NURSES' WORK IN THE CONTEXT OF MEDICATION ADMINISTRATION, ERRORS, AND ORGANIZATIONAL SAFETY

by

Sara Forsyth Hawkins

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The University of Utah Graduate School STATEMENT OF DISSERTATION APPROVAL

The dissertation of	Sara Forsyth Hawkins	
has been approved by the follo	wing supervisory committee members	s:
Janice M. Morse	, Chair	April 14, 2017 Date Approved
Teneille R. Brown	, Member	April 14, 2017 Date Approved
Lauren Clark	, Member	Oct 23, 2017 Date Approved
Nancy A. Nickman	, Member	April 14, 2017 Date Approved
Barbara L. Wilson	, Member	April 14, 2017 Date Approved
and by Patricia G. Morton		, Chair/Dean of
the Department/College/School	l of Nursing	

and by David B. Kieda, Dean of The Graduate School.

ABSTRACT

The cost of medication errors is burdensome to patients, institutions, and frontline providers. Nurses are accountable for and vulnerable to institutional safe medication practices and make this responsibility their highest priority; yet, contextual factors relevant to nurses' work encompassing medication administration are not well understood. The aim of this ethnographic study was to identify and describe nurses' work in the context of medication administration, errors, and organizational safety.

Using nonparticipant observation (92 hours) and 37 unstructured interviews with nurses, administrators, and pharmacist in a mid-sized hospital in the United States, I found the nature of nurses' work characterized by: 1) *chasing a standard of care*, 2) *prioritizing practice*, and 3) *renegotiating routines*. These characteristics were inextricably linked to organizational structures, the medication management system, competing obligations, and shifting of priorities.

Data were divided into two articles: 1) *Nurses' Work in the Context of Medication Administration: Untenable Expectations* provides a thick description of everyday experiences on the unit, medication administration, and the potential for errors. From these data, I present an emerging theoretical model. 2) *The Paradox of Safety in Medication Management* is a microanalysis of the medication use process with a specific focus on patterns of medication errors in the hospital, and the role of the pharmacists as a "stop-gap" between the physicians and patients in the recognition and interception of medication errors. These results enhance our understanding of why present efforts targeting the reduction of medication errors may be ineffective.

to Richard, Jakob, Kady and Zakary

Mrs. Newsome was assigned to me today, she almost died.

She sickened soon after I started her dialysis. Her hands, arms, and legs cramped up; She was in agony, and Then she began to convulse.

Instantly, I knew it was my fault, I must have erred in preparing the machine. Imaginings of guilt, shame, and embarrassment washed over me. Rat-like, I sniffed out possible escapes, What would you have done? Would you dare to say?

Then, I felt a presence by my side. I can't explain it; a presence came and stood. "Character," it whispered. "Equanimity," it softly spoke.

Robert Allen Bear. 2011. *Sorrows reward: A novel* (p. 100). Victoria, BC, Canada: Kingsley Publishing. Used with permission.

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CHAPTER 1

INTRODUCTION

In 2007 the Joint Commission recognized the seriousness of medication errors involving nurses and mandated efforts to introduce a culture of safety (Pronovost & Sexton, 2005). However, medication errors continue at an alarming rate despite 2 decades of policy change, changes in the education of nurses, medication procedures, and economic accountability at the local level. Previous research approaches epidemiologically or as time-motion studies—explored errors in nursing administration of medications. Medication errors were detected and described through interviews with the nurses who themselves made errors, or by direct observation. However, even though researchers recognized that medication errors are associated with the context of medication administration (for instance, "flagging" the medication nurse so that she/he will not be interrupted while giving medications), research has not yet investigated the process of giving medications in context. Only one study was found to explicate the complexity of medication administration through an ethnographic study of workplace turbulence (Jennings, Sandelowski, & Mark, 2011).

This ethnographic study extends the work of Jennings et al. (2011) and capitalizes on the description, analysis, and implications of medication administration and errors in the context of the nurses' work and organizational safety beyond the individual unit. Kant (1781) posited that knowledge is possible only for things as we experience them. In this case, the complexity associated with the process of medication administration may best be understood from within the context of an "insider's" perspective. Only this emic knowledge can provide the most complete basis for developing culturally congruent interventions (Leininger, 1991).

Background

Serious medical errors pose a significant threat to patient safety as evidenced by mortality rates and cost. Today, overall mortality associated with hospital care may be as high as 210,000 deaths per year (James, 2013). Specifically, medication error has been identified as contributing to one in five adverse hospital events at a cost that exceeds an estimated \$21 billion (Barker, Flynn, Pepper, Bates, & Mikeal, 2002; Lisby, Nielsen, Brock, & Mainz, 2010; Network for Excellence in Health Innovation [NEHI], 2011; Pham et al., 2011). Results from a study by the Committee on Identifying and Preventing Medication Errors (2007) demonstrated that the rate of medication error is between 2.4 and 11.1 errors per 100 doses. In hospitals, these errors occur most commonly in the prescribing and administration stages (Aspden, Wolcott, Bootman, & Cronenwett, 2007; Leape et al., 1995; Wahr et al., 2014). Nurses administer as many as 50 medications per shift and are most accountable and vulnerable to the effects of any breakdowns or interruptions to this process (Mayo & Duncan, 2004).

Many published studies suggest possible ways to combat error and enhance medication safety interventions through human factor engineering and technology. These studies targeted the characteristics of the medication use process and specific nursing characteristics and workload. Computerized provider order entry (CPOE), bar coded medication administration (BCMA), automated dispensing systems, and medication reconciliation processes represent some of these efforts (Barnsteiner, 2005; Larrabee & Brown, 2003; Poon et al., 2010; Pronovost et al., 2003; Vogelsmeier, Pepper, Oderda, & Weir, 2013). Other studies focused attention on specific nursing characteristics and contributing factors such as educational theory and knowledge, deviation from procedure, nursing workload, and barriers to reporting (Brady, Malone, & Fleming, 2009; Gladstone, 1995; Pape et al., 2005; Taxis & Barber, 2003a). Yet, few studies recognize that while technology has the potential to improve medication safety, it has a significant effect on nursing workflow (Elganzouri, Standish, & Androwich, 2009; Keohane et al., 2008; Larrabee & Brown, 2003). It is, therefore, worth considering technology's effect on nurses' work in the reduction of medication errors.

Efforts to quantify nursing workflow or nurses' work have been limited to work sampling, time-motion studies, and self-reporting. These studies often separate nurses' work into categories of medication-related activities and nonmedication related activities (Burke et al., 2000; Keohane et al., 2008) but fail to consider the associated cognitive workloads associated with these activities. In short, we have yet to fully achieve the opportunity to reduce patient harm, reduce overall cost, and change the approach to medication administration and nurses' work.

Severity of the Problem

The Institute of Medicine (IOM) first reported on this state of affairs in 1999 and then challenged providers to reduce errors by 50% within 5 years. Sadly, in the 15 years since the IOM report, there has been little progress toward that goal (Pronovost et al., 2009). The frequency of preventable medication errors remains cause for concern. Therefore, reducing the risks of medication errors is a national priority (Aspden et al., 2007; Patterson, Cook, & Render, 2002) and in 2010, the Patient Protection and Affordable Care Act (PPACA) made it a matter of law. PPACA calls for a National Quality Strategy to generate greater safety interventions and metrics in hospitals (United States House of Representatives, 2010). From an organizational perspective, a growing body of evidence supports the importance of the context of care which promotes a culture of safety characterized by mutual trust, collaboration, and nonpunitive responses to errors (Anderson & Webster, 2001; Blegen et al., 2010; Leape et al., 2009; Reason, 2000; Verbakel, Langelaan, Verheij, Wagner, & Zwart, 2014).

Research confirms that the administration phase of the medication use process is the locus for most errors (Barker et al., 2002; Fahimi et al., 2007; Taxis & Barber, 2003a; Tissot et al., 2003; Valentin et al., 2009; Wahr et al., 2014). Distraction, interruptions, and nursing workload also increase errors (Biron, Lavoie-Tremblay, & Loiselle, 2009; Fahimi et al., 2008; Hopkinson & Jennings, 2013; Pape et al., 2005; Tissot et al., 2003; Valentin et al., 2009; Westbrook, Woods, Rob, Dunsmuir, & Day, 2010). Hence, there is a prevailing assumption that errors can simply be reduced by streamlining, partially automating processes, and decreasing interruptions to medication administration (Jennings et al., 2011; Keohane et al., 2008).

Research Aim

Within the framework described above, this study aims to explore nurses' work in the context of medication administration, errors, and organizational safety. The effects of the medication use process (prescribing, transcribing, dispensing, administering, and monitoring), medication errors, and organizational culture, structure, and work environment provide the context. Together, these characteristics can reveal what nurses' work is and how it is accomplished.

Chapter 2 contains an extensive review of literature regarding medication errors, error reporting, and error prevention. The methods used in this study are described in Chapter 3. I present my findings as articles in Chapter 4- *Exploring Nurses' Work in the Context of Medication Administration: Untenable Expectations* and Chapter 5- *The Paradox of Safety in Medication Management.* In Chapter 6, I discuss the implications for future research, policy, and practice.

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CHAPTER 2

REVIEW OF LITERATURE

The responsibility for the administration of medications in the clinical area sits firmly on the shoulders of nursing. Patient safety and the prevention of medication errors is fully integrated into the nursing education. In the ethical training of nurses, we stress that if an error is made, immediate reporting is essential (Evans et al., 2006; Milch et al., 2006; Pham et al., 2011) so that any untoward effects may be immediately rectified. Nurses learn that any breach of protocol in handling medications may result in censure and even loss of licensure.

The "5 Rights" of medication administration (right patient, right drug, right dose, right route, and right time) represent an element of critical thinking skills employed by nurses. Nurses are responsible for:

- ensuring that the physician's order is correct in type of medication and dosage;
- ensuring that the correct medications have been delivered from the pharmacy;
- knowing the actions and interactions of the medications they administer;
- monitoring for side effects and any other untoward symptoms experienced by the patient.

An additional sixth right or "right documentation" has also been introduced as a safe practice (Donaldson, Aydin, Fridman, & Foley, 2014; Jennings et al., 2011). This

checklist, long rooted in nursing practice, provides a benchmark for judging the performance of individual nurses (Brady et al., 2009). When nurses follow the "6 Rights" with precision, medication errors can be halted before ever reaching the patient. However, as Katzman (2015) alludes, nurses are often forced to hierarchize the importance of patient care with other duties. This leads to workarounds that undermine established protocols, hence introducing the potential for active failures and latent conditions.

To reduce the chance of error in the handling of drugs, computerized unit-dose dispensing systems via automated dispensing cabinets were introduced in the late 1990s. In addition to creating medication dosage by individual units in use since the 1950s, automated dispensing systems document the time, type, and staff member's name for every medication removed. Captured data link to and become part of the patient's medical record.

Despite all efforts thus far, medication errors that cause harm to patients continue to occur in an estimated 1% to 2% of hospital inpatients and contribute to an increased hospital stay of 4.6 to 10.3 days for each affected patient (McLeod, Barber, & Franklin, 2014). This review of the literature discusses the epidemiology of medication errors, prior research approaches to identify causation, and methods to correct the problem.

Epidemiology of Medication Administration Errors

Since the release of the 1999 IOM report that drew attention to the severity of medication administration errors (MAE), many epidemiological studies tried to accurately estimate the magnitude of the problem (Balas et al., 2004; Barker et al., 2002;

Kopp, Erstad, Allen, Theodorou, & Priestley, 2006; Rothschild et al., 2005; Taxis & Barber, 2003a; Wahr et al., 2014). Researchers vary greatly in the way they study medication administration (MA), employing different methods of measurement and delineating different characteristics of error. For instance, error characteristics tracked by MedMARx, an existing reporting system of the United States (U.S.) Pharmacopeia and the Institute for Safe Medication Practices (ISMP), include: type, node, consequence/category, cause, contributing factors, day of the week of occurrence, shift of occurrence, action taken, and staff who committed error (Pham et al., 2011). Despite these criteria, a lack of clear agreement on the definition of medication errors continues to create difficulty in accurately recognizing medication errors, reporting them, and subsequently establishing accurate medication errors rates (Aronson & Ferner, 2005; Chiang & Pepper, 2006; Lisby, Nielsen, Brock, & Mainz, 2012).

Regardless, epidemiological studies using retrospective review have been useful to establish prevalence (Ashcroft, Birtwistle, Cooke, Hingley, & Moore, 2003; Brennan et al., 1991; Leape et al., 1991; Pham et al., 2011; Wahr et al., 2014) and severity of the problem. Medication errors are the most common type of medical error and account for 19% of adverse events in hospitalized patients (Brennan et al., 1991; Leape et al., 1991).

However, past studies have been criticized because only those errors that were actually reported were included in these studies. Voluntary self-reporting systems are known for reporting bias with events highly under-reported (Milch et al., 2006; Osborne, Blais & Hayes, 1999; Pham et al., 2011). To correct this problem, hospitals introduced anonymous reporting systems. Such systems remove the stigma of making mistakes and the threat of censure—a discussion of which follows shortly (Milch et al., 2006; Pham et al., 2011).

Prospective direct observation has been a favored approach and is considered to be most accurate for studying medication errors (Donaldson et al., 2014; Flynn, Barker, Pepper, Bates, & Mikeal, 2002). Three such observational studies found the incidence of MAE among nurse and/or physician participants in hospitals varied from 17% (Kopp et al., 2006) to 19% (Barker et al., 2002), to 49% (Taxis & Barber, 2003a). The significantly higher results reported by Taxis and Barber (2003a) may be attributable to a specific focus on intravenous (IV) drug errors and the use of disguised observation. Participants were told the investigators were interested in common problems with preparation and administration. The researchers intervened when they witnessed a potential error, yet still included the event in the dataset as an error (Taxis & Barber, 2003a).

While higher rates of error in medical-surgical units have been delineated (Fahimi et al., 2007; Tang, Sheu, Yu, Wei, & Chen, 2007; Wolf, Hicks, & Serembus, 2006), most of the research has been conducted in Intensive Care Units (ICU) (Fahimi et al., 2007; Kopp et al., 2006; Osmon, Harris, Dunagan, Prentice, Fraser, & Kollef, 2004; Rothschild et al., 2005; Valentin et al., 2009; Wahr et al., 2014), emergency departments (Pham et al., 2011) and pediatric units (Alsulami, Choonara & Conroy, 2014; Stratton, Blegen, Pepper & Vaughn, 2004). This focus on specialty areas occurred because of the inherent high level of patient acuity and risk associated with the work accomplished.

Consequently, this focus limits our comprehensive understanding of medication errors.

Types of Errors Explored

There is no single definition used to label medication errors (Aronson & Ferner, 2005; Brady et al., 2009; Lisby et al., 2010). One systematic review of literature revealed 45 different and generic definitions of medication error (Lisby et al., 2010). Despite efforts to standardize definitions, they are not used consistently. One commonly cited, albeit complex definition, comes from the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) (2015):

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. (para.1)

A great majority of research focused on preparation and administration of IV medications since more than 300 doses of IV medications are given daily on general medical/surgical units and intensive care in both teaching and nonteaching hospitals (Cousins, Sabatier, Begue, Schmitt, & Hoppe-Tichy, 2005; Fahimi et al., 2008; Taxis & Barber, 2003a; Valentin et al., 2009). Researchers observed higher error rates in the administration of IV medications, particularly those that required multiple step preparation and administration (for instance, drugs that required addition of a diluent, mathematical calculations, and accurate push rates) (Valentin et al., 2009).

Other errors specific to the administration sequence included wrong dose, wrong drug, wrong time, or omitted dose (Barker et al., 2002; Lisby, Nielsen, Brock & Mainz, 2005; Valentin et al., 2009; Wahr et al., 2014). Additionally, research cited problems with appropriate patient monitoring (Aronson, 2009; Rothschild et al., 2005), and with

the ordering (Rothschild et al., 2005) and dispensing stages (stocking and delivery to units) of the medication process (Kopp et al., 2006; Taxis & Barber, 2003a).

Few studies categorized medication errors on classification of medication (Barker et al., 2002; Kopp et al., 2006; Tissot et al., 2003; Wahr et al., 2014), day of the week (Pham et al., 2011), and category of harm (Lisby et al., 2005; Tissot et al., 2003; Wahr et al., 2014). The variation in rates and characteristics of MAE have led to many theories of causation and various strategies to prevent these errors.

Context and Causation of the Error

Defective medication administration systems were most associated with the one error in every five doses administered observed by Barker et al. (2002). As the complexity of the medication use process increases, so do errors. For instance, there is an increased risk of error in medications with:

- Doses that must be estimated or medications that must be mixed (Cousins et al., 2005; Taxis & Barber, 2003b)
- Complicated technology or "sound-alike look-alike" (SALA) medications (Taxis & Barber, 2003b)
- IV medications: an increase use and the number of IV medications (Bruce & Wong, 2001; Han, Coombes, & Green, 2005)
- Occupancy rates and the number of patients per nurse in larger the ICUs (Cousins et al., 2005; Valentin et al., 2009)

Additionally, some medications have doses that vary according to patient condition or weight. These "high-alert" medications, such as insulin and anti-

coagulants, require verification by two licensed providers because they are frequently involved in medication errors (Balas et al., 2004).

Ninety-seven percent of errors are human error (Taxis & Barber, 2003b). Because the nurse is primarily responsible for the actual administration of the medication, most research has focused on the nurse. Researchers have investigated nurses' knowledge (Rothschild et al., 2005; Taxis & Barber, 2003b), staffing (inadequate staffing or inexperienced staff) (Hall, Doran, & Pink, 2004; Mark & Belyea, 2009; Tang et al., 2007; Wolf et al., 2006), workload and the complexity of nursing tasks (Elganzouri et al., 2009; Jennings et al., 2011; Keohane et al., 2008; Tang et al., 2007), fatigue (Mayo & Duncan, 2004; Osborne et al., 1999), nursing interruptions and distraction (Biron, Lavoie-Tremblay, & Loiselle, 2009; Donaldson et al., 2014; Hopkinson & Jennings, 2013; Mayo & Duncan, 2004; Pape et al., 2005; Tang et al., 2007; Westbrook et al., 2010), lack of standard protocols (Tissot et al., 2003), and patient acuity (increased numbers of medications, lack of venous access, or inability of the patient to cooperate) (Taxis & Barber, 2003b). Repeated themes associated with omitted doses also include failures in communication during transitions and at handoffs (Kazaoka, Ohtsuka, Ueno, & Mori, 2007; Taxis & Barber, 2003b). Lack of pharmacist support may even constitute a latent failure in the system (Taxis & Barber, 2003b).

Characteristics of the nurse have also been investigated with more errors in medication administration occurring due to deliberate deviations from standard practices and procedures, such as not verifying the patient's name with his or her armband (Donaldson et al., 2014; Osborne et al., 1999; Tang et al., 2007; Taxis & Barber, 2003b). The ability to accurately measure medication errors requires sound epidemiological research. The next section briefly describes some varying designs used.

Research Designs

Previous research has been both qualitative and quantitative, and most of it was conducted retrospectively (Ashcroft et al., 2003; Pham et al., 2011; Wahr et al., 2014; Wolf et al., 2006). This research, along with focused ethnography, has offered important insights but none has provided "the" answer to prevent MAEs.

Qualitative researchers have interviewed nurses or have surveyed nurses asking them to recall the nature, possible cause (Tang et al., 2007), and type of errors they have made (Mrayyan, Shishani, & Al-Faouri, 2007). Wheeler et al. (2014) noted that the qualitative study of medication error has been beneficial given the high level of human factors shown to account for error.

Quantitative researchers, seeking more information about the causes of medication errors, observed and noted that more interruptions for nurses correlated with both increased errors and more severe medication administration errors (Keohane et al., 2008; Westbrook et al., 2010).

