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The Implementation of an Endotracheal Tube Cuff Pressure Management Tool to Reduce Postoperative Sore Throat

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Abstract

Phase II Site: Fort Belvoir Community Hospital (FBCH), Fort Belvoir, Virginia

Project Title: The Implementation of an Endotracheal Tube Cuff Pressure Management Tool to Reduce Postoperative Sore Throat

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Background or Problem/Issue: Anesthesia providers at FBCH did not utilize objective intraoperative endotracheal tube (ETT) cuff assessment and management. The incidence of sore throat at discharge from the post-anesthesia care unit (PACU) was unknown.

Clinical Question or Purpose: Do adult ambulatory surgical patients receiving general endotracheal anesthesia and undergoing objective cuff pressure assessment and management experience less sore throat at discharge from the PACU compared to those that do not undergo ETT pressure assessment?

Project Design: This was a process improvement project that implemented an intraoperative objective ETT cuff pressure assessment and management tool via handheld manometer. This project utilized pre and post-implementation assessment of the incidence of sore throat for patients after discharge from PACU phase 1 and phase 2.

Analysis of the Results: Assessment of ETT cuff pressure before implementing the manometer revealed that 65% of ETT Cuffs were over 30 cm H2O, 19% < 20 cm H2O, and 25% between 20-30 cm H2O. The difference between pre-implementation and post-implementation throat pain levels and incidence rates were statistically significant for PACU phase 2 but not for phase 1. In phase 1, the percentage of patients having any throat pain did not differ significantly (P=0.362) between pre-implementation (60%) and post-implementation (51%) patient groups. By contrast, in

phase 2, the median sore throat score for pre-implementation (1 [0-3]) and post-implementation (0 [0-1]) were significantly different (P=0.0101). In phase 2, the incidence of sore throat differed significantly (P=0.013) between pre-implementation (58%) and post-implementation (33%) patient groups.

Organizational Impact/Implications for Practice: This project successfully implemented the use of an intraoperative objective ETT cuff pressure assessment and management tool via handheld manometer at FBCH which resulted in a decrease in the incidence of sore throats for patients in phase II of the PACU by 43%. Other healthcare sites should analyze their methods for assessment and management of ETT cuff pressure in the operating room and consider implementing objective cuff pressure using a manometer.

Abbreviated Abstract

Project Purpose: Evidence-based implementation of an intraoperative objective cuff pressure assessment and management, using a manometer, guided towards implementing best practice and reducing post-operative sore throat.

Impact: Successful implementation of the manometer into the operating rooms at FBCH resulted in a decrease in the incidence of sore throats for patients in phase II of the PACU by 43%.

Introduction

Postoperative sore throat (POST) is the most common complaint after endotracheal intubation with the occurrence varying between 20-74% (Lee et al., 2017). Even with the current risk of a POST, the endotracheal tube (ETT) remains one of the key tools of an anesthesia provider. Endotracheal intubation protects the patient's airway and facilitates the management of the ventilator (Butterwork, Macky, & Wasnick, 2013). An ETT provides a secure airway by passing through the vocal cords and inflation of a cuff below the level of the vocal cords. The cuff at the distal portion of the ETT creates a tracheal seal when inflated. This seal provides two separate functions: reducing the likelihood of aspiration and allowing positive-pressure ventilation. (Butterworth, Mackey, & Wasnick, 2013). Although the cuff provides a level of protection to the patient from aspiration and facilitates positive pressure ventilation, the ETT cuff is not without inherent risks.

Tracheal mucosal blood flow can become occluded with high ETT cuff pressures within the trachea. The optimal pressure to maintain ETT cuff pressure is between 20 to 30 cm H2O (Dorsch & Dorsch, 2010). Pressures above 30 cm H2O decrease arterial perfusion to the tracheal tissue and can result in ischemia at the site (Smith & McArdle, 2002). Pressures below 20 cm H2O can increase the risk of micro-aspiration (Dorsch & Dorsch, 2010). Cuff pressures maintained above 30 cm H2O can cause negative effects for the patient such as an increased rate of POST (Rosero, Ozayar, Eslava-Schmalback, Minhajuddin, & Joshi, 2018). Additionally, these complications can negatively impact patient satisfaction scores. Anesthesia providers at Fort Belvoir Community Hospital (FBCH) assessed ETT cuff pressures with subjective, non-quantitative techniques through palpation of the pilot balloon. However, investigators have shown that only 34 percent of anesthesia providers can correctly identify an ETT cuff pressure

by palpation of the pilot balloon (Michlig, 2013). Therefore, the anesthesia leadership at FBCH desired an evidence-based method that ensured appropriate pressure levels in the ETT cuff. The solution to this problem was to incorporate implementation of an objective cuff pressure assessment and management tool, the manometer into anesthesia practice

Significance of the Problem

High ETT cuff pressures are associated with numerous adverse effects. These adverse effects include: sore throat, trauma, necrosis, vocal cord damage, nerve damage, and permanent voice change (Ansari et., 2014). The cuff is inflated to prevent aspiration and reduce air leaks during ventilation, however, assessing cuff pressure using a manometer is not routinely utilized in clinical practice.

Assessment and management of cuff pressures after intubation can minimize the severity of POST, which is the most common adverse event associated with endotracheal intubation. Ansari et al. (2013) found that assessment and management of cuff pressures resulted in less throat pain reported by the patient at 1 and 6-hours after surgery. Tracheal injuries following endotracheal intubation result in increased length of hospital stays with an estimated cost of $1900 (Bhatti, Mohyuddin, & Reaven, 2010). If treatment for tracheal injury is required, the length of stay is roughly 5 days with an increased cost of $11,000 (Bhatti et al., 2010).

Relevance to Military Nursing

The goal of the Military Health System (MHS) is to utilize the MHS Quadruple Aim initiatives to increase readiness through better health, better care, and lower costs. We focused on two MHS initiatives: better care and lower costs. The utilization of an objective ETT cuff pressure assessment and management tool supports best practice and the initiative of providing better care. Cuff pressure management through an objective means can mitigate the risk of

tracheal injury, which can result in reduced healthcare costs. This also supports the DHA Directors' priority of optimizing outcomes. Objective ETT cuff pressure assessment and management optimizes patient outcomes by limiting the adverse effects associated with high cuff pressures.

Objective assessment and management of ETT cuff pressures can result in improved patient outcomes, decreased adverse effects, and decreased costs. These potential outcomes benefit the MHS by decreasing the recovery time for service members resulting in less time away from work, thus increasing overall force readiness. By decreasing the number of sick call visits due to complications of an over-inflated ETT, other beneficiaries may have improved access to care and decreased wait times for appointments.

In the deployed setting, management of ETT cuff pressures is critical. Patients are intubated for a prolonged period and transferred from various level of care with a multitude of variables, including altitude, climate, and training of medical staff. The implementation of a manometer by military anesthesia providers may decrease the risk of adverse outcomes related to elevated ETT cuff pressures in the deployed setting.

Establishing a high-reliability culture of no waste and harm that emphasizes best practice yields high-value care (Porter & Lee, 2013). Using a manometer is best practice for objective assessment and management of ETT cuff pressure and helps support the Quadruple Aim initiative of providing better care. We contributed to this high-reliability culture by implementing evidence-based practice.

Problem Statement

Anesthesia providers at FBCH did not utilize an objective method of intraoperative ETT cuff assessment and management and the incidence of sore throat at discharge from the post-anesthesia care unit (PACU) was unknown.

Clinical Statement to Guide Literature Search

Do adult ambulatory surgical patients at FBCH receiving general ETT anesthesia and undergoing objective cuff pressure assessment and management, experience less sore throat at discharge from the PACU compared to those that do not undergo objective cuff pressure assessment and management?

Literature Review of Solutions

An expansive literature search was conducted using both the Uniformed Services University (USU) library resources and the assistance of a librarian. We searched PubMed and the Cumulative Index to Nursing and Allied Health Literature (CINAHL). The PubMed search combined the keywords “intubation” or “intratracheal” or “ETT” or “endotracheal tube” or “tracheal tube” or “OR intubation” or “cuff pressure” or “cuff volume” or “intracuff pressure” or “intracuff volume” and “adults” and “outcome assessment” or “OR adverse effect” or “OR outcome” or “negative effect”. The CINAHL search combined the “intubation” or “intratracheal” or “endotracheal tube” or “tracheal tube” and “cuff pressure” or “cuff volume” or “intracuff pressure” or “intracuff volume” and “adult” or “adults” and “adverse health care event” or “outcomes” or “adverse effect” or “outcome” or “negative effect”. We also looked at the references within our literature search for additional articles that provided other resources, but identified none that were not already included in our original literature search. We limited our literature search to scholarly materials including peer-reviewed journals, with access to full

text only, in English, and within the past ten years. Our inclusion and exclusion criteria can be found in the table below. The Prisma flowchart describing the number of publications screened is located in Appendix A.

