THE IMPACT OF HYBRID SIMULATION EDUCATION ON MEDICAL-SURGICAL NURSES' KNOWLEDGE AND CONFIDENCE IN TRACHEOSTOMY CARE

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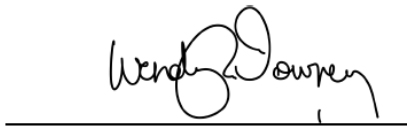

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Abstract

This study aimed to evaluate the effects of a didactic plus hybrid simulation education intervention on medical-surgical nurses' knowledge and confidence levels when providing tracheostomy care. Current literature reports a general lack of confidence and knowledge of evidence-based tracheostomy care practices amongst healthcare providers. A pretest-posttest design was used to study the effects of a brief didactic session combined with hybrid simulation on medical-surgical nurses' knowledge and confidence test scores. Nineteen medical-surgical nurses, 14 intensive care nurses, and three respiratory therapists at a small, rural hospital in southwest Virginia participated in the study. Mean scores of confidence and knowledge before and after the education intervention were analyzed using paired *t*-tests. There was a statistically significant difference in the pretest scores for knowledge and confidence compared to posttest scores for all nurses in the study. Years of experience and confidence pretest scores were found to be positively correlated to current knowledge and confidence scores, $r(34) = .30$, $p = .042$. No statistically significant correlations were found among the other variables. Limitations to this study included the small sample size and limitation to one hospital. Tracheostomy care is an important technical skill that must be performed safely and appropriately to prevent patient complications. The study results contribute to the development of best practices when teaching the important skill of tracheostomy care to increase healthcare providers' knowledge and confidence levels and improve patient outcomes.

Keywords: nursing care, tracheostomy, simulation, confidence, knowledge

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CHAPTER ONE. INTRODUCTION

Patients are vulnerable to potentially serious complications when undergoing high risk healthcare procedures such as tracheostomy care and suctioning. Approximately 1,000 serious tracheostomy related adverse events occur in the United States every year, with 500 of those incidents resulting in death (Klemm & Nowak, 2017). Tracheostomy care and suctioning are high-risk nursing skills often learned during students' undergraduate education. Decreased knowledge and skill in tracheal suctioning is evident in practicing nurses, not just undergraduate students (Day et al., 2009). These deficits in knowledge and skill competency in tracheal suctioning are significant in healthcare because they lead to patient harm, such as hypoxia, tracheal irritation, bleeding, cardiac dysrhythmias, infection, and even cardiac death (Mwakanyanga et al., 2018).

Educational interventions involving simulation have positive effects on knowledge and confidence of healthcare providers (Harjot et al., 2016). Many of these studies reportedly utilized expensive mannequin simulators requiring operator training and storage space when not used in an on-site simulation laboratory. A unique aspect of this study is the use of hybrid simulation, which combines more than one simulation modality during one educational session. This project combined a low-fidelity task trainer (Appendix F) with a standardized patient resulting in a high-fidelity simulation experience. The mobile task-trainer is low-cost and eliminates the need for an expensive simulator and the cost of operator training. Using the concepts from simulation theory and the International Nursing and Clinical Simulation and Learning (INACSL) best practice

standards, high quality simulation is possible with hybrid simulation methodology that is more cost-effective and feasible for hospitals.

Background and Significance

Tracheostomy care and patient safety became a worldwide focus in 2012 with the formation of the National Tracheostomy Safety Project (NTSP) in the United Kingdom. The NTSP began when a small group of physicians wanted to improve the care of tracheostomy patients who suffered complications, many times due to lack of knowledge of providers (NTSP, n.d.). The NTSP took a multidisciplinary approach to tracheostomy care by focusing on the key steps to prevent tracheostomy related emergencies, including training frontline staff, ensuring basic care was done well with adequate equipment, considering where these patients are managed within the healthcare system, and involving patients and families in their care (NTSP, n.d.). The Global Tracheostomy Collaborative (GTC) was also initiated in 2012 to address tracheostomy patient safety around the world through individual and institutional networking to share resources and information (GTC, 2020). The GTC reported that multidisciplinary team training/education and collaboration while collecting and evaluating data about patient care are necessary to improve patient safety.

Cheung and Napolitano (2014) reported that the number of tracheostomies in the United States increased from approximately 64,000 to over 100,000 from 1996 to 2014. Furthermore, the current COVID-19 pandemic is an evolving healthcare emergency. The number of patients requiring prolonged mechanical ventilation and tracheostomies due to this virus is currently unknown. If the current pandemic is protracted, issues of tracheostomy care integrity could become even more salient. The timing of this project is paramount to improve patient outcomes

by educating nurses on the best care practices for tracheostomy patients suffering from respiratory related complications.

Regardless of the extent of the current crisis, tracheostomy care will continue to be an issue to address, as it has been in recent years. Tracheostomy care education, particularly in non-otolaryngology healthcare providers, has been studied over the past two decades. Studies conducted over the past two decades report the further need for tracheostomy care education. Historically nurses have reportedly learned tracheostomy care skills "on-the-job" from practicing nurses. Dorton et al. (2014) reported that calling the otolaryngologist in addition to the code team when a patient emergency occurs involving a tracheostomy is appropriate, but most airway emergency treatment and troubleshooting should be initiated by the bedside nurse as first responder. Therefore, it is imperative that medical-surgical nurses be competent in tracheostomy care and how to handle tracheostomy related emergencies.

Problem Statement

In southwest Virginia, a small hospital has employed an otolaryngologist who will be performing tracheostomies, a new procedure for the medical-surgical healthcare team. There was a current need for continued tracheostomy education for all of the medical-surgical nurses in this hospital. Nurses working in non-critical care areas report a lack of knowledge and confidence when caring for patients with tracheostomies (Day et al., 2009). Tracheostomy care is considered a high-risk, low-volume procedure (Harjot et al., 2016). Studies by Clec'h et al. (2007) and Martinez et al. (2009) reported that mortality rates of tracheostomy patients increased when discharged from intensive care units to medical-surgical floors. Deficient knowledge of evidence-based tracheostomy care is shown as a major contributing factor (Dorton et al., 2014).

Current literature suggests there is a lack of evidence-based clinical practice when nurses care for patients with tracheostomies (Harjot et al., 2016). Deficient tracheal suctioning skill performance amongst nurses is a patient safety concern (Harjot et al., 2016). Identifying methods to teach those best practices is necessary to improve skill performance. Studies suggest that performance feedback and simulation improve knowledge and skill retention over time (Harjot et al., 2016). Simulation is an evidence-based teaching methodology used to improve assessment, critical thinking, and technical skills (Davis, 2019). This study combined didactic teaching with hybrid simulation to address the need to improve nurses' knowledge and confidence levels with evidence-based tracheostomy care.

Purpose Statement, Research Question

The purpose of this study was to evaluate the effectiveness of didactic plus hybrid simulation education on medical-surgical nurses' knowledge and confidence when caring for a patient with a tracheostomy. Research is lacking in studying the effects of hybrid simulation combining the use of low-cost task trainers with standardized patients for hospital continuing education. The study answered the following PICO question: For medical-surgical nurses (Population), how does a tracheostomy education session with simulation (Intervention) affect post-intervention knowledge and confidence scores (Outcomes) compared to pre-intervention scores (Comparison)? The independent variable was a simulation education intervention. Dependent variables were knowledge and confidence scores of medical-surgical nurses. The null hypothesis was there was no significant relationship between tracheostomy education with hybrid simulation and knowledge and confidence scores before and after the education session.

Theoretical Framework

Bandura's self-efficacy theory provides the primary theoretical framework for this study. Self-efficacy is the belief in one's ability to take action to overcome challenges and complete tasks appropriately. The formal definition of the theory states self-efficacy leads to behavioral changes, completion of performance tasks, and overall personal well-being (Bandura, 1997). A pictorial diagram of Bandura's self-efficacy theory is included in Appendix B. Applied to healthcare, Bandura's self-efficacy theory postulates that believing in one's ability leads to taking appropriate actions to achieve positive patient outcomes. Confidence is one of six constructs in this theory that was operationalized using a self-efficacy questionnaire in this study. Confidence along with knowledge were two dependent variables measured in this pilot study that theorized that increased confidence and knowledge will lead to appropriate care of tracheostomy patients using evidence-based guidelines for tracheostomy care.

Knowledge, another study variable, is the acquisition of information through education or experience. A brief didactic presentation plus simulation provided the opportunity for learners to acquire the knowledge needed to care for tracheostomy patients safely. Simulation enhances knowledge and confidence through experiential learning in a realistic practice setting without danger of harm to real patients. The National League for Nursing (NLN) Jeffries simulation theory proposes that an evidence-based simulation experience that provides opportunity for skill practice and knowledge acquisition results in improved learning outcomes. This simulation theory was used to design the simulation component of the education intervention. The applied assumption of using this theory to guide the development of the simulation intervention is that a well-designed simulation session will help learners acquire the knowledge and confidence needed to care for patients with tracheostomies. Coupled with Bandura's theory, the researcher

anticipated knowledge acquired through simulation learning will result in increased confidence to improve tracheostomy care resulting in positive patient outcomes.

The NLN Jeffries simulation theory is a new theory in nursing education. The Jeffries simulation framework demonstrated relationships between identified concepts in simulation and became a middle range theory in 2015. The concepts in this theory are context, background, design, the simulation experience, facilitator and educational strategies, participants, and outcomes (Jeffries, 2016, p. 40). Each concept consists of several factors (Appendix B, Figure 2). The context, background, and design influence the effectiveness of the simulation experience. With more appropriate planning in the design phase, the more pertinent and worthwhile the simulation experience is for the learner. Within the simulation experience, the interaction of the facilitator and participant is dynamic and learning must occur in order to result in a positive outcome.

In order to achieve this positive outcome, each concept of the Jeffries theory was included in the design of the hybrid simulation education in this study in a structured, intentional manner. Incorporating every concept ensures the simulation experience is experiential, collaborative, and learner centered. The concept of context encompasses the entire simulation experience. The context (setting) for the study was a rural hospital setting. The concept of background consists of learning objectives, time, and equipment. The learning objective was to increase the knowledge and confidence levels of medical-surgical nurses in performing tracheostomy care according to evidence-based guidelines. The time for the study was estimated to occur over four or five educational sessions. Equipment needs were minimal. Hybrid simulation equipment was already available along with the innovative task trainer. Space was reserved for the educational session through coordination with the hospital's clinical educator.

The simulation design was high fidelity with realistic moulage. The study incorporated all the attributes of the simulation experience concept by being experiential, collaborative, and learner centered. The concept of facilitator and educational strategies was met by involving dynamic interaction between a certified healthcare simulation educator (the researcher) and nurse learners. The independent variable, an educational intervention, in the research question aligned with this concept. The concept of participants involves attributes such as level of anxiety and self-confidence and role assignments. Participants are all medical-surgical nurses. Anxiety and self-confidence were relieved by facilitator experience in promoting an environment conducive to learning. The concept of outcome may be at the participant, patient, or system level. This study fell under the participant level on the outcomes pyramid. Ideally, future research will be conducted to evaluate the effect of competent tracheostomy care on individual patient outcomes and hospital-wide outcomes. In this study, the desired participant level outcomes were increased knowledge and confidence.

A recent study utilizing the Jeffries simulation theory discussed the effects of simulation on the competency of medication administration in nursing students. The authors discussed how the context, design, and facilitator strategies resulted in demonstrated competence of medication administration by the nursing students in the study (Jarvill et al., 2018). The principles of thoughtful planning of simulation activities along with the INACSL standards for best practice yield the best results when applied to the simulation experience concept of the Jeffries simulation theory. This study utilized this theory in designing the simulation education intervention with the aim of improving knowledge and confidence.

CHAPTER TWO. LITERATURE REVIEW

A review of the literature revealed a variety of education intervention strategies utilized to study the effects on knowledge and confidence of tracheostomy management. The literature review aided in establishing the design and appropriateness of the didactic plus simulation intervention and measurement of knowledge and confidence as dependent variables. This section discusses the factors that were considered when developing the education intervention and design of the study. Refer to the integrated/synthesized tables of evidence in Appendix D for detailed information of the review of studies discussed in this section.

Search Strategies and Search Outcomes

An integrative review of the literature was first conducted using the super search option through Radford University's McConnell Library. The super search option includes relevant fields of study pertinent to this project including the healthcare, psychological, behavioral, and social sciences. Keywords in the search included tracheostomy, nurse, simulation, and knowledge using the scholarly, peer-reviewed filter in the 2015-2020 date range. The Cochrane, OVID Medline, PubMed, and CINAHL databases were searched with confidence" and "simulation" included as additional keywords. Finally, a hand search through relevant article references, specialty journals, and Google Scholar with the same keywords and filters was conducted. After duplicates were removed and irrelevant articles were excluded, 14 articles were included in this literature synthesis. Inclusion criteria were articles discussing tracheostomy management, and pre and post licensure nurses, physicians, healthcare students, respiratory therapists, speech therapists, physical, and occupational therapists. Though reviewing articles with a simulation education intervention versus general education for practicing nurses was the focus, the inclusion criteria were broad as there was not a large number of articles pertaining to

such a specific focus, indicating a need for further research in the area of simulation education in acute care. The PRISMA diagram and search summary table are located in Appendices C and D.

An identified lack of randomized controlled studies on the best way to educate healthcare professionals on tracheostomy care also exists. The majority of the reviewed studies were Level IV evidence studies. Two studies were ranked as level III, one study ranked as level II, and one systematic review was included in this review. Levels of evidence in the summary table in Appendix D are based on the Melnyk and Fineout-Overholt (2015) rating system.

Effective Education Interventions for Tracheostomy Care

Education Modality and Its Effects

Different educational modalities have been used to improve the learners' knowledge and confidence with tracheostomy care, including didactic lectures, simulation, and didactic plus simulation sessions.

Didactic. Several studies used didactic lecture-type education as the education modality and most studies reported increased knowledge and confidence right after the education. Colandrea and Echkardt (2016) reported statistically significant differences in the group means of pretest and posttest scores of comfort and competency following a lecture with $p < 0.001$. Thirty-six nurses participated in the study to look for the effect of lecture on comfort and competence (Colandrea & Echkardt, 2016). Similarly, Harjot et al. (2016) also reported that posttest knowledge and skill scores increased after use of didactic education.

Didactic and Simulation. Dorton et al. (2014) reported increases from pre to post knowledge and comfort scores with $p < 0.0001$ for both variables following the use of a didactic and simulation educational intervention. Similarly, Mehta et al. (2019) reported statistically significant increases in knowledge and comfort scores following a didactic teaching session with

simulation, but the knowledge scores were not statistically significant at 6 months post intervention, indicating the need for re-training every 6 months. Furthermore, Davis et al. (2019) measured skill performance in addition to knowledge and confidence following a didactic plus simulation education session. The authors reported a statistically significant increase from pretest to posttest scores when assessing physicians' knowledge, skill, and comfort with tracheostomy care ($p < 0.009$ comfort, $p < 0.001$ knowledge, $p < 0.001$ skill) (Davis et al., 2019).

The McDonough et al. (2016) study, which reported increased knowledge and confidence of nurses, included the largest sample size of 1,450 hospital nurses that completed hands-on training about tracheostomy care followed by online tutorials. After the intervention, the knowledge and confidence increased. An inference from these findings is that the combined didactic plus low-fidelity hands-on simulation session was effective in improving knowledge and confidence in a short timeframe versus hours or days of training.

Sandler et al. (2020) reported increased confidence scores post intervention with didactic plus hybrid simulation when using a low-cost tracheostomy task-trainer in settings with limited resources. This finding implies that high-cost mannequin simulators and equipment may not be necessary for improving knowledge and confidence of providers and that high-fidelity education with a task-trainer can still improve knowledge and confidence of tracheostomy care.

Simulation: low fidelity versus high fidelity. Two studies reported using simulation only in the education intervention. Bayram and Caliskan (2019) reported using a virtual reality application to teach tracheostomy care to nursing students, and the knowledge scores were not statistically significant. When using high-fidelity scenarios with virtual simulation, statistically significant increases in knowledge and confidence were reported (Goldsworthy et al., 2019). These findings indicate that meaningful learning occurred when incorporating high fidelity

scenarios requiring clinical reasoning. Low-fidelity task trainers are effective for psychomotor skill acquisition. Al-Qadhi et al. (2014) concluded that an innovative chest-tube insertion task-trainer was superior to large and expensive mannequin simulators when teaching the skill to pediatric physicians. An inference from the study is that lower cost task trainers may be just as or more effective than traditional expensive mannequin simulators for psychomotor skill training. Low-fidelity task trainers combined with other simulation modalities in a hybrid manner can be used to provide a more realistic, or higher fidelity, simulation experience versus a lower fidelity simple skill check-off.

Duration and Frequency of Education Sessions

A relationship may exist between the length and frequency of the education intervention and its effects on knowledge and confidence. The literature review revealed that the duration and frequency of the education interventions ranged from 30 minutes to 4 months. Yelvert et al., (2015) and Colandrea and Eckardt (2016) used a didactic-only approach through 45 minutes to 1 hour of lecture, and knowledge and confidence increased in both of these studies. When nurses in Japan completed a 4-month-long educational program to achieve tracheostomy care certification, statistically significant improvements in patient complications, ICU readmissions, decannulations, and lengths of hospital stay occurred (Sodhi et al., 2014). However, most hospitals that do not regularly treat patients with tracheostomies very often do not have the resources and time to certify all nurses. Perhaps hospitals could consider training tracheostomy nursing care specialists to serve on a multidisciplinary care team and provide in-services and ongoing staff education for other nurse and providers. Many hospitals are considering this team-based approach but are located in urban areas with larger hospitals (Davis, 2019).

Timing of Variable Measurement

In most studies, measurements of the study outcomes occurred at the time of the education intervention up to 6 months post-intervention. When outcome variable (knowledge, confidence, and/or skills) measurement occurred immediately following the intervention compared to 6 months post-intervention, knowledge levels increased significantly no matter the timeframe in all studies except one. The effect of education has shown to persist over 6 months. Mehta (2019) studied the effects of a didactic and simulation education intervention on medical residents' post-session levels of knowledge and confidence with tracheostomy management. Post-session knowledge scores at 6 months remained increased although it was not statistically significant (Mehta, 2019). The reason for the lack of a statistically significant change in knowledge is not discussed, though several reasons exist such as exposure and experience with tracheostomy patients during the 6-month timeframe. One conclusion is that confidence levels are not always indicative of knowledge attainment and retention. This study analyzed both knowledge and confidence scores.

