SCHOLARLY PAPER: RISK FACTORS AND NAUSEA PROPHYLAXIS IN THE GYNECOLOGICAL (GYN), UROLOGICAL, AND EAR NOSE AND THROAT (ENT) SURGICAL POPULATION IN URBAN HOSPITAL SURGICAL POPULATION

by

Abby Catherine Sanders

A doctoral scholarly project submitted to the faculty of
The University of North Carolina at Charlotte
in partial fulfillment of the requirements
for the degree of Doctorate in Nursing Practice

Charlotte

2023

Approved by:

_____

Dr. Stephanie Woods

_____

Dr. Karen Lucisano

_____

Dr. Jenny Dhingra

_____

Dr. Shanti Kulkarni

_____

Dr. Shue McGuffin

ABSTRACT

ABBY CATHERINE SANDERS. Risk Factors and Nausea Prophylaxis in the Gynecological (GYN), Urological, and Ear, Nose and Throat (ENT) Surgical Population at an Urban Surgery Center
(Under the Direction of DR. STEPHANIE WOODS PHD)

This is a quality improvement (QI) project that examines post-op nausea and vomiting prophylaxis (PONV) and PONV in the Post Anesthesia Care Unit (PACU) in an Urban Hospital system. The clinical question for this QI project is: In the population of Gynecological (GYN), Urological, and Ear, Nose, and Throat (ENT) surgical patients 18 years and older, how does patient, anesthetic, and surgical risk factors for PONV and the delivery of antiemetics affect the incidence of PONV in the Urban setting?

The purpose of this project was to compare anesthetic, surgical, and patient risk factors with the number of antiemetics given, in order to determine anesthesia providers compliance with the Fourth Consensus Guidelines. Data related to patient, anesthetic, and surgical risk factors, and PONV in the PACU was collected via chart review. Data analyses were conducted to determine patient, anesthetic, and surgical risk factors, and PONV prophylaxis administration.

The Apfel score was not significantly associated with actual antiemetics. There was also no significant association between patient, anesthesia, and surgical risk factors and the risk for PONV. The percent of PONV at the Urban facility was 14.29%. Overall, 42.9% of patients did not receive the correct number of antiemetics. Education to improve the knowledge gap between understanding of the Fourth Consensus Guidelines and the application of its antiemetic interventions into practice is recommended to improve adherence to guidelines.

Keywords: PONV, gynecologic, ENT, Urologic, surgery, urban, anesthesia

TABLE OF CONTENTS

LIST OF TABLES

CHAPTER 1: INTRODUCTION/BACKGROUND

While antiemetic therapy has evolved over the past decade, those with the following risk factors: female gender and undergoing breast, middle ear, gynecological or obstetrical surgery, still experience a 70% incidence of postoperative nausea and vomiting (PONV) (Ugochukwu, 2010). Additionally, according to Smith et al. (2012), PONV is "one of the most commonly reported adverse effects of anesthesia" (p. 94). Excessive PONV leads to deleterious health effects such as electrolyte imbalance, dehydration, hypotension, and other systemic complications (Bhakta et al., 2016). The economic implication of PONV is also significant. A delay in surgical turnover due to PONV can lead to substantial financial losses (Girotto et al., 2010). In a study at the University of Rochester Medical Center, it was found that each hour of unused operative time cost $3,600 (Girotto et al., 2010).

Many risk factors can contribute to the development of PONV in surgical patients. These include patient, anesthetic, and surgical risk factors. Combining multiple risk factors can increase the potential risk for PONV development. Patient risk factors that contribute to PONV in the adult patient include female gender, nonsmoker, history of PONV and/or motion sickness, and receiving opioid analgesia (Murphy et al., 2006).

PROBLEM STATEMENT

Prevention of PONV requires assessing patient risk factors and treating the likelihood of PONV with antiemetics. A nationally recognized scoring system has been created by Apfel and his colleagues based on the consensus guidelines. The Apfel-score includes four associated risk factors for PONV: female gender, non-smoker, postoperative opioid use, and previous PONV or motion sickness (Weilbach et al., 2006). According to Apfel et al. (1999), if the patient has one risk factor, there is a 10-21% incidence of PONV. This percent risk increases to 29-78% in

patients who exhibit two or more risk factors. Each risk factor increases the percent chance of PONV by 20%, with the baseline risk never being less than 10% (Weilbach et al., 2006). Once the number of risk factors the patient presents with is identified, an estimation of how many antiemetics the patient needs is made based on the Apfel score. With a risk score of 0, no antiemetics are recommended, a score of 1-2 indicates 2 antiemetics should be given, and a score of 3-4 means 3 or more antiemetics should be administered (Gan et al., 2020).Additionally, it is important to utilize combination therapy in high-risk patients, by using antiemetic drugs of different classes in order to cover all possible physiologic receptors (Gan et al., 2020).

General anesthesia also increases the risk for PONV. Volatile anesthetics, the primary source of anesthesia for general anesthesia surgeries, independently increases PONV (Morino et al., 2012). While the exact etiology is unknown, volatile anesthetics are thought to stimulate several of the afferent pathways which stimulate vomiting (Horn et al., 2014). Nitrous Oxide is an inhalational anesthetic commonly used in the operating room. A significant decrease in PONV has been noted when nitrous oxide was avoided (Shaikh et al., 2016).

Long-acting opioids, such as morphine, are used for pain management in the postoperative anesthesia care unit (PACU) and have an increased risk for respiratory depression, urinary retention, pruritus, and PONV (Lim et al., 2016). The use of postoperative opioids doubles the risk of PONV (Pierre et al., 2003). In addition to the use of long-acting postoperative opioids, short-acting opioids like fentanyl and remifentanil are commonly used to blunt surgical stimulation during the beginning of the case. Lim and colleagues (2016) reported that patients who received 2mcg/kg of fentanyl during induction of anesthesia had a higher incidence of PONV.

With an increased length of surgery comes an increased risk for PONV. There are multiple theories and potential hypotheses of why this occurs. Shaikh et al. (2016) estimates that a surgery duration greater than 30 minutes increases the risk of PONV by up to 60%. The quality improvement project will also be assessing the patient's surgery duration as a variable in the risk of developing PONV.

PURPOSE OF THE PROJECT

Negative Patient Health Sequela

Many patients undergoing surgery continue to have an unacceptably high level of PONV. PONV can cause adverse patient health sequelae, which can have detrimental consequences for the patient. In research from Bhakta et al. (2016), postoperative nausea may lead to persistent vomiting, which can cause pulmonary aspiration syndrome, electrolyte imbalances, and dehydration. Excessive retching can lead to even more severe effects such as wound closure, bleeding, tension on suture lines, and venous hypertension (Manahan et al., 2013). In non-ambulatory surgery, the negative health effects caused by PONV can lead to increased perioperative morbidity, increased length of stay, prolonged overall recovery, and thus increase overall costs (Smith et al., 2012).

Financial Burden of PONV

The financial burden of PONV is estimated to be $1.5 million per year in lost surgical revenue (Masiongale et al., 2018). When evaluating the overall cost of PONV, hospitals have looked at the financial benefit of prophylactic treatment versus rescue treatment once the patient developed symptoms. A study at Duke University found that prophylaxis was more cost-effective and provided greater patient satisfaction than rescue treatment (Gress et al., 2020). In an audit done in the post-anesthesia care unit (PACU), supplies and medications accounted for

only 2% of the charges, with most charges coming from an increased length of stay (Gress et al., 2020).

Additionally, Gress and colleagues (2020) found that patients who did not suffer from PONV had a PACU stay duration of 171 minutes. This duration increased to 234 minutes in patients with PONV (Gress et al., 2020). Another study also showed that each event of emesis increases patient time in the PACU by an additional 20 minutes (Gress et al., 2020). Increased time in the PACU drives up the financial burden by increasing the supplies used, nursing staff needed, and backs up the surgical schedule (Parra-Sanchez et al., 2012).

PICO QUESTION

PICO: In the population of Gynecological (GYN), Urological, and Ear, Nose, and Throat (ENT) surgical patients 18 years and older, how does patient, anesthetic, and surgical risk factors for PONV and the delivery of antiemetics affect the incidence of PONV in the Urban setting?

Intra-operative processes that influence the risk for PONV include patient variables as measured by the Apfel score, anesthetic variables, surgical variables, and antiemetics administered. There are 4 specific aims derived from the PICO for this project. Aim one, patients were given an individual Apfel score based on their risk factors for PONV. Aim two determined the relationship between the Apfel score and the number of antiemetic medications administered during the intraoperative period. Aim three assessed the prevalence of anesthetic and surgical risk factors including the use of Nitrous Oxide, volatile agents, intraoperative opioids, such as fentanyl and remifentanil, and surgery length greater than 30 min. Aim four assessed PACU charting to determine if the patient developed PONV.

LITERATURE REVIEW

A literature review was conducted between January 2022 and March 2022. Databases searched included PubMed, Cochrane Database of Systematic Reviews (CDSR), Google Scholar, and ScienceDirect. The keywords used were PONV, gynecologic, surgery, surgery centers, urban, trauma, Fourth Consensus Guidelines, risk factors, nausea, PACU, volatile anesthetics, opioids, Nitrous Oxide, length of surgery, vomiting, antiemetics, negative health sequelae, and financial burden. The literature review included research studies and articles published from 1999 to 2022. Inclusion criteria were peer-reviewed articles beginning after 1999, written in the English language with full text availability. Exclusion criteria were articles that were published prior to 1999, were not in the English language, and were not peer-reviewed.

Patient Risk Factors

Female Gender

The female gender is an independent risk factor for PONV due to endocrine and hormonal differences after puberty (Golembiewski & O'Brien, 2002). Women experience PONV 3 times more often than males. When this risk factor is also combined with gynecological surgery, the incidence of PONV in this population is approximately 45%, significantly higher than the 30% average for other surgical populations (Apfel & Roewer, 2003).

