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Use of a Checklist to Facilitate the Recognition of a Transfusion Associated Adverse Event

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Use of a Checklist to Facilitate the Recognition of a Transfusion Associated Adverse Event

A Dissertation Presented

by

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USE OF A CHECKLIST TO FACILITATE THE RECOGNITION OF A TRANSFUSION ASSOCIATED ADVERSE EVENT

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DEDICATION

To Dr. Beth Henneman, my advisor and mentor who shared her knowledge, wisdom and expertise with me, making this journey possible.

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ABSTRACT

USE OF A CHECKLIST TO FACILITATE THE RECOGNITION OF A TRANSFUSION ASSOCIATED ADVERSE EVENT

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Transfusions are the most common procedure that hospitalized patients undergo. One of the risks associated with a transfusion is a transfusion related adverse event (TAAE). Transfusion associated adverse events can occur in any patient receiving a transfusion. Some patients are at risk of certain TAAEs (e.g., heart failure patients at risk of transfusion associated circulatory overload) while other events (e.g., allergic reactions) cannot always be anticipated. The severity of a TAAE can range from mildly uncomfortable to life threatening. Nurses need to be able to identify the signs and symptoms of a possible TAAE and intervene immediately by stopping the infusion of the blood product, taking immediate action to stabilize the patient and contacting the provider and transfusion medicine services/blood bank. This experimental study describes how the use of a transfusion checklist could facilitate the recognition and management of TAAEs for all clinicians and in particular, student nurses.

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CHAPTER 1

INTRODUCTION

The Problem

Transfusions are the most common procedure that patients undergo while hospitalized, according to the Agency for Healthcare Research and Quality (Pfuntner, 2013). While transfusions are generally safe, they are not risk free. Of the more than 17 million blood products transfused in 2015 in the United State alone, there were nearly 47,300 transfusion-associated adverse events (TAAE), 1,616 of which were life threatening (Sapiano, 2017). These numbers are an underestimation of the actual number of TAAEs, because TAAEs are underrecognized and as a result, underreported (Gehrie, Hendrickson, & Tormey, 2015; Hendrickson et al., 2016; Hong et al., 2016; Narick, Triulzi, & Yazer, 2012; Raval et al., 2015; Yeh et al., 2011). Mole, Hogg, and Benvie (2007) noted that nurses are the most frequent administrators of transfusions, and thus it is important that they identify TAAEs when they occur. The underreporting of TAAEs suggests that nurses are inadequately educated in the recognition of TAAEs.

Improving the education of nurses has been linked to decreased patient complications and improved outcomes (Aiken, Clarke, Cheung, Sloane, & Silber, 2003; Aiken et al., 2017; He, Staggs, Bergquist-Beringer, & Dunton, 2016; Kutney-Lee & Aiken, 2008). It is important that nurses be educated in how to identify TAAEs, so that they can intervene and take the necessary steps to mitigate these potentially life-threatening events (Sapiano et al., 2017). Education about TAAEs must begin during the prelicensure period, before nurses are given the responsibility of performing this multi-step procedure (Mole, Hogg, & Benvie, 2007).

In the study proposed here, we will introduce a checklist that nursing students can refer to as an educational guide to facilitate the recognition and reporting of TAAEs and will use the NASA Task Load Index as a measure to examine the perceived workload of the participants. Checklists have been used as clinical decision support systems (CDSSs) at the point-of-care and have been shown to help caregivers recall details and avoid missing key steps in procedures. They have been shown to improve team communication and patient safety (Anderson et al., 2015; Gawande, 2010; Haynes et al., 2009, Pronovost et al., 2003; Shulman et al., 2011; Sibbald, de Bruin., Yu & van Merrienboer, 2013). The process of making a clinical decision involves cues from various sources including patient presentation, patients' answers to questions, and review of documentation (Gillespie & Peterson, 2009). A checklist can incorporate these cues and thus support the nurses' decisions.

There is currently a lack of research examining the effectiveness of a checklist as a CDSS for nurses to facilitate the recognition of TAAEs. An educational checklist that incorporates the transfusion procedure and key indicators of TAAEs, along with the proper ways to communicate these findings to other team members, will improve patient safety by helping student nurses identify and mitigate TAAEs. In this study, eye tracking technology will be used to capture what participants are visually focusing on to provide insight into what they are analyzing when they make decisions (Doberne et al., 2015; Halevy & Chu, 2014; Sibbald, de Bruin, Yu, & van Merrienboer, 2015). The NASA task load index (NASA-TLX) a valid, multidimensional tool will be used to determine whether the use of a checklist has an impact on participants' perceived workload. The

NASA-TLX score will be obtained after the two simulation sessions are complete and results will be examined for differences within and across the participant groups.

Nursing Role Effectiveness Model

The Nursing Role Effectiveness Model (NREM) will be used to examine the role nurses play in impacting patient outcomes (Doran, Sidani, Keating, & Doidg, 2014). The NREM is based on Donabedian's (1988) structure-process-outcome model of quality care and has been previously applied to nursing (Doran, 2011). Structure variables will include the educational level of the nurse and whether or not an educational checklist is used. Process variables will include the independent and interdependent functions of the nurse, such as whether the nurse assesses the patient for indicators of a TAAE and whether the nurse communicates appropriately with other care team members about these indicators. The outcome variable will be the clinical outcome of the patient which is not evaluated in this study.

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 use the checklist, eye tracking data will be used to provide insight into how they use the checklist to make decisions in the simulation scenario. In the case of participants who do not use the checklist, the data will provide insight into where they focus their attention prior to making a decision.

Research Aims

This study will address two primary research aims and one secondary research aim. The first primary aim is was to determine the impact of a transfusion checklist on nursing students' ability to identify TAAEs. This aim has 2 hypotheses:

Hypothesis 1: The use of a transfusion checklist will increase student nurses' ability to identify TAAEs, as evidenced by a significant increase in appropriate transfusion behaviors. Hypothesis 2: There will be a significant decrease in time to identifying a TAAE following implementation of a transfusion checklist.

The second primary aim was to determine the relationship between fixation duration on the transfusion checklist and time to recognition of a TAAE by student nurses in a simulated setting. *Hypothesis 3: There will be a significant increase in fixation duration on AOIs (patient, vital signs, blood product) in the Checklist group between the preintervention period and the postintervention period.*

This study has 1 secondary aim. To determine the impact of using a TAAE checklist on perceived task load. This aim has 2 hypotheses:

Hypothesis 4: The NASA-TLX scores will be significantly lower in the Checklist group than in the PowerPoint and Sham groups.

Hypothesis 5: Students who identify the TAAE will have greater fixation duration on the AOIs than those who do not identify the TAAE.

Study Plan

The study will take place at the simulation lab at Westfield State University (WSU) and at the University of Massachusetts Center at Springfield (UMass). Nursing

students from both campuses will be recruited in person and via email messages. Inclusion criteria will be nursing students who educated in the performance of a physical assessment and who have administered medications subcutaneously, and by mouth. The recruitment script will emphasize that participation is voluntary. All participants will be given a consent form to review and sign. Only those who sign the form will be able to participate in the study.

This study will have four components:

1) An initial simulation
2) An educational intervention
3) A second simulation
4) Completion of the NASA task load index and survey form
5) Completion of a post test

In the first component, each participant will receive a handoff report and begin care for a simulated patient who develops the signs and symptoms of a febrile nonhemolytic transfusion reaction. After this initial simulation, each participant will be randomized into one of three educational session groups. Group 1 will receive a sham education session about safety via a PowerPoint presentation. Group 2 will receive an educational session about TAAEs via a PowerPoint presentation. Group 3 will receive an educational session about TAAEs in the form of a researcher developed educational checklist. The PowerPoint sessions for groups 1 and 2 will have the same number of PowerPoint slides. The PowerPoint session that covers TAAEs will have the same information as the TAAE checklist. Following the education session, each participant will take part in a simulation session in which the patient develops the signs and symptoms of transfusion-associated

circulatory overload. Participants in the checklist group will be told to bring the checklist into the simulation session so that they can refer to it during the simulation. After the second simulation session, each participant will complete a post-test, the NASA-TLX and a demographic survey form.

Summary

A TAAE must be identified in order for potentially life-saving interventions to take place. Research indicates that those who administer transfusions often fail to identify when a patient is experiencing a TAAE. Nurses are the most common administrators of transfusions, and thus they need to be educated about how to identify TAAEs. This education needs to begin prior to licensure, so that when nurses become licensed they can safely administer transfusions and can intervene promptly should a TAAE occur. The use of a checklist at the point-of-care has been shown to be superior to education alone for insuring that all safety steps in procedures are followed. But there is a lack of research on the use of an educational checklist as a tool to facilitate the identification of TAAEs by nurses. This study will examine whether the use of an educational checklist will result in higher rates of recognition and intervention of TAAEs by nursing students than education alone.

CHAPTER 2

REVIEW OF THE LITERATURE

Transfusions are the most common procedure patients undergo while hospitalized, and while generally safe, they are not without risk (Pfuntner, Wier, & Stocks, 2013). Of the more than 17 million blood product transfusions in the United States in 2015, more than 47,000 transfusion-associated adverse events (TAAEs) were reported (Sapiano et al., 2017). Transfusion-associated adverse events range in severity from mild febrile reactions that require no intervention other than stopping the transfusion to fatal events (Food and Drug Administration, 2015; Politis et al., 2016; Sapiano et al., 2017). A TAAE needs to be identified as soon as possible so that interventions can be performed to mitigate the event and improve patient outcome (Henneman, Andrzejewski Gawlinski, MacAfee, Panaccione, & Dziel, 2017).

Nurses are the most frequent administrators of transfusions. Comparison of active and passive auditing for TAAEs shows that many TAAEs go unreported, which suggests that nurses are not recognizing TAAEs when they occur (Bolton-Maggs & Cohen, 2013; Gehrie, Hendrickson, & Tomey, 2015; Hendrickson et al., 2016; Hong et al., 2016; Narick, Triulzi, & Yazer, 2012; Raval et al., 2015). This highlights a gap in the education of nurses around TAAE recognition and intervention. This study will explore the use of an educational checklist in conjunction with a simulation to teach nurses to identify and manage TAAEs. Eye tracking technology will be used to gain insight into how study participants use the educational checklist to make decisions about a simulated TAAE.

Reported Frequency of TAAE's

A transfusion-associated adverse event is an undesirable and unintentional occurrence associated with the administration of blood or one of its components (Popovsky et al., 2011). The International Haemovigilance Network, an international database of adverse events associated with transfusions, reported that of the 138.2 million blood products issued between 2006 and 2012 there were 92,850 reactions (77.5 TAAEs per 100,000 transfusions). Of these, 22,879 (24.3%) were severe and 349 (0.4%) were fatal (Politis et al., 2016). Most TAAE-related deaths were related to the respiratory system: transfusion-associated circulatory overload (TACO) (27%), transfusion-associated acute lung injury (TRALI) (19%), and transfusion-associated dyspnea (12%). Other causes of death were allergic reactions (11.2%), acute hemolytic reactions (6.9%), and bacterial infections (3.7%) (Politis et al., 2016).

In the United States, TAAE data were collected via the National Blood Collection and Utilization Survey conducted every 2 years by the AABB (formerly the American Association of Blood Banks) from 1997 to 2011 and have been collected by the Centers for Disease Control and Prevention in collaboration with the Assistant Secretary for Health since 2013 (Sapiano et al., 2017). In 2013, 55,623 TAAEs were reported (1 adverse event for every 363 components transfused), and in 2015, 47,297 TAAEs were reported (1 per 373 components transfused). Of the TAAEs that occurred in 2015, 1,616 were life threatening and required major medical interventions such as vasopressors, blood pressure support, intubation, or transfer to an intensive care unit. This represents an increase over the rate seen in 2013 (482 life-threatening TAAEs). The most common TAAEs in 2013 and 2015 were febrile nonhemolytic adverse events (1:797 in 2013 and

1:868 in 2015) and mild to moderate allergic adverse events (1:1150 in 2013 and 1:1201 in 2015). The rates of TACO, hypotensive TAAE's and transfusion associated dyspnea have all increased in 2015 with TACO at 1:9015, hypotensive TAAE's at 1:11,282, and transfusion-associated dyspnea at 1:13,582 (Sapiano, 2017).

A report by the U.S. Food and Drug Administration found that 279 people died of TAAEs from 2011 to 2015, with the most common causes being TACO and TRALI (62% in total), followed by hemolytic, microbial contamination, anaphylactic, and hypotensive TAAEs (Food and Drug Administration, 2015). Most fatalities from TAAEs are due to the development of TACO or TRALI. Transfusion-related acute lung injury is a TAAE that causes noncardiogenic pulmonary edema that develops within six hours of a transfusion in the absence of hydrostatic edema (Delaney, et al., 2016; Toy, Kleinman, & Looney, 2017). The prevalence of TRALI has decreased significantly since the donor selection has been limited to males and the testing of platelets from female donors for antibodies (FDA, 2015; Müller, Van Stein, Binnekade, Van Rhenen, & Vlaar, 2015). While TRALI remains a leading cause of fatality associated with transfusions reported to the FDA, there were only 5 definite or certain cases in 2015 and no cases reported in the 2015 SHOT report (Bolton-Maggs, 2016; FDA, 2015). As with febrile non-hemolytic TAAE and hemolytic TAAE, presentation of TRALI can include a fever. With the incidence of TRALI decreasing due to the implementation of low-risk TRALI donor strategies (Muller, van Stein, Binnekade, van Rhenen, & Vlaar, 2015), TACO is the most common cause of fatal TAAEs (see Appendix A for TAAE grid).

Underrecognition and Underreporting of TAAEs

Although the available data show that TAAEs are low-incidence, high-risk events, the actual number of TAAEs that occur is unknown; evidence suggests that TAAEs are underrecognized and underreported. In a multicenter study, Hendrickson et al. (2016) performed a retrospective review of a random sample of 4857 transfusion episodes (each episode being a blood product released to a patient within a 6-hour time period) from July through December of 2014. They found that only 30% of minor TAAEs (febrile nonhemolytic, minor allergic) were reported to transfusion services, and only 5.1% of the cases identified as TACO were reported to transfusion services. Narick, Triulzi, and Yazer (2012) performed a retrospective analysis with passive surveillance of TAAEs (specifically TACO) resulting from plasma infusions from 2003 to 2010 and found that the prevalence of TACO was 1:1566. They then performed active surveillance at the same hospital for 1 month and found a TACO prevalence of 1 in 68 infusions—none of these TACO cases had been reported to transfusion services. Like Narick et al., Raval et al. (2015) examined the rate of TACO associated with platelet transfusions from January 2000 to December 2012 and also performed a prospective, active analysis of patients transfused with platelets over a 30-day period in January 2013.Their retrospective study found 366 suspected TAAEs that had been reported to the transfusion service of the institution during the 13-year period, a calculated prevalence of platelet-associated TACO of 1:5997. Their prospective passive analysis of January 2013 identified 2 cases of TAAE, neither of which were reported. These results suggest a calculated prevalence of platelet-associated TACO of 1:167. Gehrie, Hendrickson, and Tomey (2015) retrospectively extracted data from transfusion services records of red blood cell, platelet,

and plasma transfusions at a single institution records over a 1-year period. Adverse event reports over this time period (through passive reporting) were 17 per 3496 transfusions (0.5%). When the reports were reviewed, vital sign changes associated with the transfusions revealed an additional 58 adverse transfusion events that had not been reported to transfusion services. These data suggest that 76% of TAAEs go unreported. Hong et al. (2016) presented results of active and passive surveillance of septic platelet TAAEs from 2007 to 2013, and out of 51,440 units of platelets transfused, 20 were found to be contaminated, which resulted in 5 suspected transfusion TAAEs. None of these were reported to transfusion services. Lack of recognition of even minor TAAEs is a safety concern, because the severity of TAAEs cannot be predicted (Food and Drug Administration, 2015).

