SCHOLARLY PROJECT: SUGAMMADEX AND HORMONAL BIRTH

CONTROL EDUCATION

by

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ABSTRACT

ASHLEY ALEXIS BURCH. Scholarly Project: Sugammadex and Hormonal Birth Control Education. (Under the Direction of DR. LUFEI YOUNG, PH.D., ACNP-BC)

Background

Sugammadex is an effective and safe drug to reverse surgery induced neuromuscular blockade. However, the interaction of Sugammadex and hormonal contraceptives may lead to unintended effects in surgical patients who are using hormonal birth control. There is insufficient evidence regarding the effectiveness of online education among post-anesthesia care unit (PACU) nurses, who are responsible for delivering discharge education.

Purpose

The purpose of the project is to examine the effect of a web-based education on PACU nurses' awareness and knowledge about the interaction between Sugammadex and hormonal contraceptives.

Methods

We conducted a quasi-experimental study with pre-/post-test design. The study was conducted in a surgical center located in the southeastern region of the United States. A digital survey was given both prior to and following the online educational session. The effects of web-based education were examined by comparing the differences of the pre and post-educational survey knowledge scores.

Results

Among 19 PACU nurses, their years of experience ranged from 0 to 33 years (M = 5.67, SD = 8.81, Mdn = 3). There was a significantly increased number of corrections between pre- and post-test from 4.37 ± 0.90 to 4.81 ± 0.40 (t = 2.52, p = .023).

Conclusion

The online education proves to be both feasible and effective in enhancing the knowledge of drug interactions among PACU nurses. This finding could contribute to the development of a standardized educational framework for ongoing drug education in nurses.

ACKNOWLEDGEMENTS

DEDICATION

To my late parents, Rhonda and Scott White, thank you for always encouraging me to pursue my dreams and always believing in me. I hope to make you both proud in everything I do. To my husband, Garrett Burch, there are not enough words to express my gratitude for your constant support, patience, love, and motivation throughout this journey. To my grandparents, Mary Kay and Sammy White, thank you for loving me unconditionally and supporting my educational journey every step of the way. To my pups, Harley, Beaux, and Hero, I could not have made it through Graduate school without your emotional support, puppy kisses, and constant cuddles. To the rest of my friends and family, thank you for listening to me, having confidence in me, and always pushing me to be the best version of myself. I love you all.

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LIST OF ABBREVIATIONS

CRNA   Certified Registered Nurse Anesthetist

FDA   Food and Drug Administration

HIPAA   Health Insurance Portability and Accountability Act

IRB   Institutional Review Board

PACU   Post-Anesthesia Care Unit

QI   Quality Improvement

QR   Quick Response

SD   Standard Deviation

SPO   Structure Process Outcome

U.S.   United States

SECTION 1: INTRODUCTION AND BACKGROUND

Background and Significance

Sugammadex is a drug that provides a rapid and dose-dependent reversal of profound neuromuscular blockade. More specifically, Sugammadex is a cyclodextrin that binds selectively to the steroidal neuromuscular blocking agents where it encapsulates and inactivates the neuromuscular blocking agent in the plasma, rendering it incapable of binding with receptors. Sugammadex is the most ideal reversal agent on the market right now due to its ability to reverse any depth of neuromuscular blockade. Dubovoy et al. (2020) developed a retrospective observational study conducted across 24 institutions in the United States to discover the prevalence of Sugammadex use. Researchers discovered that out of 934,798 cases that received a neuromuscular blocking agent, an average of 40% of the cases were administered Sugammadex.

Sugammadex is a highly effective neuromuscular blocking reversal agent, but it has one very important drug-drug interaction: hormonal contraception. Similar to the effects Sugammadex has on neuromuscular blocking agents, it also binds progesterone with a strong affinity and may reduce the efficacy of hormonal contraceptives. According to Hartman et al. (2019), "this interaction binds the prostagenic compound found in many hormonal contraceptives, decreasing the plasma level of progesterone" (p. 352). Richardson and Raymond (2020) state "studies indicate that Sugammadex binds progesterone, thereby reducing hormone levels to an extent that is equivalent to missing doses of oral contraceptives" (p. 1632). The Food and Drug Administration (FDA) label for Sugammadex contains a warning advising that women taking hormonal contraception use a back-up contraceptive method or abstinence for seven days after exposure to Sugammadex. According to Daniels and Abma (2018), approximately 26% of

women aged 15 to 49 use hormonal birth control and "the most common contraceptive methods currently being used were female sterilization (18.6%), oral contraceptive pill (12.6%), long-acting reversible contraceptives (10.3%), and male condoms (8.7%)" (p. 2). Lazorwitz et al. (2019) conducted a retrospective chart review at the University of Colorado Hospital and found the following:

> Out of 1000 charts reviewed, 134 were found to be women utilizing hormonal contraception at the time of Sugammadex exposure. After review of the documentation, it was revealed that only one patient received counseling. They also found one patient who did not receive education regarding Sugammadex endured an unintended pregnancy within three months of Sugammadex administration (p. 296).

