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Effects of Perioperative Medications on Hormonal Contraception: An Educational Initiative

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### **Abstract**

**Phase II Site:** Naval Medical Center Portsmouth

**Project Title:** Effects of Perioperative Medications on Hormonal Contraception: An Educational Initiative

**Authors:** Mattox, P.W., Oakman, G.M., Phillips, E.L., Smith, S.Y.

**Background or Problem/Issue:** A known interaction between certain perioperative medications and hormonal contraceptives could lead to unintended pregnancy in a female utilizing hormonal contraceptives without additional contraceptive methods. Currently, Naval Medical Center Portsmouth (NMCP) does not have a standardized procedure for identifying and ensuring these patients receive the appropriate education regarding contraceptive practices. Additionally, healthcare providers may not know of these medication interactions, potentially resulting in patients not receiving proper post-operative contraception education.

**Clinical Question or Purpose:** Among multidisciplinary perioperative healthcare professionals at Naval Medical Center Portsmouth, does the implementation of an education program compared to current practice increase knowledge and awareness of interactions between perioperative medications and hormonal contraceptives?

**Project Design:** This evidence-based project was an educational initiative based on Steven's Star Model. It utilized pre- and post-assessments to determine the efficacy of PowerPoint-based training on perioperative medication interactions with hormonal contraception.

**Analysis of the Results:** Pre- and post-assessment of teaching displayed an increase in knowledge base amongst perioperative providers. Participants' response to their likelihood to teach this knowledge to their patients increased in the Aprepitant group.

**Organizational Impact/Implications for Practice:** Ensuring that perioperative healthcare

providers consistently educate patients about these interactions throughout the surgical timeline will increase patient awareness. This knowledge allows patients to become active participants in their healthcare and future contraceptive choices, decreasing patient harm and aiding the military family and individual members' well-being.

## **Introduction**

Women who receive sugammadex or aprepitant perioperatively have an increased risk of becoming pregnant due to pharmacologic interactions with their hormonal contraception (Cada et al., 2016; Merck & Co., Inc., 2015; Merck & Co. Inc., 2020). These interactions can include significant reductions in serum progesterone, ethinyl estradiol, and norethindrone levels, increasing the risk of unintended pregnancy (Cada et al., 2016; Aapro & Walko, 2010). Unplanned conception can have detrimental effects on female service members, their families, the Military Health System (MHS), and the U.S. military at large. The current practice for patient education at Naval Medical Center Portsmouth (NMCP) includes verbal counseling on the risks and benefits of anesthesia during informed consent by the anesthesia provider in the immediate preoperative phase. It does not include standardized patient education on the risk of decreased hormonal contraception efficacy due to receiving specific perioperative medications. Based on current practice, it is likely that not all females taking hormonal contraceptives receive counseling on this interaction or the need for alternative contraception. It is essential for reproductive-aged women who may potentially receive these medications to receive standardized pre and postoperative education to increase awareness of this significant medication interaction (Fredericks et al., 2010) and the need for alternative non-hormonal contraception precautions for up to 28 days following surgery (Cada et al., 2016; Merck & Co., Inc., 2015; Merck & Co. Inc., 2020).

## **Significance of the Problem**

Perioperative medications that leave patients at risk for unintended postoperative conception include sugammadex and aprepitant, which reduce the effectiveness of hormonal contraception (Cada et al., 2016, Merck & Co., Inc., 2015; Merck & Co. Inc., 2020). Without a

standardized process to capture the at-risk patient population and provide information about the potential medication interaction, the risk of this unintended outcome goes unchecked. The potential impact of an unintended pregnancy can include psychological distress to military members and their families, increased healthcare costs, and decreased mission readiness.

### **Mechanism of Action**

Sugammadex is a relatively new selective relaxant binding agent with a high affinity for steroidal intermediate-acting neuromuscular blocking agents, specifically rocuronium and vecuronium (Barash et al., 2017, p. 554). It reverses neuromuscular blockade and prevents postoperative residual curarization (Schaller & Fink, 2013). Sugammadex encapsulates steroidal neuromuscular blocking drugs, negating their paralyzing effect. Due to a similar structure to steroidal NMBDs, progesterone and estrogen also become encapsulated by sugammadex. Progesterone is the principal component of all oral, topical, injectable, and implantable steroidal contraceptive formulations (Rivera et al., 1999). Hormonal contraceptives prevent ovulation and inhibit follicular development by maintaining elevated levels of progesterone. The administration of sugammadex (4 mg/kg) decreases progesterone levels by 34% (Et et al., 2015). This reduction of progesterone is equivalent to missing one daily dose of a hormonal contraceptive, increasing the risk for unintended pregnancy if no additional contraceptive is in use for the first seven days following administration (Cada et al., 2016). Current literature only addresses the effects of sugammadex on contraception at the standard dose of 4mg/kg. Dosing up to 16 mg/kg is recommended based on the level of residual blockade. The effect of these larger dosing regimens is unknown.

Aprepitant, a Neurokinin-1 antagonist (NK-1), is effective in the immediate postoperative phase and after discharge for postoperative nausea and vomiting (PONV) and is widely used in

protocols for PONV prophylaxis (Hemmings, 2019, p. 681). In a study conducted by the manufacturer of aprepitant, Merck & Co., findings demonstrated coadministration of a 40mg dose of aprepitant with an oral contraceptive containing ethinyl estradiol and norgestimate over 21 days decreased the area under the concentration of ethinyl estradiol levels by 4% and 29% on days 8 and 12. This progressive decrease in ethinyl estradiol levels can decrease the efficacy of hormonal contraceptives during and after the last dose of aprepitant for up to 28 days, increasing the risk for an unintended pregnancy if a back-up method is not utilized (Merck & Co., Inc., 2009). There is currently limited information on the effects of single-dose aprepitant, similar to dosing in the perioperative setting.

The short- and long-term effects of an unintended pregnancy can have significant impacts, not only on the mother but also on her family and unborn child. Mothers who report unplanned pregnancies had an increased prevalence in the development of psychological distress at nine months postpartum (Barton et al., 2017). Additionally, psychological distress can lead to a non-deployable status for military service members until cleared by a behavioral health provider (Ibis Reproductive Health, 2013). The uncertainty of such situations has demonstrated adverse outcomes such as low birth weight, preterm birth (Shah et al., 2011), and postpartum depression (Cheng et al., 2009).

Currently, NMCP does not provide standardized education to women taking hormonal contraceptives who receive sugammadex or aprepitant. This gap in current anesthesia practice to fully inform patients of perioperative risk may lead to missed delivery of vital information, depending on the discussion quality between the anesthesia provider and the patient during the general consent process that precedes their surgery. This inconsistent practice could result in decreased patient awareness, potentially increasing the occurrence of unintended pregnancies.

Therefore, to mitigate this risk and improve patient knowledge, leaders within the anesthesia department seek to provide an evidence-based solution.

### **Military Relevance**

Unintended pregnancy can have significant negative impacts among service members and their families, resulting in decreased readiness and deployability. Reproductive-aged women constitute 97% of the female active-duty population (Ibis Reproductive Health, 2013). NMCP performs surgery on approximately 1,800 females of childbearing age annually, comprising 24% of the surgical population. Military health leaders must address this issue, for it is their duty to mitigate potential problems for their service members. Preventing unintended pregnancies through perioperative healthcare provider education and awareness will indirectly increase patient knowledge and directly impact readiness. Starting with senior leadership, addressing unintended pregnancy aligns with the Defense Health Agency's (DHA) quadruple aims performance process goals. Providing individualized perioperative education will foster a safe environment, resulting in better health, better care, increased readiness, and lower costs of services rendered.

### **Clinical Question**

Among multidisciplinary perioperative healthcare professionals at Naval Medical Center Portsmouth, does the implementation of an education program compared to current practice increase knowledge and awareness of interactions between perioperative medications and hormonal contraceptives?

### **Literature Review**

To guide our literature search (Appendix A), our PICO question was, "For perioperative healthcare providers (P), does a standardized education program (I) compared to current practice

(C), increase the knowledge of interactions between hormonal contraceptives (O)?” We used the Learning Resource Center (LRC), PubMed, and Liberty University databases to collect articles to review current literature. Search terms for all databases included: “hormonal contraceptives” AND “anesthesia” OR “hormonal contraceptives” AND “anesthesia” OR “sugammadex” OR “hormonal contraceptives” AND “anesthesia” AND “effectiveness” OR “hormonal contraceptives” AND “anesthesia” AND “interaction” OR “birth control” AND “anesthesia” OR “birth control” OR “hormonal contraceptives” OR “contraceptives” AND “anesthesia” OR “surgery” OR “sugammadex” OR “sugammadex” AND “contraceptives” OR “sugammadex” OR “bridion” AND “contraceptives” OR “sugammadex” AND “in vitro” AND “progestin” OR “progesterone” OR “sugammadex” AND “in vitro” AND “hormone” OR “anesthesia” AND “contraceptives” OR “aprepitant” AND “contraceptives” OR “mechanism of action of action of hormonal contraceptives” OR “unintended pregnancy” AND “mission readiness” OR “patient education” AND “women” AND “surgery” OR “patient education” AND “surgery” OR “patient education” AND “females” OR “patient education” AND “counseling” OR “patient education” AND “counseling” AND “surgery” OR “discharge education” AND “surgery” OR “education” AND “decreased effectiveness” AND “contraception” OR “women” AND “education” AND “surgery” OR “education” AND “unintended pregnancy” OR “evidence based practice” AND “patient education” OR “readability” AND “discharge education” OR “standardized discharge education” OR “preoperative” AND “postoperative education” OR “impact of preoperative education on surgical patients” OR “teach-back method” OR “preoperative instruction” OR “postoperative instruction” OR “ambulatory surgery” OR “knowledge retention” AND “evaluation” AND “education” AND “healthcare provider” OR “knowledge retention” AND “evaluation” AND “education” AND “healthcare provider.” Our search was limited to the past

