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Development and Implementation of an Evidence-Based Practice Guideline Regarding Cricoid Pressure

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Development and Implementation of an Evidence-Based Practice Guideline Regarding Cricoid Pressure

By

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Abstract

Cricoid pressure (CP) has been a standard of practice since the 1960s. The purpose is to reduce aspiration of gastric content into the lungs in high-risk patients undergoing induction of general anesthesia. Aspiration has been identified as the most common cause of airway-related mortality for patients undergoing general anesthesia. The cause of airway-related mortality can be correlated to the application of CP. Incorrect application of CP may lead to adverse clinical events and outcomes. It has been demonstrated that when administering CP in a simulation-based environment, providers are applying pressure to the incorrect anatomical location and/or applying the incorrect amount of force. The project's primary purpose is the development of an evidence-based practice (EBP) guideline which can be utilized to possibly reduce anesthesia-related aspiration mortality for patients undergoing general anesthesia. This will be achieved by improving the quality of the application of CP through adopting an EBP approach to educate providers on the correct application. The project also includes a plan for implementing these EBP guidelines through education and training, monitoring the outcomes, and providing changes to the guidelines if the outcomes are less than desirable. The Plan-Do-Study-Act model was used as a framework to guide this scholarly project.

Introduction

Anesthesia is essential to perform many surgeries. Anesthetic medications allow for antegrade amnesia, variable pain relief, and cessation of movements to aid surgery. The use of anesthetic medications often reduces a patient's ability to maintain many vital physiologic functions. This includes maintaining patent airway reflexes and contraction of the smooth muscle that limits gastric contents to the stomach. Abolition of these functions during anesthesia may lead to pulmonary aspiration and thus adverse patient outcomes. Cricoid Pressure (CP) is a maneuver used to reduce the incidence of pulmonary aspiration/pneumonitis during airway management. Improper use or application of CP may be a contributing factor to these adverse clinical outcomes.

Significance of the Problem to Nurse Anesthesia

CP is utilized in anesthesia for those patients with the potential for aspiration of gastric content. CP is applied in trauma patients with the possibility of content in their stomach, in pregnant women who have increased intragastric pressure, those with an exacerbation of gastroesophageal reflux disease, or those who experience reflux symptoms at the time they are undergoing anesthesia. The application of CP is believed to reduce the incidence of aspiration complications that can be harmful to patients. This is significant to nurse anesthesia to reduce adverse outcomes, enhance patient safety, and reduce litigation risk.

Background

Cricoid Pressure

CP was introduced in the 1960s by Dr. Brian Sellick to reduce the prevalence of pulmonary aspiration. Sellick stated that CP is the occlusion of the esophagus through pressure to the cricoid cartilage which could be taught within seconds via demonstration (Sellick, 1961).

The cricoid cartilage is the only complete cartilaginous ring within the anatomy of the airway. It lies inferior to the thyroid cartilage which is commonly known as Adam's apple. With the application of force to the continuous ring of the cricoid cartilage, the esophagus becomes compressed between the cricoid cartilage and the sixth vertebrae (Koziol et al., 2000). Compression of the esophagus results in blockage of gastric content from the stomach into the hypopharynx and subsequently, into the lungs reducing the prevalence of pulmonary aspiration.

Pulmonary Aspiration/Pneumonitis

Pulmonary aspiration is a potentially serious complication that has been reported with an incidence of 1 in 3000 anesthetic cases (Nagelhout & Elisha, 2018). Nagelhout & Elisha (2018) defined pulmonary aspiration as the movement of gastric content from the stomach into the lungs. Despite the reported low incidence, a 2,872,600-case review of 309 hospitals captured over a year found that aspiration was the most common cause of death related to airway-related anesthesia complications (Cook et al., 2011).

Aspiration has been considered by some to occur in 15% of general anesthetic surgeries and has double the chance of occurring in emergency and cesarean section surgeries (Nagelhout & Elisha, 2018). While aspiration itself most often causes little to no harm, 215,488 general anesthetics reviewed showed 5% of the cases experienced aspiration had led to mortality from aspiration pneumonitis (Warner et al., 1993). The hallmark sign of aspiration pneumonitis was described as arterial hypoxemia but may also include cyanosis, dyspnea, tachycardia, tachypnea, leukocytosis, fever, and infiltrates demonstrated in perihilar and dependent regions of the lung noted on chest radiography (Nagelhout & Elisha, 2018). The intense inflammatory response which has been seen due to aspiration pneumonitis is apparent via radiography within 1-2 hours after the initial insult (Nagelhout & Elisha, 2018). Visualization of gastric content into the

pharynx during induction and/or emergence can aid in the diagnosis of aspiration pneumonitis when other symptoms become apparent. CP has been utilized by those who manage the airway to prevent the risk of aspiration and associated pneumonitis.

Utilization of Cricoid Pressure

Since the introduction of CP in 1961, CP has been utilized for those at high risk for pulmonary aspiration. It has been described as a "mainstay of practice" for patients who require rapid sequence intubation due to being at a higher risk for aspiration (Nagelhout & Elisha, 2018, p. 420). Some patients identified as high risk for possible pulmonary aspiration include trauma patients, obstetric (OB) patients, patients with reflux associated symptoms, patients with intestinal obstructions, and those patients with a known or suspected full stomach. Due to CP being utilized in high-risk patients and lack of use for low-risk patients, there is a correlation between the use of CP and patients with suboptimal outcomes. Research, therefore, has recently been directed at the efficacy of CP.

Support for Cricoid Pressure

The utilization of CP has been shown to reduce the incidence of aspiration. In the literature detailing England and Wales Confidential Enquires into Maternal Death, there were 52 deaths related to aspiration reported between 1964 and 1969 (Salem et al., 2017). At this time CP had only recently been introduced and was not commonly used in pregnant women. Decades later, as CP became routinely used for the parturient, deaths associated with aspiration were detailed again by the same authors. Between 1994 -2005, after CP had become a mainstay of care for pregnant women, only two deaths were reported due to aspiration and one of these deaths did not utilize CP during induction (Salem et al., 2017). 50 deaths in 5 years reduced to two deaths in roughly 10 years demonstrates a significant improvement in mortality.

Technology has also provided evidence for the use of CP. The use of magnetic resonance imaging (MRI) has been used to visualize and evaluate the effects of CP. In a seminal observational study, Rice et al. (2009) evaluated MRI scans of the post cricoid hypopharynx of 24 non-sedated adults after application of CP. It demonstrated that the application of cricoid pressure was able to produce sufficient compression in the sniffing position (35.3% ± 2.6%), in the neutral position (34.9% ± 2.5%), and in the extended position (34.1% ± 3.1%) on the anatomical structures within the alimentary tract to prohibit gastric reflux into the pharynx (Rice et al., 2009). The authors also wrote that the anatomical area of compression was found to be the post cricoid hypopharynx and not the esophagus (Rice et al.).

In another seminal observational study, Zeidan et al. (2014) used 79 subjects for real-time mechanical and visual demonstrations to evaluate the effectiveness of 30 newtons (N) of CP in anesthetized and paralyzed patients. The subjects were evaluated using three objectives. First, either a 12- or 20-gauge gastric tube was advanced into the esophagus and attempted to pass into the stomach. An assistant randomly applied CP while the provider advancing the gastric tube was unaware if CP had been applied. The second objective included visualization of the patency of the esophagus via video laryngoscope with and without CP which was done in a blind manner. The observer was not aware if CP had been applied. The third objective was observing the position and movement of the esophageal opening with the glottis during CP. Findings reported that in 100% of the patients with CP applied, the gastric tubes could not be advanced past the esophagus and into the stomach. Additionally, there was the visualization of patency of the esophagus before CP that was then obstructed after application of CP. Finally, the position of the esophagus did not change in relation to the glottis after CP (Zeidan et al. 2014). If a gastric tube

is unable to be passed into the stomach due to the application of pressure, it is inferred that gastric content will be unable to expel in the reverse direction.

Opposition to Cricoid Pressure

The use of ultrasound to evaluate the efficacy of CP has been recently examined in a prospective observational study that viewed the effects of CP on 39 healthy volunteers utilizing 30 N of force to compress the esophagus. The study found that the esophagus did not reduce in size with an application of CP, but a reduction of diameter was seen with the application of pressure near the larynx (Andruszkiewicz et al., 2016). It was noted as a limitation in their study that the esophagus and the hypopharynx function together due to a connection of ligaments and muscles but were unable to see the effects of CP on the hypopharynx due to limitations in ultrasound technology (Andruszkiewicz et al., 2016). A complete picture of compression of the area that allows for transmission of gastric content from the stomach to the lungs also was not visualized.

In 2020 a systemic review and meta-analysis of randomized control trials was published with a primary goal of determining if CP could protect against aspiration and, as a secondary goal, if its use would affect intubation conditions. The findings suggested that there was no difference in aspiration between the use and non-use of CP (White et al., 2020). Additional studies were said to be added to aid in the collection of data to support findings in the secondary outcome, which showed reduced successful first-attempt tracheal intubations, reduced time to intubation, and inferior laryngeal views with CP (White et al., 2020). This study had one paramount limitation in that it only took place with low-risk subjects (White et al., 2020).

