

Fall 12-2015

## **Intravenous Acetaminophen Reduces Opioid Use for Postoperative Pain in Obese Patients Undergoing Laparoscopic Cholecystectomy**

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INTRAVENOUS ACETEMINOPHEN REDUCES OPIOID USE FOR  
POSTOPERATIVE PAIN IN OBESE PATIENTS UNDERGOING  
LAPAROSCOPIC CHOLECYSTECTOMY

by

Kimberly Shae Burks

Abstract of a Capstone Project  
Submitted to the Graduate School  
and the Department of Advanced Practice  
at The University of Southern Mississippi  
in Partial Fulfillment of the Requirements  
for the Degree of Doctor of Nursing Practice

December 2015

## ABSTRACT

# INTRAVENOUS ACETEMINOPHEN REDUCES OPIOID USE FOR POSTOPERATIVE PAIN IN OBESE PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY

by Kimberly Shae Burks

December 2015

Opioid-induced respiratory depression is categorized as a sentinel event, which is an unanticipated occurrence that may result in severe injury or death. Although the incidence of opioid-induced respiratory depression is 0.2 to 2%, this issue persists as a substantial basis of morbidity and mortality. The obese population has multiple physiologic elements that increase their risk for opioid-induced respiratory depression. This retrospective study examined if intravenous (IV) acetaminophen reduces opioid consumption in the postoperative period in obese patients who underwent a laparoscopic cholecystectomy. Adequately controlled postoperative pain provides for greater patient satisfaction, decreased hospital length of stay (LOS), and reduced costs for the medical facility. The inclusion criterion comprised patients within the ages of 18 to 65, a body mass index (BMI) greater than 30, and those who underwent a laparoscopic cholecystectomy at the designated medical facility. Exclusion criteria included patients with a known allergy to acetaminophen, severe hepatic impairment, chronic alcoholism or use of opioids, and malnutrition; severe hypovolemia, or renal impairment. The independent group t-test was used to compare the (a) amount of opioids administered in the post anesthesia care unit (PACU), (b) amount of opioids administered for the entire LOS, and (c) LOS between the two groups. There was a significant difference found in

all of these factors. A considerable finding of this capstone project was the mean cost for patients who received IV acetaminophen was \$1,143.60, compared to \$1,406.00 for those who did not receive IV acetaminophen. This price difference was due to the variance in the total LOS.

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December 2015

## DEDICATION

I would like to sincerely thank my parents, Jean and Randy Blakeney, and grandparents, Charles and Thelma Waltman, for instilling in me the determination to achieve anything I put my mind to. To my sisters, Krystal Pollard and Karen McAlpin, thank you for your conviction and assurance in my abilities to accomplish this dream. I would like to also thank the rest of my family for their patience and encouragement while completing this capstone project. I would like to thank most of all our Lord, Jesus Christ, for his love and guidance.

This capstone project is dedicated to my mother, Jean Blakeney, who has shown unwavering love and support in all I have attempted and accomplished throughout my life.

## ACKNOWLEDGMENTS

I would like to thank my committee chair, Dr. Vickie Stuart, for all her assistance. I would also like to thank my committee member, Dr. Bonnie Harbaugh, for her valuable input and advice. In addition, I would like to extend my sincerest gratitude to my committee member, Dr. Lachel Story, for her additional support in all research related items and statistical analysis. Furthermore, I would also like to acknowledge Dr. James T. Johnson for assisting me with the statistical analysis. I could not have completed this capstone project without each one of you.



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## LIST OF ABBREVIATIONS

<i>AACN</i>	American Association of the College of Nursing
<i>ADE</i>	Adverse drug events
<i>APSF</i>	Anesthesia Patient Safety Foundation
<i>BB</i>	beta blocker
<i>BMI</i>	body mass index
<i>CAD</i>	coronary artery disease
<i>CDC</i>	Centers for Disease Control and Prevention
<i>CI</i>	confidence interval
<i>CNS</i>	Central nervous system
<i>CO<sub>2</sub></i>	Carbon dioxide
<i>COPD</i>	Chronic obstructive pulmonary disease
<i>CXR</i>	chest radiograph
<i>D/C</i>	discharge
<i>DHHS</i>	Department of Health and Human Services
<i>DL</i>	direct laryngoscopy
<i>DM</i>	diabetes mellitus
<i>DVT</i>	Deep vein thrombosis
<i>EBL</i>	estimated blood loss
<i>EKG</i>	electrocardiograph
<i>eMAR</i>	electronic medication administration record
<i>EMR</i>	Electronic medical record
<i>ETT</i>	endotracheal tube

<i>FDA</i>	Food and Drug Administration
<i>FRC</i>	Functional residual capacity
<i>GA</i>	general anesthesia
<i>GI</i>	Gastrointestinal
<i>HITECH</i>	Health Information Technology for Economic and Clinical Health
<i>HTN</i>	hypertension
<i>ICU</i>	Intensive care unit
<i>IV</i>	Intravenous
<i>IVF</i>	intravenous fluid
<i>LOS</i>	Length of stay
<i>ME</i>	Morphine equivalent
<i>Mcg</i>	microgram
<i>mg</i>	milligram
<i>ml</i>	milliliter
<i>MI</i>	Myocardial infarction
<i>MP</i>	mallampati classification
<i>NSAID</i>	Nonsteroidal anti-inflammatory drug
<i>N/V</i>	nausea and vomiting
<i>O<sub>2</sub></i>	oxygen
<i>OA</i>	osteoarthritis
<i>ORADE</i>	Opioid related adverse drug event
<i>OSA</i>	Obstructive sleep apnea
<i>PaCO<sub>2</sub></i>	Partial pressure of carbon dioxide

<i>PACU</i>	Postanesthesia care unit
<i>PE</i>	Pulmonary embolism
<i>PEN</i>	patient encounter number
<i>PICO</i>	Problem, Intervention, Comparison, Outcome
<i>PID</i>	Pain intensity difference
<i>PIN</i>	patient identification number
<i>PMH</i>	personal medical history
<i>PNA</i>	Pneumonia
<i>PNB</i>	Peripheral nerve block
<i>PONV</i>	Postoperative nausea and vomiting
<i>TKA</i>	Total knee arthroplasty
<i>TOF</i>	train of four
<i>U.S.</i>	United States of America
<i>VAS</i>	Visual Analog Scale
<i>VS</i>	vital signs
<i>V/Q</i>	Ventilation/Perfusion
$X^2$	Chi Square test
$\delta$	Delta
<i>K</i>	Kappa
<i>M</i>	Mu

## CHAPTER I

### INTRODUCTION

The management of postoperative pain is essential to many aspects of the healing process after an invasive surgical procedure. The opioid class of pain medication has and continues to be the drug of choice for the relief of pain in the perioperative setting due to their effectiveness, but these medications have numerous side effects that could cause morbidity or even mortality (Casati & Putzu, 2004). The obese population has multiple physiologic elements that increase their risk for opioid-induced respiratory depression. In addition to the potential adverse pharmacodynamic effects of opioid consumption, the physiological and pathophysiological alterations associated with obesity pose an increased risk for developing respiratory depression in the postoperative period in the presence of opioid administration (Nagelhout, 2014b). The changes of obesity coupled with the adverse side effects of opioids could lead to respiratory or cardiac arrest during the postoperative period.

#### Clinical Question

Obesity is prevalent in Mississippi, and many of these patients subsequently are diagnosed with cholecystitis/cholelithiasis, which requires surgical removal of the gallbladder. A clinical question was developed to determine if intravenous (IV) acetaminophen reduces the amount of opioid administration for postoperative pain in the post anesthesia care unit (PACU). A decrease in opioid administration for postoperative pain in the PACU could improve patient safety, patient satisfaction, and cost-effectiveness. The population of interest was patients undergoing a routine procedure, laparoscopic cholecystectomy, which was chosen because the convenience sample



reflects the demographics of the population in Mississippi exhibiting obesity and cholecystitis requiring surgical intervention. Oral and rectal acetaminophen has been used for several years and has been proven safe and effective. The IV formulation of acetaminophen, Ofirmev® (acetaminophen) was approved for administration in the United States of America (U.S.) in 2010 and was utilized at the approved clinical site for postoperative pain relief until a drastic price increase. Therefore, the following clinical question was established: Does IV acetaminophen reduce opioid use for postoperative pain in obese patients undergoing laparoscopic cholecystectomy?