12 years and included only peer-reviewed articles published in English. Conference review, notes, or summaries were excluded. As of November 2020, our search yielded 2,707 results. Thirty-two duplicates were removed, leaving 2,675 articles for screening of title and abstract. From these, 2,571 were dismissed for lack of relevance, leaving 104 for full-text screening. Full text screening was done with inclusion criteria of articles that included provider and patient education and knowledge retention evaluation. Exclusion criteria included articles with settings outside of healthcare and small study populations. Thirty-three articles were excluded for incorrect setting, 24 for inadequate patient population, 17 for inappropriate intervention, seven for unsuitable indication, two for unsuitable comparator, and one duplicate. Eleven articles were included in our literature appraisal.

Article appraisal was completed using the Johns Hopkins Nursing Quality of Evidence-Based Practice tool to assign a level of evidence and quality rating (Dang & Dearholt, 2017). Three articles were high levels of evidence IA, two level IB, and one level IIB. We included one IIIB, IIIC, two VA, and one VB supporting information for our topic and solution (Appendix B). Based on our literature review, educating providers using an online tutorial with pre, immediate post, and six-month post assessments is an effective means to increase their knowledge and awareness of the interaction between perioperative medications and hormonal contraceptives (Bell et al., 2008; Mevsim et al., 2008). Additionally, we found that patient education is most effective when delivered before surgery in small, incremental sessions (Bastable, 2016; Hovespian et al., 2017).

### **Solution Synthesis**

Patients must be better informed of these medication interactions and educated on the need for additional contraception to mitigate unintended pregnancy among patients in the

Military Health System. Current evidence supports a multimodal approach to patient education, including pre and postoperative educational interventions (Angioli et al., 2014; Fredericks et al., 2010; Hovesejian et al., 2016). To capture as many of these patients as possible at multiple points in their perioperative throughput, we first must educate the multidisciplinary providers that interact with the surgical patient at NMCP. These include surgeons, nurses within the surgical clinics, anesthesia providers, and post-anesthesia care unit (PACU) nurses.

To successfully educate perioperative healthcare providers, we must gain their support on the need to change their current practice. The three main objectives of successful provider education are: Building knowledge and positive attitudes surrounding the public health initiative, improving the application of evidence-based guidelines, and preparing providers to support and follow those guidelines (World Health Organization & JHPIEGO, 2005). This provider education will consist of evidence-based online, self-paced learning modules, including a pre and post education knowledge and awareness assessment (Bell et al., 2008; Mevsim et al., 2008). Bell et al. (2008) conducted a randomized control trial that assessed an online tutorial's effectiveness for knowledge retention among resident physicians. Their tutorial's key characteristics included an overview of learning objectives, links to primary sources, and an overview of each learning objective in an interactive manner. Questions were placed in between each learning objective, and a correct response was required before moving on. Once the correct answer was selected, the program provided an additional explanation.

They found that mean knowledge levels significantly improved between pre and posttest scores; however, knowledge levels that initially improved were found to decrease over the weeks following the intervention. An additional study by Mevsim et al. (2008) had a minor decrease in mean knowledge levels after administering a posttest six months following an educational

intervention. They attributed such a small reduction over time to consistently active use of the education that was received. We plan to utilize this method of teaching for perioperative providers at NMCP. If the intervention is successful, and providers adopt our recommendations into their daily practice, we predict retention of knowledge will improve through repetitive use. To sustain our efforts, we plan to implement systematic changes that identify surgical patients at risk and provide education at these varying points. Preoperatively, patients will complete a preoperative assessment form including a question specifically addressing hormonal contraceptive use. This will allow clinic staff to identify the need for a discussion within the preoperative clinic. This will also alert the anesthesia provider to which patients will require additional information in their informed consent process. Postoperative interventions will include confirming this information is provided again at discharge by the PACU nurses. Through these avenues, patients will hear the information at a minimum of three times before discharge.

While our project does not aim to measure compliance with informing and educating patients, we predict that our evidence-based provider education program and sustainment interventions will improve the identification and education of these patients and reduce the number of unintended pregnancies associated with the current practice.

### **Focus Area**

Our three focus areas will be the providers, processes, and patients. Our first focus area, the providers, will be achieved by disseminating a standardized online tutorial and assessment of pre and post knowledge and awareness. Our second focus area includes provider and patient process improvement. We will address provider processes by adding a question for patients to identify any hormonal contraceptive use. This will alert providers to the need for further intervention and education. Through an additional order option in standard order sets, PACU

staff will also be alerted to the need for intervention before discharge. Our third focus area, the patients, will be accomplished through early identification of at-risk patients during their preoperative appointment and repetitive education at multiple time points in their surgical experience.

### **Organizing Framework**

We will utilize the Stevens Star model of knowledge transformation (Appendix C). The Stevens Star model is commonly used in healthcare to translate evidence into practice. This model involves five steps: knowledge discovery, evidence summary, translation to guidelines, practice integration and process outcome evaluation (Stevens, 2015). Sugammadex and aprepitant are medications that have been introduced to the clinical arena within the last decade, making them newer to practitioners who have provided care prior to their release. By educating all providers to the potential interactions and implications, we will translate the research of these medications into a practice guideline for educating female surgical patients. This will allow providers to evaluate the impact of perioperative medications on health outcomes, and tailor their care to the preferences of the individual patient.

Our overall goal is to decrease the potential for unintended pregnancy related to medication interaction in the perioperative patient, and to imbed this knowledge as part of the perioperative provider's essential skill set moving forward. In doing so, the patients will receive consistent information to make educated decisions regarding their contraceptive needs. The STAR model will provide a theoretical framework to implement an evidence-based solution into a military treatment facility.

### **Project Design**

#### **General Approach**

This project is intended to assess perioperative healthcare providers' knowledge/awareness regarding specific perioperative medication interactions on hormonal contraception and provide standardized patient education throughout the perioperative arena. Armed with improved knowledge, perioperative healthcare providers will obtain the information necessary to educate the patient of the need for alternative contraception. By indirectly increasing patient awareness, we can promote better outcomes for all MTF beneficiaries.

### **Setting and Population**

The setting of this project is NMCP, located in Portsmouth, Virginia. NMCP provides health care to the largest concentration of U.S. military in the world (Naval Medical Center Portsmouth, 2017). It is a large-scale medical training center, performing over 10,000 surgeries annually, with the potential for 24% to be women of reproductive age and receive specific perioperative medications that affect hormonal contraception.

### **Procedural Steps**

A literature search and review were conducted, and it revealed that patients need to be educated about perioperative medication interaction with hormonal contraceptives. The manufacturers of sugammadex and aprepitant recommend that alternative contraceptives be used for 7-28 days, respectively (Merck & Co. Inc., 2015; Merck & Co. Inc., 2020). The team's goal is to indirectly increase patient awareness of these interactions, by directly educating perioperative providers. We will obtain approval from our local Institutional Review Board before implementation of our project.

The study will be conducted in two phases. Phase 1 will generate an email to all perioperative healthcare providers in the hospital to introduce the project, its purpose, and steps to participate in the educational program. We will obtain consent from all participants and collect

demographic information. Staff will be provided a link from the hospital's online training platform to conduct a pretest, online training module, and posttest.

After completing the pretest, participants will view a narrated PowerPoint presentation developed by our group in conjunction with our faculty mentors and formatted to an online training platform in collaboration with the information technology department. The core content will be the medications used in the surgical environment, medication interactions with hormonal contraception, and patient awareness of these interactions in the perioperative arena. In Phase 2, after completing this training module, providers will repeat the knowledge questionnaire to compare knowledge retention (posttest).

### **Data Analysis Plan**

The independent variable for this project is our educational intervention, with the range of nominal values being 0 (without standardized education) and 1 (standardized education). The dependent variables will be the mean percentage score of the pre and post knowledge assessments, calculated by counting the number of correct/incorrect questions, at each respective time frame. The possible range of values will be from 0% to 100%, and this data will be analyzed using the Kruskal-Wallis Test to differentiate the results of the two groups (Appendix E).

### **Potential Barriers and Dissemination Plan**

We anticipate three potential barriers: compliance of healthcare providers in carrying out the proposed education plan, compliance of patients in following the recommendations, and patient disclosure of current medications. All three of these elements are essential to the success of our initiative. We plan to overcome these barriers by tailoring our educational sessions to each audience, from various providers to patients, to make the issue at hand affect them individually.

For example, surgeons may not feel that the interaction of sugammadex and hormonal contraception has anything to do with their role; however, many surgeons order aprepitant for severe nausea and vomiting, and thus their educational session will be more directed towards the interaction of the latter.

