Instead, complexity theory supposes that a simple set of "deterministic relationships can produce patterned yet unpredictable outcomes" (Levy, 2000, p. 88). Complexity theory looks for patterns, feedback loops and strange attractors that can offer insight into how organizations can learn more effectively and instinctively self-organize into more erudite and organized systems that are more effective (Levy, 2000). It is through this advanced understanding that greater harm reduction can occur. Medication errors appear to be random and unpredictable, but similar to complex systems, they are created by tiny variations in behaviors and environmental factors. Complexity theory can guide the researcher to observe, value and identify the patterns of these seemingly random variations. The "web of causation" can be identified versus the individual parts contributing to errors (Levy, 2000, p. 82).

Additional insight into medication safety research that complexity theory can offer is the premise that long term prediction is difficult, if not impossible and system researchers need to be aware of the possibility of sudden change (Levy, 2000). Furthermore, complexity theory accepts that systems do not reach stages of equilibrium, or if equilibrium is reached it is particularly

brief. As a result, detailed strategic plans are of little service and instead organizations need to be deft and responsive to numerous circumstances. Studying the processes by which organizations adapt to environments can lead to insight into how they can faster adapt when chaos appears. If one views medication errors through this lens, research could be translated to determine better responses to potential medication errors or lessen the impact of medication errors when they occur.

Complexity theory stresses the importance of understanding interwoven processes that are intertwined throughout the healthcare system, it is through this understanding that sustained improvements can be achieved (Odberg et al., 2017). Complexity theory offers a novel idea of accepting the diversity and uniqueness of humans as a resource instead of a liability (Neuhaus et al., 2020). One research improvement with medication safety this could support is allowing departments to work individually and independently within the unifying structure of a common mission, culture and value system.

Complexity theory offers a conceptual framework to evaluate the entire environment and not limit findings to one cause of errors, it emphasizes the importance of understanding the relationships between environment, humans and technology. The goal of complexity theory is not to control the research context, rather to look for patterns of behavior and outcomes (Long et al., 2018). By evaluating patterns and relationships that occur between agents and the environment and adopting a long-term focus of understanding the contextual factors that affect outcomes, a deeper understanding of causes of medication errors can occur (Long et al., 2018). Closer analysis of seemingly erratic behavior can decrease missed opportunities to understand emergence (Litaker et al., 2006). Linear theories tend to ignore abnormalities as they do not fit with traditional thinking, instead complexity theory views anomalies as unique opportunities to

gain a deeper understanding of the system and relationships within the system (Woodside et al., 2018).

Conclusion

Complexity theory is a conceptual model, meaning it is more difficult to frame a research study, but history has demonstrated that traditional models have not provided the insight that will lead to improvements (Clancy et al., 2008). Through the use of complexity theory, the unique relationships that are found in healthcare and the increasing use of technology can be explored more deeply in the hopes of finding new information that will lead to further reduction in medication errors. Through this different lens a more comprehensive understanding of errors can be created and an effort to solve the puzzle can be abandoned. Instead, the environment needs to be understood as a shifting, evolving landscape to be monitored and explored. It is time to move from direct causes that lead to errors and accept that it is patterns that should be studied. Systems are not fixed in time, rather they are continually shifting, moving and re-organizing. Interventions are not a one-size fits all and that every intervention of change in a system can lead to entirely different outcomes. I suggest that through this shift in thinking to accept interdependence among nurses, environment, culture and technology we might finally be able to reduce medication errors and the harmful effects on patients, nurses and our healthcare systems. Complexity theory can offer a compelling framework to guide this body of research.

CHAPTER V: MANUSCRIPT 2, MULTILEVEL STUDY OF LATE MEDICATION OCCURRENCES IN THE ACUTE CARE SETTING

Abstract

The purpose of this research study was to explore the multilevel factors that contribute to late medication administration errors. Correlational design was used to evaluate shift, nurse and unit level predictor variables of late medication administration occurrences. Descriptive statistics and multilevel regression modeling was used to explore nested relationships among shift, nurse and unit characteristics and the count of late medication administration (LMA) occurrences for a 3-month period. Patient population, associate degree prepared RNs, and presence of a permanent charge nurse had a significant effect on the average count of late medication administrations. Nurses working in ICUs had a higher average count of LMAs compared to nurses working on medical-surgical, stepdown and mixed units. Nurses that possessed an associate degree had a higher average count of LMAs compared to bachelor's prepared RNs. The presence of a permanent charge nurse also resulted in higher average count of LMAs. These results inform further research to evaluate factors that contribute to RNs who do not have LMAs and larger samples to evaluate hospital level predictors. Complexity theory can be used to support the complex, multilevel and interdependent structure in healthcare. Medication errors, including LMAs, are an ongoing issue that affect patients, nurses and organizations. Understanding which predictor variables affect the occurrence of LMAs will help identify ways to provide a safer environment for patients.

Medication Errors

In the US preventable medication errors affect more than seven million patients across all care continuums, are the third leading cause of death and cost the US over $21 billion annually

(Lahue et al., 2012; Makary & Daniel, 2016). Medication errors have been evaluated for decades and multiple contributing factors identified, but traditionally in isolation, ignoring the complexity and interconnectedness of individual characteristics, culture and processes. As a result, findings do not always translate into practice, and error rates continue to increase (Zohr et al., 2017). Nurses are disproportionately associated with medication errors because 50-60% of medication errors are made during administration (Jember et al., 2018; Lee & Lee, 2021). I sought to consider the complexity and nested environment of healthcare to explore medication errors.

