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An Evaluation of Implementing Enhanced Recovery After Surgery Protocol Throughout the Perioperative Phase: A Quality Improvement Initiative to Enhance Patient Outcomes After

Colorectal Surgery

Lincoln Memorial University - Caylor School of Nursing

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Date of Submission: November 16, 2018

Dedication

This project is dedicated to my late brother Andre, who was extremely brilliant but passed away prematurely before having the chance to fully experience life and achieve his goals. His thirst for knowledge has inspired me to continue with my educational goals and receive a terminal degree. This is also for my parents, who always motivated us to be the best we could be and never settle for less, and teaching us that with God anything is possible. Thank you for supporting me throughout the years while I obtained each level of education and encouraging me to continue to the end. To Travis, thank you for being by side while I obtained my career goals and having an understanding heart.

Acknowledgements

I would like to thank my committee members, Dr. Crystal Odle, Dr. Jennifer Stewart-Glenn, Dr. Jane Castle, and Dr. Kim Ferguson, your guidance has helped me so much, and one day I aspire to be in your shoes and help future nurse leaders to achieve their goals and advance the nursing profession. I would also like to thank Joy Lewis, who have helped me tremendously throughout my nursing anesthesia education and doctoral education. I am so blessed to have worked with a wonderful group of people who have contributed to my knowledge exponentially and have helped mold me into a great clinical leader. Lincoln Memorial University has given me many great opportunities that have made my dreams come true. I met so many great colleagues that had a positive impact on my life, and I am proud to call myself a 'railsplitter.'

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Abstract

The Enhanced Recovery After Surgery protocol (ERAS) is a multimodal collaborative approach implemented throughout the perioperative phase to enhance patient outcomes. The key mechanism for effectiveness in the ERAS protocol is the attenuation of the surgical stress response combined with treatments that support the return of physiological function. The purpose of the scholarly project was to evaluate the results of the ERAS pilot program currently initiated at Baptist Memorial Hospital to improve patient outcomes undergoing colorectal surgery. Prior to the implementation of the ERAS protocol no standardized method was in place at the institution to improve patient recovery. There were monthly educational in-services pertaining to ERAS guidelines provided to healthcare providers taking care of ERAS patients in order to increase the levels of compliance with protocol orders. A retrospective chart review was conducted evaluating average length of stay, return of bowel function, opioid consumption, pain scores, patient satisfaction, and postoperative surgical complications in ERAS versus non-ERAS patients undergoing colorectal surgery to measure the effectiveness of the ERAS protocol at Baptist Memorial Hospital. The evaluation of this protocol will inform recommendations to modify the implementation of ERAS if needed to promote further success of the program and lead to expansion of the ERAS protocol to other surgical specialties.

Introduction and Background

In 1994, Professor Henrik Kehlet proposed a standardized protocol of evidence-based treatments throughout the perioperative period that has become known as Enhanced Recovery After Surgery (ERAS). The adoption of these principles is growing across the United States, with the intentions of decreasing variability in practice, reducing morbidity, enhancing rates of recovery, and decreasing postoperative length of stay (American Society of Colon and Rectal Surgeons, 2016).

Evidence-based practice in nursing is integral in the health care system. There is an increased focus on value-based reimbursements from insurance companies, and health care systems can tremendously reduce healthcare spending if patients receive evidence-based care. Current evidence supports reduction in variability and perioperative care protocols improve surgical outcomes and reduces cost in patients undergoing surgery (American Society of Colon and Rectal Surgeons, 2016).

Enhanced recovery after surgery (ERAS) is an integrated multimodal approach designed to help achieve an earlier recovery after surgery by continuing to maintain preoperative organ function and reduce the stress response that occurs after surgery. The ERAS protocol focuses on optimizing nutrition, pain management, anesthetic management, and early mobilization. An ERAS pilot program was first initiated in the summer of 2017 at Baptist Memorial Hospital. Presently, the ERAS program is used in patients undergoing colorectal surgery, after evaluating outcomes of the program based on set performance metrics, the decision will be made on whether to expand this program to other surgical specialties or eliminate it until further notice.

Review of Literature

A systematic review of the literature was conducted for relevant research concerning the ERAS protocol through medical and nursing databases for primary research material using the CINAHL, Medline, Google Scholar, Cochrane library, and PubMed resources. Keywords searched for this literature review included enhanced recovery after surgery, anesthesia, perioperative, abdominal surgery, ERAS protocol, ERAS pathway, ERAS implementation, fasttrack surgery, length of stay, improved patient outcomes, thoracic epidural, colorectal surgery

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and recovery, colon surgery, spinal analgesia and laparoscopic procedures, postoperative analgesia, carbohydrate loading, preoperative fasting, fasting and stress response, nursing and evidence based practice, implementing new protocols, ERAS evidence based practice education, barriers to implementing ERAS, and pain management. Studies were eligible for consideration if the focus of the study included the ERAS protocol, ERAS compliance, underwent abdominal surgery, implementation of evidence-based practice, carbohydrate loading prior to surgery, postoperative pain management, and published between the years 2013 and 2018. A total of 66 studies were found that met the criteria. The literature was reviewed for the research designs, peer-reviewed status, level of evidence, validity, reliability, rigor, and plausibility of findings. The following topics organized the literature review: ERAS protocol in colorectal patients, implementation of ERAS protocol, comparison of ERAS and conventional surgical methods, and motivation and barriers to implementing ERAS. These are all elements being evaluated in the pilot ERAS program at Baptist Memorial Hospital.

Patient Benefits

Malik, Khurshid, Chowdhri, and Parray (2013) conducted a prospective comparative study over a two-year period of patients undergoing elective colorectal surgery. Patients were matched for age, gender, co-morbidity, type of disease, American Society of Anesthesiologist (ASA) grade, type of surgery, and stoma formation. The mean post-operative hospital stay was 4 days for patients in the ERAS group compared to 8.7 days for the control group. There was no significant difference between the ERAS and control group for morbidity and mortality. Regular feeding was tolerated much earlier in the ERAS group, and bowel function returned earlier in ERAS group. The researchers concluded that treatment of colorectal surgery patients using the enhanced recovery after surgery protocols lead to faster recovery and shorter hospital stay. The results were consistent with an observational study conducted by Melchor and colleagues (2018) with two groups of patients undergoing open or laparoscopic colorectal surgery, three years before ERAS (pre-ERAS) and two years after ERAS (post-ERAS). The study consisted of a total of 679 patients with 360 patients in the pre-ERAS group and 319 patients in the post-ERAS group. This study had a larger sample size than a similar study completed by Malik and colleagues (2013) which only has a sample size of 222 subjects. The researchers found that more patients in the pre-ERAS group developed moderate or severe complications and the median length of stay in the pre-ERAS group was 17 days and 10 days in the post-ERAS group. The ERAS compliance in the post-ERAS group was 88%. The implementation of ERAS protocol for colorectal surgery was associated with a significant reduction of postoperative complications and length of stay. However, one of the major gaps with this study is the fact that even though the length of stay for ERAS patient was shorter than non-ERAS patients, it was still a longer stay than the projected duration that ERAS protocols aim to achieve. In a review of 16 randomized control trials containing 2,376 patients, Greco and colleagues (2014) found the ERAS protocol was associated with a reduction of overall morbidity, shortened hospital stay, and a significant reduction in nonsurgical complications with implementation of ERAS protocol.

Implementation and Compliance

The implementation of ERAS protocols is even more effective when there is a high percentage of compliance with the required interventions. Pedziwiatr and colleagues (2015) conducted a prospective cohort study with colorectal cancer patients undergoing laparoscopic resection. The goal of the study was to analyze the course of implementation of the ERAS protocol into daily practice by adherence to the protocol. The primary outcomes for the study were the compliance with the protocol and the influence on length of hospital stay, postoperative complications, and readmission rates. The study was subdivided into 3 groups. Group 1 had 65% compliance, Group 2 had 83.9% compliance, and Group 3 had 89.6% compliance. The median length of stay in Group 1 was 5 days, Group 2 was 5 days, and Group 3 was 3 days. Perioperative complications in Group 1 were 56%, Group 2 was 43%, and Group 3 was 9.4%. The study concluded that the introduction of an ERAS protocol is a gradual process and its compliance at the level of 80% or more requires at least 30 patients and a period of about 6 months. When implementing ERAS protocols, there should be a particular emphasis in the initial stage on continuous training of all specialties and personnel involved in the ERAS protocol. It is important to participate in regular multidisciplinary meetings because this influences the attitudes of staff and can accelerate the adoption of the changes which translates into improving the adherence to the protocol and better outcomes. Currently, at Baptist Memorial Hospital, the objective of the ERAS protocol is to have meetings once per month with multidisciplinary team leaders in order to increase compliance and adherence with the protocol. An important element when analyzing compliance with ERAS protocol the researchers should have elaborated on is the cost ratio compared to level of compliance.

Bona and colleagues (2014) conducted a prospective single-center cohort study to evaluate the implementation of an ERAS program at a large University Hospital. There were 47 patients undergoing laparoscopic colorectal resection with ERAS protocol management. The compliance with the ERAS protocol was 93% and median hospital stay was 3 days. The results from this study was similar to what previous studies have confirmed, that ERAS protocol implementation allows quicker postoperative recovery and shortens the hospitalization. The researchers should have elaborated on the cost analysis of implementing an ERAS program compared to the cost savings for patients.