Utilization of the Correct Force for Cricoid Pressure

The applied force needed of the cricoid cartilage to obstruct the flow of gastric contents from the stomach into the hypopharynx was initially described by Sellick as a “firm pressure” (Sellick, 1961, p. 405). The verbal command of exerting firm pressure is a subjective and needs to be detailed further to allow for a universal objective application of force. Subjective and objective applications of CP have been detailed by many studies since CP’s introduction.

In one of the initial studies detailing the amount of force, Fanning used recently deceased human cadavers to insert a plastic catheter into the esophagus. He noted at what amount of water (H2O) pressure fluid was unable to pass through the esophagus. Of the five human cadavers, the pressures ranged from 50-94 cmH2O pressure which gives a mean H2O pressure of 74 cm (Fanning, 1970). A later study was published which suggested utilizing force that would cause pain when applied to the bridge of the nose to validate the correct force of CP (Wraight et al., 1983). These initial studies began to detail data with hopes to offer a universal amount of force for CP, but the studies remained difficult to identify objective measurements that were clinically useful.

A foundational study in 1983 was designed to objectively define and quantify the amount of force to utilize with CP. This study measured the relationship between intraluminal CP with the amount of force applied in 24 adults, all of which had their airways secured by a cuffed endotracheal tube. It was found when applying 44 N of force to the cricoid cartilage, enough force was created to occlude the esophagus in those patients whose intragastric pressure reached what is considered the peak amount of pressure that can be generated by the stomach to produce reflux. The study then postulated that if 44 N of force is applied to the cricoid cartilage, no reflux could occur (Wraight et al., 1983).

The study completed by Wraight et al. was found to be clinically relevant as the force of newtons can be measured with the use of a conversion. The force required to give one kilogram of weight an acceleration of one meter per second squared is known as a newton (Nagelhout & Elisha, 2018). While a newton is not utilized in everyday life, a newton can easily be converted into kilograms and therefore translated to the force applied to a scale by measuring the force applied in kilogram. One kilogram is 9.81 N, or simply stated, 10 N are equal to roughly 1 kg. But is 44 N of force too much when applied as CP?

Also utilizing cadavers, Vanner & Pryle (1992) postulated that 30 N of force was sufficient while 44 N of pressure was too much as three out of ten subjects tested showed evidence of esophageal rupture. The study demonstrated no cases of regurgitation with 30 N of CP and one occurrence of esophageal rupture compared to no regurgitation and two occurrences of esophageal rupture with 40 N of pressure (Vanner & Pryle, 1992). While rupture of the esophagus on a live adult undergoing surgery is an extremely rare complication of CP, an individual case study does exist. This case study details an 81-year-old female whose subsequent death was retrospectively determined to be due to esophageal rupture exacerbated by CP (Ralph & Wareham, 1991).

When evaluating the use of CP and the possibility of its application to cause airway obstruction, Hartsilver and Vanner (2000) ventilated 52 female patients with 900 ml of tidal volume via facemask and oral airway. They determined that an expired tidal volume of fewer than 200 ml would indicate airway obstruction. It was found that 44 N of force caused airway obstruction in 18 (35%) patients while causing only one (2%) obstruction with cricoid pressure at 30 N (Hartsilver & Vanner, 2000). The use of excessive forces for CP above 40 N was shown to worsen the view of the glottis while forces of 30-40 N have been shown to improve the view of

the glottis with laryngoscopy (Vanner & Asai, 1999). These articles demonstrate that too much CP can cause complications with ventilation and laryngoscopy while lower pressures are adequate to provide an improved view of the glottis while maintaining ventilation.

More recently, 30 N have been the aim for delivery of force for the unconscious patient with CP. A study that utilized solid-state manometry concluded that the use of 30 N of force to the cricoid cartilage generated high enough pressure to prevent regurgitation (Pellrud & Ahlstrand, 2018). Zeidan et al. (2014) observed direct video laryngoscopy which showed occlusion of the esophagus along with mechanical evidence detailing inability to pass any sized gastric tube when utilizing the use of 30 N of force for CP. The Difficult Airway Society advocated for the use of 30 N of CP in an unconscious patient in their 2015 guideline (Frerk et al., 2015).

Backwards-Upwards-Rightwards-Pressure

Backwards-Upwards-Rightwards-Pressure (BURP) is a technique that may be confused with CP. BURP is utilized to improve visualization of the vocal cords by placing the glottis into view (Nagelhout & Elisha, 2018). CP is utilized to place pressure on the alimentary tract and prohibit gastric content from communicating from the stomach into the airway. Both are utilized during laryngoscopy by manipulating the larynx. Similarity of the location of the two applications and their timing during induction may allow for confusion between the two respected techniques and therefore create inaccurate data collection for the application of CP. Further studies may be needed to clarify if additional teaching should be completed to distinguish the two techniques.

Simulation-based Force Evaluation of Cricoid Pressure

The application of force of CP has been evaluated and reported to be effective at 30 N. When evaluating practitioners for the application of roughly 30 N of force for CP utilizing a mannequin and infant scale, one study found that only 18% of the 206 anesthesiologists and nurse anesthetists applied the correct amount of force to the airway (Andruszkiewicz et al., 2017). An additional study on a mannequin identified that only 26% of the 61 practitioners which included anesthesiologists, nurse anesthetists, perioperative registered nurses, and intensive care nurses were found to apply the correct amount of force (Lefave et al., 2016). These studies suggest a lack of ability for practitioners to provide the correct force with the application of CP.

Simulation-based Site Evaluation of Cricoid Pressure

In the initial introduction of CP, Sellick stated that the use of CP could be demonstrated within seconds so that assistants could apply this intervention with the intention to reduce aspiration of gastric content (Sellick, 1961). As this may be the case, recent literature has suggested that practitioners have deficient knowledge of the anatomical location of the cricoid cartilage. In a prospective observational study viewing the application of CP by 206 anesthesiologists and nurse anesthetists, it was demonstrated that only 49% of participants were able to correctly utilize the cricoid cartilage when demonstrating the application of CP (Andruszkiewicz et al., 2017). A similar study described the results from 61 participants, including anesthesiologists, nurse anesthetists, perioperative registered nurses, and intensive care nurses, found only 19.7% of participants were able to correctly identify the cricoid cartilage when demonstrating the application of CP (Lefave et al., 2016). These numbers demonstrate a deficiency of knowledge on the anatomical location to apply CP.

Effects of Muscle Memory Fatigue

CP has a psychomotor muscle memory component with its application of force. An area of health care that has a similar component to CP is the use of cardiopulmonary resuscitation (CPR). Performing high-quality CPR entails the use of psychomotor skills and muscle memory. Adequate CP, like CPR, depends on correct application of muscle memory.

The consistency of providing high-quality CPR has been extensively researched and recently has been questioned as to the frequency of its continuing recertification skills sessions. While many facilities have mandated basic life support and CPR recurring education at least every two years, it has been suggested that every two years is not frequent enough. Chest compressions and ventilation accordant to resuscitation guidelines have been subpar and have generated undesirable outcomes as health care progressed into the 20th century (Abella et al., 2005). To combat the potential for sub-optimal outcomes further research has been conducted.

High-frequency psychomotor muscle memory refreshers have been shown to increase the quality of CPR. As soon as 3- to 6- months after CPR training, participants have been found to display poor retention of psychomotor muscle memory skills needed to provide high-quality CPR. When compared to a 6-month and/or 12- month refresher, annual 2- to 3- month “rolling refreshers” for psychomotor muscle memory training utilizing 1- to 2- minutes sessions significantly improved high-quality CPR based on compression and ventilation characteristics (Niles et al., 2017, p. 214). Over a 12- month period, the use of 2- to 3- month refreshers were evaluated. The evaluation was shown to decrease the number of attempts to pass ventilation and compression skill sessions when done quarterly (Dudzik et al., 2019).

At present, there are no studies to evaluate the extent of muscle memory fatigue related to the application of CP. Beckford et al. (2018) advocated for regularly scheduled training to sustain the application of effective CP but do not provide an indication as to how often this

should occur. Other areas within health care advocate for the repeated training designed to enhance the delivery of care that utilizes the application of force.

The use of high-frequency psychomotor muscle memory refreshers may increase the application of quality CP just as it has been shown effective for CPR. High-quality CPR demands the application of the desired depth of compression which is a muscle memory technique. This is like the application of the muscle memory technique needed for an accurate CP of 30 N. It could be postulated that short 1- to 2- minute refreshers every 2- to 3- months utilized by providers who routinely apply CP could show increased retention of muscle memory for application of correct CP.

Use of Guidelines Related to CP

The American Association of Nurse Anesthesiology (AANA) has included the use of CP in its practice guidelines for OB patients undergoing general anesthetic. The AANA's practice guideline included, "Preoxygenate patient during skin prep and placement of monitors, rapid sequence induction with cricoid pressure," in the steps for airway management of OB patients (American Association of Nurse Anesthesiology [AANA], 2017, p. 13). Any parturient who is greater than 12 weeks gestation is suggested to have a full stomach, is at increased risk of aspiration and should have CP placed for general anesthesia (Nagelhout & Elisha, 2018). The guideline suggested by the AANA, which is also detailed in anesthesia textbooks, clearly suggests that the parturient should be provided with the intervention of CP.

The American Society of Anesthesiologists (ASA) 2022 practice parameter publication suggested that practice guidelines for CP would not be defined because the literature was unable to suggest harm or benefit for this intervention (Apfelbaum et al., 2022). The ASA has not provided any clear direction for practitioners with the use of CP.