Study Variables

Knowledge

The predominant dependent variables in the reviewed studies are knowledge and confidence of tracheostomy care. A few studies included skill performance as an outcome. Skill was not measured in this study due to time and feasibility. Skill measurement in small groups of nurses may result in distorted metrics as psychomotor skills are individually assessed on most checklists. The exclusion of skill measurement did not appear to affect the significance of knowledge and confidence level scores in several studies (Colandrea & Echardt, 2019; Gaur &

Mudgal, 2018; Goldsworthy et al., 2019; McDonough et al., 2016; Mehta, 2019; Sandler et al., 2020; Smith-Miller, 2006; Sodhi et al., 2014; Yelver et al., 2015).

The effect of the education intervention on knowledge was measured in this study. In this literature review, statistically significant increases in knowledge levels post-intervention were reported in all studies that measured this dependent variable except one study utilizing virtual reality (Bayram & Caliska, 2019). Knowledge retention was also a factor reported in several studies. Knowledge was reportedly retained in studies that measured posttest scores again at 6 months. However, the literature does not mention collecting information on whether these study participants who retained knowledge also gained experience and exposure to tracheostomy patients during the posttest and 6-month repeat posttest time periods. The effect of experience and exposure was collected in most studies as a demographic variable, but the literature is lacking in how influential this experience is on the retention of knowledge as opposed to the education interventions alone. Skills must be practiced to be maintained, so the question for nurse leaders is how often continuing education should be conducted to maintain staff nurse competency. Most hospitals implement annual competencies. Future research to determine the adequacy of annual training is necessary. In Yelverton et al.'s (2014) study, nurses and physicians retained tracheostomy care knowledge; however, these study participants reportedly had frequent exposure to tracheostomy patients. This finding leads to the question of which variable is more effective over time. Whether the educational intervention or frequent exposure and experience is more effective needs to be studied. A comparison study of the degree of difference in knowledge retention between study groups that do not have frequent exposure and those that do is a need for further research. This study included analysis of the following

confounding variables: prior knowledge, tracheostomy exposure, years of practice, and years of education.

Confidence

Confidence was the second dependent variable measured in this study. Seven out of 14 studies in the literature review reportedly measured the effect of educational interventions on confidence levels. Confidence levels increased in all seven studies regardless of the type of education, target population, or setting.

Linking simulation education to patient outcomes is an identified gap in simulation research (Davis et al., 2019). McDonough et al. (2016) suggested adding a patient adverse event outcome as a dependent variable to help address this gap. Linking simulation education to patient outcomes such as decreased tracheostomy complications and shorter hospital lengths of stay may be researched in future studies.

Demographic Factors

Confounding variables such as prior knowledge, education level, previous experience, and exposure to tracheostomy patients were not consistently reported in the literature. However, a few studies did identify these variables as significant factors affecting knowledge and confidence (Yelverton et al., 2014). The target populations in the reviewed studies ranged from nursing students to advanced practice nurses and physicians.

Dorton (2014) reported that medical residents had lower comfort level scores than nurse practitioners, suggesting that decreased comfort levels with tracheostomy care span across multiple healthcare disciplines and levels of education. No statistically significant differences were reported in scores of knowledge and confidence in tracheostomy care between associate-degree and baccalaureate prepared nurses (Smith-Miller, 2006). Yelverton et al. (2014) studied the effects of a targeted education program on medical residents', midlevel providers', and

nurses' comfort and knowledge levels. Post-intervention scores reportedly increased, but it is important to note that all the participants in this study stated they had frequent exposure to tracheostomy patients. A targeted education intervention is effective; however, the degree of effectiveness of education over experience is not clear. A one-way ANOVA was performed for 6-month follow-up scores and no significant change in knowledge was reported from posttest to 6-month data collection points (Yelverton et al., 2014). This finding suggests the education intervention did possibly contribute the most to increased knowledge versus exposure to tracheostomy patients in that 6-month period.

Setting and the Impact on Outcomes

The acute care hospital was the setting for most studies. Academic settings, such as universities with simulation or skills laboratories, were the sites for two studies (Bayram & Caliska, 2019; Goldsworthy et al., 2019). Knowledge reportedly increased in all of the reviewed studies except one, so the setting does not appear to be a significant factor in influencing whether the education intervention is effective.

Measurement Instruments

Validated tools to measure knowledge of tracheostomy care are lacking in the literature. In most studies, the knowledge assessment tools were piloted only, so no data exist on validity and reliability over time and repeated use. Yelverton et al. (2014) also reported the lack of validated tools for measuring tracheostomy care knowledge as a study limitation. The "Tracheostomy Pretest" was designed by and checked for face validity by otolaryngologists, otolaryngology nurse specialists, respiratory therapists, pulmonologists, a psychologist, and pediatric chief residents and can be adapted for various healthcare disciplines and specialty areas

(Davis, 2019). This “Tracheostomy Pretest” was used pre- and post-intervention. This test was also used to collect confounding variable information.

Current Practice Guidelines

Review of the most current literature on tracheostomy management confirmed a concerning lack of standardized, evidenced-based practice guidelines in the United States. The clinical consensus statement by the American Academy of Otolaryngology Head and Neck Surgery foundation contains discussion of a systematic review, Delphi surveys, and expert panel consensus resulting in 77 key statements for guidance when providing tracheostomy care (Mitchell et al., 2013). However, the American Academy of Otolaryngology have not published any national clinical practice guidelines in the United States for tracheostomy care. While the areas of tracheostomy tube care and airway management were agreed upon by the academy in the consensus statement, several other areas of acre lacked consensus such as how deep to insert a suction catheter and what type of solution to use for inner cannula cleaning (Mitchell et al., 2013). The lack of consensus in several areas of tracheostomy care and lack of standard clinical practice guidelines may be large contributing factors to the lack of knowledge and decreased comfort levels reported by nursing and other healthcare disciplines in several studies. A lack of standardized clinical practice guidelines contributes to the varying facility and unit policies and procedures, differing educational interventions, and lack of validity and reliability of measurement tools utilized in studies. Education interventions in most studies were tailored to facility policy versus key statements in the clinical consensus statement form the American Academy of Otolaryngology, considered the authority on tracheostomy care.

The level IV studies in this review utilized a pretest-posttest design. Independent t-tests and Wilcoxon signed ranks were used to analyze the data in these studies and results were

promising that an educational intervention resulted in increased knowledge, confidence, and skill for the learners.

Summary

In summary, most studies showed that education, whether didactic, simulation, or didactic, plus simulation were shown to be effective to improve the learner's knowledge and confidence after the education. However, it is difficult to ascertain which type of education intervention is most effective to improve knowledge and confidence because there is a lack of experimental comparison studies. The incorporation of high-fidelity simulation scenarios is superior to basic skill training alone and can lead to more meaningful learning by requiring clinical reasoning and reflection during the debriefing process. The effect of education was persistent when using a low-cost, hybrid simulation combined with high-fidelity simulation following presentation of didactic content. Only one valid instrument to measure nurses' knowledge and confidence was used in more than one study. There are no universally used clinical practice guidelines for providing tracheostomy care. Evidence-based guidelines from a consensus statement issued by American Academy of Otolaryngology were used in the most rigorously designed studies.

CHAPTER THREE. METHODOLOGY

Study Design

The project was a quasi-experimental, one-group pretest-posttest design. The study intervention was an educational session consisting of a didactic component followed by hybrid simulation scenarios. This study aimed to measure knowledge and confidence of nurses, though the ultimate outcome is a reduction of tracheostomy-related complications and improved patient safety.

This study incorporated evidence-based didactic content used in the Agarwal et al. (2015) and Davis et al. (2019) studies. The didactic content was based on evidence-based practice standards from the American Academy of Otolaryngology and core curriculum for otolaryngology and head-neck nursing, and education session content and teaching modalities were reviewed and approved by the regional clinical education team to align with the Donna Wright competency model required by the corporate agency. This study included hybrid, high-fidelity simulation in the education intervention since high-fidelity simulation appears to affect knowledge and confidence scores. Additionally, the researcher holds specialty certifications in clinical education, simulation, and medical-surgical nursing with a clinical practice background in otolaryngology.

In previous studies, the simulation aspect of most education interventions occurred on-site in hospitals or in academic settings with expensive mannequin simulators or in simulation laboratories. Most small, rural hospitals, such as the one in this study, lack access to mannequin simulators and do not have dedicated simulation laboratories on site. A hybrid simulation approach with a task-trainer and standardized patient was used to eliminate the need for

mannequins and with minimal equipment needs. All equipment used for this study is portable and requires minimal space.

The study fulfilled annual competency requirements for nurses working on medical surgical and intensive care units at a rural hospital. The hospital clinical educator was present for each education session to assist with attendance records and document skill performance of the participants to meet the annual competency requirements. The education session was also open to respiratory therapists who voluntarily chose to participate. The project was supported by the chief nursing officer, unit directors, and clinical education nurse leaders in the hospital.

The study participants first completed the "Tracheostomy Pretest" (Davis et al., 2019), followed by a researcher-facilitated didactic session and prebriefing prior to simulation. Then the researcher applied the tracheostomy task-trainer and assumed the role of the standardized patient. The researcher conducted a didactic teaching session followed by four brief, hybrid simulation scenarios. The "Tracheostomy Pretest" consisted of questions about confidence, knowledge, and demographics (Davis et al., 2019). The same pretest was administered after the education intervention, omitting the demographic questions. The entire education intervention lasted 90 minutes, including time to complete the pretest and posttest. This 90-minute approach was supported by the literature as studies reported increases in knowledge and confidence with both shorter and longer duration of education interventions.

Sample

The study subjects were from a convenience sample of medical-surgical nurses, intensive care nurses, and respiratory therapists employed at a rural hospital in southwest Virginia. The anticipated sample size was 20 registered nurses. The actual sample size was 36 participants. The chief nursing officer required study subjects to participate in the education intervention for

continuing education purposes to meet annual competency requirements of the corporate agency. See Appendix A to view the permission granted letter from this local hospital's chief nursing officer.

Setting

The setting for this study was a small facility in rural, southwest Virginia. LewisGale Alleghany hospital hired a new otolaryngology provider, and the nurses were in need of continued education in tracheostomy care. The equipment needed for the education intervention was portable so minimal space was needed in accordance with facility and Centers for Disease Control (CDC) guidelines to minimize infection risk from COVID-19.

Study Instrument

The "Tracheostomy Pretest" (Davis et al., 2019) was administered to the participants both pre and post intervention and measures confidence and knowledge when caring for a patient with a tracheostomy. The instrument was reported as reliable with a Cronbach $\alpha = 0.641$ and is reproducible in various training institutions (Agarwal et al., 2015; Davis et al., 2019). See Appendix E for the instrument and permission for use requested from the author.

The literature review revealed this pretest is the only instrument used in more than one study and was administered to physicians and nurses. Most researchers developed their own instruments, which results in a lot of variation from instrument to instrument. This pretest was the only instrument in the literature review that addresses all of the most common areas in which healthcare providers lack knowledge and confidence in tracheostomy care. These common areas include parts of a tracheostomy tube, differences in types of tubes, indication for trach tubes, basic care, and handling emergencies.

The instrument contains 10 self-efficacy questions and 20 knowledge questions, along with four demographic information questions. Minor wording revisions were made to correlate to the medical-surgical registered nurse scope of practice. The self-efficacy questions measured confidence using a Likert scale, while the knowledge questions are formatted as single response, multiple-choice questions. The demographic questions were revised to correspond to the sample population.

Education Intervention

Following completion of the pretest, a 20-minute didactic presentation was presented based on evidence-based guidelines from the Mitchell et al. (2013) consensus statement and the American Academy of Otolaryngology, both medical and nursing divisions. The didactic content was abbreviated to meet the needs and scope of practice standards for registered nurses. The original content is located from the Davis et al. (2019) study.

After the didactic presentation, learners began the simulation portion of the education intervention. The most recent CDC recommendations for preventing transmission of COVID-19 were incorporated into the didactic and simulation portions of the education session. The INACSL standards were followed. The researcher, who is a certified healthcare simulation and clinical nurse educator, facilitated all aspects of the education intervention including simulation. The facilitation of simulation by a certified educator and certified medical-surgical nurse is unique to the studies in the literature review. No other study mentioned facilitation of the entire education intervention and simulation by one person with certification and adequate clinical practice training. The researcher served as a standardized patient instead of the need to use a large, expensive mannequin simulator. Four short simulation sessions included scenarios

addressing respiratory distress, suctioning, accidental decannulation, mucus plugs, and respiratory arrest in a laryngectomy patient.

The researcher requested the participants attend the education sessions in small learner groups of three to four nurses. The didactic content was presented to the group with hands-on visual aids. Each individual learner was provided an opportunity to practice closed tracheal suctioning. Then the group participated in the short hybrid simulation sessions using team-based decision-making strategies. Debriefing occurred immediately after each of four short simulation experiences. Appropriate personal protective equipment was required according to infection control policies and COVID-19 guidelines of the institution.

The NLN simulation design template attached in Appendix G serves as the guidance document for the pre-briefing, simulation, and debriefing components of the simulation portion. According to the literature, non-critical care nurses need education on how to handle tracheostomy emergencies along with basic care education. Four short simulation scenarios were facilitated by the researcher pertaining to basic assessment of the respiratory system, auscultation of rhonchi, and need for suctioning. The tracheostomy inner cannula contained a mucus plug in one other scenario to allow nurses the opportunity to think critically about how to handle the situation and ensure patient safety. The objective was for the inner cannula to be removed, cleaned, and replaced while reassessing and evaluating the patient's oxygenation status. Basic stoma care and cleaning should then have been performed after ensuring a patent airway. The learning objective for the third scenario was to assess a patient after accidental decannulation to determine the appropriate action. The last scenario pertained to a patient with a laryngectomy who needed rescue breathing assistance to give the nurse learner the opportunity to think

critically about how to deliver oxygen to this laryngectomy patient. Each scenario was brief, lasting 10 minutes.

Simulation learners participate in learner-centered, hands-on reinforcement of delivered content in an environment without fear of real patient harm when making mistakes (Arnold & Diaz, 2016). Pritchett et al. (2015) reported increased parental comfort with simulation teaching of pediatric tracheostomy care, but the study also highlighted a lack of consistent instruction. Standardized simulation education of tracheostomy care addresses the problem of a lack of effective, consistent patient teaching to prevent emergencies such as airway obstruction.

When evaluating tracheostomy management, best practice standards are imperative. A literature review conducted by Khimani et al. (2015) aimed to determine whether evidence-based practices were being used by healthcare professionals while tracheal suctioning. The researchers discovered that patient safety is improved when evidence-based guidelines are followed including hyper-oxygenation, lower suction pressures, and using appropriate sized catheters (Khimani et al., 2015). McKinley et al. (2018) also concluded that best practices such as omitting routine saline instillation reduces complications due to tracheal suctioning. These evidence-based guidelines were included in the didactic portion of the education intervention.

Based on the literature review, several aspects of knowledge deficit with tracheostomy care were identified including knowledge of parts of a tracheostomy tube, differences in types of tubes, indications for tracheostomy tubes, basic care, and handling emergencies (Dorton, 2014; Smith-Miller, 2006). Therefore, these aspects were covered during the didactic portion and correlate with the chosen knowledge survey based on the American Academy of Otolaryngology clinical consensus statement and evidence-based practice guidelines.

Data Collection and Storage

The pretest and posttest versions of the "Tracheostomy Pretest" were administered and collected by the researcher and kept in a locked office in the Radford University Clinical Simulation Center. No participant names were included on the pretests and posttests. A numerical identifier was assigned to each participant. This numerical identifier was chosen by the participant and written on both the pretest and posttest.

Ethical Issues

Approval as Non-Human Subjects Research was obtained from the LewisGale and Radford University Research Compliance Offices. See Appendix H to refer to the authorization letters from each institution. All licensed nurses and respiratory therapists were eligible to participate in the study. There were no exclusion criteria such as educational background, age, sex, years of practice, or frequency of exposure to patients with tracheostomies.

Debriefing is a standard part of the simulation process. Researcher bias was minimized by using standardized methods for the simulation during the data collection points. Learners' identities were not concealed from the data collection researcher; however, the researcher is a certified healthcare simulation educator specially trained in conducting simulation. Since simulation can be stressful as learners are asked to perform independently in unfamiliar scenarios, incorporating best practices into all aspects of the simulation activities protects the psychological safety of the participants (INACSL Standards Committee, 2016).

The risk of COVID-19 transmission was reduced by following strict adherence to facility guidelines and the CDC recommendations for cleaning and disinfection.

Analysis

The first 10 questions on the "Tracheostomy Pretest" ask the learner to rate the level of confidence (dependent variable) using a Likert-type scale from 0-5 (0 = not confident at all, 5 = very confident). The possible scores of participants range from 0-50, making confidence a continuous level dependent variable. Scores on the "Tracheostomy Pretest" from the same group of participants will be compared pre and post intervention using a paired *t-test* (Polit & Beck, 2017, p. 384). The next 20 questions of the "Tracheostomy Pretest" measure the dependent variable of knowledge. These questions are in multiple-choice format with a possible range of correct responses from 0-20, making it a continuous level variable. A paired *t-test* is also appropriate for analyzing the data from the knowledge portion of the test (Polit & Beck, 2017, p. 384).

The demographic questions on the "Tracheostomy Pretest" were derived from the literature because they are possible confounding variables. These demographic questions included whether the nurse had previous tracheostomy education, length of practice experience, the approximate number of tracheostomy care patients cared for in the past year of practice, and level of education of the nurse. Pearson correlations were computed to look for relationships between confounding variables and each of the dependent variables.

A power analysis is ideal to determine the effect size (Polit & Beck, 2017, p. 260). According to a power analysis calculator for *t-test*s, a sample size for a one-tailed *t-test* (to measure whether test scores increase) with Cohen's d of 0.5, power level of 0.8, and a probability level of 0.05, the total sample size is 51 for one group (Soper, n.d.). Since the sample size was only 36, this project is considered a pilot study.