#### Problem Statement

Postoperative pain has the potential to produce several undesirable problems; therefore, opioid drugs are frequently administered for moderate to severe pain. Opioid drugs reduce pain by depressing the central nervous system (CNS) unfortunately, “analgesia and respiratory depression are mediated by the same receptor” (Nagelhout, 2014a, p. 149). Opioid drug properties are potentiated by certain medical conditions including obesity, obstructive sleep apnea (OSA), and abdominal distention (Macintyre, Loadsman, & Scott, 2011). The effects of opioids are further exacerbated, as well as the risk of apnea and hypoxemia because obese patients have (a) decreased lung compliance, (b) increased ventilation/perfusion (V/Q) mismatch, (c) diminished functional residual capacity (FRC), and (d) increased oxygen consumption (Argalious, 2009).

#### Purpose of the Project

The purpose of this capstone project is to produce a practice change in order to reduce the amount of opioids administered for postoperative pain to obese patients after undergoing a laparoscopic cholecystectomy and, therefore, reducing the opioid-related

adverse drug events (ORADE) in this population. This study determined if obese patients undergoing laparoscopic cholecystectomy receiving IV acetaminophen require less opioid narcotics for postoperative pain management as compared to patients who did not receive IV acetaminophen. Variables, including body mass index (BMI), gender, age, ethnicity, smoking status, American Society of Anesthesiologist (ASA) classification, total anesthesia time, time from IV acetaminophen to surgery start, total PACU time, total length of stay (LOS), amount of Dilaudid® (hydromorphone) given in the PACU, amount of hydromorphone given for the total LOS, adverse events experienced in and after the PACU, and discharge status. Findings of this capstone project were disseminated to key stakeholders in a white paper proposal. A white paper proposal is used to advocate a solution to a particular problem (The Writing Lab, The OWL at Purdue, & Purdue University, 2010). This white paper proposal is intended to show the benefits of administering IV acetaminophen to obese patients undergoing a laparoscopic cholecystectomy to decrease opioid consumption for postoperative pain, and therefore, minimize ORADEs.

### Background and Significance

Postoperative pain has the potential to produce several undesirable complications; therefore, opioid drugs are frequently administered for moderate to severe pain. Unfortunately, opioid administration may have detrimental outcomes, while relieving postoperative pain. The two most serious ORADEs include unintended advancing sedation and respiratory depression. (Jarzyna, et al., 2011). According to Overdyk, DeVita, and Pasero (2012), half of the patients that experience adverse respiratory events after surgery are those receiving opioids. Patients who are at an increased risk of over-

sedation and respiratory depression include (a) obese individuals, (b) patients with OSA, and (c) patients of advanced age (The Joint Commission, 2012).

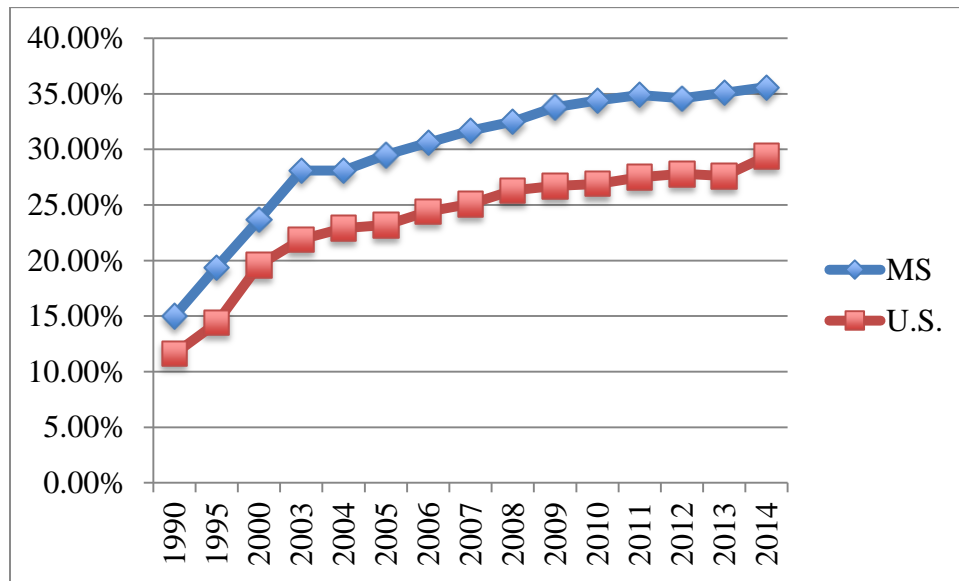
### *Obesity*

Obesity is a common occurrence in the U.S. According to the Centers for Disease Control and Prevention (CDC), the latest adult obesity rate for the U.S. and Mississippi is 35.7% and 34.6%, respectfully (CDC, 2014a; CDC, 2014b). An obese patient requiring surgery presents multiple challenges for the anesthetist managing the airway, hemodynamic parameters, and drug therapy during the perioperative and postoperative period.

Over the past 3 decades, the prevalence of morbid obesity has tripled (Ingrande, Brodsky, & Lemmens, 2009). “Over the past decade, the prevalence of obesity in the world has dramatically increased across all age groups, especially in developed countries” (Xie, Waters, & Schirra, 2012, p. 1). The obesity problem is rampant throughout the U.S., with 35.7% of Americans classified as obese (CDC, 2014a). In 2011, 9 states have obesity rates above 30% (Lowry, 2012). It has been forecasted that by 2030, 2.16 billion adults will be overweight and 1.2 billion or over 44% will be obese worldwide (Levi, Segal, St. Laurent, Lang, & Rayburn, 2012; Popkin, Adair, & Ng, 2012).

The obesity rates have been increasing for some time, especially in Mississippi. Mississippi topped the obesity charts for 8 years consecutively, from 2004 to 2011. In 2012, Mississippi came in a close second to Louisiana; and in 2013, Mississippi was tied with West Virginia for first place at a rate of 35.1% (Trust for America’s Health &

Robert Wood Johnson Foundation, 2014). If Mississippians continue on the current path, obesity rates are projected to rise to 66.7% by 2030 (Levi et al., 2012).



*Figure 1.* Mississippi and U.S. obesity rates over time. Information gathered from United Health Foundation, American Public Health Association (APHA), Partnership for Prevention, 2014; Trust for America’s Health, Robert Wood Johnson Foundation, 2015

Obesity has been associated with increasing the risks of many preventable diseases and health issues, including: (a) type 2 diabetes (DM), (b) hypertension (HTN), (c) certain types of cancer, (d) OSA, (e) coronary artery disease (CAD), (f) stroke, (g) arthritis, (h) dyslipidemia, (i) metabolic syndrome, (j) osteoarthritis (OA), and (k) Alzheimer’s disease (Hindle & Mills, 2012; Edey, 2012; Xie et al., 2012; Yaskin, Tones, & Goldfarb, 2009). Obesity can also cause an individual to suffer from: (a) chronic pain, (b) inflammation, (c) gallstones, and (d) reduced fertility in women (Crawford, 2010; Kanasaki & Koya, 2010; Wikstrand, Torgerson, & Bostrom, 2010).

Obesity is often times correlated to OSA, which decreases the oxygen carried in the blood (Hall, 2011; Kanasaki & Koya, 2010). An increase in abdominal fat corresponds to an increase in instances of OSA due to the “upper airway mechanical

loads and/or decreasing compensatory neuromuscular responses” (Schwartz et al., 2008, p. 188). OSA also increases the risk of developing DM, CAD, and HTN (Kanasaki & Koya, 2010).

Obesity is related to a decrease expansion of the intrathoracic cavity and accompanying decrease in alveolar ventilation, and FRC (Macintyre et al., 2011). General anesthesia (GA) further exacerbates these deficits, and consequently alters gas exchange more drastically in obese patients. The consequences of GA continue into the postoperative period; therefore, obese patients are at an increased risk of pulmonary complications during this time (Hans, Lauwick, Kaba, Brichant, & Joris, 2009). Because of the increased adipose tissue in obese patients, the volume of distribution is increased for all lipophilic pharmacodynamics agents (Nagelhout, 2014b).

