# DEVELOPMENT AND EVALUATION OF A NURSE ANESTHETIST DIRECTED DEXMEDETOMIDINE PROTOCOL FOR PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY IN AN ACADEMIC MEDICAL CENTER

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Title: Development and Evaluation of a Nurse Anesthetist Directed Dexmedetomidine Protocol for Patients Undergoing Laparoscopic Cholecystectomy in an Academic Medical Center

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Dexmedetomidine is an alpha-2 adrenoceptor agonist that provides sedation and has opioid-sparing effects that mitigate postoperative complications associated with opioid analgesics. The use of 1mcg/kg dexmedetomidine administered before induction of general anesthesia in patients undergoing laparoscopic cholecystectomy provided improved pain control and reduced opioid analgesic requirements. Patients over the age of 18 and with an ASA classification one to three scheduled for elective laparoscopic cholecystectomy were candidates to receive dexmedetomidine 1mcg/kg before the induction of general anesthesia. Evaluation of Morphine Milligram Equivalents (MME) received throughout the perioperative course, the presence of postoperative nausea and vomiting (PONV), total time in the post-anesthesia care unit (PACU), and highest recorded pain score were recorded. Patients receiving dexmedetomidine exhibited lower pain scores, experienced shorter time in the PACU, and had lower MME utilization. Dexmedetomidine effectively reduces opioid requirement and unwanted side effects of general anesthesia while providing improved analgesia levels and shorter lengths of stay in the hospital.

*Keywords:* dexmedetomidine, opioid-free, anesthesia, laparoscopic cholecystectomy

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## ABBREVIATIONS

DNP – Doctor of Nursing Practice

DEX – Dexmedetomidine

MME – Morphine Milligram Equivalents

PACU – Post-Anesthesia Care Unit

PICOT – Population, Intervention, Comparison, Outcome, and Time

PONV – Post Operative Nausea and Vomiting

RCT – Randomized Control Trial

VAS – Visual Analog Score

# CHAPTER ONE

# INTRODUCTION

## Problem Description

The opioid crisis in the United States (U.S.) is a growing health concern. The Centers for Disease Control and Prevention (CDC) identified opioid-related deaths as nearly four times higher in 2018 compared to 1999 (CDC, 2020a). Similarly, in 2017, 1.7 million people in the U.S. were diagnosed with an opioid-related substance use disorder resulting in 47,000 deaths (National Institute on Drug Abuse, 2020a). The financial impact of the opioid crisis is estimated to be $78.5 billion annually, with a majority of the cost related to direct health care, criminal justice system interventions, and health insurance (Pollack, 2016). In 1999 the American Pain Society urged the Joint Commission and the Veterans Health Administration to add pain as the fifth vital sign (Skolnick, 2018). In response to the addition of pain as the fifth vital sign and heavy marketing of OxyContin® to relieve noncancer pain, prescriptions for opioids rose ten-fold in the early 2000s (Skolnick, 2018). Increased exposure, availability, and the addictive nature of OxyContin® led to continued misuse and the prescriber adoption of similar opioid substances.

In Pennsylvania, opioid-related deaths declined from 2017 to 2018; however, they remain almost four times that of 1999 at a rate of 6.1/100,000 to 21.7/100,000 deaths in 2017 (National Institute on Drug Abuse, 2020b). Moreover, the rate of opioid prescriptions in Pennsylvania was 49.9 per 100 persons in 2018 compared to the national average of 51.4 per 100 persons (CDC, 2020b). Many opioid prescriptions are written following surgical interventions, and in 2016 there were over 100 million surgical

interventions performed in the U.S.(National Quality Forum, 2019). In response to the increase in opioid prescriptions and the incidence of misuse, the CDC provided recommendations to limit exposure to opioid analgesics, specifically to modify opioid prescribing practices to limit opioid exposure, prevent abuse, and stop addiction (CDC, 2020b).

Delivering analgesia during a surgical procedure is necessary for anesthesia providers to provide safe and effective care. Nurse anesthetists are advanced practice registered nurses who provide holistic, evidence-based anesthesia care across the lifespan in various settings (American Association of Nurse Anesthetists (AANA), 2017). Nurse anesthesia principles include physical comfort as a tenet of patient-centered care (Talley & Talley, 2018).

Acute pain is defined as "the physiological response to an adverse chemical, thermal or mechanical stimulus" (Macre et al., 2013 p. 1612). There are two types of pain pathways, nociceptive and non-nociceptive pain pathways. Nociceptive pain pathways have an acute onset, typical of surgical pain described as sharp, burning, and localized (Bordi, 2018). Conversely, visceral pain is associated with hollow organs, and smooth muscle pain is described as a referred or dull or achy, diffuse pain.

Patients undergoing laparoscopic procedures typically exhibit nociceptive visceral pain (Everson et al., 2020). Non-nociceptive pain is associated with inflammation (inflammatory pain) and neuropathic pain, pain not derived from a stimulus (numbness or burning) (Bordi, 2018). Surgical pain results from tissue injury caused by surgical incision, or to be more specific, pain following surgery includes inflammation and direct damage to nerves resulting in the release of local tissue

inflammatory mediators that stimulate surrounding tissue, resulting in increased excitability of the central nervous system, creating pain (Mariano et al. 2020).

When a noxious stimulus is introduced, signals are processed through transduction (Bordi, 2018). Transduction occurs when accessible nerve endings send signals via inflammatory chemical mediators innervated in the spinal cord's dorsal horn to the brain. The spinal cord transmits pain signals to the thalamus, which distributes signals to the cortex where pain perception occurs (Bordi, 2018). Therapeutic agents utilized to suppress pain by interrupting the transduction process include opioids, local anesthetics, nonsteroidal anti-inflammatory drugs (NSAIDs), serotonin antagonists, and alpha-2A agonists (Everson et al., 2020).

Opioids are traditional tools utilized by nurse anesthetists when providing analgesia (Clark et al., 2016). There are drawbacks to using opioids as the primary analgesic in balanced anesthesia techniques. The use of opioids by opioid naïve patients undergoing a surgical procedure compared to opioid naïve nonsurgical patients was reported higher in the surgical patients one year after the procedure in chronic opioid use, including laparoscopic and open cholecystectomy (Sun et al. 2016). Opioids suppress pain by modulating pathways within the brain, spinal cord, and peripheral nervous system and act by blocking mu receptors through direct inhibition of pathways, the spinal cord's dorsal horn, and the midbrain (Kramer & Griffis, 2018). The benefits of opioid analgesics include analgesia, reduction in anxiety, sedation, and euphoria (Kramer & Griffis, 2018). However, acute undesired effects of opioids are respiratory depression, dysphoria, vasodilation, bradycardia, nausea and vomiting, skeletal muscle rigidity, smooth muscle spasm, constipation,

urinary retention, pruritus, histamine release, and hormonal effects (Nagelhout & Elisha, 2018).

Enhanced Recovery After Surgery (ERAS) protocols were introduced in 1997 by physicians in Northern Europe (Taurchini et al., 2018). ERAS uses multimodal evidence-based strategies to reduce postoperative recovery time and complications (Moningi et al., 2019). The American Society of Colon and Rectal Surgeons developed the first ERAS clinical practice guidelines based on robust clinical evidence. Intraoperative recommendations include

- A multimodal, opioid-sparing pain management plan should be used and implemented before the induction of anesthesia
- Antiemetic prophylaxis should be guided by preoperative screening for risk factors for postoperative nausea/vomiting
- Preemptive, multimodal antiemetic prophylaxis should be used in all at-risk patients to reduce PONV (Carmichael et al. 2017):

Recommendations from the American Society for Enhanced Recovery actively seek additional data and research supporting ERAS protocols for other case profiles. Many organizations have developed ERAS protocols within their systems to enhance surgical patients' outcomes based on strict evidence-based practices.

Geisinger Health System instituted a version of ERAS called "Proven Recovery" for surgical patients throughout the system to reduce opioid utilization, improve pain management, and expedite healing (Geisinger, 2018a). The Proven Recovery Program's initial results demonstrated an 18% decrease in opioid utilization in bowel cases the first year (July 2017- July 2018) with a per-case cost savings of

more than $4000 secondary to more timely discharges. Additional *Proven Recovery* algorithms have been developed for spine, breast, hernia, total joint arthroplasty, and gynecological procedures. Currently, 11 *Proven Recovery* protocols are in place within the Geisinger Health System, including opioid-free modalities.

## Rationale

Laparoscopic cholecystectomy is considered less painful than open cholecystectomy. The laparoscopic cholecystectomy technique involves the surgeon making four small holes in the abdomen about 1 to 2 centimeters in length (American College of Surgeons, 2016). The surgery is performed with a small camera and instruments placed through the port sites. Laparoscopic surgery provides less invasive muscle and tissue damage reducing the need for an extended hospital stay (American College of Surgeons, 2016). However, the chief complaints that extend hospital stays are primarily postoperative pain and PONV (Bielka et al., 2018). Anesthetic and surgical procedures necessary for laparoscopy involve pneumoperitoneum, laryngoscopy, intubation, and extubation. These procedures produce a sympathetic response and autonomic reflex during the operative course. These reflexes cause pathological changes leading to increased epinephrine levels, norepinephrine, and plasma renin activity stimulating pain pathways (Moriber, 2018).

Additionally, moderate to severe abdominal and shoulder pain can exist for up to two days postoperatively in a majority of the laparoscopic cholecystectomy patient population (Bielka et al., 2018). Traditional pain management includes opioid analgesics administered throughout the perioperative period, and this period is often associated with undesired side effects, including PONV, hyperalgesia, respiratory depression, and

delirium. These undesired side effects can often lead to extended hospital stays, patient satisfaction reduction, and increased healthcare costs. The use of nonopioid analgesics during the perioperative course can significantly impact mitigating side effects of opioid analgesics while managing pain (Everson et al. 2020).

Dexmedetomidine is a highly selective alpha-2 adrenoceptor agonist with sedative and analgesic effects. It acts as a sympatholytic and does not suppress the respiratory drive (Lee, 2019). Approved in 1999 by the Food and Drug Administration for short-term sedation lasting less than 24 hours, dexmedetomidine reduces agitation and delirium in the postoperative period (Kaur & Singh, 2011). Dexmedetomidine binds to the alpha 2 subtypes in the central, peripheral, and autonomic nervous systems while maintaining a strong affinity toward alpha – 2 adrenergic receptors, reducing inhalational anesthetic requirements up to 90%. Dexmedetomidine has a plasma and elimination half-life of two hours (Kaur & Singh, 2011). The spinal cord is the primary site of pain transmission as the brain stem modulates sedative properties which is the primary location of alpha – 2 adrenergic receptors. Dexmedetomidine thereby modulates pain pathways by blocking alpha-2 adrenergic receptors by attenuating the process of transduction.

Standard delivery of general anesthesia consists of a balanced approach using inhaled anesthetics, narcotic analgesics, muscle relaxation, benzodiazepines, and sedative-hypnotic agents. Geisinger Health System has included *Proven Care* within the Epic® electronic medical record that identifies patients that would benefit from ERAS protocols (Geisinger, 2020). The use of *Proven Care* is suggested, however, not mandated, depending on the provider's clinical judgment.  Opioid-free or opioid-reduced anesthesia techniques are indicated for abdominal surgeries as well as general

laparoscopic procedures. Opioid-reduced practice suggest the use of acetaminophen, celecoxib, and gabapentin preoperatively. The use of at least two types of antiemetics, reduced anesthetic gas, ketamine, and dexmedetomidine during general anesthesia, are part of intraoperative pharmacologic management. A shortcoming of the protocol is the absence of the dose and timing of administering the opioid reducing intraoperative agents, specifically dexmedetomidine.

## Specific Aims

This project provided an evidence-based protocol for the use of dexmedetomidine by nurse anesthesia staff for patients scheduled for elective laparoscopic cholecystectomy. Laparoscopic cholecystectomy procedures were selected due to the frequency of expected cases, the population's high incidence of PONV, visceral pain related to pneumoperitoneum, and typically overall general good health of the patient population. A PICOT question established the parameters in which the quality measure assessed the outcomes of dexmedetomidine use.

The utilization of a PICOT question identifies all components of evidence-based inquiry. In patients over the age of 18 years old undergoing a laparoscopic procedure for cholecystectomy (P), how does dexmedetomidine administration before surgical incision (I), when compared to current practice (C), influence opioid utilization in the postoperative care unit (PACU) (O) over six weeks (T)?

## Definition of Terms

The following conceptual and operational definition of terms are used throughout the project:

- *Anesthesia:* a state of being insensitive to pain through the use of gases, drugs (Nagelhout, 2018 p. 20)
- *Cholecystectomy:* removal of the gallbladder (Nagelhout, 2018 p. 721)
- *Dexmedetomidine*: an alpha-2 adrenoceptor agonist (J.Nagelhout & Elisha, 2018 p. 108)
- *Laparoscopic:* visualization of the abdominal cavity through the use of a camera (Nagelhout, 2018 p 752)
- *Opioid-free:* omitting the use of narcotic analgesics in the therapeutic management of pain (SOFA, 2019)
- *Proven Care:* a proprietary term used by Geisinger Health System to describe ERAS protocols (Geisinger, 2018b)
- *Transduction:* free nerve endings that send signals via inflammatory chemical mediators, innervated in the dorsal horn of the spinal cord (Nagelhout, 2018 p. 1167)
- *Pain:* "localized or generalized unpleasant bodily sensation or complex of sensations that cause mild to severe physical discomfort (Nagelhout, 2018 p. 1167)
- *ASA Score:* American Society of Anesthesiologists "to assess and communicate the patient's pre-anesthesia comorbidities" (American Society of Anesthesiologists, 2019)

## Chapter Summary

Chapter one presented the pathophysiology of pain and the agent dexmedetomidine that reduces unwanted side effects of opioid analgesics while

mitigating the sensation of pain. The PICOT question outlines the focus and purpose of the project. Chapter two will include a review of the Johns Hopkins model for evidence-based practice, including an analysis of current evidence suggesting dexmedetomidine as an adjunct in ERAS and opioid-free anesthesia techniques.

# CHAPTER TWO

# LITERATURE REVIEW

## Search Strategy

An extensive electronic search of Medline, Ovid, PubMed, Cochran Library, and Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases utilizing the search terms laparoscopic and dexmedetomidine; laparoscopic cholecystectomy and dexmedetomidine; opioid-free anesthesia and dexmedetomidine; Precedex© and cholecystectomy revealed 611 articles for review. To ensure all evidence was recent, all search results were limited to the English language, peer-reviewed, published within the last five years, and aligned with the posed PICOT question.