Importance of Nurse Education in the Recognition and Management of TAAEs

Significant changes in vital sign values occur in patients experiencing TACO compared to those with uncomplicated transfusions (Andrzejewski et al., 2012). In the case of serious TAAEs such as TACO, immediate interventions must take place including stopping the transfusion, raising the head of the bed, and calling a rapid response team if needed (Andrzejewski, Casey, & Popovsky, 2013). Nurses working at the bedside are the most frequent administrators of transfusions. Monitoring vital signs during a transfusion can help nurses identify TACO and other TAAEs. Nurses need to be able to identify the changes in patient condition that are associated with TAAEs so that they can quickly intervene and avert dire consequences (Andrzejewski, Casey, & Popovsky, 2013; Mole, Hogg, & Benvie, 2007). It has been reported that the most influential source of information about transfusion practice are hospital transfusion

policies and educational programs, which typically include limited information on symptoms of a transfusion reactions. (Aulbach 2013) Thus, improving the education of nurses around TAAEs is key to ensuring patient safety during transfusions.

A small number of studies have examined TAAE education in prelicensure nursing programs. Mole, Hogg, and Benvie (2007) presented an educational session around transfusion safety to prelicensure nurses (n=66) that included a pretest of transfusion knowledge immediately followed by a hands-on simulation and discussion about transfusion practice. The students were retested at 4 weeks (n=41) and 12 months (n=68). There was some education about monitoring the patient during the transfusion, but the focus of the education was on ensuring that the correct transfusion was given to the correct patient. Smith, Donaldson, and Pirie (2010) examined knowledge retention of safe transfusion practices among prelicensure nurses (n=31) in the United Kingdom. The education addressed monitoring for TAAEs and included lecture, discussion, and simulation. The knowledge of students was assessed with a written exam on the day of the educational session, 4 to 6 months later, and 11 to 12 months later. The results revealed a decrease in knowledge at 6 months, but mean scores remained similar between 6 months and 12 months. A quality improvement project addressed teaching prelicensure nurses to identify TAAEs (Prentice & O'Rourke, 2013). Students (n=21) participated in a simulation that focused on various TAAEs. Pre- and post-testing revealed an increase in knowledge around TAAE identification. A similar quality improvement project compared pre- and post-education knowledge of prelicensure nurses. The experimental group (n=42) received a lecture followed by a pretest followed by a simulation session, while the control group (n=44) received a pretest followed by a simulation session. The lecture

and simulation group scored significantly higher in both pre- and posttests than did the simulation-only group. This study was limited by a small sample size and by the use of pre- and posttests that were not validated tools.

Tools for Educating Nurses about TAAE Recognition and Management

Evidence suggests that simulation and educational checklists are appropriate tools for educating nurses about TAAE recognition and management.

Simulation. Simulation has been used as an educational tool in nursing for many years (Kato & Kataoka, 2017; Meyer, Connors, Hou, & Gajewski, 2011; Severson, Maxson, Wrobleski, & Dozois, 2014; Stayt, Merriman, Ricketts, Morton, & Simpson, 2015), and has been shown to improve knowledge retention, communication, clinical performance, self-efficacy, and teamwork (Fanning & Gaba, 2007; Gaba, 2004; Gilfoyle et al. 2017; Henneman et al., 2014; Maruca, Díaz, Kuhnly, & Jeffries, 2015; Meyer, Connors, Hou, & Gajewski, 2011; Paull et al., 2013; Severson, Maxson, Wrobleski, & Dozois, 2014; Stayt, Merriman, Ricketts, Morton, & Simpson, 2015; Tubaishat & Tawalbeh, 2015). Simulation has been shown to be superior to classroom education alone (Brannan, White, & Bezanson, 2008; Brubaker et al., 2010; Steiner Sanko & Mckay, 2017) and to be an effective method for teaching technical, teamwork, error identification, and communication skills (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, Connors, Hou, & Gajewski, 2011). Given that all these skills are needed in transfusion administration,

simulation is an appropriate approach for teaching nurses about transfusions and TAAE identification.

Simulation has been found to be an effective approach in nursing education. It is comparable to traditional clinical educational experiences as a way to for nurses to learn clinical skills, and it has advantages over other teaching methods for knowledge retention. These conclusions are consistent with a systematic review done by Cant and Cooper (2009) examining simulation-based learning in nursing education and support the use of a simulation session in this research study for testing the effectiveness of a TAAE educational checklist with prelicensure nurses.

The Journal of Nursing Regulation (Hayden, Smiley, Alexander, Kardong-Edgren, & Jeffries, 2014) published a 2-year randomized controlled multisite study examining whether time in a simulation could be substituted for time in the clinical area for prelicensure nurses. Five associate degree programs and 5 baccalaureate degree programs from different areas across the United States participated. Inclusion criteria for programs to participate included a National Council Licensure Examination (NCLEX) pass rate at or above the national rate, a maximum of 10% simulation use in any current clinical course, and access to a simulation laboratory that could accommodate the students and the simulation scenarios required by the study. Eight hundred forty-seven students were randomized into three study groups (666 students completed the study). One (control) group had traditional clinical experiences and no more than 10% of clinical time spent in simulation. A second group had 25% of their clinical hours replaced by simulation, and a third group had 50% of their clinical hours replaced by simulation. Outcome data were clinical competency and course-level Assessment Technologies

Institute scores, and end-of-program outcome data were comprehensive standardized tests scores and validated tools for measuring clinical competency, critical thinking, and readiness for practice. The results revealed that there were no significant differences among the groups when up to 50% of traditional clinical experiences were replaced by simulation. Henneman et al. (2010) published a study that used simulation to identify the types and frequency of errors made by nursing students. The results revealed that students frequently made errors in verification of allergies, patient identification, and physician interactions.

Three studies have addressed transfusion education for nurses, and all three of them used simulation as part of their teaching methods. Two of the three (Mole, Hogg, & Benvie, 2007; Smith, Donaldson, & Pirie, 2010) found that simulation improved knowledge retention of the nursing students. The one study that compared knowledge retention between a simulation group and simulation plus lecture group found that participants who attended lecture plus simulation performed better on a knowledge assessment test than did the students who attended the simulation but not the lecture (Prentice & O'Rourke, 2013). This study was flawed in that it was underpowered and it did not have a group who attended lecture alone.

Checklists. Checklists serve as a clinical decision support system to organize essential criteria or help with recall of key steps and action items for particular situations and procedures (Gawande, 2010; Hales & Pronovost, 2006). They have been used in the aviation industry for many years to standardize and outline the proper steps that need to be taken to improve communication between crew members, to help prevent pilots from missing important safety steps that could lead to errors and aviation accidents

(Helmreich, 2000). To improve safety and reduce errors in healthcare, the principles of the aviation checklists have been adopted (Gawande, 2010). Their use has been shown to improve patient safety in medicine and nursing by standardizing processes and by ensuring that key steps in these processes are not missed (Anderson et al., 2015; Haynes et al. 2009; Malouf-Todaro, Barker, Jupiter, Tipton, & Peace, 2013; Pronovost et al., 2006).

Checklists are used in various health care settings and have been shown to help with recall of details, to help care providers avoid missing key steps in a procedure, to improve clinical performance in standardizing surgical procedures, and to help identify clinical errors (El Boghdady, Tang, Tait, & Alijani 2016; Gawande, 2010; Koester, de Vries, van Delden, Smorenburg, Boermeester, & van Lienden, 2013; Sibbald, de Bruin, Yu, & van Merrienboer, 2015). The use of checklists has been shown to improve patient safety by increasing communication among health care team members, shortening hospital length of stay, reducing the incidence of central line–associated bloodstream infections, and reducing 30-day post operation mortality rates (Anderson et al., 2014; Haynes et al., 2009; Pronovost et al., 2003; Pronovost, 2006; Schulman et al., 2011; World Health Organization, 2007). Checklists have been shown to improve patient outcome when they incorporate the key steps of a procedure and when they outline the key times during a procedure when communication should occur across members of the team (Gawande, 2010). Sibbald, Anique, De Bruin, and Merrienboer (2014), found that clinicians with different levels of experience all benefited from the use of a checklist in the identification of errors in the interpretation of ECG's though the experts had fewer errors to correct.

Checklists are commonly used for standardizing processes, but they have not been used extensively in nursing education in general or in transfusion education specifically. There is a lack of research on the utility of an educational checklist to guide nurses in the identification and management of TAAEs. There are educational PowerPoint slide decks and teaching packets on transfusion safety that address monitoring for TAAEs, but they do not include an educational checklist designed to be used at the point of care. A transfusion reporting system in the United Kingdom, the Serious Hazards of Transfusions (SHOT), provides a transfusion checklist, but the focus of this checklist is on positive patient identification, not the recognition and mitigation of TAAEs. Another tool, the SHOT pretransfusion risk assessment tool for TACO screening is directed at those prescribing the transfusion: it focuses on reviewing the need for a transfusion and use of body weight for proper dosing of transfusions. This checklist is also specific to TACO and does not address the need to monitor for other TAAEs.

A performance improvement study by Tseng, Spradbrow, Cao, Callum, and Lin (2016) aimed to reduce TACO risk by implementing a preprinted order set with a targeted checklist to be used by physicians to identify those at risk for TACO and intervene in cases with risk factors for TACO. During the three-month period after implementation of the order and checklist set, no incidences of TACO occurred.

While there are many studies examining the use of checklists for other aspects of patient care, there is a dearth of studies looking at checklists as they relate to transfusion safety, and there are no studies that focus on checklist use by nurses as an educational tool for transfusion safety and the recognition of TAAEs. In 2016, SHOT reported that the majority of transfusion safety incidents were the result of human error (Bolton-

Maggs, 2016) and recommended the use of checklists at the bedside when transfusions are administered to ensure that the right patient is receiving the right transfusion. The same report supported the use of a pretransfusion risk assessment tool for TACO to help identify those at risk for the development of this TAAE, but it did not include an educational checklist for nurses to use at the bedside.

Eye Tracking Technology as a Research Tool for Investigating Clinical Care

Eye tracking technology records what a person is focusing on and provides insight into what they are thinking about (Duchowski, 2007; Just & Carpenter, 1980). Capturing and analyzing eye movements thus provides insight into what a person is attempting to analyze (Duchowski, 2007). The objective data obtained from eye tracking, which includes fixation times and areas of interest, can be quantified so that groups and individuals can be compared (Doberne et al., 2015).Eye tracking is a technique that allows for the measurement of someone's eye movement so that a researcher can identify where a participant is looking at and the sequence of their eye movement from one location to another (Poole & Linden J, 2006) Specific reference points used in eye tracking that are predefined by the researcher are termed artifacts of interest (AOI). Artifacts of interest are physical items that are of interest to the researcher and are selected based on what an expert determines is relevant to the research being done (Tien, Pucher, Sodergren, Sriskandarajah, Yang, & Darzi, 2014).

Eye tracking has been used in health care settings to gain insight into decision-making and provide objective data about what health care providers consider relevant and what information they use to make decisions (Ball, Lucas, Miles, & Gale, 2003; Halevy & Chu, 2014; Henneman et al., 2017; Marquard et al, 2011; Brown et al., 2014). This

technology is superior to simple observation because of the limitations of observing a participant who is moving around and may go outside the viewing area of the observer. Eye tracking has been used to examine where clinicians focus when presented with clinical challenges such as 12-lead electrocardiogram interpretation (Bond et al., 2014), radiological image interpretation (Tourassi, Voisin, Paquit, & Krupinski, 2013), how choices are made (Konovalov & Krajbich, 2016;), and electronic health record use (Doberne et al., 2015). It has also been used to look at differences between where novices and experts focus their attention (Brown et al., 2014; Brunye, Mercan, Weaver, & Elmore, 2017; Koh, Park, Wickens, Ong, & Chia, 2011). Eye tracking has been used in combination with a checklist to compare electrocardiogram interpretation between a group who used a checklist and a group who was given an analytic prompt (Sibbald, de Bruin, Yu, and van Merrienboer, 2015). Eye tracking results revealed that the checklist was used to verify diagnoses, and that use of the checklist resulted in increased analytic scrutiny.

In nursing, researchers have used eye tracking technology to focus on patient safety. In a study by Henneman et al. (2014), nursing students (n=31) participated in a simulation scenario focused on patient safety. It was found that participants who reviewed their eye tracking results performed better in the areas of patient identification and medication allergy recognition than did participants who did not review their eye tracking results. Another study examined nurses' visual scanning patterns during medication administration to gain insight into patient identification errors (Marquard et al. 2011). The results showed that nurses who identified identification errors had the most visual fixations in a row on the patient's chart, and also scanned between the arm band

and the patient chart and completed more steps in a given time period than did the non–error identifying nurses. A study by Henneman et al. (2017) used eye tracking to gain insight into nurses' surveillance activities during a TACO simulation. Nurses who identified TACO 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 SpO2, which provide the clinical data necessary for the identification of someone at risk for developing TACO as well as for the signs and symptoms of TACO.

NASA Task Load Index as a Research Tool for Measuring Workload

The National Aeronautics and Space Administration (NASA) Task Load Index (NASA-TLX), is a subjective, multidimensional tool designed to measure perceived workload (Hart, 2006). It was developed by NASA more than twenty years ago and was originally designed for use in aviation. Its' purpose is to quantify workload during or right after the performance of a task (NASA, 1986; Hart, 2006). The NASA-TLX has been used in numerous studies and has shown good test-retest reliability and has been used in more than 300 research studies since it began being used in the mid 1970's (Hart, 2006).

Since its development it has also been used by disciplines outside of aviation, including medicine and nursing. Campoe and Giuliano (2017) used the NASA-TLX to measure the impact of interruptions while performing a procedure, on nurses' cognitive workload and frustration and found that workload and frustration both increased with increased interruptions. Henneman and colleagues (2018) also used the NASA TLX in a study evaluating the impact of an interruption management strategy and reported high

mental workload with interruptions. Additionally, mental workload scores increased when time pressure was increased. They reported TLX scores similar to those reported by France et al (2005) who used the NASA TLX to measure subjective workload and underlying dimensions of workload by emergency physicians in the presence of an electronic whiteboard. Hoonakker et al. (2011), noted that the NASA-TLX was developed outside the setting of nursing, so they tested the applicability of the NASA-TLX to nursing workload. They found that the NASA-TLX correlated highly with other subjective workload instruments finding it to be a reliable and valid tool to measure nursing workload. Weigl, Muller, Vincent, Angerer, and Sevdalis (2012) used the NASA-TLX to explore whether workflow interruptions are related to doctors' perceptions of workload and found a significant positive association of observed workflow interruptions and subsequent workload. Walters and Webb (2017) used the NASA-TLX to as a part of a study to measure workload as they looked to improve efficiency and reduce costs associated with 25 types of robotic surgery. The data from the NASA-TLX revealed that those assisting with and those performing robotic surgery felt that the workload for these surgeries had high temporal, effort, and physical demands. In the effort to reduce errors and improve patient safety, Yuan, Finley, Long, Mills, and Johnson, (2013) developed a clinical decision support system (CDSS) to be used by bedside nurses with hospitalized patients to help the nurses manage critical symptom changes. They used the NASA-TLX to measure the impact the new CDSS had on workload to the amount of cognitive and physical burden associated with using the device and found that the nurses perceived no increase in workload by the use of the system. Dubovsky et al., (2017) conducted a pilot study using the NASA-TLX with nurses in an emergency department triage simulation to

determine if a virtual reality simulation had a similar task load to an actual triage experience so that it could be used as a training tool for nurses learning to work in the triage area of the emergency department. The NASA-TLX data from this pilot study revealed that other than the physical effort, the simulation provided an equivalent task load to the actual triage area. The NASA-TLX was also used by France, et al. (2005) to measure subjective workload and underlying dimensions of workload by emergency physicians in the presence of an electronic whiteboard. They found that the faculty physicians exhibited lower subject workload scores than the residents and that temporal demand was the highest contributor to workload.