#### *Laparoscopic Cholecystectomy*

A cholecystectomy is the removal of the gallbladder, and can either be performed as an open or a laparoscopic procedure. The precipitating factor for requiring this procedure is either symptomatic gallstones or acute cholecystitis (Curet, Fanning, Brodsky, & Carvalho, 2009). Cholecystitis is “inflammation of the gallbladder epithelium, often resulting from low-grade chronic infection” (Hall, 2011, p. 786). Gallstones are formed from: “(a) too much absorption of water from bile, (b) too much absorption of bile acids from bile, (c) too much cholesterol in bile, and/or (d) inflammation of epithelium” (Hall, 2011, p. 786).

The first laparoscopic cholecystectomy was performed in 1985 by a German surgeon 103 years after the first cholecystectomy in 1882. Since 1985, the laparoscopic approach has become the gold standard (Reynolds, 2001), the quantity of

cholecystectomy procedures performed in the U.S. has increased from around 500,000 to 700,000 per year (Collins & McDowell, 2014).

The laparoscopic approach to the cholecystectomy is preferred because it is minimally invasive and allows for a quicker recovery than an open approach. “Laparoscopic cholecystectomy may be contraindicated for patients with uncorrectable coagulopathy, severe chronic obstructive pulmonary disease (COPD), or severe cardiac disease (unable to tolerate increased intraabdominal pressure)” (Curet et al., 2009, p. 575). An increased risk of having to convert to an open procedure exists if the patient has had an open abdominal procedure in the past, or if the patient has acute cholecystitis (Curet et al., 2009).

The liver secretes bile, which helps emulsify fat particles into ones that the body can absorb and use and assists in absorbing digested fat byproducts through the intestinal mucosa. Bile also assists in removing waste products from the blood and excreting them by way of the intestinal tract. After bile is secreted from the liver, it travels in the bile canaliculi into the terminal bile ducts until it reaches the hepatic duct and the common bile duct. From here, bile either enters the duodenum or the cystic duct and into the gallbladder. The gallbladder serves as a storage center for bile, holding 30 to 60 milliliters, until it is needed in the duodenum (Hall, 2011).

### *Postoperative Pain*

“Pain is a subjective feeling, and the perception of pain (pain threshold) can be influenced by affective (emotional), behavior, cognitive (beliefs and attitudes), sensory (perceptual), and physiologic factors” (Story, 2012, p. 428). The two major classifications of pain include fast pain and slow pain. Fast pain is perceived within 0.1

seconds after the incident, and slow pain is perceived after 1 second and increases in intensity. Pain experienced from surgery includes both fast pain (surgical incision) and slow pain (tissue destruction). Pain is elicited from mechanical, thermal, and/or chemical stimuli. Unlike other sensory receptors in the body, pain receptors do not become sensitized. As the pain persists, the pain receptors escalate in sensitivity, called hyperalgesia (Hall, 2011).

Postoperative pain can be detrimental to the recovery of the patient, no matter what the surgical procedure is. A few consequences of postoperative pain include HTN, tachycardia, and increased myocardial workload (Fowler & Spiess, 2013). “Insufficient pain control in the postoperative period favors rapid and shallow breathing” (Hans et al., 2009, p. 172). “Negative clinical outcomes resulting from ineffective postoperative pain management include deep vein thrombosis (DVT), pulmonary embolism (PE), coronary ischemia, myocardial infarction (MI), pneumonia (PNA), poor wound healing, insomnia, and demoralization” (Apfelbaum, Chen, Mehta, & Gan, 2003, p. 534). “Postoperative pain is associated with various complications and poor outcomes, including longer times to ambulation, longer hospital lengths of stay, higher rates of medical complications (e.g., venous thromboembolic disease from reduced activity), and decreased patient satisfaction” (Viscusi, Singla, Gonzalez, Saad, & Stepanian, 2012, p. 1).

#### *Intravenous Acetaminophen*

A possible solution to the management of postoperative pain relief without respiratory depression in obese patients in the PACU includes the addition of IV acetaminophen to opioid administration. Acetaminophen has been used for over 100 years in the oral and rectal forms to treat fever, headache, and dysmenorrhea (Ramasubbu

& Gupta, 2013). An IV preparation of acetaminophen, Perfalgan (paracetamol), was approved in 2001 for use outside the U.S., in nearly 80 countries (Buck, 2011). In November 2010, the Food and Drug Administration (FDA) approved Ofirmev® (acetaminophen) “for (a) the management of mild to moderate pain, (b) the management of moderate to severe pain with adjunctive opioid analgesics, and (c) the reduction of fever” in patients greater than 2 years old (Department of Health and Human Services [DHHS], Public Health Service, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, 2012, p. 2).

Acetaminophen’s mechanism of action remains uncertain despite being a relatively safe, effective medication. Some of the theories regarding the mechanism of action include (a) inhibition of cyclooxygenase activity and prostaglandin creation, (b) interaction or activation of endogenous pain pathways, and (c) increase in cannabinoid-like activity (Golembiewski, 2011; Ramasubbu & Gupta, 2013). Acetaminophen has insignificant effects on the circulatory, pulmonary, and coagulation systems when staying within the recommended dosages, which is less than 4 grams per day, regardless of the route of administration (Ramasubbu & Gupta, 2013; Mallinckrodt Pharmaceuticals, 2014). In cases where the patient consumed more than the recommended daily allowance, acute liver failure and death occurred in some cases (Mallinckrodt Pharmaceuticals, 2014).

Acetaminophen can be administered through three different routes. The oral form of acetaminophen has good bioavailability, 30-45 minute onset of analgesia, and the maximum analgesia is within 60 minutes of consumption. The rectal form of acetaminophen has unpredictable bioavailability, the onset of analgesia is 2 hours, and



the maximum analgesia is achieved in 2-5 hours after administration. The IV form of acetaminophen has excellent bioavailability, the onset of analgesia is less than 10 minutes, and the maximum analgesia is achieved in 15 minutes (Golembiewski, 2011).

Table 1

*Acetaminophen route comparison*

Route of Administration	Bioavailability	Onset of Analgesia	Maximum Analgesia
Intravenous	100%	10 minutes	15 minutes
Oral	60 – 70%	30-45 minutes	60 minutes
Rectal	30-40%	2 hours	2-5 hours

IV acetaminophen can be administered as a single dose or repeated dose as a 15-minute infusion. IV acetaminophen is contraindicated in patients with (a) a known allergy to acetaminophen, (b) severe active liver disease, or (c) severe hepatic impairment. Administer IV acetaminophen with caution in patients with (a) chronic malnutrition, (b) chronic alcohol consumption, (c) profound hypovolemia, or (d) a creatinine clearance less than or equal to 30 mL/min. The most common side effects of IV acetaminophen administration in adults include (a) nausea, (b) vomiting, (c) insomnia, and (d) headache (Mallinckrodt Pharmaceuticals, 2014).

In January 2011, the FDA released a safety announcement requesting drug manufacturers to limit the quantity of acetaminophen used in prescription medications to 325 milligrams (mg) and add a boxed warning. This press release is in response to the increased consumption of acetaminophen from various medications, unbeknownst to the

consumer, which may result in liver failure or accidental overdose (FDA, 2014).

“Acetaminophen is an active ingredient in hundreds of over-the-counter (OTC) and prescription medications,” including those that relieve symptoms for cough, colds, flu, allergies, sleeplessness, pain, and fever (FDA, 2015). However, acetaminophen is still a safe drug if the maximum daily allowance is not exceeded.

### *Multimodal Pain Management*

Most anesthetists utilize the concept of multimodal pain management during the intraoperative period. According to Young and Buvanendran (2012), “multimodal analgesia captures the effectiveness of individual agents in optimal dosages that maximize efficacy and attempts to minimize side effects from one analgesic” (p. 91). Generally, the use of multiple analgesic medications is associated with fewer adverse effects, enhanced pain relief, improved patient outcomes, and greater patient satisfaction (Williams & Buvanendran, 2009). A multimodal analgesic approach is advantageous for all surgery patients, especially for the obese patients due to the reduction of opioid administration and associated side effects (Hans et al., 2009).

IV acetaminophen is a valuable component in multimodal pain analgesia for most patients. IV acetaminophen “produces its analgesic effect by inhibiting central prostaglandin synthesis with minimal inhibition of peripheral prostaglandin synthesis” (Williams & Buvanendran, 2009, p. 118). IV acetaminophen is relatively safe and does not produce the unwanted side effects of opioids (respiratory depression, decreased gastric motility, and increased risk of substance abuse) or nonsteroidal anti-inflammatory drugs (NSAIDs) (impair platelet function or impaired renal function) (Viscusi et al., 2012).