The abstract required the use of dexmedetomidine as an anesthesia adjunct during the perioperative course. Nonsurgical case reviews and combination therapies with dexmedetomidine were further excluded. In total, 26 articles were evaluated using the Johns Hopkins EBP tool resulting in 23 level one, one level four, and two-level five papers (Appendix A).

## EBP Model

The Johns Hopkins, Evidence-Based Practice Model Practice Question, Evidence, and Translation (JHEBPPET) is a 19-step process that provides a structured model to implement evidence-based practice into clinical environments (Dang & Dearholt, 2018). The Practice question, Evidence, and Translation (PET) process identifies the practice problem (P), uses the problem to develop the practice question by searching through current research supporting the practice question.

Evidence is evaluated and processed based on quality by using a scale of I-V. Level I articles represent the most reliable evidence and are supported by randomized control studies. In contrast, level five articles consisted of professional or expert opinion and case reports (Appendix B).

## Available Knowledge

### Meta-Analysis

Three meta-analyses evaluated the use of dexmedetomidine as part of the general anesthetic for laparoscopic cholecystectomy. First, Wang et al. (2018) considered 40 RCT's evaluating postoperative pain in adults during general anesthesia, comparing the use of dexmedetomidine administered intravenously with that of individuals receiving normal saline as a control. Seven studies assessed dexmedetomidine administration at the end of the case, and 33 studies started dexmedetomidine at the beginning of surgery. A reduction in the requests for morphine with a weighted mean difference (WMD) of -0.93, 95% confidence interval (CI),-1.34 to -0.53, a reduced overall cumulative opioid consumption 24 hours after surgery WMD -6.76, 95% CI -10.16 to -3.35, a longer time to request for rescue analgesia WMD = 34.93, 95% CI, 20.27 to 49.59, and a reduction in pain intensity within six hours WMD = -.93; 95% CI -1.34 to -0.53 each could be used as evidence of significant clinical benefits in using intravenous dexmedetomidine as part of the general anesthesia regime.

Similarly, Tsaousi et al. (2018) reported a meta-analysis of 913 patients enrolled in 15 RCTs utilizing dexmedetomidine versus placebo group in spine surgery. Dexmedetomidine was found to have opioid-sparing effects and sedative properties. Specifically, dexmedetomidine reduced overall pain intensity, extended pain-free periods,

and decreased opioid demand of general anesthesia patients compared to the placebo group (Tsaousi et al., 2018). The dexmedetomidine intervention group showed a decrease in morphine milligram equivalents both intraoperatively (mean difference (MD) -2.69; 95% CI, -3.05 to -2.33; $p<0.001$) and postoperatively (MD, -4.36; 95% CI, -6.93 to -1.79; $p<0.001$) compared to the placebo normal saline group.

Wang et al. (2016) performed a meta-analysis of 15 RCTs representing 899 patients using dexmedetomidine for laparoscopic procedures. All patients were over the age of 18, undergoing laparoscopic procedures, and receiving an intraoperative bolus of dexmedetomidine 0.2 mcg/kg up to 2 mcg/kg. This study compared the placebo group with the or no treatment group. In eight of the RCTs, researchers utilized at least a 1mcg/kg bolus dose of dexmedetomidine. Researchers reported a reduction in postoperative nausea and vomiting in laparoscopic surgical patients (risk ratio 0.43; CI 0.28 to 0.66, $p$ <0.0001). Adverse effects of dexmedetomidine were lower heart rate and Mean Arterial Pressure (Wang et al., 2016). Findings were not conclusive in patients who experienced rescue antiemetic, dry mouth and shivering. The reduction in postoperative side effects and lower sympathetic response to surgical intervention are realized when dexmedetomidine is administered as part of a balanced anesthesia technique

**Laparoscopic Procedures**

Andjelkovic et al. (2018) described an RCT of 59 participants undergoing laparoscopic intestine resection to reduce propofol requirements during laparoscopic surgery. Study participants received either normal saline or lidocaine/ dexmedetomidine infusions before the induction of anesthesia. Researchers concluded that

dexmedetomidine reduced propofol use consumption of postoperative analgesia on postop day two and overall length of stay compared to the control groups.

Moreover, Sharma et al. (2018) described the reduction in requirements of Sevoflurane by 41% when patients received a dose of dexmedetomidine 0.5 mcg/kg before the induction of general anesthesia compared to the control group receiving normal saline ($p < 0.001$). With 100 patients undergoing laparoscopic cholecystectomy, this RCT demonstrated a significantly reduced visual analog pain score (VAS) of 12% and a reduced requirement for propofol compared with the control group receiving the same volume of normal saline. Patients in the dexmedetomidine group also exhibited a lower sympathetic response to intubation and extubation, evidenced by lower heart rate and noninvasive blood pressure suggesting that dexmedetomidine reduced the intraoperative requirement of volatile anesthetic.

Lee et al. (2018) evaluated 354 patients greater than 65 years in age in a double-blind RCT. Each patient received a dexmedetomidine bolus of 1 mcg/kg 15 minutes before the end of the surgery. Each group received either a bolus dose and continuous infusion before the induction of anesthesia or saline 15 minutes before the end of the surgery, evaluating the presence of postoperative delirium. Researchers identified a reduced incidence of delirium and VAS scores in patients receiving either a bolus dose 15 minutes before the end of surgery or an infusion before induction of anesthesia compared to the saline control group. Groups receiving dexmedetomidine had evidenced a lower use of haloperidol to control delirium than the control group ($p < 0.017$), suggesting dexmedetomidine administration during general anesthesia may reduce the incidence of postoperative delirium.

In a prospective, randomized, double-blind study by Trivedi et al. (2016), researchers compared the use of dexmedetomidine and midazolam on postoperative delirium in 90 patients undergoing surgical procedures lasting less than two hours. Dexmedetomidine dosed at 0.5 mcg/kg before induction of anesthesia showed a significant advantage over midazolam in preventing postoperative delirium than midazolam ($p < 0.001$) (Trivedi et al., 2016). Moreover, dexmedetomidine further reduced overall pain scores while maintaining hemodynamic stability.

A prospective RCT performed by Ge et al. (2015) evaluated the promotion of postoperative analgesia and recovery of patients undergoing abdominal colectomy. In a double-blinded RCT, 35 of 67 patients received dexmedetomidine 0.5 mcg/kg infusion as part of general anesthesia. The remaining participants received general anesthesia and saline infusion. Patients receiving dexmedetomidine required less activation of a morphine patient controlled analgesia with morphine than did the control group, which received a saline infusion ($p < 0.05$). Researchers found that the number of morphine administrations was less in the dexmedetomidine group (Ge et al., 2015). The dexmedetomidine group exhibited reduced pain scores using the VAS scoring system, recorded a reduced number of pushes for morphine, and maintained hemodynamic stability (Ge et al., 2015).

Panchgar et al. (2017) reported dexmedetomidine's effectiveness on perioperative hemodynamics, analgesic requirements, and reduced side effects in the RCT of 40 patients experiencing laparoscopic surgery using dexmedetomidine versus patients receiving saline. Patients undergoing laparoscopic procedures received 1 mcg/kg body weight of dexmedetomidine, followed by an infusion of 0.5 mcg/kg/hr. They experienced

less pain postoperatively for more extended periods with reduced side effects. Hemodynamic stability was maintained in the dexmedetomidine group during pneumoperitoneum as compared to the normal saline group ($p < 0.001$) and the group which underwent direct laryngoscopy ($p < 0.05$). The dexmedetomidine group exhibited reduced heart rate, a mean systolic, and a normal diastolic blood pressures during intubation ($p < 0.001$) pneumoperitoneum ($p < 0.001$), and on extubation ($p < 0.001$) (Panchgar et al. 2017).

***Dexmedetomidine Use During Laparoscopic Cholecystectomy Procedures***

Bielka et al. (2018) conducted an RCT evaluating 60 patients undergoing laparoscopic cholecystectomy, comparing normal saline to dexmedetomidine infusions of 0.5 mcg/kg starting at the induction of anesthesia and continuing to extubation. The dexmedetomidine group experienced reduced morphine consumption ($p = 0.001$), lower incidence of postoperative pain (odds ratio (OR) 9; CI 1.1-77, $p = 0.04$), more extended periods to rescue analgesia ($p = 0.001$), less PONV (OR 5; 95% CI1.1-26, $p = 0.005$), and lower fentanyl requirements during surgery (OR 14.5; 95% CI 1.7 -122; $p = 0.005$) suggesting lower opioid requirements in patients receiving dexmedetomidine (Bielka et al., 2018).

In a similar study by Chilkoti et al. (2019), 75 patients undergoing laparoscopic cholecystectomy were enrolled in an RCT comparing participants receiving either 0.25% bupivacaine infiltrated at the surgical site, 0.25% bupivacaine with 0.5mcg/kg dexmedetomidine injected at the surgical site. The third group used 0.5 mcg/kg/hr dexmedetomidine infusion starting 15 minutes before the induction of anesthesia and continued through the end of surgery in addition to infiltration of 0.25% bupivacaine at

the surgical site. Despite the reported low dose infusion, there was a significant reduction in rescue analgesia for 24 hours. Additional benefits in the obtundation of pneumoperitoneum-induced hemodynamic changes with only mild side effects of bradycardia and hypotension in the group receiving dexmedetomidine infusion (Chilkoti et al., 2019). Patients receiving intravenous dexmedetomidine experienced significantly reduced tramadol consumption compared to intraperitoneal dexmedetomidine and control groups ($p = 0.005$).

A randomized, double-blind prospective study involving 80 participants found that dexmedetomidine provided sedation, sympatholytic, and analgesic properties for patients undergoing laparoscopic cholecystectomy (Chilkoti et al., 2020). The control group received a normal saline infusion, while the study group received an infusion of dexmedetomidine 0.5mg/kg until the end of surgery. Participants in the dexmedetomidine group required significantly less milligrams of tramadol 24 hours postop (112.5 mg tramadol [+ or -] 31.52 than the normal saline control group (131.25mg tramadol [+ or - ] 33.37) (Chikoti et al., 2020). Zoroufchi et al. (2020) reported similar findings using 40 participants, either receiving dexmedetomidine 0.5 mcg/kg/hr infusion or gabapentin 300 mg by mouth 60 minutes before surgery. The dexmedetomidine group experienced more sedation and analgesia throughout the perioperative course. Participants receiving dexmedetomidine versus gabapentin required less postoperative analgesia. Both RCTs utilized low dose continuous infusions, starting at least 10 minutes before anesthesia induction without administering a bolus dose.

***Bolus Dose Dexmedetomidine***

The recommended loading dose of dexmedetomidine is 1 mcg/kg infused over 10 minutes (Nagelhout, 2018). “Dexmedetomidine exhibits a rapid distribution phase with a distribution half-life of approximately six minutes and a terminal elimination half-life of two hours” with an onset of action in about 10 to 20 minutes (Nagelhout, 2018, p.108). The pharmacokinetics of dexmedetomidine, the average length of surgery, and the outpatient nature of elective laparoscopic cholecystectomy suggest using a dexmedetomidine bolus dose to realize the benefits of the drug without undesired longer sedative effects.

Kataria et al. (2016) conducted a prospective RCT involving 60 participants evaluating dexmedetomidine, used 30 participants, and fentanyl used on 30 participants, to hemodynamic responses of pneumoperitoneum, direct laryngoscopy, and intubation during laparoscopic cholecystectomy. The use of a 1mcg/kg bolus dose of dexmedetomidine provided an improved response on the attenuation of pneumoperitoneum response and provided better pain relief than fentanyl at least 1 hour after surgery without adverse effects. Both groups experienced similar findings in the sympathetic response to intubation, extubation, and pneumoperitoneum (Kataria et al., 2016).

A randomized, double-blind study completed by Vijayan et al. (2019) evaluated 90 patients undergoing laparoscopic cholecystectomy by comparing the use of dexmedetomidine 1 mcg/kg bolus over 10 minutes before induction of general anesthesia to oral gabapentin alone and oral gabapentin with dexmedetomidine 0.5 mcg/kg bolus. The results suggested a lower narcotic requirement in the dexmedetomidine only group,

where only 10% of participants required additional fentanyl ($p$ = 0.00741). Mean VAS scores were lower in the dexmedetomidine only group 60 and 120 minutes after extubation compared to the other two groups ($p$ =0.001). The use of 1 mcg/kg bolus dexmedetomidine provided improved pain scores, lower requirement for rescue analgesia, and better sedation than comparison groups (Vijayan et al., 2019).

Zeeni et al. (2019) compared 60 obese patients using morphine 0.08 mg/kg or dexmedetomidine 1 mcg/kg 30 minutes before the end of laparoscopic sleeve gastrectomy, evaluating the difference in morphine consumption in the PACU. There was no significant difference in postoperative morphine consumption in either group; however, dexmedetomidine provided improved postoperative hemodynamic parameters than morphine (P=<0.05). Both groups had similar morphine consumption in the PACU and 24 hours post-surgery with similar pain scores. The use of dexmedetomidine provided similar analgesic effects as morphine without the undesired side effects of narcotic analgesics.

## Chapter Summary

Chapter two described the search strategy utilized to obtain information regarding the use of dexmedetomidine for patients undergoing laparoscopic cholecystectomy—the use of the Johns Hopkins Evidenced-Based Model quantifying the quality of research. A review of available research summarized the use and benefits of dexmedetomidine for laparoscopic cholecystectomy cases. Chapter three will evaluate ethical considerations, budget, analysis, and context.

# CHAPTER THREE

# METHODOLOGY

## Context

Geisinger Health System consists of a group of hospitals located in central and northeastern Pennsylvania. The hospital system consists of a tertiary teaching hospital located in Danville, Pennsylvania, six community hospitals, The Commonwealth School of Medicine, Janet Weis Children's Hospital, and Geisinger Health Plan. The Geisinger Health System's mission statement "to enhance the quality of life through an integrated health service organization based on a balanced program of patient care, education, research, and community care" (Geisinger, 2020). The Geisinger Health System values include kindness, excellence, safety, learning, and innovation (Geisinger Values, 2020). Geisinger is innovative in implementing the *Proven Recovery* Program to improve pain management by using opioid alternatives, expedite healing through preoperative initiatives and reduce the length of stay in the hospital while reducing cost (Geisinger News Release, 2018). During the *Proven Recovery* pilot program, neurosurgery and colorectal patients reduced their length of stay by nearly half, and opioid use was reduced by 18% across the organization. The *Proven Recovery* program continues to expand across surgical subspecialties based on evidence-based practice. The anesthesia department within the Geisinger System remains committed to reducing hospital length of stay and improving patient outcomes through *Proven Recovery* initiatives, specifically by lowering opioid utilization, controlling glycemic levels, managing fluid, and instituting measures to mitigate postoperative nausea and vomiting.