Summary

A significant number of TAAEs occur, with TACO being one of the most serious. Many TAAEs are not identified, which leads to underreporting of TAAEs and missed opportunities to intervene and improve patient outcomes. Education of prelicensure nurses in the identification of TAAEs is key to the recognition and mitigation of these events, and herein lies a gap in patient safety around transfusion practices. This study will address this gap by providing an educational tool for prelicensure nurses to help in the identification of TAAEs and in the steps that need to be taken to mitigate this patient safety event.

Currently, there is no transfusion education checklist to guide student nurses in the care of a patient through a transfusion that covers both the safe initiation of a transfusion and the steps for identifying and mitigating a TAAE. A transfusion education checklist that includes the key steps of the transfusion procedure, including the triggers for when to call the provider about a possible TAAE, will fill this gap and improve

patient safety around the identification, mitigation, and reporting of TAAEs. In addition, no research to date has combined the use of eye tracking technology with an educational checklist to elucidate how the checklist is being used in the identification of a TAAE. The study proposed here will fill the gap.

CHAPTER 3

THEORETICAL FRAMEWORK

Nursing Role Effectiveness Model

The Nursing Role Effectiveness Model (NREM) identifies the impact of the various roles of nurses on patient outcome (Doran, Sidani, Keating, & Doidg, 2011). This model is based on Donabedian's (1988) structure–process–outcome model of quality care, which was adapted by Doran, empirically tested, and found to be valid (Doran et al., 2011; Salgueiro, Lopes Fereira, Cardoso, & Vidinha, 2014). The variables of the NREM are the structural, process, and outcome components of nursing care (Doran et al., 2011). The structural components of the NREM are the patient, the nurse, and the organization. The variables within the patient component are patient risk factors such as age, type of illness, and comorbidities. The variables within the nurse component are the experience and knowledge levels of the nurse. The variables within the organizational component pertain to the work environment and include staffing levels, staffing mix, and workload. The process components of the NREM consist of the independent, medical care–related, and interdependent roles of the nurse. The independent roles of the nurse are actions that do not require a physician's orders, such as performing patient assessments. The medical care–related role (also known as dependent role) includes nurse-initiated care that is medically directed, such as implementing a medical order or evaluating a patient's response to medically directed care. The interdependent role includes shared activities nurses perform with other members of the health care team, including coordination of care and interdisciplinary communication. The outcome components of the NREM are the nurse-sensitive patient outcomes. They include injury prevention, functional status,

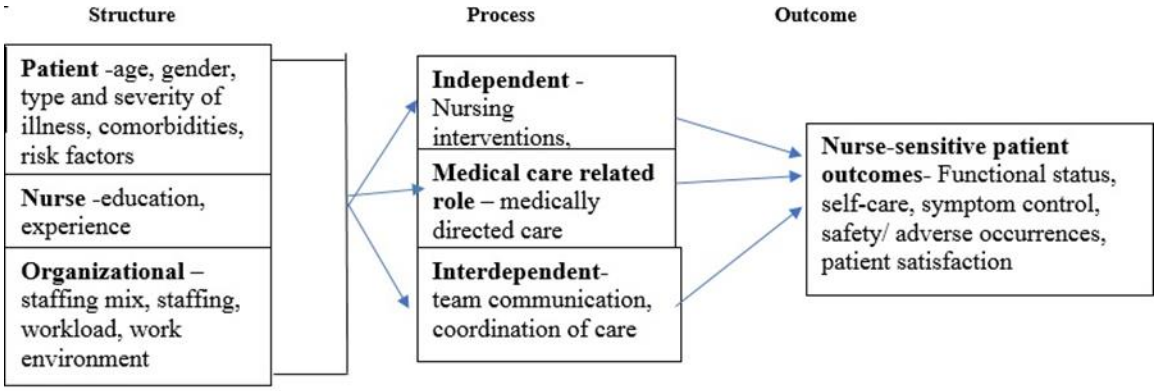
safety, adverse occurrences, symptom control, management of side effects, and patient satisfaction.

The NREM has been used in a number of studies examining the role of the nurse and how nurses impact patient outcome. Doran, Sidani, Keating, and Doidg (2014) used the NREM to investigate the relationship between evidence-based practice and patient outcomes, including pain, dyspnea, falls, and pressure ulcers, in the home care setting. An integrative review of the literature by Mok, Wang, and Liaw in 2015 used the structural components of the NREM to clarify the role of nurses as they monitor vital signs. The NREM was used to examine the relationship between the nurse's role monitoring vital signs and the identification and reporting of patient deterioration. The authors found that three organizational variables—workload, technology, and observational chart design—affected the nursing practice of vital sign monitoring. Endacott, Eliott, and Chaboyer (2009) used the NREM in an integrative review of studies examining the impact of the intensive care unit liaison nurse and outreach services on patient outcome in the United Kingdom and Australia. The authors found that the roles varied so much across studies that it was unclear how the role impacted the outcome. White, Jackson, Besner, and Norris (2015) observed registered nurses and health care aids deliver care and used the NREM to categorize the activities they performed.

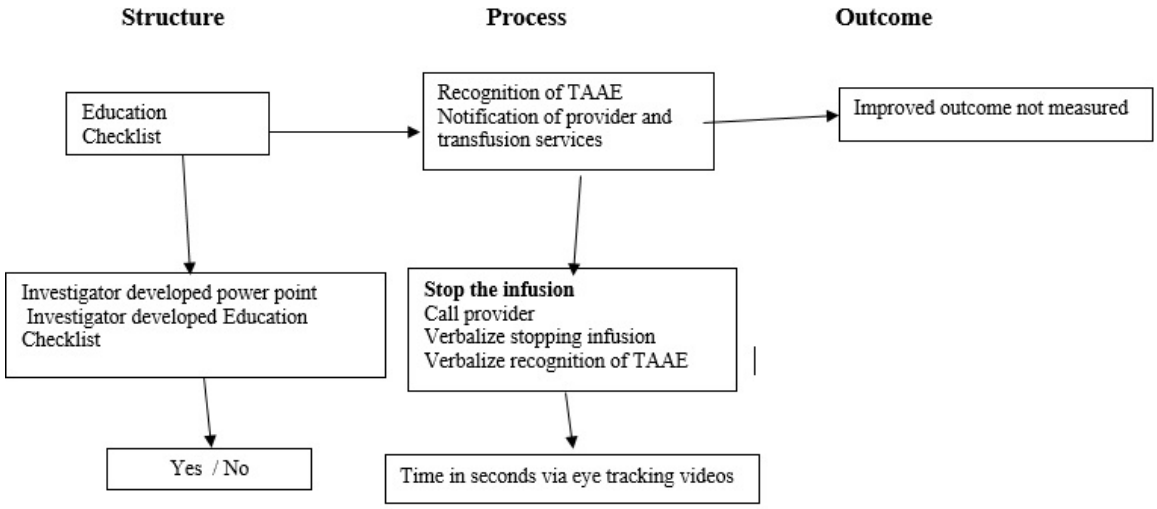
The NREM defines the questions asked in this study. The nurse structural component, which is composed of nursing knowledge and experience, speaks to the limited knowledge of a novice nurse who has little or no experience with the care of a patient receiving a transfusion. A novice nurse caring for a patient who develops a TAAE may not identify the signs, symptoms, and risk factors of this condition. Recognition of a

TAAE is important in order to prevent further transfusion-related morbidity and mortality (Sapiano et al., 2017). The use of a clinical decision support system, in this case a checklist, may have a positive impact on the novice nurse's ability to identify changes in patient condition that suggest a TAAE. Checklists have been linked to decreased morbidity and mortality when used as multidisciplinary tool to help ensure that the correct safety steps are followed prior to and during surgery and other invasive procedures (Anderson et al., 2015; Haynes et al., 2009). A TAAE checklist may be an effective tool to guide novice nurses through the correct steps in the recognition of and interventions needed to mitigate a TAAE. Checklists have been shown to help health care providers recall details, reduce errors, avoid missing key steps in procedures, improve team communication, and reduce morbidity and mortality (Gawande, 2010; Haynes et al., 2009; Pronovost et al., 2003; Shulman et al., 2011; Sibbald, de Bruin, Yu, & van Merrienboer, 2013).

Once a TAAE has been identified by a novice nurse, a checklist would guide the nurse to stop the transfusion. This action is part of the nurse's medical care–related (or dependent nursing) role within the process component of the NREM. The checklist could also guide the nurse to collaborate with the provider and transfusion service to address the TAAE. This action is part of the interdependent nursing role within the process component. While not a part of this study, the positive impact on patient outcome resulting from mitigating a TAAE would be part of the outcome component of the NREM. When a novice nurse uses a checklist as guide, the nurse must look at the checklist, read its contents and then think about what is being read so that a decision can be made. This is the basis of the Eye Mind Theory.



The Nursing Role Effectiveness Model



Nursing Role Effectiveness Model Applied to TAAE

Eye Mind Theory

The eye mind theory originated from research on reading and reading comprehension. It suggests that what a reader is focusing on is linked to what they are trying to process and interpret and that a reader will pause on words that require more processing (Just & Carpenter, 1980). Research using eye tracking technology has shown that readers spend more time focusing on the key words in a sentence in order to comprehend the meaning of the sentence (Rayner, 1977). Eye movements vary with the complexity of the content being read: fixation times increase and saccade length decreases when the material being read is more complex (Rayner, 1977). Rayner and Raney (1996) noted that eye movements are related to the intentions of the reader. They found that a reader has longer fixation times on less frequently seen words if a passage is being read for content, but that this does not occur if the reader is searching for a particular word. The main verb in a sentence is critical for comprehending the sentence and Rayner (1977) found that fixation times were longer on the main verb in the sentence, which is the key word for understanding the meaning of the sentence.

More broadly, eye mind theory suggests that what someone is looking at is related to what they are paying attention to or thinking about at the time (Henneman et al, 2017). 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. Where a person focuses their attention may also indicate what they would like to know about (Halevy & Chou, 2014). Anderson, Bothell, and Douglass (2004) found that retrieval of information from memory is not related to eye movements.

Observing where people focus their visual attention has been used to gain insight into cognitive decision making (Brunyé, Mercan, Weaver, & Elmore, 2017; Doberne, He, Mohan, Gold, Marquard, & Chiang, 2015; Gold, Stephenson, Gorsuch, Parthasarathy, & Mohan, 2016). Orquin and Loose (2013) found that if an artifact of interest is not fixated on and is outside of the area that a person is visually focusing, it probably does not play a role in the decision made at that time. They noted, however, that this is only the case when an artifact is unfamiliar to the decision maker. In a familiar scene, a decision maker may retrieve information about an artifact from memory without fixating on it visually. The authors also found that experts have shorter fixation durations than novices and tend to fixate on artifacts that are necessary to make a decision. Novices have longer fixation times, which indicates that the decision is more difficult for them to make. This is analogous to the observation that a reader fixates for a longer time on a word that they have never seen before because it takes time to associate a meaning with it.

Brunyé, Mercan, Weaver, and Elmore (2017) found that experienced pathologists examining tissue slides for cancer cells focus more on artifacts of interest that indicate the presence of cancer than less experienced pathologists do. This is consistent with research comparing experienced and novice nurses. Koh, Park, Wickens, Ong, and Chia (2015) compared the attentional strategies of experienced and novice operating room nurses to gain insight into their performance during surgical procedures. They found that the experienced nurses focused their attention on the more salient aspects of the surgical procedure, which translated into better performance. The novice nurses switched their attention among artifacts of interest more often and did not perform as well. The novice nurses were also distracted by interruptions from the circulating nurse, difficulties finding

instruments, and housekeeping duties, all of which were of lower priority than the situation at hand. These results suggest that the nurse's eye movements reveal cognitive processes. This is consistent with the results of Tanner, Padrick, Westfall, and Putzier (1987), who noted that more experienced nurses are more focused on the issue at hand than are less experienced nurses. Eye mind theory has also been used to examine the safety practices of health care staff. Marquard et al. (2011) imbedded patient identification errors in a simulation of medication administration. They found that participants who visually fixated on the artifact that contained the error were more likely to identify the error. Those who did not find the error tended to not fixate on any one artifact. They also noted that those who identified the error had a more consistent scan path than those who did not. The association between visual fixation on the artifact and the recognition of the error suggests a cognitive connection. Eye mind theory suggests that novice nurses look at many unimportant areas in a setting as they attempt to identify an issue and decide how to address it. It takes them longer to collect key data and make decisions based on them than more experienced nurses. Unlike an expert nurse, a novice nurse will likely have a difficult time making decisions if there are a lot of extraneous data that they must examine, because of their inability to separate the important data from the unimportant data.

Theoretical Definitions

Checklist

A checklist can be used as clinical decision support system to organize essential criteria or action items for a situation or procedure (Hales & Pronovost, 2006). A

checklist can help the user adhere to best practice by standardizing the approach to a situation (Hales & Pronovost, 2006) and can serve as a visual cue to enhance decision making (McCallum, Ness, & Price, 2010; Sibbald, De Bruin, Yu, & van Merrienboer, 2015). Checklists have been shown to benefit people of all levels of expertise in the identification of errors (Sibbald, Anique, De Bruin, & Merrienboer, 2014), and thus they are likely to be an effective tool to help prelicensure nurses improve patient safety during the administration of transfusions.

Procedural checklists have been available to nurses for many years to standardize care and to improve the safety of health care processes. They have been used by diverse health care organizations to direct caregivers in the performance of various nursing procedures (Henneman, Cobleigh, Avrunin, Clarke, Osterweil, & Henneman, 2008). The *Lippincott Nursing Procedure Manual* (Wolters Kluwer) and similar works contain checklists, along with tables and step-by-step instructions for essential nursing procedures. While these checklists are useful to ensure that each step of the procedure is followed in the appropriate sequence, they do not necessarily address what should be done if the outcome of a step is not met. For example, the standard transfusion checklist describes a linear process: ensure that there is a completed consent for the product, ensure that there is a medical order for the product, ensure adequate IV access, etc. However, there is no accommodation in the checklist for situations in which unexpected circumstances are encountered during the procedure. Checklists have been shown to guide decision making, and thus they should be designed to accommodate unexpected circumstances and failures. If the process of reacting to problems is left to the interpretation of the care giver, patient safety may be compromised (Henneman et al.,

2008). An effective checklist should meet the following criteria: it should make clear when it is to be used, each item on it should be actionable, it should be easy to understand, it should make the user aware of issues when they can still be corrected, and it should promote communication among team members (Gawande, 2010). A checklist that includes information about how to identify the condition that it was designed for will help the user focus on these points and identify the condition (Sibbald, De Bruin, Yu, & Van Merrienboer, 2015). The checklist to be used in this study includes the necessary steps in the administration of a transfusion and meets the above criteria. This type of checklist will increase patient safety by facilitating the recognition of TAAEs and the interventions necessary to mitigate them.