Inclusion Criteria	Exclusion Criteria
- Adults - Systematic reviews - Randomized controlled studies - Pseudo randomized controlled studies - Objective measurements - In vivo studies only	- Individuals under age 18 - Case studies and Narratives - Qualitative studies and Animal models - Emergency and prehospital patients - Critical Care patient - Subjective assessing techniques only - In vitro studies - Laryngeal Mask Airways (LMA)

Our initial literature search yielded 114 articles. We screened the abstract of those based on inclusion and exclusion criteria, which narrowed the total number of articles to 31. At this point, we screened the full text of the 31 articles and further narrowed our search down to 6 articles. Full-text review of the articles resulted in 25 exclusions for the following reasons: outcome, use of only LMAs, subjective assessment techniques only, intervention, and design. The six remaining articles included in our review of literature were appraised using the John Hopkins Nursing Evidence-Based Practice Appraisal Tool (JHNEBP). Our appraisal of the articles resulted in five Level 1B, and one Level 2B. Full details of the articles appraisal can be found in the Table of Evidence (Appendix B).

When comparing objective versus subjective cuff pressure assessment and management, the objective method more accurately maintained cuff pressures in the acceptable safe range of 20-30 cm H2O. Anesthesia providers tend to underestimate cuff pressure by manual assessment, and this resulted in cuff pressures almost two times higher than the recommended ranges (Liu et al., 2010). Additionally, anesthesia providers failed to accurately determine cuff pressures through subjective palpation in less than half of cases (Ansari et al., 2013). An objective method

to assess cuff pressures was performed using handheld manometers. Currently, there is no literature comparing different types of handheld manometers.

There were mixed conclusions in the literature regarding the frequency of objective cuff assessments. Researcher's recommendations for assessing cuff pressures varied from immediately after intubation (Liu et al.,2010), hourly (Ansari et al., 2013), and continuously (Kowalczyk et al., 2015 and Ryu et al., 2013). The overall theme was that maintaining cuff pressures in the recommended safe range via handheld manometers, measured at any frequency, reduced adverse outcomes such as a sore throat.

The Posey handheld manometer was the best choice among available manometers. It is an aneroid manometer that measures cuff pressures in centimeters of water. We chose the Posey type of manometer due to ease of use, no need for calibration or batteries, and its current use in other areas of FBCH. Upon attaching the ETT balloon to the manometer, the pressure needle will rise, displaying the pressure of the cuff. The air vent button and inflator bulb allow for easy cuff pressure adjustment. The compact and light design is ideal in deployed military settings. Since the literature did not recommend a specific frequency for ETT cuff pressure assessment, we assessed ETT cuff pressures once, immediately after intubation.

Focus Aims

This project had five focus aims. First, we completed a literature search and compared subjective versus objective cuff pressure assessment and management recommendations. Second, we determined the incidence of sore throats in the PACU. Third, we provided education to the anesthesia providers and implemented the use of handheld manometers in the operating room for all patients that received an ETT and evaluated the incidence of sore throat. Fourth, we evaluated and presented our findings to the anesthesia department leadership and providers.

Fifth, we implemented a sustainment plan to include a mandatory charting requirement for ETT cuff pressure assessment and management. We plan to disseminate our findings to a local or national conference.

Organizing Framework

We utilized the Iowa Model of Research-Based Practice to Promote Quality Care as our organizing framework. This model emphasized the use of a pilot program explicitly before the full implementation of a change (White, Dudley-Brown, & Terhar, 2016). Our pilot program for this evidence-based practice (EBP) project was the implementation of objective cuff pressure assessment and management for ETT at FBCH.

The Iowa Model follows an algorithmic approach (Appendix C) to solving a problem by first identifying either a problem-focused or knowledge-focused trigger. As student registered nurse anesthetists (SRNA) assigned to FBCH, leadership identified the clinical problem of lack of objective intraoperative cuff pressure assessment and management as a priority item. Our next step was a thorough literature search to assess whether there was a sufficient research base to make a change in practice. The evidence was graded using the JHNEBP Grading Scale. By incorporating the JHNEBP Grading Scale, we ensured that we standardized the methods we used to assess the literature. This grading scale ensured that we were objectively critiquing the evidence that applied to objective cuff pressure assessment and management. Following the literature review and analysis, we determined that enough literature was available to support a pilot program.

One of the final steps of the Iowa Model is to determine if the change is appropriate for adoption into practice. Following the completion of our pilot program and analysis of the results, we determined that the change was suitable for action and took steps to ensure that the

change was permanent at FBCH and sustainable. The Iowa Model's algorithm ensured that our team continually assessed the quality of the research and the organizational needs before the implementation of a change of practice.

Project Design

General Approach

This was a process improvement project that implemented intraoperative objective ETT cuff pressure assessment and management via handheld manometer. This project utilized a pre and post-implementation assessment of the incidence of sore throat for patients after discharge from the PACU phase 1 and phase 2.

Setting and Population

FBCH is a joint service DHA medical treatment facility located in Northern Virginia. The location and area of focus for our EBP project were the operating rooms (ORs) of FBCH. FBCH utilizes ten ORs to provide surgical and anesthesia services and performs roughly 13,000 anesthetics per year (Fort Belvoir Community Hospital, 2019). The anesthesia provider breakdown is approximately 10 anesthesiologists, 23 certified registered nurse anesthetists, and 6 student registered nurse anesthetists. Our project focused on adult outpatient surgical patients undergoing general ETT anesthesia for non-ear, nose, and throat (ENT) procedures. The specific inclusion criteria for our patient population was as follows: at least 18 years of age, ambulatory care status, surgeries that required endotracheal anesthesia. Exclusion criteria include: ENT surgery and any surgery that involved the head or neck.

Procedural Steps

The implementation of our DNP project, specifically manometers, took place in three distinct phases: pre-implementation, training and implementation, and post-implementation.

Pre-implementation: During the pre-implementation period of the project, our team educated and collected baseline data. First, we provided education to PACU staff at their staff meeting regarding the questionnaire (Appendix D) given to patients that met inclusion criteria. Education included dangers of high and low cuff pressures, manometer information, and the relationship between safe cuff pressures and patient outcomes. Following staff education, the Phase 1 and Phase 2 PACU staff administered the sore throat patient questionnaire (Appendix D) to patients that met inclusion and exclusion criteria. The questionnaire consisted of the same question asked at discharge from phase 1 and phase 2. The question was, "swallow and point to the number that shows how much your throat hurts with zero being not at all, and ten being very much" (Eccles, Loose, Jawad, & Nyman, 2003). This occurred over a six week period with a total of 50 patients.

Following collection of pre-implementation sore throat data, we collected baseline cuff pressure data that reflected subjective assessment currently used by FBCH staff. We assessed and documented all ETT cuff pressures, including those that did not meet inclusion and exclusion criteria, for two weeks using a handheld monometer. When we assessed a cuff pressure that was outside the established safe range of 20-30 cm H2O, we documented the pressure, and then corrected the pressure to within the safe range to ensure patient safety. The baseline cuff pressure data was collected by the SRNAs. The anesthesia provider filling and assessing the cuff through subjective methods were blinded from the results until the completion of the two week data collection. We assessed a total of 63 ETT cuff pressures.

Training and implementation: Following pre-implementation data collection, our next phase was education and implementation. We utilized an EBP approach to train anesthesia providers. We utilized presentations and hands-on teaching methods (Spruce, 2015) which ensured learning was experiential, so the learner was free to learn in their own way and to understand why the content is essential (Peterson, 2018). Our educational plan included explanation of the risks associated with high ETT cuff pressures in addition to a hands-on task trainer. The hands-on trainer consisted of three adult airway trainers. We instructed anesthesia providers to perform a subjective assessment of the cuff pressure on three different intubated adult airway trainers and state whether the cuff pressure was below 20 cm H2O, between 20-30 cm H2O, or above 30 cm H2O. Each intubating manikin had a different size ETT (6.0, 7.0, and 8.0) with different cuff pressure (<20 cm H2O, 20-30 cm H2O, and >30 cm H2O). Next, we instructed the anesthesia provider on the use of a manometer and demonstrated how to assess and manage the cuff pressures within the same manikins. We trained 26 of the 33 (81%) total anesthesia providers at FBCH. Individuals not trained include those current on maternity leave (1) and those who work obstetrics only (5). The purpose of this hands-on trainer assessment was to demonstrate the inaccuracy of subjective palpation cuff assessment and the importance of objective assessment using a manometer.