Unintended pregnancy can have serious health consequences to the mother and the baby. These health risks include low birthweight, increased risk of postpartum depression, and physical or psychological abuse. "Up to half of women who experience pregnancy due to contraception failure opt for termination" (Richardson & Raymond, 2020, p. 1633). Pregnancy termination may be accompanied by psychological discomfort, depression, and posttraumatic stress disorder in addition to facing escalating access difficulties (Richardson & Raymond, 2020).

Approximately 37% of pregnancies resulting in live births in the U.S. are unintended (Mosher et al., 2012). The effects of an unintended pregnancy on one's health, finances, and relationships if carried to term are also significant (Richardson & Raymond, 2020). According to the World Health Organization (2019), "globally, 74 million women living in low and middle-income countries have unintended pregnancies annually. This leads to 25 million unsafe abortions and 47,000 maternal deaths every year." According to The Commonwealth Fund, maternal morbidity conditions such as hypertensive disorders, hemorrhage, gestational diabetes

mellitus, and mental health conditions cost around 32.3 billion dollars from conception through age five of a child, with the healthcare system enduring over half of these costs (O'Neil et al., 2021). Monea and Thomas (2011) state "taxpayers financed a total of about 1.25 million unintended pregnancies in 2001 and that the average cost per publicly financed unintended pregnancy ranges from about $7,700 to about $10,000" (p. 90).

Problem Statement

Women of childbearing age who receive Sugammadex perioperatively are not receiving proper education about the need for secondary birth control for up to seven days postoperatively. One of the reasons patients do not receive proper medication education is the lack of knowledge, competency, and confidence in post-anesthesia care unit (PACU) nurses when it comes to providing patient medication education (Dahlberg et al., 2022).Unintended pregnancy may occur in women of reproductive age who receive Sugammadex during the perioperative period and who are not properly informed about the need for supplemental birth control for up to seven days after the procedure. At the study site, there were no standardized and evidence-based guidelines specifying nursing education regarding the delivery of discharge instructions about Sugammadex drug interactions.

Purpose

To address these clinical issues, the purpose of this project was to examine the effectiveness of a web-based provider education program on PACU nurses' knowledge about the drug-drug interaction between Sugammadex and hormonal contraception. The project was to highlight the need for a standardized web-based education program centered around Sugammadex and its adverse effects on hormonal contraceptives. Empowering nurses with

proper education can lead to accurate dissemination of discharge teaching and ultimately promotes positive patient outcomes.

Clinical Question

Compared to current nursing education, is a web-based education program more effective at improving knowledge on the drug-drug interaction between Sugammadex and hormonal contraception in PACU nurses who are providing Sugammadex discharge teaching for childbearing age women?

SECTION II: LITERATURE REVIEW

Existing Guideline and Education Program

While it seems intuitive to educate patients and nurses about the risks of pregnancy after receiving Sugammadex, there is a lack of a formalized process to address the issue of effective postoperative discharge teaching regarding Sugammadex and hormonal birth control. Three articles were found in current literature that suggested an education program designed to improve nurses' knowledge and counseling rate regarding drug-drug interactions with hormonal contraceptives (Hartman et. al., 2021; O'Driscoll & Parrott 2019; David et al., 2023). In a performance improvement project conducted at a Naval Hospital the investigators looked at the efficacy of an interactive education program to improve knowledge and confidence among perianesthesia nurses. After education was provided, they found a significant increase in confidence scores among the participants (O'Driscoll & Parrott, 2019). Hartman et al. (2021) found similar results in their study of 59 PACU nurses at a tertiary hospital. David et al. (2019) conducted a similar study with a different drug that affects hormonal contraception, Aprepitant (Emend), and found a significant increase in nursing knowledge after implementing an educational in-service.

The results of these studies indicated that delivering a standardized educational program may enhance the PACU nurses' capacity to communicate important details regarding drug-drug interactions such as the requirement that patients utilize a supplementary method of birth control. Even after broadening the search to include educational programs aimed at educating nursing staff about medication interactions with contraceptives, the search was fruitless..This

suggested a gap in the literature and a need for the implementation of a standardized process aimed at increasing nurses' knowledge regarding drug-drug interactions.

Evaluation of Effectiveness

Researchers implemented a pre and posttest design to assess knowledge improvement among PACU nurses (Hartman et. al., 2021; O'Driscoll & Parrott 2019; David et al., 2023). The questions were the same for the pretest and posttest. All studies performed immediate posttest following a face-to-face educational in-service and subsequent posttest to assess for long-term learning. O'Driscoll and Parrott (2019) performed their subsequent posttest two weeks following education in contrast to David et al. (2023) who performed theirs 90 days after education. The longest duration between education and subsequent post testing was performed by Hartman et al. (2021) at 30 weeks. O'Driscoll and Parrott (2019) and David et al. (2023) employed a multiple- choice format with five questions via paper format and seven questions sent out via email, respectively. In contrast, Hartman et al. (2021) developed a five question 5-point Likert scale to assess nursing knowledge via email. All of the studies showed increased scores on the posttests as compared to the pretests. Utilizing the pretest-posttest design, researchers were able to conclude that educational in-services empower PACU nurses with the knowledge and confidence to provide effective discharge teaching. The addition of subsequent post testing further proved the longevity of the educational sessions.

