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Implementing Nerve Blocks for Patients Undergoing a Bilateral Mastectomy with Immediate Reconstruction: A Practice Change

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IMPLEMENTING NERVE BLOCKS FOR PATIENTS UNDERGOING A
BILATERAL MASTECTOMY WITH IMMEDIATE RECONSTRUCTION: A
PRACTICE CHANGE

by

Corey Beene Auerswald

A Capstone Project
Submitted to the Graduate School,
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and the Department of Advanced Practice
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for the Degree of Doctor of Nursing Practice

December 2017

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by Corey Beene Auerswald

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ABSTRACT

IMPLEMENTING NERVE BLOCKS FOR PATIENTS UNDERGOING A BILATERAL MASTECTOMY WITH IMMEDIATE RECONSTRUCTION: A PRACTICE CHANGE

by Corey Beene Auerswald

December 2017

Breast cancer is one of the most commonly diagnosed cancers in women. A mastectomy is one of the first line treatments for breast cancer, but it is associated with considerable postoperative pain. Literature suggests current methods of pain management are ineffective and regional anesthesia can help reduce postoperative complications following a bilateral mastectomy with immediate reconstruction. Information from the literature review was used to inform five anesthesia providers at a rural hospital in Mississippi about the benefits of regional anesthesia for patients having a mastectomy. A presentation was given to anesthesia providers regarding the benefits of paravertebral blocks (PVB) for patients undergoing a bilateral mastectomy with immediate reconstruction. Investigator developed questionnaires were used to determine how many times nerve blocks were provided for patients undergoing a bilateral mastectomy with immediate reconstruction one month before and one month after the intervention. Descriptive statistics were used to interpret the results of the questionnaires. One month following the presentation, 20 patients at the surgery center had a bilateral mastectomy with immediate reconstruction. All 20 of these patients received nerve blocks. Anesthesia providers also reported these patients had less postoperative complications than patients who did not receive a block. Although anesthesia providers at this facility implemented

Pecs I, Pecs II, and serratus plane blocks instead of PVB blocks for this patient population, results from this project show when presented with EBP, anesthesia providers are willing to make a practice change to improve patient outcomes.

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DEDICATION

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LIST OF ABBREVIATIONS

<i>CRNA</i>	Certified Registered Nurse Anesthetist
<i>DNP</i>	Doctor of Nursing Practice
<i>EBP</i>	Evidence Based Practice
GA	General Anesthesia
HQROL	Health Related Quality of Life
LOS	Length of Stay
NK	Natural Killer
Pecs	Pectoral Nerve Block
POD	Postoperative Day
PONV	Postoperative Nausea and Vomiting
PVB	Paravertebral Block

CHAPTER I – INTRODUCTION

Background and Significance

Breast cancer is one of the most commonly diagnosed cancers in women. In the United States, breast cancer alone is expected to account for 30% all new cancer diagnoses in women (American Cancer Society [ACS], 2017). In 2017, approximately 252,710 new cases of invasive breast cancer will be diagnosed in women, as well as an estimated 63,410 additional cases of in situ breast cancer. Mississippi is expected to have 2340 new breast cancer diagnosis in 2017 (ACS, 2017).

A mastectomy is one of the first-line surgical treatments for breast cancer (Steiner, Weiss, Barrett, Fingar, & Davis, 2016). Recently, mastectomy rates increased, especially among younger women. Most patients with breast cancer having a mastectomy will require an overnight stay for management of pain, nausea, and vomiting (Bouhey et al., 2009). Furthermore, patients undergoing a bilateral mastectomy with immediate reconstruction experience longer hospital stays and more postoperative complications than patients undergoing a unilateral mastectomy (Sharpe et al., 2014).

Problem Statement and Needs Assessment

A mastectomy is associated with considerable postoperative pain. Approximately 40% of mastectomy patients experience significant acute postoperative pain, indicating current methods of treating postoperative pain are not effective (Schnabel, Reichl, Kranke, Pogatzki-Zahn, & Zhan, 2010). Additionally, “acute postoperative pain is an important risk factor for the development of persistent chronic postoperative pain in women after breast surgery” (Schnabel et al., 2010, p 8). The use of general anesthetics can cause significant postoperative nausea and vomiting (PONV), and opioid use after

surgery is associated with respiratory depression, nausea, and vomiting. Several studies and anesthesia textbooks also suggest surgical stress, general anesthetics, and opioids can decrease immune function and lead to cancer recurrence (Butterworth, Mackey, & Wasnick, 2013; Exadaktylos, Buggy, Moriarty, Mascha, & Sessler, 2006; Fodale, D'Arrigo, Triolo, Mondello, & La Torre, 2010). Regional anesthesia can reduce postoperative complications for patients undergoing a bilateral mastectomy with immediate reconstruction. However, an informal survey comprised of seven staff certified registered nurse anesthetist (CRNAs) conducted by the investigator at various hospitals in Mississippi revealed these anesthesia providers were unaware of these benefits. Also, several of these CRNAs expressed a desire to learn about regional anesthesia for this patient population.

Clinical Question

Will anesthesia providers who have received information about paravertebral blocks (PVBs) make a practice change to incorporate PVBs into the plan of care for patients undergoing a bilateral mastectomy with immediate reconstruction 1 month after receiving the information? Regional anesthesia is currently used for various surgical procedures and can be the sole anesthetic or used in combination with general anesthesia (GA). A PVB is a type of regional nerve block which can provide postoperative pain control for patients undergoing a mastectomy. Administration of a PVB requires injections at each vertebral level that corresponds to the dermatome needing be anesthetized. For example, “a simple mastectomy would require blocks at levels T3-6; for axillary node dissection, additional injections should be made from C7 through T2” (Butterworth et al., 2013, p. 1019). PVBs can provide analgesia, reduce the stress

response to surgery, and decrease the need for opioids and general anesthetic requirements. Other benefits, such as, improved postoperative pulmonary function, decreased incidence of chronic pain, and decreased cancer recurrence may be attributed to PVBs (Aufforth et al., 2012; Boughey et al., 2009; Exadaktylos et al., 2006).

Recently, utilization of PVBs for breast surgery increased (Bolin, Harvey, & Wilson, 2015). Hospitals such as the Mayo Clinic, MD Anderson, and Duke University Hospital use PVBs routinely, when appropriate, for patients having a mastectomy (Penne, 2009). Dr. Goravanchi, a physician at MD Anderson, stated:

For patients who get the paravertebral block, we see a dramatic reduction in the pain medication they take after surgery, thus eliminating the many side effects that come with that. Plus, patients are often less anxious going into surgery because they know they will wake up virtually pain-free and go home that way (Penne, 2009, para. 19).

Although a PVB can provide many benefits, there are some risks. These risks include hypotension, pneumothorax, block failure, and epidural spread. According to Bolin et al. (2015), a pneumothorax is frequently the most dreaded complication of a PVB, but the incidence of developing a pneumothorax after a PVB is only 0.5%. The incidence of hypotension is reported to be 2-5% (Cheng & Ilfeld, 2016). However, the use of an ultrasound machine can enhance the safety and improve the quality of the block. Overall, PVBs are generally considered a low risk procedure, and the majority of complications are often resolved within 24 hours.

