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Prehospital Use of Cuffed Endotracheal Tubes in Pediatric Patients: Thematic Analysis of
Barriers to Practice Change.

A DNP Project

Presented to the Faculty of the

Department of Nursing

West Chester University

West Chester, Pennsylvania

In Partial Fulfillment of the Requirements for the

Degree of Doctor of Nursing Practice

By

Thomas E. Pearson

May, 2020

Dedication

This project is dedicated to all the nurses who worked so selflessly during The Great Pandemic of 2020, those that fell ill, and in remembrance of those that succumbed to the virus in the line of duty.

Acknowledgements

There are so many who supported my doctoral journey to acknowledge.

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Abstract

The prehospital use of cuffed endotracheal tubes has become an evidence-based practice recommendation. Uncuffed endotracheal tubes continue to be used by emergency medical services (EMS) that transport injured and ill children to Nemours/Alfred I Dupont Hospital for Children (N/AIDHC). Uncuffed endotracheal tubes are being used in infants and toddlers, but also in older children and adolescents. EMS agencies that refer patients to N/AIDHC were surveyed to determine the status of their implementation and use of cuffed endotracheal tubes. Of six services, two had fully implemented the use of cuffed endotracheal tubes. Dispositional resistance to change among the EMS administrators was measured and found to be lower at the services that had implemented the use of uncuffed endotracheal tubes. Implementation of the use of cuffed endotracheal tubes was most facilitated by clinical expert involvement. Outreach education by pediatric critical care experts is indicated to assist those services that have not yet implemented the use of cuffed endotracheal tubes.

Keywords: (Endotracheal, intubation, pediatric, prehospital, cuffed, uncuffed.)

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Prehospital Use of Cuffed Endotracheal Tubes in Pediatric Patients: Thematic Analysis of
Barriers to Practice Change.

Chapter 1

Introduction and Background

The standard of care for the use of endotracheal tubes in children has been evolving over the last decade. Although the current standard of care among pediatric specialists is to use cuffed endotracheal tubes (CETT), many prehospital emergency care providers continue to utilize uncuffed endotracheal tubes (UETT). Much of what has been written on the use of endotracheal tubes in pediatric patients is ill-informed, based on outdated information, and unfortunately continues to be promulgated (De Orange et al., 2017; Litman & Maxwell 2013). In the prehospital arena, only the most clinically unstable, critically ill or injured children will require placement of an endotracheal tube to secure a patent airway. Awareness exists amongst pediatric clinicians since at least 2008 (Aker, 2008), that this potentially lifesaving intervention possesses serious risks and potential complications that are not effectively mitigated when using an uncuffed endotracheal tube. Pearson, Frizzola, and Khine (2019) report finding in their study that 44% of pediatric patients that were transferred from adult hospitals for specialty pediatric care who had an uncuffed endotracheal tube in place required urgent replacement with a cuffed tube. Great care and forethought is warranted on this matter as potential effects of poor airway control include neurological injury and death.

Costs savings have been demonstrated with the exclusive use of CETTs by eliminating UETTs from stock (Shaffner et al., 2019). According to Meg Frizzola, MD, medical director of the Pediatric Intensive Care Unit (PICU) at Nemours Alfred I. Dupont Hospital for Children (N/ADHC), replacing an UETT with a CETT in the PICU creates an expense that is

billed directly to the patient. In addition, Dr. Frizzola believes managing a patient in the PICU with a poorly functioning UETT results in an increased need for prolonged sedation, and may increase length of stay (personal communication, October 21, 2019). Despite the advantages of CETTs, UETTs continue to be used by emergency medical services (EMS) systems locally. The purpose of this quality improvement project is to determine what factors lead to the continued prehospital use of uncuffed endotracheal tubes in children.

PICOT Statement

In EMS providers (P), what factors affect the prehospital use of UETTs and how does a focused educational intervention using evidence-based principles (I) affect those factors and the rate of use of UETTs (C) in pediatric patients, aged full-term (> 40 weeks gestational age) to 14 years who have endotracheal tubes placed by EMS prior to arrival to a tertiary care, Level 1 pediatric trauma center hospital (O), within a 1 month period (T)?

Research Questions

This project sought to identify the structural and process factors at each EMS site that affect the use of uncuffed endotracheal tubes. In particular, it aimed to investigate the influence of resistance to change, implementation of policy, and the effect of the hierarchical EMS system in which each site operates. It also sought to determine if a focused educational initiative would be sufficient to change policy and procedure toward the use of CETTs.

Chapter 2

Literature Review

A review of the literature was performed regarding best practices for the use of endotracheal tubes in children, with attention to application to prehospital care. This chapter also includes a discussion of the theoretical framework for this project. The literature review features the following sections: a) History of the use of Endotracheal Tubes in Children, b) The Slow Evolution of Endotracheal Tube Technology, c) Prehospital use of Endotracheal Tubes, d) First Pass as a Marker for Success in Critical Resuscitation, e) Errors in Prehospital Airway Control, f) Special Pediatric Populations, g) Application of Evidence-Based Practice in EMS, h) Failure to Disinvest, i) PICOT Statement, and j) Conclusions.

The review process utilized a multiple search function via the Nemours intranet that simultaneously accesses Nemours library holdings in Clinical Key, Clinical Key for Nursing, Lexicomp, Ovid Medline, Pediatric Surgery NAT, PubMed, Red Book Online, Up To Date, and Visual Dx. Additional online searches were made in CINAHL via the West Chester University library website. Key words and terms included: *Pediatric, children, endotracheal tube, EMS, prehospital, cuffed, uncuffed, advanced airway, burn patient, work of breathing, failure to disinvest, and evidence-based practice*. Only articles published in peer-reviewed medical or nursing journals since 2014 were included, with the exception of two seminal articles published in 2008 and 2011 respectively, and the legacy study by Khine published in 1997. Sixty-eight articles were located for review. Duplicate articles were excluded, as well as those that were not in English. Those that were published as open source were eliminated unless verified to be from a non-predatory publisher. Fifty-one articles remained, and a review of abstracts eliminated six. The articles were fully reviewed and evaluated for strength of evidence using the Johns Hopkins

Evidence-Based Practice Evidence Level and Quality Guide (Johns Hopkins University, 2019). The studies encompassed evidence levels 1, 2, 3, and 4. Although there are a sufficient number of strong articles on the use of endotracheal tubes in children, there are fewer on the subject of using cuffed endotracheal tubes in children. The literature does not address the prehospital use of cuffed versus uncuffed endotracheal tubes in children and there were no articles found on this topic, except one published by this author (Pearson et al., 2019) in pediatric critical care transport.

Definitions

A *pediatric* patient is most commonly considered to be anyone age 14 years or under. Newborns to age 2 months are considered *neonates*. *Prehospital* refers to the arena of emergency patient care performed by 911/EMS responders prior to or during transport to a hospital. An *endotracheal tube* is a pliable, transparent polyvinyl chloride tube intended to be placed into the trachea under direct visualization for the purpose of establishing, maintaining, and protecting a patent airway in any patient that is unable to do so on their own. A *cuffed endotracheal tube* (CETT) has a soft, inflatable cuff on its distal end, typically a few centimeters or less from the tube tip, for placement inside the trachea below the level of the vocal cords and above the tracheal carina. The cuff is intended to be carefully inflated and to provide a functioning seal inside the trachea. An *Uncuffed endotracheal tube* (UETT) lacks this feature, are provided only in the smaller range of available sizes (2.5 to 6.0 millimeters internal diameter) and are typically used in the pediatric patient.

Theoretical Model

The theoretical basis for the project is found in Donabedian's Model of Healthcare Quality. Useful as a tool for outcomes assessment, Donabedian's model utilizes a simple

framework for evaluation consisting of structure, process, and outcome. Donabedian's model states that outcomes are dependent on the structural quality components of an organization and their effect on the processes of that organization (Zaccagnini & White, 2017). The Donabedian model has proven effective in evaluation of healthcare quality and is widely used, for example in the evaluation of trauma care (Moore, et al., 2015). Swiatek, et al., (2015) illustrate Donabedian's model with an example of general hospitals that lack the structural component of specialty surgical services for children, which affects the process of care decisions, and leads to the outcome of splenectomy rates for injured children at 5 times the rate of a pediatric center.

Application of Donabedian's model to this project will first look at the long-term characteristics (structure) of the study site such as standards of care, quality improvement efforts, the hierarchy of medical command and control, and the equipment that is on hand for use. Next, it will examine the clinical activities (process) that take place and that may occur at time of patient contact such as training, policy and protocol use, and the level of independent practice. Finally, it will look at results (outcomes), such as willingness to change policy, the willingness to involve clinical experts, and patient outcomes such as repeat procedures, complications, and mortality (Figure 1).

History of the Use of Endotracheal Tubes in Children

The history of the use of UETTs in children is marked by a slow evolution of understanding of the pediatric airway anatomy and an equally slow evolution of endotracheal tube technology (Pearson et al., 2019). Tobias (2014) recently studied the pediatric airway using computed tomography and magnetic resonance imaging in a significant number of patients, with varying degrees of sedation and neuromuscular blockade and debunked the common misconception that the pediatric airway is conical in shape. Unfortunately, misconceptions about

the pediatric airway remain widespread (Litman & Maxwell, 2013). Medical providers have been taught that the cricoid ring is the narrowest aspect of the pediatric airway, provides a natural cuff, and delineates the correct sizing of the UETT (Holzki, et al., 2017; Litman & Maxwell, 2013; Thomas et al., 2016). However, selecting an UETT for the pediatric patient may be disastrous if a large leak develops (Bailey, 2018).

