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USE OF STAY S.A.F.E. STRATEGY DURING MEDICATION ADMINISTRATION IN REDUCING ERRORS

A Dissertation Presented

by

CIDALIA J. VITAL

Submitted to the Graduate School of the University of Massachusetts Amherst in partial fulfillment of the requirements for the degree of

DOCTOR OF PHILOSOPHY

May 2020

Nursing

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USE OF STAY S.A.F.E. STRATEGY DURING MEDICATION ADMINISTRATION IN REDUCING ERRORS

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by

CIDALIA J. VITAL

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DEDICATION

I dedicate this proposal to my loving husband, Mark, and my wonderful children Marco and Ellie. Without their patience, love, and tireless support this would not have been possible.

I also devote this to my brother, Nuno, and my father, Rui, who have gone before us. They taught me the greatest life lessons— to persevere over tragedy and push yourself to be the best despite all the surrounding challenges.

ACKNOWLEDGMENTS

On my journey toward this degree, I have found a teacher, friend, inspiration, and role model in Dr. Elizabeth Henneman (who we all know as Beth). You are and have been a true mentor in my journey of lifelong learning. It began when I first met you in my Clinical Nurse Leader master's program here at UMASS in 2005. Your warm smile, sense of humor, and positive energy gave me a thirst for learning. As I contemplated returning to UMASS for my PhD, you took time out of your day to sit with me and discuss the program and the delicacy of work-life-school balance. So, when I was accepted and entered the PhD program, I wanted you as my dissertation chair. Beth, you provided heartfelt support, guidance and invaluable feedback to ensure my success. Due to forces outside of both our control, you were unable to continue as my chair. I want to thank you from the bottom of my heart for your kindness, patience, and motivation. You truly pushed me to my limits.

I would like to acknowledge my amazing dissertation committee whose expertise, critical appraisal, and patience helped me evolve as a PhD student, nurse, and future scientist. Dr. Jenna Marquard, Dr. Heather Hamilton, and Dr. William Soares—thank you for your detailed feedback to inform my dissertation. I appreciate the ongoing support and hope to collaborate with each of you in my future research endeavors.

Dr. Jacelon, thank you for being the light at the end of the tunnel. When you interviewed me for the PhD program, we connected immediately when you talked about your precious Portuguese water dogs and your breeding kennel ironically named Cedelia. From that moment, I knew I had made the right decision to return to UMASS. After Beth could no longer be my chair, you took me on even though your plate was full. You

helped set deadlines and pushed me to excel even though I felt like I had nothing left to give. For that, I owe you a debt of gratitude. I am truly thankful for your leadership and dedication. You have ensured we are all successful through your dedication to the college and the PhD program. Dr. Jacelon, you are a true inspiration. You will change the face of all nursing PhD programs.

I dedicate part of my dissertation to my mentor and friend Jordon Bosse. Anytime I felt stuck in my course work I knew I could reach out to you. You helped me on numerous papers, statistics courses, and phone calls about the ongoing challenges of being a PhD student. Working with you on a manuscript, which influenced much of this dissertation, was both challenging and rewarding. You showed me that having many iterations of the manuscript, and a lot of patience, would ensure its success.

I also acknowledge my friend Sue Scott for her support in writing this dissertation. With similar research interests her dissertation helped to inform mine. Thank you, Sue, for your time to answer my many questions.

To my PhD cohort—Cynthia, Ellen, Favorite, Nikki, Kristy, and Rachel—each of you inspire me to be a better person. Your thoughtful feedback, friendship, and understanding of the PhD life made us a strong cohort. Thank you all for everything. We got through this together!

I also want to acknowledge the irony during the writing of my dissertation, interruptions. We all live in a fast-paced world, juggling many life events including work, family, and school. I met many interruptions during the dissertation writing process, however those interruptions facilitated more thoughtful writing and, most importantly, breaks to enjoy the simple things in life like my family.

Lastly, I want to thank God for giving me the strength and the ability to undertake this enormous chapter of my life. Without His blessings, this would not be possible.

ABSTRACT

USE OF STAY S.A.F.E. STRATEGY DURING MEDICATION ADMINISTRATION IN REDUCING ERRORS

MAY 2020

CIDALIA J. VITAL BS ELMS COLLEGE, MS UNIVERSITY OF MASSACHUSETTS, AMHERST

Ph.D., UNIVERSITY OF MASSACHUSETTS AMHERST

Directed by: Professor Cynthia Jacelon

Healthcare related medical errors are the third leading cause of death in the United States. Interruptions and distractions can lead to an increased risk of nurses making errors in healthcare, particularly during medication administration. Student nurses should receive education during their prelicensure period on the management of interruptions especially before being given the responsibility of performing high risk tasks such as medication administration. Using a novel interruption management strategy called Stay S.A.F.E., nursing students were interrupted during a simulated medication administration. Students were evaluated on the time spent on the task and if errors were committed. Lastly, perceived workload was measured using the NASA Task Load Index (TLX) tool.

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CHAPTER I

INTRODUCTION

Introduction and Background

Every year in the United States there are an estimated 98,000 patient deaths and 440,000 preventable adverse events (James, 2013) as a result of medical errors (Kohn, Corrigan, & Donaldson, 2000) and that number continues to rise. Medication errors are the most common error in healthcare (Kohn et al., 2000) and these types of errors can occur in any stage of the medication administration process (Jennings, Sandelowski & Mark, 2011). Medication administration, one of the six phases of the medication process, is the phase of medication practice associated with the most errors (Leape et al., 1995). The Institute of Medicine, now the National Academy of Medicine (NAM), reported interruptions within the healthcare environment could lead to medical errors and decrease patient safety (Kohn et al. 2000). An interruption occurs when there is

"a break in the performance of a human activity initiated by a source internal or external to the recipient... within the context of a setting or a location...[resulting] in the suspension of the initial task by initiating the performance of an unplanned task with the assumption that the initial task will be resumed (Brixey, Johnson & Turley, 2007, p. E38)."

Interruptions during medication administration pose a significant threat to patient safety. Nurses and student nurses are at the core of preventing medication administration errors. Student nurses during their first years of education learn the theoretical underpinnings of the medication process. New registered nurses are responsible for many complex tasks including medication administration and they are expected to utilize critical thinking, judgement, and competence (Cloete, 2015; Hayes et al. 2017).

It is critical to assess student nurses' skills before they transition into the workforce. Providing them with the framework to manage interruptions during high-risk tasks such as medication administration can improve medication safety and reduce medication errors. The purpose of this proposal is to test a novel mitigation strategy, Stay S.A.F.E., to aid student nurses in managing interruptions in the clinical setting as well as when they become new nurses.

The shift in focus caused by an interruption can break or terminate the primary task (Brixey et al., 2007) which has the potential to cause an error and increase mental workload. The risk of patient harm following interruption is influenced by multiple factors including the number of interruptions and level of skill required for the task. Undergraduate nursing students practice skills, often uninterrupted, in a simulated laboratory setting or under the direct supervision of their faculty (Aggar & Dawson, 2014; Weigl, Muller, Vincent, Angerer, Sevadalis, 2012). Improving education of student nurses on interruption management has the potential to improve patient outcomes. Also, the transition of nursing students to the workforce is critical as we do not yet know the magnitude of interruptions and distractions on nursing students during their clinical experience.

Not all interruptions are harmful; some communicate critical patient information (Grundgeiger & Sanderson, 2009; Westbrook et al., 2010). At the time of an interruption, the student nurse must determine the relative importance of the interruption and decide whether and how urgently to respond (McCurdie, Sanderson, Aitken, & Liu, 2017). We do not yet know the most effective way for nurses, including student nurses, to manage interruptions or the process for determining the level of urgency with which to respond to

the interruption. The proposed research evaluated the impact of the Stay S.A.F.E. strategy on safety outcomes related to medication administration.

Stay S.A.F.E.

Stay S.A.F.E. interruption mitigation strategy was used in the study as an intervention to measure the effects of interruptions on outcomes (Henneman et al. 2018). Stay S.A.F.E., shown in Figure 1, was developed by Henneman and colleagues (2018) using the Memory for Goals Theory as its framework (Altman & Trafton, 2002). It includes the following: **Stay** physically in your current location and stay engaged in the task at hand. Physically hold any items you are working with in your hand when possible. **S**ay out loud what you are in the middle of doing, being as specific as possible while still respecting patient privacy. **A**cknowledge the person interrupting you without looking away from your task. **E**ixate on your place in the task for one to two seconds. Find a natural break in the task when you can pause. **E**stimate the time until you can attend to the interrupting person. Be reasonable but realistic. This approach is easy to remember and implement and does not add measurably to the cognitive burden imposed by the interruption (Boehm-Davis & Remington 2009).

Stay	Stay S.A.F.E. Acronym Meaning	
Stay		
	location and stay engaged in the	
	task at hand. Physically hold any	
	items you are working with in your	
	hand when possible.	
S	Say aloud what you are in the middle	
	of doing, being as specific as	
	possible while still respecting patient	
	privacy.	

A	Acknowledge the person interrupting you without looking away from your task.
F	Fixate on your place in the task for one to two seconds. Find a natural break in the task when you can pause.
E	Estimate the time until you can attend to the interrupting person. Be reasonable but realistic.

Figure 1: Stay S.A.F.E. Acronym Meaning

Note: Adapted from "The Stay S.A.F.E. Strategy for Managing Interruptions Reduces Distraction Time in the Simulated Clinical Setting," by E. A. Henneman, 2018, Critical Care Nursing Quarterly, 41(2), by Henneman. Reprinted with permission.

Prior research by Henneman and colleagues (2018) reported the Stay S.A.F.E. strategy was effective in reducing the amount of time participants were distracted from the primary task. The study, however, had several limitations including a small sample size and post tests were given soon after the simulation, potentially skewing results. More research is needed to understand the effectiveness and acceptance of Stay S.A.F.E. in the clinical setting (Henneman et al., 2018). The following study investigated the effectiveness of the Stay S.A.F.E. interruption management strategy in a simulated setting with student nurses.

Theoretical Frameworks

The study was guided by several theories. First, Memory for Goals (MFG)

Theory, which states that the mind always returns to the most active memory. MFG is also the framework for the intervention, Stay S.A.F.E. Second, the Near Miss Model which describes defenses involved in preventing errors. Lastly, The Eye Mind Theory, which suggests that what a person is focusing on is connected to what is being processed

and interpreted. The three frameworks integrated in this proposal has resulted in a new model, the Interruption Management Model.

Memory for Goals Theory

The Memory for Goals Theory (MFG) states that the mind always returns to the most active goal in central processing (Altman & Trafton, 2002). Goals are described by Altman & Trafton (2002) as the mental representation to accomplish a task including a mental or physical action. Therefore, a goal can be considered a task like medication administration. A key factor in MFG is the length of time a task is suspended or interrupted. Tasks or goals that are not attended to may decline over time which is described by Altman and Trafton (2002) as goal decay. For example, because of goal decay, longer interruptions should result in longer times to return to the primary task (if it is resumed at all).

Figure 2 is a graphic display representing how during a primary task, such as medication administration, a nurse when interrupted by a knock on the door and verbal report about a patient, delays returning to the primary task (Henneman et al., 2018). The delay or interruption lag pushes the task, medication administration, below an activation level to make room for a new task, verbal report. Activation level represents a figurative memory dividing line placing the medication administration task in a suspended state until it is needed again. The new task, verbal report, is placed in primary memory. The importance of Stay S.A.F.E. is that the nurse can take steps like mental and environmental cues to keep the primary task in active memory.

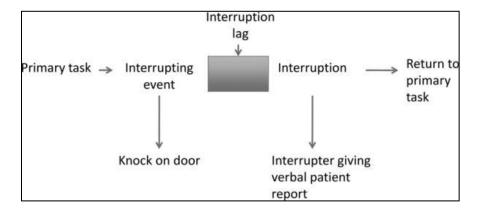


Figure 2: Interruption Effects on Primary Task

Note: Adapted from "The Stay S.A.F.E. Strategy for Managing Interruptions Reduces Distraction Time in the Simulated Clinical Setting" by E.A. Henneman, 2018, Critical Care Nursing Quarterly, 41(2) by Henneman. Reprinted with permission.

MFG theory also provides a mechanism for keeping goals active. For example, baseline activation can be increased if, during an interruption, the participant rehearses the goal. The goal rehearsal included in the Stay S.A.F.E. intervention specifically trains a nurse to say aloud what they are in the middle of doing. This keeps the primary task or goal active. Also, if cues associated with the goal are attended to during the interruption, then associative activation occurs and adds to the base level activation.

Experts have suggested that the recognition of the nature and impact of interruptions is a first step in preparing clinicians, including student nurses, to work safely in environments at high risk for interruption-related errors (Beyea, 2007). In addition, it has been suggested that a clinician who is mindful of the potentially negative consequences of an interruption may increase their focus and concentration on their work (Beyea, 2007). The Stay S.A.F.E. mitigation strategy utilized Memory for Goals to

describe how environmental and mental cues help healthcare providers to create active memory to effectively resume a task (Henneman et al., 2018).

Near Miss Model

The Eindhoven Model, first described in the chemical industry (Van der Schaaf, 1992), has been adapted for nursing as an innovative way to recognize key organizational and human factors that place patients in high-risk situations (Henneman & Gawlinski, 2004). Errors can result from both system and human factors. For example, medication administration errors are nearly doubled when a nurse is presented with four or more interruptions (Westbrook, Woods, Rob, Dunsmuir, & Day, 2010). This nursing near miss model (Henneman & Gawlinski, 2004) describes defenses involved in preventing error and places the nurse as the primary source of error recovery (Figure 3). Interruptions in healthcare pose a risk to patient safety and nurses, and nursing students must be resilient to these environmental factors. Mitigation strategies such as Stay S.A.F.E. may provide nurses and nursing students the ability to manage interruptions and improve patient safety at the bedside using adequate defenses. The Near Miss Model, specifically the segment "dangerous situation," is used to guide this study. Though not always dangerous, interruptions, when not managed, can ultimately lead to medication errors. If the interruption is left unmanaged it may result in adverse events and ultimately patient harm.

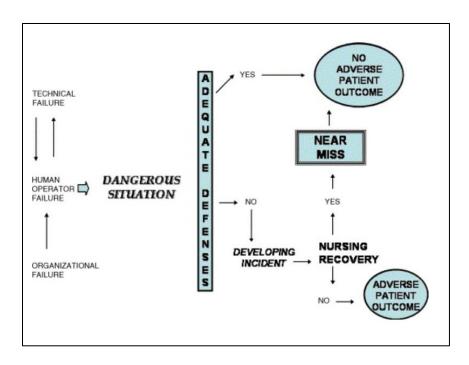


Figure 3: Near Miss Model

Note: Adapted from "A Near Miss Model for Describing the Nurse's Role in Recovery of Medical Errors," by E.A. Henneman, 2004, *Journal of Professional Nursing*, 20(3) by Henneman. Reprinted with permission.

Eye-Mind Theory

The Eye-Mind Theory states that what one is focusing on is linked to what one is trying to process and interpret (Just & Carpenter, 1980). In the case of participants who receive the intervention proposed, Stay S.A.F.E., eye-tracking glasses to measure eye movements can gain insight into how the intervention impacts the student nurse's ability to stay on task. In the case of participants who do not receive the intervention, the eye-tracking data provided insight into where they focus their attention before making a decision.

Research Questions

This study addressed two primary research questions, and one secondary question.

1. What is the impact of the Stay S.A.F.E. intervention on SN management of, and response to, interruptions in simulated clinical scenarios?

Hypotheses 1

- 1a. SNs in the experimental group will return to the primary task more quickly in post-test simulations compared to baseline.
- 1b. SNs in the experimental group will return to the primary task more quickly in post-test simulations compared to the control group.
- 1c. SNs in the experimental group will be more likely to respond appropriately to the interrupter (not take report) in post-test compared to baseline.
- 1d. SNs in the experimental group will be more likely to respond appropriately to the interrupter (not take report) in post-test compared to SN in the control group.
- 2. What is the impact of the Stay S.A.F.E. intervention on SN errors?

Hypotheses 2

- 2a. SNs who receive the Stay S.A.F.E. intervention will make fewer errors in post-test simulations compared to baseline.
- 2b. SNs who receive the Stay S.A.F.E. intervention will make fewer errors in post-test simulations compared to SNs in the control group.
- 3. What is impact of the Stay S.A.F.E intervention on SNs perceived task load?

Hypotheses 3

3a. There will be a significant difference in perceived workload across three simulation scenarios for SNs who receive the Stay S.A.F.E. intervention.

3b. SN in the control group will not perceive a significant difference in workload across the three scenarios.

Study Plan

The study took place at the simulation lab at the University of Massachusetts

Amherst and University of Massachusetts Springfield simulation lab. Nursing students

were recruited from the UMass College of Nursing. Inclusion criteria: junior or senior

nursing students from the traditional baccalaureate program and 2nd bachelors group

who have education in the performance of a physical assessment and who have

administered medications. Participation in the study was voluntary and participants gave

consent to participate in the study.

This study included the following components:

- 1) An initial simulation by all groups
- 2) Completion of the NASA Task Load Index (NASA-TLX)
- 3) An educational intervention
- 4) A second simulation by all groups
- 5) Completion of the NASA-TLX
- 6) A third simulation (7-14 days after the first two simulations)
- 7) Completion of the NASA TLX after each corresponding simulation.
- 8) Completion of a post simulation evaluation.