The risk of PONV between the genders is significant when determining the overall risk factors for PONV in the adult surgical patient. Pierre et al. (2002) found when examining the incidence of PONV, males had a lower incidence of PONV when compared to females. Another difference regarding PONV is that females often already have the underlying risk factor of motion sickness or previous PONV, while males do not (Krieser et al., 2020). A study comparing

the number of prophylactic agents given for PONV prevention showed that even with computer guidance, females received inappropriate PONV prophylaxis while undergoing general anesthesia when compared to their male counterparts (Krieser et al., 2020). For example, 96% of the time females received inappropriate prophylaxis, compared to males only receiving inappropriate prophylaxis 5% of the time (Krieser et al., 2020). This study supports that females are at a higher risk of developing PONV and are often given inadequate PONV prophylaxis, contributing to the overall increased incidence of PONV in the female patient (Krieser et al., 2020).

Age

Age also impacts the risk for PONV in the surgical patient. The highest incidence for PONV occurs in the adolescent population and has an inverse relationship with increasing age (Apfel & Roewer, 2003). The peak incidence of PONV is in school-age children, and it is not increased in females until after puberty (Rose & Watcha, 1999). This is due to the changes in female hormonal balance.

Nonsmokers

Nonsmokers have an increased incidence of PONV when compared to smokers. Although the cause of a decreased incidence associated with PONV in smokers has not been determined, there are many potential reasons. Smokers are exposed to the chemicals in tobacco smoke which may desensitize them to volatile anesthetics or cause cytochrome p450 upregulation and an increased metabolism of volatile anesthetics (Werner et al., 2008). Because the use of volatile anesthetics increases the risk for PONV, this may be a significant factor for the decreased level of PONV found in smokers (Morino et al., 2012)

History of PONV/Motion Sickness

A history of PONV and/or motion sickness increases the risk for PONV due to the disturbance of the vestibular apparatus in the inner ear. The vestibular system senses body position and helps with balance (Hromatka et al., 2015). The vestibular system also aids in sensing toxins that may contribute to PONV and need to be excreted from the body (Hromatka et al., 2015). Consequently, a disturbance to the vestibular system (i.e. a history of PONV and/or motion sickness) increases the risk for PONV (Hromatka et al., 2015).

Anesthetic Risk Factors

Volatile agents

Using volatile agents to perform a balanced general anesthetic is standard practice. The three most common volatile anesthetics used today include Sevoflurane, Isoflurane, and Desflurane. These volatile agents are used to induce and maintain anesthesia throughout surgery. Volatile anesthetics are associated with a two-fold increase in the risk of PONV (Pierre & Whelan, 2012). The risk of PONV increases with increasing the dose of volatile agent (Pierre & Whelan, 2012). It has been shown that the use of volatile anesthetics is the most important factor in predicting nausea and vomiting within the first two postoperative hours (Pierre & Whelan, 2012). Substituting propofol for a volatile anesthetic while performing total intravenous anesthesia (TIVA) reduces the risk of PONV by about 19% (Fernandez-Guisasola et al., 2020). However, no significant difference between these different volatile agents and their effect on PONV have been shown (Pierre & Whelan, 2012).

Nitrous Oxide

The emetogenic effects of Nitrous Oxide is a well discussed topic in the literature and within the hospital setting. Avoiding Nitrous Oxide can reduce the risk of PONV by 20% (Fernandez-Guisasola et al., 2020). Data shows that the increase in PONV that is seen with the

administration of Nitrous Oxide is highly dependent on the duration of exposure (Peyton & Wu, 2014). The emetogenic effects of Nitrous Oxide are not typically significant until one hour of exposure (Peyton & Wu, 2014), offering the anesthesia provider some assurance that the use of short-term Nitrous Oxide will not increase the chances of PONV. A common practice for Nitrous Oxide also includes its use at the end of surgery to help decrease the amount of maintenance volatile anesthetic being used. This helps provide amnesia towards the end of the case while also supporting a rapid wake up. Nitrous Oxide when used for a rapid wakeup has not been found to cause PONV (Peyton & Wu, 2014).

Opioids

Another anesthetic agent contributing to PONV includes opioids (Shaikh et al., 2016). Opioid receptors are located in the Chemoreceptor Trigger Zone (CTZ). The CTZ is located outside of the blood-brain barrier and allows substances in the blood and cerebrospinal fluid (CSF) to interact. Toxins or drugs, such as opioids traveling in the blood stimulate the CTZ. This stimulation sends triggers to the vomiting center of the brain, causing nausea and vomiting (Shaikh et al., 2016).

Surgical Risk Factors

Surgery Duration

Surgery duration is a strong predictor of PONV. If operating time is increased by 30 minutes, the risk for PONV may be increased by as much as 60% (Shaikh et al., 2016). It is hypothesized this is because surgery duration is directly linked to increased exposure to volatile anesthetics and potentially additional intraoperative opioid administration, both of which are emetogenic substances (Pierre, S. & Whelan, R., 2013). With increased surgical duration and an

increase in delivery of volatile anesthetics, there is an increased risk of PONV. There is a gap in the literature regarding whether the surgery duration reaches a peak emetogenic effect.

Type of Surgery

Patients undergoing some types of surgeries are more at risk for PONV than others. There is an increased risk of PONV in gynecological surgery compared to other surgical populations. According to Shaikh et al. (2016), this increased risk may be due to the location of the surgery and the potential for delays in gastric emptying, which also increases the risk of PONV. Additionally, the afferent vagal pathways are in the gastrointestinal system, which when stimulated, can activate the sensation of vomiting (Shaikh et al., 2016).

The risk of PONV following ENT surgery can be as high as 70% (Erkalp et al., 2014). One potential cause is the flow of blood entering the stomach during the procedure. The literature is undecided on whether gastric decompression following the procedure will improve the incidence of PONV or not. Other potential causes of PONV stemming from ENT surgery are stimulation of the chemoreceptor trigger zone, and stimulation of the trigeminal nerve which causes an activation of chemoreceptors and mechanoreceptors in the stomach and oropharynx (Erkalp et al., 2014).

There is currently insufficient data establishing the incidence of PONV following urologic surgery (Vukovic & Dinic, 2018). One study by Stadler et al. (2003) found that patients undergoing urology surgery have an increased risk of developing PONV compared to vascular and orthopedic surgery and less of an incidence when compared to GYN and maxillofacial surgery.

Fourth Consensus Guideline

Prevention of PONV is essential in the surgical patient. The risk factors for PONV can be patient-specific, anesthetic-specific, and surgery-specific. The Fourth Consensus Guideline promotes the assessment and calculation of the total number of patient risk factors. Giving the appropriate PONV prophylaxis medications based on patient risk factors reduces the rate of PONV (Gan et al., 2020).

Per the Fourth Consensus Guidelines, the number of risk factors that a patient has determines the number of PONV prophylaxis medications to be given. According to Gillman et al. (2019) "Adherence to PONV prophylaxis guidelines … is still remarkably low" (p. 408). Additionally, "Less than half of medium to high-risk patients receive the appropriate PONV prophylaxis" (Kumar et al., 2012, p. 58). If a patient has one to two risk factors, they should receive two prophylactic agents, and if they have greater than two risk factors, they should receive three to four prophylactic agents (Gan et al., 2020).

The Consensus Guideline also decreased the threshold for administering PONV prophylaxis to make multimodal PONV prophylaxis a common practice. The Fourth Consensus Guideline now recommends that adults with one or more risk factors receive multimodal PONV prophylaxis due to concerns that these patients were not receiving adequate prophylaxis. In support of compliance with the Consensus Guidelines, the Centers for Medicare and Medicaid Services has established a "merit-based incentive payment system (MIPS)" for those who follow the PONV prophylaxis protocol (Gan et al., 2020).

Antiemetics

Many antiemetic medications can be utilized for the prevention of PONV. Antiemetic classes are 5HT3 receptor antagonists, NK-1 receptor antagonists, corticosteroids,

antidopaminergics, antihistamines, anticholinergics, and additionally other antiemetics such as gabapentin and midazolam. These drugs can be used in combination therapy for the prevention of PONV. It was found that the combination of two or more antiemetics for prophylaxis for adults is superior to only utilizing one agent for prophylaxis (Gan et al., 2020).

Dexamethasone, a corticosteroid, ondansetron, a 5HT3 receptor antagonist, and droperidol, a dopamine antagonist, show equal efficacy in preventing PONV (Apfel et al., 2004). However, the low cost and high safety profile of dexamethasone make it an attractive first line agent for PONV (Apfel et al., 2004). Dexamethasone shows greatest efficacy when used at the beginning of surgery to decrease surgery related inflammation and is not effective as a rescue agent. Saving 5HT3 receptor antagonists to utilize as rescue treatments may be the best course of action in the management of PONV (Apfel et al., 2004). Droperidol has fallen out of favor due to causing dysphoria, as well as for the black box warning for its potential to cause torsades de pointes, a lethal heart rhythm. Additionally, droperidol, while effectively decreasing PONV in females, shows no risk reduction for men (Apfel et al., 2004).

Additional antiemetics such as scopolamine, a centrally acting anticholinergic and aprepitant, which is a NK-1 receptor antagonist is also effective in preventing PONV. Although a scopolamine patch is a cheap, highly effective drug for preventing PONV, it should be avoided in pediatric and elderly patients, as it does have negative side effects such as dry mouth, drowsiness, and visual disturbances (Elvir- Lazo et al., 2020; Kassel et al., 2018; White et al., 2007). A study by Gan et al. (2007) shows that aprepitant is superior to preventing vomiting when compared to ondansetron. However, because of its high cost, it should be reserved for extremely high-risk patients (Elvir-Lazo et al., 2020).