The AANA has made it clear that the parturient undergoing general anesthesia should receive CP. Due to the lack of clarity produced by the ASA and provided guidelines from the AANA, it can be argued that the exclusion of this intervention for any patient undergoing general anesthesia with a full stomach, potential for a full stomach, or at risk for aspiration could cause harm to the patient, and subsequently that the provider who excluded CP from their care could be held liable for that harm.

Problem Statement and PICO

Research found that many practitioners who provide airway support within the operating room (OR) are incorrectly applying CP. Suboptimal patient outcomes may be linked to the application of CP at an improper site as well as with the incorrect amount of force (Andruszkiewics et al., 2017; Lefave et al., 2016). Implementation of hands-on training and annual competencies for CP have improved long-term efficacy (Beckford et al., 2018; Purchon, 2017). To evaluate measures that satisfy safety concerns for providers applying CP, a PICO question was created. (P) In providers who utilize CP when managing patients' airways, how does the (I) development and implementation of EBP guidelines and education regarding CP compared to (C) a traditional approach, impact (O) clinical knowledge, skill proficiency, and patient outcomes?

Project Objectives

Evidence-Based Practice Guidelines and Plan for Implementation

The first objective of this project was the development of an EBP guideline for the use of CP. A thorough review of literature to uncover best practices was completed. This new knowledge can be used to guide the progression of the quality of care for patients and further improve the caliber of health care provided by practitioners. The American Association of

College of Nursing (AACN) advocates for the use of EBP to discover, integrate, and apply knowledge across disciplines from diverse sources to resolve practice obstacles (American Association of Colleges of Nursing [AACN], 2006). By utilizing EBP, a comprehensive plan has been assembled.

The second objective of this project included the development of a comprehensive plan to implement these EBP guidelines. After evaluating the literature for best practices, this project developed a comprehensive plan to disseminate and educate on the guideline. The structure is formatted to focus on the development of OR and OB suite providers who practice in a level one trauma center within the Mid-West. This project detailed a structured plan for dissemination that will be utilized to allow for cognitive and psychomotor skill acquisition. The guideline to be followed by the hypothetical hospital is provided.

The third objective included a plan to evaluate and/or monitor the EBP guideline. This includes measurement and monitoring prior to and after the installation of the comprehensive plan and guideline. Change should be evident after the comprehensive plan has been executed. If change is not evident, or if the change reflects undesired outcomes, the plan should be addressed and reassessed as to what new direction the plan will take so that the desired outcomes can be met.

The final objective of this project included a plan to adjust education and training if needed. The contingent plan can be utilized if the initial EBP plan demonstrates outcomes that do not improve from the initial findings or have outcomes that are undesired.

Summarizing the Evidence: The Literature Review for Education of Cricoid Pressure

The search strategy of literature related to CP and the education/training of CP involved a review of databases which provide published articles. These databases included the Cumulative

Index to Nursing and Allied Health Literature (CINAHL) with Full Text, Medical Literature Analysis and Retrieval System Online (MEDLINE) with Full Text, Cochrane Library, and Publisher MEDLINE (PubMed). These databases also were limited to journals which were peer-reviewed to ensure that the information provided was scholarly. Multiple databases were utilized to ensure the inclusion of medical and nursing material to allow for the most abundant amount of information specific to the education of CP be available for evaluation.

Literature Review Methods and Summary

The initial search utilizing MEDLINE with Full Text for 'Cricoid Pressure' yielded 520 results. With the addition of ('Sellick's Maneuver') OR ('Cricoid Pressure'), 536 articles were displayed. When limited to articles from 2015 to the present published in English, the results were narrowed to 124 articles. The addition of the Boolean search phrase ('Training') AND ('Sellick's Maneuver') AND ('Cricoid Pressure') provided 12 results. When exchanging ('Simulation') for ('Training') with the same search phrases, seven articles were found which yielded one previously unidentified article of interest.

CINAHL with Full Text, Cochrane Library, and PubMed were all searched utilizing the same technique. When compared to the search results from MEDLINE with Full Text, these additional databases yielded new articles. CINAHL with Full Text found 16 articles. Of the 16 articles, two previously unidentified articles of interest were found. Cochrane Library resulted in one unidentified article of interest which was not included in the results from other databases. PubMed found 25 articles, 11 of which had not been provided by other databases.

Articles that were selected for review detailed simulation-based education with an evaluation of education for CP in their title or abstract. Articles that did not display these criteria were rejected. Of the databases used MEDLINE provided seven, CINAHL provided two,

PubMed provided 11, and Cochrane Library provided one article for review. After reviewing the entire article, three articles were included which met the criteria. The articles rejected were done due to a lack of post-intervention assessments or an inaccurate description of how methods were completed, and data was obtained. A fourth article would likely have been added as the abstract provided met the criteria, but the complete article was published in German. It was therefore rejected.

The articles which met the criteria defined above were evaluated based on several characteristics. These characteristics were used to establish the quality of research and pinpoint studies that demonstrate quantitative and qualitative outcomes for the desired methods of this project. These articles are summarized in a table to evaluate their significance (see Appendix A).

An educational observational study was performed using 61 subjects, including anesthesiologists (16%), nurse anesthetists (28%), perioperative registered nurses (40%), and intensive care unit nurses (16%), that investigated each subject's anatomic application, weight-force pressure, technique, and hand used in the application of CP (Lefave et al., 2016). After the initial attempt, an instructional video along with two practice applications utilizing an accurate anatomical depiction of an airway that provided the cricoid cartilage and thyroid cartilage placed on an infant scale that gave measurements in kilograms was provided. It was found that 19.7% utilized the correct placement of CP before the educational exercise while 100% correctly utilized it post-exercise (Lefave et al. 2016). Also, only 26% of subjects applied the correct amount of pressure before the educational exercise whereas 68% of subjects applied the correct amount of pressure post-exercise (Lefave et al. 2016) This study was able to show a successful improvement with the application of educational training in participants utilizing a short-term study group.

Noll et al. provided an additional educational observational study. This study initially observed 25 attending anesthesiologists, 25 anesthesiology residents, 25 OR nurses, and 25 nurse anesthetists who applied CP to a 3-dimensional replica of the larynx on top of a Vernier force plate which rested on a carpet padding. Each of the 100 subjects was evaluated for force of CP at 5, 20, 30, and 55 seconds. Each of these four values was collected in four separate sessions for each subject. The 5 and 20-second force values were measured against the 5-15 N predetermined target for the conscious patient and the 30 and 55-second force values were measured against the 25-35 N predetermined target for the unconscious patient. To be deemed successful, each of the 5, 20, 30, and 55-second measurements applied needed to be within the predetermined target force range. In the baseline assessment, only five of the 400 trials, or 1.3%, were observed to be successful (Noll et al., 2019). A subset included 40 of the subjects in the baseline assessment who consented to further education and testing which entailed high-frequency feedback cycles. Each of the 40 participants was engaged in 30 sessions lasting one minute which measured the 5, 20, 30, and 55-second measurements and gave verbal feedback as to how much CP was applied at these times. A total of 1200 high-feedback cycles were performed and 385, or 32%, were observed to be successful (Noll et al., 2019). This is an increase of over 30%. The success rate was higher in the last 4 cycles of simulation than in the first 4 cycles, but only 4 subjects had success rates above or equal to 70% (Noll et al., 2019). These numbers reflect a trend in a positive direction but did not meet the threshold desired to be deemed a successful training exercise. A potential limitation to this study could be the use of the carpet pad.

A systematic review and meta-analysis of CP training and the efficacy of education were completed. Beckford et al. (2018) identified 204 articles on the effectiveness of education on training with the application of CP but excluded 196 of these due to duplicates, non-healthcare

subjects, no postintervention data provided, missing standard deviation needed, and non-interventional studies (Beckford et al. 2018). It was found that all eight studies identified deficient knowledge on the anatomical placement and ability to apply the correct amount of force to the cricoid and that nearly all subjects were able to apply the correct amount of force after educational intervention (Beckford et al. 2018). Also, Beckford et al. found increased success of intubation after training (95% CI = 0.157 to 0.425) and postulated that regularly scheduled training with CP could sustain the ability to effectively apply CP.

Project Overview

It is imperative that when utilizing CP, it is done with the correct application. Due to the abundance of literature that detailing incompetent application of CP, it is reasonable to infer the potential lack of knowledge of the location and lack of application of force to the cricoid cartilage is a true knowledge and skill deficit. Therefore, a plan of action has been developed to disseminate the correct implementation of CP for those who utilize CP in their scope of practice. A court case study found a provider at fault who denied their patient CP despite the detailed ambiguity for its use (Athanassoglou & Pandit, 2015). For this reason and other reasons such as patient safety the project has been established.

The project would be disseminated within a hypothetical hospital located in the Midwest that offers level one trauma and operating services. The most common cause of airway-related anesthesia deaths has been linked to aspiration as demonstrated by Cook et al. (2011). The hypothetical hospital system located within the Midwest is like the hospital detailed by Cook et al. It is the position of this project to assume aspiration is the most common cause of airway-related anesthesia deaths when reviewing the most recent year for the hypothetical hospital where the project will be completed.

The project has utilized EBP to develop a guideline that focuses on the training for the application of CP within the hypothetical hospital. The provided guideline details the simulation-based environment to be provided that is advantageous for instructing providers on the anatomical location and offer pressure training so that accurate application of CP can be achieved. Presuming education would be directed in a manner that reflects CPR competencies for retention of muscle memory on a quarterly basis. The project focuses on the site of application as the cricoid cartilage and the amount of force as 30 N (± 5 N) for the unconscious patient. This project would not advise providers when to utilize CP as that will be selectively determined by the provider through their ongoing patient evaluation.

