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Feasibility of Simulation to Teach High-Alert Medication Safety

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Feasibility of Simulation to Teach High-Alert Medication Safety

By

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Kenneth Catchpole

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Abstract

High-alert medications (HAMs) pose a significant risk to patient safety. Nurses are in a unique position to identify and prevent HAM errors before they occur. There is insufficient research on the most effective ways to improve safety when nurses are caring for patients receiving high-alert medications. Simulation-based learning (SBL) has been recommended as a strategy to help decrease HAM errors, but evidence specific to simulation and HAM safety is extremely limited. This dissertation begins the process of addressing this need. Three manuscripts are included in this dissertation. The first manuscript is an integrative review of literature on the use of SBL to improve safe performance of medication administration and decrease medication errors by nurses and nursing students. In the second manuscript, the perspectives of practicing registered nurses on factors that support or interfere with safe administration of HAMs were evaluated through a qualitative descriptive study. Finally, findings from the qualitative descriptive study informed the development of two HAM simulation scenarios. The simulations were evaluated within a feasibility study on the use of a SBL on HAM safety with nursing students. Findings of this dissertation provide the groundwork for future interventional research into the effect of SBL on HAM safety outcomes.

Introduction

Overview

Approximately 1.5 million medical errors occur in hospitals annually[1], contributing to 251,454 deaths (the third leading cause of death in the United States).[2] Medication errors occur at a rate of 19.6% for each medication administered[3] and account for over 7000 deaths annually.[4] Causes of medication errors have diverse etiologies that include a combination of systemic problems (technologic failure and flawed systems processes) and human error.[5]

Background and Problem Statement

1. Medication Errors and High-Alert Medications

A medication error is "an error (of commission or omission) at any step along the pathway that begins when a clinician prescribes a medication and ends when the patient actually receives the medication".[5] A medication error may or may not result in patient harm or death. High-alert medications (HAMs), i.e. sedative, opiate, anticoagulant, and anti-diabetic medications have an increased risk of causing considerable patient harm, especially when given in error.[6] The published incidence of error rates for HAMs range from 14.2-27.69%.[7,8] Errors occurring during the process of administration, which is most impacted by nurses, are reported to occur in 10.85-29% of these incidents.[7,8] About 6.1% of HAM errors resulted in temporary harm, 1% in permanent harm, and 2% in patient death.[8] Error risk increased when patients were transferred from one unit to another.[7] Failing to implement the five rights of medication administration due to interruptions and work load were identified as factors contributing to HAM error.[8] Information specific to HAM safety was not included in many health care

professionals' basic educational preparation.[8] These data reflect significant patient safety issues that warrant priority attention by the healthcare system and professionals entrusted in these systems, as suggested by current national efforts to improve medication safety, in particular those of HAM.

The National Action Plan for Adverse Drug Event Prevention (ADE Action Plan) was developed to address the urgent need to identify and measure adverse HAM drug events, reduce patient harm and align federal health agencies towards improvement efforts.[9] The three specific ADEs addressed in the plan are HAMs: anticoagulants, diabetes agents, and opioids. These priorities for intervention were based on factors such as frequency of errors, clinical significance of errors, and potential for prevention. The ADE Action Plan aims to improve the healthcare of patient's receiving HAMs through increased surveillance, implementation of evidence-based prevention strategies, incentives and oversight, health information technology strategies, and research. A National Patient Safety Goal of the Joint Commission is to reduce the adverse drug events associated with anticoagulant therapy to prevent patient harm.[10] Preventing patient harm from HAMs is a national priority.[9]

2. Nursing Education and High-alert Medications

Despite the magnitude of errors related to HAMs, especially during the administration phase, scant research reports on how to prevent these errors within nursing educational preparation.[7,8] Educational interventions such as computer tutorials,[11,12] didactic presentations,[13] and simulation-based learning[14] have been shown to improve HAM knowledge[11,13] and reduce HAM errors.[12,14]

A minority (28%) of health care workers received education about HAMs during pre-professional education.[8] Evidence of the impact of pre-professional education on HAM safety in practice is lacking. Results of a survey of practicing nurses and faculty in Taiwan regarding when HAM content should be taught identified that faculty believed that training should begin during nursing school (94.3%), but 48.9% of nurses felt the appropriate time was during in-hospital continuing education.[15] Several studies of undergraduate nursing students revealed that errors while administering medications during agency-based clinical experiences are common.[16,17,18] Performance and knowledge deficits by nursing students have been identified as contributing factors.[19,20] Because most nursing students are administering HAMs such as insulin, heparin, and opioids during clinical experiences, HAM education during pre-professional preparation is warranted. However, only two studies were found that reported a strategy to teach nursing students about a HAM.[14,21] An introduction to methods to reduce medication errors early in nursing programs could help alleviate this problem.

Simulation may help prepare students to safely administer HAMs. According to the Agency for Healthcare Research and Quality (AHRQ), simulation could improve safe medication administration, specifically HAM administration, by allowing students an opportunity to practice essential skills without jeopardizing patient safety.[21] High-alert medication simulation scenarios can target practices commonly associated with safe medication administration practices. Despite the growing use of simulation in nursing education, there is a need for research that specifically addresses the use of simulation to teach HAM safety practices to nursing students. Previous simulation-based learning research in nursing have not used rigorous designs; of two studies reported on HAM

simulations, one showed no improvement in students' learning, while another improved participants' use of the five rights.[14,16] Additional research could determine if simulation-based learning is an effective strategy to teach HAM safety, measuring both learner competence and patient or system outcomes.

3. Simulation

Simulation-based learning (SBL) has enhanced educational outcomes for students.[22] This active learning strategy utilizes a reality-based scenario in a life-like environment to allow learners to experience a real event.[23] SBL experiences promote learning, evaluation, and improve understanding of systems or human behaviors. Nursing students who had as much as 50% of their clinical time substituted with simulation were not statistically significantly different from students who received a traditional nursing education in terms of nursing knowledge ($p = .478$), NCLEX success rates ($p = .706$), or clinical competence.[24] A meta-analysis of nursing SBL research indicated that simulation has positive effects on the cognitive ($d = 0.85$, $p < .001$), affective ($d = 0.42$, $p < .001$), and psychomotor domains of learning ($d = 1.06$, $p < .001$).[22] Several studies have identified the beneficial effects of simulation on outcomes associated with safe medication administration and/or reduction of medication errors in nursing students, [16,25,26,27,28] and in registered nurses.[29,30,31] Paparella recommended SBL and evaluation, in HAM administration as an annual competency for nurses.[32] Based on these findings, SBL offers promise as a potential strategy to improve HAM competency in nurses and nursing students.

Although research findings support the use of educational interventions to improve knowledge of HAM administration, evidence is lacking on when nursing

students should be introduced to concepts regarding HAMs, what specific information should be included in the training, which educational strategies are the most effective to improve safe performance, and what effect the educational outcomes will have on HAM errors.

Purpose: Thus, to address these gaps, the purpose of this dissertation is to assess the feasibility of a high-alert medication simulation-based learning strategy to teach nursing students safe HAM administration.

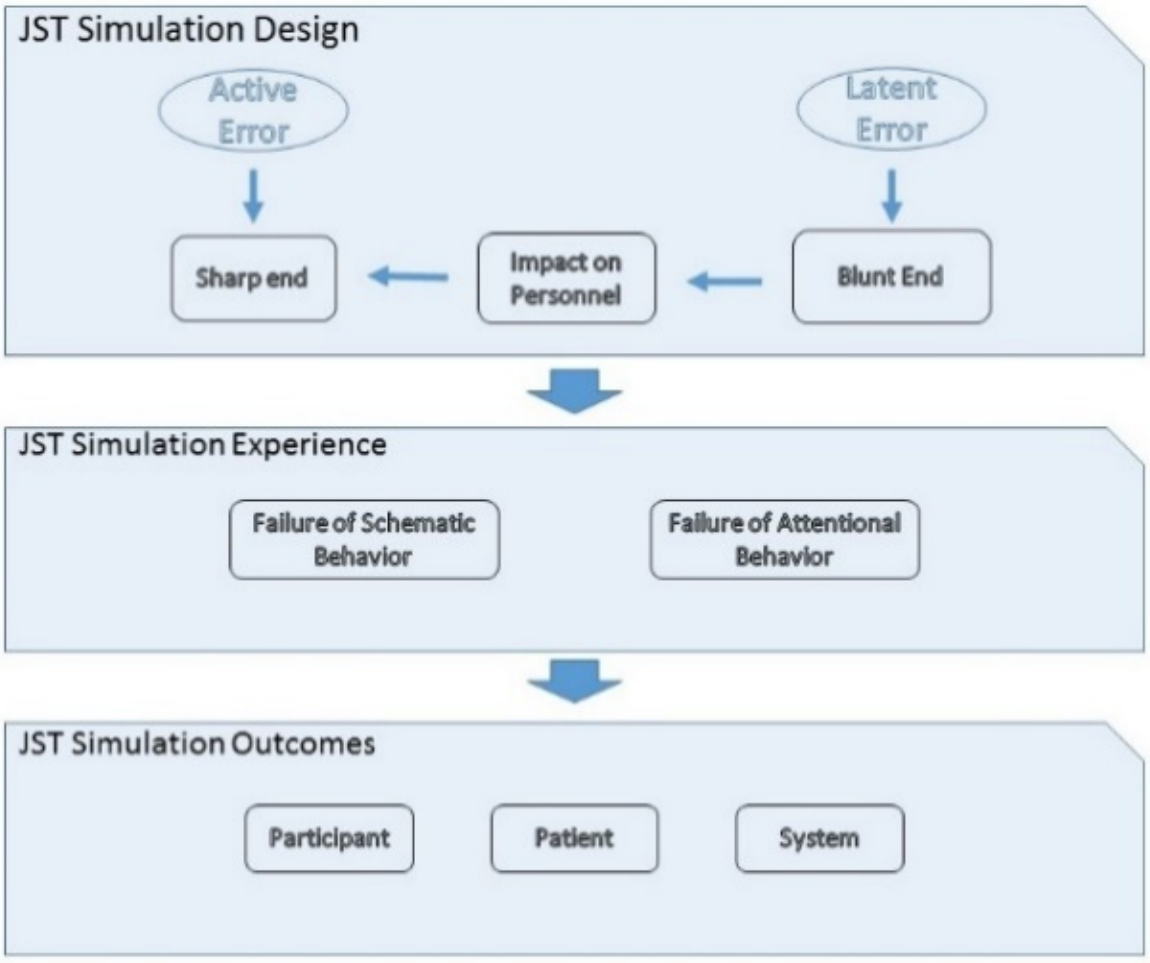
Theoretical Framework

Two theories guided this dissertation: Reason's Swiss Cheese Model (SCM) - an error prevention model - and the National League of Nursing (NLN) Jeffries Simulation Theory - a simulation learning theory. By merging these two theories, the authors utilized the science of human factors to help understand issues contributing to HAM error and integrated these factors into the simulation design that incorporated key elements of the NLN Jeffries Simulation Theory (Figure 1). Reason posits that errors occur from system failures, when the numerous protective factors used to prevent an error fail at the same moment.[33] Thus, error can be visualized as slices of Swiss cheese; when holes in the cheese align, gaps in the safeguards to prevent an error are exposed providing an opportunity for an error to occur. Reason believes that human error is inevitable, thus systems should be designed to prevent errors. According to Reason, there are two interconnected paths to error, latent failures and active failures. Latent failures are due to an organizational design (blunt end processes) that fail to safeguard against error. Active failures transpire because of slips or lapses that occur during human interactions (sharp end processes).[33]

The NLN/Jeffries Simulation Theory's (JST) three key components include: simulation design, simulation experience, and outcomes.[34] Simulation design is the basis for the development, implementation, and evaluation of the simulation scenario.[35] A well thought out simulation design is guided by the learning objectives, which determine key design features such as the complexity of problem solving skills, fidelity of the experience, participant and observer roles, progression of the scenario, and briefing and debriefing activities.[34] The simulation experience occurs within an educational context that is learner centered, collaborative, and interactive.[34] It is during the simulation experience that learner objectives are achieved. With the JST, the evaluation of outcomes is categorized in terms of the participant (i.e., satisfaction with learning, skill attainment, self-confidence), the patient (individual care outcomes), or the system (effectiveness or practice changes).[34] In this dissertation, the combined models were used to:

1) Evaluate if factors key to the JST were incorporated into simulation research during the analysis of current research on simulation and medication safety
2) Utilize the SCM to understand how error factors impacted registered nurse HAM practices
3) Incorporate factors that provided barriers to errors or contributed to unsafe practices in the design of the HAM simulation scenarios.

Figure 1. Amalgamation of Swiss Cheese Model and NLN Jeffries Simulation Theory



Compendium

High-alert medications pose a significant risk to patient safety. Nurses are in an unique position to identify and prevent HAM errors before they occur. There is insufficient research on the most effective ways to help nurses and students become the stewards of HAM safety. SBL could be the educational strategy to fill that gap, but evidence specific to SBL and HAM safety is extremely limited. This dissertation begins the process of addressing this need by developing and evaluating HAM simulations that

could be used in future interventional studies. Three manuscripts are included in this dissertation.

1) An integrative review on the use of SBL to improve safe performance of medication administration and decrease medication errors by nurses and nursing students. This review unveiled a need for sufficiently powered, randomized controlled trials that utilized reliable and valid instruments to evaluate the effect of SBL medication administration scenarios versus other educational strategies to reduce nursing medication administration errors. Research on the transferability and sustainability of competencies attained in a simulated scenario to performance outcomes in clinical settings affecting patients and health care systems is lacking.
2) Results of a qualitative descriptive study on the perspectives of practicing registered nurses on factors that support or interfere with safe administration of HAMs. This research validated previous research on factors that hindered or supported medication administration safety while identifying new information on situations specific to high-alert medications. The results of this research informed the development of two HAM simulations.
3) Results of a study on the feasibility of conducting a SBL study on HAM safety with nursing students. Findings demonstrated positive student evaluations of the SBL experiences and challenges meeting the technological requirements needed to provide simulation fidelity.

Specific Aims

For this dissertation, a feasibility study was conducted to develop and evaluate two simulation scenarios to teach safe administration of HAMs to pre-licensure nursing students. Tickle-Degnen's feasibility assessment method was used to evaluate data on the study process, resources, management, and science.[36] This feasibility method was selected to determine and remediate the potential threats to the validity of the study prior to its implementation. The study had the following aims:

Aim 1: *To develop and refine two high-alert medication administration simulation scenarios for undergraduate nursing students.*

Aim 2: *To evaluate student nurses' perceptions of design elements i.e., objectives, fidelity, problem solving, student support, and debriefing, in the high-alert medication administration simulation scenarios.*

Aim 3: *To analyze factors (i.e., potential student participation, simulation resources, technological resources and support, and management resources) that would impact the feasibility of conducting a simulation trial at Howard Community College.*

For Aim 1, interview data obtained from registered nurses informed the development of two high-alert medication administration (HAM) simulation scenarios, one for education, and one for evaluation of safety performance. After development and cognitive pretesting of the simulation scenarios in Aim 1, nursing students participated in an evaluation of both HAM simulation scenarios. Data were collected to assess nursing student perceptions of the specific design elements and overall quality of the scenarios (Aim 2). Revisions to the scenarios were implemented based on student feedback. In Aim 3, feasibility factors (i.e. process, resources, management, and

science) were evaluated to examine the potential for implementing the study at a community college.

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Improving Medication Administration Safety Utilizing Simulation-Based Learning

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Abstract

Background: Safe medication administration and the prevention of medication errors is essential to quality patient care. Medication administration is a technically complex procedure prone to systematic and human errors; human variability requires the nurse to process complex patient data to determine the correct choice of actions. Simulation-based learning (SBL) has been used for decades in nursing education and practice to enhance learner outcomes to improve patient care, including safe medication administration.

Method: Whittemore and Knafl's methodological framework and the NLN/Jeffries Simulation Theory (JST) guided the analysis and interpretation of SBL studies designed to improve medication administration outcomes. Selected reports were analyzed for the relationship of simulation-based learning to safe medication administration performance outcomes of nursing students and nurses, and indicators of effective research designs.

Results: Seven studies were retained for this review; these demonstrated that SBL improves learner performance, however, the methodology lacked rigor (insufficient sample sizes, no power analysis, limited discussion of reliability or validity of instruments), and no studies looked at outcomes beyond the participant level.

Conclusion: Although simulation-based learning may be an effective strategy to improve medication administration performance, randomized controlled trials of sufficient power that incorporate error factors are needed to evaluate the effect of simulation scenarios on patient and system error outcomes.

Keywords:

Medication error, simulation-based learning, nursing, safety

Problem Identification

About 1.5 million medical errors occur in hospitals every year (Institute of Medicine, 2007), and 21% of Americans experience a medical error (Institute for Healthcare Improvement, 2017). Approximately 7000 inpatient deaths occur in the United States every year due to medication errors (Flynn, Liang, Dickson, Xie, & Suh, 2012), and medication error rates of 19.6%-25.6% for each medication administered, and 53.3% for intravenous medications have been reported (Keers, Williams, Cooke, & Ashcroft, 2013). The most common types of errors were wrong time, omission, and wrong dosage (Keers, Williams, Cooke, & Ashcroft, 2013). Causes of medication errors range from systemic problems (technologic failure and flawed systems processes) to human error (Medication Errors, 2016).

Ensuring the six rights of medication administration (right: patient, medication, dose, route, time, and documentation) (Perry, Potter, & Ostendorf, 2018) in a complex health environment requires more than diligence alone. Safe medication administration requires clinical judgment (Bourbonnais & Caswell, 2014) based on the integration of information from multiple, complex information sources. Nurses need clinical judgment to implement safe, quality care within a technically complex environment, predisposed to errors through poor equipment designs, organizational pressures, or other systems issues (Reason, 2000). Nurses who think critically about the implications of administering a specific medication to an individual patient, taking into consideration their unique characteristics and concerns, and the challenges of the work environment may prevent medication errors. The critical thinking skills needed for safe nursing practice need to be nurtured during educational preparation.

Studies of undergraduate nursing students reveal that errors while administering medications in clinical practice environments are common (Dunn, 2014; Harding & Petrick, 2008; Reid-Searl, Moxham, & Happell, 2010; Wolf, Hicks, & Serembus, 2006), primarily due to performance and knowledge deficits (Cooper, 2012; Wolf, et al., 2006). Furthermore, medication safety practices erode from the start to the end of the nursing program (Schneidereith, 2014). Practicing medication administration on real patients is both risky and may not be effective. Nurses and nursing students need opportunities to practice clinical reasoning to enhance their ability to solve patient care issues. Simulation-based learning (SBL) that allows students to practice clinical judgment in medication scenarios might improve their ability to safely administer medications to patients without harm (Bourbonnais & Caswell, 2014).

SBL has grown exponentially over the last decade and has been used to orient new employees, advance nurses' knowledge, support certification, improve processes, and aid in the development of interprofessional collaboration (Dwyer, 2014). Successful development, implementation, and evaluation of a simulation scenario requires careful design (Groom, Henderson, & Sittner, 2014). A well thought out simulation design is guided by the learning objectives, which determine key design features such as the complexity of problem solving skills, fidelity of the experience, participant and observer roles, progression of the scenario, and briefing and debriefing activities (Jeffries, 2016). The simulation experience occurs within an educational context that is learner centered, collaborative, and interactive (Jeffries, 2016). It is during the simulation experience that learner objectives are achieved. This has demonstrated improvements in confidence (Bearnson & Wiker, 2005; Campbell, 2013; Davies, Nathan, & Clarke, 2012; Dobbs,

Sweitzer, & Jeffries, 2006; Jarzemsky & McGrath, 2008; Marvanova & Henkel, 2017; Pauly-O'Neill & Prion, 2013) and encouraged greater caution during medication administration (Breitkreuz, Dougal, & Wright, 2016). However, less is known about the impact of SBL on the ability of nurses to administer medications safely, especially when faced with issues commonly associated with medication errors.

Despite the growth of simulation in education, no systematic reviews have been found to determine if SBL is successful in decreasing medication errors. The purpose of this integrative review was to answer the question: *Does participation in simulation scenarios on medication administration improve safe performance and decrease medication errors by nurses and nursing students?* This was framed within the NLN/Jeffries Simulation Theory (JST), which has three key components: simulation design, simulation experience, and outcomes (Jeffries, 2016). With the JST, the evaluation of outcomes is categorized in terms of the participant (e.g. satisfaction with learning, skill attainment, self-confidence), the patient (individual care outcomes), or the system (effectiveness or practice changes) (Jeffries, 2016). In this integrative review, research was evaluated for evidence that the simulation design incorporated key features of the JST – learning outcomes, fidelity, briefing/debriefing – and for the effects of the simulation experience on participant, patient, or system outcomes.

Methods

This integrative review was conducted using Whittemore and Knafl's (2005) method to provide a comprehensive understanding of the subject. The steps include: problem identification, literature search, data evaluation, and data analysis (Whittemore & Knafl, 2005).