**Barriers and Facilitators.** The primary barrier to implementing the DNP project was providers adapting to different anesthetic techniques. Additional obstacles included implementing workflows surrounding the objectives related to providing opioid reduced anesthesia techniques. Previous attempts to implement opioid-free strategies by senior staff anesthesiologists were not sustainable within the department's culture, where objectives and processes were not identified. A review of current practice methodology related to dexmedetomidine among anesthesia providers at Geisinger – Danville was completed through a gap analysis. The gap analysis revealed extensive variation in dose and timing of dexmedetomidine by providers across all demographics. Established workflow and supply logistics are in place, evidenced by the provision of dexmedetomidine as a routine drug available to all anesthesia staff in the operating room pharmacy.

**Organizational Support**. Goals for the EBP project were established with the Chief Nurse Anesthetist and the Anesthesia Department Chair. Presentation in the use of dexmedetomidine in laparoscopic cholecystectomy cases aligns with organizational and departmental values in providing optimal care through the *Proven Recovery* methodology. A dedicated core group of nurse anesthetists within the department committed to providing opioid reduced anesthesia, identified through informal collaboration efforts, dedicated to the EBP support in the use of dexmedetomidine for laparoscopic cholecystectomy. The five Certified Registered Nurse Anesthetists (CRNA's) engaged in the project are experienced providers who remain committed to supporting the dexmedetomidine initiative.

**Stakeholders.** Stakeholders within the anesthesia department support the ongoing utilization of evidence-based practice which enhanced the *Proven Recovery* program. The project's stakeholders included the Chief Nurse Anesthetist, Anesthesia Department Chair, Education Coordinator, Data Analyst, Pharmacists, Staff Anesthesiologists, staff CRNA's, and the Performance Improvement Coordinator. The project outline was presented to all stakeholders with the continued support of the project outline. The establishment of ongoing quality initiatives was implemented for the department evaluating total MME when dexmedetomidine was used for any case within Geisinger-Danville and Geisinger – Shamokin (GSACH).

**Organizational Benefits.** The American Academy of Nursing identified the opioid crisis as one of five major health concerns in the U.S., and the leading reason life expectancy has declined in the last five years (Cox & Naegle, 2019). Nurse anesthetists are responsible for combating the opioid crisis by reducing exposure to opioids during surgical encounters through alternative methods that reduce pain sensation. Dexmedetomidine is one of the alternative drugs available that, when used, reduces the requirement for opioid analgesics, provides sedation, is non-habit forming, inexpensive, and is readily available in most hospital formularies.

The development of a practice change to reduce the exposure to opioid analgesics in a standard surgical procedure was the project's focus. The selection of an opioid alternative, dexmedetomidine, is used as an adjunct in providing improved outcomes of adequate pain management for surgical procedures, reduced side effects of traditional anesthesia modalities, and reduced exposure to opioids while maintaining equal or better outcome metrics for departmental benchmarks.

## Interventions

**Project Design and Setting**. A specific practice modality in the use of dexmedetomidine as an adjunct to nonopioid anesthesia had not been defined clearly in departmental guidelines or has been mentored consistently among anesthesia learners to be useful as a departmental initiative. Evaluation of the type of surgery and location was explored using analytical data supplied by the anesthesia department's quality manager. Geisinger -Danville and Geisinger -Shamokin (GSACH)performed more than 75% of all elective laparoscopic cholecystectomy cases in Pennsylvania's central region. Both facilities utilized CRNA's staff as the primary anesthesia provider for general anesthesia cases, including laparoscopic cholecystectomy procedures, while Shamokin only used CRNAs. Both facilities provided dexmedetomidine within the operating room (OR) pharmacies for use as an anesthesia agent and were available to all providers.

GSACH is a community-based institution that did not use learners as primary caregivers in the operating suite. Attending surgeons performed all procedures assisted by an experienced physician assistant (PA) or Registered Nurse First Assistant. GSACH scheduled greater than 50% of the elective laparoscopic cholecystectomy cases performed in the Geisinger central region during the last year. The same anesthesia staff and surgeons performed laparoscopic procedures in both institutions. A gap analysis was completed preceding the project implementation, identifying patients receiving dexmedetomidine for laparoscopic cholecystectomy in the preceding six months. Analysis immediately preceding the project implementation confirmed inconsistencies in dose or time of dexmedetomidine administration.

Open discussion with the Chief Nurse Anesthetist and fellow CRNA's suggested implementing a stepped approach in the use of dexmedetomidine as an adjunct to general anesthesia. Laparoscopic cholecystectomies were chosen to be evaluated due to the high incidence of cholelithiasis. Cholelithiasis, the formation of stones in the gallbladder, is the primary indication of cholecystectomy. Cholelithiasis occurs at a higher incidence in females, the presence of obesity, the use of sex hormones, reduced physical activity, and individuals with a poor diet (Stinton & Shaffer, 2012). Approximately 300,000 laparoscopic cholecystectomies are performed in the United States each year, with females having a four to one chance of having surgery (Hassler & Jones, 2020). Laparoscopic cholecystectomy is commonly performed as an outpatient procedure on persons without comorbidities, has improved recovery times requiring small amounts of narcotic analgesia, and is tolerated well without long-term side effects. Bi-weekly meetings with named stakeholders assured the internal workflow and project design aligns with the project outline. Before anesthesia induction, the decision to introduce bolus dosing of dexmedetomidine provided a preamble to anesthesia providers in the recommended regimen in dexmedetomidine use. More prolonged surgical procedures required the addition of an infusion of dexmedetomidine to realize the maximum benefit of the drug. Laparoscopic cholecystectomy is a procedure typically taking less than an hour to perform where a bolus dose of dexmedetomidine is sufficient to reduce opioid requirements without prolonged sedation.

**Inclusion-Exclusion Criteria.** The selection of persons over the age of 18 who had scheduled a laparoscopic cholecystectomy and who had an ASA score of one through three were included in the project. An ASA score of one is a healthy, non-smoking

patient. An ASA score of two is a patient with a mild systemic disease without substantial functional limitations that include smoking or obesity. An ASA score of three reflects patients with significant functional limitations and who have one or more moderate to severe disease processes. An ASA score of four or five have significant disease processes where surgery could threaten life (American Society of Anesthesiologists, 2019). Participation in the project depended on the provider's determination to use dexmedetomidine as part of their anesthetic plan. Exclusion criteria include an allergy to dexmedetomidine, documented bradycardia less than 50 beats per minute, prolonged QT via electrocardiogram, liver or kidney dysfunction, and pregnancy as each of these comorbidities go against the printed manufacturers' recommendations.

**Intervention.** Providers obtained dexmedetomidine from the operating room pharmacy window or workroom medication station before starting the case. The completion of inclusion criteria was determined during the anesthesia team's chart review and room setup. The administration of dexmedetomidine began in the preoperative area at a rate of no more than 10 mcg/min, preferably 10 mcg every 3 minutes, to avoid hypotension and bradycardia. The anesthesia provider continued administering 10 mcg boluses up to a maximum dose of 1 mcg/kg ideal body weight based on anesthesia induction's physiologic response. Based on the provider's clinical judgment, traditional anesthetic management in volatile anesthetic gas use, use of opioids, and muscle relaxants continued throughout the procedure. When surgery was completed, the CRNA transferred the patient to the post-anesthesia care unit (PACU) for recovery from general anesthesia. The patient remained in the PACU until discharged by the supervising

anesthesiologist. The patient must meet the standard criteria for discharge established by the Department of Anesthesia for Geisinger Health System.

**Project Leader.** The project leader was responsible for coordinating efforts in the presentation and follow-through to the department stakeholders. Presenting the problem to leadership, evaluating internal workflow patterns, and establishing information technology capabilities were steps completed before introducing the dexmedetomidine project. Formal presentations at unit staff meetings (anesthesia and recovery) during September and October 2020 outlined the project's rationale. Email introductions to all providers within the surgical suite of both facilities included cues for the project outline. Reminder cards outlining the project criteria were placed in operating rooms that host general surgery cases. Prompts posted in common areas, including the anesthesia workroom entrance, anesthesia department bathrooms, and lounge briefly outlined the project parameters. The project leader provided information regarding workflow coordination, answering clinical practice questions via Tiger Text ®, Email, or in-person interactions. Weekly updates during the study period served as reminders to staff to consider using dexmedetomidine for elective laparoscopic cholecystectomy cases. Establishing a request for information in data extraction included various clinical site applications, including necessary permissions and specific timelines.

**Project team.** The project team included Rebecca Stoudt, Ph.D., DNP, CRNA; Lynn Grove, DNP, CRNA, NP; and Sharon Novack, DNP, CRNA. Rebecca Stoudt was the education coordinator for the hospital system and was committed to supporting its growth through advanced education. Rebecca had extensive experience within the organization and had mentored other graduate students in project development and

design. Lynn Grove practiced as a CRNA in the operating room and a Nurse Practitioner in the organization's pain clinic. Lynn's unique background and experience provide insight across nursing disciplines. Lynn was committed to improving patient care and mentoring students. Sharon was a staff CRNA who used opioid-reduced or opioid-free techniques regularly in her clinical practice and serves as a clinical resource and advocate of the project goals

**Study of the Interventions**

The Model for Improvement (MFI) was the quality improvement model chosen to evaluate adding dexmedetomidine to the anesthetic management of patients undergoing laparoscopic surgery for cholecystectomy. The inclusion of the MFI uses the Plan, Do, Study, Act (PDSA) model to evaluate the project's effectiveness and make real-time changes ( Agency for Healthcare Research and Quality, 2013). The MFI was a variant of the current process of quality measurement used within the Department of Anesthesia. The Geisinger hospital system used a LEAN methodology for system process improvement coupled with best practice recommendations established within the organization closely associated with Proven Care's clinical pathways. The ability to trend quality metrics allowed the project coordinator to evaluate the intervention's effectiveness and make necessary changes in the dexmedetomidine protocol. Using MFI allowed other facilities within the organization to make essential changes in the use of dexmedetomidine for laparoscopic cholecystectomies based on unit-specific workflows and outcomes.

**Evaluation Plan**. The use of PDSA cycles within the trial period provided a small test of change, thereby reducing risk and providing the ability to make dynamic changes

in the process (Mascarenhas et al., 2018). The use of dexmedetomidine before the incision for laparoscopic cholecystectomy decreased narcotic analgesics during the perioperative period. The reduction in narcotic analgesic use resulted in a reduction in postoperative nausea, vomiting, delirium, improved respiratory status, improved pain scores while reducing hospital length of stay (Wang et al., 2016). Evaluation of the overall length of stay, postoperative nausea vomiting, and documented visual analog score were metrics used by the anesthesia department. Total morphine milligram equivalents (MME) were the barometer in dexmedetomidine use for patients undergoing laparoscopic cholecystectomy. Measurement in the use of dexmedetomidine in laparoscopic cholecystectomy cases was the first cycle of PDSA. Education and buy-in from providers, including the use of the proposed changes, were the primary metric. Ongoing publication of data results influenced late adapters to accept EBP initiatives in daily practice. Continued evaluation in postoperative nausea and vomiting, VAS scores, total postoperative time measurement as secondary metrics, and MME's primary measure assured compliance with the initiative.

The DNP essentials were addressed and used throughout the planning and implementation phases of the project. System leadership and interprofessional collaboration were paramount in the first PDSA cycle as dexmedetomidine's inclusion depended on physician anesthesiologists' clinical judgment combined with CRNA's and anesthesia resident's willingness to use dexmedetomidine. The capture, measurement, and analysis of data relied on information systems and technology to extract and synthesize data and healthcare policy/advocacy and reduce exposure to opioid analgesics, thereby improving health outcomes.

## Measures

The primary measure in evaluating outcome measures was the use of opioid analgesics during the perioperative period. Various types of opioid analgesics are prescribed based on clinical judgment, patient response, and institutional formularies. The use of a conversion factor that quantifies opioid dose strength in MME is the primary benchmark. Opioid analgesic side effects were one of the leading contributors to anesthesia-related undesired side effects. Reducing or eliminating opioid analgesics was the purpose of using adjuncts as part of the anesthetic regimen. The anesthesia department measured PONV as one of the department's key performance indicators (KPI). Secondary metrics of PONV, total PACU time (arrival to discharge by the anesthesiologist), and average VAS that measure pain were benchmarks that gauged the initiative's success.

**Data Collection**. A request for data of all laparoscopic cholecystectomy cases performed between September 1, 2020, and October 10, 2020, established a baseline for MME in laparoscopic cholecystectomy cases. Data results included only scheduled elective cases based on International Classification of Diseases, Tenth Revision (ICD-10) coding from Geisinger-Danville, and Shamokin. Secondary measures such as the time in PACU, presence of PONV, and VAS established a baseline to measure the effectiveness in the use of dexmedetomidine. The project evaluation period was from October 11, 2020, through November 30, 2020, and data indices continued as a departmental quality metric. The department's administrative team encouraged the continued publication of results throughout the last two quarters of the fiscal year 2021.

**Validity and Reliability**. The instruments used in competing data sets included Epic® electronic medical record (EMR) and Microsoft Excel ® software. All data obtained from Epic® had administrative approval obtained through an internal request for data. The *Request for Data* form included department, associated IRB project approval, and financial responsibility department code. All data points collected from the Epic® EMR were integrated into Microsoft Excel®. Microsoft Excel® is a valid instrument that functions independently from the EMR platform. Data points collected for the procedure included race, birth gender, age, ASA status, total narcotic received in MME (oral and intravenous agents), presence of PONV, time in PACU (arrival from OR to anesthesiologist discharge), and pain score recorded as a VAS. Completion of datapoint extraction using ICD-10 coding of the procedure laparoscopic cholecystectomy- elective-uncomplicated; ASA one, two, or three; within the outlined timeframe were included in the results. Data query subsets were present and established by the analytics team, which used individual subsets for other requests throughout the organization.

**Analysis**

A simple *t*-test compared the total MME of patients who did not receive dexmedetomidine to patients receiving up to 1 mcg/kg of dexmedetomidine before the surgical incision. The simple *t*-test measured the mean score of subjects before dexmedetomidine against those receiving dexmedetomidine. All samples were continuous based on the mean MME, subjects were random and independent of each other, and the dependent variable (MME) was continuous and normally distributed. Calculation of the mean MME of patients receiving dexmedetomidine compared to a group six weeks before the initiation of the measures exhibited a significance in the use

of dexmedetomidine as a single variant. The groups were similar in cofounding variables of age, race, gender, ASA score, and body mass index. Secondary measures of KPI include PONV, treatment in PACU for PONV, total time in PACU (admit time to physician discharge). Secondary variables measured mean scores using simple *t*-test sampling. Evaluation of outcome measures using ratio variables with the independent variable (laparoscopic cholecystectomy) and the dependent variable (dexmedetomidine) established the project's validity.