If successful, the project could reduce the morbidity and mortality caused by anesthesia-related aspiration pneumonitis. This reduction in deaths could be directly related to the EBP quality improvement (QI) process. The correlation would be demonstrated through quantitative data observed after the dissemination of the EBP project.

Theoretical Framework (PDSA)

The Plan-Do-Study-Act (PDSA) framework was used to guide this EBP project. This framework has been utilized in many recent health care studies and is significant for health care. In a systematic review utilizing 28 randomized control trials focused on continuous QI compared to current usual practice and other strategies to manage organizational change, the PDSA framework was shown to benefit the clinical process measures compared to non-continuous QI processes (Hill et al., 2020). The Director of Nursing Practice and Work Environment at the American Nurses Association advocated for the use of the PDSA framework stating that “using standardized tools such as PDSA is critical to the success of clinical improvement activities,” and that “making clinical practice decision based on evidence is a true pearl for practice” (Assi,

2014, p.8). The PDSA framework shows value when utilized in health care for improving processes.

This process utilizes four specific steps in its framework to guide QI. When utilizing the PDSA method, it is important to begin by understanding how the PDSA cycle works. The PDSA method is a cycle that can be used to test change and, if needed, review and improve the project's processes before testing it again (AHRQ, 2020). It is a cycle that may be used multiple times and is complete with the objectives/goals are met.

Plan

The initial step for the PDSA model is *Plan*. A project must know its goal, how to know if this goal is met, and what is in place or need to be put in place to achieve said goal. The *Plan* step defines the problem and structures how the other steps in the PDSA process would be carried out. Initially, a project must know what it is that is attempting to achieve and have a goal for change (AHRQ, 2020). The goal for this project is to create a guideline for a facility to achieve two objectives. The first objective is to have, at minimum, 75% of the population who instructs or apply CP to apply the correct amount of force (30 N ± 5 N) to the correct anatomical position (cricoid cartilage) with the administration of CP. The second objective is to lead to a 50% reduction in the diagnosis of aspiration-related deaths in patients undergoing general anesthesia during surgery. This objective should be evaluated after the implementation of the EBP guideline for instruction on accurate placement and pressure for the CP technique.

After establishing a goal for the project, a review of existing processes should take place. The hospital's policies, procedures, protocols, and existing guidelines should be evaluated to determine if there are processes that are focused on the development and sustainability of the CP technique. If there is literature for CP in place within hospital processes, guidelines, or policies,

it should be evaluated to note if any of the detailed structures can be utilized in the EBP education guideline.

The *Plan* also details the actions included in the EBP process. Articles containing the instruction for the application of CP should be reviewed to establish EBP recommendations. A team of OR staff, including the chief nurse anesthetist, a staff nurse anesthetist, and a registered nurse who is educated in the application of EBP, should be assembled to review and evaluate the literature to use for establishing an educational process and forming a guideline. This team formed with each respected discipline within the OR would allow many disciplines that practice in the OR to have a representative. This inclusion would allow for a smoother transition into practice as each discipline would provide input into the process. If a team is unable to be assembled or is unable to reach consensus, the chief nurse anesthetist would assemble, evaluate, and choose the EBP education to be provided to the determined population. For this project, the interdisciplinary team involved in the completion of the projects EBP guideline are those involved in the creation of this project. Once an EBP process is identified, instruction should be included on whom, when, where, and how actions would take place to guide the instruction for dissemination of the EBP education to the qualified population.

An additional goal developed in the *Plan* step includes developing or knowing how to observe if the change has occurred. To evaluate if the project has increased the percentage of the population who correctly apply CP, detailed data before and after the EBP training would be collected. Also, data that details the incidence of aspiration-related general anesthesia deaths through quantifiable markers must be available and evaluated. Literature has suggested that aspiration is the most common cause of anesthesia-related deaths associated with general anesthesia (Cook et al., 2011). Assuming this to be true for the hypothetical hospital where this

project would take place, evaluation of the quantifiable data for the application of CP would need to be measured. An interdisciplinary team would be created to establish means of acquiring and presenting such data.

The interdisciplinary team would be utilized to guide different aspects of the PDSA cycle. The team's responsibilities are laid out in the *Plan* step. A team utilizing nursing informatics, quality services, surgical services, and headed by the chief nurse anesthetist would be established to develop processes to ensure the results of the EBP guideline are available for evaluation. Nursing informatics would be called upon within the *Plan* aspect, quality services would be called upon for the *Plan* and *Study* aspects, and surgical services would be called upon for the *Plan*, *Do*, and *Study* aspects of the project. The chief nurse anesthetist would provide the project management and oversight on the development and completion of the project.

The nursing informatics department would be responsible to ensure that the provider within the OR is able to demonstrate the use of CP within the electronic medical record (EMR). A computerized EMR which is prepared to preprocess data for data mining would improve the quality of data results (Sun et al., 2018). A point-and-click charting method to indicate the use of CP would be utilized to collect this data. If the point-and-click charting system or preprocessed data-mining processes are not present, they would be introduced via the informatics department. This point-and-click marker should be made easily available and displayed within the EMR so that providers may identify if the CP intervention was utilized or not.

The nursing informatics department would also be tasked with developing a web-based education session which is designed as a review course. The course would be completed with the quarterly cricoid refresher. This course would demonstrate, via web video, the correct placement and amount of force for CP to be applied to the anesthetized patient. Also provided would be a

self-assessment that, when completed, acknowledges that the provider was able to demonstrate the correct application of CP with the use of the mannequin and scale provided. A second self-assessment question that asks the practitioner if he/she was able to apply the correct amount of CP to the mannequin with their first application would be provided. The web-based education session would end with a short assessment that utilizes a click-and-point hotspot identification system. The practitioner to identify the cricoid cartilage from a photograph of a human neck. A second question would be a fill-in-the-blank for the correct amount of pressure to be applied in kilograms. The questionnaire would have multiple attempts while each question must be answered correctly and a score of 100% would be required to pass the questionnaire.

Do

The *Do* step in the PDSA framework puts the *Plan* step into action, observes for any problems, and gathers data (Zann et al., 2021). Specifically, the EBP structure which has been developed through research and detailed in the *Plan* step would be set in motion, its effects observed, and situations that hinder the process's effectiveness would be identified. The defined population would participate in the project with EBP education. The EBP instruction would generate data points to be captured and further used in the *Study* step. Initiation of this education identifies the onset where the new guideline would be put into place for CP. Data points would be collected from the EMR to evaluate the effectiveness in the clinical setting.

The informatics and quality departments, utilized to develop monitoring systems, would be able to produce quantitative reports on patients who underwent care in the OR and OB arenas. These reports would detail when CP was and was not utilized and identify those who developed aspiration pneumonitis leading to mortality after general anesthesia. These patients must be those who sustain the injury in the immediate post-operative time frame due to aspiration pneumonitis'

rapid development within 1-2 hours following insult (Nagelhout & Elisha, 2018). Reports would be run by the quality department quarterly and assembled for further evaluation. These demographics should flag all post-operative patients who develop aspiration pneumonitis despite the use or lack of use for CP in patients who have undergone surgery. The most common time for airway reflexes to be hindered is during induction and emergence which provides the possibility for aspiration (Nagelhout & Elisha, 2018). Reports for mortality in the operative arena would be run to evaluate if there could be additional causes of aspiration-associated mortality where CP was not utilized, and it did not play a role as with emergence. Also, this would give a chance to review the EMR to determine if CP should have been utilized.

Study

The *Study* step in the PDSA cycle analyzes, compares, and evaluates results (Zann et al., 2021). This is done to determine if an improvement was made or if any new problems were developed through the process. Evaluation of the data would determine if the goals for the project were met.

Once the EBP education has been conducted and quantitative data has been aggregated, full data analysis can be completed. Initial data on the goal for improvement for the application of CP would be evaluated. The goal is to have 75% of the population who undergoes the EBP education provide the correct placement and pressure for the application of CP. This quantitative data would be compared pre-and post-education. Indicators compared would provide the validity of the EBP education on its effectiveness for the acquisition of correct application provided by the population.

After the validity of the EBP education has been gathered and evaluated, and assuming this process has met its goal, clinical practice data indicators for the integration of the guideline

would be gathered and evaluated at a later specified time. The analysis would reveal if the implementation of the project's simulation training has reduced the amount of aspiration-related mortality within a specified time frame that meets the goal previously set for a reduction of associated mortality by 50%.

Act

The *Act* step completes the PDSA cycle, but it may not always conclude the project. This step in the process asks important questions. Did the three previous steps accomplish the goal? Are there any unintended consequences that present a new safety concern? These questions would shape the next step of the project.

If the goal was met and there were no safety concerns generated through the process, the project would be considered a success. At this point, the *Act* step instructs to continue rolling out the implementation. The guideline can be utilized to establish the process of education to assist in the clinical application for correct placement and pressure of CP.

If the goal was not met or if there are new safety concerns, the *Act* step directs the project to be redesigned. This allows for modification of the previously designed *Plan* step and a natural transition into an additional cycle of the PDSA method. The cycle would then follow the redesigned plan through each of the steps until the goal is met or the safety concern is abolished.