Transfusion Associated Adverse Event

A transfusion-associated adverse event (TAAE) is an undesirable and unintentional occurrence associated with the administration of blood or one of its components. The different types of TAAEs share some common signs and symptoms, and their effects range from mild to fatal (Mazzei, Popovsky, & Kopko, 2014). While the various TAAEs may differ in etiology and treatment, they require the same monitoring process during a transfusion. If any TAAE occurs, the necessary steps include stopping the transfusion, calling the provider, and calling the transfusion service. For TAAEs that cannot be anticipated, such as febrile or allergic TAAEs, intervention and mitigation take place after the TAAE has begun and the signs and symptoms have been identified. If prelicensure nurses are not adequately educated about TAAEs, the signs and symptoms may be missed, and critical interventions such as stopping the transfusion may not take place.

This study will include a simulation of a patient developing transfusion-associated circulatory overload (TACO). TACO was selected because, unlike other TAAEs, TACO can be anticipated and possibly prevented. A relatively simple bedside screening can indicate whether a patient is at risk for TACO. Patients at high risk for TACO include those older than 70 years; those with a history of cardiac, pulmonary, or renal pathology; and those with a positive fluid balance over the last 24 hours (Andrzejewski, Casey, & Popovsky, 2013). Additionally, a patient can develop TACO if the transfusion is infused too quickly or is too large a volume for the recipient to tolerate (Andrzejewski, Casey, & Popovsky, 2013). Reviewing the patient history for risk factors is the first step in raising the awareness of the patient risk. If risk factors exist, communication among care providers will provide the opportunity to split the transfusion or infuse it at a slower rate so that the patient's cardiovascular system is not overwhelmed. Bedside biovigilance during the transfusion, including monitoring of vital signs for significant changes in pulse pressure and other clinical changes that suggest TACO, may reduce the morbidity of this preventable TAAE (Andrzejewski et al., 2012; Mazzei, Popovsky, & Kopko, 2014).

The education of prelicensure nurses around transfusion administration and TAAE safety appears to be lacking, as evidenced in the lack of research in this area (Aulbach, 2013; Mole, Hogg, & Benvie, 2007; Smith, Donaldson, & Pirie, 2010). TACO is the leading cause of transfusion-associated death in the United States, and thus it is crucial that nurses be adequately educated about this preventable TAAE.

Clinical Simulation

Clinical simulation is the use of mannequins in a simulated clinical environment to re-create real-life patient care situations (Henneman & Cunningham, 2005; Sullivan et. al. 2015). It is an accepted method of teaching nurses and has been shown to be comparable to traditional clinical experiences in the education and preparation of nursing students for clinical practice (Hayden, Smiley, Alexander, Kardong-Edgren, & Jeffries, 2014). Simulations prepare students to apply material covered in a classroom setting to a clinical setting. Simulation promotes knowledge acquisition, psychomotor skill, critical thinking skill, and teamwork (Cant & Cooper, 2009; Fisher & King, 2013; Gilfoyle et al., 2017; Kneebone, 2006; Lapkin, Fernandez, Levett-Jones, & Bellchambers, 2010; Maruca, Díaz, Kuhnly, & Jeffries, 2015), all of which are required in the administration of a transfusion.

Simulation can reproduce the physiologic responses that a patient may exhibit in a clinical situation. This makes it an ideal tool for research on transfusions and TAAEs (Decker, Sportsman, Puetz, & Billings, 2008). Simulation has been used to enhance pharmacology education in prelicensure nurses (Steiner Sanko & Mckay, 2017). Unlike actual patient situations, a simulation is designed around specific goals and objectives that the student will be guaranteed to encounter so that competence can be studied (Hogg, Pirie, & Ker, 2006; Murray, Grant, Howarth, & Leigh, 2008). Because the objectives of a simulation are predetermined, every time the participant is in the simulation session the same sequence of patient events will occur. In a transfusion simulation where the objective is to train the student to care for a patient with a TAAE, the simulated patient will always progress towards that condition and respond to the interventions of the

student in the same way. In an actual clinical setting, there is no guarantee that a TAAE will develop, so the goal may or may not be met. In a simulated scenario, students can learn from their errors without harming a patient and have the opportunity to repeat a skill until they can perform it successfully (Henneman, et al., 2010). Simulation has been used to examine the effectiveness of checklists. Therefore, simulation is a suitable method to test whether an educational checklist is superior to a didactic session in teaching students to identify TAAEs.

Artifacts of Interest

Research into eye mind theory tells us that what a person is focusing on visually is what they are thinking about. In this study, we are particularly interested in objects that contain data that will help a nurse identify a TAAE. The application of eye tracking technology to observe how participants interact with these objects will provide insight into whether the participants are thinking about a possible TAAE. Eye mind theory suggests that those participants who are focusing on these key artifacts are thinking about those artifacts and may be considering the possibility of a TAAE. The artifacts of interest in this study are the wall monitor, the checklist, the paper on which the patient's history is written, the transfusion, and the patient.

Wall Monitor. The wall monitor will display the simulated patient's heart rate, blood pressure, temperature, respiratory rate, and oxygen saturation. The wall monitor was selected as an artifact of interest because, as the simulated patient begins to develop the signs and symptoms of a TAAE, the relevant data will be displayed on the wall monitor for the participant to see. The initial simulation will represent a febrile nonhemolytic TAAE. The wall monitor display will show a change in the patient's temperature five

minutes into the simulation, when the participant obtains the 15-minute vital signs. In the second simulation, the wall monitor will display the signs of TACO, which include tachycardia and a febrile response (Andrzejewski, Casey, & Popovsky, 2013).

Checklist. Eye tracking technology will reveal whether the participant refers to the checklist and how they use it during the simulation session. Insight will be gained into whether the participant uses the checklist as a decision-making tool and whether it cues the participant to identify that a TAAE is occurring.

Patient History. This study will reveal whether participants use the patient history in conjunction with the checklist to gather data on TACO risk factors prior to decision-making. For those participants who do not have a checklist, insight will be gained as to whether they refer to the patient history when the patient begins to develop the symptoms of a TAAE.

Transfusion. If a participant identifies the changes in patient condition that represent a TAAE, eye tracking will reveal whether they look to the transfusion as the cause of the event.

Patient. In the initial simulation scenario, the patient will not have any clinical signs and symptoms other than the elevated temperature. In the second simulation the participant may look at the patient to assess for adventitious breath sounds or respiratory distress suggestive of TACO.

CHAPTER 4

METHODS

Introduction

This study addressed two primary research aims:

The first primary aim of this study was to determine the impact of a transfusion checklist on nursing students' ability to identify TAAEs. This aim had 2 hypotheses:

Hypothesis 1: The use of a transfusion checklist will increase student nurses' ability to identify *TAAEs, as evidenced by a significant increase in appropriate transfusion behaviors.*

Hypothesis 2: There will be a significant decrease in time to identifying a TAAE following implementation of a transfusion checklist.

The second primary aim was to determine the relationship between fixation duration on the transfusion checklist and time to recognition of a TAAE by student nurses in a simulated setting. This aim had 1 hypothesis: *Hypothesis 3: There will be a significant increase in fixation duration on AOIs (patient, vital signs, blood product) in the checklist group between the preintervention period and the postintervention period.*

This study also addressed 1 secondary aim with a descriptive experimental design:

It was to determine the impact of using a TAAE checklist on the perceived task load index. This aim had 2 hypotheses: *Hypothesis 4: The NASA TLX scores will be significantly lower in the Checklist group than in the PowerPoint and Sham groups.*

Hypothesis 5: Students who identify the TAAE will have greater fixation times on the AOIs than those who do not identify the TAAE.

An experiment was conducted to compare the behavior of student nurses who receive an educational transfusion checklist to that of student nurses who receive transfusion education via a PowerPoint presentation or a sham PowerPoint presentation. A convenience sample of 60 student nurses were recruited to participate in the study and randomly assigned to one of three groups. The study had a pretest posttest experimental design. The outcome measure was an assessment of the nurses' behavior in the simulated setting, including recognizing risk factors for TACO, stopping the transfusion when appropriate, and notifying the provider of the problem.

A mobile eye tracker was worn by participants to determine the relationship between fixations on the transfusion checklist and time to recognition of a TAAE. Outcome measures included the fixation time on the transfusion checklist and the amount of time before the participant to either stopped the transfusion or called the provider or blood bank.

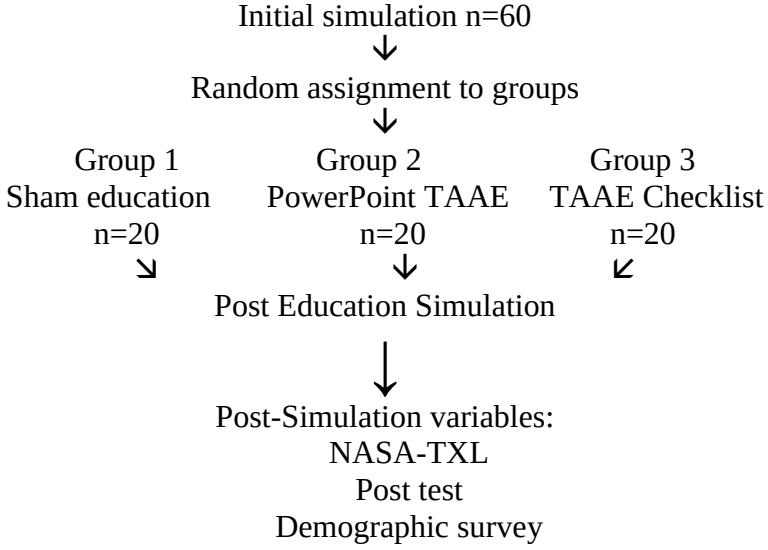
Participants

Participants were a convenience sample of nursing students from two universities enrolled in either a traditional baccalaureate nursing program or an accelerated bachelor nursing program. Inclusion criteria was nursing students educated in the performance of a physical assessment and who have administered medications subcutaneously, and by mouth. These cohorts were selected to reduce the bias that might be present if all of the participants were in the same nursing program or at the same university. Following participation in the study, participants will receive a $10.00 honorarium.

Sample Size and Groups

There were 20 participants in each of three groups. This sample size was based on power analysis using a power level of 80% and an alpha of 0.05. Group 1 was the control group. Group 1 participants will engage in a simulation of febrile nonhemolytic transfusion reactions (FNHTR), followed by sham PowerPoint safety education, followed by a simulation of TACO. Group 2 participants engaged in a simulation of FNHTR, followed by PowerPoint transfusion education, followed by a simulation of TACO. Group 3 participants engaged in a simulation of FNHTR, followed by education about transfusions that includes a checklist, followed by simulation of TACO.

Study Design



Setting

The study took place at the University of Massachusetts simulation lab in Springfield, MA (Tower Square Building, Main Street, room 007) and the Westfield State University simulation lab in Westfield, MA (Nettie Stevens Science and Innovation Center, 577

Western Avenue, room 118), both of which are simulated hospital rooms that contain human patient simulators and equipment to simulate the administration of transfusions. Participants will be oriented to the simulation environment and instructed that they will receive the patient vital signs 5 minutes after the simulation session begins. This is because the simulation begins 10 minutes after the start of the transfusion and the vital signs are taken 15 minutes after the transfusion begins.

Instruments

Eye Tracker. A wearable eye-tracking device (SMI ®) was used to measure and record participants' eye movements during the study. The eye tracking system records video of the reflection of an infrared light source on the participant's cornea. The location of the reflection relative to the center of the participant's pupil reveals the location of the participant's gaze (Duchowski, 2007). The system was calibrated for each participant while they focused on 3 triangulated points on a poster. The sampling rate of the system is 60 Hz, meaning that 60 gaze points are recorded per second. If the gaze points are in close proximity for 100 ms or longer, it is considered a fixation. Fixation data can be influenced by frequent blinking, rapid head movements, and the color of the participant's iris.

Participant Behavior Instrument. The behavioral instrument is a check sheet for recording the time in minutes to the decision to stop the transfusion or call the provider or transfusion services (Appendix D). The instrument is a previously used tool that was found to have 100% interrater reliability by two content experts (Polit & Beck, p. 455,

2008). The instrument was also validated for content validity by three clinical experts and found to not need any changes to content.

NASA Task Load Index. The NASA Task Load Index (NASA-TLX) is a scale developed by the Human Performance Group at the NASA Ames Research center more than 25 years ago. It was originally designed for use in aviation to measure subjective cognitive workload. Since its development, it has been used in other disciplines including medicine and nursing (Hoonakker et al., 2011; Walters & Webb, 2017; Weigl, Muller, Vincent, Angerer, & Sevdalis, 2012). The NASA-TLX includes six subscales: mental demand, physical demand, temporal demand, performance, effort, and frustration. Each of the subscales is represented by a line with twenty vertical tick marks dividing the 0 to 100 scale into increments of five. Participants were asked to place a mark on the line corresponding to their perception of the cognitive workload associated with each subscale (Hart, 2006). The raw workload score was then obtained by adding up the value of each subscale (0 to 100) and the resultant number reflects the workload rating of the task being examined (NASA, 1986). The following definitions of the subscales were provided to the participants:

- Mental demand: How much mental and perceptual activity was required? Was the task easy or demanding, simple or complex?
- Physical demand: How much physical activity was required? Was the task easy or demanding, slack or strenuous?
- Temporal demand: How much time pressure did you feel due to the pace at which the tasks or task elements occurred? Was the pace slow or rapid?

- Overall performance: How successful were you in performing the task? How satisfied were you with your performance?
- Frustration level: How irritated, stressed, and annoyed versus content, relaxed, and complacent did you feel during the task?
- Effort: How hard did you have to work (mentally and physically) to accomplish your level of performance?

To ensure participant confidentiality, the NASA-TLX form was modified to have a place for participant number instead of participant name.

Demographic Survey Instrument After the simulation sessions, participants were asked to complete a survey (Appendix H). The survey included questions about whether the participant had any prior experience with transfusions, including in the classroom, clinical or simulation.

Other Equipment. In the simulation lab, a Baxter SIGMA Spectrum infusion pump will be used. The infusion pump is a device that allows for introduction of a fluid into the patient (typically via a vein) at a predetermined rate in milliliters per hour. In this study it will control the flow of a blood transfusion into the peripheral IV site located in the left arm of the human patient simulator, while another infusion pump will simulate the infusion of fluid into another vein. The infusion rate for the transfusion will be preset to 100 mL/hr while the IV fluid will be preset to infuse at 75ml/hr, per the nursing handoff reports. The participant will not be required to program the infusion pump. If a participant identifies a TAAE, they will be expected to stop the transfusion by verbalizing that the transfusion has been stopped.

Operational Definitions

Checklist. The investigator checklist will include the series of steps for safe administration of blood products and decision points, based on changes in patient condition, at which the participant may be directed to call the ordering provider and transfusion services. Prior to the second simulation, subjects who are in the checklist group will receive transfusion education with the checklist as the educational material. They will then be directed to bring the checklist into the simulation so that they can refer to it as needed.

Transfusion-Associated Adverse Event. Two transfusion-associated adverse events (TAAEs) will be simulated. In the first simulation, the patient will develop the signs and symptoms of a non-hemolytic transfusion-associated adverse event. This event will be characterized by an increase in temperature (as displayed on the wall monitor) from 37˚C (98.6˚F) to 38˚C (100.4˚F). The patient will also complain of chills. The patient's heart rate will increase from the 80s to the 110s. In the second simulation, the patient will exhibit signs and symptoms of TACO and will complain of difficulty breathing. The heart rate on the wall monitor will increase from the 70s to the 120s within 5 minutes of the start of the simulation and the oxygen saturation will decrease from 95 to 89.