Violation of any of the five rights of medication administration (right patient, drug, dose, route and time) constitutes a medication error. Late medication administration accounts for 0.5 to 35.7% of medication errors, the second highest type of medication errors (Taufiq, 2015; Welton et al., 2018). Two categories of factors that contribute to medication errors have been studied: personal and organizational. Personal factors have included registered nurses' (RNs) years of experience, specialty certification, education level, and shift worked. Research findings on how these factors relate to medication errors has been conflicting. Fewer years of experience has been associated with more medication errors due to less RN confidence, gaps in pharmaceutical knowledge, and deviation from medication policies (Alomari et al., 2015; Brady et al., 2009; Davis et al., 2009; Keers et al., 2013; Murphy & While, 2012; Otaibi et al., 2018; Treiber & Jones, 2010; Wondmieneh et al., 2020). At the other end of the spectrum, expert nurses who spend more time critically assessing patients and intervening have less time for medication related tasks (Chang & Mark, 2011) and are more likely to practice outside of their scope (Bjorksten et al., 2016) which contributes to medication errors. But Wang et al. (2015) found that experienced nurses make fewer medication errors. Closely tied to experience is specialty certification, which measures nursing knowledge. One study found improved patient outcomes,

including deceased medication errors when nurses possess specialty certification (Kendall-Gallagher & Blegen, 2009). Specialty certification requires a minimum number of hours of experience in the specialty area which correlates with experience. Whereas, insufficient training, especially for a specialty area and with high alert medications, has been found to increase error rates (Sears & Goodman, 2012).

Research findings on the relationship between RN level of education and medication errors have been inconsistent. Dilles et al. (2009) found RNs with bachelor's degrees were more likely to identify adverse effects from medication administration and deviate from a scripted process based on patient conditions and needs. This can prove beneficial when reacting to patient care but can contribute to work-arounds when conditions change. Diploma-prepared RNs were more inclined to strictly follow medication administration policies and make fewer errors than nurses with bachelor's or associate degrees (Dilles et al., 2009).

Nurses who work night shift, are fatigued, work multiple shifts in a row or work overtime have been found to have increased rates of medication errors (Agyemang & While, 2010; Frith, 2013; Otaibi et al., 2018; Salami et al., 2019). High rates of medication errors while working night shift have been reported (Baghaei et al., 2015; Zaree et al., 2018). However, Pelliciotti and Kimura (2010) found no difference in rates of medication errors between day shift and night shift nurses.

Organizational factors linked to medication error rates include unit leadership and culture, size, RN autonomy, and patient population. Poor unit climate and culture are frequently cited as causes of medication errors (Drach-Zahavy et al., 2014; Gurses et al., 2009; Lawton et al., 2012; Managregada et al., 2018). Nurse managers have an intricate role in setting safety

culture for their units (Warshwasky et al., 2013), which has a direct impact on decreasing administration violations and errors (Perry et al., 2015).

Studies of medication errors and unit size have shown that larger units (either physical size or number of beds) that have a high nurse-supervisor ratio have higher error rates than smaller units with lower nurse-supervisor ratio (Drach-Zahavy et al., 2014). Direct oversight of nurses is closely tied to the RN's level of practice autonomy, again with inconsistent findings related to medication error rates. Hung et al. (2013, 2015) found that RNs with higher autonomy, typically due to less supervision and oversight, had higher rates of medication errors than nurses with more supervision. In contrast, Ko et al. (2018) found that low levels of RN autonomy led to emotional fatigue, job dissatisfaction and more medication errors than nurses with high autonomy. Patient population on a nursing unit, i.e., patient acuity level, is a primary indicator for risk of medication errors, with high numbers of medication errors associated with fast-paced intensive care units (McDowell et al., 2009; Tully et al., 2019).

Complexity has long been cited as a contributing factor to medication errors (Clancy et al., 2008) but most studies have examined either personal factors or organizational factors, rarely a combination of factors, which may contribute to conflicting results across studies. Furthermore, theories used to frame medication error studies traditionally have been mechanistic and linear, evaluating factors in isolation, rather than studying the interrelationships. Thus, this study was framed using complexity theory. Complexity theory is based on the assumption that systems are complex and interconnected, and relationships guide outcomes. Systems may appear random but are guided by rules and feedback loops that lead to constant change. Complexity theory may help explain why some factors decrease medication errors in one organization and increase errors in

another organization. Also, this provides guidance how some mitigating strategies that worked initially do not lead to the same results over time (Rickles et al., 2007).

Complexity theory can account for the nested effects found in healthcare and medication administration. The medication administration process is intertwined among providers, pharmacists, and nurses. In addition, multiple types of technology are used, for example, electronic health records, computerized provider order entry, automated dispensing cabinets and bar code medication administration. This technology increases complexity and potential for medication errors. Complexity theory offers an inclusive assessment of the many factors that can contribute to medication errors and does not force our discovery to be narrowed to a specific factor or to identify the most important factor. Complexity theory assumes that each situation is unique and unpredictable and recognizes that variations commonly discarded as noise or outliers can be integral factors. Although outcomes cannot be predicted, complexity theory conceives that all systems have patterns that are a response to rule and feedback loops. These patterns can be observed and lead to understanding about how the system will react.

The purpose of this study was to examine the multiple factors that can contribute to late medication errors to better understand the relationships between them and their impact on late medication administrations. Three aims were addressed:

Aim 1: Examine the relationships among nursing unit characteristics and amount of late medication administration occurrences per shift.

Aim 2: Examine the relationships among organizational characteristics, registered nurse (RN) characteristics and amount of late medication administration occurrences per shift.

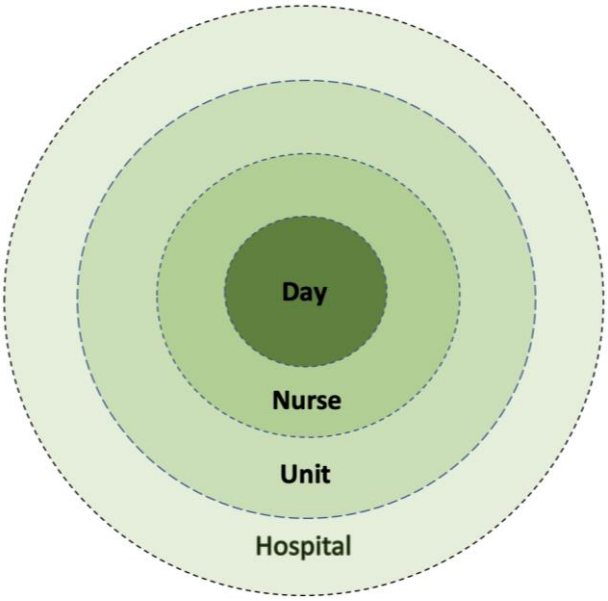
Aim 3: Examine the relationships among nursing unit characteristics and registered nurse characteristics and the occurrence of late medication administration per shift.