Education is most successful in repetitive and short sessions with reinforced reading material, and thus by including the information at multiple junctures and a pamphlet for patients to take home, we hope to increase patient compliance. Finally, to encourage full patient disclosure of medications to include hormonal contraception, we plan to begin this process at the patient's preoperative appointment.

After completing our project, we will distribute our findings to support provider practice change and encourage the new processes' permanence. We will present our findings to our local Directorate of Surgical Services to involve all surgical clinics and our anesthesia department during a weekly departmental meeting. We will deliver a virtual poster presentation at the USU 2022 Research Week and a podium presentation at the Virginia Association of Nurse Anesthetists' (VANA) Winter Workshop 2022 to ensure a broad dissemination of our findings.

### **HIPAA Concerns**

This project has minimal HIPAA concerns. We will not be collecting any PII from patients. Any staff data collection will be anonymous and will be kept on computers that require common access control (CAC) enabled and are in a secure office at NMCP. There will not be any personally identifiable information released at the completion of data collection.

### **Business Case Analysis**

NMCP can decrease unintentional pregnancies during the immediate postoperative period, resulting in increased member readiness and patient satisfaction. Implementing a low-

cost educational intervention to increase the knowledge and awareness of perioperative medication interaction with hormonal contraceptives among perioperative healthcare providers can lead to greater cost avoidance associated with unintended pregnancies and decreased readiness among military members.

NMCP performs surgical procedures on approximately 1,800 female patients of childbearing age annually. The potential cost avoidance of the 5% incidence of unintended pregnancies in this population can range from \$32,000 to \$150,000 per pregnancy (Thomson Healthcare, 2007; Russel et al., 2007). The cost avoidance associated with an additional dependent and Tricare beneficiary is well beyond those estimates and directly aligns with the Quadruple Aims of the Military Health System (MHS) for better care, better health, lower cost, and increased readiness. Our recommendation to establish a standard level of knowledge among perioperative healthcare providers will ensure that the patient has the opportunity to receive information concerning their hormonal contraceptive and perioperative medications at multiple stages in the perioperative period. Additionally, this recommendation has the benefit of not requiring any personally identifiable information (PII) and is a sustainable method of training for perioperative healthcare providers (Appendix F).

### **Project Results**

The initial sample size included 58 participants, with a range of years of experience within their specified area of practice from 0 to greater than 20 years of experience. We asked participants two qualitative questions, asking how often they teach patients about the potential interactions that Aprepitant and Sugammadex can have, rating it with a Likert scale of Never, Sometimes, or Always.

Quantitative data collected included the scores of the participants' pre - and post-test

scores. Out of the 58 total participants, 53 completed the pre-test, and 38 completed the post-test. The project team omitted those participants that did not have both a pre – and post-test score, leaving us with a total of 33 participants for analysis. In comparing the test scores, the participants were divided into their respective job titles and then placed into one of three categories: an increase in post-test score, no change, or a decrease. Overall, 59.4% of the participants saw an increase in their total score, 36.4% showed no change, and 6.3% decreased. Broadly, it displayed an increase in the knowledge base between the pre – and post-test.

Responses to the likelihood to teach patients about the interactions between Aprepitant and Sugammadex and hormonal contraceptives were translated into a numeric score, from one to three, with a higher score correlating with a greater likelihood of teaching. The scores were compared between the pre-and the post-test with the Kruskal-Wallis test, with each participant placed in a group based on their stated job title. The overall likelihood amongst providers was then compared using Wilcoxon p-values. The most significant score changes were noted in the registered nurse group, anesthesia group, and overall. When the occupation groups were compared, none were statistically significant.

### **Analysis of the Results**

Based on the results, we concluded that the overall educational initiative increased the knowledge base of healthcare providers within the perioperative environment. Regarding Aprepitant, it also translated into more providers stating that they would teach these interactions regularly.

The results with Sugammadex did not follow the expected trend of an increase in teaching. However, we considered that this may have been an error in how the post-test assessment worded the question. Additionally, some individuals did not answer the questions

altogether, further skewing the results. 13.8% of results were missing in both pre-assessments of likelihood to teach regarding Sugammadex and Aprepitant, 36.2% and 37.9% missing for Sugammadex and Aprepitant, respectively.

Our original plan discussed the additional evaluation six months past the original teaching point. However, our original teaching point became delayed due to constraints regarding the continuing COVID-19 pandemic and the addition of technical hurdles. The addition of a follow-up assessment may have further displayed the results of learning and reinforcing new knowledge leading to an increase in teaching to patients.

### **Organizational Impact and Implications to Practice and Policy**

Future recommendations for process improvement will include disseminating this training as a permanent component of NMCP Orientation. In doing this, providers will continually be made aware of these medications' potential interactions with hormonal contraception. Also, this training should involve all perioperative providers, including Surgeons, Anesthesiologists, Certified Registered Nurse Anesthetists, Registered Nurses, and Corpsmen. This will encourage dissemination of the information beginning with the patients' pre-operative appointment until discharge. We would finally recommend the patient to be discharged with instructions regarding the recommendations for alternative contraception, based on whether they received Sugammadex or Aprepitant. This will provide written reinforcement of the knowledge as a final teaching method.

The most prominent barrier to this project is frequent staff turnover, while the most notable pro is cost-efficiency. Our training is a no-cost intervention that can save thousands of dollars in healthcare costs and spare a family from the psychological impact of an unwanted pregnancy. By continuously exposing new staff members to our training in facility orientation,

we can directly increase knowledge and awareness of perioperative healthcare providers and, therefore, indirectly raise patient awareness, promoting positive outcomes for our beneficiaries.

### **Future Directions for Research and Practice**

Due to the time constraints of this project, we were unable to assess long-term knowledge retention among our participants. Ideally, we would have evaluated knowledge retention by administering the questionnaire six months post the initial training. Having this extra data set would help determine the effectiveness of the education over time and adjust accordingly to meet the learners' needs.

Additionally, for this project, our primary focus was anesthesia providers. Still, more involvement with the Pre-procedural Evaluation Clinic (PEC), Post Anesthesia Care Unit (PACU), and inpatient ward staff would benefit our vision of the patient receiving the information at three critical points in their surgical experience. This would first begin with the patient being appropriately flagged at their pre-procedural appointment by their medication reconciliation. They should receive the information a second time by their anesthesia provider in the pre-operative area on the day of surgery. Lastly, the registered nurse that is discharging the patient from the PACU or inpatient ward should be going over their discharge instructions with emphasis on the recommendations for alternative contraception. Ideally, this would be a separate set of anesthesia discharge instructions that could be easily auto populated in Clinicomp notes. The nurse may click which medication was received based upon the intraoperative record and bedside SBAR report.

### **Conclusion**

The primary intent of this project was to increase the knowledge and awareness of perioperative staff regarding the effects of certain perioperative medications on hormonal

contraceptives. Additionally, we hoped that perioperative healthcare providers would educate patients about these medication interactions after completing our educational tool, decreasing the potential incidence of unintended pregnancy. Our educational tool showed a statistically significant increase in knowledge and awareness among perioperative healthcare providers about these medication interactions. This increases the likelihood that patients will receive this information at multiple points of their perioperative experience. This aligns with the current research that promotes repetitive teaching across a continuum for the most significant knowledge retention. With our findings and the cost benefits of our educational tool, we recommend that Naval Medical Center Portsmouth (NMCP) adopt our educational tool as a part of the orientation training for perioperative healthcare providers and implement an “order-set” to include educational materials as a part of a patients’ discharge paperwork.

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# Appendices

## Appendix A: CITI Certifications



Completion Date 03-Apr-2020  
Expiration Date 03-Apr-2023  
Record ID 36123667

This is to certify that:

**Patrick Mattox**

Has completed the following CITI Program course:

**OUUSD P&R Human Research  
Biomedical Investigators and Research Study Team  
1 - Basic Course**

Under requirements set by:

**Office of the Under Secretary of Defense (Personnel and Readiness)**

Verify at [www.citiprogram.org/verify?w049a627-6561-42cf-9866-9176746ed4b0-36123667](http://www.citiprogram.org/verify?w049a627-6561-42cf-9866-9176746ed4b0-36123667)



Completion Date 22-Mar-2020  
Expiration Date 22-Mar-2023  
Record ID 35973148

This is to certify that:

**Gloria Oakman**

Has completed the following CITI Program course:

**OUUSD P&R Human Research  
Biomedical Investigators and Research Study Team  
1 - Basic Course**

Under requirements set by:

**Office of the Under Secretary of Defense (Personnel and Readiness)**

Verify at [www.citiprogram.org/verify?wafbf7bd4e-431b-4c75-b4de-66345233c0e-35973148](http://www.citiprogram.org/verify?wafbf7bd4e-431b-4c75-b4de-66345233c0e-35973148)



Completion Date 03-Apr-2020  
Expiration Date 03-Apr-2023  
Record ID 36125977

This is to certify that:

**Elsbeth Phillips**

Has completed the following CITI Program course:

**OUUSD P&R Human Research  
Biomedical Investigators and Research Study Team  
1 - Basic Course**

Under requirements set by:

**Office of the Under Secretary of Defense (Personnel and Readiness)**

Verify at [www.citiprogram.org/verify?waff1a29-4065-415c-b371-52015699cd36-36125977](http://www.citiprogram.org/verify?waff1a29-4065-415c-b371-52015699cd36-36125977)



Completion Date 18-Mar-2020  
Expiration Date 18-Mar-2023  
Record ID 35972035

This is to certify that:

**Sasha Smith**

Has completed the following CITI Program course:

**OUUSD P&R Human Research  
Social and Behavioral Investigators and Research Study Team  
1 - Basic Course**

Under requirements set by:

**Office of the Under Secretary of Defense (Personnel and Readiness)**

Verify at [www.citiprogram.org/verify?wed54027d-4f39-4a9e-bcd0-4274e50b193a-35972035](http://www.citiprogram.org/verify?wed54027d-4f39-4a9e-bcd0-4274e50b193a-35972035)

## Appendix B: USU Form 3202N



### OFFICE OF RESEARCH

4301 JONES BRIDGE ROAD

BETHESDA, MARYLAND 20814

PHONE: (301) 295-3303; FAX: (301) 295-6771

### NOTICE OF PROJECT APPROVAL

Change Number: Original

**VPR Site Number:** GSN-61-11756  
**Principal Investigator:** Mattox, Patrick  
**Department:** Graduate School of Nursing  
**Project Type:** Student  
**Project Title:** Effects of Perioperative Medications on Hormonal Contraception: An Educational Initiative  
**Project Period:** 2/16/2021 to 2/16/2022

#### Assurance and Progress Report Information:

<u>Name</u>	<u>Sup</u>	<u>Approval Type</u>	<u>Status</u>	<u>Approved On</u>	<u>Forms Received</u>
Progress Report	0			To be Submitted	N/A

#### Remarks:

This Notice Of Project Approval has been reviewed and approved. Please remember that you must submit a final Progress Report (Form 3210) upon completion of this project.

Questions regarding this approval should be directed to the following person in the Office of Research:  
 Sharon McIver, (301) 295-9814.

**RANDOLPH.TOY** Digitally signed by  
**A.V.1242107698** RANDOLPH.TOY.A.V.1242107698  
 Date: 2021.02.22 13:35:59 -05'00'

Mark G. Kortepeter, MD, MPH  
 FACP, FIDSA, FASTMH  
 COL (R) MC US Army  
 Vice President for Research  
 Uniformed Services University of the Health Sciences

cc: File  
 Dr. Kennett Radford  
 Laura Taylor

## Appendix C: MTF IR/PI Letter of Determination



### NAVAL MEDICAL CENTER PORTSMOUTH RESEARCH SUBJECTS PROTECTION DIVISION

[usn.hampton-roads.navhospporsva.list.nmcp-irboffice@mail.mil](mailto:usn.hampton-roads.navhospporsva.list.nmcp-irboffice@mail.mil)



April 20, 2021

#### MEMORANDUM

From: Naval Medical Center Portsmouth IRB Office  
To: LCDR Patrick Mattox

Subj: DETERMINATION OF NOT RESEARCH  
EIRB Reference: 937513

Ref: (a) DODI 3216.02  
(b) 2019 DASD (HRP&O) Operating Instruction  
(c) NAVMEDCENPTSVAINST 6500.9B  
(d) NAVMEDCENPTSVAINST 6500.2G

1. Your project titled NMCP.2021.0096 "Effects of Perioperative Medications on Hormonal Contraception: An Educational Initiative" has been evaluated by an Exemption Determination Official (EDO). This project DOES NOT meet the definition of RESEARCH in accordance with 32 CFR 219.102 and DoDI 3216.02.
2. An EDO must review any study design changes that may change the scope of the project to ensure that they do not affect this determination. All modifications must be submitted in EIRB.
3. Projects that do not require IRB approval are not eligible for Clinical Investigation Department travel funds.
4. Any publication resulting from this project must be cleared through the publication clearance process, which is required for all works presented or published outside of your command. Investigators at NMCP may obtain information from the CID SharePoint page. Investigators from other commands should contact their local Public Affairs Office.
5. The NMCP IRB Office may be contacted via phone at (757) 953-5939 or via email at [usn.hampton-roads.navhospporsva.list.nmcp-irboffice@mail.mil](mailto:usn.hampton-roads.navhospporsva.list.nmcp-irboffice@mail.mil).

With best regards,

[REDACTED]

Kersten N. Wheeler, MS  
Human Research Director

## Appendix D: PAO Clearance

1 of 3 people approved



Diane Seibert ([diane.seibert@usuhs.edu](mailto:diane.seibert@usuhs.edu)) approved the file

2 of 3 people approved



Kenneth Barber ([kenneth.barber@usuhs.edu](mailto:kenneth.barber@usuhs.edu)) approved the file

Approval Complete



USU Pub Clearance ([usupubclearance@usuhs.edu](mailto:usupubclearance@usuhs.edu)) approved the file

## Appendix E: Forms Used in Data Collection

Figure 1: PRISMA Flow Diagram

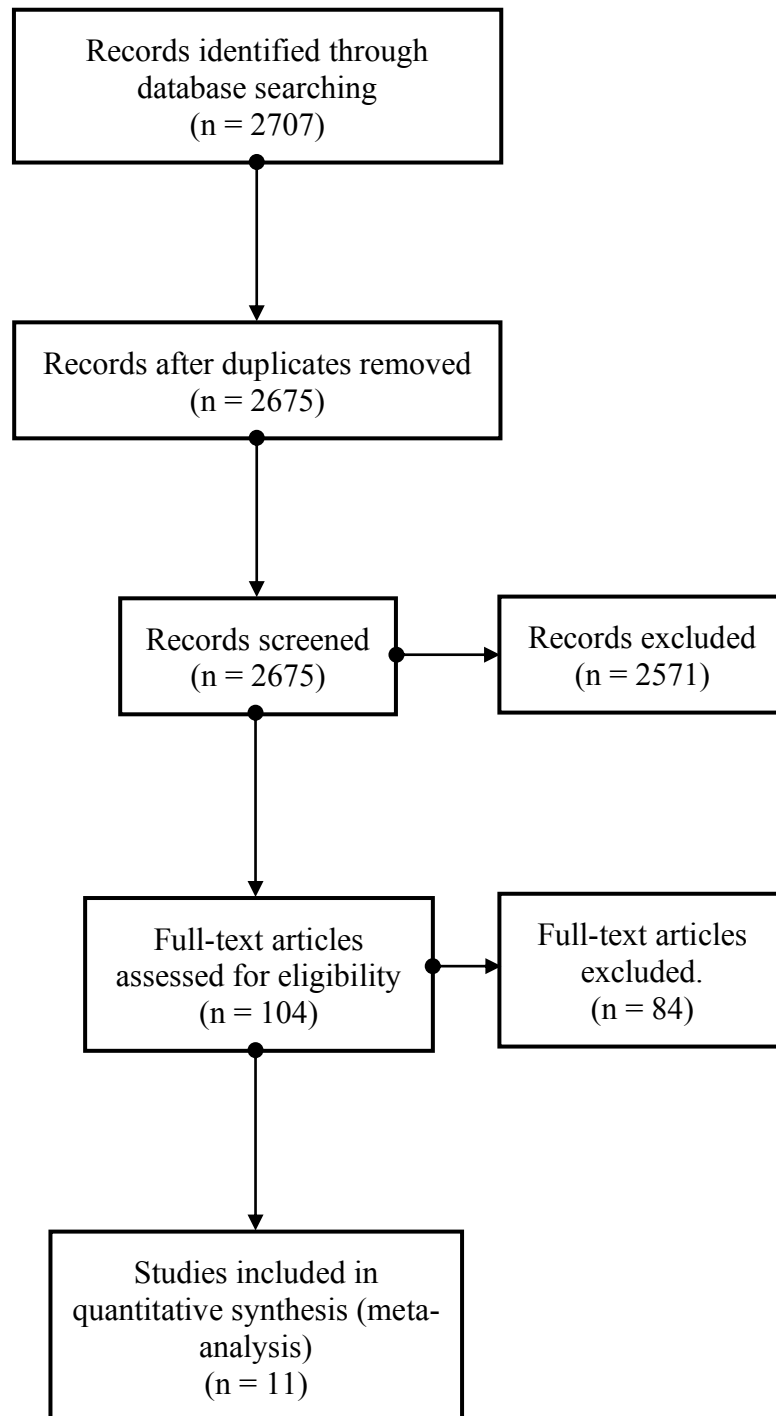
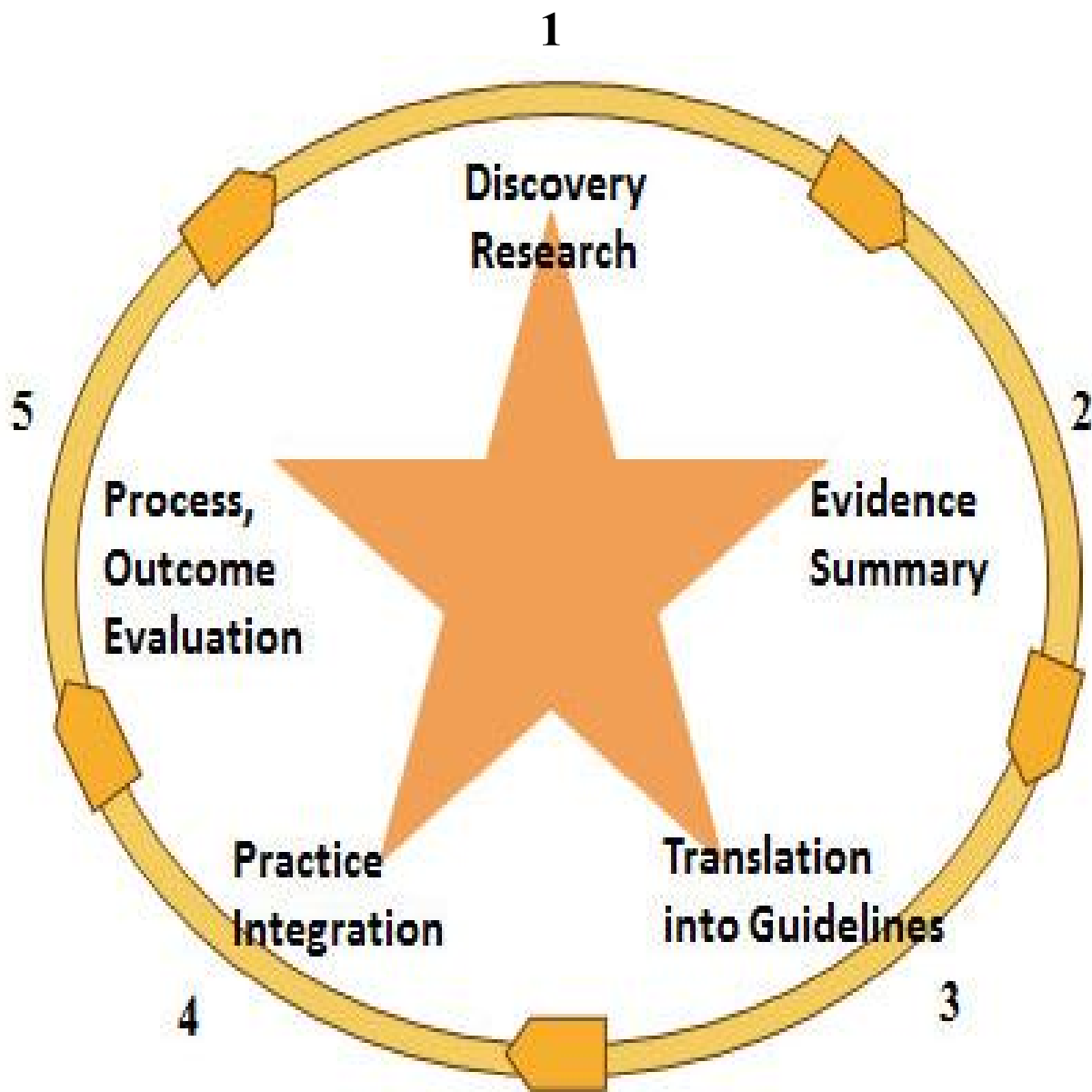


