UNDERSTANDING ANESTHESIA PROVIDERS' KNOWLEDGE AND PRACTICE OF LUNG PROTECTIVE TIDAL VOLUME SETTINGS IN OBESE PATIENTS AGED 18 AND OLDER UNDERGOING LAPAROSCOPIC SURGERIES

by

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ABSTRACT

CAITLIN MCCONNELL. Understanding Anesthesia Providers' Knowledge and Practice of Lung Protective Tidal Volume Settings in Obese Patients Aged 18 and Older Undergoing Laparoscopic Surgeries. (Under the direction of DR. STEPHANIE WOODS, PhD, RN)

Obese adults having laparoscopic surgery are at increased risk for postoperative pulmonary complications (PPCs) due to the alteration in pulmonary physiology caused by their body habitus, the use of Trendelenburg position, and abdominal insufflation required for this surgical approach. Current literature recommends utilizing lung protective ventilation (LPV) strategies to reduce the incidence of PPCs, particularly in high-risk patients like the group described. One strategy described in the literature is the use of tidal volumes of 6-8 milliliters per kilogram of ideal body weight. Despite the evidence, anesthesia provider implementation of LPV strategies is inconsistent. The purpose of this quality improvement project was to explore anesthesia providers' knowledge and utilization of lung protective tidal volume strategies in obese patients undergoing laparoscopic surgery. A survey was sent to anesthesia providers at a large urban trauma center. Results indicated that most participants have current knowledge of lung protective tidal volume recommendations and use them in their practice, although areas for improvement were identified. Recommendations include continued education and emphasis on evidence-based lung protective tidal volume recommendations for anesthesia providers.

DEDICATION

I would like to dedicate this project to my fiancé, Ryan. Thank you for standing by me through all the stress and long hours, and for being a constant source of comfort and encouragement. I truly could not have completed this without you. I would also like to dedicate this to my parents, who have supported me every step of the way. Thank you for always reminding me that giving my best was good enough. Finally, this project is also dedicated to our dog, Teddy. Thank you for your silliness and unconditional love.

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LIST OF ABBREVIATIONS

ACT	anesthesia care team
ANOVA	analysis of variance
ARM	alveolar recruitment maneuver
ARDS	acute respiratory distress syndrome
BMI	body mass index
CRNA	Certified Registered Nurse Anesthetist
DNP	Doctorate of Nursing Practice
FiO_2	fraction of inspired oxygen
IBW	ideal body weight
ICU	intensive care unit
IRB	Institutional Review Board
kg	kilogram
MDA	physician anesthesiologist
MSN	Master of Science in Nursing
LPV	lung protective ventilation
PBW	predicted body weight
PEEP	positive end-expiratory pressure
PPC	postoperative pulmonary complication
QR	quick-response
RCT	randomized controlled trial

CHAPTER I: INTRODUCTION AND BACKGROUND

1.1 Background

The delivery of general anesthesia alters normal respiratory physiology. This is compounded by the respiratory alterations induced by both laparoscopic surgery and obesity, defined by the World Health Organization as a body mass index (BMI) greater than or equal to 30 kg/m^2 (World Health Organization, n.d.). Anesthesia providers delivering mechanical ventilation to patients during surgery do so with the hope of maintaining respiratory homeostasis despite these alterations. The way in which this ventilation is delivered affects patient outcomes. The term “postoperative pulmonary complications” (PPCs) refers to a number of complications negatively affecting the respiratory system following surgery, such as atelectasis, pneumothorax, aspiration pneumonitis, pneumonia, pulmonary edema, exacerbation of pre-existing lung disease and many others (Miskovic & Lumb, 2017). PPCs can be caused by ventilator-induced lung injury, the mechanisms of which include barotrauma, volutrauma, and atelectrauma. Barotrauma results from excessive pressure, volutrauma results from excessive volume, and atelectrauma results from shear stress induced by cyclic recruitment and derecruitment of alveoli (Tsumara et al., 2017). The reported incidence of PPCs varies greatly, likely due to varied definitions. According to Miskovic and Lumb (2017), “incidence of PPCs in major surgery ranges from <1 to 23%” (p. 319). In their article referencing multiple studies, Tsumara et al., (2021) reported an incidence of PPCs of between 2-70%. PPCs increase morbidity, mortality, and healthcare costs. Lung-protective ventilation (LPV) strategies, initially shown to improve outcomes in acute respiratory distress (ARDS) patients, are a proven method to reduce PPC incidence. More specifically, LPV “minimizes damage to pulmonary epithelial and vascular endothelial cells and their associated connective tissue” (Nieman et al., 2017, p. 1517). Evidence continues to grow in support of LPV strategies, which include low tidal volumes, application of positive end-expiratory pressure (PEEP), and use of alveolar recruitment maneuvers (ARMs) among other strategies.

Traditional recommendations for intraoperative tidal volume settings have been 10-15 mL/kg of predicted body weight. Predicted body weight (PBW) and ideal body weight (IBW), often used interchangeably in the literature, are calculated based on a patient's height, not their actual body weight. The formula for PBW for adult males is: PBW (kg) = 50 + 0.91 x (height (cm) - 152.4), and for adult females it is: PBW (kg) = 45.5 + 0.91 x (height (cm) - 152.4). The formula for IBW for adult males is: IBW (kg) = height (cm) - 100, and for adult females it is: IBW (kg) = height (cm) - 105 (Barash, et al., 2017). The difference between IBW and PBW is negligible. The use of predicted or ideal body weight in calculating tidal volume helps avoid over-ventilation of obese patients, as well as underventilation of underweight patients. Current literature demonstrates a reduction in PPCs with the use of lower tidal volumes of around 6-8 mL/kg of predicted body weight (Young, et al., 2019). This lower tidal volume is closer to the average tidal volume of a spontaneously ventilating person at rest. Larger tidal volumes, which have been previously theorized to prevent atelectasis, predispose patients to volutrauma and barotrauma (Tsumara et al., 2021). The PICO question "what are anesthesia providers' knowledge and utilization of lung-protective tidal volume recommendations in obese patients (BMI≥30 kg/m^2) aged 18 and older undergoing laparoscopic surgeries?" seeks to understand current practice and the factors that may be barriers to the consistent use of lung-protective tidal volumes intraoperatively.