Next, we placed a manometer in all ten ORs within FBHC. We updated the FBCH electronic charting system (Innovian) to include a mandatory documentation field after the anesthesia provider annotated the placement of an ETT to record the ETT cuff pressure. The mandatory documentation field required the recording of ETT cuff pressure.

Post-implementation: The post-implementation data collection step utilized the same patient pre-implementation questionnaire to assess incidence and severity of sore throat. The PACU staff administered the questionnaire to patients and assessed the incidence and severity of sore throats. In addition to the question asked at discharge from PACU phase 1 and phase 2, the phase 1 PACU staff asked the anesthesia provider two additional questions: "was a manometer used to check cuff pressure?" and "was the final measured cuff pressure between 20-30 cm H2O?". This occurred over a 6-week period with a total of 51 patients. Following the completion of the three phases, we analyzed the collected data. A timeline can be found in Appendix E.

Data Analysis Plan

We used descriptive statistics to analyze the effects of manometer use on incidence and severity of sore throat and evaluated patient's response through the pre and post-implementation questionnaire. We utilized a biostatistician at FBCH to guide and review our statistical analysis.

Potential Barriers

The potential barriers we identified prior to our project's implementation included: the ability to assess pre-implementation cuff pressure without anesthesia providers changing or manipulating the pressures beforehand, compliance from anesthesia providers, anesthesia providers changing their subjective assessment technique during data collection, cooperation from PACU staff, loss of manometers, and the ability to add the required documentation field into the electronic health record.

To mitigate the barriers above, we collected pre-implementation incidence and severity of POST before assessing baseline ETT cuff pressures in our facility. This ensured that anesthesia providers would not manipulate the cuff pressures to influence the incidence or severity of POST in the pre-implementation phase. We also provided education to the anesthesia providers after

pre-implementation data was collected on the inaccuracy of subjective cuff pressure assessment. In order to prevent anesthesia providers from changing their practice during the subjective cuff pressure assessment, they were blinded from the data collection during this two week period. To gain cooperation from the PACU staff, we spoke with their leadership and provided education at their scheduled staff meetings to minimize training burden. We also provided weekly reminders to the PACU staff during pre-implementation and post-implementation. We also enlisted the assistance of the NCOIC (non-commissioned officer in charge) to add the manometers to the hand receipt to mitigate equipment loss. Lastly, our site director was an Innovian superuser and added the mandatory documentation field into the electronic anesthesia record.

Sustainment and Dissemination Plan

Our sustainment plan included leaving the mandatory documentation field of the ETT cuff pressure in Innovian. The manometers remained a hand receipt item which ensured they were available to the anesthesia provider in the ORs which facilitated the ETT cuff pressure assessment and management compliance. We disseminated our findings through a poster and podium presentation to FBCH anesthesia providers, hospital leadership, and at the annual USU Research Week, and plan to submit a manuscript to the American Association of Nurse Anesthetists (AANA) Journal.

HIPAA Concerns/Ethical Considerations

We received institutional review board (IRB) exemption for our EBP project. We did not use any patient identifiable information (PII) on paper questionnaires and we collected data outside of the patient's electronic medical record. We stored paper questionnaires in a locked drawer that was only accessed by project team members. We transferred all data from these questionnaires to an electronic source via a Common Access Card (CAC) enabled computer. We

then destroyed all paper questionnaires via a locked Health Insurance Portability and Accountability Act (HIPAA) shred bin for destruction after the completion of our EBP project.

There were no ethical concerns regarding our EBP project. The patient population selected for this study consented to an elective surgery and the administration of anesthesia. Objective assessment and management of ETT cuff pressures is a measure to deliver safe anesthesia care and does not place a patient at risk. When we assessed a cuff pressure outside of the recommended range at any point, we adjusted the cuff pressure in order to avoid potential harm to the patient.

Project Results

During the pre-implementation period, we collected baseline ETT cuff pressures from a total of 63 patients. We found that 16% were measured within the range of 20-30cm H2O, 19% were measured below 20cm H2O, and 65% were measured above 30 cm H2O. In addition, we found that the average low pressure was 14 cm H2O, and the average high pressure was 67.5 cm H2O.

A total of 50 patients were evaluated pre-implementation and a total of 51 patients were evaluated post-implementation. Based on Wilcoxon's rank sum and Chi-square tests, the differences between pre-implementation and post-implementation throat pain levels and incidence rates were statistically significant for PACU phase II but not for phase I patient groups. For PACU phase I, the median sore throat ratings for pre-implementation (2 [0-4]) and post-implementation (1 [0-3]) throat pain were not significantly different (P= 0.0985). Also, for Phase I, the percentage having any throat pain did not differ significantly (P=0.362) between pre-implementation (60%) and post-implementation (51%) patient groups. By contrast, for PACU phase II, the median sore throat rating for pre-implementation (1 [0-3]) and post-implementation

(0 [0-1]) throat pain were significantly different (P= 0.0101). Also, for PACU phase II patient groups, the percentage having any throat pain differed significantly (P= 0.013) between pre-implementation (58%) and post-implementation (33%) patient groups. The statistical analyses were performed by Dr. Hind Baydoun at FBCH.

Organizational Impact / Implications to Practice and Policy

Our project showed that using a manometer to measure ETT cuff pressures decreased the presence of a sore throat by 43% in PACU phase II. Anesthesia providers should consider using manometers or some form of objective cuff pressure measurement to minimize incidence of sore throat following extubation.

Implementation of a manometer for objective ETT cuff pressure assessment and management has moved FBCH closer to becoming a high reliability organization. Prior to this project, anesthesia providers were using subjective methods to assess ETT cuff pressures (i.e. manual palpation of the pilot balloon) to determine the amount of air necessary to occlude the trachea and it was within range only 16% of the time during the collection of baseline ETT cuff pressures. Following the completion of this project, the FBCH anesthesia department expressed a desire to permanently implement manometer use, which is best practice based on review of the current literature.

There were very few limitations that impacted the implementation of manometer usage and the assessment of patients' pain scores. The project framework did not account for factors such as: multiple intubation attempts, difficult intubation, size of ETT, duration of surgery, and provider skill level. Because of this, we were not able to determine if these factors had an effect on the incidence of sore throat, despite the use objective ETT cuff pressure assessment and management.

Future Directions for Research and Practice

As mentioned previously, collecting additional patient data regarding the intubation could provide further information on what factors affect incidence and severity of POST. Future projects could consider measuring secondary outcomes such as post-operative complications beyond sore throat and additional follow up with patients in regards to post-operative complications outside of the PACU phase 2 discharge period. Further analysis of the incidence of required medical intervention for adverse outcomes, sick call visits, and missed work days could provide valuable information regarding the influence of manometer use on military readiness. Our project implemented a single objective cuff pressure assessment and management after intubation, future studies could be conducted to determine the optimal frequency of ETT cuff pressure assessment and management.

Additionally, the use of manometers in the deployed setting may also provide valuable data on reducing adverse outcomes in patients who require prolonged intubation in intensive care units (ICU) and during transport of patients in the deployed setting. Follow-up surveys provided to anesthesia providers participating in our study could provide insight into their opinions of manometer implementation and subsequent change in practice and sustainment. Further studies could also investigate alternatives to manometer use such as continuous cuff pressure management devices and expansion of research to manometer use with laryngeal mask airways.

Conclusion

Objective ETT cuff pressure via handheld manometer is more superior to subjective manual palpation in assessing and managing cuff pressures intraoperatively. After a literature review and analysis, we conducted a pilot program at FBCH and implemented the use of the Posey manometer on all patients that received a general endotracheal anesthetic and evaluated

the incidence of sore throat. The biggest challenge in implementing manometer use was the change in practice by many anesthesia providers. By using an evidenced-based approach to educate the anesthesia staff along with a hands-on task trainer, we were able to demonstrate the inaccuracy of subjective manual palpation and gain buy-in on the use and importance of objective cuff assessment and management. Results showed a decrease in sore throat pre-implementation to post-implementation from 60% to 51% in Phase I and more significantly from 58% to 33% prior to discharge from Phase II.