Artifacts of Interest. An eye tracking system will record gaze fixation data for the following artifacts of interest: the patient simulator, the wall monitor, the medical history, the patient's most recent vital signs, and the TAAE checklist. To ensure that the eye tracking technology can differentiate between the patient history and the most recent vital signs, the history will be on the top portion of the sheet and the recent vital signs will be

on the bottom portion of the sheet, and there will be at least 12 inches of blank space between them.

Clinical Simulation. The clinical simulation will involve a human patient simulator in a simulation lab set up like a patient room in a monitored unit of a hospital. The human patient simulator will be wearing a hospital gown and will be sitting up in either a hospital bed (Westfield site) or a reclining chair (Springfield site). The transfusion will be infusing into the simulated patient via an infusion pump programmed to run at 100 mL/hr and the IV fluid (Lactated Ringer's solution) will be running at 75mL/hr. The participant will be handed a paper with vital signs including temperature, pulse, respirations, blood pressure, and oxygen saturation 5 minutes into the simulation, representing the vital signs that are required to be obtained 15minutes after the start of the transfusion. For the febrile nonhemolytic TAAE, which is the initial simulation, the temperature and heart rate will be increased when the participant obtains the vital sign check 5 minutes into the simulation. For the second simulation, in which the patient develops TACO, the vital signs will show an increased heart rate, blood pressure, respiratory rate, and decreased oxygen saturation. In the first simulation the student will be assigned a task to administer insulin and in the second simulation the student will be assigned a task to administer pain medication so that the student does not focus only on the transfusion being administered.

Study Procedure

1. Randomly assign participant to one of three groups using randomization software.
2. Ask participant to complete consent form (Appendix J).

3. The Eye tracking device was calibrated to each user. The calibration process entails the participant looking at 3 triangulated reference points in their field of view. A mark appeared on the video near each reference point when it was fixed. The marks were then adjusted to each of the specific reference points which were stored on a tape.
4. Investigator gave 1st written patient report to participant. See Appendix G for documentation form (vital signs, need for a subcutaneous dose of insulin, transfusion began 10 minutes prior, 15-minute vital signs needed in 5 minutes).
5. Provide education to participant. Participants in Group 1 will view a sham PowerPoint safety presentation (Appendix H). Participants in Group 2 will view a PowerPoint presentation on TAAEs (Appendix I). Participants in Group 3 will receive an educational checklist on TAAE's that will be reviewed with them (Appendix B).
6. The Eye tracking device was recalibrated to each user. The calibration process entails the participant looking at 3 triangulated reference points in their field of view. A mark appeared on the video near each reference point when it is fixed. The marks were then adjusted to each of the specific reference points which was stored on a tape. After calibration the tape was analyzed using the Mobile Eye software program, and a marker could be seen where the participant was gazing.
7. Investigator gives 2nd written patient report to participant. See Appendix H for documentation form (vital signs, need for an oral dose of pain medication, transfusion began 10 minutes prior, 15-minute vital signs needed in 5 minutes).
8. Ask participant to complete NASA Task Load Index (Appendix E).

9. Ask participant to complete demographic survey tool (Appendix C).
10. Ask participant to complete posttest (Appendix L)

Data Collection. The following data was collected:

Length of time in minutes before the participant identified the patient problem as a TAAE and either stopped the transfusion or contacted the provider or the transfusion service (response time). For participants who did not identify the TAAE, the simulation ended at 15 minutes.

Eye tracking data for fixation time, and number of fixations on the patient, the blood product, the checklist, patient and the vital signs were obtained

NASA task load index

Survey data, including nursing program and patient care experience outside of school

Statistical Methods. Participants were randomly assigned to one of the three groups, either the Checklist group, PowerPoint group or Sham group. The primary outcome of response time was analyzed using ANOVA (both one-way and with repeated measures). The one-way ANOVA was used for comparisons between groups (the between factor) and the repeated measure ANOVA was used to compare the groups before and after the intervention (the within factor). It was assumed that the baseline response times would be similar across groups. It was anticipated that the response time after the intervention would be moderately ($r = 0.4$) or somewhat strongly ($r = 0.8$) correlated to baseline time. Because the students had little prior transfusion education or experience in their nursing program, the assumption was that the PowerPoint group and the Checklist education group would have a shorter response time than the Sham education group.

Table 1 presents calculated sample sizes based on a power of 0.8 (beta = 20%), an alpha for the F test of 0.05, and the F test for between–within subjects adjusted with the Greenhouse-Geisser correction factor. It was expected that a sample size of 20 would be able to detect reasonably small but clinically significant differences at this level of power. Chi Square testing was done to test for a significant difference between groups of participants who identified a TAAE Pre-intervention and Post-intervention and for other inferences when the variables were counts. If a cell count was < 5, the Fisher exact test was used.

The paired t-test was used to examine mean fixation times on the patient, vital signs, and blood at the subject level for the pre and post stage. The one-way ANOVA test was used to compare TAAE across groups.

One-way ANOVA was used to compare NASA-TLX Scores for each dimension and Total scores across groups.

Secondary Analyses. To analyze the secondary outcomes, we analyzed the NASA-Task Load Index (NASA-TLX) raw scores and examined them by the three groups using analysis of variance (ANOVA) to ascertain any differences in perceived task load across the groups. We also analyzed the impact of using a TAAE checklist on the perceived task load index and compared the Task Load Index scores of those who were in the TAAE checklist group to those who were not in the checklist group using Student's t-test. We also aggregated the pre and post intervention data to be a binary *yes* or *no* if the participant identified the presence of a TAAE

The two continuous secondary outcomes (fixation time on areas of interest and NASA-TLX scores) were described as means and standard deviations. We used ANOVA with

repeated measures to assess differences between groups with the exception of the NASA-TLX scores for which we used a one-way ANOVA as pre and post data were not available.

Demographic data (subject age, gender) were collected. and a one-way ANOVA test was done to determine if there was a significant difference in ages across groups with the Chi-Square test used to test differences by gender.

Assumptions

The following assumptions underlie this research: the eye tracking technology will accurately capture the participants' fixations on areas of interest, the participants will not share information about the simulation content with other potential participants, the participants in each group will have a similar lack of experience with transfusion administration and TAAEs, and that the NASA-TXL will be completed accurately by the participants so as to capture their actual task load.

CHAPTER 5

FINDINGS

This chapter contains a description of the sample and addresses the findings of each study aim and hypothesis.

Description of the Sample

The sample consisted of a convenience sample of 60 prelicensure nursing students in two baccalaureate nursing programs in Western Massachusetts: 30 students from an accelerated nursing program at a large state university and 30 students from a traditional nursing program at a small state university. The participants ranged in age from 20 to greater than 39 years, with the majority (54%) being in the 21–26 year range (Table 1). The age of one participant was not reported. There were no significant differences in age across the Checklist, PowerPoint, and Sham groups (P = .418).

Of the 60 participants, one-third (n = 20) had no patient care experience outside of school (Table 2). The other two-thirds of the participants had various kinds of patient care experience, the most common being experience as a certified nurse aide (n = 25). Participants in the Sham group reported significantly more clinical experience than participants of the other two groups (P = .01) (Table 3).

Primary Aim 1

The first primary aim of this study was to determine the impact of a transfusion checklist on nursing students' ability to identify TAAEs.

Hypothesis 1: The use of a transfusion checklist will increase student nurses' ability to identify TAAEs, as evidenced by a significant increase in appropriate transfusion behaviors.

The behaviors indicating that the participant identified that a TAAE was occurring included 1) verbalizing that a TAAE was occurring, 2) notifying the provider, and 3) notifying the blood bank. If the participant demonstrated any one of these behaviors, they were considered to have identified the TAAE. Within all groups there was a significant increase in the number of participants recognizing a TAAE between the pre- and postintervention period (Checklist $P = .03$, Power Point $P = .002$, Sham $P = .03$) (Table 4).

There was no significant difference across groups in recognition of TAAEs ($P = .435$). In the postintervention period, all 20 participants in the Checklist and PowerPoint groups identified the TAAE, as did 18 out of 20 participants in the Sham group (Table 4). These data do not support Hypothesis 1.

Hypothesis 2: There will be a significant decrease in time to identifying a TAAE following implementation of a transfusion checklist.

The mean time in seconds to recognition of a TAAE among those assigned to the Checklist group was 614.2 seconds (SD, 218.2) in the preintervention period and 398.6 seconds (SD, 77.0) postintervention ($P \leq .001$) This result supports Hypothesis 2. A significant decrease in time to identifying a TAAE also occurred in both the PowerPoint ($P \leq .001$) and Sham ($P = .005$,) groups (Table 6).

Primary Aim 2

The second primary aim was to determine the relationship between fixation duration on the transfusion checklist and time to recognition of a TAAE by student nurses in a simulated setting.

Hypothesis 3: There will be a significant increase in fixation duration on AOIs (patient, vital signs, blood product) in the Checklist group between the preintervention period and the postintervention period.

There was a significant decrease in fixation time from the preintervention to the postintervention period in all groups for the three AOIs. In the Checklist group, the mean fixation time on the patient was 9.76 seconds preintervention and 2.15 seconds postintervention (P = .02), the mean fixation time on the vital signs was 10.24 seconds preintervention and 3.6 seconds postintervention (P = .008), and the mean fixation time on the blood was 0.53 seconds preintervention and 0 seconds postintervention (P = .07) (Table 7). These results do not support Hypothesis 3.

Secondary Aim

To determine the impact of using a TAAE checklist on perceived task load.

Hypothesis 4: The NASA-TLX scores will be significantly lower in the Checklist group than in the PowerPoint and Sham groups.

There were no significant differences in total mean NASA-TLX scores (P = .36) or for individual dimensions of the NASA-TLX across groups. The total mean scores for the NASA-TLX were 60 (SD, 9) for the Checklist group, 58 (SD, 13) for the PowerPoint

group, and 57 (SD, 11) for the Sham group (Table 11). This result does not support Hypothesis 4.

Hypothesis 5: Students who identify the TAAE will have greater fixation duration on the AOIs than those who do not identify the TAAE.

Only preintervention data is presented because in the postintervention session, 97% of participants identified the TAAE, so there was not adequate power to determine support for the hypothesis.

Among the participants who fixated on the H&P, those who did not identify the TAAE had a mean fixation duration of 24.5 seconds, while those who did identify the TAAE had a mean fixation duration of 7.89 seconds (Table 18). Thus, there was a significant difference between the fixation duration on the patient ($P \leq .001$) and the fixation duration on the H&P ($P = .007$), with the TAAE identifiers having a shorter fixation duration on the patient and the H&P than the nonidentifiers. The AOIs of blood and vital signs did not have significant differences between the identifiers and nonidentifiers. These results do not support Hypothesis 5.

CHAPTER 6

DISCUSSION

Transfusions are the most common procedure that patients undergo while hospitalized (Pfuntner, 2013), and while generally safe, transfusion associated adverse events (TAAE) do happen. Nurses are the most frequent administrators of transfusions, so it is crucial that they identify TAAEs when they occur (Mole, Hogg, & Benvie, 2007). Checklists have been shown to help caregivers recall details, avoid missing key steps in procedures, and improve team communication and patient safety (Anderson et al., 2015; Gawande, 2010; Haynes et al., 2009; Pronovost et al., 2003; Shulman et al., 2011; Sibbald, de Bruin, Yu & van Merrienboer, 2013). As workload can affect performance, the NASA Task Load Index (NASA-TLX), a validated tool that measures subjective workload, was used in this study to examine whether the checklist had an impact on participants' workload (Hart, 2006). To capture which areas of interest participants were fixated on, eye tracking technology was used as a data collection method. As the identification of a TAAE and its treatment involve recall of details, key steps that must be followed, and team communication, a TAAE checklist that incorporates indicators of a TAAE and instructions for what to do when one is identified could be a method to help facilitate patient safety around TAAEs. There is a gap in the research around a transfusion checklist for use by nursing students at the point-of-care, so this study was conducted to identify whether a TAAE checklist would facilitate the identification of a TAAE so that interventions to mitigate the event could be initiated.

This experimental study was conducted in the simulation labs of two universities in Western Massachusetts. The participants were 60 prelicensure nursing students. Thirty of

them were enrolled in an accelerated baccalaureate nursing program and 30 were enrolled in a traditional baccalaureate nursing program. The participants were randomized into one of three groups: 1) the Sham group ("Sham"), in which they were given an educational session in a PowerPoint format around general safety measures such as handwashing and medication administration safety, 2) the Transfusion PowerPoint group ("PowerPoint"), in which they were given education about transfusion safety and TAAEs in a PowerPoint format, or 3) the Checklist group ("Checklist") in which they were given a TAAE checklist that was reviewed with them and was then brought into the simulation session so that it could be referred to as needed. Each participant wore eye-tracking glasses and participated in an initial simulation session of a patient who develops a febrile TAAE. This was followed by an educational session based on the group in which the participant was randomized. Immediately after the educational session, the eye-tracking glasses were reapplied and recalibrated, and the participant attended a second simulation session in which the simulated patient developed the TAAE transfusion associated circulatory overload (TACO). After the second simulation, the participant completed a NASA-TLX, a posttest, and a demographic form. The data that were collected were used to answer the following research questions.

The first primary aim of this study was to determine the impact of a transfusion checklist on nursing students' ability to identify TAAEs. There were two hypotheses for this aim.

The first hypothesis is: The use of a transfusion checklist will increase student nurses' identification of TAAEs as evidenced by a significant increase in appropriate transfusion behaviors following implementation of a transfusion checklist.

The second hypothesis is: There will be a significant decrease in time to identifying a TAAE following implementation of a transfusion checklist.

The second primary aim was to determine the relationship between fixation duration on the transfusion checklist and time to identification of a TAAE. The hypothesis is: There will be a significant increase in fixation duration on AOIs (patient, vital signs, blood product) in the pre- and postintervention period in the Checklist group. The secondary aim was to determine the impact of using a TAAE checklist on the NASA task load index. The hypotheses are that the NASA-TLX scores will be significantly lower in the checklist group than they are in the PowerPoint and Sham groups and that the students who correctly identify the TAAE will have greater fixation times on the AOI than those who do not identify the TAAE.

