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Effect of Root Cause Analysis on Pre-Licensure, Senior-Level Nursing Students' Safe Medication Administration Practices

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by

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ABSTRACT

Effect of Root Cause Analysis on Pre-Licensure, Senior-Level

Nursing Students' Safe Medication Administration Practices

by

Kristi Miller

Aim: The aim of this study was to examine if student nurse participation in root cause analysis has the potential to reduce harm to patients from medication errors by increasing student nurse sensitivity to signal and responder bias.

Background: Schools of nursing have traditionally relied on strategies that focus on individual characteristics and responsibility to prevent harm to patients. The modern patient safety movement encourages utilization of systems theory strategies like Root Cause Analysis. The Patient Risk Detection Theory (PRDT; Despins, Scott-Cawiezell, & Rouder, 2010) supports the use of nurse training to reduce harm to patients.

Method. Descriptive and inferential analyses of the demographic and major study variables were conducted. Validity and reliability assessments for the instruments were performed.

The *Safe Administration of Medications-Revised* (SAM-R; Bravo, 2014) was used to measure sensitivity to signal. The *Safety Attitudes Questionnaire* (SAQ; Sexton et al., 2006) was used to assess responder bias; this was the first use of this instrument with nursing students.

Results: The sample consisted of 125 senior-level nursing students from three universities in the southeastern United States. The SAQ was found to be a valid and reliable test of safety attitudes in nursing students. Further support for the validity and reliability of the SAM-R was provided. A significant difference in safety climate between schools was observed. There were no

differences detected between the variables.

Conclusion: The results of this study provide support for the use of the SAQ and the SAM-R to further test the PRDT, and to explore methods to improve nursing student ability to administer medications safely.

DEDICATION

This dissertation is dedicated to my family. My husband, Wes has supported me through this entire process with good cheer, determination, humor and patience. Perhaps I could have done it without him, but it wouldn't have the same meaning. His partnership in this endeavor makes it so much sweeter. I also want to thank my children, Brent, Nicole, Riley and Trenton, who suffered from the lack of attention, but who were brave and (mostly) quiet when I needed them to be. It was a good lesson in independence and conflict resolution. I am so looking forward to spending quality time with all of you!

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will never forget trying to read it, and how inspired I continue to be by his compassionate instruction of his students. To my besties: Amber, Kassi, Angela, Arianne, Megan and Katie, I thank you. I could not have done this without your friendship and support; and I wouldn't have wanted to. Having my gang on the planet makes it all worthwhile. I won't soon forget how you let me work on my re-writes during our annual girls weekend. It was worth it. And thank you to my church – the Unitarian Universalist Congregation of Asheville kept me laughing and full of self-confidence, and brought me some incredible mentors.

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CHAPTER 1

INTRODUCTION

The purpose of the study is to examine if student nurse participation in root cause analysis has the potential to reduce harm to patients from medication errors by increasing student nurse sensitivity and responder bias. This chapter provides an overview of the problem, background information, introduction to the idea, theoretical framework, statement of the problem, purpose of the study, specific aims, hypotheses, conceptual and operational definitions, limitations, delimitations, assumptions and significance of the study.

In 2000, the Institute of Medicine (IOM) published a landmark report on the devastating effects of medical errors (Kohn, Corrigan, & Donaldson). The report, based on a 1984 Harvard Medical Practice Study and a 1992 Utah and Colorado Study, stated an incidence of between 44,000 and 98,000 deaths from medical error each year. Over the past 17 years since this report was published, experts have argued that these numbers are too low. In 2013, Classen, Resar and Griffin (2011) calculated an error rate of 1.13%, which if applied to US hospital admissions in 2013, comes to over 400,000 deaths per year. This is more than four times the Institute Of Medicine (IOM) estimate.

Not all errors cause death, but negative consequences may include temporary or lasting physical harm, increased medical costs, and emotional stress to the patient and family members, as well as to the healthcare workers involved in the error (Wachter, 2012). The IOM recommended multiple interventions to deal with this high rate of patient harm including instituting High Reliability Organizations (HROs), and adopting a culture of safety. Interventions have included Computerized Physician Order Entry, Bar-coding and use of Smart Pumps

(Aspden, Wolcott, Bootman, & Cronenwett, 2007). Despite these interventions, the rate of error has not changed (Landrigan et al., 2010).

Background Information

Medication errors are the most common type of medical error, causing approximately 7000 deaths annually (Aspden et al., 2007; Kohn, 2001; TJC, 2008). Hospital patients experience harm as a result of a medication error approximately 5% of the time (Wachter, 2012). Harm can reach a patient due to errors in any of the three phases of medication administration: ordering, dispensing and administering. Errors made in the first two stages primarily involve physicians and pharmacists. Bates (2007) reports that nurses prevent up to 70% of the errors in the ordering and dispensing phases. Nurses are primarily responsible for the administration phase. More than 40% of a nursing shift is spent administering medications (Elganzouri, Standish, & Androwich, 2009). The nurse is the primary person responsible for checking the medication before administering it to the patient (Leape, Epstein & Hamel, 2002), and for monitoring for effectiveness and adverse effects (Kohn, 2001). Nurses may be responsible for between 26% and 38% of medication errors (Bates, 2007; Leape et al., 2002). In a 2010 survey, 78% of nurses stated they had made a medication error (Jones & Treiber, 2010), making it unlikely any nurse will complete his or her career without making a medication error (Anderson & Webster, 2001).

Medication errors may occur in nearly one of every five doses (Barker, Flynn, Pepper, Bates, & Mikeal, 2002). In a study by Barker et al. (2002), pharmacists used direct observation to identify the prevalence of medication errors in 36 institutions (doses administered differently than ordered). Pharmacists observed nurses in the process of medication administration with nurse knowledge and consent. An expert panel of physicians judged clinical significance. Six

hundred and five (19%) of the doses were in error. Of these 605 errors, 260 of the errors were wrong time (43%), 181 were omission (30%), 103 were wrong dose (17%), 24 were unauthorized drug (4%), and 42 (7%) were potential adverse drug events.

Due to the significant threat to patient safety, prevention of medication errors has become a high priority. The Agency for Health Care Quality and Research (AHRQ, 2015), the Institute of Medicine (2006), and the Joint Commission (2008) are among the most widely recognized organizations that have published strategies to prevent medication errors. In his book, *Understanding Patient Safety* (2012), Robert Wachter, a leading expert in patient safety, lists interventions that have been implemented to reduce medication error: use of the five rights, double checks, preventing interruptions and distractions, unit dosing, removal of medication from certain settings, the use of clinical pharmacists, look-alike/sound-alike medications, medication reconciliation, and conservative prescribing. Many organizations have implemented some or all of the above interventions, however there is still no overall decrease in error (Landrigan et al., 2010).

In the *To Err is Human* Report, the IOM recommended instituting a culture of safety as a strategy for reducing error. A culture of safety is found in High Reliability Organizations (HROs) like aviation and nuclear power, which have utilized the principles of HROs to reduce harm from accidents (Weick, Sutcliffe, & Obstfeld, 1999). HROs are organizations that have fewer than normal accidents. There are five principles of HROs that have been identified by Weick and Sutcliffe (2006) as responsible for the "mindfulness" that prevents error when faced with unexpected situations: preoccupation with failure, reluctance to simplify, sensitivity to operations, commitment to resilience, and deference to expertise.

HROs minimize adverse events by committing to safety at all levels, from leadership to bedside staff. A culture of safety acknowledges the high-risk nature of the organization's activities, promotes a blame-free environment where staff can report errors without fear of punishment, and encourages collaboration and discourages hierarchies. Improving the culture of safety within health care is essential to reducing errors (AHRQ, 2012). Low safety culture scores are linked to increased error rates, and adoption of specific safety culture measures has been associated with lower error rates (Berry, Davis & Bartman, 2016). Nurses have consistently reported a lack of a blame-free environment, as well as problems with organizational commitment to establishing a culture of safety (AHRQ, 2012). Though hospitals routinely survey safety culture, none have been reported to achieve a culture of safety found in HROs (Chassin & Loeb, 2013). Poor teamwork and communication, a culture of low expectations, and high authority gradients all contribute to a failure to achieve a culture of safety (AHRQ, 2012).

A culture of blame still dominates nursing and rigid hierarchies and communication problems are the norm (Barnsteiner & Disch, 2012). Nurses involved in an error tend to blame themselves, and are exposed to criticism from coworkers and punitive action from healthcare agencies. Nurses have consistently attributed failing to follow the five rights and nursing incompetence as major causes for making an error (Jones & Treiber, 2010). Nurses have also reported distractions, interruptions, inadequate staffing, illegible written orders, incorrect dosage calculations, similar drug names, packaging, and failure to follow policies and procedures as reasons for making medication errors (Armitage & Knapman, 2003; Cohen, Robinson, & Mandrack, 2003; Jones & Treiber, 2010; Mayo & Duncan, 2004; Ulanimo, O'Leary-Kelley, & Connolly, 2007). In addition, new nurses were hesitant to state that a medication drawn up by an

experienced nurse was incorrect, demonstrating deference to authority as a cause of medication error (Armitag & Knapman, 2003).

One of the first skills a nursing student is taught is demonstration of medication administration using the five rights (right patient, dose, time, drug, and route). Since their inception in the 1800s, other rights have been recommended, including right assessment, right form, right response, right education, right client education, right documentation, right action, a client's right to refuse, and right evaluation of the client after the medication is administered (Wall, 2001). Despite this, there is no standard across educational or institutional settings for how many rights to use. Nursing education focuses on the responsibility of the individual in preventing medication error, resulting in a culture of blame and shame. This culture prevents reporting of errors, making it difficult to find interventions to improve the safety and quality of care (Hughes, 2008).

Introduction to the Idea

Nursing students make errors as well, though in most instances, they are stopped before the error reaches the patient. In a small study, fewer than 3% of the medication errors made by students resulted in patient harm (Wolf, Hicks & Serembus, 2006). It is difficult to know how many medication errors students make because there is no national database of errors. In the few studies of student errors, reports range between 20-80% of students admitting to making a medication error while in school (Dunn, 2014; Koohestani & Baghcheghi, 2009; Valdez, Guzman, & Escolar-Chua, 2013). Several studies have analyzed student errors retrospectively. These studies reported wrong time and wrong drug are the most frequently reported students errors (Gregory, Guse, Dick & Russell, 2007; Harding & Petrick, 2008; Valdez et al., 2013;

Wolf et al., 2006). In a simulation study by Henneman et al. (2010), students failed to verify the five rights and demonstrated poor ability to identify error. Henneman and colleagues concluded that while the 5-rights are fundamental guidelines, the spectrum of medication safety is not adequately addressed in nursing education. In a survey of student perceptions of why errors are made, Vaismoradi, Jordan, Turunen and Bondas (2014) found that students felt they were deficient in skills and knowledge related to medication management. Reid-Searl, Moxham, Walker, and Happell (2008), found students were fearful of the reporting process. Using root cause analysis (RCA), Dolansky, Druschel, Helba, and Courtney (2013), identified factors involved in a student medication error as environmental, personal, unit communication, culture, and education. A model developed by Valdez et al. (2013), provides a basis for identification of error-prone conditions, revealing factors such as performance and knowledge deficits that may cause poor adherence to the five rights of medication administration.

Nursing students are not taught to identify, report, or analyze errors in nursing school, but are expected to report errors once they enter the workforce (Cooper, 2013). Nursing students report having never been exposed to an error or near-miss event, though they are aware of protocols surrounding errors (Koohestani & Baghcheghi, 2009). Nursing students report a fear of consequences related to error reporting (Antonow, Smith, & Silver, 2000; Koohestani & Baghcheghi, 2009; Sears, Goldsworthy & Goodman, 2009). Studies have found that instructor management and attitude to error plays a big role in whether or not students will continue to report errors (Koohestani & Baghcheghi, 2009; Lin, Wu, Lin, & Lee, 2013). When nursing students hide errors, it hinders the process of error recovery in multiple ways – the data from the error is lost as well as a teaching/learning opportunity (Andrew & Mansour, 2014; Dunn, 2014; Koohestani & Baghcheghi, 2009; Lin et al., 2013)

Nursing education is at a crossroads. Recent nursing school graduates are often seen as

poorly prepared to take on the challenges in the acute care setting. In a study assessing the performance of recent nurse graduates, 10% of nurse executives surveyed believed that new graduates are ready for practice, while virtually all felt more must be done to enhance readiness for practice (Berkow, Virkstis, Stewart, & Conway, 2009). Only 41% felt new graduates were satisfactorily proficient at administering medication. In a recent IOM report (2010), *The Future of Nursing: Leading Change, Advancing Health*, called for new strategies for learning fundamental concepts and charged nursing education to cease reliance on student memorization and content burdened curricula. Nursing students should receive basic information about safety and reporting in their first year of education (Gregory et al., 2007). Error reporting and near-miss reporting should be embedded into a safety culture so students learn and experience transparency from the beginning of their educational experiences (Cooper, 2013). Deliberate focus during instruction on patient safety and the heuristics of clinical reasoning are recommended (DeBourgh, 2011). Student data related to near misses and medication errors need to be collected, aggregated, analyzed, and acted on by educators in partnership with clinical units (Gregory et al., 2007).

Despite these evidence-based directives, there are very few articles in the literature that identify teaching strategies to address the complexity of systems in which students are learning to administer medications (Miller, Haddad, & Phillips, 2016). Most focus on teaching strategies for calculating drug dosages, though the main body of literature does not reflect this as a significant factor (Harding & Petrick, 2008). Nurse educators must identify strategies that address both human and system failures that students can use to reduce medication error (Miller et al., 2016).

Theoretical Framework

The Patient Risk Detection Theory (PRDT), developed by Despins, Scott-Cawiezell, and Rouder (2010) was proposed to identify organizational and individual attributes that affect nurses' capacity to successfully detect patient risk signals. The PRDT supports the design of interventions that facilitate nurses' ability to detect and prevent error. The PRDT combines the concepts of High Reliability Theory (HRT) (Perrow, 1984; Weick & Roberts, 1993) and signal detection theory (Swets, Tanner, & Birdsall, 1961; Wickens, 2002) to describe detection of patient risk by nurses in the context of organizational attitudes and procedures related to safety (Figure 1).

HRT has been useful in examining why inherently high-risk worksites such as nuclear power plants, air traffic control centers, and missile launch facilities have relatively low accident rates (Weick et al., 1999). Weick and Sutcliffe (2006) have suggested that HRT could offer a basis for organizational changes in healthcare settings to improve patient safety. Organizations that utilize HRT are called High Reliability Organizations (HROs). Three elements of HROs have been incorporated into the PRDT: a) preoccupation with failure, b) reluctance to simplify interpretations, and c) sensitivity to operations (Weick & Sutcliffe, 2006). These three elements demonstrate an organization's ability to monitor for problems, while explaining the impact the organization can have on nurses' ability to detect and interpret patient risk signals correctly (Despins et al., 2010).

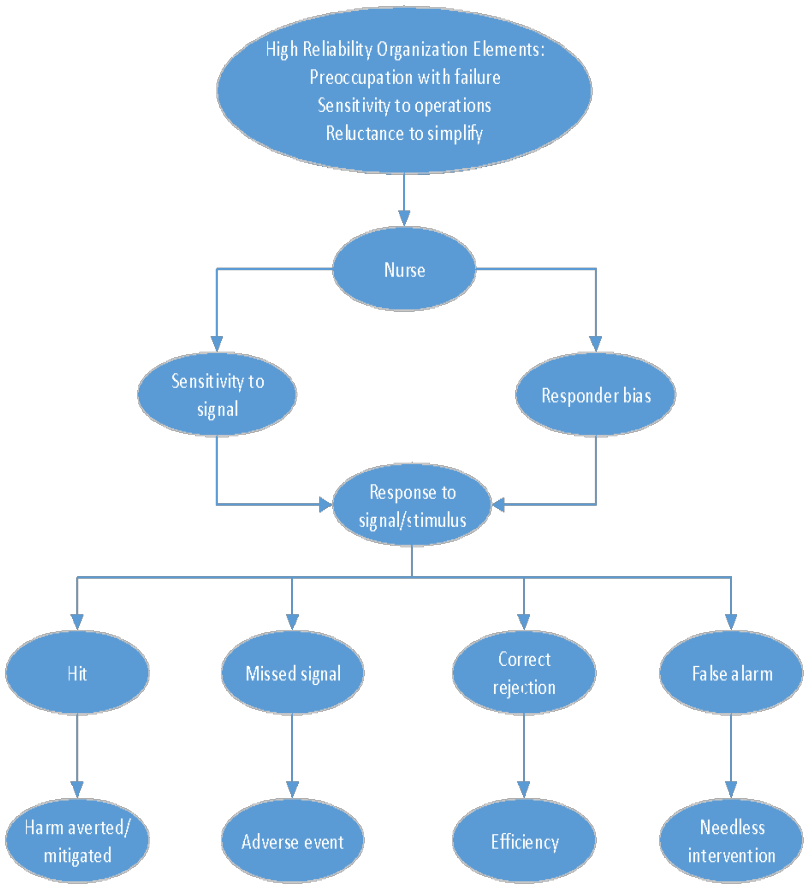

Figure 1. The Patient Risk Detection Theory

(Used with permission – adapted from Despins et al., 2010)

Swets et al. (1961) developed the Signal Detection Theory (SDT) to explain how signals are identified in the presence of extraneous information and background noise. Two key concepts determine a nurse's ability to detect when patients are at risk for harm: sensitivity to signal and responder bias. Sensitivity to signal measures the ability of an individual to distinguish signals from extraneous stimuli (MacMillan & Creelman, 2005). When an individual correctly identifies a signal, this is called a hit. A stimulus that is correctly identified as background noise is called a *correct rejection*. Misidentification of stimuli as background noise is called a miss, while

misinterpretation of background noise as a signal is called a false alarm (Wickens, 2002) (22). Factors that influence nurse sensitivity to signal include the level of training and experience of the nurse (Wickens, 2002), as well as an organizational preoccupation with failure that includes ongoing training of staff on how to scan and correctly identify patient risk signals (Despins et al., 2010).

Table 1

The Four Possible Types of Response in SDT

	Decision: (Participant's Response)	
Reality	Yes	No
Signal Present	Hit	Miss
Signal Absent	False Alarm	Correct Rejection

The second concept of the Signal Detection Theory (SDT) important to the PRDT is responder bias, which describes the willingness of a nurse to acknowledge a stimulus is a signal (MacMillan & Creelman, 2005). Nurses concerned with missing a warning signal will be more willing to identify stimuli as signal. In other words, if safety is a primary concern of the nurse, a higher number of false alarms are acceptable if it means that true risks to patient safety are being detected (Despins et al., 2010). Nurses will be more willing to detect risk signals if they are working in an organization that values safety (Hassin, Aarts, & Ferguson, 2005). When nurses are encouraged to report errors, those errors are analyzed, increasing opportunities to learn from mistakes. Organizational leaders, who listen to and correct problems brought to their attention by nurses, encourage nurses to scan and identify patient risk signals (Morath & Leary, 2004).

Statement of the Problem

The problem to be addressed in this study is a lack of evidence to support nursing education interventions that will reduce patient harm from medication error. In addition, there is little information on how the culture of an organization influences nurses' ability to detect and respond to information indicating a patient is at risk for harm. Despite nurses' historical commitment to patient safety, nurses continue to make medication errors that cause patient harm. In response to the impact of adverse events on patient health and finances, healthcare organizations have begun adopting the characteristics of HROs, yet no intervention to increase nursing ability to detect and prevent error has been tested. HROs routinely utilize Root Cause Analysis to find the systems level causes of medical error. RCA is used by HROs to put actions into place to prevent error from happening again. The American Association of Colleges of Nursing (AACN) has recommended using RCA as a pedagogical intervention to teach quality and safety in schools of nursing. Research into educational interventions like RCA, focusing on nursing students' ability to administer medications safely has the potential to reduce harm to patients.

Purpose of the Study

The purpose of this study is to determine if nursing student participation in RCA has the potential to reduce harm to patients by increasing student nurse sensitivity and responder bias (Figure 2). Evidence may also be provided for the use of the *Safety Attitudes Questionnaire* (Sexton et al., 2006; Appendix A) to measure safety culture with nursing students, and nursing student safety culture scores for clinical experiences. Additionally, insight may be gained into

nursing student perceptions of safe medication administration, including nursing student ability to detect error and interpret why the error occurred.

Specific Aims and Hypotheses

The specific aims, and hypotheses, are as follows:

Specific Aim I: To test the use of the *Safety Attitudes Questionnaire* (SAQ, Sexton et al., 2006; Appendix A) with senior level nursing students.

Hypothesis I: The SAQ will be a valid and reliable test of safety attitudes in senior-level nursing students.

Specific Aim II: To test the effect of root cause analysis on responder bias as measured by the SAQ.

Hypothesis II: Senior-nursing students will have increased safety attitudes following participation in RCA when compared to a non-intervention control group.

Specific Aim III: To test the effect of root cause analysis on sensitivity to signal as measured by the *Safe Administration of Medications-Revised Scale* (SAM-R, Bravo, 2014; Appendix B).

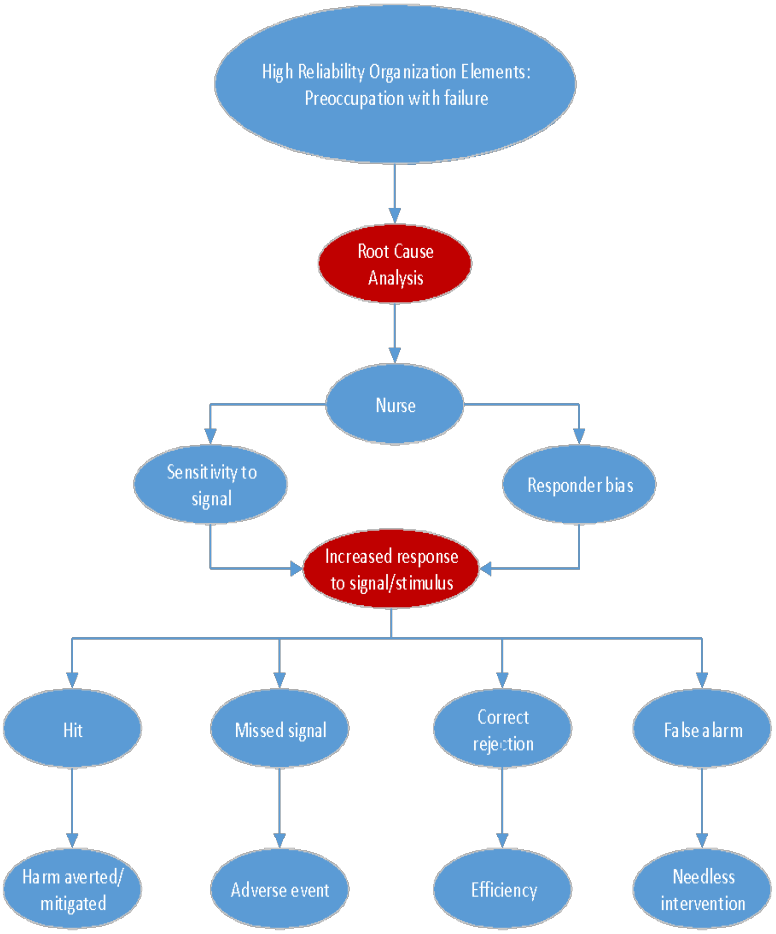

Figure 2. Root Cause Analysis in PRDT (modified with permission from the author to demonstrate how RCA training fits into the PRDT (Despins et al., 2010).