Methods

Design

An associational research design was used with a four-level hierarchical data structure and repeated measures of the same nurse working multiple shifts during the study period. Individual shifts were nested within nurses, who were nested within units, which were then nested within hospitals (see Figure 1). Late medication administration (LMA) data were collected for a 3-month period of January through March 2021.

Figure 1.B. Nested Design of Late Medication Administrations (LMAs)



Setting and Sample

Data were collected from a six-hospital system: an 815-bed tertiary care center, one rural hospital and 4 critical access hospitals that ranged in size from 25-30 beds. Thirty-four adult, inpatient units were included in the study; 26 units from the tertiary care center and 8 from the

critical access hospitals. This included 12 medical-surgical, 10 intensive care, 7 stepdown, and 5 mixed units (combined stepdown and medical-surgical beds). The studied occurred during the COIVD-19 pandemic and the number of dedicated COVID units varied from 3-6 at the tertiary care facility. The rural hospitals were not large enough to have any dedicated COVID unit. The study sample included all RNs who worked on these units and had administered a medication that was 60 minutes or more past the due time (late medication administrations [LMAs]).

The statistical power of this study was driven by multilevel modeling. For multilevel modeling, the methodological sample size literature found focuses on when persons or clusters are being randomized to conditions, which are not being done in this observational study. Thus, Jackson's (2003) N:q hypothesis was used; it recommends a minimum of 10:1 ratio guideline where for q predictor variables for a given level, a sample size of N observations on the same level per predictor are needed. In this study there four were nursing unit level characteristics, so a minimum of 40 total units would be required to jointly model them using the 10:1 guideline. Alternatively, the four characteristics could be modeled one-at-a-time but not jointly which could yield differing results. Thus, for unit-level characteristics, the study had sufficient power to detect relationships with up to 3 unit-level characteristics jointly. Given the large number of nurses and LMA occurrences (n=2611 LMAs) over the 3-month study period, the study was well powered (≥80%) to detect associations with nurse-level characteristics using Jackson's N:q sample size guidelines.

Study Variables

Study measures included shift, nurse and unit level characteristics. Operational definitions for each study variable are presented in Table 4.

Table 4. Operational Definitions of Predictor Variables

Variable	Definition
Shift Characteristics	
Shift	Day shift 0700 a.m. – 0659 p.m. Night shift 0700 p.m. – 0659 a.m.
Permanent charge nurse	Registered nurse who holds a permanent leadership position on the unit and has direct reports that was present on a given shift.
Registered Nurse Characteristics	
Years of experience	Length of time RN has worked for the organization in years.
Specialty certification	RN holds a current certification from a nationally recognized credentialing organization.
Degree	Highest nursing degree earned
Full time equivalent status	Full time equivalent - 36 hours or greater, part time - less than 36 hours a week, per diem - no confirmed hours per week.
Nursing Unit Characteristics	
Tenure of nurse manager	Years of experience at the organization.
Nurse manager degree	Highest degree earned, nursing or other.
Nurse manager certification	Nurse manager hold a current certification from a nationally recognized credentialing organization.
Unit Size	Number of hospital beds.
Patient Population	
Intensive care unit	Unit provides intensive and specialized care to critically ill patients (Marshall et al., 2017).
Stepdown unit	Unit provides care for an intermediate acuity patients, between an ICU and general medical unit (Prin & Wunsch, 2014).
Mixed unit	Unit provides care for both stepdown and general medical/surgical patients.
Medical-surgical (MS) unit	Unit provides care for a broad range of medical patients and/or patients that are preparing or recovering from surgery (AMSN, 2021).

Procedures

After university institutional review board approval and approval from the hospital professional research council were obtained, data were retrieved from electronic sources. Late medication administrations by shift were collected from a 24-hour electronic report maintained by the pharmacy. Registered nurse and nurse manager characteristics were collected from the

nursing department's Magnet® Recognition Program database. To ensure protection of human subjects all data were de-identified. Nurses' names and employee identification numbers were replaced with a unique study number and hospital names and units were replaced with a letter to represent the facility and the unit was assigned a unique letter. All data were stored on a secure, password protected server that was only accessed by the project team.

Data Analysis

Analyses were completed using the Statistical Package for the Social Science (SPSS) version 17.0 (SPSS, Chicago) and Stata 17 SE (StataCorp, LLC, College Station, TX). Preliminary data analysis included frequencies and descriptive statistics of LMAs, unit, nurse and shift characteristics. Multilevel count regression (Negative Binomial) was used to model relationships and answer study aims. To account for the nested effect of individual nurses (Level 2) and units (Level 3), Stata was used for multilevel regression with the cluster command.

An initial model for all three aims was performed that included only random effects without any predictor variables as fixed effects (Bell et al., 2013). Model fit was determined by comparison of Akaike's Information Criterion (AIC) and Bayesian Information Criterion (BIC) values for each model, with a smaller value indicating better fit (Bell et al., 2013). The AIC and BIC provide estimates of how well the model predicts the outcome variable and can be used in nested and non-nested data (Bell et al., 2013). Given only six hospitals, hospital-level predictors were not able to be modeled, but the clustering effect of hospitals was accounted for in the multilevel modeling. The use of multilevel modeling was important to account for the nested effects and prevent inflated type 1 error rates (Bell et al., 2013). Based on variance inflation factors multicollinearity was not a concern (*VIF = 1.06 to 1.83*). A two-sided p-value $<.05$ was considered statistically significant.

The reference category for patient population was selected as ICUs, as this population was significant compared to all others. Bachelor's degree was selected as the reference category for degree and full time was selected as the reference category for FTE status as these were the largest proportion of nurses in the sample.

Results

Characteristics of LMAs

A total of 2,611 LMAs occurred during the 3-month study period. The majority occurred in the ICUs (40.4%), followed by medical-surgical (28.9%), mixed (15.7%) and stepdown (14.6%) units. LMAs were higher on day shift than night shift (see Table 5). Of the medications that were given late 45.4% were verified with bar code medication administration and 48.9% patients were scanned during administration of their late medications. As expected, the majority of LMA occurrences happened at the large tertiary care facility, hospital A (89.2%) (see Table 5).