Figure 2: Evidence Table

Author(s), Year, Study Type, & Purpose	Independent Variables & Level of Measurement Total Sample Size	Dependent Variables & Level of Measurement	Statistical Analyses	Results	Study Quality (JHNEBP)
Angioli et al., 2014 Randomized Control Study To evaluate the verbal and written preoperative information in patients undergoing surgery for malignant gynecologic disease, in terms of satisfaction about preoperative received information, hospitalization days, postoperative pain experienced using visual analogue scale (VAS) and number of pain drugs used daily.	Nominal: The day before surgery Group V and Group W patients received verbal or written information, respectively, about type of surgery, hospitalization stay, pain and postoperative management. Initial: 240 Final analysis: 190 patients	Interval: Measures of patient satisfaction with the information received, information about treatment, and desire for more information. Also, total days hospitalized, postoperative pain experienced, and pain medications/day were measured.	Unpaired <i>t</i> -test were used to evaluated the results of the INFO25 and EORTC QLQ-C30 with p-values set at a significance of <0.05.	Patients of Group W had a lower number of hospitalization days (3.47 versus 4.36), mean pain VAS value (5.7 versus 6.8) and pain medications used daily (2.26 versus 2.89), comparing with Group V patients, resulting statistically significant ( $p < 0.001$ ). Additionally, in Group W, patients have a better info satisfaction (item 52, $p = 0.0008$ ), more info about treatment (items 38-43) ( $p = 0.0006$ ). Moreover, patients of Group V wish to receive more information (item 53) ( $p = 0.0002$ ).	I B
Bell et al., 2008 Randomized control study To chart the time course of retention after initial learning from an online tutorial covering principles of diabetes care and to examine the role of learner characteristics such as critical appraisal skills and self-efficacy that might modify physicians' learning and retention.	Nominal: Online tutorial covering 2 American Diabetes Association guidelines Of 197 residents invited, 91 (46%) completed the tutorial and were randomized; of these, 87 (96%) provided complete follow-up data.	Ordinal: Mean knowledge scores on pre- and post-tests	They used chi-square tests to assess associations among categorical variables and <i>t</i> tests or ANOVA tests to compare the values of continuous variables among groups. To assess the bivariate relationship between the delay time and posttest scores, they used linear regression with a 1/4-power transformation of time to account for the expected curvilinear relationship.	Before the tutorial, the final knowledge scores correlated with residency year (+0.7 points/year, $P = .005$ ) and with completion of a prior cardiology rotation (+0.9 points, $P = .05$ ), but these pretest scores were not associated with any other subject characteristic we assessed (age, gender, specialty, prior endocrine rotation, critical appraisal skill, diabetes self-efficacy, and computer attitudes). After the tutorial, increasing time delays were associated with lower scores; at 3 and 8 days, performance reflected about half of the gains seen immediately; and at 55 days, performance was equivalent to the pretest mean. Posttest scores were negatively correlated with a 1/4-power transformation of the time delay after the tutorial	I A
Choudhry et al., 2019 Prospective observational study To assess the impact that enhanced readability of patient discharge information has.	Nominal: Patient discharge instructions edited to 6th grade reading level. 1,072 patients were included, 493 before implementing the intervention, 579 afterward	Ordinal: Primary outcomes were total 30-day post-discharge telephone calls and readmission rates to our institution. Secondary outcomes included FKGL and FRES assessments of the discharge summaries.	The Pearson $\chi^2$ square test and analysis of variance were used for categorical data. Analyses of number of telephone calls before and after the intervention were adjusted for patients' GOS at hospital discharge and for independent versus dependent patient disposition. Uniformly and nonuniformly distributed continuous data were compared between the 2 groups using the Student <i>t</i> test and Wilcoxon test, respectively. All tests were 2-sided, with statistical significance set at .05. Data analysis was performed using JMP v 9.0 (SAS Institute Inc, Cary, NC).	Patient demographics, injury characteristics, and education level were similar among both groups. The median discharge instruction readability level in the postintervention group was significantly lower (10.0, 95% CI 10.0-10.2 vs 8.6, 95% CI 8.8-8.9; $P < .0001$ ). The proportion of patients calling after hospital discharge and for independent versus dependent patient disposition were decreased by 50% for every 100 patients discharged after the intervention (1.9% vs 9.0%; $P = .002$ ). The proportion of patients calling and readmissions for poor pain control significantly decreased after the intervention (7.1% vs 2.59%; $P = .0005$ and 2.8% vs 1.0%; $P = .029$ , respectively).	I B
Fredricks et al., 2010 Systematic review The specific objectives were: to describe the approach to education, mode of delivery, and dose used in providing postoperative education; to explore the extent to which variability in outcome achievement is associated with differences in the elements of educational interventions; and to investigate differences in outcomes in relation to patient characteristics in adult patients undergoing surgery.	None, due to the nature of this study. 924 articles initially reviewed; 58 met inclusion criteria for a total of 5,271 participants.	Nominal: Self-care knowledge, self-care behavior, and symptom experience based on self-reporting measures. Outcomes were coded as 0: for no statistical significance, or 1: for statistical significance favoring the experimental group.	Descriptive statistics were used to delineate the characteristics of the studies to be used in the systematic review. The effect size for the outcomes of interest was computed. Inferential statistics were not used due to the small number of studies that provided the data required to explore the relationships between outcomes and the elements used for education.	The results of this systematic review showed larger effect sizes for postoperative patient education in which the content was individualized and given in a combination of media on an individual basis and in more than one session.	II B
Gao et al., 2018 Quality improvement design was undertaken using the Model for Improvement as a framework and Plan-Do-Study-Act (PDSA) methodology. To design and implement a discharge timeout checklist, and to assess its effects on patients' understanding as well as the potential impact on preventable medical errors surrounding hospital discharges to home.	Nominal: comprehensive, multidisciplinary, and patient-centered timeout procedure utilizing a checklist at time of discharge. Over 6 months of study, 429 eligible discharges, 190 discharge timeouts were completed.	Ordinal: Percentage of discharges home that included a discharge timeout. Nominal: 6 Domains of Discharge Timeout (the presence of lines or callhears, home care plans, follow-up care, warning signs and symptoms, post-discharge contacts, and medication reconciliation)	All statistics were performed using R version 3.3.0 by the R Foundation for Statistical Computing (R Core Team 2016). P values listed are 2-tailed <i>t</i> tests for independent proportions.	Over 6 months of study, 190 discharge timeouts out of 429 eligible discharges were completed. Additional education was provided in 53 of 190 discharge timeouts (27.8%), with 62% of this education being related to medications. Twenty-one (11.1%) discharge timeouts resulted in at least one change to the discharge documentation or a good catch.	V B
Hovsepian et al., 2016 Quality improvement design To increase patient satisfaction scores for discharge teaching and improve retention of home care instructions.	Nominal: Patients were taught postoperative instructions in the preoperative phase. 432 total patients.	Ordinal: One query on patient satisfaction tool: "Written instructions for home care" rated as: excellent, good, poor, or very poor.	No formal statistical analysis was conducted due to lack of validity and reliability of patient satisfaction tool used.	Six month period of review 432 total survey responses received from both groups, 175 from patients how received postoperative teaching preoperatively and 257 from nonintervention patients. 170/175 intervention patients rated score of excellent (97.1%), 2.9% rated good, and 0 patients rated as poor or very poor. 91.4% of nonintervention patients rated excellent, 7.8% good, and 0.4% rated poor and very poor respectively.	V A
Kang et al., 2018 Systematic mixed studies review To identify the discharge education provided to general surgery patients.	None, due to the nature of this study. 468 articles initially reviewed; 7 met inclusion criteria.	Nominal: The 'who, what, when, and how' of discharge education delivery	Pluye and Hong's framework was used to describe, critically appraise and synthesize the types of discharge education delivered to general surgical patients. An inductive analysis revealed four themes: quality of discharge education influences its uptake, health care professionals' perceptions of their role in the delivery of discharge education to patients, patients' preferences for education delivery, and patients' participation in their self-care.	Discharge education was delivered at various timing and at different doses during the surgical process. Education delivered was mostly standardized and some of the discharge interventions were tailored and included a checklist for stoma care and a discharge warning tool. Four themes were identified: quality of discharge education influences its uptake, health care professionals' perceptions of their role in the delivery of discharge education to patients, patients' preferences for education delivery and patients' participation in their self-care.	III B
Mevsim et al., 2008 Randomized Control Study To find out the short and long term effectiveness of a training course on peer education.	Nominal: 11 training sessions of peer trainers took place with an average of 21.54 (min = 18 max = 27) students in each course. Each course was structured as a total 40-hour program. The training curriculum consisted of three main topics, which were reproductive health, peer education and counseling. 237 students who participated in a 40 hour Peer Trainer Training course.	Ordinal: Mean knowledge scores on pre- and post-tests	SPSS 12.0 and EpiInfo 6 was used for statistical analysis. The effectiveness of the training was measured by taking into account the ratio of correct answers in the pre-test, immediate post-test, late post-test. To compare the results of pre-test with immediate post-test, and immediate posttest with late post-test, the Wilcoxon two related sample test was run. In the evaluation of the training, participation rates were evaluated.	The average number of correct answers in the pre-test in the 11 groups trained was 69.7% while the average in the immediate post-test was 91.3% and the difference between the two rates was statistically significant ( $p < 0.05$ ). In the late post-test which was administered after 6 months, the average correct answer was 89.4% and the knowledge level decreased by 1.8% ( $p > 0.05$ ).	I A