In the first component, each subject participated in a baseline simulation. The participant received a handoff report and begin care for a simulated patient who requires medication administration. After the initial simulation, each participant completed a NASA-TLX and then was randomized into one of two groups. Group 1 received two

educational PowerPoints: Stay S.A.F.E. strategy and medication safety practices. Group 2 received education on medication safety practices. The Stay S.A.F.E. and alternate education was given via PowerPoint. Each presentation, either alternate or Stay S.A.F.E., were similar in length and scripted with a voice over. Once education was provided the participant completed simulation #2. The NASA-TLX was completed once simulation #2 was complete. The participants were asked to return in 7-14 days and take part in one last simulation in which the student administered a medication to a simulated patient. The participant completed one final NASA-TLX.

Summary

In summary, interruptions should be minimized during high-risk tasks such as medication administration. Most research investigating strategies for managing interruptions in healthcare have focused on reducing interruptions during the medication administration process on inpatient nursing units (Pape et al., 2005; Relihan et al., 2010). Strategies for managing interruptions have centered on establishing "interruption-free" zones for the nurse administering the medication. These strategies have limited applicability in many hospital settings, where clinicians are in constant, close physical proximity and medications are given frequently and not on a schedule as they are on inpatient units. Nurses should decide how to manage interruptions and researchers should identify nurses' and student nurses' decision-making processes in managing interruptions (Gao et al. 2017, Hayes et al. 2017) and characteristics of interruptions that can be successfully overcome (Grundgeiger & Sanderson 2009).

This study examined whether student nurses who receive Stay S.A.F.E. training committed fewer errors during medication administration when compared to those who

do not receive the training. The study also evaluated time to return to primary task and cognitive workload. The training provided student nurses the skill to better manage interruptions and improve patient safety and quality of care.

CHAPTER II

REVIEW OF LITERATURE

Introduction

This chapter presents a comprehensive overview of the empirical research relevant to this study. The purpose of this literature review was to synthesize the current state of knowledge regarding medication errors, interruptions, simulation as a method, eye tracking technology to investigate clinical care, measurement of perceived workload, and management strategies for interruptions including a thorough review of the Stay S.A.F.E. interruption management strategy.

Undergraduate nursing students practice skills, often uninterrupted, in a clinical setting, in a simulated laboratory setting, or under the direct supervision of their faculty (Aggar & Dawson, 2014; Weigl, Muller, Vincent, Angerer, Sevadalis, 2012). Improving the education of student nurses related to interruption management has the potential to improve patient outcomes. The impact of interruptions while administering medication on nursing students during their clinical experiences are unknown. It is critical to assess their experiences before they transition into the workforce. The purpose of this proposal is to test a novel mitigation strategy, Stay S.A.F.E., to aid student nurses in managing interruptions in the clinical setting as well as when they become new nurses.

Method of Review

A review of literature was conducted and divided into five sections to capture the importance of each component to the research study. The following describes the method of database search and includes the different topics: medication errors, interruptions and distractions in the healthcare setting, simulation as a method, eye tracking technology,

and management strategies for interruptions. Highlights from each review of literature were evaluated and synthesized.

Medication Errors

Medical errors are the third leading cause of death in the United States (US) (Makary & Daniel 2016). Medication errors are the most common error in healthcare (Kohn, Corrigan, & Donaldson, 2000) and these types of errors can occur in any stage of the medication administration process (Jennings, Sandelowski & Mark, 2011). The Institute of Medicine, now the National Academy of Medicine (NAM), reported interruptions within the healthcare environment could lead to medical errors and decrease patient safety (Kohn et al. 2000). Interruptions during medication administration pose a significant threat to patient safety. Medication administration errors are nearly doubled when a nurse is presented with four or more interruptions (Westbrook et al., 2010).

Medication administration is the most studied high-risk task. Medication-related errors account for the most common types of inpatient hospital events. Five percent of hospitalized patients will experience an adverse medication event (AHRQ, 2017). Interruptions during medication administration increased the amount of time it took nurses to complete the task (Campoe & Guiliano 2017, Trbovich et al. 2010) and increased the risk of error by 48 percent (Cottney & Innes 2015). Nurses who are interrupted during medication administration have a 1.5 increased chance of making a medication error (Feleke et al. 2015).

Literature searches were conducted using the databases: Cumulative Index for Nursing and Allied Health Literature (CINAHL) Complete and PubMed. Keywords medication errors; nursing; medication administration; and interruptions. Articles were included between 2008-2018 and if they were written in English.

Medication errors can occur in any stage of the medication administration process (Jennings et al., 2011). Medication administration includes seven rights: the right patient, drug, dose, time, route, reason, and documentation. An interruption, even brief, during one of the seven steps, can cause a medication error and compromise patient safety (Altman et al. 2013). Medication administration is the most vulnerable part of the process as interception is less likely before it reaches the patient (Leape et al., 1995).

Evaluation of the association between interruptions and errors during medication dispensing, preparation, and the administration have been conducted (Cottney & Innes 2015, Flynn et al. 1999, Johnson et al. 2017, Prakash et al. 2014, Westbrook et al. 2010). Specifically, procedural failures and clinical errors during medication administration were reported to cause patient harm when interrupted (Johnson et al. 2017, Westbrook et al. 2010). In a simulated study of nurses administering high-risk chemotherapy, when interrupted, 89 percent administered IV push medications wrong, 94 percent incorrectly identified volume in the pump, and 89 percent incorrectly identified volume in the syringe (Prakash et al. 2014).

Clinical errors, as described by Johnson et al. (2017) and Westbrook et al., (2010), have been defined as errors with medication administration. For example, clinical errors were described during the medication process as the wrong drug, dose, route, patient, time, and method of administration. Two studies described the impact of interruptions on medication administration and evaluated the risk of clinical errors. It was found that with each interruption clinical errors increased from 3.6 percent to 12.7 percent (Johnson et al.

2017, Westbrook et al. 2010). Notably, the risk of a major clinical error doubled with the presence of four or more interruptions (Westbrook et al. 2010). Limitations to both studies included limited observations on the night and evening shift as well as the potential Hawthorne effect, changing the normal behavior of nurses during medication administration (Johnson et al., 2017; Westbrook et al., 2010).

Procedural failures, another facet of medication errors, include the following: failure to read medication label, failure to check patient identification, and failure to record medication administration on chart. For example, in one study of 25 nurses and a total of 56 medication events, each interruption was associated with a 34 percent increase in procedural failure (Johnson et al. 2017). In a more extensive study of medical-surgical nurses (n=98) each additional interruption during medication preparation and administration increased the potential for a procedural failure by 12.1 percent (Westbrook et al. 2010). Both studies provide evidence to support the risk of interruptions during medication administration.

In a secondary data analysis of nearly 10,000 patient-controlled analgesia (PCA)related medication errors, distraction was one of the most common factors (37.8 percent)
reported to contribute to clinical errors which included improper drug dosage, drug
omission, and incorrect drug administration (Hicks et al. 2008). In a simulated study of
nurses programming PCA pumps, nurses reported a higher cognitive workload in the
presence of a more significant number of interruptions and an overall impact on task
performance. Though the results were not statistically significant and conducted in a
simulated setting, the nurses made 10 errors, which researchers suggest could have
reached 10 patients in the clinical setting (Campoe & Guiliano 2017).

Other healthcare providers, including pharmacists, have been studied related to medication errors and interruptions. In one observational study, clinical errors made by pharmacists and pharmacy technicians included dispensing the wrong medication, medication form, medication strength, or providing incorrect patient instructions on the label (Flynn et al. 1999). The number of interruptions and distractions during both the immediate task and the preceding half an hour significantly increased the risk of making an error, with multiple interruptions or distractions during the same task nearly doubling the rate of error (Flynn et al. 1999). However, only interruptions (not distractions) remained significant when the researchers considered workload (Flynn et al. 1999). Studies including physicians had similar findings that interruptions increased the risk for error. Specifically, there was a three-fold increase in the risk of clinical prescribing errors when a provider was interrupted (Westbrook et al. 2018).

Summary

Medication administration is the most studied high-risk task. Medication-related errors account for the most common types of inpatient hospital events. Five percent of hospitalized patients will experience an adverse medication event (AHRQ, 2017). Interruptions during medication administration increased the amount of time it took nurses to complete the task (Campoe & Guiliano 2017, Trbovich et al. 2010) and increased the risk of error by 48 percent (Cottney & Innes 2015). Nurses who are interrupted during medication administration have a 1.5 increased chance of making a medication error (Feleke et al. 2015). Medication errors are multifaceted, and interruptions can contribute to potential procedural failures and clinical errors.

Interruptions and Distractions in Healthcare

It has been suggested that interruptions and distractions can impact patient care and safety by causing a *cognitive shift*, a shift of a provider's primary attention (Potter et al. 2005), which can increase *cognitive workload*, the amount of brain power it takes to process an activity and manage incoming stimuli (Paas & van Merriënboer 1994). Cognitive shifts imposed by distractions and interruptions can increase the amount of time it takes to complete a task and loss of focus on the primary task (Potter et al. 2005), and frequent cognitive shifts can cause loss of attention, which could lead to errors.

Traditionally interruptions and distractions in the healthcare environment include conversations with others (co-workers, patients, doctors, pharmacists), alarms, phone calls, and/or pages. While there has been less focus on missing/malfunctioning equipment or equipment retrieval as types of interruption/distraction, both can impact care including the ability to perform surgery or safely deliver medications (Campbell et al. 2012).

Literature searches were conducted using the databases: Academic Search
Premier, Cumulative Index for Nursing and Allied Health Literature (CINAHL)
Complete, PubMed, PsycArticles, and PsycInfo. Keywords (error* OR adverse event*)
AND (interrupt* OR distract*) AND (nurs* OR pharmac* OR physic* or doctor* OR radiolog* OR surg*) AND (healthcare OR health care) (Interrupt* OR distractions OR disruptions) AND errors AND (healthcare OR health care).

Inclusion. Articles were included from 1995 to 2018, if they were peer-reviewed reports of research, written in English, and focused on the association between interruption or distraction and errors in any healthcare setting (clinical or simulated) by any discipline. The review of literature encompassed a large span of time to understand

how interruption and/or distraction and errors research has evolved and progressed over time.

Exclusion. Articles were excluded if they were an opinion/editorial piece, literature review, concept analysis, quality improvement project, or instrument development. Research on healthcare professionals' attitudes regarding policies and procedures to prevent errors or that which focused on error reporting or recovery was excluded from the review. In addition, studies focused solely on frequency and type of interruption and/or distraction with no link to subsequent outcomes were excluded.

Source and Type of Interruption and Distraction

The following defines the different sources and types of interruptions and distractions described by researchers in the healthcare setting. The context, content, frequency and duration of interruptions will be explained. The context (source of interruption), content (information an interruption communicates), and characteristics (frequency and duration of interruptions) of interruptions are all factors that can influence the outcome of the interruption on the task at hand (Sasangohar, Donmez, Easty, Storey, & Trbovich, 2014) and its potential to contribute to error.

Healthcare providers and patients are conventional sources of interruption and/or distraction. For example, several researchers found that nurses interrupting other nurses accounted for 25 percent to 40 percent of interruptions during nurse-patient interactions (Johnson et al. 2017, Kalisch & Aebersold 2010, McGillis-Hall et al. 2008, Verwejj et al. 2014). Nursing was also frequently interrupted or distracted by other healthcare personnel (Campbell et al. 2012, Lindberg et al. 2017). Patients accounted for 13 percent to 30 percent of all interruptions (Johnson et al. 2017, Kalisch & Aebersold, 2010, Trbovich et

al. 2010). Nurses in one study identified the administration of unscheduled medications as an interruption to their scheduled medication routine (Jennings et al. 2011).

Interruption types ranged from engaging in case-irrelevant communication (Pluyter et al. 2010) to having to respond to an emergency (e.g. patient respiratory/cardiac arrest); Palese et al. 2009). Specifically, nursing tasks were interrupted by the need to look for equipment (Palese et al. 2009) or retrieve additional supplies (Lindberg et al. 2017). Across disciplines, healthcare professionals were interrupted by internal factors such as distractibility (Campbell et al. 2012) and environmental factors like alarms, phones ringing, and people walking by (Balint et al. 2014, Campbell et al. 2012, Flynn et al., 1999, Johnson et al. 2017, Koong et al. 2015, Lindberg et al. 2017, Palese et al. 2009, Trbovich et al. 2010). Nurses responded to interruptions promptly; in one study nurses directly responded to 96 percent of interruptions and did not complete the task at hand, even when the interruption was not critical (Palese et al. 2009).

Content

Content is the information that is being communicated through an interruption including care coordination and patient care planning/delivery (McCurdie et al., 2017). The most common information exchange through an interruption was patient care specific (McCurdie et al., 2017) which may aid in the progression of care (Berg, Ehrenberg, Ostergren, Djary & Goransson, 2016; Sasangohar et al., 2015). Case irrelevant communication or conversational interruptions should be minimized during high risk task, like medication administration, as they can have adverse effects on patient

outcomes (Henneman et al., 2018; Sorensen & Brahe, 2014; Spooner, Corley, Chaboyer, Hammond & Fraser, 2015; Weigl et al., 2012; Weigl et al., 2015).

Duration

Researchers have found that length of time of the interruption, also called duration, is a factor that can contribute to error (Trafton & Monk, 2008). Interruption duration is the time that the provider has acted on the secondary task until they return to the primary task. Research has identified that interruption durations over 30 seconds typically result in disruption effects (Cane, Cauchard, & Weger, 2012; Monk, Trafton & Boehm-Davis, 2008; Oulasvirta & Saariluoma, 2006). Longer interruption durations result in resumption delays, increase error rates, and sequence errors. (Altmann & Trafton, 2004; Brumby, Cox, Back, & Gould, 2013; Hodgetts & Jones, 2006; Li et al., 2008; Monk, et al., 2008; Monk, Boehm-Davis, Mason, & Trafton, 2004; Ratwani & Trafton, 2010; Trafton et al. 2003; Trafton et al., 2011). For example, an interruption, even brief, during one of the seven steps of medication administration, can cause a medication error and compromise patient safety (Altman et al. 2013). Previous research has identified that an interruption as short as four seconds can triple the risk of a sequence error (Altman et al. 2013).

Summary

The source of interruption, information an interruption communicates, and characteristics of interruptions are all factors that can influence the outcome of the interruption on the task at hand (Sasangohar, Donmez, Easty, Storey, & Trbovich, 2014) and its potential to contribute to error. Depending on the information exchanged through an interruption, it may be critical to allow the interruption. Patient safety needs to be

considered when an interruption is occurring. Research has suggested that longer interruptions especially during medication administration can increase the likelihood of an error.

Interruptions and Increase in Safety

Four studies evaluating a direct association between interruption and error identified positive outcomes, namely by increasing patient safety (Blignault et al., 2017; Harkanen et al., 2015; Jennings et al., 2011; Scott-Cawiezell et al., 2007), and two found no relationship between interruptions and errors (Lowe & George-Gay, 2017; Kalisch & Aebersold, 2010). In an observational study of 1847 medication administrations, researchers measured wrong dose errors caused by interruptions. For every interruption, Blignault and colleagues (2017) identified the nurse administering medications were 2.5 times less likely to make a wrong dose error. However, when accounting for patient acuity, the risk of wrong route errors significantly increased (Blignault et al. 2017).

In another observational study including 1058 medication administration observations, registered nurses (RNs) who were interrupted were significantly more likely to identify the patient than a nurse who was not interrupted (Harkanen et al., 2015). However, interruptions were protective to a point; odds of failing to identify a patient increased if there were greater than five interruptions (Harkanen et al., 2015). Also, interruptions during a near miss could improve patient safety (Jennings et al., 2011).

The effect of interruptions and/or distractions was mixed in a study conducted in long-term care facilities which included registered nurses, licensed practical nurses, and nurses' aides (Scott-Cawiezell et al., 2007). Initially, an increase in interruptions led to a significant increase in errors. However, after excluding time errors related to delays, and

accounting for the effect of nurses' educational level (RN, licensed practical nurse, or certified medication tech/aide), a higher number of interruptions, led to *fewer* errors.

Summary

Interruptions were protective to a point and potentially increased safety. For example, nurses were more likely to check the patient identification the more often they were interrupted. During a near miss, an interruption, increased safety by stopping the near miss from reaching the patient. Though a few studies have identified an increase in patient safety with interruptions, most studies reviewed have identified interruptions as a factor contributing to errors.

Perceptions of Association Between Distraction, Interruption, and Error

The following section describes the association between distractions, interruptions and errors of multiple qualitative studies. Physicians, medical students, pharmacists, nurses, and nursing students were included in the review.

A large proportion of the studies reviewed were focused on healthcare providers perceptions of factors contributing to errors. Scientists reported that interruptions and distractions increased their risk of making errors (Anto et al. 2010, Chard et al. 2018, Deans 2005, Dilles et al. 2011, Donaldson et al. 2014, Dougherty et al. 2011, Ely et al. 1995, Heddle et al. 2012, Hemingway et al. 2015, Hicks et al. 2008, Krishna et al. 2015, Lear et al. 2017, Madden & Ball 2011, Mahood et al. 2012, Mayo et al. 2004, McGillis-Hall et al. 2008, Murphy & While 2012, Odberg et al. 2018, Odukoya & Chui 2013, Odukoya et al. 2015, Palese et al. 2009, Peterson et al. 1999, Petrova et al. 2010, Pham et al. 2011, Ryan et al. 2014, Sajjad et al. 2017, Sanghera et al. 2007, Sears et al. 2013, Sorra et al. 2008, Steele et al. 2018, Suresh et al. 2004, Unver et al. 2012, Wolf et al.