Barriers

When implementing new advances in the clinical setting, practitioners will always be met with some type of opposition in implementing new practices. Implementing ERAS into practice is challenging and requires important changes of clinical practice for all specialties involved. There must be time, money, and tolerance invested in order to meet the expectation of ERAS which is to reduce complications and hospital stay and improve patient satisfaction. Martin and colleagues (2017) conducted a qualitative multicenter study among surgeons, anesthesiologists, and nurses that implement ERAS protocols in medical facilities. An online survey was emailed to study participants to analyze barriers to ERAS implementation. Seventy-seven out of 146 completed the survey. The survey questions focused on participant demographics and challenges during ERAS implementation. The participants were asked to rate each component of the predefined postoperative recovery targets and perioperative care items on a semantic differential scale. The questions included subjects that concerned preoperative ERAS-specific education, intentional deviation of ERAS protocol, frequency of ERAS meetings, administration involvement, financial availability, patient related factors such as age, socio-cultural level, opposing personality, co-morbidities, and language barriers. The main motivations for ERAS implementation were reduced complications (91%), patient satisfaction (73%), and shorter hospital stay (62%). The most important barriers to implementation were time (69%) colleagues (68%), and logistical reasons (combination of organization, action, and execution 66%). A limitation to this qualitative study is it was an online survey that was sent to participants and a little more than half responded and the possibility of inflexibility with responses for participants.

Practice Problem

The implementation of the ERAS protocol leads to better outcomes for patients undergoing colorectal surgery. Even though these claims have been supported by various amounts of research, many facilities and practitioners are hesitant about implementing the ERAS protocol because it goes against traditional surgical doctrine, even though it has been well supported to be more effective than traditional approaches (American Society of Colon and Rectal Surgeons, 2016).

The ERAS protocol has been used in a variety of surgeries including colon surgery, vascular surgery, thoracic surgery, and robotic surgery. Further research is being conducted to determine its effectiveness in other types of surgery. The main objective of the ERAS protocol is to optimize physiological and psychological functions throughout the perioperative period which leads to decreased postoperative complications, decreased length of hospital stays, improvement in cardiac functions, pulmonary functions, bowel motility, and sooner resumption of normal activities (American Society of Colon and Rectal Surgeons, 2016).

Prior to the implementation of the ERAS protocol at Baptist Memorial Hospital, 28% of patients undergoing colorectal surgery were discharged before 7 days post-surgery. Between August 2017-December 2017 there were 60 ERAS patients with 64% discharged within 4 days after surgery, and 95% within 4-7 days after surgery, with more than 50% compliance to the ERAS protocol. Due to the improvements, focus is being put on educating staff and implementing this program in a more effective manner so there will be increases in ERAS protocol compliance which will result in more enhanced recovery for patients. When the ERAS protocol was initiated in August 2017, staff education was limited, and the healthcare workers involved with the care of the ERAS patients were simply provided protocol sheets. However, to

improve protocol compliance continuous education and reinforcement is necessary and one of the primary foci of this scholarly project.

To accomplish the objectives of the ERAS protocol, patients receive preoperative counseling, psychosocial counseling, nutritional counseling to avoid perioperative fasting, and receive preoperative carbohydrate loading two hours before surgery. Analgesic regimens are implemented for pain control intraoperatively and postoperatively. Early mobilization is highly encouraged. This new protocol is conflicting when compared to the typical surgical preparation which has limited it implementation into traditional surgical practice. Recent research has shown that facilities that implement the ERAS protocols as standard of care for patients undergoing major surgery have seen better recovery outcomes from patients throughout the postoperative period (American Society of Colon and Rectal Surgeons, 2016).

Purpose of the Project

The purpose of this project was to evaluate the results of patients undergoing colorectal surgery utilizing the ERAS protocol in order to improve the quality of care delivered at Baptist Memorial Hospital. The results of ERAS patients will be compared to non-ERAS patients to analyze outcomes to determine if there were any improvements for patients. Barriers and facilitators will also be identified from the organizational systems perspectives in order to make recommendations to enhance the implementation process for the ERAS protocol. The PICO question that will be analyzed for this scholarly project is: Does the implementation of ERAS protocol increase postoperative outcomes for patients undergoing colorectal surgeries than conventional surgical methods? Patients: Colorectal surgery patients

Intervention: ERAS protocol

Comparison: Conventional surgical methods

Outcomes: Increased postoperative outcomes based on decreased length of hospital stay, earlier return of bowel function, decreased postoperative pain scores, and fewer complications

Significance

In March 2017, the Agency for Healthcare Research and Quality (AHRQ) launched an initiative to increase implementation of ERAS pathways in the United States hospitals through the use of an adoption of the AHRQ Comprehensive Unit-based Safety Program. This program facilitates the hospital teams to more rapidly adopt evidence-based practices (Agency for Healthcare Research and Quality, 2017). There have been many advances in the field of anesthesia and surgical techniques, however, postoperative complications remain to be one of the major disadvantages of surgery. Surgery causes a stress response that is represented by hormonal and metabolic changes that result in hematological, immunological, and endocrine responses, and its extent parallels to the degree of tissue injury, being further amplified with postoperative complications (Scott et al., 2015). The more extensive the surgical wound, organ manipulation, tissue dissection, the more increased the stress response will become. An important element of the ERAS protocol is its effectiveness in reducing the stress responses to the injury caused by surgery. The ERAS protocol includes a variety of interventions which helps in maintaining homeostasis. The pathophysiological response to surgery can take a severe toll on patients during the recovery period and can result in subpar outcomes (American Society of Colon and Rectal Surgeons, 2016).

Thanh and colleagues (2016) conducted an economic evaluation of the implementation of an ERAS protocol for colorectal surgery to determine it cost-effectiveness. There was 331 preand 1295 post-ERAS patients included in the analysis. The ERAS cost was approximately \$826,000 the net cost savings of ERAS were estimated at \$3,091,000 or \$2,332 per patient. In terms of return on investment, every \$1 invested in ERAS would bring \$4.7 in return. The researchers found that the total savings or return on investment may be more substantial when ERAS is spread to other surgical specialties also.

Enhanced recovery programs are designed to standardize and optimize perioperative care in order to reduce perioperative physical stress and organ dysfunction in elective surgical procedures. These programs lead to improved outcomes, decreased hospital length of stay, and faster patient recovery, which also leads to a reduction in clinical complications and health care costs with increases in patient satisfaction. The nurses' role in ERAS is essential for its success. DNP leaders are the orchestrators of multidisciplinary teams and serve as educators for patients, families, and healthcare clinicians. The opportunity for expansion in nursing science lies in the patient experiences in the postoperative period with the utilization of protocol led care versus the traditional holistic care provided by nurses. A theoretical framework for protocol led care is something that can be develop for future guidance on nursing knowledge.

Conceptual and Theoretical Framework

Swanson's Theory of Caring provides the theoretical framework for the implementation of the ERAS protocol at Baptist Memorial Hospital. The ERAS protocol is considered a quality improvement initiative. Quality improvement is defined as systematic and continuous actions that lead to measurable improvements in health care services and the health status of targeted patient groups (Health Resources and Services Administration, 2011). The anesthesiology department wanted to enhance outcomes of patients undergoing colorectal surgery to improve patient satisfaction and the quality of care delivered. Swanson's Theory of Caring was derived from the Human Caring Theory which is a grand theory that was developed by Watson in the 1970s. In 1991, Swanson proposed the theory that consists of five caring processes which include knowing, which is striving to understand an event; being with, which is being emotionally present; doing for, this is where you do for the patient as they would do for themselves if they were able; enabling, facilitating the patient through life transitions which are familiar to them; maintaining belief, which is sustaining faith helps patients get through the process (Tonges & Ray, 2011). Swanson's caring processes combine nursing compassion and competence leading to the intended outcomes of patient healing and well-being which contributes to quality improvement. Patients involved in the ERAS protocol are educated on the expectations before and after surgery. Healthcare providers involved in patient care encourage the patients to remain compliant in order for interventions to be successful. This ranges from encouraging patients to consume nutrition, participate in physical activity at least three times per day, continuous education for patients, families, and healthcare staff involved in the recovery of patients in order to facilitate an enhanced recovery.

In applying Swanson's Theory of Caring to the ERAS protocol, in the knowing phase, the patient receives preadmission education and counseling. This intervention serves to help reduce anxiety, improve recovery, and enhance wound healing by providing detailed information about the surgical process so that patients will be enlightened and knowledgeable about their role in the recovery process which will improve compliance in early mobilization, nutritional requirements, and pain control. The patient is also educated on how to increase physiological and functional reserve through preoperative counseling, which includes smoking cessation, alcohol abstinence, medication therapy, and dietary preparation.

The being with phase, which characterizes being emotionally present, is very important in the ERAS protocol. Surgery is a very stressful time for patients and families, and can be very overwhelming. Therefore, healthcare providers should be there to administer the encouragement and motivation that patients and families need to get through the perioperative period.

In the doing for phase, the healthcare provider helps patients with actions that they are not capable of doing at the moment. In the ERAS protocol, this ranges from helping the patient with daily nutrition to make sure the necessary nutrients are provided for the body to heal, assisting with mobilization and hygienic care. In anesthesia through the intraoperative phase, this include keeping the patient hemodynamically stable, replacing blood loss, maintaining euvolemia, and supporting ventilation throughout the operative phase. These are functions that the anesthetized patient is no longer able to do for themselves, and as an anesthetist, these are the functions that have to be optimized to ensure that the patient has an enhanced recovery and improved outcomes. After the patient is able to do for themselves, then the enabling phase is implemented where the patient participates in physical activity, nutrition, and hygienic care without assistance. Pain management is very important in order for the patient to effectively facilitate through these phases. In the maintaining belief phase, the patient is continuously encouraged and instilled with positivity to enhance their recovery. Even though the patient is discharged from the hospital, the recovery process is still ongoing and the patient must implement rehabilitative care to continue their healing.