<p>O'Brien et al., 2013</p> <p>Cross-sectional study</p> <p>To evaluate cardiac surgery patients' perception of the effectiveness and timing of preadmission multidisciplinary written information and post-operative verbal education provided by occupational therapy.</p>	<p>Nominal: YES/ NO dichotomous 11-question written survey that elicited responses from patients about their pre- and post-operative educational experiences.</p> <p>375 surveys to patients who underwent cardiac surgery in 2009-2010; 118 surveys were returned.</p>	<p>Nominal: 1. Recollection and understanding of pre-operative written education material and adherence with post-operative precautions. 2. Patient evaluation of whether written material adequately prepared them for the six week post-operative experience. 3. Patient report of stress or anxiety regarding post-operative expectations. 4. Patient perception of quality and timing of occupational therapy services in acute care and/or in rehabilitation.</p>	<p>The data were analyzed statistically by SPSS version 20 (IBM Corp., Armonk, NY, USA). The results for open-ended questions were grouped into codes reflecting the key theme of responses. The associations between categorical data were tested using the chi-square test or Fisher's exact test where one or more cells had a frequency of less than five. A two-sided P value of &lt;0.05 was considered statistically significant.</p>	<p>89% of respondents recalled receiving and reading the pre-surgery information booklet, and this was significantly correlated with feeling prepared for the post-operative experience and adherence with precautions (<math>P &lt; 0.0001</math>). Exactly 30.4% of respondents stated that they experienced stress and anxiety in relation to post-operative expectations, and 47.3% felt the information provided in the occupational therapy education sessions would have been more beneficial for their understanding and coping if provided prior to surgery.</p>	<p>III C</p>
<p>Prochnow et al., 2018</p> <p>Prospective approach with a 1-group pre- and post-education design.</p> <p>To improve patient outcomes using a tailored, evidence-based intervention to develop, encourage, and support RN's abilities to educate and monitor patient and caregiver knowledge of new medications early in and throughout the patient's hospitalization.</p>	<p>Nominal: Education and training on the incorporation of the teach-back method into practice.</p> <p>29 RNs and 25 RNs at final analysis.</p>	<p>Nominal: Effective teaching methods/elements utilized post intervention using the observation tool. Ordinal: Results of 3-month post education follow-up of the Conviction and Confidence Scale.</p>	<p>A paired <i>t</i>-test was used to show significance 3-months after education with Conviction and Confidence Scale. McNemar's test was used to analyze the data from the observation tool.</p>	<p>Significance was shown in the CCS for conviction in importance of using teach-back, confidence in using teach-back, and frequency in use of teach-back during teaching sessions during 3-month follow-up evaluation (<math>p &lt; 0.0001</math>). Significance was shown using the observation tool in the areas of: Use plain language? Ask the patient to explain in their own words what they were told to do about: Signs and symptoms they should call the doctor for? Key medicines? Critical self-care activities? Follow-up appointments? Use non-shaming, open-ended questions? Avoid asking questions that can be answered with a yes or no? Take responsibility for making sure they were clear? Explain and check again if the patient is unable to use teach-back? Use reader-friendly print materials to support learning? Document use of and patient's response to teach-back? (<math>p</math>-value=0.05)</p>	<p>V A</p>
<p>Rajala et al., 2018</p> <p>Cross-sectional study</p> <p>The purpose of the study was to describe the quality of patient education in day surgery as evaluated by adult patients.</p>	<p>Nominal: Implementation of education (Patient-centered education, interaction of education, and goal-oriented education).</p> <p>600 questionnaires initially, 238 questionnaire returned, 2 questionnaire excluded (did not meet criteria) for a total of 236 questionnaires. 39% response rate.</p>	<p>Ordinal: The quality of patient education in the following areas: implementation (19 items) and patient education resources (11 items). A 5-point Likert scale (totally agree, partially agree, partially disagree, totally disagree, and cannot say) was chosen as it yields a dispersion in responses that are easier to handle and analyze by computer.</p>	<p>Data were collected using a modified version of the Counseling Quality Instrument (CQI), 42 which was adjusted to fit the target group of this study. The data were analyzed using SPSS Statistics 22.0 (IBM, Armonk, NY) software.</p>	<p>The implementation of patient education has been done in a patient-centered and goal-oriented way by half of respondents. Most respondents (81%) were satisfied with the interaction in patient education. The education resources were reported as good by 77% of respondents.</p>	<p>I A</p>

Figure 3: Stevens Star Model of Knowledge Transformation



**Figure 4: Pre and Post Questionnaire**

1. Sugammadex (Bridion) is a medication that is given to:
  - Reverse narcotics
  - Aid in pain control
  - Reverse neuromuscular blocking agents
  - Reduce nausea and vomiting
  
2. Does Sugammadex have any side effects that patients should be educated about?
  - Yes
  - No
  
3. Sugammadex can alter the effectiveness of which medications?
  - Antibiotics
  - Birth control medications
  - Antihypertensives
  - Opioids
  
4. Aprepitant is a medication that is given to:
  - Reduce anxiety
  - Reduce postoperative nausea and vomiting
  - Reduce postoperative pain
  - Reduce perioperative infections
  
5. Does Aprepitant have any side effects that patients should be educated about?
  - Yes
  - No
  
6. Aprepitant can alter the effectiveness of which medications?
  - Antibiotics
  - Birth control medications
  - Antihypertensives
  - Opioids
  
7. How long after Sugammadex administration should alternative contraception be used?
  - 12 hours
  - 7 days
  - 48 hours
  - 28 days

8. How often do you teach patients about Sugammadex and any interactions it may have?
- Never
  - Sometimes
  - Always
9. How often do you teach patients about Aprepitant and any interactions it may have?
- Never
  - Sometimes
  - Always
10. How long after Aprepitant administration should alternative contraception be used?
- 12 hours
  - 48 hours
  - 7 days
  - 28 days
11. Please select the closest job description from the choices below:
- Corpsman
  - Nurse
  - Anesthesia Provider
  - Surgeon
12. How many years have you been practicing in the medical field?
- 0-5
  - 5-10
  - 10-15
  - 15-20
  - 20-25
  - 30-above
13. How many years have you been practicing in your current field? (as responded in question 9)
- 0-5
  - 5-10
  - 10-15
  - 15-20
  - 20-25
  - 30-above