Hypothesis III: Senior-nursing students will demonstrate increased knowledge of safe medication administration practices following participation in RCA when compared to a non-intervention control group.

Conceptual Definitions of Terms

Root Cause Analysis. RCA is a methodology used to analyze an event by identifying systems factors that lead to error and suggest solutions to prevent similar errors from causing

harm in the future (Wachter, 2009). For the purpose of this study a previously published medication error is analyzed to determine the underlying cause(s) for the event and participants are led through the process of RCA to determine solutions.

Senior-Level Nursing Student. A nursing student is enrolled in a post-secondary educational program that leads to certification and licensing to practice nursing. The title 'nursing student' usually applies to students enrolled in an RN or practical nurse program (Dictionary.com, 2017). For the purpose of this study, a senior-level nursing student is a pre-licensure student who has not yet taken the nursing licensure exam, and who does not have the earned title of *Registered Nurse*. Students in the final year of a 4-year Bachelor of Science Nursing program from three different schools were considered.

Responder bias. The tendency to classify a stimulus as a signal based on one's goals; increases in individuals wishing to maximize hits and minimize errors, and decreases in individuals who feel pressured to get other unrelated tasks accomplished. Individuals with low responder bias may be reluctant to categorize a stimulus as a signal to avoid wasting time responding to a false alarm (MacMillan & Creelman, 2005). For the purpose of this study, responder bias is defined as a positive attitude about safety culture, which is directly related to the willingness of the student to detect risk signals (Hassin et al., 2005).

Sensitivity to Signal: Sensitivity to signal is a measure of an individual's ability to successfully distinguish signals from among a large number of different stimuli (Wickens, 2002). Sensitivity depends on level of training, degree of fatigue, and on how distinct the signal is from ambient environmental stimuli (noise) (Macmillan & Creelman, 2005). A signal conveys information about the behavior or attributes of some phenomenon. A signal, sometimes referred

to as stimuli in humans, has the potential to provide information on the status of a physical system or convey a message. Random patterns that distract from the information are called *noise*. Noise consists of background stimuli and the random activity of the nervous system of the operator (Wickens, 2002). For the purpose of this study, sensitivity to signal is defined as knowledge of safe medication administration practices as a result of training and experience, as well as ability to scan and correctly identify patient risk signals (Despins et al., 2010).

Operational Definition of Terms

Root cause analysis: For the purpose of this study, RCA is taught to nursing students using an online educational video of a voice-over of a PowerPoint. The video discusses how and why RCA is used. The steps of the RCA process are presented following guidelines described by the Centers for Medicare and Medicaid Services (CMS), the Veterans Administration (The Department of Veterans Affairs National Center for Patient Safety, 2015) and RCA^2 published by AHRQ (2014). RCA involves developing a problem statement, creating a timeline, developing a causal tree and then constructing an action plan. In the module, a previously published medication error, (Bates, 2002) is used as a case study for the RCA. The article describes an overview of an RCA done for a patient death when insulin (vs. the ordered heparin) was used to flush a blocked central line (Bates, 2002).

Senior level nursing student: For the purpose of this study, senior-level nursing students were over the age of 18, spoke and read English, and were enrolled as a senior in one of three Baccalaureate Nursing Programs in the Southeastern United States.

Responder bias was measured by the 36-item *Safety Attitudes Questionnaire* (SAQ, Sexton et al., 2006). This instrument measures safety attitudes.

Sensitivity to signal was measured using the 70-item *Safe Administration of Medications –Revised Scale* (SAM-R, Bravo, 2014). This instrument measures the level of knowledge of safe medication administration practices

Limitations

This study is limited in that only one intervention is being studied. It may be that participation in RCA does not influence patient harm. In addition, RCA may influence a variable other than harm that is not being measured. It is possible that RCA will be effective in increasing nursing student knowledge of safe medication practices, but that no effect will be seen on the rate of patient harm. Another limitation is time. The effects of the intervention may only last until the post study test. Though the hospital at which nursing students are engaged in clinical activities may qualify as an HRO, other factors may be responsible for their ability to respond appropriately to stimuli, such as fatigue or staffing. Another external threat to validity includes the interaction effect of testing; meaning some interaction between the pre-test and the intervention may cause a result that will not generalize to an untested population. In addition, participants may increase efforts and influence results because they are aware they are in an experiment.

Delimitations

Study participants will be senior level nursing students in three schools of nursing in the southeastern United States and results of this research may not be generalizable to other populations. Threats to internal validity include history, testing, selection, maturation, and attrition. During the study, an unanticipated event may occur that causes a change in the results. In addition, it can be argued that pre-testing can have an effect on the results. Using a two-group

study design minimizes both threats. Using a randomized intervention and control group will ensure that both groups experience the same history, and also negate selection as a threat. Maturation is minimized in the two-group study design, since both groups will mature at the same rate. Attrition is a threat to this study. Nursing students who begin the study may not elect to stay in the study, and thus the control and experimental groups for the post-test may not be sufficiently equivalent to draw significant conclusions. Randomly removing study participants to ensure equality between groups, or including more participants can minimize this threat.

Assumptions

Assumptions inherent to this study include that nursing students work hard and would do anything to prevent error. Nursing students do not mean to make errors and will participate in activities designed to reduce error and harm to patients. An unusually high percentage of risk-taking participants may skew the results. Many errors are not preventable, but nursing students will take advantage of strategies designed to reduce the likelihood that they will make an error. Identification of problems that endanger patients occurs primarily at the level of the individual nurse. The nurse spends the greatest amount of time with a patient, so it is assumed that any risk, or hazard should be discovered first by the nursing student (Despins et al., 2010). An increase in knowledge of safe medication administration practices is predictive of an increase in nursing student ability to detect and prevent medication error.

Significance of the Study

Harm to patients from medication errors has not been reduced in the past 15 years, despite significant efforts to the contrary (Landrigan et al., 2010). The profession of nursing has the potential to play a major role in the reduction of error; however the role of nursing students in

medication error reduction remains elusive. Nurses and nursing students make medication errors due to deficits in knowledge, calculations skills and performance, yet research efforts directed at these problem areas have affected no change (Lee & Lin, 2013; Pauly-O'Neill, 2009). The Patient Risk Detection Theory (PRDT) proposes that nurse training involving reporting and analyzing error will reduce harm to patients by improving nursing student sensitivity to signals indicating patient risk. In addition, nursing students will be more willing to respond to signals (responder bias). To reduce harm to patients, RCA training has been increasingly utilized by health care institutions, however there have been no studies to examine the impact of RCA on error prevention.

Summary

This study provides much needed evidence for the use of RCA as an educational intervention to reduce harm to patients. Evidence has been provided that the current interventions used in the healthcare industry have had little impact on reducing harm from medication errors. RCA is a potential strategy to reduce medication error. RCA is already being used in healthcare settings worldwide; this study presents support for incorporating this valuable and powerful analysis tool into nursing education to better prepare students for the workforce. This study has the potential to reduce the harm caused not only to patients, but also to nurses, students and healthcare organizations as a result of the thousands of unintentional, preventable medical errors that occur each year.

CHAPTER 2

REVIEW OF THE LITERATURE

This chapter is divided into sections, which include methods used to search the professional, literature and the review of the relevant literature divided into themes: healthcare errors; healthcare medication errors; nursing and medication errors; nursing students and medication errors; and the Patient Risk Detection Theory (PRDT). Definitions of concepts and gaps in literature will be identified.

Method of Literature Search and Databases Used

The literature review was conducted using CINAHL, PubMed, and Google Scholar. Key search terms included administration, Despins, education, error(s), identification, intervention, medication, Patient Risk Detection Theory, prevention, reporting, Root Cause Analysis, safety, strategy, and student. All key terms were cross-referenced with *nurse/nurses/nursing.* Articles were reviewed for relevance to this study. In addition, the references of the relevant articles were reviewed. Articles selected for this literature review were written in English and published in peer-reviewed journals. The focus of this review was on articles published subsequent to the Institute of Medicine (IOM) report *To Err is Human* (Kohn et al., 2000); however, older publications that have made significant contributions to knowledge of medication error were included. Publication dates ranged from 2000-2018.

Healthcare Errors

Kohn et al. (2000) estimated that between 44,000 and 98,000 people die each year due to preventable medical errors. Since then, multiple studies have reported these numbers are much too low and range from 134, 581 (Landrigan, et al., 2010) to 400,000 (Classen et al., 2011).

Makary and Daniel (2016) compared this upper number to CDC rankings for cause of death and suggested that medical error is the third most common cause of death in the US. None of these studies are reporting on care in the home, nursing homes, or outpatient sites such as ambulatory or surgical centers. Some estimate that more than one error a day occurs for each hospitalized patient (Aspden et al., 2007; Bates, 2007). One of every three patients may be harmed during their hospital stay, and one in five Medicare patients are re-hospitalized within 30 days of admission (IOM, 2012).

In the book *Human Error* (1990), James Reason presents the "Swiss Cheese" model of accident causation as a model for risk analysis and management. Reason defines error as the failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning). Errors are both the inevitable consequence of human performance and symptoms of broader systems problems, rather than causes in themselves (Reason, 1990). Lucian Leape, a national leader involved in patient safety and an author of the original IOM report *To Err is Human*, further defines errors as unintended acts, including those of *omission*, whereby a necessary action is not taken; and *commission*, whereby an incorrect action is taken (Leape et al., 2002).

There are many reports in the literature on the impact of medical error. Financial costs have been reported to be as much as $3.5 billion in additional medical costs (Aspden et al., 2007). Patients who suffer harm from error may remain hospitalized for 8 to 12 days longer than patients who do not experience harm. These added days mean their hospital stays cost $16,000 to $24,000 more (Agency for Healthcare Research and Quality [AHRQ], 2001).

The impact of error on healthcare providers is also an important factor. Schelbred and Nord (2007) studied ten nurses who had committed errors that resulted in, or had the potential to result in, significant harm to the patient. They found that making an error was devastating to both the personal and professional life of nurses, who were exposed to criticism and reproach from their supervisors. Some nurses were unable to continue their profession or find another job because they felt embarrassed and ashamed. Those nurses who continued to practice had a fear of making new mistakes, a decreased confidence in their own abilities, and felt incompetent because of supervision by their colleagues (Schelbred & Nord, 2007).

In high-risk industries such as aviation and nuclear power, using a systems analysis approach is well established; however in healthcare, responsibility for error has been attributed to the individual (Wachter, 2012). The culture of healthcare that led to the IOM report in 2000 is one of perfectibility. In *The Perfectibility Model*, Berwick and Leape (2006) propose that if a professional is sufficiently trained and is properly motivated, they will not make a mistake. Multiple studies report on the culture of blame that has permeated healthcare in the past (Cohen & Shastay, 2008; Cox et al., 2009; Morgan, 2011). In recent years, the focus of healthcare safety research has changed from one of blame and shame to a systems analysis model (Wachter, 2012).

Reason's Swiss Cheese Model uses the terms *active errors* and *latent errors* to distinguish individual from system errors. The terms *sharp end* and *blunt end* correspond to active error and latent error. Personnel at the sharp end may literally be holding a scalpel when the error is committed. The blunt end refers to the multiple contributing factors that can line up simultaneously to enable error to happen. Reason stated, "we cannot change the human

condition, we can change the conditions under which humans work" (Reason, 1990, p. 769). Hughes (2008) argues that human factors, such as a lack of experience or skill, predispose nurses to errors and near misses. Risks are magnified if the individual is fatigued, stressed, or distracted (Reason, 1990).

The patient safety literature includes many studies suggesting interventions to decrease or prevent medical error. Staff perceptions of a positive patient safety climate were found to be predictive of lower risk to patients (Singer, Shoutzu, Falwell, Gaba, & Baker, 2009). Patient harm has also been related to staffing levels. Increased nursing staff has been correlated with lower mortality and a reduction in adverse events (Elnour, Ellahham, & Al Qassas, 2008; Kane, Shamliyan, Mueller, Duval, & Wilt, 2007). Strategies to reduce errors have included institution of the principles of high reliability organizations (Despins et al., 2010), including adopting a safety culture (Berry et al., 2016), and the use of safety checklists (Gawande, 2009). Despite these interventions and some success at the organizational level, there have been no widespread decreases in patient harm from medical error (Landrigan et al., 2010).

Healthcare Medication Errors

The most common error that occurs in the hospital setting is medication error (The Joint Commission [TJC], 2008). The literature contains many overlapping terms to describe error, however for the purpose of this study a medication error is defined as a preventable adverse event (PAE). A PAE is an error which causes harm to the patient, and which occurs as a direct outcome of medication administration. The National Coordinating Council for Medication Error and Reporting (NCCMERP) (2009a) defines a medication error as,

> Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including the prescribing; order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring and use (para. 1).

There is much disagreement in the literature about type and frequency of error due to terminology and issues with measurement. Barker and colleagues (2002) have identified six "preventable" medication errors (Table 2). In a study by Hughes (2008), the most common types of medication errors that result in patient death are wrong dose (40.9%), wrong drug (16%), and

Table 2

The Six Preventable Medication Errors

Error Type	**Description**
Omission	failing to administer a prescribed dose
Unauthorized drug	administering a dose of medication that was not prescribed
Wrong dose	a dose containing the incorrect strength
Wrong route	administering medications in a different route than ordered (e.g. oral instead of intravenous)
Wrong dosage form	administering a dose in a different form than prescribed (e.g. tablets instead of liquid)
Wrong time	administering a dose of medication more than 60 minutes before or after the prescribed time

wrong administration route (9.5%). An article by Kiekkas, Karga, Lemonidou, Aretha, and Karanikolas (2011) describes the review of six studies on medication errors made by ICU nurses through direct observation. The study revealed wrong dose, wrong administration time, and rate and dose omission were most common. In a summary of six direct observation studies of

medication administration by intensive care nurses, dose omission, wrong administration time, wrong dose, and wrong administration rate, were observed as the most common types of medication errors (Kiekkas et al., 2011).

There is little consensus in the nursing research over the medication error rate. A review by Ghaleb et al. (2006) reports incidence rates obtained by self-report of 14.7 per 100 admission and 13.4 per 1000 patient days. Eight observation studies found that error rates varied between 0.6% and 27% of administrations (Ghaleb et al., 2006). These studies included observations that were disguised and undisguised, which may explain the differences in rates. In a study by Antonow et al. (2000), 40.3% of nurses surveyed stated they had observed a medication error in the previous week. Due to differences in reporting and detection of error, this is not possible to arrive at an exact medication error rate.

Medication Process

The complexity of medication administration creates an environment where many health care providers are at risk for making errors (McIntyre & Courey, 2007). Medication administration has been defined from the Nursing Interventions Classification (NIC) as preparing, giving and evaluating effectiveness of prescription and nonprescription medications (Bulecheck, Butcher, Dochterman, & Wagner, 2012). Antonow et al. (2000) describe a medication *process*, which includes ordering, prescribing, transcribing, verifying, dispensing, delivering, and administering. Medication errors made in the first phases of the process typically involve physicians and pharmacists. These errors are more commonly detected and intercepted in the early stages of medication processing due to system checks that are in place, including physician and pharmacy oversight, and use of computer programs that check for potential

medication interactions (Stratton, Blegen, Pepper, & Vaughn, 2004). It has been reported that pharmacists and nurses correct 70% of all errors before the administration phase (Bates et al., 1995).

There have been multiple interventions aimed at lowering harm from medication error including programmable infusion pumps with flow protection (Trbovich, Pinkney, Cafazzo, & Easty, 2009), the inclusion of clinical pharmacists in patient rounds (Kaboli, Hoth, McClimon, & Schnipper, 2006; Rothschild et al., 2010), standardized script writing, eliminating abbreviations, and limiting verbal orders. The results of these studies are inconclusive due to small sample sizes and differences in definition of error, error rate, and how the rate is reported. Aspden et al (2007) found that Computerized Physician Order Entry with clinical decision support, reduced medication error by 13-86%. However Ash, Berg, and Coiera (2004) and Han et al. (2005) report computer systems have the potential to worsen outcomes, with unintended consequences if CPOE implementation is not carefully planned.

Nursing and Medication Errors

Nurses have the responsibility of checking the medication before administering it to the patient, with fewer safety systems or checks by another professional (Leape et al., 2002), making nursing the profession most likely to be involved in a medication error (Kohn, 2001). In a survey study, 78% of nurses indicated they had made a medication error (Jones & Treiber, 2010). Reports have suggested that nurses are responsible for 26% to 38% of medication errors (Bates, 2007; Leape et al., 2002). The likelihood of a nurse completing a professional career without making a medication error is very low (Anderson & Webster, 2001). Despite these statistics, few

studies have documented either the type or frequency of errors that involve nurses or the types of errors recovered by nurses (Henneman et al., 2010; Reid-Searl et al., 2008).

According to Rothschild et al. (2005), nurses were responsible for 42% of interceptions of potential error. Nurses are thus "uniquely positioned to identify and correct medical errors" (Henneman & Gawlinski, 2004; p. 196), however nurses have difficulty identifying and defining what constitutes a medication error. Baker identified that nurses categorize medication errors in six different ways which include: (a) if it is not my fault then it is not an error; (b) if everybody knows then it is not an error; (c) if you can put it right then it is not an error; (d) if a patient has needs that are more urgent than the accurate administration of medication, then it is not an error; (e) if it is a clerical error, then it is not an error; and (f) if an irregularity is carried out to prevent something worse then is it not an error. Baker found that only if the error could *not* be assigned to one of these categories would it be categorized as an error (Baker, 1997, p. 156–157).

In the Baker study (1997), the top five reasons for medication errors identified by nurses included distractions, interruptions, inadequate staffing, illegible written orders, incorrect dosage calculations, and similar drug names and packaging. Other contributing factors are workplace stress, inadequate training, and fragmented information (Pape, Guerra, & Muzquiz, 2005; Schulmeister, Wright, & Wright, 2010). The findings demonstrate incongruences in the ways nurses perceive errors – nurses appear to believe that they should be capable of administering medications without errors, regardless of the external circumstances. Cohen et al. (2003) polled 779 nurses, 79% agreed that medication errors occur when a nurse carelessly neglects to follow the five rights. Thirty-six percent thought reporting an error might be professionally damaging. The same poll was conducted five years later and those numbers have increased, with 89%

agreeing in that errors are made due to incompetence, and 37% believing error reporting could be damaging to a nursing career (Cohen & Shastay, 2008). This study highlights that negative opinions and individual blame continue to be associated with error making.

Ulanimo et al. (2007) reported that 61 nurses identified failing to check the name band with the medication administration record and nurses being distracted as the two most frequent causes of error. In a survey of 983 nurses, the five most common reasons for medication errors were: difficulty reading physician handwriting, distractions, nurse fatigue, drugs with similar names, and dosage miscalculations (Mayo & Duncan, 2004). Contributing factors included illegible or unclear handwriting by physician (86%), not following 5 rights (77%), high patient nurse ration (71%), and unclear verbal orders (68%) (Jones & Treiber, 2010). Armitage and Knapman (2003) reported errors were attributed to nurses not following policies and procedures and a deference to authority – new nurses are hesitant to state that a medication drawn up by an experienced nurse is incorrect.

Calculation difficulties have been reported as causing errors, particularly when dealing with intravenous medication preparations (Hand & Barber, 2000). Very little is actually known about the types of calculation errors nurses make during medication administration – this metric has not been well measured. It is assumed that calculation skills are important for accurate medication administration. In a recent series of reports on an online instructional modality aimed at improving medication calculation skills, mistakes in calculation account for 30-40% of reported medication errors, however the sole reference for this assertion is a small study on chemotherapy medication errors (Schulmeister et al., 2010). The exact number of errors attributable to dosage calculation varies according to reporting method. Wright (2010) found

insufficient evidence to suggest that medication errors are caused by nurses' poor calculation skills. Of the 33 studies reviewed, only five articles specifically recorded information relating to calculation errors and only two of these detected errors using the direct observational approach (Wright, 2010). Research indicates nurses make 10-20% errors on written drug tests. If this number translated to errors in practice, one would assume similar percentages would appear in error reporting, but this is not the case.

In a review of medication administration calculation research, Sulosaari, Kajander, Hupli, Huupponen, and Leino-Kilpi, (2012) reported that most studies that address calculation strategies focus on the administration of surveys and calculation exams given to students and practicing nurses. Interventions that improve skills on these exams are reported, however according to the authors, the effect of a mathematical pedagogy or math skills on medication error rates has not been examined. In the review, Sulosaari and colleagues (2012) suggest that the focus in medication competence research has been on nurse student's medication calculation skills. Research is lacking in medication administration and patient education skill competency (Sulosaari et al., 2012). In a review by Kiekkas and colleagues (2011), the authors suggest that there are other more pressing aspects of nurses' preparation and administration of medications which are contributing to medication errors in practice that require more urgent attention and calls into question the current focus on calculation and numeracy skills of pre-licensure and qualified nurses.

Nursing Students and Medication Errors

Nursing education has no standard way of teaching safe medication administration practice. In keeping with worldwide initiatives for integrating quality and safety science into

nursing education and practice (Sherwood, 2011), the Quality and Safety Education for Nurses (QSEN) competencies were created in an attempt to define what it means to be a respected and qualified nurse (Cronenwett et al., 2007). QSEN standards set the expectation that students will participate in Root Cause Analysis and use organizational error reporting systems for near-miss and error reporting (Cronenwett et al., 2007).

The AACN has recommended that schools of nursing incorporate QSEN (AACN, 2015), however there is disagreement over the level of incorporation. In a survey of nurse leaders from AACN schools (n=572), Smith et al. (2007) found a high rate of QSEN adoption. This is in contrast to the results of a study of faculty and student focus groups (Cronenwett et al., 2007). Cronenwett et al. (2007) reported that though faculty agreed they should be teaching QSEN competencies, and thought they were teaching QSEN competencies, they did not demonstrate fundamental understanding of the QSEN concepts or identify educational strategies for teaching QSEN. In addition, nursing student focus groups reported they did not have QSEN learning experiences and that faculty did not have expertise in the content. Sullivan et al. (2009) reported similar results for student perceptions in a quantitative survey study. Nursing students (n=575) from 17 schools of nursing were surveyed. The knowledge topics least frequently reported to be in the curriculum were processes used in analyzing causes of errors, such as Root Cause Analysis. Students ranked safety as one of the most important competencies, second only to patient-centered care (Sullivan et al., 2009). Fifteen percent reported that these processes were not covered in any learning venue.

Traditional nursing instruction on medication administration can be traced back to the 1800s. A method for medication administration was first documented in English in *The Nursing*

Sister: A Manual for Candidates and Novices of Hospital Communities, by the Rev. L. Hinssen, a priest, who published it in 1893 and again in 1899 for nursing sisters at St. John's Hospital Training School in Springfield, Illinois (Wall, 2001). Stemming from that tradition, nursing education and practice has become accustomed to the five rights of medication administration. Nurses use the five rights of medication administration to prevent error, which include the right patient, medication, dosage, route, and time (Eisenhauer, Hurley, & Dolan, 2007). A varying number of rights have been proposed to ensure safe medication administration, with no final agreement on standardization. Documentation is listed as a sixth right in a standard nursing school textbook, *Fundamentals of Nursing* (Potter, Perry, Stockert, & Hall, 2013). Elliott and Liu (2010) report an additional three rights: action, form, and response. Other rights have also been suggested, including client education, right to refuse, assessment, and evaluation of the client after the medication is administered (Potter et al., 2013). Despite these recommendations, no standard number of rights has been adopted by schools of nursing.