Implementation of Project

In order to be successful in implementing new programs in the healthcare setting, education is imperative. The ERAS program requires interprofessional collaboration in order to be effective (Weimann et al., 2017). The first step in evaluating the success of a program is to make sure all stakeholders involved in this program are familiarized with the principles of ERAS and a primary goal of optimal patient care is developed. This will be achieved by having a meeting with the heads of surgery, nursing, nutrition, physical therapy, pharmacy, informatics, social work, and anesthesiology. The meeting with members of other disciplines is an element of the DNP Essential VI: Interprofessional Collaboration for Improving Patient and Population Health. The meeting will allow the DNP leader to address any limitations and develop communication channels between team members. It is important for all members of the ERAS team to settle any reservations regarding the ERAS protocol.

The DNP leader will serve as a staff educator to nurses involved in the care of ERAS patients, which is DNP Essential VIII: Advanced Nursing Practice. This entails educating nurses on the ERAS program, elements that affects duties such as goal-directed fluid management, early ambulation, early feeding, multimodal analgesia, and continued expectation management. The educator will clarify any concerns that nurses may have and follow-up on ERAS patients' care.

For this scholarly project, the DNP leader has consulted with the informatics team to develop software that is ideal for monitoring ERAS patients to ensure that goals are obtained and the delivery of the ERAS protocol is efficient for all stakeholders involved in the care of these patients. The utilization of patient care technology to support clinical decision making and leadership is a part of the DNP Essential IV: Information systems/technology and patient care technology for the improvement and transformation of health care.

Preoperative Optimization

Preoperative guidelines for the ERAS protocol to optimize patient outcomes include patient counseling, restricted fasting, carbohydrate loading, medications that reduce postoperative pain, nausea and vomiting prophylaxis, anticoagulants that decrease the risk of venous thromboembolism, antibiotics to prevent surgical site infections, and goal-directed fluid therapy (American Society of Colon and Rectal Surgeons, 2016). See appendix for order set.

In the preoperative phase of the ERAS protocol, the patient is educated and preparations are made to handle the physiologic effects of surgical stress during the procedure. This is one of the most crucial and overlooked aspect of the ERAS protocol that improves outcomes. Preadmission counseling is conducted to inform the patients of any personal responsibilities. Detailed information is given to the patient about the surgical and anesthesia standpoints which helps to reduce fear and anxiety and enhances postoperative recovery and decreases length of hospital stay. A clear liquid diet is continued up to 2 hours before general anesthesia and carbohydrate loading is highly encouraged in nondiabetic patients. This element is pointed out because in conventional surgical guidelines patients are encouraged to fast for a minimum of 8 hours. Preoperative carbohydrate-rich beverages reduce insulin resistance induced by surgery, which can contribute to a longer postoperative ileus and increase negative outcomes (Bilku, Dennison, Hall, Metcalfe, & Garcea, 2014). The patient is educated on the importance of smoking and alcohol cessation. Alcohol abusers have a three-fold increase of postoperative morbidity, with the most common complications being bleeding, wound and cardiopulmonary complications. One month of abstinence from alcohol and smoking consumption reduces the incidence of complications (Gustafsson et al, 2013).

Intraoperative optimization

Opioids have been the primary method of pain management in patients undergoing surgery. However, opioids are linked to an increased degree of side effects such as vomiting, nausea, bowel dysfunction, dizziness, and respiratory depression, which negatively affects postoperative outcomes. Multimodal analgesia is very important in the ERAS protocol in order to use different mechanisms to provide pain relief and target different parts of the body. The most common nonopioids used in multimodal pain guidelines include acetaminophen, alpha-2

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agonists (clonidine, dexmedetomidine), gabapentinoids (gabapentin, pregabalin), local anesthetics (bupivacaine, lidocaine), NMDA receptor antagonists (ketamine), and nonsteroidal anti-inflammatory drugs (celecoxib, ibuprofen, ketorolac, diclofenac). These drugs are administered prior to surgical incision in order to take effect and reach a level of steady state. Transverse abdominis plane blocks are being used at Baptist Memorial Hospital ERAS protocol along with epidural anesthesia for pain management. There is emphasis on hypothermia prevention, maintaining fluid balance, and avoidance of sedatives and opioids, and implementation of lidocaine infusion throughout the operative period.

Intravenous lidocaine is very beneficial in the ERAS protocol. It is a potent antiinflammatory, anti-hyperalgesic, and gastrointestinal pro-peristaltic drug. Studies have shown that lidocaine resulted in decreased pain scores, opioid analgesic consumption, and side effects when administered to patients undergoing abdominal surgery (Eipe, Gupta, & Penning, 2016). Perioperative pain management with ketamine, lidocaine, and gabapentinoids significantly decreases the requirement of opioids for adequate pain management and is currently being implement in the ERAS protocol at Baptist Memorial Hospital. The exact mechanism by which lidocaine produces systemic analgesia is largely unknown and research is ongoing to determine the mechanism of action. Current studies on lidocaine suggests that the systemic effect of lidocaine occurs predominately in damaged and dysfunctional nerves where depolarization of the neuronal membranes is prevented (Eipe et al., 2016).

Goal-directed fluid therapy (GDFT) is extremely important in an enhanced recovery protocol because it is one of the major factors that influences postoperative outcomes after abdominal surgery. Both hypovolemia and hypervolemia are associated with increased perioperative complications which furthers prolong the length of stay. Hypovolemia leads to insufficient circulation with decreased oxygen delivery to organs and peripheral tissues causing organ dysfunction and shock. Fluid overload leads to interstitial edema and local inflammation and impairs the regeneration of collagen, which weakens the tissue healing with a risk of increased postoperative wound infections, wound rupture, and anastomotic leakage (Voldby & Brandstrup, 2016). It also leads to impaired cardiopulmonary functioning. Goal-directed fluid therapy is very controversial for many clinicians and there has been a continuing debate on the amount of fluid that should be administered to patients undergoing colorectal surgery. The current protocol at Baptist Memorial Hospital for GDFT is assessed by cardiac stroke volume (which is being measured by ClearSight device), to guide fluid therapy. Intraoperative fluid maintenance should not exceed more than 1-2 ml/kg/hr to reduce the risk of fluid overload. Acute blood loss should be replaced with colloids with a 1:1 ratio (Voldby & Brandstrup, 2016).

The use of prophylactic nasogastric tubes (NGT) for stomach decompression should be avoided throughout the perioperative period. Research has shown that the original rationale for using prophylactic NGT such as reduction in wound infection, anastomotic leak, shorter length of stay, and pulmonary complications (pneumonia, atelectasis) are no longer valid reasons to use NGT, and should be avoided as prophylactic measures after abdominal surgery (Aarts, Okrainec, Wood, Pearsall, & McLeod, 2013).

Postoperative optimization

During the postoperative period, early mobilization is imperative for positive outcomes. Ambulation every 4 to 6 hours each day until discharge is very important in the reduction of venous thromboembolism, improvement in gastrointestinal, pulmonary, and circulatory functioning. Patients should resume a regular diet as soon as possible. Scientific evidence indicates that the traditional method of nil per os (NPO) until bowel function resumes does not provide optimal patient management. Early enteral feeding does not increase the rate of wound infection or anastomosis dehiscence, but strong evidence does suggest that early feeding may provide a protective effect (Aarts et al., 2013). Patients who receive early enteral feeding have a shorter length of stay. The patient is encouraged to chew gum postoperatively because studies have shown that the time to passage of first flatus and defecation was significantly shorter and there was a reduction in postoperative ileus (Aarts et al., 2013).

The interventions of the ERAS protocol are all based on scientific evidence that are combined collectively to decrease postoperative complications and accelerate recovery for patients. See ERAS protocol for Baptist Memorial Hospital in the appendix.

Design

The evaluation of the ERAS protocol is a quality improvement project to increase postoperative outcomes and patient satisfaction for patients undergoing colorectal surgeries. The ERAS protocol, if determined to be successful by set performance metrics, will allow Baptist Memorial Hospital to establish an enhanced culture of quality in the surgical department and allow the department to stand out positively with competitors in the area and encourage more surgeons to bring patients to Baptist Memorial Hospital for surgical services.

In conducting the ERAS protocol project, a team has been assembled that include healthcare providers from several disciplines since this protocol involves interprofessional collaboration. Team members of the ERAS protocol have a background in nursing, medicine, pharmacy, nutrition, physical therapy, and social work. Healthcare providers will be educated on the initiatives of the ERAS protocol in each phase of care that includes preoperative, intraoperative, and postoperative care. Patients will be evaluated on ERAS initiatives by analyzing the length of stay, time to first flatulence and bowel movement, complications and 30day readmission rates, as well as subjective outcomes such as postoperative pain, nausea, patient experience and satisfaction rates. At completion of this quality improvement project there will be enough evidence that will help develop future recommendations for the ERAS protocol, exemplify the importance of ERAS protocol as compared to traditional approaches at Baptist Memorial Hospital, and hopefully expand ERAS to other surgical specialties as well.

Method

A retrospective chart review was the method implemented to complete this DNP scholarly project. A single group pretest and posttest design was conducted through retrospective chart reviews of patients undergoing colorectal surgery at Baptist Memorial Hospital prior to the implementation of ERAS protocol and post implementation of the ERAS protocol. A chart review is the most appropriate to analyze the effectiveness of the ERAS protocol interventions due to the ability to extract data on patients, apply appropriate statistical analysis and draw inferences based on the obtained information, cost effectiveness, and the minimization of recall bias for past events. This allows clinicians to analyze the effectiveness of treatment interventions and to assess adherence to the ERAS protocol guidelines. Some challenges that arose due to chart reviews were inaccurate or incomplete information input, variation of how data was recorded in charts which limited the interpretation of certain variables, and missing data which could affect the results of the chart reviews. Incomplete charts were eliminated from the chart reviews due to the possibility of bias results.