Literature Search

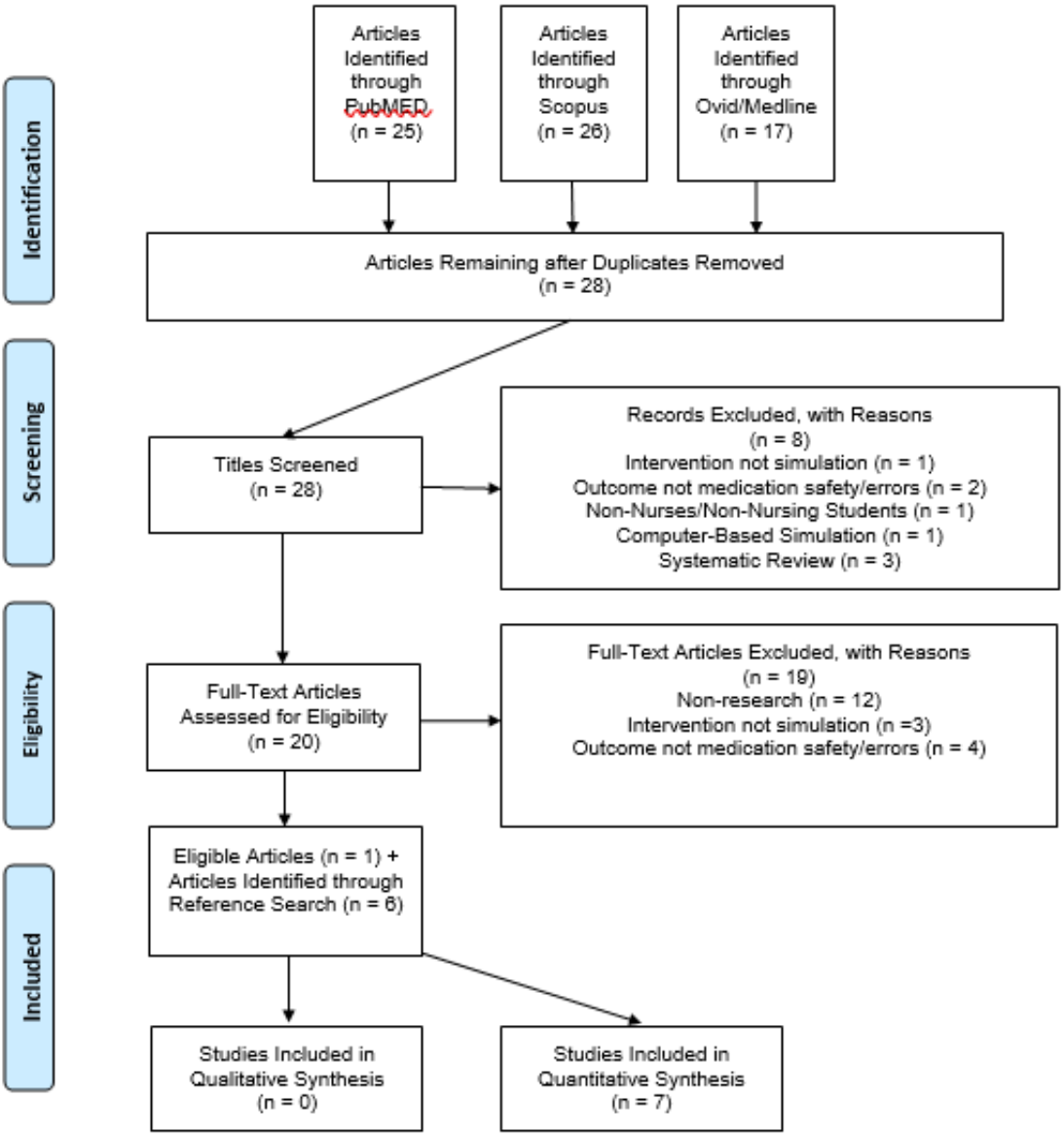
In consultation with a reference librarian, a search of the literature was conducted in PubMed, Ovid, and Scopus using the following MeSH headings and key terms: “nursing education”, “simulation”, and “medication errors”. No restrictions were placed on the searches. Based on a review of the key terms utilized in studies identified in the initial search, the terminology “drug errors” and “adverse drug events” were added as search terms. No additional results were identified with these terms.

Inclusion and exclusion criteria. Each title and abstract were reviewed to determine the presence of five inclusion criteria: Participants were nurses or nursing students; simulation (high or moderate fidelity simulators, or standardized patients) was used as the intervention; and at least one outcome measure was medication safety or prevention of medication error. Studies that were computer-based “virtual” simulations that lacked a psychomotor (hands-on skills) component were excluded from the review. If relevance was questionable, the full text was evaluated to determine if inclusion criteria were met. Finally, the reference lists of relevant studies were searched to ensure all appropriate studies had been identified. For studies that met inclusion criteria, data were extracted and placed into an Excel spreadsheet to record the following information: citation, purpose, theory, design, participants, intervention, instruments, findings, limitations, and level of evidence (LOE).

Search results. The initial search of the electronic databases returned a total of 68 papers, 25 from PubMed, 17 from Ovid, and 26 from Scopus. When the database results were compared and 40 duplicates removed, 28 papers remained for review. During the title review, eight papers were excluded. After the full text review of the

remaining 20 studies, 19 papers were excluded. Six additional studies were identified via the reference search. A total of seven papers remained in the data set for inclusion in the review. The flow diagram in Figure 1 provides details of the search and rationale for exclusions.

Figure 1. Retrieval and Selection Process



Data Evaluation

Whittemore and Knafl (2005) acknowledged that analysis and comparison of research utilizing a variety of methods and designs is a challenge. Shearer's (2013) rubric, designed to evaluate the quality of evidence in SBL research, was used to assess the quality of studies in this analysis. The scores allowed for analysis and comparison of the methodological rigor of the studies, where a higher score indicated greater rigor.

The studies were also evaluated for inclusion of elements of the JST such as SBL learning objectives, fidelity, and briefing or debriefing, and whether outcomes were measured at the participant, patient, or health care system level.

Data Analysis

Data extracted from studies included: authors/date, purpose, design, participants, intervention, and outcomes (Appendix 1). Studies were then evaluated for SBL design elements and outcomes. This allowed for comparison of data and synthesis of findings.

Results

Study Characteristics

In the seven reviewed research studies, five included nursing students as participants (Bowling, 2015; Campbell, 2013; Pauly-O'Neill, 2009; Sears, Goldsworthy, & Goodman, 2010; Unver, et al., 2013) and two included nurses (Fadale, Tucker, Dungan, & Sabal, 2014; Ford, Seybert, Smithburger, Kobulinsky, Samosky, & Kane-Gill, 2010). All studies reported quantitative results; no qualitative or mixed methods studies were identified. Only one study was an experimental randomly controlled trial (Sears, et al., 2010); the remaining six were quasi-experimental designs. Sample sizes ranged

from 16 to 232 participants. However, in one study with a sample size of 23, observers evaluated nurses' administration of 880 medications to patients (Ford, et al., 2010).

All studies reported improvement in medication administration competency by participants post SBL. The studies varied in terms of comparison groups. Two studies compared a simulation experience to a traditional clinical experience (Campbell, 2013; Sears et al., 2010). In one study, SBL was compared to a paper and pencil case study approach (Bowling, 2015), another compared SBL to a traditional lecture approach (Ford et al., 2010). Three studies used a one group pretest-posttest design to evaluate the learning outcomes of the medication administration SBL experiences. (Fadale et al., 2014; Pauly-O'Neill, 2009; Unver et al., 2013).

The studies also differed in approach to outcome evaluation. Two studies assessed medication administration competency by observing medication administrations in the hospital (Campbell, 2013; Sears et al., 2010). The remaining studies used an objective instrument to evaluate the participants' performance during a simulation designed for outcome evaluation (e.g., Objective Structured Clinical Evaluation [OSCE]).

SBL descriptions. Each of the studies was unique in the utilization of SBL. Three studies utilized high-fidelity simulators to enhance realism and allow the learner to assess the simulators physiologic responses to the medication administered (Campbell, 2013; Fadale, et al., 2014; Ford, et al., 2010). Campbell (2013) used four simulated medication exercises designed to improve safe medication procedure, pharmacology knowledge, communication and collaboration. Fadale et al. (2014) created a SBL experience on septic shock to improve administration and titration of

vasopressor medications. Ford, et al. (2010) incorporated medication errors into a SBL experience to allow learners to discover and remediate the errors. Bowling (2015) used a midlevel simulator to mimic a pediatric patient in respiratory distress and response to interventions. Two studies did not report the type of simulator used (Pauly-O'Neill, 2009; Sears et al., 2010). The SBL intervention designed by Pauly-O'Neill revolved around a pediatric patient and built in prescribing errors. Sears et al. (2010) included common emergency scenarios in obstetrics and medical surgical nursing in their SBL designed to improve critical thinking and prioritizing. Standardized patients (live actors) were used in one study to enhance communication and patient teaching around medication administration (Unver et al., 2013).

Main Findings

Utilization of theory. Bandura's Theory of Self-Efficacy guided the research within two studies (Campbell, 2013; Fadale, et al., 2014). There was evidence of the use of some of the simulation design features described in the JST in all studies. Only Bowling (2015) and Campbell (2013) specifically mention utilizing the National League for Nursing and Laerdal Medical design template to create their simulation scenarios (NLN: Simulation Innovation Resource Center, 2017). However, none of the studies examined outcomes beyond the participant level. Table 1 summarizes the study components identified in the JST.

Table 1. Elements of JST in Studies

Citation	JST Simulation Design Elements				Outcomes	
	Learning Objectives	Fidelity	Briefing/ Debriefing	Participant	Patient	System
Bowling (2015)	+	+	+	+		
Campbell (2013)	+	+	+	+		
Fadale et al. (2014)		+		+		
Ford et al. (2010)		+		+		
Pauly-O'Neill (2009)		+		+		
Sears et al. (2010)	+	+		+		

Unver et al. (2013)	+	+	+

+ Evidence of theoretical construct present

Evaluation of Evidence

Research outcomes. All seven studies measured learning outcomes at the participant, rather than the patient or system levels, per the JST. In the four studies utilizing an OSCE to measure participant performance of safe medication administration during a simulation (Bowling, 2015; Fadale, et al., 2014; Pauly-O'Neill, 2009; Unver, et al., 2013), all demonstrated improvement in medication administration performance. Bowling (2015) found no significant differences when comparing mid-fidelity simulation to paper-pencil case studies on nursing students' implementation of the five rights of medication administration. However, there was significant improvement between pre- and post-test OSCE scores for both groups ($p = .0001$). Pauley-O'Neill (2009) reported an increased percentage of students completing the rights of medication administration, assessing for allergies, and improvement in skill performance in a one-group pretest–posttest design. In 2013, Unver et al. evaluated students before and after they participated in five simulations using administrative staff volunteers as standardized patients. The objectively constructed evaluation form (OCEF) focused on the students' communication with patients, including verifying the prescription order and interviewing the patient about medication allergies. Students performed significantly better on the posttest OCEF ($p = 0.01$) (Unver, et al., 2013).

In Fadale et al's. (2014) study of the effects of a high-fidelity simulation on safe administration of a vasopressor during septic shock with critical care nurses, improvement in the number of vasopressor titrations were demonstrated, but there was

no significant difference in the speed of initiation of medication during two follow-up simulation evaluations.

In three studies, the authors measured outcomes by observing participants administer medications to patients (Campbell, 2013; Ford, et al., 2010; Sears, et al., 2010). Campbell (2013) used a quasi-experimental design to compare students who had SBL experiences as part of their clinical education to those who had a traditional clinical experience only. The author created four simulation scenarios focused on six components of safe medication practice: “safety, application of pharmacologic knowledge, clinical judgment, patient-centered care, communication, and the use of informatics” (p. 150). Clinical faculty evaluated students during the administration of a medication to a patient, and students self-reported medication errors. Results were mixed. A higher percentage of the traditional pedagogy group performed better than the SBL group on essential tasks such as checking the patient’s identification, data assessment, and dosage calculation. The SBL group performed better on tasks associated with effective nurse-patient communication, such as providing the patient information about the medication and responding to patient questions (Campbell, 2013).

In the only randomized controlled trial, Sears et al. (2010) compared students who received only traditional clinical education with students that had a portion of clinical time replaced with simulation. The simulations focused on assessments and interventions, including medication administration. Clinical faculty used a researcher-developed instrument to track student medication errors or near errors. The students in the simulation group had significantly fewer errors or near errors (Poisson distribution p

< .05; intracell variation with Poisson distribution p < .01; Chi-square p < .001) (Sears, et al., 2010).

Ford et al. (2010) evaluated the medication administration performance of registered nurses with direct observation within parallel groups (MICU and CCU nurses) to compare medication error rates before and after a SBL compared to a traditional lecture-based pedagogy. The medication error educational content was based on prior observation of nurse performance in the units where the nurses worked (Ford, et al., 2010). The simulation group had significantly lower rates of medication errors in two post intervention measurement periods (p = .0001). There was no change in the incidence of medication errors for the group that received lectures only during the first measurement period.

Level of evidence. Whittemore and Knafl (2005) acknowledged that analysis and comparison of research utilizing a variety of methods and designs is a challenge. Shearer's (2013) *evidence quality evaluation rubric* was used to measure the quality of studies in an integrative review of simulation and safety. Her rubric was applied to assess the methodological rigor of studies in this review. The findings (reported in Table 2) ranged from a low of two, indicating low methodological rigor, to 12 (high rigor). Most studies scored in the 4-5 range. Of the seven studies, all reported a positive impact of SBL on medication administration safety or decreased medication errors. However, Bowling (2015) showed no significant differences between groups. The fact that both SBL and case studies require the learner to utilize clinical judgment in response to a patient situation may explain these results. The study by Campbell (2013) showed inconsistent results – students in the clinical only group performed better on some

aspects of safe medication administration, whereas the simulation group performed better on others. The author attributed the results to potential lack of reliability of the instrument, resulting in poor quality of data (Campbell, 2013).

Most studies were quasi-experimental designs and had some methodological weaknesses (Campbell, 2013; Fadale, et al., 2014; Ford, et al., 2010; Pauly-O'Neill, 2009; Unver, et al., 2013). Two studies used only descriptive statistics to analyze outcomes (Campbell, 2013; Pauly-O'Neill, 2009). In the one randomized controlled trial (Sears, et al., 2010), authors used power analysis to determine sample size. Most sample sizes were insufficient for assuring generalizability of results (Campbell, 2013; Fadale, et al., 2014; Ford, et al., 2010; Pauly-O'Neill, 2009).

Six studies utilized investigator-developed instruments to measure medication administration safety (Bowling 2015; Campbell, 2013; Fadale, et al., 2014; Ford, et al., 2010; Pauly-O'Neill, 2009; Unver, et al., 2013). However, efforts to assure the validity of research instruments were reported in only two studies (Sears, et al., 2010; Campbell, 2013), and Campbell (2013) documented instrument reliability concerns in her study. Ford et al. (2010) blinded the observers to the participant group and established inter-rater reliability. Fadale et al. (2014) reported 100% interrater and intra-rater reliability.

Table 2. Comparison of Levels of Evidence Based on Shearer's Evaluation Strategy

Citation	Experimental Design*	Theory	Simulation Theory	IRR or Trust-worthiness	Reliability and Validity	Statistics	Sample Size	Power Analysis	Total Score
Possible Score	1 -3	1	2	1	2	1	2	3	0-14
Bowling (2015)	2		1**			1	2		6
Campbell (2013)	2	1	1**						4
Fadale et al. (2014)***	2	1		1		1			5
Ford et al. (2010)	2			1		1			4
Pauly-O'Neill (2009)	2								2

Sears et al. (2010)	3	1	2	1	2	3	12
Unver et al. (2013)	2			1	2		5

* Experimental Design: Descriptive or one group = 1, comparative group or repeated measures = 2; randomized trial = 3
** Simulation Design Template used
***N=23, but observed 880 medication administrations

Discussion

Findings from this review of SBL studies aimed to teach safe medication administration and reduce medication errors suggest there is a lack of high-level evidence to suggest that SBL is better than traditional educational strategies to teach nurses and nursing students' safe medication administration. The findings of this review are consistent with previous studies on SBL demonstrating a lack of rigor in simulation research. Most of the research had insufficient sample sizes (Campbell, 2013; Fadale, et al., 2014; Ford, et al., 2010; Pauly-O'Neill, 2009) and only Sears, et al. (2010) reported a power analysis and demonstrated the reliability and validity of their instruments. Campbell (2013) and Pauly-O'Neill (2009) did not utilize inferential statistics in their analyses.

Behavioral changes – the transfer of learning to the clinical environment – are an important component of participant outcomes in the JST (Jeffries, 2016). In the three studies that examined performance outcomes in clinical practice (Campbell, 2013, Ford et al. 2010; Sears et al. 2010) it is difficult to extrapolate the outcomes to actual clinical practice as the observers had to intervene prior to the commission of an error by the participant. Interrupting the participant to protect the patient can compromise accurate measurement of the outcome variable. Sears et al. (2010) also measured medication errors reported by students. This can be problematic as it requires self-disclosure by those involved. In several studies, under-reporting of medication errors was common,

from 30% - 50% (Antonow, Smith, & Silver, 2000; Haw, Stubbs & Dickens, 2014). This makes the accuracy of self-reported outcome data questionable.

The JST describes participant learning as changes in knowledge, skills, and attitudes (Jeffries, 2016). Four studies used a simulation-based evaluation of participant medication administration performance (Bowling, 2015, Fadale, et al., 2014, Pauly-O'Neill, 2009, & Unver, et al., 2013). This is an appropriate approach for medication safety research as it would be unethical to allow study participants to continue through the process of administering a medication to a patient after it became apparent they were making an error. In these studies, a simulation and OSCE were utilized to evaluate the participants' knowledge, skills, and attitudes. No authors reported on measures to assess the validity of the evaluation OSCE, and none determined if the outcomes attained in the simulation lab transferred to clinical practice settings (behavioral outcomes).

The research also largely lacked a follow-up assessment to determine if learned knowledge, skills, and attitudes were sustained over time. In a study by Schneidereith (2014), medication administration ability eroded from junior to senior year, with 100% of final semester nursing students failing to use at least one of the rights of medication administration. Research to evaluate if the learning outcomes are sustained is lacking as prior research presents conflicting results. In this integrative review, two studies found sustained improvements over time (Fadale, et al., 2014; Ford, et al., 2010). Fadale, et al. (2014) found a sustained effect of training at six weeks, and Ford et al. (2009) found sustained improvement in medication error rate, although the specific time intervals studied was not reported.

Few studies incorporated an evaluation of the clinical judgment needed for safe medication administration. Campbell (2013) assessed whether students were evaluating pre and post assessment data regarding the medications they were giving. Fadale et al. (2014) collected data on the time it took for nurses to interpret hemodynamic information and make a correct decision about the initiation of medication therapy. These outcomes were dependent on the participant's clinical judgment in correctly interpreting and responding to patient data, a variable that is not captured in much of the published literature. Although studies that focused solely on skills performance as an outcome measure (Bowling, 2015; Pauly-O'Neill, 2009) provide valuable information on medication administration, they did not offer insight into the challenges of learning the complexities associated with modern day medication administration and the clinical judgment needed to perform this task safely (Bourbonnais & Caswell, 2014).

Each study used direct observation to evaluate participants' medication administration performance. Although directly observing medication administration performance can generate reliable results, the knowledge of observed behavior can change the participants' normal behavior for better or worse (Waltz, Strickland & Lenz, 2010).

The use of a theoretical framework can help researchers design and guide studies, establish important constructs to measure, and facilitate data analysis and interpretation (Tappen, 2011). There was little acknowledgement of the integration of theory in these studies. Bandura's Theory of Self-Efficacy guided the research within two studies (Campbell, 2013; Fadale, et al., 2014). Fidelity was discussed in every study, but only four studies mentioned learning objectives, and two described pre-

briefing and debriefing, both important elements of the JST simulation design. The JST integrates educational best practices with research-based design elements to enhance the simulation experience. The reported studies lacked specific information on how researchers used the simulation design to implement an educational strategy that was learner centered, experiential, interactive, and collaborative (Jeffries, 2016). Jeffries (2007) discussed the importance of a unified simulation theory to help guide design of SBL experiences and allow for the comparison of results. Use of the JST emphasized a gap in current research – equation of participant learning outcomes with patient and/or system outcomes. The use of the NLN Jeffries Simulation Theory may help readers compare results across studies and allow for data to be included in a meta-analysis in the future.

Limitations

This review was limited as only English language studies were included. Other published research in other languages may have contributed to the findings. Additionally, studies were limited to nurse or nursing student participants. Studies that included interprofessional SBL experiences or other health care professionals who have a role in medication administration (e.g. anesthesiologists, respiratory therapists, nurse practitioners, or physicians) may have contributed additional insights to these findings. The preference of editors to limit publication to research which demonstrates significance in the findings may have influenced our conclusion that SBL has a positive impact on learner outcomes. Studies that show no difference in learner outcomes may be missing in the literature.

Conclusion

Although this review has demonstrated that SBL has positive participant outcomes for safe medication administration and reduction of medication errors, the methodological deficits of the literature makes any inferences based on these findings unreliable. Sufficiently powered, randomized controlled trials to evaluate the effect of SBL medication administration scenarios versus lecture-based pedagogy on reducing nursing medication administration errors are needed. The reliability and validity of instruments used to measure the impact of SBL in avoidance of medication error is critical but unreported in most studies. Assessments of the sustainability and transferability of knowledge, skills and attitudes attained during a SBL scenario to performance outcomes in clinical settings would help readers determine if the costs associated with SBL are worth the investment. An understanding of the impact of SBL outcomes at the patient and system level would contribute to this analysis. Medication errors pose a significant risk to society. Nurses are legally and ethically responsible for providing safe, quality care to their patients, especially during medication administration. Evidence based strategies that help prepare nurses to meet these responsibilities are essential.