1.2 Problem Statement

Anesthesia providers care for a variety of patient populations in many practice areas. The risk for PPCs varies across patient population and type of surgery. Having a BMI of 30 kg/m^2 or above poses an increased risk for PPCs. Obesity reduces pulmonary compliance and increases airway resistance, leading to reduced lung capacities (Dixon & Peters, 2018). Atkinson et al., (2017) state that "obesity is associated with respiratory comorbidities including restrictive lung disease, obstructive sleep apnea, and obesity hypoventilation syndrome" (p. 707). In fact, induction of general anesthesia in the obese patient reduces functional residual capacity (FRC) up to 50% compared with approximately 20% in the non-obese patient (Tsumura et al., 2021). This reduced FRC equates to a smaller oxygen reserve. Additionally, obesity increases the required work of breathing which subsequently increases myocardial oxygen consumption (Nagelhout & Elisha, 2018, p. 1001).

Intraoperative positioning can also influence the risk of developing PPCs. Specifically, laparoscopic surgeries that require use of the Trendelenburg position shifts abdominal contents cephalad, reducing pulmonary compliance and increasing peak airway pressures. The abdominal insufflation used for a laparoscopic approach further displaces the diaphragm cephalad and leads to even higher airway pressures, increased ventilation-perfusion mismatches, and further reduces pulmonary compliance (Atkinson et al., 2017). The laparoscopic approach has become increasingly common for abdominal and gynecologic procedures, making the risk for PPCs higher and the need for LPV greater. Because the obese patient undergoing laparoscopic surgery is highly vulnerable to PPCs, they have much to gain from diligent use of LPV.

Despite the growing evidence in favor of LPV strategies, they are not consistently utilized by anesthesia providers. In one study, only 50% of surveyed providers used the recommended tidal volumes of 6-8 mL/kg IBW, and only 22.3% used optimal PEEP (Tretheway, et al., 2021). LPV strategies are important for reducing the occurrence of atelectasis, ventilator-induced lung injury and subsequent PPCs. The objective of this scholarly project is to understand anesthesia providers' knowledge and current use of LPV strategies, specifically low tidal volume, in obese patients (BMI ≥ 30 kg/m^2) undergoing laparoscopic procedures.

1.3 Purpose of the Project

The purpose of this quality improvement project is to understand anesthesia providers' knowledge and utilization of lung protective tidal volume strategies in obese patients undergoing laparoscopic surgery.

1.4 Clinical Question (PICO)

What are anesthesia providers' knowledge and utilization of lung-protective tidal volume settings in obese patients (BMI ≥30 kg/m^2) aged 18 and older undergoing laparoscopic surgery?

1.5 Project Objective

The objective of this project is to help establish a baseline and direction for future education of anesthesia providers regarding lung protective tidal volume ventilation strategies in obese patients.

CHAPTER II: LITERATURE REVIEW

2.1 Literature Review

Benefits of Combined Lung Protective Ventilation Strategies

Traditional tidal volume setting recommendations for ventilated patients have been 10-12 mL/kg of predicted body weight (PBW) (Futier et al., 2013). With the advent of LPV strategies, recommendations for tidal volume settings have shifted to favor ventilation with a lower tidal volume of 6-8 mL/kg IBW/PBW. Evidence in the literature consistently shows that when combined with PEEP and recruitment maneuvers, delivering lower tidal volumes to mechanically ventilated patients leads to improved pulmonary outcomes. In their Randomized Controlled Trial of 400 adults undergoing abdominal surgery, Futier et al. (2013) investigated differences in incidence of PPCs between two ventilation strategies. PPCs were defined in this study as "pneumonia… or the need for invasive or noninvasive ventilation for acute respiratory failure" (Futier at al., 2013, p. 430). The authors found that patients who were ventilated with a combination of lower tidal volumes (6-8 mL/kg PBW), PEEP of 6-8 cmH_2O, and recruitment maneuvers every 30 minutes had a significantly lower incidence of PPCs compared to patients who received a combination of higher tidal volumes (10-12 mL/kg PBW), no PEEP, and no recruitment maneuvers. Pi et al. (2015) found similarly in their RCT of 63 adults undergoing abdominal surgery that patients who received low tidal volumes (7 mL/kg IBW), PEEP of 8 cmH_2O, and recruitment maneuvers had significantly better pulmonary function tests than patients who received high tidal volumes (9 mL/kg IBW), no PEEP, and no recruitment maneuvers.

Some studies have investigated pulmonary outcomes associated with high tidal volumes with no PEEP compared to low tidal volumes with PEEP applied, without the addition of recruitment maneuvers. A RCT investigating levels of alveolar inflammatory mediators, oxygenation indices, and incidence of pulmonary complications found that patients ventilated with lower tidal volumes (5 mL/kg total body weight) and PEEP of 5 cmH_2O had better outcomes in all three categories than patients who were ventilated with higher tidal volumes (8 mL/kg total body weight) and no PEEP (Shen et al., 2013).

Effects of Low Tidal Volume in Reducing Lung Injury

There are fewer studies investigating the role of tidal volume alone in reducing PPCs when other variables such as PEEP and recruitment maneuvers are held constant. The literature that is published is conflicting. One large randomized clinical trial of 1,236 patients found no significant difference in the incidence of PPCs between patients who received low tidal volume ventilation (6 mL/kg PBW) and conventional tidal volume ventilation (10 mL/kg PBW) intraoperatively, with both groups receiving the same PEEP of 5 cmH_2O (Karalapillai et al., 2020). Similarly, a smaller RCT of 28 patients that used the same variables, tidal volume of 6 mL/kg PBW versus 10 mL/kg PBW, with all other ventilatory parameters kept the same, found no significant difference in levels of lung injury biomarkers between the two groups (Moss et al., 2014). In contrast, a large observational study of 3,434 adult patients undergoing cardiac surgery investigated the effects of low (<10 mL/kg PBW), traditional (10-12 mL/kg PBW), and high (>12 mL/kg PBW) tidal volumes on organ dysfunction. This study found both traditional and high tidal volume ventilation to be independent risk factors for development of organ dysfunction (Lellouche et al., 2012).