**Figure 5: Project Timeline**

Project Year 1 (2020)													
Activity/Month	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	
USUHS VPR Submission and Approval													
Site IRB Submission and Approval												X	
Project Planning -Task 1: Literature review -Task 2: Stakeholder engagement meetings												X	
Project Implementation/ Data Collection													
Data Analysis													
Dissemination													

Project Year 2 (2021)													
Activity/Month	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	
USUHS VPR Submission and Approval		X											
Site IRB Submission and Approval													
Project Planning	X												
Project Implementation/ Data Collection -Task 1: Develop questionnaires -Task 2: Develop training -Task 3: Educate perioperative providers -Task 4: Complete pre- and post- questionnaire	X	X	X	X	X								
Data Analysis -Task 1: Review pre-questionnaire data -Task 2: Review post-questionnaire data -Task 3: Evaluate compliance with training						X	X						
Dissemination -Task 1: Review outcomes with perioperative leadership -Task 2: Review outcomes with perioperative providers								X	X	X	X	X	



Figure 6: Data Analysis Plan

	Variable Name	Variable Description and type of measure	Data Source	Possible Range of Values	Level of Measurement	Time Frame for Collection	Statistical Test	Decision Rule
<b>Independent Variable</b>	Pre and post standardized education knowledge assessments	Description: Pre and post standardized education assessments of knowledge on perioperative medication and hormonal contraception interactions  Type: Process Measure	N/A	0 = Without standardized educational intervention  1 = Immediately post standardized educational intervention	Nominal	N/A	None	N/A
<b>Dependent Variable</b>	Percentage of knowledge assessment (as a measure of provider knowledge on perioperative medication and hormonal contraception interactions)	Description: Mean % score on knowledge assessment - calculated by counting # correct / # incorrect questions for providers pre, immediate post.  Type: Outcome measure	Knowledge assessment results	0 to 100%	Continuous	Pre and immediately post educational intervention	Kruskal-Wallis	Based on the literature, increased accuracy of knowledge retention when assessed post intervention.

## Appendix F: Business Case Analysis

### GSN5220: Healthcare Economics and Advanced Practice Module 2 Assignment: Business Case with Value Based Care

NAME: NMCP RNA c/o 2022

DATE: 11 October 2020

#### BUSINESS CASE with VALUE BASED CARE ASSESSMENT

##### Proposed Title for Project/Initiative/Opportunity to Improve

Establishing a standard of care for perioperative education of female patients on hormonal contraception.

##### Opportunity Statement (*Description of proposed project/initiative/opportunity to improve*)

Naval Medical Center Portsmouth can decrease unintentional pregnancies related to the effects of perioperative medications on hormonal birth control in the immediate postoperative period, resulting in increased military member readiness and patient satisfaction.

##### Business Opportunity/Objectives (*Prioritize listing – macro and micro objectives*)

Macro:

- Cost avoidance related to medical care for Tricare beneficiaries with unintended pregnancy.
- Opportunity cost associated with decreased readiness related to unintended pregnancy.

Micro:

- Low-cost interventions to educate patients and providers on effects of perioperative medications on hormonal contraception.

##### Potential Impact of the Initiative/Project (*Identify outcome metrics & benchmarks/and how objectives align with Quadruple Aim, Value Based Care, and HRO goals*)

###### Potential Impacts:

- Optimize operational readiness through reduction of unintended pregnancy among active-duty military members.
- Decrease healthcare associated costs for DOD beneficiaries by preventing unintended pregnancy.

###### Measurable Impacts:

- Anesthesia provider knowledge and awareness of perioperative medication interaction with hormonal contraceptives.
- PACU nurse knowledge and awareness of perioperative medication interaction with hormonal contraceptives.
- Preoperative nurse knowledge and awareness of perioperative medication interaction with hormonal contraceptives.
- Surgeon knowledge and awareness of perioperative medication interaction with hormonal contraceptives.
- Surgical patient awareness of perioperative medication interaction with hormonal contraceptives.

##### Alternatives (courses of action) chosen for Analysis

1. Assess the impact of 1) providing standardized education on perioperative healthcare providers' knowledge on the effects of perioperative medications on hormonal contraceptives and 2) implementing an evidence-based clinical practice guideline on female surgical patients' awareness of the need for alternative contraception methods following surgery when applicable.
2. Compare the incidence of unintended pregnancies over a six-month period through electronic health record reviews and patient interviews before and after provider education and implementation of evidence-based clinical practice guidelines.
3. "Status Quo": No current standardized approach for informing female surgical patients on the effects of perioperative medications on hormonal contraceptives.

##### Analysis of Alternatives

Alternative 1:	Assess the impact of 1) providing standardized education on perioperative healthcare providers' knowledge on the effects of perioperative medications on hormonal contraceptives and 2) implementing an evidence-based clinical practice guideline on female surgical patients' awareness of the need for alternative contraception methods following surgery when applicable.
<b>Pros</b>	<b>Cons</b>
-No PII access required. -Implementation is feasible with resources currently available (time, manpower).	-Indirect measure of impact.
Alternative 2:	Compare the incidence of unintended pregnancies over a six-month period through electronic health record reviews and patient interviews before and after provider education and implementation of evidence-based clinical practice guidelines.
<b>Pros</b>	<b>Cons</b>
-Direct measure of impact.	-Requires PII. -Requires resources (time, manpower) that are not feasible.
Alternative 3:	" <i>Status Quo</i> ": No current standardized approach for informing female surgical patients on the effects of perioperative medications on hormonal contraceptives.
<b>Pros</b>	<b>Cons</b>
-No required change to current practice.	-No standardized level of knowledge and awareness among healthcare workers of perioperative medication interaction with hormonal contraceptives. -No standardized guidelines to establish baseline knowledge and awareness of perioperative medication interaction with hormonal contraceptives for surgical patients.
<b>Assumptions</b>	
<ul style="list-style-type: none"> <li>-Cost of pregnancy care</li> <li>-The average cost for an uncomplicated pregnancy, followed by vaginal delivery, is \$32,093 (Truven Health Analytics, 2013).</li> <li>-An uncomplicated pregnancy followed by cesarean delivery, increases the cost to \$51,125 (Truven Health Analytics, 2013).</li> <li>-Children that require NICU stays that exceed 12.9 days incur an additional cost of \$151,000 (Russell et al., 2007).</li> <li>-1,786 surgical cases on females of childbearing age at NMCP annually. (NMCP S-3 Oct 2019 188 cases females 10-40 years old out of 788 total cases during Oct 2019= 24% of annual cases)</li> <li>-5% incidence of unintended pregnancies per year (Frost, 2011).</li> <li>-Mothers who report unplanned pregnancies had an increased prevalence in the development of psychological distress at nine months postpartum (Barton et al., 2017).</li> <li>-Maternity/paternity leave policies can lead to a non-deployable status for military service members.</li> <li>-Non-deployable status policies related to pregnancy.</li> <li>-Surgical patients of child-bearing age are not receiving information related to the interactions between perioperative medications and hormonal contraceptives.</li> </ul>	
<b>Recommendation and Rationale</b>	
<b>Recommendation</b>	
Assess the impact of 1) providing standardized education on perioperative healthcare providers' knowledge on the effects of perioperative medications on hormonal contraceptives and 2) implementing an evidence-based clinical practice guideline on female surgical patients' awareness of the need for alternative contraception methods following surgery when applicable.	

## Rationale

Recommend Alternative 1 due to lack of PII access required, available resources (time, manpower), and cost effectiveness.

## Value Based Care - Investment Required by the Organization and the Associated "VALUE" or \$ GAINED.

Information is based on the number of females of child-bearing age that receive anesthesia care at NMCP.

### I. Volume projection based on:

Females of child-bearing age receiving anesthesia care at NMCP	Approximately 1,786 annually (NMCP S-3)
<b>Total</b>	<b>1,786</b>

Information is based on the cost of uncomplicated pregnancies with vaginal delivery, cesarean delivery<sup>1</sup>, and children that require NICU stays<sup>2</sup>. (Truven Health Analytics, 2013<sup>1</sup>), (Russell et al., 2007<sup>2</sup>).