Prior research has established that adherence to the guidelines results in a significant decrease in PONV (Stephenson et al., 2021). However, minimal research has been conducted to determine facility compliance with the Fourth Consensus Guidelines. Current research has found a knowledge gap between understanding of the Apfel scoring system and the consistent application of its antiemetic interventions into practice (Devarakonda et al., 2022). Routine education on utilizing the Apfel score as well as staff reminders to administer the proper prophylactic agents aids in significantly decreasing the percent of patients who develop PONV (Devarakonda et al., 2022). Even when antiemetics are administered, if they are not administered appropriately according to the protocol, they will not assist in preventing PONV (Gillman et al., 2019).

Research from Öbrink et al. (2015) shows preventing PONV has a four-tiered pyramid approach. The foundation begins with assessing and scoring patients PONV risk factors utilizing the Apfel scoring system. This is used in combination with providing a multi-modal opioid sparing anesthetic. The next level emphasizes the use of multi-modal PONV prophylactic medications. A step up provides a tailored anesthetic plan specific for each patient and their risk factors. Finally, if these three steps fail, rescue therapy in the form of a different class of antiemetics as the final step in the escalating pyramid (Öbrink et al., 2015).

Inappropriate PONV prophylaxis was associated with an 11% incidence of PONV compared to a 4% incidence with appropriate PONV prophylaxis according to the protocol (Gillman et al., 2019). Additionally, Gillman et al. (2019) found that compliance to the PONV prophylaxis protocol varied between surgical populations, with gynecological surgical patients only having adherence 41% of the time while urological surgical patients had a 72% adherence rate. It was also discovered that the rates of insufficient PONV prophylaxis were more

significant than both overshooting and correct PONV prophylaxis combined (Gillman et al., 2019). Gillman et al. (2019) discovered that patients with an Apfel score of 3 or greater received insufficient PONV prophylaxis in more than 50% of the cases. The study supports the need for further research on patient, anesthetic, and surgical risk factors for PONV as well as determining the compliance with the PONV prophylaxis guidelines in gynecologic, ENT, and urologic surgical patients.

Outcome Variable

PONV in the PACU

The outcome variable that was assessed was postoperative nausea and/or vomiting in the PACU. It is well established that PONV increases the PACU stay and increases resources utilized (Habib et al., 2006). Vomiting is especially detrimental, as it costs nearly 1.5 times more than an episode of nausea in the PACU costs (Habib et al., 2006). As said by Ghosh et al. 2020, although in the recent years we have seen improved anesthesia drugs, equipment, and numerous research on PONV, the incidence of PONV is still relatively high.

PONV in the Urban Perioperative Setting

Major Urban Hospitals

Major urban hospitals tend to be large teaching hospitals with more operating rooms, a high surgical volume, higher nursing ratios, and more inpatient bed availability compared to rural or suburban hospitals (Ibrahim, Hughes & Thumma, 2016). More than 25% of all surgeries performed in adult women are Obstetric and GYN procedures (Borahay et al., 2020). Of the 4 million GYN surgeries performed in the United States annually, 1.5 million are performed in the inpatient setting such as a large urban hospital (Borahay et al., 2020). Similarly, Urologic and ENT procedures are commonly performed at large Urban hospitals due to the increased

operating room space, supplies, staff, and inpatient beds. Urban hospitals have a higher number of patient beds and can provide care to a greater volume of patients than suburban hospitals (Andrulis et al., 2007). With larger capacity comes the ability to perform more surgeries per day. Patients undergoing surgery in larger urban, teaching institutions typically are in need of more complex surgical procedures and have multiple comorbidities, putting them at risk for an increased risk of complications such as PONV (Ibrahim et al., 2016).

Overall Summary

The Fourth Consensus Guideline for the Prevention of PONV is a valuable tool for guiding the management of PONV in the perioperative setting. There is a gap in the literature in determining whether anesthesia providers administer additional antiemetics based on patient, anesthetic, and surgical risk factors. Patients undergoing general anesthesia still experience 30% incidence of PONV (Pierre, S. & Whelan, R., 2013). Patient risk factors that contribute to PONV in the adult population include female gender, younger age, nonsmoker, surgery type, history of PONV and/or motion sickness, and receiving postoperative opioid analgesia (Murphy et al., 2006). Anesthetic risk factors include Nitrous Oxide, volatile anesthetics, and opioids. Surgical risk factors include length of surgery greater than 30 minutes. The outcome variable that will be assessed is PONV in the PACU. Understanding how risk factors for PONV influence the patient's anesthetic will ultimately help mitigate adverse patient health sequelae and decrease the financial burden caused by PONV.

CONCEPTUAL FRAMEWORK

The Plan-Do-Study-Act method was used to organize the research strategy. By using this conceptual framework method, one is able to clearly organize research tactics and improve upon outcomes. As mentioned by Coury et al. (2017), benefits of the Plan-Do-Study-Act method

include providing structure for the researcher to focus on a step-by-step plan for implementation of research, as well as allowing the researcher to improve upon outcomes.

Plan/Do: This project laid a foundation for a quality improvement project on PONV following GYN, Urology, and ENT procedures. A literature review on patient, anesthetic, and surgical risk factors for PONV was conducted. Additionally, the review of literature included PONV prophylaxis, negative health sequelae related to PONV, and the financial burden of PONV. Next, chart reviews were performed at an urban hospital to determine patient, anesthetic, and surgical risk factors, and PONV prophylaxis administration.

Study: After the data from the urban hospital was collected, it was analyzed and results were gathered. The incidence of PONV was determined based on postoperative anesthetic chart review. Finally, the data collected on the outcome variable, PONV in the PACU, was analyzed and compared to the number of patient, anesthetic, and surgical risk factors the patient had, as well as the number and type of PONV prophylactic medications given. The data was reviewed to determine the compliance by assessing if the number of patient risk factors is consistent with the number of PONV prophylactic medications given, as outlined by the Fourth Consensus Guidelines.

Act: Future Quality Improvement projects can determine barriers to appropriate PONV prophylaxis and differences in anesthetics. A meeting with the urban facility can be held to offer recommendations to improve PONV prophylaxis and minimize the number of modifiable risk factors. Additionally, education can be done to improve providers' knowledge on patient, anesthetic, and surgical risk factors for PONV and the recommended prophylactic treatment

CHAPTER II: METHODOLOGY

PROJECT DESIGN, TIMING, AND DATA COLLECTION METHODS

The project design for this quality improvement project on risk factors and nausea prophylaxis in the Gynecological (GYN), Urologic, and Ear Nose and Throat (ENT) surgical population was a descriptive design. A descriptive design places emphasis on objective measurements and statistical, mathematical, or numerical analysis of data collected without changing the current environment (Babbie, 2010; Nebeker, n.d.). This project consists of data collection from an urban hospital. Data was collected on the number of GYN, urologic, and ENT patients who received appropriate prophylaxis for nausea based on the Apfel score for Postoperative Nausea and Vomiting (PONV) as well as additional anesthetic and surgical risk factors.

SETTINGS/DEMOGRAPHICS

Urban Hospital

This Quality Improvement project was conducted at a major urban trauma center that has a large operating room capacity with 46 operating rooms available, not including several non-operating room anesthesia (NORA) sites. Up to 60 different types of surgeries are completed per day; specific to this project, approximately 6 GYN, 10 urologic, and 8 ENT surgeries are completed per day (Atrium Health, 2022).

The urban hospital serves a diverse socioeconomic community that is predominantly White (Niche, 2022). The neighborhood is evenly split with 49% males and 51% females, and a median age of 35. Additionally, 44% of residents are couples, 28% are single-male families, 28% are single-female families, and 16% are families with children. With over 97% having a high

school degree, 45% of the community holding a bachelor's degree and 34% have completed graduate school.

SAMPLE

Determining the sample size and composition was a crucial step to the continued implementation of the DNP project. To have a diverse sample of men and women this scholarly project included patients undergoing several surgical procedures that typically experience PONV: GYN, ENT, and urologic surgeries. Data was collected from chart review of patients who met the inclusion criteria of patients over the age of 18 receiving general anesthesia for GYN, ENT, and urologic surgeries and were cared for by certified registered nurse anesthetists (CRNAs) that maintain employment at urban data collection site. Convenience sampling was used for this project and is often used based on the accessibility in obtaining the data (Lavrakas, 2008). The convenience sample for this project consisted of the first 11 people undergoing gynecological surgery, 12 persons undergoing urological surgery, and 12 people undergoing ear, nose, and throat surgery at the Urban hospital setting. An close to equal number of patients from each surgical population was acquired.

Chart review and data collection occurred for those participants meeting the project inclusion criteria and who had surgery between the dates of August 1, 2022, and August 31, 2022. The inclusion criteria are individuals over the age of 18 years old, who had GYN, ENT, or Urology procedures performed under general anesthesia. The exclusion criteria are individuals under the age of 18 years old, who did not have general anesthesia, or who did not undergo GYN, Urology, or ENT procedures.

TOOLS/MEASUREMENTS

An excel spreadsheet was created with a list of patient, anesthetic, and surgical risk factors for PONV, as well as the prophylactic antiemetics that are outlined in the Fourth Consensus Guidelines (1999). Patient risk factors for PONV as outlined by Apfel et al. include female gender, nonsmoker, history of PONV or motion sickness, and receiving opioid analgesia post-operatively (Murphy et al., 2006). Anesthetic risk factors assessed include the use of Nitrous Oxide, volatile anesthetics, and intraoperative opioids such as remifentanil and fentanyl. Finally, the surgical risk factor assessed was the length of surgery being greater than 30 minutes. The antiemetic drugs for the prevention of PONV that are outlined in the Fourth Consensus Guidelines include 5-hydroxytryptamine (5-HT 3) receptor antagonists, neurokinin-1 (NK-1) receptor antagonists, corticosteroids, antidopaminergics, antihistamines, anticholinergics, gabapentin, intramuscular Ephedrine, and Midazolam given at the end of the case (Gan et al., 2020). This information was added to the data collection sheet for performing chart reviews.