The eighth edition of Perry and Potter's *Fundamentals of Nursing* (2013) lists steps to prevent medication errors (Potter et al., 2013). These steps are based on recommendations from the NCCMERP (2009b) for reducing at-risk behaviors, and include following the six rights of medication administration, preventing distractions and interruptions, self-care, use of technology, involving the patient and family, continuing education and participation in error recovery (Institute for Safe Medication Practices, 2009).

Faculty is present to help students identify and prevent errors. Due to these supervision and simulation lab experiences, few students make medication errors resulting in patient harm (Harding and Petrick, 2008; Wolf et al., 2006). Characteristics of medication errors made by

nursing students during medication administration were reported to a national database using the NCCMERP taxonomy (2009b). Wolf et al. (2006) examined these characteristics; finding fewer than 3% (n=1305) of student errors resulted in an adverse event. Approximately one third of the errors (26.16%) for the entire data set (nurses and students) involved omission and administration of the wrong dose of medication. *Wrong time* for students occurred three times more than *wrong time* for nurses. *Wrong patient* errors were twice what have been reported in other studies. Chief contributing factors were inexperience and distractions. Insulin was the drug involved in the most errors (17%). Similar results were found by Harding and Petrick (2008), who conducted a 3-year retrospective review of medication errors (n=77) made and reported by nursing students in a 4-year BSN program with similar results: *errors of omission* comprised 34% of errors reported. *Wrong drug* was the most common error of commission, followed by *wrong route* and *wrong patient*. A questionnaire study by Valdez et al. (2013) provides further evidence for the types of errors students make. Most medication errors committed by student nurses included *omission* (42%) and *wrong time* (40.32%) (Valdez et al., 2013). In a retrospective analysis, Gregory et al. (2007) analyzed nursing student clinical contracts (n=34) to explore unsafe patient care events (n=154). Improper medication administration was the most frequently occurring unsafe act (56.49%). The majority of the medication administration events were in the *wrong time* category (33.33%) followed by *wrong dose* (24%), *knowledge deficit* (18.4%), *wrong medication* (11.5%), *wrong patient* (6.9%) and *wrong route* (5.75%). All of these studies are in agreement that despite supervision, students make medication errors, though they rarely result in patient harm.

Recent nursing school graduates are often seen as poorly prepared to take on the

challenges in the acute care setting (Berkow et al., 2009). In a study of attitudes about recent nurse graduates, 10% of nurse executives surveyed believed that new graduates are ready for practice, while virtually all felt more must be done to enhance readiness for practice. Only 41% felt new graduates were satisfactorily proficient at administering medication (Berkow et al., 2009).

A literature review of educational strategies for preventing medication error by Miller et al. (2016) found that all of the studies reviewed included recommendations for instructional strategies to reduce or prevent student medication error, including use of Root Cause Analysis, communication strategies, situation monitoring, use of unfolding case studies, simulation and clinical experiences with error reporting, and just cultures (Cox et al., 2009; Cronenwett et al., 2007; Currie et al., 2007; Smith et al., 2007; Sullivan et al., 2009). In a case study using RCA to explore a nursing student medication error (Dolansky et al., 2013), the authors assert that use of RCA promotes a fair and just culture and helps nursing students and faculty identify problems and solutions in the systems in which they work. Despite evidence based recommendations, there are very few articles in the literature in nursing education that identify teaching strategies to address the complexity of systems in which students are learning to administer medications. Nurse educators are not utilizing strategies that address both human and system failures to reduce medication error made by nursing students (Valdez et al., 2013). In response to the lack of literature addressing methods for identifying and intercepting errors, Despins and colleagues (2010) developed the Patient Risk Detection Theory (PRDT).

The Patient Risk Detection Theory

The PRDT is a theoretical framework for how nurses can detect and respond to risk signals predicting patient harm (Figure 1). The PRDT supports understanding of organizational factors, such as those found in HROs, that facilitate nurse prevention of error. This model synthesizes components from signal detection theory (Swets et al., 1961; Wickens, 2002) and High Reliability Theory (HRT; Perrow, 1984; Weick & Roberts, 1993), and can guide research on interventions to increase patient safety in complex care environments. The PRDT (2010) predicts that better detection of patient risk signals is the mechanism by which nursing care can improve patient outcomes. Organizational culture is an important factor in better signal detection. Shekelle et al. (2013), found that staff who work for High Reliability Organizations (HROs) place a high value on safety. Internal factors such as nurse fatigue also play a role in this model. Organizations that have adopted the principles of a just culture are able to manage unanticipated events successfully by being proactive in identifying failure and prevention by using RCA (Despins et al., 2010). Although the PRDT suggests that being aware of and responding to risk signals is associated with greater patient safety, there is little evidence to support this assertion.

In a review of the literature, four studies used the PRDT as a conceptual framework for the study (Despins, 2014; Gannuscio, 2012; Gonzales, 2010; Gonzales, 2015). Only those studies using the PRDT as a conceptual framework will be further described, including a follow-up study by Despins (2014). Despins utilized the PRDT to examine organizational and individual attributes that influence patient risk detection. This experimental study found no difference in risk detection ability between groups who either received or did not receive an instructional

video on safety issues. Despins (2014) did report that nurses who reported a positive work environment were better at correct rejections. In other words, they were better able to correctly determine that a stimulus did not indicate patient risk than nurses who had a less positive work environment. This supports the responder bias component of the PRDT; nurses, who work in an environment that values safety, will be less likely to respond to extraneous information that is not useful in improving patient outcomes.

Gonzales (2010) used the PRDT as a conceptual framework for research on the importance of internal factors in nurse ability to respond to patient risk signals. Gonzales used the *Domain-Specific Risk-Taking and Risk Perception Scale* (DOSPERT; Blais & Weber, 2006), an instrument that measures risk propensity in healthcare decisions in a clinical environment. Nursing students who are risk takers are not as skilled at identification of medication errors and are thus less safe. This is supported by the PRDT, which identifies internal factors as influencing risk detection.

Gannuscio's DNP capstone project (2012) also used the PRDT as a theoretical model for the study. A retrospective analysis of electronic health records of veterans with heart failure yielded data to improve a heart failure readmission tool. The author predicted that development of a good heart failure readmission tool would increase the ability of nurses to detect signal from noise. No link has been found between risk prediction tools and a decrease in length of stay, readmission rates, or mortality.

This review of the literature shows underutilization of the PRDT to explore the role of the environment, internal factors, and nursing knowledge in a nurse's ability to detect signal from noise. Detection of patient risk signals may increase patient safety, but evidence is lacking.

Despite evidence-based directives, there are few articles in the literature in nursing education that identify interventions to address the complexity of systems in which nurses administer medications. No study has been done to determine the effect of a nursing educational intervention on nursing knowledge of safe medication administration. The QSEN competencies have identified Root Cause Analysis as an educational intervention to support student learning of patient safety concepts (Cronenwett et al., 2007).

Root Cause Analysis

In 1996 the Joint Commission mandated that all hospitals use RCA as part of their analysis of sentinel events reported to the Joint Commission (2009). The Department of Veterans Affairs (VA) National Center for Patient Safety (NCPS) implemented use of RCA in 2000 (Percarpio, Watts, & Weeks, 2008). RCA is a retrospective method borrowed from HROs used to identify systems factors that may have led to the error and suggest solutions that can prevent similar errors from causing harm in the future. The event is analyzed to determine the underlying cause(s) for the event and recommendations are made for preventative measure in the future. Two important characteristics of RCA should emerge with its use; underlying causes are fixable and the problem is uncovered within a reasonable amount of time using a reasonable amount of resources. According to Lighter and Fair (2004, p. 89), "successful RCA culminates in the identification of underlying causes of problems in the process." There are several important elements for an effective RCA: a) strong leadership and facilitation; b) interdisciplinary approach; c) those who participated in the case should tell their stories; d) invite frontline workers to help educate them in the process and demystify the ritual, and focus on the process more than the report (Wachter, 2012).

Despite widespread use, RCA had not been validated as a tool to improve patient safety, perhaps due to long-effective use in other high-risk industries. In a literature review of RCA, Percarpio and colleagues (2008) reported a weak relationship between the use of the RCA framework and improved patient safety, Since the review published by Percarpio et al. in 2008, there have been additional studies that support the use of RCA to reduce harm to patients, however RCA has still not been tested in a randomized controlled trial (Percarpio et al., 2008). The importance and visibility of RCAs in health care organizations make it an ideal intervention to test for efficacy in reducing harm to patients.

Multiple studies were found *proposing* the use of RCA as an educational intervention; however only one measured an outcome. Carter, Sidebotham, Creedy, Fenwick, and Gamble (2013) examined the effectiveness of RCA on the critical thinking skills of nursing midwifery students. A descriptive, mixed methods design was used to present the results of a survey on student perceptions of the effects of RCA on educational acceptability, impact, and preparation for practice. Students reported development of critical thinking skills.

For the purpose of this study, the RCA intervention is an online video. Online education modules have been shown to be as effective as traditional classroom education in a number of studies. In a meta-analysis of 45 studies, students in online courses performed better than those receiving traditional, face-to-face instruction (Means, Toyama, Murphy & Baki, 2013). Similar findings were reported in a meta-analysis of 14 articles. There was no significant difference between learning outcomes for e-learning vs. traditional education (Nguyen, 2015). Two studies from the field of nursing were found that utilized self-study modules as educational strategies to impact medication administration skills and knowledge. In a qualitative study, Hemingway et al.

(2012) explored the views of final year mental health nursing students regarding the usefulness of the *Medicines with Respect* (MwR) Assessment of the Administration of Medicines Competency Framework. Senior level students (n=41) reported a positive organizational gain, the acquisition of knowledge, and problem-solving and technical skills needed to administer medications (Hemingway, 2012). Lee and Lin (2013) evaluated the effectiveness of an e-learning program on pediatric medication safety for undergraduate students using a quasi-experimental historical comparison design. The e-learning program included Power Points with voice-over, video lectures, and online discussion; tracking of student's hits on each topic; and direct links to online content. Outcomes were assessed with a pediatric medication management assessment (a 50 item scale developed for the study; KR-20 = 0.79). In this quasi-experimental study, the intervention group (n=269) had significantly ($p<.05$) higher pediatric medication management scores at completion of the e-learning program than the comparison (n=80) group. (Lee & Lin, 2013).

Responder Bias

Responder bias is a concept in the PRDT referring to the tendency to classify a stimulus as a signal based on one's goals. Responder bias increases in individuals wishing to maximize hits and minimize errors, and decreases in individuals who feel pressured to get other unrelated tasks accomplished. Individuals with low responder bias may be reluctant to categorize a stimulus as a signal to avoid wasting time responding to a false alarm (MacMillan & Creelman, 2005). Responder bias is defined in this study as a positive attitude about safety culture, which is directly related to willingness to detect risk signals (Hassin et al., 2005). In the PRDT, nurses who work in an environment that values safety have a high responder bias, and will be less likely

to respond to extraneous information that is not useful in improving patient outcomes. This is in keeping with the finding that staff perceptions of a positive patient safety climate were predictive of lower risk to patients (Singer et al., 2009).

Little is known about safety culture in nursing education. No studies were found that measured safety culture in pre-licensure nursing education using a valid and reliable instrument. As previously stated, both students and nurses have reported fear of punishment as a reason for not reporting error. The Joint Commission has required healthcare facilities to measure safety culture since 2009 (Chassin & Loeb, 2013). Two instruments are recommended by the AHRQ (2012) to measure safety culture, the *Patient Safety Culture Survey* and the *Safety Attitudes Questionnaire* (SAQ).

The SAQ is one of the most commonly used tools to measure safety culture. It has been more widely used than the AHRQ tool and for a longer period of time giving greater benchmarking data. In addition, there is a large amount of psychometric data for the SAQ, and it maintains a high level of continuity with its predecessor, the FMAQ, a traditional human factors survey with a 20-year history in aviation (Sexton et al., 2006). Positive SAQ scores have been correlated with fewer medication errors, shorter lengths of stay and fewer adverse outcomes (Pronovost et al., 2006). There have been surveys of safety culture with medical and pharmacy students, however none have been found for nursing students. In a study by Dudas, Bundy, Miller and Barone (2011), the original SAQ was modified to investigate medical students attitudes towards patient safety before and after education about medication errors. The modified survey demonstrated significant changes in student knowledge and attitudes about safety for most questions derived from the SAQ.

The SAQ covers four themes: safety climate, teamwork climate, stress recognition, and organizational climate. The authors found that organizational climate plays a decisive role in setting the preconditions for success or failure in managing risk. The SAQ elicits caregiver attitudes through six factor climate scales: teamwork, safety, job satisfaction, perceptions of management, working conditions, and stress recognition. The SAQ can be used to meet the increasing demand for safety climate or safety culture assessment at the clinical area level. When used in pre-intervention/post-intervention methodology, the SAQ factors have demonstrated sensitivity to quality improvement interventions, demonstrating that climate can be targeted and improved. These improvements are associated with reductions in medication errors and with shorter lengths of stay (Sexton et al., 2006).

In a study by Taylor (2004) of safety climate and working conditions, 723 nurses were given the SAQ. The teamwork mean was 88.34 (0.03) in units without falls, compared to 75.49 (0.05) in units with falls. The Safety Climate mean was 84.55 (0.04) in units with falls compared to 76.69 (0.04) for units without falls, Job Satisfaction means were 80.61(0.04) and 70.69(0.07) respectively; Perceptions of (Unit) Management means were 74.69(0.09) and 61.49(0.07) respectively and Working Conditions means were 78.07(0.03) and 69.48(0.05). Though the SAQ has not previously been given to nursing students, mean scores for pharmacy students (n=93) ranged from 70.25 on perceptions of management to 83.20 on teamwork climate (Norden-Hagg et al., 2010, no SD given).

Sensitivity to Signal

Sensitivity to signal is a measure of an individual's ability to successfully distinguish signals from among a large number of different stimuli (Wickens, 2002). Sensitivity depends on

level of training, degree of fatigue and on how distinct the signal is from ambient environmental stimuli (noise) (Macmillan & Creelman, 2005). A signal conveys information about the behavior or attributes of some phenomenon, and has the potential to provide information on the status of a physical system or convey a message. Random patterns that distract from the information are called *noise,* which consists of background stimuli and the random activity of the nervous system of the operator (Wickens, 2002). For the purpose of this study, sensitivity to signal is defined as knowledge of safe medication administration practices as a result of training and experience, as well as ability to scan and correctly identify patient risk signals (Despins et al., 2010).

Many tools are available for direct observation of sensitivity to signal in medication administration, however validity evidence and description of educational outcomes are scarce (Gonzales, 2010). In a review of the literature, Miller et al. (2016) found three studies describing paper and pencil tests for assessing competency in medication error administration. One was not available in English (Lee & Lin, 2013), another had no psychometric data reported (Pauly, 2013), and a third, The *Revised Safe Administration of Medication Scale* (SAM-R), had well described psychometric data and was available for use (Bravo, 2014).

The SAM-R scale consists of five written cases each with two or three associated vignettes and the actions taken by individual nurses as they administer medications. Within these 14 vignettes, 17 errors are incorporated into the materials that describe hospitalized adult or pediatric patient scenarios. Each case includes demographic information (name, gender, age, medical allergies, admission date and hospital identification number). The participant taking the SAM-R scale reads the vignette and decides if the accompanying actions taken by the nurse are appropriate, and indicates what the nurse should have done if an error was committed. Short

answer responses are solicited to determine ways in which the participant would correct the error.

The SAM-R is a revision of the original SAM scale with incorporation of more challenging vignettes and decision-making. The revisions were made using expert faculty feedback and evaluation of the literature and expert sources for relevant content to guide revisions. The SAM Scale was initially developed to objectively measure performance in the safe administration of medication of nursing students (Ryan, 2007). Gonzales (2010) provided additional evidence of the validity and reliability of the SAM Scale (Cronbach's alpha of 0.77) in addition to correlational data using the *Domain-Specific Risk-Taking and Risk Perception Scale* (DOSPERT) to show a direct relationship between health/safety risk-taking behavior and performance on the SAM Scale. Gonzales (2010, 2015) also found that sophomores who completed the test routinely scored better than seniors. Content validity analysis presented by Gonzales (2015) showed the SAM scale to be too easy, containing outdated material and limited number of medications. Gonzales recommended updating the SAM scale, and constructing alternate versions of the test based upon common medication errors made by nurses and/or nursing students.

Bravo (2014) utilized Tanner's Clinical Judgment Model to revise the SAM scale as well as the "Five Rights of Medication Delivery Model" (NCCMERP, 2009b) The SAM-R was revised and tested to assess Baccalaureate Nursing Student (BSN) readiness to safely administer medications using case studies and vignettes. Classical testing and item response theory (IRT) were used to analyze item and group results from a sample of junior and senior-level BSN students (N=227). Evidence was reported for reliability, face, content and construct validity. The

revision by Bravo (2014) (n=277) yielded an average item difficulty of 0.59. (items with values greater than 0.7 are too easy, items less than 0.4 too challenging). The overall Content Validity Index (CVI) from faculty experts was 0.96. Cronbach's alpha was 0.736. Bravo (2014) found a significant difference in SAM-R scores between senior and junior level students ($p<0.001$). The overall mean score for juniors was 58.8 (SD=5.3) and for seniors (63.3 (SD=3.0). Though the revised scale was successful in increasing the level of difficulty, the item difficulty and discrimination values continue to be below desired levels. In summary, the SAM-R is a valid and reliable tool for measuring safe medication administration practices in senior level nursing students.

Summary

Harm to patients and nurses occurs when medication errors are made. The nurse is the last line of defense prior to an error reaching the patient, and nurses are the most likely health care providers to detect and prevent medication administration errors. Despite recommendations for curriculum reform, nursing education continues to use individual accountability and the five rights of medication administration to prevent medication error. The PRDT (2010) provides a framework for research that has the potential to identify interventions that would increase nursing student ability to detect and prevent error by making students more aware of the factors that contribute to error. The difficulty of measuring nursing ability to detect and prevent error while administering medications has been discussed. An instrument to measure safe medication administration has been presented, with supporting evidence that it is possible to measure a change in nursing knowledge of safe medication administration. Multiple interventions directed at reducing patient harm from medication error have been tested, yet harm to patients has not

been mitigated in the last 15 years. This literature review presents background and evidence for the need for an experimental research study examining the effect of a RCA educational intervention on nursing student knowledge of safe medication administration.

CHAPTER 3

METHOD

This chapter is a discussion of the specific methods and procedures that were utilized to carry out the study. It includes explanation of design, setting, population, and sample. The independent variables are described. A description of the operational definitions of the dependent variables including psychometric properties to support the validity and reliability of the measures are provided. The procedure (recruitment and collection of data), data management, data analysis, primary statistical analysis of the hypotheses, and protection of human subjects is also described.

Design

The purpose of this experimental pre-test, post-test research study was to test the part of the Patient Risk Detection Theory (PRDT) that predicts that training has an effect on participant sensitivity to signal and responder bias. Participant sensitivity was measured using a test of safe medication administration knowledge, the *Safe Administration of Medications-Revised Scale* (SAM-R; Bravo, 2014; Appendix B). Responder bias was measured using a survey of safety attitudes, the *Safety Attitudes Questionnaire* (SAQ; Sexton et al., 2006; Appendix A). This study tests the effects of RCA as an educational intervention on responder bias and sensitivity to signal. The following hypotheses were tested:

Hypothesis I: The SAQ is a valid and reliable test of safety attitudes in senior-level nursing students.

Hypothesis II: Participation in an online Root Cause Analysis education module, as compared to an online education module of standard safe medication administration practices will increase

participant safety attitudes for senior-level nursing students as measured by the SAQ (Sexton et al., 2006).

Hypothesis III: Participation in an online Root Cause Analysis education module, as compared to an online education module of the standard safe medication administration practices will increase knowledge for senior-level nursing students as measured by the SAM-R (Bravo, 2014).

Setting

This study was conducted with pre-licensure senior-level nursing students from universities in northeastern (NETN, *n*=23), north-central Tennessee (NCTN, *n*=75), and western North Carolina (WCN, *n*=27). The number of students at each university is between 10,000 and 15,000. Each of the three universities has a robust Baccalaureate nursing program with nursing licensure exam pass rates between 88 and 99%.

Population

Nationwide, according to AACN (2014), there are 63,857 senior-level nursing students. For the purpose of this study, any senior-level nursing students had the opportunity to be included due to the snowball effect. A convenience sample of students at these three settings was targeted for the purpose of this study from three universities from the Southeastern United States. The total number of senior level nursing students graduating each year from the three universities in this study is approximately 400 (TN.gov, 2017; NCBON, 2017).

Sample

A convenience sampling approach was used to obtain participants for the study. The sample size was determined by power analysis.

Sample size and power analysis.

Cohen provides a formula for determining sample size (1987).

$N=L(1-R^2)/ R^2 + u + 1$

Where

N = total sample size

L = effect size index

u = number of independent variables

The sample size was calculated using a medium effect size (0.30), level of significance $\alpha = 0.05$, and power $(1 - \beta)$ of 0.8 for the hypothesis (Munro, 2005). Most nursing studies have a modest effect size ranging from 0.2 to 0.4 (Polit & Beck, 2012). In the absence of effect size information from prior relevant research, an effect size of 0.30 was used for sample size determination in this study. The sample size needed for this effect was calculated to be n=45 for the experimental and control group, for a total of n=90 participants (Powerandsamplesize.com, 2017). **Inclusion criteria**: pre-licensure students over the age of 18, currently enrolled as senior-level students in good standing in a Baccalaureate of Science Nursing program. **Exclusion criteria**: Students who are currently licensed as a nurse, or in a program of study other than BSN were excluded. Those who cannot use a computer, read, or understand sufficient English to complete the study were also excluded. Instrumentation

Variables

The following section discusses the independent variables used for the study. Root Cause Analysis was presented to the experimental group, and the control group was given a module on the usual safe medication administration practices.

Root Cause Analysis: In the intervention module, a history of the patient safety movement is discussed, followed by a presentation of how and why RCA is used. The steps of the RCA process are presented following guidelines described by the Centers for Medicare and Medicaid Services (CMS), the Veterans Administration (The Department of Veterans Affairs National Center for Patient Safety, 2015) and RCA^2 published by AHRQ (2014). RCA involves developing a problem statement, creating a timeline, developing a causal tree, and then constructing an action plan. In the module, a previously published medication error, (Bates, 2002) *Unexpected Hypoglycemia in a Critically Ill Patient,* is used as a case study for the RCA. The article describes an overview of an RCA done for a patient death when insulin (vs. the ordered heparin) was used to flush a blocked central line (Bates, 2002). After each step of the RCA process was described, participants were asked to create a problem statement, causal tree statement and action plan item. The results of the RCA from the article were discussed and analyzed. The PI, to further illustrate the usefulness of RCA for discovering root causes, added additional causal tree items and action items. The RCA module ended with an analysis of the strength of the action items, and recommendations for completing a successful RCA. Participants were asked, "If these action items had been in place, do you think they would have prevented the error from happening?"

The PI, who is a certified professional in patient safety (CPPS), and worked as a patient safety officer for two years at a local hospital, created the RCA module. During that time the PI directed over 25 RCAs for medical errors. A pharmacist (Pharm-D, CPPS), and a RN (MS, CPPS) with over 10 years of experience with patient safety and quality improvement reviewed the module for content validity.