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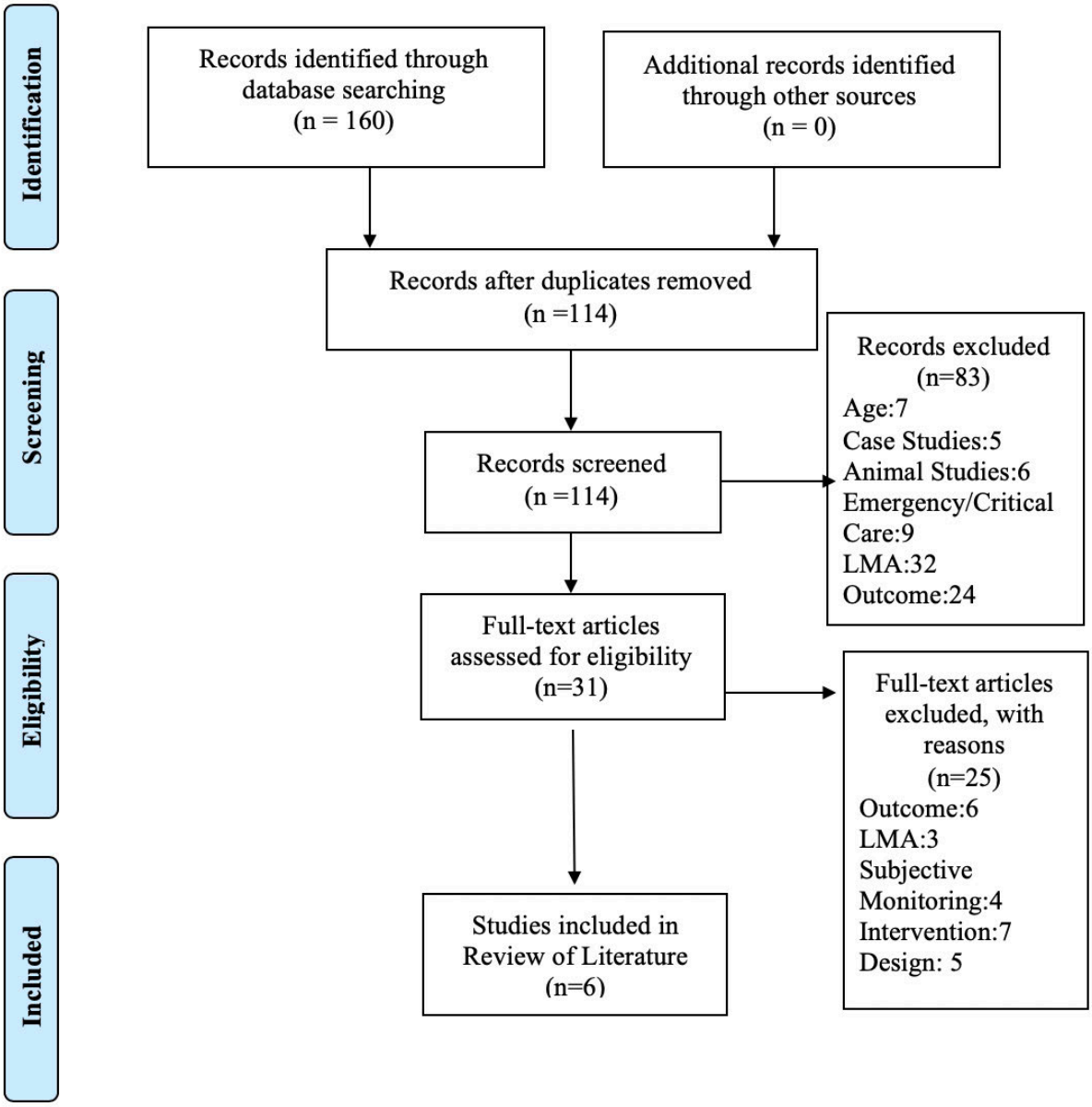
Appendix A
Prisma Flow Diagram



Appendix B
Table of Evidence

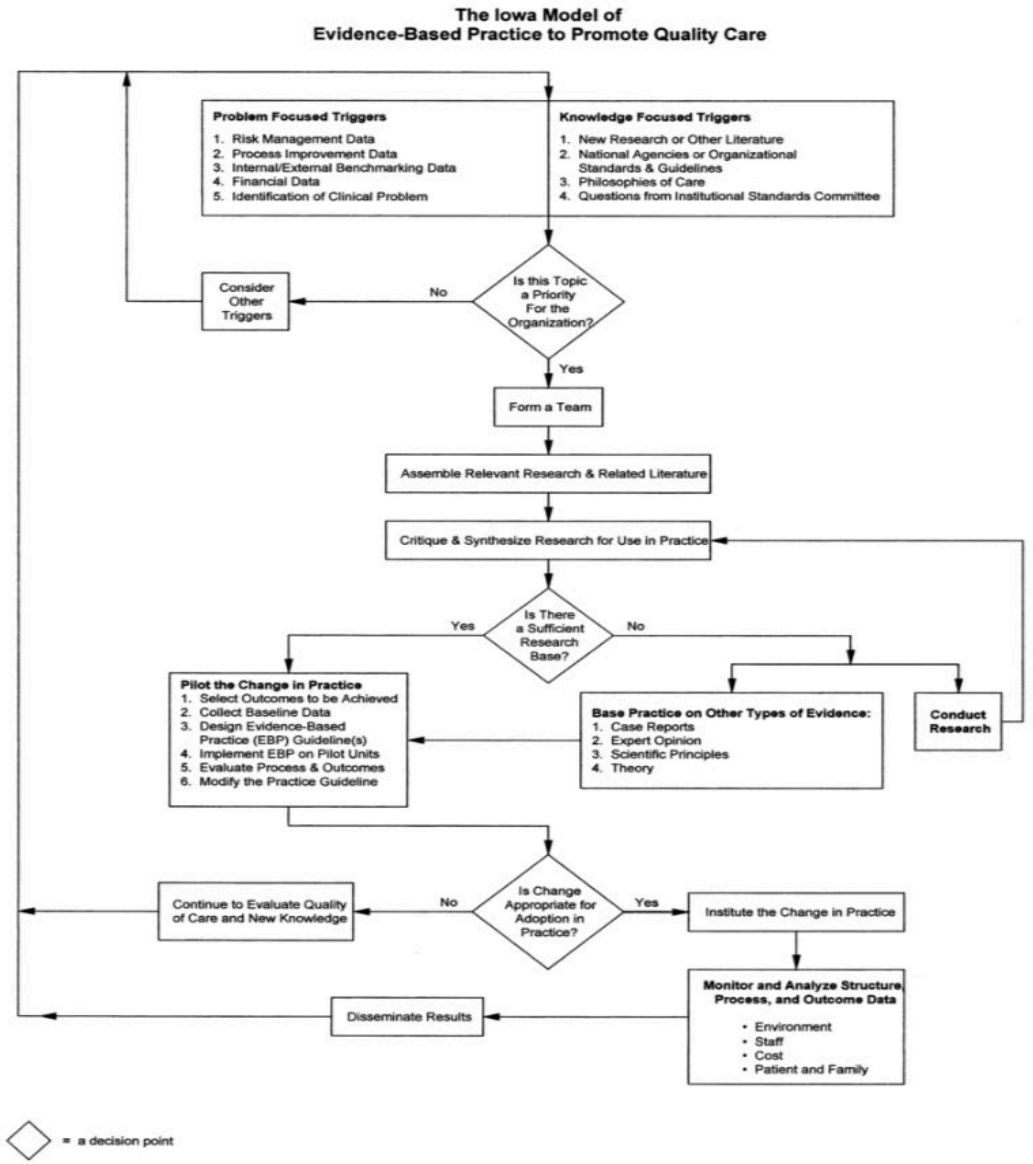
1st Author Name (Publication Yr)	Study Purpose/Aims	Research Questions/Hypotheses	Study Design	Total Sample Size	Sampling Plan	Independent Variables	Dependent Variables	Statistical Analyses	Results	Strengths	Weaknesses	Evidence rating
Ansari, Ladan (2013)	Evaluated the effect of managing perioperative ETT cuff pressure on throat pain post extubation.	If the cuff pressure was adjusted mechanically, then the incidence of throat pain would be less after extubation.	Randomized double-blind controlled clinical trial	n=43	60 patients undergoing maxillofacial sx, GETA 2- 4 hrs. >18yrs old, ASA I/II. Exclusion criteria- difficult intubation, surgeries >4 hrs., post-op analgesic, hx of tracheal injury or discomfort. 17 patients were excluded.	a) Cuff pressure NOMINAL: measured and adjusted within 20- 30 cm H20 at time of placement & hourly intraoperatively	a) Cuff pressure INTERVAL/RATIO: b) Post-op tracheal pain INTERVAL/RATIO: (VAS) at 1, 6, and 24 hrs. post extubation	Fisher's exact test & Student's t test: Significance of differences between groups. Mann-Whitney U test: Pain scores (VAS)	Study group: mean cuff pressure (CP) was 35 cm H20 on palpation, and 24 cm after adjustment with manometer Control group: the initial CP was 36 cm and 29 cm at the end of surgery. Study group pain < control group (p 0.002), but statistically insignificant at 24 hours post-op (p 0.4)	1) standardized ETT sizes (based on sex) 2) standardized anesthesia plans 3) standardized pain evaluation tool	1) sample size of only 43 patients 2) due to the nature of a maxillofacial surgery, it is not clear if the patient's perceived pain is from their surgery or injury of tracheal mucosa	Level I-B
Kowalczyk, Izabela (2015)	To determine whether continuous monitoring and adjustment of the endotracheal tube cuff pressure (ETTCP) to 15 mmHg during Anterior Cervical Spine Surgery (ACSS) would alter the incidence of postoperative dysphagia	Postoperative dysphagia is a common complication after ACSS (30-70%). Recent findings on preventative measures suggest that endotracheal intubation may contribute to ischemic changes of the tracheal mucosa resulting in sore throat, hoarseness, and dysphagia. Certain intraoperative practices may minimize this complication.	prospective, randomized control pilot study	n=50	50 patients age 21-65 y/o undergoing ACSS, arthroplasty, or fusion randomly assigned to groups: one with ETTCP maintained at 15mmHg vs. control group ETTCP monitored but not adjusted. Exclusion criteria: anterior neck surgery, malignancy, tracheostomy, previous dysphagia.	a) Objective measurement and adjustment of ETTCP- NOMINAL	a) ETTCP- interval/ratio b) Postoperative dysphagia measured by the Dysphagia Disability Index (DDI) and Bazaz-Yoo Dysphagia Scale (BYDS)- interval/ratio c) Soft tissue thickness measurement on plain lateral radiographs- nominal	Student t-test: was utilized to assess the significance of any descriptive statistics between-group differences. ANOVA: Within-group differences were compared (P <0.05) followed by the Tukey post hoc analysis.	insignificant differences(P>0.05) soft tissue thickness or DDI/BYDS scores (24 hrs post-op, 6 weeks, 3 months, 6 months). Both groups had significantly more soft tissue thickness and DDI/BYDS scores 24 hours post- op. DDI scores >10 were: 24 hrs post-op- 59%, 6 weeks- 35%, 3 months- 24%, and 6 months- 18%.	1) Standardized anesthesia induction plans 2)Standardized ETT sizes based on gender 3)Standardized evaluation tools- DDI, BYDS, and radiographs 4)Identified and reported postoperative dysphagia after ACSS	1) Did not identify patients who received artificial disks, as this has been shown to lower rates of dysphagia 2) Surgery was performed at different cervical levels, with some having multilevel fusions	Level I-B