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Appendix 1: Summary of Research Studies for Manuscript 1

Citation	Purpose	Design	Participants	Intervention	Outcomes
Bowling (2015)	Comparison of paper/pencil case study versus mid-level fidelity simulation on students' medication administration skill performance	Quasi-experimental	Pediatric students, non-equivalent control group, N=73.	Treatment group: Mid-fidelity simulation. Objectives: Assess hospitalized pediatric patient, determine and implement interventions. 30-minute simulation, 20-minute debriefing Control group: Paper/pencil case study - simulation scenario converted to case study. Students identified interventions but did not implement them. 20-minute debriefing	Significant improvement between pre and posttest OSCE for both groups [F (1,71) = 156.3 p = .0001)] but no significant differences between the two groups [F (1, 71) = 2.708, p =.104].
Campbell (2013)	Comparing simulation versus traditional clinical education on safe medication administration & medication clinical confidence, student satisfaction & self-confidence	Quasi-experimental	N=27 2nd semester ADN/diploma students in medical-surgical course volunteers. Treatment group N=15. Control group N=12.	Treatment group: Students attended 4 weekly 90-minute simulation sessions. 2 students from each group administered medications each week. All students gave medications during simulation at least once. Students not directly involved in the simulation were given a rubric to evaluate peers' performance. Simulation followed by debriefing Control group: Traditional clinical education	Results were mixed - Control group performed better on patient identification, work space organization, dosage calculation and data assessment. Treatment group performed better on patient communication of medication information and responsiveness to patient inquiries. Descriptive statistics only, no significance reported.
Fadale et al. (2014)	Does simulation increase nurse's self-efficacy and performance during vasopressor administration?	Quasi experimental pilot	N=16 critical care RNs with less than 3 years' experience, < 65 years old.	Simulation used to review septic shock pathophysiology, assessment, pharmacology and use of vasopressors	Improvement of self-efficacy, improved performance in frequency of titration
Ford et al. (2010)	Comparison of medication administration error rates before and after simulation versus traditional didactic instruction	Quasi-experimental	N= 12 MICU RNs and 11 CCU RNs	Comparison of lecture versus simulation, both based on prevention of types of medication errors identified in pre-intervention observations of the nurses	Significantly lower rate of medication errors in intervention group (30.8% vs 4.0% at first post measure and 6.2% at second measure, p = .0001. No change in error rate for control group at first measure, rate increased at second measure. No significant differences for quiz grades between groups.

Citation	Purpose	Design	Participants	Intervention	Outcomes
Pauly-O'Neill (2009)	Measured impact of simulation on ability to administer medications correctly	Quasi-experimental,	BSN students, N=20.	Treatment group: Pediatric scenarios with high risk drugs and built-in prescribing errors. Zero tolerance for errors in lab. Medication error in lab led to incident report. Control group: N/A	Pretest-posttest results: right patient 95% - 100%; right medication 30% - 100%; right route 85% - 100 %; right time 90% - 97%; right dose 88% - 83%; allergy identification 0% - 90%; identifies self 76% - not reported; explains procedure 47% - not reported; correct administration 22% - (88 to 96% depending on skill assessed)
Sears et al. (2010)	Does clinical simulation help reduce medication errors?	Randomized control trial	2nd year BSN student volunteers, N=54. Treatment group N=24, control group N=30.	Treatment group: Replaced some clinical hours with simulation; Control group: Traditional clinical education	Students in the simulation group had significantly fewer medication errors or near medication errors. $p < .05$ for Poisson distribution; $p < .01$ for intracell variation with Poisson distribution; $p < .001$ for Chi-square
Unver et al. (2013)	Effect of using standardized patients on student medication administration, and to explore student's views about the simulated patients as a teaching method in relation to the skills acquired in administering medication	Quasi-experimental	N=85 senior nursing students at a military nursing school in Turkey, all students registered in course participated	Treatment group: All students received 4 hours' instruction on "rational use of medications and rational use of medications within the nursing process". Students participated in five different human patient simulations. Control group: N/A	OCEF: Pretest mean = 24.02, SD = 16.06; Posttest mean = 54.28, SD = 14.54, significant at $p = 0.01$, $t = 14.35$. Student evaluations of the course were positive.

Nurses' Perceptions of Safety Practices During High-Alert Medication Administration: A Qualitative Descriptive Study

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Abstract

Background: The administration of high-alert medications (HAM) such as anticoagulants, antidiabetics, and opioids increase the risk of patient harm from potentially devastating adverse drug events. HAM error incidence ranges from 14-28%. Nurses protect patients by interrupting over 50% of potential medication errors at the bedside. The purpose of this research was to identify nurses' perspectives of factors that contributed to patient safety or harm when administering HAMs.

Methods: A qualitative descriptive design was used to collect and analyze data from adult medical-surgical or critical care nurses employed by two hospitals in the Baltimore-Washington DC metropolitan area. Nurses were interviewed individually using a semi-structured interview guide about their perceptions of factors that supported or hindered safety during HAM administration. Content analysis was used to identify, describe and make inferences about the qualitative data.

Results: Eighteen nurses were interviewed. Three themes were identified as contributing to safety: Culture of Safety, Collaboration, and RN Intrinsic Factors. A culture of safety included organizational values (i.e., just culture, organizational culture emphasizing safety) and organizational processes such as work flow, information resources and work load. Collaborations important to HAM safety included intraprofessional, interprofessional, and patient-nurse collaborations. Factors intrinsic to the nurse were nurse competence and nurse engagement. Nurses' identified that many of the factors affecting medication safety (distractions, patient load, and acuity) also affected HAM safety. They described common work arounds and inconsistent/incorrect use of independent double check procedures.

Conclusions: The study identified factors that commonly contribute to HAM errors and that strategies adopted for HAM safety are not consistently or correctly utilized. Clear and consistent HAM policies, methods to decrease disruptions to processes, enhanced technology to support safe administration, and better education on safe HAM practices are needed to prevent HAM errors. Areas for future research regarding the impact of just culture, nursing judgment, nurse engagement, and patient-nurse collaboration were identified.

Key Words: High-alert medications; medication errors; safety; nursing; Swiss Cheese Model

Introduction

In the United States, twenty-one percent of Americans experience a medical error (Institute for Healthcare Improvement, 2017). A common type of medical error, medication errors, can have devastating consequences for the patient. A medication error, a failure to follow processes designed to assure patient safety from the time the medication is ordered until the medication is given (Medication Errors, 2017) may or may not result in patient harm. However, approximately 7000 inpatient deaths occur in hospitals in the US every year due to medication errors (Flynn, Liang, Dickson, Xie, & Suh, 2012).

High-alert medications (HAMs) such as anticoagulants, antidiabetics, and opioids have an increased risk of causing patient harm (Institute for Safe Medication Practices [ISMP], 2014). Although harm can occur even when HAMs are used correctly, the risk of harm increases when associated with a medication error (ISMP, 2014). HAM errors occur in 14-50% of medication incidents, of which 11-29% occurred during the administration process (Cabilan, Hughes & Shannon, 2017; Manias, Williams, Liew, Rixon, Braff & Finch, 2015; Engles & Ciarkowski, 2015).

The incidence and significance of HAM errors has generated national attention. The National Action Plan for Adverse Drug Event Prevention (ADE Action Plan) was developed to stem adverse HAM drug events causing patient harm (U.S. Department of Health and Human Services [USDHHS], 2014, p. 1). The primary goal of the ADE Action Plan was to combine the efforts of various Federal health agencies to decrease national HAM ADE rates and thus patient harm. In the ADE Action Plan, three types of high-alert medications, anticoagulants, diabetes agents, and opioids, were targeted as

priorities for intervention, based on factors such as frequency of errors, clinical significance of errors, and potential for prevention. A National Patient Safety Goal of The Joint Commission – to decrease negative patient outcomes associated with anticoagulant use (2017, p. 3) – focuses on the HAM most commonly causing harm, heparin. Preventing patient harm from HAMs has been identified as a national priority (US Department of Health and Human Services, 2014, p. 1).

Current understanding recognizes that there are eight common root causes of all medical errors: communication problems, inadequate information flow, human problems, patient related issues, organizational transfer of knowledge, staffing patterns and workflow, technical failures and inadequate policies (AHRQ, 2003). Similarly, these factors contribute to HAM errors: task interruptions due to workflow issues (Engles & Ciarkowski, 2015), frequent transfers from one ward to another (Manias, Williams, Liew, Rixon, Braff, & Finch, 2015), failure to implement bar-code scanning appropriately (Miller, Fortier and Garrison, 2011), and insufficient HAM knowledge (Engles & Ciarkowski, 2015; Lu, Yu, Chen, Wang, Wu, & Tang, 2013; Hsaio, Chen, Yu, Wei, Fang, & Tang, 2010). Education on HAM safety is often not provided basic nursing education (Engles & Ciarkowski, 2015; Lo, Yu, Chen, Wang, & Tang, 2013). This research demonstrates the multifactorial nature of HAM error, and the influence of systems issues such as work load, distractions, technological complexities, and human factors on HAM errors (Reason, 2000).

Technological strategies have been developed to enhance HAM safety: e.g. technology prompts for the HAM independent double check procedure to aid in the identification of potential errors (Douglass et al., 2018; Engles & Ciarkowski, 2015).

Four quality indicators specific to HAM safety - availability of the HAM, electronic verification of the order, protocols, and visual reminders - have been identified (Smeulers, et al., 2015). Although reports on safety practices specific to HAMs have begun to emerge, there is a gap in the current literature regarding nurses' perceptions of factors that contribute to safe practices and errors when caring for patient's receiving HAMs. The insights of practicing nurses may generate new information on strategies to prevent HAM errors. The purpose of this research was to answer the question: *What are nurses' perceptions about factors that contribute to safety when caring for patients receiving high-alert medications?* Data from this analysis contributed to generate a model for HAM safety and to identify areas for further research.

Examination of a problem as multifaceted as medication errors requires a framework that recognizes the systemic factors contributing to human error. Reason's Swiss Cheese Model (SCM) framed this research, specifically the analysis of data regarding supports and barriers to safe HAM administration. Reason posits that errors occur from system failures, when the confluence of protective factors used to prevent an error fail at exactly the same moment (Reason, 2000). Thus, error is visualized as slices of Swiss cheese. When holes in the cheese align, gaps in the safeguards to prevent an error are exposed. Within this model, human error is believed inevitable; protective factors prevent latent failures at the system or organizational level (blunt end processes); and active failures occur from individual slips and mistakes (sharp end processes) (Reason, 2000). Blunt end processes are the organizational systems, policies, procedures, and resources that, when effective, contribute to safety. However, when blunt end processes fail (latent failures), sharp end processes (the patient-

clinician interaction) are relied upon to prevent error. Active failures occur when the individual makes a patient care error. Reason's model seemed particularly pertinent to our study, as it has been used in root cause analysis (AHRQ, 2018) for many years and provides a framework of the study of factors that contribute to errors. During the analysis of data, we deductively coded descriptions of participant and institutional practices according to the SCM. Safety practices that derived from institutional policies were coded as blunt end processes. Sharp end processes were coded for safety practices that occurred between the nurse and the patient. In a similar manner, data was coded as latent failures for institutional factors that contributed to HAM errors, and active failures for individual factors that contributed to errors at the bedside.

Methods

Study Design

In this qualitative descriptive study, practicing registered nurses (RNs) were interviewed regarding how they learned HAM safety strategies, their perspectives on safe practices, and barriers to safety in practice. Content analysis was used to identify, describe, and make inferences about the qualitative data captured from the RNs. Data collection and analysis strategies reported by Bradley, Curry and Devers (2007) were used to derive the inductive and deductive approach to data analysis used in this research. Processes to assure trustworthiness described by Elo, Kaarianien, Kanste, Polkki, Utriainen, and Kyngas (2014) were incorporated into the preparation, organization and reporting phases of this study. These methods provided the researchers a systematic strategy to objectively gather, quantify and describe the phenomena being studied, thereby enhancing the validity of the results. The first author

(LS) collaborated with a senior qualitative research mentor (LSN) to guide and validate the analytic methods and findings. Table 1 summarizes the data collection and analysis approach, and steps taken to enhance trustworthiness.

Participants

After institutional review board approval was obtained (MUSC Pro00063761), adult medical-surgical and/or adult critical care registered nurses (RNs) were recruited for study participation. Participant written consent was not required by the IRB. A purposive sampling strategy was used to attain a diverse (age, sex, race, ethnicity, experience) participant population. We excluded nurses self-identifying as having little-to-no experience administering HAMs from this study. Potential participants were informed of the research through an email sent by the nurse educators at each hospital. RNs responded to the researchers via return email. Follow-up emails confirmed eligibility, willingness to participate, and established the interview time and location. Participants were entered into a raffle for a $50 Target Gift Card to express appreciation for their participation.

Data Collection

Broad, open-ended semi-structured interview questions were developed to guide the RN interviews (Table 2). The questions focused on four areas: How the nurses defined high-alert medications; practices that protect patients during HAM administration; barriers to safety; and what should be included when teaching nurses about HAMs. However, the interview format was informal, allowing RN participants to lead the conversation to topics and issues they considered most relevant. The interviews were audio recorded and lasted approximately 30-45 minutes. The audio

recordings were uploaded to a secure server within two hours and the original recordings deleted. A reflexive journal was maintained, and the first author entered initial and follow-up memos to document thoughts and ideas to be explored during data analysis.

Data Analysis

The audio recordings were professionally transcribed and identifiers removed. The recordings and the transcripts were compared to ensure accuracy. All data were stored on a cloud-based, HIPAA compliant secure server. A computer assisted qualitative data analysis software program, NVivo (QSR International Pty., Doncaster, Victoria, Australia), was used to assist with data organization and analysis. Data analysis started with inductive content analysis. Preparation of the data included: collection of the data, making sense of the data, and selecting units of analysis. Transcripts were organized and coded to develop the initial conceptual codes (open coding, creating categories, and abstracting). Data collection and initial analysis occurred concurrently. Each new interview was compared to the previous interviews to determine if new codes, sub-codes, taxonomies or themes were identified. After 18 interviews, no new information was being generated and data saturation had been attained. After the creation of the initial conceptual codes, the authors reanalyzed the data through a deductive process to identify where the participant responses matched the theoretical constructs of the SCM sharp and blunt end processes, along with active and latent failures. This analysis led to the development of the taxonomies and themes that supported the development of the conceptual model of *High-Alert Medication Safety: Nursing, Collaborative and Organizational Influences.*

Results

Participants

Nineteen registered nurses (RNs) volunteered from each of two hospitals (one urban [n=12], one suburban [n=7]) in the Baltimore-Washington DC metropolitan area. One nurse was excluded for not meeting the participant criteria (pediatric nurse). Most of the RNs interviewed were female (83%), White (72%) and had a Bachelor of Science in nursing (BSN) (56%). Medical-surgical or telemetry units were the majority practice settings. Table 3 provides a synopsis of the participant characteristics.

Themes

Three themes were derived from the analysis of data: ***Culture of Safety, Collaboration, and RN Intrinsic Factors***. The inductive and deductive analysis of the 18 participant interviews related practice situations that described these themes in various forms. The following summary provides exemplars of the interviews that led to the development of sub-concepts, taxonomies and themes. These themes provided the foundation of the conceptual model derived from the data analysis. Appendix 1. Deductive and Inductive Framework used to Develop Model: *High-Alert Medication Safety: Nursing, Collaborative and Organizational Influences* maps the evolution of codes to themes.

Culture of safety. Culture of Safety is the "collective and continuous commitment by organizational leadership, managers and health care workers to emphasize safety over competing goals" (American Nurses' Association, 2016). This theme was derived from data that supported two taxonomies, Organizational Values and Organizational Processes.

Organizational values. Organizational values are the beliefs held by the members of an organization about safe, quality care. The participants in this study described two factors that contributed to the organization's values - just culture and organizational culture. Just culture describes an "environment in which staff members accept responsibility for their own actions but know the organization will treat them fairly and not blame them for something out of their control" (Frankel, Haraden, Federico, & Lenoci-Edwards, 2017). In an environment with blunt end processes that support just culture, nurses' felt safe to acknowledge and report HAM errors. This error information allowed organizations to provide appropriate care for the patient, analyze the cause of the error, and take corrective action. Participants from both hospitals provided examples of practices that supported just culture in their organizations, but also had stories of situations where they experienced unfairly punitive responses from administration or feared such responses. These fears contributed to latent and active failures where nurses described failing to confront a physician about an order, or not admitting a personal knowledge gap. The nurses perceived potential repercussions including losing the respect of peers, receiving a written warning, being fired, or losing their license to practice nursing. One nurse described an incident in which she received a written warning for cosigning a HAM before validating it was the correct form of insulin.

> I've never gotten written up for anything. I didn't think I was in jeopardy for my job, but it was straight to a written, so it skips over a medication error straight to a written… I guess anything can go straight to a termination, but I did feel like I was watching my back for the next year…

Nurses also identified that fear of repercussions could be a positive force in helping assure HAM safety. Nurses were aware of the inherent risks associated with HAM administration and felt that fear of harming a patient made them more vigilant. As one nurse said: “The last thing you want to find out is, you get an email from somebody, “oh by the way what was this about?” “You're horrified.” Another nurse stated:

> I like to say that I maintain a healthy fear of things that I have an ability to do to people, meaning I feel comfortable doing them, but I also realize how much harm can be caused by some of the things that we do as nurses.

The nurses reported that the organizational culture also contributed to the organization’s values and thus the culture of safety. Organizational culture is “the collective values, beliefs and principles of organizational members” (Needle, 2004). Nurses described work environments where they were encouraged to ask questions and report errors; the organization strived to learn from its mistakes to prevent future errors. One nurse’s comments exemplified this:

> They always say a good nurse is one that asks a lot of questions, and they try to break down that stereotype of ‘if you don't know the answer, you're stupid’. It's just the fact that you need to know. I think we're praised for asking questions.”

If the culture of the organization valued safety, nurses were informed of errors made within the hospital with the goal of preventing similar mistakes. The hospital routinely disseminated information on error prevention strategies. As one nurse who assumed personal responsibility for safety explained:

> It's not just like, “Oh, we have to do this because it's a required thing.” I think for the most part, people are like, “Yeah, we should make sure that we're doing this the right way because it's the good, safe thing to do.”

Nurses described the impact on patient care when the focus of the organization values led to a culture where safety was not prioritized. One nurse described it this way:

> There's a hospital not too far from here that has an IMC that is super crazy busy, and they give the nurses four patients and some of those patients could be very, very sick and very, very time consuming and yet because their census or their matrix says that a nurse should be able to have four patients well then, okay that's the rationale or the justification for that idea, ... But if the practice setting is such that it is incredibly busy, incredibly overwhelming, people who normally would have done better get restricted and then they make that compromise, not from a malicious standpoint but from a self-preservation and I've gotta get everything done.

Organizational processes. Organizational processes were also described as essential to maintaining the culture of safety that supported safe HAM administration. Organizational processes are the core activities and responsibilities carried out by the members of the healthcare organization. Three domains - work flow, information resources, and work load - contributed to the development of the taxonomy organizational processes.

Work flow. Work flow describes the processes that supported safe, quality nursing practice. Organizations that had effective blunt end work flow processes were considered safer for HAM administration by the nurse participants. Nurses identified

systematic inefficiencies, lack of resources, and processes that were cumbersome or complex as contributing to latent failures during HAM administration. When processes were overly complex or cumbersome, nurses develop ‘work arounds’, often bypassing safety steps (active failure), to improve efficiency. The most common work around strategies mentioned involved the independent double check and bar code scanning. Nurses described that they were frequently too busy to do the actual validation of the patient medication during the independent double check procedure. They stated that many nurses simply signed off on the medication. They also used strategies to bypass bar code scanning, particularly if the patient identification band or medication label had been damaged. One nurse participant described this scenario:

> I know something I'm guilty of is when they have a wristband and the wristband won't scan, so you get an extra wristband and you keep it at the WOW [workstation on wheels], so you can scan that. And I mean, it's ... You know your patient, but if somebody else were to come in, or a new nurse on shift, I can see that would be not the best thing. But the wristband can't scan and I'm trying to give a fentanyl bolus, and I can't get the wristband to scan, I don't have time to leave, you know, "Oh I'll be back, you keep sitting up in bed, but I'll be back in 15 minutes." Go, print out the wristband. So, I know that we'll print out extra wristbands and have them on the WOW, and then you can just scan that right while you're there doing your meds and everything.

Inability to get appropriate resources was a frequent concern. Another nurse provided an example of how inefficiencies interrupted safe patient care:

They didn't eat much. I said, “You know what? I'm going to check your sugar.” She was like 45. No D50 in the Pyxis. I have to send a message to pharmacy, have to leave your other patients and my patients, run to pharmacy, get the D50, or wait while they're making it and then get it and then administer it.

Participants identified effective policies and procedures as enhancing their ability to safely administer HAMs. RN participation in the development of these policies and procedures, and participation on hospital wide committees was seen as key to successful work flow. With these processes clearly delineated, nurses felt everyone knew their role and responsibilities. This quote illustrates the importance of this idea:

…before any policy is approved, it goes through different disciplines, so if this one discipline is a stakeholder for that policy, say nursing, then it goes to nursing first, which is the practice council. So, anybody from, let's say, if it's pharmacy is sponsoring a change or an institution of something, then, they will go ahead and present it to the practice council. The practice council will review it, will make recommendations and then, they come back again to see if those recommendations been added in or whatever it is. Then, it goes to the … Nurse Executive Council.