2006). Of the studies, 29 evaluated the medication process and perceptions of providers. In each study, researchers evaluated provider (nurse, pharmacist, physician, and student) perceptions regarding interruptions and/or distractions as related to errors. Providers reported that interruptions and distractions contributed to errors between 12 percent (Suresh et al., 2004) and 86 percent (Murphy & While, 2012) of the time.

Physicians and Medical Students

Physicians and medical students across surgical, radiological, and anesthesia-related practice identified interruptions and distractions as increasing the risk for errors such as potential left-right discrimination errors, prevention of smooth induction during delivery of anesthesia, and diagnostic inaccuracy (Balint et al. 2014; Campbell et al. 2012; Ely et al. 1995; Lear et al. 2017; McKinley et al., 2015; Pluyter et al., 2010; Sanghera et al. 2012).

Nearly half of family physicians who took part in interviews about their "most memorable error," identified being distracted as a contributing factor to their errors. They identified distractions as other patients waiting to be seen, some characteristic of the patient, or personal concerns (Ely et al., 1995).

In a study testing the effect of interruptions and distractions on the ability of medical students to discriminate right from the left during a surgery simulation, interruptions had a greater impact (McKinley et al., 2015). Interruptions included verbal statements related to patient care while auditory distractions comprised of background noise and conversation. In another study, anesthesia-related negative consequences due to interruptions included prevention of smooth induction of anesthesia, leaving a patient

unattended to retrieve equipment, and repeated attempts at procedures (Campbell et al., 2012).

Pharmacists

Pharmacists identified that interruptions and distractions, during medication ordering, dispensing, and labeling, can contribute to error (Anto et al., 2010; Madden & Ball 2011; Okukoya et al., 2015), and that interruptions continued to be seen as a risk factor for errors regardless of the number of years the pharmacist had been practicing (Peterson et al., 1999). Pharmacists and pharmacy technicians also reported the cognitive burden of interruptions during medication preparation which would lead them to forget which part of the task they were working on and require them to start over (Odukoya & Chui 2013).

Nurses and Nursing Students

In a secondary data analysis of nearly 10,000 patient-controlled analgesia (PCA)related medication errors, distraction was one of the most common factors (37.8 percent)
reported to contribute to clinical errors such as the wrong drug dosage, drug omission,
and incorrect drug administration (Hicks et al., 2008). Similarly, nurses identified that
interruptions could potentially lead to making errors during intravenous (IV) medication
administration (Dougherty et al., 2011; Santomauro et al., 2018). In a long-term care
facility, 40 percent of nursing staff reported interruptions were a major barrier to safe
medication practices (Dilles et al., 2011). Student nurses in a mental health facility
identified distractions as an environmental barrier to safe medication administration
(Hemingway et al., 2015).

Summary

Physicians, medical students, pharmacists, nurses and nursing students reported that interruptions and distractions increased their risk of making errors. Of the studies, 29 evaluated the medication process and perceptions of providers. Providers reported that interruptions and distractions contributed to errors between 12 percent (Suresh et al., 2004) and 86 percent (Murphy & While, 2012) of the time.

Simulation as a Method

Simulation has been used in nursing schools as an educational tool for many years (Kato & Kataoka, 2017; Meyer, Connors, Hou, & Gajewski, 2011; Severson, Maxson, Wrobleski, & Dozois, 2014; Stayt, Merriman, Ricketts, Morton, & Simpson, 2015). Simulation, an interactive educational tool, has been shown to improve clinical performance, knowledge retention, communication, and teamwork (Gaba, 2004; Gilfoyle et al. 2017; Henneman et al., 2014; Meyer et al., 2011; Paull et al., 2013; Severson et al., 2014; Stayt et al., 2015; Tubaishat & Tawalbeh, 2015).

Literature searches were conducted using the databases: Cumulative Index for Nursing and Allied Health Literature (CINAHL) Complete and PubMed. Keywords: research design; simulation; simulation training; education. Articles were included if they were published between 2001-2019 and written in English.

Simulation has been useful in nursing education and is comparable to traditional clinical educational experiences. Simulation offers students an ability to learn clinical skills and it has benefits over other traditional teaching modalities for knowledge retention (Brannan, White, & Bezanson, 2008; Bruppacher et al., 2010). Simulation is effective for instruction on technical skills, teamwork, communication, and error

identification (Alinier, Hunt, Gordon, & Harwood, 2006; Gilfoyle et al., 2017; Henneman & Cunningham, 2005; Henneman, Fisher, Henneman, Pham, Campbell, & Nathanson, 2010; Henneman, Marquard, Fisher, & Gawlinski, 2017; Kato & Kataoka, 2017; Marquard, Henneman, He, Jo, Fisher, & Henneman, 2011; Meyer et al., 2011). In the United States military, simulation has improved the competency of new military nurses through instruction on higher level cognitive skills such as airway management and exposure of a series of complex patient simulations (Eaves & Flagg, 2001).

In a study of emergency room physicians, analyzing accuracy of interpreting electrocardiograms (ECG) for ST- segment elevation myocardial infarction (STEMI) in task switching simulations compared interrupted and non-interrupted scenarios. Findings indicated that there was no significant difference in accuracy of interpreting ECGs when comparing interrupted and non-interrupted simulation scenarios (Soares et al. 2019). Study limitations related to simulation as a method included the difficulty to replicate a time pressured emergency room and the inability to over-generalize the findings.

In an experimental study by Henneman and colleagues (2014) three student simulation-based feedback mechanisms were compared. Verbal debrief only, eye-tracking only, and a combination of verbal debrief and eye-tracking. Findings suggested that eye-tracking offered objective data about student behaviors during simulation especially during safety practices such as patient identification. Another study by Henneman and colleagues (2008) used simulation to identify the types and frequency of errors made by nursing students during patient care. The results revealed that 40 percent of nursing students frequently made errors in verification of allergies during medication administration. Eye-tracking, as a tool, was used to analyze the students focus, next steps,

and record their voice. Similarly, nursing students who participated in simulation with debriefing as a component had improved performance on safety measures such as patient identification (Radhakrishnan et al., 2007).

Summary

Simulation offers the ability for researchers to study errors without causing harm to patients (Henneman, Roche, Fisher, Cunningham, Reilly, Nathanson & Henneman, 2008, Radhakrishnan et al., 2007). Simulation offers a high fidelity for research under a low risk setting. Soares et al. (2019) emphasized that findings from simulation-based studies should be viewed as exploratory and utilized to emphasize factors that could be improved in the clinical setting.

Eye Tracking Technology to Study Clinical Care

Eye-tracking is an approach for measuring and recording an individual's eye-movements as they perform a task (e.g., verifying patient data on a medication label). The premise underlying the use of eye-tracking is that there is a relationship between where an individual is looking and what he or she is attending to, thinking about, or concerned about at that point in time. The Eye Mind Theory suggests that a dynamic trace of an individual's eye-movements can provide insight into their cognitive processes (Just & Carpenter, 1980). Cognitive processes are complex, and it is possible that an individual may be looking at one thing but contemplating other things at the same time (Reichle et al., 1998). Nonetheless, the premise that the data point an individual is looking at is, at a minimum, in the forefront of their thoughts regarding what they consider important at that moment, is arguably the case in most situations (Just & Carpenter, 1980; Deubel et al., 2000). For example, if a nurse's eye movements involve

fixations on the patient's name, then the name would constitute the nurse's area of interest.

Eye-tracking records a person's focus and provides insight into cognitive processes by measuring eye movements (Duchowski, 2007; Just & Carpenter, 1980; Poole & Linden J, 2006). Measuring and analyzing eye movements provides understanding into what an individual is trying to examine (Duchowski, 2007). The objective data obtained from eye-tracking, such as fixation times, can be calculated to compare groups and individuals (Doberne, He, Mohan, Gold, Marquard, & Chiang, 2015). Eye-tracking is superior to standard observation because of the ability for eye-tracking to capture the participant's movements throughout the simulation environment. Standard observation by a researcher, even with video capability, has limitations when the researcher is unable to track the subject when going outside the viewing area.

Eye-tracking has been used in aviation and the automobile industry to provide feedback on safety features such as with automobile driving (Fisher et al. 1996; Pradhan et al. 2009). In the healthcare industry, eye-tracking has been used as a method to examine clinicians reading 12-lead electrocardiograms (Bond et al., 2014), radiological image interpretation (Tourassi, Voisin, Paquit, & Krupinski, 2013), electronic health record use (Yoon et al., 2016; Doberne et al., 2015), and comparison between novices and expert clinicians (Brown et al., 2014; Brunye, Mercan, Weaver, & Elmore, 2017; Koh, Park, Wickens, Ong, & Chia, 2011). Eye-tracking gains insight into decision-making through eye movements (Ball, Lucas, Miles, & Gale, 2003; Halevy & Chu, 2014; Henneman et al., 2017; Marquard et al., 2011; Brown et al., 2014).

There are key terms that are important to define when integrating the Eye Mind Theory and eye-tracking. When establishing an eye-tracking study, many researchers will establish areas or artifacts of interest (AOI). AOI are physical items that are of interest to the researcher and are selected based on what an expert determines is relevant to the research (Tien, Pucher, Sodergren, Sriskandarajah, Yang, & Darzi, 2014).

Fixation is defined as the amount of time, in milliseconds, the eye is still in a position which can correspond to the time it takes for information intake (Kok & Jarodzka, 2016). The typical value for fixation with eye movements is 200-300 milliseconds (Jacob & Karn, 2003). According to the Eye Mind Theory, eye movements can reflect cognitive processes (Ericsson & Simon, 1980). Multiple fixations in one area of interest (AOI) can correspond negatively with visual search efficiency (Jacob & Karn, 2003). Task difficulty is directly related to the number of fixations.

Duration of fixation is measured in milliseconds and an overall mean score reported. Longer fixations have been interpreted as a participant's difficulty in understanding the task (Jacob & Karn, 2003). A sequence of fixation or a scanpath can also correlate with deeper processing (Jacob & Karn, 2003).

In healthcare, scientists have used eye-tracking technology for patient safety research. Henneman and colleagues (2014) evaluated the efficacy of three types of feedback with student nurses, in simulated safety practice scenarios including hand washing, verification of patient identification and allergies, and evaluation of appropriateness of treatment. Researchers evaluated debriefing only, eye tracking only, and combination of both eye tracking and verbal debrief. Students who wore the eye-tracking, when compared to verbal debrief group with no eye-tracking, performed better

in the areas of patient identification and medication allergy recognition. Limitations of the study included a small sample size and 25 percent loss of eye tracking data.

In another study using eye-tracking as an evaluation method, Marquard and colleagues evaluated the differences in nurses' behaviors and visual scanning patterns during medication administration. Nurses administered medications in three separate scenarios in a simulated environment with embedded errors. Nurses who identified the error completed the process steps in a shorter time frame and had fixations in a row on the patient's chart when compared to the nurses who did not identify the error.

Participants who did not identify the error also tended to increase their duration of off-topic conversation. Researchers gained insight into patient identification errors using eye tracking. Their results showed error identifying nurses had predictable eye movements while non-error identifying nurses had random eye fixation sequences. Similar to Henneman and colleagues (2014), limitations included a small sample size and loss of eye tracking data.

Henneman and colleagues (2017) used eye-tracking to attain deeper knowledge into nurses' surveillance activities during a transfusion event. Nurses who identified the transfusion event had the longest total duration of eye fixations on information about the patient's current status, past medical history, IV infusion rates, bedside monitor, documentation flowsheet, and oxygen saturation, which provided the clinical data necessary for the identification of someone developing a transfusion reaction.

Summary

Eye tracking is an approach for measuring and recording an individual's eyemovements as they perform a task. The premise underlying the use of eye tracking technology is that there is a relationship between where an individual looks (fixates) and what he or she is paying attention to or thinking about at that point in time.

Cognitive Load and Working Memory

In addition to the relationship between where an individual looks and attention there is also a component of cognitive load that should be evaluated. Cognitive load refers to the effort used in working memory. Researchers have identified that there is a limited amount of information that working memory can process (Cohen, 2004). Interruptions disrupt working memory and hence have the potential to increase cognitive load, which can impair the task at hand (Cranford et al., 2014). Current consensus is that both high and low levels of mental workload have a negative impact on performance. Workload is defined as the load imposed on a person's cognitive system when a person is performing a specific task (Paas & van Merriënboer, 1994). Interruptions reduce attentiveness and memory processes which are key in the resumption of the interrupted task (Weigl et al., 2012). For example, after an interruption, nurses reported a loss of concentration or focus (McGillis-Hall et al., 2010; Rivera, 2014), extended time on task (Rivera, 2014), and forgetfulness (Rivera, 2014). Individual differences such as working memory capacity, a measure that predicts performance, may influence an individual's likelihood to make an error (Foroughi et al., 2016).

Researchers have stressed the need to assess cognitive load in the workplace as it relates to patient safety (Rosen et al., 2012). One measure of cognitive workload frequently used in nursing and medicine is the National Aeronautics and Space Administration Task Load Index (NASA-TLX) (Weigl et al., 2014 & Weigl et al., 2012), which is usually administered immediately after a task is completed (NASA, 1986; Hart,

2006). One example was a prospective study of 29 physicians. Their workflow interruptions were assessed along with the subjective workload (NASA-TLX) during clinical shifts. It was reported that an increase in workflow interruptions was linked to increase workload of doctors (Weigl et al., 2012; Weigl, et al., 2014). Deeper analysis revealed that interruptions during the workflow were a major contributing factor to increased workload. Weigl and colleagues (2012) recommended reducing unnecessary interruptions and distractions to improve workflow efficiencies, physician performance, and an increase in perceived quality of care (Weigl et al., 2014).

The NASA-TLX was created more than 20 years ago by NASA to be utilized by the aviation industry. The tool has been used in more than 300 research studies, translated into various languages, and demonstrates a good test-retest reliability (Hart, 2006). The NASA-TLX measures the perceived workload of a task by assessing performance demands across six dimensions: mental, physical, temporal, effort, performance, and frustration as well as overall workload. Hart (2006) described that a combination of the six dimensions likely represent workload. The selection of these specific dimensions was completed by analysis of various factors that people subjectively experience when performing various tasks including flying an aircraft. The NASA-TLX is typically administered to subjects right after the performance of a task (NASA, 1986; Hart, 2006). Each dimension is rated on a scale from 1 to 100 (least to most tasking) and then a mean workload score is calculated. A short form for the NASA-TLX is available and is used in this study. The short form offers a 21-point scale and raw scores which were calculated for this research. In measuring mental demand on the short form, for example, participants are asked "how mentally demanding was the task?" The response is

calculated on a 21-point gradient which includes very low to very high. The following defines each component (Appendix H):

- **Mental demand:** How mentally demanding was the task?
- **Physical demand:** How physically demanding was the task?
- **Temporal demand:** How hurried or rushed was the pace of the task?
- **Performance:** How successful were you in accomplishing what you were asked to do?
- **Effort:** How hard did you have to work to accomplish your level of performance?
- **Frustration:** How insecure, discouraged, irritated, stressed, and annoyed were you?

Summary

Workload as measured by the NASA-TLX has be utilized by several different healthcare disciplines including nursing and medicine. In relation to interruptions, the NASA-TLX, is an effective tool to measure the workload of providers when facing several different types of workflow interruptions.

Management Strategies for Interruptions

Most research investigating strategies for managing interruptions in healthcare has focused on reducing interruptions during the medication administration process (Pape et al., 2005; Relihan et al., 2010). Strategies for managing interruptions have centered on establishing "interruption-free" zones for the nurse administering the medication.

Cumulative Index of Nursing and Allied Health Literature (CINAHL), Pubmed and PsychInfo were searched for articles on management strategies of interruptions from

2008-2018. Key words included interruptions, distractions, errors, management, and healthcare.

The aviation industry established *The Sterile Cockpit Rule* in 1981 to eliminate all unnecessary distractions during critical phases of flight, including takeoff and landing (Sumwalt, 1993). In nursing, airline safety practices have been studied with attempts made to study the effects of the sterile cockpit rule on medication administration. In a quasi-experimental study, using three groups (sterile cockpit group, medsafety protocol group, control group) nurses in the sterile cockpit group experienced significant reduction in distractions during medication administration (Pape, 2003). Another study implemented the sterile cockpit technique during medication administration which led to a 43 percent decrease in medication error rates (Fore, Sculli, Albee, & Neily, 2013). In a study by Federwisch and colleagues (2014), which tested a sterile cockpit on a 35-bed medical unit, it was determined that there was a low compliance of the sterile cockpit rule. There was no change in the frequency of interruptions during medication administration. Though preliminary evidence suggests the improvement of care after implementation of aviation standards on medication administration, caution should be undertaken when comparing the aviation industry with healthcare; as healthcare is a more complex multifaceted work setting (Grundgeiger & Sanderson, 2009; Federwisch et al., 2014).