Outcomes Measures

The primary outcomes measures include: postoperative length of hospital stay, time to first bowel motility, complications during perioperative phase, readmission rate, pain scores based on a visual analog scale the day of surgery and the subsequent 3 days following, patient

satisfaction and experience.

Sample

The records of colorectal surgery patients at Baptist Memorial Hospital were reviewed. Inclusion criteria to ensure a homogenous sample for patients' records used in this evaluation were: patients undergoing elective colorectal surgery — laparoscopic or open, American Society of Anesthesiologists (ASA) scores of 3 or less, admitted ERAS patients between August 2017 through July 2018, adults ages 20 years to 80 years. Exclusion criteria are patients less than 18 years of age, outpatients, emergency operation, chemotherapy treatment, and systemic inflammatory diseases. Patients undergoing ERAS protocol received preoperative counseling and education before surgery, no bowel preparation, oral carbohydrate solution loading until 2 hours before surgery, goal-directed fluid therapy, early mobilization, early enteral feeding, transverse abdominis plane block, postoperative nausea and vomiting treatment, thromboembolism prophylaxis, perioperative high content oxygen therapy, and no drain insertions unless necessary. Patients who underwent conventional surgical methods did not receive patient preoperative counseling before surgery, but did receive the necessary education from healthcare providers as required. These patients received bowel preparation, conventional fluid management and fasting prior to surgery, conventional mobilization, intravenous patient controlled analgesia pumps, postoperative nausea and vomiting control as needed, and no low content oxygen therapy.

Data Collection

The data source that was utilized to extract information was EPIC[™] electronic medical records that contain anesthesia records, nursing notes, physical therapy notes, nutrition notes, social worker notes, and physician progress notes. This content was assessed for accuracy and completion, which determined the usefulness and generalizability of the extracted data.

Statistical analysis of data was conducted using SPSS software and with consultation with a statistician.

Patient Confidentiality

Patient confidentiality is very important when conducting chart reviews. Extreme caution was taken when dealing with sensitive patient information. Informed consent was not required beforehand because no more than routine clinical information was used for analysis and there were no patient identifiers included in this project. After permission and approval was obtained from Baptist Memorial Hospital and Lincoln Memorial University Institutional Review Board, data was collected for this scholarly project. Any identifying information from the record was removed. Data was only accessible by authorized personnel only and was collected in a manner so that subjects was not able to be identified directly. The data was coded into an alpha-numeric format on an Excel spreadsheet on a password protected USB drive for concealment with the coding key only for the principal investigator. The principal investigator acted in accordance with HIPAA regulations. Data on the password protected USB will be maintained for a minimum of 3 years after the scholarly project is completed in a locked medical record room at the study site. CITI training and a financial conflict of interest (FCOI) compliance training was completed for this scholarly project.

Results

The study included a total of 98 patients (n=98) who received elective colorectal surgery at Baptist Memorial Hospital. The two groups included patients who received perioperative treatment based on the ERAS protocol and treatment based on conventional surgical methods. There were 49 patients in each group. The compliance of the ERAS protocol varied, with details of the perioperative adherence elaborated in the subsequent paragraph. Postoperative outcomes among the patients who were treated with the ERAS protocol were better in comparison to patients who were managed through conventional surgical methods. The median length of stay for colorectal ERAS patients was 5 days, the mean return of bowel function was 2.96 days, with 0 readmissions, complications in 11 (22.4%), and average pain scores of 3. The median length of stay for conventional colorectal patients was 6 days, the mean return of bowel function was 4.2 days, with 1 readmission, complications in 20 (40.8%), and average pain scores of 5. The ERAS protocol was associated with decreased complications, length of stay, pain scores, and sooner resumption of bowel motility. Increased ERAS compliance was correlated with fewer complications and shorter hospital admission. See tables below for illustration of results.

| | N | Mean | Std. Deviation | Skewness | | Kurtosis | |
|--------------------|-----------|-----------|----------------|-----------|------------|-----------|------------|
| | Statistic | Statistic | Statistic | Statistic | Std. Error | Statistic | Std. Error |
| ASA | 98 | 2.582 | .5358 | 333 | .244 | 886 | .483 |
| Age | 98 | 56.959 | 11.9258 | 538 | .244 | 359 | .483 |
| Boweldays | 98 | 3.582 | 1.2837 | .263 | .244 | .049 | .483 |
| Pain | 98 | 3.92 | 1.703 | .066 | .244 | 116 | .483 |
| LOSdays | 98 | 6.306 | 3.1341 | 1.673 | .244 | 3.710 | .483 |
| Valid N (listwise) | 98 | | | | | | |

Descriptive Statistics

Table 1. This table checks for the assumption of normality. This is done for each continuous outcome using skewness and kurtosis statistics. The criterion is that the skewness and kurtosis statistics have to be less than an absolute value of 2.0.

You can see that the assumption was met, with the exception of LOS days.

| | Group | Ν | Mean | Std. Deviation | Std. Error Mean |
|-----------|--------------|----|--------|----------------|--------------------|
| ASA | Conventional | 49 | 2.673 | .5548 | .0793 |
| | ERAS | 49 | 2.490 | .5051 | .0722 |
| Age | Conventional | 49 | 55.306 | 12.2291 | 1.7470 |
| | ERAS | 49 | 58.612 | 11.5015 | 1.6431 |
| Boweldays | Conventional | 49 | 4.204 | 1.0404 | .1486 |
| | ERAS | 49 | 2.959 | 1.2069 | .1724 |
| Pain | Conventional | 49 | 4.84 | 1.067 | .152 |
| | ERAS | 49 | 3.00 | 1.732 | .247 |

Group Statistics

Table 2. The comparison of the two groups on the outcomes that met the assumption of normality using independent samples t-test.

| Levene's Test for E Variances | | | for Equality of nces | | t-test for Equality of Means | | | | | |
|----------------------------------|-----------------------------|-------|-------------------------|--------|------------------------------|-----------------|------------|------------|-------------------------|---------------------------|
| | | | | | | | Mean | Std. Error | 95% Confidenc Differ | e Interval of the ence |
| | | F | Sig. | t | df | Sig. (2-tailed) | Difference | Difference | Lower | Upper |
| ASA | Equal variances assumed | .249 | .619 | 1.714 | 96 | .090 | .1837 | .1072 | 0291 | .3964 |
| | Equal variances not assumed | | | 1.714 | 95.165 | .090 | .1837 | .1072 | 0291 | .3965 |
| Age | Equal variances assumed | .096 | .758 | -1.379 | 96 | .171 | -3.3061 | 2.3983 | -8.0667 | 1.4544 |
| | Equal variances not assumed | | | -1.379 | 95.641 | .171 | -3.3061 | 2.3983 | -8.0669 | 1.4546 |
| Boweldays | Equal variances assumed | 1.089 | .299 | 5.469 | 96 | .000 | 1.2449 | .2276 | .7930 | 1.6968 |
| | Equal variances not assumed | | | 5.469 | 93.960 | .000 | 1.2449 | .2276 | .7929 | 1.6969 |
| Pain | Equal variances assumed | 4.190 | .043 | 6.319 | 96 | .000 | 1.837 | .291 | 1.260 | 2.414 |
| | Equal variances not assumed | | | 6.319 | 79.866 | .000 | 1.837 | .291 | 1.258 | 2.415 |

Independent Samples Test

Table 3. There was a non-significant difference between the groups on ASA, p = 0.09, and Age, p = 0.17. There was a statistically significant difference between the groups in terms of "Bowel Days," p < 0.001, with Conventional being significantly higher than ERAS.

| | Pain | LOSdays |
|------------------------|----------|----------|
| Mann-Whitney U | 377.500 | 703.000 |
| Wilcoxon W | 1602.500 | 1928.000 |
| Z | -5.943 | -3.572 |
| Asymp. Sig. (2-tailed) | .000 | .000 |

Test Statistics^a

a. Grouping Variable: Group

Table 4. There was a statistically significant difference between the groups for pain, p < 0.001. There was a statistically significant difference between the groups for LOS days, p < 0.001.

| | Group | | Statistic |
|---------|--------------|---------------------|-----------|
| Pain | Conventional | Median | 5.00 |
| | | Interquartile Range | 2 |
| | ERAS | Median | 3.00 |
| | | Interquartile Range | 2 |
| LOSdays | Conventional | Median | 6.000 |
| | | Interquartile Range | 3.0 |
| | ERAS | Median | 5.000 |
| | | Interquartile Range | 2.5 |

Descriptives

Table 5. Pain was significantly higher in the Conventional group versus the ERAS group. LOS days was significantly higher in the Conventional group versus the ERAS group.

| Crosstab | | | | | | | | | |
|----------|--------------|----------------|-------|-------|--------|--|--|--|--|
| | | | Se | ex | | | | | |
| | | | F | М | Total | | | | |
| Group | Conventional | Count | 22 | 27 | 49 | | | | |
| | | % within Group | 44.9% | 55.1% | 100.0% | | | | |
| | ERAS | Count | 19 | 30 | 49 | | | | |
| | | % within Group | 38.8% | 61.2% | 100.0% | | | | |
| Total | | Count | 41 | 57 | 98 | | | | |
| | | % within Group | 41.8% | 58.2% | 100.0% | | | | |

Chi-Square Tests

| | Value | df | Asymp. Sig. (2-sided) | Exact Sig. (2- sided) | Exact Sig. (1- sided) |
|------------------------------------|-------------------|----|--------------------------|--------------------------|--------------------------|
| Pearson Chi-Square | .377 ^a | 1 | .539 | | |
| Continuity Correction ^b | .168 | 1 | .682 | | |
| Likelihood Ratio | .378 | 1 | .539 | | |
| Fisher's Exact Test | | | | .682 | .341 |
| N of Valid Cases | 98 | | | | |