Guideline Implementation

To employ a standard of education for those who are providing airway management or supporting care for those who provide airway management within the OR or OB suite, a guideline was developed (Figure 1 and Appendix B). This guideline would be enacted in the facility and its relevance would be evaluated on a yearly basis by the department of anesthesia and the department of surgical services.

Figure 1

Evidence-Based Practice Guideline to Increase the Correct Application of Cricoid Pressure

Hospital X	Guideline
TITTLE: Evidence-Based Practice Guideline to Increase the Correct Application of Cricoid Pressure	**NUMBER:** 1-234
ISSUE DATE:	**EFFECTIVE DATE:**
DEVELOPED/REVISED BY: William H. Carson II	
REVIEWED BY: Department of Anesthesiology Surgery/Anesthesia	**DATE REVIEWED:**
APROVED BY:	

SCOPE: This guideline is in effect for the following Hospital X system business units: Hospital AAA

STATEMENT OF PURPOSE:

The purpose of this guideline is to provide evidence-based practice recommendations regarding the education for the anatomical application and amount of pressure to be utilized when applying cricoid pressure (CP) to the unconscious patient.

DEFINITIONS:

- **Cricoid Cartilage:** The only true ring of cartilage within the airway which is palpable just below the thyroid gland while corresponding to the beginning of the trachea and esophagus.
- **Cricoid Pressure:** The application of posterior displacement to the cricoid cartilage against cervical vertebra during general anesthesia to prevent regurgitation and possible aspiration of stomach content.
- **Newton:** The amount of required force to accelerate one kilogram of weight one meter per second. Ten newtons of force equal 0.981 kilograms of force. For ease of application, this guideline will recognize the application of ten newtons of force as a conversion to one kilogram of force.

POLICY:

This guideline applies to the education of those practitioners who provide airway maintenance or may be used as an assistant to those practitioners establishing an airway within the operating room or obstetric surgical suite. This guideline is intended to assist practitioners on the application of CP. This guideline DOES NOT designate the appropriate candidate for the use of CP. Designation for the use of CP is at the discretion of the care provider as this guideline is not a substitute for clinical judgement and does not establish legally enforceable requirements.

GUIDELINE:

1) A simulation-based educational application of CP will be introduced to stimulate didactic and muscle memory acquisition for CP
   a) This education will be directed
      i) at employees who will be employed within the operating room and obstetric surgical suite who provide direct patient care
         [1] at the time of practitioner new higher via training session

(2) at the time of introduction of guideline via training session

2) Simulation-based training equipment will include
   a) Life-sized adult laryngotracheal mannequin which correctly displays the thyroid cartilage and cricoid cartilage
   b) An infant scale which can measure weight in Kilograms (Kg) ranging from 0 to 20 Kg and fluctuates in increments of 0.01 Kg
3) Visual training aid will include
   a) A visual demonstration of the correct anatomical application of CP to a human adult model
      i) This will detail the difference between the thyroid and cricoid cartilages, identifying the cricoid cartilage as the only location to apply CP
   b) The amount force which should be applied to the cricoid cartilage displayed in newtons and Kg to the unconscious patient
      i) The amount of force to be given is 3 Kg aka 30 newtons
4) Training will include
   a) Initial uneducated application of CP to the life-sized laryngotracheal mannequin on an infant scale
      i) The display of the infant scale will only be displayed to an observer and not the practitioner
      ii) The observer will
         (1) Document the amount of force applied noted as Kg
         (2) Document the location of force applied to the laryngotracheal model
   b) The practitioner will be given the amount of force which was applied during simulation
   c) The practitioner will then watch the visual training aid
   d) The practitioner will then be instructed to practice the correct application of CP to the mannequin
      i) During the post-education application, the scales display will be visible to the practitioner as a practice session to establish muscle memory for the application of CP
      ii) The observer will be available to answer questions
   e) After practice, the observer will ask the practitioner to again apply CP to the mannequin
      i) The scale display will only be visible to the observer
      ii) The observer will
         (1) Document the amount of force applied noted as Kg
         (2) Document the location of force applied to the laryngotracheal model
   f) After simulation-based training exercise is complete, quarterly critiques will utilize
      i) Physical application of CP on the adult laryngotracheal mannequin and infant scale
         (1) Available within the employee simulation lab alongside the CPR mannequin
         (2) CP application should be completed prior to CPR recertification due to muscle fatigue associated with CPR
      ii) Web-based education
         (1) Pre- and post-tests evaluations will be completed on
            (a) The site of application for CP
            (b) The amount of force of CP for the unconscious patient

REFERENCES:

Setting and Population

The setting where this guideline would be enacted is a theoretical level one health care center located in the Mid-West region of the United States found in the inner-city which offers surgical and obstetric services. The target population includes those providers within a hospital OR and OB unit who directly provide airway management or assistance and currently work for the health care center or begin their employment following the onset of the guideline. The population may include, but is not limited to, anesthesiologists, resident anesthesiologists, nurse anesthetists, nurse midwives, student nurse anesthetists, registered nurses, anesthesia technicians, and surgical technicians. The target population would notified through e-mails sent to OR and OB staff. Participation would be mandatory for those who are employed by the health care center.

Implementation

Putting a hospital guideline into action takes more than just research and design. It requires permission, funding, and support from stakeholders. Detailing the method for change provides the outline for stakeholders to understand the process and how they would be needed to provide the spark for change. Implementation includes detailing the EBP steps found in the guideline.

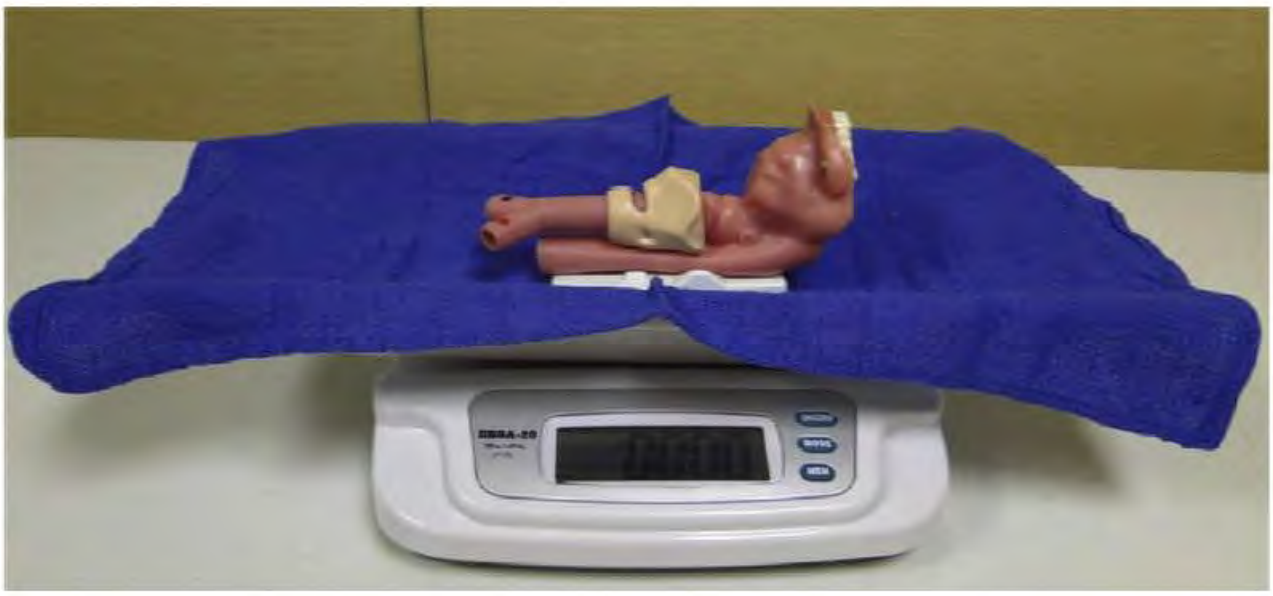
The use of the infant scale and laryngotracheal mannequin has been validated and utilized over the past few decades. Within the literature these objects have been found to be effective for demonstrating the ability to evaluate knowledge of practitioner's application of CP and for the utilization of a hands-on training adjunct to instill correct CP application and force within practitioners. Herman et al. (1996) reported that the use of these instruments allowed for “more quantifiable and reproducible means of assessing effort” while evaluating the application of CP

(p. 826). Beavers et al. (2009) utilized these instruments and found a lack of knowledge in the anatomical application and force of CP. In an additional study, these instruments were utilized to gather that providers lacked prior knowledge on the application site and amount of pressure when applying CP while it was also effective when utilized as a part of an instructional hands-on learning technique that demonstrated correct follow-up application of CP (Lefave et al., 2016).

A life-sized mannequin depicting the laryngotracheal anatomy of an adult would be utilized. The mannequin would have airway anatomy that depicts the cricoid cartilage and thyroid cartilage. The mannequin would be placed on an infant scale with the ability to measure weight in kilograms by increments of 0.01 kg with a range from 0-20 kg total weight (See Figure 2). A towel would be applied under the mannequin and the digital display would be directed in a manner that the practitioners would not be able to read the display during the assessment. An investigator would be able to view and record the findings. The scale would be zeroed after applying the towel and mannequin.

Figure 2

Training Instruments



Note. Lefave et al., (2016).