The Slow Evolution of Endotracheal Tube Technology

Prior to the 1940's endotracheal intubation in the pediatric patient was a rare occurrence due to the limited availability of appropriately sized tubes (Aker, 2008). This continued until the 1990's when cuffed polyvinyl chloride tubes in pediatric sizes with a high volume, low pressure cuff became available (Shah & Carlisle, 2019).

For the EMS practitioner, inconsistencies in internal and external tube diameters between various manufacturers complicates selecting a properly fitting endotracheal tube in the pediatric patient even more (Rafiq et al., 2016).

Prehospital Use of Endotracheal Tubes

There are marked disadvantages to the use of uncuffed endotracheal tubes in pediatric patients. Some results showed that UETTs leaked at a consistently higher rate compared to CETTs (Chambers, et al., 2018). To demonstrate the efficacy of CETTs, centers that used cuffed endotracheal tubes in pediatric surgical patients reported decreased use of anesthetic gas volumes, with decreased atmospheric contamination (Thomas et al., 2016). Ventilation with an UETT may be unreliable, and can require increased tidal volumes to compensate for loss of volume and pressure (Aker, 2008; Chambers, et al. 2018). Capnography is the accepted standard to continuously monitor correct tube placement. An accurate exhaled CO₂ reading is essential to safe and effective patient care (Freeman, et al., 2016). In the prehospital patient with an UETT,

exhaled carbon dioxide readings via capnography may be inaccurate (Chambers, et al., 2018). Aspiration of gastric contents remains a risk in the EMS patient and the incidence is increased in the patient with an UETT, evidenced by a higher incidence of pepsin (a specific marker for gastric contents) in the tracheas of patients with UETTs (Taylor et al., 2011). A reduction in the incidence of microaspiration and pneumonia was found by Blot et al. (2016) when using a CETT in high-risk surgical patients.

Post-extubation stridor and sore throat is often cited as reason to not use cuffed endotracheal tubes in pediatric patients. When utilizing CETTs in the pediatric patient care must be taken to maintain cuff pressures in a safe range (less than 25-27 cm. of water) to avoid tracheal irritation and post-extubation stridor (Schneider, et al., 2016). Increasing endotracheal tube cuff pressures (exceeding 50 cm. of water) when ascending to altitudes that are often traversed by prehospital air medical crews requires frequent monitoring of cuff pressures during EMS flights (Orsborn et al., 2016). Prehospital practitioners must be aware of cuff pressures and take simple measures to monitor and adjust continuously.

An additional argument against the prehospital use of CETTs is the increase in work of breathing associated with the slightly smaller internal diameter of the cuffed tube compared to the uncuffed tube. An in vitro study was performed by Thomas et al. (2018) to determine the amount of increased work of breathing when a CETT is utilized. They found a 10.27% increase in work of breathing, easily off-set by implementing an increase in pressure support via the mechanical ventilator, such that the differences are minimal. Ventilation is better when using a CETT, as ventilator settings can be maximized without compensating for a leaking UETT (Chambers, 2018). In a study of 231 pediatric critical care transport patients 44% of those children with UETTs needed urgent or emergent replacement with a CETT to allow proper

management of ventilation (Pearson et al., 2019). In this study, mortality for the UETT group was slightly higher (10.9% versus 8.9% for CETT). Statistical significance was not adequate to establish a correlation between UETT use and increased mortality; therefore, Pearson et al., (2019) suggested further study.

First Pass as a Marker for Success in Critical Resuscitation

“First pass” or successfully placing an endotracheal tube on the first attempt, is hampered by many factors. Environment, training, equipment, anatomy, and other factors all play a role, with each succeeding attempt increasing the difficulty of the next (Bernhard et al., 2015).

Multiple intubation attempts are associated with increased rate of occurrence of serious morbidities such as hypoxia, aspiration, bradycardia, and cardiac arrest (Bernhard et al., 2015).

In a multicenter study with over 2200 subjects utilizing a national American Heart Association database, Stinson et al. (2017) found that for the pediatric patient in acute respiratory compromise failure to place an endotracheal tube on the first attempt is independently associated with progression to cardiac arrest. According to Dr. Stinson, multiple factors likely play into the progression to cardiac arrest but the retrospective study could not specify which have the most impact. She believes time delays caused by factors such as provider skill (primarily training and experience) consume the scant oxygen reserves of the hypoxic child, leading to respiratory collapse and cardiac failure (personal communication, August 12, 2018).

In the legacy article on the use of CETTs in children, Khine et al. (1997) wrote that the trial-and-error method of sizing an UETT in the pediatric patient leads to multiple intubation procedures with all accompanying risks, reporting that of 251 patients intubated with a cuffed tube, 3 required reintubation to resize the tube (1.2%) while of 237 patients intubated with an uncuffed tube 54 needed reintubation to resize the tube (23%). There is evidence that repeated

laryngoscopies to replace poorly fitting UETTs is more problematic than using CETTs (Herbinger, 2018).

Errors in Prehospital Airway Control

In the last decade adults that suffer cardiac arrest out-of-hospital have experienced improvements in survivability, gains unfortunately not enjoyed by the pediatric population (Hansen et al., 2017). Despite studies suggesting better outcomes with manual mask ventilation and little benefit from prehospital endotracheal intubation in pediatric cardiac arrest patients, endotracheal intubation remains a primary modality for airway control (Dyson et al., 2018; Hansen, Meckler, Lambert et al., 2016; Hansen et al., 2017;). Simons et al., (2017) studied prehospital patients arriving in Helsinki University Hospital's emergency department with radiographic analysis of endotracheal tube position. Less than a third had proper safe tube positioning and twenty percent resulted in clinical issues including left lung hypoinflation with atelectasis further resulting in two incidents of unnecessary thoracotomy. EMS providers typically intubate a child only once every four to five years (Hansen, Loker et al., 2016). The lack of experience by EMS practitioners due to the relative infrequency of endotracheal intubation in children, results in a low prioritization of the procedure for training and skill maintenance. Hansen et al. (2015) wrote that not only are endotracheal tubes infrequently placed by EMS but when they are used they have low success rates, particularly in infants 1 to 12 months of age and links this to low levels of training and to provider distress when caring for children. Emergency physicians demonstrated a 97% to 99% success rate placing endotracheal tubes (in all patients, including adults), while EMS practitioners had a success rate of 81% (Hansen et al., 2015). Air medical crews have rates of success with endotracheal intubation higher than ground EMS crews, but less than ED physicians, indicating that increased training

and exposure to more critically ill patients may increase their success rate (Hansen et al., 2015). Similar rates were reported for paramedics and physicians (Bernhard et al., 2015). In a national survey of prehospital providers 75% of respondents listed lack of experience as their primary concern leading to errors when providing advanced airway interventions in children. Advanced airway management was in the top three safety concerns reported and endotracheal intubation was the leading contributor to prehospital safety events (Hansen, Meckler, O'Brien et al., 2016).

EMS providers misplacing endotracheal tubes continues to be a persistent and prevalent issue in the United States (Hansen, Meckler, Lambert et al., 2016; Miller et al., 2016). Up to 30% of endotracheal intubations performed in an emergency result in inadvertent bronchial intubation (Tessaro et al., 2015). Almost 40% of patients in the pediatric emergency department suffered from incorrectly placed endotracheal tubes and researchers recommend radiographic confirmation immediately after placement (Miller, et al., 2016). Complications from misplaced endotracheal tubes include hypoxemia, increased risk of aspiration, poor ventilation, atelectasis, and pneumothorax (Miller et al., 2016). Confirmation of tube placement by ultrasound has been demonstrated to be effective (Sun et al., 2014; Tessaro et al., 2015).

Capnography, one way to confirm placement, may be essential to reducing the incidence of unrecognized misplaced or displaced endotracheal tubes prehospital according to one researcher (Freeman et al., 2016). Further, capnography also reliably indicates adequate ventilation when using a laryngeal mask airway or bag-mask ventilation as alternatives to intubation (Freeman et al., 2016).

Complications that result in a poor patient outcome also adversely affect the practitioner and result in increased risk of burnout and other adverse effects (Van Gerven et al., 2016).

Special Pediatric Populations

In addition to the critically ill pediatric patient in acute respiratory compromise, (Stinson et al., 2017), two additional populations of note exist. First, the neonate less than three kilograms in body weight may benefit from the use of a CETT. The elliptical shape of the neonatal airway lends itself to improved tracheal seal and decreased tracheal injury when using a high volume, low pressure cuffed tube (Thomas et al., 2017). Second, the pediatric patient with a severe burn injury who requires endotracheal intubation prior to the development of facial and airway edema (which may be rapid and severe) requires a CETT (Dorsey et al., 2010). As edema grows following the first day after a severe burn, increasing ventilation pressures are required. If an UETT is placed it may not be able to deliver adequate tidal volumes and replacing it with a CETT may be impossible, possibly resulting in death.

Evidence-Based Practice

In 2006 the Institute of Medicine (IOM) issued recommendations for the EMS community to develop evidence-based treatment guidelines and in 2008 the first national EMS evidence-based guidelines conference was held (Wright, 2014). Despite an increased awareness in evidence-based practice, the EMS community experienced difficulties implementing evidence-based treatment guidelines (Adelgais, 2018). Of five U.S. states reviewed by Adelgais' study, two attempted implementation of evidence-based treatment guidelines and failed, two failed to attempt at all, and one implemented, but only locally. In the US, prehospital care is based on delegated, not independent, practice. Medical oversight is provided at the state or other governmental level, and practitioners carry out prehospital care under protocol or by direct medical command by local authorized command physicians. This results in clinical practice primarily driven by expert opinion rather than by evidence-based practice (Brown et al., 2014).

In addition, as a public service, resources for most EMS agencies are limited, while implementation of EBP is resource-intensive. It is common to see multiple EMS regions within any given state all with independent and varying protocols (Brown et al., 2014).