Focused ethnography is particularly useful in showing the contextual variables that play a significant role in MAE (Jennings et al., 2011; Patterson et al., 2002; Taxis & Barber, 2003a, 2003b).

Reporting of Error

The decision to report a medication error is perhaps as complex as defining what constitutes a medication error. The psychology of decision-making is grounded in

cognitive processes that result in a selection of belief or course of action (Lamb & Sevdalis, 2011). This resultant choice may or may not prompt an action and may be influenced by individual or organizational needs, culture, values, priorities, emotions, and logic. From a nursing perspective, nurses ground their clinical reasoning in knowledge from many fields to help them grasp the medical and nursing implications of a situation, read a patient's condition over time, and master ever-changing healthcare environments (Benner, Sutphen, Leonard, & Day, 2009).

Despite improved reporting tools, Kagan and Barnoy (2013) cite the concerning statistic that only 44.1% of nurses often or always report medication errors. This study corroborates the results of other studies suggesting high levels of underreporting (Blegen et al., 2004; Chiang & Pepper, 2006; Chiang, Lin, Hsu, & Ma, 2010; Espin, Levinson, Regehr, Baker & Lingard, 2006; Espin et al., 2007; Espin, Wickson-Griffiths, Wilson, & Lingard, 2010; Stratton et al., 2004; Trockmorton & Etchegaray, 2007).

A lack of clear agreement on the definition of medication errors creates difficulty for nurses in recognizing errors and in the decision to report them (Espin et al., 2010; Kagan & Barnoy, 2013; Lisby et al., 2012; Milch et al., 2006; Treiber & Jones, 2010). Nurses are likely to define medication errors in terms of deviations from standards of practice and subsequently base the decision to report on the severity of the error in terms of patient harm (Espin et al., 2007, 2010; Osborne et al., 1999; Throckmorton & Etchegaray, 2007). In fact, when no harm occurred, nurses in many studies would selfcorrect, perhaps report the error only informally, and move on (Chiang et al., 2010; Espin et al., 2006, 2007, 2010).

As the largest segment of healthcare providers, nurses play a significant role in

improving patient medication safety. While nurses report taking this role very seriously, they deliberately decide not to report medication errors (Dickson & Flynn, 2012; Kingston, 2011; Mayo & Duncan, 2004; Wakefield et al., 2001). This makes little sense. Nurses with experience in underreporting perceive more reporting barriers. This negatively influences their future decisions to report (Chiang et al., 2010). A nurse's experience in making mistakes seems to propagate a belief in their sound judgment regarding the level of severity so that when errors are not life-threatening, they can best be corrected and managed quietly without reporting or charting (Chiang et al., 2010; Espin et al., 2006, 2007, 2010).

Further, nurses indicate that underreporting is related to fear of repercussion, lack of workplace support, desire to save-face with peers, fear of legal repercussions, and threats to licensure (Blegen et al., 2004; Chiang & Pepper, 2006; Chiang et al., 2010; Qin, Xie, Jiang, Zhen, & Ding, 2014; Stratton et al., 2004; Wolf, Serembus, Smetzer, Cohen & Cohen, 2000). Despite the adoption of culture of safety initiatives in hospitals, nurses remain afraid to report. A fear of censure, loss of employment or licensure, and legal action are deep-seated cultural attributes in healthcare that are difficult to overcome (Gorini, Massimo, & Pravettoni, 2012; Waring, 2005).

Interventions and Integration a Safe Culture

Interventions combating MAE were designed from both the human factors and the system perspective with goals to improve accuracy and clarity of orders, reduce reliance on memory, and increase access to information (Bates, 2000; Fontan, Maneglier, Nguyen, Loirat, & Brion, 2003; Koppel et al., 2005). Information technology systems such as CPOE have been effective at intercepting prescribing and administration errors 86% of the time (Bates et al., 1999).

Other interventions include improving communication on nursing teams through interdisciplinary collaboration (Propp et al., 2010), double-checking processes related to high-risk medications and populations (Alsulami et al., 2014), and removing distractions. Some innovative approaches to reducing distractions include "Do Not Disturb" signage (Pape et al., 2005), checklists and reminders (Pape, 2003), and the creation of "No Interruption Zones" (Anthony, Wiencek, Bauer, Daly, & Anthony, 2010).

Leape et al. (2009) noted that regulations alone are inadequate and impractical for safe care. They described the need to transform healthcare by requiring a major cultural change that demands a culture of safety. Safety does not depend on measurement, practices and rules. It depends on a culture of trust, reporting, transparency, and discipline. The human condition cannot be changed, but the conditions under which humans work must be changed (Reason, 2000). Hence, "culture of safety" literature reports on the importance of managing the practice environment (Dickson & Flynn, 2012; Gorini et al., 2012; Hofman & Mark, 2006; Kagan & Barnoy, 2013; Katzman, 2015; Leape et al., 2009; Mardon, Khanna, Sorra, Dyer, & Famolaro, 2010; Verbakel et al., 2014).

Analysis of the literature suggests multiple strategies for improving safety:

- Basic monitoring with IV medications
- Nonpunitive incident reporting systems (Blegen et al., 2004)
- Better hand-off communication at change-of-shift
- Centralized medication preparation areas (Valentin et al., 2009)

- No interruption medication preparation zones (Anthony et al., 2010)
- Improved education of health professionals (Leape et al. 2009)
- Increased sense of value in role of nurses and nurse clinical reasoning (Dickson & Flynn, 2012)
- Higher "culture of safety" scores

Higher scores in culture of safety measures seem to indicate greater transparency and trust at all levels of the organization (Anderson & Webster, 2001; Hofman & Mark, 2006; Mardon et al., 2010; Richter, McAlearney, & Pennell, 2014; Vogus & Sutcliffe, 2007).

Ramifications of Medication Administration Errors

Patient Harm

Though there are many potential ways to define medication errors, a helpful way to organize them for study is to categorize medication errors in terms of a combination of deviation from the intended use and by the consequence of the medication error to the patient. The NCCMERP (2001) defines patient harm as impairment of physical, emotional, or psychological function or structure of the body, pain, or death. NCCMERP also used an index to categorize medication error types and subsequent outcomes as shown in Figure 2.1. Of primary concern are categories E through I. These categories represent errors that result in patient harm. Errors resulting in harm or death represent 56% of all possible outcomes. In the observational study performed by Barker et al. (2002) 7% of the drugs involved in errors threatened harm to the patient. In other words, a small minority of drugs caused the majority of untoward outcomes.

NCC MERP Index for Categorizing Medication Errors



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Figure 2.1 NCC MERP definitions and categorizations of patient harm resulting from medication errors.

In Valentin et al. (2009), participants self-reported that 0.9% of the study population experienced Category G (permanent harm) or Category I (death because of medication errors at the administration stage). The authors acknowledge however that this number may be an underestimate given the self-report.

Nurse Harm

Medication errors have severe, long-term emotional effects reminiscent of posttraumatic stress disorder (PTSD) (Rassin, Kanti, & Silner, 2005). Many of the repercussions appeared self-imposed as nurses struggled with feeling self-critical and insecure in their roles (Rassin et al., 2005; Treiber & Jones, 2010). Interestingly, none of the studies included in this review confirmed legal action, loss of employment, or loss of licensure against nurses who have erred.

In fact, Hwang and Park (2014) found the medication error experience was not significantly associated with nurses' intent to leave the profession. Only one study validated that nurses fear blame or loss of face with colleagues (Ullström et al., 2014).

Two separate media reports help illustrate the real ramifications of medication error for both nurse and patient. While the following events may be viewed as apocryphal and uncommon, they are real and sobering (S. Richardson, personal communication, August 25, 2015).

Seven months after a mathematical error that led to an overdose and subsequent death of an infant, Kimberly Hiatt committed suicide. Hiatt was 50 years old with nearly 3 decades of nursing experience. Media reports of the incident indicated that after the event, Hiatt was placed on administrative leave and later dismissed from her employment setting off a downward spiral of isolation, despair, and depression (Aleccia, 2011; Institute for Safe Medication Practices [ISMP], 2011).

A more recent headline reveals a Utah jury ordered a former nurse and care facility to pay \$1.4 million for the death of a man who was given a wrong medication. The news media reported that after the nurse recognized she gave the wrong medication, she falsified the medication record. The care facility denied responsibility for the actions of its nurse, commenting that had she simply reported the error they could have rescued the patient. Consequently, the nurse was put on license probation for 3 months and has since allowed the license to expire (Miller, 2015). The nurse in this story may move on with life, but there are real and painful ramifications for the deceased man's family.

Theoretical Framework

Nearly 2 decades after the Institute of Medicine's (IOM) 1999 report, medication errors continue to occur at an alarming rate. Interventions have not been effective in reducing errors. Nevertheless, two landmark studies introduced a new perspective for examining nurses' work and medication administration (Jennings et al., 2011; Patterson et al., 2002).

In 2002, Patterson et al. conducted an observational study of bar-code medication administration (BCMA). They identified five problems: "1) nurses became confused by technology of BCMA, 2) coordination was degraded between nurses and physicians, 3) nurses dropped activities to reduce workload during busy periods, 4) prioritization of monitored activities during goal conflicts was increased, and 5) there was decreased ability to deviate from routine sequences" (p. 540). Figure 2.2 shows the activities that



Figure 2.2 Interruptions during medication administration prior to BCMA. (Source: Patterson, E. S., Cook, R. I., & Render, M. L. (2002). Improving patient safety by identifying side effects from introducing bar coding in medication administration. *Journal of American Medical Informatics Association*, (9), 540-533. Used with permission.)

were considered a higher priority and superseded medication administration.

Pressures on nurses' work time resulted in tension between actual time (clock time) and perceived time (process time) (Davies, 1994). Davies (1994) characterizes process time as unpredictable, nonlinear, and not predetermined. For example, feeding an elderly person may take an unknown amount of time. It may involve periods of waiting during which the nurse may complete other "parallel" tasks (p. 280). As a nurse's workload increases, the perception of clock time decreases while process time may increase or decrease. Process time may be increased by maximizing efficiency. Jennings et al. (2011) noted that workload may be:
1) *Clustered:* combining with other tasks, or combining medication times. For example, combining both 8 am and 10 am medications.

2) *Multi-tasked:* conducting several tasks simultaneously. For example, talking on the cell phone or to family members while drawing up medications.

 Managed: developing individualized techniques for managing temporal load.
 For example, developing workarounds to established procedures or checklists to mark off as tasks are completed.

Examining nurses' work as tumultuous activity, in the context of competing perceptions of time, Jennings et al. (2011), noted that "medication administration entailed a complex mixture of often varied and competing demands that temporally structured the nurses' entire work day" (p. 1441).

Medication administration, Jennings et al. (2011) noted, was not simply giving drugs. It also did not have defined temporal boundaries as shown in Figure 2.3. Rather, it was inseparable from nurses' other work as depicted in Figure 2.4.

Because administering medications inherently includes interruptions from patients and families, or inquiries from other nurses or physicians, research that emphasizes reducing interruptions as an intervention for decreasing medication errors is invalidated. The inseparability of medication administration from other nursing work "challenges the very idea that other nursing work and the work of medication administration can interrupt each other" (p. 1442). The numbers of doses of medications both scheduled and unscheduled (both STAT and PRN) in a medical and surgical unit forced the nurse to rush through care "just to keep up" (p. 1444). Nurses did not have time to assist patients, respond to requests, or give patients their full attention. Nurses found it was impossible



Figure 2.3. Research designs segmenting medication administration from nurses' work.



Figure 2.4. Research exploring medication administration as a component of nurses' work.

to establish a routine, and unscheduled medications paradoxically also interrupted the routine. Patients' needs such as expressions of pain or complaints of pain and need for PRN medications also disrupted workflow, with nurses aware that when patients were in pain "five minutes feels like 20 to the patient" (p. 1444). Further, when several patients required medications at the same time, "the time demand on the nurse increased exponentially because of numerous steps involved in medication administration" (p. 1445).

The flow of medication administration was further complicated by the nurses' assessment of patients and the need to contact physicians to request orders to alleviate symptoms, or for renewal of medications. When nurses entered patient rooms to administer medications, patients would request assistance to the bathroom or to have other needs addressed. Jennings et al. (2011) noted that nurses estimated that it took 20 minutes in a patient's room but occasionally a single medication pass was "as long as 120- or 140-minute event" (p. 1446). If a code occurred, medications for other patients were delayed. The needs of other patients also interrupted the "temporal rhythm" of medication administration. The result is that nurses sequence medication administration with the goal of giving "as many medications 'on time' as possible" (p. 1448). Nurses' work therefore occurs within a chaotic environment. While the Jennings et al. (2011) study was not primarily focused on medication errors, it is in the *context of nurses' work that errors occur*.

Ultimately, giving medications cannot be separated from other tasks. Even when nurses reprioritize their workday to increase efficiency by clustering other activities, multitasking, and developing timesaving workarounds, this does "...not allow them to isolate medication administration as a discrete uninterruptible event. This showed that prevailing research approaches to understanding medication administration rested on *an inherently faulty premise*" (Leeman & Sandelowski, 2012, p. 176, italics added).

I base the theoretical framework for this study (see Figure 2.5) on two studies: Jennings et al. 2011; and Patterson et al. 2002. This study extends the work of Jennings et al. (2011) by conducting an observational study in a medical unit and extending the scope of the study beyond the unit to consider the hospital as a system. Using Jennings' study as theoretical context, my interview perspectives included participants from pharmacy, quality management, and administration. Furthermore, collected data of past medication errors were examined not as single isolated events, but from the Patterson et al. perspective of prioritization of competing tasks and the Jennings et al. perspective of nurses' work.

Recommendations for policy and nursing education is missing from the literature



Figure 2.5. Hypothetical model for data collection. Researcher perceives medication administration as defining nurses' work with other tasks scheduled around, clustered, or multitasked with medication administration.

thus far. While the nature of my qualitative investigation cannot predict such results, the firm description and theoretical contributions of these investigators provide important foundational advantages to this project. This study provides a new perspective on medication errors by not considering errors as a breakdown in a linear process or a failure to follow simple instructions, but as a part of the chaotic and complex conditions of the context of nurses' work.

Other investigators have decontextualized medication errors and examined them apart from nurses' work or have deconstructed nurses' work in order to operationalize its components. Jennings et al. stated very clearly that this context stripping invalidates such analyses. Additionally, the impact of these errors, and the possible changes they have made in the way the nurses subsequently work, may inform the style of nursing that others may use to control the "disorder and turmoil" in nursing practice (Jennings et al., 2011, p. 1442).

Research Questions

This study explores nurses' work in the context of medication administration, errors, and organizational safety. The following research questions guided this study:

- 1. Given the complexity of nurses' work, how do nurses prioritize medication administration within a medical unit and the hospital environment?
- 2. What is the nurses' experience with medication errors, patient care, their work environment, and the organizational culture of safety?

a. What do nurses experience in the immediacy and aftermath of a medication error?

b. How does setting affect medication error, including contextual events leading up to and following the error?

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CHAPTER 3

METHODS

Ethnography has developed over the years and become highly adaptable for diverse purposes and settings. Early nurse researchers such as Pamela Brink (1982, 1989), Madeline Leininger (1979), and Agnes Aamodt (1975) introduced applied ethnography within the community to enhance the understanding of nursing care. The first ethnography conducted within a hospital was Carol Germain's (1979) *The Cancer Unit*, designed to understand nurses' work and the patient's experiences of illness and care that could not be captured by quantitative inquiry (De Chesnay, 2015). Ethnographic methods became more focused in the next decades to focus on the experience of care giving, nurse patient interaction, and the illness experience for particular patient problems (Morse, 2015c).

In this project, I used ethnographic methods to explore nurses' work in the context of medication administration. Using the methods and theoretical perspective developed by Jennings et al. (2011) and Patterson et al. (2002), the primary focus was a medical unit and its staff (including physicians, unit pharmacists, and unit clerks or support staff). However, the scope of this study also extended to those departments involved with patient safety (quality management and code team), pharmacy, hospital administration, and risk management. Thus, this study extended our understanding of the influences of medication management and safety beyond that described by Jennings et al. (2011) and Patterson et al. (2002), and contributed an additional layer of understanding to the problem.

To collect data, I employed nonparticipant observation and unstructured interviewing in the hospital. I also explored nurses' work (with a focus on medication administration) using pertinent documents such as medication administration records, patient notes, policies and procedures, hospital quality data, and error rates. The nurses' experiences with medication management could not be separated from nurses' work.

The overarching goal in this study was to achieve an understanding that is rounded—fully-developed—and not segmented. Hence, the stages of field work were flexible and involved observation and interviews that mutually interacted simultaneously or sequentially across all possible events (Agar, 1980; Hughes, 1992).

Stages of Field Work

My ethnographic method moved from the general to the specific as I became more familiar with the setting, gained insight into "what was going on," and gained the participants' trust.

Phase I

The research process began initially with becoming acquainted with the setting. This phase included broad nonparticipant observation which, in this case, was a fluid process of observing nurses' work flow, nurse-patient interaction, and becoming familiar with the daily routines (Morse & Field, 1995). These minimal and unobtrusive observations of everyday practice permitted me to track patterns of behavior and process interactions as they occurred in the setting; including those that were embedded, implicit, or unconscious (Morse & Field, 1995). I observed the daily repeated routines and activities associated with medication administration in the hospital to determine the structure of any given day (Jennings et al., 2011). Broad observations occurred in a minimum of 3-hour increments and covered the 24-hour day, all days of the week.

At the beginning of the observational period each day, I "rounded" the unit introducing myself to the staff and patients. I informed patients of the research and obtained verbal permission to observe them. Further I reminded staff of the project and obtained necessary consents. I noted the locations of staff members or patients who had declined to participate in the study so that I could avoid or omit observations of their care. Consent to participate in this study was considered processual consent. That is, staff had the opportunity to withdraw their consent at any time or to enter the study at any point. In addition, I routinely confirmed permission to enter into field notes any pertinent information obtained through casual conversations.

To begin data collection, I interviewed administrators to initiate a top-down approach to selecting study participants. This approach ensured that trust with unit participants would not later be brought into question. However, as data were needed later in the project, administrators were reapproached.

Phase II

Once familiar with the setting, observations became more focused. I shadowed nurses who gave their permission for periods of 1 to 3 hours during their shifts on the

unit, followed by a period of intense recording of field notes. The purpose of the shadowing was to collect microanalytic data of nurses' work (Jennings et al., 2011). I scheduled time for these focused observations directly with the nurses. My observations include nurse routines and the nurses' work in their totality. While focused on medication administration, I was also interested in all that the nurse did.

Fieldwork also included attendance at hospital meetings, for example, general nursing orientation and staff meetings. While attendance at a Root Cause Analysis (RCA)—real-time investigations of medication errors that the facility found important within the focus area—would have benefited this study (De Chesnay, 2015), hospital administration did not grant permission.

During my observations, I did not engage in patient care, nor interfere with nursing care delivery. To establish the proper identity, I wore a white lab coat and a "researcher" name tag at all times.

Phase III

Phase III provided maximal data collection. Staff members acclimated to me so my presence had little effect on staff behavior. Staff volunteered information and considered themselves even as co-researchers. Staff also involved me in jokes; I was becoming "one of them." Nevertheless, I did not disclose research findings the staff at this point.

For me, the results were beginning to form and make sense. I could predict what would happen, know how staff would act, and anticipated nurse-patient interactions.

By the end of Phase III, I was very comfortable among the staff. However, I

recognized that I was losing objectivity and the ability to separate my own experiences from that of the participants. At this time, I warned the staff that data collection would be terminating in 2 weeks.