Control: The control module was designed based upon lecture materials shared with the PI by the NCTN school of nursing, Perry and Potter's *Fundamentals of Nursing* (2013), and ATI NCLEX preparation testing resources utilized by students in many nursing programs nationwide (2017). In the module, a brief history of the patient safety movement is given, and the basics of safe medication administration are discussed. The module includes how medication administration is taught in schools of nursing, common errors made by nurses and nursing students, strategies currently used by healthcare and nursing to prevent medication error, and a discussion of just culture. The module includes consequences for patients, nurses and the healthcare industry of being involved in medication error. RCA is mentioned as a strategy, but no details of the RCA process are given. The hypoglycemia medication error (Bates, 2002) was also used in this module. Students analyzed the error using the six rights of medication administration, and were asked, "why do you think this error occurred?" and "what would you do to prevent this error from happening again?" The PI drew on 8 years of experience as a nurse educator in both BSN and ADN programs to design the control module. The same Pharmacist and RN who reviewed the RCA module reviewed the control module.

The educational modules were initially designed for face-to-face delivery. A PowerPoint presentation was created for both the intervention and control groups using similar fonts and backgrounds. Each module was designed to last approximately 2 hours. Modules included handouts, as well as time for participant interaction and response to PI led questions. Questions included, "why do you think this error occurred?" and "what could have been done to prevent this error?" In the RCA modules, participants were directed to analyze a timeline, create a problem statement, contribute to a causal tree, and an action plan based on the hypoglycemia

case study. After *Phase One*, describe in the *Procedures* section below, both modules were put online as described in *Redesign* in the *Procedures* section. The PI used iMovie to create an Mp4 file with voiceover for each slide show. Each video is approximately 75 minutes long. All handouts and questions were included from the original modules, with suggested points in the video for participants to pause and answer questions. Participants were encouraged to write down answers to questions, and to share them with the PI if desired. No participants chose to communicate with the PI with answers to the questions. The iMovie was uploaded to YouTube under "Private" settings and the link to the video was embedded into the online REDCap data collection application, described in the *Data Collection* Section below.

Procedure

Recruitment: The first round of recruitment occurred in the fall of 2016 following initial East Tennessee State University (ETSU) Institutional Review Board (IRB) approval for the study. The instructor placed a link to the recruitment script (Appendix F) and informed consent on the website for the course, and sent out an email to all students letting them know the time and place for learning more about the study. The PI travelled to the institution and presented the study to a group of students who were interested (n=25). The PI collected email addresses of those who were interested and arranged a time and place to meet to obtain informed consent and complete pre-testing.

Phase One Procedure and Data Collection: Eleven students subsequently met with the PI to sign informed consent and complete paper and pencil demographic and SAQ survey as well as the SAM-R. The PI instructed the participants to choose a confidential identification number, word, symbol, or combination on each survey and test and place the forms in a sealed envelope

in the back of the room. The final student sealed the envelope, signed and dated it, and the sealed envelope was kept in a locked case with the PI or in the home of the PI at all times. Due to scheduling difficulties, the PI collected student availability via email, and set up a time that allowed most students to be present. Students were randomly divided into two groups, with the intervention group meeting from 10 am-12 pm (n = 5), and the control group meeting from 12pm - 2 pm (n = 6). Due to further scheduling issues, the PI mailed the post education SAQ survey and SAM-R test via the U.S. Postal Service to each participant, with instructions for completion and a self-addressed envelope with appropriate postage. The PI received three control and five intervention post education responses. The PI placed the unopened envelopes in the locked case with the pre-education forms.

Redesign Recruitment: Due to the difficulties encountered with scheduling participants who had been randomized to each arm of the study, the PI chose to move the study online (Figure 3). After obtaining approval from the dissertation committee, IRB approval of the modified informed consent and delivery method was obtained. Students known to the PI, and those who had participated in the study were asked to refer senior-level nursing students via the snowball method in the modified recruitment script (Appendix G). All students who participated elected to sign the consent. The PI sent a script describing the study to all students, including a link to informed consent. The PI was notified by email via REDCap when a participant completed the consent form. Participants were then randomized to the intervention or control group using REDCap. With IRB approval, informed consent was also placed on REDCap.

Redesign Procedure: The PI created a video for both the intervention and control education modules by recording a voice-over of PowerPoint slides and uploading them to YouTube. To

test REDCap set-up, the initial participants signed the revised consent and completed the 30-day post SAQ and SAM-R online, entering the identification codes they had created for themselves at the beginning of the study. Eight participants completed the 30-day post test/surveys. Randomization was achieved by using a random list of zeroes and ones generated by an online random number generator (Statrek, 2017). After randomization, the PI manually assigned the participant to either the control or intervention REDCap project and sent an email to the participant with a link to either the corresponding arm of the study.

Redesign Data Collection: Online data collection utilized the REDCap web application. REDCap is a secure web application for building and managing online surveys and databases, and was designed to support online or offline data capture for research studies and operations. Participants in both arms of the redesign phase filled out a demographic survey, the SAQ and completed the SAM-R scale in REDCap (Figure 3). At the end of the SAM-R test, a link was

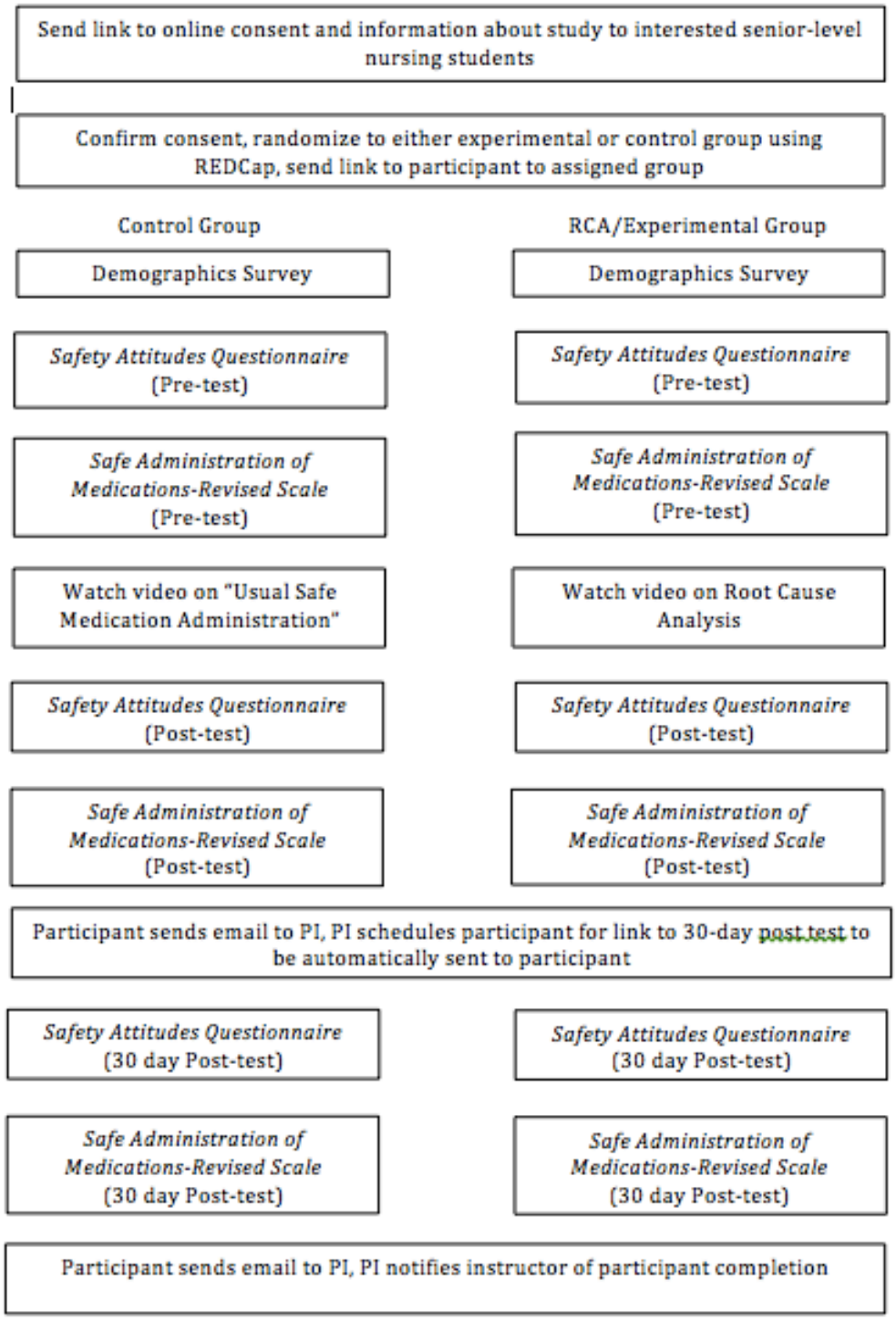

Figure 3. Experimental Design

embedded to either the intervention or control video. After watching the video, participants were directed to an embedded link to the post-video SAQ and SAM-R. When a participant completed the SAM-R, the PI was notified via email from REDCap and manually set up a post-test email to be automatically sent out 30 days after completion of the SAM-R. The email contained a link to the final SAQ and SAM-R. Once participants completed the final SAM-R, the PI was notified via email from REDCap and manually emailed the participant and instructor that the participant had completed the study.

All participants were asked not to share information about the RCA intervention or testing with colleagues until after the study to prevent the exposure of the control group to the intervention. Participants were instructed at the beginning of each round of testing to work alone in a quiet setting, using only a drug book and a calculator. Participants were reminded they could stop participating in the study at any time. Participants were told they could stop and start completion of surveys and tests as needed, and rejoin a previous session with a password known only to them via REDCap.

Instruments

Demographic Survey: A general demographic survey (Appendix C) was given after consent, but prior to the SAQ. The SAQ contains some demographic questions, however additional demographic data were sought to increase generalization of results. Demographic data included date consent was signed, race, sex, age, education and licensure status, employment status, and familiarity with RCA.

Safety Attitudes Questionnaire: *The Safety Attitudes Questionnaire* (SAQ, Sexton et al., 2006; Appendix A) was used to indirectly measure changes in the responder bias of nurses. Permission

to use the SAQ was obtained (Appendix D). Responder bias is a measure of how willing a nurse is to respond to a signal. Studies have found that nurses working in High Reliability Organizations are more willing to respond to signals (Berry et al., 2016). The SAQ was derived from a questionnaire widely used in commercial aviation, the *Flight Management Attitudes Questionnaire*, created after researchers found that most airline accidents were due to breakdowns in interpersonal aspects of crew performance such as teamwork, speaking up, leadership, communication and collaborative decision making (FMAQ; Sexton, et al. 2006). Vincent's framework for analyzing risk and safety and Donabedian's Model for assessing quality were used to modify the FMAQ to the SAQ, which is medically focused. Twenty-five percent of the FMAQ questions were retained due to their utility in medical settings. Additional items were added with input from healthcare providers and subject matter experts. The authors also relied on Vincent's framework for analyzing risk and safety (which was included in the RCA module). Initial analysis of the additional items yielded four themes: safety climate, teamwork climate, stress recognition, and organizational climate. The items were further evaluated through pilot testing and exploratory factor analyses, which consistently yielded 6 factor-analytically derived attitudinal domains (Sexton et al., 2006).

The original SAQ had 60 items, but has since been modified into a 36 item short-form (Appendix A) and takes approximately 5-10 minutes to complete. Each of the 36 items is answered using a five-point Likert-type scale (disagree strongly (1), disagree slightly (2), neutral (3), agree slightly (4), agree strongly (5). The SAQ item scores reflect the respondent's level of agreement with individual item statements. Units with higher proportions of percent agreement have more reports of positive safety norms and behaviors (Schwendimann, Zimmerman, Kung,

Ausserhofer, & Sexton, 2013). A single composite score comprised of the six SAQ dimensions (Table 3) does not reflect the multidimensional nature of safety culture in a specific clinical area. Schwendimann et al. (2013), reported ongoing research using cluster analyses and culture profiles to support the use of multidimensional safety culture scores over single composite indices. There is growing evidence that the SAQ measures attitudes that are responsive to interventions associated with clinical outcomes. The SAQ provides a snapshot of the climate in a given clinical area. High scores on the SAQ are a standard outcomes measure for HROs (Schwendimann et al., 2013).

The SAQ has well reported psychometric properties. Composite scale reliability for the SAQ was assessed via Raykov's coefficient, which was 0.90, indicating strong reliability. Raykov's reliability rho tests the assumption that a single common factor underlies a set of variables. Raykov demonstrated that Cronbach's alpha may over- or under-estimate scale reliability, and underestimation is common (Munro, 2005). Raykov's coefficient is now preferred and may lead to higher estimates of true reliability. Raykov's coefficient is assessed in the same manner as Cronbach's (scores above 0.70 indicate a high reliability). Fit was demonstrated by Sexton et al. (2006) with multi-level confirmatory factor analyses (RMSEA=0.045; CFI=0.941; TLI=0.934).

Table 3

The SAQ Six Safety Attitudes Items

Dimension	Items
Teamwork Climate	1-6
Safety Climate	7-13
Job Satisfaction	15-19

Stress Recognition	20-23
Perception of Management	24 -28 (measured at *two* levels – unit and hospital)
Working Conditions	29-32

(item 14 and items 33-36 are not scored as part of a safety dimension, see Appendix A for individual item questions)

Scoring directions are provided on the University of Texas, Memorial Hermann Texas Medical Center, Center for Healthcare Quality & Safety website (2018). Results are calculated as the percentage of respondents who report *positive* perceptions (those who *agree slightly* or *agree strongly*). A score of 75% is equivalent to responses of *agree slightly* and *agree strongly*.

To calculate the 100 pt. scale for an individual respondent:

1. Reverse score all negatively worded items (2, 11 & 36)
2. Calculate the mean of the set of items from each subscale
3. Subtract 1 from the mean
4. Multiply the result by 25

The equation: (((Mean of items)-1)*25).

Safe Administration of Medications – Revised Scale: The SAM-R scale (Appendix B) was designed to measure respondent knowledge of safe medication administration practices. Permission to use the SAM-R was obtained from the author (Appendix E). The SAM-R was developed with input from faculty experts, students and pharmacy experts to support content validity. These experts gave input on the clarity, level of congruence with current clinical practice, the likeliness of errors presented actually happening, and if there was sufficient information presented in each vignette for the subject to make a determination related to medication administration. High scores on the SAM-R are associated with knowledge of safe medication administration practices.

The SAM-R consists of five written cases with two or three associated vignettes describing the actions taken by individual nurses as they administer medications. Each case includes demographic information for the patient (name, gender, age, medical allergies, admission date and hospital identification number). Within these 14 vignettes, 17 errors are incorporated into the materials that describe hospitalized adult or pediatric patient scenarios. At the end of each of the 14 vignettes respondents are presented with the 5 rights of medication administration (right dose, right drug, right patient, right route, right time) and are asked whether any of the rights was not followed in the vignette. The participant taking the SAM-R scale reads the vignette and decides if the accompanying actions taken by the nurse are appropriate, and indicates what the nurse should have done if an error was committed. There are a total of 70 response items (5 for each of the 14 vignettes). The SAM-R takes between 1-2 hours to complete. Participants are allowed a calculator and a drug book when taking the SAM-R.

The internal consistency reliability of the scale was 0.736. This number meets the suggested level of 0.7 for new scales (DeVon et al., 2007). The average item difficulty was 0.59; items with difficulty values greater than 0.7 are considered too easy, and items with values less than 0.4 are considered too challenging (Royal, Gilliland, & Kernick, 2014). Discriminatory values were as follows: 9 items had values of 0.3 and above (medium discriminatory effect), 45 had values between 0.1 and 0.29 (small effect), 12 items had values less than 0.1. The high level of internal consistency indicates that the items on the instrument fit together conceptually. In a study by Bravo (2014), Junior and Senior level BSN students from five campuses of a single midwestern college of nursing took the SAM-R. Junior students (n=196) were in the second half of a Pharmacology course and senior level students (n=31) were within three months of graduation. SAM-R scores between senior-level students and junior-level students ($p<.001$) was significantly different. The juniors mean score was 58.8 (SD = 5.3) and for seniors 63.3 (SD = 3). Bravo (2014) showed that all items from Vignettes 9 and 14 performed in a consistently positive manner using both problematic fit statistics and corrected item-total correlation values. The Content Validity Index (CVI) from faculty experts was 0.96. Known groups testing established that the SAM-R scale could differentiate between known groups of two different ability levels.

Data Management

After all data were collected, and phase one data from paper and pencil tests was entered into REDCap, the data were exported to Statistical Package for the Social Sciences (SPSS) software version 25 on the principal investigator's personal, password protected computer. Data

were backed-up on a password protected flash drive stored in the locked office of the PI, and on a password protected Google drive.

Data Analysis

De-identified data were downloaded from REDCap, and scoring of the SAQ was done using SPSS as previously described. Using this method, it is not possible to score surveys for which participants had marked "not applicable" for all answers. SAQ surveys that included "not applicable" for all answers were labeled as missing data.

Scoring of the SAM-R was performed with SPSS. Data were transferred from REDCap and coded from "correct action" and "incorrect action" into numerical values. One point was given for each correct answer, according to scoring directions from the instrument author (Bravo, 2014). During analysis the PI discovered that the original answer key for the SAM-R contained two errors. In Case 2, Vignette 4, the *Right Time* should have been marked as "No". In Case 4, Vignette 9, the *Right Patient* should have been marked as "No". These were corrected in SPSS. Data from incomplete SAM-R scales and the SAQ was marked as coming from incomplete forms and data were analyzed both with and without the data from the incomplete forms.

Descriptive statistics were used to describe demographic data characteristics. Mean, range and standard deviation were calculated for continuous variables and frequencies and percentages for categorical variables. Chi square analysis was performed on demographic variables to demonstrate no significant difference existed between the control and intervention groups ($p<0.05$).

Primary statistical analysis

Hypothesis I: The SAQ is a valid and reliable test of safety attitudes in senior-level nursing students. Statistical analysis was done using Cronbach's alpha to test for reliability. Cronbach's alpha is the most widely used method for evaluating internal consistency (Polit & Beck, 2012). Cronbach's alpha was compared for pre-test, post-test and 30 day post-test SAQ scores to determine reliability. Face validity has been established previously (Sexton et al., 2006). To establish construct validity, an independent, two-tailed t-test was performed on SAQ pre-module scores between schools, and to compare participant knowledge and understanding of RCA, and experience with healthcare to SAQ scores ($p<0.05$). To establish concurrent validity, a Pearson's r was conducted to show correlation between scores on the SAQ and the SAM-R. Concurrent validity was also established by comparing SAQ subscale scores with those in the literature.

Hypothesis II: Participation in an online Root Cause Analysis education module, as compared to an online education module of standard safe medication administration practices will increase participant safety attitudes for senior-level nursing students as measured by the SAQ (Sexton et al., 2006).

Hypothesis III: Participation in an online Root Cause Analysis education module, as compared to an online education module of the standard safe medication administration practices, will increase knowledge for senior-level nursing students as measured by the SAM-R (Bravo, 2014). Statistical analysis of the second two hypotheses was done with a two-factor, repeated measures, mixed ANOVA ($p<.05$). The two-factor, repeated measures ANOVA allows determination of an interaction between variables or a main effect of either variable. ANOVA is the best test to determine significant differences between the mean test scores for the SAM-R and SAQ from the

intervention and control group (Polit & Beck, 2012). ANOVA tests whether there is greater response variability on the SAM-R and SAQ between groups compared to within groups. The ANOVA is more powerful and flexible than nonparametric techniques, allowing the study of multiple variables, as well as the study of their interaction. When assumptions of an ANOVA are met, the test is fairly robust, however if assumptions are not met, the probability of making a type I error increases. The underlying assumptions for an ANOVA are that the observations are independent and randomly selected from normal populations with equal variances. Heterogeneity of variance can influence results and cause incorrect rejection of the null hypothesis (type I error). Independence of observations will be maintained by preventing participants from being in both groups.

In addition, for hypothesis two, the percentage of positive scores (those above 75%) was compared, and an ANOVA of the mean scores for each of the six safety attitudes (Table 10) items was calculated for pre and post surveys. Chi square analysis was performed to test for significant differences between the percent positive scores.

To further test hypothesis 3, all items with a Corrected Item-Total Correlation below 0.1 were removed and the composite scores were analyzed separately from the overall score using ANOVA to determine a significant difference between the means.

Protection of Human Subjects

Risks to participants during the intervention are minimal. The Principal Investigator is a Registered Nurse in the state of North Carolina with a Master of Science in nursing degree and has extensive experience in constructing and administering educational interventions. Approval for this study was obtained from the Institutional Review Board (IRB) of the East Tennessee

State University. The Principal Investigator is accountable for reporting study variances to the IRB. Participants were instructed that participation was voluntary and that they could withdraw from the study at any time without threat.

Confidentiality of information and protection of participant information was maintained as described in *Phase One* and using REDCap. The consent form contained a warning about the possibility of the interception of data sent over the internet by third parties. Every effort was made to ensure student names were not linked with answers. Students entered no identifying information in the data collection site. Through REDCap, there is no link between the modules and no connection between the email address entered and the responses collected. To ensure confidentiality of data, REDCap tracks responses by attribution to an email address, however PIs are not privy to this information. Access to the association between the individual who took the survey and the survey responses is restricted in the database and can only be accessed by authorized privileged users. There is a link "behind the scenes" and REDCap / REDCap support personnel (system engineers, database admins) are really acting as an "Honest Broker:" information is provided to investigators in such a manner that it would not be reasonably possible for the investigator or others to identify the corresponding patients-subjects directly or indirectly. REDCap holds the key to the code. All data files will be kept for six (6) years and then destroyed.

Summary

This study tested the PRDT (et al., 2010) by measuring differences in mean scores on the SAM-R and SAQ after participation in RCA compared to the usual nursing education received in

the same time frame. The relationship between scores and demographic variables was also examined to support the design of educational interventions to reduce medication error.

CHAPTER 4

RESULTS

This study was designed to examine if senior-level nursing student participation in root cause analysis has the potential to reduce harm to patients from medication errors by increasing student nurse sensitivity and responder bias. This chapter is divided into the following sections: description of the sample, design, setting, population, sample, independent variables, dependent variables, procedure (recruitment and collection of data), data management, data analysis, primary statistical analysis of the hypotheses, and protection of human subjects.

The study was intended to expand information as outlined in the following specific aims and hypotheses:

Specific Aim I: To test the use of the *Safety Attitudes Questionnaire* (SAQ, Sexton et al., 2006; Appendix A) with senior level nursing students.

Hypothesis I: The SAQ will be a valid and reliable test of safety attitudes in senior-level nursing students.

Specific Aim II: To test the effect of root cause analysis on responder bias as measured by the SAQ.

Hypothesis II: Senior-nursing students will have increased safety attitudes following participation in RCA when compared to a non-intervention control group.

Specific Aim III: To test the effect of root cause analysis on sensitivity to signal as measured by the Safe Administration of Medications-Revised Scale (SAM-R, Bravo, 2014; Appendix B).

Hypothesis III: Senior-nursing students will demonstrate increased knowledge of safe medication administration practices following participation in RCA when compared to a non-intervention control group.

These specific aims were tested using a sample of senior-level nursing students from three universities, in the Southeastern United States.