CHAPTER FOUR. RESULTS

Thirty-six study participants completed the study. One study participant was called away to direct patient care and missed at least 50% of the education session and did not complete the confidence level questions on the posttest. These missing data were deleted. Nineteen participants were medical surgical nurses, 14 participants were intensive care nurses, and three were respiratory therapists. Data were collected between December 1, 2020 and January 6, 2021 during several sessions on eight different days.

Research Question Analysis

For medical-surgical nurses, how does a 1.5 hours tracheostomy education session with hybrid simulation affect post-intervention knowledge and confidence scores compared to pre-intervention scores?

Major study variables included the education intervention of the independent variable and two dependent variables, knowledge and confidence. Paired samples t-tests were conducted using IBM SPSS 25 statistical software to compare mean test scores of knowledge and confidence on all study participants before and after the education intervention (Table 1). There was a significant difference in the pretest scores for knowledge ($M = 51.53$, $SD = 10.61$) compared to posttest scores ($M = 80.14$, $SD = 11.24$); $t(35) = -12.112$, $p < .001$. There was also a significant difference in the pretest scores for comfort ($M = 21.51$, $SD = 9.17$) compared to posttest scores ($M = 37.6$, $SD = 7.31$); $t(34) = -10.143$, $p < .001$. Based on these results, the null hypothesis was rejected.

Table 1

Paired Samples t-test Results for All Study Participants (n = 36)

Confidence score	Mean score ± SD	Paired *t-test* value	df	p value
Pretest	21.51 ± 9.17	-10.14	34	< .001
Posttest	37.6 ± 7.31			
Paired	-16.09 ± 9.38			
Knowledge score	Mean score ± SD	Paired *t-test* value	df	p value
Pretest	51.53 ± 10.61	-12.11	35	< .001
Posttest	80.14 ± 11.24			
Paired	-28.61 ± 14.17			

Paired samples t-tests were then conducted for the subgroups of medical-surgical nurses, intensive care nurse, and respiratory therapists. In medical-surgical nurses, there was a significant difference in the pretest scores for knowledge (M = 50.53, SD = 10.92) compared to posttest scores (M = 80.26, SD = 10.73); t(18) = -12.076, p < .001. There was also a significant difference in the pretest scores for comfort (M = 19.89, SD = 10.02) compared to posttest scores (M = 38.50, SD = 6.19); t(17) = -8.76, p <. 001 (Table 2).

Table 2

Paired Samples t-test Results for Medical Surgical Nurses (n = 19)

Confidence score	Mean score ± SD	Paired *t-test* value	df	p value
Pretest	19.89 ± 10.02	-8.76	17	< .001
Posttest	38.5 ± 6.19			
Paired	-18.61 ± 9.02			
Knowledge score	Mean score ± SD	Paired *t-test* value	df	p value
Pretest	50.53 ± 10.92	-12.08	18	< .001
Posttest	80.26 ± 10.73			
Paired	-29.74 ± 10.73			

The results for intensive care unit (ICU) nurses were similar to medical-surgical nurses. There was a significant difference in the pretest scores for knowledge (M = 51.07, SD = 11.12) compared to posttest scores (M = 81.07, SD = 10.03); t(13) = -6.89, p < .001. There was also a significant difference in the pretest scores for comfort (M = 21.64, SD = 7.81) compared to posttest scores (M = 37.5, SD = 6.25); t(13) - 9.026, p < .001 (Table 3).

Table 3

Paired Samples t-test Results for Intensive Care Unit Nurses (n = 14)

Confidence score	Mean score ± SD	Paired *t-test* value	df	p value
Pretest	21.64 ± 7.81	-9.03	13	<.001
Posttest	37.5 ± 6.25			
Paired	-15.86 ± 6.57			
Knowledge score	Mean score ± SD	Paired *t-test* value	df	p value
Pretest	50.53 ± 11.12	-6.90	13	<.001
Posttest	81.07 ± 10.03			
Paired	-30.0 ± 16.29			

The results for respiratory therapists differed from medical-surgical and ICU nurses. There was not a significant difference in the pretest scores for knowledge (M = 56.67, SD = 7.64) compared to posttest scores (M = 75.0, SD = 21.79); t(2) = -1.408, p = 0.294. There was also not a significant difference in the pretest scores for comfort (M = 30.67, SD = 5.51) compared to posttest scores (M = 32.67, SD = 16.92); t(2) -0.266, p = 0.815 (Table 4).

Table 4

Paired Samples t-test Results for Respiratory Therapists (n = 3)

Confidence score	Mean score ± SD	Paired *t-test* value	df	p value
Pretest	30.67 ± 5.51	-0.27	2	.294
Posttest	32.67 ± 16.92			
Paired	-2.00 ± 13.0			

Knowledge score	Mean score ± SD	Paired *t-test* value	df	p value
Pretest	56.67 ± 7.64	-1.41	2	.815
Posttest	75.0 ± 21.79			
Paired	-18.33 ± 22.55			

Additional Statistical Analysis

A Pearson correlation coefficient was computed to assess the relationship between prior knowledge, experience, education level, and years of practice to current knowledge and confidence scores (Table 5). Years of experience and confidence pretest scores were found to be positively correlated, $r(34) = .30$, $p < 0.05$. The researcher hypothesized predicted positive relationships among the confounding variables and knowledge and confidence scores; therefore, one-tailed tests were computed.

Table 5

Pearson Correlations Among Knowledge and Confidence Scores (n = 36)

	Prior trach knowledge	Recent experience	Years of practice	Years of education
Knowledge pretest				
Pearson's r	0.027	0.015	-.051	-0.129
p-value	0.438	0.465	0.388	0.231
Knowledge posttest				
Pearson's r	-0.055	0.00	0.097	0.025
p-value	0.377	0.500	0.292	0.443
Confidence pretest				
Pearson's r	-0.133	-0.133	0.302*	-0.191
p-value	0.223	0.233	0.042	0.136
Confidence posttest				
Pearson's r	-0.184	0.101	0.246	-0.286
p-value	0.149	0.284	0.084	0.051

* Correlation is significant at the 0.05 level (1-tailed).

Table 6 contains descriptive data comparing pretest and posttest scores for each question on the "Tracheostomy Pretest." The purpose of reporting these data was to determine the specific areas of tracheostomy care in which participants scored lower in confidence and knowledge. The

percentages of "confident" and "very confident" responses are compared between the pretest and posttest. The percentage of change in scores is also reported. Reported confidence scores increased in all subject matter areas in this section. The percentages of correctly answered knowledge questions on the pretest and posttest along with percentages of change are included. The percentage of correct responses on the knowledge portion of the test increased on 18 out of 20 questions. The two questions with no change in knowledge referenced the purpose of the inner cannula and the most common cause of tube obstruction.

Table 6

Descriptive Data Comparing Pretest Posttest Scores for Each Question on the Tracheostomy Pretest (n = 36)

Item	Pretest	Posttest	change
Confidence: % confident or very confident responses			
1. I.D. parts of a tracheostomy tube	19.5	62.8	+43.3
2. Understand function of Passy-Muir valve	19.4	74.3	+54.9
3. Suctioning a tracheostomy patient	38.9	85.7	+46.8
4. Knowing when to use cuffed vs. uncuffed trach tube	11.1	54.3	+43
5. Cricothyrotomy, tracheostomy, laryngectomy differences	8.6	57.6	+49
6. I.D. patient with tracheostomy vs. laryngectomy	13.9	68.6	+54.7
7. Changing tracheostomy tube	17.2	60	+52.8
8. Managing airway compromise with trach or laryngectomy	17.2	62.8	+45.6
9. Identify "red flags" in patient with new tracheostomy	19.5	68.5	+49
10. Replacing a trach after accidental decannulation	16.7	51.5	+34.8
Knowledge: % correct responses			
1. Anatomic location for trach placement	27.8	94.4	+66.6
2. Physiologic changes with tracheostomy	36.1	69.4	+33.3
3. Trach patients can't speak without finger occlusion because	80.6	94.4	+13.8
4. False statement regarding tracheostomy	27.8	66.7	+38.9
5. Purpose of the inner cannula	88.9	88.9	0.00
6. Which is not an indication for tracheostomy	69.4	77.8	+8.4
7. Which is a false statement? (cuffed vs. uncuffed tubes)	19.4	66.7	+47.3
8. Which improves phonation with a Passy-Muir valve?	55.6	61.1	+5.5
9. Which is associated with 10mL frank blood when suctioning	50.0	52.8	+2.8
10. What is best next step for patient with laryngectomy	25.0	58.3	+33.3
11. When is tracheostomy tract considered established?	36.1	91.7	+55.6
12. POD#2 tracheostomy next action	8.3	77.8	+69.5
13. Tracheostomy placed 1 month ago next action	52.8	80.6	+27.8
14. Accidental decannulation, unresolved resp compromise	19.4	63.9	+44.5

15. What is common cause of trach tube obstruction?	97.2	97.2	0.00
16. Replacing a trach tube	66.7	77.8	+11.1
17. Mechanical ventilation problem with uncuffed trach tube	75.0	94.4	+19.4
18. How often must a fresh trach patient be suctioned?	50.0	83.3	+33.3
19. How often must established trach patient be suctioned?	50.0	88.9	+38.9
20. Which are not part of “Trach Go bag”?	83.3	88.9	+5.6

The study purpose was accomplished through analyzing results that indicated a 90-minute didactic and hybrid simulation education session did increase knowledge and confidence scores in medical-surgical nurses with statistical significance. Intensive care unit nurses were added to the study and the data revealed similar significant results as reported for medical-surgical nurses. The data for the three respiratory therapists included in the study revealed no statistically significant difference in pretest and posttest knowledge and confidence scores following the education session.

The test consisted of 10 confidence level questions and 20 knowledge questions. Participant responses of feeling confident or very confident on the pretest and posttest were reported. The first 10 items addressed confidence levels. Confidence levels were measured on a Likert type scale from not confident at all to very confident (0-5). A total numerical score was tallied by calculating the sum of the responses. Possible scores ranged from 0-50. The knowledge portion of the test consisted of 20 multiple-choice items. A percentage score was calculated by dividing the number of correct responses by the total number of questions. Possible scores ranged from 0-100.

CHAPTER FIVE. DISCUSSION

The results of this study answer the research question by suggesting that a 90-minute hybrid simulation education session does improve knowledge and confidence levels of medical-surgical and intensive care unit nurses. The nurses within this hospital did not feel either confident performing all aspects of care associated with tracheostomies or they had a strong baseline understanding of tracheostomy anatomy, the function and indication of types of tracheostomy tubes, complications of tracheostomies, and how to manage tracheostomy related emergencies.

Though posttest scores increased significantly, understanding the specific areas where nurses struggle with tracheostomy care is important for clinical educators to address these gaps in knowledge. Respiratory therapists reportedly felt more confident than nurses before and after the education session. The change in knowledge scores was not statistically significant for respiratory therapists possibly due to an overall higher baseline knowledge of tracheostomies and respiratory aspects of patient care in their daily routines.

Limited, hands-on education is offered on tracheostomy care for all healthcare providers. This lack of education can lead to decreased knowledge and confidence in handling related complications and emergencies. Results from other studies indicated healthcare professionals and students are generally not comfortable caring for patients with tracheostomy or laryngectomy tubes (Argawal et al., 2019; Davis et al., 2019; Goldsworthy et al., 2019; McDonough et al., 2016; Sandler et al., 20210; Yelverton et al., 2015). Dedicated tracheostomy education sessions increased confidence and knowledge in all of these studies.

Relationship of Findings to Prior Research

This study yielded similar results as other studies in the literature review. The specific deficiencies of nurses in this study were identifying the anatomy and physiology associated with tracheostomy tube placement, indications for cuffed versus uncuffed tubes, differences between tracheostomies and laryngectomies, speaking valve physiology and care, determining actions based on maturity of tracheostomy, and handling complications and tracheostomy related emergencies such as accidental decannulation. In Dorton et al.'s (2014) study of primary health care providers and tracheostomy education, the identified deficiencies were knowing types of tubes, speaking valve physiology, and slow recognition of a tube obstruction emergency.

Nurses are most often the first responders at the bedside to assess patients with tracheostomies and handle related complications (Dorton et al., 2014). The nurses and respiratory therapists in this study scored the highest on feeling confident with suctioning and knowing the most common cause of tube obstruction. Hesitancy in recognizing and responding to tube obstruction was not observed in this study of nurse and respiratory therapists. An explanation for the differences in study findings between primary care providers compared to nurses and respiratory therapists is scope of practice for various disciplines. Nurses and respiratory therapists perform routine care and suctioning whereas physicians are usually notified of complications after other providers have seen the patient. Physicians are not exposed to tracheostomy complications as first responders as often as other providers.

Education Modality

A significant increase in knowledge was reported in all previous studies discussed in the literature review in spite of education modality. Higher confidence levels were reported in the majority of studies that included simulation. The modalities of simulation used in previous studies were high-fidelity mannequins, virtual reality, or task trainers. A unique aspect of this

study is the incorporation of a hybrid simulation combining use of standardized patient with a wearable task trainer. No prior studies reported using standardized patients to enhance the fidelity of the simulation component. The significant increase in knowledge and confidence with hybrid simulation is reassuring. Many hospitals do not have dedicated simulation laboratories and trained simulation facilitators for in situ simulation training. An inexpensive task trainer is feasible and sustainable for repeated use in education sessions at hospitals and other settings to incorporate increased realism without high fidelity mannequin simulators.

Simulation alone may be effective to increase knowledge and confidence scores, but the modality of simulation is important (Goldsworthy et al., 2019). The incorporation of hands-on learning with the didactic content and hybrid simulation was effective in increasing both knowledge and confidence scores in this study. Currently, many facilities utilize online and virtual learning to meet competency requirements. It is important to note that at least one prior study revealed insignificant pre- and post-simulation knowledge scores when virtual reality was used alone for education (Bayram & Caliskan, 2019). Gaur and Mudgal (2018) reported the significant effects of simulation on knowledge in a study comparing education sessions with and without a simulation component. This research supports the use of hands-on learning and simulation in continuing education sessions to improve knowledge and confidence of healthcare providers with tracheostomy care.

Education Content

Most previous studies did not report on the specific education content and identified areas of deficiencies. Overall increases in reported “confident” and “very confident” in confidence responses ranged from 34.8% to 54.9% (Table 6). This result suggests that nearly half of participants were not confident in all areas of tracheostomy education ranging from anatomy and

physiology to handling tracheostomy related emergencies. Even though the didactic information included in this session was originally used in studies for medical residents, the nurses and respiratory therapists in this study reported it was beneficial for them to know and feel confident with all aspects of tracheostomy care in their own practices to ensure patient safety.

The highest reported increase in confidence was understanding the function of a Passy-Muir valve. Only 19.4% of participants reported feeling confident or very confident on the pretest and 74.3% on the posttest resulting in a 54.9% overall increase following the education session (Table 6). Most study participants reported seeing a Passy-Muir valve in practice, but could not verbalize its function, correct use, or precautions to take when applying the valve to the patient's tracheostomy tube. Passy-Muir valves can occlude the airway if used improperly. It is highly likely that nurses and respiratory therapists may assist patients with using Passy-Muir valves, especially when speech therapists are not available. Discussion about Passy-Muir valves is important to include in tracheostomy care education. Understanding speaking valve physiology was a deficiency of physicians noted in Dorton et al.'s (2014) study also.

No changes in pre and posttest scores were found for knowing the purpose of the inner cannula and most common cause for tube obstruction. The pretest scores are high at 88.9% correct and 97.2% correct for these two topics respectively (Table 6). These findings suggest the participants had a strong knowledge base in these areas prior to the education session as posttest scores remained the same. The findings may suggest practicing nurses retain knowledge of this content and more time and effort may need to be dedicated to other content when developing tracheostomy education sessions. Bayram and Caliskan (2019) studied specific tracheostomy care skills of inner cannula cleaning, stoma care, and suctioning. There were no statistically significant differences in skill performance after the education session, suggesting nurses were

already competent in the basic skills of tracheostomy care prior to the education session (Bayram & Caliskan, 2019). This suggestion aligns with this study's findings with no significant differences in knowledge attainment possibly due to preexisting knowledge and confidence in these skills. The nurses and respiratory therapists in this study stated they were comfortable with suctioning and did not hesitate or stall when demonstrating this skill during simulation.

The lowest pretest knowledge score of 8.3% was caring for an immature or fresh tracheostomy tube on postoperative day two (Table 6). 77.8% of participants answered this question correctly on the posttest showing a 69.5% increase, the highest increase of any knowledge question (Table 6). This knowledge question was a situational question requiring critical thinking versus recall of information. It is important for nurse leaders and educators to include higher level thinking activities in tracheostomy education to help nurses with applying knowledge, analyzing assessment findings, and synthesizing a plan of action. This study incorporated didactic information with hands-on learning in combination with hybrid simulation offering opportunities for critical thinking and action throughout the session, which likely affected the large increase in scores.

Pretest scores for knowing the indications for cuffed and uncuffed tubes were also low with 19.4% of participants answering this question correctly (Table 6). Almost 67% (66.7%) answered the question correctly after the education intervention (Table 6). This content was covered using the Tracheostomy Observation Model (Tracheostomy T.O.M.®) for hands-on learning during the didactic content presentation. Visualizing the anatomy and having the ability for learners to insert cuffed and uncuffed tracheostomy tubes and see the effects of balloon inflation is believed to be one specific reason for this large increase in knowledge scores after the education session. All participants verbalized the usefulness of seeing a three-dimensional model

of the neck anatomy. Participants also stated that handling the actual tracheostomy and laryngectomy tubes during the session helped them feel more comfortable with what they will actually see in practice.

In Table 6, 16.7% of participants reported feeling confident or very confident in replacing a tracheostomy tube after accidental decannulation before the education session compared to 51.5% after the education session. The increase of 34.8% was the lowest reported increase of the 10 confidence questions. Though the increase is smaller when compared to other questions, it is important to avoid the assumption that participants were more confident in this skill than others. One of the four simulation vignettes included in the education session addressed accidental decannulation; yet the posttest score of 51.5% suggests only half of participants felt confident after one education session. Nurses and respiratory therapists in this study stated they are not as comfortable in replacing tubes as they are in other aspects of tracheostomy and laryngectomy tube care. Accidental decannulation is a rare emergency these study participants reported not experiencing in their own practice settings. This participant feedback suggests nurses need continued education and skill practice with handling tracheostomy related emergencies.