Impact of a TAAE Checklist on Identification of a TAAE

In answer to the first primary aim, the time to identification of the TAAE in the second simulation was significantly shorter than it was in the first simulation across all groups. While the Checklist group identified the TAAE sooner than the other groups in the second simulation (398 seconds by the Checklist group, 400 seconds by the PowerPoint Group, and 460 seconds by the Sham group), there was no significant difference between groups in time to identification of the TAAE ($P = .19$). All groups showed significant within-group improvement in the time to identification of the TAAE from the preintervention period to the postintervention period (Checklist $P = .03$, PowerPoint $P = .001$, Sham $P = .03$). The improvement may be attributed to the educational intervention and/or the students' participation in the simulation. This

observation of improved performance is consistent with other research revealing improved performance after an educational intervention in the form of classroom instruction or a simulation session (George & Quatrara, 2018; Henneman et al., 2014; Ortega, Gonzalez, de Tantillo, & Gattamorta, 2018; Singleton, Allen, Li, McNerney, Naber, & Braga, 2018). Repeated simulations have also been shown to improve preintervention and postintervention simulation performance (Henneman et al., 2014). That the TAAE checklist did not seem to facilitate the identification of the TAAE is inconsistent with the literature, as it is well accepted that checklists, if used properly, have been shown to improve performance (Haynes et al., 2009; Gawande, 2010; Levy et al., 2012; Neal et al., 2012). This disparity may have been because the education or simulation improved the participants' performance, thus biasing the effect of the checklist (Sanko & Mckay, 2017). Had there not been a preintervention simulation, or if the postintervention simulation had taken place more than three months later to allow for decay of knowledge gained by the education or by the first simulation, a significant difference may have been found across the groups with the checklist positively impacting time to identification of the TAAE (McCallum, Ness, & Price, 2010; Sullivan et al., 2015)

Relationship Between Checklist Fixations and Time to Identify TAAE

The results for the second primary aim suggest that there was no significant correlation between the fixation time on the checklist and the time it took for the participants in the Checklist group to identify the TAAE ($P = 0.11$). Two of the participants had no fixation time at all on the checklist, and they identified the TAAE sooner than all but one other participant in the Checklist group. Additionally, the PI observed during the simulation

that some participants either only glanced at the checklist briefly or ignored the checklist entirely. Some participants were seen placing other paperwork on top of the checklist so that it was not visible at all throughout the simulation. Another reason why a significant relationship between the checklist fixations and time to identify the TAAE was not found may be have been because the participants were not provided with education about how to use the checklist. This is consistent with the literature about checklists and their use. It should not be assumed that checklists are self-explanatory and that their mere presence will improve patient safety. For a checklist to function as designed and to be effective, users must be committed to using the checklist and there must also be education and instruction on how to use the checklist (Everett et al., 2017; Levy, et al., 2012). Because there was no education on proper use of the checklist, the participants may have not realized that it was pertinent for decision-making and so did not see it as a pertinent AOI. This is consistent with eye tracking literature that reveals that fixation times on pertinent AOIs are longer than fixation times on nonpertinent ones (Tien, 2014).

Another point to consider is that, because the participants in the study were novices, they may not have been able to identify what information on the checklist was relevant to the situation (Henneman et al., 2010; Marquard et al., 2011; Sibbald, de Bruin, & Merrienboer, 2014). Finally, those participants who made fixations on the checklist may have simply looked at the checklist but either did not process the information on it or did not focus on the correct information on the checklist. That key content on the checklist was not focused on may be supported by the fact that only 8 members (40%) of the Checklist group verbalized calling the blood bank, even though there was large, bold, red lettering in three different places on the checklist instructing users to call the blood bank

if the patient exhibited indications of TAAE. This is consistent with the eye tracking literature in which patient identification errors were made by care providers who fixated on patient identification information but did not notice that it was incorrect (Henneman et al., 2010; Henneman**,** Marquard, Fisher, & Gawlinski, 2017).

Differences in Fixation Duration on AOIs Between TAAE Identifiers and Non-identifiers

The final question was to compare the participants who identified the TAAE with those who did not identify the TAAE. In the preintervention simulation, there were longer fixation times on the AOIs of patient, vital signs, H&P, and blood by the TAAE nonidentifiers than by the TAAE identifiers, though only fixation times on the patient ($P \leq .001$) and the H&P ($P = .007$) were significantly shorter in the postintervention period. The longer fixation times by nonidentifiers is consistent with the literature, as nonidentifiers of medication errors were found to have random eye-fixation sequences on nonessential AOIs (Marquard et al., 2011). Though not specifically measured in this study, observation of the eye tracking videos revealed that nonidentifiers appeared be looking at random areas of the simulation environment, as if searching for an answer, rather than focusing on AOIs relevant to the simulation. This observation is consistent with the findings of Marquard and colleagues (2011).

In this study, the simulation sessions of the nonidentifiers lasted the maximum amount of time (15 minutes), whereas the identifiers' simulation sessions ended when they identified the TAAE. Because of the design of the study, the identifiers' sessions were shorter than 15 minutes because the simulation was ended upon identification of the

TAAE. The non-identifers sessions lasted the entire 15 minutes, which may have contributed to the nonidentifiers' longer fixation times. For the postintervention portion of the study, the question of fixation times on AOIs between identifiers and nonidentifiers could not be answered because there were only two participants (6%) who did not identify the TAAE, so there was not adequate power to compare the groups postintervention.

An additional finding regarding fixation times on AOIs was that there was a direct relationship between the fixation times on the patient and vital signs AOIs for the PowerPoint and Checklist groups, which was not seen in the Sham group. Though whether the fixation on the patient and vital signs impacted identification of a TAAE could not be elucidated in this study due to inadequate power, the Checklist and PowerPoint groups did identify the TAAE sooner than the Sham group, though the difference was not significant. Another observation by the PI was that the TAAE checklist was not used by most of the participants. Only three out of the 20 participants in the Checklist group were noted to be using the checklist as a guide, and one of these three did not call the blood bank despite the instruction on the checklist to do so.

NASA Task Load Index Scores

Question 3 pertained to the NASA-TLX scores of the participants. The NASA-TLX score is considered high if it is above 60, while it is considered low if it is below 40 (Cao, Chintamani, Abhilash Pandya, & Ellis, 2009). The perceived task load index scores were all above 40 for all the subscales except for Physical Demand, which ranged from 22 to 24 across the three groups. The scores for the subscales of Mental Demand (how complex

the task is), Effort (how hard the participant has to work to accomplish the task), and Frustration (how stressed participants felt during the task) were highest, 60–65, 58–62, and 49–58 , respectively, which is consistent with the research around NASA-TLX workload scores for a participant in the role of decision-maker, particularly in a setting where no feedback was provided during the simulation, as was the case in this study (Botzer, Meyer, & Parmet, 2016; Brown et al., 2018; Hart, & Staveland, 1988). The higher mean Frustration scores were consistent with the study by Brown et al. (2018), who found comparable higher scores with those in the role of decision-maker. As the participants were nursing students with little clinical experience, a higher Mental Demand score is consistent with findings by McInnis et al. (2017) who found that students experienced higher Mental Demand scores than those clinicians with more than 5 years' experience. Tien, et al. (2015) found similar results of NASA-TLX scores between experts and novices. Hudson, Kushniruk, & Borycki, 2015 found that those unfamiliar with a process scored higher in Mental Demand. Nineteen (35%) of the participants who completed the simulation evaluation form reported either that they were unsure of what they were supposed to do or that they did not know what was expected of them in the simulation, and this may have been reflected in the higher Mental Demand scores.

The Temporal Demand scores were very similar between groups and were the next to the lowest scores of all subscales. As participants were not aware that there was 15-minute end time to each simulation, there was no temporal demand placed on them, though some students participated in the study during their lunch break or between classes, which may have impacted their Temporal Demand score. The Physical Demand score was lowest of all of the subscales. That was not unexpected, as the simulations took

place in a small space and participants did not have to reposition or lift the patient or walk more than 10 feet in any direction to address any issues or needs. The low Physical Demand score was consistent with the results of Brown et al. (2018), who found that decision-makers had lower Physical Demand scores in a scenario in which they were not required to perform tasks.

Impact of the Checklist on NASA-Task Load Index Scores

Checklist use by a novice should reduce cognitive load by reducing the need to keep relevant information in working memory (Sibbald, de Bruin, & van Merrienboer, 2013). Sibbald, de Bruin, Cavalcanti, & van Merrienboer (2013) found that the use of a checklist decreased cognitive load in both novices and experts. The NASA-TLX scores of the participants in the Checklist group were not significantly different than the scores of the participants in other groups, suggesting that the checklist did not decrease the task load. This may be because many of the participants did not use the checklist to guide their decision-making around the TAAE. The participants were not specifically trained in how to use the TAAE checklist, and so did not know how to use it or see its value. This is consistent with the findings of other researchers who identified that barriers to checklist use included inadequate education and training for the checklist (Conley, Singer, Edmondson, Berry, & Gawande, 2011; Russ et al., 2015; Sokhanvar Kakemam, & Goodarzi, 2018). The comments on the simulation evaluation questionnaire suggested that the checklist was not considered or used by all of the participants in the Checklist group. Only 15% mentioned the word *checklist* on the simulation evaluation form. Forty-

five percent referred to *education* between the simulations as being helpful with no reference to a checklist, and 40% did not mention either *education* or *checklist*.

The NASA-TLX scores were only obtained after the second simulation, so there were no preintervention scores to be contrasted with the postintervention scores.

The Impact of the Simulations on the Identification of a TAAE

Simulation has been used as an educational tool in education for many years and has been shown to improve communication and clinical performance (Gilfoyle et al. 2017; Kato & Kataoka, 2017, Henneman et al., 2014; Maruca, Díaz, Kuhnly, & Jeffries, 2015; Meyer, Connors, Hou, & Gajewski, 2011; Paull et al., 2013; Severson, Maxson, Wrobleski, & Dozois, 2014; Stayt, Merriman, Ricketts, Morton, & Simpson, 2015; Tubaishat & Tawalbeh, 2015). Given that simulation is such an effective educational method, it may be that participation in the pre-intervention simulation influenced the performance in the post-intervention. The educational benefit of participating in the initial simulation may have been why all groups demonstrated a significant decrease in time to identify a TAAE in the post-intervention simulation.

Limitations

This study had a few limitations. The difference between the Checklist, PowerPoint, and Sham groups in the identification of the TAAE was not significant, but a larger sample size would have provided more power and may have revealed a significant difference. Because of the small sample size, the fact that the Sham group had significantly more self-reported clinical experience around transfusions ($P = .01$) than the other groups may have biased the difference between the groups. Fifteen percent of the eye tracking data were lost due to technical issues with the eye tracking recorder. While this is consistent

with other studies that used eye tracking (Henneman, et al., 2010; Henneman, et al., 2014), it may have impacted the eye tracking results.

Another limitation is the timing of the postintervention simulation. It is well established that simulation is an effective teaching method and that repetition of simulations improves performance. The performance of all three groups may have been different had there only been one simulation session or if the second simulation had been later rather than shortly after the first session, so that the groups would not have benefitted from knowledge that may have been gained from the first simulation session. A study in which the second TAAE simulation takes place at a later time, rather than immediately after the first simulation, may address the possible bias that the first simulation had on the performance of those in the PowerPoint and Sham groups in the identification the TAAE.

A third possible limitation was that the participants were from two different nursing programs with different demographics, and exposure to clinical, simulation, and classroom experiences varied. This was done so that the results would be more generalizable. Randomly assigning participants to one of the three groups may have successfully addressed any variance in demographics as demographics were not found to have impacted results. A fourth possible limitation was that the NASA-TLX was obtained only after the second simulation, so we were unable to compare how the workload may have changed after the intervention. Finally, in this study there was no education as to how the checklist should be used, which may have impacted the performance of those in the Checklist group.

Suggestions for Further Research

The results of this study highlight the importance of educating those who are using a checklist. Simply providing information without direction and education is not useful. Given that the participants did not consistently use the checklist, a similar study comparing trained and untrained groups using a checklist could be valuable to highlight the importance of checklist education prior to checklist implementation.

As this was a pilot study, replicating this study with a larger sample size may reveal significant differences in the groups, particularly in those areas where the *P* values were close to being significant.

Implications for Nursing

Nursing administrators and educators need to be aware that, while checklists have been shown to improve patient safety and guide clinical decision making, they cannot simply be introduced to users. Though they may appear to be intuitive, for them to be effective their implementation must be preceded by education about their purpose and how to properly use them.

Summary and Conclusions

Transfusions are commonly administered by nurses, and TAAEs, while not an everyday occurrence, do occur. To promote patient safety, TAAEs need to be identified as soon as possible so that they can be addressed and mitigated. Nurses need to be able to identify TAAEs because nurses are typically the clinician at the point of care when a transfusion is being administered. As a result of their lack of experience, a novice nurse may not

identify a TAAE, which could compromise patient safety. This study examined whether the use of a TAAE checklist as a clinical decision support system would facilitate the identification of a TAAE by a student nurse. The results of this study suggest that the TAAE checklist did not improve identification of TAAEs. This may have been because all participants attended a simulation session about TAAEs prior to the implementation of the checklist, and the knowledge they gained in the preintervention simulation may have improved their performance in the postintervention simulation, thereby biasing the results of the checklist. Checklists are not self-explanatory, and as simulation is an effective teaching tool, simulation could be used as a method of education in the use of a checklist prior to its implementation to help insure that the checklist will be used as intended.

APPENDICES

APPENDIX A

TRANSFUSION GRID

Type of Reaction	Cause/ Pathophysiology	Predisposing Factors	Presentation	Nursing Interventions
Acute Hemolytic Immune	Patient ID Error at blood sampling or at time of administration (SHOT, 2016)	Inadequate education; (Bolton-Maggs, 2016)	Fever, chills dyspnea, hypotension (Bolton-Maggs, 2016)	Stop Transfusion; call the provider and the transfusion services
Acute Hemolytic Non-immune	incompatible solutions administered with the blood	Inadequate education	Fever, chills, (Bolton-Maggs, 2016)	Stop transfusion; call the provider and the transfusion services
Febrile Non-hemolytic	proinflammatory cytokines or recipient antibodies to donor antigen (Delaney, 2016;)	N/A	Fever, chills, (Bolton-Maggs, 2016)	Stop transfusion; call the provider and the transfusion services
TACO	Hydrostatic effects of fluid overload caused by transfusion administered faster than patient can tolerate. (Andrzejewski, 2013; Delaney, 2016; LI, 2011).	History of renal failure, heart failure, positive fluid balance	acute respiratory distress, with evidence of circulatory overload (Bolton-Maggs, 2016); Vital sign changes (increased temp; increased pulse pressure); Andrzejewski, 2012	Stop transfusion; call the provider and transfusion services (Andrzejewski, 2013)
TRALI	nonhydrostatic, inflammatory pulmonary edema	sepsis, shock, chronic alcohol abuse, major burn, inflammatory response (Bolton-Maggs, 2016)	acute onset of hypoxemia bilateral infiltrates chest x-ray; no evidence of circulatory overload	Stop the transfusion; call the provider and transfusion services
Allergic	Antigen-antibody reaction	Predisposition to allergic reaction (Savage et al, 2015)	urticaria, rash with pruritis; if severe: respiratory compromise (stridor, bronchospasm) or hypotension (Bolton-Maggs, 2016)	Stop the transfusion; call the provider and transfusion services
Microbial Contamination	Contamination of sample		Increased temp, rigors hypotension, tachycardia (Bolton-Maggs, 2016)	Stop transfusion; call provider and Transfusion services

APPENDIX B

TRANSFUSION CHECKLIST / HANDOFF FORM

Pre-Transfusion

- ☐ Review patient history and risk factors for transfusion associated adverse event (TAAE)
  - Advanced age
  - Multiple units transfused in previous 24 hours
  - History of heart or renal failure
- ☐ Confirm presence of informed consent
- ☐ Confirm positive patient ID
- ☐ Confirm that IV catheter is functioning
- ☐ Complete physical assessment (lung sounds and skin assessment)

Vital sign values obtained and documented

If there are any abnormal findings NOTIFY Physician and Transfusion Services

Intra-Transfusion

- ☐ Evaluate patient 15 minutes after transfusion starts
- ☐ Obtain and document vital signs and focused physical assessment findings
- ☐ Assess for evidence of TAAE: New onset temperature > 100.4, chills back pain, urticaria, dyspnea, tachycardia, cough, crackles, hypotension, hypertension, widened pulse pressure, decreased O2 saturation

If there are any signs of suspected TAAE STOP the infusion and NOTIFY Physician and Transfusion Services.