Conclusions

A significant gap exists in the literature as there were no studies found that directly addressed the use of cuffed versus uncuffed endotracheal tubes in the pediatric EMS patient. Endotracheal intubation with CETTs in the pediatric patient has been limited in use for over a century based on a study performed in 1897. While progress is being made, the EMS community has not played a significant part in that progress. Children that are intubated prehospital should have a correctly sized cuffed tube placed in one attempt to minimize the incidence of mortality (Bernhard et al, 2015; Stinson et al., 2017). CETTs can increase the accuracy of end-tidal CO₂ monitoring, thus reducing tube placement errors, and can facilitate the effectiveness of ventilation. Current CETTs have incorporated high volume, low pressure cuffs that are safer than their predecessors. UETTs have limitations in the critically ill patient in respiratory failure and further research is required to determine the validity of the use of CETTs in children by prehospital practitioners. Therefore, this project focuses on an evidence-based program evaluation to determine the potential factors leading to the continued prehospital use of uncuffed endotracheal tubes in children.

Chapter 3

Methods

Project Design

This quality improvement project utilized a mixed method design to evaluate current practice. It consisted of two components: First, retrospective quantitative data was collected using patient records found in the hospital-based electronic medical record (EPIC) at N/AIDHC. The primary goal of this retrospective data phase was to establish the frequency that prehospital endotracheal intubation occurs and if the prehospital providers had employed cuffed or uncuffed tubes. Second, a non-experimental mixed-method phase was conducted to examine various environmental factors surrounding the continued prehospital use of UETTs.

Setting

This project was conducted at N/AIDHC, a full-service children's hospital, and level one American College of Surgeons-verified pediatric trauma center. It is the closest geographic pediatric specialty hospital location, and one of two level-one pediatric trauma centers, accessible for EMS providers in Delaware, northeastern Maryland, Southeastern Pennsylvania, and Southern New Jersey. N/AIDHC is located in the city of Wilmington, DE. Wilmington has a population of 70,635 in 2010, 23.2% under 18 years and 6.9% under age 5 years. Eighty-seven percent of Wilmington residents have a high school diploma, 28.3% a bachelor's degree or higher. (US Census Bureau, 2019).

The clinical site visits were conducted in Delaware County, Pennsylvania, Chester County, Pennsylvania, Philadelphia, Pennsylvania, and Sussex County Delaware utilizing professional prehospital EMS providers.

Philadelphia County, the most populous of sixty-seven counties in Pennsylvania, is located in the southeastern corner of the Commonwealth and shares a border with the state of New Jersey. 2010 census data showed a population of 1,584,138 citizens. Eighty-three percent of Philadelphia County citizens over the age of 25 years have a high school diploma, with 28.6% holding a bachelor's degree or higher. Pediatric citizens, those under age 18 years, make up 21.7% of the population, 6.6% are under the age of 5 years. Of all citizens under the age of 65 years, 8.2% have no health insurance (US Census Bureau, 2019).

Delaware County is also located in the southeastern corner of the Commonwealth and shares a border with Philadelphia County and the State of Delaware. 2010 census data showed a population of 564,751 citizens. Ninety-two percent of Delaware County citizens over the age of 25 years have a high school diploma, with 38.3% holding a bachelor's degree or higher. Pediatric citizens, under age 18 years, make up 21.9% of the population, 5.9% are under the age of 5 years. Of all citizens under the age of 65 years, 5.6% have no health insurance (US Census Bureau, 2019).

Chester County, again located in the southeastern corner of the Commonwealth, shares a border with the State of Delaware. 2010 census data showed a population of 522,046 citizens. Ninety-three percent of Chester County citizens over the age of 25 years have a high school diploma, with 51.8% holding a bachelor's degree or higher. Pediatric citizens, under age 18 years, make up 22.6% of the population, 5.5% are under the age of 5 years. Of all citizens under the age of 65 years, 6.3% have no health insurance (US Census Bureau, 2019).

Sussex County, Delaware is the southernmost of three counties in the state, and has a population of 229,286. The population with at least a high school diploma is 87.7%, with 26.5% of those over 25 years of age holding at least a bachelor's degree. Pediatric citizens, under age

18 years, make up 18.6% of the population, 5.0% are under the age of 5 years. Of all citizens under the age of 65 years, 7.2% have no health insurance (US Census Bureau, 2019).

Clinical Sites

JeffSTAT is a medical transport provider operated by Thomas Jefferson University Hospital, part of the Jefferson Health System and based in Philadelphia. In addition to air and ground ambulance transport among Jefferson-affiliated hospitals, three JeffSTAT air-medical helicopters also respond to 911/EMS emergency scenes. JeffSTAT helicopters have a medical crew that consists of one registered nurse and one EMT-paramedic. JeffSTAT is certified as a transport service by the Commission on Accreditation of Medical Transport Systems (CAMTS). As an accredited service, JeffSTAT possessed several attributes that made it an ideal subject site for this project. First, CAMTS accreditation mandates that they engage in quality improvement and continuing education activities and that served to encourage participation in this project. Second, JeffSTAT has an academic relationship with N/AIDHC through Thomas Jefferson University. Some disadvantages to using JeffSTAT as a subject site included the need to compete for finite time and resource availability from administrative staff, compounded by recent administrative turnover that included the program director and the education coordinator. For this project, JeffSTAT represents one of two prehospital services that have implemented the use of cuffed endotracheal tubes in pediatric patients.

Southern Chester County Emergency Medical Services (SCCEMS) has been in operation in southwestern Chester County, Pennsylvania since 1983, operating as part of Jennersville Hospital. SCCEMS responds to an average of 2,800 calls for 911 assistance annually. SCCEMS employees 8 full-time, and 9 part-time certified paramedics (SCCEMS, 2019). SCCEMS is an ideal subject site for this project as they are the sole provider for a significant portion of Chester

County and treat and transport ill and injured children directly to the emergency department at N/AIDHC. Potential disadvantages to using SCCEMS as a subject site is that they are not CAMTS certified and not directly affiliated with N/AIDHC or a university.

Crozer Emergency Medical Services (CEMS) is located in Delaware County, Pennsylvania and responds to an average of 21,000 emergency requests for assistance annually, covering a significant part of the county. Crozer-Chester Medical Center, Springfield Hospital, Taylor Hospital, and Delaware County Memorial Hospital are part of the CEMS system. CEMS is an ideal subject site for this project as they are the sole 911 emergency provider for a significant portion of Delaware County and treat and transport ill and injured children directly to the emergency department at N/AIDHC. They also have a robust management system, were quick to respond to requests and were thorough in their participation. Potential disadvantages to using CEMS as a subject site is that they are not CAMTS certified and are not directly affiliated with N/AIDHC or a university (Crozer Keystone, 2018).

Riddle Memorial Hospital Paramedics are part of the Main Line Health system. They have been in continuous service since 1983 and provide 911 emergency and critical care transport services with an average run volume of 12,000 per year. They are not associated with N/AIDHC but much of their coverage area is geographically close and they transport patients directly when indicated. They are not a certified service and have no university affiliation.

Brandywine Hospital EMS/Medic 93 is located in Coatesville, Chester County, Pennsylvania. Medic 93 is a suitable site for participation because they refer pediatric patients to N/AIDHC either directly or via an air medical service. A potential disadvantage to including Medic 93 is that they are not affiliated with N/AIDHC or a teaching institution.

Sussex County Emergency Medical Services (SCEMS) is located in Sussex County, Delaware. SCEMS operates 10 paramedic response stations throughout the county responding to over 26,000 calls per year (SCEMS, 2018). SCEMS is accredited by the Commission on Accreditation of Ambulance Services. One of three county-run EMS operations in Delaware, SCEMS is an ideal site for participation as they are active in the care of children in the state, and have been exclusively utilizing cuffed endotracheal tubes in children prehospital for over 5 years. A disadvantage to utilizing SCEMS in the project is that although they refer directly to N/AIDHC they are distant geographically, critically ill or injured pediatric patients often go first to a Sussex County facility and then are transferred to N/AIDHC by critical care transport team, or by helicopter, making data collection more difficult.

Sampling

For the retrospective data phase, subjects were selected by purposive sampling and consisted of patients transported by 911/EMS to the emergency department at N/AIDHC in Wilmington, Delaware. The primary source of access to the patient records was the admission database maintained by the pediatric intensive care unit (PICU) at N/AIDHC, using Virtual Patient Systems version 2, and were supplied by the data analyst employed by the PICU. The following search terms were used: Age, gender, race, age at ICU admission, hospital admit date, ICU admit date, procedure name, present on admission, cuffed, patient origin, referring hospital, chief complaint (Table 3). Some patients who arrived to N/AIDHC were not admitted to PICU (primarily those that died in the emergency department) so additional records were located using the database maintained by the N/AIDHC Trauma Program, utilizing Digital Innovations Collector, version 5 using the key term “Prehospital procedures” and the following search terms:

Injury date, injury time, admit date, injury mechanism, tube type, injury cause, and mode of arrival.

Inclusion criteria consisted of patients aged 14 years or under who had an endotracheal tube placed in the field, in the setting of an emergency (not at a referring full-service hospital) by an employee of an EMS service that routinely transports patients to N/AIDHC. The endotracheal tube may be placed either by direct medical command or by protocol. Exclusion criteria were neonates under full gestational age born precipitously in the field. The date range for inclusion was January 1, 2017 through December 31, 2019.

For the combined quantitative survey and qualitative interview phase, the subject sample size for each service is one upper level administrator. Demographic data collected on the interview subjects included name, provider certification/licensure level, approximate length of experience in years, and an email address. Monetary compensation to the survey subjects was not provided by the project. Subjects were provided contact information via business cards distributed at the time of the interview.