## *Opioids*

Opium, “the brownish residue observed after the poppy’s juice is desiccated,” is the basis of over 20 opiate alkaloids (Ogura & Egan, 2013, p. 253). “Opioid is a term used to refer to a group of drugs, both naturally occurring and synthetically produced, that possess opium- or morphine-like properties” (Nagelhout, 2014a, p. 145).

The first IV opioid was administered in 1853, after the invention of the syringe and needle. However, Greek literature refers to opium being used as early as 300 BC (Nagelhout, 2014a).

According to Ogura and Ergan (2013), the term opioid “is used to designate all substances, both natural and synthetic, that bind to opioid receptors (including antagonists)” (p. 253). There are three major opioid receptors in the human body, including mu ( $\mu$ ), Kappa ( $\kappa$ ), and delta ( $\delta$ ) (Scott & Ballantyne, 2013). Stimulation of the  $\mu$  opioid receptor produces the following effects: (a) supraspinal and spinal analgesia; (b) bradycardia; (c) respiratory depression; (d) CNS effects including euphoria, sedation, mild hypothermia, prolactin release, indifference to environmental stimulus, and catalepsy; (e) miosis, or contraction of the pupils; (f) inhibition of peristalsis, nausea, and vomiting; (g) urinary retention; (h) pruritus; and (i) physical dependence. Stimulation of the  $\kappa$  opioid receptor produces the following results: (a) supraspinal and spinal analgesia; (b) possible respiratory depression; (c) CNS effects including sedation, delirium, and dysphoria; (d) miosis; (e) diuresis due to inhibition of vasopressin release; (f) low physical abuse probability; and (g) antishivering. Activation of the  $\delta$  opioid receptor yields the following outcomes: (a) supraspinal and spinal analgesia; (b) respiratory

depression; (c) urinary retention; (d) pruritus; and (e) physical dependence (Nagelhout, 2014a).

Table 2

*Opioid Receptors and their effects*

Opioid Receptor	Effects
Mu ( $\mu$ )	Supraspinal and spinal analgesia; bradycardia; respiratory depression; CNS effects including euphoria, sedation, mild hypothermia, prolactin release, indifference to environmental stimulus, and catalepsy; miosis, or contraction of the pupils; inhibition of peristalsis, nausea, and vomiting; urinary retention; pruritus; and physical dependence
Delta ( $\delta$ )	Supraspinal and spinal analgesia; respiratory depression; urinary retention; pruritus; and physical dependence
Kappa ( $\kappa$ )	Supraspinal and spinal analgesia; possible respiratory depression; CNS effects including sedation, delirium, and dysphoria; miosis; diuresis due to inhibition of vasopressin release; low physical abuse probability; and antishivering.

The effects of opioid medications are produced when the opioid agonist binds to the mu, kappa, or delta opioid receptor, “which couple to G proteins and inhibit adenylyl cyclase” (p. 299). This binding results in the inhibition of voltage-gated calcium channels and the opening of potassium channels, leading to hyperpolarization or inhibition of the transmission of the sensation of pain (Fuller, 2012). Three main classifications of opioids exist: (a) phenanthrene alkaloids, (b) piperidine derivatives or phenylpiperidines, and (c) diphenylheptanes. Phenanthrene alkaloids consist of natural occurring (morphine, codeine), semisynthetic (hydrocodone, hydromorphone, oxycodone, and oxymorphone), and synthetic (butorphanol). Piperidine derivative

classification includes phenylpiperidines (Demerol) and 4-Anilidopiperidines (fentanyl, sufentanil, alfentanil, and remifentanil) (Nagelhout, 2014a).

Opioids reduce ventilation, mainly in the form of respiratory rate, as well as increase the partial pressure of carbon dioxide ( $\text{PaCO}_2$ ). An increase in  $\text{PaCO}_2$  blunts the response to carbon dioxide ( $\text{CO}_2$ ), which enables apneic episodes to become more likely (Butterworth, Mackey, & Wasnick, 2013). Opioid drug properties are potentiated by certain medical conditions including obesity, OSA, and abdominal distention (Macintyre et al., 2011). Because obese patients have (a) decreased lung compliance, (b) increased V/Q mismatch, (c) reduced FRC, and (d) increased oxygen consumption; the effects of opioids are further exacerbated, as well as the risk of apnea and hypoxemia (Argalious, 2009).

The use of opioids in obese patients for the management of postoperative pain in the PACU could produce significant pulmonary complications including respiratory depression that could lead to death. Obese patients are already at a greater risk of pulmonary complications due to the increase in intrathoracic pressure that inhibits the lungs from fully expanding, with subsequent decrease in FRC and alveolar ventilation. The addition of IV acetaminophen to opioid administration for moderate to severe pain management in obese patients may reduce the risk of respiratory depression and death.

Opioid-induced respiratory depression is classified as a sentinel event, which is an unanticipated occurrence that may result in severe injury or death. The incidence and significance of opioid-induced respiratory depression are not well documented in the literature. One source approximated the incidence to be 0.5% with a range of 0.2 to 2% (Dahan, Niesters, Olofsen, Smith, & Overdyk, 2013). The Anesthesia Patient Safety

Foundation (APSF) (2011) noted “clinically significant, drug-induced respiratory depression in the postoperative period remains a serious patient safety risk that continues to be associated with significant morbidity and mortality” (p. 1).

### Conclusion

Uncontrolled postoperative pain after any surgical procedure can have devastating effects for the healing process. Opioids are predominately administered for analgesia during the perioperative period. However, side effects of opioids could be fatal, particularly for the obese patient. Obese patients are at a higher risk for adverse events during the perioperative period due to changes in body habitus. Because changes associated with obesity combined with unfavorable side effects of opioids is a dangerous mixture, the addition of IV acetaminophen during the preoperative period is beneficial in decreasing opioid administration for postoperative pain in the obese surgical patient.

## CHAPTER II

### REVIEW OF LITERATURE

This paper contains a synthesis of literature regarding the following topics: (a) IV acetaminophen for the reduction of postoperative pain, (b) multimodal therapy, and (c) ORADEs. The following databases were utilized for this review of literature: EBSCOhost, MEDLINE, PubMed, ScienceDirect, and Google Scholar. The key words used in the search included: (a) Ofirmev, (b) Paracetamol, (c) IV acetaminophen, (c) obese, (d) obesity, (e) opioids, (f) laparoscopic cholecystectomy, (g) opioids and respiratory depression, and (h) opioid-related adverse drug events.

#### Intravenous Acetaminophen for the Reduction of Postoperative Pain

Memis, Inal, Kavalci, Sezer, and Sut (2010) preformed a quantitative single randomized controlled trial that evaluated the analgesic efficacy, adverse outcomes, and time to extubation in 40 adult intensive care unit (ICU) patients after complex abdominal or pelvic surgery. The participants received IV paracetamol (acetaminophen) as an adjuvant to IV meperidine or only IV meperidine for postoperative pain. This study found that pain scores, time to extubation, and the incidence of sedation and postoperative nausea and vomiting (PONV) were considerably lower in the group that received both IV acetaminophen and meperidine.

Wininger et al. (2010) conducted a double blind, placebo-controlled, parallel-group study at 17 different sites in the U.S., with 244 adult participants.

This study assessed the analgesic effectiveness and safety of repetitive doses of IV acetaminophen over a 24-hour period when compared to a placebo after abdominal laparoscopic surgery. The four groups in the study included: (a) IV acetaminophen 1000

mg every 6 hours, (b) IV acetaminophen 650 mg every 4 hours, (c) IV placebo every 6 hours, and (d) IV placebo every 4 hours for 24 hours postoperatively. Both treatments of IV acetaminophen were associated with analgesic efficacy in these patients.

A prospective randomized, double-blind clinical trial, that included 142 total participants, was led by Konstantatos, Smith, and Angliss (2012). The aim of this study was to assess whether IV acetaminophen will reduce postoperative pain and time to discharge from the PACU and the hospital. The three groups investigated included (a) the pre and postoperative placebo, (b) the IV intraoperative and postoperative oral acetaminophen, and (c) the pre and postoperative oral acetaminophen. Konstantatos et al. (2012) found that the mean pain scores and the time to discharge over 24 hours during the postoperative period was not significantly different between the 3 groups. The researchers did indicate that the anesthetists could use fentanyl and morphine as needed for pain during the intraoperative period, and the surgeons were allowed to use local anesthetic as desired. Another limitation was that the population was predominately young, healthy males.