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 20.50.

b. Computed only for a 2x2 table

Table 6. There was a non-significant difference between the groups for gender, p = 0.54.

| crossian | | | | | | | | | |
|----------|--------------|----------------|--------|---------------|--------|--|--|--|--|
| | | | Compli | Complications | | | | | |
| | | | No | Yes | Total | | | | |
| Group | Conventional | Count | 29 | 20 | 49 | | | | |
| | | % within Group | 59.2% | 40.8% | 100.0% | | | | |
| | ERAS | Count | 38 | 11 | 49 | | | | |
| | | % within Group | 77.6% | 22.4% | 100.0% | | | | |
| Total | | Count | 67 | 31 | 98 | | | | |
| | | % within Group | 68.4% | 31.6% | 100.0% | | | | |

Crosstah

Chi-Square Tests

| | Value | df | Asymp. Sig. (2-sided) | Exact Sig. (2- sided) | Exact Sig. (1- sided) |
|------------------------------------|--------------------|----|--------------------------|--------------------------|--------------------------|
| Pearson Chi-Square | 3.822 ^a | 1 | .051 | | |
| Continuity Correction ^b | 3.020 | 1 | .082 | | |
| Likelihood Ratio | 3.864 | 1 | .049 | | |
| Fisher's Exact Test | | | | .081 | .041 |
| N of Valid Cases | 98 | | | | |

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 15.50.

b. Computed only for a 2x2 table

Table 7. There was almost a significant difference between the groups for rate of complications, p = 0.051. It appears that ERAS had a 22.4% rate of complications versus the much higher rate for Conventional at 40.8%. This is still a solid finding, despite the fact that it did not reach statistical significance.

Statistical Methods

The statistical assumption of normality was assessed using skewness and kurtosis

statistics. If either statistic was above an absolute value of 2.0, then the assumption was violated. Levene's Test of Equality of Variance was used to check for the assumption of homogeneity of variance. When both statistical assumptions were met, then independent samples t-tests were used to compare conventional and ERAS patient groups on continuous outcomes. Means and standard deviations were reported for the t-tests. When statistical assumptions were violated, then non-parametric Mann-Whitney U tests were used for comparing the groups on outcomes. Medians and interquartile ranges were reported for the Mann-Whitney U analyses. Chi-square tests were used to compare the treatment groups on categorical outcomes. Statistical significance

was assumed at an alpha value of 0.05 and all analyses were conducted using SPSS Version 22 (IBM Corporation: Armonk, NY).

Statistical Results

The assumption of normality was violated for the LOS outcome and the assumption of homogeneity of variance was violated for the pain score comparison. Mann-Whitney U tests found a significant difference between the treatment groups for pain scores, U = 377.5, p < 1000.001, and for LOS, U = 703.0, p < 0.001. Medians and interguartile ranges for these findings can be found in Table 1. For the normal comparisons, a statistically significant difference was found between the treatment groups for "bowel days," t(96) = 5.47, p < 0.001. Non-significant differences were found between the groups for ASA, t(96) = 1.71, p = 0.09, and for age, t(96) = -1.38, p = 0.17. Means and standard deviations for the findings can be found in Table 1. For the categorical analyses, Chi-square tests found non-significant differences between the groups in terms of gender dispersal, $\chi^2(1) = 0.38$, p = 0.54. A significant difference was not found between the treatment groups for complications, $\chi^2(1) = 3.82$, p = 0.051, but the researcher believes that this may have been a Type II error. A Type II error is the error of not rejecting the null hypothesis when the alternative hypothesis is the true state of nature. The Ha: colorectal patients have better postoperative outcomes with the implementation of ERAS protocol. The Ho: colorectal patients undergoing conventional methods have similar enhanced outcomes to ERAS patients. Rates of complications for the treatment groups can be found in Table 1.

Table 1.

| - T | ` | a | C T | | a 1 ' | | • |
|------------|-----------------|-------------|----------|------------|--------------|---------------------|----------------------|
| | LOCOMINATING TO | N'totiotio | a tom I | Lotyroom 1 | h 100 | ta 1 'an | D DL D D L DL D DL D |
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| - | | ~~~~~~ | | | | | 10001100110 |
| | | | | | | | |

| Descriptive Statistics | 101 Detween Budgeets Col | inpui isons | | |
|------------------------|--------------------------|----------------|-----------------|--|
| Outcome | Conventional | ERAS | <i>p</i> -value | |
| Age (years) | 55.31 (12.23)* | 58.61 (11.50)* | 0.17 | |
| ASA | 2.67 (0.56)* | 2.49 (0.51)* | 0.09 | |
| "Bowel days" | 4.20 (1.04)* | 2.96 (1.21)* | < 0.001 | |
| Pain score | 5.00 (2.00)** | 3.00 (2.00)** | < 0.001 | |
| LOS | 6.00 (3.00)** | 5.00 (2.5)** | < 0.001 | |
| | | | | |

| Gender (male) | 27 (55.10%)*** | 30 (61.20%)*** | 0.54 |
|---------------|----------------|----------------|-------|
| Complications | 20 (40.80%)*** | 11 (22.40%)*** | 0.051 |

Note: * Mean (Standard deviation), ** Median (Interquartile Range), *** Frequency (Percentage)

| | ERAS | ERAS | ERAS | ERAS |
|--------------------|-----------|-----------|-----------|------------|
| | 0-60% | 60-70% | 80-90% | 90-100% |
| Bowel motility | | | | |
| 0-3 days | 2 (66.7%) | 2 (28.5%) | 12 (80%) | 20 (83.3%) |
| 4-7 days | 1 (33.3%) | 5 (71.4%) | 3 (20%) | 4 (16.7%) |
| >/= 8 days | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| Pain scores (0-10) | | | | |
| 0-3 | 1 (33.3%) | 1 (14.3%) | 12 (80%) | 20 (83.3%) |
| 4-7 | 2 (66.7%) | 4 (57.1%) | 3 (20%) | 4 (16.7%) |
| 8-10 | 0 (20%) | 2 (28.6%) | 0 (0%) | 0 (0%) |
| Length of stay | | | | |
| 1-3 | 0 (0%) | 1 (14.3%) | 1 (6.7%) | 11 (45.8%) |
| 4-7 | 2 (66.7%) | 2 (28.6%) | 12 (80%) | 13 (54.2%) |
| >/=8 | 1 (33.3%) | 4 (57.1%) | 2 (13.3%) | 0 (0%) |
| Complications | 0/5 | 1/7 | 6/15 | 4/24 |
| | (0%) | (14.3%) | (40%) | (16.7%) |

Figure 1. Outcomes based on ERAS compliance



Figure 2. Colorectal Postoperative Complications

The ERAS protocol compliance was also explored on patients who underwent colorectal surgery for the evaluation of this pilot program. The patients were divided into four groups based

on the individual compliance rates. The corresponding rates were 0-60%, 60-70%, 80-90%, and 90-100%, and the number of patients in each group was, 3, 7, 15, and 24, respectively. The ERAS compliance at Baptist Memorial Hospital was based on the implementation of the following criteria:

- Regional anesthesia (Epidural or Transversus Abdominis Plane Block)
- Lidocaine infusion intraoperatively
- Administration of non-opioid multimodal analgesics (Ofirmev, Ketamine, Gabapentin, NSAIDs)
- Administration of postoperative nausea and vomiting prophylaxis
- Administration of gut motility agents
- Administration of carbohydrate beverage within 2 hours prior to surgery

The overall incidence of postoperative complications was 0%, 14.3%, 40%, and 16.7%. The median length of hospital stay (in days) was 6, 9, 5, and 4 days. The median return for bowel motility (in days) was 3, 4, 3, and 2. The median pain scores were 5, 4, 3, and 2. This suggests that the higher the compliance with the ERAS protocol the sooner resumption of bowel motility, better pain control for patients, less postoperative complications, and shorter length of hospital stay. (See Figure 2).



Figure 3. Association between the compliance to the ERAS protocol and comparison of length of stay, bowel motility, and pain scores.

Discussion

This evaluation aimed to analyze the impact that the implementation of the ERAS protocol has on patient outcomes and clinical effectiveness. The data showed that the ERAS protocol has a statistically significant difference between bowel motility, length of stay, and pain scores (p<.001) when compared to conventional surgical care at BMH. There was no significant difference between the 2 groups in terms of age (p=.17), ASA score (p=.09), or gender (p=.54). The impact of surgical experience and volume on the clinical outcomes was not evaluated, this is something that should be taken into consideration in future analyses.

Postoperative ileus is a common occurrence after colorectal surgery and this tremendously impacts the hospital length of stay for patients, which furthers increases patient costs and the risk of nosocomial infections. Patients who underwent surgery with the ERAS protocol had a decreased occurrence of postoperative ileus (4%) when compared to conventional methods (20%). A study done by Keller and Stein (2013) found that postoperative ileus is associated with a 29% increase in hospital days with costs exceeding \$1.75 billion in the United States. The administration of Entereg was implemented in order to stimulate gut motility preoperatively, this is an aspect that should be implemented in all colorectal patients regardless if ERAS protocol is applied or not. This can help improve practice and patient outcomes at BMH Colorectal Surgery Department. For patients without complications, the length of stay is largely determined by the duration of the postoperative ileus.