Instruments

An untested, project-specific quantitative survey consisting of an 11-question Likert scale was created to examine the experiences and preferences of the subject related to endotracheal intubation in pediatric patients. To explore the willingness for change on the part of the survey participants, a validated 17-question Likert scale tool on individual dispositional resistance to change, the Resistance to Change (RTC) scale (Oreg, 2003), was utilized. Oreg (2003) evaluated resistance to change across four dimensions: Routine seeking, emotional reaction, short-term focus, and cognitive rigidity. Hypothesizing that failure to disinvest in the use of UETTs may be a result of resistance to change, the RTC scale was used here to explore if the prehospital clinical

providers employed a dispositional resistance to change. Permission for its use was granted by Oreg (Appendix A). The qualitative interview survey tool that was designed for this project was based on application of Donabedian's Model of Healthcare Quality and explored the structural and process components of the EMS worksite itself. The goal of the interview was to explore factors that include the work environment, staff training levels, quality assurance procedures, type of equipment available to the clinical crews, the opinions of the administrators and the medical director, and the autonomy of the clinical providers to make decisions on which type of endotracheal tube to use in the moment. Of special interest were the thoughts expressed by subjects as to why their EMS system was slow to adopt change.

Data Analysis

Retrospective data was migrated from the PICU and Trauma databases into Microsoft Excel and each record was given a unique identifier number to ensure de-identification and block association with protected information. SPSS-compatible headings and formatting were used for later transfer for univariate and bivariate analysis (Appendix B). Due to the small sample size, multi-variate analysis was not utilized. The frequency of use of UETTs, particularly those used recently, was the primary interest.

The quantitative part of the survey/interview began with an 11 item survey designed to explore the experience of the subject. Initially conceived as a "yes" or "no" response tool, affirmative responses were expanded to include "yes always", "yes frequently", and "yes rarely" to allow for the varied experiences with CETT's among some EMS programs. None were reverse coded. There were no neutral responses (Appendix C). For the second quantitative survey, the RTC scale was used as published (Oreg, 2003), with 17 questions in a Likert-scale format (Appendix D). Two items (4 and 14) were reverse coded. There were no

neutral responses, with “inclined to disagree” and “inclined to agree” forcing a response from those with no strong tendency between strongly agreeing and strongly disagreeing. The total RTC score is the mean of the 17 items. Subscale scores were calculated on routine seeking via items 1-5, emotional reaction via items 6-9, short-term focus via items 10-13, and cognitive rigidity via items 14-17. RTC scale score results range from 1 (low dispositional resistance to change), to 6 (high dispositional resistance to change).

For the interactive interview, each response was recorded in writing, by the PI exclusively. The interview consisted of a 10-page outline under the headings, Structure, Process, and Outcomes. Subheadings included Work Environment and Equipment, Quality Improvement, and Continuing Education, followed by a free response section (Appendix E). Verbatim transcription was used to facilitate content analysis. When all interviews were complete, concepts were coded then analyzed. A theoretical thematic analysis was conducted using open coding, including data relevant to Donabedian’s Model (Braun & Clarke, 2012; Maguire & Delahunt, 2017). Closed-ended questions in the interview were analyzed quantitatively.

Rigor

Subjects for the quantitative portion were selected from a database maintained by a trained registered nurse data analyst. Accuracy of the data input is assured by frequent review and is secured by the Nemours Health System’s information technology department. An attempt was made prior to each interview to not discuss the full nature of the project to avoid response bias, particularly on the quantitative surveys.

There were no validated collection tools available for the experiences/preferences survey and the qualitative interview. Trustworthiness of the qualitative data was ensured by basing the

documents on a thorough and extensive review of the literature, on adaptive application of Donabedian's model to the structure and content of the collection tools, and on the extensive experience of the PI. Verbatim responses were reported. An independent coder with qualitative research experience as a registered nurse reviewed the results and identified major themes. The independent coder was obtained via the ACCEL program at Nemours and was able to participate freely in data review. Contrasting research methods were used to compare the reported and actual behaviors of the participants and prolonged engagement was utilized to enhance understanding the nuances of the data collection (Amin et al., 2020).

The RTC is a published validated tool that has been in use for over 15 years. The RTC was validated using a series of 7 studies. Reliability was found to be 0.82 overall, with alphas of 0.68 for routine seeking, 0.78 for emotional reaction, 0.76 for short term thinking, and 0.76 for cognitive rigidity (Oreg, 2003). The RTC is a valid and effective tool for determining the occupational interests and performance of individuals noting a correlation of 0.91 between RTC scores tested on the same subject 30 days apart (Oreg, et al., 2009).

Ethical Considerations

This project was reviewed by the Nemours institutional review board (IRB) and determined to be quality improvement and therefore exempt from further IRB review. Subsequently the project was reviewed by the West Chester University IRB and approved without need for continuing review (Appendix F).

Confidentiality

N/AIDHC information technology has multiple counter measures in place to avoid the loss or hacking of data. Patient specific data was not necessary to select records and was not

needed for reporting. All records were de-identified. All access to electronic medical record information was password protected.

Budget and Timeline

The budget for the project focused primarily on costs for travel and producing interview materials (Table 1). There were no unexpected expenses and costs decreased after moving the project online. Compensation was not provided to the participants. The timeline (Table 2) was dictated by the West Chester University class schedule.

Changes in Methodology

At the outset of the project it was determined that all interviews would be conducted in person. However, it became apparent that some agencies would be unable to participate due to time constraints and distance. After completing three interviews, face-to-face meetings were no longer possible due to social distancing from the COVID-19 pandemic. The process was changed to email the self-survey sections after receipt of signed copies of the approval letter and consent form, and then interviews were conducted live online, via FaceTime. The interviews and surveys were conducted solely by the primary investigator (PI), were limited to one hour to respect the busy work schedule of the subject, and were in a semi-structured format. Both closed and open-ended questions were included. Notes were taken by the author by hand on a prepared form as noted. No recording devices were used.

Chapter 4

Results

This chapter presents the results of the data analysis including results of the quantitative retrospective data, the quantitative survey, and the qualitative interview.

Response Rate

Seven 911/EMS agencies that make direct patient referrals from the field to N/AIDHC were contacted via phone and email. Six agencies participated in the survey and interview process (85%). From those that participated, no surveys were incomplete, and none declined after starting the interview.

Demographics

Non-responders differed from responders only in gender. All respondents were male, with a mean of 27.6 years of experience in EMS (range = 13 years to 40 years), and a mean age of 43 years (range = 37 to 58 years of age). Five respondents were associated with a hospital-based 911/EMS system, one with a county government-run system. The non-responding agency was affiliated with a county government-run system. JeffSTAT was the only respondent that provided 911/EMS response by helicopter.

Findings

Retrospective Clinical Data

Patient data was collected during a three-year period, 2017 through 2019 inclusive. Forty-two subjects arrived with an endotracheal tube inserted outside of N/AIDHC. Of 2744 trauma patients, 1895 arrived via 911/EMS, 138 of those by helicopter. Prehospital care procedures were performed on 515 patients, with 15 (2.91%) of those procedures identified as prehospital endotracheal intubation. Filtering the two databases for tubes placed by EMS

providers only, 29 records were found. Seven of the 29 were over 14 years of age. Age 14 years was selected as the upper limit as patients 15 years and older will not likely be intubated with an endotracheal tube small enough to be an uncuffed type, based on the formula for estimating pediatric cuffed tube size (Khine, 1997). None of the seven subjects eliminated were in fact intubated with a UETT. An additional two subjects received alternative airways placed by EMS rather than endotracheal tubes (a King airway, and an oropharyngeal airway). The resulting sample size (N) was 20.

Preliminary analysis of the quantitative and retrospective data showed that UETTs were utilized in all participating agencies during the testing period, with the exception of SCEMS. JeffSTAT began the exclusive use of CETTs in January of 2020. All subjects retained an endotracheal tube that had been placed by an EMS provider when they arrived at N/AIDHC. The median age of subjects at admission was 4.0 years (M = 5.25 years, SD = 4.4 years, range = 0.1 years to 14.8 years). Gender was equally divided between male and female. Fourteen (70%) subjects came directly from the scene of their accident or illness, the remainder were taken to local hospitals and then transferred to N/AIDHC. Twelve (60%) survived to PICU admission, the remainder expired in the emergency department. Three subjects did not survive to discharge from PICU, resulting in a total mortality rate of 55%. The chief complaint of the subjects varied, the most common being cardiac arrest and drowning (Table 3). Complications included emergent replacement of two UETTs due to excessive leak and one unrecognized esophageal intubation. Twelve (60%) arrived with a UETT in place. The younger the subject the more likely they were to have a UETT (Table 4). The correlation between the subjects age and the use of UETTs lacked statistical significance ($r^2 = 0.289$, $p = 0.16$). However, effect size for age

and the use of UETTs was large (Cohen's $d = 1.18$). Four subjects under age 8 years had UETT's placed that were undersized, two were too small by a full tube size.

Experiences and Preferences Survey

All respondents indicated that they perform endotracheal intubation as part of their job duties. Five respondents indicated that both CETTs and UETTs are available at their respective sites. Only one responded that only CETT's are available for use with the others indicating varied availability for CETT's and UETT's. All stated they have used both cuffed and uncuffed tubes in pediatric patients at some point in their careers. Only the two services that have implemented the exclusive use of CETT's indicated a strong preference for using CETT's and for not using UETT's in children under 8 years of age. All respondents believed there is an increased risk of airway injury when using a CETT in a patient under 8 years of age, but also believe the risk is worth it. For the question "A cuffed endotracheal tube provides benefits that an uncuffed tube does not" one responded "No, never".