Effectiveness of Web-based Programs

Technology advancements like web-based education have improved nurses' ability to learn new information by offering engaging content in a flexible setting. The abundance of computer-facilitated learning alternatives suggests that nurses are becoming more interested in this type of learning. Berger et al. (2009) conducted a study and gave the participants the choice

between a web-based format versus a face-to-face format and out of 1661 participants, 1544 chose the web-based training style. Learner's enjoyment of the material is essential to their participation and motivation of learning new concepts. Several studies found that learners who participated in web-based continuing education conveyed satisfaction with the educational format (Harris et al., 2022; Moattari et al., 2014; Berger et al., 2009). In a study involving around 6,000 participants, over 80% indicated satisfaction with the web-based training (Harris et al., 2022). Likewise, a Quasi-experimental research study was performed across five teaching hospitals and discovered similar satisfaction rates among participants in regard to the web-based training format at over 80% (Moattari et al., 2014). Berger et al. (2009) questioned participants on their satisfaction with the web-based training and the results were 72% of participants indicated that they were satisfied. However, Rosvall and Carlson, (2017) and Bond et al. (2017) experienced criticism from their participants noting a lack of face-to-face interaction with colleagues and received suggestions for combining both formats for the best educational experience.

Not only are web-based programs favored for their flexibility, but they are also a cost-effective alternative to traditional face-to-face learning. Multiple studies have shown that web-based programs offer a beneficial alternative to classroom teaching (Berger et al., 2009; Rosvall & Carlson, 2017; Lim & Yeojin, 2021). Due to the large number of nurses needing continuing education, Berger et al. (2009) found that web-based training was the most cost-effective method. Utilizing a convergent mixed-method design, Rosvall and Carlson (2017) also discovered that educating large groups through web-based training is the most flexible and cost-effective strategy. Researchers also found "learning in digital environments allows the individual to study at his/her own pace since the educational material is available 24 hours a day" (Rosvall

& Carlson, 2017, p. 4778). In a randomized control trial conducted across three hospitals, Lim and Yeojin (2021) found "unlike offline training, web-based education has the advantages of greater accessibility and self-directed repetitive learning without limitations regarding time and place" (p. 2). Web-based learning offers many advantages to learners and facilities and is seen as an effective means of education.

Reaching the target audience effectively is vital to assure their competency so they can deliver patient-centered care. Liaw et al. (2016) found that the knowledge and abilities of hospital nurses in assessing, managing, and reporting were dramatically improved by a web-based educational program. A number of studies found that in comparison to face-to-face learning, web-based learning was just as effective (Berger et al., 2019; Lahti et al., 2014). Berger et al. (2019) discovered that "the achievement of learning objectives with web-based instruction has been reported to be similar with that of traditional face-to-face instruction for equivalent participants" (p. 128). Lahti et al. (2014) found that there were no statistically significant differences between the web-based learning participants and the face-to-face learning participants in terms of comprehension. Nursing comprehension is the first step in ensuring effective patient comprehension of discharge teaching.

Development and Implementation of Patient Education

There are barriers preventing patients from understanding the side effects of Sugammadex. One obstacle is the timing of discharge teaching. According to Hartman et al. (2021), anesthesia providers do not know if Sugammadex will be given until the time of surgery which leads to inconsistency in discharge teaching to women of childbearing age. Patients receive many medications throughout the perioperative area which leads to unpredictable recall. Hospitals are challenged to determine when teaching is most effective and

at what point of the perioperative continuum should these patients receive this vital information. "Current recommendations are to wait up to two hours after the end of anesthesia to deliver discharge instructions and that verbal instructions should be supplemented with written instructions" (Hartman et al., 2021, p. 352).

Given the various degrees of health literacy among patients and caregivers, understanding discharge instructions is a crucial factor to consider. DeSai et al. (2021) state, "studies have shown that approximately one-third of Americans have low health literacy" (p. 1). A patient's health literacy can determine whether they are compliant with discharge instructions. In this instance, non-compliance can lead to adverse events, such as pregnancy. There have been many studies aimed at uncovering effective discharge teaching strategies. Implementing standardized discharge processes that focus on nurses' expertise in the delivery of postoperative teaching is important for patient retention.

One method that has been supported by substantial evidence is the teach back method. This approach involves asking patients to rephrase teaching material previously discussed in an effort to determine adequacy of teaching. This method has been shown to significantly increase patient comprehension, validate information, and enhance health outcomes (Nurhayati et al., 2019; Hartman et al., 2021). In addition to the teach back method, written instructions are a great supplement and resource for patients upon discharge. "The Joint Commission recommends a fifth-grade reading level for all health care documents" (Hartman et al., 2021, p. 352). Simplicity is a crucial component in enhancing comprehension of discharge materials. In order to categorize discharge instructions, simplification is characterized as using shorter sentences, simpler terms, bullet points, and bolded font (Choudhry et al., 2019). Simplifying discharge instructions, eliminating medical jargon, and

utilizing the teach back method are all effective strategies for increasing patient comprehension and ultimately decreasing the risk of adverse events.

Conceptual/Theoretical Framework

Donabedian's quality framework, also known as Structure-Process-Outcome (SPO), was used to guide this quality improvement project. The SPO model has been widely utilized in healthcare quality research for six decades (Ayanian & Markel, 2016). This model is flexible and comprehensive enough to be applied in various healthcare organizations. It consists of three interrelated concepts. First, the structures of healthcare are defined as the physical and organizational aspects of care settings. Second, the processes of patient care are positioned in the middle of the model because they rely on the structures to provide resources and mechanisms for healthcare providers to carry out patient care activities. The third concept, on the far right, is the outcomes of patient care.