Nurse Characteristics Associated with LMAs

The data revealed that 942 individual RNs were associated with at least one LMA, this included RNs working on 34 different units in the six hospitals. There was a large amount of missing data across several predictor variables: FTE status 35.6% missing, maximum education 46.7% missing, and specialty certification 35.3% missing (see Table 5). The majority of LMAs were associated with RNs who worked full time (51.1%), had several years' experience at the organization (M=7.3 years, SD±8.4), held either a bachelor's (30.5%) or associate's degree (20.5%) and did not have specialty certification (55.2%). The maximum number of LMA occurrences per shift associated with one nurse was 19, with the majority of RNs having only

one (61%) or two (24.7%) LMAs per shift (M=1.8, *SD*±1.6). A permanent charge nurse was present on 37.1% of the shifts.

Table 5. Hospital, Nurse and Unit Characteristics of the LMA Occurrences (*n* = 2611)

Variable	Characteristics	Frequency	Percent
	Facility Characteristics		
Hospital	Hospital A	2,329	89.2
	Hospital B	68	2.6
	Hospital C	102	3.9
	Hospital D	53	2.0
	Hospital E	46	1.8
	Hospital F	13	0.5
	Shift Characteristics		
Day shift	Yes	1,532	58.7
	No	1,079	41.3
Permanent unit charge nurse	Yes	968	37.5
	No	1,643	62.9
	Nurse Characteristics		
FTE status	Full-time	1,334	51.1
	Part-time	229	8.8
	Per diem	112	4.3
	Missing	936	35.8
Highest degree earned	Bachelor's	797	30.5
	Associate's	535	20.5
	Master's	59	9.5
	Missing	1220	46.7
Specialty certification	Yes	248	9.5
	No	1,441	55.2
	Missing	992	35.3
RN years at organization	Range	Mean (SD)	
	0-43 years	7.3 ± 8.4	
	Unit Characteristics		
Nurse manager certification	Yes	161	6.2
	No	2,450	93.8
Patient population	ICU	908	34.8
	Mixed	287	11.0
	Medical-surgical	652	25.0
	Stepdown	272	10.4
	Missing	492	18.8
Unit size	Range	Mean (SD)	
	15-44 beds	29.9 ± 10.8	

Note. FTE = full time equivalent.

Aim 1. Relationships Among Organizational Characteristics, Nursing Unit Characteristics and LMAs per Shift

Three models were run, where an initial model with no fixed-effect predictors and only random effects for both nurse and unit was first performed (see Table 6). The second model added the level one predictor of permanent charge nurse as a fixed effect. The third model was run with each of the unit characteristics, patient population, unit size and nurse manager certification as fixed effects. Based on the sample size guideline from Jackson (2003), a maximum of three unit characteristics could be jointly modeled.

There were a total of 34 different units and the range of LMAs was 3-290 (M = 70.6, *SD*±10.23). The final (third) model showed medical-surgical, mixed and stepdown were statistically significantly different in average LMA occurrences (medical-surgical *p*<.001, mixed *p*<.001, SD *p*<.001*)* when compared to ICUs. The fit statistics for the initial model using Akaike's Information Criteria (AIC) and Bayesian Information Criteria (BIC), respectively, were 8229.35 and 8252.82 and for the final model, 6709.97 and 6760.89, indicating it was a better fit.

Table 6. LMA Random Effects for Nurse and Unit Only

Count LMAs	Coefficient	SE	P	95% CI	
_cons	1.643	.034	<.001	1.577	1.711
/lnalpha	-3.708	.449	-	-4.588	-2.828
First_lastVar (_cons)	.082	.026	-	0.440	.153
LocationName var(_cons)	.0138	.025	-	.0004	.457

The initial model shows the lnalpha of -3.708 (-4.588, -2.828). This number excludes 1 which indicates the data has overdispersion and the negative binomial is the better count model to run. A test for random effects revealed a Chibar2(01) = 177.67, p <.001, which indicates

multilevel negative binomial is the better model. Model findings that included level 2 fixed effects for unit characteristics are given in Table 7.

Table 7. Negative Binomial Modeling of Fixed Effects Unit Characteristics for LMAs

Count LMA	Exp(b)	SE	P	95% CI	
Charge Nurse	1.034	.046	.461	.946	1.130
Patient population					
ICU[RC]	-	-	-	-	-
MedSurg	.619	.070	<.001	.496	.773
Mixed	.554	.067	<.001	.436	.703
Stepdown	.606	.072	<.001	.480	.764
Unit Size	1.009	.005	.083	.999	1.019
NM certification	1.238	.216	.221	.880	1.741
_cons	1.713	.194	<.001	1.371	2.140
/lnalpha	-3.804	.552	-	-4.886	-2.723
Nurse Var(cons)	.056	.033	-	.018	.176
Unit Var(_cons)	.022	.033	-	.001	.409

Note. RC = reference category. LMA = late medication administrations. ICU = intensive care unit. MedSurg = medical-surgical. NM = nurse manager.

In the final model all non-ICU patient population groups were statistically significantly different when compared to the reference category of ICU. The predicted average count of LMAs for nurses working on a medical-surgical unit was 38.1% lower than for nurses working in an ICU when controlling for the other predictors in the model and nurse and unit clustering (Exp(*b*) = .619, 95% CI = [.50, .77], $p < .001$). The predicted average count of LMAs for nurses working on a mixed unit was 44.6% lower than for nurses working in the ICU when controlling for the other predictors in the model and nurse and unit clustering (Exp(*b*) = .554, 95% CI = [.44, .70], $p < .001$). Finally, the predicted average count of LMAs for nurses working on a stepdown unit was 39.4% lower than for nurses working in the ICU when controlling for all other predictors in the model and nurse and unit clustering (Exp(*b*) = .606, 95% CI = [.48, .76], $p < .001$). Unit predictors that were not statistically significant included the presence of a permanent charge nurse (p=.46), unit size (p=.083), and NM certification (p=.22). However, these non-

significant unit characteristics could be a result of low power due to the smaller number of units in the study and future research should continue to investigate their effects on LMAs.