Phase IV

Planning and preparing for Phase IV, the termination of data collection began when I entered the field (De Chesnay, 2015; Hammersley & Atkinson, 1995). However, once I announced my withdrawal, data collection entered a frenzied pace. Those who had not been interviewed offered to be interviewed and staff provided additional information to ensure that I had the story right. When the time came for me to terminate the observations, I requested permission to contact staff should a problem or query arise from the analysis. I also made a commitment to the staff to return and present findings at a later time.

Data Collection

Collection of Demographic Data

Following informed consent and explanation of the project, I collected demographic information (see Appendix E) from nonpatient participants. This included age, gender, cultural background, educational background, and length of service. Demographic data collected from patients were compiled on a separate form, as shown in Appendix F.

Unstructured Interviews

I conducted unstructured ethnographic interviews with nursing staff, physicians, administrators, risk managers, and pharmacists using a variety of techniques. Techniques included: friendly conversation (Agar, 1980; Spradley, 1979), "man on the street" interviews to elicit targeted explanations, and more formal unstructured interviews (Corbin & Morse, 2003). However, as Spradley (1979) described, regardless of the technique, unique elements remained consistent: the explicit purpose, ethnographic explanations, and ethnographic questions.

Establishing rapport was essential in generating accurate data. It was necessary to restate the purpose of the interview and remind the participants with each interview of the interview goals. Processes of ongoing consent (Morse & Field, 1995) required repeatedly providing an explanation of the project. Finally, each question asked in the interview served a specific function:

- Descriptive questions assessed the participant's language.
- Structural questions elicited how the participants organized their knowledge.
- Contrasting questions revealed what participants meant by the specific terms they used.

The type of questions asked changed as my knowledge of the setting and the problem matured.

As participants volunteered to be interviewed for this study, I made private appointments for face-to-face interviews or for telephone interviews (per the participant's preference) at a time convenient for the staff member. To protect the participants' privacy and identity, I carefully arranged for private places for the interviews. I also arranged for times and places that prevented competing demands of clinical care from interfering with the interviews. I conducted interviews in the clinical setting, during breaks, or on the participant's own time. I used a digital audio-recorder for all interviews.

Initially, all unstructured interviews began with a "grand tour" question. For example, I asked, "Tell me about a typical shift on the med/surg floor." Based on participant responses, I refined questions using an open ended iterative approach to further clarify concepts or to elicit more in-depth discussion when indicated. To make associations, verify assumptions, and understand the topic from the participant's perspective, I employed active listening for implicit and explicit meaning in the explanations and descriptions (Spradley, 1979).

The Targeted Interview

Although I gained a great deal of insight from the early unstructured interviews, it was sometimes necessary to return to ask more targeted questions designed to elicit further information.

A targeted interview began with a specific question; "Tell me...," or for verification, "Have I got this right?" Or to elicit variations, "Some people say____; is this how it is for you?" While interviewing nurses who have made medication errors, I asked: "What was going on that day?" "Tell me about that day?" "What was the unit like that day?" "How has that changed the way you think about your work now?" "Tell me, has it changed the way you do your work?" Agar (1980) referred to this process as "narrowing the focus." The targeted interview essentially became a method I used to obtain a complete understanding of participant responses.

Institutional Documents and Statistics

Hospitals keep a tremendous amount of quantitative data which measure patient acuity, hospital case mix index, quality metrics, and human resource statistics. Such statistics were useful in understanding the context of nurses' care and confirming trends and patterns. These data were used to check impressions or validate information provided by participants (Morse & Field, 1995; Morse, 2015a).

Setting 8 1

This study was conducted in an urban acute-care facility in the United States which employs approximately 1100 nurses. The facility uses a shared governance model, so to enhance the potential for applicability, I designed this project with input and approval from the hospital's Research Council, which served as a key gatekeeper.

Fieldwork occurred in the Adult Medical Unit of the hospital. These units have an increased risk for medication errors due to a higher number of internal factors such as high volumes of aging adults with complicated prescriptions or inadequate nurse staffing (Hall et al., 2004; Mark & Belyea, 2009; Tang et al., 2007).

Sample

Recruitment began in unit staff meetings where I introduced the project, answered questions, and distributed materials including the informed consent forms. Unit staff had an abbreviated copy of the proposed study available and were invited to ask questions.

As participants volunteered, I compiled a detailed log of potential participants and assigned participant numbers.

The ongoing analysis of data results guided sampling strategies and the determination of participants within the notions of categorization and saturation (Mayan, 2009; Morse, 2015c); ensuring replication and confirmation (Morse, Barrett, Mayan, Olson, & Spiers, 2008; Morse, 2015b).

Data Collection

Before I collected any data, I obtained Institutional Review Board (IRB) approval from the University of Utah and the participating facility. A researcher's ability to establish rapport and collect data through nonparticipant observation, interviews, and other methods (which in this case included collection of institutional data and statistics) is the key to successful ethnography. Participants signed written consents for observation and interviews. I did not include in the data any observations without such consent.

To begin, I completed administrative level interviews including (but not limited to) the Assistant Chief Nursing Officer, Director of Pharmacy, Director of Quality, and Risk Management. These were followed by interviews with members of the code team, other people from pharmacy, quality assurance, physicians, risk management, and nursing staff. Observations in the unit were conducted in short "blocks" of time (of approximately 3 hours), selected throughout the 24-hour period. After each of these observations, I recorded my field notes into the digital recorder. Other minimal field notes were recorded during the observations.

During the nurse observation periods, I asked the nurse to "think-aloud"

(Lundgrén-Laine & Salanterä, 2010) so I could record multitasking and clustered tasks. As the study proceeded, nurses received pocket recorders and lapel microphones to record their competing thoughts and actions during busy and less busy times. The recordings produced verbatim transcriptions for data comparison.

It was important to remain free from biasing influences, so I did not engage in discussion of unit politics with staff members. However, I expected to elicit information about unit stressors which included polarizing issues including unit politics and the like. These discussions occurred only as part of data gathering and not to gain confidence of informants. Initially some participants were suspicious of my motives and made false assumptions about my role with administration. A systematic approach to the interview process (for instance, interviewing administrators early before unit staff) helped mitigate suspicion and establish rapport and trust with the unit nurses.

I accessed patient records to record patient diagnosis, medications (including STAT and PRN medications), and other information I deemed pertinent. I informed patients of the study and recorded their comments in the context of receiving medications. I also noted observations of patient responses to care delivery.

Data Analysis

Data Transcription

I digitally recorded and transcribed interviews verbatim on the same day they occurred. Verbatim transcription has become a standard data management strategy in nursing research, as well as widely accepted in health care research (Halcomb & Davidson, 2006). Transcription took up to 4 hours per interview; hence I limited myself

to one interview a day. All transcripts were corrected and analyzed for accuracy increasing the confidence in the data.

Content Analysis

This study used conventional content analysis for the unstructured interviews. Field notes used codes defined during the data analysis in order to achieve a richer understanding of the data (Hsieh & Shannon, 2005). This approached yielded a high level of validity, but may have been less reliable due to the subjective nature of the coding (Morse & Field, 1995). Regardless, forming categories was important for highlighting the overt intent and underlying meaning of the informant's communication (Morse & Field, 1995). Additionally, I found this approach important for the subsequent development of a taxonomy to identify relationships (Morse, 2008).

In the case of this ethnography, the inductive nature of the study provided data for the development of emerging themes representing the context for nurses' work. I used process oriented analysis beginning with the actual collection of data (Morse & Field, 1995). As I gained insights, I refocused my questions and tested new questions. Hence, analysis began with the process of recording and analyzing field notes and interviews. The principal objective of the analysis was to code the data to facilitate category recognition and analysis, and to note behaviors (Morse & Field, 1995).

First, I aggregated demographic information for reporting and then coded transcripts and field notes by highlighting and labeling persistent words, phrases, themes or concepts within a qualitative data analysis software, QDA-Miner® with WordStat®. Similar data were sorted into the same place, then arranged and refined into categories and subcategories. This arrangement enabled me to identify and describe the characteristics of the category (Morse, 2008) as well as identify emerging themes.

I placed analytic memos with relevant text in all capitalized letters within the electronic files. These memos allowed me to document and reflect on the coding process and code choices, consider how the process of inquiry took shape, and identify emerging patterns (Saldaña, 2013). I coded the memos too and categorized them according to their content. While this analysis neither led to the development of a theory, nor the essence of an experience (as in a phenomenology), it did provide additional insight and understanding of the nature of nurses' work and the development of a theoretical model.

Maintenance of Rigor

In this qualitative inquiry, I built verification strategies into data collection and analysis procedures. The process was iterative, with data systematically collected, checked, and concurrently and constantly confirmed (Morse et al., 2008, 2015a, 2015b). Reflexivity strengthened the integrity of this process and the validity of this ethnographic study through verification, congruence, and complementarity of results (Finlay, 2002).

Reflexivity

There is a reflexive character in social research. The implication is that in data collection and analysis, the researcher's orientation will be shaped by their values, interests, and socio-historical locations (Hammersley & Atkinson, 1995). This simply meant that early findings directed later data collections and refined questions asked in the interviews. This continual process of reflection allowed me the opportunity to examine

my own assumptions, preconceptions, and bias, thus strengthening the overall integrity of the research (Finlay, 2002). A research journal and working audit trail contained these reflections. As understanding emerged, my awareness increased about how the research relationship affects decisions and responses.

Ethical Considerations

I took several steps to ensure data integrity and anonymity. Safeguards included the use of a single researcher who took every precaution to preserve privacy and confidentiality of the data. Only informed consent documents contained names. I deidentified the recorded interviews and field notes. I also de-identified verbatim transcripts, removing any identifying links. All institutional identifiers, including any acknowledgements were not published; any acknowledgements did not include the institution, city, or state. To ensure accuracy, I transcribed verbatim and reviewed and edited all field notes and interviews as quickly as possible after events occurred.

Even minimal risk studies (such as this one) represent a degree of risk related to privacy, confidentiality, coercion, and emotional distress. I informed participants of this risk. They were also given permission to stop the interview at any time and offered the opportunity for a postinterview debriefing.

This research involved many departments in the hospital. An article about the study appeared in the hospital newsletter informing all hospital personnel of the study. I sent memos describing the study and the data collection procedures to departments (such as pharmacy, code team, Hospitalists, and physical therapy) from which personnel may casually enter the unit during observations. In addition, I placed a sign at the entrance of

the unit announcing and describing the research. This helped remind personnel of the research and informed relatives and others who may have wished to obtain information about the study. Thus, written informed consent was not obtained from everyone entering the unit.

Nursing staff, attending physicians, those who formally agree to be interviewed participants from pharmacy, hospital administration, quality management, and risk management—all signed written informed consent forms. Patients who agreed to be observed or informally interviewed and whose medical records were accessed also gave verbal consent. If patients were unable to provide consent, informed consent was obtained from their next of kin or guardian.

Participants' names were coded for transcription and the only demographic information recorded about them pertained to job or education-related data. A cell phone captured images of relevant policies and other documents deemed pertinent. Transcripts were stored in password-protected files on an encrypted device.

Participants did not receive compensation for interviews or observations. Administrative staff on their respective units were unaware of someone's participation, unless they chose to divulge that information.

In consultation with members of my research committee, this study included information obtained in the process of data collection that had not been formally reported to the institution. I did not disclose to the organization incidents that occurred in the past (any time prior to the interview) and posed no risk for ongoing harm. I also included clear instructions in the informed consent to participants that even though they were participating anonymously, they should not report anything in confidence they did not want included in the research report.

Risks to Participants

There was a risk of emotional upset or distress during the interview process. While this never occurred, I reminded participants of the opportunity to withdraw from the interview or study at any time. I took thoughtful precautions to protect the participants and approached interviews with consideration and compassion.

Risk also existed in the possibility of observing a breach of protocol in relation to medication administration. There were no events which required intervention to prevent the possibility of harm. Still, participants were informed that "near miss" incidents would become a part of the data collection, but not reported to the institution.

Risks to Institution

The potential for risk to the institution was primarily related to disclosure of institutional identity. Other risks included costs incurred and practical inconveniences. For example, observations may have been viewed as a distraction or disruption to the staff. Interviews may have impacted productivity. I was clear with the research council and hospital IRB that I understood these risks and negotiated steps to reduce them.

Implications

Implications of this study include influencing how we support nurses who may have committed an error to how we educate future nurses in preventing errors. There is the potential to impact future research as well as formulate policy that fosters safety, increased reporting, and patient disclosure.

Qualitative inquiry is generalized through the emerging theory. Depending on the level of abstraction of the findings in the study, the results have the potential to be generalized. For example, during a discussion with a group of nurses about medications, I observed that nurses checked their assumptions with one another before recognizing that an error had occurred. This learning though social interaction is supported by observations of staff social networks within mid-sized hospitals. These social interactions are a significant factor in building a supportive work environment (including the management of medication errors). In large medical centers, personal relationships among staff can be much more difficult to establish as there is less time in which they can gather and discuss their work day. The social networks of the mid-sized hospital are therefore lost within the large urban medical center. The education/social recommendations would be to develop relevant strategies to help establish relationships or build teams in the larger urban workplace.

In the following Chapters 4 and 5, I present the findings of this study as articles for publication. The first article, *Exploring Nurses' Work in Medication Administration: Untenable Expectations*, presents the principle findings and a new theoretical model for nurses' work. The second article, *The Paradox of Safety in Medication Management*, presents a microanalysis of the overall medication management system. Lastly, in Chapter 6, I present a comprehensive discussion and critique of the study as well as the implications for further research, education, and policy.

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CHAPTER 4

EXPLORING NURSES' WORK IN MEDICATION ADMINISTRATION: UNTENABLE EXPECTATIONS

Abstract

The purpose of this ethnographic study was to explore nurses' work in the context of medication administration, errors, and organizational safety. Data were collected using nonparticipant observation, unstructured interviews, and think-aloud experiences. Pertinent document analysis supplemented the data. Findings of this study revealed the nature of nurses' work was characterized by: *chasing a standard of care, prioritizing practice,* and *renegotiating routines*. A rich description emerged showing that nurses' work is cyclical and comprised of chaotic and complex characteristics. This is in contrast to prevailing studies that explain nurses' work as linear. A new theoretical model illustrates the inseparability of nurses' work from the contextual contingencies. This enhances our understanding of how the components of work cascade on the nurses so that their day can spin entirely out of control. These results have the potential to enhance our understanding of why present efforts targeting the reduction of medication errors may be ineffective.

Introduction

Demonstrable reductions in medication errors have been insufficient and a continued cause for concern in the years since the Institute of Medicine (IOM) first challenged providers to meet the goal of a 50% reduction in errors. Following the IOM report, the Patient Protection and Affordable Care Act (PPACA) called for a National Quality Strategy aimed at reducing harm caused in the delivery of care (Aspden et al., 2007; Department of Health & Human Services [HHS], 2011; Patterson, Cook, & Render, 2002). As defined by The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) (2015), medication errors are:

...any preventable event that may cause or lead to inappropriate medication use or patient harm... 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. (para 1)

Simply put, the competence of an individual, the controls which surround the medication use process, and the culture of the organization are central elements to consider in the goal towards a reduction of medication errors (Barber, Rawlins, & Franklin, 2003; Leape et al., 2009; Reason, 2000). There is little doubt that the role of the registered nurse in medication safety warrants significant consideration. Previous research provided several strategies intended to impact nurses' competency, control of practice, and organizational culture (Barber et al., 2003; Kagan & Barnoy, 2013; Koehn, Ebright, & Draucker, 2016). However, those investigations have lacked appreciation of the contextual nature of nurses' work within the organization and its subsequent impact on medication safety (Jennings, Sandelowski, & Mark, 2011).

This article presents the findings of an ethnographic study designed to explore
nurses' work in the context of medication administration, error, and organizational safety at a mid-sized hospital in the United States. Two studies (Jennings et al., 2011; Patterson, Cook, & Render, 2002) were used as the framework to explore the underlying models for nurses' work in context.

Results presented here include a broad description of the nurses' day, extending that of Jennings et al. (2011) and they contribute to new knowledge by: 1) providing a description of an "open awareness of the problem" context between the organization and the nurse, and 2) drawing attention to the fact that patient care becomes secondary to the conventions of medication administration, and 3) developing a theoretical model that adds insight to, and understanding of, the conditions that cause the workday to cascade to the point of being out of control.

Method

I chose ethnography as my method of inquiry because it allowed me to describe the problem within context using processes to learn about people by learning from them (Spradley, 1979). Approved by the university and hospital's Institutional Review Boards and the hospital's Research Council for Shared Governance, I collected data for this study between December 2015 and March 2016 on one medical unit of a mid-sized hospital located in the United States. Data were generated from man-on-the street interviews, 92 hours of nonparticipant observations, 3 think-aloud interactions, and 37 unstructured interviews with licensed nursing personnel, pharmacists, physicians, and administrators.

Potential participants were initially informed of the study and invited to

participate at two regularly scheduled staff meetings where staff members received information about the study and a copy of the informed consent for review. A question and answer period followed. Participants subsequently provided informed, voluntary, written consent prior to any focused observations or scheduled interviews. I then took care at the beginning of each observational period to remind staff of the project goals and obtain verbal permission to observe them. This processual consent allowed for participants to reaffirm (or not) their wish to continue in the study.

Although there were no interviews scheduled with patients, observations included patients. With them, I continued the consent process to ensure they were aware of their rights, including their right to refuse to have their care interactions observed. With appropriate permissions, I noted observations of patient responses to care delivery and recorded their comments in the context of receiving medications. I further reviewed key documents including hospital policies and data collected by the facility on daily census and medication administration.

Sample

For a purposive sampling, the principal participants for analysis featured in this article included 25 licensed registered nurses (RN) and three licensed practical nurses (LPN) responsible for medication administration on the medical unit. Four of the 28 nurses were male (14%). The average age of the nurses was 37 years, with ages ranging from 20 to 56. All but three participants (11%) worked full-time with a range in experience from 5 months to 26 years. Exactly 50% of the nurses on this unit had fewer than 5 years of experience. Longevity on the unit averaged 5 years.

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In additional to nurses on the medical unit, this study included data collected from other administrative and ancillary employees (n = 9) whose roles included: Associate Chief Nursing Officer, Director of Quality, Director of Pharmacy, Medical Floor Director, Quality Staff RN, RN Staff Educator, House Supervisor, Physician, Unit Pharmacist, and Central Pharmacist. The interview responses collected from administrative level participants provided an opportunity for comparison of dichotomous perspectives: the ideal versus reality. To maintain a high level of trust among the unit nurses and staff, I completed all administrative level interviews first.

Data Collection

Data collection spanned a 4-month period which began with the use of broad observations in the unit to observe the physical setting, unit activities, and participant interactions. This enabled the staff to become accustomed to me and provided me the opportunity to become oriented to both the workflow and staff. Using Jennings' (2011) protocol, observations were done in 4-5-hour increments, covering the full 24 hours of the day, 7 days per week.

Early in the period of observation, man-on-the street interviews comprised of short, information seeking questions focused on the participant insights and opinions that were used to determine and engage key informants on the unit (Schütz, 1946). For the analysis featured here, I conducted individual unstructured interviews which ranged in length from 25 to 60 minutes. These private in-depth interviews took place during work breaks or after shift. All interviews were digitally recorded, transcribed verbatim, and de-identified.

Interviews began with demographic questions including age, years of experience, and time on the unit followed by open ended questions such as "Tell me about your typical day on the unit." Other questions evolved out of the course of the conversation. Based on participant responses, more targeted questions such as "Some people say

_____; is this how it is for you" were useful in verifying data and increasing the credibility of the data (Leininger, 1994; Sandelowski, 1986). In some instances, second interviews took place allowing participants to verify or validate findings.

Three participants agreed to participate in a more in-depth data collection method using the think-aloud technique (Lundgrén-Laine & Salanterä, 2010). These nurses wore a lapel microphone for periods up to 2 hours and verbalized their thinking while performing patient care. This technique provided insight into factors that guided decision making and other daily activities on the unit.