METHODS

The sample population was limited to 35 patients aged 18 years or older undergoing GYN, urologic, and ENT procedures between August 1, 2022, and August 31, 2022. This included the first 35 patients which meet the inclusion criteria from each surgery type: GYN, urologic and ENT. The sample was collected from the electronic health record (EHR). Data collection remained consistent by setting limitations on the sample population. The data collection sheet outlined above was utilized to organize the data.

Once a thorough and well-planned data collection sheet was created, an EHR champion was recruited to decode the EHR. The EHR champion was educated on the risk factors and prophylactic medications for PONV before they collect the data from the EHR charts. The EHR

champion provided education on how data on PONV risk factors and prophylactic medications are recorded in the chart. This allowed the ability to be confident the variables needed were accurately conveyed on the data collection sheet.

Once the data was collected, each patient encounter was assessed on four variables. First, the patient received an Apfel score of 0-4 based on patient risk factors for PONV as outlined above. Second, additional anesthetic and surgical risk factors were tallied. Third, the amount and type of antiemetics the patient received during the intraoperative period was counted. Finally, an assessment of compliance with the Fourth Consensus Guidelines was determined based on the number of antiemetics given compared to the number of patient risk factors. Compliance was determined by comparing this data to the recommended number of prophylactic agents as outlined by the Apfel score. After these four variables were assessed and counted, a tally of each individual risk factor was counted for all 35 patients.

Accuracy of data retrieved from the chart was ensured by limiting the sample to patients aged greater than 18 and undergoing GYN, Urologic, and ENT procedures, as well as by reviewing the same patient, anesthetic, and surgical risk factors, and prophylactic medications for each patient. The data collector thoroughly reviewed the input placed in the excel sheet to ensure it was accurate. Close communication with the data collector continued to answer any questions which arose.

INTERVENTION/PROJECT PROTOCOL

The data collection protocol consisted of a patient, anesthetic, and surgical risk factors, antiemetic, and PONV in the PACU at the Urban facility. Data collection occurred from August 1, 2022 to August 31, 2022. This provided an ample amount of time to achieve a sample size of 35 patients having GYN, Urological, or ENT surgery. Once data was collected, the

statistical analysis was completed, and a conclusion formed based on the statistical significance of the data results.

DATA MANAGEMENT STRATGIES & CONFIDENTIALITY OF DATA

The EHR used was Epic. To protect patient privacy, only the data collector had access to identifying patient data. The sample population was de-identified before the researcher was granted access to the patient data. The patient names and MRN numbers were only available to the data collector and not listed in the data collection sheet. The data management program used was Excel.

TIMELINE

Chart reviews began August 1, 2022. Analysis of the data occurred September of 2022. The final draft of the project defense began in the beginning of October of 2022. The final written project defense was submitted in November 2022. The oral defense of the project was presented in the beginning of December 2022.

DATA ANALYSIS AND EVALUATION

Data analysis was completed with basic descriptive statistics. After data was collected and compiled, missing data was identified and managed. The identification and management of the missing information was an essential step in evaluating the data that was collected.

The statistical analysis was conducted based on the DNP project clinical question. Descriptive analysis of the sample characteristics was conducted on data gathered from the urban surgical facility. Descriptive analysis included a description of the sample, risk factors and PONV prophylactic medications. The mean Apfel score, the mean number of anesthetic risk factors, the mean number of surgical risk factors, as well as the mean number of antiemetics given was determined. A paired t-test was used to calculate the statistically significant difference

between the mean of each individual risk factor. Additionally, descriptive analysis of the data was collected and the Apfel scores were completed and summed. This included the frequency for the individual patient risk factors according to the Apfel score, anesthetic risk factors, and surgical risk factors. For example, the number of patients who received Nitrous Oxide. These frequencies were turned into a percentile. Next, the aggregate mean Apfel score was calculated and compared with the aggregate mean number of prophylactic antiemetic medications given to determine the Urban facility compliance with the Fourth Consensus Guidelines.

ANALYSIS DESCRIPTION

The data-collection correlation was done utilizing multiple linear regression. The number of patient risk factors was correlated to the number of prophylactic medications given. The number of patient risk factors was also correlated to whether the patient experienced PONV. This determined if a higher number of patient risk factors correlated to more prophylactic agents being given, and if more risk factors equate to a higher incidence of PONV. This also determined if there was statistically significant data between what was the expected amount of antiemetics given and the actual amount given. It was expected that with increased patient risk factors, there should be an increase in the number of PONV prophylactic medications given. On the contrary, it was also expected that more risk factors will show a higher incidence of PONV.

CHAPTER III: FINDINGS

Aim 1: The patient was given an individual Apfel score based on their risk factors for PONV which include female gender, history of PONV and motion sickness, non-smoker, and the administration of postoperative opioids. The patient population for this quality improvement project included 35 patients undergoing GYN, ENT, and Urology surgery at an Urban hospital. Table 1. shows the percent of each risk factor for PONV that was accounted for in this surgical

population. Of the 35 patients, 65.71% were female. A low percentage of 2.86% of the patients had a history of PONV or motion sickness. The highest risk factor for PONV which was found in this surgical population was being a non-smoker. Of the 35 patients, 92.29% of patients were non-smokers. Finally, 28.57% of patients were administered postoperative opioids.

Table 1.

Apfel Risk Factors Descriptive Statistics

Apfel score risk factors	Urban (n = 35)
Female	65.71
History of PONV/motion sickness	2.86
Non smoker	94.29
Post op opioids	28.57

Note. All values are percentages

From these individual risk factors an Apfel score was created. The Apfel score is an assigned number the patient received which correlated to their risk for PONV. The average Apfel score was 1.9, with a standard deviation of 0.84. The lowest was 0 and the highest score was 4. The mode was 2.

Table 2.

Apfel Score Descriptive Statistics

Apfel score:	
Average	1.9
Standard Deviation	0.84
Minimum	0
Maximum	4
Mode	2

Aim 2: The second aim determined the relationship between the Apfel score and the number of antiemetic medications administered during the intraoperative period. Multiple linear regression tested associations of Apfel, anesthesia risk, surgical risk with actual antiemetics

given. Apfel was not significantly associated with actual antiemetics, nor did the anesthesia risk factor or the surgical risk factors predict actual antiemetics. Paired-sample *t*-test showed that the actual antiemetics given ($M = 2.03$, $SD = 0.76$) was not significantly different from the expected antiemetics ($M = 2.23$, $SD = 0.94$), $t = 1.04$, $p = .304$ which are given based on the Apfel score.

Table 3 shows that actual antiemetics administered v. recommended number and highlights several important factors. First, the Fourth Consensus Guidelines does not recommend the administration of any antiemetics for patients with 0 risk factors for PONV. However, two patients had zero risk factors for PONV, and both received 3 antiemetics. For patients with an Apfel score of 1, 66.67% did not receive enough prophylactic antiemetics. Additionally, patients with and Apfel score of 2 should receive 2 antiemetics. Based on the results, 14.3% received an inadequate amount, only 1 or 0 antiemetics. An additional 14.3% of the patients with two risk factors received a third antiemetic, one over the recommended number of 2. The correct number of antiemetics was given 71.4% of the time to patients with an Apfel score of 2. Patients with an Apfel score of 3 were given less than the correct number of antiemetics 60% of the time (only 2 antiemetics were administered). Only 40% received the correct number of 3-4 antiemetics. One patient had an Apfel score of 4 and was given the correct number of antiemetics, which is 4. No patients had an Apfel score greater than 4. Overall, 42.9% of patients did not receive the correct number of antiemetics.

Table 3.

Actual Antiemetics administered v. recommended number

Apfel score total (Patient risk factors)	Actual number of antiemetics administered	PONV Prophylaxis – number of antiemetics recommended per Apfel score based on Fourth Consensus guidelines
Less than 1	2 patients received 3 antiemetics	0
1	4 patients received 1 antiemetic 2 patients received 2 antiemetics	2
2	1 patient received 0 antiemetics 2 patients received 1 antiemetic 15 patients received 2 antiemetics 3 patients received 3 antiemetics	2
3	3 patients received 2 antiemetics 2 patients received 3 antiemetics	3-4
4	1 patient received 4 antiemetics	3-4
More than 4	-	3-4

Aim 3: Assessed the prevalence of anesthetic and surgical risk factors including the use of Nitrous Oxide, volatile agents, intraoperative opioids, such as fentanyl and remifentanil, and surgery greater than 30 minutes.

Table 4.

Surgical, Anesthetic, and Antiemetic Descriptive Statistics

	Urban (n = 35)
General anesthesia	100.00
Volatile Anesthetics	100.00
Nitrous Oxide Use	40.00
Intraoperative opioids	94.29
Surgical risk factors	88.57
5-HT3 receptor antagonist	97.14
NK-1 receptor antagonist	0.00
Butyrophenones	0.00
Metoclopramide	2.86
Phenothiazine	2.86
Prochlorperazine	0.00
Antidopaminergics	0.00
Versed	0.00
Gabapentin	0.00
Anticholinergic	25.71
Antiemetic steroids	74.29

Note. All values are percentages

As seen in Table 4, 100% of patients received general anesthesia with volatile anesthetic. 40% of patients received Nitrous Oxide. Intraoperative opioids were used 94.29% of the time. Surgery lasted greater that thirty minutes 88.57% of the time. The most frequent antiemetic given was 5-HT3 receptor antagonist at 97.14%. The second most frequent antiemetic was antiemetic steroids at 74.29% followed by anticholinergics at 25.71%. Both Metoclopramide and Phenothiazine was used 2.86% of the time.

Aim 4: PACU charting was assessed to determine if the patient developed PONV. The percent of PONV at the Urban facility was 14.29. Logistic regression tested associations of risk factors with incidence of post-op nausea and vomiting (PONV). The Apfel, anesthesia and surgical risk factors did not predict PONV. Actual antiemetics administered also did not predict PONV.