Resistance to Change Results

The RTC scale survey results did not indicate a high level of dispositional resistance to change among the EMS administrators but it did indicate some variability between the programs that had implemented CETTs and those that had not. The cohort RTC score was 2.92 (range = 1.94 to 3.47). Cohort RTC sub-scores were: routine seeking, 2.64; emotional reaction, 3.29; short term focus, 2.67; and cognitive rigidity, 3.29. The two programs that have successfully made the change to the exclusive use of CETTs (JeffSTAT = 1.9 and SCEMS = 2.5) had RTC scores significantly below those that did not (3.0 to 3.47).

Interview Results

As a result of the thematic analysis, four key themes emerged:

1. Education.
2. Implementation of evidence-based practice.
3. Patient safety.
4. Facilitating change.

Education.

The lack of adequate education was a shared experience of the cohort. Initial training as a prehospital provider and continuing education and skill maintenance throughout their careers were noted to be insufficient. None of the services had provided training relevant to the use of CETTs in children. Only one service of the six provided endotracheal intubation skill maintenance via live practice, while the others utilized low-fidelity simulation. The following quotes indicate the current situation:

- “Medics typically get live training in class then only SIM thereafter.”
- “If you can’t practice should you be doing it?”
- “PALS glosses over the subject.”
- “There would have to be a very large education component (to institute a change to exclusive use of cuffed tubes).”

Implementation of Evidence-Based Practice.

The cohort indicated that there was a lot of work to be done on the use of evidence-based practice in the 911/EMS community and that historically, it has not been a strong component of practice decisions. Some responses indicated a defeatist attitude while others expressed optimism that awareness of evidence-base principles results in improvement:

- “Old school attitudes, old guys are stuck in their ways, all we’ve ever known attitude.”
- “Issues aren’t settled, the science isn’t good enough yet.”

- “Data that is old, reluctance to change.”
- “We use whatever the hospital provides us.”
- “You hand me something I’m gonna use it.”
- “I’m about ventilation and oxygenation, when we get to the hospital they can worry about respiration.”
- “They haven’t done their research, they haven’t read the literature.”
- “Both (CETTs and UETTs) are just another tool in the tool box.”
- “My hunch is we are going away from tubing.”

Patient Safety.

The overriding concern for the use of CETTs in children is their safety and this was expressed by the cohort:

- “Should we be tubing kids?”
- “Liability to practice is a huge concern.”
- “Tube is secured better with a cuff, movement is decreased. Less leaks.”
- “Airway protection, aspiration protection (when using a CETT).”
- “Put a tube in and nobody checks the cuff pressure and does damage.”
- “We require cuff pressure be monitored.”

Facilitating Change.

The benefit of expert consultation and the application of current research as means to facilitate change and improve patient outcomes were indicated by the following:

- “Influence of experts has been the key factor for change at our program.”
- “They haven’t done their research, they haven’t read the literature.”

- “More-educated programs would do it (make the switch to exclusive use of cuffed tubes).”

Project Evaluation

During the planning phase of the project, preliminary discussions between the PI and administrators at JeffSTAT unexpectedly led to the summary introduction of the exclusive use of CETT’s in all pediatric sizes to their care processes. Ultimately, JeffSTAT participated fully in this project.

There is sufficient evidence-based literature on the subject available to educate and guide practice for the general hospital-based pediatric practitioner, but extremely little available specifically for the prehospital provider. The intent at the formation of the project was to conduct an educational intervention and later look for changes in policy or procedure at the subject site with the goal of having the prehospital clinicians initiate the exclusive use of CETTs. Despite offering continuing education credit without charge, no clinicians agreed to attend. Both administrators and clinicians revealed they prefer to complete mandatory continuing education hours online or through other passive means such as state and mandatory work-related education. Because their recertification cycle is two years, at least half of the clinicians already had their mandatory education hours and would not be interested in participating until 2021. The project focus was then changed to a program evaluation format, eliminating the educational intervention and interacting only with upper level managers or administrators at each 911/EMS site. The educational opportunity was offered to each site for future use after data collection and was followed up by the critical care outreach coordinator at N/AIDHC.

Although the change to remote interviewing was forced on the project by uncontrollable circumstances, it was well received and would have been a good choice from the beginning.

Having paper versions of consents and surveys proved to be a constraint when attempting to move the project online and remain compliant with IRB approvals as written. It would have been wise to include an option for online participation in the IRB application. There was no perceptible difference in the quality or length of conversation between the in-person and the remote interviews.

Positives included access to two detailed databases to locate subjects for the quantitative phase, access to clinical experts such as Dr. Henry Khine the author of the legacy article on CETTs in children, and access to PhD researchers via the Nemours participation in the ACCEL program.

Chapter 5

Discussion

Review

The scientific literature demonstrates clear advantages to the use of CETTs in pediatric patients. Advances in the manufacturing technology of endotracheal tubes and better understanding of the pediatric airway have made CETTs not merely feasible for use in the care of children, but preferred over UETTs. Experts in pediatric critical care recommend the routine use of CETTs in children. Yet, many EMS systems have protocols remaining in place that discourage the use of CETTs, and UETTs continue to be used in the prehospital arena in the highly vulnerable population of critically ill children.

This project intended to determine the factors that inhibit the prehospital use of CETTs and to explore strategies to encourage their routine use. The key findings include the need for expert involvement to facilitate EMS policy change, a systemic lack of focused education and application of evidence-based practice in EMS practice, and a lower level of dispositional resistance to change for the cohort subjects within programs that have implemented the use of CETTs. The outcomes of this project indicate that experts in pediatric critical care must increase involvement in education and outreach, and influence the formation of EMS policy and procedure.

Sample Characteristics

The sample population was small however it was composed of key people that can make decisions that directly affect the care provided at their respective sites. Five of the sites were in Pennsylvania and one in Delaware. There are very different policies in place between the two states, with Delaware specifying the use of CETTs in all three counties (as of January 2020) and

Pennsylvania mandating that all EMS sites carry both cuffed and uncuffed tubes with only UETTs available for infants and small children. Pennsylvania also has some volunteer fire company-based EMS systems that perform paramedic level care while Delaware only allows county-run professional paramedics to perform advanced care. Of the Pennsylvania-based participants only JeffSTAT was affiliated with a major university health system. EMS has traditionally been a male-dominated profession, with paramilitary and fire company backgrounds, so it was not unexpected that none of the participants were female.

Results Discussion

Retrospective Clinical Data Discussion

The mortality rate for EMS endotracheal tube placement in patients was substantial (55%). Prehospital endotracheal intubation is not an elective procedure. The chief complaints for those patients were severe (cardiac arrest and drowning, for example) and demonstrate that endotracheal intubation is performed prehospital in the most ill or injured children, and intended as a life-saving intervention when the risk of performing the procedure is eclipsed by the risk of not performing it. Two patients needed emergent replacement of their endotracheal tubes on arrival at the ED. One had an excessive leak and was replaced to allow effective ventilation and to obtain an accurate end-tidal CO₂ reading. The other was an unrecognized esophageal intubation that was pulseless with no end-tidal CO₂ reading. These two cases illustrate the value of end-tidal CO₂ monitoring for verification of proper tube placement and how difficult verification is in the patient without a pulse. Advanced methods for verification of correct endotracheal tube placement such as ultrasound visualization are available (Tessaro et al., 2015) but are not in use by any of the subject sites.

Seventy percent of the patients came directly to N/AIDHC. It is unknown how many patients went first to another hospital and were admitted or died there. Further study should be performed to look at outcomes of critically ill or injured children who are taken by EMS to the closest hospital versus those taken directly to the pediatric specialty center (N/AIDHC).

The results indicated a large effect between patient age and the use of an UETT. This was true for the very youngest, but surprisingly was more of a factor than expected for all subjects. Of 15 patients with tube size under 6.0, only 3 were with a CETT. While one may expect to find the smallest endotracheal tubes to be uncuffed, and that was demonstrated here (5 of 5 tubes in size 4.0 or smaller were uncuffed), it was also true that the majority of tubes in size 5.0 were uncuffed (4 of 6). All participant sites had CETTs available in size 4.5 and larger. This indicates that the overwhelming choice of the practitioner placing the tube was an UETT, despite a CETT being readily available. This is likely a result of outdated EMS protocols that specify an UETT in patients 8 years of age or younger. Four subjects had tubes placed that were too small (based on an age-calculated internal diameter tube size) and this may also be a result of using an outdated protocol. It was noted that all subject sites stated they utilized state-wide protocols. JeffSTAT was the only Pennsylvania site that had requested and been granted a waiver by the state to use CETTs in all patients (after the retrospective data collection period), effectively creating their own protocol and demonstrating that flexibility exists in the protocol process at the state level.

Survey Discussion

In the experiences and preferences survey, all respondents indicated they had some experience with CETTs but there was a clear variation in the demonstrated knowledge base. One service responded that a CETT provides no benefits compared to an UETT. This site will be

targeted for outreach education. All indicated they had used both CETTs and UETTs in their careers, which is noteworthy as Pennsylvania protocol clearly favors UETTs in children. This may be participation bias or the respondents may have included patients over 8 years of age when formulating their response.

Resistance to Change Survey Discussion

RTC score results did not show a high propensity for resistance to change among the cohort subjects, but neither did it show a low propensity among all participants either. As the role of a leader is to facilitate change, one may anticipate low scores across the board. The dichotomy between scores for the subjects at sites that have implemented CETTs and those that have not were of interest. It could not be determined here, but is worth investigating the role that the environment played on the RTC scores. Do leaders with low RTC gravitate toward progressive programs, or does the environment at progressive programs train leaders to lower their RTC over time?