Determination of effect size involved the comparison of standardized means of MME between two groups. The effect sample size used a comparison of patients who received dexmedetomidine to those who did not receive the drug. The standardized means derived through *t*-test using Cohens -*d* in which a group, independent of sample size, suggested significance in the intervention outcomes (Kim & Mallory, 2017; Rice, 2009). The calculation of means using Cohens-*d* proved a significant effect on change if greater than 0.8 or a small effect on change is between 0.8 and 0.2. The remaining data points used quantitative analytical methods calculated in percentages where comparison graphs were generated. Once completed, charts were generated comparing the total MME and secondary variables, with and without dexmedetomidine.

**Budget**

Anesthesia billing practices are unique and are dependent on the type of surgery performed. Surgical packages, defined by the Centers for Medicare and Medicaid Services (CMS), encompass all supplies and professional services encountered for the scheduled procedure (CMS, 2020). When scheduling a patient for laparoscopic cholecystectomy, the surgical package included a blanket coverage of a fixed dollar

amount depending on demographic, location, type of institution (academic, rural, critical access), and type of surgical encounter (open vs. laparoscopic) associated with the level of difficulty based on comorbidities. CMS has an established coding system that reimburses the institution a one-time, flat facility fee for services rendered that include operating room time, pre- and post-admission time, preoperative evaluation, reusable and disposable supplies, anesthesia medications, and equipment (American Hospital Association, 2017). Professional fees are not included in the facility fee and remain separate.

**Funding Sources.** CMS uses a diagnosis-related grouping (DRG) to establish the reimbursement for the individual in a specific demographic location. If the hospital can provide safe and effective care for less than what is reimbursed, the hospital, in turn, earns money. A revenue loss ensues when the hospital's procedure costs more than reimbursement revenue (Davis, 2020). Reimbursement is dependent on the payer, as fee schedules are negotiated through private insurance or set through government policy for Medicare and Medicaid policyholders.

**Cost Analysis**. The operating room utilization cost varies significantly from $30 per minute to over $100 a minute (Childers & Maggard-Gibbons, 2018). Postoperative care in the PACU is estimated at $3 and $10 per minute. Overall direct cost factors vary much based on payer mix, contractual arrangements, type of surgery, inflation indices, depreciation, and surgical profile.

There were no capital purchases necessary for the use of dexmedetomidine for laparoscopic cholecystectomy as operating suites are equipped for surgery to include anesthesia machines, operating room equipment, computers for documentation, operating

room tables and beds, and medication dispensing devices (Omnicell ®). All operating rooms are regulatory compliant with proper utilities and scavenging systems. There was no capital equipment cost associated with the project.

The use of dexmedetomidine reduces perioperative opioid requirement, thereby reducing postoperative side effects. Reducing postoperative side effects supports earlier discharge reducing direct labor costs and minutes spent in the recovery area (Chacar et al. 2018). There are minimal side effects with dexmedetomidine during the perioperative course that do not increase surgery length and reduce side effects enabling earlier discharge (Kamali et al. 2018). Administering 1 mcg/kg of dexmedetomidine effectively reduces the minimum alveolar concentration dose concentration up to 41% when administered before the induction of anesthesia, reducing the amount of inhaled anesthetic gas required (Di et al., 2018). Geisinger's direct contractual cost of Sevoflurane ($67.47), Desflurane ($156.23), Isoflurane ($8.47) are based on June 2020 purchase orders. The most common agents used in the anesthesia department are Sevoflurane and Desflurane, related to properties that support quicker wakeups and earlier discharge. The cost of implementation and maintenance based on case volume is budget neutral when a patient is discharged five minutes earlier than average. Conservative calculation of postoperative time spent in the PACU at $3 a minute would offset the EBP initiative's cost with a 5-minute earlier discharge (Appendix F). Logic dictates the reduction of inhaled anesthetic gases, the avoidance of unplanned admission for anesthesia-related complications, increased patient satisfaction, and reduced opioid use supports the use of dexmedetomidine in laparoscopic cholecystectomy cases through cost savings.

The department absorbed the project costs as an initiative for quality improvement. Discussion with Chris Torres, CRNA- Chief Nurse Anesthetist, and Carolyn James- QA Coordinator used data extracted from the project as an ongoing quality initiative. Time in establishing data sets and establishing reporting profiles were one-time investments for the department at an estimated cost of $1,250. The DNP project's information was intended to be added as an addendum as a budgeted quality metric for the department in Q3-Q4 FY 2021.

## Ethical Considerations

Multimodal anesthesia in multiple pharmacologic interventions is prepared and administered throughout the surgical encounter reducing and even omitting the need for opioid analgesia. The management of pain specifically addresses the prima facia elements of ethical care, including autonomy, beneficence, nonmaleficence, and justice. Ethical considerations of paternalism, surrogacy, and futility were additional considerations related to acute pain management.

The first element of autonomy states that a patient has the right to make decisions independently that affect an outcome. Each patient is entitled to the options related to the type of anesthesia modality that would meet their individual needs. To fulfill the autonomy principle, the patient must be free of coercion in the ability to make a personal choice (Sun et al., 2016). A person's ability to understand the consequences of informed consent and the freedom to choose self-determination are the pillars of providing an autonomous relationship (Pierce & Smith, 2013). Nonopioid analgesics use similar effects in providing analgesia for acute pain through pain pathways distinct from those used by opioids (Brandal et al., 2017). Avoiding opioids but offering the same level of

improved comfort has many benefits, including mitigating the side effects of respiratory depression, constipation, nausea, vomiting, hallucinating, and shortening hospital length of stay (Brandal et al., 2017).

Nonopioid anesthetics meet nonmaleficence criteria in providing equal or better outcomes in mitigating acute surgical pain and eliminating the significant side effects of opioid analgesia. Patients experience less pain, fewer side effects, and less time in the hospital (Brandal et al., 2017). Justice often accompanies autonomy and beneficence in providing the patient with the ability to make informed decisions regarding their surgical management and pain control expectations. The use of nonopioid versus opioid anesthetics provides a model of distributive justice. Paternalistic choices in the surgical setting are based on the physiological response to surgical incision. The nurse anesthetist has the duty of overriding the natural patient/provider decision of autonomy based on paternalism in providing beneficence (Lepping, 2016). Continuing the development of opioid-free anesthesia techniques provides beneficence to society through distributive justice while maintaining patient autonomy and nonmaleficence (Pierce & Smith, 2013).

**Protecting Human Subjects.** Wilmington University's Human Subjects Review Committee (HSRC) application as part of the curriculum was approved before implementing the project (Appendix C). The project was deemed not research and approved through expedited review. Collaborative Institutional Training Initiative (CITI) in Human Subject Research training assured compliance with institutional standards in protecting human subjects. The HSRC application required institutional approval obtained through Geisinger Institutional Review Board (IRB). The project was determined not to meet the research definition and approved without further evaluation

(Appendix D). Geisinger Health System required completion of the CITI training program in CITI Good Clinical Practice, Biomedical Research – Basic, and RCR for Researchers, Research Staff, and Administrators (Appendix E).

## Chapter Summary

Chapter three presented organizational background and instrumentation related to dexmedetomidine as an adjunct to opioid reduced anesthesia. A review of the methods and measures in data collection, analysis, and statistical significance summarized the project's validity. Ethical considerations protecting the welfare of participants and budget depicting economic benefits were discussed. Chapter four will provide the results of this evidence-based practice project.

# CHAPTER FOUR

# RESULTS

Chapter four describes the statistical analysis of the data collected. The chapter describes the demographic information and project results. Descriptive statistics are reported, followed by reliability statistics from IntellectusStatistics® software. The chapter concludes with a summary supporting the EBP change.

## Sample Characteristics

Data were extracted from the electronic medical record of elective laparoscopic cholecystectomy cases beginning on September 1, 2020, and continuing through November 30, 2020, at Geisinger – Danville and GSACH. Inclusion criteria included elective laparoscopic cholecystectomy, greater than 18 years of age, and ASA score of one to three. Of the 131 patient records provided by the organization for review who had an associated ICD-10 diagnosis code for laparoscopy cholecystectomy, 66 charts met the inclusion criteria. The remaining 65 patient records were excluded as they underwent secondary procedures, including esophagogastroduodenoscopy (EGD), restrictive gastric procedures, or were less than 18 years of age. The number of participants was less than expected due to reduced elective procedure volume secondary to the COVID-19 pandemic.

Seventeen patients received dexmedetomidine at least 0.5 mcg/kg up to 1 mcg/kg of their ideal body weight before the surgical incision as part of the anesthesia plan. Data extraction was limited to discrete variables identified before implementing the project defined by organizational requirements and only includes specific data points. Administrative approval granted access to 131 charts with the ICD-10 diagnosis coding

for laparoscopic cholecystectomy in Geisinger-Danville and GSACH. Associated ICD-10 diagnosis coding during the surgical encounter was eliminated for 66 charts. These patients underwent additional interventions, including EGD, restrictive gastric procedures, or were less than18 years of age.

## Results

Participant demographics were equally distributed in relation to gender, age, and ASA scores. The mean age for patients not receiving dexmedetomidine (n=49) was 51.9 years with the range of 18 and 85. Conversely, the mean age of patients receiving dexmedetomidine (n=17) was 42.7 years, and age range betweem18 and 79 years of age (Table 1).

**Table 1**

*Summary Statistics for Participants Age*

| Variable | *M* | *SD* | *n* | Min | Max |
|---|---|---|---|---|---|
| Pre-Intervention | 51.90 | 17.10 | 49 | 18.00 | 85.00 |
| Post-Intervention x/Dex | 42.71 | 20.15 | 17 | 18.00 | 79.00 |

Notes. *M* = Mean; *SD* = Standard Deviation, *n*= number of participants

Gender was recorded as either male or female as assigned at birth. Slightly more females than males did not receive dexmedetomidine, 26 females (53%) and 23 males (47%). Of those who received dexmedetomidine, nine (53%) were males, and eight (47%) were females. Table 2 presents the summary statistics according to the participants' gender.

**Table 2**

*Frequency Table for Participants Gender*

| Variable | *n* | *%* |
|---|---|---|
| Pre-Intervention | | |
| Female | 26 | 53.06 |
| Male | 23 | 46.94 |
| | | |
| Post Intervention w/Dex | | |
| Female | 8 | 16.33 |
| Male | 9 | 18.37 |

Moreover, ASA scores were similar between both groups, with the mean of 2.45 for those that did not receive dexmedetomidine and 2.35 for those who did. The dexmedetomidine for laparoscopic cholecystectomy protocol parameters allowed participants with an ASA score of three or less to receive dexmedetomidine due to the high comorbidity of those scoring more than a score of three. Table 3 outlines the ASA scores for both groups of patients.

**Table 3**

*Summary Statistics ASA Scores*

| Variable | *M* | *SD* | *n* | Min | Max |
|---|---|---|---|---|---|
| Pre-Intervention | 2.45 | 0.50 | 49 | 2.00 | 3.00 |
| Post-Intervention w/Dex | 2.35 | 0.61 | 17 | 1.00 | 3.00 |

Notes. *M* = Mean; *SD* = Standard Deviation, *n*= number of participants

PONV was recorded affirmative or negative in the electronic medical record. Documentation of medications to prevent PONV was beyond the evaluation scope in data collection and, therefore, was unable to be determined. A majority (n=45,92%) of those not receiving dexmedetomidine did not experience PONV, whereas 15(88%) of patients

who did receive dexmedetomidine did not experience PONV. Results of such are provided in Table 4.

**Table 4**

*Frequency Table for Post-Operative Nausea Vomiting (PONV)*

| Variable | *n* | *%* |
|---|---|---|
| PONV | | |
| No | 45 | 91.84 |
| Yes | 4 | 8.16 |
| PONV Dex Group | | |
| No | 15 | 88.23 |
| Yes | 2 | 11.76 |

Notes. *n*= number of participants

Time in the PACU was measured in minutes from the time anesthesia ends until the patient meets discharge criteria following an anesthesia provider's evaluation. As a result of dexmedetomidine, there was a reduction in PACU time by 29 minutes. Table 5 reflects the PACU length of stay summary statistics for both groups.

**Table 5**

*Summary Statistics for Total Time in PACU*

| Variable | *M* | *SD* | *n* | Min | Max |
|---|---|---|---|---|---|
| Pre-Intervention | 140.29 | 109.47 | 49 | 47.00 | 493.00 |
| Post-Intervention w/Dex | 111.12 | 43.03 | 17 | 42.00 | 202.00 |

Notes. *M* = Mean; *SD* = Standard Deviation, *n*= number of participants

A two-tailed paired sample *t*-test was utilized to examine differences in the mean PACU length of stay between patients who did and did not receive dexmedetomidine reflected in Table 6. The broad SD and Cohen's *d* of both pre-and post-intervention is explainable by random variation.

**Table 6**

*Two-Tailed Paired Samples t-Test for the Difference Between PACU Minutes and PACU Minutes Dex Group*

| PACU Minutes | | PACU Minutes Dex | | | |
|---|---|---|---|---|---|
| *M* | *SD* | *M* | *SD* | *p* | *d* |
| 140.29 | 109.47 | 111.12 | 43.03 | .356 | 0.23 |

Notes. *M* = Mean; *SD* = Standard Deviation; *d* represents Cohen's *d.*

Evaluation of the protocol was designed to reduce MME utilization in patients receiving dexmedetomidine. In cases not using dexmedetomidine, the mean MME utilization was 20.31 with a range of 7.5 - 50.8. Conversely, in patients receiving dexmedetomidine, the mean MME was 16.78 and ranged between 2 - 40. Table 7 represents these data points.

**Table 7**

*Summary Statistics for Total MME*

| Variable | *M* | *SD* | *n* | Min | Max |
|---|---|---|---|---|---|
| Pre-Intervention | 22.02 | 10.56 | 49 | 7.50 | 50.80 |
| Post-intervention w/Dex | 16.78 | 10.45 | 17 | 2.00 | 40.00 |

Notes. M = Mean; SD = Standard Deviation, n= number of participants

A two-tailed paired sample *t*-test was utilized to examine differences in the mean MME of patients who did and did not receive dexmedetomidine reflected in Table 8. The broad SD of both coupled with a Cohen's *d* and *p*-value greater than 0.05 are explainable by random variation.