Atef and Fawaz (2008) conducted a randomized, double blind, prospective, placebo-controlled study with 76 adult subjects aged 16-40 years old, scheduled for elective bipolar diathermy tonsillectomy to evaluate the efficacy of IV paracetamol (acetaminophen) for pain control. The experimental (n=38) group received 1-gram acetaminophen and the control (n=38) group received normal saline all participants received the designated treatment every 6 hours. Rescue analgesia during the first 24 hours postoperatively was available to all patients. Rescue analgesia was required in 100% of patients in the placebo group and 29% of patients in the acetaminophen group.



Therefore, the authors concluded that IV acetaminophen did provide effective pain relief and provided a significant opioid sparing effect in their target population.

Anand et al. (2013) performed a parallel, randomized, double blind, comparative study that included 180 patients to establish if IV acetaminophen or IV ketorolac delivered better analgesia after parathyroidectomy. One group (n=90) was administered 1 gram IV acetaminophen at the beginning of the surgical procedure, and the other group (n=90) received 30 mg IV ketorolac at the close of the fascia. The researchers concluded that the ketorolac group had lower pain scores than the acetaminophen group ( $3.9 \pm 1.9$  vs.  $4.8 \pm 2.4$  at 45min,  $p=0.009$ ;  $3.4 \pm 1.7$  vs.  $4.5 \pm 2.1$  at 60min,  $p=0.04$ ; and  $3.2 \pm 2.1$  vs.  $4.4 \pm 2.1$  at 75min,  $p=0.03$ ).

A retrospective analysis was directed by Smith and Hoefling (2014) to determine if IV acetaminophen could decrease visual analog scale (VAS), opioid exposure, and ORADEs in spinal surgery patients. A total of 68 electronic medical records (EMRs) were assessed and reviewed. The experimental group (n=34) received 1 gram IV acetaminophen either preoperatively or postoperatively, and the control group (n=34) did not receive IV acetaminophen. The results of this study indicated that the acetaminophen group used less opioids (11.3 mg morphine equivalent [ME]) than the control group (20.6 mg ME) ( $P=0.015$ ). The only administration of naloxone was in one control group patient. Although this analysis indicated that IV acetaminophen reduced opioid consumption, VAS scores or the administration of antiemetic and laxatives did not differ between the two groups.

A systemic review, directed by Tzortzopoulou et al. (2011) assessed the efficacy and safety of IV propacetamol (acetaminophen) for the treatment of postoperative pain in

adults and children. This review examined 36 randomized, double-blind, placebo- or active-controlled single dose clinical trials, which included a total of 3,896 participants. The results of this systematic review showed that 37% of the participants that received IV acetaminophen had a decrease in pain of 50% over 4 hours, compared to 16% that received the placebo. The study also indicated that the IV acetaminophen group required 30% less opioids over 4 hours than the placebo group. However, no significant difference in the number of ORADEs between the IV acetaminophen and the placebo groups was noted.

Singla et al. (2014) reviewed two double-blind, parallel-group, multicenter, randomized, placebo-controlled clinical trials to determine the efficacy and safety of IV acetaminophen for postoperative pain after hip arthroplasty. Both clinical trials were terminated early due to particulate matter and altered pH in the placebo vials. The 2 studies yielded 130 participants, all with similar demographics. Mean pain intensity difference (PID) of IV acetaminophen group was consistently higher than placebo with significant ( $P < 0.5$ ) differences from T0.25 to T5 in the first study and T0.5 to T4 in the second study, which indicated that IV acetaminophen relieved postoperative pain compared to placebo. VAS scores were consistently superior in IV acetaminophen than placebo. IV acetaminophen decreased opioid consumption for up to 6 hours in the first study and up to 4 hours in the second study. The mean time for rescue analgesia for IV acetaminophen was 4.72 compared to placebo 1.4 in the first study, and  $>4$  and 1.25, respectively in the second study. The reviewers concluded that IV acetaminophen improved postoperative analgesia with a rapid onset, and decreased opioid consumption more than 50% when compared to placebo.

### Multimodal Therapy

A qualitative systematic review that was led by Ong, Seymour, Lirk, and Merry (2010) evaluated the efficacy of combining acetaminophen and a NSAID versus administration of each medication alone in varied acute pain models. This systematic review included 21 studies, with a total of 1909 patients. This review indicated that combining acetaminophen and a NSAID provides additional analgesic efficacy when compared with either drug alone.

Macario and Royal (2010) conducted a systematic review to evaluate the analgesic effects of IV acetaminophen for acute pain in adults. The review included 22 studies from 9 countries, and a total of 1,464 patients were examined. The researchers reported that IV acetaminophen had similar analgesic effects as an active comparator (IV parecoxib [n=3], IV metamizol [n=4], and oral ibuprofen [n=1]) in 7 out of 8 studies. Patients who received IV acetaminophen versus a placebo had decreased postoperative pain in 12 of 14 studies.

A retrospective chart review was done by Lewis, Gunta, Mitchell, and Bobay (2012) to evaluate the outcomes of multimodal analgesia in total knee arthroplasty (TKA). The chart review consisted of a control group of 45 patients from 2009 and a multimodal group of 66 patients from 2010. A multimodal protocol for TKA was developed that consisted of several oral and IV analgesics, along with a femoral continuous peripheral nerve block (PNB). Although this chart analysis had several limitations, the researchers concluded that the multimodal had less pain scores and decreased incidence of PONV in the postoperative area. The length of stay (LOS) in the

multimodal group was reduced by 0.5 days compared to the control group (3.22, 2.75,  $p < .01$ ).

Xiromeritis, Kalogiannidis, Papadopoulos, Prapas, and Prapas (2011) conducted a prospective, randomized trial to evaluate postoperative pain when multimodal therapy is used in females undergoing uterine fibroid surgery. A total of 92 participants took part in the study and were allocated into either the multimodal group ( $n=47$ ) or the control group ( $n=45$ ) using sealed envelopes. Pain scores were documented at 2 and 8 hours postoperatively. This study indicated that the mean pain scores were significantly lower in the multimodal group when compared to the control group (2 hours postoperatively:  $4.7 \pm 0.7$  vs  $7.1 \pm 0.9$ ,  $P < 0.0001$ ; 8 h postoperatively:  $2 \pm 0.6$  vs  $4.5 \pm 0.8$ ,  $P < 0.0001$ ). The multimodal group also had a reduced hospital LOS compared to the control group, which is thought to indicate a faster recovery time ( $11 \pm 5$  vs  $26.8 \pm 5.8$  h,  $P < 0.0001$ ).

#### Opioid-Related Adverse Drug Events

A retrospective cohort study was completed by Minkowitz, Gruschkus, Shah, and Raiu (2014), which included 6,285 patients, 18 years and older, who had inpatient surgical procedures within 11 hospitals in the Houston metropolitan area in the year 2010. ORADEs and the associated risk factors were examined in this study. The researchers found that 99.8% ( $n=6,274$ ) of the participants were administered opioids in the postoperative period, and of those, 11.0% ( $n=689$ ) experienced ORADEs. The most frequently occurring ORADEs involve the gastrointestinal (GI) system (6.3%,  $n=396$ ), whereas those involving the respiratory system was 2.9% ( $n=182$ ) of patients. The researchers identified multiple risk factors that were linked to ORADEs, and included: (a) advanced age, (b) male gender, (c) prior opioid use, (d) COPD, (e) cardiac

dysrhythmias, (f) regional enteritis, (g) diverticulitis, and (h) ulcerative colitis. Higher hospital costs correlated with increasing number of risk factors for ORADEs.

Oderda et al. (2007) investigated the impact of ORADEs on hospital LOS in a retrospective matched cohort study. The ORADE group (n=741) were identified by a computer surveillance program, then each ORADE was matched with 15 control cases, making the control group (n=10,116). The researchers concluded that the ORADE group when compared with the control group had an increase in hospital costs (7.4%,  $p<0.001$ ), and an increase in mean LOS (10.3%,  $P<0.001$ ). The higher the dose of opioids corresponded to the rate of ORADEs.