The four simulation vignettes addressed suctioning, tube obstruction, accidental decannulation, and recognizing a laryngectomy versus tracheostomy tube. The content of the simulation vignettes aligned with the didactic information. Increased knowledge scores correspond to observed performance in the simulation experiences. Recorded performance review was not included in this study, but it was apparent to the researcher when participants were hesitant to act or verbalized they did not know what to do in a given situation. Participants struggled with the accidental decannulation and laryngectomy scenarios most often, which correlates with the findings that nurses were already somewhat knowledgeable with suctioning

and tube obstruction prior to the session. It would be beneficial in future studies to record performance or include a trained observer to record actions on a standard checklist in future studies versus subjective reports of participant feedback. Reviewing specific questions in Table 6 is important to identify practice and knowledge gaps to target for future tracheostomy education courses. This study helps address a gap in research by reporting specific areas of educational need of nurses.

Duration and Frequency of Education

This study's findings reveal that a 90-minute education session was effective for increasing knowledge and confidence in this cohort. Previous studies discussed in the literature review included education sessions lasting from 45 minutes to months-long programs. Healthcare facilities are often challenged with validating competencies of providers in a short amount of time. Meeting this challenge is especially difficult, yet important, for high-risk, low-volume skills related to tracheostomy care. The significant increase in knowledge and confidence of nurses in this study is useful for clinical educators and hospital administrators when considering training feasibility, sustainability, and costs.

Confounding variables

Prior knowledge, prior exposure to tracheostomy patients, years of practice, and years of education were correlated with knowledge and confidence pretest and posttest scores. The only significant correlation found was between years of practice and the confidence pretest scores. One interpretation for this weak positive correlation is that increased confidence does not translate to increased knowledge. The participants may have gained a new awareness of what they did not know about tracheostomies before the education session, explaining the lack of a significant increase in confidence on the posttest.

The findings regarding the confounding variables in this study are similar to previous studies. Comfort levels increased after a tracheostomy education session, but no statistically significant relationship was reported between level of education and years of experience with knowledge and confidence scores in one previous study of licensed nurses (Smith-Miller, 2006). These findings suggest nurses are generally not comfortable with tracheostomy patients despite increased knowledge and experience.

Observations

The pretest data in this study demonstrate a lack of confidence and knowledge in tracheostomy care. Current educational practices are not preparing nurses for the high-risk, low-volume incidences of tracheostomy related emergencies to ensure safe, competent patient care. There was statistically significant improvement in nurses' knowledge and confidence scores following this evidence-based, didactic education session with hybrid simulation in this study compared to other studies using other modalities of simulation. Nurse leaders in education should be aware of specific tracheostomy care topics in order to develop education sessions that include challenging subject matter versus repeating the same information without studying the usefulness of the content.

Starting with indications for tracheostomy tubes and basic anatomical and physiological aspects of care is helpful versus assuming nurses already know why a patient has a tracheostomy tube. All participants stated the "Tracheostomy Pretest" was very challenging. Both nurses and respiratory therapists stated the information on the knowledge portion of the test was unfamiliar to them, but felt it was worthwhile participating in the session. The didactic information used in this study was evidence-based according to the most current clinical consensus statement from the American Academy of Otolaryngology. The content was utilized in at least two previous

studies and remains current. The lack of standardized education content for tracheostomy education remains a problem, but using the evidence-based content in this study is one step toward formalizing content for any healthcare facility.

Evaluation of Theoretical Model

The significant increase in knowledge and confidence scores in this study align with the constructs in Bandura's self-efficacy theory. Confidence was operationalized by a mean test score. The increase from pretest to posttest scores corresponded to the study participants' verbal statements of feeling more comfortable with tracheostomies and better prepared to care for their patients. Formal data was not collected regarding how the participants felt about the delivery of the content during the education session. However, most participants stated they appreciated the hands-on aspects and were especially satisfied with the simulation component. Incorporating simulation using the constructs in the Jeffries simulation theory yielded similar results as a 2014 study in which subjects rated the effectiveness of simulation laboratory higher than a lecture only approach (Dorton et al., 2014).

Continuation of this research will benefit from including a skill component as another dependent variable to validate whether increased knowledge and confidence translates to improved performance as Bandura's theory suggests. Assessment, clinical decision-making skills, and suctioning were included as part of the simulation component but were not formally measured. However, the researcher observed the study participants' response times and skill performance. Two to four participants were in each small group. The researcher observed improvement and faster action by each subsequent participant after watching the first participant complete a simulation. Learning through direct observation is another aspect of Bandura's theory recommended to research in future studies.

The NLN Jeffries simulation theory proposes that an evidence-based simulation experience that provides opportunity for skill practice within a scenario requiring clinical reasoning results in improved learning outcomes at the participant level. Improved learning outcomes ultimately lead to improved patient and system outcomes. Including simulation in annual competency check-offs is beneficial for hospital administrators, healthcare providers, and patients.

Limitations

The sample size was small and limited to nurses at one hospital. To achieve an effect size of 0.5 and a power level of 0.8 with a probability level of 0.05, 51 participants were needed. The study should be replicated to include more medical-surgical nurses in multiple facilities. The study was originally designed for medical-surgical nurses. However, due to the need to use the session for annual competency check-offs, the study was open to intensive care nurses, and respiratory therapists. A larger study of medical surgical nurses would increase confidence in the generalizability of results. The results in this study are applicable to other small hospital settings. However, since no significant correlation was identified between knowledge and experience, prior education, and prior exposure to tracheostomy patients, it is difficult to ascertain if this study's results apply to other healthcare settings that treat tracheostomy patients more frequently.

The literature reported many variations in providing tracheostomy education. The lack of standardized clinical practice guidelines compounded the challenge of developing a standardized education session designed solely for nurses with the most current evidence-based practice. The education session and "Tracheostomy Pretest" used in this study was originally designed for medical residents. However, the didactic information was current and validated by an expert, multidisciplinary panel including nurses. Some questions were modified by replacing "resident"

with “nurse.” More than one correct answer was accepted for one question to align with the registered nurse scope of practice. The pretest and posttest were reportedly very difficult and time-consuming for participants, but the majority of participants stated it was helpful and challenged them to think.

The time constraint for completing this study was prohibitive in evaluating the effects of the education session on knowledge retention and patient outcomes over the long term. Confidence and knowledge were measured in prior studies at intervals ranging from 4 weeks to 2 years after the educational intervention. Colandrea and Eckardt (2016) reported increased knowledge and comfort along with improved patient outcomes (length of hospital stay and complication rates) over a 2-year period. Lengthening the timeline of the study would allow for measurement of knowledge retention and patient outcomes.

Implications for Future Research

Future studies should include the effect of the education session on patient outcomes and knowledge retention. Since tracheostomy emergencies occur infrequently in most healthcare settings, it is difficult to obtain a large sample size at a single facility. A multi-site study over a longer period of time would be helpful to obtain a larger sample size and more generalizable results. A reduction in patient complications related to tracheostomies, readmissions, and shortened lengths of stay were reportedly linked to tracheostomy education in one study, but the length of training occurred over 4 months (Sodhi et al., 2014). Replicating this study and including measurement of knowledge retention and patient outcomes in future research will be useful in determining the best approach to educating providers in the most effective, yet feasible and affordable way.

Learners verbalized more confusion regarding the use of cuffed and uncuffed tracheostomy tubes than other presentation topics. Verbal feedback was obtained from study participants. Additional survey questions on the posttest would be helpful to capture this data with an opportunity for participants to confidentially comment on the session. Learner feedback is important to determine which topics should be emphasized when planning future education sessions.

Video review is commonly used in simulation debriefing to enhance learner reflection and recall of performance. However, due to time constraints and a lack of audio-visual resources in a hospital setting, sessions were not recorded in this study. Researchers should consider adding video review in the simulation portion of the education session for future studies.

There is a lack of research on the effect of simulation education with tracheostomy care on patient outcomes. More research is needed, and sustained, repeated education sessions with hybrid simulation can fulfill that need. A unique aspect of this study is the low-cost, high-fidelity approach with hybrid simulation. The researcher, who is a clinical educator, serving as the patient was an effective approach to ensure appropriate content was covered. The researcher also had the unique perspective of being immersed in the simulation scenarios and was able to evaluate learners in real time and provide appropriate cues to ensure the learners were able to meet the learning objectives.

Future studies should investigate how often tracheostomy education with simulation should be required for nurses. The literature supports the need for more frequent education with a lack of knowledge retention reported when didactic information alone is used (Gaur & Mudgal, 2018). All participants in this study verbalized appreciation for the experience and stated they gained knowledge and feel more confident with tracheostomy care. Both nurses and respiratory

therapists stated they learned at least one or more new pieces of information in the session. This study does not answer the question of how long the knowledge and confidence is retained by nurses and how often education is needed.

Implications for Practice/Health Policy/Education

There is a need for improved tracheostomy education for healthcare providers, especially for those working in rural area hospitals who do not encounter tracheostomy patients as often as other providers. The didactic education and hybrid simulation combination was effective in improving knowledge and confidence in this study. This study was low-cost and feasible to implement at any facility. The education session can be replicated by clinical educators to include into annual training and competency check-offs. This hybrid simulation approach can also be used to educate patients, family members, and caregivers after tailoring the content to the level of the learner.

The didactic content used in this study is evidence-based and current, and was used in at least two other similar studies (Argawal et al., 2016; Davis et al., 2019). However, there are no detailed descriptions about the method of presentation of the material including hands-on and visual aids in reported studies. A unique aspect of this study is the incorporation of hands-on models and equipment as presentation of didactic content was learner-paced with frequent opportunities for clarification and questions.

The majority of the feedback from the study participants was positive. They appreciated the fact that the session was well organized, using an easy-to-follow format with hands-on practice and simulation. Based on the study findings, this simulation education intervention can be used (in future studies) in other settings such as home-health, outpatient services, and long-term care homes where resources and space for continued education are limited.

A unique aspect of this study was the inclusion of nurses and respiratory therapists in the implementation phase. The literature does not address the positive attributes of including multiple disciplines in education sessions. In current practice, interprofessional education is growing in popularity as a means to enhance interdisciplinary communication and patient safety. Healthcare facilities could save time in offering interprofessional education sessions versus discipline specific sessions. Learners could benefit from learning about the roles of other disciplines they work with every day. Interprofessional tracheostomy education sessions is another area for future research for practice, policy, and education.

Conclusion

There is a need for standardized and evidence-based tracheostomy education for healthcare providers. This study found a significant increase in knowledge and confidence scores among nurses following a 90-minute tracheostomy education session with didactic and hybrid simulation components. The education content was evidence-based according to the American Academy of Otolaryngology. A unique aspect of this study was the inclusion of descriptive data about the specific content areas of tracheostomy care. Including low-cost hybrid simulation with didactic content is effective to educate nurses about tracheostomy care and related complications. Using the concepts from simulation theory, high-quality simulation is possible with low-fidelity equipment that is more cost-effective and attainable for various healthcare facilities. Recommendations for future research include studying effects of tracheostomy education with hybrid simulation on knowledge retention and patient outcomes while including providers from multiple disciplines.

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Appendix A

Permission letter from LewisGale Hospital Alleghany

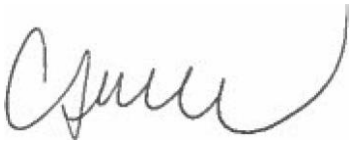
April 8, 2020

Cynthia Akers
Chief Nursing Officer
LewisGale Hospital Alleghany
I Arh Ln.
Low Moor, VA 24457
540-676-2834, cynthia.akers@hcahealthcare.com

RE: REQUEST FOR PERMISSION TO CONDUCT RESEARCH IN HOSPITAL

Dear Ms. Keller,

I grant permission for this research to be conducted at Lewis-Gale Hospital Alleghany. I understand your research consists of a tracheostomy simulation teaching intervention involving medical-surgical nurses. This hospital employs an otolaryngologist who is or will be performing tracheostomies, which is a new procedure for our healthcare team. Based on a current need for continued education for all of our medical-surgical nurses, I welcome the opportunity to provide the nurses with this learning opportunity. Currently, this hospital employs approximately twenty full-time registered nurses (or RNs + LPNs) on our medical-surgical unit. I understand the study is projected to be completed in the fall of 2020. The researcher will supply materials and equipment for the study, and I will grant time for the nurses (1 hr) to complete the education intervention consisting of a brief didactic portion followed by a hybrid simulation and debrief session. Nurses will complete a pre and post survey measuring knowledge and confidence. The aim of this study is to increase the knowledge and confidence of nurses when caring for a patient with a tracheostomy in hopes to decrease complications, improve emergency response actions when encountering a tracheostomy related complication, and enhance overall patient safety.



Cynthia Akers, RN, MSN

Figure 1. Permission letter from Alleghany Hospital Chief Nursing Officer.

Appendix B

Theoretical Framework

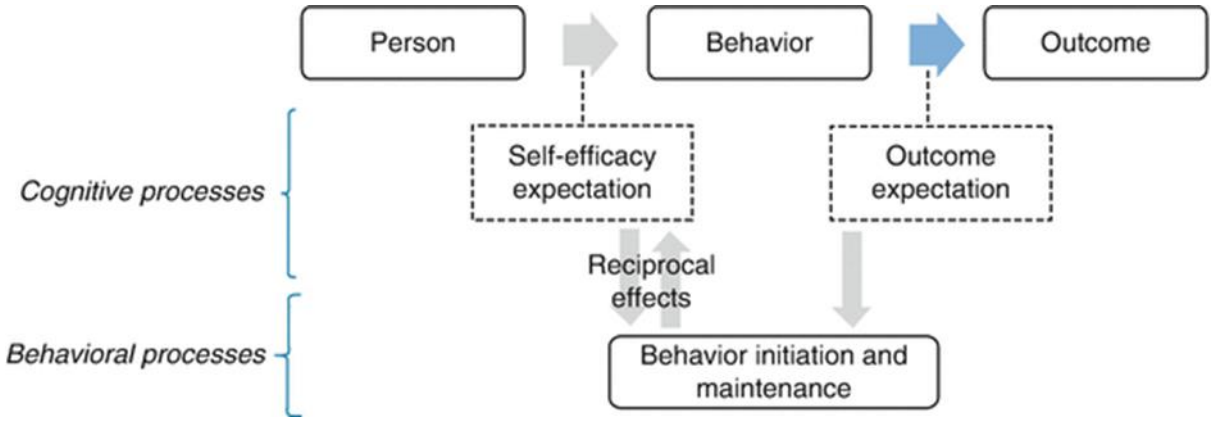


Figure 1. This illustration is a diagram of The Bandura Self-Efficacy Theory.

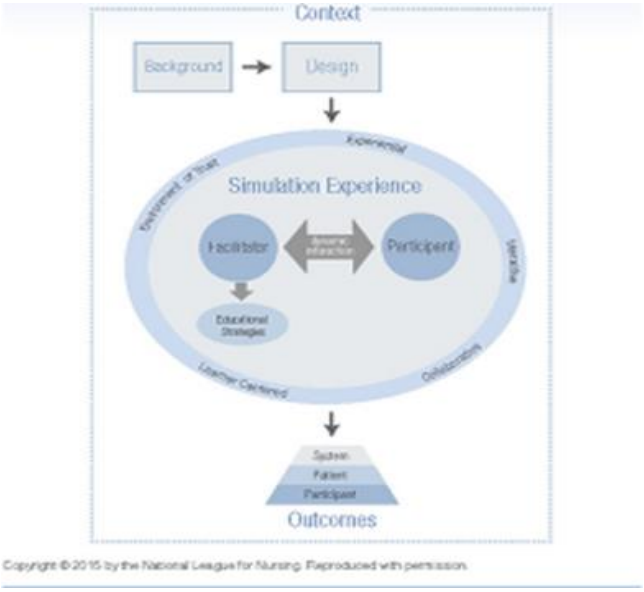
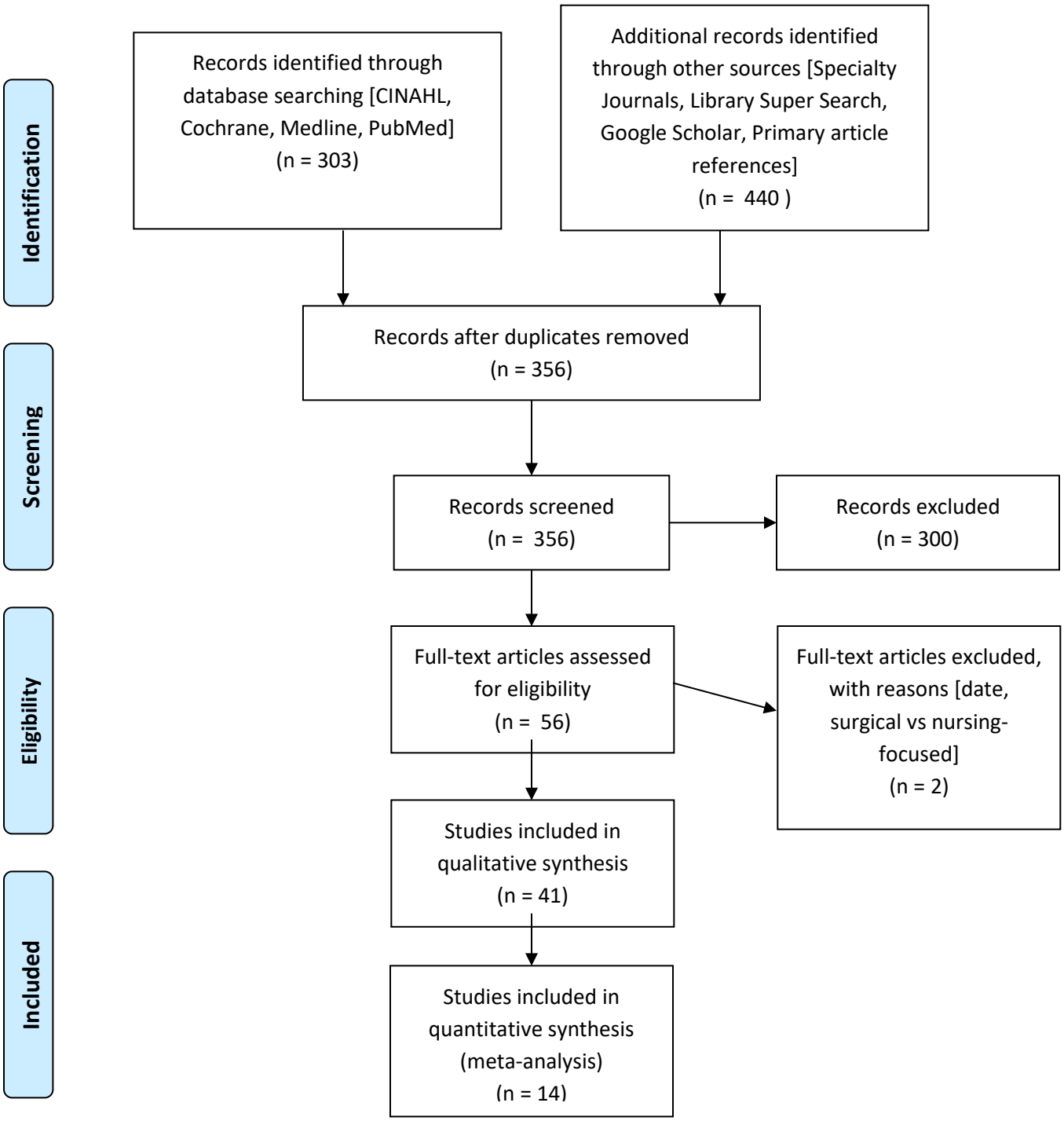


Figure 2. This illustration is a diagram of The NLN Jeffries Simulation Theory.