**Table 8**

*Two-Tailed Paired Samples t-Test for the Difference Between MME and MME with Dex*

| MME | | MME Dex Group | | | |
|---|---|---|---|---|---|
| *M* | *SD* | *M* | *SD* | *p* | *d* |
| 22.02 | 10.56 | 16.78 | 10.45 | .221 | 0.31 |

Notes. M = Mean; SD = Standard Deviation; *d* represents Cohen's *d.*

Pain scores were measured on a scale of one to 10, and during the perioperative stay, the highest pain score was recorded. Patients receiving dexmedetomidine had a lower overall mean pain score than patients that did not receive dexmedetomidine. The results remain statistically insignificant but have clinical significance. The highest pain score recorded for the dexmedetomidine group, which was 9/10, compared favorably with the 6/10 score, which was the highest in the dexmedetomidine group. Table 9 represents these data points.

**Table 9**

*Summary Statistics for Pain Score*

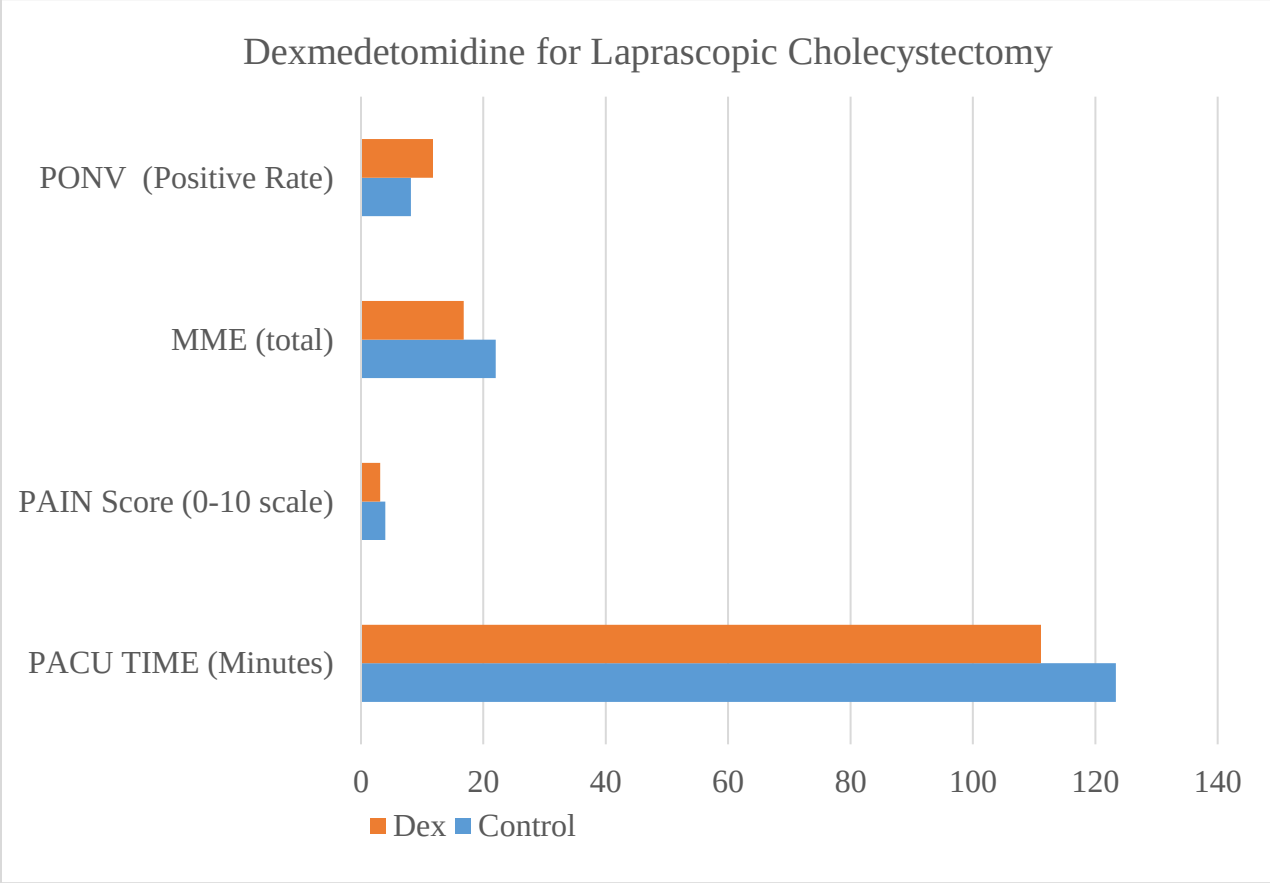
| Variable | *M* | *SD* | *n* | Min | Max |
|---|---|---|---|---|---|
| Pre-Intervention | 3.96 | 1.99 | 49 | 0.00 | 9.00 |
| Post-Intervention w/Dex | 3.12 | 1.90 | 17 | 1.00 | 6.00 |

Notes. *M* = Mean; *SD* = Standard Deviation, *n*= number of participants

The use of dexmedetomidine as an adjunct to an opioid-reduced anesthesia plan had added value in reducing MME, pain scores, and time in the PACU. There was a 17.4% decrease in the use of MME by the patients that received dexmedetomidine as part of the anesthetic plan compared to those not receiving dexmedetomidine. A 22% reduction in the highest pain score was realized in patients receiving dexmedetomidine. A concurrent 10% reduction in PACU time was recognized in patients receiving dexmedetomidine compared to the population receiving a traditional anesthetic. The percentage of individuals experiencing PONV (n=2, 11%) remained higher in the dexmedetomidine group than the pre-intervention group (n=4, 8.1%), but such may be attributed to a low number of patients. A display of outcome metrics is depicted in Table 10.

**Table 10**

*Summary of Key Dexmedetomidine Metrics*




## Chapter Summary

Chapter four describes the sample characteristics and results of the initial protocol for the use of dexmedetomidine for patients undergoing laparoscopic cholecystectomy, a detailed review of qualitative data, and a summary of key findings. Chapter five will present the interpretation, limitations, implications for practice, sustainability, and the application of the AACN DNP Essentials.

# CHAPTER FIVE

# DISCUSSION AND IMPLICATIONS

Chapter five will discuss the association between dexmedetomidine use for patients undergoing laparoscopic cholecystectomy and overall MME outcomes, pain scores, time in PACU, and PONV. The use of ERAS protocols improved patient outcomes and reduced healthcare costs. Limitations to the project design and development will be discussed and the implications for advanced nursing practice. Sustainability concerning the use of dexmedetomidine in the anesthetic plan for various surgical procedures will be reviewed. Application of AACN DNP Essentials (2006) achieved during the project will be presented.

## Interpretation

As described in chapter one, the project objectives were to reduce the overall narcotic utilization, reported as MME, in patients undergoing laparoscopic cholecystectomy. Data were extracted from the EMR. A total of 66 patients meeting the criteria outlined in the project were enrolled.

The focus on the use of dexmedetomidine for laparoscopic cholecystectomy procedures was to realize a reduction in required narcotic analgesics. A reduction in the use of narcotic analgesics also reduced unwanted side effects, including PONV. PONV was recorded as a yes or no response. Institutional *Proven Care* guidelines suggest using at least two interventions to prevent PONV for all laparoscopic procedures. Most commonly, the use of ondansetron and dexamethasone are used by providers within the Geisinger organization. Determination of the presence of PONV was one of the leading quality metrics for the anesthesia department. The presence or absence of PONV was

reported and suggestive of reduced narcotic utilization. There was a higher reported incidence of PONV in the dexmedetomidine group (*n*= 2) than the benchmark (*n*=4), which can be attributed to individual response and surgical intervention. The total time of surgery was not recorded, including the time of pneumoperitoneum. Pneumoperitoneum does impact the incidence of PONV, as reported by Lopez et al. (2021), who found that the incidence of PONV and hospitalization for outpatient procedures increased with pneumoperitoneum greater than 100 minutes.

The pain scores were obtained from the PACU record, where the highest recorded pain score on a scale of one to 10 was reported; as institutional procedures outline, pain score must be at three or less to meet discharge criteria. The use of dexmedetomidine lowered the average highest pain score from a four to a three. The highest recorded pain scores were lower in the dexmedetomidine group, who received less narcotic analgesic, suggesting improved pain management.

Dexmedetomidine can reduce undesired side effects and the requirement for additional narcotic analgesics. Side effects related to the use of opioids include increased drowsiness, pain, PONV, respiratory depression, and delirium, each of which would increase the overall length of stay in the PACU. The sedative effect of dexmedetomidine also may impede earlier discharge if the patient does not meet Aldrete score criteria. Participants receiving dexmedetomidine experienced less time in the PACU compared to individuals not receiving dexmedetomidine.

The primary indicator in the established baseline was the measurement of MME. As discussed in chapter one, when dexmedetomidine is administered before induction for laparoscopic cholecystectomy cases, there was a reduced requirement for narcotic

analgesics and the associated complications related to opioid analgesics. The use of dexmedetomidine before induction of anesthesia for laparoscopic procedures provided adequate analgesia while mitigating unwanted side effects of opioids.

Dexmedetomidine aligned with the system initiative of *Proven Care* in enhanced recovery after surgery. Decreasing unwanted side effects, reducing the PACU time, and effectively managing pain with reduced opioid analgesics. Such a decrease in unwanted side effects also meets organizational and national initiatives in achieving improved outcomes. The practice of adding dexmedetomidine to the anesthetic plan had minimal cost to the department and was limited in the individual providers' decision to use the drug. Familiarity, experience, and providers' willingness to modify their anesthesia practice were the limiting factors in the widespread utilization of dexmedetomidine.

## Limitations

Part of *Proven Care* within the Geisinger system included transversus abdominis plane (TAP) block. The surgeon performing the procedure is responsible for utilizing a TAP block that is a recommendation but not required. The blind TAP block technique is easily achieved using multiple injections relying on multiple (pops) at a single-entry point at Petit's triangle, making the blind technique unpredictable in achieving abdominal wall analgesia (The New York School of Regional Anesthesia, 2009). Information regarding the use of the TAP block was not obtained as an adjunct to laparoscopic cholecystectomy. It is undetermined which patients received a TAP block or the TAP block's effectiveness in providing analgesia.

Evaluation in the use of narcotics by participants was not identified, either by prescription or recreational use. The Food and Drug Administration (FDA) defines an

individual opioid-tolerant if the individual has received an MME of 60 mg for at least one week (Adesoye & Duncan, 2017). A phenomenon of opioid tolerance is believed to develop from the downregulation of opioid receptors on the synaptic and cellular levels. Ideally, early identification of opioid use by surgical patients assessing for opioid tolerance would help the surgical team provide adequate analgesia; however, participants were not identified as opioid-tolerant or opioid naïve. Therefore, such potentially skewing the established metrics.

Prevention of PONV was a primary metric within the anesthesia department. *Proven Care* guidelines focus on providing at least two pharmacologic agents to prevent PONV for high-risk surgeries. Laparoscopic surgery was considered a high-risk surgery in which banners within the electronic medical record reminded providers to administer antiemetic agents. The project did not evaluate the use of any specific antiemetic and instead only assessed the presence of PONV. The use of dexmedetomidine was not the sole factor in preventing PONV. A higher percentage of individuals experienced PONV in the dexmedetomidine group than in the control group. The conclusion was that dexmedetomidine does not have antiemetic properties but reduced the risk of PONV from a reduced opioid utilization. Such was a limitation found within the project.

Dosing dexmedetomidine as recommended will reduce the MME of narcotic analgesics, thereby decreasing the undesired side effects outlined in chapter one. Dexmedetomidine minimizes the amount of volatile anesthetic gas required enabling individuals to recover faster by eliminating agents more quickly. The time from admission to the PACU to discharge was evaluated in minutes. The dexmedetomidine group showed a shorter time spent in PACU than the control group. The discharge note

entered by the anesthesiologist determined the total time in the PACU when discharge criteria was met. Discharge criteria included the absence of PONV, pain level of three or less, and an Aldrete Score of at least eight. The Aldrete Scoring System was determined by five categories: consciousness, mobility on command, breathing, circulation, and color (American Association of Nurse Anesthetists, 2019). The primary nurse assesses the patient and calls the anesthesiologist for discharge. The time the participant meets discharge criteria and actual discharge was not determined within the study parameters.

The extent of limitations was mitigated by presenting a single factor in the use of dexmedetomidine for laparoscopic cholecystectomy cases. Making small changes in the anesthetic plan aligned with the PDSA cycle and introduced more contemporary concepts to practice. Selecting one readily available agent, dexmedetomidine, significantly impacted reducing opioid requirements was the project's goal. The addition of a readily available drug, premixed by the pharmacy and commonly used by anesthesia providers, eliminated additional workflow issues and the educational component of introducing elements of an unfamiliar pharmacological agent. The dose and timing of dexmedetomidine was the practice change that had a significant impact on patient outcomes.

## Implications for Advanced Nursing Practice

The opioid epidemic is one of the nation's leading health concerns. Reducing exposure to opioid analgesics has many benefits in reducing unwanted side effects such as the requirement for opioid prescriptions, development of chronic pain syndromes, improved patient satisfaction, and anesthetic influences of cancer progression. Dexmedetomidine is one drug in a host of alternative modalities that can limit the use of

opioids during the perioperative period. Additional pharmacological agents that reduce opioid requirements include lidocaine, ketamine, esmolol, and various local analgesic agents used in regional techniques. The use of preventable analgesia continues to be studied, and advanced practice nurses are at the forefront of patient education, advocating improved patient outcomes.

## Plan for Sustainability

Strategic actions are directly related to leadership qualities, by which leaders develop a positive culture in supporting EBP initiatives as part of routine workflows. Strategic activities include using guidelines, establishing a positive unit environment, and aligning with organizational processes that include *Proven Care*. Functional activities include ongoing education, performance monitoring through quality measurement, and inspiring groups formally and informally (Fleiszer et al., 2016). Leadership by advanced practice providers and DNP-prepared leaders can positively influence sustaining EBP initiatives by using functional and strategic actions.

Fleiszer et al. (2016) describe the findings in their quality improvement initiative of sustainability. In this study, the front-line staff was responsible for implementing and sustaining change through reminders, education/training, communication, performance evaluation, and the integration of changes within other practices. The use of reminders embedded with the Epic charting system will prompt providers that patients scheduled for laparoscopic cholecystectomy are candidates for *Proven Care* in the use of dexmedetomidine as part of EBP reduction of perioperative narcotic use. The use of ongoing reporting of QA outcomes to all anesthesia staff will serve as a reminder. First, reeducation second to use EBP initiatives established by the department. Team

orientation within the unit is provided access to all organizational EBP guidelines through a *SharePoint* file maintained by anesthesia staff. Quick links are provided for easy access from any anesthesia workstation throughout the institution. Quality metrics sent via e-mail and posts kept on the quality board contribute to culture change within the department.