Some researchers have taken their studies outside of the operating room and have looked at the effects of lower tidal volume in mechanically ventilated patients in the intensive care unit (ICU). A large, multicenter, randomized trial of 911 patients with acute respiratory distress syndrome and acute lung injury found a 22% decrease in mortality for patients ventilated with a tidal volume of 6 mL/kg PBW compared to 12 mL/kg PBW (Brower et al., 2000). One small randomized clinical trial of 16 patient in the ICU with ARDS found that patients ventilated with tidal volumes of 6 mL/kg IBW for 30 minutes had improved cardiac indices and oxygen delivery compared to patients ventilated with 10 mL/kg IBW for 30 minutes (Natalini et al., 2013). In contrast, Simonis et al., (2018), conducted a large randomized clinical trial investigating the impact of lower tidal volume ventilation (6 mL/kg PBW versus 10 mL/kg PBW) on ventilator-free days after 28 days, and again found no significant difference between the two groups. Despite the inconsistent data on the role of tidal volume alone, it remains clear that when combined with at least PEEP, patients do have better outcomes.

Tidal Volume in Obese Patients

Various observational studies have been conducted to investigate anesthesia providers' utilization of established LPV strategies, including the use of tidal volumes of 6-8 mL/kg PBW or IBW. A recurring theme in many of these studies is the overventilation of obese patients. One study investigating ventilation practices of 2,960 patients found that BMI was associated with the use of larger tidal volumes of >10 mL/kg IBW (Jaber et al., 2012). Another large study of provider practice conducted by Ball et al., (2018) found that the average tidal volume delivered to obese patients, defined as a BMI greater than or equal to 30, was 8.8 mL/kg PBW. Of note, patients in this study with BMIs greater than or equal to 40 were ventilated with an even higher tidal volume of 9.8 mL/kg PBW. In their study of intraoperative ventilation practices, Fernandez-Bustamante et al., (2011), found that 34% of patients with a BMI greater than or equal to 30 received tidal volumes of greater than 10 mL/kg PBW. The evidence suggests that anesthesia providers consistently deliver tidal volumes that are too large to the obese, a population that is already at risk for postoperative pulmonary complications.

To summarize, the use of lower tidal volumes for mechanical ventilation, when combined with other lung protective strategies, leads to improved outcomes for patients. There is conflicting data regarding the use of lower tidal volume as a singular strategy for lung protection, and more research is needed to determine its effectiveness.

Conclusion of Literature Review

The literature demonstrates a clear benefit in mechanically ventilated patients undergoing general anesthesia who receive a combination of low tidal volume ventilation, application of optimal PEEP, and use of alveolar recruitment maneuvers. Patients who receive this combination of LPV strategies have a reliably lower incidence of PPCs than those who do not. Obese patients undergoing laparoscopic surgery encounter multiple risk factors that predispose them to PPCs. These patients demonstrate better outcomes when they receive LPV strategies, particularly PEEP and ARMs. More research is needed to ascertain whether low tidal volume alone is beneficial, although as previously stated, the incidence of PPCs decreases when it is combined with other lung protective strategies.

Although the evidence supporting the use of LPV strategies is abundant, their utilization varies among anesthesia providers. Studies have shown that anesthesia providers' utilization of lung protective strategies is insufficient, especially in the obese population. It is recommended that anesthesia providers consistently implement LPV strategies to mitigate PPCs, facilitate optimal respiratory mechanics, and reduce morbidity and mortality, especially in the obese population undergoing laparoscopic surgery.

2.2 Conceptual/Theoretical Framework

This quality improvement project's framework followed the Plan-Do-Study-Act (PDSA) method. For this project, the "plan" was to complete an in-depth review of the literature surrounding the identified clinical problem and lung protective tidal volume settings. A validated survey was created to assess current knowledge and practice habits regarding LPV strategies among anesthesia providers. The survey was distributed to the identified anesthesia providers, which made up the “do” component of this method.

The “study” component included analyzing survey responses and identifying trends surrounding the knowledge and use of LPV strategies, specifically low tidal volume, amongst those who completed the survey. Areas for improvement were identified by comparing survey responses with evidence-based practice guidelines. The “act” component was completed via presentation of the survey findings and discussing identified areas in which responses deviate from practice recommendations in the evidence.

CHAPTER III: METHODS

3.1 Project Design

This quality improvement project's methodology utilized a descriptive design. The project aimed to investigate anesthesia providers' knowledge and use of lung protective tidal volume strategies in obese patients (BMI $\geq$ 30kg/m^2) via a survey. This project exists as part of a larger quality improvement investigating anesthesia provider use of other lung protective ventilation strategies in obese patients including positive end-expiratory pressure and alveolar recruitment maneuvers.

3.2 Sample

The sample for this project consisted of certified registered nurse anesthetists (CRNAs) and physician anesthesiologists (MDAs) practicing at a large urban trauma center. CRNAs have completed their undergraduate studies with a Bachelor of Science in Nursing, which is then followed by at least one year of critical care/intensive care unit (ICU) experience prior to entering their nurse anesthesia programs. The CRNAs at the data collection site have acquired either their doctoral or master's degree in nurse anesthesia practice. The MDAs have completed four years of medical school, four years of residency, and some complete another one to two years of specialized fellowship training. Sample exclusion criteria included anesthesia providers not currently practicing at the data collection site, and anyone who was not a board-certified anesthesia provider.

The operating rooms at the large urban trauma center where this project took place function in a team approach following the Anesthesia Care Team (ACT) model. In the ACT Model, MDAs are responsible for up to five simultaneously functioning operating rooms with care managed by CRNAs, who are present throughout the entire anesthetic. The MDAs, who are present on the induction and emergence of anesthesia, may also perform specialized skills including insertion of central venous catheters and performance of regional anesthesia for multimodal analgesia. The MDAs visit the patient prior to the surgery to perform and document a thorough preoperative assessment. The CRNAs are responsible for one patient per case, allowing them to provide vigilant care and safe passage for patients undergoing anesthesia. The CRNAs also perform a preoperative assessment and tailor a patient-specific anesthetic plan in collaboration with the MDA and surgeon. This quality improvement project used a convenience sample with the project survey sent to 165 CRNAs and 72 MDAs practicing at the data collection site.