Lastly, records relevant to this analysis included daily census records and hospital policies. I examined de-identified records from December 2015 through February 2016 for total admissions, transfers to- and from- the unit, discharges, and deaths. I included a total of 1696 events in the dataset and analyzed for number of turnover events by month and time of day. These texts were used alongside the observation and interview data for more complete understanding and to prevent potential bias (Hodder, 2000). I requested, but was denied, access to medication error rates specific to the unit. In addition, a request to observe a Serious Event Analysis (SEA), or Root Cause Analysis (RCA), was prohibited by the institution with the rationale that doing so would compromise the privacy and confidentiality of those involved. The institution agreed to provide only broad numbers reflecting hospital-wide medication error rates over a 3-month timeframe.

Data Analysis

Data analysis began in the early phases of observation as I transcribed field notes and interviews. After each interview and field observation, I transcribed data verbatim. Transcript analysis began immediately following corrections. I embedded analytical notes and memos into the transcripts adding emerging insights and reflection. Additionally, I maintained a research journal and working audit trail during the data collection period (Sandelowski, 1986). I used a qualitative data analysis software, QDA-Miner[®] with WordStat[®], to manage transcripts, coding, and analysis.

I approached analysis as an iterative process using conventional content analysis. Initially I classified and coded text line by line into broad categories and then created specific categories representing patterns and similar meaning. This approach offered the advantage of gaining participant insights without imposing preconceived perspectives (Hsieh & Shannon, 2005) and allowed me to ask questions of the data such as, "what's going on here" (Morse, 2017). As such, descriptions of behaviors and developing patterns emerged central to the concept of nurses' work.

Trustworthiness and Rigor

In this ethnographic study, I rigorously used methods of nonparticipant observation, man-on-the-street interviews, think-aloud encounters, and unstructured interviews to collect sufficient data for in-depth analysis, redundancy of themes, and comprehension (Morse, 1994). Objectivity during the collection and organization of observational data was carefully maintained to overcome the potential observer bias. Validation of findings and reflexivity provided credibility and fittingness (Angrosino & Mays de Pérez, 2000; Leininger, 1994; Sandelowski, 1986). I worked closely with my research advisor (an expert in qualitative methods) and other committee members with expertise in pharmacy and law. They provided me ample opportunities to review my findings and discuss the data.

At the completion of data analysis, I prepared an ethnography of nurses' work including descriptive categories and analysis for the context of medication administration, errors, and organizational safety.

Findings

Participant stories and observations offered rich insight into the contextual nature of nurses' work. The following categories emerged from the raw data: 1) *chasing a standard of care*, 2) *prioritizing practice*, and 3) *renegotiating routines*.

Chasing a standard of care was described as organizational structure that encompassed both internal and external standards. Prioritizing practice included forced reorganization and shifting priorities demanded by medication schedules and patient turnover. Renegotiating routines included managing competing obligations and contained elements of sloppy practice and indifference. Further, miscommunication, forgetfulness, and cognitive overload were factors leading to medication errors, despite the mood of the day.

Lastly, analysis revealed that Administration had an open awareness (Glaser & Strauss, 1964) regarding patient safety and was sensitive to the true nature, identity, and contextual contingencies of nurses' work in day-to-day interactions.

Following a brief description of the unit, I provide an analysis of each theme with

identification of its associated components to portray the characteristic nature of nurses' work.

Description of the Unit

This study was conducted on a medical floor of a locally managed hospital. This facility, part of a larger parent corporation, employed over 1,000 credentialed and/or licensed employees. The medical floor catered to both acute and chronically ill adults with a variety of co-morbidities including cancer. The average census during the observation period was 29. The unit was newly remodeled reflecting a trendy, warm atmosphere. The nurses' station was the central hub with long hallways branching north, south, east, and west. The design integrated upgraded informational technology (IT) systems in each private patient room. One room at the end of each corridor was reserved as space for nursing staff and storage (this room could easily be transformed into a licensed bed should the need arise).

There were two supply rooms adjacent to the nurses' station that contained supplies, a medication refrigerator, and patient nutrition items. The automated medication dispensing unit sat in the main hallway directly across from the staff elevators and adjacent to a pneumonic tube system (see Figure 4.1).

In all, the unit employed 34 licensed Registered Nurses (RNs) and five licensed Practical Nurses (LPNs) in addition to a cadre of unlicensed assistive personnel (UAPs). All UAPs were expected to cross-train the roles and responsibilities of unit secretary and certified nursing assistant (CNA). Leadership included one RN Director and five RN Clinical Supervisors or charge RNs. A unit pharmacist was an integral member of the



Figure 4.1. The main automated medication dispensing unit on the medical floor. Nurses could be seen lining up four to five deep during peak hours of the shift. In instances when an inventoried med was absent, the nurses walked to other units for their patients' doses.

team and had a workspace directly adjacent to the nurse's station. During a typical 12hour shift, nurses could expect a nurse-to-patient ratio of 1:5 during the day and 1:6 during off-peak hours. Based on strict productivity guidelines, staffing typically consisted of:

- a) one charge nurse
- b) one RN patient care coordinator (PCC)

c) five staff-level nurses (RNs and LPNs)

d) three unlicensed personnel (which may or may not include a unit secretary)e) one community volunteer once per week when available.

The unit adhered to *Relationship Based Care* (RBC), the prevailing professional practice model introduced by the nursing administrator at general nursing orientation. By formal definition, RBC states, in part, that the nurse holds primary responsibility, authority, and accountability for patient care decisions (Person, 2004). Participants could not explain exactly what this meant and it became clear that each nursing unit of the hospital worked from different conceptions of their role with the patient.

I observed that this medical unit operated using a differentiated practice model with the charge nurse overseeing the work of the nursing staff and UAPs, and the PCC overseeing the work of the LPNs. Historically, staff explained, neither the charge nurse nor the PCC carried a patient load assignment which allowed the PCC (an experienced RN) to absorb the bulk of admissions and discharges, respond to code situations, and act as a resource for struggling staff by picking up the slack. During the period of observation though, it became apparent that this model was evolving because of pressures to meet productivity requirements. The PCC, in addition to supervising the LPNs, now took on their own patient load while also trying to act as a resource for others.

Chasing a Standard of Care

Aiming for zero patient harm, this mid-size hospital focused significant resources and attention to developing systems and processes that prevent untoward patient outcomes. This drive towards zero harm has had a significant trickledown effect largely dependent on changed behaviors in nursing staff. Participants in this study talked about the difficulties encountered and feeling a burden of responsibility in the context of organizational structures and standards.

Organizational Structure

Federal-level mandates—including value-based reimbursements, patient satisfaction and core measures, corporate-level mandates surrounding budgetary constraints, and productivity—surfaced frequently. These variables placed significant pressure on the nurses to achieve optimal conditions for patient care and contribute to the success of the facility. During the timeframe of this study, a shared governance structure for nursing was in its infancy. Thus, participants were not able to offer information on the contextual factors of shared governance. Figure 4.2 details specific examples of structure. Below I provide detailed examples of internal and external standards. Particularizing the medication management system is reported elsewhere (Chapter 5).

Internal Standards. For participants in this study, productivity quickly emerged as a prevailing internal standard governing everyday activity. Staff adhered strictly to staffing matrices with strategies heavily geared towards compliance. This left little room for reserve and interfered with opportunities for innovation and customization based on local values and norms within the facility (which was already feeling the sting from understaffing and declining recruitment). Nursing administration admitted:

The patients are very sick and somewhat demanding. Our productivity is pushed to the absolute limit. There's no extras, there's not a person that [sic] is not doing something that can help you. You understand there just physically aren't as many bodies around to be able to help backfill and help with the work.

Structure

Internal Standards

- Policy
- Interactions across disciplines
 - Lack 10,000-foot view
- Staffing & Productivity
 - Patient load of 5-6 patients at the limit for safety
 - Cross trained unlicensed personnel
 - Poor communication and competency
- Medication management system

External Standards

- "Others can do it, why can't you?"
- Compliance measures
 - Patient satisfaction

Figure 4.2. Examples of organizational structure.

The hospital itself was a subunit of a much larger parent corporation with accompanying corporate expectations. Productivity matrices established at the corporate level compared like units across the network. The benchmark of "man hour per stat" measured productivity and was based on certain hours of care (man hour) per patient (the statistic). Many hospitals adopted such productivity models during hospital restructuring in the 1990s (Rankin & Campbell, 2006; Weinberg, 2003). The models were based on assumptions for the average time associated with caring for an average patient and likely, a comparable average census.

This focus on the "average" might allow for greater flexibility in staffing so that, when necessary, staff would have leeway to work within those contingencies. The reality expressed by nursing administrators was that if the control hospital had a light season and could achieve a lower man hour per stat, the research hospital was held to the very same standard regardless of the actual census and patient. In this way, corporate failed to consider that there are no "averages" in present-day patient populations. The overall comparison failed to consider the complexity of the patient or the extent of comorbidities and multiple medications at the local level. This resulted in grossly underestimating local staffing. Consequently, nurses' budgeted workload calculation was not based on their average, but on the minimum capacity defined by corporate.

Implementing flex staffing accommodated fluctuations in patient census and patient status. Staff were either called in or expected to take higher patient loads when census trended upwards, when patients required one-on-one care, or when nurses called in sick. During less busy shifts, nurses were either placed on call, asked to voluntarily take the day off (with or without pay), or told to go home. Flexing up was not easy.

With sick calls and understaffing, the float pool is that buffer. Lately the float pool has been maxed out as well. We haven't been able to get a float pool nurse no matter what. We just did best with what we could—you see, that was what the PCC [patient care coordinator] was for, a buffer for when one of the nurses was just too busy hanging blood, or doing something like that. The PCC would say, 'Okay, I can give those medications.' Usually even just [someone] giving one patient a set of medications will give you enough steam that you can catch up.

Nurses were quick to reveal these real and perceived inadequacies and

ramifications of staffing (Henderson, Willis, Blackman, Toffoli, & Verrall, 2016).

Notably, the charge nurses had the formidable task of making the best call regarding

staffing during crisis moments of any given shift.

I called for a nurse when [productivity] didn't call for one, knowing darn well that I was going to get in trouble for over staffing—but you know sometimes— I don't care. You know [another charge nurse] was saying the same thing. That she'd been struggling all day with a patient. They were giving blood. They had admits coming up. They were overstaffed and the director comes up and says, 'You're overstaffed, you have to send two home.' 'How do I send *two home? We've got*—'. '*Doesn't matter you're overstaffed, send two home.*' Thus, the metrics for productivity and staffing affected the way work was accomplished. Decisions about workload were left in the hands of those far removed from the front lines. As workloads increased, anxiety heightened. Nurses found the fastest ways to get things done to save time and "*survive the shift.*" For example, some felt less overwhelmed by considering the 12-hour shift as three 4-hour shifts.

Of greater concern were the holes in medication policies that put both patients and nurses at risk. Policies lacked a clear definition of medication error or what constituted a reportable medication error. Safety practices were not consistently documented as policy. For instance, one practice was developed following The Joint Commission's (2014) release of a sentinel event alert on managing the risk of tubing misconnects. Nurses were required to trace intravenous (IV) lines from the bag to the pump and to the patient at each handoff to ensure the right fluids, rates, and connections. This was expected practice at this facility and while leadership developed formal competencies (training at orientation), it was not formalized in policy. An adverse event that involved Pitocin[®] in the labor and delivery unit illustrates the lack of formalization:

An experienced nurse had set the [IV] lines up, while the novice nurse programed the pump. She programmed them backwards. This patient got big ol' [sic] dose of Pitocin[®], contracted down, baby was coming fast, they ended up doing an emergency C-section. When they got to the OR suite, they figured out what they'd done. Thinking there were problems, they were giving a bolus of saline which, instead, was a bolus of Pitocin[®] so it only made it worse. A root cause analysis was done and we talked about what went wrong. We didn't use the sticker to identify which line was the Pitocin[®]. We didn't trace [the lines]. We thought this had been taught and was part of our culture. We found it wasn't part of our culture at all. They didn't know what trace was. It was introduced to them in orientation but nobody had done it; it wasn't part of our culture.

External Standards. The Department of Quality measured compliance with

federal and other external regulatory standards. This department also placed substantial importance on tracking the following: patient throughput (the efficiency of cycling patients through the hospital), hospital acquired conditions, core measure compliance, readmission rates, and patient satisfaction. Administrators described efforts to increase staff accountability for quality by using "*accountability score cards*." There was an assumption that unit directors reviewed scorecards with their employees on a quarterly basis as a tool to increase awareness of hospital metrics and to explore trends. This would provide a context for the nurses to better "*understand the why of what they do*."

This facility made it a goal to improve patient satisfaction and measures on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS[®]) survey. Participants communicated that administration expected them to round hourly on their patients during the day shift and every 2 hours during night shift to see if there were unmet patient needs. The clinical supervisors were expected to round on all patients every day.

The words they want us to use is 'I have time'. That is very difficult, very difficult when we're doing all the discharges, admissions and things like that. Those kinds of things are hard to accomplish but they [administration] keep saying that there are hospitals that are doing it. I have asked, 'Send me to those hospitals to see what they're doing that we're not'. Well, the answer is 'No'.

The nurses perceived themselves as flexible and somewhat tolerant of these added pressures they faced. They expressed a desire to meet a high standard of care, to make real connections with their patients, and to improve patient satisfaction. They also expressed great frustration and let down concerning the reality of the outcomes, particularly in the face of the comparison to other facilities. *"Yeah, it's like we come do everything you ask us to, we've done everything! And our [patient satisfaction] numbers*

aren't changing...". Hence, these expectations not only increased the complexity of the work environment, but also contributed to added tension and a sense of inadequacy. A nurse administrator shared this conclusion:

It puts a lot of pressure and focus on the nurses to be amazing communicators, amazing coordinators, [and] amazing clinicians. There is a huge whirlwind of things that they are responsible for now. It's not enough to be just a good clinician anymore.

The implementation of a standardized electronic information systems has been widely adopted to reduce variation and improve practice in healthcare (Balka, Bjorn, & Wagner, 2008). The 2009 Health Information Technology for Economic and Clinical Health Act (HITECH) also made such implementation a matter of law. While standardized electronic records have been designed to perform certain functions (such as capture data regarding compliance measures), participants were candid as they expressed their frustration in the counter intuitive nature of the programs and their rigid designs. Respondents, particularly from administration and medical staff, saw the use of electronic health records (EHR) as contributing to an insular perspective and narrower, taskoriented focus among nurses. Medical staff described:

[Nurses] are so extremely task oriented, but that's the nature of the game nowadays. All they can do is focus on a computer and the EHR. Answering this screen and that screen. They lose that 10,000-foot view.

Additionally, nearly all informants said the recent implementation of computerized provider order entry (CPOE) included problematic configurations which contributed to confusion and facilitated several missed orders and medication errors. To cite one example, towards the end of a day shift, there was great confusion about an order for blood administration. At one point, I observed four different nurses standing around the computer reviewing the EHR order. Forty-five minutes into the ordeal, lab results were reviewed, and the charge nurse made the call to "transfuse the unit."

Simultaneously, the oncoming nurse placed a call to the provider for clarification. The transfusion was started just as they received clarification for the intent of the order: to only *hold* two units of blood. Because the blood was initiated, the charge nurse had to justify the decision to the provider.

Prioritizing Practice

Figure 4.3 shows the association between forced reorganization and shifting priorities with medication schedules and patient turnover. Nurses revealed how managing the added expectations to their daily work placed the patient secondary to completing tasks and caused the day to cascade out of control.

Forced Reorganization and Shifting Priorities

Medication Schedules

- Admission, Discharge, & Bridging orders
- Medication Reconciliation
- CPOE
- Distribution /packaging
- Waiting
- Scanning compliance & 6 Rights
- Independent double checks
- Nurses' Taxonomy and Classification of Error

Patient Turnover

- Patterns of admissions & discharges different from day to day
- Hourly patient rounding
- Service Recovery

Figure 4.3. Examples of forced reorganization and shifting priorities.

Reorganization and Shifting Priorities

Thinking aloud, nurses conveyed the scope and strain of coordinating activities on a given day:

I can only be in one room at one time. I got this new patient—do I concentrate on this new guy and let the other four get ignored? Do I do a little bit and then do meds over here and then get back to this one and then back to these guys? It's tough. It's really tough.

To negotiate this strain, nurses were forced to reorganize and shift priorities. The influence of medication schedules and patient turnover affected the mood of the day and proved consequential to patients.

Medication schedules. One of the most striking features was the focused attention on the medication administration process. Over a period of 3 weeks, nurses administered a total of 10,030 medications. That is an average of 3,343 medications on any given week or 16 doses per patient per day. Facility policy requires nurses to deliver medications within 30 minutes of the scheduled time, with compliance tracked closely. With limited time to divide among all their patients, it was common for the medication administration schedule to dictate nurses' daily routine in terms of patient assessment and interaction.

I'll probably give at least 50 [medications] this shift, because I've got a guy that's on pain medicine every two hours and a couple of other people with lots of medications and lots of problems. I kind of like it [this way] because it gives me an excuse to check on [my patients] again. I feel like I'm not just checking on them for no reason, it's like, 'Oh hey, I've got your medicine'.

Nurses used the time while pushing intravenous medications to ask the patient for information and to determine real concerns from those presented during handoff report. During these moments, nurses met immediate patient needs, perhaps assistance to the bathroom or repositioning, but seldom anything more. Thus, the inseparability of medication administration from other tasks became readily apparent. Medication administration became the catalyst for nurse-patient interaction. The nurse-patient relationship became victim to a rudimentary process of triage and the patient became secondary to the goal of staying "*caught up*" in the timely administration of medications.

I'm okay giving meds an hour early because more often than not, I'll be more than an hour late. If I start an hour early, my latest will be an hour late. Get all the meds done, all the assessments done by 1000. But today is not going to be like. Now it's 1015 and I'm late on my own routine. But sometimes it's like that. Sometimes you don't even get your 0800 assessments done until after shift change and then you finally sit down do it and you got to [chart] the whole day.

Not surprisingly, discussion of patient turnover and the hospital's system for cycling patients through the hospital quickly frequently co-occurred with a discussion of medication administration demands.

Patient turnover. Patient turnover varied from day to day and created a high level of intensity and turbulence (Jennings et al., 2013; Salyer, 1995). Cases of admissions and transfers to the unit averaged 778 per month while discharges—transfers out of the unit and death—averaged 807 per month. The average length of stay was not calculated. Most of the turnovers occurred during the day shift (7 am to 7pm) occurring mainly in the hours leading up to and including change of shift as shown in Figures 4.4 and 4.5.

The charge nurses had access to a real time electronic patient tracking system that was intended to allow the unit to control patient flow by updating which beds were available and when patients could be admitted. This technology had little impact on the issue of patient stacking in the emergency department and the tendency to send up admits right at change of shift. This strained communication and coping between all members of the team and the organization. I observed feelings and expressions of frustration,





December 2015 (N = 790)

Figure 4.4. Display of patient admission events by time of day for December 2015, January 2016, and February 2016. Bar with stippled marking denotes evening meal time while solid filled bar denotes 7 PM shift change. The cognitive load associated with admissions is peaked from 5 PM-7 PM.



Figure 4.5. Display of patient discharge events by time of day for December 2015, January 2016, and February 2016. Bar with stippled marking denotes evening meal time while solid filled bar denotes 7 PM shift change. The cognitive load associated with discharges is peaked between 1 PM- 5 PM.

Discordance, and incivility. The unit director, while aware, seemed powerless and

offered little support, other than to state the need for better communication.