The median length of stay for ERAS patients was 5 days, the median length of stay for conventional patients was 6 days (p<.001). However, the higher the compliance with the ERAS protocol the more reduced the length of stay. There should be more focus on improving the compliance rates and implementation of ERAS to further enhance the outcomes. Monthly reviews of ERAS cases can assist ERAS leaders in the management and analyzing of this program, which will help guide education and focal points to improve colorectal perioperative care. Baptist Memorial Hospital would benefit from the application of an interactive audit system that facilitates the implementation and monitoring of compliance to ERAS protocols. This would further help increase patient recovery times, reduce complications, educate healthcare providers, increase accountability and engagement of clinicians throughout the perioperative process, which would further enhance patient outcomes.

The median pain scores for conventional patients was 5, and ERAS patients had a median pain score of 3. There was a statistically significant difference between the groups for pain, (p<.001). The multimodal analgesia approach is a key component of the ERAS protocol. Pain has several adverse implications on recovery, which includes prolonging hospital length of stay, increased use of opioids, and the associated side effect profiles. The use of multimodal analgesia optimizes pain control by acting on several different receptors synergistically to provide adequate pain control for the patient. This aspect can be implemented in all surgeries to impact patient outcomes regardless whether ERAS or the conventional approach is utilized.

The patients with patient controlled analgesia (PCA) pumps had a higher incidence of postoperative ileus and longer length of hospital stay. There were 3 patients in the ERAS group who had a PCA pump, and 7 patients in the conventional group who had a PCA pump. There were 40% of patients with PCA pumps who had complications. The complications included increased nausea and vomiting (10%) and postoperative ileus (30%). The median length of hospital stay for the patients with PCA pumps was 6.8 days. Gan and colleagues (2015) completed a retrospective analysis to study the impact on postsurgical opioid use and ileus on economic outcomes in gastrointestinal surgeries. The analysis found that the use of opioids in patients who developed an ileus following surgery was associated with prolonged hospitalization, greater costs, and increased readmissions. The higher the dosage of opioid the more increased risk for postoperative ileus. Opioid-induced hyperalgesia is very prevalent postoperatively due to the increased sensitivity from opioids to noxious stimuli. The utilization of the ERAS protocol with limited opioid consumption can help patients in the prevention of this incident for pain control. As the opioid crisis continues to progress it is very important for clinicians such as nurse leaders to attempt to combat the problem. The use of the ERAS protocol has the potential to help alleviate the opioid epidemic by reducing the postoperative opioid prescriptions.

Other research studies that evaluated the implementation of ERAS protocols had similar results, such as the Ripolles-Melchor and colleagues (2017) study that concluded the ERAS protocol was associated with a significant reduction of postoperative complications and length of

stay, with an overall ERAS compliance of 88%. A downfall to the ERAS program at Baptist Memorial Hospital is the lack of resources provided to help with the implementation and efficiency of this protocol which is a cost-related issue due to the expense and complexities of the program. Stone and colleagues (2016) evaluated the potential annual net cost savings of implementing an ERAS program at a quaternary academic medical center which found that the implementation of an ERAS program can lead to net financial savings for hospitals due to the program costing approximately \$552,783, however, this price was offset by greater savings in the first year of nearly \$948,500, yielding a net savings of \$395,717. This is an important element when hospitals take into consideration value-based reimbursement models.

Strength and Weaknesses

Research has shown that ERAS protocols increase postoperative outcomes, decrease complications, and increase patient satisfaction (American Society of Colon and Rectal Surgeons, 2016). The implementation of ERAS at Baptist Memorial Hospital has the possibility to create a culture of excellence that focuses on the latest evidence based practice to improve quality care. This program will also create more leadership opportunities for clinicians and facilitate interprofessional collaboration. Due to the ability of the ERAS protocol decreasing hospital length of stay this creates more opportunities to perform more surgical procedures due to vacancy in hospital beds. However, weaknesses of the ERAS program include resistance to change from staff which affects compliance with protocol orders and lack of qualified staff to implement orders. Even though the ERAS protocol is effective, in some cases there may need to be individualized care in order to provide optimal care in some patients. Any modification to ERAS protocol for patients should be communicated clearly in order to avoid errors and miscommunication. Modified ERAS protocols are something that can add to the nursing body of

knowledge. Patients who require modified ERAS protocols can be evaluated more extensively and separate ERAS protocols can be developed for patients with similar characteristics and comorbidities. A weakness of this evaluation of the ERAS protocol was the sample size. A small sample size decreases statistical power which increases the margin of error. Due to this evaluation being a retrospective chart review missing, inaccurate, and conflicting data also hindered the analysis of this evaluation. Co-morbidities were analyzed, however, it was not included in the prospectus, along with early mobilization which was not included due to unreliable variations of charting in multiple charts. Future analysis should examine surgical complication costs, pre- and post- procedure TAP block comparison, and epidural vs TAP block pain management at Baptist Memorial Hospital. Future research should be implemented to examine the outcomes of using information technology software applications to facilitate and improve ERAS pathways for clinicians and for patients, which should also evaluate patients' compliance rates to recommended treatment.

Timeline

Scholarly Project Timeline:

- Confirm preceptors for DNP scholarly project and secure clinical contract for Lincoln Memorial University and Baptist Memorial Health Care Center by February 28, 2018
- Conduct an ERAS meeting with multidisciplinary staff leaders to go over expectations and objectives with ERAS protocol monthly starting in January 2018 and on a continuing basis once per month
- Conduct ERAS educational meetings with nursing staff on the ERAS recovery unit bi-monthly to improve compliance with protocol
- Conduct ERAS educational meetings with anesthesia providers on intraoperative management

and multimodal analgesic management

- Submission of DNP Proposal to committee members via Lincoln Memorial University BlackBoard Dropbox by April 2, 2018
- Submission of Baptist Memorial Health Care Center Institutional Review Board application following committee approval by March 28, 2018
- Submission of Lincoln Memorial University Institutional Review Board application following Baptist Memorial Health Care Center IRB approval — submit by April 2, 2018
- Analyze, synthesize, and evaluate data by August 2018
- Submit final scholarly project manuscript to DNP committee for review by September 2018
- Present final scholarly report to committee by October 2018
- Disseminate scholarly project results at Final Oral Presentation of Project
- Disseminate scholarly project results at Tennessee Association of Nurse Anesthetist

Conference for formal presentation in October 2018

• Submit DNP scholarly project for publication by December 2018

Conclusion

The field of healthcare is constantly advancing, and it is important for nursing leaders to translate the latest evidence based practice into the clinical settings in order to improve the care delivery systems. The goal of this project was to evaluate the impact of the ERAS protocol on patient outcomes and effectiveness. This project supports having significant benefits for patients undergoing colorectal surgeries. Implementing a comprehensive protocol is a tedious, collaborative process, however, the effects seen from enhanced recovery pathways for patients and cost savings in healthcare is well worth it. An enhanced recovery protocol at Baptist Memorial Hospital can be tailored and expanded to other specialties to improve the delivery of patient care.

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Appendix A

Image retrieved from: http://medsci.org

ENHANCED RECOVERY AFTER SURGERY ACHIEVE EARLY RECOVERY BY: Maintain preoperative organ function. Reduce profound stress response following surgery - attempt to manipulate and attenuate the physiological and psychological responses to major surgery. **KEY ELEMENTS:** Multi-disciplinary ownership of patient's surgical experience. 0 Preoperative counseling. 0 0 Optimization of nutrition. Avoidance of perioperative fasting. 0 Carbohydrate/Protein loading from 5 days prior to 2 hours preoperatively. 0 Standardized analgesic and anesthetic regimen using minimal opioid analgesics 0 (Epidural, TAP block and non-opioid multimodal therapy). Early mobilization. ٩ PREOP Preoperative weight and compare to pre-admit weight. Replace loss with Albumin or LR 0 (No NS). Up to 2 hours before surgery (4 hours if diabetic). 9 Ensure Clear or 20oz electrolyte enhanced drink. 0 Alvimopan 12mg PO x 1 (10 min to 5 hours before) - Do not use if patient has had 3 0 doses of opiate pain medicine during the last week. 0 Acetaminophen 1g or 650mg <70kg (PO or IV). Gabapentin 900mg PO (Decrease to 600mg for age > 65 years old). 0 Thoracic epidural 0.2% Ropivacaine in 500ml NS. Give 250 - 500ml Albumin while setting 0 up for epidural. Bilateral TAP blocks with catheter as alternative to failed epidural attempts x 3. SERVICE MARKED AND A MARKED AND A CONTRACT AND A CONTRACT AND AND A CONTRACT AND AND AND AND AND AND AND AND AN

Appendix B – Baptist Memorial Hospital ERAS Protocol

INTRAOP - INDUCTION

- Lidocaine 1.5mg/kg IV.
- Propofol 1-2mg/kg IV use 0.5 1mg if using Ketamine.
- Ketamine 0.5mg/kg IV.
- Esmolol if needed.
- Muscle relaxer.

INTRAOP - MAINTENANCE

- Antibiotics per surgeon.
- Decadron 4mg prior to incision.
- Ketamine infusion 3 5 mcg/kg/min or hourly 0.5 mg/kg boluses. Stop 45mins to 1hr prior to end of case.
- 0.5 to 1 MAC volatile anesthetic.
- Consider lidocaine infusion at 2mg/kg/hr if epidural unsuccessful.
- Muscle Relaxer.
- Magnesium 1-2mg (NMDAR modulator/antagonist)
- LR @ 3ml/kg/hr.
- Clear Site or Edwards Flotrac. Use stroke volume as guide to fluid therapy. If SVV >15%, give 250ml fluid bolus. If stroke volume increases by 10%, repeat. When stroke volume no longer increases by 10%, use pressors to maintain MAP > 75mmHg. Use 100-150ml fluid bolus with known diastolic dysfunction or low EF.
- Toradol 30 60mg IV/IM at end of case . (at surgeon discretion)
- Zofran 4 mg at end of case .
- Glucose control with goal 140 180mg/dL.
- Normothermia Goal core temp > 36.5°C.
- $\circ~$ FiO2 > 80% with TV 8ml/kg (IBW) plus Peep 5cm H2O throughout case.
- Tidal volume should be set to 6-8ml/kg of IBW.
- Epidural infusion at 4 6ml/hr and bolus as needed so patients emerges at an acceptable sensory block. Adjust rate as needed.
- OGT to be removed at end of case if used.