3.3 Setting

This quality improvement project took place at a large, 874-bed, urban trauma center. This institution serves the needs of a large Southern city and its surrounding regions. It is the only Level 1 trauma center and transplant center for heart, kidney, liver, and pancreas transplants in the region. The center is also a teaching hospital that provides residency training. This facility is equipped to serve many medically complex patients. There are 45 operating rooms at this facility, not including obstetric operating rooms and procedural areas. Approximately 150 to 200 surgical cases are performed each day. Around 60 to 70 CRNAs are staffed each day, along with about 15 to 20 physician anesthesiologists.

3.4 Data Collection

Data was collected via a quantitative electronic survey sent to anesthesia providers (CRNAs and MDAs) practicing at the previously described facility. Survey questions were based on recommendations for lung protective ventilation found in the literature and validated by CRNA faculty and clinical experts. Taking into consideration the survey fidelity and design of study, the project addressed possible setbacks and challenges in implementation at the outset to ensure consistency throughout the study's course (Bellg et al., 2004). The project's intent was to understand anesthesia providers' knowledge and current practices of lung protective tidal volume ventilation.

3.5 Measurement Tools

The survey consisted of 24 Likert scale questions that aimed to elicit anesthesia providers' knowledge and utilization of evidence-based recommendations for LPV strategies, with eight questions pertaining to use of PEEP, eight pertaining to tidal volume settings, and seven pertaining to alveolar recruitment maneuvers. The questions pertaining to PEEP and alveolar recruitment maneuvers were part of a larger quality improvement project and are not part of the current analysis. One question pertained to the general use of lung protective ventilation strategies. Each question had six response choices, ranging from "Extremely likely" to "Extremely unlikely". As previously noted, survey questions were reviewed by CRNA faculty and clinical experts prior to dissemination to establish reliability of questions.

3.6 Data Collection Procedures

The survey was conducted via the SurveyMonkey platform. It was delivered to anesthesia providers via their email addresses as well as made available via QR code. QR codes were placed in break rooms, work rooms, and various ORs. Participants were able to complete the survey on their mobile devices. Email reminders were sent out 2 and 3 weeks after the survey opened. The survey was closed after 4 weeks. Participants could only complete the survey one time.

3.7 Data Analysis

Basic data analysis was performed via the SurveyMonkey platform. The results were also exported to Microsoft Excel for more advanced analysis. Once exported to Microsoft Excel, responses were organized into one of three ventilation parameters to which they pertained: tidal volume, positive end-expiratory pressure (PEEP), and alveolar recruitment maneuvers (ARMs). The results were analyzed to assess trends in anesthesia providers' knowledge and use of lung protective ventilation strategies and how these practices compare to evidence-based LPV recommendations. Frequency tables organizing the responses to each survey question were created and frequencies of responses were calculated. The data was stratified by each subgroup. Subgroups included job title and education, age, and years of experience. Stratifying data based on these subgroups allowed for evaluation of patterns in clinical practice and schools of thought by each of these groups. The groups' responses were compared using ANOVA.

3.8 Ethical Considerations

The SurveyMonkey responses and Microsoft Excel data were password-protected and only accessible to the project committee. Survey responses were anonymous with only basic demographic data collected, including age, professional title, location of practice, educational background, and years of experience as an anesthesia provider. Survey participants indicated the range that their age and years of experience fell into to avoid jeopardizing confidentiality in any way.

CHAPTER IV: PROJECT FINDINGS/RESULTS

Sample Characteristics

Fifty-two individuals completed the survey out of a total of 237 who were invited to participate, yielding a response rate of approximately 22%. Participants each answered all survey questions. Anesthesiologists made up 13% of participants (n=7). CRNAs made up the other 87% of participants (n=45). Of the participants that were CRNAs, 27% DNP prepared (n=12), and 73% were MSN prepared (n=33). In regard to years of experience, 15% of participants had 0-5 years (n=8), 42% had 6-10 years (n=22), 25% had 10-15 years (n=13), and 17% had >15 years of experience (n=9). Age ranges of participants were also collected; 15% of participants were ages 20-30 (n=8), 42% were ages 31-40 (n=22), 25% were ages 41-50 (n=13), and 17% were >50 years old (n=9). (See Tables 1-3).

Table 1

Title of Respondents

Role	Number of Responses
Anesthesiologist	7
CRNA, DNP	12
CRNA, MSN	33

Table 2

Years of Experience Among Respondents

Years of Experience	Number of Responses
0-5	8
6-10	22
10-15	13
>15	9

Table 3

Ages of Respondents

Age (years)	Number of Responses
20-30	8
31-40	22
41-50	13
>50	9

Survey Results

Table 4 shows the mean responses of survey participants for each question regarding tidal volume. An "answer" column is included to indicate the Likert scale answer most aligned with the literature recommended lung protective tidal volumes. A "meaning" column is included to indicate what the mean response translates to on the Likert scale.

Table 4

Lung Protective Tidal Volume Survey Findings

Item	Answer	Mean Response (standard deviation)	Meaning of Mean Response
Q2: Your patient presents for a roux-en-y procedure. He is male, **5 foot 9 inches (175 cm)** tall, and weighs **200 kg**. How likely would you be to use an initial tidal volume of **450 mL**?	5	2.63 (1.30)	Unlikely to Likely
Q5: How likely are you to use an initial tidal volume of greater than 8 mL/kg of ideal body weight/predicted body weight for an obese patient?	0	1.37 (1.22)*	Very unlikely to Unlikely

Table 4

Lung Protective Tidal Volume Survey Findings (continued)

Q8: Your patient presents for a roux-en-y procedure. He is male, **5 foot 9 inches (175 cm)** tall, and weighs **70 kg**. How likely would you be to use an initial tidal volume of **450 mL**:	5	3.00 (1.33)	Likely
Q11: Your patient presents for a roux-en-y procedure. He is male, **5 foot 9 inches (175 cm)** tall, and weighs **70 kg**. How likely would you be to use an initial tidal volume of **700 mL**?	0	0.52 (0.78)*	Extremely unlikely to Very unlikely
Q14: Your patient presents for a roux-en-y procedure. He is male, **5 foot 9 inches (175 cm)** tall, and weighs **200 kg**. How likely would you be to use an initial tidal volume of **700 mL**?	0	0.92 (1.10)*	Extremely unlikely to Very unlikely
Q17: I was taught in my anesthesia training to deliver tidal volumes of 6-8 mL/kg of ideal or predicted body weight.		3.90 (1.43)	Likely to Very Likely

Table 4

Lung Protective Tidal Volume Survey Findings (continued)

Q20: How likely are you to consider the BMI of the patient when setting tidal volume for general anesthesia?	0	2.67 (1.52)*	Unlikely to Likely
Q23: Setting tidal volumes based on ideal body weight in obese patients may contribute to the development of atelectasis.	0	1.85 (1.18)	Very unlikely to Unlikely
Q24: How likely are you to incorporate lung protective ventilation strategies as part of your anesthetic plan in obese patients?	5	4.21 (0.91)	Very likely to Extremely Likely

Note: 0 = extremely unlikely, 1 = very unlikely, 2 = unlikely, 3 = likely, 4 = very likely, 5 = extremely likely.