Post-Transfusion

- ☐ Obtain/document VS
- ☐ Perform focused physical assessment
- ☐ Assess for evidence of TAAE (temp > 100.4, chills back pain, urticaria, dyspnea, tachycardia, cough, crackles, hypotension, hypertension widened pulse pressure, decreased O2 saturation)
- ☐ If no sign of any type of TAAE discard blood product and blood tubing.
- ☐ Document infused volume in patient medical record

☐ Include information regarding any transfusion related issues/concerns including: number of units transfused in last 24 hours, significant laboratory values, changes in VS presence of a positive Fluid Balance, i.e., I>O, need for daily weights, any identified/reported adverse transfusion events, plans for further transfusions

Handoff

- ☐ Convey transfusion related issues/concerns including:
  - Number of units transfused in last 24 hours
  - Significant laboratory values
  - Changes in VS presence of a positive Fluid Balance, i.e., I>O,
  - Need for daily weights
  - Any identified/reported adverse transfusion events
  - Plans for further transfusions

APPENDIX C

PARTICIPANT DEMOGRAPHICS SURVEY

Participant No: _____

Nursing Program (Check one)

- ☐ WSU
- ☐ UMass

Prior experience with clinical simulation (Check all that apply)

- ☐ None
- ☐ During medical school
- ☐ Hospital orientation
- ☐ Continuing education
- ☐ Other: _____

Prior experience with transfusions in

- ☐ Classroom
- ☐ Clinical
- ☐ Simulation
- ☐ None

Prior experience with administration of po medications in

- ☐ Classroom
- ☐ Clinical
- ☐ Simulation

Prior experience with administration of subcutaneous medications

- ☐ Classroom
- ☐ Clinical
- ☐ Simulation

Prior experience with cardiac monitoring

- ☐ Classroom
- ☐ Clinical
- ☐ Simulation
- ☐ None

Patient care experience outside of school

- ☐ CNA
- ☐ Lab tech
- ☐ Phlebotomist
- ☐ Orderly
- ☐ Other _____

Age ☐ 21-26 ☐ 27-32 ☐33-38 ☐ 39-44 ☐45-50 ☐>50

Gender ☐ Female ☐ Male ☐ Other

APPENDIX D

PARTICIPANT BEHAVIORAL EVALUATION FORM

Participant No: _____

Sim Start Time _____

Behavior	Yes	No	**Comment**
Obtains 15-minute vital signs 5 minutes into sim			
Verbalizes increased patient temp			
Assesses patient for other S&S of transfusion reaction			
Asks about how much blood in the pt so far			
Verbalizes the heart rate is			
Verbalizes pt's BP			
Asks what lungs sound like			
Asks if SOB			
Asks if pt has back pain			
Asks if pt has hives			
Stops transfusion			
Verbalizes Calls provider			
Verbalizes Calls transfusion services			

Time to stop transfusion _____

Time to call provider_____

Time to call Transfusion services_____

APPENDIX E
NASA TASK LOAD INDEX

PARTICIPANT NUMBER _____

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

Performance How successful were you in accomplishing what you were asked to do?

Perfect Failure

Effort How hard did you have to work to accomplish your level of performance?

Very low Very high

Frustration How insecure, discouraged, irritated, stressed and annoyed were you?

Very low Very high

NASA TASK LOAD INDEX DEFINTION OF TERMS

Mental Demand- How much mental and perceptual activity was required? Was the task easy or demanding, simple or complex?

Physical Demand- How much physical activity was required? Was the task easy or demanding, slack or strenuous?

Temporal Demand- How much time pressure did you feel due to the pace at which the tasks or task elements occurred? Was the pace slow or rapid?

Overall Performance -How successful were you in performing the task? How satisfied were you with your performance?

Frustration Level- How irritated, stressed, and annoyed versus content, relaxed, and complacent did you feel during the task?

Effort -How hard did you have to work (mentally and physically) to accomplish your level of performance?

APPENDIX F

SCRIPTS FOR SIMULATION SESSIONS

Script used during handoff for Scenario# 1 (prior to education)

Hi I'm Sue Scott, Mrs. Allen's nurse. Mrs. Allen is a 77-year-old woman with a history of smoking 1 pack a day for 50 years, insulin dependent diabetes mellitus and COPD. Last week she underwent a colonoscopy because she noted some blood in her stool. A biopsy was taken of a polyp during the colonoscopy and was found to be cancerous so 2 days ago she underwent a colon resection. Her surgery was uneventful, and she has been stable since returning from PACU. She's alert and oriented x 3, her breath sounds are clear bilaterally, her abdomen is soft and slightly tender. She has bowel sounds and takes sips of water. I gave her a dose of oxycodone 6 hours ago for abdominal pain which brought her pain down from 8 to 3. She can get more if she needs it. It's ordered every 6 hours prn. She got up to the bathroom and urinated 400mL clear yellow urine. Her abdominal dressing is dry and intact, and she has no skin breakdown. She has an IV in her left forearm with Lactated Ringer's running at 75mL/hr. Her H&H is only 7 and 21 so the MD ordered a unit of blood which I just started an IV angio in her right forearm. The only thing she needs right now is 4 units of regular insulin SC, because her blood sugar was 188 and her 15-minute vital signs for the transfusion need to be done in 5 minutes.

Progress through the Simulation Scenario# 1

As soon as the participant enters the room, the patient will tell the participant that she is having incisional pain and wants to know when her next pain pill is due. Five minutes after handoff to the study participant, the patient will begin to exhibit signs and

symptoms of a TAAE. At the time when the participant should obtain the 15 minutes vital signs there will be patient changes. The patient develops the nonhemolytic febrile reaction will have a temperature increase from 37˚C (98.6˚F) to 38 ˚C (100.4 ˚F) and develop chills. The patient's heart rate increases from the 80's to 110's. Simulation ends when participant either stops transfusion, calls the provider or 15 minutes elapses

Script used during handoff for Scenario# 2 (after education)

Hi I'm Sue Scott, Mrs. Frank's nurse. Mr. Frank is a 71-year-old woman with a history of emphysema. She quit smoking 2 years ago after having an anterior myocardial infarction She is a noninsulin dependent diabetic. She was diagnosed with lung cancer 3 weeks ago and today underwent a left sided pneumonectomy. Her surgery was uneventful, and she has been stable since returning from PACU. She is alert and oriented x 3, her breath sounds are clear on the right and absent on the left, her abdomen is soft and nontender. She has bowel sounds and takes sips of water. I gave her a dose of Percocet 4 hours ago for incisional pain which brought her pain down from 7 to 2. She can get more if she needs it. It's ordered every 4 hours prn. Her left chest dressing is dry and intact, and she has no skin breakdown. She has an IV in his left forearm with Lactated Ringer's running at 50mL/hr. Her H&H is only 8 and 24 so the MD ordered a unit of blood which I just started an IV angio in her right forearm. She may need more pain med. She has been asking for it pretty much every 4 hours. The only thing she needs will be the 15-minute vital signs for the transfusion. I hung the blood 10 minutes ago need so she'll need them done in 5 minutes

Progress through the simulation #2

As soon as the participant enters the room, the patient will tell the participant that she is having incisional pain and wants to know when she can get her pain pill. Five minutes after handoff to the study participant, the patient will begin to exhibit signs and symptoms of a TAAE. At the time when the participant should obtain the 15 minutes vital signs there will be patient changes. The patient develops TACO and will complain of difficulty breathing. Her heart rate increases from the 70's to 120's. and her oxygen saturation will decrease from 95 to 89.

Simulation ends when participant either stops transfusion, calls the provider or 15 minutes elapse

APPENDIX G
DOCUMENTATION FORM FOR PARTICIPANTS

Pre-transfusion	**VITAL SIGNS** Temp _____ HR_____ Resp rate _____ SBP _____DBP_____ O2 sat _____	**FOCUSED ASSESSMENT FINDINGS** Neuro status Lung sounds Bowel sounds Peripheral pulses Patient complaints ☐ None ☐ Pain (location) _____ ☐ Dyspnea ☐ Cough ☐ Other (specify) _____
Vital signs 15 minutes after start of transfusion	Temp _____ HR_____ Resp rate _____ SBP _____DBP_____ O2 sat _____	Neuro status Lung sounds Bowel sounds Peripheral pulses Patient complaints ☐ None ☐ Pain (location) _____ ☐ Dyspnea ☐ Cough ☐ Other (specify) _____
Post-transfusion	Temp _____ HR_____ Resp rate _____ SBP _____DBP_____ O2 sat _____	Neuro status Lung sounds Bowel sounds Peripheral pulses Patient complaints ☐ None ☐ Pain (location) _____ ☐ Dyspnea ☐ Cough ☐ Other (specify) _____

APPENDIX H
SHAM EDUCATION FOR GROUP 1

1/17/2018

Patient Safety Considerations for Medications and Transfusions

Prior to administration of medications or transfusions

- Patient must be able to swallow, if pills or liquids are ordered
- Adequate IV access must be in place for IV meds or blood products
- Positive patient ID must be established before med or blood product administration

Safety Precautions

- Hand washing before entering and after leaving a patient room and before and after touching a patient
- Positive patient identification before medication and blood product administration

Safety points for specific meds or transfusions

- Blood pressure and pulse must be obtained prior to administration of antihypertensives or antidysrhythmic meds
- Blood glucose must be checked prior to administration of hypoglycemic meds
- Resp rate must be checked prior to narcotic administration
- A full set of vital signs must be obtained just prior to the start of a transfusion

Prior to administering medications or transfusions

- Confirm a clear indication for the need for the medication or blood product
- Confirm that there is a medical order indicating the medication or blood product to be administered
- Dose, route, frequency of administration must be included the order
- The patient may refuse a medication or transfusion
- Wash hands and don gloves prior to med or transfusion administration

Monitoring after the start of a med or a transfusion

- BP and pulse should be checked after administration of an antihypertensive
- Resp rate should be checked after a narcotic
- The patient should be monitored during the first 15 minutes of, 15 minutes after and at completion of a transfusion
- Changes in VS, neuro or resp status may indicate an adverse event related to medications or transfusions

If an adverse event is suspected

- If it's a medication
  - Call the provider to ask if the medication should be discontinued. Follow any medical orders given
- If it's a transfusion
  - Stop the transfusion, notify the provider and the blood bank; follow transfusion reaction protocol orders

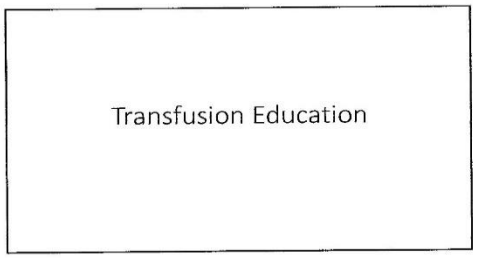
After the medication / transfusion is complete

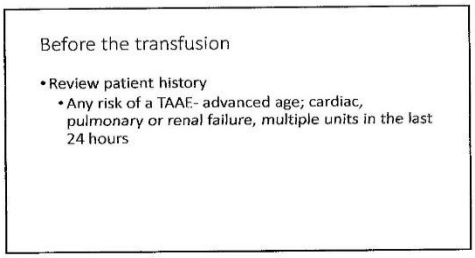
- Discard the transfusion container and tubing in a biohazard container
- IV medications may be discarded in regular trash
- Any portion of a narcotic not given to the patient must be witness/wasted
- Complete documentation of administration

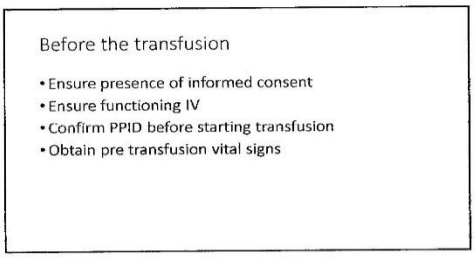
APPENDIX I

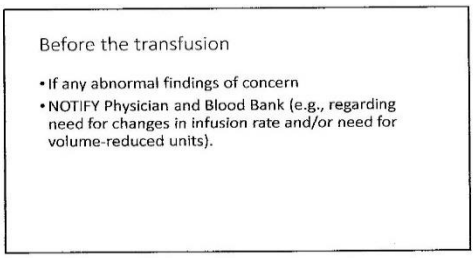
TRANSFUSION EDUCATION FOR GROUP 2

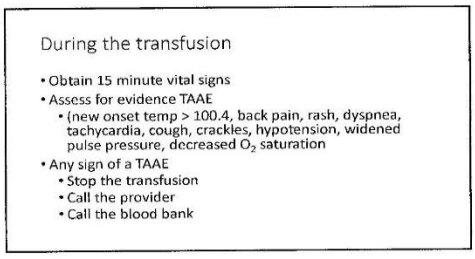
1/17/2018

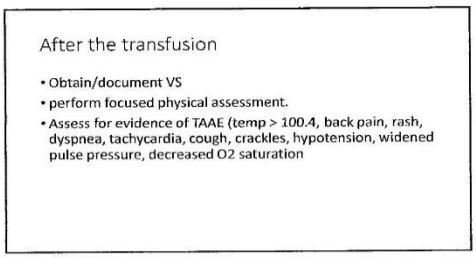












1

After the transfusion

- If any signs of suspected TAAE:
  - NOTIFY both Physician and Blood Bank
  - Send blood product, paperwork, and laboratory specimens to Blood Bank as requested/per institutional protocol

Post transfusion handoff

- Include information regarding any transfusion related issues/concerns including
  - number of units transfused in last 24 hours
  - significant laboratory values
  - changes in VS presence of a positive Fluid Balance, i.e., I>O
  - need for daily weights
  - any identified/reported adverse transfusion events, plans for further transfusion

APPENDIX J
Consent Form for Participation in a Research Study

University of Massachusetts Amherst

Researcher(s): *Elizabeth Henneman, Susan S. Scott*
Study Title The role of an educational intervention in the recognition of a patient adverse event

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.

This consent form will give you the information you will need to understand why this study is being done and why you are being invited to participate. It will also describe what you will need to do to participate and any known risks, inconveniences or discomforts that you may have while participating. 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.

2. WHO IS ELIGIBLE TO PARTICIPATE?

All nursing students in the third year of the Baccalaureate Nursing program at Westfield State University and nursing students in the Spring semester of the Accelerated Bachelor of Science in Nursing program at the University of Massachusetts Amherst. Subjects must be at least 18 years old to participate.

3. WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to identify if an educational intervention will have a positive impact on clinical performance in a simulated setting.

4. WHERE WILL THE STUDY TAKE PLACE AND HOW LONG WILL IT LAST?

This study is taking place in the simulation lab in either the Nettie Stevens Science Center at Westfield State University or the UMass simulation lab in Tower Square in Springfield MA in the Spring of 2018. Each session will last up to 30 minutes. You will not be contacted after completion of the study.

5. WHAT WILL I BE ASKED TO DO?

There are two parts to the research study. In the first part you will be asked to listen to an educational session and then participate in a patient simulation in which you will play the role of a nurse caring for a hospitalized patient. The second part of the study will entail completion of the NASA Task Load Index tool which you will be given instruction on how to complete. You may skip any question you feel uncomfortable answering

6. WHAT ARE MY BENEFITS OF BEING IN THIS STUDY?

You will benefit from this study by learning about patient safety. We hope that your participation in the study may contribute to the field of patient safety.

7. WHAT ARE MY RISKS OF BEING IN THIS STUDY?

We believe there are no known risks associated with this research study; however, a possible inconvenience may be the time it takes to complete the study.