In the context of this project, the 'structure' referred to the community hospital PACU selected for this study. The 'process' involved developing and implementing a web-based education program on the drug-drug interaction between Sugammadex and hormonal contraceptives. Therefore, the specific 'outcome' was the increased nursing knowledge (see Figure 1). Patient outcomes depend on the quality of care delivered to the patients. Discharge teaching plays a vital role in providing high-quality care to surgical patients. It is reported that the frequency and quality of discharge medication teaching are significantly associated with the knowledge and competency of PACU nurses regarding drug information (Hayajneh et al., 2020). To improve patient outcomes, we developed an online education program to enhance PACU nurses' knowledge, competency, and confidence in providing accurate, evidence-based, and patient-centered discharge drug education.

STRUCTURE	PROCESS	OUTCOME
Community Hospital Surgical Unit	Increasing patient education through nursing education	Increase nursing knowledge
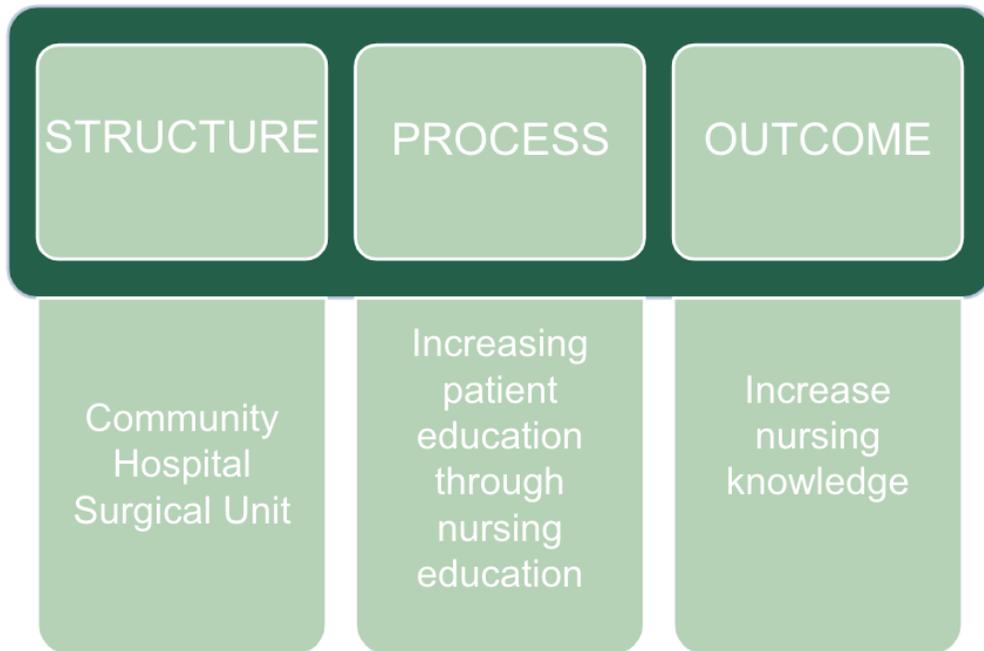
Figure 1: SPO Model

SECTION III: METHODOLOGY

Project Design

A quantitative, quasi-experimental project was conducted using a pretest posttest design. The project included 3 phases: 1) pre-education survey, 2) web-based education session, and 3) post-education survey. The purpose of this project was to examine the effectiveness of a web-based provider education program on PACU nurses' knowledge regarding the drug-drug interaction between Sugammadex and hormonal contraception. The project investigated the following PICOT question: Compared to current nursing education (C), is a web-based education program (I) more effective at improving knowledge about the drug-drug interaction between Sugammadex and hormonal contraception (O) in PACU (T) nurses who provide discharge teaching for childbearing age women receiving Sugammadex (P)? The scores on pre- and post-education tests were compared to assess intervention effect. SQUIRE 2.0 guidelines were used to organize and report our project findings (Ogrinc et al., 2016). Institutional Review Boards approvals were obtained from both the study site and the university prior to the implementation of the project (see Appendix B and Appendix C for IRB approval letters).

Study Participants

The sample utilized for the project was a convenience sample that consisted of approximately 28 PACU nurses at a community hospital. The reason PACU nurses were chosen as the study participants was because PACU nurses primarily provide patient discharge teaching. Our hypothesis was that increased knowledge among PACU nurses about the drug interaction of Sugammadex might lead to a higher frequency of patients receiving education on drug interactions prior to discharge. This, in turn, could potentially reduce preventable birth control

failures due to a lack of awareness about the need for a secondary form of birth control for up to seven days after the administration of Sugammadex. The study included PACU nurses with any amount of experience at each facility working full or part time in the adult PACU. The study excluded pediatric PACU nurses and any ancillary staff who are not responsible for patient discharge teaching.

Setting

The facility this quality improvement project was implemented at included a community hospital. The community hospital was a 391-bed hospital that served the Southeastern Region of the U.S. This facility focused on orthopedic, neurospine, cardiovascular, gynecological, ear nose and throat, urology, and general surgery throughout 12 operating rooms and provided approximately 50 anesthetics per day. This facility's PACU consisted of 15 beds. The community hospital utilized Sugammadex in female patients between the ages of 18-65 approximately 1380 times per year.