**Reversed score, i.e., a lower score indicates an answer that aligns with the literature on lung protective tidal volumes.*

Question 20 asked how likely respondents are to consider the BMI of the patient when setting tidal volume for general anesthesia. The mean score for this question was 2.67, meaning that respondents overall fell between "unlikely" and "likely" to consider the BMI when setting tidal volume. DNP prepared CRNAs were more likely than MSN prepared CRNAs to report considering the BMI when setting tidal volume (p = .04). Since the literature suggests a benefit to using IBW or PBW instead of total body weight to set tidal volume, the patient's BMI is not a necessary consideration (Futier et al., 2013; Pi et al., 2015; Shen et al., 2013; Young et al., 2019).

Questions 2 and 8 were designed to investigate if respondents would report using a tidal volume of 6 mL/kg IBW for both an obese patient and a non-obese patient. Mean responses for questions 2 and 8 were 2.63 and 3.00, respectively, meaning that respondents answered they were in the “unlikely” to “likely” range to use a tidal volume of 6 mL/kg IBW in both scenarios. Respondents were more likely to report that they would use this tidal volume on the non-obese patient ($p = .033$). DNP prepared CRNAs were more likely to use a tidal volume of 6 mL/kg IBW for an obese patient ($p < .001$) as well as for a patient with a normal BMI ($p < .001$).

Questions 11 and 14 were designed to investigate if respondents would report using a tidal volume of >9 mL/kg IBW for both an obese patient and a non-obese patient. The patients in questions 11 and 14 were both 5 foot 9 inches (175 cm) tall. Using the formula for IBW in males, IBW (kg) = height (cm) - 100, the ideal body weight for both patients is calculated to be 75 kg. A tidal volume of 700 mL for a patient whose IBW is 75 kg is >9 mL/kg IBW. Mean responses for questions 11 and 14 were 0.52 and 0.92, respectively, meaning that respondents said they were in the “extremely unlikely” to “very unlikely” range to use a tidal volume of >9 mL/kg IBW on either patient in the scenario. These responses indicate that respondents are aligning their practice with the lower tidal volumes of 6-8 mL/kg IBW or PBW recommended in the literature (Brower et al., 2000, Futier, et al., 2013, Natalini, et al., 2013, Pi et al., 2015, Young, et al. 2019). However, respondents were more likely to report that they would use the larger tidal volume of >9 mL/kg IBW on the obese patient ($p = < .001$). There was no significant difference in responses between demographics on the likelihood of using a tidal volume of >9 mL/kg for either an obese patient or a patient with normal BMI.

The mean response for question 5, which asked participants how likely they would be to use an initial tidal volume of greater than 8 mL/kg of IBW, was 1.37. This falls in the “very unlikely” to “unlikely” range. 7 participants responded that they were likely to do so, and 1 responded that they were extremely likely to do so. There were no significant differences among demographic groups.

Question 17 asked participants if they were taught in their anesthesia program to deliver tidal volumes of 6-8 mL/kg IBW/PBW. The mean score was 3.90, which falls within the “likely” to “very likely” range. Providers with greater than 15 years of experience were less likely to report being taught this in their training (p = .007). Providers greater than or equal to 50 years old were also less likely than providers 20-30 years old to report being taught this (p = .021).

Question 23 stated that setting tidal volumes based on IBW in obese patients may contribute to the development of atelectasis. The mean response for this question was 1.85, which falls within the “very unlikely” to “unlikely” range. As previously stated, the literature suggests that using IBW instead of total body weight is most appropriate to avoid postoperative pulmonary complications including atelectasis (Futier et al., 2013; Pi et al., 2015; Shen et al., 2013; Young et al., 2019). Providers 50 years and older (p = .008) were more likely than younger groups to report that using a tidal volume based on IBW in obese patients can contribute to atelectasis. On the other hand, providers with greater than 15 years of experience were less likely to report this than providers with 0-5 years of experience (p = .010).

Despite the varied responses to use of individual lung protective tidal volume strategies, when asked in question 24 how likely providers were to incorporate lung protective ventilation strategies as part of their anesthetic plan in obese patients, the mean score of respondents was 4.21, which falls between “very likely” and “extremely likely”. There were no significant differences between demographic groups for this question.

CHAPTER V: SIGNIFICANCE AND IMPLICATIONS

5.1 Discussion of Results

The results of the survey indicate that the majority of participants are utilizing tidal volumes of 6-8 mL/kg IBW in obese patients undergoing laparoscopic surgery, which is recommended in the literature as lung-protective (Brower et al., 2000, Futier et al., 2013, Lellouche et al., 2012, Natalini et al., 2013, Pi et al., 2015, Young, et al., 2019). In fact, when asked if they would incorporate lung protective ventilation strategies in their practice for obese patients, only 1 out of 52 participants indicated that they were not likely to do so. There is, however, room for improvement. In the scenario-based questions, anesthesia providers were more likely to deliver a lower tidal volume to a patient with a normal BMI compared to a patient with a BMI $\geq$30 kg/m^2, and more likely to deliver a tidal volume above the recommended range to a patient with a BMI $\geq$30 kg/m^2 compared to a patient with a normal BMI. This indicates a possible discrepancy in the tidal volumes delivered by providers to obese and non-obese patients. Despite this difference, only 10% of participants indicated that they would deliver a tidal volume of >9 mL/kg of IBW to an obese patient. In a separate question, 85% of respondents indicated that they were not likely to use an initial tidal volume greater than 8 mL/kg of IBW on an obese patient. This is a promising percentage of providers that report aligning their practice with this lung protective ventilation strategy.