Appendix C

PRISMA Flow Diagram



Appendix D

Literature Review Tables

Table 1

Search Strategies and Results

Date of Search: Feb-March 2020

Database	Keyword (s)	# references	Inclusion criteria	Yield	Method of locating
Super Search					
McConnell Library Super Search	Tracheostomy AND nurse AND knowledge	269	Scholarly, peer-reviewed filter; 2015-2020 date range; added simulation keyword	7	Radford University McConnell Library www.radford.edu
Databases					
CINAHL	(tracheostomy OR tracheotomy OR trach) AND (nurse OR nurses OR nursing) AND (skills OR competence OR knowledge)	170	2000-2020 date range (rationale: older articles contained outdated trach care guidelines); Nursing care related; education intervention	23	Radford University McConnell Library >> LibGuides >> Doctorate of Nursing Practice>> Finding articles>>CINAHL
Cochrane	tracheostomy, tracheotomy	34	2000-2020 date range must include nursing care, *not* surgical approach (medical focus)	1	Radford University McConnell Library >> LibGuides >> Doctorate of Nursing Practice>> Finding articles>>Cochrane
Medline	tracheostomy care AND nursing knowledge	45	2000-2020 date range Nursing care focused, hospital setting	28	Radford University McConnell Library >> LibGuides >> Doctorate of Nursing Practice>> Finding articles>>Medline
PubMed	tracheostomy AND nursing AND knowledge	54	2000-2020 date range Nursing care focused	16	Radford University McConnell Library >> LibGuides >> Doctorate of Nursing Practice>> Finding articles>>PubMed

Individual Journals					
Society for Simulation in Healthcare journal	tracheostomy	22	Education focus on tracheostomy care Peer-reviewed	1	www.ssih.org requires membership login to access online journal
Clinical Simulation in Nursing Journal	tracheostomy AND knowledge	29	Education focus on tracheostomy care Peer-reviewed	3	www.inacsl.org requires membership login to access online journal
National League for Nursing	Tracheostomy, simulation	10	Tracheostomy care focus	1 systematic review	Nursing Education Perspectives Research Journal for NLN https://journals.lww.com/ requires NLN membership login
Academy of Medical-Surgical Nurses (AMSN)	tracheostomy	10	Peer-reviewed; focus on tracheostomy care	1 systematic review	MEDSURG Nursing Journal @ www.amsn.org requires membership login to access online journal
Other: Hand Search (references from primary articles, Google Scholar)					
Primary article references; Google Scholar	tracheostomy AND nursing care AND knowledge AND confidence AND simulation	100	Scholarly articles; 2010-2020 date range	53	Reference listings from primary articles & Google Scholar

Table 2

Synopsis Table for All Studies Related to Intervention

	Author, Year	Design/Level of Evidence (LOE)	Target Population (N=)	Setting	Interventions Methods	Findings/ Results	Comments: Strengths/ Weakness
1	Bayram & Caliskan (2019) Aim: determine the effects of a game-based virtual reality phone application on trache-ostomy care education for nursing students	Single-blind RCT **LOE = II**	86 1st year nursing students (began with 238, after exclusion criteria applied [attended theoretical class, took first or last skill performance already, 86 included with block randomization)	Gazi Univer-sity, metropolitan city in Turkey	IV = VR phone app on trach care education DVs = knowledge & skill Tools = Tracheostomy care knowledge test (created by researchers according to the literature: 23 five-option multiple choice questions), validated with Cronbach's alpha = 0.706) when administered to 76 nursing students; group of specialists opinions resulted in Kendall's W = 0.302; p = 0.589 and test was modified based on specialist opinion. Tracheostomy Care Skill Checklists created by researchers according to literature, expert opinion, one measurement and assessment expert and one language expert. 3 skills assessed: cleaning inner cannula, cleaning peristomal area, suctioning	VR phone app created by researchers based on trach care skills checklists Control & exp groups participated in theoretical class (60 min.), took 1st knowledge test then small group practice in lab(90 min), next day trach care skills performed using Objective Structured Clinical Examination with Trach care skills checklists. After 7 days knowledge test and clinical skills exam given again. Exp group used VR app during 7 days, control group did not. No statistically significant difference between first and last knowledge scores ($p > 0.05$). Mean scores for inner cannula cleaning in exp group > control ($p = 0.000$). Increase in mean scores in exp group for suctioning skill $p = 0.017$.	No sig between groups according to descriptive characteristics (including educational level); Cleaning inner cannula procedural skill without much critical thinking so didactic and hands on one time effective for learning this skill No sig. increase in knowledge perhaps due to introduction of a new intervention (the app). Weakness: did not study knowledge retention over longer period than 7 days. Key finding: didactic + hands on showed sig effects on knowledge and skills even though the VR app use did not.

2	Colandrea & Eckardt (2016) Study Aim: develop and test a clinical care pathway and nursing education program to improve tracheostomy patient outcomes	Quasi-experimental pilot study 3 Phases Phase 1 = administer Readiness for Hospital Discharge to tracheostomy patients Phase 2 = provide nurses with an educational program pre and posttest assessment Phase 3 = Implement critical care pathway and evaluate patients' readiness for discharge **LOE = IV**	Phase 2 Convenience sample Med/Surg nursing staff at VA facility N = 36 26 = RNs Majority BSN 3 = LPNs 7 = nursing assistants Average yrs practicing = 12.5 yrs	Tertiary care Mid-Atlantic Veterans Affairs facility	IVs = critical pathway, nursing education program DVs = length of hospital stay (LOS), 30-day readmission rates, Readiness for Hospital Discharge Score **nurses' comfort and competence with tracheostomy care also analyzed in relation to LOS and complication rates Nursing education program: 1. Anatomy & physiology of tracheostomy 2. Trach care 3. Discharge education 4. Early signs of complications 11 question pretest, 1 hr lecture, same test administered after lecture to evaluate knowledge gain 9 knowledge questions, 2 comfort level questions	Paired sample t-test Competency: p<0.001 for pre and posttest mean scores Expert consensus for face validity obtained from speech therapist, otolaryngology head and neck surgeon, and respiratory therapists. Comfort: p<0.001 for pre and posttest mean scores in "providing trach care" p<0.001for pre and posttest mean scores in "providing tracheostomy discharge education" Comfort level measured on scale 0-10; 0 = not comfortable, 10 = very comfortable Cronbach alpha = 0.92 (internal consistency)	Length of study = 24 months Informative study but lengthy CE credit for nurse motivation to participate Nurse education program offered multiple times to encourage increased participation Difficult to assess "competence" with pretest posttest. Articles states "competence" but knowledge test administered. No skills check off. Face validity obtained from other disciplines, not nursing. Questions may not target specific nursing care for different levels of nursing staff (RNs, LPNs, CNAs). Education level not varied among nurses. RNs, LPNs, and CNAs. No discussion of score differences between RNs, LPNs, and CNAs

3	Davis, et al., (2019) Study aim: assess and improve comfort with knowledge of and proficiency in trach and laryngec-tomy care	Prospective observation, Pre/posttest, one group **LOE = IV**	N= 122 Physician trainees from medicine, ER medicine, and anesthesia	Hospital	IV = education intervention, didactic + simulation DVs = knowledge, skill, comfort Skill = trach change proficiency Procedure = • Pre test • Didactic session *including laryngectomy and trach • Hands on trach change practice • Simulation scenarios with mannequins • Posttest • 6 month follow-up Intervention: "Trainees completed a simulation session consisting of: 1. Didactics (approx. 1 hour): Presentation on tracheostomy and laryngectomy principles (see Supplemental Digital Content 3 for copy of presentation, http://links.lww.com/SIH/A454). 2. Hands-on demonstration: Performing a routine tracheostomy change. 3. Case-based simulation: Application of knowledge by completing 3 emergency clinical cases, on interactive, high-fidelity, simulation Mannequin Statistical analysis: Comfort level and skill data were nonparametric and analyzed using Kruskal-Wallis for preintervention and postintervention comparisons. Objective knowledge data were normally distributed and analyzed using analysis of variance. Wilcoxon signed-rank test was used for subgroup analysis. A $\chi 2$ comparison of inpatient mortality from 2015 to 2016 (preintervention period) was compared with inpatient mortality from 2017 to 2018 (postintervention period)."	***Comfort*** measured by Likert scale: mean scores improved 2.12 to 4.43 p<0.009 ***Knowledge*** measured by objective test, content validity ensured by review of specialty experts: mean scores improved from 57% to 82%, p < 0.001 ***Skill*** measured by observing trach change proficiency from 41% to 84%, p < 0.001 6 month follow-up of comfort and knowledge: Statistically sig result for retention of comfort- p=0.002 and knowledge- p=0.026. Knowledge and comfort assessments administered online with Survey Monkey Scores matched to anonymous identifiers. Clinical outcome data also collected: inpatient mortality data between 2015-2018 using ICD 10 codes (laryngectomy, tracheostomy, tracheostomy complication)	Strength- validated tools, knowledge test based on EBP from American Academy of Otolaryngology. Face validity established through expert review (otolaryngology physicians, nurses, and RTs). Permission requested from author to use these tools: 1. Comfort: Likert scale assessment of self-perceived comfort with tracheostomy and laryngectomy care (see Supplemental Digital Content 1, which includes comfort assessment used, http://links.lww.com/SIH/A452) 2. Knowledge: Objective multiple-choice evaluation (see Supplemental Digital Content 1, which includes knowledge assessment used, http://links.lww.com/SIH/A452) 3. Skill: Task-based assessment of participant ability to perform a routine tracheostomy change on a mannequin (see Supplemental Digital Content 2, which contains the skill assessment tool used, http://links.lww.com/SIH/A453) Resources readily shared encouraging replicability of study. Trained debriefers used, but no specific debriefing model was prescribed. More experience not predictive of increased proficiency. Having experience (perhaps not performing correct actions) does not necessarily correlate to being knowledgeable and skillful and following best practices. Also, comfort did not necessarily imply knowledge and skill. Nurses included on expert review panel for tool validity but not studied.

4	Dorton, Lintzenich, & Evans (2014) Study aim: evaluate the competency of healthcare providers managing patients with tracheostomies and assess need and efficacy for multidisciplinary educational program incorporating simulation	Prospective observational study, pretest posttest **LOE = IV**	N = 87 Primary care providers including nurse practitioners, med students, anesthesiology residents, pulmonary and critical care fellows, & physician assistants	Tertiary care hospital	IV = educational session including simulation DVs = knowledge, comfort level Other outcome variables = course eval & observational data Tools: Comfort-Tracheotomy Education Self-Assessment Questionnaire; no statistical info on validity; 10 questions; Likert scale 1 = strongly disagree (uncomfortable) to 5 = strongly agree (very comfortable) Knowledge-Tracheotomy Education Objective Test; 15 multiple-choice questions to test trach care knowledge; no statistical data about validity & reliability	Paired two-tailed t-tests of mean pre and posttest scores $p<0.0001$ statistically sig increase in comfort pre to posttest 56 participants completed $p<0.0001$ statistically sig increase in knowledge pre to posttest 57 participants completed Design: Demo info obtained, knowledge and comfort surveys administered, education session checked for accuracy by otolaryngologist residents and faculty consisted of 30 min. narrated Ppt and 90 minute simulation with 3 scenarios (assessment, accidental decannulation, & plugged tube), posttests administered immediately following + @ 6 months	Knowledge and comfort sustained after simulation interventions. Tools not validated, lacks discussion of how tools evaluated for accuracy and reliability. Did not include "ward" nurses even though author mentioned importance of med/surg nurses need for trach care competency. Attrition- no discussion.

5	Gaur & Mudgal (2018) Study aim: assess and enhance nurses' knowledge of trach care to improve patient outcomes	Quasi-experimental pretest-posttest control group **LOE = III**, no randomization of control and experimental group allocation	120 staff nurses in tertiary hospital in Rajasthan N = 120	Hospital	IV = Education intervention package DV = knowledge Day 1: Structured knowledge questionnaire (SKQ) administered (40 multiple choice questions re: trach care, complications, etc.). Content validity established after 7 experts, physicians and nurses, took test using test and re-test method. Coefficient correlation = 0.87, reliable tool. Day 2- Interventional package delivered for experimental group Day 14- posttest delivered to experimental and control group	Level of knowledge increase statistically significant in exp group $p < 0.01$. t value 12.30 at df (118) at 0.01 level of sig IP concluded to be an effective strategy. No sig different mean scores in control group. From pretest to posttest.	Demographic data obtained: age, gender, education, professional experience. Majority male 89.17%. May not have similar results in American, with majority female nurses. Majority of nurses had 1-5 yrs experience. May be more familiar and comfortable with simulation if that modality used in their education programs. Interventional Package not discussed in article.

6	Goldsworthy, et al. (2019) Study aim: determine if hybrid simulation improves confidence and competence in recognition and response to deteriorating patients	Quasi-exp pre/post **LOE = IV**	Nursing students (3rd yr undergraduate bachelor program) N = 59		IV = Hybrid simulation education DV = CSE, knowledge Treatment group – 16 hr simulation intervention, over 2 days that were 2 weeks apart, also completed 2 virtual sims Each session = 8 hrs, 2 sessions, 6 high fidelity simulation scenarios total Procedure: control group- Clinical Self Efficacy (CSE) and knowledge test administered, 16 hrs of simulation, posttests Experimental group- also exposed to virtual sim cases before posttest Tools: CSE- high internal consistency (0.91). Multiple choice knowledge test administered to tx group posttest. Validity not discussed.	Sig difference in CSE scores in tx group ($p<.001$ – $p<.008$) No sig improvement in CSE scores in control group ($p<.154$ – $p<.900$) Paired and independent t-tests Demographics collected: age, gender, primary language, education level Post intervention knowledge test administered to tx group: statistically sig. difference for 3/5 content areas: sepsis ($p<.033$), MI($p<.001$), asthma (.029) at $p<.05$ sig level	Weakness: One site. Small sample size. Strengths: Simulations designed using INACSL standards and best practice standards in simulation. Plus/delta debriefing used as faculty debriefers have varied backgrounds and simulation experience. Timing of virtual sim as an enhancement needs to be studied further. Future: add skills checklists and compare to knowledge and confidence scores Immediate post intervention + 6 months

7	Harjot, Kumar, & Krishan (2016) Aim: assess effectiveness of teaching intervention on knowledge and practice re: ETT suctioning among staff nurses	Quasi experimental, one group, pretest/posttest **LOE = IV**	35 staff nurses Convenience sampling	Hospital, India	IV = teaching intervention DVs = knowledge & skill Tools: structured knowledge questionnaire & observational checklist	Teaching intervention results in sig. change in knowledge ($p < 0.000$) and skill ($p < 0.000$)	Lacks discussion of tool validity. No details about teaching intervention. Unable to replicate study. No details re: education level of staff nurses. Education likely differs from American nursing programs. Educational qualification only sig difference amongst socio demographic variables (age, education, yrs experience in ICU, type of hospital, past clinical experience, attended in-service education) practice score associated with educational qualification

8	McDonough, et al., 2016 Study aim: to evaluate the effect of a nurse training program on knowledge and self-efficacy with tracheostomy and laryngectomy care	Prospective, pre and posttest design to evaluate nursing education program on knowledge and self-efficacy of trach and laryngectomy care **LOE = IV**	N = 1450	Tertiary care hospital	IV = Trach Group Session Didactic + Simulation DV = knowledge, self-efficacy Hands-on training (30 min.) followed by online tutorial Responses examined per demographics: gender, age range, nursing education, # yrs practicing, practice environment, # patients with tracheostomy/month, # patients with laryngectomy/month, completed nurse competence day, completed healthstream course	Chi square and t-tests; sig level 0.05 Statistically higher knowledge and self-efficacy scores	23% response rate (338 surveys completed) Survey Monkey used Pre and post survey numbers unequal 165 before/173 after and not correlated with each other; not necessarily same people completed pre and post surveys. Post surveys not done on site but sent online afterward with 4-week window for completion. Identified knowledge gap that nurses do not know the difference between tracheostomy vs laryngectomy

9	Mehta, et al., 2019 Study aim: To perform a needs-based assessment for tracheostomy care education for nonsurgical first responders in the hospital setting and to implement and assess the efficacy of a targeted tracheostomy educational program	One Group Pre and Post Prospective obs study **LOE = IV**	Medical residents N = 85	Hospital	IV = tracheostomy education session DV = knowledge, confidence Pre/posttest pilot study Tools: Objective knowledge survey administered immediately post intervention and again at 6 months. Clinical comfort tool: "Self-Assessment Questionnaire" Likert scale comfort level questions 1-5 (5 strongly agree) Intervention: 1 hr didactic + simulation session	Goal-determine specialty-specific curriculum P < .05. Significant improvement in knowledge immediately following intervention. Findings not significant @ 6 months for knowledge. Significant increases in comfort reported pre to post intervention and remained significantly increased at 6 months	Knowledge retention a weakness of intervention. Confidence reportedly remained increased. Knowledge quiz not validated, not included in study report. Consensus statement key points included but "revised" by a faculty member.