As seen by statistical results, there was no significant association between patient, anesthesia, and surgical risk factors and the risk for PONV. A study with a sample size of 130 patients was conducted by White et al. (2008) and found that even though the use of prophylactic antiemetics is frequent, an Apfel risk score of three or four was associated with a higher incidence of PONV within the first 24 hours. The results of White et al. (2008) study is in contrast to findings from this project. At the urban hospital where data was collected no association between the Apfel score and the risk of PONV was found. This may be due to a smaller sample size of thirty-five patients in this study.

CHAPTER IV. DISCUSSION

IMPLEMENTATION FOR PRACTICE

In Aim one the patient was given an individual Apfel score based on their risk factors for PONV. All patients at the Urban facility should receive an individualized Apfel score. The Fourth Consensus guideline reminds us that use of a PONV risk assessment score, such as the Apfel, to guide antiemetic administration has been shown to reduce the rate of PONV (Pierre et al., 2002). Ensuring all patients receive an Apfel score, allows the anesthesia provider a tool for guidance on antiemetic administration.

The second aim determined the relationship between the Apfel score and the number of antiemetic medications administered during the intraoperative period. At the Urban facility the Apfel score was not significantly associated with actual antiemetics administered. In fact, 14.29% of patients were given over the suggested number of antiemetics based on their Apfel score. In addition, 28.57% of patients were administered under the suggested number of antiemetics. A total of 42.9% of patients were administered the incorrect number of antiemetics based on the Apfel scoring system. With the administration of additional antiemetics beyond the

recommended amount as provided by the Apfel score, there is an increased cost associated with this practice. In addition, administering unneeded medication to this patient population increases the risk of side effects and adverse drug reactions which can be seen with antiemetic use (Encinosa & Davidoff, 2017). This indicates that the urban facility should place a greater emphasis on the applying the Apfel score to clinical practice in order to increase compliance with the Fourth Consensus Guideline on the prevention of PONV.

As researched by Devarakonda et al. 2022, electronic medical record reminders have been shown to increase adherence to PONV prophylaxis guidelines. Additionally, Wax et al, 2007, tells us that implementation of a visual interactive electronic reminder regarding administration of medications is associated with increased compliance with guidelines. According to Alidina et al, 2018, successful implementation of cognitive aids in the OR increases compliance with a multi-step implementation process. A visual chart of the Apfel scoring system and its recommended antiemetics could be posted in each operating room to assist with successful prophylactic antiemetic administration.

Anesthetists administer many medications throughout any surgical case majority of the time not required to scan these medications. The Anesthesia Safety Foundation recommends using medication barcode scanning for all medications given by an anesthesia provider (Brown, 2014). Scanning the drugs, similar to the requirement for blood products to be scanned, would increase the patient's safety and ensure appropriate antiemetic prophylaxis was being administered versus hand charting the medications. Additionally, it was found that the barcode medication administration systems increased documentation capturing (Dunn & Anderson, 2019).

Based on the findings in this quality improvement project, anesthesia providers give 2 antiemetics 57.14% of the time regardless of the apfel score. Giving two antiemetics is common within anesthesia practice. Assessing anesthesia providers willingness to change is the first step to increase compliance to the fourth consensus guidelines. Gabutti et al. 2022, tells us that organizations which encourage bottom up communication respond better to timely requests of change. Communication must be had with the nurse anesthetist on the negative implications of PONV and the willingness to change their practice to follow the fourth consensus guidelines.

Aim 3 assessed the prevalence of anesthetic and surgical risk factors including the use of Nitrous Oxide, volatile agents, intraoperative opioids, such as fentanyl and remifentanil, and surgery greater than 30 minutes. Both anesthesia risk factors and surgical risk factors did not predict the actual antiemetic administered. Yosief et al. (2022), says that each 30-minute increase in duration of surgery leads to an 18% increased risk of PONV. At the Urban hospital, 88.57% of patients had a surgical time greater than 30 minutes. Anesthesia providers should take into consideration how increased surgical time affects the risk of PONV.

Although specific surgeries increasing your risk for PONV varies among the literature, there is a consensus that laparoscopic and gynecological surgery increase the risk for PONV. In this quality improvement project, 11 patients underwent gynecologic surgery. Based on the knowledge from the literature that these patients may experience higher rates of PONV, anesthesia providers should take this into consideration when determining the amount of antiemetics to administer.

There are many antiemetics that anesthesia providers can choose from to administer to their patients. However, it can be difficult to have them all memorized. Additionally, a barrier to administration of the correct number of antiemetics could be related to patient specific allergies.

If a patient is allergic to decadron or Zofran, this narrows the available options for which antiemetics to administer and the anesthesia provider may not know what other antiemetics are available to supplement with. A medication list could be posted in the operating room highlighting the different antiemetics that anesthesia providers can choose from in order to reach the correct number of antiemetics recommended based on the Apfel score and Fourth Consensus Guidelines.

Aim 4 assessed PACU charting to determine if the patient developed PONV. Incidence of PONV can only be found in the anesthesiologist note. A check box should be made available for nursing staff to check if the patient experiences PONV so the data is more readily available. As the Fourth Consensus Guidelines mentioned, treating PONV with appropriate rescue antiemetics is essential. For a patient suffering from PONV in the PACU, it is vital to treat them with an antiemetic from a different drug class than the one they received. There was no benefit shown in giving the same class of antiemetic as rescue therapy. Additionally, The Fourth Consensus Guidelines does not recommend a particular combination of antiemetics to treat established PONV. Still, it is recommended that practitioners make a clinical decision based on the antiemetics already administered and stress the importance of treating established PONV with a different class of antiemetic than already administered (Gan et al., 2020). Healthcare providers assessing the patient for additional causes of PONV, such as bowel obstruction, is also essential (Gan et al., 2020).

LIMITATIONS AND STRENGTHS OF PROJECT

Limitations to this project included a small sample size of only 35. A larger sample size may have yielded an association between patient risk factors and PONV in the PACU. An

additional limitation was the transition to Epic electronic health record shortly before data was collected. As providers were learning to use this new electronic health record platform, human error made have occurred which would skew our data.

A strength of this project included data being collected from a close to even number of GYN, Urology, and ENT patients allowing for equal analysis of the risk for PONV in all three surgical population. Additionally, the analysis of the Urology and ENT surgical population allowed for the inclusion of the male population into the data. Reviewing the application of the Fourth Consensus Guidelines and Apfel scoring system in the GYN, Urologic, and ENT surgical population allowed for data to be collected on both the male and female gender with 65.71% being female and 34.29% male. Since the female gender increases the risk for PONV and earns an immediate Apfel score of 1, this allowed the assessment of the male population which could potentially of had an Apfel score of 0.

RECOMMENDATIONS

Data collected from the Urban surgical site showed that a total of 42.9% of patients received the incorrect number of antiemetics based on the Apfel scoring system. In order to increase compliance with the Apfel scoring system and the Fourth Consensus Guidelines a reminder should be programmed into the charting system which provides the anesthesia provider with an Apfel score and a recommended number of antiemetics to administer. Another way to translate this quality improvement project into practice would be to keep a visual copy of the Apfel scoring system and recommended antiemetics in each operating room as a visual aid. Cognitive aids in the operating room have been shown to increase compliance with multi-step implementation processes such as the Apfel scoring system and its antiemetic administration.

Additionally, implementing a medication barcode scanning requirement for antiemetics in the EHR may be one step in helping adherence to the Fourth Consensus Guidelines and reducing PONV. Using a bar code medication administration charting would increase overall patient safety and more accuracy of documentation of antiemetic medications.

The literature is clear that using combination therapy is the best method for preventing PONV. However, after the two most common drugs, Zofran and Decadron are given, what should the third line antiemetic agent be? The Fourth Consensus Guidelines do not dictate which specific antiemetics to give, but rather provide a comprehensive list of potential options, including all of the options listed in table 4. Some of the most common and readily available antiemetics that have a high efficacy for preventing PONV include: Scopolamine, gabapentin, promethazine, haloperidol, droperidol, intramuscular Ephedrine, and Aprepitant (4th consensus). Anesthesia providers should receive education on the various types of antiemetics which can be administered if a third antiemetic is required.

In order to assess providers willingness to change, a survey can be administered which asks anesthesia providers how willing they would be to follow the fourth consensus guidelines if a visual aid was implemented into the charting system. Assessing willingness to change in the urban facility is the first step towards increasing compliance with the fourth consensus guidelines. Additionally, the survey should include a spot for providers years of experience in order to determine if the amount of experience has any correlation to the anesthesia provider's antiemetic administration habits. It may be found that with more years of experience, the providers are less likely to change personal practice based on evidence based practice guidelines.

Educating the anesthesia and PACU staff on proper rescue antiemetic administration is crucial to treating already established PONV. Making these providers aware of the necessity for

an assessment of the different classes of antiemetics administered and treating some potential causes of PONV when occurring in the PACU. Additionally, anesthesia providers should receive education on how different types of surgery have an increased risk for PONV. Because gynecologic and laparoscopic surgeries have a higher incidence of PONV, it should be recommended to anesthesia providers to administer an additional antiemetic to this patient population.