Purpose of the Project

The primary goal of this project was to create a practice change in which anesthesia providers incorporate PVBs into the plan of care for patients undergoing a bilateral mastectomy with immediate reconstruction. Informing anesthesia providers about the impact of postoperative complications in this population and providing education regarding the benefits regional anesthesia offers can create an awareness that a practice change needs to be made. Providing onsite training can further increase the likelihood PVBs will be performed for these patients.

A secondary goal of this project was to improve postoperative outcomes for patients undergoing a bilateral mastectomy with immediate reconstruction. A bilateral mastectomy with immediate reconstruction is associated with more complications than a unilateral mastectomy and an increased incidence of chronic pain or post mastectomy pain syndrome (Kahn, 2011; Sharpe et al., 2014). In bilateral mastectomy patients, “69% reported pain at 2 years, which affected sleep in 36% and daily activities in 22%”, and the women who are affected the greatest by chronic pain are the ones who opt for a contralateral mastectomy (Kahn, 2011, p. 2134). Several studies have reported the effectiveness of PVB in decreasing postoperative complications in this population. If implemented, PVBs can improve patient satisfaction, increase revenue, and decrease cost to the facility.

Review of Literature

An initial literature search was performed using PubMed and Primo at The University of Southern Mississippi in order to obtain articles involving patients undergoing a mastectomy, PVBs, and postoperative outcomes. Search terms used were

mastectomy, nerve block, postoperative, pain, nausea, and vomiting. Of the 17 articles located using PubMed, 12 were within published within the last 10 years. This number was further reduced to five articles due to relevance. Thirteen articles published within the last 10 years were found using Primo. Six of these articles were duplicates of the PubMed search and six were not relevant. A total of six articles were reviewed from this initial search. These articles revealed PVBs were most beneficial to patients having more extensive surgery, such as a bilateral mastectomy with immediate reconstruction. This finding led to a change in the focus of the project from mastectomy patients to patients undergoing a bilateral mastectomy with immediate reconstruction. Additional searches of Academic Premiere, Health Source, MEDLINE, CINAHL, and PubMed using combinations of the terms *bilateral mastectomy, mastectomy or breast surgery, paravertebral block, postoperative, chronic pain, pain, and cancer recurrence* resulted in the discovery of 12 new relevant articles. These articles can be found in the synthesis matrix (Appendix B).

Postoperative Pain

Studies conducted by Beyaz, Ergonenc, Altintoprak, & Erdem (2012); Bhuvaneswari, Wig, Mathew, & Singh (2012); Boughey et al., (2009); Parikh, Sharma, Guffey, & Myckatyn (2016); Pei et al. (2015); Schnabel et al. (2010); Tahiri et al. (2011); and Terkawi et al. (2015) included various types of mastectomies and showed less postoperative pain for patients in the group receiving a PVB compared to those who did not receive a PVB. Agarwal et al. (2015) discovered for patients undergoing a unilateral or bilateral mastectomy those in the PVB group experienced less postoperative pain immediately, but not on postoperative day (POD) 1 when compared to those who

did not receive a PVB. In another study, patients in the PVB group had less postoperative pain scores than the non-PVB group, but no statistical significance was found (Shimizu et al., 2015). Nine studies found patients in the PVB group used less pain medications postoperatively (Aufforth et al., 2012; Beyaz et al., 2012; Fahy et al., 2014; Glissmyer et al., 2015; Parikh et al., 2016; Schnabel et al., 2010; Tahiri et al., 2011; Terkawi et al., 2015). Furthermore, the greatest reduction in narcotic use was seen in patients undergoing immediate reconstruction (Fahy et al., 2014; Parikh et al., 2016). Patients receiving a PVB were converted to oral narcotics sooner (Coopey et al., 2013; Parikh et al., 2016) and required less intraoperative opioids and general anesthetics (Pei et al., 2015; Shimizu et al., 2015; Terkawi et al., 2015). Two of the studies did not address postoperative pain (Exadaktylos et al., 2006; Fodale et al., 2014).

Six studies reported less chronic pain after a mastectomy with a PVB. Patients receiving a PVB reported 20- 50% reduction in chronic pain (Beyaz et al., 2012). Meta-analyses by Schnabel et al. (2010) and Terkawi et al. (2015), revealed the relative risk for chronic pain was lower in the PVB group 6 months after surgery. Bolin et al. (2015); Schnabel et al. (2010); Shimizu et al. (2015) discovered less chronic pain 12 months after surgery in patients who received GA in addition to a PVB. Karmakar et al., (2014) concluded patients who receive a PVB report less severe chronic pain, exhibit fewer symptoms and signs of chronic pain, and also experience better physical and mental health related quality of life (HQROL).

Postoperative Nausea and Vomiting

Four studies noted PONV was significantly less in the PVB group (Beyaz et al., 2012; Coopey et al., 2013; Schnabel et al., 2010; Terkawi et al., 2015). Likewise, higher

antiemetic use was required for patients not receiving a PVB (Fahy et al., 2014).

Aufforth et al. (2015) noted slightly less PONV for the PVB group. PONV was not statistically significant between the two groups in two of the studies (Bhuvaneswari et al., 2012; Boughey et al., 2009). Eight of the 16 articles did not address PONV.

Length of Stay

The length of stay (LOS) for patients receiving a PVB was significantly less than those who did not receive a PVB (Beyaz et al., 2012; Boughey et al., 2009; Coopey et al., 2013; Glissmyer et al., 2015; Parikh et al., 2016; Terkawi et al., 2015). Boughey et al. (2009), discovered patients having extensive breast surgery were less likely to require an overnight stay if they received a PVB and were discharged sooner than those receiving GA alone. Of the studies looking at chronic pain, only one reported patients in the non-PVB group were discharged sooner than the PVB group (Fahy et al., 2014). However, this study included patients undergoing various types of mastectomies and patients having a less extensive surgery were more likely to be discharged sooner than those undergoing a bilateral mastectomy.

Cancer Recurrence

Surgery causes stress to the body, and studies show after surgery recurrence of neoplastic disease can occur. “The body’s response to surgical stress causes the release of chemical mediators, which determine the upregulation of malignant pathways, disruption of tumor homeostasis, and promotion of cancer recurrence” (Fodale et al., 2014, p. 2). Immune surveillance refers to the body’s ability to recognize self from non-self or the cancer cells. The body then tries to eliminate the cancer cells. Since surgery causes immunosuppression, some tumor cells are able to evade immune control (Fodale et al.,

2014). Volatile anesthetics can further decrease immune function and pain can inhibit immune surveillance. Regional anesthesia can block the body's neuroendocrine response to surgical stress by blocking transmission of neuronal signals to the central nervous system. Locoregional anesthesia can help preserve natural killer (NK) cell function and decrease the amount of GA required intraoperatively. Therefore, a PVB is associated with lower risk of cancer recurrence (Fodale et al., 2014; Schnabel et al. 2010). Exadaktylos et al. (2006) reported patients receiving a PVB in addition to GA group had less cancer recurrence/metastasis (3/50) compared to the GA group (19/50). Furthermore, the PVB with GA group had a slower time to recurrence than the GA group (Exadaktylos et al., 2006). A multicenter randomized trial is currently being conducted in the U.S. to determine the efficacy of PVBs in reducing cancer recurrence.