Colligan and Bass (2012) conducted interviews of pediatric nurses to identify strategies for safe medication administration and report ways in which nurses manage interruptions. A four-level taxonomy was described by nurses which allows or blocks interruptions. The four-level taxonomy includes engaging, multitasking, mediation, and

blocking. *Engaging* includes suspension of the primary task as the secondary task is considered higher priority. For example, the nurse completes the secondary task such as giving a pain medication for 10/10 pain before resuming the primary task, the scheduled 12 noon medication pass. *Multi-tasking* is described as the primary and secondary task having similar priority and both tasks are performed at the same time. For example, the nurse is answering a phone call while measuring a medication in a syringe. *Mediation* occurs when a high priority task is generated before the primary task is suspended. An example as described by Colligan and Bass (2012) occurs when a nurse is collecting all medications for their medication pass. As the nurse is collecting the medications a colleague asks for a narcotic witness, the nurse puts aside the medications and attends to the secondary task. Lastly, *blocking* occurs when the nurse blocks the incoming secondary task to attend to the primary task. Like the aviation industry, much of the research to date has focused on blocking or barrier methods.

Barrier intervention studies as described by Gao and colleagues (2017) include dedicated medication spaces, do not disturb signage, sterile cockpit or interruption free zones, medication pass sashes/tabards, or policies and procedures related to interruptions. For example, Westbrook and colleagues (2017) studied the effectiveness of a do not interrupt bundled intervention to reduce interruptions during medication administration. Using a randomized control trial approach, the intervention group had a 30 percent reduction in interruptions during medication administration demonstrating the intervention was effective. Limitations in the study included potential Hawthorne effect among participants and error rates were not measured to understand the outcome of intervention. Similarly, Anthony and colleagues (2010) implemented a no interruption

zone (tape around the medication machine) and realized a 40 percent reduction in interruptions. Sustainability of barrier methods need further evaluation and researchers should consider longitudinal studies.

Perceptions by nurses who participated in the Safe Zone protocol (quiet space for medication preparation, checklist, and use of a vest) reported a perceived improvement in reduction of errors but actual reduction of error was not discovered (Yoder et al., 2015).

Summary

The goal of barrier methods in medication error prevention is to remove or reduce unnecessary and ineffective interruptions increasing likelihood of making errors (Weigl et al., 2012). Researchers have investigated a number of interventions aimed at reducing interruptions during medication administration including using visual alerts (e.g., red vests, signage) (Pape et al., 2005; Westbrook et al., 2017), checklists (Pape et al., 2005), or combinations of interventions. These interventions were shown to be effective in reducing the rate of interruptions by more than half (Relihan et al., 2010; Westbrook et al., 2010).

Stay S.A.F.E. Intervention

The Stay S.A.F.E. intervention was created by Henneman and colleagues (2018) and was modeled after the Memory for Goals Theory by Altman and Trafton (2002). Stay S.A.F.E. aids nurses in staying on task following an interruption and provides a pneumonic for students and nurses to remain focused on the task at hand while acknowledging the person interrupting. The Stay S.A.F.E. acronym has been shown to be easy to remember and implement in a simulated setting. It includes the following: **Stay** physically in your current location and stay engaged in the task at hand. Physically hold

any items you are working with in your hand when possible. **S**ay out loud what you are in the middle of doing, being as specific as possible while still respecting patient privacy. **A**cknowledge the person interrupting you without looking away from your task. **F**ixate on your place in the task for 1 to 2 seconds. Find a natural break in the task when you can pause. **E**stimate the time until you can attend to the interrupting person. Be reasonable but realistic. This approach is easy to remember and implement, so will not add measurably to the cognitive burden imposed by the interruption (Boehm-Davis & Remington 2009).

In a recent study, a pilot test of the Stay S.A.F.E. management intervention, Henneman and colleagues (2018) demonstrated a significant reduction in time away from the task/patient following implementation of Stay S.A.F.E. Most participants used the entire Stay S.A.F.E. strategy when responding to the interrupter, demonstrating the ease of use. The key finding of the study was that the distraction time from the primary task with the use of the Stay S.A.F.E. strategy decreased from 134.4 seconds to 6.08 seconds (P < 0.05). Participants also commented that the strategy would be beneficial for other clinicians to use including student nurses.

Discussion

Interruptions and distractions can lead to an increased risk of making errors in healthcare, particularly during medication administration, which could result in patient harm. Cottney & Innes (2015) identified that only interruptions that required the nurse to leave the patient resulted in medication errors. The researchers suggested that nurses should avoid non-emergent calls when providing direct care and/or documenting. Rivera & Karsh (2010) also proposed limiting interruptions during high risk tasks such as

medication administration; however, eliminating all interruptions was not recommended due to the complexity of healthcare and demand for communication and coordination of care.

Rather than trying to eliminate interruptions, it could be more useful to teach healthcare professionals, including student nurses, how to manage unnecessary interruptions by prioritizing tasks and, when possible, eliminating the time away from a patient to minimize the risk of patient harm and support decision-making. Little is known about the preparation of student nurses in relation to interruption management strategies and the effects on error rates and patient outcomes.

Nurses should decide how to manage interruptions and researchers should identify nurses' and student nurses' decision-making processes in managing interruptions (Gao et al. 2017, Hayes et al. 2017) and characteristics of interruptions that are successfully overcome (Grundgeiger & Sanderson 2009). Henneman and colleagues (2018) demonstrated a significant reduction in time away from the task/patient following implementation of Stay S.A.F.E. More research is needed to evaluate the effects of Stay S.A.F.E. on student nurses' performance of medication administration.

Conclusion

Despite the increased awareness of the negative impact of interruptions in healthcare, a gap is still present in student nurses' ability to perform medication administration in the presence of interruptions. While student nurses are given tools during their didactic education, such as medication safety practices, simulations do not include environmental and systems factors such as interruptions which could increase the risk of error. Building upon Henneman and colleagues (2018) work, this study evaluated

an interruption management strategy, Stay S.A.F.E., on medication administration and its influence on patient outcomes.

CHAPTER III

THEORETICAL FRAMEWORKS

This chapter presents a comprehensive overview of three distinct theoretical frameworks relevant to this study. Each theory is introduced with the major concept and implications to the proposed study. First, Memory for Goals Theory, which states that the mind always returns to the most active memory. Second, the Near Miss Model which describes defenses involved in preventing errors. Lastly, The Eye Mind Theory, which suggests that what a person is focusing on is connected to what is being processed and interpreted. The three frameworks integrated in this proposal has resulted in a framework Interruption Management Framework which guided the research.

Memory for Goals

Memory for Goals (MFG) is an activation-based model which helps to describe the cognitive management of goals. Goals are defined as "mental representation of an intention to accomplish a task, achieve some specific state of the world, or take some mental or physical action" (Altman & Trafton, 2002, p. 39). MFG states that memory always returns to the most active goal in central processing (Altman & Trafton, 2002). MFG states that if a nurse is interrupted in the middle of a task, for example, they may set an intention to resume the task later. Goals that are not attended to, though, may decay over time. Resuming a task at the proper point or step without skipping steps can be a threat to safety including life or death; this is particularly true in the field of aviation (Altman & Trafton, 2002). In healthcare it can be similarly detrimental. For example, medication administration is a task that has the potential if resumed inappropriately or at

the wrong step could cause an adverse event. MFG offers insight into the cognitive processes and the way in which individuals store and resume goals.

Memory for Goals describes several key concepts to describe the total task time from the start of the primary task to the end of the primary task with an interruption at some point in the time frame involving a secondary task. *Interrupting task* is the activity required as a result of the interruptions. This is also considered the secondary task. For example, a nurse is at a patient bedside preparing to administer a medication (primary task), when a nurse's aide interrupts to alert the nurse her patient in the next room is complaining of chest pain (secondary task). *Interruption time* is the time involved to perform an intervening task. For example, this is the time the nurse's attention, both visual and physical, is focused on the secondary task of addressing the patient with chest pain. Interruption lag is the time parameter defining the first seconds after the nurse is made aware of the interruption. *Interruption duration* is the time period to perform a secondary task as a result of being interrupted. In the scenario described, this is the time it takes for the nurse to assess the patient's chest pain before they go back to the primary task of medication administration. Resumption lag is the time parameter defining the return of cognitive focus back to the primary task. For the purpose of this study, the time to return to primary task or the interruption time was measured. This was critical to address the effectiveness of the Stay S.A.F.E. intervention.

In the role of interruptions and duration of delay, goal decay, longer interruptions should result in longer times to return to the primary task (if it is resumed at all). This theory also provides a mechanism for keeping goals active (Altmann & Trafton, 2002). For example, baseline activation can be increased if, during an interruption, the

participant rehearses the goal. In addition, if cues associated with the goal are attended to during the interruption, then associative activation occurs and adds to the base level activation.

Near Miss Model

The Near Miss Model, as it relates to the proposed study, offers an understanding on how the healthcare environment and the human operator (i.e. nurse) influences patient care (Henneman & Gawlinski, 2004; van der Schaaf, 1992). Contributing factors to near misses and adverse patient outcomes include organizational, system, and human failures (Henneman & Gawlinski, 2004). Eye tracking technology used in this study offers insight into how interruptions, system failures, during high-risk task such as medication administration, influence the cognitive processes of the human operator (nurse) and ultimately patient safety.

The Eindhoven Model first described in the chemical industry (Van der Schaaf, 1992), has the been adapted for nursing as an innovative way to recognize key organizational and human factors that place patients in high risk situations (Henneman & Gawlinski, 2004). This nursing near miss model (Henneman & Gawlinski, 2004) describes defenses involved in preventing error and places the nurse as the primary source of error recovery. Most importantly, safety training such as Stay S.A.F.E. can provide adequate defenses for nurses to help mitigate error.

The original Eindhoven *Model of Incident Causation* includes sequential phases: initial failure, dangerous situation, inadequate defenses, and recovery (van der Schaaf, 1992). During the last phase of recovery, the human operator may detect, understand, and correct the developing incident. The recovery is influenced by the human operator's

experience, intuition, and flexibility. The recovery of the developing incident is considered a near miss rather than an adverse outcome.

Sources of errors that are described in the model include: technical failure, organizational failure, and human failure (van der Schaaf, 1992). Each failure, either alone or simultaneously, can lead to adverse outcomes. Van der Schaaf (1992) described the three failures as the very beginning of a chain of events. From a chemical industry perspective, human or operator failures were described as the most dominant source of failure (50 percent) but emphasis was on all three failures leading to an adverse outcome.

Examples of technical failures in healthcare include software or equipment that are not available or not correctly functioning. For example, in healthcare, malfunctioning equipment such as a patient-controlled analgesia (PCA) pump or a long-term computer downtime could be considered technical failures. Organizational failures include complex factors that can impact the workflow for example policies, protocols, and organizational culture.

Human failures include skills, rules, and knowledge failures (Henneman & Gawlinski, 2004). Registered nurses bring into their practice internal schemata which includes knowledge and past experiences which help them cognitively manage clinical situations and the corresponding steps taken in decision making (Wilkinson, Cauble & Patel, 2011). Student nurses, however, obtain skills from their clinical experiences as well as from their work in simulated settings.

Nurses' human capital include the skills, experiences, and education that influence their ability to care for patients (Covell, 2008). Specific nurse characteristics which can impact patient care include assessment (Henneman & Gawlinski, 2004),

monitoring patient status (Rothschild et al., 2006), surveillance (Henneman et al., 2006; Rothschild et al., 2006; Hurley et al., 2008; Jeffs, MacMillan & Maione, 2009; Rothschild et al. 2009; Dykes, Rothschild & Hurley, 2010; Henneman et al., 2010a; Yang et al., 2012), anticipation (Henneman et al., 2006), double checking (Henneman et al., 2006; Henneman et al., 2010), awareness of big picture (Henneman et al., 2006), clinical experience (Chipps et al., 2011; Wilkinson, Cauble & Patel, 2011), education (Henneman & Gawlinski, 2004; Rothschild et al., 2006; Rothschild et al., 2009), strong clinical judgment (Dykes, Rothschild & Hurley, 2010), and certification (Rothschild et al., 2006; Henneman et al., 2010).

The Near Miss Model includes adequate defenses which allow for adequate human recovery. Interruptions during medication administration may develop into incidents. If nurses and student nurses are trained to change their practice and better manage interruptions, they could improve patient safety and outcomes. In nursing, the Eindhoven Model has been used as the theoretical framework (Henneman et al. 2014; Henneman et al. 2010) in studies on patient safety. Experienced nurses in one study seemed more likely to identify and correct more errors when compared to their novice counterparts (Henneman et al. 2010). When looking at rule-based errors though, it seemed more likely that novice nurses would catch those errors as they focus more on rules (Henneman et al. 2010).

Eye Mind Theory

The Eye Mind Theory originated from research on reading and reading comprehension. The main tenants of the Eye Mind Theory suggest that what a reader is focusing on is connected to what is being processed and interpreted (Just & Carpenter,

1980) and is related to their thoughts and attention (Henneman et al, 2017). While reading, the reader will pause on words that need more processing (Just & Carpenter, 1980). The Eye Mind Theory suggests that an individual's eye movements can offer insight into cognitive processes (Just & Carpenter, 1980). Cognitive processes are complex, and it is possible that an individual may be looking at one thing but contemplating other things at the same time (Reichle et al., 1998). Research using eye-tracking technology has demonstrated that readers spend more time focusing on the main words in a sentence in order to understand the meaning of the sentence (Rayner, 1977). Eye movements vary with the difficulty of the content being read. Research outside of reading suggests that the amount of time a person spends looking at something (gaze duration) reflects the amount of time it takes for them to process what they are looking at.

Research has demonstrated that where participants focus their visual attention offers insight into cognitive decision making (Brunyé, et al., 2017; Doberne, et al., 2015; Gold, Stephenson, Gorsuch, Parthasarathy, & Mohan, 2016). Orquin & Loose (2013), found that experts have shorter fixation durations, or time spent looking at the area of interest, when compared to novices. Experts also fixate on areas of interest that are essential in decision-making while novices may not fixate on the areas of interest due to its unfamiliarity. Novices also have longer fixation times, which indicates they need more time to process the information or task at hand.

In healthcare research, when comparing novice and expert pathologists, experienced pathologists examining tissue slides for cancer focused more on the areas of interest, predetermined by the researcher, when compared to novice pathologists (Brunyé et al., 2017). This is consistent with research comparing experienced and novice

perioperative nurses. Experienced perioperative nurses focused more of their attention on the important aspects of the surgical procedure, such as surgical counts and maintaining a sterile environment, when compared to a novice nurse (Koh, et al., 2015). The novice nurses frequently switched their attention among areas of interest. The novice nurses were also distracted by interruptions. Interruptions included difficulty finding instruments, conversation with other perioperative nurses, and housekeeping duties. These interruptions were all of lower priority than the current situation. These results suggest that the nurse's eye movements reveal cognitive processes.

The Eye Mind Theory has also been used to examine the safety practices of health care providers. Marquard and colleagues (2011) imbedded patient identification errors in a simulation of medication administration and found participants who visually fixated on the area of interest that contained the error were more likely to identify the error. Participants who did not discover the error tended to not fixate on any one area of interest. The link between the visual fixation on the area of interest and the identification of the error suggests a cognitive connection. The Eye Mind Theory suggests that novices may look at unimportant areas during decision making. It also takes the novice longer to collect key data and make decisions when compared to experienced nurses. Unlike an expert nurse, a novice nurse will likely have a difficult time making decisions especially if there are a lot of extraneous data to examine.

Interruption Management Framework

Integration of essential components of the Memory for Goals, Near Miss Model, Eye Mind Theory, and the foundations of the Stay S.A.F.E. resulted in a new framework which helped to guide much of the research. The Interruption Management Framework was created and will be tested and validated in future studies.

The Interruption Management Framework is the amalgamation of human factors, adequate defenses, and outcomes which play a role in the recovery of a dangerous situation caused by an interruption. Interruptions within healthcare are frequent and do not always result in negative outcomes, therefore, defenses described in the framework include cognitive defenses, time management, and prioritization. Integration of the Stay S.A.F.E. cognitive rehearsal including acknowledgement of the interruption, fixation on task, and talking out loud are key concepts in the framework.

Adequate defenses may include organizational, technical, or human factors within healthcare that improve patient safety and mitigate error. Examples of organizational factors which may provide adequate defenses include cultures of safety, organizational safety programs, safety-focused leadership teams, and patient safety plans. These organizational cultures have been identified in settings which error recovery was more likely to be recognized and system-wide improvements would take place (Faye et al., 2010; Gaffney, Hatcher & Milligan, 2016; Gaffney, et al., 2016; Henneman et al., 2010; Hurley et al., 2008; Jeffs, Affonso & MacMillan, 2008; Rothschild et al., 2006; Speroni et al., 2014).

This study is focused on human factors and adequate defenses which may or may not improve the ability for a student nurse to intercept a potentially dangerous situation. Demographic factors collected in this study include intellectual capital variables such as healthcare experience (i.e. nurse's aide) and education (junior versus senior).

Many interruptions in healthcare do not develop into a near miss or adverse event. When an interruption becomes a developing incident, as described by the framework, then there is a potential for a near miss or an adverse event. The last component of the framework provides a spectrum from a non-event to an adverse event affecting a patient outcome. For example, a near miss, if not stopped, has the potential to become an adverse event (Jeffs, Affonso & MacMillan, 2008). Understanding both near miss and its relationship to adverse events is important in clarifying the effectiveness of the Stay S.A.F.E. strategy and interruptions (Jeffs, Affonso & MacMillan, 2008).