Letvin, et al. (2018)	Compared frequent versus infrequent monitoring of endotracheal tube cuff pressures and the occurrence of ventilator-associated events (VAE).	Investigation to find the optimal frequency of endotracheal tube cuff pressure monitoring to improve clinical outcomes and reduce respiratory-related complications.	Randomized prospective study	n=305	305 patients randomly assigned to odd or even numbers. Odd #- (146) received "infrequent cuff pressure monitoring" = (Post intubation and if evidence of cuff leak or loss of tidal volume). Even #- (146) received "Frequent cuff pressure monitoring" = at intubation in addition to assessment at the beginning of every 8-h shift.	a) Frequency of endotracheal tube cuff pressure measurement. (infrequent 336 vs frequent 1,531 monitoring events)	a) Ventilator Associated Events (VAE) b) Ventilator Associated Pneumonia (VAP) c) Mortality d) 30-day readmission All INTERVAL/RATIO	t- test: normally distributed aspiration events vs. 30-day mortality vs. median length hospital stay. Kaplan-Meier curve: Cumulative survival rates Mann-whitenyU: non-normally distributed data. Chi-square-Categorical data	(Frequent vs. Infrequent) # of VAEs rare and similar in both (3.6% vs 5.8%, P =.37). AE's(0.6% vs 0%, P= .36), VAP (0% vs 0.7%, P= .27), 30-d mortality (31.3% vs 30.2%, P= .83), Median hospital stay (10 d vs 11 d, P=.34), 30-d readmission <frequent group. No difference or superiority between methods.	1) All assessments of VAE/VAP were blinded to results and room assignment significance. Completed by the infection prevention dept. remotely. 2) Standardized MICU protocol for vented patients. 3. Standardized ETT for all patients.	1) Didn't record values of the cuff pressure measurements, may have been variance in values of cuff pressure between the groups. 2) No airway exams to identify early injury. 3) Only completed in Medical ICU. 4) Limited generalizability of data, only at single center and may be varying protocols among institutions	Level I-B
Liu, et al. (2010)	Compared objective monitoring and maintenance of ETT cuff pressure vs. subjective management and the incidence of endotracheal intubation-related respiratory complications.	Hypothesis: An appropriate ETTc pressure even in short procedures would reduce endotracheal intubation-related morbidity.	Randomized, prospective, and observational study	n = 509	509 patients evaluated, 273 (male/female 112/161) were in control group and 236 (male/female 81/155) were in study group. >18yrs old, ASA I/II, GETA. Exclusion- hx cough and sore throat, double-lumen ETT, difficult endotracheal intubation oral and laryngopharyngeal surgery.	b) Cuff Pressure (Study) NOMINAL: Cuff pressure initially set via palpation, measured objectively and adjusted to maintain between 15-25 cm H20 c) Cuff Pressure (Control) NOMINAL: Subjective pilot balloon palpation method	e) Cuff Pressure INTERVAL/RATIO f) NOMINAL: Adverse outcomes (cough, sore throat, hoarseness, blood- streaked expectorant, and/or lesions on trachea) with no quantifiable data makes the level of measurement nominal.	T- test: Used to compare/test the difference between the control and study group. Median Test: Applied for categorical data.	Mean CP by palpation was 58 cm H20 and 27 cm H20 in study group ($p < 0.001$). Control group post- op sore throat (POST) 119 vs 81 (p 0.033), hoarseness 30 v 8 (p 0.001), blood-streaked expectoration 30 v 9 (p 0.002). Cough insignificant (p 0.187)	1) Standardized first adjustment of inflation of the ETTc with accurate manometer. (XB- 11B; Shanghai Medical Instruments Co., Ltd, Shanghai, China) within a range of 15 to 25 mm	1) Unable to measure pain from intubation vs ETTc pressure 2) Only 40 patients in post op fiberoptic examination 3) Difficult to effect of patient positioning and effects on edema in neck/cervical area.	Level I-B