Other Regional Techniques Used for Breast Surgery

Wound Infiltration is the direct infiltration of local anesthetic at the surgical site which avoids the complications associated with other regional techniques. However, data from 15 randomized controlled trials (RCTs) failed to prove wound infiltration was effective in reducing postoperative pain (Cheng & Ilfeld, 2016). Wound infusion involves the placement of a catheter at the surgical site and allows for an infusion or boluses of local anesthetic to be administered. Like wound infiltration, studies determined wound infusion did not provide statistically significant benefits for breast surgery (Cheng & Ilfeld, 2016).

Pectoral Nerve Blocks (Pecs) are an interfascial plane block and have been used as an alternative to a PVB for simple mastectomy procedures and chest wall procedures involving the axilla. A Pecs I block anesthetizes the pectoral nerves and can be used for

mastectomies that do not involve axillary node dissection (Cheng & Ilfeld, 2016). A modified version of the Pecs I block is the Pecs II block. A Pecs II block anesthetizes the medial and lateral pectoral nerves and the lateral branches of the intercostal nerves by injecting local anesthetic between the pectoralis minor and anterior serratus muscles. A Pecs II block can be used for more extensive breast surgery involving the axilla (Bolin et al., 2015). However, only one RCT involving radical mastectomy procedures has been concluded a Pecs block with GA reduces postoperative pain compared to GA alone. A Pecs I and Pecs II block lack the risk of sympathectomy, which can cause hypotension and bradycardia, and can still be performed if the patient is anticoagulated. Risks associated with Pecs II blocks are thoracoacromial artery injection, pneumothorax, and puncture of the axillary fascia. As of 2015, no formal studies comparing Pecs II blocks to PVBs were identified in the literature. Unlike a PVB, Pecs I and II blocks cannot be used as a sole anesthetic for a mastectomy (Bolin et al., 2015). This literature review found no evidence to conclude Pecs I or II blocks were superior to PVBs for reducing postoperative complications in patients undergoing a bilateral mastectomy with immediate reconstruction.

A thoracic epidural infusion has been documented as an effective technique for major breast surgery. Although, thoracic epidurals are effective in decreasing postoperative complications, they carry more side effects than PVBs. Side effects of a thoracic epidural include profound hypotension, headache, spinal cord injury, and spinal cord hematoma (Bolin et al., 2015). Also, a thoracic epidural can only be used in a hospital setting.

Thoracic epidurals and PVBs are the only techniques confirmed to provide reliable, effective postoperative pain relief for breast procedures, and PVBs are the only regional technique proven to decrease post mastectomy pain within 12 months (Bolin et al., 2015; Cheng & Ilfeld, 2016). Literature revealed Pecs blocks are becoming more popular for chest wall procedures, but there is a lack of evidence to support they are better than PVBs at decreasing postoperative complications in patients undergoing extensive breast surgery. According to Bolin et al. (2015), PVBs are the “gold standard” regional technique of choice for breast procedures when compared to other techniques. This literature review revealed PVBs are most effective in reducing postoperative complications, such as postoperative pain, PONV, chronic pain, and cancer recurrence, and LOS in patients having a mastectomy with immediate reconstruction.

Theoretical Framework

The model for evidence-based practice (EBP) change, developed by Rosenwurm and Larrabee, is the change theory that was used for this project to create a practice change. The first step is to assess the need for a change in practice (Melnik & Fineout-Overholt, 2015, p. 288). This step includes identifying the practice problem. For this project, the problem was a lack of awareness among anesthesia providers regarding the evidence that PVBs can improve postoperative outcomes for patients undergoing a bilateral mastectomy with immediate reconstruction. Moreover, the problem should be a priority to anesthesia providers and the institution. One way to make this practice change a priority is to inform anesthesia providers and the hospital they can bill separately for these blocks because they are provided for postoperative pain. Therefore, providing a PVB can increase reimbursement. Also, a PVB used in addition to GA could be cost

saving to the institution by decreasing the amount of narcotics used and length of stay for patients.

Next, a review of current literature is done to identify EBP. The 3rd step involved appraising the literature; synthesizing the evidence; and assessing the benefits, feasibility, and risks of implementing the practice change (Melnyk & Fineout-Overholt, 2015). Step 4 of the model for EBP was designing a practice change by identifying resources, design evaluation, and designing a plan for implementation. The new practice should be supported by the evidence from Step 3 (Melnyk & Fineout-Overholt, 2015).

Step 5 involves implementation and evaluation of the practice change. In this step, CRNAs and anesthesiologist at the institution would provide PVBs in addition to GA to bilateral mastectomy patients having immediate reconstruction. The practice change would then be evaluated to see if it is cost saving to the institution, increases revenue, and improves patient outcomes. Finally, the practice change would be integrated and maintained. This step also includes monitoring outcomes periodically and disseminating results of the project outside of the institution (Melnyk & Fineout-Overholt, 2015).

Doctor of Nursing Practice Essentials

This doctoral project meets the eight Doctor of Nursing Practice (DNP) essentials which are listed in Appendix A. The main essentials this project addressed were Essential II, III, and VI. Essential II: Systems Thinking, Healthcare Organizations, and the Advanced Practice Nurse Leader guides DNP nurses to assess current healthcare policies and create policies that improve healthcare outcomes at an organizational level (Zaccagnini & White, 2014). For example, this project aimed to create a practice change which incorporates PVBs for patients undergoing a bilateral mastectomy in order to

improve postoperative outcomes. Essential III: Clinical Scholarship and Analytical Methods for Evidence-Based Practice involves research translation and the dissemination and implementation of new knowledge (American Association of Colleges of Nursing, 2006). A review of literature found PVBs can improve postoperative outcomes for mastectomy patients. These findings were disseminated to CRNA's to improve practice. Essential VI: Interprofessional Collaboration for Improving Patient and Population Health Outcomes was met through collaboration with physicians, anesthesiologist, and CRNAs so that PVBs can be implemented for patients having a bilateral mastectomy with immediate reconstruction to decrease LOS, improve postoperative outcomes, and increase patient satisfaction.

Summary

Surgery for breast cancer is associated with a significant amount of postoperative complications. DNP prepared nurses use nursing science to improve patient outcomes, and this project sought to create a practice change to implement PVBs for patients undergoing extensive breast surgery by educating anesthesia providers about the benefits PVBs can provide to these patients. By following the steps in the model for EBP change, nerve blocks were implemented in order to decrease postoperative complications for patients undergoing a bilateral mastectomy with immediate reconstruction.