Education Discussion

Lack of focused continuing education pervades the entire issue of the use of UETTs and was a topic expressed by all subjects. Budgetary constraints and completion for scarce time resources limits the amount of educational opportunities presented and has raised fears that endotracheal intubation should not be done on children prehospital. Further compounding the issue; the typical paramedic experiences limited opportunity to perform endotracheal intubation on a child. This project located only 29 prehospital intubations in pediatric patients in a 36-month period. These conditions may be resulting in reliance on inflexible protocols and deferred interest in effective continuing education and skill maintenance. It is difficult to name a circumstance in the scope of prehospital care more onerous than placing an endotracheal tube in

a child, given the risk of poor outcome and possible legal ramifications ever present. One participant raised concern that initiating the routine use of CETTs would require a massive education commitment. In fact, Nemours offers the training without charge, and paramedics are already trained in the use of both CETTs and UETTs. In addition, no longer stocking UETTs would realize a net cost savings. Continuing education and skill maintenance would be enhanced by investing in high-fidelity simulation training in lieu of practice on live subjects, which was available only to JeffSTAT through their association with Thomas Jefferson University Hospital. The lack of clinician interest in attending the offered educational session was surprising. There is an expectation that the EMS system provides continuing education and training, yet there is also an expectation that the individual clinicians participate in expanding their knowledge and improving their skills for the sake of their patients. This was at a single site and may have been affected by unknown circumstances, however it raised concern.

Evidence-Based Practice Discussion

The cohort recognized that evidence-base practice is important, but not being instituted as effectively as they would like. One of the structural components of this project was examination of the quality assurance program at each site for evidence of data driven processes; utilizing data from their own structured reviews. None of the programs identified an intentional process linking content that was evaluated in their quality improvement efforts and that which was included in continuing education. They appeared to typically rely on their charting software to flag cases for review. None had a specific plan for loop closure related to issues identified by their quality improvement activities, but rather addressed problem resolution on an ad hoc basis.

The two programs that have implemented CETTs expressed that they made the change by researching the latest evidence, being willing to use new data, and rejecting old methods that

lack validation. Both also expressed a belief that those sites that have not made the change have failed to do so based on willful reluctance to change and reliance on old information.

Patient Safety Discussion

The strongest argument to be made for the use of CETTs is increased patient safety. The evidence from the current literature strongly supports their use (De Orange et al., 2017). The cohort recognized the need for safety and effectiveness and could state how CETTs protect from aspiration, facilitate ventilation, and help to secure the endotracheal tube while the patient is being moved during transport. One subject expressed that he did not allow the use of CETTs because of fears that the patient would experience tracheal injury from an unrecognized overinflated cuff. This complication has been thoroughly debunked by the literature and is easily remedied with simple inexpensive monitoring devices (Orsborn et al., 2016).

Facilitating Change Discussion

The programs that were successful in implementing CETTs illustrated the path to change very well. Each sought out the input of pediatric critical care experts, evaluated that input via the current literature, and then acted on it. For JeffSTAT, contact with this author to discuss the possibility of involvement in this project was enough to pique their interest. There was a concern that if they were not providing the best care possible, they did not want to wait months for the study to progress, while additional patients were treated by their crews. They consulted with their medical command physicians, contacted critical care physicians at N/AIDHC for advice, and sought the input of neonatal experts at Thomas Jefferson Hospital. They then made the decision to move forward and requested a waiver from the state. According to Dr. Ross McGargle, State Medical Director for EMS in Delaware, SCEMS followed a similar path 5 years

ago, and utilized expert input from N/AIDHC physicians (personal communication, January 11, 2020).

Implications

Practice

It has been argued throughout this manuscript that CETTs should be in routine use for prehospital care. The structure of care at the EMS site will need to be altered to incorporate the use of CETTs and eliminate UETTs, provide training, and focus quality assurance efforts to support the change.

Education

Paramedics already know how to use CETTs. Education would be beneficial for pediatric principles and for the need to verify cuff pressures. A major effect of education would be to dispel the decades of misinformation surrounding CETTs in children.

Policy

Care processes will require alteration to include new written policies and protocols based on current evidence-based principles with the overarching goal of patient safety. The most difficult change will be policy as written by the state. A strategy of waivers submitted site by site could be effective in changing state policy over time, as could having a large metropolitan EMS service, such as Philadelphia or Pittsburgh, make the change.

Research

When EMS delivers a patient with an UETT to the children's hospital it falls on the intensive care physicians to manage that patient. It was suggested in chapter 1 that managing a child with a poorly functioning UETT in the PICU may increase the need for sedation and

possibly extend the child's stay in the hospital. Verifying this would be a valuable study to perform and the findings could potentially further support the prehospital use of CETTs.

Extending this project to a larger cohort, including New Jersey and Maryland EMS services would be of value to establish statistical significance and generalizability. Investigating whether there is a correlation between the prehospital use of UETTs and patient mortality in a large multi-center study would be beneficial. There was no literature available on the process of implementation of CETTs at the state level. Surveying and investigating the process of policy approval in each state in the U.S. would be beneficial in order to focus change efforts.

Limitations

Bias

Bias may have been present in this project due to the small sample size, the lack of gender inclusivity, and the preconception on the part of the PI that UETTs should be eliminated. Care was taken in the creation of the qualitative data collection tools to avoid bias and the tools were evaluated by an independent researcher who suggested edits to reduce bias.

Generalizability

With the small sample size and the limitation of using only services that bring patients to N/AIDHC, it may be difficult to establish external validity for the findings for application to varied EMS systems in other parts of the United States. However, the evidence-based principles on which the project was constructed still stand and while the method of implementation may vary by geography, the central message remains intact.

Conclusion

The prehospital use of UETTs is a problem that affects the care of a highly vulnerable patient population. The continued prehospital use of UETTs is based on tradition, decades of weak data, and a lack of resolve to effect change. The choice to utilize an UETT in prehospital care may have detrimental effects on the patient before arriving at the hospital, and after admission. Clinicians may desire change to take place but without affecting policy at the highest level, the EMS system will become reduced to a patchwork of varied policy. The solution is for pediatric critical care experts to become involved, provide training, guidance, and become involved in political advocacy for the use of CETTs. Critical care nurses are as well suited for this endeavor as physicians, and certified prehospital providers should be involved as well.

This project has demonstrated that expert intervention was the primary factor for motivating clinical change, that EMS administrators do not have an inherent aversion to change, and that application of evidence-based principles can help the prehospital clinician, who may be starving for education, to provide the best care possible to their intubated pediatric patients.

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Table 1*Project Budget*

Activity	Cost Per Unit	Frequency	Cost
IT/Computer	Provided by Nemours	6	\$0
Travel	\$12	3	\$36.00
Printing	\$6	1	\$6.00
Paper	\$8	1	\$8.00
Stationery	\$2	6	\$12.00
Postage	\$0.55	6	\$3.30
Total			\$65.30

Table 2*Project Timeline*

Date	Planning	Pre-implementation	Implementation	Evaluation
10/10/19	Meet with mentor candidates	Dr. Diaz, Dr. Lawless, Dr. Fishlock	Diaz deferred until November; Fishlock not committed.	Dr. Lawless accepted
10/11/19	WCU IRB app	Process via D2L/Dr. Monturo/WCU IRB Office.	Drafts completed and reviewed	Final draft in 10/29/19 Approved 1/9/20 & 2/10/20
10/18/19	Nemours IRB application.		Turned in 10/21/19	Approved 10/24/19
10/19/19	Contact JeffSTAT	Spoke with clin director and nurse educator and they are interested. Asked to determine need for legal agreement (JS and Nemours in same academic system).		
10/19/19	Contact NCCEMS	Interest expressed at meeting, awaiting return call. May go to medical director if no response by 10/31		No response. No participation.

11/1/19	Prepare survey document	Paper and Redcap versions		
11/2/19	Prepare PowerPoint	Revise existing critical care transport/ED version.		
11/5/19	Arrange meetings with Subject sites.	Ascertain data availability.		
11/6/19	Contact PICU rep for critical care data.	Will not include deaths in the ED.		Obtained full list.
11/7/19	Contact Outreach Coordinator for assistance with JeffSTAT visit.	May provide funding for food or travel. Discuss options for other site visits in the event NCC and JS drop out.	Not implemented.	No compensation for participants.
11/7/19	Create final working version of Excel sheet.	Existing sheet needs formulas and aesthetic changes. Follow SPSS conventions for later transfer.	Merged data.	Moved into SPSS at completion.
11/20/19	Meet with Dr. Diaz to discuss implementation with NCCEMS.	Brief meeting already occurred to discuss possible need for advisory committee physician liaison intervention.		NCCEMS not participating.
12/21/19	Obtain approval for RTC from Dr. Oreg.	Survey base ETT knowledge and attitude toward change. Base evaluation on Donabedian.	Emailed request.	Obtained.
02/15/20	Meet with CCMC	Conduct interview		In person
2/24/20	Meet with SCCEMS	Conduct interview		In person
3/1/20	Meet with Riddle	Conduct interview		In person
3/8/20	Meet with Medic 93	Conduct interview		Via FaceTime
3/11/20	Meet with SCEMS	Conduct interview		Via FaceTime
3/15/20	Meet with JeffSTAT	Conduct interview		Via FaceTime
2/15/19	Review data from EPIC.	Any uncuffed tubes still in use in last 3 years?		20 subjects included.
1/2/20-4/20/20	Write chapters 1-5.			Per class schedule.
4/15/20	Full project completed and submitted for graduation deadline.			Per class schedule.
4/22/20	Create and present ppt to committee.		COVID pandemic restrictions in effect.	Via Zoom meeting.