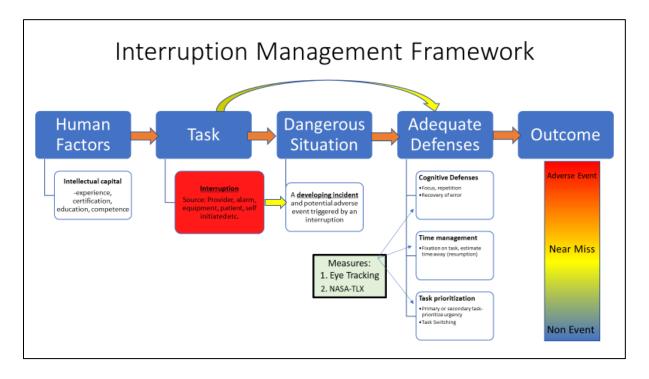


Figure 4: Interruption Management Framework Model

Theoretical Definitions

The following section defines the important concepts that frame the study. The key concepts included: interruption, distraction, error, near miss, adverse event, and workload. Each one is defined and an example of its use in healthcare is provided.

Interruption

Several researchers have defined interruptions in different contexts. For the purposes of this research the following definition by Brixey and colleagues (2007) was used:

"a break in the performance of a human activity initiated by a source internal or external to the recipient... within the context of a setting or a location...[resulting] in the suspension of the initial task by initiating the performance of an unplanned task with the assumption that the initial task will be resumed (p. E38)."

Interruptions, unlike distractions can come from within or outside the individual. For example, a nurse starting a conversation with another staff member during a task or data entry would be a self-initiated *interruption* (Biron et al. 2009, Johnson et al. 2017). A key feature that distinguishes an interruption from a distraction is the break or pause in task performance to complete another task, which requires a shift in cognitive focus. When a nurse has to leave the bedside to answer a question from another nurse asking for help and intends to return to the bedside to complete the task, the task is *interrupted*. Some researchers provide a time frame for the break in task such as five seconds or 10 seconds (Sorensen & Brahe, 2014; Kosits & Jones, 2011). For the purposes of this study, the

focus was on task switching and suspension of the primary task to attend to the secondary task.

Distraction

Distraction "occurs when a person's attention is partially diverted from a primary task to another task but performance on the primary task is not fully suspended" (Sanderson & Grundgeiger 2015, p. 86). Distractions are an outside stimulus that may only *briefly* sidetrack a healthcare provider and may include unrelated conversations (Campbell et al. 2012), music/radio, and case-irrelevant communication (distractions in the operating room that may influence concentration of surgeon) (Pluyter et al. 2010). For example, a surgeon may be *distracted* from their current task, performing surgery, to attend to a question by a circulating nurse. The surgeon *continues with the current task*, but their attention is briefly diverted to answer the question. Distractions and interruptions were used interchangeably in much of the literature. Defining it for the study was critical so that readers understand the intent of the study was focused on interruptions and not distractions.

Error

An error is defined as "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim" (Kohn et al. 2000, p. 28). Types of medical errors include diagnostic (e.g. error or delay in diagnosis), treatment (avoidable delay in treatment), preventative (inadequate follow up), and other (equipment failure) (Leape et al. 1993).

Two types of errors that have been described previously include clinical errors and procedural failures. Both can occur with different tasks but in the context of this

research, clinical errors and procedural failures are focused on medication administration. Clinical errors occur when a provider does not follow one of the seven rights of medication administration such as: right dose, right drug, right time, right patient, unordered drug administered, etc. (Westbrook et al. 2010). Procedural failures occur when the person completing a task does not follow proper procedure. During medication administration, for example, procedural failures include: not verifying patient identification, not double-checking high-risk medications, and failure to check blood pressure prior to administering an antihypertensive (Johnson et al. 2017, Westbrook et al. 2010).

Near Miss

A near miss is defined as "halted somewhere in its progression before it develops into a full-blown error with serious consequences then it is less likely to manifest itself as a complete adverse event" (Wilkinson, Cauble & Patel, 2011, p. 213). For example, when the nurse can recover the error, it is deemed a near miss (Henneman & Gawlinski, 2004; Henneman et al., 2006). The Eindhoven Model describes the near miss as an outcome of the recovery process (Henneman & Gawlinski, 2004). A near miss, if not intercepted, has the potential to become an adverse event (Jeffs, Affonso & MacMillan, 2008).

Adverse Event

An adverse event is defined as a patient injury as a result of medical mismanagement and not associated with the patient disease process (Rothschild et al., 2009). A near miss, if not intercepted, has the potential to become an adverse event (Jeffs, Affonso & MacMillan, 2008).

Workload

Workload is defined as the load imposed on a person's cognitive system when a person is performing a specific task (Paas & van Merriënboer, 1994). Workload, also known as cognitive workload, has three dimensions including mental load, mental effort, and performance. When a nurse is interrupted, there is a cognitive shift which is a shift of focus from the primary task. This cognitive shift imposed by an interruption can increase the amount of time it takes to complete a task, a loss of focus on the primary task (Potter et al. 2005), and increase in mental workload (Weigl et al., 2012). For the following study, workload was measured using the NASA-TLX.

Summary

Experts have suggested that the recognition of the nature and impact of interruptions is a first step in preparing clinicians, including student nurses, to work safely in environments at high risk for interruption-related errors (Beyea, 2007). In addition, it has been suggested that a clinician who is mindful of the potentially negative consequences of an interruption may increase their focus and concentration on their work or current goal (Altmann & Trafton, 2002; Beyea, 2007). Stay S.A.F.E. attempts to place the goal in active memory while helping the healthcare provider manage any incoming interruptions (Henneman et al., 2018).

The theoretical frameworks including Memory for Goals, Eye Mind Theory, Near Miss Model, and the Interruption Management Framework guided the research, the study questions, variable measurements, and data analysis. The data analysis further evaluated the framework and whether changes and modifications were needed. Key terms and

concepts were defined so that the reader has a baseline understanding of the concepts in the context of the research.

CHAPTER IV

METHODS

Introduction

This chapter addresses the design and methodological procedures that were applied in this study. Including: study purpose, setting, questions, sample, and methods. The research design and method of this study were structured to gain a better understanding of how the intervention, Stay S.A.F.E. education, influence the student nurses' performance during medication administration.

Design and Purpose

The experimental study utilized a randomized prospective trial of the Stay S.A.F.E. intervention, an interruption-training program, on student nurses' (SN) response to interruptions, performance (procedural failure and error rate), and perceived mental workload during simulated medication administration with an interruption compared to the control group.

Study Setting

The study was conducted at the University of Massachusetts, Amherst and University of Massachusetts, Springfield simulation laboratory which includes simulated hospital rooms that contain human patient simulators and equipment to simulate the administration of medications. Equipment in the simulation included lab monitors, IV pumps, EKG leads, oxygen saturation monitor, simulated medications, and routine supplies.

Research Questions and Hypothesis

To achieve the goal of the proposed study, the following research questions and hypotheses were evaluated:

1. What is the impact of the Stay S.A.F.E. intervention on student nurse (SN) management of, and response to, interruptions in simulated clinical scenarios?

Hypotheses 1

- 1a. SNs in the experimental group will return to the primary task more quickly in post-test simulations compared to baseline.
- 1b. SNs in the experimental group will return to the primary task more quickly in post-test simulations compared to the control group.
- 1c. SNs in the experimental group will be more likely to respond appropriately to the interrupter (not take report) in post-test compared to baseline.
- 1d. SNs in the experimental group will be more likely to respond appropriately to the interrupter (not take report) in post-test compared to SNs in the control group.
- 2. What is the impact of the Stay S.A.F.E. intervention on SN errors?

Hypotheses 2

- 2a. SNs who receive the Stay S.A.F.E. intervention will make fewer errors in post-test simulations compared to baseline.
- 2b. SNs who receive the Stay S.A.F.E. intervention will make fewer errors in post-test simulations compared to SNs in the control group.
- 3. What is impact of the Stay S.A.F.E. intervention on SNs perceived task load?

Hypotheses 3

3a. There will be a significant difference in perceived workload across three simulation scenarios for SNs who receive the Stay S.A.F.E. intervention.3b. SNs in the control group will not perceive a significant difference in workload across the three scenarios.

Participants

Participants were recruited by researcher and research assistants from a convenience sample of nursing students in their junior or senior year of a traditional baccalaureate nursing program and the second bachelors group. Both groups had education on the performance of a physical assessment and experience administering medications subcutaneously and by mouth.

Inclusion Criteria

Participants were current student nurses with education in the performance of a physical assessment and who have administered medications. The participants must be able to attend the simulations at the University of Massachusetts, Amherst and/or University of Massachusetts, Springfield campus.

Exclusion Criteria

Student nurses who require the use of glasses which cannot be worn consistently during the simulation.

Sample Size

To identify an appropriate sample size, a power analysis was performed. The following criteria were used for the analysis: (a) α = 0.05, (b) power = 0.80. A-priori power analyses were conducted using G*Power (Faul, 2014) with effect sizes identified

in prior literature. Pilot data from Stay S.A.F.E. (Henneman et al., 2018) demonstrated a large effect in within-subject in duration of interruption and response to interrupter. Because a between-subjects effect is not known, a more conservative effect was utilized (*f*=0.25). Power analysis suggests that a total sample size of 28 is necessary to identify within- and between-subjects' effects in interruption duration (question 1) and perceived task load (question 3) for two groups with three measurements each. In one study evaluating the effectiveness of interventions to reduce error during high-risk (chemotherapy) medication administration, nurses who completed the simulated scenario after medication verification interventions had been implemented, were 94 percent less likely to make an error in IV push medication administration when they were interrupted during the simulation compared to nurses who completed the same simulation prior to implementation (OR=0.06, 95%CI=0.00-0.33; Prakash et al., 2014). Power analysis using this odds ratio suggests a total sample size of 30 is necessary to identify a similarly large reduction in odds of making a medication error post-intervention (Faul, 2014).

The largest total sample required based on power analyses is 30. However, a sample that is 30 percent larger was recruited to account for possible subject attrition and potential lost data (up to 25 percent) from the eye tracker technology. Thus, the target sample for the proposed study is 40, with 20 students being assigned to each group.

Participant Recruitment & Eligibility Screening

All procedures were approved by the University of Massachusetts Institutional Review Board (IRB), prior to beginning the study. Participants were recruited by scripted presentations in classes on both Amherst and Springfield campuses. Three undergraduate nursing students were research assistants and helped in the recruitment process.

Recruitment also occurred through word of mouth and interested subjects were encouraged to inform fellow classmates of the research study.

Participants were student nurses from UMass Amherst and UMass Springfield. Following the eligibility screening, potential participants were encouraged to ask questions via email or phone call to clarify purpose, design, or other study specific questions. The researcher enrolled subjects until the desired sample size was reached.

Study Instruments and Measures

Eye Tracker

All subjects wore an eye tracking device (SMI ®) during the simulation to measure participants' eye movements and were used to identify the study outcomes: time to return to the primary task and fixation time on interrupter (Duchowski, 2007). The eye tracker is a lightweight, tetherless system that can be worn by participants who must move freely through a study environment. The device includes a scene camera, optics, and reflecting mirror all mounted on safety glasses. The scene camera records a video of the area in front of the wearer and uses pupil—corneal reflection to measure the position of the eye. The ASL system uses the pupil to corneal reflection technique to determine the relationship between the pupil and the cornea to compute the location of the gaze in the scene environment. The eye tracking device is calibrated for each participant. The calibration process involves having the subject fixate on three points of reference in their visual field. Once calibrated, the eye tracker software program overlays cross hairs on a video, showing the exact locations in a scene where the individual is gazing throughout the simulated scenario. The eye tracker system can be used on subjects with and without glasses. The participants need to wear the glasses consistently through the simulation and cannot take them on and off. If they wear both contacts and glasses, then they were asked to wear contacts.

Data collected from the eye tracker for this study included the time to return to primary task measure in seconds, time to answer interruption, and error rate. The eye tracker video was used to code procedural failures, response to interrupter, and evaluate components of medication administration. Data was inspected visually by examining the cross hairs of the video indicating the fixation point overlaid on the scene. Appendix J includes the data collection tool used when evaluating and coding the eye tracking videos. The researcher C.V. and research assistant A.D. evaluated the videos independently to measure the time to return to primary task, time to answer interruption and error rate, and both researchers were not blinded to the groups or outcomes. The videos were replayed and evaluated independently. The points of reference, i.e. cross hairs, were used to identify where the participant was looking, and the eye tracker software measured the time of each event. The error rate was a subjective measurement by the researcher and research assistant when the videos were replayed. Errors were evaluated using the data collection tool.

NASA Task Load Index

Subjective workload assessment was measured with NASA Task Load Index (NASA-TLX) (Hart & Staveland, 1988), developed by the NASA Ames Research Center for aviation, but used increasingly in human factors research (Hart, 2006). Since its development, it has been used in nursing and medicine. The NASA TLX consists of seven sub scales, each of which measures a different component of subjective workload. Possible scores range from 0-7 (scaled score) or 0-100 (raw score) with higher scores

indicating higher perceived cognitive workload. Raw scores were used in this study. The NASA-TLX has been used in various settings including aircraft cockpits, simulation, and laboratory settings and has demonstrated adequate reliability and validity. The instrument is provided in Appendix A.

Demographic Data

All participants completed a demographic form which included: age, gender, race, ethnicity, and grade point average. Other covariates to be collected included: year in nursing program, amount of prior healthcare experience (e.g. work as patient care assistant (PCA) or certified nurse's aide (CNA), level of comfort with simulation, and how frequently they have taken part in simulation.

Study Procedures

Subjects participated in three simulations over the course of two to four weeks.

All three simulation scenarios included the administration of a medication and an interruption by another nurse looking to give report to the participant about a patient admission.

Each subject participated in the research study on two days (7-14 days apart) for approximately 45 minutes each day for a total of 1.5 hours. On the first day, subjects provided demographic data as well as informed consent. They also agreed to record audio and video through the eye tracker during their simulations. The researcher introduced the participants to the simulation environment and briefly described the process of simulation testing. Simulation laboratory training took about 10 minutes. A simulated patient room was set up with a bed, table, and simulation mannequin. A simulated mannequin was equipped with intravenous line, IV tubing, and IV bag. Subjects were informed about the

eye tracking device (goggles) that captures a video of the scene in front of them and places cross hairs on the video showing exactly where they were looking as they perform a task.

Baseline Simulation Scenario

At baseline, following informed consent, orientation to study procedures, and receiving \$25 cash honorarium, the participants were instructed to administer medications as they normally would in the practice setting. They were provided a medication administration record listing the medications to be given to the patient. The medications were labeled with the patient's name, date of birth (DOB), medication name, and dose. The patient also had a wrist band with the same information. They were interrupted at a designated time during the medication administration. The simulation ended once the participant administered the medication and completed all medication steps, including documentation.

Once the simulation and NASA-TLX was completed, participants were randomized to receive either the Stay S.A.F.E. intervention, or an alternate education presentation. Randomization was completed prior to the start of the study. A computer generated number generator was used to determine groups.

(https://www.graphpad.com/quickcalcs/randomize2/).

Intervention

The Stay S.A.F.E. strategy intervention is designed to provide student nurses the techniques to keep the primary task of medication administration in active memory. The intervention aided student nurses in managing the simulation environment including embedded interruptions. Participants in the intervention group learned the Stay S.A.F.E.

acronym. The 5-minute educational interventions were provided immediately after the first simulation session. The following outlines the two groups:

- Control Group: participants viewed a pre-recorded PowerPoint presentation on the topic of Medication Safety Practices.
- Experimental group: Participants viewed a pre-recorded PowerPoint
 presentation on management of interruptions in the clinical setting (Stay S.A.F.E. training; Henneman et al., 2018) and a pre-recorded PowerPoint on the topic of Medication Safety Practices.

The subjects in both groups then participated in a second simulation where they administer a medication and were interrupted at a designated time period. Appointments for the final simulation, simulation #3, were scheduled before the participant left for the day. Appointment reminders were sent via email 24-48 hours in advance of the next session.

Post-Test Simulation

Participants were asked to return in 7-14 days later to take part in one additional simulation. Subjects were asked to administer a medication and were interrupted at designated time periods during the medication preparation process. Once the simulation was complete, the NASA-TLX was completed after each simulation.

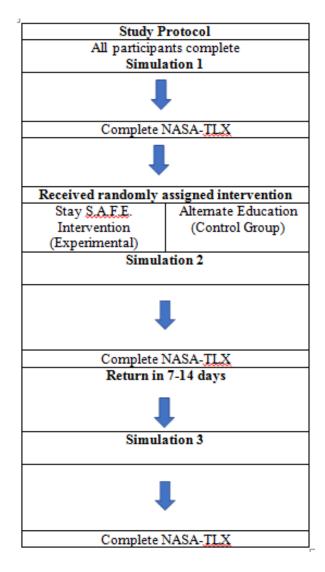


Figure 5: Study Protocol

Detailed Steps for The Procedure

- 1. Obtain written informed consent
- 2. Participant received stipend and signed receipt form
- 3. Collected demographic data
- 4. Oriented participant to simulated environment (eye tracker, equipment, resources, documentation forms)
- 5. Calibrated eye tracker
- 6. Provided participant with a written patient report, patient medication administration record
- 7. Begin Simulation #1
- 8. Interrupted participant at designated time period
- 9. Simulation ended when participant completed medication administration
- 10. Completed NASA TLX
- 11. Randomized participant to intervention or control group
- 12. Control group received PowerPoint presentation on Medication Safety Practices
- 13. Experimental group received PowerPoint presentation on Stay S.A.F.E. Interruption Management Training
- 14. Begin Simulation #2
- 15. Interrupted participant at designated time periods
- 16. Simulation ended when participant completed medication administration
- 17. Completed NASA TLX
- 18. Participant returned in 7-14 days
- 19. Recalibrated the eye tracker
- 20. Begin Simulation #3
- 21. Completed NASA TLX
- 22. Remove eye tracker
- 23. Completed post test

Blinding

Participants were randomized into one of two groups. Research participants were blinded to the groups. The researcher and research assistant, however, were not blinded to the groups. The data coders were also not blinded to the group of participants.