CHAPTER II - METHODOLOGY

Overview

The literature review has shown PVBs are superior to other methods of regional anesthesia and can improve postoperative outcomes for breast cancer patients undergoing breast surgery. This project aimed to create a practice change to implement PVBs by informing anesthesia providers about the benefits of PVBs for bilateral mastectomy patients having immediate reconstruction. Once implemented, PVBs can fulfill the secondary goal of this project which was to improve postoperative outcomes for those undergoing breast cancer surgery with reconstruction.

Target Population

The target population for this study was anesthesia providers, CRNAs and anesthesiologist, in Mississippi. The convenience sample used for this project consisted of anesthesia providers at a 111 bed hospital in the Southern U.S. Healthcare providers who were not an anesthesiologist or CRNA were excluded. Those excluded from the study included registered nurses and physicians.

Design

An in-service was held for anesthesia providers at the facility detailing the benefits of PVBs and how to perform them. The in-service included information compiled from the literature review. Immediately following the in-service, anesthesia providers were asked to perform PVBs for bilateral mastectomy patients undergoing immediate reconstruction. A protocol was developed for administration of PVBs and is included in Appendix C. Training and a step by step guide for performing PVBs was provided from The New York School of Regional Anesthesia's website at

www.nysora.com. Additional onsite training was provided by a healthcare provider employed at the hospital with knowledge of PVBs.

Anesthesia providers were asked to complete an investigator developed questionnaire regarding their anesthesia practice one month prior to the presentation. The initial questionnaire can be found in Appendix D. A tally sheet was provided to the anesthesia providers in order to track the number times they provided an anesthetic to a patient undergoing a bilateral mastectomy with immediate reconstruction over a one month time period. After the one month time period, an investigator created questionnaire was administered to the anesthesia providers to determine if they had performed any type of nerve block for patients having breast cancer surgery with immediate reconstruction. The follow-up questionnaire can be found in Appendix E. Completion of the questionnaire indicated informed consent to participate in the study.

Data was gathered from the tally sheet and the questionnaire. Information obtained from the questionnaire included how many times a nerve block was provided, whether or not the anesthesia provider felt the in-service was effective, and whether the anesthesia provider felt the nerve blocks decreased postoperative complications. Descriptive statistics was used to determine the percentage of anesthesia providers changed their practice to incorporate nerve blocks.

Design-Ethical Considerations – Protection of Human Subjects (IRB)

Approval for the study was obtained from The University of Southern Mississippi (17022302, Appendix F) and the facility (Appendix G). All questionnaires were anonymous. Data obtained for this project will be deleted and/or shredded 6 months after completion of graduation requirements.

If the nerve blocks are administered preoperatively for postoperative pain control, extra income can be generated for the anesthesia provider and the facility. Training for administration of PVBs required additional time for the anesthesia provider and could be considered an inconvenience. Because the procedure was new to this facility, there could have been a learning curve. During this time, patients could have been unsatisfied with their anesthetic, which could reflect negatively on the anesthesia provider. On the other hand, several sources have cited that PVBs are easy to learn, which could mean patient satisfaction would improve. Additionally, there were potential risks to the patient receiving a PVB, such as pneumothorax, hypotension, or failed anesthetic. However, there is a low risk for developing these complications especially if an ultrasound machine is used.

Assumptions

One assumption of this project was the postoperative care of bilateral mastectomy patients' needs to be improved, and patients would agree to have a PVB. Another assumption was anesthesia providers will attend the in-service, and CRNAs would be authorized by the facility to administer PVBs. A list of assumptions can be found in the logic model (Appendix H).

Resource Requirements

Resources needed for this project included the anesthesia staff, preoperative rooms, and operating rooms (OR) rooms. Equipment, such as monitors, an ultrasound machine, and emergency airway equipment are needed to safely perform the blocks. Other supplies needed include sterile gloves, skin prep solution, emergency drugs, preoperative medications, nerve block medications, and nerve block needles. Another

resource required for this project was time. Administration of a PVB may require additional time, which could initially increase operating room turnover time and necessitate coordination between the anesthesia provider, surgeon, and OR staff.

Summary

Implementing PVBs for patients undergoing a bilateral mastectomy with immediate reconstruction required training, time, collaboration with other healthcare providers, and additional resources compared to current methods of anesthesia. However, PVBs can benefit patients by reducing postoperative complications and anesthesia providers due to additional revenue and increased patient satisfaction. Through the use of descriptive statistics, this study determined if anesthesia providers at a surgery center in the Southern U.S. made a practice change to incorporate PVBs into the plan of care for patients having extensive breast surgery in order to make inferences about the population of anesthesia providers in Mississippi.

CHAPTER III - RESULTS

Overview

A 20-minute presentation was given to the anesthesia providers at a surgery center in Mississippi. The presentation was held in the conference room of the surgery center in the morning prior to any surgical cases. The sample included five of the six anesthesia providers. Ages ranged from 32-62, and the mean age was 52.2. Years of experience as an anesthesia provider were 6-33 with a mean of 25.2. Of the five participants, three (60%) were female and two (40%) were male. Participants were administered a questionnaire immediately following the presentation and again one month after the presentation.

Statistical Analysis

Descriptive statistics were used to interpret the results of the questionnaires. All five of the anesthesia providers who attended the presentation completed the initial questionnaire. Two of the five (40%) participants completed the 1-month questionnaire.

Initial Questionnaire Results

Anesthesia providers were asked to provide information for the month prior to the presentation. During this time period, a reported 22 patients had undergone a bilateral mastectomy with immediate reconstruction at the surgery center. None of these patients received a PVB. However, five (22.7%) of the 22 patients did receive a Pecs I, Pecs II, and serratus plane block. These nerve blocks were performed during a one week time period preceding the presentation. All of the anesthesia providers felt the information presented was relevant to their practice. There was no correlation between age or gender and administration of the nerve blocks.

Table 1

Initial Questionnaire Results

Initial Questionnaire Results						
						Total
Participant	1	2	3	4	5	
Age	58	62	32	50	59	
Gender	M	F	M	F	F	
Number of years as an anesthesia provider	32	33	6	25	30	
Number patients who received a bilateral mastectomy with immediate reconstruction in the past month	5	5	5	3	4	22
Number of patients who received a PVB	0	0	0	0	0	0
Number of patients who received another type of nerve block	1	1	2	0	1	5
Was the information presented relevant to your practice	Yes	Yes	Yes	Yes	Yes	

Follow-up Questionnaire

One month following the presentation, a reported 20 patients at the surgery center had a bilateral mastectomy with immediate reconstruction. None of these patients received a PVB. Twenty (100%) of the patients received a Pecs I, Pecs II, and serratus plane block. All of these blocks were administered immediately following the induction of anesthesia. None of the blocks were used as the sole anesthetic for a bilateral mastectomy with immediate reconstruction. The only complication was minor skin

irritation at the injection site in one patient (0.05%). Anesthesia providers reported patients used less narcotics and a decrease in postoperative complications since the implementation of the nerve blocks. All anesthesia providers who participated in the follow-up questionnaire stated they would continue to perform nerve blocks for this patient population. There was no correlation between age and willingness to perform nerve blocks. However, all of the nerve blocks performed in the month following the presentation were done by the male anesthesia providers.