The mean response when asked how likely they were to consider the BMI of the patient when setting tidal volume indicated that participants do have room to improve in this area. As previously stated, it is not necessary to consider the patient's BMI when setting a tidal volume based off of IBW. 54% of participants indicated that they were either extremely likely, very likely, or likely to do so. It is possible that acquiescence bias affected the responses to this question, and participants were more likely to agree with the question than do so in practice.

When asked if using low tidal volumes based on IBW would contribute to atelectasis in obese patients, the mean response indicated that most providers are aware that it does not. This is also promising and indicates that most participants are aware that the recent literature indicates that lower tidal volume ventilation (6-8 mL/kg IBW) is not associated with increased atelectasis compared to ventilation with larger tidal volumes (Cai, et al., 2007).

In the scenario-based questions, DNP prepared CRNAs were more likely to indicate that they would use a tidal volume of less than 6 mL/kg IBW for both an obese and non-obese patient. There were no other differences between demographics for this question. DNP prepared CRNAs are more likely to be freshly out of training since nurse anesthesia programs only began to be required to confer doctorate degrees in 2023. Prior to this requirement, most nurse anesthesia programs conferred master's degrees. Since DNP prepared CRNAs are more likely to be freshly out of training, they may have received a more in-depth education on lung protective ventilation than CRNAs who have been out of training for longer. DNP prepared CRNAs, however, were more likely to respond that they would consider the BMI of the patient when setting tidal volume for general anesthesia, which is not a necessary consideration when using lung protective tidal volume ventilation.

As expected, providers with greater than or equal to 15 years of experience as well as providers greater than or equal to 50 years of age were less likely to report being taught in their training to deliver tidal volumes of 6-8 mL/kg IBW or PBW. The concept of lung protective ventilation strategies is relatively new, so it comes as no surprise that younger providers were more likely to have been taught about using lower tidal volumes for mechanical ventilation in their training. Despite this difference, most older and more experienced providers aligned their responses with lung protective tidal volume strategies for all other survey questions. This indicates that providers are likely staying up to date with current tidal volume recommendations, despite what they may have been taught in their training.

The scenario-based questions in this survey offer insight into the issue of knowledge versus practice of the surveyed anesthesia providers. In some instances in healthcare, proper knowledge of the literature is not the barrier to utilization; providers may know the literature recommendations but choose not to implement them. The results of this survey indicate that surveyed anesthesia providers both know the literature recommendations regarding lung protective tidal volumes and implement them into their practice.

Several observational studies in the literature found that providers were more likely to use tidal volumes larger than the recommended 6-8 mL/kg IBW in patients with a BMI greater than or equal to 30 (Ball et al., 2018; Fernandez-Bustamante et al., 2011; Jaber et al., 2012). In this survey, respondents were significantly more likely to report that they would use a tidal volume of greater than 9 mL/kg IBW for an obese patient compared to a non-obese patient. However, the mean score for these questions indicated that providers were still unlikely to report that they would use this tidal volume for either patient. Notably, the studies in the literature were observational, while this project used a survey to ask providers directly about their use of lung protective tidal volumes.

5.2 Limitations

A major limitation of this project was the low response rate to the survey. Only 22% of 237 providers responded. This low response rate limits the insight and generalizability of this survey. Since survey completion was voluntary, the knowledge and practice of lung protective ventilation strategies by practitioners who chose not to participate were missed. The demographic distribution among participants was also uneven. There was a lack of anesthesiologist participation, with CRNAs making up 87% of participants. The other demographics were slightly more evenly distributed, but the convenience sampling method limited the ability to stratify between demographics.

Another limitation of this project is associated with the survey platform. A potential limitation of all surveys is the potential for participants to try to pick the “correct” answer, instead of reflecting their own practice habits in their responses. It is possible that survey participants are aware of literature recommendations, answered according to them on the survey, but do not necessarily incorporate them into their practice. There is no way to control for this possibility on a survey.

5.3 Implications for Nursing Practice

The results of this survey demonstrated that anesthesia providers have a basis of knowledge regarding lung protective tidal volume ventilation, but that improvements can be made in their use of lung protective tidal volumes in obese patients. Education regarding the benefits of lung protective ventilation strategies, including use of a physiologic tidal volume of 6-8 mL/kg IBW, should be continued and amplified. A focus on strategies to reduce PPCs in obese patients should occur within anesthesia departments. Educational points should focus on the use of ideal body weight for tidal volume settings, emphasizing that the use of larger tidal volumes is not beneficial for obese patients despite their larger body habitus.

5.4 Recommendations

Future research should focus on provider use of a combination of multiple lung protective ventilation strategies, including the use of positive end-expiratory pressure, alveolar recruitment maneuvers, and other strategies such as use of the lowest possible fraction of inspired oxygen. The literature review demonstrated the strongest correlation between a reduction in postoperative pulmonary complications and the use of multiple LPV strategies (Futier et al., 2013; Pi et al., 2015; Shen et al., 2013). The results of this project indicate that most surveyed anesthesia providers are incorporating lung protective tidal volume strategies into their practice. Future research to learn if and how providers are combining both lung protective tidal volumes and other strategies, especially in obese patients would be beneficial.

Continuing provider education regarding lung protective tidal volumes, as well as all lung protective ventilation strategies in combination, should be a focus in the future. At the trauma center where data for this project was collected, a presentation or continuing education program highlighting the benefits of combining lung protective ventilation strategies could be a way to improve provider utilization. This type of education could also bridge the potential knowledge gap for more experienced providers that may not have received this type of education in their training.

In addition to research, another recommendation is to implement lung protective ventilation reminders in the electronic medical record. An automated message that reminds anesthesia providers to use a tidal volume of 6-8 mL/kg IBW/PB, along with other LPV strategies, could improve adherence to LPV recommendations.