When there was an absence of policies and procedures to follow, the nurses were forced to utilize outside resources to determine their course of action, leaving them unsure of the correct intervention. One of the nurses explained:

Honestly, our hospital has deleted a lot of protocols. So, there's no protocols. And, it's just because a lot of us have experience, we'll help the newer nurses. …So, if I was new, I wouldn't know where to go. I would probably direct people to

> go to maybe Lippincott, but I don't know if it's actually in Lippincott. The last time I asked somebody, because I had a student with me, I was told, "Well you go here, and you get part of it, and then you go here, and you'll get the other part of it," but there was nothing put together. I'm like, “a new nurse can't deal with this.”

Information resources. Information resources contributed to blunt end processes that were identified by every nurse as necessary to enhance HAM safety. Based on the nurses’ descriptions, information resources were defined as the two-way flow of information to provide safe, quality care. Information resources identified by the nurses included HAM protocols, access to medication and patient information, and HAM warnings and alerts. When there was a failure in the nurse’s ability to access information resources, safety during HAM administration was compromised, contributing to active failures. Participants identified three types of information resources that enhance HAM safety: protocols, access to information, and alerts and warnings. Protocols are institutionally based instructions that guide the care of a patient or the performance of a procedure.

> The heparin, you know, we start it at this rate and you draw a PTT [partial thromboplastin time], if the PTT is higher or lower, you adjust the heparin by this. And that's all in the MAR ... So, we have a protocol, I think for anything that's titratable, like the insulin, the heparin, that would all have a protocol. It's very specific... There's no wiggle room. If it's this, you do this. If it's this, you do that. And there's always, at the bottom, call the provider if this.

Nurses relied on the availability of protocols, not only to direct the implementation of care, but as a resource to help them advocate for patient safety.

> …maybe a new doctor will not get a PTT before heparin, and they wanted to go off the grid, they wanted to do non-protocol heparin at the rate they want, which they're allowed to, to override the set policies and protocols, and yet they will say, "Just do it." I'm like, "Okay, that's great; you're allowed to do that. But what about a PTT first, the baseline?" "Do we have to?" "Yes."

Having the technology aligned with the protocol was an important contributor to safe practice. One nurse described how the computer algorithm calculated the next insulin rate for a patient on an insulin drip. "You can go in and within the medication administration record, plug in your new blood sugar and compare it to the last one, and then you know if you're increasing your infusion rate, if you're maintaining it, or decreasing." She went on to emphasize that nurses should continue to verify the computer's results. "Just using some common sense just to make sure like, "Their blood sugar dropped this much. Yes, it does make sense to … not increase the rate."

Another component of information resources, access to information, described the ease of obtaining the information necessary to provide safe, quality patient care. Nurse participants emphasized the need to be able to access information:

> We have policies and procedures on our intranet that we can access from any of the hospital computers …We have a thing called Micromedex that's also on the internet where we can check compatibility, learn all about the reasoning why this prescription might be given or prescribed to an individual, what it treats, what the side effects are, what to monitor for and then the policies and procedures give you a more guided, focused way, like if you're giving this medicine you have to stay in the room for this amount of time or you push over five minutes.

Access to information also included rapid access to patient data, e.g. having the latest potassium level before hanging an insulin drip, or partial thromboplastin time before adjusting a heparin dose. When information was missing, or the nurse had to go to great lengths to access data, the ability to make good clinical judgments was compromised. As one nurse described:

> I would use that [the computer resources] more often if it was easier to get access too. The way our system works is you have to go to the interweb, then you have to go to, it's basically like five clicks, and then you're to the protocols. Then you have to go through this big list of protocols before you find the proper one.

While computer-based access to information was important, nurses also identified the need to have other sources of information available. Having printed protocols at the nurses' station and badge buddies listing the names of all high-alert medications were identified as important sources of information. Although nurses felt that "technology is helping to keep us accountable and making sure our patients are safe" they also recognized that the nurse must be willing and able to utilize the technology to access essential information.

Alerts and warnings was the third variable identified as an information resource important in preventing active failures. Alerts and warnings are the visual and technologic cues that prompted the nurse to perform an action safely, for example, errors identified during bar code scanning, cueing for the independent double check, requirements that certain assessments be documented prior to medication administration. They also included non-technologic reminders, like bright labels on the

medication itself reminding the nurse it was a high-alert medication and checklists to document the steps of a procedure as it was completed. One participant described the alerts and warning system as:

> …if you're scanning the wrong drug…it will give you an alert saying, “hey, do you really want to continue.” Or, “this medication is not found on your patient's profile.” So, that's actually a good way, like a safety net for that particular nurse, if she doesn't ignore the warning for those high-alert meds.

Work load. Work load issues were universally cited as one of the most important issues impacting safety when giving HAMs. Work load referred to the job responsibilities that place demands on the nurse’s time and attention. Nurses’ voiced their frustrations with how latent factors such as patient load, patient acuity, constant interruptions and distractions lead them to feeling overwhelmed and exhausted, contributing to active failures. An example of work load issues is described by one nurse participant:

> You're giving medications, you're doing the right thing. You're checking name, date of birth, you're looking at the medication, checking the dosage, checking everything else, then get a phone call that they need you in Room 3 for something else. Well, what am I supposed to do? I'm giving these high alert medications … and then they want me to go to Room 3.

Nurses felt compelled to answer these calls because their response time was being measured and they could be penalized for a slow response. They acknowledged a greater risk of making an error when they were tired or rushed, as was exemplified by one nurse’s statement:

> You got the warning on an IV pump, are you sure? Are you sure? … if the heparin rate particularly, something to do with the time, or an antibiotic that's outside the norm, based on that person's blood culture. It's a nice double check system, computer is asking you, 'Are you sure you know what you're doing?' It's just rushing or tired and it's just, "Yeah, yeah, whatever." It's just click, click and done and then you've forgotten about it, so the next day you get called in and you're asked, "Why did you give the medication early?" "I don't know."

Collaboration. Participants talked about the impact of peer support, interprofessional collaboration, and patient influences on safe practice during HAM administration. Collaboration, defined as two or more people working together to achieve a desired outcome, was another essential theme that arose from the analysis of data. Organizational cultures with blunt end processes that encouraged and supported collaboration contributed to HAM safety, but the nurses recognized that ineffective collaboration contributed to active failures. One nurse described the importance of collaboration in her practice: "it's just, the people are just awesome. The staff is just very, very conducive to learning and it's been great. "

Intraprofessional collaboration. Intraprofessional collaboration, two or more nurses working together to deliver safe, quality care, was described by all participants during interviews. Nurses reported that they relied heavily on team members, the charge nurse, the nurse manager, unit specialists and educators as sources of information and support during HAM administration. Activities commonly described included the independent double check and peer-to-peer communication regarding the correct way to implement care.

> …on a PCA pump the other day, we were changing the dose and I had the charge nurse come in with me and we actually filled out the paper together. She was there watching, and we were talking it through.

Conversely, nurses described situations where they did not feel safe to ask for help. As one nurse stated, “if you get that one experience where, I asked somebody for help, they looked at me like I was stupid, I'm not going to ask again.”

Interprofessional collaboration. During interprofessional collaborations, members of the health care team work together to support high quality patient care. Nurses rely on interprofessional collaborations to provide safe, quality care.

> …in critical care, during the day shift, we have a pharmacist on the floor and she's awesome, so you can ask her anything about any med. She'll put orders in for you, she'll double-check things for you. She'll run down to pharmacy, so that's definitely a resource.

They also talked about the importance of verifying the work of their collaborators. This verification process helped prevent active failures, and the nurses’ role as an advocate had an integral part in preserving patient safety. Poor communication processes hindered collaboration. The abolition of verbal orders and initiation of computer provider order entry were important improvements in blunt end processes to prevent latent and active errors, and to improve the effectiveness of collaboration. Despite these processes, participants clearly saw advocacy as a key component of their role during collaboration. One participant described a patient advocacy intervention:

> The patient was ordered a medication from the nursing home… it was transcribed on paper as so many milligrams. The doctor read it to be 10 times the

> dose. It was written as 10 times the dose, and it was given as 10 times the dose, basically. The patient suffered a sentinel event because of it. Just because the doctor's ordered it doesn't mean he knows that it's right either. As a clinician, you have the accountability to know if it's really the right dose or not, and if it's not, you have to do something about it.

Patient-nurse collaboration. Patients and families were discussed by a few of the nurses as partners in HAM safety. During patient-nurse collaboration, the patient, family, and nurse work together to achieve a health outcome. Several nurses described the importance of educating the patient and family about the medication so that they could help keep the nurse informed of problems they were experiencing. “But I think maybe if we could educate people, like this is for this, but if this, this, or this happens, you need to call us right away.” Many of the participants described that patients often interfered with safety practices. They described situations where patients were non-adherent to the protocol, refusing bloodwork, and/or medications.

> Then, you have the noncompliant patients. A lot of them, they come and you tell them they’re NPO, they don't want to be stopped to get a finger stick every hour, they don't want a BMP every two hours. You try to give them potassium replacement, they're refusing.

Effective patient-nurse collaboration could help patients adhere to the complex medication regimens associated with some high-alert medications.

RN intrinsic factors. RN intrinsic factors, the inherent beliefs and abilities of the professional nurse, emerged as an important theme. RN competence and RN

engagement were two nurse characteristics that contributed to the sharp end processes that enhanced patient safety during HAM administration.

RN competence. RN competence, knowledge, skills, and judgment to deliver safe, quality care, was discussed by all participants. Errors associated with RN competence were often attributed to latent failures related to lack of training, insufficiently oriented agency nurses, or assigning nurses outside of their capabilities.

> I was floated one time to labor and delivery to monitor someone who bled out and who was on her fourth transfusion…That's not my level of expertise by any means, … I noticed her blood pressure rising slightly. I let the nurses know and of course the nurse hands me the phone. "You need to call the doctor and get an order for a magnesium drip. She could be preeclamptic"' I said, "No problem." Dialing it in. What am I asking for? I mean, if the doctor tells me this and that and I write that down and it's wrong, how am I going to know it's wrong? I don't know that it's ... I understand magnesium aliquots if it's somebody who's low magnesium. In the ER we give it IV push for respiratory distress because it's a muscle relaxant, but I'm in this area here and I really don't understand what I'm asking for.

Active failures were attributed to lack of knowledge or experience, for example, the inability to correctly calculate medication dosages (especially when required to mix the dose on the clinical unit), unfamiliarity with how to access hospital resources, or overdependence on the computer. Many of the nurses interviewed did not have a clear definition of what "high-alert medication" meant. Participants defined HAMs as medications that had look-alike, sound alike names, or related that HAMs only caused

harm if a medication error occurred. This lack of understanding was best summarized by one participant:

> So, we call them high-alert, high-risk, whatever, but, I can say that all I want, but if the person who's going to be doing it doesn't understand what the high-risk, high-alert means, and why we said that, then it's kinda a moot point.

Participants noted that HAM safety often came down to the nurse's knowledge and clinical judgment.

> It's like your platelet count's low today. Did the doctor even look at that? Now they wanted to get them started on maybe Lovenox or something, … like how much knowledge does she [the nurse] have as far as that's concerned? You can't just say, "This is the order. This is what I must do." You have to think, "Does this still make sense for the patient?"

RN engagement. RN engagement guides nurses to act with commitment, integrity and honesty as they strive to deliver excellent patient care. Nurses who are engaged in their professional responsibilities implement sharp end processes to protect patients during HAM administration. Nurses described active failures, situations where nurses routinely ignored computer alerts, were not accountable for their knowledge gaps, completed HAM administration by rote, and ignored policies and protocols designed to safeguard the patient during HAM administration. Although participants were more likely to cite latent failures for nurses bypassing safety measures, many reported that some nurses seemed to lack a sense of obligation regarding fulfillment of their professional responsibilities. One participant explained:

> So many times, I think they [the hospital] do have resources, but how valuable are they if you don't take the time to stop and see what's there. So many people come to work, clock in, and they go right onto their shift, so there's a lot of ... sometimes the boards change in the break room, and somebody put time and effort into this, but people don't read them.

Factors relevant to RN engagement that contributed to HAM safety were described as nurses being accountable for their own knowledge and being willing to advocate for themselves. Safe nurses were described as never complacent, they understood the risks associated with HAMs and made sure to remain vigilant when caring for patients on these medications. One nurse participant self-described her sense of accountability: “Because I cringe whenever I go and give those meds... You never get comfortable. Because if you start getting comfortable, then, that's when you start making mistakes or doing your little work arounds …”

Discussion

Analysis of the results identified three overarching themes for HAM safety: Culture of Safety, Collaboration, and RN Intrinsic Factors. Each theme is supported by taxonomies and sub-concepts (Figure 1). Together, these give a holistic view of the various influences on HAM safety.

Figure 1. Sub-concepts, Taxonomies and Themes

Research specific to safe HAM administration is emerging, and while several studies corroborate these findings, the analysis identified several gaps in the current literature.

Culture of Safety

Many previous findings from research related to causes of medication errors (not specific to HAMs) were corroborated by the participants in our study. A culture of safety has been acknowledged as important to medication safety. Concerns identified by participants in this study, including lack of feedback on errors, inconsistent use of the independent-double check, work load, system complexities, and fear of punishments were identified as factors contributing to medication errors in other studies (Mansour, James, & Edgley, 2012).

Organizational Processes. Interruptions and workflow issues contributed to errors in past research on HAM administration (Engles & Ciarkowski, 2015), as well as all overall medication errors (Blignaut, Coetzee, Klopper & Ellis, 2017; Cabilan, Hughes & Shannon, 2017; Johnson, et al., 2017; Thomas, Donohue-Porter & Fishbein, 2017; Raban & Westbrook, 2014; Keers & Cooke, 2013; Kosits & Jones, 2011; Trbovich, Prakash, Stewart, Trip, Savage, 2010; Brady, Malone, & Fleming, 2009). These represent ineffective blunt end processes, findings confirmed by the participants in our study. Miller, Fortier and Garrison (2011) described the potential of barcode scanning to reduce HAM errors but identified frequent nurse workarounds (failure to scan the armband or drug), recommending the need to continuously assess and improve processes to support effective use of this technology. A review of factors for safe HAM administration found four quality indicators specific to HAM - availability of the HAM, electronic verification of the order, protocols and visual reminders (Smeulers, et al., 2015) that were also identified and discussed by participants in this research.

Although a higher number of transfers from one unit to another can increase the chance of a HAM error (Manias, 2014), participants of this study did not report this concern. Several nurses did note the risks associated with inaccurate medication reconciliation from outpatient settings.

Organizational values. An organizational commitment to safety support enhances medication safety. Gimenes et al. (2016) identified themes of “medication system shapes patient safety” and the “feeling of helplessness in the face of the prevailing organization culture” from nurse participants. A “Nurses’ Rights of Medication Administration” could help assure the responsibility, accountability, and authority of the

nurse to intervene to prevent medication errors (Jones & Treibler, 2018). Blunt end processes that support just culture may improve HAM safety. Research is currently lacking in this area.

Collaboration

Intraprofessional collaboration. Research on the independent double check, a form of intraprofessional collaboration, demonstrates this practice is often successful in error detection, but is routinely performed incorrectly (Miller, Fortier & Garrison, 2011) and may contribute to errors when one nurse persuades another to take an incorrect action (Douglass et al., 2018). Although this procedure is part of the organization safety plan, our research confirmed that nurses were not implementing this consistently, potentiating an active failure due to ineffective sharp end processes. Collaboration in the form of knowledge sharing has not been addressed in the literature on medication safety.

Interdisciplinary collaboration. Interdisciplinary collaboration and medication safety was reported in a review that noted five areas of interdisciplinary collaboration: communication tools, pharmacists included in rounds, collaborative medication reviews, workshops and conferences, and complexity of role differentiation and environment (Manias, 2018). The nurses in our study reaffirmed the importance of interdisciplinary collaboration, especially with the pharmacist, to ensure HAM safety.

Patient-nurse collaboration. Although studies often cite the patient and family as contributing to distractions, there is little research into the potential advantage of forming a partnership between the patient/family and nurse to improve medication safety (Wimpenny & Kirkpatrick, 2010). Several nurses in this study identified the

potential safety ramifications of pursuing greater patient-nurse collaboration around HAM safety.

RN Intrinsic Factors

RN competence. Sharp end factors intrinsic to the nurse have also been acknowledged as essential to safe HAM administration. The importance of nurse competency to HAM safety emerged as important theme from the participant interviews. Accountability for medication knowledge and clinical judgment were frequently emphasized. This is reflected in the literature as well (Engles & Ciarkowski, 2015; Lu, Yu, Chen, Wang, Wu & Tang, 2013; Hsaio, Chen, Yu, Wei, Fang & Tang, 2010). Nurse competence in terms of general medication knowledge and dosage calculation is well documented as essential for patient safety (Johnson et al., 2017; Cabilan, Hughes & Shannon, 2017; Keers & Cooke, 2013; Wimpenny & Kirkpatrick, 2010; Brady, Malone, & Fleming, 2009). Clinical judgment in any medication administration warrants further research (Rohdes and Domm, 2017).

RN engagement. Research into RN engagement is limited. One study reported a correlation between work commitment ("an interest or willingness to spend time and energy for work") and medication errors (Rezaiamin, Pazokian, Tafreshi, & Naisiri, 2017). Although research described nurses committing active errors like failing to follow the rights of medication administration or participate in the independent double check, there has been little discussion of the effect of the nurse's dedication to deliver safe care and its impact medication safety.

This is the first study to comprehensively examine nurses' perceptions about factors that contribute to safety when caring for patients receiving high-alert

medications. The results illustrate that this is a multi-faceted issue. Several new findings were identified. Intraprofessional collaborations in terms of peers as a source of HAM information were extremely important. The interprofessional collaboration deemed very important for HAM safety was the unit-based clinical pharmacist. Participants also emphasized a need to increase the patient's role in assuring HAM safety. Although a culture of safety emphasizes the importance of a non-punitive environment, several nurses discussed the idea that the potential loss of their nursing license, and thus their livelihood, was a motivating factor for safe practice. Another finding included the importance of nurse representation on committees that developed policies affecting their practice. It was felt that this would enhance the practicability of any policy or protocol implemented. Finally, RN engagement was considered essential to safety. Participants felt that nurses who were not dedicated professionals were more likely to ignore safety practices during HAM administration. Table 4 summarizes the barriers and facilitators to safe HAM administration described by participants.

Model Generation

The three themes - Culture of Safety, Collaboration, and RN Intrinsic Factors - define the parameters needed for safe HAM administration. However, as Reason describes in the Swiss Cheese Model, when gaps exist, the alignment of those gaps can precipitate a medication error. Reason's model allowed us to elucidate factors that influenced HAM safety. The findings provided a framework to understand the complexities underlying safe patient outcomes when nurses care for those receiving HAMs. To this end, the authors proposed a descriptive model of nursing practice to prevent high-alert medication error: *High-Alert Medication Safety: Nursing, Collaborative*

and Organizational Influences (Figure 2). The model proposes that three interconnected themes are essential to safe HAM administration. In an organization that prioritizes a culture of safety, nurses who are engaged in their profession and have a high degree of competence work collaboratively to implement safe HAM care. Nurses whose judgment leads them to believe there is a safety concern with a HAM feel compelled to solve the problem because of their professional engagement. Nurses feel safe to address the issue because the organization makes patient safety a focus of all care. Nurses can trust they will not be unjustly penalized for problems outside of their control. Nurses will collaborate with their peers to validate their concerns. They may access information resources to identify solutions to the problem, and then collaborate with the pharmacy or health care provider to remediate the problem. Nurses will negotiate organizational functions to deliver care, and when problems develop, will participate in remediation strategies to develop more effective processes.

Limitations

The goal of this research was to generate a model of influences of HAM safety and identify areas for further research. The results of this study are not generalizable. The population lacks participants from rural or under-resourced hospitals. Nurses without access to technological and human resources may have viewed HAM safety differently. Also, nurses who elected to participate in this study may have done so due to negative experiences with HAM administration. This may have skewed the results. Although an effort was made to recruit participants of diverse races and both genders, most participants were White females. A larger study with subjects inclusive of greater hospital and nurse diversity could add additional insight to this topic.

Conclusion

This research revealed three areas that influence HAM safety - culture of safety, factors intrinsic to the nurse and collaboration. The findings corroborate known factors that interfere with safe medication administration (i.e. interruptions, inefficient workflow, fear of retribution for errors, ineffective collaboration, and insufficient nurse knowledge) published in other research regarding medication and HAM safety. Participants in this study described that safety measures such as bar code scanning and, specific to HAM administration, the independent double check, are inconsistently and incorrectly applied. They identified that a lack of clear and consistent HAM policies, disruptions to processes, and ineffective technology contributed to nurses' frustration and potential errors when administering HAMs. Enhancement of nurse education into and accountability for safe HAM practices could lead to improvement in patient safety outcomes. The impact of just culture, nursing judgment, professional commitment, and patient-nurse collaboration are ripe areas of future research following up on this study.