Intervention

For the web-based education, an animated educational video was designed. The website Animaker (2015) was used to create the animated educational video. Animaker is a video animation software that utilizes fully customizable characters and templates that users can produce animated videos with. Once the animated educational video was created it was embedded into Survey Monkey. The video began with an introduction to Sugammadex, followed by Sugammadex's mechanism of action, side effects, drug-drug interactions, and patient teaching recommendations. The video consisted of sound and subtitles to accommodate different learning styles. The content validity of the education intervention was established by the dissertation committee member who was a licensed pharmacist with doctoral level education and extensive

teaching experience, as well as Certified Registered Nurse Anesthetist (CRNA) faculties. The video was available in English. It took participants approximately five minutes to complete. Participants accessed the video via a quick response (QR) code with a smartphone device. Participants were given six weeks to access the educational session.

The following strategies were used to enhance and maintain the intervention fidelity. For study design, a clear and detailed intervention protocol was developed that outlined specific education components and expected outcomes. Standardized education materials that align with the intervention protocol were developed. To improve the intervention fidelity, all team members participated in developing online surveys and web-based education modules. To ensure the delivery and receipt, the average time spent on completing the online education modules was regularly monitored and scheduled team meetings were used to identify and troubleshoot any challenges encountered by the participants in completing the online learning module. Emails were sent to encourage active participation and completion and provided guidance on how to access the web-based learning module. The emails also identified areas that may need further clarification. For enactment, the online animated video encouraged participants to apply the knowledge and skills they gained into their clinical practice. By addressing each of these components in the design, training, delivery, receipt, and enactment stages of the educational intervention, the intervention fidelity was improved, ensuring that the intervention was implemented as intended and produced meaningful outcomes.

Data Collection

In Phase I, both pre- and post-education surveys were constructed to collect participants' demographic and clinical information including gender, age, years of experience, and educational background. The subsequent portion of both surveys comprised five questions to

assess PACU nurses' knowledge of Sugammadex and its effects on hormonal contraception and their current practice in providing Sugammadex related discharge teaching. One question was in yes or no format, whereas the other four questions were multiple choice format (See Appendix A). A scoring system was utilized to quantitatively measure the survey responses. All surveys were scored the same. A correct answer was given a one and an incorrect answer was given a zero. The content validity of the surveys was confirmed by all committee members and CRNAs before being distributed. The pre-education survey was administered among PACU nurses in an effort to assess their baseline knowledge. Survey Monkey was used to create surveys. The participants had access to the pre-education survey by scanning the provided QR code.

In Phase II, participants reviewed self-paced online educational material. In Phase III, immediately following the educational session, participants were prompted to complete a post-education survey, which was identical to the pre-education survey. The survey results were collected electronically via a QR code that was linked to the Survey Monkey website. All responses submitted through Survey Monkey were confidential and collected in real time. Once the data collection period ended, all responses were made anonymous.

To increase participation and completion rates, we sent out weekly reminder emails to the PACU manager providing an update on the project's current participation count. The PACU manager encouraged their staff to participate during their daily huddle sessions. The completion rate was 57% at the study site.

Data Management and Security

The online education module was preset to only show the computer IP address the participants used to complete the learning module. Each participant was assigned a unique study ID, which was used for data entry, tracking, and analysis. Each participants' ID was stored in a

secured, IRB approved web-based folder. This web-based folder is password protected and only accessible by the project personnel. A consent form was provided to participants prior to completing the module. This consent informed participants that their years of experience and provider role would be used for study purposes. Participants were reassured that their identity remained confidential and secure.

Furthermore, Survey Monkey, an online password protected site, was utilized to store data. Survey Monkey was only accessible to the project personnel, the sponsor of this research, IRB, and any other persons required by law. Both university and the participating healthcare facilities shared a uniform policy on the protection of patient privacy that satisfied all the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The project team abided by both organizations' policies, and strictly adhered to the detailed human subject protection regarding data analysis, which was utilized throughout this project period to preserve participants' privacy and security. Participants were provided the option to opt out of participating in the project.

Data Analysis and Evaluation

All statistical analyses were performed using R (version 4.0.2) with a significance level of < 0.05 (De Micheaux et al., 2013). Pre-analysis data screening was performed prior to statistical analysis to examine coding errors, outliers, and data skewness to determine if any data cleaning procedures are needed. Coding errors often occur when the questionnaires are used as assessment tools. To reduce coding errors, the statistician was consulted, and statistical procedures were used to recode the study questionnaires. Additionally, the missing data caused by unanswered questions was reviewed for patterns that would introduce bias in the result. Participants were asked to go back and fill out the questionnaires completely. If some data items

remained missing, these issues were resolved via consultation with the statistician and major advisor.

Descriptive statistics (means, standard deviations, or median, interquartile range, or number, percentages, and frequencies) were calculated for all variables. Demographic characteristics of the study population were analyzed as means and standard deviations (SD) for continuous variables and as frequencies and percentages for categorical variables. All statistical tests are 2-tailed. The variables were checked for normality and the mean and SD was used as a measure of central tendency since the data are normally distributed.