References

Andrulis, D. P., & Duchon, L. M. (2007). The changing landscape of hospital capacity in large cities and suburbs: implications for the safety net in metropolitan America. *Journal of urban health : bulletin of the New York Academy of Medicine*, *84*(3), 400–414. https://doi.org/10.1007/s11524-007-9163-9

Apfel, C. C., & Roewer, N. (2003). Risk assessment of postoperative nausea and vomiting. *International anesthesiology clinics*, *41*(4), 13–32. https://doi.org/10.1097/00004311-200341040-00004

Apfel, C. C., Korttila, K., Abdalla, M., Kerger, H., Turan, A., Vedder, I., Zernak, C., Danner, K., Jokela, R., Pocock, S. J., Trenkler, S., Kredel, M., Biedler, A., Sessler, D. I., Roewer, N., & IMPACT Investigators (2004). A factorial trial of six interventions for the prevention of postoperative nausea and vomiting. *The New England journal of medicine*, *350*(24), 2441–2451. https://doi.org/10.1056/NEJMoa032196

Atrium Health. *(*2022). *Surgery Schedule*. Retrieved February 24, 2022, from Canopy-PowerChart.

Atrium Health (personal communication, February 25th, 2022).

Babbie, Earl R. *The Practice of Social Research*. 12th ed. Belmont, CA: Wadsworth Cengage, 2010; Muijs, Daniel. *Doing Quantitative Research in Education with SPSS*. 2nd edition. London: SAGE Publications, 2010.

Bhakta, P., Ghosh, B. R., Singh, U., Govind, P. S., Gupta, A., Kapoor, K. S., Jain, R. K., Nag, T., Mitra, D., Ray, M., Singh, V., & Mukherjee, G. (2016, December 23). *Incidence of*

postoperative nausea and vomiting following gynecological laparoscopy: A comparison of standard anesthetic technique and propofol infusion. Acta Anaesthesiologica Taiwanica. Retrieved January 25, 2022, from https://www.sciencedirect.com/science/article/pii/S1875459716300145

Borahay, M. A., Wethington, S. L., Wang, K. C., Christianson, M. S., Martin, S., Lawson, S. M., Esguerra, C., Lippitt, M. H., Wu, H., Handa, V. L., Satin, A. J., & Fader, A. N. (2020). Patient-Centered, Gynecology-Specific Prioritization of Nonurgent Surgeries during the COVID-19 Pandemic: Proposal of a Novel Scoring System. *Journal of minimally invasive gynecology*, *27*(6), 1429–1433. https://doi.org/10.1016/j.jmig.2020.05.026

Centers for Medicare and Medicaid Services. (2022, January 19). *Ambulatory surgery centers*. CMS.Gov. Retrieved January 24, 2022, from https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplian c/ASCs

Clark, L. T., Watkins, L., Piña, I. L., Elmer, M., Akinboboye, O., Gorham, M., Jamerson, B., McCullough, C., Pierre, C., Polis, A. B., Puckrein, G., & Regnante, J. M. (2018, November 9). *Increasing diversity in clinical trials: Overcoming critical barriers*. Current Problems in Cardiology. Retrieved January 24, 2022, from https://www.sciencedirect.com/science/article/pii/S0146280618301889

Committee opinion Health Disparities in Rural Women. (2014). *Obstetrics & Gynecology*, *123*(2), 384–388. https://doi.org/10.1097/01.aog.0000443278.06393.d6

Coury, J., Schneider, J.L., Rivelli, J.S. *et al.* Applying the Plan-Do-Study-Act (PDSA) approach to a large pragmatic study involving safety net clinics. *BMC Health Serv Res* **17**, 411 (2017). https://doi.org/10.1186/s12913-017-2364-3

Devarakonda, B. V., Goel, A., Singh, S., Kumar Sreevastava, D., Vadapalli, K., & Mohan Reddy, M. (2022). Efficacy of evidence-based institutional protocol for prevention of postoperative nausea and vomiting: A prospective observational study. *Medical journal, Armed Forces India*, *78*(1), 36–41. https://doi.org/10.1016/j.mjafi.2020.02.004

Encinosa W, Davidoff AJ. Changes in Antiemetic Overuse in Response to Choosing Wisely Recommendations. *JAMA Oncol.* 2017;3(3):320–326. doi:10.1001/jamaoncol.2016.2530

Erkalp, K., Kalekoglu Erkalp, N., Sevdi, M. S., Korkut, A. Y., Yeter, H., Ege, S. S., Alagol, A., & Erden, V. (2014). Gastric Decompression Decreases Postoperative Nausea and Vomiting in ENT Surgery. International journal of otolaryngology, 2014, 275860. https://doi.org/10.1155/2014/275860

Elvir-Lazo, O. L., White, P. F., Yumul, R., & Cruz Eng, H. (2020). Management strategies for the treatment and prevention of postoperative/postdischarge nausea and vomiting: an updated review. *F1000Research*, *9*, F1000 Faculty Rev-983. https://doi.org/10.12688/f1000research.21832.1

Fast facts on U.S. Hospitals, 2021. American Hospital Association. (2021). Retrieved February 15, 2022, from https://www.aha.org/statistics/fast-facts-us-hospitals

Fast facts on U.S. hospitals - 2017 pie charts: AHA. American Hospital Association. (2017). Retrieved February 16, 2022, from https://www.aha.org/statistics/2016-12-09-fast-facts-us-hospitals-2017-pie-charts

Fernandez-Guisasola, J., Gomez-Arnau, J., Cabrera, Y., & Garcia del Valle, S. (2020, March 17). *Association between nitrous oxide and the incidence of postoperative nausea and vomiting in adults: a systematic review and meta-analysis*. Anaesthesia - Peri-operative medicine, critical care and pain. Retrieved March 26, 2022, from https://associationofanaesthetistspublications.onlinelibrary.wiley.com/doi/10.1111/j.1365-2044.2010.06249.x

Gan, T. J., Apfel, C. C., Kovac, A., Philip, B. K., Singla, N., Minkowitz, H., Habib, A. S., Knighton, J., Carides, A. D., Zhang, H., Horgan, K. J., Evans, J. K., Lawson, F. C., & Aprepitant-PONV Study Group (2007). A randomized, double-blind comparison of the NK1 antagonist, aprepitant, versus ondansetron for the prevention of postoperative nausea and vomiting. *Anesthesia and analgesia*, *104*(5), . https://doi.org/10.1213/01.ane.0000263277.35140.a3

Gan, T. J., Belani, K. G., Bergese, S., Chung, F., Diemunsch, P., Habib, A. S., Jin, Z., Kovac, A. L., Meyer, T. A., Urman, R. D., Apfel, C. C., Ayad, S., Beagley, L., Candiotti, K., Englesakis, M., Hedrick, T. L., Kranke, P., Lee, S., Lipman, D., Minkowitz, H. S., Philip, B. K. (2020). Fourth Consensus Guidelines for the Management of Postoperative Nausea and Vomiting. *Anesthesia and analgesia*, *131*(2), 411–448. https://doi.org/10.1213/ANE.0000000000004833

Gan, T. J., Diemunsch, P., Habib, A. S., Kovac, A., Kranke, P., Meyer, T. A., Watcha, M., Chung, F., Angus, S., Apfel, C. C., Bergese, S. D., Candiotti, K. A., Chan, M. T., Davis, P. J., Hooper, V. D., Lagoo-Deenadayalan, S., Myles, P., Nezat, G., Philip, B. K., Tramèr, M. R., … Society for Ambulatory Anesthesia (2014). Consensus guidelines for the management of postoperative nausea and vomiting. *Anesthesia and analgesia*, *118*(1), 85–113. https://doi.org/10.1213/ANE.0000000000000002

George Washington University. (2021, July 7). *Differences: Academic vs. Community Medical Centers: GW University*. George Washington University. Retrieved January 23, 2022, from https://healthcaremba.gwu.edu/blog/the-differences-between-community-and-academic-medical-centers/

Ghosh, S., Rai, K. K., Shivakumar, H. R., Upasi, A. P., Naik, V. G., & Bharat, A. (2020). Incidence and risk factors for postoperative nausea and vomiting in orthognathic surgery: a 10-year retrospective study. *Journal of the Korean Association of Oral and Maxillofacial Surgeons*, *46*(2), 116–124. https://doi.org/10.5125/jkaoms.2020.46.2.116

Gillmann, H. J., Wasilenko, S., Züger, J., Petersen, A., Klemann, A., Leffler, A., & Stueber, T. (2019). Standardised electronic algorithms for monitoring prophylaxis of postoperative nausea and vomiting. *Archives of medical science : AMS*, *15*(2), 408–415. https://doi.org/10.5114/aoms.2019.83293

Girotto, J. A., Koltz, P. F., & Drugas, G. (2010). Optimizing your operating room: or, why large, traditional hospitals don't work. *International journal of surgery (London, England)*, *8*(5), 359–367. https://doi.org/10.1016/j.ijsu.2010.05.002

Gao, J. (2020). P-values – a chronic conundrum. *BMC Medical Research Methodology*, *20*(1). https://doi.org/10.1186/s12874-020-01051-6

Golembiewski, J. A., & O'Brien, D. (2002). A systematic approach to the management of postoperative nausea and vomiting. *Journal of perianesthesia nursing: official journal of the American Society of PeriAnesthesia Nurses*, *17*(6), 364–376. https://doi.org/10.1053/jpan.2002.36596

Gress, K., Urits, I., Viswanath, O., & Urman, R. D. (2020). Clinical and economic burden of postoperative nausea and vomiting: Analysis of existing cost data. *Best practice & research. Clinical anaesthesiology*, *34*(4), 681–686. https://doi.org/10.1016/j.bpa.2020.07.003

Habib, A. S., Chen, Y. T., Taguchi, A., Hu, X. H., & Gan, T. J. (2006). Postoperative nausea and vomiting following inpatient surgeries in a teaching hospital: a retrospective database analysis. Current medical research and opinion, 22(6), 1093–1099. https://doi.org/10.1185/030079906X104830

Hall, M., & Owings, M. (2013, August). *NCHS Data Brief, number 126*. NCHS Data Brief. Retrieved January 25, 2022, from https://www.cdc.gov/nchs/data/databriefs/db147.pdf

Hamai, T., Nagata, A., & Nishikawa, H. (2017). *Japanese journal of public health*, *64*(11), 672–683. https://doi.org/10.11236/jph.64.11_672