### II. Reimbursement calculated for:

Uncomplicated pregnancy followed by vaginal delivery.	\$32,093
Uncomplicated pregnancy followed by cesarean delivery.	\$51,125
Children that require NICU stays that exceed 12.9 days.	\$151,000
<b>Total average for vaginal/cesarean delivery:</b>	<b>\$78,072</b>
<b>Total average for vaginal/cesarean delivery + NICU stay exceeding 12.9 days:</b>	<b>\$229,072</b>

### III. Costs:

#### Variable Costs:

Supplies (Paper, Ink, misc.)	\$1,000 est.
Training/hour is \$296	\$12,099

**For purposes of this budget plan, 26 MDAs, 21 CRNAs, and 37 PACU**

per MDA, \$148 per CRNA, \$35 per nurse, and \$ per surgeon (salary figures from Salary.com)		<b>nurses, XX Preop Clinic nurses, and XX surgeons compensated for 1 hour of pay for the 1 hour training.</b>
<b>Total</b>	<b>\$ 13,099</b>	

Fixed Costs:

None	\$ 0
<b>Total</b>	<b>\$ 0</b>

**IV. Forecasted P&L statement:**Revenues:

~89 potential avoided unintended pregnancies		
-Uncomplicated pregnancy followed by vaginal delivery	\$ 2,856,277	
-Uncomplicated pregnancy followed by cesarean delivery	\$ 4,550,125	
<b>Total revenues</b>	<b>\$2 Million-</b>	<b>\$4 Million</b>

**For purposes of this budget plan, 1,786 female surgical cases/year. Based on assumption data, 1,786 female surgical cases had a 5% incidence of unintended pregnancy. \$78,072 average for vaginal/cesarean delivery**

Costs:

Variable costs	\$ 13,099
Fixed costs	\$ 0
<b>Total costs</b>	<b>\$13,099</b>

**PROJECTED PROFIT     \$ 1,986,901- 3,986,901**

**Risks and Mitigation Plan**

<b>Risks</b>	<b>Plan</b>
1. Patient adherence to recommendations of perioperative healthcare providers.	1. Provide perioperative education to patients with signed confirmation of understanding.
2. Compliance of perioperative healthcare providers to distribute information.	2. Implement metrics and standards for preoperative and post-operative documentation in the electronic health record.
3. Incomplete patient disclosure of medications.	3. Ensure medication reconciliation is completed appropriately.
4. Leadership challenges/resistance.	4. Obtain buy-in with leadership by reviewing the minimal impact this can have on their workflow versus the possible benefit to the patient.
5. Challenges in requesting CliniComp note change with CAG.	5. Ensure convincing argument for changes

Implementation Plan		
Phase 1:	Gather Evidence	
Milestone Description:	Conduct literature search.	
Deliverables	Due Date	Accountable Person
Evidence with relevant literature and synthesis table.	Two months	Principle POC/ Project lead for EBP
Resources Needed		
Access to research databases, time to perform critique of articles, and appraisal of literature.		
Expected Level of Benefit		
This will provide identification of educational deficits within perioperative teaching to surgical patients utilizing hormonal contraceptives.		
Phase 2:	Assess baseline knowledge and awareness of perioperative healthcare providers.	
Milestone Description:	Utilize a questionnaire to determine baseline knowledge and awareness of perioperative medication interaction with hormonal contraceptives.	
Deliverables	Due Dates	Accountable Person
Baseline metrics from questionnaire.	One month	Principle POC/ Project lead for EBP
Resources Needed		
Access to questionnaire results, and time for review.		
Expected Level of Benefit		
Analyze institutional practices and establish tailored training for staff.		
Phase 3:	Dissemination of findings.	
Milestone Description:	Review research findings and questionnaire results with perioperative healthcare providers.	
Deliverables	Due Dates	Accountable Person
Produce a professional presentation using slides, posters, and handouts.	One month after completion of data collection.	Principle POC/ Project lead for EBP
Resources Needed		
Time to perform tasks, access to technical professional support, scheduling based on institutional and department requirements and protocol.		
Expected Level of Benefit		
Obtain approval to include patient teaching as a requirement for discharge. Gather buy-in from leadership.		
Phase 4:	Generate training to establish a standard level of knowledge and awareness among perioperative healthcare providers.	
Milestone Description:	Create training to standardize the patient education process among perioperative healthcare providers.	
Deliverables	Due Dates	Accountable Person
100% perioperative staff exposure	Two months	Principle POC/ Project lead for EBP

<b>Resources Needed</b>		
Time for all personnel to attend training, access to technical professional support, scheduling based on institutional and department requirements.		
<b>Expected Level of Benefit</b>		
Department-wide adoption and compliance with new patient teaching process.		
<b>Phase 5:</b>	Provider compliance assessment.	
<b>Milestone Description:</b>	Peer chart reviews.	
<b>Deliverables</b>	<b>Due Dates</b>	<b>Accountable Person</b>
Compliance rates according to chart reviews and follow-up questionnaire	Ongoing, but report to leadership at six months and then annually	Principle POC/ Project lead for EBP
<b>Resources Needed</b>		
Time for access to peer chart reviews.		
<b>Expected Level of Benefit</b>		
Verify compliance, identify deficiencies, and provide information to decide whether change is cost effective and beneficial.		



**DOCTOR OF NURSING PRACTICE PROJECT  
Completion Verification Form**

The DNP Project titled: **Effects of Perioperative Medications on Hormonal Contraception: An Educational Initiative**

was completed at Naval Medical Center Portsmouth by the following student(s):

*(Student Name)*

Patrick W. Mattox  
Gloria M. Oakman  
Elsbeth L. Phillips  
Sasha Y. Smith

*(Digital Signature)*

MATTOX.PATRICK.W  
ESLEY.1397968304 Digitally signed by MATTOX.PATRICK.WESLEY.1397968304  
Date: 2022.04.25 10:15:54 -04'00'

OAKMAN.GLORIA  
A.M.1387240183 Digitally signed by OAKMAN.GLORIA.M.1387240183  
Date: 2022.04.25 12:09:31 -04'00'

PHILLIPS.ELSPETH.  
LAURA.1271182771 Digitally signed by PHILLIPS.ELSPETH.LAURA.1271182771  
Date: 2022.04.25 10:23:23 -04'00'

SMITH.SASHA.YA  
LOA.1235576097 Digitally signed by SMITH.SASHA.YALOA.1235576097  
Date: 2022.04.27 07:32:30 -04'00'

The DNP Practice Project Team verifies that the following components of the DNP project, accomplished by the above students, is of sufficient rigor and demonstrates doctoral level scholarship to meet the requirements for USUHS GSN graduation:

- Presentation of DNP project to the leadership/stakeholders at the Phase II Site,
- Abstract/Impact Statement (*Appendix F*), and
- DNP Project written report (*Appendix E*).

Verified by:

<i>(type name)</i>	<i>(Digital Signature)</i>	
<u>LCDR Todd Batteau, CRNA, DNP</u>	BATTEAU.TODD.ANTHONY.1235562878 <small>Digitally signed by BATTEAU.TODD.ANTHONY.1235562878 Date: 2022.04.26 13:28:51 -04'00'</small>	Senior Mentor
<u>CDR Katherine Kidde, DNP, CRNA</u>	Katherine Kidde, <small>Digitally signed by Katherine Kidde, Date: 2022.04.26 22:04:04 -04'00'</small>	Team Mentor & Phase II Site Director

**For RNA Students only** - add the following additional signature for final verification of project completion:

<u>LCDR Kenneth Barber</u>	BARBER.KENNETH.D OUGLAS.1177263644 <small>Digitally signed by BARBER.KENNETH.DOUGLAS.1177263644 Date: 2022.04.28 11:06:45 -04'00'</small>
RNA Project Director <i>(type name)</i>	<i>(Digital Signature)</i>



**DOCTOR OF NURSING PRACTICE PROJECT**  
**DNP Project Clinical Question and Team Mentor (Committee Membership) Agreement Form**

**Graduation Year:**

**Name(s) of DNP Project Student Team:**

- 1. LCDR Patrick Mattox Phase II Site: AGCNS  FNP  PMHNP  RNA  WHNP
- 2. LT Gloria Oakman Phase II Site: AGCNS  FNP  PMHNP  RNA  WHNP
- 3. LCDR Elspeth Phillips Phase II Site: AGCNS  FNP  PMHNP  RNA  WHNP
- 4. LCDR Sasha Smith Phase II Site: AGCNS  FNP  PMHNP  RNA  WHNP

**The tentative title of the DNP Project Proposal for this student group is:**

Effects of Perioperative Medications on Hormonal Contraception: An Educational Initiative

**Committee Approved DNP Project Clinical Question:**

Among multidisciplinary perioperative healthcare professionals at Naval Medical Center Portsmouth, does the implementation of an education program compared to current practice increase knowledge and awareness of interactions between perioperative medications and hormonal contraceptives ?

**Names of DNP Project Team Mentors (*type the name and obtain signatures*):**

I agree to serve as a member of the DNP Project Team (Team Mentors) for the above DNP Student Project Team. As a Project Team Mentor, I agree to the duties and responsibilities outlined within the DNP Project Manual which include but are not limited to the provision of consultation and guidance supporting the entire DNP project journey and to ensure the DNP project is of sufficient rigor and demonstrates doctoral level scholarship to meet the requirements for USUHS GSN graduation.

*Note: You may have 3-4 DNP Team Mentors [committee members including your DNP Senior Mentor (Chair)]. The Phase II Site Director may also be a member of the group, as well as other USUHS faculty or others who may serve as content experts. All non-USUHS faculty selected as a Team Mentor must be approved by the DNP Project Director.*

Senior Mentor (Chair): LCDR Todd Batteau Signature: BATTEAU.TODD.ANTHONY.1235562878 Date: 31DEC2020  
Digitally signed by BATTEAU.TODD.ANTHONY.1235562878 Date: 2020.12.31 08:05:52 -05'00'

Team Mentor (Committee): LCDR Katherine Kidde Signature: Katherine Kidde, Date: 31Dec2020  
Digitally signed by Katherine Kidde, Date: 2020.12.31 11:54:45 -05'00'