The $\chi 2$ were performed to describe and compare frequencies. The student t-test were utilized to test for significant differences between pre and post-survey scores. Pearson's correlation coefficients were used to determine the relationships between key concepts. Univariate and multivariate logistic regression or linear regression analyses were performed to determine the relationships between the pretest and posttest.

Timeline

December 2022 marked the finalization of the project's topic. In March 2023, a review of the literature was done. In April 2023, the proposal defense was successfully finished. In July 2023, permissions were received from the institutional review boards of the university and the clinical site, subsequent to the proposal defense. August and the first few days of September 2023 were used for data collecting and intervention. By the end of September 2023, the data analysis and report creation were complete (Appendix D).

SECTION IV: SURVEY RESULTS

Sample Characteristics

Out of the 28 employed PACU nurses at this facility, 19 individuals participated in this study, with 16 of these individuals completing both the pre and posttest (a response rate of 67.9%). All the study participants were female. Their age ranged from 26 to 62 years old ($M = 42.74$, $SD = 12.05$, $Mdn = 44$). Their years of experience ranged from 0 to 33 years ($M = 5.67$, $SD = 8.81$, $Mdn = 3$). In terms of education, 57.9% had a bachelor's degree, and 42.1% had an associate degree (see figure 1). Demographics did not relate to either pretest or posttest scores, $ps > .123$.
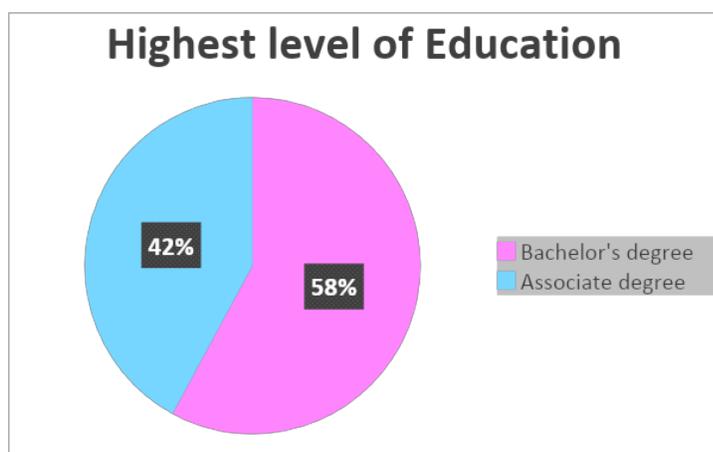
Figure 2: Highest level of Education

Survey Results

There was no statistically significant difference between the pretest and posttest scores for any of the five questions, as indicated by all p-values greater than 0.05 (see Table 1 and Figure 2). However, the average number of correct responses significantly improved from 4.37 (SD = 0.90)

to 4.81 (SD = 0.40) following the intervention ($t = 2.52$, $p = 023$), demonstrating that the

intervention was effective with improving participants' overall knowledge about Sugammadex

drug interactions with hormonal contraceptives. The proportion of correct answers for each of

the five questions is provided in Table 1 for a more thorough breakdown of the participants'

performance. This enables a deeper analysis of their answers and the identification of any

knowledge gaps or areas of stability.

Table 1: Pretest and posttest comparison for each question and total score

	Pretest ($n = 19$) % correct	Posttest ($n = 16$) % correct	p-value
1. What is the mechanism of action of Sugammadex?	63.2	81.2	.421
2. Which form of birth control does Sugammadex NOT affect?	84.2	100	.291
3. If given Sugammadex, how long should women of childbearing age use additional birth control for?	89.5	100	.545
4. How does Sugammadex render hormonal birth control ineffective?	100	100	1.00
5. Do you offer additional discharge teaching about Sugammadex to women of childbearing age?	100	100	1.00
Total score	4.37 (0.90)	4.81 (0.40)	.023

Note. *p*-values for the individual questions were based on chi-squared tests. The p-value for testing total score difference was based on paired t-test.
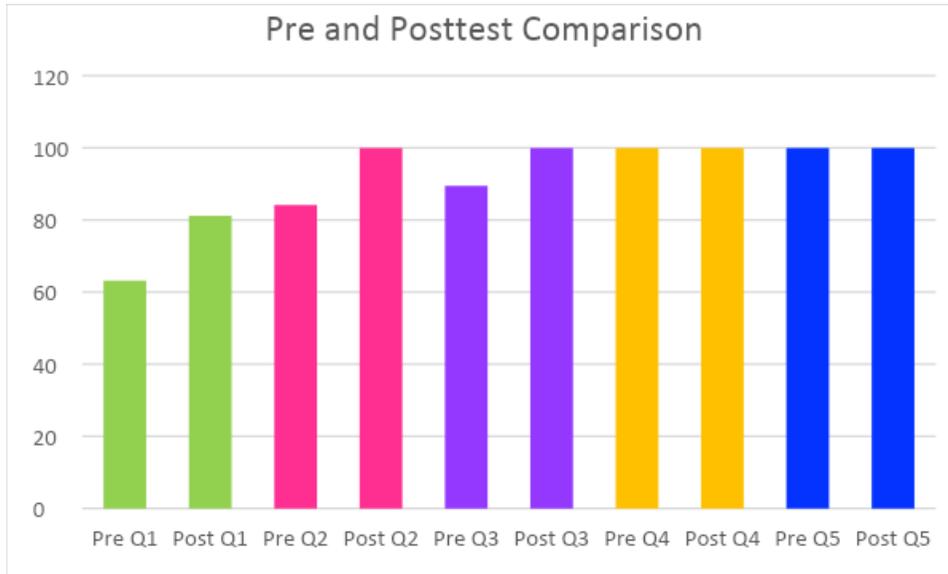
Figure 3: Pre and Posttest Comparison