Ryu, et al. (2013)	Evaluated effects of objective monitoring and adjustment of ETT cuff pressures during thyroidectomy on the incidence of postoperative sore throat (POST), hoarseness, dysphagia, and cough.	Hypothesized that monitoring and adjusting the cuff pressure during thyroidectomy could reduce the incidence and degree of POST after thyroidectomy.	Prospective, randomized, and controlled study. Patients and outcome assessors were blinded to the group assignments.	n = 88	90 patients ASA I/II, 19–70 yrs. old, elective thyroidectomy GETA Pre-op larynx exam w/ 70-degree rigid laryngoscope to assess vocal fold mobility those freely movable included. Exclusion- URI within 2 weeks, sx history of oral cavity or pharynx, difficult airway (> two attempts or more than 15s for endotracheal intubation). 96 patients considered, 6 were excluded and 2 removed due to	a) Group A NOMINAL: Cuff pressure set to 25 cm H2O, monitored continuously with manometer, unless outside 20–50 cm H2O. b) Group B NOMINAL: Cuff pressure monitored continuously and maintained at 25 cm H2O.	a) Cuff pressure INTERVAL/ RATIO b) Incidence of airway complications NOMINAL: postoperative sore throat (POST), hoarseness, dysphagia, and cough.	SPSS: Expressed as standard deviation. t test: Comparison of cuff pressures at each time point. Repeated measures ANOVA: comparison of cuff pressures over time. Chi- square test: Incidence of POST, hoarseness, dysphagia, and	CP increased in group A during anesthesia (P< 0.05) Mean cuff pressure was 30.6 cm H2O in group A and 24.8 cm H2O in group B (P< 0.001). Incidence and severity of POST group B < group A at 2 hrs. (61% vs. 86 %; P 0.008) and at 24 hrs. (43 % vs. 66 %; P 0.032) severity decrease (P 0.043).	1) Standardized anesthesia plans & ETT size. 2) Standardized POST evaluation scale and criteria. 3) Independent observer and questionnaire to assess. 4) Appropriate exclusion criteria. 5) Patients and outcome assessors were blinded to the group assignments.	1) Female >Male (shown to be at increased risk of POST). 2) Total thyroidectomy with neck dissection Group A > Group B(potential skew in pain scores.) 3) Limited to thyroidectomy. 4) Cough not recorded. 5) No postoperative bronchoscopy.	Level I-B
Yildirim, et al. (2010)	Investigated ETT pressure alteration during laparoscopic cholecystectomy.	That CP's would elevate in lap. Chole. sx due to pneumoperitoneum and changes in head and neck position and increase incidence of postoperative sore throat.	Quasi- experimental l: prospective, controlled single-blind study (does not specify randomization, but demographics shown to be statistically significant)	n = 40	40 patients, ASA I–II, elective lap. chole. (group I) or open abd sx (group II), Exclusion- tracheotomy, hx laryngeal disease or surgery, difficult intubation (two or more attempts), smokers, nasogastric tube use (did not provide a breakdown of number excluded)	a) Group I (Laparoscopic cholecystectomy)- NOMINAL b) Group II- (Open abdominal surgery)- NOMINAL	a) Cuff pressure INTERVAL/RATIO: Initial pressure set to 30 cmH2O and measured every 5 min. b) Laryngotracheal complaints INTERVAL/RATIO: Sore throat, dysphasia, and hoarseness at discharge from PACU and 12 hrs. post extubation (VAS; 0 = no discomfort and 10 = worst discomfort	t-test: Demographic data, duration of surgery, and anesthesia time ANOVA: cuff pressure measurements Chi-square test: severity of the lesions between the two groups.	ETTC pressures Group I > Group II at all time points studied. (P< 0.05). Pressures > 30 cmH2O after 5 min in group I max 35 cmH20. Sore throat group I > group II in the PACU and at 1 hr. and 12 hrs. (p <0.05) - Supports objective measurement of cuff pressures to reduce POST.	1) Standardized ETT sizes (based on sex). 2) Standardized anesthesia plans. 3) Standardized POST evaluation scale and criteria. 4) Laryngotracheal complaints were evaluated via standardized scale by an independent observer.	1) Severity of lesions was not discussed in detail or displayed in data chart. No PRISMA flowchart. 2) Does not specify randomization of subjects. 3) Only single-blinded study. 4) Possible positioning effects on POST.	Level II-B

Appendix C

The Iowa EBP Model



(White, Dudley-Brown, & Terhar, 2016)

Appendix D

Pre-implementation Questionnaire

Inclusion Criteria:
All 18 years+ patients for Non-ENT outpatient surgeries.
Only patients who had an Endotracheal Tube.

Question at the end of PACU Phase 1:
Swallow and point to the number that shows how much your throat hurts with zero being not at all, and ten being very much

0-1-2-3-4-5-6-7-8-9-10

Question at the end of PACU Phase 2:
Swallow and point to the number that shows how much your throat hurts with zero being not at all, and ten being very much

0-1-2-3-4-5-6-7-8-9-10

Post-implementation Questionnaire

Inclusion Criteria:
All 18 years+ patients for Non-ENT outpatient surgeries.
Only patients who had an Endotracheal Tube.

Ask Anesthesia provider during handoff:

Was a Manometer used: Yes or No
Final measured cuff pressure between 20-30cmH2O: Yes or No

Question at the end of PACU Phase 1:
Swallow and point to the number that shows how much your throat hurts with zero being not at all, and ten being very much

0-1-2-3-4-5-6-7-8-9-10

Question at the end of PACU Phase 2:
Swallow and point to the number that shows how much your throat hurts with zero being not at all, and ten being very much

0-1-2-3-4-5-6-7-8-9-10

Appendix E
Project Timeline

Project Year 1 (2019)												
Activity/Month	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Upload DNP Project Team Mentors			X									
Presentation: Background and Literature Review			X									
Project Planning			X	X	X	X	X	X	X	X	X	
Submit Final DNP Proposal												X
DNP RNA Project Presentations											X	
Project Year 2 (2020)												
Activity/Month	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Site IRB Submission and Approval	X	X										
Pre-Implementation Data Collection			X	X								
Baseline Cuff Pressure Data Collection						X						
Educational Interventions						X						
Implementation						X						
Post-Implementation Data Collection						X	X					
Data Analysis								X				
Project Results Analysis								X				
Senior Mentor Discussion									X	X		
Project Year 3 (2021)												
Activity/Month	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEPT	OCT	NOV	DEX
Oral Presentation to FBCH Leadership	X											
Oral Presentation to DNP Project Team	X											
Upload Completed Milestone Checklist			X									
Upload Signed DNP Project Senior Mentor Approved Abstract/Impact Statement Form				X								
Upload Electronic Version of the Senior Mentor Approved Poster				X								
Print Final Approved Poster				X								
Oral Presentation Given to GSN/USU					X							

Appendix F

Data Analysis Plan

		Variable Name	Variable Description (VD) and Type of Measure (TOM)	Data Source	Possible Range of Values	Level of Measurement	Time Frame for Collection	Statistical Test	Decision Rule
EVENT	**Independent Variable (IV) (Descriptive Variable)**	**IV #1:** Objective cuff pressure with manometer training	**VD:** Anesthesia staff to receive educational intervention on endotracheal cuff pressure manometer during anticipated date of October 2019. **TOM:** Process Measure	Staff Development office records Competency form created for this project	0 = not received training 1 = received training	Dichotomous (nominal)	October 2019 (anticipated date): • Before staff trained February 2020 (anticipated date): • After staff trained	None	N/A
		IV #2: Cuff Pressure	**VD:** Pressure within cuff or endotracheal tube **TOM:** Outcome Measure	Electronic Health Records (EHR): Innovian	0-120 cm H_2O	Ratio	Oct 2019-Feb 2020	None	N/A
	Dependent Variable (Outcome Variable)	**DV: 1a** Anesthesia staff compliance with objective cuff pressure monitoring	**VD:** EHR used to measure staff competency and compliance in objective cuff pressure measurement **TOM:** Process Measure	Innovian	0 = Staff not doing objective cuff pressure measurement 1 = Staff doing objective cuff pressure measurement	Dichotomous (nominal)	Oct 2019-Feb 2020	Chi-square test	
		DV: 1b Cuff pressure	**VD:** Pressure within cuff of endotracheal tube. Measurement of cuff pressure to measure educational intervention **TOM:** Outcome Measure	Innovian	0 – 120 cm H_2O	Ratio	Oct 2019-Feb 2020	T-test for independent groups or Mann-Whitney U test (non-parametric alternative)	Based on literature there is no consensus on what tool should be used to measure cuff pressure, only that it should be measured objectively.
		DV: 1c Sore throat pain measurement via numerical pain rating scale	**VD:** Patient pain measurement via subjective scale **TOM:** Outcome Measure	Numerical Pain Scale measured by PACU nurse (Phase 1&2)	0-10	Ratio	Oct 2019-Feb 2020		Based on literature, increased cuff pressure is associated with throat pain.
		DV: 2 Sore throat pain measurement via numerical pain rating scale	**VD:** Patient pain measurement via subjective scale based on IV #2 **TOM:** Outcome Measure	Numerical Pain Scale measured by PACU nurse (Phase 1&2)	0-10	Ratio	Oct 2019-Feb 2020	T-test for independent groups or Mann-Whitney U test (non-parametric alternative)	Based on literature, increased cuff pressure is associated with throat pain.