10	Mitchell, et al., (2013) Clinical consensus statement, systematic review, Delphi method On tracheostomy best practice guidelines	Systematic review **LOE = I**	53 guidelines, 99 systematic reviews or meta-analyses Exclusion criteria: duplicates, not related to tracheostomy, did not use systematic review methodology, non-English language articles. 18 articles remained.	Inpatient, Outpatient, Home Multiple databases search with PICOS criteria: Population: Children or adults with tracheotomy or tracheostomy Intervention: Postoperative care, home care, emergency care Comparison: Any techniques Outcome: Any Setting: Inpatient, outpatient, or home	Systematic review using Delphi method used with expert multidisciplinary panel. Process: Conference call, Survey, conf call 2, Delphi survey 1, conf call 3, Delphi survey 2, conf call 4. Used validated search filter strategy. Conducted by information specialist with Cochrane ENT Disorders Group. Included clinical practice guidelines, systematic reviews, and meta-analyses re: trach care in peds and adults through April 2011. 2nd lit search: RCTs, observational studies, and case series published through 2011.	Resulted in 77 statements on pediatric and adults achieving consensus. Survey responses scored from low to high.	Trach tube care and airway management statements achieved the greatest consensus. Infrequently occurring: severe bleeding, tracheoesophageal fistula, and airway stenosis implying focus of education on trach tube care, cleaning , suctioning, speech, etc. Identified need to defined trach care protocols and clinical practice guidelines for healthcare staff and patients and families. Utilization of a defined

11	Sandler, et al. (2020) Study aim: improve pediatric tracheostomy care in resource-limited settings	Quality improvement project involving pilot study Boston Children's Hospital & Rwanda Teaching Hospital collaboration **LOE = IV**	Nursing staff and otolaryngology residents in Rwanda N= 10 Female = 7 Male = 3 RN = 8 Resident = 2 Average yrs experience at hospital = 9.38	Inpatient & outpatient setting at University Teaching Hospital Kigali, Rwanda	IV = education intervention DV = confidence 3 Phases, Focus on education intervention to assess confidence of nurses and residents: 2-day, 4-hour/day training course taught by Boston Children's Hospital nurse educator: 1. didactic + 2. simulated skill practice (trach tube change & suctioning) 3. hands on practice in inpatient & outpatient settings Pre and post education intervention questionnaires on self-efficacy on suctioning, trach tie change, emergency situations	10-point Likert-scale. Only media scores reported: 8 (7, 9.75), 8 (5.25, 9), 5 (0.25, 6.75), 7 (3.25, 7.75), 6.5 (5.25, 9) pre scores 10 (10,10), 10(10,10), 9(8,10), 10(9,10), 10(9,10) post scores	Low sample size Low-cost tracheostomy care kit intended for healthcare workers, caregivers, Addresses knowledge deficit and limited training supplies Simulation used

12	Smith-Miller, C., 2006 Study aim: To examine new graduate nurses' comfort level before and after a tracheostomy inservice educational session	One group pre and posttest **LOE = IV**	N = 134 divided into subsets new graduate nurses: BSNs (n = 68), ADNs (n = 31), diploma (n = 4) Next subset: (n= 31) experienced nurses varied backgrounds 1-34 yrs experience	hospital	IV = education intervention DV = comfort, knowledge "inservice education session" no details Tools: Likert-scale comfort level Med-Surg Tracheostomy knowledge test "Focus on Tracheostomy" Hickey, 2002 Hickey, M. (2002). Focus on tracheostomy. Perspectives-Recovery Strategies from the OR to Home, 4(3), 1-8. References Responses and correct answers discussed prior to inservice education, which included hands on practice (no details on exact method)	Basic trach knowledge scores tabulated + comfort level scores. Means compared between ADN/diploma (n=35) and BSN (n=65) knowledge: BSN scores slightly higher but not statistically significant. 2 tailed t-tests performed. ADN/diploma posttest statistically higher @ t = 4.614×10^{-10} when compared to pre-educational and hands-on skill practice; higher than BSN group @ t=4.51×10^{-7} (2 tailed). ADN/diploma baseline comfort level of 6.83 not statistically significant to BSN of 5.75. Post intervention, differences still not significant. Experienced nurses: knowledge scores only slightly higher than new graduate nurses. No relationship between comfort level and experience.	Assumption in nursing that ADN-trained nurses enter practice with broader skill set and comfort; this is not the case with tracheostomy care. Differences of scores of baseline knowledge were not statistically significant between experienced and new graduate nurses despite experience nurse reporting higher comfort levels. Perceived comfort and knowledge not necessarily related. Experienced nurses reporting increased comfort and experience nurse who reported decreased comfort levels had similar knowledge level scores (r=.70). Nurses are not comfortable with trachs despite knowledge level with this type intervention. Even experienced nurses need ongoing education. "the discrepancy between experienced nurses' comfort level and demonstrated knowledge warrants further study and exploration to develop effective strategies to minimize this gap." "hands-on skills content should be a priority for inclusion into nurse residency programs, particularly with specialized, high-risk, low-incidence nursing skills, regardless of how comfortable nurses report they are with a given patient population"

13	Sodhi, Shrivastava, & Singla (2014) Study aim: Study the impact of dedicated tracheostomy care nurse program on outcomes of tracheostomized patients.	Retrospective cohort **LOE = III**	42 non critical care nurses	Hospital, Japan	IV = tracheostomy care nurse program DVs= 1. trach care complications 2. ICU readmissions 3. decannulations (not accidental) 4. average length of stay (ALOS) 4-month education program over 4 months to certify non critical care nurses in tracheostomy care Chart review conducted to evaluate DVs before the use of specially trained trach care nurses and after the incorporation of specially trained trach care nurses Control group = trach patients from 1/2011 – 11/2011 Study group = 12/2011- 10/2012 Manual chart review completed.	t-test or Wilcoxon rank-sum test compared clinical variables between pre-intervention (control) and post-intervention (study) groups $p < 0.05$ considered statistically sig DVs: 1. difference in complications sig @ $p<0.05$ 2. readmission rate difference sig @ $p<0.05$ 3. # of decannulations not sig @ $p>0.05$ 4. ALOS difference statistically sig @ $p<0.05$	All DVs difference statistically sig except # of decannulations possible due to the overall increase in attempts to help patients meet criteria for decannulation as soon as possible Though this education intervention and QI approach showed sig improvements in patient outcomes, the education of these specially trained nurses is ongoing with monthly inservices and other criteria to maintain certification.

14	Yelverton, et al., (2015) Study aim: evaluate effectiveness of an educational curriculum on general trach care principles and determine the effect of this educational curriculum on the level of provider comfort with trach care	Cross-sectional questionnaire pre and post education **LOE = IV**	94 medical and surgical residents, medical students, midlevel providers, and nursing staff	Academic medical center	IV = targeted educational program DVs = comfort, knowledge 45 minute education program: trach care key aspects encountered by multidisciplinary teams including physicians, nurses, and respiratory therapists Curriculum based on Clinical Consensus Statement from American Academy of Otorynolaryngology Administered by 2 ENT residents in lecture form 26-item multiple choice and true/false knowledge test given pre-education intervention and post. 25 items knowledge based and 1 item asks comfort level with faces scale 0-100. Validity addressed by administering to Otolaryngologist for expert opinion. No statistical data on validity or reliability. Same 26 item quiz used at 6 months post education intervention.	Paired t-test compared pre and posttest scores. One factor ANOVA tested the effect of education level changes in test scores and comfort. Repeated measures ANOVA for pre, post, and 6-month comparison. Tukey's used to control for type I error of 5%. Mean improvement from pre to posttest statistically sig @ $p<0.001$. (1^{st} 25 questions) Confidence question measured before and after education, mean improvement was statistically sig @ $p<0.001$. At 6 month follow up, only 6 participants completed re-test. No sig change from posttest values but sig increase from pre to 6 mo. @ $p<.0.02$.	Participants reportedly had frequent exposure to tracheostomy patients No hands-on component but results still sig likely due to experience and exposure to trach patients Lecture form of educational intervention lends itself to transition to self-directed learning computer module. Attrition: very high. Possibly due to graduating participants.

Table 3

Trach Care Education and Its Effects for Healthcare Providers (n=14).

			Intervention F1	Intervention F2	Intervention F3	Intervention Strategies F4	Intervention F5	Outcome 1.	Outcome 2.	Outcome 3.
	Author, Year	Design	Target Population	Setting	Methodology	Duration/ Frequency of Intervention	Measurement of outcomes	Knowledge	Confidence /comfort	Skill
1	Bayram & Caliskan (2019)	RCT	Nursing students	Academic	Simulation VR app education	90 min	Pre post & 7 days	NS	Not measured	↑
2	Colandrea & Eckardt (2016)	One group pretest/ posttest	Med/Surg nursing staff: RNs, LPNs, CNAs	VA hospital	lecture	1 hr	Pre/post lecture	↑	↑	Not measured
3	Davis, et al. (2019)	One group Pre/ post	Medical residents	Hospital	Didactic + simulation	1 hr didactic + 1 hr time for simulation	Pre/post + 6 months	↑	↑	↑
4	Dorton, Lintzenich & Evans (2014)	One group Pre/ post pro-spective	Physicians and advanced practice nurses	Hospital	Didactic + simulation	2 hr education intervention with pre and posttest; Repeat-tests @ 6 months	Pre post + 6 months	↑	↑	Observed but no tool discussed
5	Gaur & Mudgal (2018)	Pre/ Post control group	Staff nurses	Hospital	Interven-tional package (IP)	14 days	Knowledge pre and post IP/ no IP	↑	Not measured	Not measured
6	Goldsworthy, et al. (2019)	Pre/ post	RN students	Academic	HFS + virtual simulation	14 days	Self-efficacy pre & post; knowledge post only for tx group	↑ tx group 3/5 content areas	↑tx group NS control group	Not measured
7	Harjot, Kumar, Krishan (2016)	Pre/ post	Staff nurses	Hospital	Teaching interven-tion (no details)	Not reported	1 data collection point	↑	Not measured	↑
8	McDonough,	Pre/ post	nurses	Hospital	30 min. online +	Once	4 weeks post interven-	↑	↑	Not measured

	et al. (2016)				hands on		tion to complete survey			
9	Mehta (2019)	One Group Pre/Post prospective	Medical residents	Hospital	Didactic + simulation	Once	Post-Session + 6 months	↑ posttest NS @ 6 mo	--	Not measured
10	Mitchell, et al. (2013)	Systematic review	Peds and adults	Inpatient, outpatient, and home	Systematic review	Delphi method	Results in 77 consensus statements	--	--	--
11	Sandler, et al. (2020)	QI Pre/post	Nurses, otolaryngology residents	Hospital	Didactic, simulation, clinical patients	2 days, 4 hr session each day	1 data collection point	Not measured	↑	Not measured
12	Smith-Miller, (2006)	3 group pre/post intervention	New graduate nurses and experienced nurses	Hospital	Didactic + hands on skill practice; no simulation	Once during new nurse residency program; one data collection point for experienced nurses	Baseline/ pretest & posttest	↑	NS	Not measured
13	Sodhi, Shrivastava, & Singla (2014)	Retrospective cohort pre and post intervention	Non critical care nurses	Hospital	4-month certification program	Chart review before and after cert program	Chart review of pre and post education program	Measured once post education to achieve certifica-tion	Not measured	Not measured
14	Yelverton et al. (2015)	Pretest posttest, one group	Physicians, nurses, medical students	Hospital	didactic	45 minutes	Pre, post, + 6 months	↑	↑	Not measured

NS = non-significant ($p > 0.05$); HFS = high fidelity simulation

Appendix E

Tracheostomy Pretest Study Instrument

Permission letter

From: Agarwal, Amit
To: Keller, Christina
Subject: Re: tracheostomy assessment tools
Date: Tuesday, April 7, 2020 10:11:03 PM
Attachments: image001.png

Hi Christina

I would be glad to share the tool.
I am happy it is useful, Please do put the reference the 2015 article. Do you need permission from publisher .

Please let me know if I can help in anyways

Amit Agarwal MD
Associate Professor
Department of Pediatrics and sleep medicine
Medical Director Chronic Ventilator service line
Arkansas Children's hospital agarwalamit@uams.edu
Phone- 501-364-1006

From: Keller, Christina <cdkeller@RADFORD.EDU>
Sent: Wednesday, April 1, 2020 7:40 AM
To: Agarwal, Amit
Subject: tracheostomy assessment tools

Hello Dr. Agarwal,

My name is Christina Keller, and I am currently a DNP student at Radford University developing a tracheostomy teaching project for medical-surgical nurses.

I am kindly requesting permission to use the tools mentioned in your 2015 study *Improving Knowledge, Technical Skills, and Confidence Among Pediatric Health Care Providers in the Management of Chronic Tracheostomy Using a Simulation Model* and referenced by Davis et al.

(2019), *Using Didactics and Simulation to Enhance Comfort, Knowledge, and Skills of Nonsurgical Trainees Caring for Patients With Tracheostomy and Laryngectomy.* It is challenging to obtain validated tools assessing tracheostomy care knowledge, skill, and confidence. I would like to revise the tools mentioned below to meet the learning needs of medical-surgical nurses in my study.

Your consideration is greatly appreciated.

Sincerely, Christina

See below:

1. Comfort: Likert scale assessment of self-perceived comfort with tracheostomy and laryngectomy care (see Supplemental Digital Content 1, which includes comfort assessment used, http://links.lww.com/SIH/A452)
2. Knowledge: Objective multiple-choice evaluation (see SupplementalDigital Content 1, which includes knowledge assessment used, http://links.lww.com/SIH/A452)
3. Skill: Task-based assessment of participant ability to perform aroutine tracheostomy change on a mannequin (see Supplemental Digital Content 2, which contains the skill assessment tool used, http://links.lww.com/SIH/A453)

Christina D. Keller MSN, RN, CNE, CNEcl, CMSRN, CHSE
Radford University Clinical Simulation Center
Instructor, School of Nursing
304 Cook Hall
Radford, VA 24141
540-831-2491 Office

From: Edgar-zarate, Courtney L

To: Keller, Christina

Subject: RE: Tracheostomy pretest

Date: Monday, June 22, 2020 11:12:49 AM

Attachments: image001.png

Christina,

I sincerely apologize for the delay. I am not the first author to the paper nor senior author. I had to reach out to everyone to ok this. You do have permission to use these resources. We ask that you please reference these appropriately and make sure to give our institution and authors credit for this material.

Courtney Edgar-Zarate, MD

Internal Medicine-Pediatrics

Associate Professor, Hospital Medicine in Pediatrics and Internal Medicine
Associate Program Director for Med/Peds and Pediatric Residency Program
1 Children's Way Slot 512-8

Little Rock, AR 72202
501-364-4361

From: Keller, Christina <cdkeller@RADFORD.EDU>

Sent: Thursday, May 28, 2020 7:53 AM

To: Edgar-zarate, Courtney L <CLEdgarzarate@uams.edu>

Subject: FW: Tracheostomy pretest

From: Keller, Christina
Sent: Monday, April 27, 2020 12:35 PM

To: cledgarzarate@uams.edu

Subject: Tracheostomy pretest

Hello Dr. Edgar-Zarate,

My name is Christina Keller, and I am currently a DNP student at Radford University developing a tracheostomy QI project for medical-surgical nurses. I am a full-time, certified simulation educator at a regional simulation center primarily serving pre-licensure nursing students. I am very interested in translational research and desire to take simulation education to the bedside for practicing nurses with a mobile task-trainer and high fidelity simulation making it practical and efficient enough to be a sustainable method of continuing education. Ultimately, I would like to conduct follow-up studies to assess the impact of hybrid simulation on patient outcomes such as length of hospital stay and tracheostomy related complications.

Medical-surgical nurses often don't have the time to attend hours of continuing education courses nor do rural hospitals have the space and resources to utilize expensive mannequin simulators for continued education. I want to take mobile, hybrid simulation to them.

I am kindly requesting permission to use the tools mentioned in your 2019 study, *Using Didactics and Simulation to Enhance Comfort, Knowledge, and Skills of Nonsurgical Trainees Caring for Patients With Tracheostomy and Laryngectomy.* It is challenging to obtain validated tools assessing tracheostomy care knowledge, skill, and confidence. I would like to revise the tools mentioned below to meet the learning needs of medical-surgical nurses in my study. I have asked Dr. Agarwal about the tool also as mention in the 2015 study, *Improving Knowledge, Technical Skills, and Confidence Among Pediatric Health Care Providers in the Management of Chronic Tracheostomy Using a Simulation Model.* He has shared his willingness to share the tool pending publisher approval. The tracheostomy pretest your team and Dr. Agarwal used is the most valid tool and only tracheostomy knowledge survey I am able to find used in more than one study during my literature review.

Your consideration is greatly appreciated.

Sincerely,
Christina

See below:

1. Comfort: Likert scale assessment of self-perceived comfort with tracheostomy and laryngectomy care (see Supplemental Digital Content 1, which includes comfort assessment used, http://links.lww.com/SIH/A452)
2. Knowledge: Objective multiple-choice evaluation (see Supplemental Digital Content 1, which includes knowledge assessment used, http://links.lww.com/SIH/A452)
3. Skill: Task-based assessment of participant ability to perform a routine tracheostomy change on a mannequin (see Supplemental Digital Content 2, which contains the skill assessment tool used, http://links.lww.com/SIH/A453)

Christina D. Keller MSN, RN, CNE, CNEcl, CMSRN, CHSE Radford University Clinical Simulation Center

Instructor, School of Nursing
304 Cook Hall
Radford, VA 24141
540-831-2491 Office

Tracheostomy Pretest, Same for Posttest except demographic info.

Permission requested from Dr. Agarwal for use and will need to be revised and tailored to medical-surgical nurses. The tool was validated with expert opinion from a panel consisting of an otolaryngologist, tracheostomy nurse specialist, and respiratory therapist. Has been used in 2 previous studies. Plan to remove physician scope of practice scenario questions to focus on nursing aspects of tracheostomy care covered in the educational intervention.

TRACHEOSTOMY PRETEST

Confidence Level

Describe your confidence level with the following on a scale

from 0 (not confident at all) to 5 (very confident).