Table 1. Approach to Data Collection and Analysis

Phase	Method	Strategies Utilized
1. **Preparation Phase**		
Data Collection Strategy	Semi-structured interviews	Interview questions reviewed for appropriateness by specialists in field of human factors. Questions pre-tested with RNs and revised prior to data collection
Sampling Strategy	Purposive and snowballing	The initial purposive sample included adult acute care RNs recruited via email from the hospital Director of Nursing Education. Participants were then encouraged to reach out to other RNs for participation
Selection of Unit of Analysis	Determined based on review of literature	Unit of analysis: RN perceptions of influences on HAM safety
2. **Organization Phase**		
Categorization and Abstractions	Integrative approach	Inductive coding with each idea coded separately. Constant comparison to determine sub-codes. Deductive coding to integrate concepts identified in previous literature
Interpretation	Analysis	Data analyzed to develop taxonomies, themes and theory
Representativeness	Trustworthiness of process	Process validated with experienced qualitative researcher
	Trustworthiness of representativeness of data	Results verified with non-participant RNs
3. **Reporting Phase**		
Reporting Results	Reporting of results evaluated against COREG standards	Report reviewed by senior researchers for clarity, logical flow of information, transferability of results, systematic use of quotations and interpretation of results
Reporting analysis process	Reporting of results evaluated against COREG standards	Report reviewed by senior researchers for description of analysis process and trustworthiness of content analysis

Table 2. Semi-structured Interview Guide

Initial Questions	Follow-up Questions	Probe
How would you define high-alert medications?	What high-alert medications do you use in your practice?	
Do you remember when you first heard the term high-alert medication?	Will you describe for me how you learned about high-alert medications?	
What factors help you feel confident to administer high-alert medications safely?	Do you feel these safety measures are adequate to protect patients during high-alert medication administration? Why or why not?	Describe for me the steps you take when administer a HAM on a typical day.
What policies and procedures are in place at your facility to assure patient safety during high-alert medication administration?	Can you provide an example of how you use these protocols?	Do you feel the policies and procedures at your hospital are working to keep patients' safe? Why or why not?
What barriers do you think interfere with a nurse's ability to follow these policies and procedures?		
Can you describe any factors that you feel interfere with your ability to safely administer high alert medications?		
What factors can cause a nurse to make a medication error when administering a high-alert medication?	Can you give me an example of a high-alert medication error?	What factors do you feel contributed to this error?
Some nurses have ways to "work around" hospital procedures. Are you aware of any "work around" strategies nurses use in your agency when giving high-alert medications?	Can you give me an example of what work arounds you are seeing in practice?	
Imagine that you have to teach a nurse how to safely administer high-alert medications. What information would you consider essential for the nurse to know?		

Table 3. Characteristics of Participants

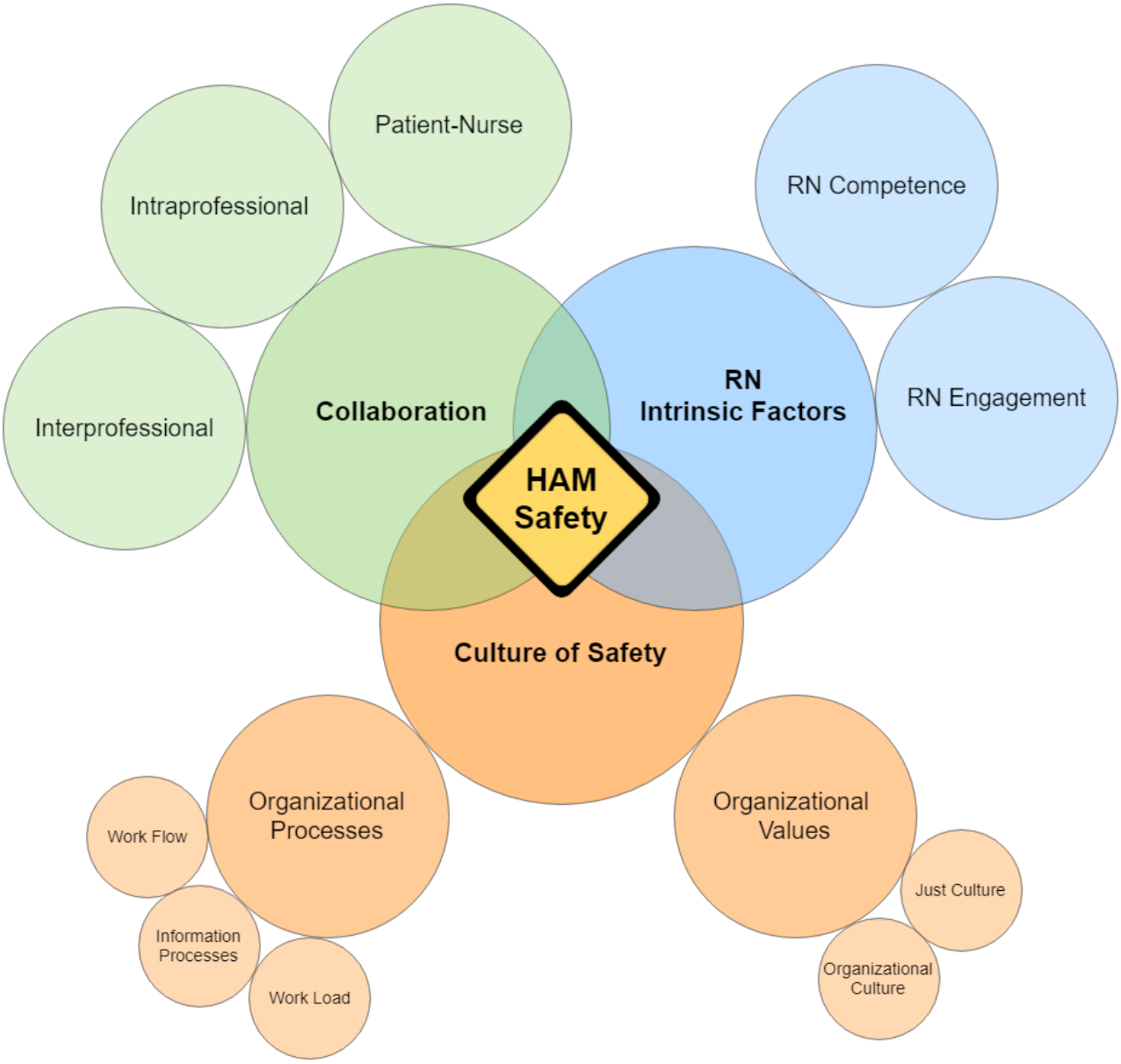
All Participants (n = 18)	n(%)
Age	
20-30	9(50)
31-40	3(17)
41-50	3(17)
51-60	2(11)
Over 60	1(5)
Gender	
Female	15(83)
Male	3(17)
Race	
White	13(72)
Black	4(22)
Asian	1(7)
Years of Experience	
Less than 1	1(0.6)
1-5	10(56)
6-10	3(17)
11-15	2(11)
26-30	1(0.6)
More than 40	1(0.6)
Practice Area	
Medical Surgical	7(39)
Critical Care	2(11)
Emergency	2(11)
Telemetry	7(39)
Highest Level of Education	
ADN	3(17)
BSN	10(56)
Master's	3(28)
Current Student	
Yes	6(33)
No	12(67)

Table 4. Barriers and Facilitators Related to Safe HAM Administration

Themes	Barriers	Facilitators
Culture of Safety		
Just Culture	Fear of retribution Fear of confronting physician Fear of admitting a knowledge gap	Root cause analysis Rewards and acknowledgment Disciplinary actions for flagrant disregard of safety policies and procedures
Organizational Culture	Safety not a priority Culture inhibits questions Culture inhibits error reporting	Safety part of mission and values of organization Safety is an expectation for all members Support culture of questioning Routine communications re: errors and prevention
Work Flow	Cumbersome or overly complex processes Work arounds Lack of technology (insufficient number of smart pumps, computers) Technology failure (unable to scan) Resources hard to access Distractions	Process analysis to improve work flow RNs involved in development of policies that impact work flow Protocols and policies tested before implementation Needed resources (medications, equipment) easily accessible Minimize distractions during HAM administration
Information Resources	Cumbersome or overly complex protocols, policies or procedures Information incomplete (missing patient data, policies, procedures, protocols) Alerts and warnings inconsistently applied Technology failure	Policies and procedures not overly complex or cumbersome RNs involved in development of procedures and protocols Information resources comprehensive and accurate Technologies efficient, effective and easy to access Computer algorithms Computerized provider order entry eMAR associated data link (medication monograph, patient lab data) Smart pumps Availability of technology support Essential information on medication label Printed protocols at nurses' station Badge buddies
Work Load	Patient acuity Number of assigned patients Patient non-cooperative Nurse fatigue and loss of focus	Increasing staffing based on patient acuity, cooperation Adjusting load during HAM administration

RN Intrinsic Factors		
RN Competence	Lack of knowledge about HAM Inexperience with HAMs Dosage calculation skills inadequate Mixing HAM on unit Nurse does not know how to access resources Overdependence on computer Lack of institutional specific training Staff and agency nurses caring for patient's outside of their competency	HAM education Ham simulation experiences Competency evaluation RN self-advocacy Facility orientation for new hires and agency nurses Continued RN development on HAMs, Assignments with HAMs based on competency
Professional Commitment	Lack of nurse commitment to HAM safety No personal accountability for knowledge gaps RN not doing what they know needs to be done Rote administration of HAM	Institutional accountability of evaluation of RN competence Rewards and acknowledgment for safety behaviors
Collaboration		
Intraprofessional	Not holding peers accountable for HAM safety behaviors Peers complicit in work arounds	Peer collaboration encouraged Peer resource identified and accessible (team members, charge nurse, nurse manager, nurse supervisor) Standardized communication strategies employed Independent double check
Interprofessional	Lack of interprofessional trust Lack of standardized safety communication strategies (CUS) Verbal orders	Interprofessional collaboration encouraged Unit based clinical pharmacist available during HAM administration
Patient-Nurse	Patients' not aware of HAM safety concerns	Patient as partner in safety when receiving HAM

Figure 2. High-Alert Medication Safety: Nursing, Collaborative and Organizational Influences



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Appendix 1: Deductive and Inductive Framework used to Develop Model: *High-Alert Medication Safety: Nursing, Collaborative and Organizational Influences*

Concepts	Sub-Concepts	Taxonomies & Examples	Themes
Latent failures - Fear of confronting MD, fear of admitting a knowledge gap, fear of repercussions **Sharp end processes** - Fear of losing license, fear of repercussions **Blunt end processes -** Rewards and acknowledgment	Just Culture – "An environment in which staff members accept responsibility for their own actions, but know the organization will treat them fairly and not blame them for something out of their control." (Frankel, Haraden, Federico, Lenoci-Edwards, 2017).	Organizational Values – The beliefs held by the members of a healthcare organization about safe, quality care Examples: *The paper's right there on the computer, you can look at it. I just point to it and they look at it. Sometimes they look, sometimes they don't, and that's how we go.*	Culture of Safety – "A collective and continuous commitment by organizational leadership, managers and health care workers to emphasize safety over competing goals." (American Nurses' Association, 2016)
Latent failures - Culture inhibits questions, lax culture, not reporting error **Blunt end processes** - Culture of questioning, encouraged to report errors, routine communication about errors made in organization, information dissemination on error prevention	Organizational Culture – "The collective values, beliefs and principles of organizational members" (*Needle, 2004).*		
Latent failures - Medications in many locations, pharmacy error, cumbersome processes, distractions, complexity of protocol, protocols inconsistent, work arounds, information hard to find, missing patient data, lack of technology (insufficient number of smart pumps), resources hard to access, technology failure (unable to scan) **Active failures** - Work arounds **Blunt end processes** - Policies	Work Flow – Processes that support safe, quality nursing practice.	Organizational Processes – Core activities and responsibilities carried out by members of an organization. Examples: *Some of the barriers again are while you're trying to take care of some of these things, your phone's ringing constantly. It's again, it's the interruptions and the lack of ability to focus. And I think that's where a lot of the mistakes or the errors, or you*	

Concepts	Sub-Concepts	Taxonomies & Examples	Themes
and procedures, RN involved in policy development, computer algorithms, medication reconciliation		*know, the reason for not following a protocol happens.*	
Latent failures - Complexity of protocol, protocols inconsistent, work arounds, information hard to find, missing patient data, lack of technology (insufficient number of smart pumps), resources hard to access, technology failure (unable to scan) **Active failures** – Not utilizing available resources **Blunt end processes** - Computer algorithms, computerized provider order entry, ease of access to information, eMAR, associated data link in eMAR, medication monograph in computer, smart pumps, availability of technology, technology support, essential information on medication label, printed protocols at nurses' station, badge buddies	Information Resources – A two-way flow of high-quality information to provide safe, quality care.		
Latent failures – Acuity, load, patient non-cooperative, overwhelmed Barrier - nursing is hard **Active failures** – Nurse fatigue, focus **Blunt end processes** - Adjusting work load during HAM, staffing	Work Load – Job responsibilities that place demands on the nurse's time and attention. Overwhelming workload interferes with attention causing distraction and loss of focus.		
Active failures – Lack of knowledge about HAM, lack of knowledge, inexperience, dosage	RN Competence – The knowledge, skills, and judgment needed to deliver safe, quality	Examples: *You've got people that will cosign but not actually look at anything.*	RN Intrinsic Factors – Inherent beliefs and abilities of the professional nurse.

Concepts	Sub-Concepts	Taxonomies & Examples	Themes
calculation, pulling or mixing dose in unit, does not know how to access resources, overdependence on computer **Latent failures** - Lack of training, staff and agency nurses caring for patient's outside of their competency **Sharp end processes** - RN education, judgment, knowledge, self-advocacy **Blunt end processes** – Orientation, continued RN training, competency evaluation, assignments based on competency	care.	*They'll just, "Yeah, okay." Sometimes it's out of pure busyness... like I said you're being pulled. It's not like ... Once again, that doesn't mean you're not a decent person. You're a human being. You know what I'm saying? I think people try to do the right thing.* *I think some nurses are pretty happy, but a lot of them are not happy with the work or how things are going and that disquieted, that anger, that discontent, it shows in the quality of the work they do, how they treat the patients and their relationship with other coworkers. It just comes through, even if they try and hide it.*	
Active failures - Lack of nurse integrity, ignore computer alerts, no accountability for knowledge gap, RN not doing what they know needs to be done, rote administration of HAM **Sharp end processes** - Self-accountability for knowledge gap, self-advocacy, never complacent, make no assumptions	RN Engagement – guides nurses to act with integrity and honesty as they strive to deliver excellent patient care		
Sharp end processes - Collaboration with nurse peers (team members, charge nurse, nurse manager, nurse supervisor), peer communication, independent double check Active failure – Not holding peers accountable	Intraprofessional Collaboration – Two or more nurses working together to deliver safe, quality care.	Examples: *Sometimes I think they think if you're checking the medication [they feel] like they don't know what they're doing or because you've been a nurse longer than they have or you've been on that unit longer than they have, like you're doubting their ability. It's really not about them. It's about safety for the patient.*	Collaboration – Two or more people working together to achieve a desired outcome

Concepts	Sub-Concepts	Taxonomies & Examples	Themes
		On my unit now, we have some nurses that have been nurses for about a year and they're doing charge. When I work with them, they want to be charge, I'm fine with them being charge, but they know I'm there. I'm a resource. If you have a problem, come to me, I can help.	
Active failures - Lack of trust (not conferring with MD) **Latent failures** – Poor communication (verbal orders) **Sharp end processes** – interprofessional collaboration (pharmacy HCP/MD, lab), RN verification of orders, patient as partner	Interprofessional Collaboration – members of the health care team work together to support high quality patient care	Examples: *… in the last year or so that we finally got clinical pharmacists 24/7 on the unit. They'll be there in codes. They'll be there for tPA administration, all that kind of stuff, so they're fantastic. Also, just having somebody right next to you to just say, 'Hey, does this look right to you?'* *That's when you appreciate, because then you come into a situation where then two doctors don't agree, so the next day, the day after that whoever is covering on this non-protocol heparin, and that can be a serious yin-yang of coagulation. That's a huge risk I think on this floor, because you're putting the person at risk of a stroke from a clot a PE, something. You don't realize how important, they just go of the grid.*	

Concepts	Sub-Concepts	Taxonomies & Examples	Themes
Active failures - Patient non-cooperative, non-adherent **Sharp end processes -** Patient education, having patient communicate HAM problems	Patient-Nurse Collaboration - the patient and family work with the nurse to achieve a health outcome	*You just look at them [the patient] and you're like, "Well," you got to use all your good nursing skills to really tell them, say, "Listen, I know you're feeling lousy," or they want to leave AMA. You say, "You can't leave now. I mean, you're competent, you can leave, but you'd just be right back."* *"I just don't assume. I might go in now and say, "I'm giving you this medication. Do you understand why you're getting this?" It's always important for me to have that understanding from the patient"*	

Use of Simulation to Teach High-Alert Medication Safety: A Feasibility Study

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Abstract

Background: Despite the significant risk of harm when administration errors of high alert medications (HAM) occur, nurses receive little training on HAM best practices.

Aim: To evaluate the satisfaction with and feasibility of a simulation-based learning intervention to improve student nurse competence to safely administer HAMs.

Methods: Student nurses were recruited from an associate degree nursing program to evaluate design elements of two simulation scenarios created to teach safe HAM administration. Two survey instruments on simulation (Simulation Design Scale, Debriefing Assessment for Simulation in Healthcare (DASH) Student Version©) were completed and focus group data were obtained. Feasibility outcomes of a simulation-based learning trial at a community college (potential student participation, simulation resources, and technological and administrative support) were also assessed.

Results: Thirty-three student nurses (23.4% of those eligible) participated in the study. Participants rated the simulations highly on both the Simulation Design Scale (Simulation 1: M = 4.86, SD = .4; Simulation 2: M = 4.86, SD = .422) and the Debriefing Assessment for Simulation in Healthcare (Simulation 1: M = 6.84, SD = .476; Simulation 2: M = 6.86, SD = .410). Participants reported increased confidence and competence in caring for patients receiving HAMs following study participation. Feasibility assessment revealed many resources to support a simulation intervention: high quality simulators, smart pumps, computers, audio-visual recording, rooms for pre- and debriefing, and secure areas for data storage. Barriers to feasibility included lack of electronic medical record (EMR) and electronic medication administration systems (eMAR), and lack of access to participants during regular semester hours.

Conclusion: The simulation scenarios are appropriate for use in a future study. Access to an EMR and EMAR, coupled with institutional support allowing student participation during regular semester hours would be needed for an interventional study. A multisite study is recommended to improve sample size.

Key words: Simulation-based Learning, high-alert medications, medication error, feasibility, Jeffries Simulation Theory, Swiss Cheeses Model

Introduction

Medical error is the third leading cause of death in the United States (U.S.) (Makary & Daniels, 2016), and approximately 1.5 million medication errors, a specific type of medical error, occur in hospitals every year (The Institute of Medicine, 2007). A medication error is defined as "an error (of commission or omission) at any step along the pathway that begins when a clinician prescribes a medication and ends when the patient actually receives the medication" (Medication Errors, 2018, pp. 2). Medication errors may or may not result in patient harm, however, approximately 7000 inpatient deaths occur in hospitals in the U.S. every year due to medication errors (Flynn, Liang, Dickson, Xie, & Suh, 2012). High-alert medications (HAMs) have an increased risk of causing serious harm to a patient even when administered correctly, but risk increases when associated with a medication error (Institute for Safe Medication Practices [ISMP], 2018, pp. 1). Examples of HAMs include opiate, anti-coagulant, and anti-diabetic medications. Previous researchers have reported HAM errors as occurring within 14% and 50% of medication incidents; approximately 11-29% occurred during the administration process (Cabilan, Hughes, & Shannon, 2017; Manias, Williams, Liew, Rixon, Braff, & Finch, 2015; Engles & Ciarkowski, 2015). Many factors contribute to HAM errors, including: Nurse knowledge (Engles & Ciarkowski, 2015; Lu, Yu, Chen, Wang, Wu, & Tang, 2013; Hsaio, Chen, Yu, Wei, Fang, & Tang, 2010), interruptions and workflow issues (Engles & Ciarkowski, 2015), frequent transfers from one unit to another (Manias, Williams, Liew, Rixon, Braff, & Finch, 2015), and failure to implement bar-code scanning appropriately (Miller, Fortier and Garrison, 2011). These findings support the understanding that medication errors result from gaps in the safety

processes of complex systems, when humans fail to identify the problem and intervene before the patient receives the medication (AHRQ, 2018; Reason, 2000). Strategies to reduce HAM medication errors include: availability of the HAM, electronic verification of the order, protocols and visual reminders (Smeulers, et al. 2015) technological assistance (bar code scanning) (Miller, Fortier, & Garrison, 2011), high-alert medication procedures (independent double check) (Douglass et al., 2018; Engles & Ciarkowski, 2015), and increased awareness through education (Brady, Malone, & Fleming, 2009).

One educational strategy that may help prepare students for safe HAM administration is simulation-based learning (SBL). A well designed SBL could enhance knowledge, skills, and attitudes (Jeffries, 2016) needed for safe medication administration, specifically HAMs, by allowing students an opportunity to practice essential skills without jeopardizing patient safety (Improving Patient Safety Through Simulation Research, 2018). Studies of medication administration by students suggest medication errors are common, thus, methods to reduce errors should begin early in nursing programs (Dunn, 2014; Schneidereith, 2014; Cooper, 2012; Reid-Searl, Moxham, & Happell, 2010; Harding & Petrick, 2008; Wolf, Hicks, & Serembus, 2006). SBL scenarios could be designed to target organizational and human practices commonly associated with HAM errors. Despite the growing use of simulation in nursing education, little research specifically addresses the use of SBL to teach HAM safety practices to nursing students. Three studies were identified that describe incorporating HAMs in simulation. Fadale et al. (2014) demonstrated that a simulation on safe administration of a vasopressor during septic shock improved the number of nurse-initiated vasopressor titrations, but not the speed of initiation of medication therapy.