SECTION V: DISCUSSION

Summary

This Quality Improvement (QI) project was the first reported project that examined the effect of a web-based education module on PACU nurses' knowledge regarding the drug-drug interaction between Sugammadex and hormonal contraception. Despite the FDA label for the warning of drug-drug interaction between Sugammadex and hormonal contraceptives, less than 1% of women using hormonal contraception received appropriate education regarding this interaction (Devoy et al., 2023; Lazorwitz et al., 2020). Without proper education, an unwanted pregnancy may occur in female patients taking oral contraceptive pills within the same cycle as her exposure to sugammadex. One of the reasons patients do not receive proper medication education is the lack of knowledge, competency, and confidence of PACU nurses who are responsible to provide patient medication education. To improve the quality and frequency of patient education, we conducted this project aimed to examine the effectiveness of a web-based provider education program on PACU nurses' knowledge about the drug-drug interaction between Sugammadex and hormonal contraception. The main finding showed the web-based education was feasible and effective to enhance PACU nurses' overall knowledge about the drug-drug interaction between Sugammadex and hormonal contraception.

The literature was lacking in studies about Sugammadex and a formalized educational program with only two papers found that addressed this important topic. These studies' findings suggested that providing a uniform teaching program might improve PACU nurses' ability to convey crucial information about drug-drug interactions, such as the need for patients to take an additional form of birth control for up to seven days after receiving Sugammadex. The

researchers of these studies concluded that educational in-services offer PACU nurses the skills and assurance they need to deliver successful discharge instructions.

A knowledge deficit was clearly identified after implementing a standardized educational program centered around Sugammadex at a community hospital. The question that scored the lowest on the pre and posttest was "What is the mechanism of action of Sugammadex". The mechanism of action of a drug refers to the way a drug affects the body. Knowing the mechanism of action of a drug, such as Sugammadex, increases the ability of an individual to perform adequate drug education to patients. Out of the five survey questions, three of the questions showed improvements in scores on the posttest, indicating a knowledge gap that was successfully filled through the educational video that was presented. None of the survey questions showed statistical significance at this facility. The lack of significance can be attributed to multiple reasons such as the small sample size, the possibility that the PACU nurses at this facility have adequate baseline knowledge of Sugammadex due to nursing training provided by this facility. There is also the possibility that the survey questions were too simple. For the posttest, the question regarding how long women of childbearing age should utilize additional birth control after receiving Sugammadex, all 16 participants chose the correct answer. This question addressed the critical time frame that the FDA recommended for women to follow after being administered Sugammadex perioperatively. In order to effectively provide discharge education about Sugammadex, it is imperative to know the timeframe that Sugammadex could render hormonal birth control ineffective. This could ultimately save a woman from having an unintended pregnancy. Following surgery, discharge education provided by PACU nurses is patient-centered, safety-focused, and designed to minimize risks and accelerate recovery. Equipping PACU nurses with information on anesthesia providers' operating room drugs that

impact the patient in the days following surgery enables them to instruct patients confidently and successfully prior to discharge.

Limitations and Challenges

There are several limitations in this project. We employed a pretest-posttest study design. The most significant limitation of this type of design is the lack of a control group, potentially introducing bias and threats from confounding factors. The results may not be generalizable to all healthcare settings, as it was a QI project conducted in one institution. We used a small convenience sample of PACU nurses from one urban hospital, which could affect the validity of the results. Our study is limited by measuring the short-term effect of the online education program. Due to feasibility and time constraints, we were unable to assess the long-term effect of the online education program.

During the study, we had difficulty in recruitment and enrollment. The initial plan for this QI project was to keep the surveys open for two weeks. At the two-week mark, there were less than 10 participants. Due to this, the project was extended for a few additional weeks. Another limitation would include the time frame that was utilized for implementation. The project was open for a total of six weeks. If the project would have been able to be opened for a longer period of time, there may have been more participation. This project only assessed immediate knowledge gain. Several platforms were utilized for this project such as Survey Monkey, Animaker, and QR code generator. Each of these platforms came as a hefty expense. Pediatric PACU nurses were excluded from this project for a number of reasons, including the fact that we had a tight deadline and that our educational video was intended to inform adults about Sugammadex rather than children. IRB clearance would have taken longer if the project

mentioned pediatric patients. Future efforts to increase participation may involve allocating more time, money, and developing recruitment techniques.

Lessons Learned

Many lessons were learned throughout this project. A QR code was utilized to access the surveys by PACU nurses', but these QR codes that were posted throughout the units were often moved to places that made them not easily visible. Therefore, in the future utilizing QR codes may not be the best way to gain participation. If a QR code is used, Survey Monkey creates QR codes for no additional cost. This was not known at the time of this project so the additional expense of generating a QR code could have been avoided. All in all, it truly takes patience to implement a project in a healthcare setting.