## Application of the AACN DNP Essentials (2006)

### *Scientific Underpinnings for Practice*

The application of scientific underpinnings for practice was developed throughout the project using various nursing theories to disseminate evidence-based knowledge to peers, students, and colleagues. Development of human behavior in integrating applied nursing sciences, expanding the understanding of ethical, analytical, and organizational considerations was used during the project implementation. Building on the foundations of nurse anesthesia practice which combines solid scientific knowledge with nursing principles was essential to any practice change success.

Understanding human behavior and how individuals interact with the environment is critical in developing evidence-based initiatives. Introducing the DNP project to clinical staff with various experience levels meant recognizing the spectrum of abilities to adapt to new practice methods. Development and implementation of opioid-free anesthetic techniques in the use of dexmedetomidine for laparoscopic cholecystectomy procedures can be applied to multiple surgeries using the laparoscopic approach. The project opens the door for additional EBP opioid-free initiatives to be introduced into anesthesia practice.

*Organizational and Systems Leadership for Quality Improvement and Systems Thinking*

Creating relationships with organizational leadership is a crucial element in establishing practice improvements. Within the anesthesia department, stakeholders are encouraged to meet *Proven Care* models' expectations in reducing exposure to narcotic analgesia during surgical encounters. The addition of dexmedetomidine to the anesthesia care plan aligns with organizational goals to optimize patients for surgery by decreasing the probability of undesirable side effects of anesthesia. The advanced practice nurse uses advanced communication skills to create quality improvement metrics to reduce side effects related to anesthesia's narcotic analgesics. The project, approved by Geisinger and Wilmington University IRB boards, supported the ethical implementation of EBP guidelines. There was a significant cost reduction in billing time of service (operating room and PACU time), as evidenced by the DNP project outcomes, reducing unwanted side effects, improved pain management without opioids, and reducing overall healthcare dollars.

*Clinical Scholarship and Analytical Methods for Evidence-Based Practice*

The integration of learned behaviors in coursework had translated to clinical practice, where recent research was used to define clinical answers to positive outcomes in providing opioid-free anesthesia techniques for laparoscopic procedures. The ability to discern strong from weak evidence is a foundation in developing EBP development. The final project has real-world outcomes, and these outcomes use EBP quality measures to incorporate into departmental quality measures. The introduction of opioid-free or opioid-reduced practice techniques continues to evolve within the department as proponents for EBP introduce concepts to improve patient outcomes.

*Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care*

The use of information systems in completing the DNP project was essential to reporting findings, evaluating outcomes, and disseminating information. The reliance on technology to connect with multiple stakeholders had been vital in developing and implementing practice changes, specifically during the COVID pandemic. Using conference programs eased factors such as face-to-face meetings, logistical issues of distance and work schedules, and disseminating information quickly. Without using Workday® and Zoom®, many of the DNP project elements would not have been as impactful to stakeholders vital in project completion. Data extracted and analyzed required the use of statistical software for accuracy, timeliness, and appropriateness. Various stakeholders were included in the project to gather and disseminate information aligned with anesthesia departmental goals and objectives for patient-centered outcomes. Patient-centered goals include reducing anesthesia-related side effects, reduced length of stay, and anesthesia delivery complications.

*Health Care Policy for Advocacy in Health Care*

The opioid epidemic remains one of the leading causes of mortality in the U.S., specifically for individuals under the age of 50. Reducing the exposure to opioid analgesics during a surgical procedure is one intervention aligned with the national objectives to minimize exposure to opioid painkillers. Nurse anesthetists can use a multimodal approach to provide opioid-reduced or opioid-free anesthesia through various pharmacology alternatives and regional anesthesia techniques. Front line providers in anesthesia, including CRNA's, SRNA's, and staff anesthesiologists, engaged in

discussions surrounding the use of dexmedetomidine as an analgesic alternative. The inclusion of the dexmedetomidine protocol was included in departmental quality metrics to reduce anesthesia-related side effects. Attending meetings directly aligned to *Proven Care's* organizational objectives opened a dialogue in the use of dexmedetomidine for other surgical procedures. The opportunity to educate stakeholders in alternative anesthesia techniques exceeded all expectations of the project goals. Ongoing evaluation of outcome metrics and plans to extend *Proven Care* guidelines remain agenda items within the organization's enhanced recovery efforts.

*Interprofessional Collaboration for Improving Patient and Population Health Outcomes*

The DNP project allowed three distinct facets of interprofessional collaboration to develop during the project. Outside of educating CRNA's regarding the use of dexmedetomidine as an adjunct for opioid-free anesthesia techniques, the ability to work with the nursing staff, physicians, and non-clinical stakeholders to effectively communicate and work collaboratively assured the successful implementation of the project. Working with nursing staff in the post-anesthesia care units posed challenges similar to educating the CRNA staff. Many individuals were reluctant to adapt to changes in practice based on levels of experience and education. Experienced nursing staff relied on clinical expertise and experience with ineffective dexmedetomidine use by anesthesia providers. Presentation and follow-up of standard guidelines, education in drug pharmacology, and expected clinical presentation increased acceptance by nursing staff. Consistency in reporting findings, addressing clinical concerns, and nursing staff experience will allow further acceptance of dexmedetomidine use.

The ability to present clear evidence in dexmedetomidine usage to physician leaders was another challenge in translating evidence to practice. Physician leadership was supportive of the initiative; however, staff physician buy-in remained fractured. The ongoing structure of *Proven Care* was a recommendation and not a policy. Therefore, providers were reluctant to use the guidelines in favor of practicing based on clinical judgment.

The most engaged individuals were the non-clinical stakeholders who have a general interest in anesthesia techniques. The ability to present and reinforce information regarding the opioid epidemic to clinical and non-clinicians remains a resource for positive regulatory support to combat the opioid crisis and showcase advanced practice nurses' abilities. The presentation of alternative therapies to manage analgesia during the perioperative period included community civic and business leaders, a state legislator, and multiple law enforcement agencies.

*Clinical Prevention and Population Health for Improving the Nation's Health*

CMS outlined quality measures specific to anesthesia. Regardless of either CRNA or physician, the provider must report quality measures that align with the practice environment. Quality measures centered on criteria established by CMS are based on population needs assessment. Metrics established by CMS must meet a threshold and must be reported annually to assure reimbursement. Two of CMS's quality indicators include tracking PONV and multimodal pain management.

The introduction of dexmedetomidine for laparoscopic cholecystectomy cases was designed to meet both objectives. The reduction in the use of opioid analgesics mitigated potential side effects, including PONV. When used correctly, dexmedetomidine

provided reduced opioid requirements during the perioperative period. The use of opioids had a direct correlation in causing PONV. Dexmedetomidine reduced the required anesthetic gas, which also correlated to a higher incidence of PONV. According to CMS(2018), when anesthesia providers use dexmedetomidine as part of their anesthetic plan, multimodal pain management criteria are met. Meeting CMS criteria is not primarily designed to maximize reimbursement but to improve outcomes in care delivery.

Advocating for the use of alternative methods of analgesia during perioperative care was the overall guiding premise behind the DNP initiative. Using dexmedetomidine is only a fraction of multimodal pain therapy. Introducing the use of dexmedetomidine brings the global issue of opioid dependence into view as a significant influence on health status and opens the door for further discussion.

*Advanced Nursing Practice*

Completing a comprehensive and systematic assessment of the health issue of opioid addiction impacting the population's health is the foundation in determining the DNP project's focus. The use of opioid-free anesthesia techniques aims at reducing exposure to opioid analgesics to surgical patients. Robust research techniques involving evidence-based anesthesia practice led to dexmedetomidine development to reduce or eliminate opioids during the surgical encounter. An extensive review of opioid-sparing methods provided improved analgesia when coupled with multiple adjuncts, including dexmedetomidine.

The expanded knowledge base of anesthesia providers in the proper dosing and timing of dexmedetomidine reduces the incidence of narcotics-related complications. Complications such as respiratory depression, PONV, ileus, intraoperative hypotension,

and opioid dependence contribute to favorable outcomes in avoiding opioids in the anesthesia plan. ERAS protocol development includes the reduction of opioids during the perioperative course. The administration methods of dexmedetomidine translate across multiple surgeries using similar techniques, thereby reducing required narcotic utilization. Opportunities involving EBP and ERAS emerged through departmental discussions, education, and mentoring of peers and nurse anesthesia students.

Increased awareness of the opioid epidemic, education supporting established ERAS protocols named *Proven Care* within the organization, and inclusion of outcome metrics into departmental goals set through the DNP project have enlightened providers concerning opioid-free anesthesia techniques. Opportunities to involve multiple stakeholders have given vigor to current ERAS protocols within the department. Engaging in organizational activities of quality, cost reduction, and patient satisfaction have reinforced the value of advanced practice nurses and their impact on healthy populations.

## Conclusion

The use of dexmedetomidine is beneficial in providing adequate pain control in patients undergoing laparoscopic cholecystectomy. Dexmedetomidine provides a mechanism to reduce opioid analgesics as part of the anesthetic plan, reducing unwanted side effects of opioids. The project results were consistent with current evidence providing for lower overall pain scores,  reduced MME during the perioperative period, shorter length of stay in the PACU, potential to mitigate PONV, and provided lower overall pain scores. The initial projects' results failed to amend the anesthetic plan of several anesthesia providers even though workflow and information regarding the

protocol were readily available. Continued education of anesthesia staff and reporting quality measures coupled with *Proven Care* banners' recommendations may benefit additional patients. Ongoing education and champions of ERAS within the department, reviewing the benefits of non-opioid anesthesia techniques, and displaying monthly quality metrics will increase the awareness and willingness of anesthesia providers to use dexmedetomidine as a non-opioid adjunct as part of their anesthesia plan.

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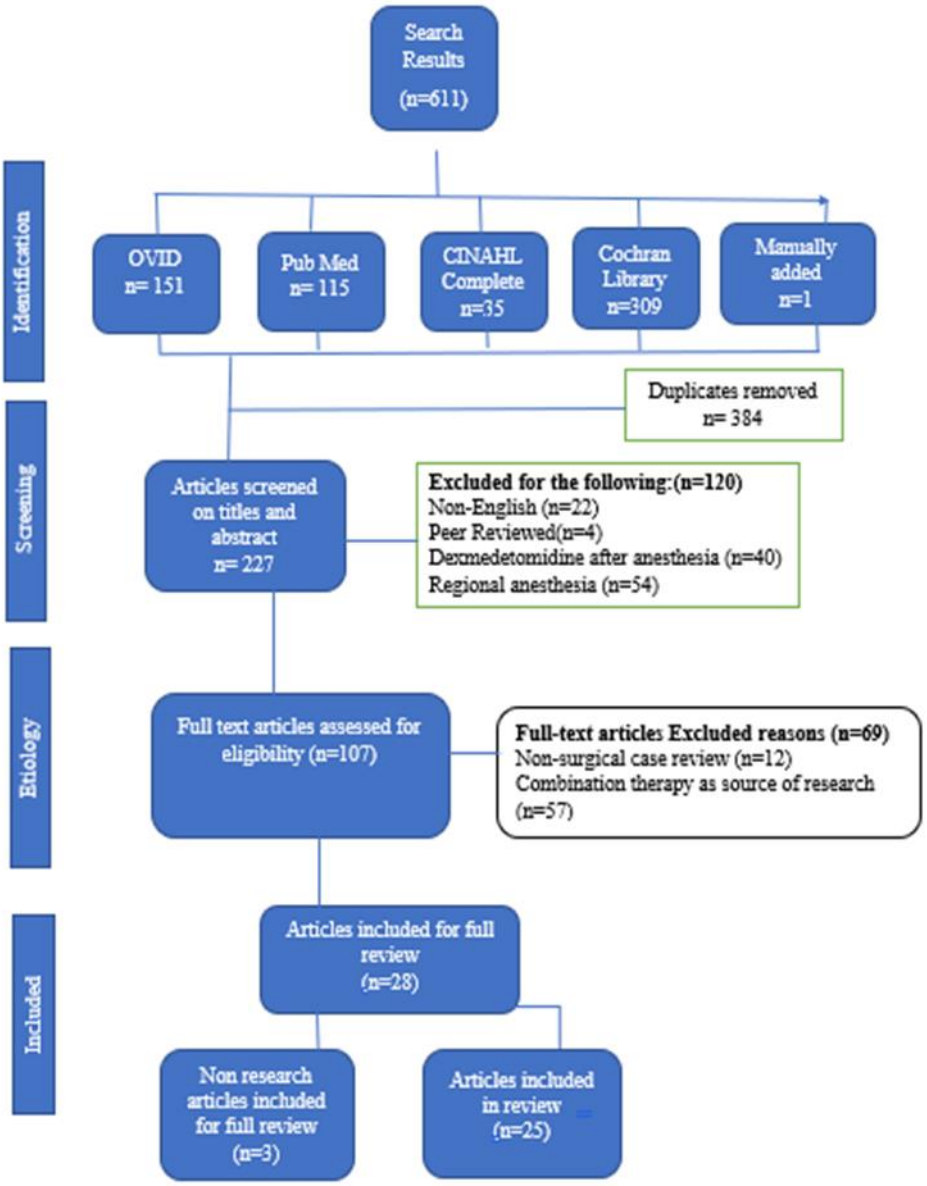
# Appendix A