Table 2

Follow-up Questionnaire Results

Follow-Up Questionnaire Results			
			Total
Participant	1	2	
Age	58	32	
Gender	M	M	
Number of years as an anesthesia provider	32	6	
Number patients who received a bilateral mastectomy with immediate reconstruction in the past month	10	10	20
Number of patients who received a PVB	0	0	0
Number of patients who received a different type of nerve block	10	10	20

Table 2 (continued)

If patients received another type of nerve block, what type was performed	Pecs I, Pecs II, and serratus plane block	Pecs I, Pecs II, and serratus plane block	
Phase of Care when nerve block was provided	Immediately after induction	Immediately after induction	
Number of times a nerve block was contraindicated	0	0	0
Number of patients who experienced a complication related to the nerve block	1 – minor skin irritation at injection site	0	1
Will you continue to perform Pecs I, Pecs II, and serratus plane blocks for this patient population	Yes	Yes	

Summary

Although this surgery center did not choose to administer PVBs, a practice change was made to incorporate Pecs I, Pecs II, and serratus plane blocks into the plan of care for bilateral mastectomy patients undergoing immediate reconstruction. Participants in this study reported a decrease in immediate postoperative complications for the patients who received these blocks. The next chapter will discuss recommendations, implications for future practice, and the conclusion.

CHAPTER IV – DISCUSSION

Overview

The literature review revealed current methods of pain control following a bilateral mastectomy with immediate reconstruction to be suboptimal. The addition of regional anesthesia to the anesthetic plan for these patients has been shown to improve patient outcomes. Recently published articles have shown other types of nerve blocks to be effective in reducing immediate postoperative complications for patients having breast cancer surgery. Abdallah et al. (2017) demonstrated Pecs I and II blocks in addition to a serratus plane block were effective in reducing postoperative narcotic use and PONV for breast cancer patients in an ambulatory care setting. Kulhari, Bala, Bala, & Arora (2016) compared Pecs II blocks to PVBs for patients having a modified radical mastectomy and concluded Pecs II blocks to be just as effective as PVBs in reducing immediate postoperative pain. However, no articles to date have been found comparing the Pecs I and II blocks in addition to serratus plane block to PVBs for bilateral mastectomy patients undergoing immediate reconstruction. Also, no studies have proven the Pecs blocks or serratus plane blocks to be effective in reducing chronic postoperative pain. This surgery center chose Pecs I, Pecs II, and serratus plane blocks over PVBs for patients undergoing a bilateral mastectomy because of the ease of administration and low risk of complications associated with the Pecs I, Pecs II, and serratus plane blocks. In addition to determining whether or not a practice change was made, this project also obtained information about how patients have been impacted by the practice change.

Implications

One month after the presentation, regional anesthesia was implemented for all patients undergoing a bilateral mastectomy with immediate reconstruction. Although all the participants in the initial questionnaire expressed interest in implementing nerve blocks for this patient population, the majority of the nerve blocks were administered by two providers. In the follow up questionnaire, these two anesthesia providers reported less narcotic use, less postoperative complication, and better outcomes when a Pecs I, Pecs II, and serratus plane block were used. These results are similar to those found by Kulhari et al. (2016). The healthcare providers at this facility determined nerve blocks to be so beneficial; they now offer nerve blocks for all mastectomy procedures. The facility where the nerve blocks were implemented has also begun to advertise improved pain control following a mastectomy.

Limitations

One limitation to this study is the small sample size. Low participation for the follow-up questionnaire was because the two providers participating in the follow-up questionnaire administered all the nerve blocks in the month following the presentation. An attempt was made to increase participation by providing the questionnaires during times that were convenient for the anesthesia providers. Some of the anesthesia providers reported on the initial questionnaire they had already begun performing Pecs I, Pecs II, and serratus plane blocks for patients undergoing a bilateral mastectomy with immediate reconstruction. Administration of the nerve blocks prior to the presentation and the decision to make a practice change may have been due to the surgeon's involvement in the study. Ideally, the presentation would have been done prior to the surgeon's arrival at

the facility, but due to scheduling conflicts it was not possible to present the material at an earlier date. Lack of materials and lack of buy in from healthcare providers and administrators may make these results difficult to replicate. However, this project is useful because it demonstrated that when presented with EBP, the anesthesia providers at this facility were willing to make a practice change in order to improve patient outcomes.

Recommendations

This project ended during step 5 of Rosswurm and Larrabee's model for change to EBP. The next step would be to evaluate the effectiveness of the practice change, and then determine if the practice change has been maintained. In addition to the evaluation of this study, subsequent studies could attempt to replicate the results of this study at another facility or with a larger sample size. Also, future studies could examine to what extent these blocks decrease postoperative complications or if these blocks are effective at decreasing length of stay, chronic pain, or cancer recurrence. More studies are needed comparing other forms of relevant nerve blocks to PVBs to determine which is more effective. This DNP project focused on implementing nerve blocks for patients undergoing a bilateral mastectomy. A continuation of this project could be to create a practice change at other facilities to provide nerve blocks for all types of mastectomies.

Dissemination

Results from this project will be disseminated to anesthesia providers at current clinical sites and future sites of employment. Informal conversations have already been held with CRNAs at a another facility that does not currently utilize nerve blocks for mastectomy patients regarding the results of this project. Due to the outcome of this project, CRNAs at the facility where nerve blocks are not performed expressed an interest

in administering Pecs blocks to mastectomy patients. This project will also be disseminated through Aquila and possibly at future conferences.

Conclusion

Although PVBs were not implemented at this facility, other nerve blocks were incorporated into the plan of care for bilateral mastectomy patients having immediate reconstruction. Literature shows nerve blocks can improve patient outcomes following surgery for breast cancer. Future studies are needed to examine to what extent these block decrease immediate postoperative complications and to determine their effectiveness in decreasing length of stay, chronic pain, and cancer recurrence. Due to the effectiveness of the nerve blocks at this facility, Pecs I and II blocks are now offered for all types of mastectomies. The results from this project can be used at other facilities to implement nerve blocks for patients at undergoing breast surgery for cancer.

APPENDIX A - DNP Essentials

Table A1

DNP Essentials

DNP Essentials	Clinical Implications
Essential I: Nursing Science and Theory: Scientific Underpinnings for Practice	Theories provide a foundation for understanding patient’s healthcare needs and help to identify the best interventions to meet those needs (Zaccagnini & White, 2014). The model for EBP change, developed by Rosenwurm and Larrabee, is a change theory that will be used implement a practice change.
Essential II: Systems Thinking, Healthcare Organizations, and the Advanced Practice Nurse Leader	This essential guides DNP nurses to assess current healthcare policies and create policies that improve healthcare outcomes at an organizational level (Zaccagnini & White, 2014). For example, this project aims to create a practice change to incorporate PVBs for patients undergoing a bilateral mastectomy in order to improve postoperative outcomes.
Essential III: Clinical Scholarship and Analytical Methods for Evidence-Based Practice	Involves research translation and the dissemination and implementation of new knowledge (American Association of Colleges of Nursing [AACN], 2006). A review of literature found PVBs can improve postoperative outcomes for mastectomy patients (Schnabel et al., 2010, p 8). These findings will be disseminated to CRNA’s to improve practice.
Essential IV: Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care	This essential ensures DNP nurses are proficient in the use of healthcare technology to “create web-based learning or intervention tools to support and improve patient care” (Zaccagnini & White, 2014, p. 134). One of the goals for this project is to create a website to inform anesthesia providers about the benefits of PVBs.