Next, a video demonstration detailing the correct placement of CP to the cricoid cartilage and the correct application of 30 N (3 kg) of force would be viewed by the practitioners. After the video was viewed by the practitioners, they would be able to practice the application of CP on the mannequin with the display of the scales visible. Once the practitioners have practiced, a post-education assessment that mirror the initial assessment would be completed and data detailing the amount of force and anatomical location of force would again be collected.

Following the simulated education session, practitioners would reevaluate their muscle memory application for pressure applied to the cricoid cartilage at ongoing cycles that are in sync with quarterly CPR training recommended by recent studies (Dudzik et al., 2019; Niles et al., 2017). The mannequin and scale would be readily available alongside mannequins that are needed to perform ongoing CPR muscle memory critique. Providers would be able to complete these two muscle memory techniques simultaneously. Providers would be instructed to utilize the CP muscle memory critique prior to CPR due to CPR's increased intensity and possibility to promote muscle fatigue.

Also, a web-based educational session would be developed. This web-based education would demonstrate the correct placement and correct amount of pressure for the unconscious patient. This would be a short, 1- to-2-minute web-based education session that includes a hotspot, a fill-in-the-blank questionnaire and an honor-based check-off acknowledgment.

After establishing the EBP method for education, the need for change would be further demonstrated to hospital stakeholders by providing data. One type of data provided would show the highest cause of general anesthesia deaths is related to aspiration. This would be established through a retrospective EMR chart review over the previous year's anesthesia-related deaths. An

additional area of data collection would be providing examples of the cost and character damages from aspiration-related hospital-acquired death. The hospital's legal department would be called upon to provide quantitative data that displays the cost of wrongful death lawsuits within the past five years, as these matters take time to resolve. Many of these cases are settled out of court and payouts are not of public knowledge due to legal restraints associated with settlements. In some cases, wrongful death lawsuits can cost hospitals millions of dollars while also implicating the hospital in the process.

Timeline

Along with the presentation of the guideline, a timeline would be presented to stakeholders. The timeline would be broken into several phases. The structuring of this project would include an introduction, rolling out the EBP guideline to practitioners, and evaluation of the clinical response of the guideline. After the collection of data from these parts, a final evaluation can then be completed.

The initiation of the project would include a team that gathers, assesses, and provides information to develop an EBP guideline. The team would also construct the plan to implement and evaluate this guideline. Construction of the guideline would be developed over the course of one month. During this month, a weekly meeting would be scheduled for each team member to provide assembled information for the development of the project. This initial phase would be completed prior to meeting with stakeholders to provide that accurate information be detailed for the stakeholders during said meeting. This process has been enacted though this scholarly project.

The project assessment and implementation phase for the EBP guideline would include a two-week schedule. The first week would have a Monday-Wednesday-Friday schedule, while

the second week would have a Tuesday-Thursday schedule. The expected time allocation for each practitioner to complete the educational process is no more than 30 minutes. The education alone would account for no more than 15 minutes while the remaining 15 minutes is provided to account for travel and refreshment time. The day staggering hopes to provide an opportunity for the target population to be present during their work hours. Time would be consistent each day and practitioners would be provided time to complete the educational task as rounders would provide breaks from OR tasks to complete the education. Time would include the EBP project implementation from 10 A.M. to 4 P.M. If a practitioner misses the implementation, they would be included in the next education session for new-hire employees.

The EBP guideline would also be included in the new-hire orientation for those who are providing care within the OR and OB operative arenas. After the new-hire orientation, the practitioner would continue to follow the quarterly rolling refresher previously detailed.

Following completion of EBP education project, a week would be given to allow for data collection and evaluation. If the project did not demonstrate results that meet the projected goal, the project would return to the *Plan* phase of the PDSA cycle to restructure the education allowing for refinement. It would be suggested that any refinement through the PDSA cycle be completed within two weeks.

Once the EBP education can show desired results, the guideline would be authorized allowing the project to proceed into the collection and evaluation phase. This phase would remain for one year. After completion of the year, a week would be allowed to synthesize the data to show collected results. Data for this phase would be reviewed with stakeholders in a yearly meeting to review, evaluate, and address gathered outcomes.

The completion of this project would take approximately 15 months. A large portion of this project is in the collection phase. The length of this phase is established to generate a reliable amount of information. The length of the collection phase is directed to reflect the length of previously described studies that demonstrated aspiration as the most common cause of general anesthesia-related deaths over the course of one year.

Budget

The estimated budget for this project would be disclosed to stakeholders prior to the administration of the project. The estimated budget would be given in phases. The budget would be juxtaposed against the potential cost for wrongful death lawsuits which may arise from aspiration-induced mortality.

Phase I

The initial phase of the budget details the *Plan* step of the PDSA framework. This step requires a team to collaborate while creating the framework for the project. The team would utilize the chief nurse anesthetist, a staff nurse anesthetist, and a surgical registered nurse to provide assembly of the EBP education. Assembly, evaluation, and selection of an EBP action to utilize would be completed within two meetings. The projected time involvement of these two meetings is roughly one hour for each meeting and one hour for the time involved away from the meeting focused on the meeting's content. The projected cost for the chief nurse anesthetist is $500 ($125 per hour), for the staff nurse anesthetist is $300 ($75 per hour), and $120 ($30 per hour) for the registered nurse. The total for the collaboration is $920 (See Table 1).

An additional two meetings would be budgeted for the *Plan* framework of the project. These meetings would utilize the chief nurse anesthetist, a staff nurse anesthetist, an informatics representative, and a quality representative. These meetings would be to build the documentation

needed for the evaluation of the project. The projected time involvement of these two meetings is roughly one hour for each meeting and one hour for the time involved away from the meeting focused on the content of the meeting. The projected cost includes the chief nurse anesthetist at 500 ($125 per hour), the staff anesthetist at $300 ($75 per hour), the informatics department at $300 (75 per hour), and the quality department at $120 ($30 per hour) for a total of $1,220 (See Table 1).

Table 1

Phase I

Specialty	**Hourly Wage in Dollars**	**Preparation Hours**	**Meeting Hours**	**Number of Meetings**	**Total Hours**	**Cost in Dollars**
Chief Nurse Anesthetist	125	1	1	4	8	1000
Staff Nurse Anesthetist	75	1	1	4	8	600
Registered Nurse	30	1	1	2	4	120
Informatics Specialist	75	1	1	2	4	300
Quality Specialist	30	1	1	2	4	120
Phase I Total $						**$2,140**

Phase II

The second phase of the projected budget details the *Do* step of the PDSA framework. This step includes the dissemination of the EBP education. Education would be required for the theoretical hospital staff which houses the 24 OR rooms and 1 OB delivery suite. Coverage would be needed for staff within these rooms. A designated provider from each specialty would round from 10 a.m. to 4 p.m. on the specified days. The hospital staff includes 25 anesthesiologists, 40 nurse anesthetists, 100 registered nurses (including OR and OB nurses), and

50 surgical technicians. Each of these practitioners would need 30 minutes of coverage to complete initial training. To calculate the expenses for these specialties, rates would include $300 per hour for anesthesiologists, $75.00 per hour for nurse anesthetists, $30 per hour for registered nurses, and $20 per hour for surgical technicians. The room to provider ratio includes 1 anesthesiologist per 4 rooms, one nurse anesthetist per room, two nurses per room, and two surgical technicians per room. To cover these positions for 30 minutes within the 25 OR and OB rooms between the hours of 10 a.m. and 4 p.m., one rounding anesthesiologist, two rounding nurse anesthetists, four rounding surgical technicians, and four rounding registered nurses would be needed. This would give an estimated budget of $1,800 per day for the anesthesiologist, $900 per day for the nurse anesthetists, $480 per day for the surgical technician, and $720 per day for the registered nurse. A total of 5 days of coverage reaches $19,500 (See Table 2).

Table 2

Phase II: Staff Training

Rounding Coverage	**Hourly Wage in Dollars**	**Providers Needed for 25 OR/OB Surgical Suites**	**Number of Providers Needed to Cover Training**	**Six-hour Shift Coverage Cost**	**Five Day Total**
Anesthesiologists	300	7	1	1800	9000
Nurse Anesthetist	75	25	2	900	4500
Registered Nurse	30	50	4	720	3600
Surgical Technicians	20	50	4	480	2400
Training Total $					**$19,500**

Also included in the *Do* stage for the EBP project, equipment is needed to complete the education. To keep providers moving smoothly through the education session, five stations would be needed. The cost of the airway model is $225 apiece, totaling $1,125 for stations needed. Five infant scales that measure kilograms would be needed. Three would be borrowed

from units within the hospital and two additional scales would be purchased and remain with the laryngotracheal models after the training sessions for quarterly critiques. The amount allocated for two infant scales which display kilograms includes $3000. The visual demonstration provided would be shown via TV acquired from the education department. The total for the equipment needed includes $4,125 (See Table 3).

Table 3

Phase II: Equipment

Equipment	**Cost**	**New Items Needed**	**Cost**
Laryngotracheal Model	225	5	1125
Infant Scale	1500	2	3000
Equipment Total $			**$4,125**

Additional staff would be utilized for evaluation and data collection. Five registered nurses would be utilized as observers to man these stations at a rate of $30 per hour, six hours per day, for 5 days to evaluate the application of CP. The total includes $4,500 for registered nurses. To complete the data analysis on the before-and-after application of CP, the quality department would be utilized. A total of 2 hours would be allotted at $30 per hour to generate this data. These additional staff would accrue $4,560 (See Table 4).