Administration commented:

There are strategies, I mean we do talk about it. The ER has to meet [core measures] and they look at throughput times. Their goal is to [transfer to] the inpatient unit within 30 minutes. [The ER administrator] said, 'You know if you have your clinical supervisor call our clinical supervisor, we can try to stagger those, hold them, do what we can.' But depending on what the ER is like, they may not. They may just say, 'Too bad they're coming up'. There's not really a

strict strategy to help that, I think it's more of just good communication, working together as departments. If we're able to say 'Listen, we're getting 5 admits in this hour and I don't even have staff to be able to settle them, it's right at shift change'—it should help.

I further observed a concomitant rise in requirements of the medication process associated with increased turnover. The admission process required medication reconciliation, retrieval of home medications, as well as receipt and acknowledgement of new admission orders. Sometimes patients arrived from the emergency department with only bridging orders which expired in 24 hours. This led to disruption and delay in care as nurses waited for physicians to see patients and enter admission orders. In the interim, some newly admitted patients went mostly unseen by the nurse until new orders arrived.

The clash of expectations between the patient and the process compounded the turbulence created by the number of admissions and discharges. Early in the study, a patient dressed in street clothes was observed holding personal belongings, standing at the nurses' station watching with intent eyes as his nurse worked. The patient did not speak, just stood and watched while the nurse completed the medication reconciliation process and discharge paperwork. The nurse quipped, "*We kind of ignore them, someone is always breathing down our neck*".

During a rare opportunity to join nursing staff during the lunch break, the nurses on the unit angrily recounted another patient encounter over a discharge plan. Mimicking the patient, a nurse commented, "*The doctor said we could go home*". This launched the group into a discussion about how patients expected that the discharge would happen at that moment.

I guess they think that's how it works. Which is all about communication, but how do you get in there to tell them. I mean the whole reason we don't have the discharge done is because we're busy! So how do you get in there to tell them

that 'it's going to be a while, like this is a process'.

From the standpoint of the facility, the goal was to discharge patients before noon. The nurses went on to say they planned for the discharge process to take a minimum of 2 hours to complete given the patient population. *"You know rarely are we able to discharge patients before noon. When the docs round in the morning and discharge eight patients at one time, it's impossible to get everyone out by noon!"*

The Mood of the Day

I observed that as the day got busy and the expectations became untenable, problems began to outweigh solutions and the day quickly cycled from a "*good day*" to a "*shit storm*". The busyness of the day, however, did not appear to directly correlate to the presence or absence of medication errors. In this study, I noted errors even on good days. Serious errors were a relatively rare event during the period of participant observation. Although I did not observe serious errors, the events included in the descriptions below were remarkable.

Good day. Overwhelmingly, a good day on the unit was measured by the amount of time nurses spent with patients. The opportunity to converse with the patients, build rapport, and provide individualized attention made the nurses feel positive that they had accomplished their best work.

It just takes a few minutes, doesn't have to be very long to make a connection with the patient. Whether a joke or tell a story or ask how they feel...just connect. Then that person feels that you care for them, which you do—you wouldn't be in this profession if you didn't care for them—and then because you have a connection they will tell you when they need something. They won't feel neglected because they'll know that you're busy.

On a good day, nurses completed their documentation requirements throughout the day

and could be done by end of shift. They were in control of their work and the atmosphere was calm.

Nurses said common examples of medication errors observed on good days included missed orders in the HER, miscommunication on insulin sliding scales resulting in wrong doses, wrong medications resulting from sound alike look alike (SALA) medications in the automated dispensing unit, and errors resulting from inexperience. For instance, at change of shift, the oncoming nurse discovered a continuous infusion of Protonix[®] was turned off. The previous nurse, a new graduate, did not "*recognize the need for the continuous drip.*"

Bad day. As the day cycled to bad, work load interfered with the nurses' ability to exceed the standard of care and they regretted not spending enough time with their patients. On bad days, nurses had to wait; patients had to wait and they were just "*not able to catch up*". They sacrificed basic care such as oral care or repositioning. Bad days included a high number of admissions, discharges, with explanations and apologies required. When patient admissions began to ramp up, nurses anticipated the need for added staff. On one occasion, during a day shift with a patient census of 30 and four patients on 1:1 care, nurses were forced to reorganize and shift priorities as three direct admits were anticipated. Thinking aloud, the charge nurse stated: "*I have to take somebody off one on one, so I can put them out on the floor*".

Nurses described medication errors on bad days as missed doses due to "forgetting" to open the roller clamp on secondary infusions, late administration of medications, and administration of wrong doses when excess narcotic medications were not wasted in advance of administration. *Crazy day.* Nurses used "crazy day" and "bad day" sometimes interchangeably. As the day became crazy, patient relationships suffered as nurses attended the more acutely ill patients longer. They would send messages through other staff to their other patients about why they were absent. However, despite this, even during crazy days, events could be synced and the nurse remained in control. I observed constant problem solving, but there were also solutions. Nurses readily could recall crazy shifts. The competing obligations nurses face are evident in the following account from one nurse:

I had two [patients]that were seizing, and had to run back and forth between those rooms and run and get my vitals on my blood patient. I got no charting done that whole shift. I didn't do a single bit of charting until after my shift was over. I think I was here until 10:30 or 11 charting. I'm sure I missed stuff, because I didn't remember it all by that point, I was too tired.

I observed medication errors on a crazy day. One particular error stands out. A medication administration documentation failure coupled with poor communication between nurses resulted in a duplicate dose administered for a transferred patient. Later, the transferring nurse returned to the medical floor having taken Dilaudid[®] home in her pocket. *"I forgot to waste*". She then asked the floor nurse to witness the waste of Dilaudid[®]; she did not want others in her own unit to know of her error or "get fired."

Shit storm. When a "storm hits" nurses described how the management of events became overwhelming. "Patients are coming off the elevator from the emergency department and from doctor's offices and you haven't even told the nurses they are getting new patients". No immediate solutions were apparent and only the minimum standards of care were given to patients. Medications were hours late and there was a palpable tension and element of panic in the air.

You have five patients during the day. They all have typically five to fifteen medications that you have to check and make sure you know what they are and

when you're giving them. A lot of times they [the patients] are full care—you know—they're two assist, they're incontinent. They have a patient tonight that has cirrhosis of the liver. You give her 40 of Enulose[®] three times a day. She stands up and jumps out of bed and slips and skids on her own stool and she almost falls. And, she's having micro seizures that are constant until ten minutes ago, [pause] we finally got them in control. And that's just one patient, so then you've got four others that have their needs. Well, you spend [pause] an hour with a neurologist pushing medications titrating to effect. You don't have time to take care of those other four patients who are eating and needing help with their dentures and washing their face. You just can't do that.

While in a patient's room, I observed that events became circular and usual routines were lost. Without routines in the day, the storm took on more power. Similar narratives (Burke, 2012) illustrate how this happens because once the nurse goes in the room, they never seemed to come out.

During a "shit storm", all manner of medication errors were possible. And while the assumption may be that medication errors are more likely to be attributed to the busyness of the day and to happen more frequently in chaos, I do not have the data to support such a claim.

Renegotiating Routines

The momentum created by the internal and external standards of the organization, the turbulence of patient turnover, and the medication management system provided cues to the inseparability of medication administration to other nursing responsibilities. The dynamic created a condition of cognitive overload and indifference surrounding medication safety for the bedside nurse to negotiate. Inconsistencies in the medication administration process were evident when medication errors were recognized only when they reached the patient and reported only when they were perceived to cause harm. The findings presented in the following paragraphs detail nurses' efforts to cope with cognitive overload and find their way through the uncertainty of the day by relying on overt and covert strategies as shown in Figure 4.6.

Overt Strategies

Nurses responded to the needs of patients, families, colleagues, providers, and other ancillary staff with patterned routines, short cuts, and time saving strategies. See Figure 4.7.

For instance, there were no designated medication preparation areas on the unit. This meant that medication preparation activities subsequently occurred at the bedside. Once scanned, injections were pulled from vials, pills were crushed, or antibiotics reconstituted at the bedside. During more urgent situations, overrides from the automated dispensing unit were performed, bypassing the order verification process of the pharmacists. If an independent double check for high alert medication was required, it was done without thought by another nurse who was just as cognitively overloaded as the primary nurse. And if the nurse required a witness to waste medication they often slipped the medication into their pocket and found someone to later witness the waste.

Nurses in the department of quality responsible for reviewing reported medication errors and attending root cause analyses remarked that a culture of "*normalization of deviance*" contributed to medication errors:

It's kind of like you get away with it and so then it just seems like it's okay. You've gotten away with it so many times. There are so many things, so many rules and so many people just trying to get by.

A second example provided insight into learned, but not always acceptable behavioral norms on the unit.

Cognitive Overload & Ambiguity

Overt Strategies

- Sloppy practice
- Work arounds
- Social networks & support

Covert Strategies

- Indifference
- Normalization of deviance
 - Underreporting

Figure 4.6. Strategies to combat competing obligations.



Figure 4.7. Fingers crossed, this nurse relied on the hope that crossing her fingers would remind her to get a Tylenol[®] for her colleague's patient.

Whenever I have to give Humalog[®], I always check their blood glucose on [the EHR] because when it's written up here [on the whiteboard] and it's timed at 2000 [hours] - that could have been from yesterday! Somebody had done that and they gave insulin for a blood sugar of like 170 and the person was only 96 that night. We had to give them a bunch of D-10 throughout the night. And so, I always check.

White boards in patient rooms were intended to be used for patient centric information—phone numbers, goals for the day, and upcoming therapies. In this case, communication that was in the EHR was bypassed on the white board to save time and control the workday. While the nurse above always checked the EHR, the continued use of the white board indicated that some nurses routinely used this workaround.

Covert Strategies

At times, nurses bypassed MA safeguards. Underreporting of medication errors became a recognized strategy in dealing with the ambiguity resulting from insufficient organizational definitions of medication errors. Many participants could offer a technical definition for medication error, yet no formal policy existed with a shared organizational definition. That was left to individual and unit convention. Administrators acknowledged the lack of clearly defined expectations, *"I don't think they know totally what to report. Do they have the structure around them to help? I think they do.*" Hence, an attitude of indifference to reporting surfaced among some participants. On the surface, it was not that reporting resulted in a punitive response from administration or a burdensome process. Nurses were open about administration's efforts to introduce standards: *"The powers that be use it as a teaching tool and really, we try to teach each other and learn a little bit..."* Yet nurses exhibited a level of indifference *"We are supposed to* [report], *but I am not going to."*

Open Awareness Context

Administrators articulated an open awareness of problems faced by the organization in terms of the physical environment (lack of dedicated medication preparation areas and an automated dispensing unit in the main thoroughfare), human resources (strict productivity and budgetary constraints; declining recruitment and retention of experienced nurses), and the greater trends reshaping healthcare in the United States (the sweeping burden of healthcare reform). Yet they continued the pretense that the blame for medical errors lay in the notion that the nurses themselves were the obstacle to reducing medication errors. They repeatedly emphasized that nurses were task focused, and lacked education, training, and/or a 10,000-foot view.

Discussion

In the analysis presented here, the experiences of nurses in their everyday work environment revealed an environmental complexity crucial for understanding contextual contingencies characteristic of any organization (Child, 1973) or in this case, a medical unit of an acute care corporate hospital. The affiliation with a parent corporation brought in added insights and discourse centered on company fiscal restraints, policies, and other internal and external standards known to structure an organization.

Chasing a standard of care exposed an organizational arrangement that involved a shifting locus of control between the nurses and the organization within the constraints of time, human resources, and technology. Nurses recognized their own limitations when confronted with the pressure to exceed the average and compensated by focusing on strategies to reduce workload and uncertainty. They focused on one small thing at a time to suppress the feelings of being overwhelmed, stressed, and even incompetent. They did their work according to learned efficiencies such as approaching patients according to medication times, clustering activities, delegating, and multitasking, which are well documented in the literature (Flaherty, 2003; Jennings et al., 2011; Kohtz, Gowda, & Guede, 2017; National Council of State Boards of Nursing, 2016; Rankin & Campbell, 2009; Southerton, 2003; Strauss, 1988).

There was consistent evidence in these data that relentless negotiation with processes, patients, and peers was integral to the nurses' work day. The ability to compensate for environmental conditions, generate solutions to rapid fire predicaments, and maintain character necessitated it. Preserving character when faced with the immediacy of understaffing, patient crises, or the immediacy of a medication error shaped the outcome for many nurses. The effects of steady stress, failure, and fatigue on productivity, attrition, and wellbeing have well been well documented in the literature and in poems and narratives (Bear, 2011; Gordon, 2005; McGibbon, Peter, & Gallop, 2010; Rankin, 2009; Weinberg, 2003).

More significant in these findings was that nurses heavily valued the routinization of care to effectively manage their time. Without routines in the day, the demands of the day were out of sync; problems exceeded solutions, errors occurred, and the nurse lost control. This phenomenon of losing routine (losing control) is a common narrative in everyday nurses' work (Burke, 2012; Jennings et al., 2011; Weinberg, 2003).

Lastly, this research uncovered how nurses used overt and covert strategies to regain a sense of control in their work. Literature documenting efforts to reduce

uncertainty and enhance efficiencies in the workday shows similar evidence of this concept (Berlinger, 2016; Rankin, 2009; Rankin & Campbell, 2009). The decision to voluntary report a medication error was clearly linked to attitude and intention (Farag, Blegen, Gedney-Lose, Lose, & Perkhounkova, 2017; Hung, Chu, Lee, Hsiao, 2015).

The perspectives presented here highlight what appears to be an intentional distance placed between administration and the bedside nurses. This distancing is not new. Other literature describes how leadership minimizes nursing's attempts to adjust to rapidly changing environment by implying they are unwilling to adjust (Rankin & Campbell, 2009; Weingberg, 2003). Administration's passing the responsibility of errors onto nursing occurred despite an open awareness within each discipline, and each department. As early as 1964, Glaser and Strauss described the interdependency of internal departments and the identity of the total organization. For the attainment of institutional safety and quality, every department must be aware of, and responsive to, the ramification of their actions and performance on other units.

This study applied the perspectives of Jennings et al. (2011) of nurses' work as an orchestration of activities inseparable from medication administration and Patterson et al. (2002) of prioritization of competing tasks. Findings from this study supported these perspectives. What differs—and is significant—is that this research moved beyond the exploration of the narrative for nurses and extended it to include the stories of administration, pharmacy, and medical staff. Adding broader organization input confirmed that the context of medication errors was not just a breakdown of linear processes, but rather part of a chaotic and complex set of conditions. The previous models presented in Chapter 2 (see Figures 2.3-2.5) were far too simplistic. Study

findings here provide an emerging new model that challenges the prevailing theories. This has the potential to inform clinical practice, enhance our understanding of why present efforts targeting the reduction of medication errors may be ineffective, and encourage innovative new solutions.

The proposed theoretical model (see Figure 4.8) illustrates a more accurate framework for understanding the nature of nurse's work and the tension between contextual contingencies and the temporal structure of a day. The increased workload from anticipated and unscheduled tasks initially forces nurses to work faster and faster until workload spins out-of-control and ultimately cycles into chaos.

This study provides greater understanding of why nurses remain at the "sharp end" of the responsibility for medication errors (Reason, 2000, p. 768) and why there is no one to intercede. According to Reason (2000), hospitals are still failing to meet the criteria of highly reliable organizations. As such, this study must inform policy and education, and reform corporate and administrative practices for the clinical setting.

Limitations

One major limitation of the present study is that data collection remained focused on the medical unit of the hospital. Morse and Field (1995) delineate that this narrow area of inquiry may not reflect an accurate description of nurses' work in other units of the hospital, or in other hospitals. While the participants may share connections with the overall hospital culture, the unique experiences of nurses on other units may differ in behavioral norms or language surrounding medication administration and errors. Future studies should explore a more holistic view and should compare nurses' work from a



Figure 4.8. A model for nurses' work. Irregular components of nurses' work cannot be accommodated within a timed schedule. Instead, the components cascade on the nurses' routine and impinge on their time so that their day spirals entirely out of control.

variety of unit perspectives.

Furthermore, as Angrosino and Mays de Pérez (2000) emphasize, it can no longer be assumed that the reality of a culture or society can be singularly described through ethnography. Hence, the objective truth about contextual nature of nurses' work cannot be fully established because there will inevitably be conflicting versions about what happened. Future researchers ought to consider investigations using participatory research methods which focus on a high level of collaboration with participants.

Conclusion

Using an ethnographic approach, this study explored and analyzed the contextual nature of nurses' work on a medical unit. In contrast to prevailing studies which attempted to explain nurses' work as linear, this study revealed that nurses' work is cyclical and comprised of chaotic and complex characteristics. Observations and interviews with nurses, administrators, pharmacists, and medical staff provided data that enriched this understanding. The findings presented in this article not only supported the work Jennings (2011) and Patterson (2002), but also expanded their views by providing a rich description from a broad range of perspectives. The emerging model illustrates the inseparability of context within nurses' work —particularly surrounding medication management—from other work they do. It also reveals the cascading nature of the work that cycles the day toward chaos and back again.

These results have the potential enhance our understanding of why present efforts targeting the reduction of medication errors may be ineffective. They also point to the urgent need for new institutional strategies that promote high reliability within organizations (Reason, 2000) and reinforce nursing practice in terms of involvement and influence over hospital policies and patient care.

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CHAPTER 5

THE PARADOX OF SAFETY IN MEDICATION MANAGEMENT

Abstract

The reduction of medication errors depends largely upon the structure of medication management system and the role of the pharmacist in the acute care hospital setting. The significance of this claim became evident in an ethnographic study of nurses' work in which data were generated from extensive observations, formal interviews, and document reviews. This was followed by a microanalysis of each step of medication management from ordering to administering to identify the spaces and places where error emerged. Pharmacists became a surprising "stop-gap" between the physicians and patients. Pharmacists (far removed from the bedside) recognized and intercepted medication errors and did not formally support the reporting of all errors. Understanding the complexity of this process and these roles reminds us that there is no fool proof plan to reduce medication errors. The implication: a culture of safety remains elusive.

Introduction

Errors and the underreporting of errors remains problematic despite the introduction of strategies focusing on human factors engineering and technology

designed to mitigate risk (Alex, Adenew, Arundel, Maron, & Kerns, 2016; Kagan & Barnoy, 2013). The majority of errors occur in the initial prescription and administration phases of medication delivery (Bates, Cullen, Laird, et al., 1995; Cabilan, Hughes, & Shannon, 2017). Many researchers have published literature on the success of computerized provider order entry (CPOE), bar coded medication administration (BCMA), automated dispensing systems (ADS), and medication reconciliation processes in reducing both latent and active failures in the medication process (Barnsteiner, 2005; Flynn, 2010; Larrabee & Brown, 2003; Poon et al., 2010; Pronovost et al., 2003; Truitt, Thompson, Blazey-Martin, NiSai, & Salem, 2016; Vogelsmeier, Pepper, Oderda, & Weir, 2013). Fewer studies, however, have documented the unintended facilitation of errors or interprofessional disruption caused by these systems (Elganzouri, Standish, & Androwich, 2009; Keohane et al., 2008; Khanna & Yen, 2014; Koppel et al., 2005; Larrabee & Brown, 2003; Weinstein, Shechter, & Gorodischer, 2016).

In Chapter 4, an analysis of the contextual nature of nurses' work revealed:

1) internal and external organizational structures required nurses to focus on strategies to reduce workload,

2) competing obligations necessitated that the nurse hierarchize work and place the patient secondary,

3) forced reorganization and shifting of priorities resulted in ambiguity surrounding safety and manifested in the way nurses recognized and reported medication errors.

Amid these results, the processes and procedures comprising the medication management system emerged as a scaffold linking each characteristic of nursing practice together.

This article explores the distinct dynamics of the medication process to examine in greater detail the associated behaviors, interactions, and responses (Morse, 2006). This microanalysis also considers unintended consequences of the processes by analyzing the specific practice of the pharmacists and revealing the interplay with nursing.