Aim 2. Relationships Among Nurse Characteristics and LMAs per Shift

Three models were run, where an initial model with no fixed-effect predictors and only random effects for unit was first performed is given in Table 8. The second model added the shift predictor of a permanent charge nurse as a fixed effect. The third model added the following nurse characteristics: highest education level obtained, time of shift worked, presence of specialty certification and FTE status. The final model (third model) showed the presence of a permanent charge nurse was statistically significant, adjusting for the other predictors in the model (p<.001). The fit statistics, AIC and BIC, respectively, were 8,227.70 and 8,245.30 for the initial model and 4,259.724 and 4,311.906 for the final model, indicating better fit for the final model. A test for random effects revealed a Chibar2(01) = 177.32, p < .001 which again indicates multilevel negative binomial is a better model.

Table 8. Nurse Characteristics and LMA Random Effects Only Model

Count LMAs	Coefficient	SE	P	95% CI	
_cons	1.645	.034	<.001	1.579	1.713
/lnalpha	-3.665	.425	-	-4.499	-2.831
Unit var(_cons)	.095	.012	-	.074	.123

Note. LMA = late medication administrations.

The final model results with fixed effects for level 2 nurse characteristic predictor variables are given in Table 9.

Table 9. Negative Binomial Multilevel Modeling of Fixed Effects Nurse Characteristics for LMAs

Count LMAs	Exp(b)	SE	P	95% CI	
Charge Nurse	1.354	.063	<.001	1.236	1.483
Shift					
0700am – 0659 pm[RC]	-	-	-	-	-
0700pm – 0659 am	.996	.049	.931	.905	1.096
Highest Education					
Bachelor's[RC]	-	-	-	-	-
Associate's	1.019	.052	.716	.922	1.125
Master's	.851	.104	.186	.670	1.081
RN Specialty certification	1.143	.0852	.074	.987	1.323
FTE					
Full-time[RC]	-	-	-	-	-
Per-diem	1.019	.087	0.822	.863	1.205
Part-time	1.001	.068	0.990	.876	1.143
RN Years at Organization	.995	.003	0.152	.989	1.002
_cons	1.530	.136	<.001	1.286	1.821
/lnalpha	-5.275	2.744	-	-10.653	-.103
Nurse var(_cons)	.040	.011	-	.024	.068

Note. RC = reference category. LMA = late medication administration. FTE = full time equivalent.

In the final model only the presence of a permanent charge nurse was statistically significantly related to LMA occurrence. The predicted average number of LMAs for nurses working on a shift with a permanent charge nurse was 35.4% higher than for nurses working on a shift with a relief charge nurse when controlling for the other predictors in the model and nurse clustering (Exp(*b)* = 1.354, CI = [1.24, 1.48], $p < .001$). Nurse predictors that were not significant were shift worked (p =.931), highest nursing degree (Associate's p =.72, Master's p =.19), specialty certification (p = .07), FTE status (per diem p = .82, part-time p = .99) and years at the organization (p = .15).

Aim 3. Relationships Among Organizational Characteristics, Nursing Unit Characteristics, Nurse Characteristics and LMAs per Shift

Three models were run, where an initial model with no fixed-effect predictors and only random effects for both nurse and unit was first performed is given in Table 10. The second model added the shift predictor of a permanent charge nurse as fixed effects. The third model was run that included fixed effects for all shift, nurse, and unit predictor variables. The fit statistics were AIC and BIC respectively, 8,227.70 and 8,245.30 for the initial model and 3,570.34 and 3,650.99 for the final model, indicating the final model was a better fitting model. A maximum of three unit level predictors were modeled based on Jackson's (2003) guidelines for sample size.

Table 10. Unit Characteristics, Nurse Characteristics and LMAs Random Effects Only Model

Count LMAs	Coefficient	SE	P	95% CI	
_cons	1.643	.034	<0.001	1.577	1.711
/lnalpha	-3.708	.449	-	-4.588	-2.828
Nurse var(_cons)	.082	.026	-	.044	.153
Unit var(_cons)	.014	.025	-	.0004	.457

Note. LMA = late medication administrations.

The initial model shows the lnalpha of -3.708 (-4.588, -2.828). This number excludes one which indicates the data have overdispersion and negative binomial is the correct model to run. Chibar2(01) = 177.67, $p < 0.001$ which indicates multilevel negative binomial is a better model. The final model results are presented in Table 11.

Table 11. Fixed Effects Unit Characteristics, Nurse, and Shift Characteristics and LMAs

Count LMAs	Exp(b)	SE	P	95% CI	
Permanent charge nurse	1.053	.063	.384	.937	1.183
RN years of experience	.998	.003	.655	.992	1.005
Shift					
07:00 am - 06:59 pm[RC]	-	-	-	-	-
07:00 pm - 06:59 am	.957	.050	.398	.863	1.060
Highest Education Level					
Bachelor's[RC]	-	-	-	-	-
Associate's	1.098	.058	.079	.989	1.219
Master's	.854	.109	.215	.666	1.096
RN specialty certification	1.111	.084	.162	.959	1.287
Unit size	1.000	.006	.963	.989	1.013
Patient population					
ICU[RC]	-	-	-	-	-
Medical-surgical	.626	.091	.001	.470	.832
Mixed	.643	.093	.002	.485	.854
Stepdown	.599	.089	.001	.448	.801
Nurse manager specialty certification	1.092	.240	.688	.710	1.679
FTE Status					
Full time[RC]	-	-	-	-	-
Part-time	1.011	.072	.874	.880	1.163
Per-diem	1.023	.088	.789	.865	1.210
_cons	2.159	.382	<.001	1.527	3.054
/lnalpha	-15.320	432.022	-	-862.068	-831.429
Nurse var(_cons)	.026	.009	-	.013	.053

Note. RC = reference category. LMA = late medication administration. FTE = full time equivalent.