## Search Strategy



# Appendix B

## EBP Model

**EBP Question: Does the use of dexmedetomidine during anesthesia for laparoscopic procedures reduce the opioid demand in recovery room/post-anesthesia care unit (PACU)?**

| Category (Level Type) | Total Number of Sources/Level | Overall Quality Rating | Synthesis of Findings Evidence That Answers the EBP Question |
|---|---|---|---|
| **Level I**<br>▪ Experimental study<br>▪ Randomized controlled trial (RCT)<br>▪ Systematic review of RCTs with or without meta-analysis<br>▪ Explanatory mixed method design that includes only a Level I quaNtitative study | IA = 10<br>IB = 15 | A/B | Dexmedetomidine consistently lowers total opioid utilization in general anesthesia cases.<br>Dexmedetomidine blunts<br>Reduced use and quantity of rescue opioid utilization.<br>There is a consistent and repeated benefit when dexmedetomidine is used during general anesthesia cases for postoperative side effects, including reduced nausea, vomiting, and overall PACU length of stay.<br>Dexmedetomidine provides hemodynamic stability, reduces postoperative delirium in elderly (age >70) |
| **Level II**<br>▪ Quasi-experimental studies<br>▪ Systematic review of a combination of RCTs and quasi-experimental studies, or quasi-experimental studies only, with or without meta-analysis<br>▪ Explanatory mixed method design that includes only a Level II quaNtitative study | N/A | N/A | N/A |
| **Level III**<br>▪ Nonexperimental study<br>▪ Systematic review of a combination of RCTs, quasi-experimental and nonexperimental studies, or nonexperimental studies only, with or without meta- analysis<br>▪ QuaLitative study or meta- synthesis<br>▪ Exploratory, convergent, or multiphasic mixed-methods studies<br>▪ Explanatory mixed method design that includes only a level III QuaNtitative study | N/A | N/A | N/A |

| Category (Level Type) | Total Number of Sources/Level | Overall Quality Rating | Synthesis of Findings Evidence That Answers the EBP Question |
|---|---|---|---|
| **Level IV**<br>▪ Opinions of respected authorities and/or reports of nationally recognized expert committees or consensus panels based on scientific evidence | IVA = 1 | A | Potentiates the use of opioids, reducing overall demand for narcotic analgesics<br>Suggested that using dexmedetomidine will reduce overall anesthetic requirements.<br>Predictable hemodynamics |
| **Level V**<br>▪ Evidence obtained from literature or integrative reviews, quality improvement, program evaluation, financial evaluation, or case reports<br>▪ Opinion of nationally recognized expert(s) based on experiential evidence | VA = 1<br>VB = 1 | A/B | No postoperative delirium when used without opioids. Pt experienced delirium in previous conventional anesthesia: a case report<br><br>Expert opinion that dexmedetomidine reduces the intraoperative opioid demand and reduces undesired side effects.<br>Use of dexmedetomidine preferred as a multimodal anesthesia practice. |

# Appendix C

## HSRC APPROVAL

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**WILMINGTON UNIVERSITY**
**HUMAN SUBJECTS REVIEW COMMITTEE (HSRC)** HSRC-1

**RECORD AND REVIEW OF DOCTOR OF NURSING PRACTICE (DNP) PROJECT**

Student: Krammes (Last) Mark (First) K (Middle Initial)

Student ID: W 00318337

DNP Project Chair: Dr. Aaron Sebach

**Academic Level**

☒ 1. DNP Project

**Forms Check List**

☒ 1. DNP Project Protocol

☒ 2. CITI Training Certificate*

* Check with the DNP Program Chair for training requirements
* Training certificate cannot be older than 3 years

☐ 3. Instrument(s) *(as needed)*

☐ 4. Other Click here to enter text.

*This section is to be completed by the HSR Committee*

Archive Number: Click here to enter text.

DNP Category: Choose an item.

Final Approval Date: Click here to enter a date.

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## Complete This Worksheet Prior to Completing This Form

**Purpose:** The purpose of this worksheet is to provide support for making Quality Improvement Project determinations when there is uncertainty regarding whether the quality activity contains Human Subjects.

**Directions:** For a proposed DNP project to be classified as containing only Quality Improvement activities—which permits use of the DNP HSRC form—answers to all of the questions in the worksheet must be 'TRUE' for each activity proposed in the DNP project. If one or more answers is 'FALSE', the project requires completion of the HSRC standard form and committee review.

| TRUE | FALSE | |
|---|---|---|
| ☒ | ☐ | The intent of the proposed activity is to assess and/or improve the quality of a practice, product or program to ensure established educational, clinical or program service standards are met or best evidentiary practices attained. |
| ☒ | ☐ | No activity proposed provides less than standard of care, services or instruction to participants. |
| ☒ | ☐ | No practice, product or program changes proposed are experimental and no test interventions or research questions are added that go beyond established or evidentiary best practice. |
| ☒ | ☐ | The proposed activity does not: (1) include a 'control group' in whom care, products, services or educational instruction are intentionally withheld to allow an assessment of its efficacy or (2) assign participants to receive different procedures, therapies or educational instruction based on a pre-determined plan such as randomization. |
| ☒ | ☐ | The proposed activity does not involve the prospective evaluation of a drug, procedure or device that is not currently approved by the FDA for general use (including "off-label" indications). |
| ☒ | ☐ | The proposed activity does not test an intervention or add research questions that go beyond established evidentiary best practice and/or are intended to generate generalizable knowledge. |
| ☒ | ☐ | The proposed activity would not increase harm—physical, psychological, social or economic—than would normally be encountered by the individual if s/he was not participating in this activity. |
| ☒ | ☐ | The lead person on the project has organizational responsibility and authority to recommend or impose a corrective action plan based on the outcome(s) of the activity, as applicable. |
| ☒ | ☐ | Interpretation of the data or any feedback to those who would benefit from the findings will not be deliberately delayed. |
| ☒ | ☐ | The proposed activity has merit and will likely be conducted regardless of any possibility of publication or presentation that may result from it. |

*Adapted from Rutgers HRP-309 (2017) with permission from Judith Neubauer, PhD.*

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## DNP Project Information

Title of DNP Project (12 to 15 words maximum):

Development and Evaluation of a Nurse Anesthetist Directed Dexmedetomidine Protocol for Patients Undergoing Laparoscopic Cholecystectomy in an Academic Medical Center

Problem Description:
Provide a short summary of the clinical practice problem you will address with your DNP project. What is the gap in practice and what evidence will you be translating to practice?

The opioid epidemic is a significant concern in the United States. In 2018, over 130 people died from opioid-related overdoses, 10.3 million people misused prescription opioids, and over two million people had a related opioid dependence (U.S. Department of Health and Human Services, 2019). The introduction of opioids in opioid naïve patients undergoing surgical procedures increases the incidence of chronic opioid use (Sun, Darnell, Baker, & Mackey, 2016). Opioids are effective in blocking pain pathways; however, undesirable side effects include nausea, vomiting, pruritus, respiratory depression, dysphoria, physical dependence, opioid-induced hyperalgesia, and contain immunosuppressant effects (Kremer & Griffis, 2018). The use of non-opioid anesthesia techniques reduce the exposure to opioids, modulate pain pathways requiring less postoperative exposure to opioids, reduce undesirable side effects of opioid analgesics, and effectively manage perioperative analgesia.

The use of Dexmedetomidine in a balanced anesthesia technique contributes to reducing opioid requirements in patients undergoing laparoscopic procedures for cholecystectomy (Zeeni, et al., 2019). Dexmedetomidine up to 1 mcg/kg, administered before surgical incision, reduces the requirement of inhaled anesthetic gas, the use of intraoperative opioids, and provides sedative properties (American Association of Nurse Anesthetists, 2016). Utilization of Dexmedetomidine does not increase the length of stay but is effective in reducing postoperative delirium, and side effects of opioid analgesics (Du, Song, Zhang, & Ma, 2019).

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## External Projects

If the DNP project involves other organizations, it may be necessary to obtain permission from these organizations prior to collecting data. Some organizations have Institutional Review Boards (IRBs), and it may be necessary to obtain formal approvals from these IRBs. In other cases, a document from an appropriate organizational executive, specifically approving the DNP project, would be sufficient. The DNP student is responsible for determining what type of approval is required and obtaining approval.

In cases where approval from Wilmington University's HSRC is required as a precondition to obtaining approval from another organization, the HRSC's approval will be provisional, requiring the additional step of obtaining DNP project approval documents from other organizations before receiving full approval from Wilmington University's HSRC.

If the DNP project involves other organizations, please answer these questions.

| | YES | NO |
|---|---|---|
| Do these organizations require approval by their IRBs? | ☒ | ☐ |
| Has IRB approval been obtained? If **YES**, please attach the approval to this submission | ☐ | ☒ |
| Have other permission documents been obtained? If **YES**, please attach the approvals to this submission. | ☐ | ☒ |

Other relevant information or comments:

Geisinger IRB approval is pending; application submitted July 2, 2020

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## Population Information

Population: Gender(s) All Age(s) ➢ 18 Race/ethnicity(ies) All

PICOT Question:
Include the PICOT Question in a complete sentence and then break down each section, Population -; Intervention -; Comparison -; Outcome -; Time -. Include sufficient detail so that someone unfamiliar with the project would understand all aspects of the proposed DNP project.

In patients over the age of 18 undergoing a laparoscopic procedure for cholecystectomy (P), how does Dexmedetomidine (DEX) administration before surgical incision (I) when compared to patients not receiving DEX (C) influence opioid utilization in the postoperative care unit (PACU) (O) over six weeks (T)?

P – (Patient, population, or problem) Patients over the age of 18 undergoing a laparoscopic procedure for cholecystectomy
I – (Intervention) how does Dexmedetomidine (DEX) administration before surgical incision
C- (Comparison) when compared to patients not receiving DEX
O- (Outcomes) influence opioid utilization in the postoperative care unit (PACU) (O)
T – (Time) over six weeks

How many participants (patients, providers, etc.) are anticipated for the DNP project?

The average number of elective laparoscopic cholecystectomy cases performed in the operating room at Geisinger Health System- Central Region is 20 cases every week. All counted cases meet inclusion criteria based on average numbers extracted from Epic© charting platform between July 1 and December 31, 2019. Based on the average case volume of candidates that meet inclusion criteria, I am estimating 50% inclusion for the quality analysis for a total of 60 cases. The estimated inclusion accounts for provider reluctance to use a new methodology and the introduction of new processes
There are 40 attending anesthesiologists, 14 resident anesthesiologists, more than 100 certified registered nurse anesthetists, and 17 student nurse anesthetists' students providing care at Geisinger Health System – Central Region.

How will participants be selected for participation? (from PICOT question)

Participation in the project will depend on the provider chooses to participate by using Dexmedetomidine as part of their anesthesia care plan. Patients will be excluded if they have an allergy to Dexmedetomidine, documented bradycardia, prolonged QT, liver dysfunction or kidney dysfunction based on pharmaceutical manufacturer's recommendations.
Participants scheduled for elective cholecystectomy, meeting inclusion criteria of greater than or equal to age 18, American Society of Anesthesiologists (ASA) classification I- III, will receive 1 mcg/kg of Dexmedetomidine, no greater than 10 mcg/min bolus, prior to surgical incision.

- Patients scheduled for elective laparoscopic cholecystectomy within the Geisinger Health System- Central Region, will administer Dexmedetomidine who meet inclusion criteria as listed above.
- The nurse anesthetist (CRNA) or anesthesia resident will obtain Dexmedetomidine from the operating room pharmacy and administer it as a standard of care for patients meeting inclusion criteria.
- The anesthesia provider will evaluate the patient during the routine preoperative examination for exclusion criteria, chart review, and patient interview.
- The administration of Dexmedetomidine will begin in the perioperative area in conjunction with preoperative sedation.
- Continued administration of Dexmedetomidine up to 1 mcg/kg, no faster than 10 mcg/min, will continue through induction of anesthesia before surgical incision. Standard induction will commence based on the patient's clinical presentation and the judgment of the anesthesia provider.
- The use of standard anesthesia management throughout the case, based on the anesthesia provider's professional judgment, will proceed using all aspects of anesthesia practice.
- When the case is complete, the patient will be discharged to the postoperative care unit for recovery from general anesthesia.
- The patient will be discharged to home based on American Society of Anesthesiologists (ASA) criteria for discharge.
- The evaluation period will commence on or about October 5, 2020, and run for six weeks.
- Every Friday, a query for elective laparoscopic cholecystectomy cases based on ICD – 10 coding's of patients age 18 and older will be sent to the project leader. The query will

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What are the procedures that the participants will undergo in the proposed DNP project including the physical location and duration of participation? Provide a step-by-step outline of the project from start to finish. **Attach a copy of all DNP instruments, e.g., surveys, questionnaires, interview questions, etc. (if being utilized):**

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contain the location of surgery, age, gender, race, weight in kilograms, the dosage of narcotic analgesics (Fentanyl, Morphine, Hydromorphone), and dosage of Dexmedetomidine. Additional queried information will include the presence of postoperative nausea/vomiting (+/-), Visual analog score (VAS) for determination of the level of discomfort, total time in the PACU, and Aldrete score. The additional queried information is current quality indicators for the anesthesia department.

- Calculation of total Morphine Milligram Equalevant (MME) will be determined by the primary investigator and placed in an Excel © file of all patients undergoing the procedure.
- Evaluation of all potential inclusion cases receiving Dexmedetomidine, based on location, will be reviewed for inclusion/exclusion criteria.
- Report findings of cases will be emailed to all anesthesia providers every two weeks until the project is complete.
- A final evaluation of findings will be reported to the anesthesia department chair, chief nurse anesthetist, and anesthesia providers.

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## Confidentiality and Security

Select **YES** to certify that:

| | YES | N/A |
|---|---|---|
| Procedures have been taken to ensure that individuals cannot be identified via names, digital identifiers (e.g., email address, IP address), images or detailed demographic information. | ☒ | ☐ |
| Code to name association data/information is securely and separately stored. (Participants are given codes and the codes are securely stored separately from their answers.) | ☐ | ☒ |
| All data is maintained in encrypted and/or password protected digital/electronic files. | ☒ | ☐ |
| Individually identifiable information will be securely maintained for three years past the completion of the research, and then destroyed rendering the data unusable and unrecoverable. | ☒ | ☐ |

Describe the procedures you are taking to maintain anonymity, confidentiality, or information security.

All cases included will be devoid of name, medical record number, and residence. Data extracted will include the procedure, drugs used during anesthesia and PACU (limited to narcotics and Dexmedetomidine), Visual Analog Score (VAS), total time in PACU, Aldrete Score, and presence of nausea/vomiting. Additional data will include age, birth, gender, and race.
All data will remain within the institutional server; data points will only be presented through data analytics processor for anesthesia extracted from the Epic © charting platform.
Data will be maintained on the institutional server for a period of three years, then permanently removed according to institutional policy.
All data for quality programs must be approved by the facility IRB and maintained within the facility according to organizational policy. The project leader will follow all institutional policies and procedures for EBP and quality programs.

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## DNP Protocol

Does this DNP project involve?

| | YES | NO |
|---|---|---|
| Prisoners, probationers, pregnant women (if there is a medical procedure or special risk relating to pregnancy), fetuses, the seriously ill or mentally or cognitively compromised adults, or minors (under 18 years) as participants | ☐ | ☒ |
| The collection of information regarding sensitive aspects of the participants behavior (e.g., drug, or alcohol use, illegal conduct, sexual behavior) | ☐ | ☒ |
| The collection or recording of behavior which, if known outside the research, could place the participants at risk of criminal or civil liability or could be damaging to the participant's financial standing, employability, insurability, or reputation | ☐ | ☒ |
| Procedures to be employed that present more than minimal risk[1] to participants | ☐ | ☒ |
| Deception | ☐ | ☒ |
| Possible or perceived coercion (e.g., a concern in power relationships such as teacher/student, employer/employee, senior/subordinate) | ☐ | ☒ |
| Benefits or compensation to participants (beyond the general benefits of the knowledge to be gained or small gifts/lottery prizes) | ☐ | ☒ |
| A conflict of interest (e.g., the researcher's material or other interests may bias collection, interpretation, or use of data) | ☐ | ☒ |

If you answered "**NO**" to all of the questions please proceed to the next page.