Data Analysis Plan

Prior to analyses, all data was evaluated for skewness and kurtosis, and any necessary transformations were performed. In addition, assumptions of each statistical test being used was evaluated. Descriptive statistics will be presented for all relevant

study variables. The descriptive statistics were summarized as counts and frequencies for binary or categorical data and as means, standard deviations, medians, and interquartile ranges (the 25th and 75th percentiles) for continuous data.

To compare independent means (for example, the means between the Control and Experimental groups for a single Simulation), the Student's t-test was used. To compare medians, the Mann-Whitney test was used. To compare frequencies and proportions between two independent groups, the Chi-Square test was used unless a cell-count was < 5. In this case, the Fisher's exact test was used. To compare paired frequencies, the McNemar test was used. To compare paired medians, the Wilcoxon matched-pairs signed-ranks test was used.

To determine whether SNs who receive the Stay S.A.F.E. intervention are more likely to respond appropriately to the interruption (question 1, H1c & H1d), we compared the proportion of correct responses between groups with the Chi-Square or Fisher's exact test (mostly the Fisher's Exact test due to small cell sizes). To compare repeated means within the Control or Experimental groups, a simple repeated ANOVA model was used with a Box correction to derive the adjusted p-values. To compare trends across the three simulations, both in all participants and within the control and experimental groups, Cuzick's non-parametric test for trend was used. All p-values < 0.05 were considered statistically significant. All analyses were done using Stata/MP 15.1 for Windows StataCorp, LP College Station, TX).

Protection of Human Subjects

All procedures were approved by the Institutional Review Board at the University of Massachusetts prior to implementing the study. Participant info remained confidential

and identifying information was not stored with the participant info and instead each participant was given a random number. Servers and computers where the data and images are stored were password protected. Paper demographic information was kept in a locked room. Images and data were assigned a code number, which was used in place of participant names. Only the Principal Investigator, research chair, and research assistants were granted access to the data. The data was used for research and educational purposes, such as teaching, publications, and/or presentations and may be viewed by students, other trainees, and professional colleagues. Participant identification was not included.

Physical, psychological, and confidentiality risks were identified. There is little likelihood of any physical risk as a result of participation in this research project.

Participants are not asked to perform any tasks that are outside of the normal duties of a student nurse. Participants were asked to perform medication administration in a simulated setting with the typical equipment found in a nurses' work environment.

Participants were asked to provide demographic data (age, gender, education, race/ethnicity). Their participation in the simulated scenario requires critical thinking and engagement in the task at hand while interruptions are being performed. Student nurses with inexperience with simulation may experience some psychological stress. This simulation has low psychological risk. Despite careful precautions, there was a risk that personal identifying information, including measurements taken and the log of participation in this study, could become available to an unauthorized third party. The researcher took every precaution to minimize this risk by securing all protected information in compliance with all state and federal regulations.

Data Management and Security

Demographic data and video files were secured with a unique ID and password and were kept on password protected equipment, including laptop and backup drives and accessed using a secure internet connection. Only the researcher, committee chair (Dr. Cynthia Jacelon), and members of the research committee which may include undergraduate research assistants had access to the data. Data was available to the chair of the research committee in the College of Nursing with no other individual allowed to have access other than the PI and committee members.

Potential Problems and Alternative Strategies

One potential problem was contamination introduced by student nurse participants talking to one another about the scenarios and the Stay S.A.F.E. training being used in the study. The researcher requested that students not talk about the study with their colleagues. Although we did not focus on interruptions, it was possible that the subjects inferred the intent of the study from the baseline simulation. Over recruitment of student nurses was completed to help with participant attrition.

Anticipated Outcomes

After implementation of Stay S.A.F.E. in acute care settings, nurses will build resilience to interruptions and practice autonomously. Overall, the Stay S.A.F.E. training will establish a strategy to improve patient safety and reduce errors in an interruption laden healthcare environment.

CHAPTER V

FINDINGS

The purpose of this research was to test a novel mitigation strategy, Stay S.A.F.E., to aid student nurses in managing interruptions in the clinical setting. The existing gaps in the literature regarding the impact of mitigation strategies to aid nurses in managing interruptions is limited. Most literature has focused on reducing the number of errors. The following section presents the results by study aims and hypotheses.

Data Preparation

Participant variables were summarized as counts and frequencies for binary or categorical data and as means, standard deviations, medians, and interquartile ranges (the 25th and 75th percentiles) for continuous data. To compare independent means between variables, the Student's t-test was used and to compare medians, the Mann-Whitney test was used. Frequencies (i.e. proportions) between two independent groups were measured using the Chi-Square test; unless a cell-count was < 5. In this case, the Fisher's exact test was used. Paired frequencies were compared using the McNemar test while paired median were compared using the Wilcoxon matched-pairs signed-ranks.

For each inference test t-test and/or chi-square test, the null hypothesis was that the two groups were similar (i.e., have the same means, or same proportions, or come from the same distribution). If there was a significant p-value, the null hypothesis was rejected and statistical evidence supports that the two groups were different.

To compare repeated means within the control or experimental groups, a repeated ANOVA model was used with a Box correction to derive the adjusted p-values. To compare trends across the three simulations, Cuzick's non-parametric test for trend was

used. All p-values < 0.05 were considered statistically significant. All analyses were done using Stata/MP 15.1 for Windows (StataCorp, LP College Station, TX).

Description of Sample

The sample consisted of a convenience sample of 41 prelicensure nursing students in the baccalaureate nursing program either in the traditional or second bachelors track, at the University of Massachusetts Amherst. The participants were randomized into the intervention or control group. Two participants were not included in the analysis, due to problems calibrating the eye tracker. Of the 39 included in this study, nineteen students were from the accelerated second bachelors track and 20 were from the traditional undergraduate track. The participants ranged in age from 18 to 38 with most students ranging from 18-26 (74 percent), see Table 1.

Of the 39 participants, most of the sample (92 percent) had experience with simulation either during nursing school, hospital orientation, and/or continuing education. A little more than half of the participants had some patient experience (67 percent). The majority of the sample were female and White (77 percent). Other ethnicities included Asian (13 percent) and Black (7 percent).

Table 1: Study Characteristics

	Control	Experiment
	N = 19	N=20
% Second Bachelor Track	42%	55%
Experience with Simulation	90%	95%
Experience giving by mouth medication		
Clinical	21%	20%
Classroom, clinical and simulation	37%	80%
Both clinical & simulation	42%	20%
Patient Care Experience	68%	65%
Age		
18 to 26	84%	65%

27 to 32	11%	25%
33 to 38	5%	10%
Gender (% Male)	11%	5%
Ethnicity		
Hispanic/Latino	5%	0%
Asian	2%	25%
Black	11%	5%
White	84%	70%
Highest Level of Education		
Current Undergraduate	58%	45%
Bachelor	42%	55%

Simulations

The design of the study tested all participants in a simulated setting. Each simulation required the participant to administer a medication, whether by mouth or subcutaneously. During a similar point in the simulation, the participant was interrupted by the researcher or research assistant. The interruption, to give a report on a new admission, was evaluated whether the participant took report. The simulation ended once the participant completed the medication administration. For the purposes of clarity of the description of simulations, the design of the study is outlined below:

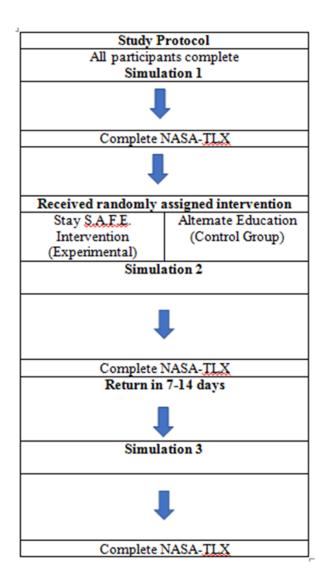


Figure 6: Study Protocol

Analysis of Study Aims

Aim 1

The first aim of this study was to determine the impact of the Stay S.A.F.E. intervention on student nurse management of, and response to, interruptions in simulated clinical scenarios.

Hypothesis 1a: Student nurses in the experimental group will return to the primary task more quickly in post-test simulations (simulation #2 & #3) compared to baseline

The hypothesis evaluated whether the participants in the experimental group (Stay S.A.F.E), after being interrupted, returned to the primary task of medication administration in less time (seconds) in simulation #2 and #3 when compared to baseline. Hypothesis 1a was supported. Table 2 demonstrates that the Stay S.A.F.E. (experimental group) was significantly faster in returning to the primary task of medication administration in Simulation #2 and #3 compared to Simulation #1 (baseline simulation). The change in time to return to task for the control group was not significant.

Table 2: Time to Return to Primary Task in Seconds

	Control	Experimental
Simulation #1	N = 16 25.2 (13.3) 20.5 [13.3, 37.9]	N = 17 30.1 (13.5) 34.0 [15.9, 40.0]
Simulation #2	N = 19 20.8 (10.4) 18.9 [12.0, 30.0]	N = 20 12.4 (6.0) 11.9 [10.0, 13.5]]
Simulation #3	N = 19 19.3 (14.2) 12.0 [8.9, 38.0]	N = 18 13.0 (6.7) 12.0 [10.9, 13.9]
p- value Comparing Simulation #2 to #1	0.098	0.003
p- value Comparing Simulation #3 to #1	0.255	0.005

Note: Mean (SD); Median [25th, 75th percentile]

P-value calculated using the Wilcoxon matched-pairs signed-ranks test

Hypothesis 1b: Student nurses in the experimental group will return to the primary task more quickly in post-test simulations compared to the control group

The intervention, Stay S.A.F.E., was provided to the experimental group after the baseline simulation. Each participant watched a 2.5-minute PowerPoint on the interruption management strategy, Stay S.A.F.E. The participants then partook in simulation #2. Simulation #3, took place 7-14 days later. Hypothesis 1b was partially supported. Table 3 demonstrates that there was a significant difference in return to primary task times (seconds) in simulation #2 when comparing the Stay S.A.F.E. experimental group with the control group. There was not however a significant difference in return to primary task in simulation #3. So, there was some evidence that the experimental group did better when compared to the control group.

Table 3: Time to Return to Primary Task by Group and Simulation in Seconds.

	Control	Experimental	p- value
Simulation #1	25.2 (13.3);	30.1 (13.5);	0.331*
Start to Finish Time	20.5 [13.3, 37.9]	34.0 [15.9, 40.0]	
Simulation #2	20.8 (10.4);	12.4 (6.0);	0.007*
Start to Finish Time	18.9 [12.0, 30.0]	11.9 [10.0, 13.5]	
Simulation #3 Start to Finish Time	19.3 (14.2); 12.0 [8.9, 38.0]	13.0 (6.7); 12.0 [10.9, 13.9]	0.543*

Note: Mean (SD); Median [25th, 75th percentile]

Additional analysis evaluated the three means (time in seconds) using a repeated ANOVA analysis over the three simulations. The three means were significantly different in the experimental group (p<0.001 with a Box correction). Cuzick's test for trend also shows that there was a significant trend in the experimental group, means decreasing over

^{*} Mann-Whitney Test

the three simulations (p<0.001). Figure 7 demonstrates the difference in time to return to primary task using a box plot.

However, in the control group, the three mean times were not significantly different using a repeated ANOVA with a Box Correction (p = 0.366). Cuzick's test for trend also showed that there was a non-significant trend, means decreasing over the three simulations (p=0.071). Figure 7 below provides a visual comparing the control and experimental group return to primary task in seconds.

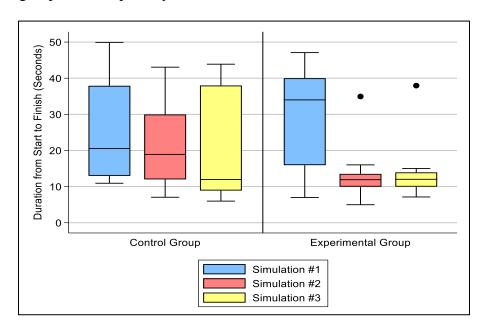


Figure 7: Time to Return to Primary Task

Hypothesis 1c: Student nurses in the experimental group will be more likely to respond appropriately to the interrupter (not take report) in post-test (Simulation #2 and #3) compared to baseline

The simulation was designed so that participants needed to prioritize which task was more critical at the time of the interruption. The interruption involved another nurse attempting to give the participant report about an incoming patient admission. The

experimental group, using the Stay S.A.F.E. strategy, should have evaluated the interruption and decided on which was more important. Medication administration should have remained the focus and the outcome evaluated if the participant took the report from the interrupter. Hypothesis 1c was supported. Table 4 demonstrates the percentage of participants either in the Stay S.A.F.E. (experimental group) or control group who took patient report. Findings indicated that the experimental group had a significant improvement in appropriate response (not taking report) in Simulation #2 and #3 compared to Simulation #1 (baseline simulation). The control group however, did not have a significant difference in appropriate response from Simulation #2 and #3 compared to Simulation #1 (baseline simulation).

Table 4: Response to Interrupter Across Simulations

	Control	Experimental
Simulation #1	7/16 (43.75%) *(19.75%, 70.12%)	11/17 (64.71%) *(38.33%, 85.79%)
Simulation #2	7/19 (36.84%) *(16.29%, 61.64%)	1/20 (5.00%) *(0.13%, 24.87%)
Simulation #3	5/19 (26.32%) (9.15%, 51.20%)	1/18 (5.56%) (0.14%, 27.29%)
p- value Comparing Simulation #2 to #1	1.000	0.002
p- value Comparing Simulation #3 to #1	0.625	0.008

Note: McNemar's paired test P-value

*95% Confidence intervals- binomial exact (i.e., non-parametric)

Hypothesis 1d: Student nurses in the experimental group will be more likely to respond appropriately to the interrupter (not take report) in post-test compared to student nurses in the control group

Hypothesis 1d was supported. Table 5 demonstrates a significant difference in participants who responded to the interrupter in simulation #2 between the control and experimental group (p=0.020). The control group was more likely to take report during the second simulation when comparted to the experimental group. The experimental group was consistently low in responding to the interrupter in simulations #2 and #3 compared to baseline simulation #1 and most participants in the Stay S.A.F.E. group did not take the report.

Table 5: Response to Interrupter Across Groups

	Control	Experimental	p- value
Did they take report;	(7/16)	(11/17)	0.227
Simulation #1	44%	65%	
Did they take report;	(7/19)	(1/20)	0.020*
Simulation #2	37%	5%	
Did they take report;	(5/19)	(1/18)	0.180*
Simulation #3	26%	6%	

Note: * Fisher's exact test

Aim 1 Summary

Aim 1 was met. The findings demonstrate a significant decrease in time to return to primary task in the experimental group when compared to the control group. The experimental group also demonstrated an improvement in time to return to primary task when compared to their baseline simulation. A pattern was identified in simulation #2 with both time to return to primary task and response to interrupter in the experimental group.

Aim 2

The second aim of this study was to determine the impact of the Stay S.A.F.E. intervention on student nurse errors.

Hypothesis 2a: Student nurses who receive the Stay S.A.F.E. intervention will make fewer errors in post-test simulations compared to baseline

Each participant was evaluated during each simulation (total of three), preinterruption and post-interruption for procedural failures. Procedural failures included
failure to verify medication label, failure to verify patient identification, and failure to
verify medication administration record (MAR). Participants were observed if they
administered the correct medication, correct dose, and correct site. Tylenol was also on
the MAR but was not indicated to be given. The students committed an error if the
Tylenol was administered. Hypothesis 2a was not supported. There was no significant
difference among the errors in the experimental group when comparing baseline
simulation (#1) through simulation #2 and simulation #3 (Table 6).

Table 6: Total Number of Errors by Simulation

	Control	Experimental
	N = 19	N = 20
Simulation #1	3.0 (1.6)	2.9 (1.8)
	3 [2,4]	3[1.5, 4]
	N = 19	N = 20
Simulation #2	2.4 (1.4)	3.4 (1.0)
	2 [1, 3]	2 [2, 3]
	N = 19	N = 19
Simulation #3	2.2 (1.3)	2.3 (1.0)
	2 [1, 3]	2 [1, 3]
p- value Comparing Simulation #2 to #1	0.175	0.137
p- value Comparing Simulation #3 to #1	0.084	0.072

Note: Wilcoxon matched-pairs signed-ranks test

Hypothesis 2b: Student nurses who receive the Stay S.A.F.E. intervention will make fewer errors in post-test simulations compared to student nurses in the control group

Hypothesis 2b was not supported. There was no significant difference in errors in the control group when comparing baseline (simulation #1) through simulation #2 and simulation #3 (Table 6). There was, however, a difference in simulation #1 and simulation #2 (p=0.031) in failure to record on the medication administration record in the control group.

Further analysis of Aim 2 was completed by evaluating the total number of errors pre-interruption and post-interruption between the control and experimental group using Cuzick's non-parametric test for trend. There was a significant decrease in the total number of errors over the three simulations (p = 0.037). However, when examining the data by control (p = 0.087) or experimental Group (p = 0.217), there was no difference, in part, because there was a smaller sample size. Repeated ANOVA analyses with a Box correction for the Control group (p = 0.110) and for the Experimental group were also non-significant (p = 0.149).