Appendix G
Citi Certificates

CITI PROGRAM

Completion Date 29-Aug-2018
Expiration Date 28-Aug-2021
Record ID 28312513

This is to certify that:

Joshua Medlin

Has completed the following CITI Program course:

Good Clinical Practice (U.S. FDA Focus) (Curriculum Group)
GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus) (Course Learner Group)
1 - GCP (Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

CITI Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?we20d86c9-fec2-4e4e-9fe0-7d0bab8f9b19-28312513

CITI PROGRAM

Completion Date 29-Aug-2018
Expiration Date 28-Aug-2021
Record ID 28312514

This is to certify that:

Joshua Medlin

Has completed the following CITI Program course:

Responsible Conduct of Research (RCR) (Curriculum Group)
Responsible Conduct of Research (RCR) (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

CITI Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w7c6b7eeb-e3fc-4c1b-afcc-140820fc44f2-28312514

CITI PROGRAM

Completion Date 29-Aug-2018
Expiration Date 28-Aug-2021
Record ID 28312512

This is to certify that:

Joshua Medlin

Has completed the following CITI Program course:

OUSD P&R Human Research (Curriculum Group)
Biomedical Investigators and Research Study Team (Course Learner Group)
1 - Biomedical Investigators (Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

CITI Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w67b46dae-2cab-4d35-a673-59c40db9b596-28312512

CITI PROGRAM

Completion Date 29-Aug-2018
Expiration Date 28-Aug-2021
Record ID 28330936

This is to certify that:

Talitha Moton

Has completed the following CITI Program course:

Good Clinical Practice (U.S. FDA Focus) (Curriculum Group)
GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus) (Course Learner Group)
1 - GCP (Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

CITI Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?wf902d56a-459a-4fad-9842-56596e58e1c5-28330936

CITI PROGRAM

Completion Date 29-Aug-2018
Expiration Date 28-Aug-2021
Record ID 28330937

This is to certify that:

Talitha Moton

Has completed the following CITI Program course:

Responsible Conduct of Research (RCR) (Curriculum Group)
Responsible Conduct of Research (RCR) (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

CITI Collaborative Institutional Training Initiative

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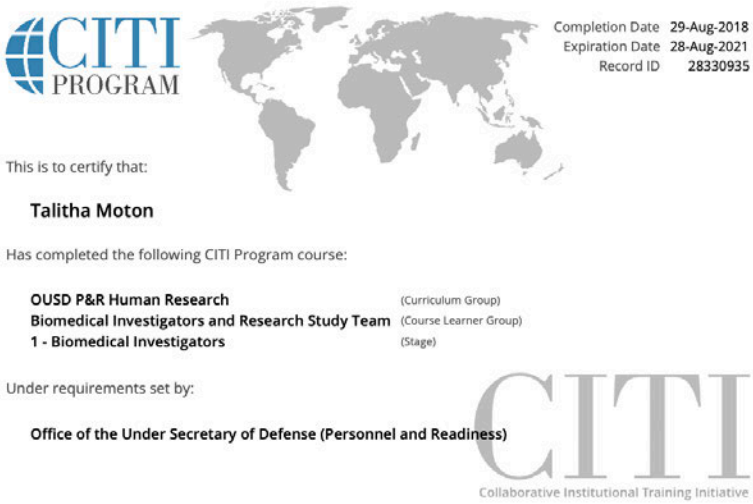

CITI PROGRAM

Completion Date 29-Aug-2018
Expiration Date 28-Aug-2021
Record ID 28330935

This is to certify that:

Talitha Moton

Has completed the following CITI Program course:

OUSD P&R Human Research (Curriculum Group)
Biomedical Investigators and Research Study Team (Course Learner Group)
1 - Biomedical Investigators (Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

CITI Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w8ec8001c-6047-4848-9d6b-a687a6422d3b-28330935

Completion Date 28-Aug-2018
Expiration Date 27-Aug-2021
Record ID 28243709

This is to certify that:

Melanie Budnik

Has completed the following CITI Program course:

Good Clinical Practice (U.S. FDA Focus) (Curriculum Group)
GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus) (Course Learner Group)
1 - GCP (Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w1ee518a5-d8f8-42c5-b4e6-883b1ef172b1-28243709

Completion Date 28-Aug-2018
Expiration Date 27-Aug-2021
Record ID 28243710

This is to certify that:

Melanie Budnik

Has completed the following CITI Program course:

Responsible Conduct of Research (RCR) (Curriculum Group)
Responsible Conduct of Research (RCR) (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w5d2bda3f-b21b-4207-8f39-11cea52ed7ec-28243710

Completion Date 22-Aug-2018
Expiration Date 21-Aug-2021
Record ID 28243708

This is to certify that:

Melanie Budnik

Has completed the following CITI Program course:

OUSD P&R Human Research (Curriculum Group)
Biomedical Investigators and Research Study Team (Course Learner Group)
1 - Biomedical Investigators (Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w1b09f323-cf20-4067-93a6-dedc8222dff3-28243708

Completion Date 21-Aug-2018
Expiration Date 20-Aug-2021
Record ID 28246984

This is to certify that:

John Staads

Has completed the following CITI Program course:

Good Clinical Practice (U.S. FDA Focus) (Curriculum Group)
GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus) (Course Learner Group)
1 - GCP (Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w52bbc3f2-af17-427b-9f22-ec6513e0747e-28246984

Completion Date 21-Aug-2018
Expiration Date 20-Aug-2021
Record ID 28246985

This is to certify that:

John Staads

Has completed the following CITI Program course:

Responsible Conduct of Research (RCR) (Curriculum Group)
Responsible Conduct of Research (RCR) (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w209a9d9e-ed8f-49e0-8e05-a8a997f54f94-28246985

Completion Date 21-Aug-2018
Expiration Date 20-Aug-2021
Record ID 28246983

This is to certify that:

John Staads

Has completed the following CITI Program course:

OUSD P&R Human Research (Curriculum Group)
Biomedical Investigators and Research Study Team (Course Learner Group)
1 - Biomedical Investigators (Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w2b7c7225-1380-431c-a529-12cbce853947-28246983

Appendix H

USU VPR Form 3202N

USU
Uniformed Services University

OFFICE OF RESEARCH
4301 JONES BRIDGE ROAD
BETHESDA, MAYLAND 20814
PHONE: (301) 295-3303; FAX: (301) 295-6771

NOTICE OF PROJECT APPROVAL

Change Number: Original

VPR Site Number:	GSN-61-11186
Principal Investigator:	Staads, John
Department:	Graduate School of Nursing
Project Type:	Student
Project Title:	Improving Patient Outcomes and Pain Scores with the Implementation of Manometers, an Objective Endotracheal Tube Cuff Pressure Management Tool
Project Period:	3/27/2020 to 4/6/2020

Assurance and Progress Report Information:

Name	Sup	Approval Type	Status	Approved On	Forms Received
Progress Report	0			To be Submitted	N/A

Remarks:
This Notice Of Project Approval has been reviewed and approved. Please remember that you must submit a final Progress Report (Form 3210) upon completion of this project.

Questions regarding this approval should be directed to the following person in the Office of Research:
Sharon McIver, (301) 295-9814.

[redacted]

Toya V. Randolph, Ph.D., MSPH Date
Acting Vice President for Research
Uniformed Services University of the Health Sciences

cc: File
Radford, Kennett
Taylor, Laura

Appendix I

FBCH IRB/PI Letter of Determination

DEFENSE HEALTH AGENCY
FORT BELVOIR COMMUNITY HOSPITAL
9300 DEWITT LOOP
FORT BELVOIR, VIRGINIA 22060-5901

DATE: 13 February 2020

FROM: Fort Belvoir Community Hospital (FBCH) Department of Research Programs (DRP) Determinations

TO: John Edward Staads, BSN, RN, CPT, AN, USA, FBCH

SUBJECT: FBCH DRP Determinations Review of Project # 921723; Reference # 921723

PROJECT TITLE: "The Implementation of an Endotracheal Tuff Cuff Pressure Management Tool to Reduce Postoperative Sore Throat"

SUBMISSION TYPE: New Project

ACTION: Determination of "Not-Research" ("Other Activity" / Evidence-Based-Practice)

DECISION DATE: 13 February 2020

1. Thank you for your submission of the abstract, plan, survey, and/or supporting materials for this project. The FBCH DRP has determined the activity as described does not meet the full definition of research as defined in 32 Code of Federal Regulations 219.102(l). Rather, the purpose of the project is to improve a program, service, process, or quality of patient care. The outcome of this project is not intended to develop or contribute to "generalizable" knowledge as in the case of research, and does not involve randomization of individuals. The findings are expected to directly affect local institutional practice and may identify corrective action(s) needed.