Description of The Sample

The total number of participants recruited and consented was N=125 (*n*=63 control, *n*=62 intervention), however only 94% participated (*n*=59 control, *n*=58 intervention). The majority of participants self-identified as white (79%), female (82%), under 30 years of age (68%), and employed (60%). The control and intervention groups are similar based upon demographic answers about race, gender, age, employment status and experience with RCA (Table 4). In the control group, 13% of participants stated they had a clear idea of what RCA is and how to use it, whereas in the intervention group only 1% indicated this level of understanding of RCA, however this represents a small group and may not be indicative of the larger population (*n*=8). A chi-square test was performed to compare demographics between the control and intervention groups and no relationship was found, suggesting these groups are equivalent with respect to race, C (*n*=107) = 0.1, *p*=0.7; sex, X^2_2 (*n*=111) = 0.8, *p*=0.4; age, X^2_2 (*n*=108) = 0.1, *p*=0.8; or employment, X^2_2 (*n*=110) = 1.1, *p*=0.3 (Table 5).

Table 4

Participant Descriptive Statistics

	Variable	Control (*n* = 59)	%	Intervention (*n* = 58)	%
Race	Asian	0	0.0	1	1.7
	Black or African American	5	8.5	5	8.6
	More Than One Race	2	3.4	2	3.5
	Unknown/not reported	5	8.5	5	8.6
	White	47	79.7	45	77.6
Sex	Female	46	78.0	50	84.7
	Male	9	15.2	6	10.2
	Unknown/not reported	4	6.8	2	3.4
Age	18-24	27	45.8	30	51.7
	25-30	16	27.1	6	10.3
	31-35	2	3.4	8	13.8
	36-40	3	5.1	7	12.1
	41-45	4	6.8	2	3.5
	46-50	1	1.7	0	0.0
	51-55	1	1.7	1	1.7
	56-60	0	0.0	0	0.0
	Over-60	0	0.0	0	0.0
	Not reported	5	8.5	0	0.0
Employment	Full time	9	15.3	4	6.8
	Part time	18	30.5	12	20.3
	PRN	8	13.6	12	20.3
	Unemployed	5	8.5	7	11.9
	Not reported	15	25.4	20	33.9
	I have Participated in RCA (Yes):	3	5.1	3	5.2
Knowledge of RCA	I can explain what it is, and I have used it.	0	0.0	1	1.7
	I have a clear idea of what it is and how to use it.	8	13.6	1	1.7
	I have heard of it, but don't know what it is.	9	15.2	12	20.3
	Some idea of what it is, but don't know how to use it.	21	35.6	21	35.6
	I have never heard of it.	16	27.1	19	32.2
	unknown/not reported	5	8.5	4	6.8
School	North Eastern TN	33	55.9	37	63.8
	North Central TN	11	18.6	9	15.5
	Western NC	15	25.4	12	20.7

Table 5

Statistical Analysis of Demographic Data

Variable	Control *n*	Intervention *n*	X^2	*p*
Race:	54	53	0.1	0.7
White	47	45		
Non White	7	8		
Sex:	55	56	0.8	0.4
Female	46	50		
Male	9	6		
Age:	54	54	0.1	0.8
Under 35	45	44		
Over 35	9	10		
Employment Status:	55	55	1.0	0.3
Employed	40	35		
Unemployed	15	20		

Statistical Analysis of Hypotheses

This section describes the results of data analysis for each of the three hypotheses.

Hypothesis I: The SAQ is a valid and reliable test of safety attitudes in senior-level nursing students. Cronbach's alpha was conducted on the responses for pre-module, post-module, and 30 day post-module Safety Attitudes Questionnaire (SAQ) to determine reliability. All results demonstrated () $\alpha > 0.97$: pre-module (n=102), $\alpha = 0.98$; post-module (n=85), $\alpha = 0.98$; 30-day post-module (n=21). For all scores combined $\alpha = 0.98$ (N=208).

The Corrected item–total correlation for the survey questions ranged from 0.6 for item 20 to 0.9 for item 1, demonstrating that all questions had a sufficient discriminatory index. The Cronbach's alpha values for subscale-to-subscale correlations of the SAQ were above 0.7 (Values of $\alpha > 0.7$ are considered acceptable). Table 6 lists the Cronbach's alpha for the six dimensions of the SAQ. Item-to-item correlations ranged from 0.1 to 1.0.

Table 6

SAQ Dimensions

Dimension	**Items**	**Cronbach's alpha**
Teamwork Climate	1-6	0.94
Safety Climate	7-13	0.93
Job Satisfaction	15-19	0.93
Stress Recognition	20-23	0.90
Perceptions of Management (Hospital)	24-28	0.95
Perceptions of Management (Unit)	24-28	0.95
Working Conditions	29-32	0.90

(for the complete SAQ, see Appendix A)

Concurrent validity was tested. A 2-tailed Pearson's *r* was performed on pre-module SAQ and SAM-R scores to determine if a positive relationship exists between safety attitudes and knowledge of safe medication administration. SAQ and SAM scores have a statistically significant, positive linear relationship (p=0.02) as seen in Figure 4. Construct and face validity were previously tested for this instrument as described in chapter 3.

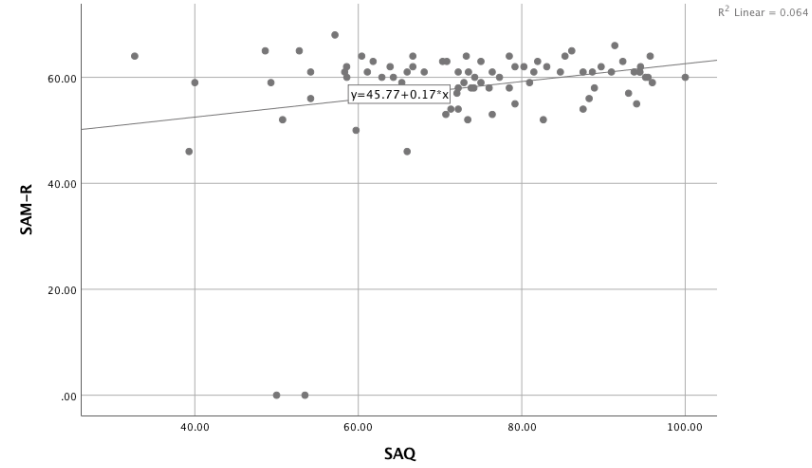

Figure 4. Correlation between SAM-R and SAQ scores

The safety climate for schools participating in the study was not equal (Table 7). An independent T-test (equal variances not assumed) was conducted on pre-module SAQ scores (only pre-SAQ scores were analyzed – statistical analysis of post-module scores was not possible due to small group size). Students attending the NCTN averaged statistically lower SAQ scores M=63.4 (SD 15.1) (n=16) than students attending NETN M=73.7 (SD 12.7) (n=47); ($t_{22.6}$=2.4, p=0.02) (Table 7). Students attending WNC averaged statistically higher SAQ score M= 82.5 (13.4) (n=16) than students attending NETN M=73.7 (SD 12.7) (n=47); ($t_{24.7}$=2.3, p=0.02) (Table 7). A two-factor ANOVA of school scores was conducted to further analyze differences between SAQ scores for the three schools. Results of the ANOVA indicated there was a significant difference between schools and SAQ scores ($F_{2, 74}$ = 4.8, p 0.01)

Table 7

Relationship of School to Scores

Pre-module SAQ							**Pre-module SAM-R**					
School	Mean	*n*	SD	Min	Max	Range	Mean	*n*	SD	Min	Max	Range
NETN	73.7	47	12.7	48	95	47.1	59.6	48	4.2	46	66	20
NCTN	63.4	16	15.1	32	88	55.6	59.4	21	4.9	50	68	18
WNC	82.6	16	13.4	49	100	50.7	59.8	18	2.7	53	63	10
Total	73.4	79	14.5	32	100	67.4	59.6	87	4.1	46	68	22

An independent T-test (equal variances not assumed) was conducted on SAQ scores in relationship to experience with healthcare and with RCA. Students with experience working in healthcare had lower SAQ scores M=70.1 (SD 16.3) (n=24) than those who did not M=74.3 (SD 14.0) (n=73), but there was no statistically significant difference between the means (t_{95} =0.9, p=0.2), however SAM-R scores were significantly higher for nursing students who worked in healthcare M=60.4 (SD 4.2) (n=23) than for those who did not M=56.1 (SD 12.6) (n=75); (t_{96}=-

2.5, p=0.01). Participants with experience with RCA had lower mean SAQ scores (M=65.8) (SD 9.5) (n=4) compared to those with no experience with RCA (M=74.0) (SD 14.5) (n=90), but the

Table 8

Demographic Variables and Scores

Variable	**Statistic**	**SAQ**	**SAM-R**
Not employed in healthcare	Mean	74.3	56.1
	n	73.0	75.0
	Std. Deviation	14.0	12.6
	Range (Min-Max)	61.0 (39.0-100.0)	68.0 (0.0-68.0)
Employed in healthcare	Mean	70.1	60.4
	n	24.0	23.0
	Std. Deviation	16.2	4.2
	Range (Min-Max)	74.0 (32.0-95.0)	57.7 (46.0-66.0)
RCA Experience	Mean	74.0	57.7
	n	90.0	94.0
	Std. Deviation	14.5	9.9
	Range (Min-Max)	67.0 (32.0-100.0)	68.0 (0.0-68.0)
No RCA Experience	Mean	65.8	61.0
	n	4.0	3.0
	Std. Deviation	9.5	2.6
	Range (Min-Max)	22.0 (56.0-78.0)	5.0 (58.0-63.0)
Never heard of RCA	Mean	70.2	53.0
	n	29.0	31.0
	Std. Deviation	13.7	15.4
	Range (Min-Max)	61.0 (39.0-100.0)	65.0 (0.0-65.0)
Some idea of what RCA is	Mean	74.8	60.4
	n	56.0	57.0
	Std. Deviation	15.0	3.5
	Range (Min-Max)	63.0 (33.0-96.0)	18.0 (50.0-68.0)
Clear idea of RCA	Mean	75.8	59.2
	n	8.0	8.0
	Std. Deviation	16.0	4.4
	Range (Min-Max)	38.0 (56.0-94.0)	13.0 (50.0-63.0)

difference was not statistically significant (t_{92}=1.6, p=0.2), and is not meaningful due to the low number of participants with experience with RCA (n=4). Participants who had never heard of

RCA (*n*=29) had lower mean SAQ scores (M=70.2) (SD 13.7) than those who had heard of RCA (M=74.6) (SD 14.9) (*n*=68), however there was no statistically significant difference (t_{95}=-21.4, *p*=0.2). SAM-R scores were stable across RCA experience and knowledge of RCA (Table 8).

Table 9

SAQ Means for Pre- and Post-Module Data

	Pre-module		**Post-module**	
Dimension	Control	Intervention	Control	Intervention
Overall	72.1 (16.1) *n*=47	74.3 (13.1) *n*=50	76.2 (16.4) *n*=37	72.4 (15.2) *n*=47
Teamwork Climate	79.0 (18.3) *n*=47	78.3 (16.0) *n*=50	81.6 (19.3) *n*=37	75.2 (17.8) *n*=47
Safety Climate	74.0 (18.5) *n*=47	77.4 (15.2) *n*=50	78.3 (20.9) *n*=37	73.8 (17.7) *n*=46
Job Satisfaction	76.1 (22.3) *n*=45	77.9 (22.2) *n*=48	82.6 (21.2) *n*=34	77.44(20.0) *n*=43
Stress Recognition	67.4 (25.6) *n*=44	73.5 (22.3) *n*=49	66.3 (25.2) *n*=36	74.7 (18.4) *n*=47
Hospital Management	65.4 (21.3) *n*=42	71.1 (18.4) *n*=39	71.8 (23.1) *n*=32	67.6 (21.2) *n*=31
Unit Management	74.1 (17.7) *n*=41	75.0 (19.7) *n*=42	69.5 (17.1) *n*=29	70.0 (22.6) *n*=40
Working Conditions	67.6 (24.4) *n*=46	66.6 (24.7) *n*=47	72.7 (21.8) *n*=36	68.8 (21.2) *n*=42

Means for SAQ survey responses overall and by the six SAQ dimensions are similar to those found in other studies (Table 9). The dimensions of teamwork, job satisfaction, and safety ranked the highest, which concurs with rankings found in multiple other studies (Norden-Hagg et al., 2010; Sexton et al., 2006, Taylor, 2004), (Table 9). The sample sizes in Table 9 vary because some participants left all items in a particular dimension blank, leaving that dimension with a score of zero.

Hypothesis II: Participation in an online Root Cause Analysis education module, as compared to an online education module of standard safe medication administration practices will increase participant safety attitudes for senior-level nursing students as measured by the SAQ (Sexton et al., 2006). For both the control and intervention groups, only 20% of participants were retained for all three time points: pre-module, post-module, and 30-day post-module (SAQ: pre-module n=97, post-module n=84, 30-day post-module n=19; SAMR: pre-module n=97, post-module n=79, 30-day post-module n=21). Though 117 participants participated in the pre-module, 17% (n=20) of the SAQ survey responses were not scored because all responses were either blank or "not applicable". The sample size for the 30-day post-module data was too small for statistical analysis.

To demonstrate equivalence between the control and intervention groups regarding pre-module SAQ scores, an independent T-test was conducted (equal variances not assumed). No significant difference was found between the means scores of the control, M=72.2 (SD 16.1) (n=47) and the intervention group, M=74.3 (SD 13.1) (n=50) for the SAQ pre-module scores (t_{95} =-0.7, p = 0.5) (Table 9).

The authors of the SAQ (Sexton et al., 2006) recommend scoring the SAQ by calculating the number of participants scoring 75% and over on the SAQ. Due to the prevalence of this scoring method in the literature, the percentage of positive scores is presented in this study in Table 10. For the pre-module group, the percentage of positive scores ranged from 38.1 (perceptions of hospital management) to 68.3 (teamwork). Post-module scores ranged from 41.4 (perceptions of unit management) to 75.5 (job satisfaction). The mean for the scores below 75 (n=51) was 62.5 (SD 10.1), and the mean for the "positive scores" (n=46) was 85.5 (SD 7.3).

To demonstrate the significance of differences in an increase in the number of positive scores in the pre- and the post-module groups, an independent T-test was conducted (equal variances not assumed). For the control group, no significant difference was found between the means scores of the pre-module, M=85.8 (SD 7.3) (n=23) and the post-module group, M=86.0 (SD 8.8) (n=24) (t_{45} =44.1, p = 0.9). For the intervention group, no significant difference was found between the means scores of the pre-module, M=85.1 (SD 7.5) (n=23) and the post-module group, M=84.0 (SD 6.4) (n=23) (t_{44} =43.0, p = 0.6).

Table 10

Percentage of Positive Scores for SAQ Survey Responses

	Pre-module		**Post-module**	
Dimension	Control	Intervention	Control	Intervention
Overall	48.9 (23/47)	46.0 (23/50)	64.9 (24/37)	48.9 (23/47)
Teamwork Climate	63.8 (30/47)	65.3 (32/50)	73.0 (27/37)	61.7 (29/47)
Safety Climate	55.3 (26/47)	64.00(32/50)	64.9 (24/37)	60.9 (28/46)
Job Satisfaction	60.0 (27/45)	66.7 (32/48)	75.5 (25/34)	67.4 (29/43)
Stress Recognition	47.73(21/44)	65.3 (32/49)	47.2 (17/36)	68.1 (32/47)
Hospital Management	38.1 (16/42)	46.2 (18/39)	56.2 (18/32)	51.6 (16/31)
Unit Management	53.7 (22/41)	61.9 (26/42)	41.3 (12/29)	55.0 (22/40)
Working Conditions	47.8 (22/46)	48.9 (23/47)	58.33(21/36)	50.00(21/42)

Percentage of positive scores (number of scores at 75 or above/total number of scores)

To further test hypothesis two, a two-factor ANOVA of pre-module and post-module SAQ scores was conducted. There was no significant difference between the groups ($F_{1, 74} = 0.1$, $p = 0.7$) (Table 11, Figure 5). A post hoc power analysis was not done due to the small F-ratio for the two-factor ANOVA ($F_{1, 74} = 0.1$, $p = 0.7$). The effect size was also very small, further suggesting no difference between the measurements. The sample size was adequate in the search for effect in the face of such small variance ($F_{1, 74} = 0.1$).

Table 11

Two-Factor ANOVA of Safety Attitudes

Variables	**Intervention**				**Control**			
SAQ	n	Mean	SD	Range (Min-Max)	n	Mean	SD	Range (Min-Max)
Pre-module	42	71.9	14.1	61.0 (39.0-100.0)	34	75.5	17.2	63.0 (33.0-96.0)
Post-module	42	72.7	13.8	61.0 (36.0-97.0)	34	76.1	16.9	71.0 (29.0-100.0)

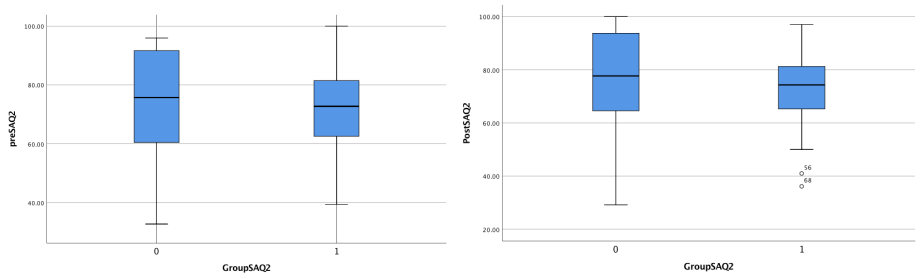

Figure 5. Comparison of Means for Pre and Post SAQ Paired Data

Hypothesis III: Participation in an online Root Cause Analysis education module, as compared to an online education module of standard safe medication administration practices will increase participant knowledge for senior-level nursing students as measured by the SAM-R (Bravo, 2014). To test this hypothesis, the mean scores on the SAM-R were compared. An independent T-test was conducted (equal variances not assumed) and no significant difference was found between the means scores of the control, M=58.8 (SD 4.8) (n=46) and the intervention group, M=59.9 (SD 3.9) (n=51) for the SAM-R pre-module scores (t_{96} =1.2, p = 0.2) (Table 12), demonstrating that the pre-module groups were equivalent with respect to safe medication administration knowledge.

Table 12

Means for SAM-R Scores

	Pre-module	**Post-module**

SAM-R	Control	Intervention	Control	Intervention
Mean	59.9	58.8	59.9	60.0
n	46	51	38	41
SD	3.9	4.8	4.6	4.7
Range (Min-Max)	20(46-66)	22 (46-68)	20 (48-68)	17 (49-66)

When the SAM-R data were analyzed with a two-factor ANOVA (Table 13, Figure 6) no significant difference was found between the means for the pre-module and post-module groups, ($F_{1, 72}$= 0.3, p = 0.6).

Table 13

Two-Factor ANOVA of Safe Medication Administration Knowledge

	Intervention				**Control**			
	n	Mean	SD	Range (Min-Max)	n	Mean	SD	Range (Min-Max)
Pre-module	42	58.9	4.8	22 (46-68)	32	60.8	3.5	14 (52-66)
Post-module	42	60.0	4.7	17 (49-66)	32	59.0	6.9	37 (31-68)

Items with Corrected Item–Total Correlation (CITC) values below 0.1 were removed from the SAM-R to determine if the modified tool would be more sensitive to the effects of the intervention. All scores were converted to percentages for purposes of comparison. A two-tailed Pearson's *r* was conducted to determine if there is a relationship between the SAM-R and the SAM-LDIR. There is a strong (ρ=0.9), statistically significant (p=0.01), positive relationship between the SAM-R (n=99) and the SAM-LDIR (n=98).

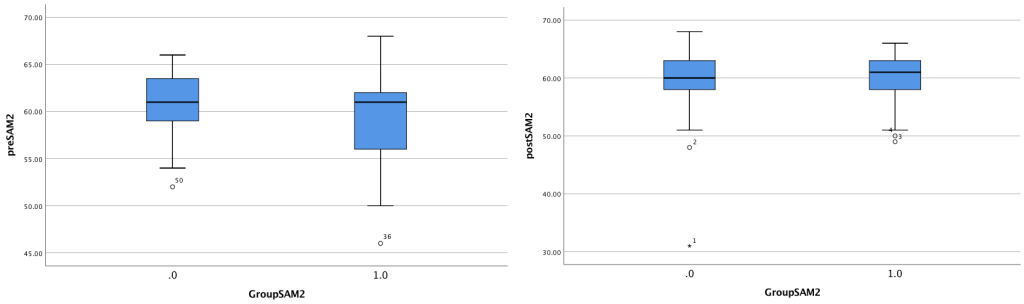

Figure 6. Comparison of SAM-R Means

A two-factor ANOVA was conducted to compare the pre-module scores for the original SAM-R and the pre-module scores for the SAM-R with low discriminatory items removed (SAM-LDIR). There was no significant difference between pre-module scores for the original SAM-R and pre-module scores for the SAM-R LDIR ($F_{1,95}$=1.7, p = 0.2), suggesting these two versions are statistically equivalent for this study. This supports that the shorter SAM-LDIR might be useful for future measurement of safe medication administration knowledge due to its shorter length.

To further analyze the use of the SAM-LDIR to test hypothesis 3, a two-factor ANOVA was conducted to compare the mean pre-module and post-module scores for the SAM-R LDIR. There was no significant difference between the pre-module and the post module scores for the SAM-R LDIR ($F_{1, 71}$ = 1.4, p = 0.2).

Summary

This chapter provides results of the data analysis for three hypotheses about the effect of RCA on senior-level, pre-licensure nursing students attitudes and knowledge of safe medication administration practices. Results are presented on the use of the SAQ and SAM-R with senior level nursing students (N = 125) from three southeastern schools of nursing.

CHAPTER 5

DISCUSSION

This chapter provides a discussion of the findings, sample, hypotheses, theoretical implications, nursing implications, strengths and limitations, and recommendations for future research. This study was done to examine if student nurse participation in root cause analysis has the potential to reduce harm to patients from medication errors by increasing student nurse sensitivity and responder bias. The purpose of this experimental pre-test, post-test research study was to test the part of the Patient Risk Detection Theory (PRDT) that predicts that training has an effect on participant sensitivity to signal and responder bias.

Discussion of the Findings

Major industries such as nuclear power and aviation have reduced harm to workers and consumers by adopting the characteristics of High-Reliability Organizations (HROs) through the use of Root Cause Analysis (RCA). Healthcare has this goal as well. Despite recommendations that RCA training be incorporated into nursing school curricula, nursing students have had little experience with RCA (Miller et al., 2016). Though RCA has been used in healthcare to respond to sentinel events since 1994, there is little information on the impact of its use on the rate of medical error. The most common medical errors are those made during medication administration, which is a primary nursing duty. Nursing students are traditionally taught individual responsibility as the primary way to prevent medication errors. There is a lack of understanding of how educational strategies focusing on systems solutions, such as RCA, impact nursing students' ability to administer medications safely.

The Patient Risk Detection Theory (PRDT) states that increased knowledge and improved safety attitudes will positively impact patient safety (Despins, 2014). Increased patient safety and reduction in harm from error is directly related to scores on safety culture surveys such as the *Safety Attitudes Questionnaire* (SAQ), however there is not a reliable and valid tool for measuring safety culture in nursing students. Measuring safe administration of medications and reduction in harm is difficult as outlined in chapter 2. No studies were found that have tested educational interventions such as RCA, to improve nursing student ability to administer medications safely. The *Safe Administration of Medications – Revised Scale* (SAM-R) is the only reliable and valid instrument found to assess student knowledge of safe medication administration in a paper and pencil format.