Pauly-O'Neill (2009) incorporated high-risk medications and built-in prescribing errors in a pediatric simulation that improved participant implementation of the five rights of medication administration in nursing students. In an early study, Dobbs, Sweitzer, & Jeffries (2006) measured student perceptions of simulation design with an insulin simulation. Improvement in student performance outcomes were not attained.

The purpose of this research was to determine the feasibility of simulation-based learning as a strategy to teach nursing students' safe administration of high-alert medications. Two specific aims included: 1) to develop and evaluate two high-alert medication simulation scenarios and 2) to evaluate the feasibility of conducting a SBL interventional study incorporating the two simulations at a community college associate degree nurse education program.

The development of the SBL scenarios required an organizing framework to assure a quality SBL experience. However, it was also essential to include error factors that contributed to HAM error. The framework for the inclusion of error factors needed to incorporate the understanding that causes of HAM medication errors are multifaceted and largely result from organizational systems failures that are supposed to protect patient safety. For this reason, two theories were blended to inform this feasibility study: Reason's Swiss Cheese Model (SCM) and the NLN Jeffries Simulation Theory (JST). The JST guided the design and implementation of the HAM simulation scenarios. The JST has three key components: simulation design, simulation experience, and outcomes (Jeffries, 2016). The simulation design is the basis for the development, implementation, and evaluation of the simulation scenario (Groom, Henderson, & Sittner, 2014). A well thought out simulation design is guided by the learning objectives,

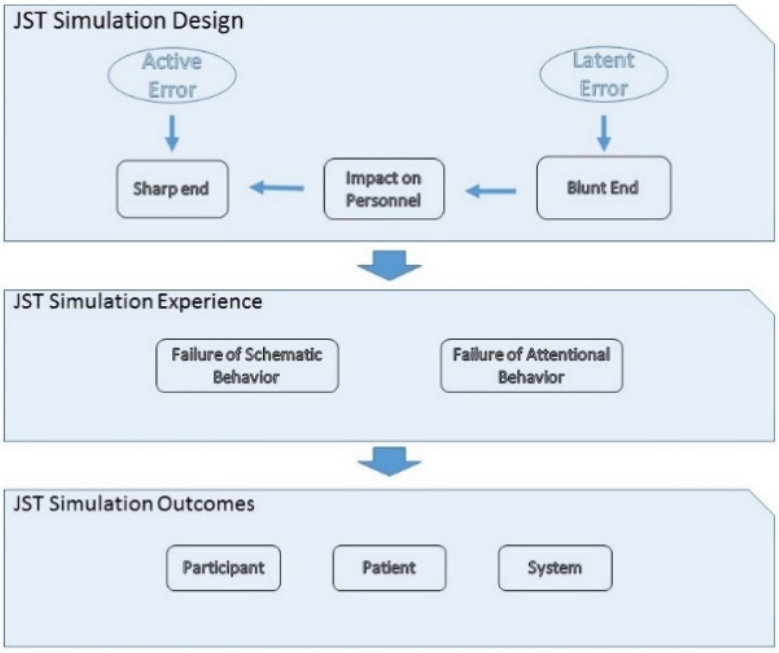
which determine key features of the design such as the necessary complexity of problem solving skills, fidelity of the experience, participant and observer roles, progression of the scenario, and briefing and debriefing activities (Jeffries, 2016). The simulation experience occurs within an educational context that is learner centered, collaborative, and interactive (Jeffries, 2016). It is during the simulation experience that learner objectives are achieved. With the JST, the evaluation of outcomes is categorized in terms of the participant (e.g., satisfaction with learning, skill attainment, self-confidence), the patient (individual care outcomes), or the system (effectiveness or practice changes) (Jeffries, 2016).

System failures occur when the confluence of protective factors used to prevent an error fail at exactly the same moment (Reason, 2000). Visualizing errors as slices of Swiss cheese, when holes in the cheese align, gaps in the safeguards to prevent an error are exposed providing an opportunity for an error to occur. According to Reason, human error is inevitable, and systems should be designed to include protective factors to prevent errors that are latent (caused by poor organizational designs) and errors that are active (caused by individual's slips and mistakes) (Reason, 2000).

Our study's simulation design incorporated factors relevant to latent errors to improve the realism of the design, as well as active error prevention, e.g. incorporating situations that require problem-solving and clinical judgment. Registered nurse interviews provided key information regarding individual and latent factors needed in a HAM scenario (Sessions, Nemeth, Kelechi, & Catchpole, submission pending). The Agency for Healthcare Research and Quality (2018) recommended incorporating the SCM into a healthcare facilities' safety plan to prevent errors. No other nursing research

that combined the use of the SCM and JST in the simulation design was found. By merging the SCM and JST, this study evaluates the outcomes based on the inclusion of factors contributing to human errors into the simulation design and experience.

Figure 1. Amalgamation of Swiss Cheese Model and NLN Jeffries Simulation Theory



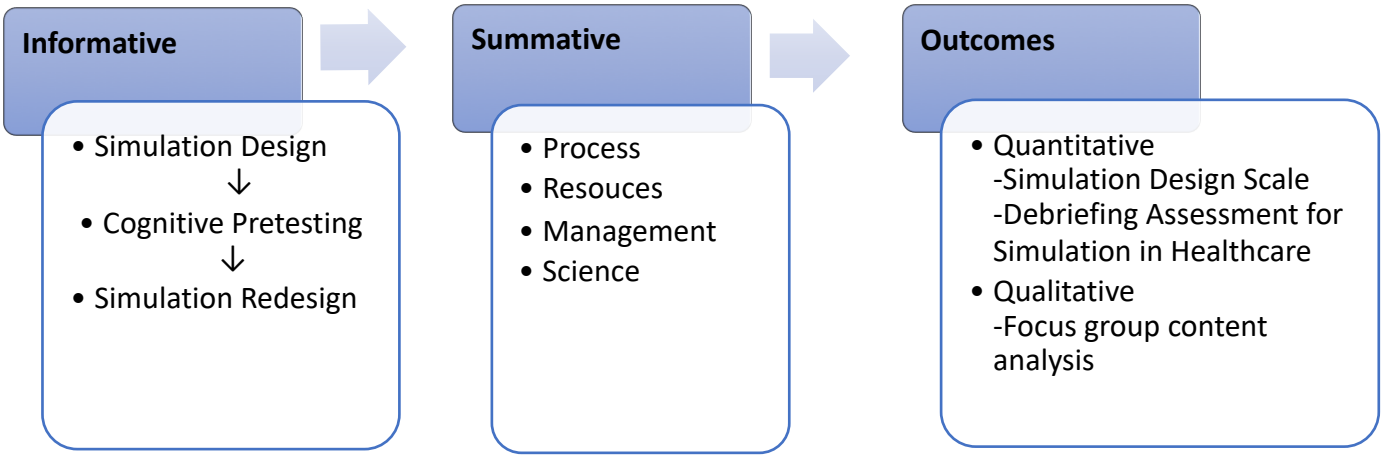
Methods

Study Overview

This research was conducted in two arms, informative and summative. See Figure 2: SBL Feasibility Study Design. During the informative phase, two simulation scenarios on HAM administration were developed; one as a HAM educational intervention, and one for a post intervention evaluation of learner HAM safety behaviors. Both simulation scenarios were evaluated via a cognitive pre-test procedure, and redesigned based on the analysis of the results.

During the summative phase, a feasibility assessment was conducted to evaluate the possibility of conducting a SBL research study at a community college in the mid-Atlantic region. Tickle-Degnen's (2013) feasibility assessment method was used, to obtain data on the study process (potential participant recruitment, retention, and adherence), resources (physical capacity, access to technology and resources, adequacy of time frame, administrative and personnel support), management (efficacy of study documents, data entry processes and resources), and science (quality and acceptability of SBL scenarios developed for intervention and evaluation) to complete this analysis.

Figure 2: SBL Feasibility Study Design



Informative: Simulation Scenario Development

Both simulation scenarios were designed based on the JST and the International Nursing Association for Clinical Simulation and Learning (INASCL) Standards of Best Practice: Simulation Design (INASCL Standards Committee, 2016). These included: 1) Needs assessment, 2) Measurable objectives; 3) Theory-based format, 4) Contextual

learning experience, 5) Fidelity, 6) Facilitative approach, 7) Pre-briefing, 8) Debriefing, 9) Evaluation of SBL experience, 10) Preparation material, and 11) Pilot testing of SBL experience. A preliminary qualitative descriptive study of registered nurses (RN) on HAM safety informed the development the high-alert medication administration (HAM) simulation scenarios (Sessions, Nemeth, Kelechi, & Catchpole, submission pending). This approach was utilized to assure the scenarios included potential latent and active failures to safe HAM administration common in current clinical practice. Several safety practices were included in the design of the simulations: HAM protocol, independent-double check procedure, a nursing drug guide, and a HAM documentation record for students to record HAM administration. The potential for latent and active failures in HAM practices were also built into in the simulation scenario designs: distractions, absence of needed patient data, and colleagues who deliberately failed to follow HAM procedures.

Informative: Scenario Designs

A heparin infusion was selected as the HAM scenario because it requires the nurse to follow a protocol and to interpret patient and diagnostic data to make clinical judgments. The heparin protocol was designed based on a protocol described by Schreiber (2015). The simulated patient in the scenarios developed a venous thrombosis after spraining her ankle during a marathon. Initially treated with a subcutaneous low molecular weight heparin (LMWH), the patient was admitted for heparin therapy after showing signs of an allergic reaction to the LMWH. The first simulation started when the patient was transferred from the emergency department to the patient care unit. After a pre-brief and orientation to the simulation environment, the

educator (the principal investigator [PI] in the role of the emergency department nurse) provided the learners with report. The learners' main task was to hang the intravenous heparin infusion safely based on the heparin protocol and their assessment findings. The learners were hindered in accomplishing this task, however, by distractions and the lack of cooperation from the student assigned to provide the independent-double check. At the completion of the scenario, learners participated in debriefing where the educator encouraged them to identify barriers to safe HAM administration and strategies to enhance safety.

The second scenario had the learners caring for the same patient several hours later. The heparin infusion had been off for one hour based on the results of the diagnostic data. The learners were tasked with resuming the heparin infusion based on diagnostic findings and interpretation of the protocol.

Both scenarios were designed for use with moderate to high fidelity simulators in a simulation lab environment. SimMan 3G, a high-fidelity simulator by Laerdal, Inc. was used in this study. The simulation lab contained mock patient rooms with head wall systems and private debriefing rooms. Available equipment included a hospital bed, patient monitor, simulated wall oxygen and suctioning, a medication dispense system, and smart pump. Efforts to enhance fidelity included the use of moulage to simulate a red streak on the patient's leg and bubble wrap under the elastic bandage to simulate edema. A wig and jewelry were placed on the manikin to help simulate female gender. A control room with digital audio-video recording equipment allowed investigators to run and record the simulations. The simulation lab had a simulation coordinator responsible for creating the simulation schedule, ordering equipment and supplies and setting up

the simulation prior to the first running. The college had technicians available Monday through Friday from 8 am – 11 pm to assist with equipment problems.

Informative: Cognitive Pretesting

Once the simulation scenario designs were completed, two RNs with HAM experience participated in the cognitive pretesting of the simulations to determine if they covered essential components of HAM administration, were realistic, and clinically relevant. As the RN participants trialed the simulations, they were digitally video recorded, and instructed to “think aloud” (Koskey, 2016) as they completed each simulation, verbalizing their thoughts on how to complete tasks, their frustrations, concerns, and kudos. RN participants then viewed their recordings and participated in follow-up probing, where the investigator asked open ended questions to gather additional data on their perceptions of the simulation scenario. The cognitive pretesting identified opportunities to improve the simulations, for example attending to the fidelity of the simulation, Despite the availability of a patient ID band, a paper medical record and medication administration record, neither nurse completed the rights of medication administration. During probing, both stated that since the scenario equipment did not contain an electronic medical record (EMR) or electronic medication administration system with bar-code scanning (eMAR), they concluded that following the rights was not an expected step in the simulation. The PI worked with a computer scientist to develop an eMAR with bar code scanning to complete the research study. Additional revisions were made to both HAM simulations based on the cognitive pretesting to improve the scenario fidelity.

Summative: Feasibility Testing Procedures

An evaluation of the feasibility of a SBL study at a mid-Atlantic community college was conducted. Assessment of process, resources, management, and science were completed according to criteria established by Tickle-Degnen (2013). See Appendix 1: Feasibility Assessment Strategy. Study process data were collected, including the number of students who volunteered to participate, retention and adherence rates. College resources were evaluated for access to the simulation lab, availability of equipment to run the simulations, and study management resources (i.e., time constraints, expertise of personnel, data management). Management of the study was assessed focusing on an evaluation of the study documents, data entry and storage, and the collaboration between the college and the investigators. The science assessment focused on the evaluation of the scenario designs including adequacy of pre- and post-simulation briefing, simulation fidelity, availability of support during simulation, availability of equipment and resources and acceptability of the simulations to participants. Student nurse focus group interviews included specific questions related to the quality of the simulation scenarios (based on the JST and INASCL guidelines) and the feasibility of the simulation scenarios.

A journal of ongoing documentation on the feasibility measures being collected related to study process, resources, management and science was maintained throughout the summative portion of the study. Institutional review board (IRB) approval was obtained from the university (MUSC Pro00063761) and the community college (HCC-2017-05-23) participating in the research prior to participant recruitment. Written consent was not required by either IRB.

Summative: Sample and Setting

Senior associate degree nursing students were invited for inclusion in this research. Students in their first year were excluded as they would have little experience with simulation or HAMs. The community college nurse education program admitted approximately 200-240 associate degree nursing students every year. Information about the study was posted on the announcement page of the course learning management system. The PI attended class sessions to explain the research, answer questions, and provide contact information for those interested in participating in the study. Students choosing to participate contacted the PI via email, phone, or in person. Interested students were given an IRB approved study information sheet. Student who chose to participate used an online scheduling application to register into a simulation group during a time frame that best met their needs. Groups were limited to six participants per research session.

Summative: Study Implementation

Students who registered to attend received an email with basic information about the HAM scenario: patient diagnosis, treatment plan, learning objectives, and learning resources. Once arriving to the simulation lab, students were provided a description of study processes and participant expectations. Students' verbally acknowledged understanding of expectations. Students then participated in a scenario pre-brief and were randomly assigned roles in the scenario: primary nurse, secondary nurse, significant support person, unit secretary, charge nurse, or observer. Participants were given role cards explaining their role in the scenario. For example, the student in the unit secretary role was charged with distracting the nurse during critical safety steps of HAM administration (e.g., paging the primary nurse to the desk to take report from the

emergency department nurse on a new patient). After receiving pre-brief and role assignments, participants were given a brief tour of the resources in the simulation suite and received an SBAR (situation, background, assessment and recommendations) report. This report was scripted so every group received the same information. After completing the first scenario, students were debriefed utilizing the reaction, analysis, and summary method to promote reflective thinking (Decker et al., 2013; Rudolpf, Simon, Raemer, & Eppich, 2008). During the reaction phase, participants were encouraged to share their initial thoughts about: 1) their simulation performances, 2) what they perceived as challenging, and 3) their response to those challenges. During the analysis phase, participants were encouraged to probe events to develop a more comprehensive understanding of their strengths and deficits during the simulation. In the summary phase, participants were encouraged to share their most important insights gained from the experience. After simulation 1 debriefing concluded, students completed two simulation assessment instruments as part of a quality assessment of the simulation, then participated in a focus group interview to provide participant perspectives on factors that were effective or needed enhancement in the design of simulation 1. Roles were then reassigned, and participants completed the second scenario following the same format to collect participant feedback on simulation 2. As part of the second focus group, students were also asked to share their opinions about which simulation should be used as a learning experience and which should be used for outcome evaluation.

Summative: Instruments

Participants completed two reliable and valid instruments, one on the simulation design (Simulation Design Scale, student version ©) and one on the simulation debriefing (Debriefing Assessment for Simulation in Healthcare (DASH) Student Version©) after completing each scenario and prior to focus group discussion. The Simulation Design Scale (SDS) is a 20-item instrument that uses a five-point scale to assess the design features of a simulation, including: objectives/information, support, problem solving, feedback, and fidelity. Participants rated simulation design features with a score of 1 (strongly disagree with the statement) through 5 (strongly agree with the statement). Ten content experts helped establish content validity of the Simulation Design Scale. Reliability assessment demonstrated a Cronbach's α of 0.92 for presence of features, and 0.96 for the importance of features (NLN: SIRC Simulation Innovation Resource Center, 2018). The Debriefing Assessment for Simulation in Healthcare (DASH) was developed to evaluate student views about the strategies and techniques used during a simulation debriefing (Brett-Fleegler, Rudolph, Eppich, Monuteaux, Fleegler, Cheng, & Simon, 2012). The DASH measures participant thoughts regarding pre-briefing and debriefing discussions on a scale of 1-7 where a 1 is extremely ineffective/detrimental and a 7 is extremely effective/outstanding. The DASH has demonstrated reliability and validity (intraclass correlation coefficient – 0.74, Cronbach α 0.89) (Brett-Fleegler, Rudolph, Eppich, Monuteaux, Fleegler, Cheng, & Simon, 2012).

Summative: Focus Groups

After completing the instruments, student nurses participated in focus groups to provide qualitative data on the simulation scenarios. Factors associated with simulation design efficacy were incorporated into the semi-structured interview questions used

during the focus groups (Arthur, Levett-Jones, & Kable, 2013; Groom, Henderson, & Sittner, 2014). See Appendix 2: Focus group semi-structure interview questions. Each focus group contained the four to six students who participated in the simulations. The first author led the focus groups, which lasted approximately 30 minutes. After each research session, investigators reviewed information obtained during the focus groups and made changes to each simulation scenario based on participant feedback.

Summative: Data Management and Analysis

Participants completed a demographic survey describing their age, sex, race, ethnicity, simulation experience, current course, and two SDS and DASH surveys (one for each simulation scenario). Survey data were entered into an Excel spreadsheet. All paper forms were kept in a locked cabinet, in a locked office, or on a cloud-based, HIPAA compliant secure server. Audio recordings of focus group sessions were professionally transcribed by a secure transcription service. The recordings and the transcripts were compared to ensure accuracy and all personally identifying data was removed. No personal identifying data were kept in association with the data used for analysis. A deductive approach (Bradley, Curry, & Devers, 2007) was used for analysis of data based on existing theory-based definitions (JST) and from substantial research on factors that improve simulation effectiveness (INASCL Simulation Design Standards). Investigators developed a priori codes based on the INASCL simulation design best practice standards and the JST. Focus group data were coded and analyzed to make inferences about factors that enhanced simulation design quality or were problematic for participants.

Summative: Statistical Analysis

The Statistical Package for the Social Sciences (SPSS) Version 25 (SPSS, Inc, Chicago, IL) was utilized to calculate descriptive statistics. Frequencies and percentages were calculated for categorical variables (sex, race) and means and standard deviations for continuous variables (age, SDS, DASH). Findings from the surveys and focus groups were merged, and results compared to inform interpretation of feasibility data.

Summative: Results

Feasibility

Using the method described by Tickle-Degnen (2013), investigators collected data on study processes, resources, management, and science. See Appendix 1: Feasibility of Assessment Strategy.

Processes. Potential recruitment at the research site was evaluated within the study process domain (Tickle-Degnan, 2013). Out of a potential 141 candidates for participation, 40 responded with inquiries regarding the study, 36 registered to attend a simulation session, and 33 (23.4% of all potential participants; 91.7% of those agreeing to participate) completed the simulations, focus groups, and all assessment instruments. Participants verbalized understanding of the purpose of the focus group and contributed many valuable insights which were utilized to enhance the simulation designs. They had no difficulty understanding and completing the SDS. The DASH was slightly more challenging. Many participants did not understand the need to give an overall rating for each element. Directions called for them to skip questions that they felt did not pertain to them and this contributed to much of the missing data in this instrument.

Participants. Thirty-three student nurses, ranging in age from 20-58 (*M* = 30.33, *SD* = 8.59), participated in this feasibility study. Three were male (9.1%), 30 were female (90.9%). Racial minorities accounted for 39.4% of participants and most participants identified as non-Hispanic (93.9%). See Table 1: Race/Ethnicity of Participants. Participants.

Table 1: Race/Ethnicity of Participants

Race/Ethnicity (n = 33)	#	%
White	18	54.5
Black	10	30.3
Asian	2	6.1
Native American	1	3
Non-response	2	6.1
Hispanic	2	6.1
Non-Hispanic	31	93.9

Resources. Assessment of resources included evaluating the physical capacity of the simulation lab, access to technology and resources, the adequacy of the time frames available to complete research requirements, and administrative and personnel support. The simulation lab was a dedicated lab for the Health Sciences Division, however, the Emergency Medical Services Program had a separate simulation lab. Other Health Sciences programs at the college only participated in simulation as part of nursing created interdisciplinary simulations. The simulation suite had four simulated hospital rooms, all with high fidelity manikins, and four debriefing rooms. The lab was

well resourced with access to laptops, smart pumps, audio-video capture, and two medication dispense systems. The Nurse Education Program did not have access to a simulated electronic medical record, electronic medication administration system, or electronic documentation system. Few of the computer support technicians at the college had been trained to troubleshoot problems with SimMan 3G. The Dean of the Health Sciences Division stipulated that the research could only be conducted when students were not taking a clinical nursing course, limiting the availability of students, and lab time available for research.

Management. Management feasibility assessments included an evaluation of the efficacy of study documents, data entry processes and resources. The demographic survey was completed fully, apart from ethnicity and race. One student did not document their race, another did not document ethnicity or race. The SDS and DASH were used to evaluate the quality of the simulation scenarios. No instrument to assess student performance outcomes was used in this study. The data was easily handled on site. The PI had access to a secure computer and locked cabinets in a locked office to store data.