In the final model patient population unit type was statistically significant (medical-surgical p = .001, mixed p = .002, SD p = .001) and associate's degree versus bachelor's degree was approaching significance (p=.08). Similar to the model for **Aim 1**, all non-ICU patient populations were significantly different compared to ICU units. The predicted average count of LMAs for nurses working on a medical-surgical unit was 37.4% lower than for nurses working in an ICU when controlling for the other predictors in the model and nurse clustering (Exp(b) = .626, 95% CI = [.47, .83], p = .001). The predicted average count of LMAs for nurses working

on a mixed unit was 35.7% lower than for nurses working in the ICU when controlling for the other predictors in the model and nurse clustering (Exp(*b*) = .643, 95% CI = [.49, .85], *p* = .002). Finally, the predicted average count of LMAs for nurses working on a stepdown unit was 40.1% lower than for nurses working in the ICU when controlling for the other predictors in the model and nurse clustering (Exp(*b*) = .599, 95% CI = [.45, .80], *p* = .001). RNs with an associate's degree versus bachelor's degrees approached significance, where the predicted average count of LMAs for nurses with an associate's degree was 9.8% higher versus nurses with bachelor's degrees and controlling for other predictors in the model, and nurse clustering (Exp(*b)* = 1.098, 95% CI = [.99, 1.23], *p* = .08).

Unit predictors that were not statistically significant were the presence of a permanent charge nurse (*p* = .38), unit size (*p* = .96), and nurse manager certification (*p* = .69). Individual nurse predictors that were not significant included years of experience at the organization (*p* = .66), shift worked (*p* = .40), specialty certification (*p* = .16), and FTE status (per diem *p* = .79, part-time *p* = .87*)*. For nonsignificant findings, caution could be taken in interpreting these results as the number of units relative to number of modeled unit characteristics was lower. Future research should continue to investigate these relationships to rule out false negative errors.

Discussion

Complexity theory focuses on the complex and interconnected nature of systems and offers an alternative framework to the fragmented, linear approaches often used to study medication errors. This study found that in isolation, several predictor variables were statistically significant yet when combined with other nurse and unit level predictors they were not significant. Both individual nurse and unit characteristics appear to influence the occurrence of

LMAs on nursing units. In two analytic models, nurses who work in ICUs had a higher average number of LMAs when compared to nurses working on other adult units. The other variable that was significant was the presence of a permanent charge nurse, which led to a higher average number of LMAs. Although not statistically significant, unit size and nurses with an associate's degree approached significance indicating the average number of LMAs increased slightly (.9%) for each additional bed on the unit and slightly for nurses with an associate's degree (9.8%). Several predictors identified in prior research did not impact LMAs in this study. These were specialty certification (held by either the RN or Nurse Manager), shift, FTE status and years of experience.

Similar to findings of this study, higher rates of medication errors have been found in ICUs (Tully et al., 2019). ICU patients are inherently sicker, typically receive a higher number of medications and having changes to medications regularly during a shift, which provides more opportunities for error. The presence of a permanent charge nurse increased the predicted mean count of LMAs. Presence of a permanent charge nurse can affect nurse autonomy, which has been shown to both increase and decrease medication errors (Drach-Zahavy et al., 2014; Hung et al., 2013; Hung et al., 2015; Ko et al., 2018). Unit size is a predictor of nurse autonomy (Drach-Zahavy et al., 2014) and findings of this study showed that the average number of LMAs increased slightly as unit size increased.

One factor that could have influenced the study results was missing nurse characteristics data; this was associated with significant use of temporary staff during the study period. Data on education, experience and specialty certification were not captured for them because a different onboarding process was used and their time at the organization was limited. Missing data can decrease the ability to detect relationships and possibly bias results. Consequently, the amount of

missing data should be considered when evaluating the study findings. With almost half of the data missing for some variables, comparing our findings, both statistically significant predictors and those not significant with findings that have been reported by other researchers should be cautiously considered.

Although the aims did not directly address bar code medication administration (BCMA), the descriptive results related to this process should be considered. Scanning rates were exceptionally low on LMAs, only 45.4% of medications were scanned and only 48.9% of patients were scanned. The organization holds a BCMA goal of 95% for all medications given. This is another area that should be considered for additional research as a marker for potential medication errors, workload exceeding human capacity or predictor of system level effort.

BCMA data was the one aspect of this research that was focused on process measures as opposed to structure. The medication administration process is a combination of both structure and process, and where structures are easier to measure, i.e., acuity of patient population, number of RNs working on a shift, and unit size, process measures are harder to capture. Additional research that focuses on measuring medication administration processes can add further insight into LMAs and other medication errors. Potential process measures could include analysis of medications removed from automatic dispensing cabinets, interruptions or time patients are off the unit for procedures or tests. Ideally additional process measures would be gathered electronically to aid in data collection, but future research would benefit from this comprehensive analysis of the complex process of medication administration.

Three aspects of this study were unique when compared to other medication error studies. First, the study evaluated characteristics of nurses that had LMA occurrences but did not analyze characteristics of nurses that did not have LMA occurrences; it would be important to include the

latter in future studies. The second unique aspect is only one type of medication error was evaluated – LMAs. Few other studies focused on only one category of administration errors and this should be considered when evaluating the results. Third, LMAs have received little study despite their high rate of occurrence, upwards of 25% as identified by Welton (2017), and their correlation with missed nursing care (Kalisch et al., 2009; Lake et al., 2017). Further investigation of factors contributing to LMAs is warranted, particularly because the data available about them through the electronic medical record.

There were several limitations with this study. It was difficult to obtain accurate data for RN degree and RN specialty certification from the organization. Most organizations do not have an incentive to collect and archive this information unless they are seeking Magnet® status. The study institution was preparing to apply for Magnet® designation and so was collecting data on nurse education and certification status using a manual process of the nurse manager following up with each RN to verify education and certification status and enter the data into the Magnet® database. In addition, most specialty certifications require biannual renewal, so re-validation of the data by the employer is required every two years to ensure accuracy.

The large amount of missing data contributed to the inability to analyze all predictor variables. Analyses modeling nurse manager highest degree obtained and tenure did not converge due to the large amount of missing data. Facility predictors (level 4) could not be analyzed either due to only six hospitals in the study. Based on Jackson's (2003) sample size guidelines, a minimum of ten hospitals would be needed to model facility-level predictor variables.