This study provides data supporting the use of the SAQ with pre-licensure nursing students to assess student safety culture attitudes. Supporting evidence is provided for the use of online educational modules to improve safe medication administration practices. This study also presents the use of the SAM-R in an online, non-proctored format, as well as the use of a modified, shorter version: the *SAM-R with Low Discriminatory Items Removed* (SAM-LDIR). This chapter provides a discussion of the findings from this study, implications, and recommendations for future research.

Sample

The sample of predominately white, female, participants under the age of 30 was similar to that found in the national student nurse population (National League for Nursing, 2014). Though none of the differences between the control and intervention groups regarding demographic data are statistically significantly different, there are some differences that bear

discussion. In Table 4 there is a difference between the number of participants with a "clear idea" of what RCA is between the control (*n*=8) and intervention (*n*=1) group. This difference could have played a role in the outcomes for the study. In addition, though RCA has been required for sentinel event analysis since 1994, and is recommended for inclusion into nursing school curricula, 32% (*n*=35) of the participants in the study had never heard of it, and only 3.4% (*n*=4) had actually participated in a RCA (Table 4). In addition, though the number of participants was 117 (*n*=58 control, 59 intervention) the answers to the demographic questions were not *forced* answers to prevent identification of students by demographic data, so many students did not answer all of the questions. This is reflected in the number of "not reported" responses in Table 7. Students were not asked what school they attend to prevent identification in that manner, and if they were unable to be identified by other responses on the demographics survey and questionnaire, then it was not possible to know what school they attended. This loss of data may have impacted the findings. Data from the students in *Phase One* of the study did not differ significantly from the overall data, so the data were pooled.

Hypothesis I: The SAQ is a valid and reliable test of safety attitudes in senior-level nursing students. The psychometric properties of the SAQ are provided in Chapter 4, however the SAQ had not previously been used with the nursing student population. This study supports that the SAQ is a reliable and valid tool for measuring safety attitudes with pre-licensure, senior level nursing students. The reliability of the SAQ is supported by a sufficiently high Chronbach's $\alpha > 0.98$ (*n*=117), as well as discriminatory values above 0.5. In addition, the six SAQ safety dimensions individually had Cronbach's alpha scores above 0.7 (Table 6)

Construct validity was supported by the similarity of SAQ scores to other studies (Table 6). It was difficult to find studies for comparison due to the wide variety of reporting styles for the SAQ. There is a website listing studies that cite the original Sexton et al. (2006) SAQ article, and a review of the first ten articles on the list gave ten different results regarding the version of SAQ used, the method of scoring, or both. A search of the Internet yielded only one study that had administered the SAQ to students, and none that had administered the SAQ to nursing students (Memorial Hermann Texas Medical Center, 2018).

Concurrent validity for the SAQ in a pre-licensure setting lies in the difference in SAQ scores for the three schools participating in the study (Table 7). The ranking of the SAQ scores for the three schools of nursing in the study is the same as the ranking for their NCLEX pass rate (North Carolina Board Of Nursing, 2017; Tennessee State Board of Nursing, 2017). Schools of nursing might consider administering the SAQ to senior level students and advertising the results. The SAQ is open access and can be downloaded from the website and scored with the instructions. Teaching students to be aware of the availability of the SAQ is an important step in increasing awareness of safety culture. From the results of this study, students interested in a school with high safety culture scores would be more likely to choose the school in WNC over NETN or NCTN. Schools interested in improving safety culture now have the SAQ as a tool for measuring baseline as well as change over time. These results may be confounded by the discovery that the three schools of nursing in this study offered varied forms of credit to students participating in the study. Students receiving extra credit may have been motivated differently than those receiving optional clinical hours.

Additional evidence for the concurrent validity of the SAQ includes the positive linear relationship (p=.01) between the SAQ and the SAM-R, though the magnitude of the relationship is mild ρ=0.2 (n=85) (Figure 4). This correlation suggests that participants with positive safety culture attitudes also have increased knowledge of safe medication administration practices. Studies have shown high safety culture scores are directly related to increased patient safety. Concurrent validity for using the SAQ to measure safety attitudes with nursing students may also be supported by demographic data. Study participants who worked in healthcare demonstrated a lower SAQ score, M=70.1 (16.2) (n=24) than those who did not, M=74.3 (14.0) (n=73), though the difference was not significant. This finding suggests working in healthcare may negatively impact safety attitudes. Participants with experience with RCA had lower mean SAQ scores M=65.8 (SD 9.5) compared to those with no experience with RCA M=74.0 (SD 14.5) (n=90), but the difference was not statistically significant, and is probably not meaningful due to the low number of participants with experience with RCA (n=4). Participants who had never heard of RCA (n=29) had lower mean SAQ scores M=70.2 (13.7) than those who had heard of RCA M=74.6 (14.9) (n=68), however, again there was no significant difference.

The findings from H1 may contribute to understanding of patient safety by demonstrating the reliability and validity of an instrument to measure safety culture in senior level, pre licensure nursing students.

Hypothesis II: Participation in an online Root Cause Analysis education module, as compared to an online education module of standard safe medication administration practices will increase participant safety attitudes for senior-level nursing students as measured by the SAQ (Sexton et al., 2006). This study does not provide supporting evidence for hypothesis two. If the control and

intervention data are pooled, there is a 21% increase between the percent positive pre-module and post-module scores on the SAQ, suggesting that both the "usual education" and education on RCA is effective in improving safety culture attitudes, though without a "no education module" group to compare to, this result is conjecture.

Providing evidence for hypothesis II is complicated by the difficulty with scoring the SAQ. Though instructions for scoring the SAQ are provided by Sexton et al. (2006), the literature demonstrates a wide variety of methods, as well as a lack of information on how to score incomplete items. Only 97 of the 117 (82.9%) pre-module SAQ survey responses were scored because 20 were either completely blank or all answers were marked "not applicable." No instructions were given for how to score "not applicable items" so they were removed from the scoring equation. In the literature, Sexton et al. (2006) recommends analyzing the percentage of positive responses to the SAQ (those equal to or over 75%) however in the literature, studies vary in the cut-off point for "positive scores" with some studies using 65%, others 70% and still others 80% (Memorial Hermann Texas Medical Center, 2018).

The findings from H2 may contribute to understanding of safety culture by demonstrating that online, educational modules may improve safety attitudes.

Hypothesis III: Participation in an online Root Cause Analysis education module, as compared to an online education module of standard safe medication administration practices will increase participant knowledge for senior-level nursing students as measured by the SAM-R (Bravo, 2014). This study provided no evidence supporting this hypothesis, however the concurrent validity of the SAM-R is supported. Scores were significantly higher for those who worked in healthcare M=60.4 (4.2) (n=23) than for those who did not M=56.1 (12.6) n=75 (t_{95}=-

2.5,p<=0.02). This suggests that the clinical experience of administering medications has an impact on knowledge of safe medication administration. It may be that participation in RCA has an impact on safety attitudes, while the usual safe medication administration has an impact on knowledge of safe medication administration practices.

Despite the lack of evidence supporting hypothesis III, additional evidence is provided for the usefulness of the SAM-R with nursing students. This study provides evidence for a modified form of the SAM-R, which takes less time. The SAM-R can take from 1-2 hours to complete and involves a high level of analytical thinking. Bravo (2014) reported that 13 items in the SAM-R had corrected item–total correlation values below 0.1 (2014, Vignette 1, patient and drug; Vignette 3, dose and route; Vignette 4, time; Vignette 5, drug; Vignette 6, dose; Vignette 11, route; Vignette 12, time, and Vignette 13, drug, time, and route). CITC values below 0.3 have a low discriminatory index. The 13 items with low discriminatory value were removed from the SAM-R score and a new score, the SAM-LDIR was calculated. Both scores were converted to percentages for purposes of comparison. Though the SAM-LDIR is 47 items instead of 60, there was no significant difference in the mean scores calculated across time points, and a the correlation between the SAM-R and SAM-LDIR scores was strongly positive, indicating the SAM-LDIR could be used in future studies, though it is unclear how partial items would be removed, given the structure of the test (Appendix B).

The findings from H3 may contribute to improved patient safety by supporting the concurrent validity of the SAM-R, and by providing evidence for the use of a shorter version of the SAM-R, the SAM-LDIR.

In summary, evidence is provided to support the use of the SAQ as a valid and reliable tool for measuring safety attitudes with senior-level nursing students, however there was no evidence to support the efficacy of the RCA intervention on SAQ or SAM-R scores. Additional support for the validity of the SAM-R was provided.

Theoretical Implications

The Patient Risk Detection Theory (PRDT) has been used to guide this study. It is a theoretical framework for how nurses detect and respond to risk signals predicting patient harm (Figure 1). In the PRDT there are two main components that impact patient safety: sensitivity to signal (measured by the SAM-R) and responder bias (measured by the SAQ). The PRDT predicts that better detection of patient risk signals can result in improved patient outcomes (Despins et al., 2010). Factors that influence sensitivity to signal include the level of training and experience of the nurse (Wickens, 2002), as well as an organizational preoccupation with failure that includes ongoing training of staff on how to scan and correctly identify patient risk signals (Despins et al., 2010). Organizations that have adopted the principles of a just culture can proactively manage medical error by using RCA (Despins et al., 2010). This study provides evidence to support that being aware of and responding to risk signals is associated with greater patient safety. Despins et al. (2010) reported nurses who felt they worked in a positive environment were better able to correctly determine that a stimulus did not indicate patient risk than nurses who had a less positive work environment. Nursing students exposed to online patient safety education modules may be less likely to respond to information that is not useful in improving patient outcomes.

The relationship of sensitivity signal to patient harm is further elucidated by the significantly higher SAM-R scores found for the study participants who work in healthcare (Table 4). Nurses who work in healthcare have increased training and knowledge about how to administer medications safely, and thus perform better on the SAM-R. The finding supports the PRDT by providing an additional instrument to measure nursing student knowledge of safe medication administration practices, a crucial component needed for research into the PRDT.

The positive correlation between the SAQ and SAM-R (Figure 4) supports both responder bias and sensitivity to signal as important components in patient safety outcomes. The correlation demonstrates a relationship between positive safety attitudes and the ability to identify patient risk. The SAM-R is a tool that measures ability to differentiate correct and incorrect nursing actions within medication administration vignettes. Despins et al. (2010), utilized the PRDT in an experimental study and found no difference in risk detection ability between groups who either received or did not receive an instructional video on safety issues; similar to the results of this study in which scores on the SAM-R were not significantly different for control and intervention groups. This study provides support for using the SAQ in conjunction with the SAM-R as a measurement paradigm to link safety attitudes and risk detection ability.

Nursing Implications

Recent nursing school graduates are often seen as poorly prepared to take on the challenges of in-patient care and the often overwhelming task of safety administering medications to all patients (Berkow et al., 2009). A survey of student perceptions of why errors are made reported that students felt they were deficient in skills and knowledge related to

medication management (Vaismoradi et al., 2014). In a study of student errors, Henneman et al. (2010), observed students failing to verify the five rights and found students have a poor ability to identify error. The authors concluded that though the five rights are fundamental guidelines, they do not cover the spectrum of medication safety. In a recent IOM report, *The Future of Nursing: Leading Change, Advancing Health*, patient safety experts called for new strategies for learning fundamental concepts such as medication administration, recommending nursing educators move away from memorization and curricula that is overwhelmed with increasing content (IOM, 2010).

RCA should be incorporated into nursing curricula, which has been recommended as part of the Quality and Safety Education for Nursing (QSEN) curriculum reform project funded by the Robert Wood Johnson Foundation. The goal of the QSEN project, began in 2005, was to address prepare future nurses with the knowledge, skills, and attitudes (KSAs) necessary to participate in continuous quality improvement of the safety of healthcare systems (Cronenwett et al., 2007). QSEN standards include the expectation that students will participate in error analysis and use organizational error reporting systems for near miss and error reporting (Cronenwett et al., 2007). Thirty percent of the participants in this study stated they had never heard of RCA, and only four had participated in an RCA (Table 4). A study of nursing curricula reported the topics least likely to be in the curriculum were processes used in analyzing the causes of errors. In a study by Sullivan et al. (2009), 15% of the students surveyed reported that these processes were not covered in any learning venue. Students ranked safety as one of the most important competencies, second only to patient-centered care (Sullivan et al., 2009). This study provides

support for teaching RCA to pre-licensure nursing students as a strategy for preparing new nurses for a safer work place.

A culture of blame, rigid hierarchies, and communication problems continue to permeate nursing (Barnsteiner & Disch, 2012). There is a lack of commitment by organizations to establishing a culture of safety (AHRQ, 2012). In this study, the school specific results of the SAQ suggest that a culture of blame continues to dominate schools of nursing (Table 7). Nurses involved in error tend to blame themselves, and are often criticized by coworkers and punished by healthcare agencies; this is also true of nursing students. A survey study found students were fearful of the reporting process (Reid-Searl et al., 2008). Instead of focusing on blame and shame, when a student makes an error, educators should direct students into RCA. When error is identified, it is interrupted and corrected (Henneman et al., 2010). Participation in RCA can help shift focus from individual accountability to systems level thinking. According to Lighter and Fair (2004), "successful RCA culminates in the identification of underlying causes of problems in the process" (p. 89). It allows focus on potential solutions other than "being more careful."

One of the biggest hurdles to reducing medication error is measurement. Insight has been provided by this study into measurement issues with both the SAQ and the SAM-R. Schools of nursing should use the SAM-R to measure student medication administration abilities. Without valid and reliable measures of safe medication administration there is no ability of nurse educators to share results between schools or even between cohorts. Using a valid and reliable tool such as the SAM-R would provide schools of nursing and researchers with a common language to communicate about student abilities. This study supports that use of an instrument

like the SAM-R can yield valuable data about the ability of nursing students to safely administer medications.

Nursing school faculty and administration should consider self-assessment with measures of safety culture as evidenced by the correlation of SAQ scores with NCLEX pass rates. Measuring safety culture is the first step towards culture change. RCA was used to identify factors involved in a student medication error (Dolansky et al., 2013), and environmental, personal, unit communication and culture, and education were all found to play a role. A culture of safety has been linked to reduced harm to patients and improved patient outcomes (Norden-Hagg et al., 2010). Potential nursing students should request safety culture scores when considering schools of nursing, and schools of nursing should consider utilizing high safety attitudes scores in advertising and promoting the hiring of new graduates. As nursing students enter the work force, they should request high quality education on error prevention, and seek out healthcare organizations with high safety culture scores. When using the SAQ, it is important to follow the scoring guidelines and to reference previously published research on the SAQ, to ensure future data gathered is obtained and reported in a way that allows comparison.

Ongoing, high quality education is necessary for safe medication administration. A model developed by Valdez et al. (2013), provides a basis for identification of error-prone conditions, revealing factors such as performance and knowledge deficits may cause poor adherence to the "five rights" (2013). The significant increase in SAM-R scores related to work experience suggests that simulated clinical experiences will improve knowledge of safe medication administration. In addition, though causation has not been determined, the positive correlation between SAM-R and SAQ scores supports the use of both tools in conjunction. Using both

instruments may provide additional information about the needs of students, with an additional goal of gaining predictive value from continued co-administration.

Strengths and Limitations

The strengths of this study include data supporting the use of RCA as an educational intervention. Despite the use of RCA for sentinel events since 1994 and the recommendation that RCA be incorporated into nursing school curricula, no research was found to support the use of RCA as a strategy to reduce medication error. This study provides the first data supporting the use of RCA as an educational intervention with the potential to improve safety culture and safe medication administration knowledge. The SAQ has been used to measure safety attitudes since 2006 in over 100 studies, however it has never been used to measure safety attitudes in nursing students. In addition, no studies were found reporting nursing student safety attitudes as measured by any other tool. Finally, though data on the reliability and validity of the SAM-R has been published, this study presents the first time the SAM-R has been used in a pre/post test study. This is also the first use of the SAM-R in an online setting. In addition, few studies in nursing are multi-site, with most being small, single site studies with convenience samples. This study is one of few randomized, controlled trials at multiple schools of nursing.

Assumptions inherent to this study include that nursing students work hard and would do anything to prevent error. Nursing students do not mean to make errors and will participate in activities designed to reduce error and harm to patients. A limitation of the study is that these assumptions are not true. It is possible that the students who participated did not work hard, and did not care about error prevention. There is no way to know if the students who participated in the online portion of the study did so according to directions. They may have used additional

resources including other students, access of Bravo's (2014) SAM-R dissertation containing the answers to the test, the Internet, or other unknown resources. They may have been influenced by unknown factors prior to or while taking the survey and tests. There is also now way to know if the students actually viewed the educational modules or paid attention during the in-person educational sessions. None of the answer items in any of the surveys or tests were *forced* so students could have clicked on each instrument without filling it out, or filled it out randomly to receive course credit. The success of this study is predicated on the assumption that students care, and there is no way to know if they did, however it is possible to link questions embedded in the online modules to a study data collection tool, making it possible to assess student engagement and participation in online video modules in the future.

There are several aspects to study design that limit this study. Only one intervention was studied. RCA may influence a variable that was not measured. In addition, the lack of a "no education" group means the increased scores seen after viewing the education modules may be a result of student maturation or of some other, unmeasured factor. The first ten participants had a different experience than the other 107 participants. The change from a seated, in-class study to an online study may make skew the results, though the data were analyzed with and without *Phase One* data to mitigate this limitation. Another limitation is time. The effects of the intervention may only last until the 30-day post module time-point. An unanticipated limitation was the lack of support for the REDCap study platform. The platform is complex and the support personnel at the institution at which the platform was provided were not always able to assist with correct study design. Trial and error was required to achieve the correct flow of the study, which may have impact on the results. It was difficult to link pre-module, post-module and 30-

day post module results due to these difficulties, and some data that would have been available for ANOVA analysis was lost due to lack of identification.

Design of the instruments was another limitation. The demographic survey did not ask for the student's school, and answer choices were not *forced* to protect student identity, however this led to many non-reported answers. There is no way to know if students answered honestly when they did respond. In addition, it is of concern that many students in nursing school identified themselves as RNs, and had difficulty determining their current level of education (students in their final year of nursing school variously reported their education status as: 3-years of education, 4-years of education, high school only).

Though the study authors provide directions for administering the SAQ, it had not been previously given to nursing students. Due to the novelty of the situation, no additional instructions were given to assist students in determining what facility should be assessed with the tool. Though the hospital at which student nurses are engaged in clinical experiences may qualify as an HRO, other factors may be responsible for their ability to respond appropriately to stimuli, such as fatigue or staffing. In addition, the clinical site most likely changed over time, and even the healthcare institution at which the student was placed may have changed between SAQ surveys. A better approach might have been to direct students to score the environment at their school, or to only administer the first two dimensions of teamwork and safety climate. In addition, it was unclear how to score SAQ responses that were blank or "not applicable". Ultimately the PI decided to leave out these responses, which may skew the results or cause a result that will not generalize. Though statistical analysis of the SAQ results support the SAQ as a valid and reliable tool with nursing students, this may not be the case, and the results may not

generalize to all pre-licensure nursing students. Finally, the SAQ may not be sensitive enough to measure changes in safety attitudes. It is possible that a large enough proportion of students had a maximal score for the pre-module student that measuring effective change would not be possible.

Limitations surrounding the SAM-R include that it had not been used in a pre/post test study design. The length and complexity of the SAM-R may have caused student fatigue with the test itself. The SAM-R can take up to two hours to complete. In addition there were items on the SAM-R, which had low discriminatory value. Frustration with unclear wording in these items may have impacted performance on other items. Removal of these items for scoring did not cause a change in results. This focuses the participant on individual culpability and away from identification of systems level root causes. Another external threat to validity includes the interaction effect of testing; meaning some interaction between the pre-module surveys and tests and the intervention may cause a result that will not generalize to an untested population.

Attrition was another major limitation to the study. The study called for recruitment of 90 participants for a medium effect side and sufficient power. Though 125 participants were recruited, only 117 participated, and of those only 20% finished all time points. The small sample size for the final time point makes it difficult to make significant conclusions that are generalizable to the population of pre-licensure nursing students. There are several possible explanations for this retention rate. One is that the study was time consuming, taking 8 hours over 6 weeks to complete, requiring students to keep track of passwords and logins. Students were sent reminder emails with direct links to the study, however the life of a senior-level nursing student is already complicated and it is not surprising that students dropped out as the

semester progressed. Despite use of the snowball method for recruitment, no students outside the three schools described elected to participate.

Providing incentives for students to finish the study, such as gift cards or payment may increase retention, but also may contribute to response bias. It is possible that students who were motivated to complete the study had stronger opinions about safety attitudes and/or increased knowledge of safe medication administration. Due to the anonymous nature of this study, it is not possible to contact participants to determine response bias. An analysis of these factors did not show any link, however the small sample size makes it difficult to generalize the results.

Recommendations for Future Research

Based on the results of this study and a review of the literature, the following recommendations are made for future research.

Nurses are expected to report errors once they enter the workforce, yet they are not taught to identify, report, and analyze errors in nursing school (Cooper, 2013). Students report having never been exposed to an error or near-miss event, though they are aware of protocols surrounding errors (Koohestani & Baghcheghi, 2009). Students report a fear of consequences related to error reporting (Antonow et al., 2000; Koohestani & Baghcheghi, 2009; Sears, Goldsworthy & Goodman, 2009). Studies have found that instructor management and attitude to error plays a big role in whether or not students will continue to report errors (Koohestani & Baghcheghi, 2009; Lin et al., 2013). When students hide errors, it hinders the process of error recovery in multiple ways – the data from the error is lost as well as a teaching/learning opportunity (Andrew & Mansour, 2014; Dunn, 2014; Koohestani & Baghcheghi, 2009; Lin et al., 2013)

Nursing students should receive basic information about safety and reporting in their first year of education (Gregory et al., 2007). Error reporting and near-miss reporting should be embedded into a safety culture so students learn and experience transparency from the beginning of their educational experiences (Cooper, 2013). Student data related to near misses and medication errors needs to be collected, aggregated, analyzed and acted on by educators in partnership with clinical units (Gregory et al., 2007).

A literature review of educational strategies for preventing medication error by Miller et al. (2016) stated that all of the research in the review made recommendations for instructional strategies to reduce or prevent student medication error, including use of Root Cause Analysis, communication strategies, situation monitoring, use of unfolding case studies, simulation and clinical experiences with error reporting, and just cultures. In a case study using RCA to explore a nursing student medication error (Dolansky et al., 2013), the authors assert that use of RCA promotes a fair and just culture and helps nursing students and faculty identify problems and solutions in the systems in which they work. Causal factors for the medication error identified were environmental, personal, unit communication and culture, and education (Dolansky et al., 2013). RCA should be added to every nursing school curricula. Students should be taught about RCA and involved in simulated RCA experiences. RCA should be used in schools of nursing to deal with student errors and those errors should be reported to a national database.

A culture of safety has been linked to a reduction in harm to patients and improved patient outcomes (Norden-Hagg et al., 2010). Safety culture should be assessed at all schools of nursing. The SAQ, or some other safety attitudes measurement tool should be given to all senior level-nursing students, and scoring of the SAQ should follow the authors recommendations for

comparison to the literature. All results should be analyzed and reported in concordance with previously published results. Schools of nursing should publish results of SAQ assessments and seek out educational interventions improve safety culture attitudes.