Science. Students rated the quality of the simulation designs very highly. The overall SDS score for simulation 1 were *M* = 4.86, (*SD* = .4). For simulation 2 *M* = 4.86, (*SD* = .422). Table 2.1 lists the SDS results for each survey component. Missing data for the SDS was < 1% for each simulation.

Table 2.1. Descriptive Statistics for Simulation Design Scale Sub Scores

SDS Sub Scores	Simulation 1		Simulation 2	
n = 33	M	*SD*	M	*SD*

Objectives and Information	4.85	.360	4.84	.383
Support	4.95	.245	4.96	.195
Problem Solving	4.70	.582	4.77	.495
Feedback/Guided Reflection	4.90	.348	4.87	.530
Fidelity	4.98	.123	4.88	.373

Students also scored the pre-briefing and debriefing for both simulations highly with the DASH. For simulation 1, the total *M* = 6.84 (*SD* = .476), and for simulation 2, the total *M* = 6.86 (*SD* = .410). Missing data accounted for 3.2% of responses, most likely due to DASH instructions that stipulated participants were to leave items blank that they felt did not pertain to their simulation experience.

Table 2.2. Descriptive Statistics for Debriefing Assessment for Simulation in Healthcare

DASH Element Sub Scores	Simulation 1		Simulation 2	
n = 33	M	*SD*	M	*SD*
Element 1: Pre-brief	6.75	.561	6.81	.498
Element 2: Engaging Context	6.93	.283	6.95	.215
Element 3: Organized Debriefing	6.84	.426	6.83	.431
Element 4: Stimulate Reflection	6.77	.678	6.79	.516
Element 5: Feedback	6.80	.443	6.88	.373
Element 6: Improvement	6.93	.259	6.92	.309

After each study session, the PI reviewed the focus group feedback for factors in either scenario that required improvement. The best example of this was the heparin

protocol. The initial protocol design was complex requiring participants to interpret the activated partial thromboplastin time and then complete several math calculations to determine the correct dose adjustment. In the first several research sessions, no students were able to determine the correct heparin rate in the scenario. Participant feedback on the heparin protocol and electronic documentation form led to changes to improve the clarity and usefulness of both documents.

Qualitative focus group data was merged with quantitative data based on the INASCL guidelines and the JST to create a holistic assessment of study outcomes. See Table 3: Triangulation of Quantitative and Qualitative Data Based on INASCL and JST. Participants described the simulation scenarios as realistic and representative of what they would face in clinical practice. They felt that the information they received prior to the simulation helped them prepare adequately and that the learning objectives were clear and attainable. Participants engaged in active communication with the manikin and family member, and completed nursing assessments and interventions. They felt that they had adequate resources to complete the simulation within the time frame. Debriefing allowed participants to analyze their performance and develop new knowledge and strategies to improve their nursing care.

The participants provided many suggestions on ways to improve each simulation. For example, they recommended providing the SBAR handoff report at the bedside to enhance realism. The challenges they faced during the simulation fell into two areas: use of the technology and interpreting the protocol. As the eMAR was a new technology to them, some struggled with the barcode scanning feature. If not done in the proper sequence, the technology would fail and need to be restarted. This flustered several

students and the investigator had to intervene to restart the technology and retrain the students, interfering with the flow and fidelity of the simulation experience.

Students felt that the inclusion of SCM latent and active factors that contribute to HAM errors added to the realism of the scenarios and allowed them to develop strategies to handle these situations in the future. Many commented that they came in expecting the patient to develop a pulmonary embolism but were surprised at how challenging it was to administer the HAM in a scenario when being interrupted with numerous distractions and having to hold a peer accountable to implement a standard of professional behavior. As one student stated:

> I liked the affirmation that it's okay to say, "Hold on. Let's take a moment. This is time that I need for my patient." I know I'm certainly a people pleaser and so it was good to have in simulation say ... Like the unit secretary comes over and says, "Hey, we need you," and it's okay to be like, "This is my priority right now," be able to prioritize your patient, make sure that you don't make mistakes, and don't feel like you're pulled in 15 different directions, potentially causing a med error or something.

The opportunity to analyze and practice communication strategies when in conflict with a peer were also important to the participants. They valued the chance to role play a potentially challenging intraprofessional interaction. As one participant stated: “I feel like also as a new nurse, I would think, ‘Oh, if I have to ask them repeatedly to check it, they might think I'm incompetent.’ I feel like it'd be easy to feel like that when you're new.” Another student put it like this:

> I know as new graduates we're going to go into the field and be scared to say anything. So, we might have a seasoned nurse come in … and be like, "I don't have time for this". We need to be able to communicate and instead of just scanning her badge say, "No, I'll get another nurse".

Overall the students were very excited and pleased with the simulation. One student summarized their comments best when she stated:

> We're so busy in nursing school. So, if I'm going to spend time doing something, I want to make sure it's going to be worth my time. And this, I felt like it was, because a lot of the things were realistic, like adding in the distractions and making things real like the nurse being too busy. Real life things that really happen.

When designing simulation learning experiences, it is important to determine the purpose of the simulation, whether for research or training (Monroe, Buckley, Curtis, and Morris, 2016). This question was addressed with participants during the focus group sessions. Most felt that the first simulation (where they were required to hang the initial heparin infusion) should be used for post intervention assessment and the second scenario (requiring greater interpretation of the diagnostic data and more clinical decision making) should be the intervention simulation. Participants felt that the second scenario required additional knowledge and skills that were not as thoroughly covered in the first.

Table 3. Triangulation of Quantitative and Qualitative Data based on INASCL and JST

NLN/Jeffries Simulation Theory (Jeffries, 2016)	INASCL Standards of Best Practice: Simulation Design (INACSL Standards Committee, 2016)	Criterion Implementation	Qualitative Participant Feedback	Quantitative Data
Context: Circumstances, setting and purpose of the simulation (education or evaluation)	Criterion 1: Performs a needs assessment	Review of literature on HAM safety Qualitative Research on HAM Safety	"I also liked the scenario that you picked with the DVT because it's so common I feel like … so many patients on the med surg floor are on Heparin or insulin or things like that which is a high alert medication as well. I feel like that's gonna prepare us better." "When we do our evaluation, that first one would have been better for the evaluation because you're doing what you know, you're going in, you're assessing the patient, focused assessment, and you're hanging the bag for the first time. That's more of an evaluation versus the second one. … when you said it, it was so clear in my head the second one doesn't seem like an evaluation it's more teaching"	SDS Q19: The scenario resembled a real-life situation Sim 1: *M* = 4.97, *SD* = .177 Sim 2: *M* = 4.82, *SD* = .465
Background: Goals and expectations	Criterion 2: Measurable Objectives	Based on Quality and Safety Education for Nurses Pre-licensure Competencies	"I think looking at the objectives, I can point out every single time those were used. I think they were perfect and they went right with the simulation that we did. I think looking at it beforehand I'd	SDS Q2: I clearly understood the purpose and objectives of the simulation. Sim 1: *M* = 4.85, *SD* = .364 Sim 2: *M* = 4.91, *SD* = .292

NLN/Jeffries Simulation Theory (Jeffries, 2016)	INASCL Standards of Best Practice: Simulation Design (INACSL Standards Committee, 2016)	Criterion Implementation	Qualitative Participant Feedback	Quantitative Data
			be like well yeah, that makes sense, but now having done the simulation and seeing what they did, I'm like I can point out exactly what they did and how they did those objectives." Re: Attainable objectives "Yes, I don't think those were unrealistic, either."	
Background: Theoretical perspective Design: Utilize specific learning objectives to guide development/selection of simulation activities	Criterion 3: Format based on purpose and theory	SBL Purpose: Improve safety during HAM administration Theory: Reason's Swiss Cheese Model	"What do you think the scenario was asking you to do?" "Administer heparin safely." "Do you feel like these simulations require you to use your nursing judgment?" "Prioritization over the distractions, and pretty much just the whole patient safety, like, that is our number one priority and making sure that we're doing that correctly when you have to think about all of that."	SDS Q2: I clearly understood the purpose and objectives of the simulation. Sim 1: *M* = 4.85, *SD* = .364 Sim 2: *M* = 4.91, *SD* = .292
Design: Participant and observer roles, progression of activities	Criterion 4: Design scenario to provide context for the simulation-based experience. Include	NLN simulation design template used. Structured written situation and backstory created	"Medical records: It was like real life in the hospital." "What I liked is that there were so many expanded roles that	SDS Q1: There was enough information provided at the beginning of the simulation to provide direction and encouragement.

NLN/Jeffries Simulation Theory (Jeffries, 2016)	INASCL Standards of Best Practice: Simulation Design (INACSL Standards Committee, 2016)	Criterion Implementation	Qualitative Participant Feedback	Quantitative Data
Participant attributes considered in scenario design	a case or backstory, participant roles, clinical progression and time frames	including medical record files and SBAR report. Role cards directing student performance (e.g. nurse, secondary nurse, family, unit secretary). Clinical progression and cues developed. Simulation timeframe allowed for achievement of outcomes. Evidence based performance measures identified.	made it more realistic to a hospital setting because even at clinicals … they're (the RN) getting distracted. Some kind of interference from somewhere is coming through, so I thought it was neat having a secondary nurse come in and kind of rush around, like, "Gotta go," or the unit secretary calling in and saying, "Hey, this is going on." It really mimicked what real life can be. It's not always quiet." "I don't think that there were any challenges that were outside of reason. … It was just because of human error that maybe certain steps were taking that weren't necessary"	Sim 1: *M* = 4.94, *SD* = .242 Sim 2: *M* = 4.88, *SD* = .331 SDS Q12: The simulation was designed for my specific level of knowledge and skills. Sim 1: *M* = 4.79, *SD* = .485 Sim 2: *M* = 4.88, *SD* = .331
Design: Physical fidelity - equipment, moulage	Criterion 5: Use of various types of fidelity	Simulation lab resources Moulage Development of electronic medical record and electronic medication administration	"I thought it was very realistic. It felt very much like being in the actual hospital setting, so I thought that was good." Re: Physical fidelity "Well, the medication was in the room. And then the tubing and stuff – that was not realistic."	SDS Q20: Real life factors, situations, and variables were built into the simulation scenario. Sim 1: *M* = 4.79, *SD* = .485 Sim 2: *M* = 5.00, *SD* = .000

NLN/Jeffries Simulation Theory (Jeffries, 2016)	INASCL Standards of Best Practice: Simulation Design (INACSL Standards Committee, 2016)	Criterion Implementation	Qualitative Participant Feedback	Quantitative Data
		system with bar-code scanning	Re: eMAR "And that electronic chart." "It was pretty awesome." "It's very close to what we use, so it was super realistic, and it was much easier than saying alright I'm checking this against this, so you know, whereas you can see us doing it."	
Design: Conceptual fidelity - predetermined facilitator responses to participants' interventions (cues) Simulation experience: Experiential, interactive, collaborative, and learner centered Facilitator and educational strategies: Skill, educational techniques, preparation. Responds to learner needs	Criterion 6: Participant centered facilitative approach driven by objectives	Facilitator SEL II trained Scripted report Built in learner cues	"I felt like we were set up for success, like we had everything that we needed." Re: Concept fidelity Being blown off by the second nurse checking the medication. I mean she's got her own patients and dependent on the census of the hospital and the ratio of the patients, she could have six other patients getting the same thing" "They are very realistic, but I almost think I gained more from their situation with me being a bad second nurse, that you're gonna have those people that aren't nice to you. And I felt like I learned more from that, to just	SDS Q 6-9 re: Support Sim 1: *M* = 4.95, *SD* = .245 Sim 2: *M* = 4.96, *SD* = .195 DASH Q1D: The instructor made me feel stimulated to share my thoughts and questions about the upcoming simulation and debriefing and reassured me that I wouldn't be shamed or humiliated in the process. Sim 1: *M* = 6.88, *SD* = .331 Sim 2: *M* = 6.88, *SD* = .331

NLN/Jeffries Simulation Theory (Jeffries, 2016)	INASCL Standards of Best Practice: Simulation Design (INACSL Standards Committee, 2016)	Criterion Implementation	Qualitative Participant Feedback	Quantitative Data
			be like, 'Okay. No thank you. You're busy too'." "I think the only thing that would make it slightly more realistic is if there was actually another patient to attend to."	
Design: Pre-briefing activities	Criterion 7: Pre-briefing	Scripted pre-brief topics based on objectives Simulation orientation to resources before scenario implementation	"Something I liked in other simulations that this one didn't have, sometimes during pre-conference when we have questions that we go over beforehand to sort of review things."	SDS Q1: There was enough information provided at the beginning of the simulation to provide direction and encouragement. Sim 1: *M* = 4.94, *SD* = .242 Sim 2: *M* = 4.88, *SD* = .331 DASH Q1A: The instructor introduced him/herself, described the simulation environment, what would be expected during the activity, and introduced the learning objectives. Sim 1: *M* = 6.94, *SD* = .348 Sim 2: *M* = 6.91, *SD* = .384
Design: Debriefing activities Facilitator and educational strategies: Provides appropriate feedback	Criterion 8: Debriefing	The reaction, analysis, and summary method used for debriefing	Re: Debriefing "You know your strengths or weaknesses, what you did good, what you need to work on, and just hearing it from the observing party."	SDSQ 15-18 re: Feedback and Guided Reflection Sim 1: *M* = 4.90, *SD* = .348 Sim 2: *M* = 4.87, *SD* = .530 DASH Q2D: The focus was on learning and not making people

NLN/Jeffries Simulation Theory (Jeffries, 2016)	INASCL Standards of Best Practice: Simulation Design (INACSL Standards Committee, 2016)	Criterion Implementation	Qualitative Participant Feedback	Quantitative Data
			"I think when we do debrief, one of the things that we should be able to do is actually, it should be a learning experience, and so what I've found in other simulations, that when you come to the table with debriefing there's some attitude, there's some negative feelings, and I like this situation where it's a learning experience, so I'm okay with somebody saying to me, I could do something better or did you try this, as opposed to not taking that criticism"	feel bad about making mistakes. Sim 1: *M* = 6.97, *SD* = .174 Sim 2: *M* = 7.00, *SD* = .000 DASH Q6A: The instructor helped me learn how to improve weak areas or how to repeat good performance. Sim 1: *M* = 6.84, *SD* = .369 Sim 2: *M* = 6.88, *SD* = .331
Outcomes: Measured in terms of participant, patient or system	Criterion 9: Evaluation	Scenario quality outcomes measured with SDS, DASH and focus group feedback Participant outcomes – focus groups "what did you learn?'	"I feel like I actually learned something" "I definitely learned ... I gained a lot. It was overwhelming because I didn't know but I had the resources to be able to ask and figure it out at the end of it all. "	SDS total scores Sim 1: *M* = 4.86, *SD* = .4 Sim 2: *M* = 4.86, *SD* = .422 DASH total scores Sim 1: *M* = 6.84, *SD* = .476 Sim 2: *M* = 6,86, *SD* = .410
Background: Access to and allocation of resources	Criterion10: Preparation material and resources	Textbook resources and Intravenous Heparin Infusion (2016). JBI Recommended Practice sent via	Re: preparation materials: "I thought they were very, very clear and especially with the summary that we've got about the intravenous heparin and you also provided us with the	SDS Q3: The simulation provided enough information in a clear matter for me to problem solve the situation Sim 1: *M* = 4.70, *SD* = .467 Sim 2: *M* = 4.78, *SD* = .491

NLN/Jeffries Simulation Theory (Jeffries, 2016)	INASCL Standards of Best Practice: Simulation Design (INACSL Standards Committee, 2016)	Criterion Implementation	Qualitative Participant Feedback	Quantitative Data
		email to participants before the scheduled session.	page number, so we knew exactly where to look and what to read, sometimes with the book you tend to read a little too much or a little too less, but it was exactly what we needed for this scenario."	
	Criterion 11: Pilot test SBL	Science feasibility	"It was great." "I don't know what it is about sim. I have a terrible memory, but I always remember sim!"	SDS total scores Sim 1: *M* = 4.86, *SD* = .4 Sim 2: *M* = 4.86, *SD* = .422 DASH total scores Sim 1: *M* = 6.84, *SD* = .476 Sim 2: *M* = 6,86, *SD* = .410

Discussion

The simulations as designed are a feasible method for providing a HAM safety SBL intervention and for evaluating HAM safety competency post intervention. The simulations were well-designed, clinically relevant, and realistic. The feasibility assessment found many attributes that supported the use of the community college as a site for a future randomized controlled trial: A diverse participant pool, access to high-fidelity simulators, realistic simulation rooms, room for pre-briefing and debriefing, and technology such as computers, laptops, smart pumps and audio-visual recording.

Several factors limited the feasibility of the site for a randomized controlled trial. The number of potential participants was insufficient. The effect size for simulation research learning outcomes has been reported as medium to large (Cant & Cooper, 2017; Shin, Park, & Kim, 2015). Higher effect sizes were reported for outcomes related to affective, psychomotor and cognitive outcomes. Assuming a medium effect size (Cohen's d = .50), α = .05 and power of .80, sample size for a randomized controlled trial (RCT) would need to include a minimum of 64 participants per group (Polit, 2010, p. 421). Inadequate sample size is a frequent criticism of simulation research (Cant & Cooper, 2017). In the current study, recruitment was a challenge due to the limited time frame permitted by the nurse education program administration. Data collection was limited to the winter break of 2017-2018. When the spring 2018 semester commenced, many students reported that they would have participated if they simulations occurred during a time they were already on campus. Coming on

campus during their winter break was not an option for them. Inconvenience is a known barrier to recruitment efforts (Tappen, 2011, p. 200) and recruitment and study participation during regular semester hours would be needed to make the study feasible. But, even were this opportunity made available, there is limited simulation technology support available, especially during evening and weekend hours.

Lack of access to simulated EMR and eMAR posed a serious threat to simulation fidelity. Although an EMR and eMAR system were created, and participants valued the opportunity to complete barcode scanning and electronic signature for the independent double-check procedure, the platform was unstable requiring frequent intervention by the PI, disrupting the flow of the simulation. It is also unknown if the system would be scalable for a larger study. As an alternative, multiple laptops with the software and charts loaded could be available if the eMAR failed during a simulation.

Reporting of simulation-based research has been inconsistent, and a review of simulation research in healthcare noted that most studies do a poor job of describing research context, the design elements of the instructional intervention, and the study outcomes (Cook, Hatala, & Brydges, 2011). In this study the investigators addressed these issues by following INASCL guidelines for simulation design and utilizing the JST as the underlying theoretical framework for this study. Incorporating findings from a qualitative research study on latent and active factors contributing to HAM administration errors based on Reason's SCM also enhanced the clinical relevance of the simulation designs.

Analysis of the SDS and DASH, along with the content analysis of the focus groups, confirm this conclusion. Participant comments about the simulations were largely positive. One student stated, “It was a good learning experience because it made you sit and think wow, these are really things that happen out in the real world and we need to be conscious about it.” Another noted “it pulled skills that you have learned, … at the same time, introducing new challenges.” Our findings support the use of the HAM simulations for use in a randomized controlled trial.

Although not a purpose of this research, we did note that participants improved in their ability to manage latent and active error factors such as distractions and non-cooperative peers during the second scenario, improving their ability to safely administer the heparin. This finding supports the results of several published studies on SBL and medication administration, that SBL is correlated with improved medication administration outcomes (Bowling, 2015; Campbell, 2013; Fadale, Tucker, Dungan, & Sabal, 2014; Ford, Seybert, Smithburger, Kobulinsky, Samosky, & Kane-Gill, 2010; Pauly-O’Neill, 2009; Sears, Goldsworthy, & Goodman, 2010; Unver, et al., 2013). Research on the efficacy of SBL to enhance the safety practices of medication administration during high-stakes medication administrations, such as HAM administration, is lacking.

Limitations

Common criticisms of SBL research include the lack of reporting on steps taken to assure the quality of the interventional and evaluation simulations, and

non-reporting of the reliability and validity of the instruments used to assess outcomes. Although this study did establish the quality of the simulation scenarios, the research would be more rigorous by including the assessment of a reliable and valid assessment instrument to evaluate participant HAM competency in conjunction with the evaluation simulation.

Conclusion

Improving HAM administration competence is an important goal to assure patient safety (AHRQ, 2018; The Joint Commission, 2017). Research supports the need to develop reliable and effective methods to teach and practice HAM safety. As a first step in this process, we developed and implemented simulations to assess feasibility for a larger powered randomized controlled (RCT) study. Our research demonstrated that simulations developed based on established theoretical frameworks and best practices criteria were rated highly by participants. A larger participant pool and resources such as an electronic medical record and medication administration system increased the feasibility of an intervention design appropriate for a well powered randomized controlled trial.