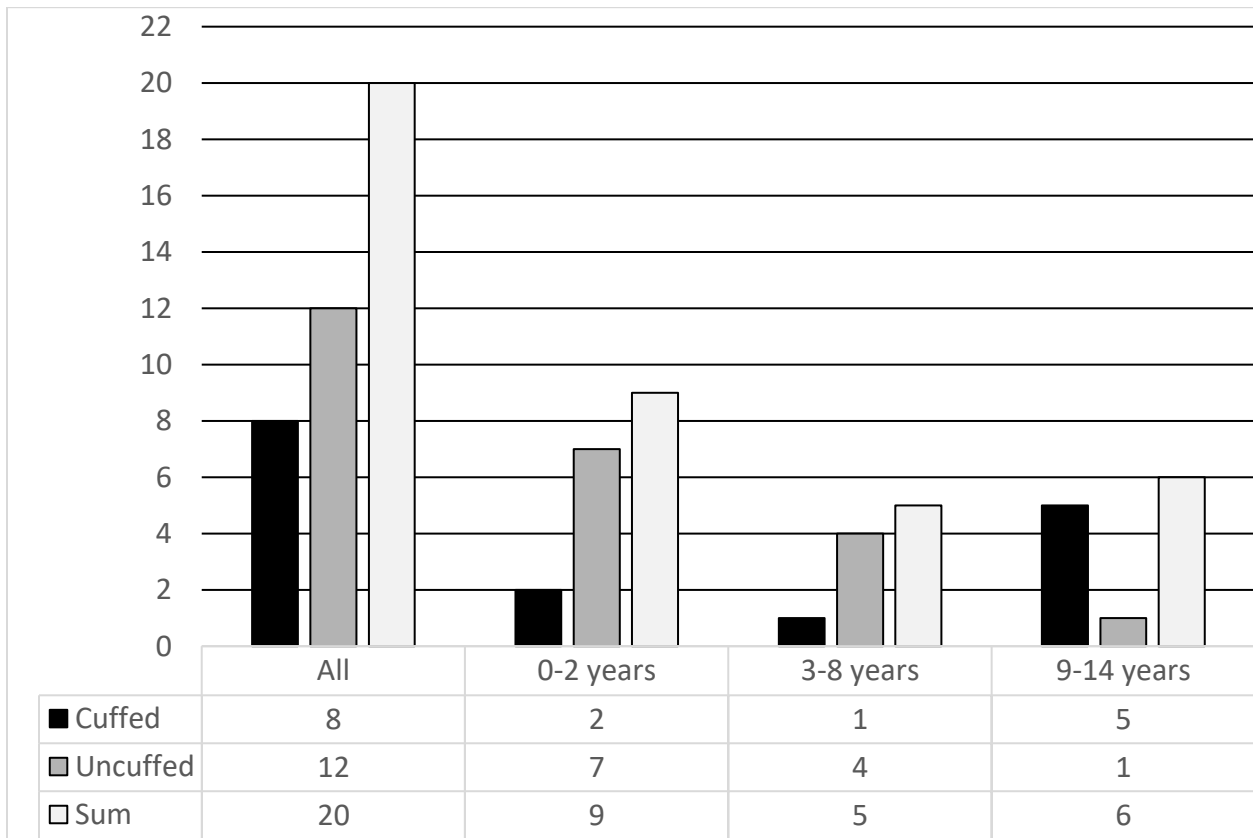
Table 3*Mechanism of Injury for Patients Intubated Prehospital*

Mechanism	Frequency	Percent	Valid Percent	Cumulative Percent
Cardiac arrest	4	20.0	20.0	20.0
Cerebral aneurysm	1	5.0	5.0	25.0
Child Abuse	1	5.0	5.0	30.0
Choking on food	1	5.0	5.0	35.0
Co-sleeping	1	5.0	5.0	40.0
Drowning	4	20.0	20.0	60.0
Fell off bike	1	5.0	5.0	65.0
GSW	1	5.0	5.0	70.0
Hit by a car	1	5.0	5.0	75.0
MVC	2	10.0	10.0	85.0
Possible poisoning	1	5.0	5.0	90.0
Suicide attempt	1	5.0	5.0	95.0
TBI	1	5.0	5.0	100.0
Total	20	100.0	100.0	

Note: GSW = gunshot wound; MVC = motor vehicle collision; TBI = traumatic brain injury.

Table 4

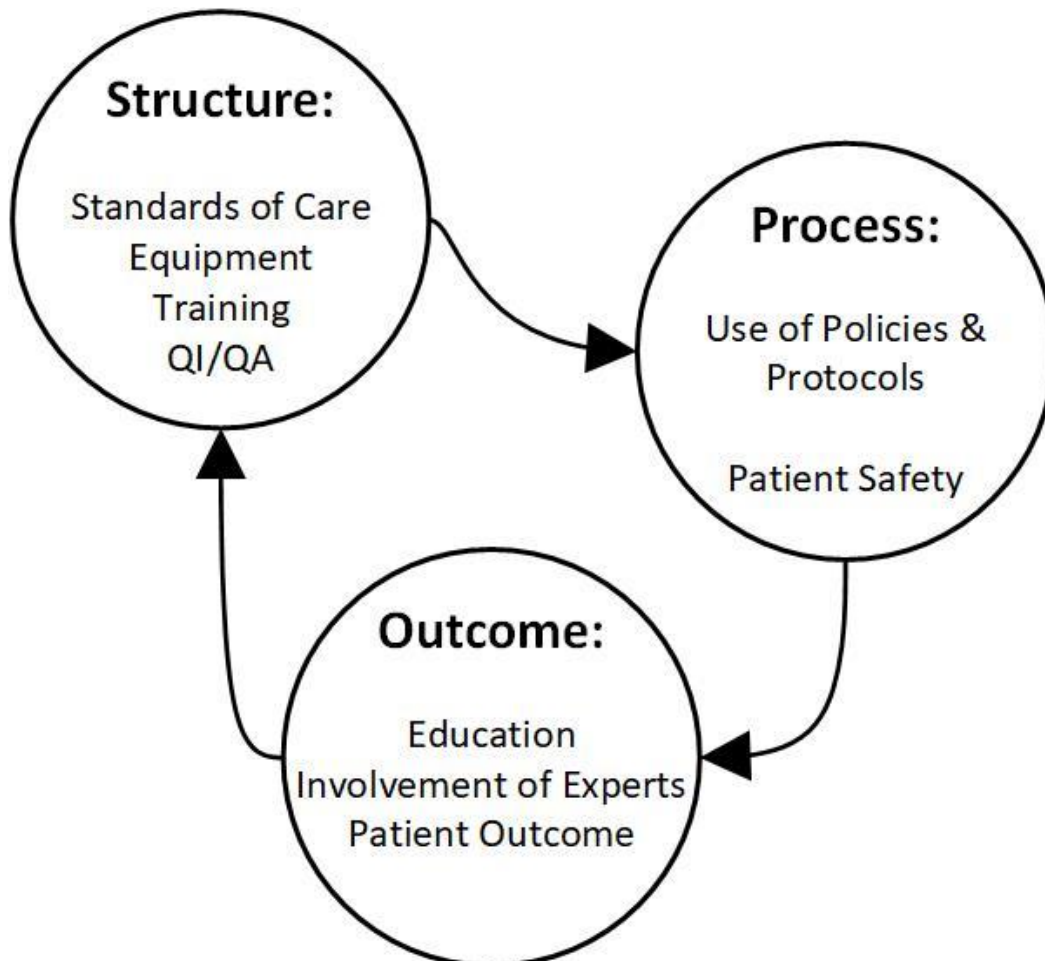
Frequency of Use of Uncuffed Endotracheal Tubes by Age Group (N = 20)



Note: Includes patients arriving at Nemours/Alfred I Dupont Hospital for Children’s emergency department via emergency medical services from January 1, 2017 through December 31, 2019.

Figure 1

Donabedian's Model of Healthcare Quality Adapted to the Implementation of Cuffed Endotracheal Tubes at a Prehospital Service.



Note: Created by the author and adapted from Donabedian's Model of Healthcare Quality (Donabedian, 1966/2005).

Appendix A

Shaul Oreg's Email Allowing use of the RTC

Pearson, Thomas

From: Shaul Oreg <shaul.oreg@mail.huji.ac.il>

Sent: Monday, December 9, 2019 1:46 PM
Pearson, Thomas

Subject: Re: Resistance to change scale

**This is an External Email - Please DO NOT open attachments or click links from unknown senders or unexpected email.

If you wish to use the scale for research

If you wish to use the scale for research purposes, please feel free to do so.

Shaul

Sent from my mobile phone. Please excuse brevity and typos.

On 9 Dec 2019, at 18:47, Pearson, Thomas <Thomas.Pearson@nemours.org> wrote:

Mr. Oreg,

I am inquiring about the possibility of utilizing your resistance to change scale, from the Journal of Applied Psychology (2003) article in a doctor or nursing practice project I am commencing at West Chester University in Pennsylvania, USA. I am interested in investigating the resistance to change among prehospital 911/emergency medical services providers, and would use the scale as part of a survey during an educational session.

Would that be possible and how would I go about getting permissions?

Thomas Pearson, MSN, RN, CFRN, PHRN, NREMT
Trauma Research and Performance Improvement Coordinator Nemours/Alfred I. duPont
Hospital for Children
1600 Rockland Road
Wilmington, DE
ARB-168
Cell: 302.290.8316 Office: 302.651.