Many tools are available for direct observation of medication administration, however validity evidence and description of educational outcomes are scarce (Gonzales, 2010). Standardized, valid, and reliable tools should be used to measure knowledge of safe medication administration, and the results should be aggregated and shared within and between schools of nursing as well as with the healthcare institutions that support them. Nurse researchers should continue to revise, expand, and create additional versions of the SAM-R.

Online modules have been shown to be as effective as traditional classroom education in a number of studies. A meta-analysis of 45 studies found that students in online courses performed better than those receiving traditional, face-to-face instruction (Means et al., 2013). Schools of nursing should increase utilization of low fidelity simulation like online modules to allow students self-paced learning in a private, safe environment. An example is to create a video in which actual physicians, nurses, pharmacists and a patient advocate run through RCA of real medication error scenarios. Online modules need to be interactive to support student engagement and should be designed to collect qualitative and quantitative data for revision and research.

There should be a focus on predictive factors. Research should focus on tools to determine factors that predispose nurses to make medication errors. Gonzales (2010) used the PRDT as a conceptual framework in a study focused on the importance of internal factors in nurse ability to respond to patient risk signals. Gonzales used the Domain-Specific Risk-Taking and Risk Perception Scale (DOSPERT; Blais & Weber, 2006), to measures risk propensity in

healthcare decisions in a clinical environment and found that nursing students who are risk takers are not as skilled at identification of medication errors and are thus less safe.

Nurses and nurse educators should engage in rigorous research with valid and reliable instruments. Conducting large, multi-site studies utilizing experimental design will expand nursing knowledge. Research design needs to be purposive and not convenient. Researchers must resist using the classroom in front of them at the risk of missing out on generalizable results. Resist using easily available tools and seek out previously published instruments for measurement. Seek out grant funding to fund nurse participation in studies. Their time is valuable and should be valued.

Conclusion

Harm to patients from medication errors has not been reduced in the past 15 years, despite significant efforts to the contrary (Landrigan et al., 2010). The profession of nursing has the potential to play a major role in the reduction of error; however, the role of the nurse in medication error reduction remains elusive. Nurses and nursing students make medication errors due to deficits in knowledge, calculations skills, and performance, yet research efforts directed at these problem areas have affected no change (Lee & Lin, 2013; Pauly-O'Neill, 2009). The Patient Risk Detection Theory (PRDT) proposes that nurse training involving reporting and analyzing error will reduce harm to patients by improving student nurses' sensitivity to signals indicating patient risk. In addition, student nurses will be more willing to respond to signals (responder bias).

Nurses are no exception to the rule when it comes to the inevitability of error; however, this study provides support for error mitigation. This study provides the first evidence for the use

of RCA training as a tool to improve nursing student safety attitudes and knowledge of safe medication administration – two factors that make it less likely the nursing student will make an error that harms a patient. To reduce harm to patients, RCA training has been increasingly utilized by health care institutions, however there have been no studies to examine the impact of RCA on error prevention until now. This study provides support for adding RCA to the list of interventions discussed by Robert Wachter (2012) in Chapter One, and provides much needed evidence for an educational intervention that will improve student nurse ability to detect and respond to patient risk signals. Student nurses eventually become nurses; however, both work directly with patients. Reducing the number of medication errors made by student nurses will thereby reduce harm to patients.

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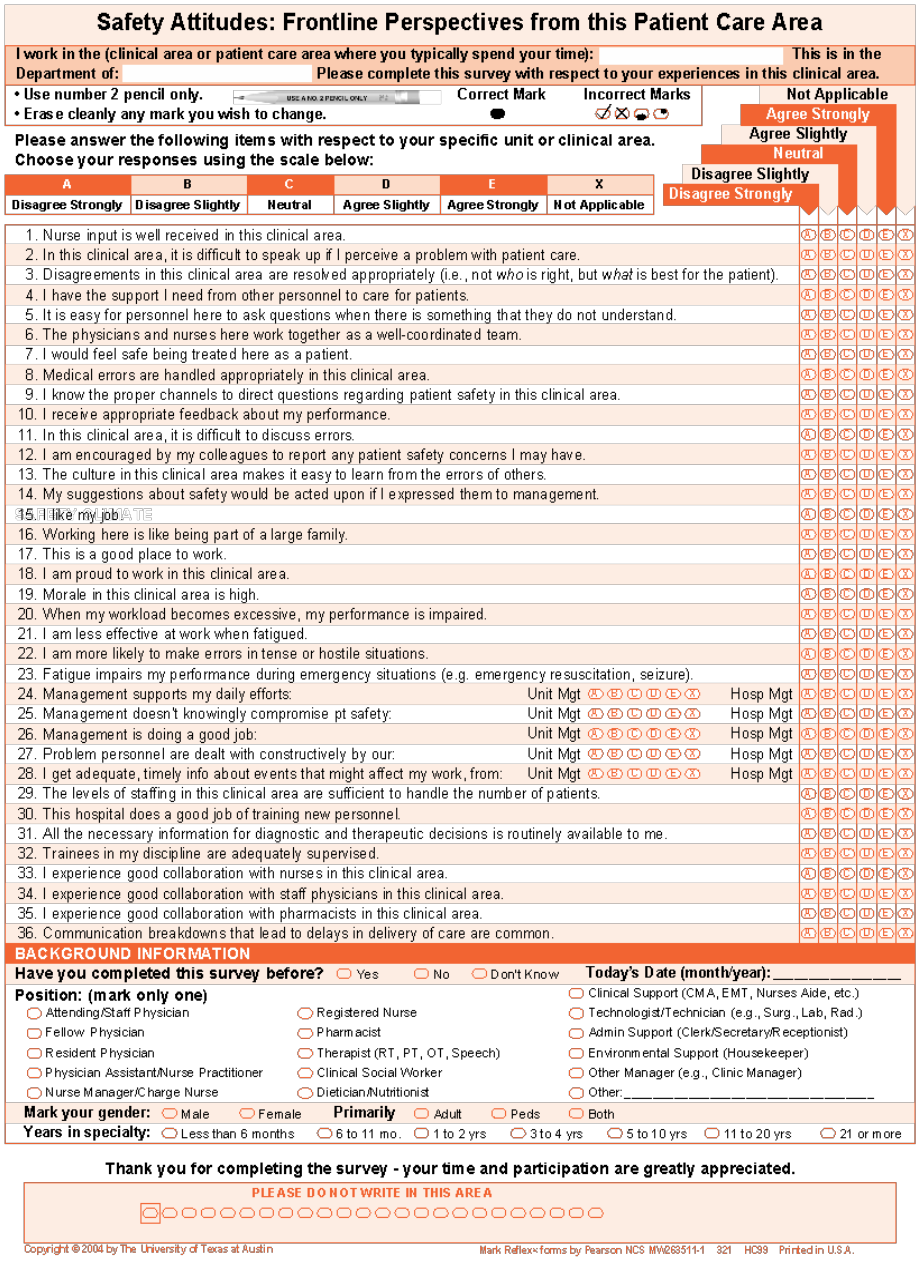
APPENDICES

Appendix A

Safety Attitudes Questionnaire



Safety Attitudes: Frontline Perspectives from this Patient Care Area

I work in the (clinical area or patient care area where you typically spend your time): This is in the Department of: Please complete this survey with respect to your experiences in this clinical area.

- Use number 2 pencil only.
- Erase cleanly any mark you wish to change.

Correct Mark ● Incorrect Marks ✓ ✗ ◒ ◔

Please answer the following items with respect to your specific unit or clinical area.
Choose your responses using the scale below:

A	B	C	D	E	X
Disagree Strongly	Disagree Slightly	Neutral	Agree Slightly	Agree Strongly	Not Applicable

Not Applicable
Agree Strongly
Agree Slightly
Neutral
Disagree Slightly
Disagree Strongly

1. Nurse input is well received in this clinical area.
2. In this clinical area, it is difficult to speak up if I perceive a problem with patient care.
3. Disagreements in this clinical area are resolved appropriately (i.e., not *who* is right, but *what* is best for the patient).
4. I have the support I need from other personnel to care for patients.
5. It is easy for personnel here to ask questions when there is something that they do not understand.
6. The physicians and nurses here work together as a well-coordinated team.
7. I would feel safe being treated here as a patient.
8. Medical errors are handled appropriately in this clinical area.
9. I know the proper channels to direct questions regarding patient safety in this clinical area.
10. I receive appropriate feedback about my performance.
11. In this clinical area, it is difficult to discuss errors.
12. I am encouraged by my colleagues to report any patient safety concerns I may have.
13. The culture in this clinical area makes it easy to learn from the errors of others.
14. My suggestions about safety would be acted upon if I expressed them to management.
15. I like my job.
16. Working here is like being part of a large family.
17. This is a good place to work.
18. I am proud to work in this clinical area.
19. Morale in this clinical area is high.
20. When my workload becomes excessive, my performance is impaired.
21. I am less effective at work when fatigued.
22. I am more likely to make errors in tense or hostile situations.
23. Fatigue impairs my performance during emergency situations (e.g. emergency resuscitation, seizure).
24. Management supports my daily efforts: Unit Mgt Hosp Mgt
25. Management doesn't knowingly compromise pt safety: Unit Mgt Hosp Mgt
26. Management is doing a good job: Unit Mgt Hosp Mgt
27. Problem personnel are dealt with constructively by our: Unit Mgt Hosp Mgt
28. I get adequate, timely info about events that might affect my work, from: Unit Mgt Hosp Mgt
29. The levels of staffing in this clinical area are sufficient to handle the number of patients.
30. This hospital does a good job of training new personnel.
31. All the necessary information for diagnostic and therapeutic decisions is routinely available to me.
32. Trainees in my discipline are adequately supervised.
33. I experience good collaboration with nurses in this clinical area.
34. I experience good collaboration with staff physicians in this clinical area.
35. I experience good collaboration with pharmacists in this clinical area.
36. Communication breakdowns that lead to delays in delivery of care are common.

BACKGROUND INFORMATION

Have you completed this survey before? Yes No Don't Know Today's Date (month/year): _____

Position: (mark only one)

- Attending/Staff Physician
- Fellow Physician
- Resident Physician
- Physician Assistant/Nurse Practitioner
- Nurse Manager/Charge Nurse
- Registered Nurse
- Pharmacist
- Therapist (RT, PT, OT, Speech)
- Clinical Social Worker
- Dietician/Nutritionist
- Clinical Support (CMA, EMT, Nurses Aide, etc.)
- Technologist/Technician (e.g., Surg., Lab, Rad.)
- Admin Support (Clerk/Secretary/Receptionist)
- Environmental Support (Housekeeper)
- Other Manager (e.g., Clinic Manager)
- Other: _____

Mark your gender: Male Female Primarily Adult Peds Both

Years in specialty: Less than 6 months 6 to 11 mo. 1 to 2 yrs 3 to 4 yrs 5 to 10 yrs 11 to 20 yrs 21 or more

Thank you for completing the survey - your time and participation are greatly appreciated.

PLEASE DO NOT WRITE IN THIS AREA

Mark Reflex× forms by Pearson NCS MW263511-1 321 HC39 Printed in U.S.A.

Appendix B

Revised Safe Administration of Medications Scale

Please note: the SAM-R scale study was conducted in an on-line format (Blackboard). This paper copy is provided to you as an example of what the tool would look like in a paper/pencil format. For this KEY - the "X" denotes an error on the part of the nurse in the vignette.

Instructions for completion of the Safe Administration of Medications Scale (SAM-R)

This scale is designed to assess your ability to apply the five rights of administering medication safely.

1. Attached you will find five Clinical Cases that incorporate a total o f fourteen vignettes of nurses administering medications.

2. Each Case incorporates two or three vignettes that describe the administration o f medication by a nurse to a hospitalized patient.

3. Read each vignette and determine if the actions taken by the nurse, in the process of administering the medication is the correct action or an incorrect action.

4. Use the Case response table associated with each vignette to indicate a correct action by placing "yes" in the corresponding box and "no" if the action the nurse took was incorrect.

   Item #

   Case I Right Patient Right Drug Right Dose Right Time Right Route

   Vignette I

   In the space provided describe a short narrative description of what the nurse should have done, if you determine the action the nurse took was incorrect. If all actions were correct write No Errors.

   Provide correct nursing action for each identified error.

   _____
   _____
   _____
   _____
   _____

   Do Not Put Your Name on the Forms.

Case 1

Patient: Gary Molesom

Sex: Male

Age: 75 years old

Allergies: Midazolam (Versed)

Date: 6/12/12

Hospital ID #29475963

Chief Complaint

Mr. Molesom presents to the Emergency Department with a complaint of pain in the right upper quandrant. He states that the pain came on suddenly and it has not gotten any better over the last three hours. *Dr. J. Thomas*

History & Physical Exam

Mr. Molesom appears to be acutely ill and in a great deal of discomfort. He has a low-grade fever of 101.2 degrees Fahrenheit. He describes a recent history of being bothered by fatty foods, and also feels discomfort and mild nausea after a meal. Admission weight/height: 76 kg, 182.5cm. *Dr. J. Thomas*

Diagnosis: Acute Gallbladder Attack

Physician Orders

1. Admit to inpatient unit, room #D6548
2. Clear liquids, NPO after midnight
3. Laparoscopic cholecystectomy
4. Ultrasound scan of upper and lower abdomen
5. Labs: WBC, AST, LD, serum bilirubin level
6. D5 NS with 20 mEq KCL/liter at 60 ml/hr

Dr. J. Thomas

Medication Orders:

1. Demerol 75mg IM q 3-4 hours PRN
2. Hydroxyzine 25mg IM on call to O.R.

Dr. J. Thomas

Case 1. Vignette 1

Katherine Jones is the nurse caring for Mr. Molesom. When she arrived on the floor at the start of her shift, Mr. Molesom activated his call light and requested pain medication. Ms. Jones looked at the Electronic Medical Record (EMR) and noted that it had been four hours since Mr. Molesom's last pain medication. She then did the following:
Nurse Jones accessed the Demerol from the narcotics cabinet. She selected Demerol for injection, 100 mg/ml. She drew up 75 mg (0.75ml) in a syringe and checked the dose with another nurse. She also had the other nurse witness her disposal of the remaining Demerol.

RN Jones proceeded to the patient room, introduced herself to Mr. Molesom and let him know that she would like to take an additional set of vital signs before giving his pain medication to make sure that nothing had changed since his last set of routine vitals. While obtaining the set of vitals, RN Jones set the syringe filled with Demerol on the patient's bedside table. RN Jones obtained the following values T-100.4, P - 62, R - 14, BP - 87/42. RN Jones reached for the patient's ID band to verify his name by looking at his name and ID#.

Before she could locate the patient's armband her hospital-assigned mobile cell phone rang. It was Dr. Thomas calling to check on Mr. Molesom. He wanted RN Jones to access the patient's electronic medical record and read off the last set of lab work values that were obtained on Mr. Molesom. RN Jones moved to the hallway to access the electronic medical record. After retrieving the lab values for the M.D., RN Jones returned to Mr. Molesom's room and re-verified that the syringe contained 0.75mL. She asked the patient to position himself on his left side for ease of delivery. She then gave the injection in his right ventrogluteal muscle.

Item #	1	2	3	4	5
Case 1	Right Patient	Right Drug	Right Dose	Right Time	Right Route
Vignette 1	X			X	

Provide correct nursing action for each identified error

_____
_____
_____
_____
_____

Go To Next Page

Gary Molesom
ID #29475963

Case 1. Vignette 2

At 10:00AM the OR called for Mr. Molesom and Nurse Jones prepared his pre-op medication. She had a vial of Hydralazine 20mg/ml. She drew up 1.25ml, checked his armband and ID# against the data in the EMR and gave the injection in his left ventrogluteal muscle.

Item #	1	2	3	4	5
Case 1	Right Patient	Right Drug	Right Dose	Right Time	Right Route
Vignette 2		X			

Provide correct nursing action for each identified error

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_____

End of Case 1

Case 2

Patient: Peter Johnson

Sex: Male

Age: 5 years old

Allergies: pollen, dust mites & molds

Date: 5/02/12

Hospital ID#39294023

Chief Complaint

Peter Johnson was brought to the emergency room by his mother at 2:00pm. His mother states that he was playing outside with some children in the neighborhood. He came inside because he was having difficulty breathing. She called the pediatrician. The pediatrician told her to bring Peter to the emergency department immediately.

History & Physical Exam

Peter is a five-year-old African American male, sitting in mother's lap, presenting with respiratory rate of 36/minute, heart rate of 132, pulse oximetry reading of 88% on room air, substernal retractions, bilateral inspiratory and expiratory wheezing on auscultation. Peter has a history of allergies to pollen, dust mites and molds. He was admitted to the hospital six months ago with similar symptoms and was diagnosed with asthma. During that hospitalization, Peter's breathing status was difficult to manage and he needed ventilator therapy for 48 hours. This is his second significant episode of difficulty breathing since his diagnosis. He has also had milder bouts of asthma that were managed at home with an albuterol inhaler. *J Thomas M.D.*

Diagnosis: Status Asthmaticus **Admission weight/height**: 16 kg, 108 cm

Physician Orders

Admit to Pediatric Critical Care Step-down Unit: Room D123 @ 3:30pm

Bedrest or in mother's lap

02 2L/min via nasal cannula Keep 02 sat >95%

Pulse oximetry

Arterial blood gasses (done in ER)

Chest x-ray (done in ER)

D5 1/4 NS with 20 mEq KCL/liter at 70 cc/hr

Call physician for increased respiratory distress or no improvement after the third dose of Albuterol

NPO, Monitor intake and output q4 hrs and daily weights. *J.Thomas M.D.*

Medications

Nebulized albuterol with 02 @6 liters flow 0.15mg/kg/dose (max 5mg/dose) every 20 minutes up to 1 hour (Done by Respiratory Therapist)

Prednisone 16mg po QID (0800,1400, 2000, 0200)

25mg/kg/dose Magnesium Sulfate in 50mL D5 NS IVPB to run over 2 hours x one dose
J. Thomas M.D.

Go To Next Page

Peter Johnson

ID #39294023

Case 2. Vignette 3

Laura Stone is the nurse assigned to care for Peter Johnson. She reviews the orders that came with Peter when he was transferred from the Emergency room at 3:30pm. Peter arrived on the unit with an IV in place and the following information on the label.

Peter Johnson	Rm: Pediatric D123
Hospital ID #39294023	
Magnesium Sulfate : 1 gram/50mL D5 NS	
IV Rate: 10 mL/hour	
Date: 5/02/12 Expires: 5/03/12	

The nurse checks the IV label against the EMR and determines it is what has been ordered. The IV site is soft, dressing is dry and intact and medication is compatible with IV fluid and KCL. She checks the IV pump for this medication and determines that it is set at 10 mL/hr to deliver the drug over 120 minutes.

Item #	1	2	3	4	5
Case 2	Right Patient	Right Drug	Right Dose	Right Time	Right Route
Vignette 3	X				

Provide correct nursing action for each identified error

_____
_____
_____
_____
_____

Go To Next Page
Peter Johnson

ID #39294023

Case 2. Vignette 4

At 4:00pm, Nurse Stone prepares to give Peter his prednisone. The prednisone comes in liquid version and the label reads Prednisone 5mg/ml. She verifies the label on the liquid medication against the EMR order. The nurse uses a 10mL oral syringe and draws up 6.2ml. She checks his armband for name and ID# and proceeds to give the prednisone to Peter while his mother holds him across her lap. RN Stone administers the medication orally. Peter spits out the medication.

Item #	1	2	3	4	5
Case 2	Right Patient	Right Drug	Right Dose	Right Time	Right Route
Vignette 4			X		

Provide correct nursing action for each identified error

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Go To Next Page

Peter Johnson

ID #39294023

Case 2. Vignette 5

The nurse notifies the doctor and uses SBAR technique to report the situation that just happened as she was attempting to deliver the oral Prednisone to Peter. The MD changes the order to: Methylprednisolone 1mg/kg/day IV now and then 1 mg/kg/day, divided dose, q 12h. *J. Thomas M.D.*

Pharmacy sends up a vial in a plastic bag labeled Peter James ID# 28769233. The vial provides 50mg/ml. The nurse determines Methylprednisolone is compatible with Magnesium Sulfate, verifies the new order in the EMR, draws up 0.5 ml, checks the patient's armband and injects it slowly into the IV line port over five minutes.

Nurse Stone recognizes that she needs to complete an incident report on the oral Prednisone that was not delivered as per the doctor's original order. She accesses the facilities on-line incident report system to complete this incident report.

Item #	1	2	3	4	5
Case 2	Right Patient	Right Drug	Right Dose	Right Time	Right Route
Vignette 5	X		X		

Provide correct nursing action for each identified error

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End of Case 2

Case 3 Patient: Jason Hardy

Sex: Male

Age: 1 week old

Allergies: None Known

Date: 4/24/12

Hospital ID#5838298

Chief Complaint: Mother states that Jason has "not been eating well, he falls asleep after only a few minutes of breast feeding and he has fewer wet diapers." "He just doesn't seem right, I wonder if I should give him formula instead of breast feeding." *J. Horton, M.D.*

History & Physical Exam

Jason was born on April 17th, 2012 at 5:37am, at Thomasville Community Hospital. He weighed 7lbs. 9oz. He was diagnosed with a ventricular septal defect (VSD) and referred to a cardiologist for further diagnostic studies. He was discharged to home on April 18, 2012 and has an appointment with a cardiologist scheduled for May 2nd, 2012. Over a period of several days, his mother noted that his breathing was more rapid and he was falling asleep after only a few minutes of breast-feeding. He also has had fewer wet diapers. She called the cardiologist and he admitted Jason to Children's Medical Center for evaluation. He was diagnosed with mild congestive heart failure, tachypnea (50-70 breaths/minute) and decreased urine output. He was scheduled for a cardiac catheterization. *J.Horton, M.D.*

Current Weight: 7 lbs 8oz (3.4 kg) **Current Length**: 50 cm

4/24/12 Progress Note

Jason had a cardiac catheterization on 4/24/12, and has just returned to the unit. He is sleeping but will be able to resume breastfeeding when he wakes up. His mother has been instructed to keep his right leg straight, and notify the nurses if he has any bleeding from his pressure bandage. *J.Horton, M.D.*

Post-catheterization orders:

1. Admit to cardiac step-down unit
2. Diagnosis: VSD
3. Status: Post catheterization (right femoral)
4. Condition stable
5. Diet: breast-feeding

6. Daily weights
7. Intake & output
8. 02 @ 2L/min per nasal cannula
9. Observe pressure dressing for bleeding, keep leg straight
10. Check pedal pulses in both lower extremities with vital signs
11. Monitor vital signs q/15 minutes for 1st hour, then q 1hr. *J.Horton, M.D.*

Medication Orders:

Furosemide 1mg/kg PO stat & then q12 hrs (available stock: 10 mg/mL)

Captopril 0.05 mg/kg/day PO stat for first dose then divided q8hrs (available stock: 0.75mg/ml_)

Digoxin 8 mcg/kg PO stat & then qd (available stock: elixir 50 mcg/mL)

J.Horton, M.D.

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Jason Hardy

ID #5838298

Case 3. Vignette 6

Carol Jones RN is the nurse assigned to care for Jason. Jason has been admitted to the cardiac ICU step-down unit after his cardiac catheterization. It is 9:45am.

The nurse does an initial assessment with the following findings. Mother holding & breastfeeding infant, bilateral pedal pulses present with apical heart rate 124, good capillary refill, right foot slightly cooler than left foot, no edema, dressing dry and intact over right groin area. Informed mother of need to keep affected leg straight and notify nurse of any bleeding or color changes in right leg or foot.