Hollenbeck, B. K., Dunn, R. L., Suskind, A. M., Zhang, Y., Hollingsworth, J. M., & Birkmeyer, J. D. (2014). Ambulatory Surgery Centers and Outpatient Procedure Use Among

Medicare Beneficiaries. *Medical Care*, *52*(10), 926–931. https://doi.org/10.1097/mlr.0000000000000213

Hromatka, B. S., Tung, J. Y., Kiefer, A. K., Do, C. B., Hinds, D. A., & Eriksson, N. (2015). Genetic variants associated with motion sickness point to roles for inner ear development, neurological processes and glucose homeostasis. *Human Molecular Genetics*, *24*(9), 2700–2708. https://doi.org/10.1093/hmg/ddv028

Ibrahim, A. M., Hughes, T. G., Thumma, J. R., & Dimick, J. B. (2016). Association of Hospital Critical Access Status With Surgical Outcomes and Expenditures Among Medicare Beneficiaries. *JAMA*, *315*(19), 2095–2103. https://doi.org/10.1001/jama.2016.5618

Jeon, B. G., Kim, H. J., Jung, K. H., Kim, S. W., Park, J. S., Kim, K. H., Kim, I. D., & Lee, S. J. (2016). Prolonged operative time in laparoscopic appendectomy: Predictive factors and outcomes. *International Journal of Surgery*, *36*, 225–232. https://doi.org/10.1016/j.ijsu.2016.10.035

Joyce, A. (2020, April 23). *Interactive maps highlight urban-rural differences in hospital bed capacity*. KFF. Retrieved January 23, 2022, from https://www.kff.org/health-costs/press-release/interactive-maps-highlight-urban-rural-differences-in-hospital-bed-capacity/#:~:text=While%20metro%20and%20non%2Dmetro,to%202.8%20in%20urban%20areas.

Kassel, L., Nelson, M., Shine, J., Jones, L. R., & Kassel, C. (2018). Scopolamine Use in the Perioperative Patient: A Systematic Review. *AORN journal*, *108*(3), 287–295. https://doi.org/10.1002/aorn.12336

Kneebone, E. (2016, July 29). *The growth and spread of concentrated poverty, 2000 to 2008-2012*. Brookings. Retrieved January 23, 2022, from https://www.brookings.edu/interactives/the-growth-and-spread-of-concentrated-poverty-2000-to-2008-2012/

Krieser , K. A., Riley , J. B., Baus, J. E., Hoffman , J. T., & Sullivan , J. N. (2020). Ponv prophylaxis failure disproportionately affects female patients, despite intraoperative computerized decision support guidance. *Graduate Medical Education Research Journal*, *2*(1). https://doi.org/10.32873/unmc.dc.gmerj.2.1.091

Langford, D & Woods, S. (2022). 8642: Mapping Out the Project [Slides 15-16;18]. Department of Graduate Nursing, University of North Carolina at Charlotte.

Lim, H., Doo, A. R., Son, J. S., Kim, J. W., Lee, K. J., Kim, D. C., & Ko, S. (2016). Effects of intraoperative single bolus fentanyl administration and remifentanil infusion on postoperative nausea and vomiting. *Korean journal of anesthesiology*, *69*(1), 51–56. https://doi.org/10.4097/kjae.2016.69.1.51

Lavrakas, P. J. (2008). *Encyclopedia of survey research methods* (Vols. 1-0). Thousand Oaks, CA: Sage Publications, Inc. doi: 10.4135/9781412963947

Manahan, M. A., Basdag, B., Kalmar, C. L., Shridharani, S. M., Magarakis, M., Jacobs, L. K., Thomsen, R. W., & Rosson, G. D. (2013). Risk of severe and refractory postoperative nausea and vomiting in patients undergoing diep flap breast reconstruction. *Microsurgery*, *34*(2), 112–121. https://doi.org/10.1002/micr.22155

Manjusruthi, B., Reddy, G., & Jyothsna, G. (2019). Postoperative nausea and vomiting prophylaxis: A comparative study of ramosetron and palonosetron in patients undergoing laparoscopic cholecystectomy – a prospective randomized trial. *Anesthesia: Essays and Researches*, *13*(1), 68. https://doi.org/10.4103/aer.aer_192_18

Masiongale, A. J., Garvin, J. T., Murphy, M. J., Hooper, V. D., Odom-Forren, J., Masiongale, J. I., & Looney, S. W. (2018). Reexamining Metoclopramide's role in the prevention of postoperative nausea and vomiting: A secondary analysis. American Association Nurse Anesthesia Journal, 86(3), 213–219.

Mathis, M. R., Naughton, N. N., Shanks, A. M., Freundlich, R. E., Pannucci, C. J., Chu, Y., Haus, J., Morris, M., & Kheterpal, S. (2013). Patient selection for day case-eligible surgery: Identifying those at high risk for major complications. *Anesthesiology*, *119*(6), 1310–1321. https://doi.org/10.1097/aln.0000000000000005

Morino, R., Ozaki, M., Nagata, O., & Yokota, M. (2012). Incidence of and risk factors for postoperative nausea and vomiting at a Japanese cancer center: First large-scale study in japan. *Journal of Anesthesia*, *27*(1), 18–24. https://doi.org/10.1007/s00540-012-1468-5

Moore, C., Bledsoe, R., Bonds, R., Keller, M., & King, H. (2021, April). *Preventing postoperative nausea and vomiting during an ...* Preventing Postoperative Nausea and Vomiting During an Ondansetron Shortage. Retrieved March 19, 2022, from https://www.aana.com/docs/default-source/aana-journal-web-documents-1/moore-r.pdf?sfvrsn=3eb87dbe_4

Murphy, M. J., Hooper, V. D., Sullivan, E., Clifford, T., & Apfel, C. C. (2006). Identification of risk factors for postoperative nausea and vomiting in the perianesthesia adult patient. *Journal of perianesthesia nursing : official journal of the American Society of PeriAnesthesia Nurses*, *21*(6), 377–384. https://doi.org/10.1016/j.jopan.2006.09.002

Nahm FS. What the *P* values really tell us. *Korean J Pain*. 2017;30(4):241-242. doi:10.3344/kjp.2017.30.4.241

Nebeker, C. (n.d.). *Descriptive Studies*. Research design: Descriptive studies. Retrieved February 17, 2022, from https://ori.hhs.gov/education/products/sdsu/res_des1.htm

Niche.com. (2022). *Dilworth demographics*. Retrieved February 20, 2022, from https://www.niche.com/places-to-live/n/dilworth-charlotte-nc/residents/

Niche.com. (2022). *Pineville demographics and statistics*. Retrieved February 20, 2022, from https://www.niche.com/places-to-live/pineville-mecklenburg-nc/residents/

Öbrink, E., Jildenstål, P., Oddby, E., & Jakobsson, J. G. (2015). Post-operative nausea and vomiting: Update on predicting the probability and ways to minimize its occurrence, with focus on ambulatory surgery. *International Journal of Surgery*, *15*, 100–106. https://doi.org/10.1016/j.ijsu.2015.01.024

Parker, K., Horowitz, J. M., Brown, A., Fry, R., Cohn, D. V., & Igielnik, R. (2020, May 30). *Demographic and economic trends in urban, suburban and rural communities*. Pew Research Center's Social & Demographic Trends Project. Retrieved February 15, 2022, from https://www.pewresearch.org/social-trends/2018/05/22/demographic-and-economic-trends-in-urban-suburban-and-rural-communities/

Parra-Sanchez, I., Abdallah, R., You, J., Fu, A. Z., Grady, M., Cummings, K., Apfel, C., & Sessler, D. I. (2012). A time-motion economic analysis of postoperative nausea and vomiting in ambulatory surgery. *Canadian Journal of Anesthesia/Journal Canadien d'anesthésie*, *59*(4), 366–375. https://doi.org/10.1007/s12630-011-9660-x

Peyton, P. J., & Wu, C. Y. (2014, May 1). *Nitrous oxide–related postoperative nausea and vomiting depends on duration of exposure*. American Society of Anesthesiologists. Retrieved March 26, 2022, from https://pubs.asahq.org/anesthesiology/article/120/5/1137/13778/Nitrous-Oxide-related-Postoperative-Nausea-and

Pierre, S., Benais, H., & Pouymayou, J. (2002). Apfel's simplified score may favourably predict the risk of postoperative nausea and vomiting. *Canadian Journal of Anesthesia/Journal Canadien D'anesthésie*, *49*(3), 237–242. https://doi.org/10.1007/bf03020521

Pierre, S., Benais, H., & Pouymayou, J. (2003). *Apfel's simplified score may favourably predict the risk of postoperative nausea and vomiting*. General Anesthesia. Retrieved March 26, 2022, from https://link.springer.com/content/pdf/10.1007%2FBF03020521.pdf

Pierre, S., & Whelan, R. (2012, August 11). *Nausea and vomiting after surgery*. OUP Academic. Retrieved March 26, 2022, from https://academic.oup.com/bjaed/article/13/1/28/281153

Pierre, S. & Whelan, R. (2013). Nausea and vomiting after surgery, *Continuing Education in Anaesthesia Critical Care & Pain*, 13(1), 28-32. https://doi.org/10.1093/bjaceaccp/mks046

Rascol, N., Schneider, E., Gindre, G., & Schoeffler, P. (2006). Progress in ambulatory anesthesia applied to gynecological surgery. *Journal de gynecologie, obstetrique et biologie de la reproduction*, *35*(3), 237–241. https://doi.org/10.1016/s0368-2315(06)78307-7

Ricci, S., Tergas, A. I., Long Roche, K., Fairbairn, M. G., Levinson, K. L., Dowdy, S. C., Bristow, R. E., Lopez, M., Slaughter, K., Moore, K., & Fader, A. N. (2017). Geographic disparities in the distribution of the U.S. gynecologic oncology workforce: A Society of Gynecologic Oncology study. *Gynecologic oncology reports*, *22*, 100–104. https://doi.org/10.1016/j.gore.2017.11.006