Essential V: Healthcare Policy for Advocacy in Healthcare	The purpose of this project is to change healthcare policy by disseminating evidence based information to the CRNAs at a facility in Mississippi.
Essential VI: Interprofessional Collaboration for Improving Patient and Population Health Outcomes	Through collaboration with physicians, anesthesiologist, and CRNAs PVBs can be implemented for patients undergoing a bilateral mastectomy with immediate reconstruction to decrease length of stay, improve postoperative outcomes, and increase patient satisfaction.
Essential VII: Clinical Prevention and Population Health	The goal of this essential is to promote patient health and prevent illness/disease (AACN, 2006). Studies have shown PVBs can decrease the incidence of chronic pain and possibly cancer recurrence (Schnabel et al., 2010, p 8). Educating anesthesia providers about the benefits of PVBs can lead to implementation PVBs and improve the health of mastectomy patients.
Essential VIII: Traditional Advanced Practice Roles for the DNP	This project meets Essential VIII by educating anesthesia providers on evidence based findings in order to improve clinical practice.

APPENDIX B – Synthesis Matrix

Table A2

Synthesis Matrix

Author/Year	Postoperative Pain	Postoperative Nausea/Vomiting	Chronic Pain	Length of Stay	Cancer Recurrence
Agarwal, R., Wallace, A., Madison, S., Morgan, A., Mascha, E., & Ilfeld, B. (2015, April).	Patients receiving a PVB had significantly lower pain scores than patients who did not receive a PVB immediately after surgery. However, at noon on POD1 there was not a statistically significant decrease in pain scores in the PVB group.				
Aufforth, R., Jain, J., Morreale, J., Baumgarten, R., Falk, J., & Wessen, C. (2012).	Patients having immediate reconstruction with a PVB used less opioids on post-op day 1 than the non-PVB reconstruction group.	Slightly less postoperative nausea and vomiting (PONV) was noted in the PVB group, 3.3% compared to 4.2% in the non-PVB group.			

Beyaz, S., Ergonenc, T., Altintoprak, F., & Erdem, A. (2012, August 27).	A thoracic PVB can provide better postoperative pain management and decrease opioid consumption compared to general anesthesia (GA).	A PVB prevents PONV better than GA.	Many of the studies demonstrated a 20-50% reduction in chronic post mastectomy pain	PVB can decrease the length of hospital stay and increase patient satisfaction	Cited findings by Exadaktylos, A., Buggy, D., Moriarty, D., Mascha, E., & Sessler, D. (2006)
Bhuvanseswari, V., Wig, J., Mathew, P., & Singh, G. (2012).	Intraoperatively, patients in the 0.25% bupivacaine + epi + fentanyl and the 0.5% bupivacaine + epi groups was less than the 0.25% bupivacaine + epi and the group who received no PVB. Patients receiving a PVB with 0.25% bupivacaine + epinephrine + fentanyl and the group receiving a PVB with 0.5% bupivacaine + epi had significantly better postoperative analgesia compared to the group receiving GA alone.	PONV was not statistically significant			

Bolin, E., Harvey, N., & Wilson, S. (2015, March 31)			Less chronic pain at one, six, and 12 months reported in patients who received a PVB compared to those receiving GA alone.		
Boughey, J., Goravanchi, F., Parris, R., Kee, S., Frenzel, J., Hunt, K., ... Lucci, A. (2009, September-October).	The patients receiving a PVB reported less pain in the immediate postop period which continued until the next day for patients undergoing a total mastectomy and/or axillary node dissection. Immediately postop, 81% of patients receiving a PVB reported a pain score of 0 compared to 57% of the non-PVB group. At 4 hours postop, 71% of the PVB group reported a pain score of 0 compared to 38% of the non-PVB group. At 8 hours postop, 60% of the PVB group and 36% of the non-PVB	The difference in PONV was not statistically significant.		Length of stay (LOS) for patients having a total mastectomy or more extensive breast surgery was significantly less for those who received a PVB. Patients undergoing extensive breast surgery were less likely to require an overnight hospital stay if they received a PVB.	

	group reported a pain score of 0.				
Coopey, S., Specht, M., Warren, L., Smith, B., Winograd, J., & Fleischmann, K. (2013, April).	The PVB group was converted to oral narcotics sooner than the non-PVB group.	Incidence of nausea and vomiting was significantly less in the PVB group compared to the non-PVB group.		Mean LOS was significantly less in the PVB group, which was 42 hours compared to 47 hours in the non-PVB group.	
Exadaktylos, A., Buggy, D., Moriarty, D., Mascha, E., & Sessler, D. (2006, October).					Patients in the PVB with GA group had less cancer recurrence/metastasis (3/50) compared to the GA group (19/50). Additionally, the PVB with GA group had a slower time to recurrence than the GA group.
Fahy, A., Jakub, J., Dy, B., Eldin, N.,	Although no difference in pain scores was	The amount of patients requiring		Patients in the non-PVB group	

Harmsen, S., Sviggum, H., & Boughey, J. (2014, October)	noted on the day of surgery, opioid uses was higher in the non-PVB group. Patients undergoing immediate reconstruction had the greatest reduction in postoperative opioid use.	postoperative antiemetics was higher in the non-PVB group (57%) compared to the PVB group (39%).		were discharged sooner than the PVB group.	
Fodale, D'Arrigo, Triolo, Mondello, & La Torre. (2014)					Surgery is stressful and studies show after surgery recurrence of neoplastic disease can occur. Volatile anesthetics can decrease immune function and pain can prevent immune surveillance, and opioids can inhibit cellular and humoral immunity. Regional anesthesia can

					block the body's neuroendocrine response to surgical stress by blocking transmission of neuronal signals to the central nervous system. Locoregional anesthesia can help preserve natural killer (NK) cell function and decrease the amount of GA required intraoperatively. PVB anesthesia is associated with lower risk of cancer recurrence.
Glissmyer, C., Johnson, W., Sherman, B., Glissmeyer, M., Garreau, J., &	Ninety-one patients were included in this study. The 51 patients not having reconstruction had an			Average LOS was less (1.3 days) for the reconstruction group with PVB	