Appendix B

Quantitative Data Collection Tool

Admit_Date	Tube_Placed_by	Referral_Location	Transport_Agency	Tube_Size	Cuffed	Admit_Location	Deceased	Chief_Complaint	Notes
7/25/2017 4:39	EMS intubated	XYZ Hospital	EMS	3.5	n	ED	y	co sleeping	Tube rep

Appendix C
Experience and Preferences Survey

Clinician Survey

Name _____

Cert/License type: _____ Years as a Provider: _____

Email Address: _____

		Yes, Always	Yes, Frequently	Yes, Rarely	No, never
1	Performing endotracheal intubation is part of my duties at my practice site.	1	2	3	4
2	Cuffed endotracheal tubes are available in all pediatric sizes at my practice site.	1	2	3	4
3	Uncuffed endotracheal tubes are available in all pediatric sizes at my practice site.	1	2	3	4
4	I have used uncuffed endotracheal tubes for patients under 8 years of age.	1	2	3	4
5	I have used cuffed endotracheal tubes for patients under 8 years of age.	1	2	3	4
6	I prefer to use uncuffed endotracheal tubes in patients under 8 years of age.	1	2	3	4
7	I prefer to use cuffed endotracheal tubes in patients under 8 years of age.	1	2	3	4
8	If a patient is under 8 years of age I would prefer to use a cuffed endotracheal tube only if they were in critical respiratory distress.	1	2	3	4
9	Using a cuffed ETT in a patient under 8 years of age increases the risk of airway injury.	1	2	3	4
10	The possibility of risk when using a cuffed ETT in a patient under 8 years of age is worth it for the benefits it provides.	1	2	3	4
11	A cuffed endotracheal tube provides benefits that an uncuffed endotracheal tube does not.	1	2	3	4

Appendix D
Resistance to Change Survey

Provider Change Survey

		Strongly Disagree	Disagree	Inclined to Disagree	Inclined to Agree	Agree	Strongly Agree
1	I generally consider changes to be a negative thing.	1	2	3	4	5	6
2	I'll take a routine day over a day full of unexpected events any time. Generally, change is good.	1	2	3	4	5	6
3	I like to do the same old things rather than try new and different ones.	1	2	3	4	5	6
4	Whenever my life forms a stable routine I look for ways to change it.	1	2	3	4	5	6
5	I'd rather be bored than surprised.	1	2	3	4	5	6
6	If I were informed that there's going to be a significant change regarding the way things are done at work, I would probably feel stressed.	1	2	3	4	5	6
7	When I am informed of a change in plans, I tense up a bit.	1	2	3	4	5	6
8	When things don't go according to plans, it stresses me out.	1	2	3	4	5	6
9	If my boss changed the criteria for evaluating employees, it would probably make me feel uncomfortable even if I thought I'd do just as well without having to do any extra work.	1	2	3	4	5	6
10	Changing plans seems like a real hassle to me.	1	2	3	4	5	6
11	Often, I feel a bit uncomfortable even about changes that may potentially improve my life.	1	2	3	4	5	6
12	When someone pressures me to change something, I tend to resist it even if I think the change may ultimately benefit me.	1	2	3	4	5	6
13	I sometimes find myself avoiding changes I know will be good for me.	1	2	3	4	5	6

14	I often change my mind.	1	2	3	4	5	6
15	Once I've made plans, I'm not likely to change them.	1	2	3	4	5	6
16	I don't change my mind easily.	1	2	3	4	5	6
17	My views are very consistent over time.	1	2	3	4	5	6

Note: Used as published. (Oreg, S., 2003).

Appendix E
Site Survey

Site Survey Based on Donabedian's Model
STRUCTURAL COMPONENTS

Describe the work environment: (911, critical care transport, BLS transport, mixed).

How many of the following on staff?

RN: _____

Physician: _____

Paramedic: _____

EMT: _____

Other: _____

What is the typical elapsed time since initial advanced provider training for your staff?

Do you currently utilize cuffed tubes in children? Exclusively?

Has any specific education been provided on the subject of pediatric airway control with cuffed v. uncuffed endotracheal tubes?

What is the availability of both cuffed and uncuffed tubes in all pediatric sizes at the provider site?

What is the experience and credentials of the medical director?

What are the stated preferences of the medical director?

What are the airway control policies of the site?

Quality Improvement

Describe the QI/QA program:

What quality assurance monitoring related to endotracheal intubation in children is performed at the site? (Attach sample if possible).

What other pediatric airway metrics are tracked?

Describe loop closure for airway issues.

Do you hold periodic incident review sessions?

Is this review open to all staff?

What criteria do you use for inclusion to review a case/incident?

Do you include outside stakeholders in QA/QI or review processes?

Continuing Education

What continuing education training is provided to clinicians?

Is any CE specific to pediatric airway?

How often does CE training occur?

How is the continuing education that you provide linked to data obtained from QI/QA or incident reporting?

Is there mandatory OR time for live intubation practice? How often? How many tubes/year?

Is simulation utilized to supplement or replace live intubation practice?

What mandatory EMS protocols are in place?

Equipment

What manufacturer(s) do you obtain ET tubes from?

Do you purchase ET s tubes system-wide for bulk discount?

Do you use a Just In Time or a similar process to keep par levels of stock of ET tubes consistent and low?

Do you have mechanical ventilators available for pediatric prehospital (911/EMS) patients?

If yes, which brand?

How often do you choose to use BVM ventilation over a mechanical ventilator?

Is there a policy that specifies when to use mechanical ventilation? (If yes, describe).

Do you have Mapleson style BVM available for ventilating pediatric patients?

PROCESS

Do you have a written policy for where to transport pediatric prehospital (911/EMS) patients?

How do you determine your closest access to pediatric care?

How do you determine your closest access to pediatric **specialty** care?

How do you determine your closest access to pediatric **critical** care?

How does your agency estimate patient age and weight?

How does your agency estimate appropriate or approximate tube size?

Are clinicians free to independently choose the tube type (cuffed/uncuffed) at the time of procedure?

Does any advanced provider have permission to intubate or is it limited to certain staff?

Does your agency have the ability to provide sedation and paralysis to facilitate intubation and ventilation?

What tube placement confirmation procedures are utilized? Are they tracked for compliance?

Have you ever had any reported difficulties with confirming tube placement?

What do you believe are the primary factors for retaining the use of uncuffed endotracheal tubes in children?

What do you believe are the primary factors for advancing to the use exclusive of cuffed endotracheal tubes in children?

Who in your agency would you identify as a change agent (non-administrative level)?

Who in your agency would you identify as a change agent (administrative level)?

OUTCOMES

Has your QA/QI process revealed any issues pertaining to the use of endotracheal tubes in pediatric patients in the past 3-5 years?

Note: Created by the author and adapted from Donabedian's Model of Healthcare Quality (Donabedian, 1966/2005).

Appendix F

IRB Approvals



Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Protocol ID # 20200113A

This Protocol ID number must be used in all communications about this project with the IRB.

TO: Thomas Pearson
FROM: Nicole M. Cattano, Ph.D.
Co-Chair, WCU Institutional Review Board (IRB)
DATE: 1/9/2020

Project Title: Strategies to Increase the Prehospital Use of Cuffed Endotracheal Tubes in Pediatric Patients
Date of Approval: 1/9/2020

Expedited Approval

This protocol has been approved under the new updated 45 CFR 46 common rule that went in to effect January 21, 2019. As a result, this project will not require continuing review. Any revisions to this protocol that are needed will require approval by the WCU IRB. Upon completion of the project, you are expected to submit appropriate closure documentation. Please see www.wcupa.edu/research/irb.aspx for more information.

Any adverse reaction by a research subject is to be reported immediately through the Office of Research and Sponsored Programs via email at irb@wcupa.edu.

Signature:

A handwritten signature in black ink, appearing to read 'Nicole M. Cattano'.

Co-Chair of WCU IRB

WCU Institutional Review Board (IRB)
IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155



Office of Research and Sponsored Programs | West Chester University | Wayne Hall
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

TO: Thomas Pearson and Cheryl Monturo
FROM: Nicole M. Cattano, Ph.D.
Co-Chair, WCU Institutional Review Board (IRB)
DATE: 2/10/2020

Protocol ID # 2020113A-R1

Project Title: Strategies to increase the prehospital use of cuffed endotracheal tubes in pediatric patients

Date of Approval for Revision:** 2/10/2020

****Please note that the original end date of your approved protocol still applies****

Expedited Approval

This protocol has been approved under the new updated 45 CFR 46 common rule that went in to effect January 21, 2019. As a result, this project will not require continuing review. Any revisions to this protocol that are needed will require approval by the WCU IRB. Upon completion of the project, you are expected to submit appropriate closure documentation. Please see www.wcupa.edu/research/irb.aspx for more information.

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Signature:

Co-Chair of WCU IRB

WCU Institutional Review Board (IRB)
IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155



Nemours Office of Human Subjects Protection
Nemours/Alfred I. duPont Hospital for Children
1600 Rockland Road
Wilmington, DE 19803
Fax: 302-651-4683
Office: 302-298-7613

DATE: October 24, 2019
TO: Thomas Pearson, MSN
FROM: Nemours IRB 1
STUDY TITLE: [1515065-1] Factors affecting the pre-hospital use of cuffed endotracheal tubes in pediatric patients transported to AIDHC Emergency Department.
IRB #: 1515065
SUBMISSION TYPE: New Project
ACTION: NOT RESEARCH
REVIEW DATE: October 24, 2019

Thank you for your submission of New Project materials for this project. Nemours IRB 1 has determined this project does not meet the definition of research under the purview of the IRB according to federal regulations.

Please note that any project modifications that may alter this non-research determination must be submitted to the IRB for review.

Reviewed documents in this submission:

- Application Form - Application - REQUEST for Research Determination v01-18 PEARSON.docx (UPDATED: 10/22/2019)
- Proposal - Addendum to Application - Request for Research Determination PEARSON.docx (UPDATED: 10/22/2019)

If you have any questions, please contact Soniya Anis at AI duPont Hospital for Children 1600 Rockland Road, ARB Room 162-D, Wilmington, Delaware 19803 at (302) 651-6807 or Soniya.Anis@nemours.org. Please include your study title and reference number in all correspondence with this office.