Aim 2 Summary

Aim 2 was not met. There was no difference between the control and Stay S.A.F.E. group regarding the number of errors (i.e. procedural failures) committed by participants. There was, however, a difference between simulation #1 and simulation #2 (p=0.031) in failure to record on the medication administration record in the control group.

Also, when reviewing all errors across the three simulations in both groups, there was a significant decrease in the total number of errors. This may demonstrate an overall effect on simulation as a tool. However, when looking at the two groups separately there was no difference in number of errors committed, mostly due to the smaller sample sizes.

Aim 3

The third aim of the study was to determine the impact of the Stay S.A.F.E. intervention on student nurses perceived task load.

Hypothesis 3a: There will be a significant difference in perceived workload across three simulation scenarios for student nurses who receive the Stay S.A.F.E. intervention

Hypothesis 3a was supported. Table 7 demonstrates a significant difference in NASA TLX scores across the three simulations in the experimental group. The repeated ANOVA test for the experimental group assessing if the means of the NASA-TLX scores are the same across simulations has a p= 0.005 with Box Correction. Thus, the three means are significantly different. However, when tested for a trend, the Cuzick's test for trend (i.e., did the mean values decrease over the three simulations) was non-significant: p= 0.094.

Table 7: Mean NASA-TLX Scores Across Simulations: Experimental Group

	Experimental
Simulation #1	26.0 (15.8)
Simulation #2	25.5 (16.3)
Simulation #3	18.2 (12.5)
p- value	0.022*
p- value	0.587^{a}

Note: *Repeated ANOVA with a box correction

^a Cuzick's test for trend

Hypothesis 3b: SN in the control group will not perceive a significant difference in workload across the three scenarios

Hypothesis 3b was not supported. There was a significant difference across the three simulations in the control group as well. The repeated ANOVA for control group assessing if the means of the NASA-TLX scores are the same across simulations, p= 0.022 with Box Correction. Thus the three means are significantly different. However, when tested for a trend, the Cuzick's test for trend (i.e., did the mean values decrease over the three simulations) was non-significant: p= 0.587.

Table 8: Mean NASA-TLX scores Across Simulations: Control Group

	Control
Simulation #1	24.0 (9.4)
Simulation #2	30.3 (12.3)
Simulation #3	22.5 (11.8)
p- value	0.005*
p- value	0.094 ^a

Note: *Repeated ANOVA with a Box Correction

a Cuzick's test for trend

Mean NASA-TLX scores when evaluated for each simulation between groups had no significant differences (Table 9).

Table 9: NASA-TLX Scores Across Simulations

NASA-TLX Mean Score	Control	Experimental	p- value
Simulation 1	24.0 (9.4)	26.0 (15.8)	0.636
Simulation 2	30.3 (12.3)	25.5(16.3)	0.311
Simulation 3	22.5 (11.8)	18.2 (12.5)	0.274

Note: Raw scores 0-100. SD= (); Higher scores indicating higher perceived cognitive workload.

Each component of the NASA-TLX evaluated mental, physical, temporal, performance, effort, and frustration. When evaluating differences in each component between the experimental and control group, there were no significant differences using both a t-test and Mann-Whitney. Table 10 displays means for simulation #1, Table 11 displays means for simulation #2 and Table 12 displays means for simulation #3.

Table 10: NASA TLX Component Means: Simulation 1

	Control	Experimental	p- value *	p- value ^a
Mental	31.6 (15.6) 30 [20, 40]	36.3 (25.6) 35 [20, 55]	0.496	0.792
Physical	10.0 (8.3) 5 [5, 15]	8.7 (5.7) 10 [5, 10]	0.574	0.902
Temporal	22.9 (18.0) 20 [10, 30]	24.5 (27.5) 20 [5, 25]	0.835	0.646
Performance	21.6 (11.6) 15 [15, 30]	31.3 (17.9) 35 [15, 50]	0.054	0.111
Effort	43.4 (22.5) 50 [20, 65]	31.8 (21.0) 25 [15, 50]	0.11	0.094
Frustration	14.5 (14.1) 10 [5, 20]	23.4 (18.6) 20 [5, 35]	0.103	0.122

Note: *t-test, aMann-Whitney

Table 11: NASA TLX Component Means: Simulation 2

	Control	Experimental	p- value *	p- value ^a
Mental	42.9 (21.2) 50[20, 60]	36.5 (27.0) 25 [15, 50]	0.418	0.247
Physical	15.5 (12.2) 15 [5, 20]	11.5 (8.6) 10 [5, 15]	0.240	0.260
Temporal	28.2 (19.0) 25 [15, 40]	21.0 (22.4) 15 [5, 30]	0.290	0.118
Performance	25.5 (12.6) 20 [15, 35]	27.5 (15.6) 25 [15, 42.5]	0.667	0.691
Effort	45.3 (22.1) 50 [20, 65]	37.5 (27.7) 32.5 [12.5, 50]	0.342	0.215
Frustration	24.5 (17.6) 20 [10, 40]	19.3 (16.2) 15 [5, 25]	0.341	0.315

Note: *t-test, aMann-Whitney

Table 12: NASA TLX Component Means Simulation 3

	Control	Experimental	p- value *	p- value ^a
Mental	26.6 (18.5) 20 [10, 45]	23.9 (19.3) 20 [10, 35]	0.671	0.606
Physical	10.7 (6.1) 10 [5, 15]	8.2 (6.3) 5 [5, 15]	0.208	0.215
Temporal	24.7 (17.4) 20 [10, 40]	16.8 (21.5) 10.0 [5, 20]	0.221	0.059
Performance	22.9 (15.2) 15 [15, 30]	22.1 (16.3) 15 [10, 25]	0.878	0.598
Effort	35.5 (21.7) 40 [15, 50]	25.5 (19.9) 15 [10, 40]	0.147	0.134
Frustration	14.7 (12.4) 10 [5, 25]	12.4 (13.3) 10 [5, 15]	0.573	0.373

Note: *t-test, aMann-Whitney

When we examined the mean values over the three simulations within each group (i.e., just within control or within experimental participants), there were some differences in the mental, effort, and frustration components. Table 13 shows differences in the mental, effort, and frustration components in each group.

Table 13: Mean NASA-TLX with Box Correction for Simulation #1-3

	Control p-value	Experimental p-value
Mental	0.023	0.014
Physical	0.137	0.135
Temporal	0.414	0.158
Performance	0.400	0.116
Effort	0.010	0.016
Frustration	0.044	0.030

Table 14 demonstrates the trend over time for each subcomponent of the NASA-TLX. The table examines the presence of a trend over the three simulations by using the Cuzick's test. There was a trend in frustration domain over time in the Stay S.A.F.E. experimental group. Figure 8 also visually displays the decreasing frustration scores in the Stay S.A.F.E. group.

Table 14: NASA-TLX Trend Over Time Across Three Simulations

	Control	Experimental
	p-value	p-value
Mental	0.289	0.105
Physical	0.508	0.709
Temporal	0.749	0.421
Performance	0.913	0.090
Effort	0.182	0.262
Frustration	0.968	0.034
Overall Mean Score	0.587	0.094

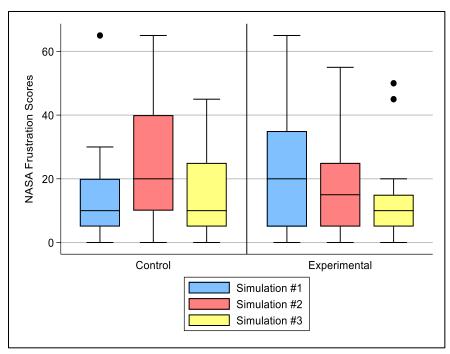


Figure 8: NASA-TLX Frustration Score

Aim 3 Summary

Aim 3 was partially met. There was a significant difference in NASA-TLX scores between the three simulations with the experimental group. There was also a significant difference in NASA-TLX scores between the three simulations with the control group. When reviewing each simulation, within each group there were some differences in mental, effort, and frustration components. In the experimental group only, there was a decreasing trend in frustration overtime.

Summary

This research demonstrated a significant decrease in time to return to primary task in the Stay S.A.F.E. group when compared to the control group. The Stay S.A.F.E. group also improved the time to return to primary task comparing post-intervention (simulation #2 & #3) to pre-intervention (simulation #1).

There was no difference between the control and Stay S.A.F.E. group regarding the number of errors (i.e. procedural failures) committed by participants. There was, however, a difference in simulation #1 and simulation #2 in failure to record on the medication administration record in the control group (p=0.031). Also, when reviewing all errors across the three simulations in both groups, there was a significant decrease in the total number of errors. This may demonstrate an overall effect on simulation as a tool.

The NASA-TLX, as a measurement of cognitive load, evaluated each participant post simulation. Each participant completed three NASA-TLX surveys. There was a significant difference in NASA-TLX scores between the three simulations with the experimental group and control group. When reviewing each simulation, within each group there were some differences in mental, effort, and frustration components. The Stay S.A.F.E. group demonstrated a decreasing frustration score overtime.

Table 15: Summary of Findings

Hypothesis	Aims	Supported
Determine the impact of the Stay S.A.F.E. intervention on student nurse management of, and response to, interruptions in simulated clinical scenarios.	1a: SNs in the experimental group will return to the primary task more quickly in post-test simulations (simulation #2 & #3) compared to baseline.	Yes
simulated crinical scenarios.	1b: SNs in the experimental group will return to the primary task more quickly in post-test simulations compared to the control group.	Partially
	1c: SNs in the experimental group will be more likely to respond appropriately to the interrupter (not take report) in post-test (Simulation #2 and #3) compared to baseline.	Yes
	1d: SNs in the experimental group will be more likely to respond appropriately to the interrupter (not take report) in post-test compared to SNs in the control group.	Partially
What is the impact of the Stay S.A.F.E. intervention on student nurse errors?	2a: SNs who receive the Stay S.A.F.E. intervention will make fewer errors in posttest simulations compared to baseline.	No
	2b: SNs who receive the Stay S.A.F.E. intervention will make fewer errors in posttest simulations compared to SNs in the control group.	No
What is impact of the Stay S.A.F.E. intervention on student nurses perceived task load?	3a: There will be a significant difference in perceived workload across three simulation scenarios for SNs who receive the Stay S.A.F.E. intervention.	Yes
	3b: SN in the control group will not perceive a significant difference in workload across the three scenarios.	No

CHAPTER VI

DISCUSSION

Overview

In this chapter, a discussion of results will be presented. Interpretation of the results examining the impact of the Stay S.A.F.E. strategy on time to return to primary task, number of errors, and cognitive load during medication administration will be discussed. Research limitations, implications for nursing, recommendations for future research, and conclusion will follow. Finally, in this chapter I discuss how the study results fit within the current state of the science and how they might impact future research.

Aim one, to determine the impact of the Stay S.A.F.E. intervention on student nurse management of and response to interruptions in simulated clinical scenarios was supported. This research demonstrated that it could be more useful to teach student nurses how to manage unnecessary interruptions and minimize the time away from high risk tasks such as medication administration. Aim two, what is the impact of the Stay S.A.F.E. intervention on student nurse errors, was not supported. Though this study did not find an increase in error rate with interruptions, other studies found that interruptions that require a nurse to leave the patient resulted in medication errors (Cottney & Innes, 2015).

Impact of Stay S.A.F.E. on Interruption Response Time

The major finding of this research was the decreased time to return to primary task (Aim 1), when comparing the Stay S.A.F.E. group to the control group. Consistent with Henneman and colleagues (2018), those who received the Stay S.A.F.E. training spent less time distracted from the primary task of medication administration. The control group, however, took longer to complete the task of medication administration which

confirms that interrupted tasks take longer to complete (Campoe & Guiliano 2017, Odukoya & Chui 2013, Palese et al. 2009, Pluyter et al. 2010, Trbovich et al. 2010). In an observational study, researchers observed medication administration rounds and in only 3.7 percent of the observations did the registered nurse take care of interruption after completing the entire medication round. Nurses addressed the interruptions even when the interruptions were less critical (e.g. answering the phone) or could have possibly been handled by other staff (e.g. patient call bells) (Palese et al. 2009). Findings of the current study suggest that the intervention strategy, Stay S.A.F.E., was effective in decreasing interruption time and potentially modifying student nurse behavior. Further research on behavior modification using Stay S.A.F.E. should be evaluated.

As previously described, not all interruptions are harmful; some communicate critical patient information (Grundgeiger & Sanderson, 2009; Westbrook et al., 2010). At the time of an interruption, the student nurse must determine the relative importance of the interruption and decide whether and how urgently to respond (McCurdie, Sanderson, Aitken, & Liu, 2017). Most notably, there was a significant difference post intervention (Simulation #2) between the control and experimental group in responding to the interrupter. The control group was more likely to take verbal report from the interrupter. The Stay S.A.F.E. group used the strategy to evaluate the importance of the primary task, medication administration, when compared to the secondary task, verbal report for an incoming patient admission. Also, the Stay S.A.F.E. group was less likely to take report from the interrupter in post intervention simulation #3 indicating a potential in knowledge retention from the original education provided via PowerPoint. Experts have suggested that the recognition of the nature and impact of interruptions is a first step in preparing

clinicians including student nurses to work safely in environments at high risk for interruption-related errors (Beyea, 2007). Clinicians, like students, should be mindful of the potentially negative consequences of an interruption (Beyea, 2007). In this study, the Stay S.A.F.E. group were less likely to respond to the interrupter, potentially increasing their time, focus, and concentration on the task of medication administration.

Impact of Stay S.A.F.E. on Number and Types of Errors

There was not significant difference in the error rate between groups. Prior research related to medication administration errors demonstrated that nurses who are interrupted during medication administration have a 1.5 increased chance of making a medication error (Feleke et al. 2015). In the current research study, the participants were presented with one interruption per simulation. Participants in the control group from simulation #1 to simulation #2 had a significant increase (p=0.037) in failure to document on the medication administration record.

Further analysis evaluated the total number of errors pre (simulation #1) and post intervention (simulation #2 & #3) for both groups. There was a significant decrease in the total number of errors over the three simulations (p = 0.037). However, when examining the data by control (p = 0.087) or experimental group (p = 0.217), there was no difference in part because there was a smaller sample size. These findings may indicate a retention in knowledge of both medication safety practices and the Stay S.A.F.E. intervention. Simulation as an educational tool may have also impacted the decrease in error rate over the three simulations.

Task Load Index Scores

Aim 3 of this study evaluated the NASA-TLX scores of the participants. Each participant completed three NASA-TLX surveys immediately following the baseline simulation (simulation #1), post intervention (simulation #2), and post intervention (simulation #3). The highest NASA-TLX scores, reported as raw scores, were related to mental demand and effort. The lowest score was physical demand. Table 16 and Table 17 provide the means for the control group and the experimental group. Other descriptive statistics (e.g., standard deviations) are presented in Tables 10-12.

Table 16: Control Group Mean Scores: NASA-TLX

	Simulation 1 Mean	Simulation 2 Mean	Simulation 3 Mean
Mental	31.6	42.9	26.6
Physical	10.0	15.5	10.7
Temporal	22.9	28.2	24.7
Performance	21.6	25.5	22.9
Effort	43.4*	45.3*	35.5*
Frustration	14.5	24.5	14.7

Note: *Highest means

Table 17: Experimental Group Mean Scores: NASA-TLX

	Simulaion 1 Mean	Simulaion 2 Mean	Simulaion 3 Mean
Mental	36.3*	36.5*	23.9
Physical	8.7	11.5	8.2
Temporal	24.5	21.0	16.8
Performance	31.3	27.5	22.1
Effort	31.8	37.5*	25.5
Frustration	23.4	19.3	12.4

Note: *Highest means

In this study, a decrease in frustration scores among the experimental group over the three simulations was a significant finding. The NASA-TLX question on frustration asks specifically about "How insecure, discouraged, irritated, stressed, and annoyed were you?" In a similar study by Campoe & Giuliano (2017) frustration scores over the different simulation conditions were not significant though means between the conditions were different. In a prior study by Sorenson & Brahe (2014), nurses reported that interruptions during medication administration is a source of frustration. The decrease in frustration overtime within the experimental group demonstrates that the Stay S.A.F.E. intervention has an impact on management of interruptions specifically with insecurity, discouragement, irritation, and annoyance. This should be further evaluated in future studies.

The mental demand dimension of the NASA-TLX asked participants "How mentally demanding was the task." Findings indicated a significant difference across the three simulations in the control (p=0.023) and experimental (p=0.014) group. The participants were nursing students with little clinical experience, indicating a higher mental demand score which is consistent with other research findings. In an interdisciplinary study including students, clinicians were assessed on workload associated with identifying burn patient conditions and priority settings. Students experienced higher mental demand scores than clinicians with more than five years' experience (McInnis et al. 2017). Tien, et al. (2015) found similar results of NASA-TLX scores between experts and novices, and those unfamiliar with a process, such as medication administration, scored higher in mental demand (Hudson, Kushniruk, & Borycki, 2015).

The NASA-TLX was an effective tool for collecting perceptions of cognitive workload in the three simulations. Prior research has indicated that less experience is associated with an increased workload which may potentially contribute to an increase in error rates and decrease patient safety (McInnis et al. 2017).