Johnson, N. (2015).	average morphine equivalent (MSE) of 37.9. Of the 40 patients undergoing reconstruction, 33 received a PVB with an average MSE 42.6, and 7 received only GA with an average MSE of 71.1.			compared to the reconstruction group with no PVB (2 days).	
Karmakar, M., Samy, W., Li, J., Lee, A., Chan, W., Chen, P., & Ho, A. (2014, July-Aug)			Patients who receive a TPVB report less severe chronic pain, exhibit fewer symptoms and signs of chronic pain, and also experience better physical and mental health related quality of life (HQROL).		
Parikh, Sharma, Guffey, & Myckatyn, (2016)	Breast cancer patients undergoing a mastectomy with autologous breast reconstruction who received a PVB were needed less IV opioids			LOS was significantly less (mean of 95hrs) for the PVB group compared to the non-PVB group	

	postoperatively, were converted to oral narcotics sooner, and had less pain at 2 and 24 hours compared to the non-PVB group.			(mean of 116hrs).	
Pei, L., Zhou, Y., Tan, G., Mao, F., Yang, D., Guan, J., ... Huang, Y. (2015, November 20).	Patients receiving a PVB with propofol anesthesia required less sevoflurane, less intraoperative fentanyl, and had less postoperative pain than patients who received GA. However, patients in the PVB with propofol anesthesia group required more propofol than the GA group.				
Schnabel, A., Reichl, S. U., Kranke, P., Pogatzki-Zahn, E. M., & Zhan, P. K. (2010, October, 14).	There was significantly lower pain scores at rest in the 2-24 hour period and lower pain scores at movement for all time intervals in the group that received a PVB in addition to GA compared to the group that received GA alone.	Patients receiving only a PVB had less PONV than women undergoing surgery with GA.	Relative risk for chronic pain was lower in the PVB group 6 months after surgery. Twelve months after surgery two studies reported a lower chronic pain when patients had a		Evidence indicates surgery can release tumor cells into circulation, volatile anesthetics can impair immune function,

	The number of patients requiring postop opioids was significantly lower in the PVB group.		PVB in addition to GA.		opioids can further impair immune function and promote angiogenic factors, and pain alone is associated with cancer recurrence. This study shows patients receiving a PVB in addition to GA or alone required less postoperative pain medications, which could indicate a decreased incidence of cancer recurrence.
Shimizu, H., Kamiya, Y., Nishimaki, H.,	Forty-nine patients were included in the study. The dose of remifentanil used		Patients who reported chronic pain had significantly higher		

Denda, S., & Baba, H. (2015).	intraoperatively was less in the PVB group. Pain scores were significantly lower 6-24 hours postoperatively for patients who received a PVB. However, even though pain scores tended to be lower in the PVB group, no statistical significance was found in pain scores 0-6 hours after surgery and 24 hours after surgery.		pain scores 3-6 hours postoperatively. The incidence of chronic pain was significantly less 1 year postop for the PVB group (5/23) compared to the group receiving GA alone (12/23).		
Tahiri, Y., Tran, D., Bouteaud, J., Xu, L., Lalonde, D., Luc, M., & Nikolis, A. (2011).	Nine of the 11 studies reported a complication rate less than 2.6%. The PVB group reported less pain than the general anesthetic group, and postoperative opioid consumption was less in the PVB group compared to the general anesthetic group.				

<p>Terkawi, A., Tsang, S., Sessler, D., Terkawi, R., Nunemaker, M., Durieux, M., & Shilling, A. (2015, September/October).</p>	<p>Pain at rest and movement was modestly but significantly less for the PVB group at 2, 24, 48, and 72 hours after surgery. The addition of fentanyl to local anesthetic decreased pain with movement in the PVB group at 24 and 72 hours. Intraoperative and postoperative opioid use was significantly less for those who received a PVB compared to the control group with heterogeneity.</p>	<p>A statistically significant decrease in PONV with heterogeneity was noted in the PVB group.</p>	<p>Patients who received a PVB reported significantly less chronic pain at 6 months with no heterogeneity noted.</p>	<p>A statistically significant decrease in LOS was found for the PVB group with heterogeneity.</p>	
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APPENDIX C – Paravertebral Block Protocol

Candidates: Women diagnosed with breast cancer undergoing a bilateral mastectomy with immediate reconstruction

Indication: To decrease postoperative pain, nausea/vomiting, and hospital length of stay for patients undergoing a bilateral mastectomy with immediate reconstruction

Absolute Contraindications:

- Patient refusal
- Local anesthetic allergy
- Infection near injection site
- Tumor at injection site
- Severe hypovolemia

Relative Contraindications:

- Severe coagulopathy
- Severe respiratory disease
- Spinal deformities
- Unspecified neuropathy

Supplies:

- Emergency airway equipment
- Emergency drugs (including 20% intralipids)
- Ultrasound machine
- Nerve stimulator
- Sterile gloves
- Skin prep solution
- Lidocaine and 25-gauge needle for local injection
- 22-gauge nerve block needle or spinal needle
- 0.5% bupivacaine
- 1:200,000 epinephrine

Benefits:

- Postoperative pain control
- Decreased postoperative nausea/vomiting
- Decreased hospital length of stay
- Decreased incidence of chronic pain

Table A3

Paravertebral Block Protocol

Patient Preparation <ul style="list-style-type: none">• Verify patient name and date of birth	<ul style="list-style-type: none">• NIBP, O₂saturation, HR, respiratory rate, CBC
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<ul style="list-style-type: none"> • Obtain vital signs and review pertinent lab work • Obtain informed consent 	<ul style="list-style-type: none"> • Include risks and benefits associated procedure
<p>Process</p> <ul style="list-style-type: none"> • Premedicate patient with Versed (1-3 mg IV) and Fentanyl (25-100 mcg) • Place patient in sitting position • Ultrasound guided PVB at T1, T3, and T5 using 0.5% bupivacaine with 1:200,000 epinephrine. <ul style="list-style-type: none"> ○ Inject 3-5ml at each level bilaterally (not to exceed 30ml or 3mg/kg) 	<ul style="list-style-type: none"> • Neck flexed with chin to chest, shoulders in a collapsed position, and back arched • Begin scanning 5-10 cm laterally to identify ribs and pleura. Move transducer medially until transverse processes are identified. Once transverse processes have been identified, insert needle out-of-plane until the transverse process is contacted. Then, direct needle caudad (approximately 1-1.5 cm) into the paravertebral space. Aspirate and inject 3-5 ml of local anesthetic. Repeat this procedure for each level to be blocked. Injection of local anesthetic should result in displacement of the pleura. • If a nerve stimulator is used begin with current at 2-2.5mA with the goal of eliciting an intercostal muscle twitch. Observe twitch and decrease mA to 0.8 while advancing needle into paravertebral space.
<p>Post Procedure Care</p> <ul style="list-style-type: none"> • Monitor patient for 30 minutes after block for complications, hypotension, and anesthetic toxicity. 	

APPENDIX D – Initial Questionnaire

Initial Questionnaire

1. What is your age

2. What is your gender
 Male Female

3. How long have you been an anesthesia provider?

4. How many times did you provide anesthesia for a patient undergoing a bilateral mastectomy with immediate reconstruction in the past month?

5. How many times did you perform a paravertebral block for these patients?

6. Of the patients undergoing a bilateral mastectomy with immediate reconstruction, how many times was a paravertebral block contraindicated?