Another confounding factor was that the organization was experiencing high RN turnover rate and high use of temporary nursing staff. The study data were collected during the COVID-

19 pandemic. Patient populations, acuity and length of stay were impacted with the pandemic as the number of elective surgeries decreased and medical admissions increased. The 3-month data collection period was chosen to minimize dramatic shifts in hospital census. The census for this study quarter was in line with the average census for the past 12 months, 690 average census compared to 685 average census and length of stay was 5.53 days compared to 5.58 days for the past 12 months. Patients were waiting longer to be seen and often had delayed preventative care, resulting in high acuity and comorbidities which may have increased the number of medications being administered and thus the potential for LMAs. Increased use of personal protective equipment (PPE) was required during the pandemic. Donning and doffing PPE likely took time away from direct patient care, including medication administration.

The amount of data that could be collected determined the models that could be run to some extent. Most data were level 1 (shift) and level 2 (nurse) data, as a result of capturing shift and some nurse characteristics from the pharmacy's LMAs report. As data were added for the level 3 (units) and level 4 (hospitals), the amount of data decreased. Thus, when level 4 data were added, the models did not converge.

Future Research

Hierarchical data is found everywhere in healthcare, but multilevel modeling is infrequently used for data analysis. Using multilevel modeling will aid in reduction of type 1 errors, for the approach conceptually maps onto the actual structure of healthcare and could help to account for the inconsistent and sometimes contradictory findings about medication errors. Given the data structure of this study, i.e., a large number of LMAs, 942 RNs, 34 units and six hospitals, larger studies are warranted to better understand organizational effects on LMAs. The study was conducted in only one hospital system located in the Southeast, limiting

generalizability. Similar studies should be considered for a larger number of organizations and different geographic locations. Lastly, this study looked only at predictors for LMA occurrences; future research should include medication administrations without errors to investigate if different predictors have a positive effect on patient safety.

CHAPTER VI: MAJOR FINDINGS

Manuscript 1: Complexity Theory

Complexity theory was used to frame this research study. The majority of prior research on medication errors has used a mechanistic lens to breakdown medication administration processes and study different factors that independently affect the process and outcomes. Given the complex and embedded nature of healthcare this perspective may be too narrow to generate helpful information for addressing the problem of medication administration errors. In contrast, complexity theory recognizes that when systems are broken into their parts, they are no longer systems. Research using complexity theory as a framework may lead to different results because predictor variables are not isolated in the analysis and findings that the mechanistic lens would have discarded as noise are evaluated. With complexity theory, differing outcomes are expected, as each system is understood to be unique. Based on this, when research findings are translated into practice it would be an unbiased and flexible process that would change and adapt to the unique circumstances.

The first manuscript for this dissertation, "Using Complexity Theory to Frame Medication Safety Research," presented an analysis of complexity theory as a framework for research about medication safety and the potential it can provide to improve medication error research. Complexity theory transforms the fundamental unpredictability of healthcare through the discovery of new, ever-changing patterns found in systems. Complexity theory views systems as non-linear, dynamic, governed by rules and feedback loops, strange attractors, fuzzy boundaries and emergence. As a foundation for research this mandates that the system be looked at in its entirety, versus broken apart into individual pieces, as is done when using mechanistic theories. Complexity theory contends that systems are not linear and predicable, meaning a

mathematical equation for reactions cannot be determined. Mechanistic theories propose that changes occur in a linear fashion, for example, each increase in x equals an increase in y. Complexity theory, however, seeks to explore relationships that are guided by norms and feedback loops that create patterns which guide behavior. The research moves from cause-and-effect outcomes to identification of relationships and patterns which can guide behaviors. I proposed that medication error research designed based on complexity theory could offer an understanding of the processes by which nurses adapt to the units they are working on and self-organize to either contribute to medication errors or decrease medication errors.

The following are examples of how complexity theory can be used to understand the context of my study. Complexity theory incorporates the concept of fuzzy boundaries, that systems are open and interact with the environment around it. As a result of the current pandemic, there is greater fluidity in nursing. Initially, I had predicted 31 nursing units as the sample size, but the final study results represent 34 units. The increase was a result of "flex" units that were opened by the study hospitals to handle the surge of COVID-19 patients during the study period. Additionally, missing data became a problem because of the large number of travel and temporary nursing staff that were hired by the hospital system. One recent survey reported that 90% of hospitals used travel nurses and 80% had lost staff to travel nurse opportunities during the pandemic (Muoio, 2021). With the on-going nurse shortage and continued job growth, the use of travel nurses is likely to continue beyond the pandemic (Stephenson, 2021). In addition, nursing staff are increasingly being floated to different units as patient needs and acuity change within a hospital. This staffing practice also exemplifies the fuzzy boundaries found in nursing. This fundamental change in nurse staffing will require new perspectives and insight to ensure medications are administered safely.

A second example of using complexity theory to understand the context for this study is the value of understanding self-organization. With complexity theory, all systems will self-organize. This self-organization is based on rules or norms and recursive feedback loops. Even if given a defined way to perform a job or task, a unit will change this procedure based on the unique circumstances they experience and patient needs. One potential example of this is bar code medication administration (BCMA). BMCA for medications given late were performed less than 50% of the time compared to the organizational average BMCA rate of 95%. Nurses might be self-organizing, i.e., deciding that BCMA is not important when they are behind in tasks. One alternative to consider is rather than being rigid and overly defined, clear outcomes and safety metrics are determined and allow for flexibility in processes. Although this directly violates the safety principle of standardization, it might lead to decreased medication errors and harm.

Complexity theory is a grand theory and more abstract by nature. This can make it harder to use when framing a research study, but makes it better suited to study complex issues that arise in healthcare (Florczak et al., 2012). The fact that complexity theory is abstract and nonlinear furthers the difficulty in translation to a research study, especially given that reductionism has been the primary method for research over the past several decades (Mitchell, 2011). This more comprehensive and inclusive framework for research can potentially lead to results that reflect the medication administration process more comprehensively and provide new insights into reducing medication errors, a goal that has been recognized for years, yet not obtained.