PACU 100% NRB for 6hrs post op and then wean to BNC. 0 LR infusion @40ml/hr. 0 Epidural infusion at 4 - 6ml/hr. Adjust rate as needed. 0 POSTOP NIGHT AFTER SURGERY Postoperative labs. 0 0 Clear liquid diet per surgeon's discretion. Ensure Clear added to diet tray. May DC when patient eating soft diet. 0 Chewing gum and hard candies are encouraged. Ø Stand patient for postop weight to assess volume loss. Adjust for any loss of 0 organ/tissue during case. Ambulate night of surgery 4 hours after arrival if stable. 0 Ø Zofran 4 mg IV Q 6hrs x 5 doses then change to PRN. Ofirmev 1g or 650mg IV q six hours times 4 doses then change to PO. 0 • LR infusion @40ml/hr. Epidural infusion at 4 - 6ml/hr. Adjust rate as needed. 0 POSTOP DAY 1 Daily weights. Continue Ensure Clear. 0 Toradol 15 - 30mg IV Q 6hrs. Duration up to five days. Monitor patient creatinine and 0 hold if Crt > 1.5. • Alvimopan 12mg PO BID x 7 days or until patient has bowel movement. Oxycodone 5 - 10mg q 4 - 6 hours PRN for pain. 0 0 Minimum ambulation x3 in hallway and out of bed to chair for 5 hours. Magnesium oxide 400mg PO daily. 0 Start soft diet at surgeon discretion. 0 0 Discontinue foley.

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DISCHARGE CRITERIA (VARIES WITH SURGEON)

- Increase ambulation and out of bed most of day.
- Pt must pass flatus or have bowel movement.
- Pt with ostomy must put out 500cc.

• Pain is well controlled on oral analgesia. Epidural is removed POD # 3 if not discharged sooner.

Appendix C – Baptist Memorial Hospital ERAS Pain Rounds Evaluation

| Pre-op/OR | Post-op day of | Day 1 | Day 2 | Day 3 | 6 month Follow Up |
|------------------|------------------|------------------|------------------|------------------|-------------------|
| Pain Score | Pain Score | _ Pain Score | Pain Score | Pain Score | Pain Soora |
| Pre-op meds: | Additional Meds: | Additional Meds: | Additional Meds: | Additional Meds: | Notes: |
| | | | | | |
| Intra-op meds: | | | | | |
| Dolophine | _ | | | | |
| Ketamine | | | | | |
| Ofirmev | | | | | |
| Lidocaine gtt | | | | | |
| Fentanyl | Notes: | Notes: | Notes: | Notes: | |
| Other: | | - | | | |
| | | | | | |
| | | | | | |
| Block Used/dose: | | | | | |
| | | | | | |
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Appendix D – Financial Conflict of Interest Tutorial Certificate of Completion



Appendix E – Healthcare Provider Education Brochure and PowerPoint Outline



ERAS

An integrated multimodal approach designed to help achieve an earlier recovery after surgery by continuing to maintain preoperative organ function and reduce the stress response that occurs after surgery.

ERAS focuses on optimizing nutrition, pain management, anesthetic management, and early mobilization.

Controlling surgical stress and maintaining homeostasis

Preventing stress and minimizing the stress response is the central mechanism around the concept of ERAS. This response encompasses all elements associated with surgery:

- Anxiety Fasting
- . Tissue damage
- Hemorrhage .
- . Hypothermia Fluid shifts
- .
- . Pain
- Hypoxia Bedrest . .
- . lleus
- Cognitive imbalance •

INTERVENTION IN ERAS

Preoperative

- Evaluation and optimization of existing organ function .
- Ensuring good nutritional status Improving physical fitness
- .
- Patient education Minimal starvation .
- . Oral carbohydrate drink
- . No mechanical bowel preparation

Intraoperative

- Pre-operative antibiotic, acid suppression and pro-kinetic
 Thoracic epidural
- analgesia/Transversus abdominis plane
- block Elective use of nasogastric decompression, urinary catheterization and abdominal drainage
- Goal directed fluid therapy Maintaining normothermia .
- •
- Minimal tissue handling Minimize operative time . .
- Minimal access surgery

Postoperative

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- Pre-emptive and adequate analgesia Post-operative nausea and vomiting prophylaxis
- Early removal of all drains and tubes
- . Early enteral nutrition Early enforced ambulation
- . Ensure follow-up after discharge

WHY IMPLEMENT ERAS

- ERAS has been associated with 35-40%
- reduction in length of hospital stay Studies have found that there is a . decrease in surgical complications such as anastomotic leaks as well as nonsurgical complications such as nosocomial infections in the postoperative period.
- There is an earlier return to work and productivity for patients .

Enhanced Recovery After Surgery

| | Active Patient Involven | nent | |
|--|---|-----------------------------|--|
| Pre-operative | Intra-operative | Post-operative | |
| Pre-admission education | Active warming | Early oral nutrition | |
| •Early discharge planning | •Opioid-sparing technique | • Early ambulation | |
| Reduced fasting duration | Surgical techniques | •Early catheter removal | |
| •Carbohydrate loading | Avoidance of prophylactic NG tubes & drains | •Use of chewing gum | |
| No/selective bowel prep | no tobes a trains | •Defined discharge criteria | |
| Venous thromboembolism prophylaxis | •Goal directed peri-o | perative fluid management | |
| Antibiotic prophylaxis | • Pain & nau | sea management | |
| •Pre-warming | | | |
| | Audit of compliance & outco | omes | |
| | Whole Team Involveme | ent | |

3/26/18

1 ENHANCED RECOVERY AFTER SURGERY (ERAS)

Jerica Hill, DNPc, CRNA

2 Enhanced recovery after surgery (ERAS)

What is it:

An integrated multimodal approach designed to help achieve an earlier recovery after surgery by continuing to maintain preoperative organ function and reduce the stress response that occurs after surgery.

ERAS focuses on optimizing nutrition, pain management, anesthetic management, and early mobilization.

3 Introduction of ERAS video

4 ERAS

The main objective of the ERAS protocol is to optimize physiological and psychological functions throughout the perioperative period.

By optimizing these functions patients have

- decreases in postoperative complications
- decreased length of hospital stays
- improvement in cardiac functions
- Improvement in pulmonary functions
- Improvement in bowel motility
- sooner resumption of normal activities

5 Goal directed fluid therapy

Optimal perioperative fluid management is an component of ERAS pathways.

Fluid management within ERAS should be viewed as a continuum through the preoperative, intraoperative, and postoperative phases because each phase is important for improving patient outcomes, and suboptimal care in one phase can undermine best practice within the rest of the ERAS protocol.

■ The goal of preoperative fluid management is for the patient to arrive in the operating room in a hydrated and euvolemic state (prolonged fasting is not recommended and mechanical bowel preparation should be avoided).

6 Goal directed fluid therapy

Administering excessive amounts crystalloid can result in edema of the gut wall and prolonged ileus.

■ Even a modest positive salt and water balance that cause a weight gain of 3 kg after elective colonic resection has been shown to be associated with delayed recovery of gastrointestinal function, increased rate of complications, and extended hospital stay.

Maintenance fluid requirements are 1-3 mL/kg/hr to achieve zerobalance fluid therapy with the aim to maintain preoperative weight (central euvolemia)

7 Multimodal analgesia

Acetaminophen, gapapentin, NSAIDs, local anesthetics (TAP blocks, thoracic epidurals)

Decrease the use of opioids

Eliminates side effects – nausea, vomiting, respiratory depression, delayed gastric motility

8 Why implement ERAS

ERAS has been associated with 35-40% reduction in length of hospital stay

•

Studies have found that there is a decrease in surgical complications such as anastomotic leaks as well as non-surgical complications such as nosocomial infections in the postoperative period. 55

3/26/18

There is an earlier return to work and productivity for patients

Early discharge for patients means reduced patient turnover times which decreases healthcare costs and allows institutions to be able to serve more patients within the available infrastructure

Studies have found that there is a 28-32% decrease in incurred healthcare costs when ERAS is implemented

9 Recommendations for perioperative pain management for colorectal resections

10 Baptist ERAS Protocol

Preoperative phase:

- Patient education & counseling
- Optimization of nutrition Ensure or electrolyte enhanced drink up to 2 hours prior to surgery
- Entereg 12 mg PO x 1 (gut motility stimulator)
- Acetaminophen 1g or 650 mg (PO or IV)
- ■Gabapentin 900 mg PO

11 Baptist ERAS protocol

Postoperative phase (night after surgery)

- Postoperative labs
- Clear liquid diet per surgeon's discretion
- Ensure clear added to diet try
- Chewing gum and hard candies are encouraged to increase time of passage of first flatus and bowel movement and reduce postoperative ileus
- Ambulate night of surgery 4 hours after arrival if stable
- Zofran 4 mg IV q6hrs x 5 doses then change to PRN
- Ofirmev 1g or 650 mg IV q6hs x 4 doses then change to PO
- LR infusion at 40 mL/hr
- Incentive spirometer

3/26/18

4

12 Baptist ERAS protocol

Postoperative phase (Day 1)

- Daily weights
- Continue Ensure clear
- Toradol 15-30 mg IV q6hrs, duration up to 5 days. Monitor patient creatinine and hold if creatinine greater than 1.5
- Entereg 12 mg PO BID x 7 days or until patient has bowel movement
- ■Oxycodone 5-10 mg q 4-6 hours PRN for pain
- Minimum ambulation x 3 times in hallway and out of bed to chair for 5 hours
- ■Magnesium oxide 400 mg PO daily
- Start soft diet at surgeon discretion
- Discontinue foley
- Incentive spirometer

13 Baptist ERAS protocol

- Discharge criteria (varies with surgeon)
 - Increase ambulation and out of bed most of day
 - Must pass flatus or have bowel movement
 - ■Patients with ostomy must put out 500 cc
 - Pain is well controlled on oral analgesia, and epidural is removed postoperative day 3 if not discharged sooner.