Method

Design

The microanalysis featured here was derived from a larger ethnographic study of nurses' work. In that study I explored medication administration errors and organizational safety using unstructured interviews, nonparticipant observation, and content analysis. The hospital's institutional review board and its independent research council for shared governance granted approval for the study and I collected data between December 2015 and March 2016. Participants were introduced to the study and invited to participate through the hospital newsletter, personalized letters to administrative and medical staff, as well as through regularly scheduled staff meetings. All participants and staff involved gave written informed consent and had the opportunity to withdraw their consent at any time or to enter the study at any point.

Sample and Setting

Using a purposive sampling approach, I completed unstructured interviews first with administrative level participants in nursing, quality, education, and pharmacy. I followed these with interviews of medical staff, central pharmacists, unit-based pharmacists, and registered nurses on a medical floor. In total, 37 hospital employees participated over the 4 month period of data collection in this mid-sized hospital in the United States. Participants were licensed registered nurses (81.1%), licensed practical nurses (8.1%), licensed pharmacists (8.1%), and board certified medical staff (2.7%). Participants were predominantly female (67.6%), with an average age of 38.9 years (SD =10.1). They had an average of 10.6 years (SD = 9.5) of experience and 6.6 years (SD =7.1) in their current positions.

Data Analysis

I used conventional content analysis of the data based on a combination of steps previously described elsewhere (Hsieh & Shannon, 2005). For reporting, I aggregated demographic information, and then coded transcripts and field notes by highlighting and labeling persistent words, phrases, themes or concepts within a qualitative data analysis software, QDA-Miner® with WordStat®. Similar data were sorted and arranged into categories and more refined subcategories. This arrangement enabled me to identify and describe the characteristics of the category (Morse, 2008) and emerging themes. I collected sufficient data for in-depth analysis, redundancy of themes, and comprehension (Morse, 1994).

Summary of Findings

Despite affiliation with a larger parent corporation, strategies of safe medication practices were largely acquired through informal socialization, individual experience, informal rules, and deeply rooted routines among all participants. I observed that individuals built their commitment to medication safety based on established processes, experiential knowledge, and by association with social networks among colleagues. While the purpose of this article was not about socialization, my findings identified the components of the medication management system that most contributed to the culture of safety with direct implications for nursing practice.

This study identified three cornerstone processes as being the foundation for medication safety and error prevention in this hospital: 1) clinical pharmacist review, 2) automated distribution process, and 3) barcode scanning compliance among nurses—confirming the "6-Rights" of medication administration. The medication management system in its entirety, however, was much more complex (see Figure 5.1). This article delineates prevalent routines, practices, and procedures, and concludes with a description of participants' attitudes towards defining and reporting error.

Step 1. Provider Order Entry

The hospital in this study has used full computerized provider order entry (CPOE) since 2014, yet not all orders are entered electronically and/or entered by a prescribing provider. The resulting hybrid process allows exceptions to the CPOE policy for some long-time physicians (who were granted grandfathered status), as well as for some procedural areas that still use paper orders. Additionally, telephone and verbal orders remained in consistent use. I observed that some physicians, despite having the technology at their finger-tips on smart phones or tablets, simply found it more convenient to provide verbal/telephone orders to the nursing staff or pharmacist.



Figure 5.1. Steps of medication management system for the prevention of medication errors in a mid-sized U.S. hospital. The arrows with a dashed line represent associations between disciplines.

While eliminating errors from poor physician handwriting, CPOE introduced new unanticipated errors. Most problematic to the nursing staff were medication orders entered into the wrong field. Nurses described an increase in missed orders because the order was placed in the nursing intervention field or in a "Z Process" order instead of in the medication order field. Z orders are unique orders that fall under a specific department processes or procedures. They may be a one-time order or a revision of an existing order. Consequently, nurses frequently missed these orders unless noticed by the nurse and presented in nursing hand-off report. This resulted in administration errors.

I discovered a med error from the nurse on day shift—one of our new grads. It was the way the doctor wrote it; it was just completely missed. They [the providers] know they want you to do something but they don't know what exactly (laughs). He wrote "Stop insulin drip", and instead of DC IV fluids as a medication order, which should be really easy to do, he wrote "Hep-lock IV" in the nursing instructions- and it was missed. In [the provider's] mind that meant stop all IV fluids including D5. In the nurse's mind that's not what that said. (Pause) So, the insulin drip was stopped, but [the patient] had D5 going on all day; her blood sugars were back up to the 2-300 range. [The nurse] watched it go up. It ended up keeping the patient staying another 12 hours longer than she should have

Nurses also described challenges and obstacles navigating the medication prescribing phase using CPOE despite their professional identify as nurses. One significant challenge was that nursing staff had no authority to hold physicians accountable to the process. This was particularly problematic for new inexperienced nurses who may have lacked the wisdom to question a physician. Nursing had lacked a voice in the development of the process for CPOE. Retrospectively, nursing administration recognized that during implementation of CPOE, the priority goals were to help physicians reduce and ease their workload and to that end, they "*broke nursing*" in the process. We had no intentions to break nursing, but they were used to a piece of paper that came across and told them their hospital orders. Now, they electronically flow and they go into the abyss of these [EHR] lists of orders. They [nurses] had to completely rethink the way that they were processing the care because they didn't have their orders. Their whole system is completely messed up. So, we set them up and they failed.

Step 2. Mechanical Checking by Central Pharmacist

All medication orders required verification by the central pharmacist before they became active orders profiled to the patient's medical record. The central pharmacist routinely scheduled Monday through Friday—either screened the majority of orders that physicians entered (or delivered verbally to nursing staff members) for appropriateness of dosing, timing, and interactions. Hence, pharmacists verified orders entered by a physician. The pharmacist also completed verification when a nurse entered the orders. If the pharmacist entered the orders, no additional verification from a pharmacist was required: "*But that's the only case in which an order really only goes through one person.*"

The central pharmacist has the authority to make the appropriate substitution and changes according to their scope of practice and professional judgment. Substitutions and changes, referred to as clinical interventions, were common. Clinical interventions ranged from simply making recommendations for different drugs or dosing, "*switching [an injectable] medication from being a stock item to an IV room type of medication*", to entering "*overrides*" to safety alerts, and in some cases, editing a physician's order.

We might have a lab value come back that now looks like their [the patient's] renal function is becoming diminished so, we need to adjust a renal dosed medication accordingly. Or some other change in status might require that we make some recommendations for a different drug or different dose or whatever that might be. In addition to just plain processing the orders that are coming their way from the things that the physicians and nurses have captured, we're also responsible for making our own recommendations according to our training and what we do as a discipline.

During microanalysis, a prevailing theme became apparent: that of the pharmacists taking on a substantially greater role in all phases of the medication process. This included prescribing. Participants in this study had some reticence admitting the reality of this expanding role stating that not everyone was willing to foster this adjustment to their scope of practice.

There's a few doctors that are just downright ornery about things if you get them to sign off on things. Even with simple therapeutic substitutions. A lot of doctors, this is my opinion, they don't like things to be out of their hands and so they don't want auto subs for lots of things but they don't want to be bothered either and so it's, it's kind of one of those things where, you know, either way, you're not going to make a lot of them happy.

On the opposite extreme, some participants believed pharmacists' role should be expanded, particularly regarding medication reconciliation. Upon admission, nursing is mandated to obtain accurate lists of the patient's home medications and compare them with new or currently ordered medications, resolving any discrepancies or conflicts. The process continued with patient discharge, when the nurse reconciles inpatient medication lists with any changes at discharge. The process is hugely time consuming and I observed that it took a minimum of an hour to consolidate medication lists accurately, depending on volume of medications to be reconciled.

Some medical staff argued medication reconciliation should be a pharmacy driven and pharmacy led initiative.

I don't think they [nurses] ever have enough time to sit there and do med rec. That should not be the nurses' job. They do other things better. They could spend a better time taking care of patients rather than dealing with med rec type of stuff. So, upon admission that should be a pharmacist thing. Upon discharge, now a nurse gets to know the patient a lot better, that should be kind of a combination thing—both nurses [and pharmacy].

Adding to the pharmacist's role is not without its own consequences. Pharmacists are potentially expected to review over 100 medication orders an hour. This daunting work leaves the pharmacist prone to fatigue. Consequently, large order sets used by anesthesiology and the postanesthesia care unit, for example, were not reviewed as carefully due to the volume of short-term orders on an as-needed-basis for use.

This patient doesn't have any allergies so I really don't need to worry about anything there, they've got good renal function, they are an appropriate age so I just push them all through. Sometimes that's the case.

There are certain things that are going to kick up a red flag. Number one, is if it's something I haven't seen before and I'm not familiar with, I'm going to, obviously, look closer at it for that if it's something I've seen but I know that it's a higher risk medication, then I'll probably spend a little bit more time looking at it. There's some warning fatigue in [the EHR system]. But there are certain warning screens that are more likely to catch my eye.

Step 3. Unit Pharmacist

The unit-based pharmacist was physically stationed on the floor with the responsibility for more detailed clinical reviews. Unit pharmacists were staffed 7 days per week and covered the duties on additional floors and the central pharmacy over the weekend. During the weekends, the unit pharmacists mostly performed order verifications and ensured the function and flow of drug distribution throughout the hospital.

Day-to-day clinical reviews required an examination of patient medication profiles throughout the day to double check the appropriateness of dosing parameters. Additionally, this pharmacist addressed issues or questions from nursing, providers, other disciplines, patients, and/or patient family members. Using computer software to data mine the facility's electronic health records (EHR) system, pharmacists were able to review and flag concerning lab values or patient changes on a real-time basis. They spent most of the day responding to these alerts, assessing them, and making recommendations accordingly.

The unit pharmacists attended the daily Hospitalist rounds report. During these daily touch points, pharmacists gained deeper perspectives into the patient's disease state, status, and medication profile. Again, they were expected to make recommendations according to their discipline's training and scope of practice.

We like to think that if we're part of the decision-making process for the plan of care at the very start then we're more likely to, based on the recommendations we make, avoid some potential errors, pick you know better line of therapy with respect to drugs and everything because we are part of that whole process more upstream rather than downstream.

Visibility of the unit pharmacist allowed both medical and nursing staff to have direct communication and collaboration with them without delay. Nurses were often heard to say, "*I am going to talk to pharmacy to see if I'm doing this guy justice, if I should give him this [or not]. I'm not a pharmacist.*" This opportunity for a high level of cooperation relieved an underlying tension that nurses carried throughout the day by creating an immediate structure of support. This was particularly valuable when waiting for the opportunity to speak to medical staff directly.

Step 4. Nurse Review

Prior to the final step of administration, a licensed nurse was required to acknowledge all active orders on the medication administration record throughout the day (see Figure 5.2). New orders entered directly into the electronic system (whether



Figure 5.2. Step 4. Nurse review. This illustrates the nurses first check point of medication orders and responsibility for ensuring appropriateness for patient according to assessments, lab work, diagnostics, and knowledge of pharmacology. Communication patterns for changes to medication orders are also represented.

scheduled or unscheduled) showed up on a task management system in the EHR called Status Board. The charge nurses electronically entered hand-written orders arriving to the floor on paper (once noticed by the unit secretary) and flagged them for pharmacy review. The nurses would then receive a hard copy of the order for review.

Not uncommonly, nursing staff had to look in either the computer, the physical chart, or both to ensure ordered medications were captured into the system accurately. I observed that nurses were notified of new or changed medication orders only when the

physician discussed the plan of care directly with them, in a hand-off report, or in rare cases when the patient informed them. Consequently, medications errors (new or change orders delayed or missed) occurred if the nurse: was unable to speak directly to the primary care provider; received a superficial hand-off report; or discovered that the orders were entered into the wrong field or were vague.

Order sets or standardized protocols added a layer of complexity because they could not be entered as a set, but rather each as a separate and independent order. Patient Controlled Analgesia (PCA) orders were a common example of this on the medical floor. Medications associated with the PCA were easily acknowledged by the nurse and populated the electronic medication administration record (eMAR). However, nurses could easily miss the remaining monitoring components—whether dosing parameters for reversal agents or lab work—since these orders were separate and classified as Z orders or nursing instructions.

Nursing staff have a hard time unless you've been a nurse for a long time and you just know, hey – I know PCA requires this monitoring. I know we can give Narcan if the patient has decreased respiratory status. But a brand new grad coming in and not knowing the protocols, that causes some major issues. There's no longer [one order set], they're all separated into medication and labs, and blood bank, and it does create a [new] process flow.

The act of acknowledging medications represented a crucial step in the medication management process. To acknowledge an order required the nurse to have a keen knowledge of the patient, the patient's history and current status, lab work, other diagnostics, and allergies. Moreover, nurses needed comprehensive knowledge of the medications, indications, contra-indications, dosages, side effects, compatibility, and potential adverse reactions. Without a grasp of these data, or any lack of understanding of the patient trajectory or physician's plan of care diminished the ability of the nurse to

confirm appropriateness of the medication for the patient.

This created a risk to the nurse's ability to manage this high level of cognitive burden for his/her entire patient load without a level of cognitive indifference. The ability of nurses to think critically though the acknowledgment process became diminished when the unit was understaffed, or when they were busy with rapid patient turnover, high volumes of medications per patient, and ultimately, competing obligations. Nurses compensated by trusting the eMAR to be correct and by superficial and mechanical reviews. At times, they did not comprehend alerts or even ignored system generated alerts.

I had the craziest orientation ever. My first day, I gave three units of blood. It was just like that the entire orientation, and so, I was trying to do too many things at once and I wasn't focusing when I was doing my med draw. I realized that [it] was the right patient, but it was the wrong drug. So, you know how- when you pull it out and it says, 'pull it from this drawer number', I pulled it from the one behind it or the one in front of it, so I actually gave the wrong antibiotic because of that. And so - it was not a big deal, the antibiotic, because it was the same drug class and it covered that, and so I told the doctor and he was like, 'That covers it anyways, so I don't really care.' (laughs) So it wasn't a big deal, but it was, it scared me to death and I was so worried that I was going to kill my patient. I was checking on him every hour. 'Hope you're not allergic to this.' [Scanning] did [alert me], but it was popping up saying, something it didn't say that this wasn't on the MAR. It said something else, and so I wasn't understanding what it was saying.

Step 5. Distribution Model

Once acknowledged, medication orders populated the eMAR and were available for administration. From the pharmacist's perspective, the automated medication dispensing process was one of the three overarching mechanisms in place for the prevention of errors. The bulk of medications were stored and available to nurses directly on the unit at the point of use.

With most of our medications available on the floor already in an automated

dispensing cabinet, it really is left in the hands of the nurses. As soon as they are ready, if it has been profiled, they can go give it. If [a medication] is due in an hour from now and I get that time in an hour from now; I just simply go to the cabinet, pull the medication go and give it to the patient. If it's a STAT order, something needed right away, it's right there already available on the floor. I'm not waiting on the pharmacy, the robot, the technician to pull it from the shelf because it's already on my floor. So literally the second the pharmacist verifies an order as being correct and profiles it to the medication record for that patient, it's available for nursing to go grab.

Based on inventoried needs, a pharmacy technician stocked the unit's automated dispensing cabinets twice daily, typically occurring around change of shift at 7 a.m. or 7 p.m. The technician scanned and safety checked each barcoded medication prior to placing it into the unit. This practice resulted in delays at times when the system required rebooting or problem solving. Long lines formed by 8 a.m. as all six nurses prepared to pull morning medications.

The two dispensing units were in the main thoroughfare directly across from the employee elevators. Additionally, nurses needed to locate medications in four other places. The bulk of intravenous medications delivered were stored in wall hanging cabinets down each hallway called nurse servers. Medications requiring refrigeration were stored in the supply room. A new medication may be sent through a pneumatic tube system and stored in a lock box on the wall. And lastly, if the medication was not found in those places, a check at the nurses' station often proved fruitful.

The complexity of storage, distribution, and presentation of medications to nursing affected workflow and efficiencies (it was not uncommon to observe that the nurses would find a pocket empty in the automated dispensing unit and have to walk to another floor to obtain the needed medication). It also increased the potential for error (see Figure 5.3).



Figure 5.3. The automated dispensing system. The propensity to select the wrong medication or to find the wrong medication stocked in the wrong pocket was ever present given the layout of the automated dispensing system and the presence of look-alike medications in proximity. Nurses experienced practical problems in handling medications associated with the variety of commercial packaging options.

Human factors added to discrepancies and the risk for error. These included

inventory not accurately tracked, medications misloaded into the units or chosen

incorrectly, and labels placed incorrectly.

With pharmacy errors that I've had, it's made it through me, through the computer system and hung and it's been wrong. So, they've slapped the label a right label on the wrong amount of fluid of potassium. It was a problem through really, three: the pharmacist's hands, the pharmacy tech who made it, the pharmacist approved it, and it made it through my hands. When feeling it, I should have known that it was not a 250 mL bag. [I am] in a hurry, she's been having potassium the whole time, time for more potassium! I scanned it, hung it, and it went through. We all make mistakes.

Step 6. Administration

At the point of medication administration (see Figure 5.4), the eMAR highlighted in green administration times for "medications due." Past-due medications were notated in a bright red font. A summary screen provided nurses an at-a-glance review which assisted them in prioritizing the day. By facility policy, nurses were allowed a half-hour leeway to administer medications without them being considered administered at the wrong time. Seeking to improve efficiencies, nurses often combined doses within the hour, often around other time critical medications such as insulin. Nurse administrators were aware of such strategies and talked about them openly:

There are some critical meds that have to be given within a certain timeframe. Obviously, you can't just choose when you're gonna [sic] give insulin during the day for it to be most effective. There are other time critical medications that we've had to identify in a policy. Well, as a nurse, if you know you have to give insulin and four other medications, are you gonna [sic] give your insulin and then get around later to give the four other meds? No! You're gonna [sic] do them all together.

Beyond simply clustering medications, I observed that nurses employ other work arounds to meet the demands of the day. Some intentionally administered medications over an hour early with the rationale described here:

I'm okay with giving [a patient] their med an hour early because more often than not, because of situations like [today], I'll be more than half an hour late. So, if I start an hour early, my latest will be an hour late.

Once at the bedside, the nurses logged into the eMAR and began the process of patient verification by requiring the patient to state two identifiers, by scanning the patient armband and then scanning each medication one by one. Administration closely monitored scanning compliance and when nurses missed the mark, scanning rates were displayed in the unit to motivate nurses to improve. Nurses were aware of the policies



Figure 5.4. Step 6. Administration. This illustrates the point of medication administration at the patient bedside. The nurse is vulnerable and may rely too heavily on technology and less on critical thinking, may cut corners to gain efficiencies, or encounter factors beyond their control.

surrounding medication administration times and scanning compliance. However, the fact remained that for some, it was enough to know that even though the medications were late, they all were given. "On my last shift, I was giving 0900 meds at 1100. But they all got given. [I] can only do one thing at a time".

The expectations surrounding medication times and scanning compliance seemed to demonstrate a set of vague dynamics and perhaps hidden rules between administration and staff. With few exceptions, everyone expected work arounds. However, one particular work around emerged that warrants attention: the propensity to administer medications before scanning. While I did not directly observe this, administrators in quality management shared the following event:

What happened is that an IV medication was hung on the wrong patient. It was [for] a previous patient in that room. They [the nurse] grabbed the med out, they hung it (short pause) and started it. And then scanned it, [at least] it's what it looks like because half of it was gone. And [the nurse] said it hadn't scanned. So, it's like I don't know...but it was the wrong patient and wrong med.

As each medication was individually scanned, pop-up alerts appeared based on the need for a documented pain rating or blood pressure reading. Nurses had to be prepared with recent lab results, injection sites, and/or assessments done in order to pass onto the next screens. Other cautions or alerts for co-signers popped up and were either noted or entered through until completing the final prompt to file and save all medications to be given.