7. Was the information provided on paravertebral blocks relevant to your practice?
 Yes
 No

8. If a paravertebral block was performed (select all that apply)
 For the majority of patients a paravertebral block was beneficial
 A paravertebral block was not beneficial
 Overall, the paravertebral blocks were easy to perform
 The paravertebral blocks were not easy to perform
 I will continue to administer paravertebral blocks for these patients
 I will not continue to perform paravertebral blocks for these patients
 Other _____

APPENDIX E – Follow-up Questionnaire

Follow-up Questionnaire

1. What is your age
2. What is your gender
 Male Female
3. How long have you been an anesthesia provider?
4. How many times did you provide anesthesia for a patient undergoing a bilateral mastectomy with immediate reconstruction in the past month?
5. How many of these patients received a paravertebral block in addition to general anesthesia?
6. How many of these patients received a pecs block in addition to general anesthesia?
7. At what phase of patient care was the nerve block provided?
 Preoperative
 Intraoperative
 Postoperative
8. Did the patients who received a nerve block experience less postoperative complications than those who received only general anesthesia?
 Yes
 No
9. Was regional anesthesia used as the sole anesthetic for any of the patients undergoing a bilateral mastectomy with immediate reconstruction?
 Yes
 No
10. Will you continue to perform nerve blocks for this patient population?
 Yes
 No
11. Of the patients undergoing a bilateral mastectomy with immediate reconstruction, how many times was a nerve block contraindicated?

APPENDIX F – IRB Approval Letter



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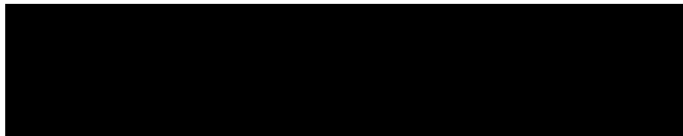
NOTICE OF COMMITTEE ACTION

The project has been reviewed by The University of Southern Mississippi Institutional Review Board in accordance with Federal Drug Administration regulations (21 CFR 26, 111), Department of Health and Human Services (45 CFR Part 46), and university guidelines to ensure adherence to the following criteria:

- The risks to subjects are minimized.
- The risks to subjects are reasonable in relation to the anticipated benefits.
- The selection of subjects is equitable.
- Informed consent is adequate and appropriately documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of all data.
- Appropriate additional safeguards have been included to protect vulnerable subjects.
- Any unanticipated, serious, or continuing problems encountered regarding risks to subjects must be reported immediately, but not later than 10 days following the event. This should be reported to the IRB Office via the "Adverse Effect Report Form".
- If approved, the maximum period of approval is limited to twelve months.
Projects that exceed this period must submit an application for renewal or continuation.

PROTOCOL NUMBER: 17022302
PROJECT TITLE: Implementing Paravertebral Blocks for Patients Undergoing a Bilateral Mastectomy with Immediate Reconstruction
PROJECT TYPE: New Project
RESEARCHER(S): Corey Auerswald
COLLEGE/DIVISION: College of Nursing
DEPARTMENT: Advanced Practice
FUNDING AGENCY/SPONSOR: N/A
IRB COMMITTEE ACTION: Exempt Review Approval
PERIOD OF APPROVAL: 02/24/2017 to 02/23/2018
Lawrence A. Hosman, Ph.D.
Institutional Review Board

APPENDIX G – Facility Approval Letter



01/23/2017

RE: Corey Auerswald Request for Letter of Support

I am the director of [REDACTED] and I am offering this letter of support of the doctoral student, Corey Auerswald, in her doctoral project titled *Implementing Paravertebral Blocks for Breast Cancer Patients Undergoing a Bilateral Mastectomy with Immediate Reconstruction*.

I understand that Corey Auerswald is a full-time student registered nurse anesthetist (SRNA) in the Doctor of Nursing Practice-Nurse Anesthesia Graduate Program at the University of Southern Mississippi who is planning to graduate in December 2017. This letter of support will be included in The University of Southern Mississippi Institutional Review Board (IRB) application.

I understand that open participation will be presented to anesthesia providers at [REDACTED]. I understand that participation is completely anonymous and voluntary. Providers at this facility may choose not to participate or withdraw from the study at any time and there will be no penalty. I understand the planned dates are from February 2017 to July 2017 after USM IRB approval is received. Her Chair contact information is Lachel Story at lachel.story@usm.edu and at (601) 266-6384.

I look forward to hearing the results of this study and the implications on clinical practice.

Sincerely,
[REDACTED]

APPENDIX H – Logic Model

Table A4

Logic Model

Inputs	Activities	Outputs	Outcomes		
			Initial	Long-term	Impact
<p>Facilities – OR rooms</p> <p>Staff – CRNAs, anesthesiologist, surgeons</p> <p>Equipment – monitors, emergency airway equipment</p> <p>Supplies – equipment for block, medications</p>	<p>Search databases such as PubMed, CINAHL, Primo at The University of Southern Mississippi, clinicaltrials.gov, and MEDLINE regarding different methods of administering anesthesia for patients undergoing a bilateral mastectomy with immediate reconstruction.</p> <p>Collect data about the postoperative</p>	<p>Provide education on the benefits of PVBs to patients, physicians, and anesthesia staff</p> <p>Implement a policy for routine administration of PVBs for patients undergoing a bilateral mastectomy with immediate reconstruction</p>	<p><u>Provider Outcomes</u> Anesthesia providers will adequately administer PVBs to patients undergoing breast surgery with immediate reconstruction</p> <p><u>Patient Outcomes</u> Patients have decreased postoperative nausea and vomiting following surgery</p>	<p><u>Provider Outcomes</u> Anesthesia providers will routinely administer PVBs to patients undergoing breast surgery with immediate reconstruction</p> <p>Anesthesia providers will experience satisfaction when administering PVBs to these patients.</p>	<p>Improved quality of life for bilateral mastectomy patients having immediate reconstruction</p>

	<p>outcomes of mastectomy patients undergoing a mastectomy with immediate reconstruction, like the level of postoperative pain, nausea, and vomiting</p> <p>Collect data about the cost of different methods of anesthesia</p> <p>Analyze data in order to determine if administration of a PVB compared to other methods of anesthesia would be beneficial and cost effective for mastectomy patients undergoing a bilateral mastectomy with immediate reconstruction</p>		<p>when PVB are used</p> <p>Patients will be discharged earlier</p> <p><u>Hospital</u> Hospital expenditure on narcotics will decrease</p> <p>Revenue will increase</p>	<p><u>Patient Outcomes</u></p> <p>Long term – Decreased incidence of chronic pain</p> <p>Decreased incidence of cancer</p> <p><u>Hospital</u> Decreased use of medical equipment and earlier discharge of patients will decrease cost to the hospital</p>	
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	<p>Develop a policy to implement PVBs patients undergoing a mastectomy with immediate reconstruction if they are shown to be beneficial</p> <p>Inform CRNAs about online training for administration of PVBs</p>				
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Assumptions

- The postoperative care of bilateral mastectomy patients' needs to be improved
- Patients will agree to have a PVB
- CRNAs will be authorized by the facility to administer PVBs
- Anesthesia providers will attend the in-service

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