Table 4

Phase II: Data Collection

Specialty	**Hourly Wage in Dollars**	**Hours Participating**	**Cost**
Registered Nurse	30	30	4500
Quality Specialist	30	2	60
Total $			**$4,560**

Phase III

The third and final phase of the budget includes data collection and evaluation which details the *Study* and *Act* steps of the PDSA framework. Data for the use of CP on patients undergoing general anesthesia and the number of those patients who subsequently developed mortality due to aspiration would be collected. Each quarter the quality department would utilize 2 hours at $30 per hour to gather information on topics within the project. This would total $240 (See Table 5).

The final collaboration would take place once the project is complete. The initial team who developed the EBP guideline which includes the chief nurse anesthetist, a staff nurse anesthetist, a registered nurse along with stakeholders, a representative from the quality department, and a representative from the informatics department would review the data generated by the EBP project. The meeting would last no longer than one hour. The total cost for this meeting includes $335.

Table 5

Phase III

Specialty	**Hourly Wage in Dollars**	**Time Allocated in Hours**	**Cost**
Chief Nurse Anesthetists	125	1	125
Staff Nurse Anesthetist	75	1	75
Registered Nurse	30	1	30
Informatics Specialist	75	1	75
Quality Specialist	30	9	270
Total $			**$575**

Total Budget vs Legal Action

A total of each phase would be provided to stakeholders prior to the initiation of the project. The initial *Plan* step, phase I of the project budget, includes four meetings which last roughly two hours each. The total cost involved in establishing the framework is projected to be $2,140. The *Do* step of the project is the most labor-intensive step, totaling $28,185. The *Study*

and *Act* steps total $575. The grand total of the project is $30,900 (See Table 6, see Appendix C for a collection of budget totals detailed in one area).

Table 6

Total Cost

Phase	**Cost**
Phase I	2140
Phase II	28,185
Phase III	575
Total $	**$30,900**

Stakeholders would be given the total of the project with a comparison for legal action due to a wrongful death lawsuit associated with aspiration. A wrongful death lawsuit can cost the hospital anywhere from $250,000 to $1,000,000 per case. The project cost of $30,900 is substantially less than accruing costs associated with one wrongful death lawsuit.

Data Collection

Data collection is paramount to demonstrate the need for this project. The collection of data during and after the completion of the EBP project would detail the effectiveness or lack of effectiveness of the project. Data collection would be completed in multiple ways.

Data would be obtained evaluating the before-and-after location and amount of force applied for the application of CP. This data would demonstrate the effectiveness of the selected EBP education in the immediate timeframe. A success rate of 75% of practitioners meeting the correct application and amount of pressure must be present post-education for the release of the guideline and following data extrapolation to take place.

Data would also be collected using computerized markers developed by the chief nurse anesthetist, a staff nurse anesthetist, the nursing informatics department, and the quality department. These computerized markers would identify if CP was or was not utilized for any

patient undergoing general anesthesia. Also, the number of patients who demonstrated aspiration-related mortality after undergoing general anesthesia would be generated. An additional computerized marker that would generate quantitative data detailing the 1st time pass rate in the quarterly refresher for CP would be extrapolated to evaluate the long-term effects of the EBP educational project and the potential for didactic fatigue. Qualitative data would be evaluated to review if providers were able to apply the correct amount of CP to the mannequin on their first attempt.

Evaluation of Education Outcomes

There are two goals that need to be met for the education aspect of this project. The first goal includes 75% of the population who undergo the EBP education to demonstrate the correct amount of force at the correct site for the application of CP after completing the education session. The second goal is to reduce the amount of mortality associated with aspiration induced general anesthesia by 50%. If these goals are not met, adjustments would be made.

To increase the number of providers who correctly utilize CP on a mannequin if goals are not met, the use of video-based education would be removed, and in-person one-on-one education sessions would be utilized with designated CP champions. This would allow the opportunity for practitioners to be shown demonstrations and ask questions prior to providing return demonstrations.

If the amount of aspiration-related mortality is not reduced by 50%, the data must first be evaluated to identify if the mortality took place on patients who received CP or not. If these patients did receive CP, the application of CP must be addressed. To decrease the number of aspiration-related mortality, the quarterly refreshers would be completed in person with a designated CP champion and the web-based refreshers would be eliminated. This would allow

for immediate feedback and the ability to provide explanations and answer questions. If mortality was found in patients who did not receive CP other questions should be entertained. The first topic to discuss is if these patients should have had CP. The second topic to evaluate is the timing of aspiration. Could this be an issue that takes place during emergence? Should the emergence process be evaluated? If so, the PDSA framework would be utilized to develop an EBP guideline to treat emergence-associated aspiration.

Conclusion

CP is a technique utilized by practitioners to reduce the risk of aspiration associated with the induction of general anesthesia. An EBP guideline for the education on the application of CP, a plan for the guideline's implementation, and a plan to evaluate the guideline's outcomes have been created. This guideline, if utilized correctly, should further the care and safety of patients, and increase the competence of providers while reducing the risk of hospital-related mortality for patients undergoing general anesthesia.

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Appendix A: Literature Review

Citation	Conceptual Framework	Design/Method	Sample/Setting	Outcomes	Findings	Level of evidence	Quality of evidence
Beckford, L., Holly, C., & Kirkley, R. (2018). Systematic Review and Meta-Analysis of Cricoid Pressure Training and Education Efficacy. *AORN Journal*, *107*(6), 716–725. https://doi.org/10.1002/aorn.12150	Examine the evidence of the effectiveness of education and training on cricoid pressure. Due to validity and performance of cricoid pressure in question.	The authors focused on the effects of training programs for cricoid pressure and utilized the P-values of the analyzed studies to interpret the gathered data	Of the 204 studies found, 174 did not meet exclusion criteria. An additional 21 were removed due to wrong methodology, lack of post intervention assessment, duplicate studies, non-health professional participants, missing standard deviation. Final sample included 8 studies	Scales used include test for heterogeneity (ie, variation) of the effect using the x2 test. Tested the potential for publication bias with using Egger's test and combined the P-values using Fisher's test.	Using the random-effects model, the success rate increased after training by a positive value (change in success from 0.157 to 0.452)	Meta-analysis of eight studies: systematic review of correlational / observational studies Level III	The evidence supported simulation for training was able to guide achievement of desired cricoid pressure.
Lefave, M., Harrell, B., & Wright, M. (2016). Analysis of Cricoid Pressure Force and Technique Among Anesthesiologists, Nurse Anesthetists, and Registered Nurses. *Journal of PeriAnesthesia Nursing*, *31*(3), 237–244. https://doi.org/10.1016/j.jopan.2014.09.007	To assess the ability of anesthesiologists, nurse anesthetists, and registered nurses to correctly identify anatomic landmarks of cricoid pressure and apply the correct amount of force	An educational intervention with a single group pretest-post-test design. Participants demonstrated cricoid pressure on a laryngotracheal model. After an educational intervention video, participants were asked to repeat cricoid pressure on the model.	Inclusion: anesthesiologists, nurse anesthetists, preoperative registered nurses, intraoperative registered nurses, postoperative registered nurses, and registered nurses working in the intensive care unit at a 635-bed tertiary care hospital. Exclusion criteria included participants unable to speak English. Sample size was limited to consenting participants actively working at the hospital during the study dates.	Wilcoxon signed rank test evaluated differences between the identification of cricoid anatomy pretest and post-test. A Kruskal-Wallis test evaluated pretest post-test differences between participant occupations. Pearson correlation analysis evaluated pretest and post-test forces and years	Only 2 (14%) were able to correctly answer what correct cricoid force should be used. 19.7% participants identified the cricoid cartilage pretest compared to 100% posttest. None applied cricoid pressure with correct force prior to education. 41 did	Single correlational / observational study Level IV	Quality of evidence for this study is fair. This study could increase its validity with increased sample size and inclusion of emergency room physicians and nurses, as well as first line providers (medics)

				of applying pressure.	after educatio n		
Noll, E., Shodhan, S., Varshney, A., Gallagher, C., Diemunsch, P., Florence, F., Romeiser, J., Bennett-Guerrero, E. (2019) Trainability of cricoid pressure force application: A simulation-based study. *Obstetric Anesthesia Digest, 39*(2), 82-83. http://doi.org/10.1097/01.aoa.0000557667.40775.ad	To assess the effective training of application of target force of CP via simulation-based education	Clinicians applied CP to a Vernier plate simulator and pressure measurements were taken four times over 60 seconds, two measurements before LOC and two after LOC. After initial assessment which included four cycles of measured CP for each participant, man clinicians underwent self-regulated practice and were then evaluated again via 30 1-minute cycles of simulation to evaluate any change in performance.	Clinicians included 25 anesthesiologis ts, 25 anesthesia residents, 25 nurse anesthetists, and 25 operating room nurses. 40 clinicians were involved in the education post initial assessment.	The initial assessmen t, 96% of clinicians did not provide the recommen ded amount of force for CP. After one hour of simulation -based training, clinicians increased their success rates by 45% compared to initial assessmen ts. While there were increases in success, the increase did not meet the previously defined passing threshold	Simulato r-based training increase d proficien cy in CP applicati on while the success rate which was desired was not reached. Participa nts showed increase d success rates in the last 4 cycles preform ed. Initially only 5/400 were successf ul (1.3%) and after training 385/120 0 were successf ul (38%)	Single correlati onal / observati onal study Level IV	Quality of evidence for this study is moderat e. Of the initial 100 clinician s, only 40 complete d the high-frequenc y feedback training. Evaluati ng initial values versus a smaller group could create some variabilit y of outcome s. Overall, well develope d and carried out. More similar studies and participa nts could help this study.