Implications for Nursing Practice

Sugammadex is a widely used medication in the perioperative setting at many hospitals. There is a significant drug-drug interaction between Sugammadex and hormonal contraception. As a result, the FDA even issues a warning about the need for additional birth control for up to seven days after receiving Sugammadex. Otherwise, unwanted pregnancy may occur, emphasizing the necessity of a standardized education program on Sugammadex and its negative effects on hormonal contraceptives. To date, there has been no evidence-based guideline on the best approach and timing to provide patient education about Sugammadex drug interaction. PACU nurses play a crucial role in providing discharge teaching related to Sugammadex drug interaction and reducing the risks of birth control failure. In order to provide accurate medication education, PACU nurses must be knowledgeable, feel competent, and be confident in delivering medication education. Our study adds evidence that may help develop and implement a

standardized educational session for PACU nurses about Sugammadex drug interaction, thus improving patients' discharge education and preventing negative patient outcomes.

Recommendations

Due to the surveys only testing immediate knowledge gain, it is recommended that there be an additional survey that ensures long-term learning occurs after the educational session. Sending out the educational material to employees emails instead of posting QR codes throughout the unit may increase the participation rate and could also allow participants to watch the video anytime they need a refresher on Sugammadex. If an employee was not at work during the time period that the QR codes were posted, they would have never known about the project but if they received an email they could have participated from anywhere. The institution this QI project was implemented at did not have any pre-existing guidelines about Sugammadex education for PACU nurses therefore a standardized education program needs to be established.

Conclusion

Sugammadex is a neuromuscular blocker reversal agent that can uniquely reverse any depth of neuromuscular blockade. It is widely utilized in healthcare facilities throughout the US in the operating room by anesthesia providers. It is an ideal medication except for one caveat– it has a drug-drug interaction with hormonal contraceptives resulting in ineffective birth control coverage for up to seven days after receiving a dose of Sugammadex. The average number of correct responses on the pre and posttest improved after implementing a web-based education for PACU nurses that focused on the drug-drug interaction Sugammadex has with hormonal contraceptives. The major conclusion demonstrated that improving PACU nurses' general understanding of the drug-drug interaction between Sugammadex and hormonal contraception through web-based education was both possible and beneficial. In an attempt to prevent any

negative patient outcomes following the administration of Sugammadex, standardized teaching

guidelines for PACU nurses on drug interactions should be created and implemented.

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APPENDIX A: SUGAMMADEX SURVEY

Demographic questions:

1. What is your gender?

    a. Male

    b. Female

    c. Non-binary

2. What is your age?

    a. FILL IN THE BLANK

3. How many years of experience do you have as a PACU nurse at Atrium?

    a. FILL IN THE BLANK

4. What is your educational background?

    a. Associate degree

    b. Bachelor's degree

    c. Master's degree

    d. Doctorate degree

Survey Questions:

1. What is the mechanism of action of Sugammadex?

    a. It opens up sodium channels to allow entrance of sodium into the nerve ending

    b. It adheres to postsynaptic cholinergic receptors of the motor end plate

    c. It encapsulates the steroidal neuromuscular blockers and prevents them from binding to Nicotinic receptors

    d. It noncompetitively binds to the NMDA receptor and blocks the influx of calcium

2. Which form of birth control does Sugammadex NOT affect?

    a. Hormonal Intrauterine device (IUD)

    b. Oral birth control

    c. Nexplanon

    d. Condom

3. If given Sugammadex, how long should women of childbearing age use additional birth control for?

    a. 3 days

    b. 7 days

    c. 24 hours

    d. 28 days

4. How does Sugammadex render hormonal birth control ineffective?

    a. It encapsulates the progesterone and estrogens contained within hormonal birth control

    b. It encapsulates the sodium contained within hormonal birth control

    c. It prevents ovulation

    d. It promotes follicular development.

5. Do you offer additional discharge teaching about Sugammadex to women of childbearing age?

    a. Yes

    b. No

APPENDIX B: WAKE FOREST IRB APPROVAL LETTER

MEMORANDUM

To: Danielle Brown
                Atrium/Carolinas Healthcare System

From: Douglas Yoder, Chair
                Institutional Review Board

Date: 6/22/2023

Subject: Exempt Protocol: IRB00097769
                Sugammadex and Hormonal Birth Control Education- A Quality Improvement
                Project

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

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.

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

To:	Ashley Burch
	University of North Carolina at Charlotte
From:	Office of Research Protections and Integrity
Approval Date:	21-Jul-2023
RE:	Notice of Determination of Exemption
Exemption Category:	1
Study #:	IRB-24-0008
Study Title:	Sugammadex and Hormonal Birth Control

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.

APPENDIX D: PROJECT TIMELINE

	12/22	1/23	2/23	3/23	4/23	5/23	6/23	7/23	8/23	9/23	10/23	11/23	12/23	1/24	2/24

DNP Project Timeline
- Topic Proposal
- Oral Defense of Proposal
- IRB application/approval
- Developing educational video
- Visit facilities to hang up QR codes
- Go Live!!
- Data Analysis
- Final corrections for project defense
- Project Defense
- Presentation of DNP scholarly project