The Fit of the Theory/Framework

A key factor in Memory for Goals is the length of time a task is suspended or interrupted. Tasks or goals that are not attended to may decline over time which is described by Altman and Trafton (2002) as goal decay. For example, because of goal decay, longer interruptions should result in longer times to return to the primary task (if it is resumed at all). Though the Stay S.A.F.E. strategy (experimental group) decreased the overall interruption time from the task of medication administration it did not however decrease the error rate when compared to the control group.

The Eye Mind Theory suggests that a person's focus is connected to what is being processed and interpreted (Just & Carpenter, 1980) and is related to their thoughts and attention (Henneman et al, 2017). Research outside of reading proposes that the amount of time a person spends looking at something (gaze duration) reflects the amount of time it takes for them to process what they are looking at. In this study, the control group were more likely to respond to the interrupter and had a longer duration of fixation on the interrupter when compared to the experimental group. Though there was not a significant increase in error rate with the control group, there were procedural failures that were committed by both control and experimental groups including failure to record on the medication administration record.

This nursing near miss model (Henneman & Gawlinski, 2004) describes defenses involved in preventing error and places the nurse as the primary source of error recovery. Interruptions, though not always dangerous, when not managed can ultimately lead to medication errors. In this study, the total number of errors pre and post intervention between the control and experimental group was significant, demonstrating a decreasing trend in the total number of errors over the three simulations (p = 0.037). Nurses and nursing students must be resilient to interruptions as environmental factors. Though the experimental group did not have a statistically significant decrease in error rate after the intervention, management strategies such as Stay S.A.F.E. may provide nurses and nursing students the ability to manage interruptions. The strategy could improve patient safety at the bedside by providing nurses with adequate defenses. A developing incident caused by an interruption that is left unmanaged may result in adverse events and ultimately patient harm.

The three theories were a good fit for the study and a new framework, Interruption Management Framework, could be evaluated in future studies.

Days Between Simulation

Participants in both groups were asked to return to the simulation lab 7-14 days after baseline (simulation #1) and post-intervention (simulation #2). Retention of knowledge and shift in behavior when responding to an interruption, especially with the intervention group, Stay S.A.F.E. was evaluated in post intervention simulation #3. Findings indicated that the correlation between total number of errors in simulation #3 and days between simulation #2 and #3 was not significant. Simulation, an interactive educational tool, has been shown to improve clinical performance, knowledge retention,

communication, and teamwork (Gaba, 2004; Gilfoyle et al. 2017; Henneman et al., 2014; Meyer et al., 2011; Paull et al., 2013; Severson et al., 2014; Stayt et al., 2015; Tubaishat & Tawalbeh, 2015). Retention of the Stay S.A.F.E. strategy for the experimental group was also evaluated. Findings indicated that most of the participants followed the strategy. Eye contact and fixation were the lowest with compliance for both post intervention simulation #2 and simulation #3. These findings however were not statistically significant due to the small sample size.

Post Simulation Evaluation

Participants completed a post evaluation tool which inquired about interruptions, training, and previous experience with simulation and eye tracker interference. The first question inquired: "In your own words, describe some ways that interruptions could affect your work." Most participants, in both groups, used words like error, medication error, forget, concentration, and patient harm when describing interruptions. The following are some of the responses which reveal there is a negative connotation to interruptions in the workplace.

- "interruptions will throw me off which could make me give a wrong med"
- "interruptions can be distracting causing you to miss a step in the task you are attempting to perform"
- "interruptions could affect your work because they affect your train of thought and your plan. If you are on a tight schedule, interruptions delay and could make you forget things"
- "interruptions can lead to errors in patient care and could have very serious consequences"

- "they could prevent you from doing your work with 100 percent accuracy.
 They can distract you from your work"
- "full concentration needed for accurate assessment; interruptions break your concentration"

Participants were evaluated on the training, Stay S.A.F.E. or the medication safety practices, and how they may use some of the techniques in the future. Those who received the Stay S.A.F.E. strategy described the intervention as important and participants reported they would "absolutely use the strategy." Participants stated that key components of the Stay S.A.F.E. strategy were "keeping their eyes on the medication" and letting the person interrupting them know when they would be available to attend to their needs. They also noted key components were focusing on the current task, "being assertive," and saying no or delaying the interruption until the current task is complete.

Participants' suggestions for improving the fidelity of the simulation included having similar equipment for medications and documentation as the hospital setting, a more extensive patient report, and improvement in the physical layout of the room. The setting varied in one of the campuses making it difficult to separate the participant and researcher. Increasing the awareness of being watched during the simulation was a reported finding.

Implications for Nursing

Interruptions and distractions can lead to an increased risk of making errors in healthcare, particularly during medication administration, which could result in patient harm. Interruptions that required the nurse to leave the patient, resulted in medication errors (Cottney & Innes, 2015). Limiting interruptions during high risk tasks such as

medication administration may be beneficial; however, eliminating all interruptions was not recommended due to the complexity of healthcare and demand for communication and coordination of care (Rivera & Karsh, 2010). Rather than trying to eliminate interruptions, this research demonstrated that it could be more useful to teach student nurses how to manage unnecessary interruptions and minimize the time away from high risk tasks such as medication administration.

This study along with research by Henneman and colleagues (2018) demonstrated a significant reduction in time away from the task/patient following implementation of Stay S.A.F.E. While student nurses are given tools during their didactic education such as medication safety practices, simulations do not include environmental and systems factors, such as interruptions, which could increase the risk of error.

Strengths and Limitations

One strength of the study was that students were from the same university potentially controlling the differences in education. The two tracks, traditional and 2^{nd} bachelors, were randomized controlling for the differences among students.

Another strength included data coding. The researcher (CV) was the primary reviewer of the eye tracking videos and primary data coder. A secondary research assistant (AD) reviewed a small sample, 15, of the videos for interrater reliability. There were no changes in findings reviewed by the researcher and research assistant indicating good interrater reliability.

Location of the simulations varied. Participants were not consistently in the same simulation room potentially decreasing the fidelity of the simulation and adding unnecessary confounders (Cheng et al., 2014).

Four percent of the eye tracking data were lost due to technical issues with the eye tracking recorder. Also, participant attrition was a concern, two participants were unable to continue with the study due to problems calibrating the eye tracker. Though lost eye tracking data was less than other studies, it was a limitation identified during the sample size estimations (Henneman, et al., 2010; Henneman, et al., 2014).

The researcher and research assistants were not blinded to the groups during the simulations as well as when coding the data. This can contribute to the observer bias during the simulation and confirmation bias during data coding.

Future Research

Further research on the Stay S.A.F.E. strategy is needed. Incorporation of the strategy into nursing curriculum is recommended to help student nurses manage environmental factors such as interruptions in their clinical training. Sustainability of the strategy into the clinical setting post-graduation should also be evaluated. Future studies should also test the Stay S.A.F.E. strategy in a longitudinal study to assess if the strategy alters participants behavior.

Conclusion

This study evaluated an interruption management strategy, Stay S.A.F.E., on medication administration and errors. Student nurses in the control group reported a higher mental demand, increased effort, and frustration. Those who received the Stay S.A.F.E. training had a decreasing frustration overtime and spent more time on the task of medication administration. Future studies should build upon this research and further evaluate overall frustration. Larger samples should be considered to evaluate the error potential.

APPENDIX A

UMASS IRB APPROVAL LETTER



University of Massachusetts Amherst 108 Research Administration Bldg.

70 Butterfield Terrace Amherst, MA 01003-9242 Research Compliance Human Research Protection Office (HRPO)

Telephone: (413) 545-3428 FAX: (413) 577-1728

Certification of Human Subjects Approval

March 20, 2019 Date: Cidalia Vital, Nursing To: Other Investigator: Cynthia Jacelon, Nursing

Lynnette Leidy Sievert, Chair, UMASS IRB

Protocol Title: USE OF STAY SAFE STRATEGY DURING MEDICATION ADMINISTRATION IN REDUCING ERRORS Protocol ID: 2019-5372

Review Type: EXPEDITED - NEW Category: Approval Date: 03/20/2019

No Continuing Review Required

UM Proposal #:

This study has been reviewed and approved by the University of Massachusetts Amherst IRB, Federal Wide Assurance # 00003909. Approval is granted with the understanding that investigator(s) are responsible for:

Consent forms - A copy of the approved consent form (with the IRB stamp) must be used for each participant (Please note: Online consent forms will not be stamped). Investigators must retain copies of signed consent forms for six (6) years after close of the grant, or three (3) years if

Use only IRB-approved study materials (e.g., questionnaires, letters, advertisements, flyers, scripts, etc.) in your research.

Revisions - All changes to the study (e.g. protocol, recruitment materials, consent form, additional key personnel), must be submitted for approval in e-protocol before implementing the changes. New personnel must have completed CITI training.

Final Reports - Notify the IRB when your study is complete by submitting a Final Report Form in the electronic protocol system.

Serious Adverse Events and Unanticipated problems involving risks to participants or others - All such events must be reported in the electronic protocol system as soon as possible, but no later than five (5) working days.

Annual Check In - HRPO will conduct an annual check in to determine the study status.

Please contact the Human Research Protection Office if you have any further questions. Best wishes for a successful project.

APPENDIX B

PARTICIPANT RECRUITMENT SCRIPT

We are currently conducting a nursing research study titled "Use of *Stay S.A.F.E.* During Medication Administration"

Eligible subjects are junior or senior nursing students from UMass Amherst.

During the simulation, you will be asked to wear an eye tracking device (goggles) that allow us to track what you are looking at during the simulation. The total time of your participation will be no more than one hour total.

Please note: If you need glasses that need to be taken on and off while you are providing care in the simulation (e.g., reading glasses), the eye tracker will not work so you will not be able to participate in the study. Otherwise, glasses and contact lenses are okay.

You will be compensated \$25.00 for your participation.

The study will take place at UMass Springfield Campus.

If you are interested and/or need more information, please let us know and we will get back to you.

APPENDIX C

PARTICIPANT CONSENT

Consent Form for Participation in a Research Study University of Massachusetts Amherst

Researcher(s): Cidalia Vital, RN, Primary Student Researcher- PhD Candidate

Cynthia Jacelon, PhD, RN, Faculty Sponsor

Study Title: Use of Stay SAFE Strategy during Medication Administration in

Reducing Errors

1. WHAT IS THIS FORM?

This form is called a Consent Form. It will give you information about the study so you can make an informed decision about participation in this research. We encourage you to take some time to think this over and ask questions now and at any other time. If you decide to participate, you will be asked to sign this form and you will be given a copy for your records.

WHAT ARE SOME OF THE IMPORTANT ASPECTS OF THIS RESEARCH STUDY THAT I SHOULD BE AWARE OF?

- You are being asked to provide consent to participate in this research and your participation is voluntary.
- 2) The purposes of the research are to evaluate an educational intervention during medication administration. You are expected to participate in two separate sessions for a total time of about two hours. You will be asked to wear eye tracking googles and complete a few surveys.
- 3) We believe there are minimal risks associated with this research study; however, a risk of breach of confidentiality always exists and possible inconvenience to complete the study and you may feel uncomfortable being observed during the simulation.

3. WHY ARE WE DOING THIS RESEARCH STUDY?

The purpose of this research study is to evaluate an education intervention during medication administration in the simulated setting.

4. WHO CAN PARTICIPATE IN THIS RESEARCH STUDY?

Junior and senior nursing students and 2nd bachelors students from the UMass Amherst, College of Nursing are eligible to participate in this study. If you need glasses that need to be taken on and off while you are providing care in the simulation (e.g., reading glasses), the eye-tracker will not work so you cannot participate in the study. Otherwise, glasses and contact lenses are OK.

WHERE WILL THIS RESEARCH STUDY TAKE PLACE AND HOW MANY PEOPLE WILL PARTICIPATE?

The study will be conducted at University of Massachusetts, Amherst and/or Springfield Simulation Laboratory. The entire clinical simulation will require no more than 2 hours of your time. A total of 40 participants are expected to be enrolled.

IRB OFFICE USE ONLY

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Proposit F 2019-5372
BG Signature: Theory C. January

APPENDIX D

INTERVENTION EDUCATION: STAY S.A.F.E.



All steps (S-A-F-E) should occur but can be performed in whatever order is most comfortable for the person being interrupted.

APPENDIX E

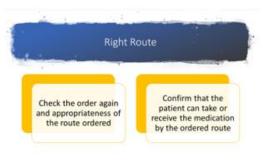
CONTROL EDUCATION: MEDICATION SAFETY PRACTICES



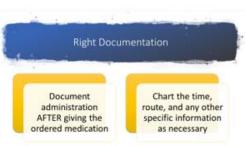














APPENDIX F

SIMULATED MEDICATION ADMINISTRATION RECORDS

Patient 1

John Smith
MR# 55552223
Allergies: None

DOB: 2-28-1939

Date	Time	Medication	Time	Signature
			Administered	
		Metoprolol 25 mg, by mouth,		
		do not give if HR <60 or BP < 100 systolic		
		or < 60 diastolic, 0730		
		Tylenol 650 mg, by mouth, for pain >4/10		
		or fever >101.5 every 4 hours as needed		

Patient 2

Jane Doe MR#62845732 DOB: 11-18-69 Allergies: None

Date	Time	Medication	Time	Signature
			Administered	
		Heparin 5000 units subcutaneous every 12		
		hours, left upper arm, 1930		
		Tylenol 650 mg, by mouth, for pain >4/10		
		or fever >101.5 every 4 hours as needed		

Patient 3

Betty Jones	DOB 5-9-1949	
MR#22889988		
Allergies: None		

Date	Time	Medication	Time	Signature
			Administered	
		Atorvastatin 10 mg, by mouth daily, 0730		
		Tylenol 650 mg, by mouth, for pain >4/10		
		or fever >101.5 every 4 hours as needed		

APPENDIX G

SIMULATION SCENARIOS

Simulation #1

Mr. Smith is an 80-year-old man with a history of coronary artery disease and hypertension. He is post op day 1 for a total hip replacement of the left hip. Last set of vitals @ 4 a.m. were: Temp 98.9, HR 60, BP 120/70, RR 20, O2 sat 98% on room air. His surgery was uneventful, and he has been stable since his surgery. He is alert and oriented x 3, breath sounds are clear bilaterally, abdomen is soft and non-tender. Left hip dressing clean dry and intact. Abductor pillow in place and compression boots on and cycling. He received 1 dose of oxycodone ER 5 mg at 4 a.m. for hip pain which decreased the pain from a 7 to a 2. IV in right forearm with LR running. He is tolerating PO. He has 0730 medications due to be given. It is now 0730.

Simulation #2

Ms. Doe is a 50-year-old woman with a history of colon cancer discovered one month ago after a routine colonscopy. She has a history of high cholesterol but does not have any other medical history. Prior to her diagnosis she was active and exercised five days a week. She underwent a laparoscopic colon resection with a colostomy two days ago. Last set of vitals @ 4 p.m. were Temp 99.0 HR 85, BP 110/70, RR 20, O2 sat 100% room air. Her colostomy is putting out light brown liquid and her stoma is pink. Her pain is well controlled. Her last dose of pain medication was at 3:30 p.m., in which she received 2mg morphine IV in her right forearm for pain 6/10 and her pain decreased to a 3. She otherwise is alert and oriented x3, lungs clear, abdomen soft- tender near her surgical site,

lap sites dry and intact. She is ambulating the hallways and has great family support. She has 1930 medications due. It is now 1930.

Simulation #3

Mrs. Jones is a 60-year-old with a history diabetes, high cholesterol, obesity and hypertension. She is post op day 1, arrived to the unit at 11 p.m. last night after a long stay in PACU for nausea. She had a total hip replacement of the right hip. Last set of vitals were Temp 98.0, HR 80, BP 140/90, RR 16, O2 sat 98% on room air. Last blood sugar was 85 at noon. She is alert and oriented x 3, breath sounds are clear bilaterally, abdomen is soft and non-tender. Right hip dressing clean dry and intact. Abductor pillow in place and compression boots on and cycling. Her pain 1/10 and is receiving morphine IV for pain as needed. IV in right forearm with LR running. She has 0730 medications due. It is now 0730.

APPENDIX H

NASA TASK LOAD INDEX TOOL

NASA Task Load Index

Hart and Staveland's NASA Task Load Index (TLX) method assesses work load on five 7-point scales. Increments of high, medium and low estimates for each point result in 21 gradations on the scales.

Mental Demand	How mentally demanding was the task?
Very Low	Very High
Physical Demand	How physically demanding was the task?
Very Low	Very High
Temporal Demand	How hurried or rushed was the pace of the task?
Very Low	Very High
	How successful were you in accomplishing what you were asked to do?
Perfect	Failure
	How hard did you have to work to accomplish your level of performance?
Very Low	Very High
	How insecure, discouraged, irritated, stressed, and annoyed wereyou?
Very Low	Very High

APPENDIX I

PARTICIPANT POST EVALUATION

Subject ID:
Please answer the following questions. The answers to these questions will not reflect on your academic evaluation in any way. Thank you.
1. In your own words, describe some ways that interruptions could affect your work
2. The training you just received talked about strategies to help with the current task Describe some techniques you would likely use to accomplish this?
3. Have you ever previously participated in a simulation? If yes, when?
4. Did the eye tracker glasses interfere with your ability to function in the simulation? If yes, how?
5. What suggestions do you have regarding what would have been helpful to make it easier to care for the patient in the simulated setting?
Other comments:

APPENDIX J

PROCEDURAL FAILURES DATA COLLECTION TOOL

Procedural Failures
Failure to verify medication label
Failure to verify patient identification
Failure to verify medication administration record (MAR)
Medication administered
Tylenol given
Medication given in the wrong site
Wrong dose given

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