8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

The following procedures will be used to protect the confidentiality of your study records. All data collected will be deidentified. The researchers will keep all study records, including any codes to your data, in a secure location in a locked file cabinet in Sue Scott's office. Research records will be labeled with a code. A master key that links names and codes will be maintained in a separate and secure location. The master key will be destroyed 3 years after the close of the study All electronic files including data bases and spreadsheets containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

9. WILL I RECEIVE ANY PAYMENT FOR TAKING PART IN THE STUDY?

You will receive a $10 gift card for participating in this study.

10. WHAT IF I HAVE QUESTIONS?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this project or if you have a research-related problem, you may contact the researchers, Sue Scott at 413.531.5852 or Elizabeth Henneman at 413.545.0405. If you have any questions concerning your rights as a research subject, you may contact the University of Massachusetts Amherst Human Research Protection Office (HRPO) at (413) 545-3428 or humansubjects@ora.umass.edu."]

11. CAN I STOP BEING IN THE STUDY?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate.

12.WHAT IF I AM INJURED?

The University of Massachusetts and Westfield State University do not have a program for compensating subjects for injury or complications related to human subjects research, but the study personnel will assist you in getting treatment.

13. SUBJECT STATEMENT OF VOLUNTARY CONSENT

When signing this form, I am agreeing to voluntarily enter this study. I have had a chance to read this consent form, and it was explained to me in a language which I use and understand. I have had the opportunity to ask questions and have received satisfactory answers. I understand that I can withdraw at any time. A copy of this signed Informed Consent Form has been given to me.

_____	_____	_____
Participant Signature:	Print Name:	Date:

By signing below, I indicate that the participant has read and, to the best of my knowledge, understands the details contained in this document and has been given a copy.

_____	_____	_____
Signature of Person Obtaining Consent	Print Name:	Date:

APPENDIX K

Sample Size Estimates Based on a Power of 80 and an Alpha of .05

Baseline Mean Time in minutes for all 3 groups at Baseline	Correlation	Sham Education Mean Time in minutes After Intervention	Transfusion Education Mean Time in minutes After Intervention	Transfusion Checklist Mean Time in minutes After Intervention	Sample Size for Between Effects	Sample Size for Within Effects
15	0.8	12	11	10	19	4
15	0.4	12	11	10	15	7
15	0.8	12	10	10	15	3
15	0.4	12	10	10	12	6
15	0.8	12	11	11	54	7
15	0.4	12	11	11	42	19
10	0.8	8	7	6	19	4
10	0.4	8	7	6	15	7
10	0.8	8	6	6	15	3
10	0.4	8	6	6	12	6
10	0.8	8	7	7	54	7
10	0.4	8	7	7	42	19

APPENDIX L

Safety Post-Test

Participant No: _____

1) Hand washing should be performed
    a. Prior to entering a patient room
    b. Prior to leaving a patient room
    c. After touching a patient
    d. All of the above

2) The patient's respiratory rate must always be checked
    a. Just prior to the administration of all antihypertensive medications
    b. Just prior to the administration of a narcotic
    c. Just prior to the administration of insulin
    d. Just prior to the administration of any analgesic

3) When administering a transfusion
    a. A full set of vital signs must be obtained just prior to beginning the transfusion
    b. A full set of vital signs must be obtained one hour after the transfusion has finished
    c. A full set of vital signs are only necessary if the product administered is red blood cells
    d. A full set of vital signs is not necessary just prior to the transfusion; only the patient's temperature must be taken

4) A functioning IV must be confirmed to be in place
    a. Prior to obtaining a blood product from transfusion services
    b. For 48 hours after the completion of any IV medication
    c. For 12 hours prior to the administration of a blood product or IV medication
    d. For 2 hours after a blood product or IV medication has finished

5) Prior to administering insulin to a patient, the nurse should
    a. Verify that the patient is not hypoglycemic
    b. Always obtain a set of vital signs
    c. Be sure the patient is not NPO
    d. Check the number of calories the patient has taken in, in the last 12 hours

6) Prior to the administration of any blood product the nurse should
    a. Check the patient's history for risk factors for a transfusion associated adverse event
    b. Check the patient for a history of diabetes
    c. Ask the patient if there is a family history of unexplained bleeding
    d. Ask the patient if either of his parents had an adverse reaction to anesthesia

7) A transfusion associated adverse event may
    a. Be identified by a change in heart rate, blood pressure, respiratory rate and/ or temperature
    b. Only occur while the transfusion is running
    c. Be reversed by speeding up the infusion rate of the blood product
    d. Be prevented by keeping the patient NPO during the transfusion

8) If a transfusion associated adverse event is suspected the nurse should immediately
    a. Administer naloxone to the patient and call the provider
    b. Stop the transfusion and call the provider
    c. Stop the transfusion and discard the blood product
    d. Switch the blood product to a different IV site

9) Unless there is an emergency, a consent form must be obtained prior to

a. Administering any medications
b. Admitting someone to the hospital
c. Administering a transfusion
d. Placing the patient on telemetry

10) Positive patient identification needs to be done
a. Right after administering a transfusion or medication
b. Right before administering a transfusion or medication
c. Only at the start of your shift
d. Only at the end of your shift

APPENDIX M

Recruitment Script

Hello, my name is Sue Scott. I am in the PhD program at UMass Amherst and am conducting a research study looking at patient safety. I am looking for nursing students who are interested in participating in the study. To be able to participate you need to have been educated in the administration of p.o. and subcutaneous medications, in the performance of a physical assessment, and have participated in human patient simulations. The study itself will take about 30 minutes of your time and you will receive $10 for your participation. The study will begin in February and will continue until we have gotten 60 participants. Please email me at susan_scottrn@comcast.net or call me at 413 531.5852 if you are interested in participating.

APPENDIX N

Pre and Post Intervention Process

	Sham Group	PowerPoint Group	Checklist Group
Pre-intervention	Simulation of febrile TAAE	Simulation of febrile TAAE	Simulation of febrile TAAE
Educational Intervention	Sham safety Powerpoint	TAAE Powerpoint	TAAE checklist education
Post-intervention	Simulation of TACO TAAE	Simulation of TACO TAAE	Simulation of TACO TAAE

APPENDIX O

Simulation Evaluation Questionnaire

Participant number _____

We are looking for feedback form the participants of this study. Please take a minute to answer these two questions. All feedback will be anonymous and confidential.

1) What did you find most useful in the simulation?

2) What did you find most stressful in the simulation?

Thank you for your input!!!

TABLES

Table 1 Age of Participants Across Groups

Age	Checklist n=20	PowerPoint n=20	Sham n=20
	No. of participants		
20	0	2	2
21-26	12	10	10
27-32	5	3	4
33-38	2	0	3
39+	1	4	1
No data	0	1	0

Chi Square alpha .05 df= 4

No significant difference in ages across groups Fisher's Exact *P* = .418

Table 2 Participants Experience Outside of School

Experience	No. of Participants
Has experience	40
Certified nurse aide	25
Emergency medical technician	3
Emergency department technician	2
Pharmacy technician	2
Lab technician	2
Other	6
Does not have experience	20

Table 3 Clinical Experience Across Groups

Clinical exp	Checklist N=20	Power Point N=20	Sham N=20
No	15 75%	18 90%	10 50%
Yes	5 25%	2 10%	10* 50%

Chi square test for across groups alpha .05; df=2;

Pearson chi2; = 8.0438 *P* = 0.018

*Significantly more clinical experience than other groups

Table 4 Number of Participants who Identified a Transfusion Associated Adverse Event Pre-intervention and Post-intervention Across Groups

Checklist n=20			PowerPoint n=20			Sham n=20			*P* across groups
Pre	Post	*P* within group	Pre	Post	*P* within group	Pre	Post	*P* within group	
14	20	.031*	10	20	.002*	12	18	.031*	.435

Chi Square Test for across groups alpha .05; McNemar's test for within groups
Abbreviation: No. ID, number of participants who identified a transfusion-associated adverse event. * Significant, $P < .05$.

Table 5 Mean Time to Identification of a Transfusion-Associated Adverse Event, in Seconds

	Checklist n=20			PowerPoint n=20			Sham n=20			*P* across groups
	Pre	Post	*P* within group	Pre	Post	*P* within group	Pre	Post	*P* within group	
	mean time (SD)			mean time (SD)			mean time (SD)			
Recog TAAE	614.2 (218.2)	398.6 (77.0)	<.001*	672.1 (239.6)	400 (111.2)	<.001*	612.1 (244.9)	460.9 (165.3)	.005*	.60

Paired t-test for within groups alpha .05 ; Repeated measures ANOVA for across groups alpha .05 . Abbreviations: pre, preintervention; post, postintervention; recog, recognition, TAAE, transfusion-associated adverse event. * Significant, $P < 0.05$.

Table 6 Repeated Measures ANOVA for Across Groups

	Partial SS	df	MS	F	Prob >F
Model	1457817.6	5	291563.52	8.31	0.0000
Group	97173.564	4	24293.391	0.69	0.5989
Pre vs Post	1360644	1	1360644	38.76	0.0000*
Residual	4001905.6	114	35104.435		
Total	5459723.2	119	45880.027		

Number of observations 120; R squared 0.2670; Adjusted R squared 0.2349; Root MSE 187.362 *significant

Table 7 Fixation Time on the Patient, Vital Signs and Blood Pre-intervention and Post-intervention in Seconds

AOI	Checklist n=20			PowerPoint n=20			Sham n=20			*P* across groups
	Pre	Post	*P* within group	Pre	Post	*P* within group	Pre	Post	*P* within group	
	mean time			mean time			mean time			
Patient	9.76	2.15	.027*	29.83	2.31	.002*	24.44	5.76	.01*	.69
VS	10.24	3.65	.008*	10.69	3.36	.006*	8.27	3.47	.02*	.13
Blood	0.53	0	.73	0.49	0	.002*	0.31	0	.01*	.82

Paired t-test for within groups, alpha .05; Repeated measures ANOVA for across groups alpha .05 Abbreviations: AOI, artifact of interest; pre, preintervention; post, postintervention; VS, vital signs. * Significant *P*=.05.

Table 8 Repeated Measures ANOVA for Fixation Times on Patient

	Partial SS	df	MS	F	Prob >F
Model	2.017e+09	5	4.035e+08	3.28	0.0087
Group fixation times	9.805e+08	4	2.451e+08	0.56	0.6917
Pre fix time vs Post fix time	2.770e+10	1	2.770e+10	14.04	0.0003*
Residual	1.204e+10	98	1.228e+08		
Total	1.406e+10	103	1.365e+08		

Number of observations 104; R squared 0.1435; Adjusted R squared 0.0998; Root MSE 11083.2

No significant difference across groups; *Significant difference within groups over time. Alpha =.05

Table 9 Repeated Measures ANOVA for Fixation Times on Vital Signs

	Partial SS	df	MS	F	Prob >F
Model	3.732e+09	5	7.465e+08	4.47	0.0010
Group fixation times	1.205e+09	4	3.012e+08	1.80	0.1345
Pre fix time vs Post fix time	2.531e+09	1	2.531e+09	15.15	0.0002*
Residual	1.638e+10	98	1.671e+08		
Total	2.011e+10	103	1.952e+08		

Number of observations 104; R squared 0.1856; Adjusted R squared 0.1441; Root MSE 12927

No significant difference across groups; *Significant difference within groups over time. Alpha =.05

Table 10 Repeated Measures ANOVA for Fixation Times on Blood

	Partial SS	df	MS	F	Prob >F
Model	2.850e+10	5	5.700e+09	9.04	0.0000
Group fix. times	9.805e+08	4	2.451e+08	0.39	0.8161
Pre fix time vs Post fix time	2.770e+10	1	2.770e+10	43.96	0.0000*
Residual	6.176e+10	98	6.302e+08		
Total	9.026e+10	103	8.763e+08		

Number of observations 104; R squared 0.3158; Adjusted R squared 0.2808; Root MSE 25103.7 No significant difference across groups; *Significant difference within groups over time. Alpha =.05

Table 11. Comparison of NASA-TLX Scores for Each Dimension and Total Scores for the Checklist, PowerPoint Education, and Sham Education Groups

	Checklist (n=20)	PowerPoint (n=20)	Sham (n=20)	*P* Value*
	score, mean (SD)			
Mental demand	66 (13)	61 (16)	63 (15)	.56
Physical demand	24 (19)	22 (16)	22 (16)	.93
Temporal demand	44 (23)	44 (19)	45 (20)	.99
Performance	53 (14)	49 (21)	50 (15)	.75
Effort	61 (14)	58 (20)	62 (13)	.67
Frustration	58 (21)	59 (29)	49 (24)	.41
Total mean score	60 (10)	59 (13)	57 (11)	.36

One- way ANOVA alpha.05. There were no significant differences between groups within each dimension or for total score.

Table 12. One-Way ANOVA Comparison NASA TLX Scores for Mental Demand

	SS	df	MS	F	Prob > F
Across groups	250.833333	2	125.416667	0.58	0.5639
Within Groups	12353.75	57	216.732456		

No significant difference across or between groups. *P*=.05

Table 13. One-Way ANOVA Comparison NASA TLX Scores for Physical Demand

	SS	df	MS	F	Prob > F
Across groups	40.8333333	2	20.4166667	0.07	0.9353
Within Groups	17377.5	57	304.868421		

No significant difference across or between groups *P*=.05

Table 14. One-Way ANOVA Comparison NASA TLX Scores for Temporal Demand

	SS	df	MS	F	Prob > F
Across groups	5.83333333	2	2.91666667	0.01	0.9932
Within Groups	24252.5	57	425.482456		

No significant difference across or between groups. *P*=.05

Table 15. One-Way ANOVA Comparison NASA TLX Scores for Performance

	SS	df	MS	F	Prob > F
Across groups	180.833333	2	90.4166667	0.32	0.7254
Within Groups	15962.5	57	280.04386		

No significant difference across or between groups *P*=.05

Table 16. One-Way ANOVA Comparison NASA TLX Scores for Effort

	SS	df	MS	F	Prob > F
Across groups	202.3	2	101.15	0.40	0.6734
Within Groups	14478.55	57	254.009649		

No significant difference across or between groups *P*=.05

Table 17. One-Way ANOVA Comparison NASA TLX Scores for Frustration

	SS	df	MS	F	Prob > F
Across groups	1125.83333	2	562.916667	0.90	0.4117
Within Groups	35598.75	57	624.539474		

No significant difference across or between groups. *P*=.05

Table 18. Comparison of Fixation Times on Artifacts of Interest for Non-identifers

	TAAE Non-identifiers n=22		TAAE Identifiers n=30		*P* Value
AOI	mean time (SD)	95% CI	mean time (SD)	95% CI	
Patient	56.60 (39.61)	39.03-74.16	15.35 (16.77)	9.09-21.62	<.001*
Blood	2.60 (3.35)	1.11-4.09	16.61 (33.19)	.42-29.01	.31
VS	20.38 (19.35)	11.80-28.97	12.80 (15.37)	7.06-18.54	.12
H&P	24.51 (23.48)	14.10-34.93	7.89 (19.13)	.74. -15.03	.007*

2 Sample T-test with equal variances alpha 0.5 df = 50

Abbreviations: TAAE, transfusion-associated adverse event; AOI, artifact of interest; VS, vital signs; H&P, history and physical.

* Significant, $P \leq 0.05$. P values based on original means in milliseconds; Times rounded to hundredths of a second for legibility of table.

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