Most striking at this juncture of medication administration is that once the risk for error was near the patient, nurses had no safety net. There was no pharmacist to step in and exercise a clinical intervention. Risk compounded when nurses ignored the scanning process. While high alert medications, such as insulin or heparin, required a second witness or review by a licensed nurse, the quality of the second nurse review was deficient. These independent double checks were completed, but done superficially and without thought.

[The previous nurse] had got[sic] a patient admitted, but she had wrote [sic] on the [white] board the insulin scale, our regular sliding scale, our typical sliding scale I should say. She had given insulin and gone over it [with me]. Then I gave insulin off the sliding scale off the board and didn't double check on the thing [eMAR]. And none of the nurses that double checked me didn't check either, just went off of what I said and what was on the board also. And so, I'd given three doses too. The next morning, I go in, [the previous nurse] had given it [insulin], I think again, and then was checking [the patient]. His blood sugar had been like 400 and something and so she was checking to see if the doctor needed called. So, she was checking and realized [we should have been giving] three units instead of two.

Defining Error and Reporting

Monthly medication error reports specific to the medical unit were not made available; instead the Department of Quality provided a summary of reported hospital wide medication events by fiscal year. The summary detailed an average of 424 medication events reported between fiscal years 2012-2015 with a 12% decline noted after implementation of CPOE in 2014. A lack of voluntary reporting of errors, however, was a common occurrence on the unit. Among nurses, the willingness to report errors had less to do with punitive responses from administration and more to do with vague, tenuous standards surrounding reporting and, to a certain extent, elements of indifference.

It became evident that differences in defining errors and the inability to recognize an event as an error contributed to underreporting. Nurses had an awareness of what "technically" constituted an error but there was also a normative belief (regardless of role and licensure status) that a medication error was conditional based on its proximity to the patient. These perceived differences created disparate reporting expectations. From the perspective of pharmacy, clinical interventions performed by pharmacy which happened remotely from the patient were not medication errors by definition, nor were they reported.

Fundamentally, most of us tend to think of an error as something that made it through two or three holes in the Swiss cheese that lined up—actually, made it to the patient. Or we had to order additional labs, or you know we had to change the dose, we had to do something different to the patient's therapeutic regimen, as a result of this error we had to change something. And so that is a medication error. As pharmacists, we know we underreport what should be the technical definition of a medication error—which is basically, anything wrong that either potentially or actually could result in patient harm, you know, due to an error being made. For an example of that, the pharmacist who primarily does order-verification, day in and day out. Through their job, they go through and make fixes and corrections to medication orders. They don't report every single time they fix something, correct something; every time they call physician, and [say] 'did you really mean this?' They don't, right then, turn to the occurrence reporting system and say, "I just called Dr. so and so, they really didn't mean to prescribe that. I corrected the error." Those don't go into the system. And if you ask our pharmacist why it didn't go into the system, [they would say] 'that's just my job, that's what I do, that's my existence, why would I report that?' kind of thing.

Only after an event reached a patient directly, regardless of whether there was a

consequence, should the event be reported as a medication error. Policies did not outline

a definition for medication error nor did they prescribe what should be reported.

The unit nurses instead defined medication errors as events that reached the patient. Reportable medication errors caused some level of harm. During discussion with a group of nurses about medications, I observed that nurses would check their assumptions with one another before recognizing that an error had occurred.

And so, I'd given three doses too, I mean still it is an error, right? It's wasn't, a big deal, but you know it was just one unit was missed basically every time, so it wasn't like we overdosed them or anything like that.

A level of confusion and ambiguity resulted for nursing staff on what should be recognized and reported as actual errors. Messages from others minimizing errors hindered reporting. One of the most common events on the unit, according to the nursing staff, was forgetting to unroll the roller clamp on a secondary bag of antibiotics. But when another nurse caught that 12 hours later, and notified the provider, they responded with, "*Oh that's fine just start the next dose*". The nurses admit, "*those are not reported*".

In a separate interaction, I observed a nurse asking the charge nurse to "*look at this order*". The medication order read to administer 2 units of insulin. However, in the nursing instructions, the instructions read: 2 units for every 50 mg/dL above 150. Based on blood glucose results, the nurse had calculated the need to give 4 units, but the computer alerted her that she was exceeding the appropriate dose. She shows the charge nurse that the nurse in the previous day has just been giving 2 units despite the blood glucose range. When inquired if this would trigger an occurrence report, she stated "*supposed to*" and walked away.

Only with an institutionally agreed upon definition can staff know what should be reported. There was no indication that lack of reporting was due to punitive responses. Instead the message was more of a nonchalance or a "*normalization of deviance*".

I think a lot of it is culture. Normalization of deviance—you get away with it and so then it just seems like it's okay. You've gotten away with it so many times. There are so many things, so many rules. I mean, people are just trying to get by.

In summary, the culture of safety remained elusive. Nursing staff and pharmacists did not fully recognize the benefits of reporting even near misses. Physicians, whose mistakes were consistently interceded, seemed only to benefit.

Discussion

The medication management system of this mid-sized hospital was illustrative of a structured and formalized program of organizational safety measures. The program was well aligned with national standards and pharmaceutical protocols, as well as consistent with existent literature on the use of technology and clinical pharmacist reviews in the reduction of medication errors (Gallimore et al., 2016; Kaboli et al., 2006; Truitt, Thompson, Blazey-Martin, NiSai, & Salem, 2016). Notwithstanding the systems in place, however, my findings echo previous research which shows that theoretical benefits are not always realized in practice (Alex et al., 2016; Khanna & Yen, 2014; Koppel et al., 2005). While medication management systems are viewed as infallible, in fact, this is where the system collapses.

A growing body of research supports the expanded role of the clinical pharmacist as part of the patient care team. Doing so has improved delivery of care and clinical decision making, and reduced medication errors (Alex et al., 2016; Gallimore, Sokhal, Zeidler Schreiter, & Margolis, 2016; Sorensen, Pestka, Sorge, Wallace, & Schommer, 2016). While this recognition of the essential role of pharmacists is not new (Kaboli, Hoth, McClimon, Schnipper, 2006), the renewed focus of inquiry highlights a critical opportunity for pharmacists to provide advanced services.

However, we cannot ignore the role of the pharmacist in facilitating safety lapses. For example, the contrast between reporting errors that *reached the patient* and those far removed or *remote* from the patient was a startling indication of the existence of contradictory norms. Although a clinical review by central pharmacy helped to reduce medication errors through the identification and correction of prescribing errors, the absence of reporting them was alarming.

Pharmacy was using clinical interventions to correct ordering errors of physicians. If such errors are never reported or called out to physicians, the physician may never learn. Such practice explains underreporting and supports other studies that identify interprofessional hierarchies (Gordon & O'Connor, 2012) and underreporting as symptoms of flawed systems (Farag, Blegen, Gedney-Lose, Lose, & Perkhounkova, 2017; Mayo & Duncan, 2004). Other studies also report that knowledge-based factors and CPOE link to the actual enablement of prescribing errors (Cabilan et al., 2017; Khanna & Yen, 2014; Koppel et al., 2005).

Likewise, the behaviors of nurses captured in this study echoed previous research that shows the provision of safe, patient-centered care is diminished when nursing staff lack specific patient-centered care competencies, teamwork and collaboration, evidence based practice, and quality improvement competencies, safety commitment, and appropriate informatics training (Cronenwett et al., 2007; Latimer, Hewitt, Stanbrough, & Andrew, 2017). For example, the role of nursing in medication error prevention has long been formalized in the "6 Rights" procedural checklist and in protocols for independent double checks (Aronson, 2009; Cabilan et al., 2017; Latimer et al., 2017; Mayo & Duncan, 2004). Electronic automated dispensing units, eMAR, and barcode scanning made the work of the "6 Rights" inconvenient, awkward, and maladroit. Instead, misguided trust and an overreliance on technology circumvented ordinary competencies (Cohen & Smetzer, 2017) particularly in the presence of cognitive overload.

Implementation of CPOE and other technologies to support clinical decision making can neither replace human activity nor can they address judgment errors (Bates et al., 1998; Cohen & Smetzer, 2017). Bates et al. (1998) speculated that an overload of information leads to a level of indifference that causes providers to ignore serious warnings or procedural steps. This may explain the underpinnings of the emerging concept *normalization of deviance* described in the findings above.

Throughout the data gathering, I observed that medication administration was not simply the giving of drugs with defined temporal boundaries, but rather it was

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inseparable from nurses' other work (Jennings, Sandelowski, & Mark, 2011). Errors presented in this article were examined not as a single isolated event, but from the perspective of a prioritization of competing tasks as reported by Patterson, Cook, and Render (2002). As the busyness of the day increased and the shift cascaded out-ofcontrol (Chapter 4), nurses were not only forced to shift priorities, but also their commitment to safety. Safety became an ambiguous term, as did the definitions of a medication error and a reportable error.

The microanalysis presented here explored each stage of the medication management process in a mid-sized hospital. The findings were consistent with, and confirm, much of the extant literature on medication management and the reduction of errors. A strength of this study was triangulating multidisciplinary perspectives to provide a rich description of medication management. The findings add ethnographic evidence to the literature by providing detailed descriptions of several conditions contributing to medication errors such as the complexity of medication management, and our incomplete understanding of the protocols, systems, and events that precede and/or prohibit medication errors and reporting.

The dichotomy between medication safety attitudes and actual medication safety behaviors resulted in a "safety paradox". This paradox can be best explained by a complex combination of ambiguity and human limitations that included complacency, a lack of vigilance, overreliance on technology, fatigue, and deeply rooted interprofessional hierarchies (Cohen & Smetzer, 2017; Gordon & O'Connor, 2012; Institute for Safe Medication Practices [ISMP], 2016). The emergence of the role ambiguity plays suggests the need for tactics that reduce cognitive overload and bolster resilience through better support for key stakeholders: prescribers, pharmacists, patients, nurses, and policymakers. Hence solutions to this paradox will require bold leadership and forthright discussions to explore incongruence in practice.

Limitations

I did not set out to explore the impact of the medication management system and I was surprised to learn that pharmacy played such a pivotal role. To better evaluate the impact of the process, it would have been ideal to obtain data on medication error rates and types. Despite these limitations, this study was novel in its exploration of the pharmacist's role in medication error.

Recommendations

Future research is needed to refute or resolve the safety paradox either by more accurately interpreting the phenomenon or by building comprehensive models that will better expose the complex nature of the phenomenon. Additionally, studies comparing the categorization of medication-errors-not-interceded to categories previously established would prove useful in determining present-day classifications of medication error and trends (Barker, Flynn, Pepper, Bates, & Mikeal, 2002). As well, future inquiry should focus on mixed method approaches to explore nursing judgment and the concepts of indifference or normalization of deviance in relation to nurses' intent to recognize and report medication errors.

Conclusion

The analysis presented in this article provided a fresh view of the cultural context of safety that lies beneath medication management and decision making by illustrating each step of the medication use process with general statements and associated conclusions. Complex practices and assumptions underlying the paradox of safety remind us there is no fool proof plan in the fight to reduce medication errors. There always remain spaces and places for error. We should not consider such potential error points as system failures but rather as process weaknesses. Finally, this microanalysis implies that there could be great value in assessing an expanded role of the pharmacist two distinct ways: first, in reconciliation of medications, and second, reporting remote errors (clinical interventions) in greater detail. These measures, in concert with providing meaningful support and solutions for the tenuous working model facing nursing practice, could significantly reduce medication errors.

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CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

Introduction

Ethnography is a method of inquiry that allows the researcher to describe a problem within context through the lens of culture (Spradley, 1979). The aim of this study was not to understand the essence of nurses' work as in a phenomenological study, nor was the intent to set out on a quantitative investigation of the nurse's day. Rather, the aim of this inquiry was to explore the empirical nature of nurses' work in the context of the medication administration, error, and organizational safety. The extant literature designed to enhance our understanding of present efforts targeting the reduction of medication errors have lacked appreciation of the contextual nature of nurses' work. Subsequently, the contextual contingencies affecting nursing practice remain poorly understood. This is an important undertaking given the sweeping reforms occurring within the U.S. healthcare system intent on improving access, quality, safety, and cost. As such, the following research questions guided this study:

- 1. Given the complexity of nurses' work, how do nurses prioritize medication administration within a medical unit and the hospital environment?
- 2. What is the nurses' experience with medication errors, patient care, their work environment, and the organizational culture of safety?

a. What do nurses experience in the immediacy and aftermath of a medication error?

b. How does setting affect medication error, including contextual events leading up to and following the error?

This study was framed by the perspectives of Jennings et al. (2011) describing nurses' work as an orchestration of activities inseparable from medication administration, and from Patterson et al. (2002) regarding the prioritization of competing tasks. In this chapter, I discuss research findings in light of the empirical and theoretical literature for each research question. My conclusions emerge from a new understanding of the nature of nurses' work within contextual contingencies. Lastly, I present a discussion of the research methods, study limitations, implications for practice and recommendations for future research are addressed.

Summary of Findings

Research Question 1

Given the complexity of nurses' work, how do nurses prioritize medication administration within the context of a medical unit and the hospital environment? The first major finding described in Chapter 4, *Exploring Nurses' Work in the Context of Medication Administration: Untenable Expectations* elucidated how nurses, faced with competing obligations, (Jennings et al., 2011; Jennings, Sandelowski, & Higgins, 2013), structured activities around the medication schedule. It was not that nurses were prioritizing medication administration within other work responsibilities, but rather that they were prioritizing other work responsibilities within the context of medication administration. Nurses needed a reason to enter the patient room. In the face of competing obligations, patient needs were secondary. This new finding diminishes the immediacy of nurses' work—meaning, if nurses do not do something, someone else suffers immediately. Nurses' work cannot pile up. Current research has provided several explanations for why patient needs may become secondary such as understaffing, inexperience, and patient turnover (Ebright, Patterson, Chalko, & Render, 2003; Henderson, Willis, Blackman, Toffoli, & Verrall, 2016; Jennings et al., 2011, Jennings, 2013). However, the complexity of this phenomenon has yet to be fully explained.

Nurses did turn to normative behaviors such as clustering and combining tasks to increase efficiencies and reduce workload (Jennings et al., 2011). The effect on these measures to reduce cognitive overload (and decision making), however, was not clear. I observed that as the busyness of the day increased, regard for patient-centered care diminished further, problems exceeded solutions, and the workday spun out of control. This cascade of events can be further explained by the participants' loss of routine, both in a given shift and over time given changes in the practice environment. This is a common narrative found not only in the medication administration literature, (Burke, 2012; Jennings et al., 2011; Weinberg, 2003) but also in studies pertaining to falls (Ebright et al., 2003). My observations add to the body of literature that suggests the need to better understand the nature of cognitive load while in practice with patients (Ebright, 2003; Potter et al., 2005; Sönmez, Oğuz, Kutlu, & Yildirum, 2016).
Research Question 2

What is the nurses' experience with medication errors, patient care, their work environment, and the organizational culture of safety?

a. What do nurses experience in the immediacy and aftermath of a medication error?

b. How does setting affect medication error, including contextual events leading up to and following the error?

The second major finding was unexpected and provided evidence of the crucial role of the central pharmacist and how the nurses continue to carry the burden of responsibility for medication errors. The role of pharmacists and their specific actions detailed in Chapter 5, *The Paradox of Safety in Medication Management*, are well supported in the literature (Bates et al., 1998; Carter, 2016; Kaboli, Hoth, McClimon, Schnipper, 2006; Mansur, 2016). My observations and interviews show that the central pharmacists acted as a "stop-gap" between the physicians and patients; pharmacists recognized and intercepted medication errors that occur far from the bedside. Pharmacy was using clinical interventions to correct ordering errors of physicians. However, the absence of reporting was alarming. While literature supports the effectiveness of the clinical pharmacist review in reducing medication errors (Alex, Adenew, Arundel, Maron, & Kerns, 2016; Gallimore, Sokhal, Zeidler Schreiter, & Margolis, 2016), errors not reported by the pharmacist will not benefit providers in their ability to identify breach of standards.

This underreporting was widespread among nurses as well. The lack of a clear definition of medication errors explained this to some degree (Espin et al., 2010; Kagan

& Barnoy, 2013; Lisby et al., 2012; Milch et al., 2006; Treiber & Jones, 2010). For the nursing staff, social structures determined what and was not an error. Data showed that participants defined medication errors in relation to the severity of patient harm (Espin et al., 2007, 2010; Osborne et al., 1999; Throckmorton & Etchegaray, 2007).

Precipitating causes of error in this study were also related to the perils of technology. This was consistent with the literature indicating that there are interface flaws with standardized templates in health information systems (Bjørn et al., 2009; Khanna & Yen, 2014; Koppel et al., 2005). Likewise, precursors to medication errors included ambiguity in policy expectations and procedure (Tissot et al., 2003), communication (Kazaoka, Ohtsuka, Ueno, & Mori, 2007; Taxis & Barber, 2003b), and busyness.

While studies have shown that there is an increased incidence of errors associated with nursing workload (busyness) (Elganzouri, Standish, & Androwich, 2009; Jennings et al., 2011; Keohane, Bane, Featherstone, Hayes, & Woolf, 2008; Tang et al., 2007), I did not fully explore this area of inquiry. Future studies that more fully categorize types of medication errors by the busyness of the day would be useful to validate current categorizations of error (Barker, Flynn, Pepper, Bates, & Mikeal, 2006).

In this study, there were no significant findings illustrating experiences in the immediacy and aftermath of an error, except for references to emotional responses, decision to report, and root cause analysis involvement. The lack of more descriptive findings suggests theoretical and methodological weakness. From the evidence that was described, I concluded that nurse errors affected workplace relationships by leaving a negative shadow over the nurse of embarrassment and a reluctance/fear. At the same

time, nurses recognized lessons learned (Koehn et al., 2016).

These findings presented here are not unique and can be generalized. Similar findings have been alluded to in the literature since the early 1990s with the emergence of hospital restructuring and market driven care. Weinberg's (2003) writings document the clash between organizational structure, the nursing workforce, and patient care in Boston. Her work supports what I found in this study about the distance between administration and the bedside nurse that threatens patient safety. The theoretical model, presented here, illustrates this clash and calls into question our current understanding of this enduring nursing crisis. The difficulty remains in administrators who are not listening to staff. Instead, they tell nurses that other hospitals are doing it (keeping up with mounting expectations), but not how they are doing it. This is uncivil. Further, the conclusions drawn from the data contribute to a growing body of literature which strives to increase awareness of and support for the tensions and challenges that permeate the everyday activities of nurses (Gordon, 2005; Henderson et al., 2016; Jennings et al., 2011, 2013; Rankin, 2009; Rankin & Campbell, 2009; Weinberg, 2003).

Nurses are vulnerable because they do not have the pharmacist as a safety net as physicians do. Instead, they have faulty double checks, look-alike medications in bins that do not prevent grabbing the wrong item, ambiguous orders (blood), time constraints (queue up for the automated dispensing unit), nowhere to put meds except in pockets, and work arounds. Other studies replicate many of these findings in other units and other hospitals (Cabilan, Hughes, & Shannon, 2017; Jennings et al., 2011; Koppel et al., 2005). It is not just a local phenomenon. I do not know if my findings for errors in this hospital are worse or better than at other hospitals. However, medication errors remain a nationwide epidemic.

Discussion of Research Methods and Limitations

This study used a valuable combination of interviews validated with observation and documentation (Hodder, 2000). The combination served as an effective tool for comparison and for reducing inherent bias that accompanies one method alone. Even so, the quality of observation can only be measured by what was recorded. I bring in my own talents and interpretations and am acutely aware of my own limitations. Hence, the authority for this study is only based on this researcher's personal experience, reflexivity, and systematic approach to gathering, analyzing, and verifying data (Clifford, 1983).