Pizzi et al. (2012) undertook a retrospective chart review to determine if ORADEs had an impact on postoperative hospital LOS. A stratified, random sample of patients (n=402), 18 years or older who underwent spine, hip, knee, or shoulder surgery during 2007, were selected, and data gathered from each patient's EMR. This study found that at least 1 ORADE occurred in 54.2%, 2 ORADEs occurred in 18.4%, and 3 or more ORADEs occurred in 7.2% of the participants. However, the number of ORADE showed no correlation to the type of surgical procedure. The ORADEs that caused a significant increase in LOS included constipation, emesis, and confusion.

Eckstrand et al. (2009) completed a retrospective, cross-sectional study to examine opioid-related over-sedation and respiratory depression after naloxone administration (n=419) during the perioperative period. A computerized surveillance system was used for identification of adverse drug events (ADEs), including naloxone administration at Duke University. Out of 419 cases of perioperative naloxone administration that were identified, 101 doses were given postoperatively, and 69 were

confirmed as ADEs after chart review. The researchers found a rate of 1.89 ADEs/1000 surgical encounters across both the inpatient and ambulatory settings within Duke University during the postoperative period.

#### Needs Assessment

The addition of IV acetaminophen for the management of postoperative pain in obese patients undergoing laparoscopic cholecystectomy is not the standard of care, but should it be? Postoperative pain in any population may produce adverse consequences, and could be exaggerated in the obese population. The gold standard for the treatment of postoperative pain is opioids, but these medications may produce harmful side effects.

Obesity has become a national epidemic, and Mississippi, unfortunately, has been leading the way for several years (Trust for America's Health & Robert Wood Johnson Foundation, 2014). "In the obese patient, the goal of postoperative pain management is provision of comfort, early mobilization and improved respiratory function without causing inadequate sedation and respiratory compromise" (Schug & Raymann, 2011, p. 73). The maintenance dosages of opioids for the management of postoperative pain in the PACU "should be cautiously reduced because of the higher sensitivity of the obese patient to their depressant effects" (Casati & Putzu, 2004, p. 134). Another source adds that the serious complications of opioids can conceivably lead to respiratory depression and death (Overdyk et al., 2012).

Effective management of postoperative pain is the goal of each anesthetist, especially for the obese patient. If postoperative pain is adequately managed, not only does patient satisfaction increase, but also the risks of postoperative complications decrease. Postoperative pain is typically treated with opioids, which may cause apnea

and other undesirable effects in the obese patient (Schug & Raymann, 2011). The desired outcome for this capstone project is to assess whether the administration of IV acetaminophen in obese patients undergoing laparoscopic cholecystectomy reduces the amount of opioids required for the management of postoperative pain.

Decreasing the prevalence of postoperative pain and opioid consumption along with their adverse side effects will improve patient outcomes and satisfaction. Because this project is a retrospective chart review, buy-in from the facility was accomplished since there are no added work or costs. Risks of a retrospective chart review include collecting incomplete or inadequate documentation to complete all aspects of the project. The outcome analysis of this capstone revealed and answered the question if IV acetaminophen will decrease opioid use for postoperative pain in obese patients undergoing laparoscopic cholecystectomy, and results will contribute to a possible change in practice.

### Conceptual Framework

The Theory of Goal Attainment is a middle-range theory. A middle range theory is more focused when compared to grand theories, and the concepts of the middle range theory can form a testable hypothesis (Eldridge, 2014). Imogene King introduced the Theory of Goal Attainment in the 1960s. The essential concept of this theory is that the patient and nurse correspond with one another to develop goals and then act to attain the desired goals (Nursing theory, 2013).

The basic assumptions of the theory include individuals are (a) social, (b) sentient, (c) rational, (d) reacting, (e) perceiving, (f) controlling, (g) purposeful, (h) action-oriented, and (i) time-oriented beings. Other basic assumptions of the theory that impact

the interaction process include: (a) views of the nurse (b) views of the patient (c) goals, wishes, and beliefs of the nurse goals, wishes, and beliefs of the patient. In addition to these assumptions, persons are entitled to information regarding their health; and persons are also entitled to partake in decision-making that will impact their long-term care and wellbeing. The Goal Attainment Theory also states that persons are entitled to accept or decline care and treatment; and the goals of nurses and patients may be different (King, 1981). The major concepts of the Theory of Goal Attainment include (a) personal, (b) interpersonal, and (c) social (Nursing theories, 2012).

#### *Application of the Theory of Goal Attainment to Capstone*

The Theory of Goal Attainment emphasizes a holistic approach and describes the nursing profession as a process that is collaborative in nature (Whetsell, Gonzalez, & Moreno-Fergusson, 2011). A lack of sufficient pain control after surgery has the potential to cause quick and shallow respirations (Hans et al., 2009). The main agent used to control pain management in the PACU is opioids. “Unintended advancing sedation and respiratory depression are two of the most serious opioid-related adverse events” (Jarzyna, et al., 2011, p. 118). According to Overdyk et al. (2012), the administration of opioids in the postoperative period is said to be responsible for half of the adverse respiratory events during that period. The APSF (2011) reported that adverse respiratory events caused by opioids in the PACU continue to be linked with substantial illness and death.

#### *Analysis of the Theory of Goal Attainment-Capstone Fit*

The Theory of Goal Attainment is based on the King Conceptual System.



This system indicates that the goals of the patient are met through the interaction between the nurse and the patient. This interaction happens over time, comprises a transaction, and ultimately the goal is met (Whetsell et al., 2011). The Theory of Goal Attainment includes awareness, communication, and collaboration between the patient and the nurse (Nursing Theories, 2012). This communication between the nurse and patient is important in the early recognition and treatment of postoperative pain.

#### *Future Practice Implications for the Theory of Goal Attainment*

A middle-range theory integrates nursing practice and research into concepts that are fundamental to the discipline (Terry, 2012). The Theory of Goal Attainment is applicable for every setting in healthcare and always will be. Nursing is based on goal-setting and patient-centered care. In health care, the affiliation of the patient and the nurse exists to assist that patient in accomplishing his or her objectives for their health (Nursing theory, 2013).

#### Doctorate of Nursing Practice Essentials

Doctorate of Nursing Practice (DNP) Essential I is scientific underpinnings for practice. This essential allows for the development and assessment of clinical practice solutions based on theories from nursing and other disciplines (Chism, 2013a).

Intravenous acetaminophen administration reduces the amount of opioids used in the postoperative period. This evidence-based practice approach is created using many other disciplines including pathophysiology, pharmacology, anatomy, and physiology. The use of IV acetaminophen to reduce postoperative pain is particularly imperative for obese surgical patients due to the pharmacodynamics and pharmacokinetics of opioid administration.

DNP Essential II is organizational and systems leadership for quality improvement and systems thinking (Chism, 2013a). This capstone project is focused on the reduction of opioid administration for postoperative pain in obese patient who underwent laparoscopic cholecystectomy. The administration of IV acetaminophen may improve postoperative pain without the negative side effects of multiple doses of opioids (Viscusi et al., 2012). If this proves true, a practice change will likely be established to improve patient safety and satisfaction.

DNP Essential III is clinical scholarship and analytical methods for evidence-based practice (Tymkow, 2014). Dreher (1999) stated, “clinical scholarship is about inquiry and implies a willingness to scrutinize our practice” (p. 26). This capstone project assessed the methods currently used to prevent postoperative pain in obese patients.

DNP Essential IV is information systems or technology and patient care technology for the improvement and transformation of healthcare. According to Chism (2013a), Essential IV is imperative to the DNP graduate. This essential allows for evaluation and implementation of quality improvement programs, data extraction from patients’ EMR, and knowledge of ethical and legal issues regarding the patient’s EMR (Chism, 2013a). Performing a retrospective chart review, patient data was extracted from the patients’ EMR, de-identified, and protected to avoid ethical and legal issues. Other electronic databases were utilized for the review of literature and other pertinent information dealing with laparoscopic cholecystectomy in the obese patient, postoperative pain in the obese patient, opioid administration in the obese patient, and IV acetaminophen for the reduction of postoperative pain.

DNP Essential V is healthcare policy for advocacy in healthcare. Mund (2014) asserted, “the complexity of today’s healthcare environment and the increase in volume of scientific knowledge demand the involvement of nurses educated in the legislative process and prepared to influence policy on the local, state, and national levels” (p. 177). If the assumptions of this capstone project prove true, advocacy for a practice change will be required for the reduction in opioid administration for postoperative pain in the obese patient after a laparoscopic cholecystectomy, and the reduction of ORADEs in this population.