1. Identifying the parts of a tracheostomy tube.
2. Understanding the function of a Passy-Muir valve.
3. Suctioning a tracheostomy patient.
4. Knowing the indications for a cuffed vs. uncuffed tracheostomy tube.
5. Knowing the differences between a tracheostomy and laryngectomy.
6. Changing tracheostomy ties.
7. Cleaning and/or replacing the inner cannula along with stoma care.
8. Evaluating and managing the airway of a patient with a tracheostomy or laryngectomy with respiratory compromise.
9. Identifying "red flags" in patients with a new tracheostomy.
10. Responding to an accidental decannulation event.

Anatomy

1. The standard anatomic location where tracheostomies are placed is
a. Between hyoid bone and thyroid cartilage
b. Between thyroid cartilage and cricoid cartilage
c. Between the cricoid cartilage and the first tracheal ring
d. Between the tracheal rings 2 and 3.
e. Just above the suprasternal notch

Physiologic changes associated with tracheostomy

2. The following physiological changes occur with a tracheostomy except
a. The anatomical dead space of respiratory system is reduced by up to 30- 50%
b. Humidification of inspired air is reduced

c. Sense of taste and smell can be diminished
d. Temperature of the inspired air is reduced
e. The patient's ability to swallow is severely affected

3. Tracheotomy patients can't speak without finger occlusion because
a. Air which would normally pass through the vocal cords is now bypassed to the tracheotomy
b. Tracheostomy tubes pass through the vocal cords thus obstructing cord movement
c. Vocal cords are paralyzed during the surgical placement of tracheostomy tubes
d. The recurrent laryngeal nerve is often injured during the tracheostomy tube placement
e. Tracheostomies cause vocal cord edema thus interfering with vocal cord movement

Pro's / Con's

4. Which of the following is a false statement regarding tracheostomies?
a. Tracheostomies can relieve an upper airway obstruction.
b. Tracheostomies provide less trauma to surrounding airway structures than ET tubes.
c. Tracheostomies pass through the vocal cords thus allowing for mechanical ventilation.
d. Tracheostomies allow for decreased sedation and pain medication requirements.
e. Tracheostomies make weaning from ventilator easier than endotracheal tubes.

Parts of a Trach

5. What is the purpose of the inner cannula of a tracheostomy tube?
a. Allows for mechanical ventilation.
b. Provides a place to suture to and/or place ties to secure the tracheostomy when necessary.
c. Assists with insertion of tracheostomy making insertion less traumatic.
d. Is easily removed making cleaning tracheostomy tube easier and providing a safety measure to remove an obstructing mucus plug.
e. Provides the cuff in cuffed tracheostomies.

Indications for Trach

6. Which of the following is not an indication for tracheostomy?
a. Facilitate ventilation weaning in chronic respiratory failure
b. Relieve obstruction of the upper airway from cancer or trauma
c. Secure the airway from bleeding in the upper aerodigestive tract
d. Obstructive sleep apnea
e. Mechanical ventilation for 2 days

Types of Tracheotomy tubes

7. Which of the following is a false statement?

a. Uncuffed trachs allow for speech in conjunction with speaking valves
b. Cuffed trachs make swallowing easier than uncuffed trachs
c. Uncuffed trachs lessen local airway trauma
d. Cuffed trachs allow for positive pressure ventilation
e. All of the above are true

Accessory Equipment – Passy Muir, Trach collar, artificial nose

8. A patient is started on a Passy-Muir valve trial after a recent tracheostomy placement but is having difficulty with phonation. Which of the following would improve phonation attempts?
a. Changing to a cuffed tracheostomy tube to improve airway pressures
b. Gradually increasing amount of time using valve to acclimate patient to device
c. Ensuring appropriately sized tracheostomy tube to increase air flow around the tube
d. B and C
e. All of the above

Tracheostomy Complications

9. A patient was admitted over 1 month ago to MICU for acute respiratory failure likely secondary to obesity hypoventilation syndrome. After initial stabilization, wean off of ventilator support failed on multiple occasions so a tracheostomy was placed 3 weeks ago. In the last 24 hours about 10 mLs of frank blood was suctioned from the tracheostomy tube on two separate occasions. Which of the following is most likely associated with the bleeding?
a. High placement of tracheostomy tube
b. Infection
c. Tracheo-esophageal fistula
d. Granulation tissue
e. Tracheo-innominate fistula

Laryngectomy

10. A 67 yo woman with history of COPD, CHF, and laryngeal cancer status post laryngectomy on home trach collar comes to ED with 24 hours of respiratory distress and 2 hours of worsening lethargy. Physical exam is notable for lethargy requiring aggressive verbal stimulation to arouse, respiratory distress with diffuse end expiratory wheezing and diffuse crackles. CXR shows interstitial prominence with no apparent areas of consolidation. ABG is 7.05 / 90 / 65 / 23.8. RR on exam is 35. What is the next best step?
a. Apply appropriately sized mask to face and begin bag-mask ventilation
b. Apply appropriately sized mask to face and begin BiPAP
c. Oropharyngeal endotracheal intubation and begin mechanical ventilation
d. Insert cuffless tracheostomy tube into stoma and begin mechanical ventilation
e. Insert cuffed endotracheal tube into stoma and begin mechanical ventilation

Trach Maturation

11. When is a tracheotomy tract considered established? i.e. an established tracheotomy
a. POD 3 after ENT has performed the first tracheotomy change
b. POD 7 after ENT has performed the first tracheotomy change
c. POD 10 after ENT has performed the first tracheotomy change
d. POD 14 after ENT has performed the first tracheotomy change
e. POD 21 after ENT has performed the first tracheotomy change

12. A 52 yo man is POD#2 from a tracheostomy because of a progressive neuromuscular disorder. You are a 2nd year resident in the ICU and you are called to the patient's bedside because of respiratory distress. Once you enter the room you find the trach tube lying on the bed. Which of the following is the MOST appropriate next step?
a. Insert the tracheostomy tube into the stoma with an obturator or use one size smaller
b. Insert a small endotracheal tube into the stoma
c. Apply positive pressure ventilation to the face, cover stoma, and call ENT STAT
d. Apply mask to stoma, begin positive pressure ventilation, and call ENT STAT
e. Emergently perform transoral endotracheal intubation and call ENT STAT

Decannulation / Complications with Recannulation

13. A 52 yo man had a tracheostomy placed a month ago because of a progressive neuromuscular disorder. You are a 2nd year resident in the ICU and you are called to the patient's bedside because of respiratory distress. Once you enter the room you find the trach tube lying on the bed. Which of the following is the MOST appropriate next step?
a. Insert the tracheostomy tube into the stoma with an obturator or use one size smaller
b. Insert a small endotracheal tube into the stoma
c. Apply positive pressure ventilation to the face, cover stoma, and call ENT STAT
d. Apply mask to stoma, begin positive pressure ventilation, and call ENT STAT
e. Emergently perform transoral endotracheal intubation and call ENT STAT

14. A 57 yo man who is tracheostomy dependent patient and is currently being mechanically ventilated had an accidental decannulation of his trach. The tracheostomy tube was urgently replaced by the RT; however, O2 saturations have not recovered, remaining in mid to high 80's despite increased FiO2 and PEEP settings. On examination you find the trach is placed in the stoma and developing crepitus around it. On auscultation you notice distant breath sounds. What is the most likely problem?
a. Poor connection with mechanical ventilator circuit
b. Tracheal perforation
c. False Passage
d. Tracheoesophageal fistula
e. Mucous Plugging

15. What is the most common cause of tracheostomy tube obstruction?
a. Tracheostomy tube end positioned against back wall of trachea
b. Mucous plug
c. Over-inflation of tracheostomy cuff
d. Tracheostomy tube malfunction
e. False passage

16. What should not be done when attempting to change a tracheostomy tube and it cannot be replaced with the same size tube?
a. Force the same size tracheostomy tube back into the stoma
b. Apply a bag-valve mask to face device to gently ventilate the patient after covering stoma with gloved hand
c. Call rapid response team
d. Try replacing tracheostomy with a size smaller than current trach size
e. Suction stoma and place oxygen

17. A 48 yo man with history of CHF and tracheostomy dependence secondary to squamous cell carcinoma of the oropharynx is received via direct admission to the MICU on mechanical ventilation for respiratory failure secondary to community acquired pneumonia. He is on trach collar at home via a 6-0 uncuffed tracheostomy tube but has required mechanical ventilation for the past 7 days and has clinically worsened. On exam you note the patient is being mechanically ventilated via his home size 6 uncuffed tube and target tidal volumes are not being achieved. The next best step in management is:
a. Call ENT for evaluation
b. Change the trach to a size 8 cuffless tube
c. Change the trach to a size 6 cuffed tube
d. Change the trach to a size 6 fenestrated tube
e. Change the trach to a size 4 cuffed tube and place a passy muir valve

Routine Care

18. How often must a fresh tracheostomy patient be suctioned
a. Every 2 hours and as needed
b. Every 4 hours and as needed
c. Every 4-6 hours and as needed
d. Every 6-8 hours and as needed
e. As needed

19. How often must an established tracheostomy patient be suctioned
a. Every 2 hours and as needed
b. Every 4 hours and as needed
c. Every 4-6 hours and as needed

d. Every 6-8 hours and as needed
e. As needed

20. Which of the following are not a part of a "Trach Go bag"
a. Clean tracheostomy tube of current size set with obturator
b. Water soluble lubricant
c. Suction catheter
d. Tracheostomy tube size bigger than current size
e. Tracheostomy tube size smaller than current size

Demographic information/confounding variables

21. Have you ever taken a course in Tracheostomy and/or Laryngectomy prior to this course?
a. Yes
b. No
[dichotomous variable]

22. ~~Please indicate which training program you are associated with?~~ Have you cared for patients with tracheostomies in the past 12 months?

a. Yes

b. No

[dichotomous variable]

[This question is N/A as I will be studying medical-surgical nurses.]

a. ~~Internal Medicine / Medicine-Pediatrics~~

~~b. Family Medicine~~
~~c. Emergency Medicine~~
~~d. Pediatric Emergency Medicine fellowship~~
~~e. Anesthesiology~~
~~f. Critical Care fellowship~~
~~g. Other~~

23. ~~Please indicate which year of post-graduate training you are in.~~ Question not applicable.
How long have you been practicing as a nurse?
years _____ [continuous variable]

[dichotomous, nominal variable]

24. Please indicate your level of education.

[in the form of # years as a continuous variable]

Key:

1. D
2. E
3. A
4. C
5. D
6. E
7. B
8. D
9. D
10. E
11. B
12. C
13. A
14. C
15. B
16. A
17. C
18. A
19. E
20. D

Appendix F

Tracheostomy Neck Piece Simulated Task Trainer

SSH
Society for Simulation in Healthcare
Accredited Program
Teaching/Education

International Meeting on Simulation in Healthcare (IMSH) 2018
Spectrum of Ideas Submission #426
Tracheostomy Neck Piece for IPE Task Training (#ID 852)
Submitter: Christina Keller MSN, RN, CHSE

Appendix G

NLN Simulation Design Template

National League for Nursing

Simulation Design Template

(revised May 2019)

(name of patient) Simulation

Date:	**File Name:**
Discipline: Nursing	**Student Level:** Licensed Medical/Surgical Nurse
Expected Simulation Run Time:	**Guided Reflection Time:** Twice the amount of time that the simulation runs.
Location:	**Location for Reflection:**
Today's Date::	

Brief Description of Client

Name: Daisy Willis

Date of Birth: 12/20/1974

Gender: female **Age**: 45 **Weight**: 160 lbs **Height**: 5'8"

Race: Caucasian **Religion**: unspecified

Major Support: Husband **Support Phone:** 838-8833

Allergies: penicillin/ rash **Immunizations:** up to date

Attending Provider/Team:

Past Medical History: colitis

History of Present Illness: traumatic injury, passenger MVC, rebar into neck

Social History: married, mother of 2 children, non-smoker, occasional alcohol intake

Primary Medical Diagnosis: severe neck injury/tracheal trauma, s/p tracheotomy

Surgeries/Procedures & Dates: appendectomy age 7, C-section 2005

Psychomotor Skills Required of Participants Prior to Simulation

Tracheal care and suctioning
Auscultation skills

Cognitive Activities Required of Participants Prior to Simulation

Completion of last annual skill competency requirements

Simulation Learning Objectives

General Objectives (Note: The objectives listed below are general in nature and once learners have been exposed to the content, they are expected to maintain competency in these areas. Not every simulation will include all of the objectives listed.)

1. Practice standard precautions.
2. Employ strategies to reduce risk of harm to the patient.
3. Conduct assessments appropriate for care of patient in an organized and systematic manner.
4. Perform priority nursing actions based on assessment and clinical data.
5. Reassess/monitor patient status following nursing interventions.
6. Communicate with patient and family in a manner that illustrates caring, reflects cultural awareness, and addresses psychosocial needs.
7. Communicate appropriately with other health care team members in a timely, organized, patient-specific manner.
8. Make clinical judgments and decisions that are evidence-based.
9. Practice within nursing scope of practice.
10. Demonstrate knowledge of legal and ethical obligations.

Simulation Scenario Objectives (One objective per each of 4 short simulation vignettes)

1. Assess patient for respiratory distress and determine appropriate action.
2. Assess patient after accidental decannulation and determine appropriate action.
3. Assess patient for respiratory distress and perform appropriate action.
4. Assess patient with laryngectomy and perform appropriate action.

For Facilitator: References, Evidence-Based Practice Guidelines, Protocols, or Algorithms Used for This Scenario:

Desired outcomes:
1. Recognize rhonchi and need for suctioning
2. Recognize tracheostomy is considered mature and replacing trach tube with same size or one size smaller.
3. Recognize suction catheter will not pass, does not force catheter, and removes tube to clear airway of mucus plug.
4. Recognize patient in respiratory arrest, call for help, and administer oxygen via laryngectomy stoma versus bag valve mask to face.

Mitchell, Clinical Consensus Statement American Academy of Otorhinolaryngology (2013)

Setting/Environment

☐ Emergency Room ☒ Medical-Surgical Unit ☐ Pediatric Unit ☐ Maternity Unit ☐ Behavioral Health Unit	☐ ICU ☐ OR / PACU ☐ Rehabilitation Unit ☐ Home ☐ Outpatient Clinic ☐ Other:

Equipment/Supplies (choose all that apply to this simulation)

Simulated Patient/Manikin/s Needed:
Facilitator/CHSE RN as standardized patient
Tracheostomy task trainer neck piece
Recommended Mode for Simulator:
Hybrid, standardized patient

Other Props & Moulage:

Equipment Attached to Manikin/Simulated Patient:	**Equipment Available in Room:**
☐ ID band ☐ IV tubing with primary line fluids running at __mL/hr ☐ Secondary IV line running at ___mL/hr ☐ IVPB with _____ running at mL/hr ☐ IV pump ☐ PCA pump ☐ Foley catheter with ___mL output ☒ 02 ☐ Monitor attached ☒ Other: portable suction **Other Essential Equipment:** Trach care kit Suction catheter Extra trach tube Speaking valve **Medications and Fluids:** ☐ Oral Meds: ☐ IV Fluids: ☐ IVPB: ☐ IV Push: ☐ IM or SC:	☐ Bedpan/urinal ☒ 02 delivery device (type) ☐ Foley kit ☐ Straight catheter kit ☐ Incentive spirometer ☐ Fluids ☐ IV start kit ☐ IV tubing ☐ IVPB tubing ☐ IV pump ☐ Feeding pump ☐ Crash cart with airway devices and emergency medications ☐ Defibrillator/pacer ☒ Suction ☒ Other: bag valve mask

Roles

☐ Nurse 1 ☐ Nurse 2 ☐ Nurse 3 ☐ Provider (physician/advanced practice nurse) ☐ Other healthcare professionals: (pharmacist, respiratory therapist, etc,)	☐ Observer(s) ☐ Recorder(s) ☐ Family member #1 ☐ Family member #2 ☐ Clergy ☐ Unlicensed assistive personnel ☐ Other:

Guidelines/Information Related to Roles

Learners in role of nurse should determine which assessments and interventions each will be responsible for, or facilitator can assign nurse 1 and nurse 2 roles with related responsibilities.

Information on behaviors, emotional tone, and what cues are permitted should be clearly communicated for each role. A script may be created from Scenario Progression Outline.

Pre-briefing/Briefing

Prior to report, participants will need pre-briefing/briefing. During this time, faculty/facilitators should establish a safe container for learning, discuss the fiction contract and confidentiality, and orient participants to the environment, roles, time allotment, and objectives.

For a comprehensive checklist and information on its development, go to http://www.nln.org/sirc/sirc-resources/sirc-tools-and-tips#simtemplate.

Report Students Will Receive Before Simulation

(Use SBAR format.)

Time: real time

Person providing report: facilitator as nurse reporting off

Situation: 45 year old female s/p MVC suffering severe neck trauma necessitating tracheostomy placement 10 days ago

Background: insignificant hx, healthy

Assessment: transferred from ICU 2 days ago, VSS, maintains O2 > 94% on humidified air via trach collar, anticipated discharge next day

Note: background story changes based on scenario. Facilitator must inform learners during prebriefing of any changes.

Scenario Progression Outline

Patient Name: Daisy Willies **Date of Birth:** **12/20/1974**

Timing (approx.) Each scenario vignette approximately 5 minutes with 5 minute debrief	Manikin/SP Actions	Expected Interventions	May Use the Following Cues
0-5 min per scenario	Coughing and unable to speak Tap chest for help Try to cough Close eyes	**Learners should begin by:** • Performing hand hygiene • Introducing selves • Confirming patient ID • Assess airway • Auscultate lung sounds	**Role member providing cue:** **Cue: cough** **Appear anxious.** **Close eyes in respiratory arrest.**
		Learners are expected to: Identify rhonchi Need to suction Unable to pass catheter Remove inner cannula Clean cannula Replace and suction Reappy humidified oxygen Apply oxygen to laryngectomy stoma versus face	**Role member providing cue:** **Cue: cough, appear anxious**

Debriefing/Guided Reflection

Note to Faculty

We recognize that faculty will implement the materials we have provided in many different ways and venues. Some may use them exactly as written and others will adapt and modify extensively. Some may choose to implement materials and initiate relevant discussions around this content in the classroom or clinical setting in addition to providing a simulation experience. We have designed this scenario to provide an enriching experiential learning encounter that will allow learners to accomplish the listed objectives and spark rich discussion during debriefing. There are a few main themes that we hope learners will bring up during debriefing, but if they do not, we encourage you to introduce them.