Sample selection was the greatest contributor to reliability and validity (Morse & Field, 1995). I acknowledge that participants on the medical floor represented a minority of nurses in this mid-sized hospital isolated to the northwest region of the United States. These considerations might have influenced the behavioral and cultural norms identified, as well as the taxonomy surrounding medication administration and errors. However, the involvement of administrators from nursing, quality, medical staff, and pharmacy added to and clarified important dimensions of nurses' work and contributed to the adequacy of the sample.

As an experienced nurse educator, I shared a proximity to the field of investigation that affected my ability to negotiate preconceptions, situational identity, and data analysis. This proximity fostered the conception of the researcher as an insider. Consequently, some interviews became awkward and limited the depth of participant responses. This was because staff assumed that they were interviewed by someone who already knew the answers, despite my efforts to act as the ignorant bystander.

Approaching administrative staff first for targeted interviews was an effective strategy that helped foster trust with the unit employees. Most administrators were very optimistic in the organization's responses to safety and culture and seemed to explain they were not involved or aware of errors. There was evidence of pretense awareness (Glaser & Strauss, 1964) between the researcher and the administrator. Because of their role in representing the system and the level of risk perceived in a discussion of errors, the administrator may have misread cues as to the reality of our interaction and therefore suppressed information. One example that illustrated this response to a perceived risk was the refusal to provide requested documents. Dedicated, targeted observation of administrative staff may have been useful to overcome this strain; however, it may have led unit staff nurses to believe I was on an errand by the administration and in collusion with them.

Unfortunately, the think-aloud technique did not serve as a reliable tool for capturing the decision-making process as I found the nurses were challenged to articulate their decision-making out loud because it was so complex and fast paced. Observation not only became a powerful source for validation, but it also afforded high level interaction and dialogue. Traditional ethnographers may critique this contemporary view of observation with the argument that ethnographers operate at a distance because a "failure to do so would mean the investigator has gone native" (Angrosino & Mays de Perez, 2000, p. 674), hence sacrificing validity and supplanting bias due to the propensity for those being observed to change their behaviors. However, in the perspective of contemporary social scientists, dialogue and collaboration during observation supplements the process (Adler & Adler, 1994; Angrosino & Mays de Perez, 2000).

Nursing staff did not seem bothered by my presence. In fact, they acknowledged my presence with greetings, engaged in casual conversation and offered snacks, making it difficult to remain completely distant and removed as a nonparticipant observer. Prior to the termination of data collection, indeed, I had crossed the line to friendship.

Despite this, the use of observation as well as comparison with participant responses and document reviews gave insight into what may have been underreported in other studies. Journaling and field notes further contextualized findings such as understanding the significance of the social nature and behaviors of nurses in recognition and management of medication errors. While segmented components of the nurses' workday have been examined before (Gordon, 2005; Gordon & O'Connor, 2012; Jennings et al., 2011, 2013; McGibbon, Peter, & Gallop, 2010; Sönmez et al., 2016; Weinberg, 2003), this study was novel in its exploration of nurses' work beyond the unit. Additionally, it is the first to examine from the nursing perspective the role pharmacy plays in the context of nurses' work, medication management, and reduction of medication error.

Implications for Practice

This distressing context of nurses' work has implications for all aspects of patient care and safety. The most significant implication concerns the prevention of medication errors and events leading up to them. The toll of medication errors on the patient and the organization clearly indicates that the potential benefits of a changed strategy outweigh the risks. Perhaps the greatest gains in patient safety may be made through administrative changes. There is enough evidence to support a shared leadership structure. Nurses may be more likely to stay in the unit where they feel supported, reducing the potential toll on nurses caused by attrition and retention concerns.

Further, the development of courage (Hawkins & Morse, 2014) in novice nurses and the strengthening of courage in experienced practitioners has the capacity to improve patient safety by cultivating control of emotions and risk-taking action.

Though not part of the aims of this study, there are implications for the use of disclosure, apology, and reporting in the immediacy and aftermath of medication errors. Lay literature has polarized healthcare providers and the public by highlighting and publicizing medication errors. These stories tend to lay blame, give only a glimpse into the context for error, and ultimately engender fear in the lay public.

Lastly, I present the following recommendations for the hospital system based on my findings:

- Create unambiguous definitions of medication error for all levels of staff. Clearly define what an error is, what types of errors require reporting, and when reporting is required based on regulatory law. The definition offered here is: Report "any preventable event that may cause or lead to inappropriate medication use or patient harm" (National Coordinating Council for Medication Error Reporting and Prevention [NCCMERP], 2015
- 2. Formalize the pharmacist's role to facilitate medication safety practices. More than a presence on the unit or in a Hospitalist's huddle, I recommend that pharmacists round on each patient, manage medication reconciliation, assist with independent double checks, and facilitate patient transitions.

- 3. Build the principles of medication safety into future structural design. Lobby for facility resources to carve out a footprint for a dedicated medication room.
- 4. Remove the burden of responsibility for patient load from the shoulders of the charge nurse or PCC. Maintain this important resource particularly for nurses with less than 5 years of experience.
- 5. Capitalize on potential successes of shared governance and engage the research council to study its effectiveness in engaging nurses. Shared governance was in its infancy at the start of this study. Evidence continues to support the benefits of this structure in advancing the nurses' control over practice (Hess, 2004, 2017).

Recommendations for Future Research

While a commonly held assumption is that medication errors may reflect the complexity of competing priorities, this study found that medication errors happened regardless of the mood of the day. I recommend future researchers pursue granular mixed method studies comparing the nature and likelihood of medication error categories on good days to bad. Doing so would provide further insight into specific nursing strategies useful for combating preventable errors in practice.

A cost-benefit analysis would be useful to address the clinical effectiveness of better partnering with pharmacists, ensuring workflow ideals match the work being done. Such transparency may be necessary to achieve an authentic culture of safety.

Another worthy study would be to follow up on the assumption that staff social networks within hospitals are a significant factor in building a supportive work environment—including the recognition, reporting, and management of medication

errors. What do nurses do to reinforce positive medication safety practices and diminish negative ones? Future observations of the effects of such networks could be powerful to the development of relevant strategies to help establish relationships or build teams both internal and external to nursing, particularly in large, urban settings.

Intrinsic to present-day healthcare delivery, and this study, is the quiet assumption that modern nurses lack the 10,000-foot view and perspective necessary to deliver safe, quality care. The onus is on nurses to either change the way they deliver care or on nurse educators to transform the way they prepare nurses so they can function in ambiguous contexts. A phenomenological study to examine the experiences of nurses would determine if this assumption is true and may inform curricular and pedagogical strategies for nursing education.

Ethnography assumes that culture is a learned phenomenon and while this study solely focused on one medical unit of the hospital, I recognize the context of nurses' work is indeed broader. I recommend further study using participatory models of inquiry not only to achieve a mutual understanding and comparison of experiences on other units of a hospital, but also to use that understanding to address medication errors. Such perspectives would enhance an understanding of how hospital units are connected, and how policies and practice may foster safety from unit to unit.

Conclusion

There is limited research on the nature of nurses' work in the context of medication administration, errors, and organizational safety. Conclusions drawn from this ethnographic study highlight significant characteristics of our work. This knowledge gained can serve to enhance our understanding of why present efforts targeting the reduction of medication errors may be ineffective. This 4-month study used nonparticipant observation, unstructured interviewing, and pertinent document reviews to explore the empirical nature of nurses' work.

The major findings of this study shed light on an open awareness of the problems faced by the organization in terms of physical environment, human resources, and greater trends reshaping healthcare in the United States. This awareness remains muted and ignored, perpetuating fallibility in nurses' work. These results replicate the findings of numerous clinical and institutional ethnographies which overwhelmingly document the burden of responsibility experienced by the nursing workforce (McGibbon et al., 2010; Rankin & Campbell, 2009; Weinberg, 2003). In addition, the findings contribute to the voice of Suzanne Gordon (2005; 2012) and many other descriptions of nurses' work found in blogs, literature (Burke, 2012), and poems (Bear, 2011; Masson, 1999) that candidly portray the crisis continuing to plague the nursing profession. But no one is listening.

I found that the nature of nurses' work was characterized by: 1) *chasing a standard of care*, 2) *prioritizing practice*, and 3) *renegotiating routines*—each inextricably linked to organizational structures. These characteristics show evidence that the locus of control for nurses' work is shifting and being reshaped now by layers upon layers of regulations and calculations of workload driven by considerations other than local processes. This perpetuates vulnerability among nurses. With imposed roles and tasks of care, nurses have little capacity to focus on the actual nursing process. Instead, the identity associated with nurses' work is that of task completion which can lack

perspective and knowledge.

This study provides greater understanding of why nurses remain at the "sharp end" of the responsibility for medication error (Reason, 2000, p. 768) and why there is no one to intercede. Pharmacists on the unit provide a safety net for the physician or provider, not for nurses. There is and should be concern for the future of nursing practice.

According to Reason (2000), hospitals are still failing to meet the criteria of highly reliable organizations. It begs the questions of who is ultimately responsible for medication safety and the errors, and where is the prevention support? Magnet status (an award offered to hospitals that met a set of criteria measuring the quality of their nursing staff) is a start, but is it contributing to meaningful change at the bedside, or is it institutional window dressing? This study provides an opening to begin a new dialogue on the ambiguous dimensions of nurses' work. It also contributes a new perspective on interdisciplinary collaboration.

To reduce mediation errors and address the challenges inherent in nurses' work, we must respond proactively with critical reflection on society's reliance on nurses. These data presented here have the potential to shape new responses to error and contribute to the design of mitigation strategies and the reform of corporate and administrative practices for the clinical setting.

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APPENDIX A

CONSENT AND AUTHORIZATION FORMS

Consent and Authorization Document- NURSING STAFF

for Minimal Risk Research

BACKGROUND

You are being asked to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask me if there is anything that is not clear or if you would like more information. Take time to decide whether you want to volunteer to take part in this study.

The purpose of this research study is to explore of the nurses' work in the context of medication administration, errors and organizational safety. I am doing this study because I am trying to understand nurses' work in the context of responsibilities with medication, as you experience it in your day-to-day work.

STUDY PROCEDURE

This study involves direct observation of your work in the unit and an interview. Periods of observation of approximately three hours per session. You will also be invited to an interview at a time at your convenience. Questions will be asked about your typical day on the unit.

RISKS

The risks of this study are minimal. You may feel upset thinking about or talking about personal information related to medication administration or medication errors. These risks are similar to those you experience when discussing personal information with others. If you feel upset from this experience, you can tell the researcher, and she will tell you about resources available to help.

BENEFITS

There are no direct benefits for taking part in this study. However, I hope the information I get from this study may help develop a greater understanding of nurses' work in the future.

PERSON TO CONTACT

If you have any questions complaints or if you feel you have been harmed by this research please contact one of the following from the University of Utah, College of Nursing:

Sara Hawkins, <u>s.hawkins@utah.edu</u>, 208-709-4178 (available 24-hours a day) Janice Morse, <u>janice.morse@nurs.utah.edu</u>, 801-585-3930 (available Mon- Friday, 8 am – 5 pm)

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at <u>irb@hsc.utah.edu</u>.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at <u>participant.advocate@hsc.utah.edu</u>.

VOLUNTARY PARTICIPATION

Research studies include only people who choose to take part. You can tell me that you don't want to be in this study. You can start the study and then choose to stop the study later. This will not affect your relationship with the investigator.

COSTS AND COMPENSATION TO PARTICIPANTS

There are no costs and/or compensation associated with your participation in this study.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow me, the researcher in this study, and others working with me to use some information about your health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like: age, gender, race and ethnicity, level of education, work experience.

How we will protect and share your information:

 We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

- There are some cases in which a researcher is obligated to report issues, such as serious threats to public health or safety.
- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with me on this research:
 - o Members of the research team and the Hospital
 - The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
 - The Hospital IRB
- I will not share your name or identifying information. I will label your information with a code number, so your identity will not be known.
 If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at the Hospital.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell me anytime that you do not want to be in this study and do not want us to use your health information. You can also tell me in writing. If you change your mind, I will not be able to collect new information about you, and you will be withdrawn from the research study. However, I can continue to use information I have already started to use in my research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

CONSENT:

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to participate in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

Participant's Name

Participant's Signature

Date

Name of Person Obtaining Authorization and Consent

Signature of Person Obtaining Authorization and Consent Date

Consent and Authorization Document - ADMINISTRATION AND OTHER STAFF

for Minimal Risk Research

BACKGROUND

You are being asked to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask me if there is anything that is not clear or if you would like more information. Take time to decide whether you want to volunteer to take part in this study.

The purpose of this research study is to explore of the nurses' work in the context of medication administration, errors and organizational safety. I am doing this study because I am trying to understand nurses' work in the context of responsibilities with medication.

STUDY PROCEDURE

This study involves an interview. You will also be invited to an interview at a time at your convenience. Questions will be asked about your knowledge of medication administration within the organization.

RISKS

The risks of this study are minimal. You may feel upset thinking about or talking about information related to medication administration or medication errors. These risks are similar to those you experience when discussing personal information with others. If you feel upset from this experience, you can tell the researcher, and she will tell you about resources available to help.

BENEFITS

There are no direct benefits for taking part in this study. However, I hope the information I get from this study may help develop a greater understanding of nurses' work, medication administration, and safety.

PERSON TO CONTACT

If you have any questions complaints or if you feel you have been harmed by this research please contact one of the following from the University of Utah, College of Nursing:

Sara Hawkins, <u>s.hawkins@utah.edu</u>, 208-709-4178 (available 24-hours a day) Janice Morse, <u>janice.morse@nurs.utah.edu</u>, 801-585-3930 (available Mon- Friday, 8 am – 5 pm)

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Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at <u>participant.advocate@hsc.utah.edu</u>.

VOLUNTARY PARTICIPATION

Research studies include only people who choose to take part. You can tell me that you don't want to be in this study. You can start the study and then choose to stop the study later. This will not affect your relationship with the investigator.

COSTS AND COMPENSATION TO PARTICIPANTS

There are no costs and/or compensation associated with your participation in this study.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow me, the researcher in this study, and others working with me to use some information about your health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like: age, gender, race and ethnicity, level of education, work experience.

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.
- However, if you disclose information that gives study staff a reason to believe

that a child or disabled or elderly adult has been subjected to abuse or neglect, study staff will report that information to Child Protective Services, Adult Protective Services, or the nearest law enforcement agency to the extent required by law.

- There are some cases in which a researcher is obligated to report issues, such as serious threats to public health or safety.
- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with me on this research:
 - Members of the research team and the Hospital;
 - The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
 - o The Hospital IRB
- I will not share your name or identifying information. I will label your information with a code number, so your identity will not be known.
 If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at the Hospital.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell me anytime that you do not want to be in this study and do not want us to use your health information. You can also tell me in writing. If you change your mind, I will not be able to collect new information about you, and you will be withdrawn from the research study. However, I can continue to use information I have already started to use in my research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

CONSENT:

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to participate in this research study and authorize you to use and disclose

health information about me for this study, as you have explained in this document.

Participant's Name

Participant's Signature

Date

Name of Person Obtaining Authorization and Consent

Signature of Person Obtaining Authorization and Consent Date

Consent and Authorization Document- PATIENT

for Minimal Risk Research

BACKGROUND

You are being asked to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask me if there is anything that is not clear or if you would like more information. Take time to decide whether you want to volunteer to take part in this study.

The purpose of his research study is to explore nurses' work in the context of medication administration, errors and organizational safety. You are a part of this study because I want to understand medication administration from your perspective, as you experience it.

STUDY PROCEDURE

This study involves observation of your care and an informal interview. Periods of observation will be limited to your care as it pertains to your medications. I will also be accessing your patient care record.

RISKS

The risks of this study are minimal. You may feel upset thinking about or talking about personal information related to medication administration or medication errors. These risks are similar to those you experience when discussing personal information with others. If you feel upset from this experience, you can tell the researcher, and she will tell you about resources available to help.

BENEFITS

There are no direct benefits for taking part in this study. However, I hope the information I get from this study may help develop a greater understanding of nurses' work in the future.

PERSON TO CONTACT

If you have any questions complaints or if you feel you have been harmed by this research please contact one of the following from the University of Utah, College of Nursing:

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Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at <u>irb@hsc.utah.edu</u>.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at <u>participant.advocate@hsc.utah.edu</u>.

VOLUNTARY PARTICIPATION

Research studies include only people who choose to take part. You can tell me that you don't want to be in this study. You can start the study and then choose to stop the study later. This will not affect your relationship with the investigator, your caregivers, or the hospital.

COSTS AND COMPENSATION TO PARTICIPANTS

There are no costs and/or compensation associated with your participation in this study.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow me, the researcher in this study, and others working with me to use some information about your health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like: age, gender, race and ethnicity, level of education, work experience.
- Related medical information about you like family medical history, current reason you are in the hospital, allergies, current and past medications or therapies, and information from physical examinations, such as blood pressure reading, heart rate, temperature, and lab results

How we will protect and share your information:

• We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and

electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

- However, if you disclose information that gives study staff a reason to believe that a child or disabled or elderly adult has been subjected to abuse or neglect, study staff will report that information to Child Protective Services, Adult Protective Services, or the nearest law enforcement agency to the extent required by law.
- There are some cases in which a researcher is obligated to report issues, such as serious threats to public health or safety.
- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with me on this research:
 - Members of the research team and the Hospital;
 - The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
 - The Hospital IRB
- I will not share your name or identifying information. I will label your information with a code number, so your identity will not be known.
- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at the Hospital.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell me anytime that you do not want to be in this study and do not want us to use your health information. You can also tell me in writing. If you change your mind, I will not be able to collect new information about you, and you will be withdrawn from the research study. However, I can continue to use information I have already started to use in my research, as needed to maintain the integrity of the research. This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

CONSENT:

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to participate in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

Participant's Name

Participant's Signature

Date

Name of Person Obtaining Authorization and Consent

Signature of Person Obtaining Authorization and Consent Date

APPENDIX B

PARTICIPANT DEMOGRAPHIC FORMS

Participant Demographic Form- Staff

Participant Information

1. Age: _____ (in years)

2. Your gender:

(0) Male (1) Female

3. Your ethnic background (select one):

_____(1) Not Hispanic or Latino _____(2) Hispanic, Latino, or of Spanish Origin

4. Your racial background (select one or more):

_____(1) Asian

_____(2) Black or African American

_____(3) Native Hawaiian or Other Pacific Islander

_____ (4) American Indian or Alaska Native

- ____ (5) White
- _____ (6) Other ______

5. Highest level of education completed:

(1) 8 th gr	ade or l	less
------------------------	----------	------

(2) Some high school (3) High school graduate (4) Technical school graduate

8. Level of licensure:

____ (1) RN _____(2) LPN ____ (3) MD _____(4) Not applicable ____ (5) Other

9. Work status:

_____(1) Full-time _____(2) Part-time _____(3) Per-diem/ Float pool

- 10. Your experience: _____ (in years)
- 11. Length of employment on unit: _____ (in years)

(5) Some college

(6) College graduate

(7) Postgrad/Professional

Participant Demographic Form- Patient

Participant Information

1. Age: _____ (in years)

2. Your gender:

____ (0) Male _____(1) Female

3. Your ethnic background (select one):

(1) Not Hispanic or Latino _____ (2) Hispanic, Latino, or of Spanish Origin

4. Your racial background (select one or more):

_____(1) Asian

_____(2) Black or African American

_____ (3) Native Hawaiian or Other Pacific Islander

- _____ (4) American Indian or Alaska Native
- _____(5) White

_____(6) Other ______

5. Highest level of education completed:

(1) 8th grade or less (2) Some high school

(3) High school graduate (4) Technical school graduate

9. Work status:

- _____(1) Full-time
- _____(2) Part-time
- (3) Retired (4) Other

10. Diagnosis and other pertinent medical history:

11. Medication regimen:

(5) Some college

(6) College graduate

(7) Postgrad/Professional