DNP Essential VI is interdisciplinary collaboration. Interdisciplinary collaboration is vital to any clinical setting in order to adequately care for the patient. For the obese surgery patient, interdisciplinary collaboration between the anesthetist and the PACU nurse is vital for patient safety and includes informing the PACU nurse of adverse or unanticipated events during the perioperative period, how the patient responds to certain medications, and any problems that could possibly occur. Interdisciplinary collaboration can be developed by respecting the knowledge and expertise of other team members, asking for input from other team members, and communicating “effectively by utilizing active listening, compassion, and empathy” (Chism, 2013c, p. 76).

DNP Essentials VII is clinical prevention and population health for improving the nation’s health (Schadewald & Pfeiffer, 2014). Clinical prevention is defined by the American Association of the Colleges of Nursing (AACN) (2006) as “health promotion and risk reduction/illness prevention for individuals and families” (p. 15). The administration of excessive opioids produces harmful side effects, especially in the obese patient. These adverse side effects could cause respiratory depression and detrimental

effects on the patient's health and postoperative recovery (Nagelhout, 2014b). This project evaluated the use of IV acetaminophen and opioid administration in the postoperative period, which could potentially improve the outcomes for this population.

DNP Essentials VIII is advanced nursing practice (Chism, 2013a). This essential emphasizes holistic assessment, implementation, and evaluation of health care interventions to enhance patient care and improve patient outcomes. Effective communication among all members of the healthcare team, along with the patient is an essential key to achieving this goal (Chism, 2013a). Communication throughout the perioperative period is crucial for any surgical procedure in order to provide the desired outcomes for that patient. This communication should be continued during the postoperative period so that the patient receives optimal care. Minimizing the use of opioids in PACU in a patient with a low tolerance to these medications, as evidenced by their reaction during induction of anesthesia, is vital to their recovery. This information should always be communicated to the PACU nurse who will be caring for that patient. The use of IV acetaminophen will reduce postoperative pain and the quantity of opioids required to manage pain. The reduction of opioid use for postoperative pain may improve patient outcomes and decrease the number of adverse events during the postoperative period.

Leadership skills are essential for the advanced practice registered nurse (APRN), especially in initiating a change in clinical practice that will be effective and beneficial for patient safety and outcomes. A few approaches for being an effective leader in order to improve adverse events for obese patients in the PACU, with regards to postoperative pain management, include giving a thorough perioperative report to the PACU nurse,

giving the PACU nurse a chance to ask questions, and giving positive feedback (Center for Creative Leadership, 2013). Additional leadership skills in order to address this clinical practice issue include: (a) effective communication, (b) fearlessness, (c) being a role model, (d) knowledge and clinical competence, (e) compassion, (f) being trustworthy, and (g) empathy (Chism, 2013b).

#### Evaluation Plan

The desired outcome of this capstone project is to decrease the amount of opioid administration for postoperative pain, along with ORADEs in obese patients undergoing laparoscopic cholecystectomy with the use of IV acetaminophen. This outcome was measured using a retrospective chart review of the amount of opioid administration during the postoperative period and the entire LOS for those patients who did and did not receive IV acetaminophen in the desired population. This outcome was measured and evaluated in each group using the *t*-test. “The *t*-test analyzes the size of the difference between the means of two groups while taking into account the sample size and the spread of the scores across the possible range of scores (i.e., the standard deviation)” (Brown, 2014, p. 179-180).

#### Assumptions

The assumption for this project is that there will be adequate documentation of medication administration and any adverse events that occurred during the perioperative period. These assumptions are unlikely due to the advent of the EMR. The medical facility where this study took place uses the EPIC EMR. According to Menachemi and Collum (2011), the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 gave U.S. medical facilities an initiative to enact and use the

EMR. Potential advantages “include clinical outcomes (improved quality, reduced medical errors), organizational outcomes (financial and operational benefits), and societal outcomes (improved ability to conduct research, improved population health, and reduced costs)” (p. 47).

### Conclusion

The majority of studies found that IV acetaminophen decreases postoperative pain, opioid consumption, and LOS. IV acetaminophen, along with other NSAIDs should be considered in every surgical patients plan of care, specifically obese patients. This multimodal approach to analgesia is utilized to reduce the ORADEs while providing adequate pain relief. Another vital aspect of analgesia is communication between the patient and PACU nurse. According to theory of goal attainment, patient-nurse interaction is critical for providing exceptional care in the postoperative period.

## CHAPTER III

### METHODOLOGY

Using the PICO (population/intervention/comparison/outcome) question structure, the following research question was developed: ‘In obese patients undergoing laparoscopic cholecystectomy, does IV acetaminophen reduce opioid use for postoperative pain?’ A retrospective comparison quantitative approach was used to answer this research question. A retrospective study was chosen because the proposed intervention and the proposed effect have occurred in the recent past (Grove, Burns, & Gray, 2013). The researcher documented all patient information on the data collection form (DCF) so that subjects cannot be identified, directly or indirectly. Confidentiality of patient information was maintained during the study.

#### Setting

This retrospective study was conducted at a large, level II regional trauma center in the southeast. This facility houses 17 operating rooms, and delivers care to patients undergoing multiple types of procedures, including (a) general and thoracic surgery, (b) urology, (c) plastic surgery, (d) otolaryngology, (e) ophthalmology, (f) dentistry, (g) oral and maxillofacial surgery, (h) open heart procedures, (i) neurology, (j) minimally-invasive laparoscopic procedures, and (k) vascular procedures.

#### Population

The population of interest for this retrospective chart review was obese adults with a BMI greater than 30 aged 18-65, who underwent an elective laparoscopic cholecystectomy. Obesity is a common occurrence in the U.S., especially in Mississippi. Obesity is associated with many disease processes, including (a) OSA, (b) type 2 DM, (c)

dyslipidemia, (d) CAD, and (e) stroke (Hindle & Mills, 2012; Eddey, 2012; Xie et al., 2012; Yaskin, Tones, & Goldfarb, 2009). Obese patients are also at higher risk for adverse events associated with anesthesia, including (a) hypoxemia due to difficult bag mask ventilation, (b) difficult intubation due to excessive redundant tissue, and (c) increased pulmonary complication due to a decreased FRC.

### Sampling

After IRB approval was received from the medical facility and USM (IRB #15012803), a sampling plan was implemented. A sampling plan was used to augment representativeness, decrease bias, and reduce the sampling error (Grove, Burns, & Gray, 2013). The sampling frame was provided by the medical facility, and included a list of patient encounter numbers (PENs) for all patients that underwent a laparoscopic cholecystectomy from May 1, 2013 to December 31, 2014.

The inclusion criteria for this project included patients within the ages of 18 to 65, a BMI greater than 30, and who underwent an elective laparoscopic cholecystectomy during the specified dates. Exclusion criteria include patients with a known allergy to acetaminophen, patients who are currently pregnant, patients with severe hepatic impairment, severe acute liver disease, chronic alcoholism/opioid use, chronic malnutrition, severe hypovolemia, severe renal impairment, or patients who underwent an emergent laparoscopic cholecystectomy.

The sampling frame consisted of 1109 PENs, along with (a) case date, (b) date of birth, (c) surgery type (scheduled or emergency), and (d) surgery description. From the list of 1109 patients, the following patients were automatically excluded: (a) 261 older than 65 years old, (b) 4 younger than 18 years old, (c) 95 emergent procedures, (d) 30



with additional procedures, (e) 24 that converted to an open procedure, and (f) 1 which was aborted. Therefore, 694 charts audited for inclusion and exclusion criteria. The following patients were also excluded from the study: (a) 264 with BMI less than 30, (b) 13 for chronic opioid use, (c) 3 pregnant, (d) 36 with ESRD, (e) 29 with liver disease, (f) 5 with pancreatitis, (g) 1 because the file was restricted, and (h) 27 had a PCA pump ordered for postoperative pain. Consequently, this left 316 patient charts available for the study.

The sampling frame of 316 PENs were entered into a spreadsheet, and separated into those who received IV acetaminophen (Group T) and those who did not receive IV acetaminophen (Group NT). Group T included 128 PENs, and Group NT included 188. The 128 included in Group T were divided by 40, and every third PEN was included in the study. Group NT included 188 and was divided by 40, and every fourth PEN was included in the study. Group T includes subjects who received 1 gram of IV acetaminophen during the preoperative period, and Group NT includes subjects who did not receive IV acetaminophen while undergoing laparoscopic cholecystectomy.