2. This project is a Nursing Anesthesia Service initiative to implement intraoperative endotracheal cuff pressure monitors via handheld manometers and to measure the incidence of sore throat for patients after discharge from the PACU.

3. Please register your project with the FBCH Department of Quality Management at https://fbchintranet.departments.med.ds.osd.mil/qualitymgt/SitePages/Home.aspx

4. If there are any changes in personnel or project procedures as outlined in the original submission, a Modification to the original project must be submitted in EIRB and a Determinations Official will review the project again to ensure that the proposed changes do not impact the original determination of "Not-Research".

5. This is not an approval to receive extramural resources (i.e. personnel, drugs, supplies, equipment, money, and gifts from any source outside of FBCH). You must coordinate extramural resource approvals with the NCR Business Office at (301) 295-8248. If any extramural resources are received without DOD or MEDCOM approval, the individual who receives them may be found in ethics violation and prosecuted for criminal misconduct.

6. If the project involves standardized information gathering via instruments (including, but not limited to, a report form, application form, questionnaire, request for proposal, interview, interview guide, oral communication, report, survey, system, website, phone request/phone script, mailer, interview script, focus group, automated/electronic/mechanical/other technological collection technique, or other tool used to collect information"), the Team Leader is likely subject to DoDD 8910 (Information Collection and Reporting), as well as DoDI 1100.13 (Survey of DoD Beneficiaries). For "Component Internal Information Collections", please contact the Office of USD for Personnel and Readiness (P&R) Health Affairs Component Information Management Control Officer (IMCO) Ms. Kim Frazier at kim.l.frazier2.civ@mail.mil or 703-681-3636/703-681-8818/703-681-3627 prior to starting your project. To find out more about the requirements and review process, go to http://www.dtic.mil/whs/directives/collections/index.html.

7. You may begin work pursuant to any additional required approvals and/or agreements.

8. Once project activities cease, within 30 days you are required to submit a complete Closure Form in EIRB, explaining any non-initiation, partial completion, full completion, or any other type of closure, stoppage, or termination of the project. Project data remains the property of FBCH and may not be removed without prior command authorization.

9. Any publications, posters, presentations, or manuscripts arising from this work presented outside our institution must be submitted and cleared through the publication clearance process. Many journals are interested in publishing these type of items. If you do decide to disseminate your findings, please use paragraph headings such as "issue", "procedures for collecting and evaluating information", "information found", "lessons learned", etc. and avoid using headings such as "research questions", "methods", "results", "study limitations", etc.

10. If you have any questions or concerns, the POC is the undersigned at [redacted] Please include your project title and project number (921723) in all correspondence with this office.

[redacted]

Kristin E. Beltz, MA, CIP
DOD CIV
Determinations Official
Department of Research Programs/Clinical Investigations (DRP/CI)

Appendix G: Daniel K. Inouye Graduate School of Nursing
DNP Project Completion Verification Form

DOCTOR OF NURSING PRACTICE PROJECT
Completion Verification Form

The DNP Project titled:

The Implementation of an Endotracheal Tube Cuff Pressure Management Tool to Reduce Postoperative Sore Throat

was completed at: Fort Belvoir Community Hospital

by the following student(s):

(type student name)	*(signature)*	*(date)*
John Staads	[redacted]	12/15/2020
Melanie Budnik		12/15/2020
Joshua Medlin		12/15/2020
Talitha Moton		12/15/2020

The DNP Practice Project Team verifies that the following components of the DNP project, accomplished by the above students, is of sufficient rigor and demonstrates doctoral level scholarship to meet the requirements for USUHS GSN graduation:

- Presentation of DNP project to the leadership/stakeholders at the Phase II Site,
- Abstract/Impact Statement (*Appendix F*), and
- DNP Project written report.

Verified by:

	(type name)	*(signature)*	*(date)*
Senior Mentor:	Dr. Sandra Bruner	[redacted]	12/28/20
Team Mentor:			
Team Mentor:			
Phase II Site Director:	MAJ Keith Lathrop	[redacted]	12/16/20

For RNA Students only *- add the following additional signature for final verification of project completion:*

CDR Ken Radford	[redacted]	1/21/21
RNA Project Director *(type name)*	*(Signature)*	*(Date)*

Form Version: 26 Aug 2017/17 Sept 2020

REQUEST FOR PUBLIC RELEASE

(This form is to be used at Fort Belvoir Community Hospital in requesting review and clearance of DoD information for public release in accordance with DoDD 5230.09)

1. DOCUMENT DESCRIPTION

a. TYPE	b. TITLE	
DNP Manuscript, Abstract, Poster, and Presentation	The Implementation of an Endotracheal Tube Cuff Pressure Management Tool to Reduce Postoperative Sore Throat	
c. DATE OF SUBMISSION 20210214	d. PAGE COUNT 40	e. RESEARCH OR PUBLIC CLEARANCE? Public Clearance, Reference Number 921723
f. CLEARANCE REQUESTED BY *(YYYYMMDD) (All submissions require a minimum of 10 days for review)* 20210315		

2. AUTHOR/SPEAKER *(If more than one author, include names of additional authors on separate sheet.)*

a. NAME *(Last, First, Middle Initial)*	b. AFFILIATION *(Armed service, civilian, contractor)*	c. RANK
Staads, John, E	US Army	CPT(P)
d. DEPARTMENT/CLINIC Department of Anesthesia		

3. PRESENTATION/PUBLICATION DATA *(Date, Place, Event)*

May 11, 2021- May 13, 2021, Uniformed Services University, Bethesda MD. USU Research Days 2021

Oral and Poster Presentation at USU Research Days 2021
All documents uploaded into the USU Archives.

4. POINT OF CONTACT

a. NAME *(Last, First, Middle Initial)*	b. EMAIL	c. TELEPHONE NO.
Staads, John, E	John.staads@usuhs.edu	763-350-8999

5. STAFF JUDGE ADVOCATE (SJA) COORDINATION

a. NAME *(Last, First, Middle Initial)*

b. REMARKS

The following disclaimers should be included. The paper does mention some commercial information (e.g., the brand of manometer), so that both disclaimers are appropriate: "The views expressed in this article are those of the authors and do not necessarily reflect the official policy or position of Fort Belvoir Community Hospital, the Defense Health Agency, Department of Defense, or U.S. Government. Reference to any commercial products within this publication does not create or imply any endorsement by Fort Belvoir Community Hospital, the Defense Health Agency, Department of Defense, or U.S. Government." Paper (page 13): "FBCH is a joint service DHA medical command located in Northern Virginia." must be changed because FBCH is not a command. No legal objection with changes implemented.

c. SUBMISSION IS: ○ APPROVED ◉ APPROVED WITH QUALIFICATIONS *(See REMARKS, block 5b)* ○ NOT APPROVED

d. SIGNATURE DAVIS.DEBBIE.L.1363302633 Digitally signed by DAVIS.DEBBIE.L.1363302633 Date: 2021.03.26 07:18:06 -04'00' | e. DATE SIGNED *(YYYYMMDD)*

6. PUBLIC AFFAIRS OFFICER (PAO) COORDINATION

a. NAME *(Last, First, Middle Initial)*
Brown, R.P.

b. REMARKS

Clearance granted with inclusion of disclaimers as written above.

c. SUBMISSION IS: ○ APPROVED ◉ APPROVED WITH QUALIFICATIONS *(See REMARKS, block 6b)* ○ NOT APPROVED

d. SIGNATURE [redacted] | e. DATE SIGNED *(YYYYMMDD)*
20210326

Submitted documents require both Staff Judge Advocate (SJA) and Public Affairs Officer (PAO) approval in blocks 5c and 6c above before public release. Please note any qualifications for approval, which will be included in the REMARKS block (if applicable). If approved by both SJA and PAO, the material is approved for public release and clearance for open publication is recommended under the provisions of DoDD 5230.09

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