Themes for this scenario:

- Assessment first, Nursing Process
- Identify need to maintain airway patency
- Apply knowledge and demonstrate confidence in handling complication

We do not expect you to introduce all of the questions listed below. The questions are presented only to suggest topics that may inspire the learning conversation. Learner actions and responses observed by the debriefer should be specifically addressed using a theory-based debriefing methodology (e.g., Debriefing with Good Judgment, Debriefing for Meaningful Learning, PEARLS). Remember to also identify important concepts or curricular threads that are specific to your program.

1. How did you feel throughout the simulation experience?
2. Give a brief summary of this patient and what happened in the simulation.
3. What were the main problems that you identified?
4. Discuss the knowledge guiding your thinking surrounding these main problems.
5. What were the key assessment and interventions for this patient?
6. Discuss how you identified these key assessments and interventions.
7. Discuss the information resources you used to assess this patient. How did this guide your care planning?
8. Discuss the clinical manifestations evidenced during your assessment. How would you explain these manifestations?
9. Explain the nursing management considerations for this patient. Discuss the knowledge guiding your thinking.

10. What information and information management tools did you use to monitor this patient's outcomes? Explain your thinking.
11. How did you communicate with the patient?
12. What specific issues would you want to take into consideration to provide for this patient's unique care needs?
13. Discuss the safety issues you considered when implementing care for this patient.
14. What measures did you implement to ensure safe patient care?
15. What other members of the care team should you consider important to achieving good care outcomes?
16. How would you assess the quality of care provided?
17. What could you do improve the quality of care for this patient?
18. If you were able to do this again, how would you handle the situation differently?
19. What did you learn from this experience?
20. How will you apply what you learned today to your clinical practice?
21. Is there anything else you would like to discuss?

Appendix H

Research Compliance Office- Not Human Subjects Determination

RADFORD UNIVERSITY
Research Compliance Office

Institutional Animal Care and Use Committee / Institutional Review Board

November 13, 2020

TO: Christina Keller, MSN, RN, CNE, CNEcl, CMSRN, CHSE
RE: Not Human Subjects Research (NHSR) Determination
STUDY TITLE: The Impact of Hybrid Simulation Education on Medical Surgical Nurses Knowledge and Confidence in Tracheostomy Care
IRB REFERENCE #: HCA Healthcare C.A.R.R.I.E. ID# 2020-645
SUBMISSION TYPE: Initial
Submission ACTION: NHSR
DATE OF DETERMINATION: November 13, 2020

The Radford University Institutional Review Board concurs with the determination of HCA Healthcare Alleghany Hospital, the above-referenced project is not human subjects research (NHSR).

This determination applies only to the activities described in the documents submitted to the Radford University IRB and does not apply should any changed be made. If changes are considered and there are questions related to whether or not IRB review is needed, please reach out to the IRB for a determination.

If you have any questions, please contact the Research Compliance Office at 540.831.5290 or irb-iacuc@radford.edu. Please include your study title and reference number in all correspondence with this office.

Good luck with your project!

Anna Marie Lee

Radford University Institutional Review Board (IRB)
Research Compliance Office
540.831.5290
Irb-iacuc@radford.edu
https://www.radford.edu/content/research-compliance/home.html

cc: Wendy Downey, DNP, MSEd, RN, C

View xForm - IRB Screening xForm (aka CARRIE)

Initial Applications

Initial Data Entry and Exempt Screen

Application Header

Step 1: Demographic Information About The Research, Researchers and Research Site

First let's get to know the demographics about the study personnel and location.

User Filling Out The Form

Thomas, Linda

What is the official (full) title of your study?

[If there is a grant affiliated with this project, please use the official title as approved in the grant.]

The impact of Hybrid Simulation Education on Medical Surgical Nurses Knowledge and confidence in Tracheostomy care.

Example: "A Study Comparing 6 Month Retention Of Information Delivered Originally Between Classroom Versus Virtual Learning"

Example: "A Retrospective Data Study Showing

Which institution is taking on the responsibility as the Primary Institution (i.e. the one with the most senior coordinating oversight)?

Site: Virginia: LewisGale Hospital Alleghany

Not a Good Example: "Diabetes Study"
*If the facility is not listed, please select the "*HELP! My Site*

Will other HCA hospitals be involved in this project?

irb@hcahealthcare.com to have your facility added.

No

Is this research to be credited toward one of these educational, accreditation or certification programs?

None Applicable

KEY CONTACTS

Please input the following key contacts:

NOTE: If you are trying to add an HCA email and have found they do not exist in the system, please use the following link to add a new contact to the system and *note that their account may need to be validated (by their logging in the system at least once) before you can add them below*.

User had the option to start a different form here.

What is your Local Institutional Approver's HCA email address?(This is the person at the local institution who gives the final administrative permission to conduct this study). IF THE INDIVIDUAL IS NOT FOUND, click the link above to request their addition in the system. Note that they will need to log once before you can add them.

NOTE: IRB approval or exemption alone is NOT final permission to conduct your research. The institution gives final approval for your research project.

For GME related scholarly activity, your Local Institution Approver is your Division Director of GME Research.

For Nursing studies, your Local Institution Approver is your Chief Nursing Officer If you are unsure who administratively approves your studies, please ask your supervisor.

Sutphin, Christy

Email: Christy.Sutphin@hcahealthcare.com **Phone:**

What is the HCA email address of the Principal Investigator of this study? (If the PI does not have HCA Single Signon Permissions (e.g. not an HCA employee with a 3-4 ID), please list the HCA employee most responsible for the conduct of the research project). IF THE INDIVIDUAL IS NOT FOUND, click the link above to request their addition in the system. Note that they will need to log once before you can add them.

Linda Thomas. Email: Linda.Thomas@hcahealthcare.com

Please check any and all HCA keywords that apply to the research project.

Please check any HCA standard Medical Specialty keywords that apply to the research.

*Other Medical Specialty(ies) (Not Listed)

So that we may consider adding it in future updates, please specify the "other" medical specialty that your research would apply to.

Traceostomy care

Please check any HCA standard Service Line keywords that apply to the research

Representations and Warranties

Step 2: Representation and Warranty Of Conditions. This page gathers certain representations and warranties from you, the submitter, towards the requirements to prepare for and conduct research with human subjects or their identifiable data as well as the making public of the resulting information.

Use of Protected Health Information Preparatory To Research

To respect and protect the privacy of individuals who have entrusted us with some of their most sensitive information, especially when the information used is Protected Health Information, requires the use of only the *minimally necessary information* when preparing your research protocol. The following attestations are required for using (or encountering in any way) any HIPAA Protected Health Information in the preparation of the research and must be agreed to in order to proceed. Whenever accessing identifiable information for purposes preparatory to research, you represent that the following are and will remain true at all times:

(A) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;

(B) No protected health information is to be removed from the covered entity (HCA) by the researcher in the course of the review; and

(C) The protected health information for which use or access is sought is necessary for the research purposes.

The above conditions can and shall be adhered to by all research staff.

Use of Protected Health Information of Decedents

While research and privacy regulations offer protections for living individuals, privacy regulations extend their privacy protections to those that are deceased. To respect and protect the privacy of deceased individuals (and their successors), especially when the information used is Protected Health Information, requires the use of *only the minimally necessary information*. The following attestations are required for using (or encountering in any way) any HIPAA Protected Health Information of decedents and must be agreed to in order to proceed. Whenever accessing identifiable information of decedents, you represent the following are and will remain true at all times:

(A) The use or disclosure sought is solely for research on the Protected Health Information of the decedents;

(B) If requested, documentation of the death of such individuals must be provided to the institution; and

(C) The Protected Health Information for which use or disclosure is sought is necessary for the research purposes.

The above conditions can and shall be adhered to by all research staff.

Intellectual Property Rights.

HCA shall be the sole and exclusive owner of any research results (including interim results), patent applications, patents, trademark applications, trademarks, copyright applications, copyrights, data or any other intellectual property or other proprietary rights resulting directly or indirectly from the research. The researchers are a "work for hire" and shall not acquire any rights of any kind whatsoever as a result of this activity unless expressly agreed upon by HCA. In the event that HCA (or its affiliated or partnering entity) decides to file one or more patent, trademark, copyright or other similar applications covering any intellectual property resulting from the research, the researchers shall assist in the preparation and prosecution of such application(s) and shall execute all documents reasonably deemed necessary by HCA for the filing thereof and/or for the vesting in HCA of title thereto.

The above conditions can and shall be adhered to by all research staff.

Making The Activity or Its Results (Including Interim Results) Known Outside of HCA Requires Permission

For purposes herein, "Publication" is considered any release of research results, including interim results, or data outside of HCA. This includes articles, posters, presentations, abstracts, case reports, datasets etc.

a) Publication Requires Clearance. At no time shall the researchers be free to proceed with external publication, posting or presentation or any other disclosure of this activity or its results (or interim results) outside of HCA without receiving written clearance in compliance with applicable policies and processes. This applies not only to the finished product itself but also to any data sharing plans.

b) No Guarantee of Publication. Nothing herein shall be construed as an obligation of HCA to permit the researchers to make public the results (or interim results) of this research nor give final approval in a format acceptable to the authors.

c) Turnaround Time of Clearance: While turnaround time is strived to be within industry norms (30-60 days), no turnaround time for final clearance can be guaranteed by HCA.

The above conditions can and shall be adhered to by all research staff.

By clicking the signature box below, it is confirmed that the research is and shall at all times remain consistent with the HCA Conditions of Receipt and Use of Company Data for Research Purposes and all other applicable policies and instructions.

Signed Thursday, September 3, 2020 2:29:56 PM ET by Thomas, Linda

Dataset Classification

Step 3: Dataset Classification for Certain Privacy And Possible IRB Exemption Purposes.

We universally use the HIPAA "Safe Harbor" de-identification method laid out at 45CFR164.514(b)

(2) as our standard to determine a de-identified dataset no matter who the research subjects are (meaning your research subjects could be patients, providers, staff, visitors etc and we apply the same standard of de-identification). Should you desire an alternate method of certifying de- identification, please indicate so herein. Also, this section addresses other regulatory limitations that may apply, such as certain restrictions on the secondary use and disclosure of data related to alcohol/substance abuse.

PLEASE NOTE THE FOLLOWING MYTH: "Only patients are research subjects". When you gather information for research purposes, the human subjects of the research may also include employees, providers, visitors etc. While HIPAA protects Protected Health Information, all subjects of the research must have their privacy protected through separate and often similar protections.

The following questions pertain to ANY living person who may be the subject of your research, not just patients.

Will you be obtaining, using, studying, analyzing, or generating any individual level data (i.e. will you have records or a dataset where each row or record represents an individual person/patient/provider etc.)?

Yes, I will be obtaining, using, studying, analyzing, or generating individual level data for the research.

To determine if your dataset is "de-identified" (using the HIPAA standard), please indicate any of the below "HIPAA Safe Harbor" identifiers that you will gather from or about individual research subjects. Note that this is not limited to just patients but any subjects of the research who can be identified, meaning providers, staff, visitors or any other natural person. This includes information gathered for the research from medical records, documentation on any surveys or questionnaires the subject completes, any notes taken by the researchers during interviews and observations etc.

To see a list of the truncated Zip Codes that must be replaced with "000" please click here.

No answer provided.

Please confirm that NONE of the above identifying information are being gathered and/or used for the proposed

Will the researchers be given any kind of "re-identification code" or other means of record re-identification that allows the researcher to query the data source for additional data pertaining to that individual (regardless if that additional data is de-identified or not)?

Yes

Is the code or other means of record identification a) derived from or related to any of the above identifying information about the individual or b) capable of being translated so as to identify the individual?

Examples:

- **YES: Subject initials + Year of Birth (e.g. "DMV1969")**
- **YES: Reversing the last 5 digits of the medical record number and adding the year of birth**
- **NO: A randomly generated number**
- **NO: A purely sequential row number (i.e. 1,2,3,4...) NO: A "one way" cryptographic hash**

No. The code or other means of record re-identification is NOT derived from or related to information about the individual and is NOT otherwise capable of being translated so as to identify the individual.

Will the data source use or disclose the code or other means of record identification for any other purpose? Or will the data source disclose the mechanism for re-identification?

No

Your dataset is classified as de-identified according to established privacy standards. Please acknowledge the classification of your dataset based on your responses. You cannot gather additional data other than what was described herein without revalidating this decision as this dataset classification may change and alter the IRB exemption decision.

I acknowledge that my dataset is classified as "de-identified" via the "HIPAA Safe Harbor" method.

Links to key supporting regulations and guidance:

- *De-Identified Dataset (HIPAA Definition) Regulation*
- *HHS Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule*
- *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule, Chapter 8A: De- identifying Protected Health Information Under the Privacy Rule Other Issues Relating to De-identification*

T

The following signature is for the restrictions and conditions required of a HIPAA Data Use Agreement under 45CFR164.514(e) necessary for receipt and use of a Limited Data Set but are applicable to all use of data for research purposes. You are required to read this and sign indicating your agreement.

Limited Use: The researchers assigned to this project may receive and use the subject's data only for the approved research project herein. The data may not be further used for any other purpose without permission unless required by law. Once use of the data is complete (including the expiration of any research data retention requirements), it should be destroyed in accordance with company policy.

No Disclosure (or Further Use) Without Subsequent

Permission: This determination for use does NOT give permission for the researchers to disclose any portion of the data outside of HCA. If data is to be disclosed outside of HCA (i.e. to a non-HCA employee for research collaboration or as part of a data transparency requirement to publish research in a specific journal), proper permission and contracts for external data release must be obtained. Even if permissible by law (i.e. through de-identification), the researchers are not given permission via this process to further use or disclose the information.

Reporting of Unauthorized Use or Disclosure: It must be reported to the local Privacy Officer if we become aware of any use or disclosure of this information outside of this research.

Appropriate Safeguards: The researchers will use appropriate safeguards, consistent with institutional policies to prevent use or disclosure of the information other than for this research.

No Re-Identification Or Contact: When given a Limited Data Set or a De-identified Dataset, the researchers may not attempt to re-identify the individuals the information pertains to or contact the individuals.

Other Laws or Protections May Apply: I understand that other laws (i.e. State laws) may have additional restrictions on my use of the information and agree to

abide by those as well.

I, the undersigned, agree to the above terms of a HIPAA Data Use Agreement, regardless of the classification of the research dataset, and agree to assure that any assigned researchers are aware of these restrictions and conditions.

Signed Thursday, September 3, 2020 2:40:57 PM ET by Thomas, Linda

Want an Exempt Determination?

Do you want to run your protocol through the decision trees to determine if you need IRB oversight? NOTE: If you do not select "Yes" to this question, you will not receive an IRB exempt determination from this system.

Yes

FDA, HSR and Exempt PreScreen

Determination of Need for IRB Oversight

The following steps will gather information about your proposed research to help determine if you are engaging in research with human subjects that requires prospective and possibly concurrent oversight by an Institutional Review Board (IRB) in accordance with applicable regulations and/or HCA compliance policies. **Note that this is based on United States laws thus research conducted outside of the United States (i.e. HCA International)must follow the local country's process here.**

First let's see if your activity is subject to FDA oversight.

Does your research involve prospectively administering drugs, medical devices, biologics or nutritional supplements to living individuals?

No

Does your research evaluate the use of software (e.g. computer code, mobile apps, websites, social media networks or other software solutions) for medical purposes? No

It appears that your research activity is NOT governed by the FDA. If any of the above answers change, this decision

T

Although not governed by FDA, there are other reasons prospective and concurrent IRB oversight may be required either by regulation

or company policy. But first, we must consider if your activity is considered "research with human subjects" using the "Common Rule" at 45CFR46 and the supporting guidance from the HHS Office for Human Research Protections as our guide.

For the following purpose, a *"human subject"* is defined at 45CFR46.102(e)(1) as a living individual about whom an investigator (whether professional or student) conducting research (i) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens, or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Is the proposed activity a systematic investigation (including research development, testing and evaluation) designed to develop or contribute

to generalizable knowledge?

Yes

*Example of "Yes": Exploring a hypothesis to draw general conclusions **beyond the scope of the institution** or to a broader population.*

*Example of "Yes": Aiming to **produce new knowledge to contribute to a broader endeavor**.*

*Example of "Yes": Standard procedures or normal activities are **altered by the need to examine/study them**.*

*Example of "No": Assessment of how well a process, product or program is working **in a specific context**.*

*Example of "No": Assessment of a program **as it exists (or would exist) absent the evaluation**.*

*Example of "No": Any intended publication/presentation is **only relevant to your institution**, leaving reader(s) to draw their own conclusions as to relevance to their own institution(s); i.e. not implying the results are applicable to external institutions.*

The activity meets the regulatory definition of "research". Now lets see if it is determined to meet the regulatory definition of "research with human subjects".

Does the research involve obtaining **information about and/or biospecimens from living individuals**?

No

Based on the answers above, your research can be categorized as "Not Research With Human Subjects". Please check the box below to acknowledge that all the above information is accurate.

Yes, all of the above information is accurate.

Exempt Final Determination

Based on the information submitted, your project has been determined as "Not Research With Human Subjects" and therefore IRB oversight is not required unless your local institutional policies require it.

If you believe there is an error in this determination or in the system, please contact irb@hcahealthcare.com. Thank you.

Otherwise, please read and confirm acceptance of the below.

I understand that this determination is not permission to conduct the research but only a determination that the research can be classified as "Not Research With Human Subjects". Final approval to conduct the research always rests with the institution's administration which may, among other things, require a local IRB to review or make this determination.

I understand that changes to the research that alter any of the answers herein may not be made without first revisiting this determination (except to prevent immediate harm to subjects or others).

I agree to only access data for this project in compliance with HCA data access and use for research policies.

I understand that although not requiring IRB oversight, I must promptly report to my local research supervisors any unexpected problems involving risks to subjects or others (i.e. within one week of their occurrence).

I understand that there may be periodic review or audits of this research to determine continuance and compliance.

Do you need the system to generate a "Letter To Publishers" for you to put on your letterhead indicating this status?

Y

Ready To Submit?

I have read The Belmont Report and agree to conduct the research in accordance with its principles.

Yes

Please sign here (one last time) to attest that all of the information submitted is accurate.

Signed Thursday, September 3, 2020 2:49:23 PM ET by Thomas, Linda