If you answered "**YES**" to any of the questions, provide evidence that you have taken the training module or modules that relate to this risk and discuss what you learned about reducing the risk from the training in the textbox below and/or by attaching the evidence to this document.

Click here to enter text.

[1] Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in everyday life or during the performance of routine physical or psychological examinations or tests

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## Obligations of DNP Student

Any substantive changes made to the DNP protocol must be reported to and reviewed by your college's HSRC representative(s) prior to implementation of such change. Any complications, adverse reactions, or changes in the original estimates of risks must be reported at once to the HRSC chairperson before continuing the project.

Select **YES** to certify that:

| | YES |
|---|---|
| DNP data will be retained for a minimum of three years past the completion of the project in accordance with federal regulations | ☒ |
| The DNP student will submit document and form revisions and updates, as appropriate | ☒ |
| The DNP student will submit a renewal petition if the data collection has not been completed within one year of the most recent HSRC approval* | ☒ |

* **Note**: HSRC approval expires after one year, requiring renewal of the HSRC Protocol

The DNP student's signature below certifies that he/she has (a) read and understands the obligations as a DNP student, (b) DNP project approval expires one year after the final approval date shown on page 1, and (c) that the information contained in and submitted with this HSRC protocol is accurate and complete.

***DNP Student***:

Print name: Mark K Krammes

Signature: *Mark Krammes* Date: 6/23/2020

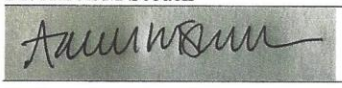
## Obligations of the DNP Project Chair

The DNP Project Chair has two major obligations. First, the DNP Project Chair must ensure the DNP Student completes all relevant training courses. Second, the DNP Project Chair must ensure the DNP Student submits all document and form revisions and updates, as appropriate for the research.

The DNP Project Chair's signature below certifies that he/she has (a) read and understands the obligations as a DNP Project Chair and (b) that the information contained in and submitted with this HSRC protocol is accurate and complete.

***DNP Project Chair***:

Print name: Dr. Aaron M Sebach

Signature:  Date: 6/29/2020

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**HUMAN SUBJECTS REVIEW COMMITTEE (HSRC)** HSRC-12

# PROTOCOL REVIEW

*This section is to be completed by the HSR Committee.*

DNP Student: Mark Krammes

Date Submitted: 7/7/2020

The protocol and attachments were reviewed:

The proposed DNP project is approved as:

☐ Exempt ☐ Expedited ☐ Full Committee ☒ Provisional (see External Projects section)

The proposed DNP project was approved pending the following changes:

☐ See attached letter

☐ Resubmit changes to the HSRC chairperson

The proposed DNP project was disapproved:

☐ See attached letter for more information.

| | YES | N/A |
|---|---|---|
| The HSRC representative sent a copy of the HSRC Protocol to the VP of Academic Affairs for research requiring access to Wilmington University students, employees, or data. | ☐ | ☒ |

HSRC Chair or Representative: Angela Herman, DNP, RN
Printed Name

Angela Herman, DNP, RN
Signature

Date 7/7/2020

HSRC Chair or Representative: Click here to enter text.
Printed Name

Signature

Date Click here to enter a date.

# Appendix D

## Geisinger IRB Approval

**Geisinger Institutional Review Board (GIRB)**
FWA # 00000063 IRB# 00008345

100 N. Academy Avenue
Danville, PA 17822-3069
570-271-8663
IRB@geisinger.edu

Geisinger

**IRB Determination Notice**
**Activity Does Not Meet the Definition "Research"**

July 21, 2020

Rebecca S Stoudt DNP PhD CRNA
GMC - Anesthesiology

IRB **#: 2020-0598 (Dex for Lap Chole)**, entitled **Development and Evaluation of a Nurse Anesthetist Directed Dexmedetomidine Protocol for Patients Undergoing Laparoscopic Cholecystectomy a Non-Randomized Prospective Study**

RE: Initial Review Submission Form, 07/17/2020 03:59:49 PM EDT

Dear Rebecca S Stoudt DNP PhD CRNA:

The above proposal was reviewed on 07/21/2020 by Geisinger IRB staff/member(s).

From the information you have provided, the proposal does not meet the definition of *Research* as defined in 45 CFR 46.102(d): *a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge*. Therefore, this proposal is not subject to human subjects research regulations and does not require oversight by Geisinger Institutional Review Board (GIRB). This means you do not need to submit your proposal to the IRB for further review/approval. However, this proposal may be subject to other non-research regulations, institutional policies or requirements.

If APPLICABLE: **Case reports** of 3 or less individuals are not research. However, Geisinger has other requirements that must be completed prior to submitting case report(s) for external presentation or publication:

- It is important to adhere to any applicable publication guidelines for informed consent.
- We recommend that you obtain permission from the patient(s) to use their information to generate your case report(s) using the *CONSENT FOR THE PUBLICATION OF MEDICAL IMAGES, RESULTS, AND CLINICAL INFORMATION IN A MEDICAL JOURNAL*.
- You must also obtain HIPAA compliant authorization signed by the patient (or his/her legally authorized representative) to submit your case report for publication or presentation if it is not fully de-identified in compliance with Geisinger policies. If the publishing entity requires you to submit the signed patient consent, your case report is NOT de-identified and requires this signed patient authorization. Please note the authorization cannot be combined with any other form.

Full Accreditation

Geisinger

- If you do not obtain written HIPAA authorization, your de-identified case report(s) must be submitted to the Privacy Office at systemprivacyoffice@geisinger.edu for review and approval.
    - Use the subject line: *Research Case Review*
    - Include where you wish to publish or present the case report(s).

If you have questions or need assistance, please contact Geisinger IRB at (570) 271-8663 or via email (irb.geisinger.edu).

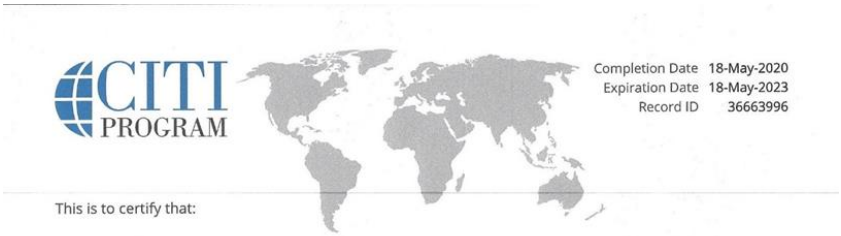
Sincerely,

Geisinger Institutional Review Board (IRB)

cc: Mark Krammes

# Appendix E

## CITI Training Certificates



CITI PROGRAM

Completion Date 18-May-2020
Expiration Date 18-May-2023
Record ID 36663996

This is to certify that:

**Mark Krammes**

Has completed the following CITI Program course:

Not valid for renewal of certification through CME. Do not use for TransCelerate mutual recognition (see Completion Report).

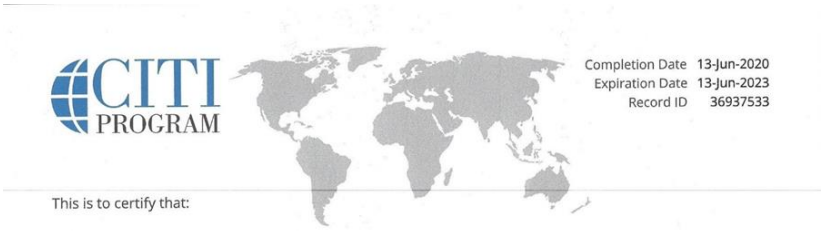
**Human Subjects Research** (Curriculum Group)
**Health Professions - Human Subjects Research** (Course Learner Group)
**1 - Basic** (Stage)

Under requirements set by:

**Wilmington University**

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w2dbaeafe-5746-4440-a9e5-911fe65a222d-36663996



CITI PROGRAM

Completion Date 13-Jun-2020
Expiration Date 13-Jun-2023
Record ID 36937533

This is to certify that:

**Mark Krammes**

Has completed the following CITI Program course:

Not valid for renewal of certification through CME. Do not use for TransCelerate mutual recognition (see Completion Report).

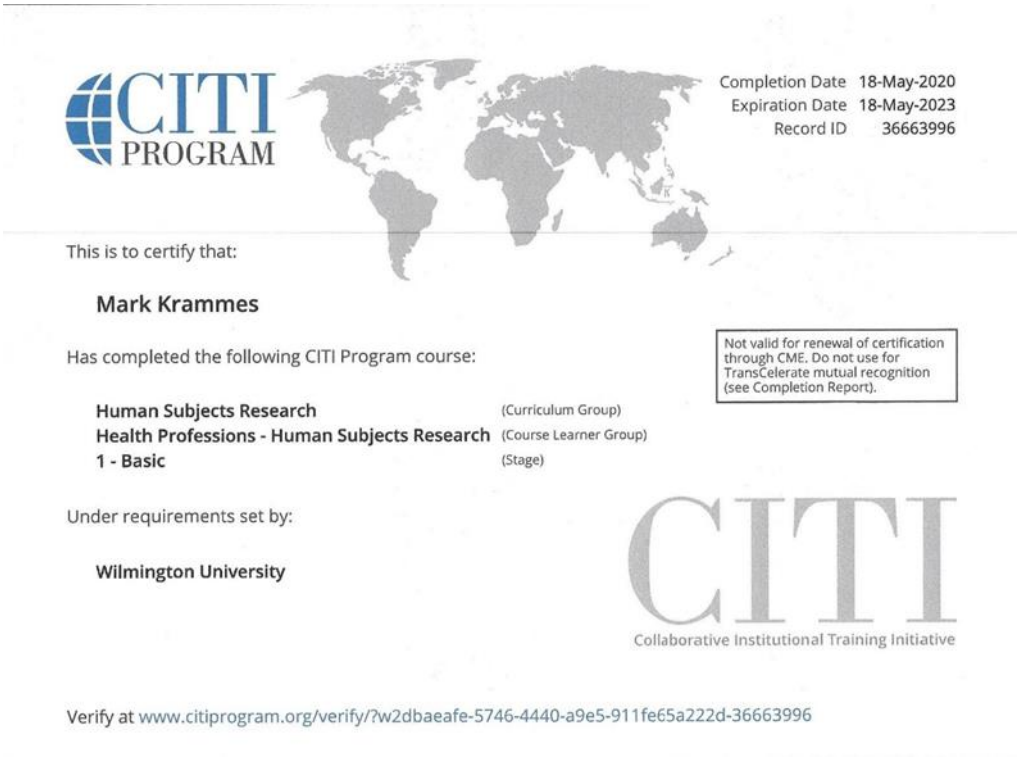
**CITI Good Clinical Practice** (Curriculum Group)
**CITI Good Clinical Practice Course** (Course Learner Group)
**1 - GCP** (Stage)

Under requirements set by:

**Geisinger**

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w73725c81-f6d0-4d2a-ac18-315f48c2f8ec-36937533



CITI PROGRAM

Completion Date 18-May-2020
Expiration Date 18-May-2023
Record ID 36663996

This is to certify that:

**Mark Krammes**

Has completed the following CITI Program course:

Not valid for renewal of certification through CME. Do not use for TransCelerate mutual recognition (see Completion Report).

**Human Subjects Research** (Curriculum Group)
**Health Professions - Human Subjects Research** (Course Learner Group)
**1 - Basic** (Stage)

Under requirements set by:

**Wilmington University**

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w2dbaeafe-5746-4440-a9e5-911fe65a222d-36663996

CITI PROGRAM

Completion Date 10-Jun-2020
Expiration Date 10-Jun-2023
Record ID 36937534

This is to certify that:

**Mark Krammes**

Has completed the following CITI Program course:

Not valid for renewal of certification through CME. Do not use for TransCelerate mutual recognition (see Completion Report).

**RCR for Researchers, Research Staff, and Administrators** (Curriculum Group)
**RCR for Researchers, Research Staff, and Administrators** (Course Learner Group)
**1 - Basic Course** (Stage)

Under requirements set by:

**Geisinger**

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?wd3b09401-f000-4608-ba0f-aefb85e8d3af-36937534

# Appendix F

## Budget

DEX BUDGET PROPOSAL 5

| | 2020 | 2021 | 2022 | Notes |
|---|---|---|---|---|
| INCOME | | | | |
| Case Volume | 780 | 800 | 820 | Anticipated growth based on 5-year trend |
| Cost savings PACU | $11,700.00 | $12,000.00 | $12,300.00 | 5 min reduced discharge time related to the absence of postoperative anesthesia complications. PACU time calculated at $3/min |
| EXPENCES | | | | |
| Data Abstractor | $500.00 | $250.00 | $250.00 | Allocate 8 hours for the initial setup in Tableau. 2 hours per quarter for revisions. $31.60/hour average |
| Admin Assist Time | $145.00 | $145.00 | $145.00 | Distribution of quarterly findings to anesthesia staff 2 hours per quarter. $18.00/hr average |
| QA Coordinator | $276.00 | $276.00 | $276.00 | Synthesis and distribution of data, 2 hours per quarter $34.50/ hour |
| IT Time | $590.00 | $590.00 | $590.00 | Initial setup of "alerts," revisions and updates. 5 hours/quarter $29.50/hr |
| Education | $420.00 | $420.00 | $420.00 | The project chair establishes educational materials as part of the DNP project, no cost. Placement into SharePoint, with edits/updates 1 hour/quarter at $105/hr |
| Drug cost | $3,120.00 | $3,200.00 | $3,280.00 | Compounding: syringe, normal saline, dexmedetomidine, and labeling: $2.00 /syringe (40 mcg/10 ml) average use of two (2) syringes based on 80 kg. |
| Pharmacist | $7,020.00 | $7,020.00 | $7,020.00 | Compounding an expected additional 10 syringes/day (15 min/day) x 5 working days (78 hours/yr) $90.00/hr |
| Office Supplies | $200.00 | $50.00 | $50.00 | Presentation of flyers for the initial introduction, educational materials |
| Total Expences | $12,271.00 | $11,951.00 | $12,031.00 | |
| Cost Savings | $11,700.00 | $12,000.00 | $12,300.00 | |
| Profit | (571.00) | $ 49.00 | $ 269.00 | The project remains budget neutral if 5 min earlier discharge is realized |