5.5 Summary

Anesthesia providers overall report good knowledge and use of lung protective tidal volume settings for mechanically ventilated patients under general anesthesia. Their mean scores were better than observational studies of anesthesia provider use of lung protective tidal volumes in obese patients in the literature. Although participants were more likely to say they would deliver a larger tidal volume to an obese patient compared to a non-obese patient, the actual number of participants who reported they would use the larger tidal volume was still low. Although older and more experienced providers were less likely to have been taught to use tidal volumes of 6-8 mL/kg IBW in their training, their mean scores on other survey questions indicate that they have a current knowledge of lung protective tidal volume settings. Anesthesia provider education on lung protective ventilation techniques, especially in obese patients, should be continued and emphasized.

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APPENDIX A: LUNG PROTECTIVE VENTILATION SURVEY

1. How likely are you to set PEEP between **5-9 cmH2O** for most obese adult patients undergoing laparoscopic surgery?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

2. Your patient presents for a roux-en-y procedure. He is male, **5 foot 9 inches (175 cm)** tall, and weighs **200 kg**. How likely would you be to use an <u>initial</u> tidal volume of **450 mL**?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

3. Your obese patient presents for a laparoscopic total hysterectomy for uterine fibroids. Her **BMI is 37 kg/m^2**. How likely are you to administer a <u>post-induction</u> alveolar recruitment maneuver while still in the supine position?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

4. During any part of the procedure, how likely are you to increase PEEP to **10 cmH2O or above** in an obese patient undergoing laparoscopic surgery?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

5. How likely are you to use an <u>initial</u> tidal volume of greater than 8 mL/kg of ideal body weight/predicted body weight for an obese patient?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

6. Your patient (**BMI 40 kg/m^2**) is about to undergo laparoscopic pelvic surgery. After being positioned into steep Trendelenberg their oxygen saturation is 99% with stable hemodynamics. How likely are you to administer a <u>post-induction</u> alveolar recruitment maneuver?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

7. How likely are you to keep PEEP the same throughout a case so long as the patient is oxygenating and ventilating adequately?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

8. Your patient presents for a roux-en-y procedure. He is male, **5 foot 9 inches (175 cm)** tall, and weighs **70 kg**. How likely would you be to use an <u>initial</u> tidal volume of **450 mL**:

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

9. Your patient (**BMI is 37 kg/m^2**) is undergoing a laparoscopic total hysterectomy for uterine fibroids. During the <u>maintenance phase</u> of anesthesia in this hemodynamically stable patient, how likely are you to administer an alveolar recruitment maneuver while in Trendelenberg?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

10. How likely are you to routinely increase PEEP upon abdominal insufflation in an obese patient?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

11. Your patient presents for a roux-en-y procedure. He is male, **5 foot 9 inches (175 cm)** tall, and weighs **70 kg**. How likely would you be to use an <u>initial</u> tidal volume of **700 mL**?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

12. How likely are you to administer an alveolar recruitment maneuver <u>every 30 minutes</u> throughout the surgical procedure?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

13. How likely are you to routinely increase PEEP upon placing an obese patient in the Trendelenburg position?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

14. Your patient presents for a roux-en-y procedure. He is male, **5 foot 9 inches (175 cm)** tall, and weighs **200 kg**. How likely would you be to use an <u>initial</u> tidal volume of **700 mL**?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

15. How likely are you to incorporate alveolar recruitment maneuvers as a routine part of your anesthetic plan?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

16. How likely are you to <u>increase</u> PEEP if you notice elevated plateau pressures in an obese patient undergoing laparoscopic surgery?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

17. I was taught in my anesthesia training to deliver tidal volumes of 6-8 mL/kg of ideal or predicted body weight.

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

18. How likely are you to administer an alveolar recruitment maneuver to your patient to improve oxygen saturation prior to adjusting the fraction of inspired oxygen (FiO2)?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

19. How likely are you to titrate PEEP based on driving pressure (plateau pressure minus PEEP) throughout laparoscopic surgery on an obese adult?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

20. How likely are you to consider the BMI of the patient when setting tidal volume for general anesthesia?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

21. How likely are you to administer an alveolar recruitment maneuver to decrease the driving pressure on your obese, hemodynamically stable patient in a steep Trendelenberg position undergoing laparoscopic surgery?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

22. After insufflation and Trendelenburg positioning have been achieved, how likely are you to titrate PEEP at regular time intervals throughout the maintenance phase of the case?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

23. Setting tidal volumes based on ideal body weight in obese patients may contribute to the development of atelectasis.

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

24. How likely are you to incorporate lung protective ventilation strategies as part of your anesthetic plan in obese patients?

Extremely unlikely, very unlikely, unlikely, likely, very likely, extremely unlikely

APPENDIX B: RESULTS ACROSS DEMOGRAPHICS

Role	Total	Anesthesiologist (n =7)	CRNA DNP (n = 12)	CRNA MSN (n = 33)	p-value
Likely to incorporate	4.21 (0.91)	4.57 (0.79)	4.75 (0.62)	3.94 (0.93)	.014
Q1. 200kg, 450ml	2.63 (1.30)	2.29 (1.50)	3.83 (0.83)	2.27 (1.15)	< .001
Q2. 8 ml/kg	1.37 (1.22)	1.43 (1.40)	1.17 (1.59)	1.42 (1.06)	.819
Q3. 70kg, 450 ml	3.00 (1.33)	2.00 (1.63)	4.08 (0.79)	2.82 (1.18)	< .001
Q4. 70kg, 700 ml	0.52 (0.78)	0.29 (0.76)	0.08 (0.29)	0.73 (0.84)	.031
Q5. 200kg, 700 ml	0.92 (1.10)	0.43 (0.53)	0.42 (0.67)	1.21 (1.22)	.041
Q6. 6-8 ml/kg	3.90 (1.43)	3.71 (1.60)	4.67 (0.89)	3.67 (1.49)	.108
Q7. Atelectasis	1.85 (1.18)	2.14 (1.68)	1.25 (1.14)	2.00 (1.03)	.130
Q8. BMI	2.67 (1.52)	2.29 (1.25)	1.83 (1.59)	3.06 (1.43)	.040