Manuscript 2: Multilevel Modeling

The second manuscript of the dissertation is a report of the study design and results. A database that included LMA occurrences, and data about shift, nurse and unit characteristics

from a six-hospital system was created. Multilevel Negative Binomial regression was used to evaluate the relationship between predictor variables and the count of LMAs. Results of the study found that nurses working in ICU settings had a higher average count of LMAs compared to nurses working on other adult units (medical-surgical, stepdown and mixed) when controlling for all the other predictors in the model. Nurse with an associate's degree had a higher average count of LMAs compared to nurses who possessed a bachelor's degree and the presence of a permanent charge nurse was associated with a slightly higher average count of LMAs.

Multilevel regression has not been widely used in nursing research, but can help to address the conceptual and statistical restraints of nested data (Slater et al., 2006). Multilevel modeling should be used when data is nested, or embedded as complexity theory defines the concept (Slater et al., 2006). When data are clustered, either in families, units or communities, they tend to be more alike when compared to data outside of the cluster (Slater et al., 2006). This study compared nurses that worked together on individual units to nurses working on other units. The cluster effect must be accounted for to ensure significance tests are correct and to prevent correlated errors terms (Bell et al., 2013; Slater et al, 2006).

Multilevel modeling also allows the researcher to address all levels of data found in healthcare as opposed to picking just one level and prevents errors of "fallacy of composition" or errors of inferring a relationship at a higher level from data on a lower level (Slater et al., 2006, p. 378). The use of multilevel modeling also reduces the potential for type 1 errors with clustered data (Bell et al., 2013; Slater et al., 2006). multilevel modeling allows for a richer, more flexible analysis of data, and when the most appropriate method is used, it can paint a story from the data (Shirilla et al., 2021).

The results of this study showed varying outcomes when compared to prior research results; some are in line with prior results and others differ. For example, ICUs were found to have higher rates of medication errors, which was consistent with the findings from prior studies. However, no differences in the average count of LMAs were found based on years of experience. Some of the differences could be based on the use of multilevel modeling. As stated, multilevel modeling allows for multiple levels of data to be analyzed together, it also accounts for any overlap of variance that can be found in clustered data. Complexity theory also recognizes that findings are unique to the data set studied and therefore prior research could have different outcomes based on initial conditions and system uniqueness. These differences in statistical methods and theoretical approach could account for the differences and could lead to new insight into contributing factors for late medication errors.

Limitations

Limitations from a research perspective pertained to data collection and analysis. The structure of multilevel modeling requires different levels of data to model all the nested levels. In this study there was a large amount of LMAs and nurses who administered the LMAs, but smaller numbers of units the nurses worked on and even smaller number of hospitals. This limited and even prohibited analysis of the higher, level 4 predictors.

The COVID-19 pandemic contributed to the large amount of missing data pertaining to nurse characteristics. Nurse turnover and changing staffing models are being seen nationally with the higher use of temporary staff. At the study site these changes led to gaps in nurse characteristics data.

Implications for Practice and Future Research

The study laid the foundation for using complexity theory and multilevel modeling to evaluate and mediate medication errors. Potential findings that can translate into practice relate to the increased count of LMAs that were identified in the ICU patient population. The ICU setting has been linked to increased error rates in prior studies (McDowell et al., 2009; Tully et al., 2019). Given the acuity and vulnerability of patients in the ICU, additional care and precaution should be used to keep patients safe. Research could in identifying differences between time sensitive medications and non-time sensitive medications that are given late. Per the CMS definition, time sensitive medications are allotted a 30-minute window before and after the scheduled administration time due to criticality and pharmacokinetics of the medication. The lens of complexity theory can aid in understanding that additional technology such as BCMA can product outcomes different than intended and harness the potential of understanding patterns and self-organization to allow units to adapt faster to their environments.

Research studies using multilevel modeling and complexity theory can add new knowledge by allowing researchers to consider a holistic view of medication errors. Given that the majority of data in healthcare has a nested quality, multilevel modeling can account for this and minimize errors that occur when this is ignored. Complexity theory allows for the researcher to consider nonlinear systems, the fuzzy boundaries frequently found in healthcare, and differing outcomes based on sensitivity to initial conditions. For example, one ICU that is staffed with long-term, highly skilled nurses will have different outcomes compared to an ICU staffed with travel nurses.

The use of BCMA technology is widely accepted as a best practice when administering medications in the hospital, Leapfrog, a national non-profit organization dedicated to improving

quality and safety, has set a standard compliance rate of 95% (Leapfrog, 2021). Given the study finding that the scanning rate for late LMAs was approximately half of the organizational goal (45.4% vs. 95%), this should be further evaluated. Lower scanning rates are associated with increased medication errors including wrong medication, wrong dose and wrong patient (Broome et al., 2020). Complexity theory could view this from the perspective of fuzzy boundaries and unanticipated consequences with technology. This additional layer of technology could provide the unintended consequences of decreased use when the nurse is presented with late medication administrations occurrences. This bypassing of technology when already stretched could present the opportunity for increased error rates. Further evaluation of BCMA scanning rates may offer insight into nurses who need additional coaching, technology issues or workload that exceeds human capacity.

Given the hierarchical structure of nurses nested within units that are nested within facilities and Jackson's (2003) N:*q* hypothesis for sample adequacy, future studies should evaluate a larger number of hospitals to evaluate hospital level predictor variables. In addition, this study only evaluated RNs who were associated with LMA occurrences. Future research should include investigation into RN characteristics that were not associated with LMA occurrences to validate if the predictor variables identified in this study are consistent.

Organizational theory includes the study of both structure and processes. To fully understand the factors that impact LMAs, future research should include evaluation of both of these pillars. The findings with BCMA are the one aspect of this study that focused on process measures of the medication administration process while the other factors related to structure. Literature supports there are between five rights of safe medication administration process to 28 steps in the process identified by one researcher (Johnson, 2011). Being able to identify and

measure these process steps further could lead to valuable insight into how and why LMAs and other medication errors occur.

Nursing is a complex profession and medication administration is a complex process. Using traditional linear approaches to address patient safety needs to be augmented by more inclusive, relationship-based theories, such as complexity theory, that consider the multiple, interconnected factors that contribute to medication errors. Through this new lens, a deeper understanding of factors related to medication errors can be further researched and addressed.

Complexity theory may help us to understand how systems can learn more effectively and spontaneously self-organize into more sophisticated systems that are better adapted to their environment.

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