Appendix B: Guideline

Hospital X **Guideline**	
TITTLE: Evidence-Based Practice Guideline to Increase the Correct Application of Cricoid Pressure	**NUMBER:** 1-234
ISSUE DATE:	**EFFECTIVE DATE:**
DEVELOPED/REVISED BY: William H. Carson II	
REVIEWED BY: Department of Anesthesiology Surgery/Anesthesia	**DATE REVIEWED:**
APROVED BY:	

SCOPE: This guideline is in effect for the following Hospital X system business units: Hospital AAA

STATEMENT OF PURPOSE:

The purpose of this guideline is to provide evidence-based practice recommendations regarding the education for the anatomical application and amount of pressure to be utilized when applying cricoid pressure (CP) to the unconscious patient.

DEFINITIONS:

- **Cricoid Cartilage:** The only true ring of cartilage within the airway which is palpable just below the thyroid gland while corresponding to the beginning of the trachea and esophagus.
- **Cricoid Pressure:** The application of posterior displacement to the cricoid cartilage against cervical vertebra during general anesthesia to prevent regurgitation and possible aspiration of stomach content.
- **Newton:** The amount of required force to accelerate one kilogram of weight one meter per second squared. Ten N of force equal 0.981 kg of force. For ease of application, this guideline will recognize the application of 10 N of force as a conversion to 1 kg of force.

POLICY:

This guideline applies to the education of those practitioners who provide airway maintenance or may be used as an assistant to those practitioners establishing an airway within the operating room or obstetric surgical suite. This guideline is intended to assist practitioners on the application of CP. This guideline DOES NOT designate the appropriate candidate for the use of CP. Designation for the use of CP is at the discretion of the care provider as this guideline is not a substitute for clinical judgement and does not establish legally enforceable requirements.

GUIDELINE:

1) A simulation-based educational application of CP will be introduced to stimulate didactic and muscle memory acquisition for CP
    a) This education will be directed
        i) at employees who will be employed within the operating room and obstetric surgical suite who provide direct patient care
            (1) at the time of practitioner new higher via training session
            (2) at the time of introduction of guideline via training session
2) Simulation-based training equipment will include

a) Life-sized adult laryngotracheal mannequin which correctly displays the thyroid cartilage and cricoid cartilage
b) An infant scale which can measure weight in kilograms ranging from 0 to 20 kg and fluctuates in increments of 0.01 kg

3) Visual training aid will include
   a) A visual demonstration of the correct anatomical application of CP to a human adult model
      i) This will detail the difference between the thyroid and cricoid cartilages, identifying the cricoid cartilage as the only location to apply CP
   b) The amount force which should be applied to the cricoid cartilage of the unconscious patient, which should be displayed in newtons and kilograms
      i) The amount of force to be given is 3 kg (± 0.5 kg) aka 30 N (± 5 N)
4) Training will include
   a) Initial uneducated application of CP to the life-sized laryngotracheal mannequin on an infant scale
      i) The display of the infant scale will only be displayed to an observer and not the practitioner
      ii) The observer will
         (1) Document the amount of force applied noted as kilograms
         (2) Document the location of force applied to the laryngotracheal model
   b) The practitioner will be given the amount of force which was applied during simulation
   c) The practitioner will then watch the visual training aid
   d) The practitioner will then be instructed to practice the correct application of CP to the mannequin
      i) During the post-education application, the scales display will be visible to the practitioner as a practice session to establish muscle memory for the application of CP
      ii) The observer will be available to answer questions
   e) After practice, the observer will ask the practitioner to again apply CP to the mannequin
      i) The scale display will only be visible to the observer
      ii) The observer will
         (1) Document the amount of force applied noted as kilograms
         (2) Document the location of force applied to the laryngotracheal model
   f) After simulation-based training exercise is complete, quarterly critiques will utilize
      i) Physical application of CP on the adult laryngotracheal mannequin and infant scale
         (1) Available within the employee simulation lab alongside the CPR mannequin
         (2) CP application should be completed prior to CPR recertification due to muscle fatigue associated with CPR
      ii) Web-based education
         (1) Pre- and post-tests evaluations will be completed on
            (a) The site of application for CP
            (b) The amount of force of CP for the unconscious patient

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Dudzik, L., Heard, D. G., Griffin, R. E., Vercellino, M., Hunt, A., Cates, A., & Rebholz, M. (2019). Implementation of a low-dose, high-frequency cardiac resuscitation quality improvement program in a community hospital. *The Joint Commission Journal on Quality and Patient Safety*, *45*(12), 789–797. https://doi.org/10.1016/j.jcjq.2019.08.010

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Appendix C: Budget

Phase I						
Specialty	**Hourly Wage in Dollars**	**Projected Preparation Hours**	**Projected Hours per Meeting**	**Projected Meetings**	**Total Hours**	**Projected Costs in Dollars**
Chief Nurse Anesthetist	125	1	1	4	8	1000
Staff Nurse Anesthetist	75	1	1	4	8	600
Registered Nurse	30	1	1	2	4	120
Informatics Department	75	1	1	2	4	300
Quality Specialist	30	1	1	2	4	120
Phase I total						**2,140**

Phase II: Staff Training					
Rounding Coverage	**Hourly Wage in Dollars**	**Providers Staffed for 25 OR/OB Surgical Suites**	**Number of Providers Needed to Cover Training**	**Cost Associated with 6-hour Shift to Cover OR/OB**	**Daily Cost x5 Days**
Anesthesiologists	300	7	1	1800	9000
Nurse Anesthetists	75	25	2	900 (75x6x2)	4500
Registered Nurse	30	50	4	720 (30x6x4)	3600
Surgical Technicians	20	50	4	480 (20x6x4)	2400
Training total					**19,500**

Phase II: Equipment			
Equipment	**Cost**	**New Equipment Needed**	**Total**
Laryngotracheal model	225	5	1125
Infant scale	1500	2	3000
Equipment total			**4,125**

Phase II: Data Collection			
Specialty	**Hourly wage in dollars**	**Total Hours Participating**	**Total Cost**
Registered Nurse	30	30	4500

Quality Specialist	30	2	60
Total			**4560**

Phase III			
Specialty	**Hourly Wage in Dollars**	**Time Allocated in Hours**	**Cost**
Chief Nurse Anesthetist	125	1	125
Staff Nurse Anesthetist	75	1	75
Registered Nurse	30	1	30
Informatics Specialist	75	1	75
Quality Specialist	30	9	270
Total			**575**

Phase	**Cost**
Phase I	2,140
Phase II	28,185
Phase III	575
Total	**30,900**

Appendix C
Otterbein University
IRB Exemption Statement

Conversation between IRB Chair, Dr. Noam Shpancer and Dr. John Chovan, Department of Nursing Chair.

From: Shpancer, Noam <nshpancer@otterbein.edu>
Sent: Wednesday, October 13, 2021 9:44 AM
To: Chovan, John <jchovan@otterbein.edu>
Subject: Re: IRB and DNP Projects

John: The way I see it, a project is not subject to IRB review unless and until it collects data from human participants. So, I agree with you that these projects will not need IRB approval until someone decides to implement them for data collection, at which point that person may apply for IRB approval.

Thanks, Noam.
From: Chovan, John <jchovan@otterbein.edu>
Sent: Wednesday, October 13, 2021 9:10 AM
To: Shpancer, Noam <nshpancer@otterbein.edu>
Subject: IRB and DNP Projects

Good morning, Noam,

I could use some advice -- maybe a conversation -- about the Doctor of Nursing Practice final scholarly projects and submitting for IRB approval. The projects parameters from our accreditors for some of the projects have changed. The list of acceptable projects now includes the option of writing a plan for a project that is not implemented. So, it can effectively stop at the proposal stage, and then these projects can be available for a future student to implement if someone has that interest. I have at least two questions.

1. The IRB Guidelines states "Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." Most of these projects are not intended to develop or contribute to generalizable knowledge. They are clinical change projects that are intended to eventually change a clinical practice of health care professionals (humans) in one identified setting. They have the possibility of contributing to generalizable knowledge in that each would be an instance of a clinical change that, if implemented in other places by others, could eventually be generalized. But that is not the primary intent of the projects. Would they be considered research? I think they would not.

2. If indeed they are considered research and should be submitted for review by the IRB, at what point in the process should IRB approval be obtained? I would think that although implementation is not part of the initial project, review by IRB would be helpful to the original team in shaping their project plan. Yet if this proposal is not going to be implemented, then the approval to move forward would be moot. But if a second team eventually reads the proposal and wants to implement it, would they be the ones seeking IRB approval?

If you would prefer that we talk in real time, I am open to that. Or perhaps you could visit one of our faculty meetings for a discussion?

Thank you.

Best,

John

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Chief Nurse Administrator
Otterbein University

"A comprehensive institution with a strong liberal arts base"
jchovan@otterbein.edu; 614-823-1526, voice; he/him/his
"The world is starved for grace. If we are going to work at restoring fellowship and reaching people, we need grace now more than ever."
- Pastor John Swadley, Forest Park Baptist Church, Joplin, Missouri