Rose, J. B., & Watcha, M. F. (1999). Postoperative nausea and vomiting in paediatric patients. *British journal of anaesthesia*, *83*(1), 104–117. https://doi.org/10.1093/bja/83.1.104

Shaikh, S. I., Nagarekha, D., Hegade, G., & Marutheesh, M. (2016). Postoperative nausea and vomiting: A simple yet complex problem. *Anesthesia: essays and researches*, *10*(3), 388–396. https://doi.org/10.4103/0259-1162.179310

Skledar, S. J., Williams, B. A., Vallejo, M. C., Dalby, P. L., Waters, J. H., Glick, R., & Kentor, M. L. (2007). Eliminating postoperative nausea and vomiting in outpatient surgery with multimodal strategies including low doses of nonsedating, off-patent antiemetics: is "zero tolerance" achievable?. *TheScientificWorldJournal*, *7*, 959–977. https://doi.org/10.1100/tsw.2007.131

Smith, A. (2020, November 24). *Rural areas send their sickest patients to cities, straining hospitals*. Kaiser Health News. Retrieved January 23, 2022, from https://khn.org/news/rural-areas-send-their-sickest-patients-to-cities-straining-hospitals/

Smith, H.,Smith, E., & Smith, B. (2012). Postoperative nausea and vomiting. *Annals Of Palliative Medicine*, 1(2), 94-102. Retrieved from https://apm.amergroups.com/atricle/view/1035

Stadler, M., Bardiau, F., Seidel, L., Albert, A., & Boogaerts, J. (2003). Difference in risk factors for postoperative nausea and vomiting. *Anesthesiology*, *98*(1), 46–52. https://doi.org/10.1097/00000542-200301000-00011

Stephenson, S. J., Jiwanmall, M., Cherian, N. E., Kamakshi, S., & Williams, A. (2021). Reduction in post-operative nausea and vomiting (PONV) by preoperative risk stratification and adherence to a standardized anti emetic prophylaxis protocol in the day-care surgical population. *Journal of family medicine and primary care*, *10*(2), 865–870. https://doi.org/10.4103/jfmpc.jfmpc_1692_20

The Trustees of the University of Pennsylvania. (n.d.). *What It Means to Be an Academic Medical Center*. Pennmedicine.org. Retrieved January 23, 2022, from https://www.pennmedicine.org/about/benefits-of-an-academic-medical-center

Ugochukwu, O., Adaobi, A., Ewah, R., & Obioma, O. (2010). Postoperative nausea and vomiting in a gynecological and obstetrical population in South Eastern Nigeria. *The Pan African medical journal*, *7*, 6. https://doi.org/10.4314/pamj.v7i1.69111

Urbach, D. R., & Baxter, N. N. (2004). Does it matter what a hospital is "high volume" for? Specificity of hospital volume-outcome associations for surgical procedures: analysis of administrative data. *BMJ (Clinical research ed.)*, *328*(7442), 737–740. https://doi.org/10.1136/bmj.38030.642963.AE

Vukovic, N., & Dinic, L. (2018). Enhanced Recovery After Surgery Protocols in Major Urologic Surgery. Frontiers in medicine, 5, 93. https://doi.org/10.3389/fmed.2018.00093

Weilbach, C., Rahe-meyer, N., Raymondos, K., Weissig, A., Scheinichen, D., & Piepenbrock, S. (2006). Postoperative nausea and vomiting (PONV): usefulness of the Apfel-score for identification of high risk patients for PONV. *Acta anaesthesiologica Belgica*, *57*(4), 361–363.

Weisz, D., Gusmano, M. K., Wong, G., & Trombley, J. (2015). Emergency department use: a reflection of poor primary care access?. The American journal of managed care, 21(2), e152–e160.

Werner, J., Fernandez, S., & Awad, H. (2008). The role of smoking history in the development of postoperative nausea and vomiting. *Anesthesiology*, *109*(1), 156–157. https://doi.org/10.1097/aln.0b013e31817b5afd

White, P. F., Sacan, O., Nuangchamnong, N., Sun, T., & Eng, M. R. (2008). The relationship between patient risk factors and early versus late postoperative emetic symptoms. *Anesthesia and analgesia*, *107*(2), 459–463. https://doi.org/10.1213/ane.0b013e31817aa6e4

White, P. F., Tang, J., Song, D., Coleman, J. E., Wender, R. H., Ogunnaike, B., Sloninsky, A., Kapu, R., Shah, M., & Webb, T. (2007). Transdermal scopolamine: an alternative to ondansetron and droperidol for the prevention of postoperative and postdischarge emetic symptoms. *Anesthesia and analgesia*, *104*(1), 92–96. https://doi.org/10.1213/01.ane.0000250364.91567.72

Wilper, A. P., Woolhandler, S., Lasser, K. E., McCormick, D., Bor, D. H., & Himmelstein, D. U. (2009). Health insurance and mortality in US adults. *American journal of public health*, *99*(12), 2289–2295. https://doi.org/10.2105/AJPH.2008.157685

Yosief PK, Beraki GG, Mayer S, Mengistu MB, Tesfamariam EH (2022) Incidence and Risk factors of Postoperative Nausea and Vomiting after ENT Surgery. Int J Anesthetic Anesthesiol 9:132. doi.org/10.23937/2377-4630/1410132

APPENDIX A: UNCC IRB APPROVAL

From: **Runden, Catherine Price** Received: **27-Jul-2022**

To: **Sanders, Abby Catherine** - *University of North Carolina at Charlotte*
Dr. Woods, Stephanie Joan - *School of Nursing*

CC: **Ross, Rebekah Caroline Peterson** - *University of North Carolina at Charlotte*
Sullivan, Meghan Marie - *University of North Carolina at Charlotte*
Dr. Woods, Stephanie Joan - *School of Nursing*

Subject: **IRB-23-0040 - NHSR Submission Acknowledged**

UNIVERSITY OF NORTH CAROLINA CHARLOTTE | RESEARCH AND ECONOMIC DEVELOPMENT

To:	Abby Sanders University of North Carolina at Charlotte
From:	Office of Research Protections and Integrity
Date:	27-Jul-2022
RE:	Determination that Research is not Human Subjects and does not require IRB Approval
Study #:	IRB-23-0040
Study Title:	Assessing Risk Factors and Nausea Prophylaxis in the Gynecologic, Urologic, and Ear, Nose and Throat Surgical Population

This submission was reviewed by the Office of Research Protections and Integrity, which has determined that this submission does not constitute human subjects as defined under federal regulations 45 CFR 46.102(e) and 21 CFR 56.102(e) and does not require IRB approval.

Study Description:
This is a quality improvement (QI) project chosen by the Safety and Quality Coordinator for Metro and Anesthesia Departments across multiple Atrium Health facilities. The project addresses practice, quality, and safety issues related to anesthesia providers. Participants of the QI project are Gynecologic, Ear Nose, and Throat, and Urologic surgery patients greater than 18 years old at Atrium Health Pineville, Atrium Health Carolinas Medical Center, and Atrium Health One Day Surgery Center. These individual hospitals are covered by one anesthesia team who provides care across multiple sites. PONV causes negative health sequelae, increases the financial burden, and decreases patient satisfaction. The purpose of this project is to compare anesthetic, surgical, and patient risk factors with the number of antiemetics given, in order to determine anesthesia providers compliance with the Fourth Consensus Guidelines, a guideline created for clinicians to utilize to prevent PONV. Our proposed instrument is an Excel spreadsheet with a list of risk factors for PONV, as well as the prophylactic antiemetics that are outlined in the Fourth Consensus Guidelines. Chart reviews and data analysis will be conducted to determine patient, anesthetic, and surgical risk factors, and PONV prophylaxis administration. A t-test will be used to calculate a statistically significant difference between the mean of each individual risk factor. The project design is a descriptive design; a comparative study design will also be implemented by comparing the data collected from the urban, suburban, and ambulatory hospitals utilizing a Chi-square test. Keywords: PONV, gynecologic, ENT, Urologic, surgery, ambulatory surgery centers, urban, suburban, anesthesia

Please be aware that approval may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records), even though IRB approval is not required.

If your study protocol changes in such a way that this determination will no longer apply, you should contact the above IRB before making the changes.

APPENDIX B: WAKE FORREST IRB APPROVAL

Memorandum

To: Karen Lucisano

Clinical and Translational Science Institute {CTSI}

From: Brian Moore, Director

Institutional Review Board

Date: 7/14/2022

Subject: Not Human Subjects Research: IRB00085740

Assessing Risk Factors and Nausea Prophylaxis in the Gynecologic, Urologic, and Ear, Nose and Throat Surgical Population

The Wake Forest University School of Medicine Institutional Review Board has reviewed your protocol and determined that it does not meet the federal definition of research involving human subject research as outlined in the federal regulations 45 CFR 46. 45 CFR 46.102(f) defines human subjects as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

The information you are receiving is not individually identifiable. In recent guidance published by the Office of Human Research Protections (OHRP) on the Guidance on Research Involving Coded Private Information or Biological Specimens, OHRP emphasizes the importance on what is being obtained by the investigator and states "if investigators are not obtaining either data through intervention or interaction with living individuals, or identifiable private information, then the research activity does not involve human subjects."

Note that only the Wake Forest University School of Medicine IRB can make the determination for its investigators that a research study does not meet the federal definition of human subject research. Investigators do not have the authority to make an independent determination that a study does not meet the federal requirements for human subject research. Each project requires a separate review and determination by the Board. The Board must be informed of any changes to this project, so that the Board can determine whether it continues to not meet the federal requirements for human subject research. If you have any questions or concerns about this information, please feel free to contact our office at 716-4542.

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.