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Appendix F – Postoperative Multimodal Pain Management Guidelines BAPTIST MEMORIAL HOSPITAL – MEMPHIS Postoperative Multimodal Pain Management PURPOSE: Multimodal pain management has been shown to reduce opioid requirements, adverse effects, and length of stay in surgical patients. The purpose of this protocol is to provide alternative, non-opioid, analgesic medications with appropriate dosing and duration recommendations. PROTOCOL: Pre-operative Acetaminophen 1,000 mg PO, 2 hours pre-op Celecoxib 400 mg PO, 2 hours pre-op \checkmark Gabapentin 300 mg PO, 2 hours pre-op V □ Methocarbamol 500 mg PO, 2 hours pre-op ✓ Clear dietary nutrition supplement (Ensure) Post-operative Alternative (non-opioid) Analgesics: Patients may receive one or more of the following analgesic medications for the treatment of post-surgical pain if Dosing: 1,000 mg IV Q6H x 24h . Then: 650 mg PO Q6H PRN (mild pain 1-3) . • Duration: 4 days post-surgery Contraindications: Severe hepatic impairment □ Gabapentin^{1,2} Dosing: 200 mg TID Hemodialysis: 100 mg daily Duration: 4 days post-surgery 0 □ Ibuprofen² ○ Dosing: 400 mg Q6H □ Ketorolac (IV)⁵ OR Duration: 4 days post-surgery 0 ○ Dosing: 15 mg Q6H \circ Duration: max = 3 days Contraindications: Ξ. Asthma . Urticaria Neuraxial administration Bleeding or recent bleed -Nursing mothers Concomitant NSAID Peptic ulcer disease, active Concomitant pentoxifylline or history or probenecid Renal impairment, Hemostasis advanced or risk of renal failure Post-operative Multimodal Pain Management Proposal 3 - September 2017

□ Lidocaine infusion (IV)⁶

- Product: Lidocaine 2 gm/500 mL in D5W
- Dosing:
 - 1.5 mg/kg bolus at initiation given slow IV push over 2-4 minutes
 - Followed by 0.5-2 mg/kg/hr
 - Dose can be increased or decreased by 0.25-0.5mg/kg/hr based on pain score or signs of toxicity
- \circ Duration: max = 3 days
- Safety: decreased dosing and cardiac monitoring for patients with cardiac, hepatic, or renal dysfunction and in those deeply sedated or anesthetized

Opioid Analgesics

- □ Oxycodone 5mg PO Q4H PRN moderate pain (4-6)
- □ Hydromorphone 0.5mg IV Q3H PRN severe breakthrough pain
- ✓ Naloxone 0.08mg IV Q2min PRN opioid reversal, respiratory depression

Anti-emetic:

- ✓ Ondansetron 4 mg IV/PO PRN for N/V
 - o Precautions: QTc prolongation

Bowel Regimen Options:

- ✓ Docusate 100 mg BID
- ✓ Senna 8.6-17.2 mg BID PRN
- □ Polyethylene glycol 17 g daily
- □ Bisacodyl 10 mg tablet daily
- □ Bisacodyl 10 mg enema or suppository PRN

Literature Review

• See Appendix A

References:

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Post-operative Multimodal Pain Management Proposal 3 – September 2017

| | | Appendix A: Clinical studies on the use of | of multimodal pain managen | gent |
|--------------------------------------|---|--|--|---|
| Reference | Study Design | Intervention | Outcome | Results |
| Clarke et al. (2014) ¹ | Randomized, double-blind, placebo-controlled Total knee arthroplasty n = 212 | Gabapentin 600 mg 2h pre-op + 200 mg TID POD 1-4 vs. placebo All patients received celecoxib 400 mg 2h pre-op + opioid regimen post-op | Pain scores (NRS) and post-surgical function | No difference in pain Increased knee range of motion in hospital, p < 0.05 Decreased 24h opioid use, p < 0.01 |
| Rafiq et al. (2014) ² | Randomized, controlled, open- label Cardiac surgery n = 180 | Dexamethasone 8 mg IV + ketorolac 30 mg IV at extubation with ibuprofen 400 mg QDr, gabapentin 300 mg BID, acetaminophen 1,000 mg QID POD 1-4 vs. Morphine 5-25 mg IV at extubation with morphine 10 mg QID, acetaminophen 1,000 mg QID POD 1-4 | Pain scores using numeric rating scale (NRS) of 0-10 | Decreased pain days 0-4, p < 0.05 Decreased nausea and vomiting, p < 0.001 No difference in rescue analgesia between groups |
| Clarke et al. (2015) ³ | Randomized, double-blind, placebo-controlled Total hip arthroplasty n = 184 | Pregabalin 150 mg 2h pre-op + 75 mg BID POD 1-7 vs. placebo All patients received celecoxib 400 mg 2h pre-op and opioid regimen post-op | Pain scores (NRS) and post-surgical function | Decreased pain days 0-7, p < 0.05 Decreased 24h opioid use, p < 0.01 Decreased pruritus and nausea, p = 0.019 |
| Mamoun et al. (2016) ⁴ | Randomized, double-blind, placebo-controlled Cardiac surgery n = 147 | Acetaminophen 1,000 mg IV Q6H x 24h vs. placebo | Cumulative opioid consumption and pain scores (NRS) | - Decreased pain scores with acetaminophen, $p \le 0.001$ - No difference in opioid consumption, $p = 0.28$ |
| Russo et al. (2012) ⁵ | Randomized, prospective Population: renal surgery n = 80 | 24h ketorolac and morphine continuous infusion vs. 24h continuous infusion morphine + ketorolac bolus Q8H for 24h postoperatively | Pain scores | - Decreased pain scores with ketorolac bolus group (6 vs. 3) |

Post-operative Multimodal Pain Management Proposal 3 – September 2017 - 1



Appendix G – Swanson's Caring Theory



Image retrieved: https://sites.google.com/site/theoryofcaringposticusyndrome/the-theory-of-

caring/theory-evaluation

Appendix H – Certificate of Authorship

LINCOLN MEMORIAL UNIVERSITY CAYLOR SCHOOL OF NURSING DOCTOR OF NURSING PRACTICE PROGRAM

CERTIFICATE OF AUTHORSHIP

The Final DNP Project student paper must include the following Certification of Authorship statement:

I certify that I am the author of this paper titled An Evaluation of Implementing Enhanced Recovery After Surgery

Protocol Throughout the Perioperative Phase: A Quality Improvement Initiative to Enhance Patient Outcomes After and that any assistance I received to its preparation is fully acknowledged and disclosed in the paper. I have also cited Colorectal any sources from which I used data, ideas, or words, either guoted directly or paraphrased. I also certify that this paper Surgery was prepared by me specifically for this course. I understand that falsification of information will affect my status as a graduate nursing student.

Jerica Hill

Jerica Hill

0292821 10/29/2018 Student's Signature Student ID Number Date

_____ Student's Name (Print)

Appendix I – Institutional Review Board



M. Ammar Hatahet, M.D. Chair Baptist Memorial Hospital Memphis Patty Claiborne, Pharm.D. Vice-Chair Baptist Memorial Hospital Memphis

May 14, 2018

RE: BMH-IRB 18-26 (Existing Medical Record Review)

Study Title: "An Evaluation of Implementing Enhanced Recovery After Surgery Protocol throughout the Perioperative Phase."

Dear Jerica:

The designated IRB reviewer has reviewed your Application to Conduct Research Using Existing Medical Records in order to evaluate the enhanced recovery after surgery (ERAS) protocol on patients undergoing major abdominal surgery and analyze how the implementation and compliance of this protocol effect patients' outcomes.

The reviewer determined that your research is eligible for expedited review per 45 CFR 46.110 (b) (1) category 5 "Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis)."

The following criteria have been satisfied for the Baptist Institutional Review Board to approve a waiver of HIPAA authorization under the Privacy Rule per 45 CFR 164.512 (i) (1) (i):

- 1. The use or disclosure of protected health information (*See Privacy & Security Data Request Form and Approval*) involves no more than a minimal risk to the privacy of individuals, based on the presence of the following elements:
 - o an adequate plan to protect the identifiers from improper use and disclosure;
 - an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
 - adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
- 2. The research could not practicably be conducted without the waiver or alteration; and
- 3. The research could not practicably be conducted without access to and use of the protected health information.

The request for waiver of requirement to obtain informed consent is approved in accordance with 45 CFR 46.116(d). The IRB finds and documents that:

- 1. The research involves no more than minimal risk to the subjects;
- 2. The waiver will not adversely affect the rights and welfare of the subjects;
- 3. The research could not practicably be carried out without the waiver.

6025 Walnut Grove Road, Suite 404, Memphis, Tennessee 38120 Phone (901) 226-1677 Fax (901) 226-1680

Document Security. The signature is in a multicolored block and the watermark is based on the Baptist logo.