Years of experience	0-5 (n = 8)	6-10 (n = 22)	10-15 (n = 13)	> 15 (n = 9)	p-value
Likely to incorporate	4.30 (0.91)	4.50 (0.58)	4.12 (0.99)	4.00 (1.00)	.718
Q1. 200kg, 450ml	2.89 (1.40)	1.50 (1.00)	2.75 (1.16)	2.38 (1.12)	.202
Q2. 8 ml/kg	1.33 (1.27)	0.00 (0.00)	1.50 (1.07)	1.77 (1.17)	.084
Q3. 70kg, 450 ml	3.41 (1.28)	2.25 (2.22)	2.62 (0.92)	2.62 (1.19)	.134
Q4. 70kg, 700 ml	0.37 (0.69)	0.00 (0.00)	0.62 (0.92)	0.92 (0.86)	.090
Q5. 200kg, 700 ml	0.78 (1.05)	0.00 (0.00)	1.12 (1.36)	1.38 (1.04)	.116
Q6. 6-8 ml/kg	4.33 (1.27)	3.25 (2.06)	4.50 (0.76)	2.85 (1.34)	.005
Q7. Atelectasis	1.48 (1.12)	1.50 (1.29)	1.88 (0.99)	2.69 (1.03)	.017
Q8. BMI	2.44 (1.72)	3.00 (1.41)	3.25 (1.16)	2.69 (1.32)	.594

Age	20-30 (n = 8)	31-40 (n = 22)	41-50 (n = 13)	> 50 (n = 9)	p-value
Likely to incorporate	4.12 (0.99)	4.36 (0.90)	4.00 (0.91)	4.22 (0.97)	.723
Q1. 200kg, 450ml	2.88 (1.25)	2.86 (1.46)	2.23 (1.01)	2.44 (1.33)	.504
Q2. 8 ml/kg	1.12 (1.13)	1.09 (1.31)	1.77 (1.01)	1.67 (1.32)	.343
Q3. 70kg, 450 ml	3.88 (0.83)	3.14 (1.52)	2.46 (0.88)	2.67 (1.41)	.089
Q4. 70kg, 700 ml	0.25 (0.46)	0.36 (0.73)	0.62 (0.87)	1.00 (0.87)	.140
Q5. 200kg, 700 ml	0.88 (1.46)	0.68 (0.95)	1.00 (1.08)	1.44 (1.13)	.376
Q6. 6-8 ml/kg	4.75 (0.46)	4.05 (1.53)	3.92 (1.19)	2.78 (1.56)	.030
Q7. Atelectasis	1.12 (1.36)	1.55 (1.06)	2.15 (0.80)	2.78 (1.20)	.008
Q8. BMI	1.88 (1.64)	2.59 (1.65)	3.23 (1.01)	2.78 (1.56)	.257

APPENDIX C: WAKE FOREST IRB APPROVAL LETTER

Association for the Accreditation of Human Research Protection Programs, Inc. Full Accreditation

ARD

WAKE FOREST UNIVERSITY HEALTH SCIENCES

MEMORANDUM

To: Karen Lucisano
Clinical and Translational Science Institute {CTSI}

From: Jeannie Sekits, Senior Protocol Analyst
Institutional Review Board

Date: 7/19/2023

Subject: Exempt Protocol: IRB00098451
Understanding Anesthesia Providers' Utilization of Lung Protective Ventilation Strategies in Obese Patients Undergoing Laparoscopic Surgery

No protected health information will be used or disclosed in this research proposal; therefore the requirement for individual Authorization does not apply.

null (Category null).

Note that only the Wake Forest University School of Medicine IRB can make the determination for its investigators that a research study is exempt. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt. Each project requires a separate review and approval or exemption. The Board must be informed of any changes to this project, so that the Board can determine whether it continues to meet the requirements for exemption.

The Wake Forest School of Medicine IRB is duly constituted, has written procedures for initial and continuing review of clinical trials; prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with requirements of FDA regulations 21 CFR Parts 50 and 56, HHS regulations 45 CFR 46, and International Conference on Harmonisation (ICH) E6, Good Clinical Practice (GCP), as applicable. WFSM IRB is registered with OHRP/FDA; our IRB registration numbers are IRB00000212, IRB00002432, IRB00002433, IRB00002434, IRB00008492, IRB00008493, IRB00008494, and IRB00008495.
WFSM IRB has been continually fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2011.

Medical Center Boulevard, Winston-Salem, NC 27157-1023 (336) 716-4542 / fax (336) 716-4480

APPENDIX D: UNIVERSITY OF NORTH CAROLINA AT CHARLOTTE IRB APPROVAL LETTER

CHARLOTTE
DIVISION OF RESEARCH

To: Cameron McClane
University of North Carolina at Charlotte

From: Office of Research Protections and Integrity
Approval Date: 25-Jul-2023
RE: Notice of Determination of Exemption
Exemption Category: 2
Study #: IRB-24-0045
Study Title: Understanding Anesthesia Providers' Utilization of Lung Protective Ventilation Strategies in Obese Patients Undergoing Laparoscopic Surgery

This submission has been reviewed by the Office of Research Protections and Integrity (ORPI) and was determined to meet the Exempt category cited above under 45 CFR 46.104(d). This determination has no expiration or end date and is not subject to an annual continuing review. However, you are required to obtain approval for all changes to any aspect of this study before they can be implemented and to comply with the Investigator Responsibilities detailed below.

Your approved consent forms (if applicable) and other documents are available online at Submission Page.

Investigator's Responsibilities:

1. Amendments **must** be submitted for review and the amendment approved before implementing the amendment. This includes changes to study procedures, study materials, personnel, etc.
2. Researchers must adhere to all site-specific requirements mandated by the study site (e.g., face mask, access requirements and/or restrictions, etc.).
3. Data security procedures must follow procedures as described in the protocol and in accordance with OneIT Guidelines for Data Handling.
4.Promptly notify the IRB office (uncc-irb@charlotte.edu) of any adverse events or unanticipated risks to participants or others.

5.Five years (5) following this approval/determination, you must complete the Admin-Check In form via Niner Research to provide a study status update.
6.Be aware that this study is included in the Office of Research Protections and Integrity (ORPI) Post-Approval Monitoring program and may be selected for post-review monitoring at some point in the future.
7. Reply to the ORPI post-review monitoring and administrative check-ins that will be conducted periodically to update ORPI as to the status of the study.
8. Complete the Closure eform via Niner Research once the study is complete.

Please be aware that approval may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records).