The nurse prepares to give Stat Medications. The following information is on the label for Jason's first dose of Captopril.

Jason Hardy	Bed 2
Hospital ID#5838298	
Captopril Elixir 0.75 mg/mL	
Expiration 4/26/12	

Medications are available on the unit at 10:00am. The nurse checks the Captopril medication label against the original order. She calculates the Captopril dose for Jason and determines she needs to administer 0.22mL. She informs the mother of the medication she is giving, checks Jason's apical pulse for 60 seconds (apical heart rate is 120) and checks his armband and ID#. She then administers the medication PO using an oral syringe.

Item #	1	2	3	4	5
Case 3	Right Patient	Right Drug	Right Dose	Right Time	Right Route

Vignette 6

Provide correct nursing action for each identified error

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_____

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Jason Hardy

ID #5838298

Case 3. Vignette 7

It is now lunchtime and Carol Jones, RN, has promised to meet a co-worker in the cafeteria at 12:05PM for lunch. She glances at Jason's EMR and decides to give the scheduled Furosemide dose before going off the unit for lunch. Carol returns to Jason's room with 3.4 mL of Furosemide, rechecks Jason's armband & ID# against the EMR and administers the medication orally. Jason is resting quietly in his mother's arms. Carol lets the mother know she is going to lunch and will be back by 1PM.

Item #	1	2	3	4	5
Case 3	Right Patient	Right Drug	Right Dose	Right Time	Right Route
Vignette 7			X	X	

Provide correct nursing action for each identified error

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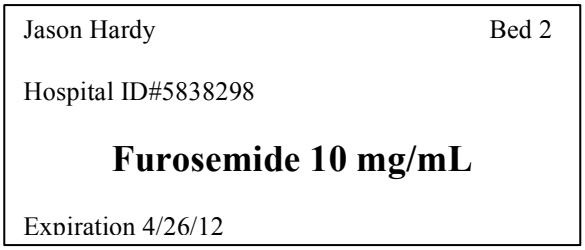
Go To Next Page

Jason Hardy

ID #5838298

Case 3. Vignette 8

Nurse Philips arrives on the unit to do her 7:00pm - 7:00am shift. She gets report from Carol Jones who is ending her shift. “Jason is a 1-week-old infant who had a cardiac catheterization this AM. Mom is at the bedside and she is breastfeeding him. His heart rate has been 120-126 beats/minute. He has had 6 wet diapers.” At 10:00pm Nurse Philips prepares his Furosemide.



Nurse Philips checks the medication sheet with the EMR. She notes that Furosemide was ordered stat at 10:00am but given at 12:00 noon. Since the order stated q 12 hours she plans to wait until 12:00 midnight to give the second dose. At midnight nurse Philips calculates the dosage and draws up 0.16mL in an oral syringe. She enters the patient room and sees that both the patient and his mother are sleeping. The nurse gently rouses the patient, checks Jason’s armband and ID# against the EMR and administers the medication orally.

Item #	1	2	3	4	5
Case 3	Right Patient	Right Drug	Right Dose	Right Time	Right Route
Vignette 8			X		

Provide correct nursing action for each identified error

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_____

End of Case
Case 4

Patient: Mr. James Jones

Sex: Male

Age: 53

Allergies: None Known

Date: 10/02/12

Hospital ID#39294023

Chief Complaint

Mr. James Jones arrived in the emergency room at 8:00AM, with a painful and slightly swollen right calf. He stated: "My leg began to feel sore yesterday while I was at work. It seems to be swollen and feels warm." *Dr. G. Jackson*

History & Physical Exam

Mr. Jones states that his is a bricklayer and he fell three feet from a scaffolding two days ago. At the time of the injury, his right leg hurt a little but not enough to stop working. In comparison to his left calf, his right calf is slightly swollen, warn and red. This is the first time he has experienced these symptoms. He is being treated for arthritis of both hands, but states "this pain is different." Mr. Jones was hospitalized three months ago for gallbladder surgery three and had an uneventful stay. He has no known history of thrombosis. *Dr. G. Jackson*

Admission weight - 72.5 kg. **Admission height** - 175 cm

Diagnosis: Deep Vein Thrombophlebitis (DVT) of right calf.

Physician orders

Admit to hospital: Room E237 @ 9:45am

Complete bed rest with bathroom privileges, Elevate legs on two pillows.

Avoid rubbing or massaging the affected calf

Thigh high elastic compression stockings

Peripheral IV Normal Saline with 20 Meq KCL/liter at KVO

Regular diet, monitor intake and output q8 hrs

Lab Work: APTT q6 hrs

Monitor for indication of bleeding. *Dr. G. Jackson*

Medications Ordered

IV heparin: Initial IV bolus 80 units/kg (5800 units) given in ER @ 0930 M. Paul RN

Upon arrival to the unit, begin continuous heparin at 17 units/kg/hr (1200 units/hr)

Celebrex 100mg, PO BID (takes at 8:00am and 8:00pm)

Dr. G. Jackson

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Mr. James Jones

ID # 39294023

Case 4. Vignette 9

Susan Ross, RN, is the nurse assigned to care for Mr. James Jones. Mr. Jones has just arrived on the unit at 10:00am and is in room E237. The nurse does an admission assessment and informs Mr. Jones that she will be getting his medications as ordered by the physician. He received his bolus dose of heparin 5800 units in the emergency room and should be started on his continuous heparin dose upon arrival to the floor. Nurse Ross receives an IV bag from the pharmacy that has the following information on the label.

Mr. James Jones Room E237

Hosp. ID #3929402

Heparin 25,000 units/500 mL of Normal Saline

Dose Ordered: 1200 units/hour

IVRate: 34 mL/hour

Date: 10/02/12 prepared by J. Parker, PharmD

Expires: 10/03/12 @ 10:00am

The nurse checks the physician's medication orders against the original order form. Nurse Ross goes to room E237 at 10:15am and says, "Good morning Mr. Jones, how are you feeling today?" as she checks his ID # and armband, IV site and medication label. "I have the medication Dr. Jackson ordered for you." She proceeds to hang the Heparin and sets the IV pump to deliver 34 mL/hr.

Item #	1	2	3	4	5
Case 4	Right Patient	Right Drug	Right Dose	Right Time	Right Route
Vignette 9			X		

Provide correct nursing action for each identified error

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Go To Next Page

Mr. James Jones

ID #39294023

Case 4. Vignette 10

At the same time that she is administering the Heparin, Susan Ross, RN, also has Mr. James Jones' arthritis medication and states to the patient, "This is your morning dose." She checks his armband & ID # against the EMR and administers 100mg Celexa (Two 40mg tablets and One 20mg tablet) PO with water.

Item #	1	2	3	4	5
Case 4	Right Patient	Right Drug	Right Dose	Right Time	Right Route
Vignette 10		X			

Provide correct nursing action for each identified error

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Go To Next Page

Mr. James Jones

ID #39294023

Case 4. Vignette 11

Kathy Smith, RN, is the nurse assigned to care for Mr. James Jones the next day. Mr. Jones had an uneventful first 24 hours. Kathy checks the EMR to assess the patient's lab values. She sees the following:

Laboratory Test	Date/Time	Patient Value	Normal Range
APPT	10/02/12 @ 1300	60 seconds	25.0-38.00 seconds
INR	10/02/2012 @ 1300	1.9	0.9-1.2

The nurse informs Mr. Jones that she will be changing his IV medications shortly to decrease the Heparin dose due to recent lab values. The new order is Heparin 1080 units/hour. Nurse Smith receives an IV bag from the pharmacy that has the following information on the label.

Mr. George Jones Room F327

Hosp. ID#32049293

Heparin 25,000 units/250mL of Normal Saline

Dose Ordered: 1080 units/hour

IVRate: 9 mL/hour

Date: 10/03/12 prepared by J. Parker, PharmD

Expires: 10/04/12 @10:00am

Nurse Smith goes to room E237 at 10:00am and says, "Good morning Mr. Jones, how are you feeling today? I have the medication that Dr. Jackson ordered for you." The nurse states that the dose is lower than yesterday. She checks his IV site, armband and ID# against the EMR. She then proceeds to hang the medication and sets the IV pump to deliver 9 mL/hr. The nurse states, "I will be back to check on you. Use your call light if you need anything." She then leaves the

room.

Item #	1	2	3	4	5
Case 4	Right Patient	Right Drug	Right Dose	Right Time	Right Route
Vignette 11	X		X		

Provide correct nursing action for each identified error

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End of Case 4

Case 5

Patient: Patricia Henry

Sex: Female

Age: 61

Allergies: None Known

Date: 4/23/12

Hospital ID#4528495

Chief Complaint:

Ms. Henry was having "trouble breathing" during the night and had to "sit on the side of the bed." She was still "short of breath" and called her son, who took her to the Emergency Department (E.D.).

History & Physical

Ms. Henry, a 61-year-old female was admitted to the coronary care unit from the E.D. at 6:00am. Patient appears tired and anxious, skin cool and moist, capillary refill slow, peripheral pulses weak bilaterally, mild pitting edema in lower extremities. Breath sounds: inspiratory crackles. Home medications are Enalapril 5 mg po BID and Carvedilol 6.25 mg po BID.

J. Jones, M.D.

Vital Signs
Heart rate = 120 beats/min, irregular

Respiratory rate = 24 breaths/min shallow

Blood pressure = 140/70 mm Hg

Temperature = 38.10 degrees Celcius

Wt: 154 lbs (70kg) HT: 5'6"

Diagnosis: Congestive Heart Failure/Pulmonary Edema

Physician Orders:

1. Admit to E461
2. Bedrest with HOB elevated 45 degrees
3. 02 via NC @ 2 liters/min
4. IV D5W @ KVO
5. Chest xray & EKG
6. Cardiac monitor
7. Foley catheter
8. Daily weights, Low sodium diet
9. Labs: ABG, CBC, Electrolytes, UA
10. Digoxin level @ 8 hours after first Digoxin dose. *J.Jones, M.D.*

Medications:

Lasix 40mg IV @ 8:00am (Now)

Carvedilol 6.25mg PO BID

Enalapril 5mg PO BID

Digoxin 0.35 mg IV Stat @ 2:00am (given in ER @ 2:30am by K. Smith, RN)

Digoxin 0.175 mg IV @ 8:00am and 2:00pm

Potassium Chloride 30 mEq PO qd @ 2:00pm *J. Jones, M.D.*

Go To Next Page

Patricia Henry

ID #4528495

Case 5. Vignette 12

Nurse Miller completes an assessment of Ms. Henry and prepares to give her 8:00am medications. Nurse Miller verifies the medication orders with the EMR. She prepares three medications: Digoxin, Lasix, and Potassium Chloride.

The first order is for 0.175 mg Digoxin IV. The ampule contains 0.25 mg/mL. Nurse Miller calculates that she will need to withdraw 0.7 mLs of Digoxin for Ms. Henry. The nurse uses a 1mL syringe and withdraws the medication until it reaches 0.7 mL. She then labels the syringe with patient name and drug name/dose.

The nurse then proceeds to Ms. Henry's bed and tells her she has her Digoxin and checks her armband and ID # against the EMR. The nurse takes an apical pulse for 60 seconds, and proceeds to administer the Digoxin IM in her right deltoid.

Item #	1	2	3	4	5
Case 5	Right Patient	Right Drug	Right Dose	Right Time	Right Route
Vignette 12					X

Provide correct nursing action for each identified error

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Go To Next Page

Patricia Henry

ID #4528495

Case 5. Vignette 13

Nurse Miller also has her second 8:00am medication, Lasix 40mg, IV to be given over 5 minutes. The dose on hand is 5 mg/mL. The nurse draws up 6 mL of Lasix, in a 10 mL syringe and labels the syringe. The nurse verifies the order in the EMR, checks the patient's armband & ID #. She notes the IV site is dry and intact without swelling or redness. Nurse Miller gives the Lasix by injecting it slowing into the patient's maintenance IV line over 5 minutes.

Item #	1	2	3	4	5
Case 5	Right Patient	Right Drug	Right Dose	Right Time	Right Route
Vignette 13			X		

Provide correct nursing action for each identified error

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Go To Next Page

Patricia Henry

ID # 4528495

Case 5. Vignette 14

At the same time that she is delivering the digoxin and lasix, Nurse Miller also has the patient's third medication, Potassium Chloride 30 mEq PO, qd. The liquid potassium chloride comes in individual 30 mEq/15 mL containers. The nurse prepares one individually packaged oral Potassium Chloride. The nurse then checks the patient's armband and ID # against the EMR and gives Ms. Henry her Potassium Chloride by mouth.

Item #	1	2	3	4	5
Case 5	Right Patient	Right Drug	Right Dose	Right Time	Right Route
Vignette 14				X	

Provide correct nursing action for each identified error

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End of Case 5

Appendix C

Demographic Survey

1. Race
   a. American Indian / Alaska Native
   b. Asian
   c. Native Hawaiian or Other Pacific Islander
   d. Black or African American
   e. White
   f. More Than One Race
   g. Unknown / Not Reported

2. Sex
   a. Female
   b. Male
   c. Other

3. What is your age?
   a. 18-24
   b. 25-30
   c. 31-35
   d. 36-40
   e. 41-45
   f. 46-50
   g. 51-55
   h. 56-60
   i. 61-65
   j. 66-70
   k. over 70

4. Which of the following best describes your employment status?
   a. Full time
   b. Part time
   c. PRN
   d. Unemployed
   e. Other

5. If other, please describe

6. Have you ever participated in a Root Cause Analysis?
    a. Yes
    b. No

7. Which of the following best describes your familiarity with Root Cause Analysis?
    a. I have never heard of it.
    b. I have heard of it, but don't know what it is.
    c. I have some idea of what it is, but don't know how to use it.
    d. I have a clear idea of what it is and how to use it.
    e. I can explain what it is, and I have used it.

Appendix D

Permission to use SAQ

Medical School
University of Texas at Houston-Memorial Hermann
Center for Healthcare Quality and Safety

November 16, 2015

Dear Kristi Miller,

You have our permission to use any of the following Safety Attitudes Questionnaires and the corresponding scoring keys:

Safety Attitudes Questionnaire – Short Form
Safety Attitudes Questionnaire – Teamwork and Safety Climate
Safety Attitudes Questionnaire – Ambulatory Version
Safety Attitudes Questionnaire – ICU Version
Safety Attitudes Questionnaire – Labor and Delivery Version
Safety Attitudes Questionnaire – Operating Room Version
Safety Attitudes Questionnaire – Pharmacy Version
Safety Climate Survey

Please note, we do not have editable versions for any of the SAQ surveys but feel free to modify the surveys to meet your research endeavors.

Respectfully,

University of Texas at Houston-Memorial Hermann
Center for Healthcare Quality and Safety Team

6410 Fannin Street
UTPB Suite 1100
Houston, TX 77030
https://med.uth.edu/chqs/

Appendix E

Permission to use SAM-R

Bravo, Katherine S Apr 6 (8 days ago)

to me

Kristi,
Thank you for your patience. This has been a very busy semester. We re-deployed the Safe Administration of Medications scale with 288 undergraduate students on March 18th so this has been taking up all of my time.
The statistical analysis from Spring 2015 indicated that there was little need for revision of the SAM-R.
I thought in one of our previous conversations you stated you have a copy of my dissertation. The complete revised scale should be contained within that document.
As you also recall, I do have reservations about your plans for use of the SAM-R as they do not call for statistical analysis with item response theory, as the original creator intended. This issue must remain up to you and your dissertation committee to resolve.
You do have my permission to use the Revised Version of the Safe Administration of Medications Scale.
Sincerely,
Kati Bravo

From: Kristi Miller [mailto:millerks@goldmail.etsu.edu]
Sent: Tuesday, March 22, 2016 8:03 PM

Appendix F

Recruitment Script – Phase I

I would like to invite you to participate in a research study entitled: Effect of Root Cause Analysis on Student Nurses' Safe Medication Administration Practice.

The purpose of this research study is to determine if nurse participation in Root Cause Analysis (RCA) has the potential to increase safe medication administration practices and reduce harm to patients. Root Cause Analysis is a process that looks for all possible reasons for errors. The goal of Root Cause Analysis is to find solutions that will prevent the same error from occurring again. Nurse ability to safely administer medications will be measured with a knowledge test and nurse willingness to report errors will be measured with a safety attitudes questionnaire. The results of this research will provide evidence for the use of RCA as an educational strategy to reduce harm to patients by preventing medication errors.

Participants will be involved in the study for a total of 8 hours over a period of 6 weeks. In one week, I will collect informed consent forms from those who choose to participate. If you choose to participate, you will take a test of medication safety knowledge, fill out a questionnaire about medication safety attitudes and complete a survey before the intervention (approximately 1 hour). You will then be randomized to either the control group (standard medication error prevention education) or the intervention group. The intervention group involves working through a root cause analysis of an actual medication error with a group of 3-6 fellow students. I will be facilitating the RCA (approximately 2 hours). The control group will receive a 2-hour (approximate) lecture on safe medication administration, which I will provide. After the intervention/control sessions, all participants will take the post-test and fill out the questionnaire

a second time. You will then switch groups. If you were in the RCA intervention group, you will participate in the control/lecture; if you were in the control/lecture group, you will participate in the RCA intervention (each session will take approximately 2 hours). Subsequently, you will all take the post-test and questionnaire a third time (approximately 1 hour). In 30 days all participants will take the knowledge test and fill out the questionnaire for the third time (approximately 1 hour). After taking the 30-day post-test, students who elect not to participate in the study will be offered the chance to experience the root cause analysis experience, the medication safety lecture, and may take the test and survey.

The data collected will be confidential and will not be identifiable.

I have been an RN for over ten years. I am currently working on my PhD in nursing because I am passionate about patient safety. I hope the results of this study will help nurses create a safer environment for patients, reducing harm from medical errors.

To participate, you must meet the following criteria for the study:

1. Be an undergraduate student in good standing at the ETSU school of nursing
2. Be an adult 18 years of age or older
3. Be enrolled in a first or final year undergraduate nursing course

Please let me know if you are interested by signing up on the clipboard I am passing around, and by taking a copy of the informed consent. I will contact you in one week to enroll interested students in the study and have you sign the informed consent.

Kristi Miller RN, MSN, PhD candidate

Email: millerks@etsu.edu phone: 828 230 2032

Appendix G

Recruitment Script – Re-Design

I would like to invite you to participate in a research study entitled: Effect of Root Cause Analysis on Student Nurses' Safe Medication Administration Practice. Medical errors are responsible for thousands of patient deaths each year, yet there is little evidence for error reducing strategies. In fact, since 2000, when the Institute of Medicine made the general public aware of the high rate of medical error, there has been no reduction in that rate. Root Cause Analysis has been used in the aviation and nuclear power industry to increase consumer safety. The Joint Commission now requires the use of RCA for sentinel events (2009). Participation in this study will give you the chance to learn more about Root Cause Analysis. In addition you will help future students by providing evidence for best educational practice. Last but not least, you may help create knowledge that reduces medical error, and harm to patients.

The purpose of this research study is to determine if ~~nurse~~ participation in Root Cause Analysis (RCA) has the potential to increase safe medication administration practices and reduce harm to patients. Root Cause Analysis is a process that looks for all possible reasons for errors. The goal of Root Cause Analysis is to find solutions that will prevent the same error from occurring again. Nurse ability to safely administer medications will be measured with a knowledge test and nurse willingness to report errors will be measured with a safety attitudes questionnaire. The results of this research will provide evidence for the use of RCA as an educational strategy to reduce harm to patients by preventing medication errors.

Participants will be involved in the study for a total of approximately 8 hours over a period of 6 weeks. This invitation includes the website address for the informed consent. After

reading the informed consent, if you choose to participate, you will click on the word "agree" which will take you to the study. You will then be randomized to either the experimental or the control group. You will take an online test of medication safety knowledge, fill out an online questionnaire about medication safety attitudes and complete an online demographic survey (all three items will take approximately 1-2 hours to complete). If you are in the intervention group, you will work through a root cause analysis of an actual medication error by participating in an online activity, which will take approximately 2 hours to complete. The control group will participate in and online activity on safe medication administration, which will take approximately 2 hours to complete. After the intervention/control sessions, all participants will take the online post-test and questionnaire a second time (which will take between 1-2 hours). In 30 days you will take the knowledge test and fill out the questionnaire for the third time (approximately 1-2 hours). After taking the 30-day post-test, students who elect not to participate in the study may request access to all study materials.

The data collected will be confidential and will not be identifiable. If you do consent, you may withdraw from the study at any time with no penalty.

I have been an RN for over ten years. I am currently working on my PhD in nursing because I am passionate about patient safety. I hope the results of this study will help nurses create a safer environment for patients, reducing harm from medical errors.

To participate, you must meet the following criteria for the study:

1. Be an undergraduate student in good standing at a school of nursing., enrolled in your final year of nursing school.
4. Be an adult 18 years of age or older

If you are interested in reading the informed consent for this study please go to the following website: https://etsuredcap.etsu.edu/surveys/?s=83JE7ANE44. I need to recruit at least 90 students for this study, so I would very much appreciate it if you would forward this email to any senior-level-nursing students you know. If you have been approved for clinical or volunteer hours for participation, send me an email to let me know you are enrolling. Please contact me with any questions about the study,

Kristi Miller RN, MSN, PhD candidate

Email: millerks@etsu.edu phone: 828 230 2032

Modified 3/19/17 ksm

Approximate timing for study:

Once you begin the study, you can stop and save your survey responses and watch the video at any time and come back to them later.

Pretesting: complete the demographic survey, pre study questionnaire and pre study knowledge test within one week of beginning.

Pretest:

Demographics survey: 10 minutes

SAQ 1: 10-15 minutes

SAM-R 1: 1-2 hours

VIDEO: 1-2 hours - watch within one week of pretesting

Evaluation of educational materials: 10 minutes

post-test

SAQ 2: 10-15 minutes - begin and complete SAQ 2 & SAM-R 2 within one week of watching video

SAM-R 2 1: 1-2 hours

30 day wait time between finishing SAM-R 2 and taking SAQ 3

30 day post-test

SAQ 3: 10-15 minutes –begin and complete SAQ 3 & SAM-R 3 within one week of starting.

SAM-R 3: 1-2 hour

VITA

KRISTI MILLER

Education:	Associate Degree Nursing, Asheville Buncombe Technical Community College, Asheville, North Carolina 2006
	Bachelor of Science in Nursing, Western Carolina University, Cullowhee, North Carolina, 2008
	Master of Science in Nursing, Western Carolina University, Cullowhee, North Carolina, 2010
	PhD in Nursing, East Tennessee State University, Johnson City, Tennessee, 2018
Professional Experience:	Instructor, University of North Carolina, Asheville, North Carolina, 2000-2001 & 2018
	Instructor, Mars Hill University, Mars Hill, North Carolina, 2015-2016
	Associate Chair of Nursing, Asheville Buncombe Technical Community College, Asheville, North Carolina 2010-2012
Publications:	Miller, K., Haddad, L., Phillips, K. (2016). Educational Strategies for Reducing Medication Errors Committed By Student Nurses: A Literature Review. *International Journal of Health Sciences Education. 3*.
	Miller, K.S. (2014). The Effect of Simulation Activities on Maternal-Newborn Knowledge in a Practical Nursing Course: Implications for Practice. *International Journal of Childbirth Educators,* 29(1), 41-45.
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	Mary Lewis Wyche Fellowship; North Carolina Foundation for Nursing, 2014
	Graduate Fellowship, East Tennessee State University, 2011