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Appendix 1. Feasibility Assessment Strategy

Purpose	Feasibility Assessment Question	Data Collection Method	Participant
Process - Participants	Number of students eligible to participate	Study journal	PI
	Number of students expressing interest in study participation	Study journal	PI
	Number who volunteer	Study journal	PI
	Number who complete evaluation	Study journal	PI
Process - Data	Are the data collection methods clear to the participant?	Qualitative content analysis	Student Nurses
	Are the data collection methods clear to the investigator?	Qualitative content analysis	PI
	Are the data collection instruments easy to use?	Qualitative content analysis	PI
Resources	Was the Simulation Lab available for use during times students were free to participate?	Study journal	PI
	Was the SimMan™ available for use during times students were free to participate?	Study journal	PI
	Was the SimMan™ in working order?	Study journal	PI
Management	Were technological support people available to handle equipment malfunction if needed?	Study journal	PI
	Could data be secured on site?	Study journal	PI
Science	Simulation intervention design quality	Cognitive Pretesting	RN
	Assessment of the objectives/information, support, problem solving, feedback, and fidelity of the simulation	Simulation Design Scale	Student Nurses
	Assessment of the student views about the strategies and techniques used during	Debriefing Assessment for Simulation in Healthcare	Student Nurses

	simulation pre-briefing and debriefing		
	What problems did students encounter during the simulation? (Did they understand the scenario, did they have equipment issues, did they understand what was expected of them, did they feel it improved their learning)	Qualitative content analysis	Student Nurses

Appendix 2: Focus Group Semi-Structured Interview Questions

- What was of value to you in this scenario?
- What do you wish you knew prior to the simulation experience?
- What do you wish you knew about the Simulation Lab and equipment prior to the simulation experience?
- Were the expectations of what you would be doing in the simulation made clear before you started the scenario?
    - Were the objectives clear? Why or why not?
- How did the preparation actives help you prepare for the simulation?
    - How would you enhance these activities?
- What challenges did you experience when completing the simulation?
    - What can we do to fix these for future students?
    - Describe the challenges you experienced working with the SimMan™.
    - What equipment do you wish you had that was not available to you during the scenario?
- How could the room be made to simulate a more realistic environment?
- Was there enough information in the patient's medical record for you to provide safe patient care?
    - What information needs to be added to the patient record so that you feel you could provide safe patient care?
    - What information could be removed from the patient record?
- What about the scenario was realistic? What was not realistic?
- In what ways did the scenario match the objectives? Where could the objectives be enhanced?
- What was the scenario was asking you to do?
- In what ways did the scenario require you to use your nursing judgment to care for the patient?
- In what ways did you feel supported during the scenario? How could support be enhanced?
- In what ways was the scenario realistic? How could realism be enhanced?
- Please describe the impact of the debriefing experience. How was it effective? What could have been improved?
- Describe your level of comfort during debriefing. What would have increased your level of comfort?
- In what ways did the debriefing discussion add to your understanding of caring for a patient receiving a high-alert medication?
- What were the most important things you learned about safely administering a high-alert medication during the scenario and debriefing?
- In what ways did this experience affect your ability to safely administer high-alert medications?
- Overall, how could this learning experience be improved?

Summary

The research completed for this dissertation has added to our understanding of high-alert medication (HAM) safety and has lain the groundwork for future randomized controlled trials on whether simulation-based learning (SBL) can improve student nurse competency when administering HAMs. This compendium's integrative review and two studies provide context for HAM simulation: An integrative review on the use of simulation to teach medication safety competencies, a qualitative descriptive study on nurse perceptions of factors that contribute to or hinder HAM safety, and a feasibility study to evaluate the fidelity, clinical relevance, and acceptability of two simulations designed for a future randomized controlled trial on a simulation-based educational strategy to improve HAM competency.

Manuscript 1

The purpose of the integrative review – Improving Medication Administration Safety Utilizing Simulation-Based Learning - was to evaluate the state of the science on the relationship between SBL strategies and medication administration safety in nurses and nursing students. Using Whittemore and Knafl's methodological framework[1], seven reports (five studies of nursing students, two of practicing nurses) were evaluated for the rigor of the research design and outcomes on participant safety performance. Although the results demonstrated that SBL improves learner performance, the studies lacked methodological rigor (insufficient sample sizes, no power analysis, and limited discussion of reliability or validity of instruments). The research was also

assessed for the inclusion of outcomes based on participants, patients and systems as identified in the NLN/Jeffries Simulation Theory (JST).[2] This analysis demonstrated that authors failed to report on important design elements such as student learning outcomes (3, 43%), and briefing/debriefing (5, 71%). There were no studies that evaluated outcomes beyond the participant level. The integrative review demonstrated that although SBL may be an effective strategy to improve medication administration performance, randomized controlled trials of sufficient power based on established simulation design criteria are needed to establish the extent of the relationship of SBL interventions and medication safety performance. Additional studies are also needed to determine if there is a relationship between safe medication administration SBL and patient and system error outcomes.

Manuscript 2

For this study, a qualitative descriptive design was used to collect and analyze data on nurses' perceptions of HAM safety practices. Eighteen nurses from two hospitals in the Baltimore-Washington DC metropolitan area were interviewed about HAM safety practices and factors that interfered with safe HAM administration. Content analysis was conducted to identify, describe and make inferences about the qualitative data captured from the RNs. Three themes were identified as contributing to safety: Culture of Safety, Collaboration, and RN Intrinsic Factors. A culture of safety included the organizational values (i.e., just culture, organizational culture emphasizing safety) and organizational processes such as work flow, information resources, and work load. Collaborations

important to HAM safety included intraprofessional collaboration as well as interprofessional, and patient-nurse collaborations. Factors intrinsic to the nurse were nurse competence and nurse engagement. Study results confirm that several factors affecting HAM safety (i.e., distractions, patient load, and acuity) have been reported in the medication safety literature. Nurses in this study report safety violations specific to HAM including work arounds and inconsistent/incorrect use of independent double check procedures. The results identified a need for clear and consistent HAM policies, methods to decrease disruptions to processes, enhanced technology to support safe administration, and better education on safe HAM practices. Based on these findings, we created a model for HAM safety: *High-Alert Medication Safety: Nursing, Collaborative and Organizational Influences.* Future research needs were identified, including the relationship of nursing judgment, nurse engagement, and patient-nurse collaboration to safe HAM administration.

Manuscript 3

For the final report in the compendium, a feasibility study was conducted. The theoretical basis of the study depended upon two synergetic frameworks, the NLN/Jeffries Simulation Theory and the Swiss Cheeses Model. The aim of this study was two-fold: To design and evaluate two HAM simulation scenarios for quality, fidelity, clinical relevance, and acceptability, and to assess the feasibility of an associate degree nursing program for it's potential as a research site for a future randomized controlled trial on SBL and HAM. This study had three phases, development of the HAM SBL scenarios, cognitive pre-testing and revision of the

scenarios, assessing the feasibility of the study and quality of the SBL scenarios. Two registered nurses with extensive HAM experience participated in the cognitive pretesting of the scenarios. Many recommendations for improvement were made, the most significant being the need for an electronic medication record and bar code scanning to enhance simulation fidelity. Following scenario revisions, thirty-three senior level student nurses participated in the simulations, evaluated each simulation with the Simulation Design Scale (SDS)[4] and the Debriefing Assessment for Simulation in Healthcare (DASH)[5], and participated in focus groups discussions evaluating the simulations. During this phase of the research, we also documented on factors that would impact the feasibility of conducting a simulation trial at a community college (i.e. potential student participation, simulation resources, management and technological support).

Overall evaluations of the simulations were positive. Results demonstrated a combined SDS score of *M* = 4.86, (*SD* = .4) for simulation 1, and *M* = 4.86, (*SD* = .422) for simulation 2 (scale 1-5 where 5 = strongly agree with the statement). Responses on the DASH were also strongly positive: *M* = 6.84 (*SD* = .476) for simulation 1, and *M* = 6.86 (*SD* = .410) for simulation 2. Participants reported that the scenarios were very realistic and clinically relevant, stating they felt more confident about caring for patients receiving HAMs after completing the scenarios. Analysis of the feasibility of the community college nursing program as a potential future study site revealed challenges to subject recruitment. The lack of a simulated medical record system would also impact the fidelity of the

simulation in a future study. A multisite study was recommended to improve sample size for a clinical trial.

Limitations of dissertation research/lessons learned

The integrative review had several limitations. It included only English language studies. Published research in other languages may have contributed to the findings. Additionally, studies were limited to nurse or nursing student participants. Studies that included interprofessional SBL experiences or other health care professionals who have a role in medication administration (i.e., anesthesiologists, respiratory therapists, nurse practitioners, or physicians) may have contributed additional insights to these findings. The preferential publication of research that demonstrates positive findings may have influenced our conclusion that SBL has a positive impact on learner outcomes.

The qualitative descriptive research also had several limitations. The results of this study were not generalizable as the population lacked participants from rural or under-resourced hospitals. Nurses without access to technological and human resources may have viewed HAM safety differently. Also, participant self-selection bias may have influenced the results. All nurses who chose to participate were concerned about HAM safety. Those who were not concerned may have felt the safety practices in their organizations were adequate or excessive and related a different perspective on safety interventions. The study would have been improved by a more diverse participant pool to reflect the diversity of the nursing population and health care settings.

The feasibility study lacked an assessment to determine acceptability, reliability and validity of an instrument to measure SBL participant outcomes. The site also demonstrated an insufficient potential subject pool. A pilot study for instrument assessment and to determine if a multisite trial is feasible could address these issues.

Importance of theory to guide research – implications

The research in this compendium was guided by two theories: NLN/Jefferies Simulation Theory (JST)[2] and Reason's Swiss Cheese Model (SCM)[3]. The integrative review revealed that much of the research on SBL for medication administration was not theory based. In our study, the Swiss Chess Model was an integral component of the development of the semi-structured interview guide and the deductive content analysis of the nurse interviews. This analysis allowed us to determine common, clinically relevant active and latent factors impacting HAM safety to incorporate into the simulation scenario designs. Use of the JST allowed us to integrate educational best practices with the research-based design elements identified with the Swiss Cheese Model to create high-quality simulation experiences that were experiential, interactive, collaborative and learner centered.

Research trajectory

This research provides the first steps towards a future randomized controlled trial to test the hypothesis that SBL improves student nurse competency for HAM administration. To accomplish this goal, research steps include:

1) A pilot study to assess the acceptability, reliability and validity of a medication administration instrument for use in conjunction with the SBL HAM evaluation simulation
2) Assessment of the feasibility of a multisite trial to improve potential subject recruitment.

An aim of a future RCT would be to measure outcomes immediately and at 6 months to determine if students retain knowledge and skills gained during SBL. Outcomes could also be measured to determine if student behaviors attained during their basic education translate to clinical practice environments.

An additional study would be to conduct a RCT with practicing nurses to determine if the simulation model would impact outcomes at the patient and system levels as per the JST.

Finally, it would be interesting to conduct a future qualitative descriptive study to determine if the factors identified as contributing to HAM safety, and that led to the generation of the model: *High-Alert Medication Safety: Nursing, Collaborative and Organizational Influences*, are identified as significant components of other high-risk nurse-patient interactions.

Contribution of research to nursing and clinical care

This research contributes to the body of nursing simulation and safety science in several ways:

1. Improving patient safety is a primary responsibility of practicing nurses. This research identified relevant factors needed to assure HAM safety in the clinical setting.

2. The model *High-Alert Medication Safety: Nursing, Collaborative and Organizational Influences* could be developed and used as an instrument to assess HAM safety practices in a clinical environment, to identify gaps in safe practice, and to remediate those deficits.

3. Current research on SBL in nursing lacks reporting of measures taken to assure the quality and acceptability of the simulation scenarios used for intervention and evaluation. This methodological gap is significant, as it is difficult to determine if non-significant results are due to the SBL educational approach, or the quality of the specific simulation design or the measurement model to assess patient outcomes. This study provides a framework for future researchers to implement to assure the scenarios developed for a research study are theory based, reflective of current clinical practice, clinically relevant, and acceptable to participants.

References

1. Whittemore R, Knafl K. The integrative review: Updated methodology. J AdvNurs. 2005*;52*(5): 546-553.

2. Jeffries PR, editor. The NLN Jeffries simulation theory. Philadelphia: National League for Nursing; 2016.

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4. NLN:SIRC Simulation Innovation Resource Center. Research. 2018. Available from http://sirc.nln.org/mod/page/view.php?id=88

5. Brett-Fleegler M, Rudolph J, Eppich W, Monuteaux M, Fleegler E, Cheng A, Simon R. Debriefing assessment for simulation in healthcare: Development and psychometric properties. Simul Healthc. 2012 Oct; 7 (5): 288-294.

Appendices

Institutional Review Board for Human Research (IRB)
Office of Research Integrity (ORI)
Medical University of South Carolina

Harborview Office Tower
19 Hagood Ave., Suite 601, MSC857
Charleston, SC 29425-8570
Federal Wide Assurance # 1888

APPROVAL:
This is to certify that the research proposal **Pro00063761** entitled:
Feasibility of Simulation to Teach High-Alert Medication Safety

and submitted by: **Laura Sessions**
Department: **Medical University of South Carolina**

For consideration has been reviewed by **IRB-I - Medical University of South Carolina** and approved with respect to the study of human subjects as adequately protecting the rights and welfare of the individuals involved, employing adequately methods of securing informed consent from these individuals and not involving undue risk in the light of potential benefits to be derived therefrom. Additionally, the Institutional Review Board for Human Research (IRB) recommends approval of the investigator's request for Waiver of Signed Consent in accordance with 45 CFR 46.117(c)(1),(2) because the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality and/or because the research presents no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context. No IRB member who has a conflicting interest was involved in the review or approval of this study, except to provide information as requested by the IRB.

Original Approval Date: **6/16/2017**
Approval Expiration: **6/15/2018**

Type: **Expedited**

Chairman, **IRB-I - Medical University of South Carolina**
Mark Hamner*

Statement of Principal Investigator:

As previously signed and certified, I understand that approval of this research involving human subjects is contingent upon my agreement:

1. To report to the Institutional Review Board for Human Research (IRB) any adverse events or research related injuries which might occur in relation to the human research. I have read and will comply with IRB reporting requirements for adverse events.
2. To submit in writing for prior IRB approval any alterations to the plan of human research.
3. To submit timely continuing review reports of this research as requested by the IRB.
4. To maintain copies of all pertinent information related to the research activities in this project, including copies of informed consent agreements obtained from all participants.
5. To notify the IRB immediately upon the termination of this project, and/or the departure of the principal investigator from this Institution and the project.

∗ ***Electronic Signature****: This document has been electronically signed by the IRB Chairman through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.*

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Date: May 23, 2017

PI Name: Laura Sessions

Study #: HCC-2017-05-23

Study Name: Feasibility of Simulation to Teach High-Alert Medication Safety

Original IRB approved: April 18, 2017

IRB Change approved: May 23, 2017

The change to your original IRB application has been conditionally approved. This application has been approved as an exempt project. You may use Howard Community College as a research site. As an exempt project, a signed consent form is not required though you are expected to present an information sheet about your study to potential student participants.

This project will fulfill the dissertation requirement of your doctoral program at the Medical University of South Carolina. Please forward approval from MUSC's IRB. Once received, I will provide a final approval from HCC's IRB.

Please retain a copy of this notice for your reference, and contact me with questions (slichtinger@howardcc.edu, or 443-518-4289).

Shannon Tinney Lichtinger

Shannon Tinney Lichtinger
Institutional Review Board, Chair
Associate Director of Research and Planning
Planning, Research, and Organizational Development (PROD)

SAINT AGNES
HOSPITAL

RPN #: 2016-047

March 31, 2017

Laura Petri, RN
Saint Agnes Healthcare, INC
900 Caton Avenue
Baltimore, MD 21229

Research Protocol Title: Feasibility of Simulation to teach High- Alert Medication Safety

Dear Laura Petri:

During the St. Agnes HealthCare Institutional Review Board (SAHC IRB) full board meeting on **January 9, 2017,** the members voted to approve the above research protocol. Waiver of consent and HIPAA is also approved.

Approval will expire on **January 8, 2018**.

The following items were reviewed: Chart review submission form, Protocol outline, request of waiver, conflict of interest forms, and NIH certifications of training in Human Research Subject protections
No subjects may be involved in any study procedure prior to the approval date or after the expiration date. It is highly recommended you submit continuation requests by the 15th of November 2018 prior to the expiration date, to avoid any lapse in continuation.

As always, we expect full compliance with all applicable federal regulations and SAHC IRB policies. The SAHC IRB must be notified of any: 1) any and all unanticipated problems; 2) any modifications; 3) recruitment materials; and 4) termination of the research protocol.

You may direct any questions Rachel Duffie, IRB Coordinator. She can be reached at 667-234-3312 or Rachel.Duffie@stagnes.org.

Sincerely,

Frederick E. Kuhn, M.D.
Chairman, SAH Institutional Review Board

BALTIMORE WASHINGTON MEDICAL CENTER
UNIVERSITY OF MARYLAND MEDICAL SYSTEM

Human Subjects Review Committee
Executive Summary

Title: Feasibility of Simulation to Teach High-Alert Medication

Principal Investigator(s): Laura Sessions RN, MScN

Local Investigator/ Contact: Laura Sessions RN, MScN

Address: 6041 Misty Arch Run
Columbia, MD 21044

Phone Number: 443.980.5262 (cell), 443.518.4408 (work)

Email Address: lsessions@howardcc.edu **(work);** sessionl@musc.edu **(school)**

Department/ Location of Study/Protocol: Nursing

Description (limit to ½ page):
Approximately 7000 inpatient deaths occur in hospitals annually due to medication errors (Flynn, Liang, Dickson, Xie, & Suh, 2012). High-alert medications (HAMs) are "drugs that bear a heightened risk of causing significant patient harm" (Institute for Safe Medication Practices [ISMP], 2016, pp. 1). Despite the growing use of simulation in nursing education, there is a paucity of research that specifically addresses how nurses learn HAM safety practices. To remediate this gap in the literature, the Principal Investigator (PI) will be conducting a feasibility study to determine and remediate the potential threats to the validity of a study on the use of simulation to teach high-alert medication administration safety to pre-licensure nursing students. The PI will use information collected from registered nurses to develop and assess the use of a simulation intervention to teach safe administration of HAMs to nursing students. For this study, interview data obtained from registered nurses (RN) will inform the development of two HAM simulation scenarios, one for education, and one for evaluation of safety performance. After development and cognitive pretesting of the simulation scenarios, nursing students will receive both HAM simulation scenarios.

Study Objectives: Although there are data to support the use of education to improve knowledge of HAM administration, evidence is lacking on when nursing students should be introduced to concepts regarding HAMs, what specific information should be included in the training, which educational strategies are the most effective to improve safe performance, and what effect the educational outcomes will have on HAM errors. For the first aim of the study, the PI will interview practicing RNs to gather data to inform the development of the education intervention (simulation scenarios). This will be done to assure the simulation scenarios are realistic and clinically relevant. For Aim 1, adult medical-surgical and/or adult critical care registered nurses will be interviewed in a private setting of their choosing at a time convenient for the participant.

Required sample size: 10-20 registered nurses from BWMC. A purposive sampling strategy will be used to attain a diverse (age, sex, race, ethnicity) participant population. Initially, 10 newly licensed registered nurses with 6-12 months of acute care experience and 10 RNs with ≥ 3 years' experience will be recruited from two hospitals (one urban, one suburban) in the Baltimore-Washington metropolitan area. Six to twelve months of experience should ensure that the new RNs will have completed the hospital-based orientation and will have had the opportunity to administer HAMs in their hospital. These participants will be able to discuss how they learned HAM safety strategies. The experienced RNs will add perspective on safe HAM practices and barriers to safety in practice. Exclusion criteria include RNs self-identifying as having little to no experience administering HAMs. Recruitment procedures are described below.

Study: The purpose of Aim 1 is to ascertain the RNs perceptions about how they learned to administer HAMs, what nurses need to know to safely administer HAMs, what education strategies they believe would be most effective to support learning about HAMs, and what content should be included in a HAM scenario. The PI will use a semi-structured interview guide that contains broad, open-ended questions. The interview will take approximately 30-60 minutes. Data gathered from these interviews will inform the development of both HAM administration scenarios. After the content analysis is complete, the PI will use the information to create two HAM scenarios. Once the simulation scenarios are developed, two RN volunteers will trial the HAM scenarios for the purpose of cognitive pretesting. Revisions will be made to the scenarios based on RN feedback.

Data Collection and Management. The interviews will be recorded, professionally transcribed, and data stored on Box. Box is a cloud-based, secure server that is HIPAA compliant. No personally identifying data will be kept in association with the data used for analysis.

Cost analysis: There is minimal cost to BWMC. The PI will request that an email be forwarded to registered nurses employed by BWMC from the Director of Nursing Education. In this email, the PI will explain the study and ask for volunteers. The email will contain the contact information of the PI. If insufficient participants respond, the PI will ask for the contact information of the unit managers so she can ask permission to attend a nursing staff meeting to recruit participants in person. Once a few participants have been identified, a snowball sampling strategy will be employed to recruit additional participants. So the costs associated with this process are minimal, requiring the time of the Director of Nursing to send the email and/or provide contact information to the PI, and the time of the unit managers to discuss the study with the PI.

Describe the resources necessary to complete the study (personnel, equipment, supplies, etc): If the participant prefers to be interviewed at BWMC, the PI will need a quiet location to conduct the interview. The interviews will not be conducted during work hours, but may be conducted before or after the start of the RN's shift.

Please describe any reimbursement to BWMC: None

Please describe any incentive that the ~~patient~~ registered nurse receives: Participants will not be paid for participating in this study. However, in return for their time and effort, their name

will be entered in a drawing to receive a $50.00 gift certificate from Amazon.com

Office Use Only:

Date:

Human Subjects Review Committee:

- **X Approved**
- ❑ **Not Approved**
  - **Reason:**

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Manuscript 2

1. Appendix 1. Deductive and Inductive Framework used to Develop Model: *High-Alert Medication Safety: Nursing, Collaborative and Organizational Influences*

Manuscript 3

1. Appendix 1. Feasibility Assessment Strategy
2. Appendix 2. Focus Group Semi-Structured Interview Questions