After the systematic sampling of the PENs eligible for incision was complete, the EMR system was accessed for chart reviews. The DCF, created by the researcher, was utilized during this process. A patient identification number (PIN) was assigned to each subject and included three different aspects. The first aspect of the PIN was the designated group, T or NT, and indicates if the patient was administered IV acetaminophen (T) in the preoperative period. The second aspect of the PIN was 01-40 and indicates the number of the subject in that group. The last portion of the PIN was the

last three digits of the patient account number in order to ensure that patient's data was not duplicated in the study.

#### Target Outcomes

The desired goal of this capstone project was to determine if obese patients who underwent a laparoscopic cholecystectomy required less opioid narcotics in the PACU if IV acetaminophen was administered in the preoperative period. A retrospective chart review was performed. After the data were analyzed from the retrospective chart review, a poster presentation and a white paper proposal was developed in order to attempt a change in practice for the obese population.

#### Barriers

Barriers to implementing a practice change in the clinical setting are vast, and include educational, economic, and motivational factors. To facilitate a practice change related to the administration of IV acetaminophen in the obese population, education regarding the differences in pharmacodynamics and pharmacokinetics in these patients need to be reinforced. Economic buy-in and motivation are important and necessary for the medical facility to allow IV acetaminophen to be administered in obese patients, which is addressed in the cost-benefit analysis.

Interdisciplinary collaboration is vital to any clinical setting in order to overcome barriers for practice change. Interdisciplinary collaboration can be developed by respecting the knowledge and expertise of other team members, asking for input from other team members, and communicating “effectively by utilizing active listening, compassion, and empathy” (Chism, 2013c, p. 76). Gardner (2005) added, for effective

collaboration to take place, one must learn to value and manage diversity, cultivate constructive conflict resolution skills, and understand that collaboration is a journey.

### Research Strategies

Using the PICO (population/intervention/comparison/outcome) question structure, the following research question was developed: Did IV acetaminophen reduce opioid administration for postoperative pain in obese patients who underwent a laparoscopic cholecystectomy? The research method carried out for this capstone used a retrospective, comparison, quantitative study. A retrospective study was chosen because both the proposed intervention and the proposed outcome have already occurred (Grove, Burns, & Gray, 2013).

### Methods

Once the sample for each group was established, data were collected from the preoperative record, including: (a) age; (b) BMI; (c) gender; and (d) ASA classification. The ethnicity of the patient was found in the history and physical report generated by the surgeon. The electronic medication administration record (eMAR) was evaluated for the time IV acetaminophen was administered, if given. The data gathered from the anesthesia record included: (a) anesthesia start time; (b) time in the PACU; (c) anesthesia end time; and (d) the time admitted to the PACU. The PACU nursing notes were analyzed and pertinent data obtained for any events that took place in PACU. Data were gathered from the eMAR during the postoperative period that included the administration amount and time of hydromorphone. Confidentiality of patient information was sustained during the study. Patient data were collected so that subjects cannot be identified, directly or indirectly.

Some items on the DCF created by the researcher in the planning stage were not collected and not needed for statistical analysis. Procedure date, height, weight, current medications, and personal medical history (PMH) were reviewed for verification of that subject meeting the study criteria. Other data not needed for this study includes: (a) surgeon, (b) previous surgeries, (c) chest radiograph (CXR), (d) electrocardiograph (EKG), (e) mallampati classification (MP), (f) past anesthetic complications, (g) beta blocker (BB) administration, and (h) abnormal finding on preoperative assessment. Airway data, including (a) direct laryngoscopy (DL) information; (b) size and depth of the endotracheal tube (ETT); and (c) extubation information was not necessary for this study. Intraoperative adverse events, vital signs (VS), train of four (TOF), intravenous fluid (IVF) administration, and estimated blood loss (EBL) data was also unnecessary for this study. Time to ambulation and pain scores were not documented and therefore unavailable to obtain.

After the data were gathered from the selected PENSs, it was entered into a spreadsheet and coded for analysis in SPSS software. The first column was the PINs and the corresponding data in each particular row. The second column indicated whether that patient received IV acetaminophen (T) or did not receive IV acetaminophen (NT). The next column listed the patient's age in years, then gender (0 = female, 1 = male). Another column contained the patient's BMI, and another their smoking status (0 = no smoking, 1 = smoker, and 2 = former smoker). The variables coded in minutes included: (a) total anesthesia time, (b) total PACU time, (c) total LOS, and (d) time from administration of IV acetaminophen to surgery start when appropriate. Additional variables include: (a) ASA, (b) amount of hydromorphone given in the PACU and for the

total LOS in mg, (c) adverse events that occurred in PACU (0 = none, 1 = decreased oxygen (O<sub>2</sub>) saturation less than 90%, 2 = nausea, 3 = nausea and vomiting (N/V), and 4 = decreased O<sub>2</sub> saturation and N/V), and (d) if the patient was discharged (d/c) home or admitted for observation after leaving PACU (0 = discharged home, 1 = admitted). See Table 3 for patient demographics for both groups and the total sample.

### Statistical Analysis

The independent group *t*-test was utilized for this capstone project. “The *t*-test analyzes the size of the difference between the means of two groups while taking into account the sample size and the spread of the scores across the possible range of scores (i.e., the standard deviation)” (Brown, 2014, p. 179-180). The independent group *t*-test was used to compare multiple variables between Group T and Group NT, including (a) total anesthesia time; (b) total amount of hydromorphone administered in PACU and total LOS; (c) total PACU time; (d) total LOS; and (e) if the patient was discharged home or admitted.

After the data were analyzed, a white paper proposal was prepared and disseminated to key stakeholders at the medical facility. A white paper proposal is used to advocate a solution to a particular problem (The Writing Lab, The OWL at Purdue, & Purdue University, 2010). A practice change was also attempted through a poster presentation and manuscript submission to a peer-reviewed journal. Poster presentations provide another venue for distributing evidence-based material to a professional audience, who can in turn implement the practice change within their healthcare institution (Betz, Smith, Melnyk, & Rickey, 2011). Submission of research for publication is imperative since “it provides a peer review of the researcher’s work,” and it

“allows networking to occur with individuals who have similar research interests” (Terry, 2012, p. 181).

### Significance and Implications

This capstone project determined if IV acetaminophen reduced the amount of opioid narcotics needed for postoperative pain in obese patients who underwent a laparoscopic cholecystectomy. The obese population has an increased risk of anesthetic complications during the perioperative period due to the physiologic changes associated with their body habitus. These risks are compounded by the administration of opioids in the postoperative period. Although the incidence of respiratory depression due to opioid administration is rare, 0.5% with a range of 0.2 to 2%, it is classified as a sentinel event, and can result in severe morbidity or mortality (Dahan et al., 2013). Postoperative pain has serious implications on the healing process, and the anesthesia provider is charged with the task to control this complication.

### Conclusion

The following research question was employed for this capstone project: ‘In obese patients undergoing laparoscopic cholecystectomy, does IV acetaminophen reduce opioid use for postoperative pain?’ A retrospective chart review was performed with a convenience sample. The data were evaluated to determine any significant results between the groups who received IV acetaminophen and the control group. The results of this study will potentially decrease opioid administration in the postoperative period for the obese surgical patient.

## CHAPTER IV

### ANALYSIS OF DATA

This capstone project reflects chart reviews of 80 EMRs, 40 in Group T and 40 in Group NT. The confidence interval (CI) for this sample size is +/- 4.79 with 95% confidence level, calculated by the Confidence Interval Calculator for Proportions (McCallum Layton, 2015). All participants in Group T received 1 gram IV acetaminophen in the preoperative period only, however, no additional doses were administered. Midazolam was administered to each patient in the preoperative period, and ranged from 1 to 5 mg. Fentanyl was given intraoperatively to blunt the airway response and pain control as needed, and varied from 100 micrograms (mcg) to 300 mcg.

This project utilized independent samples t-tests to assess the differences in principal outcomes between Group T and Group NT. The t-tests were executed using SPSS by the statistician and Microsoft Excel for Mac 2011 (version 14.4.0) by the researcher. Results that were considered to be significant were those with a p value less than 0.05 or 95%. A computer program, G\*Power 3.1 created by Faul, Erdfelder, Buchner, & Lang (2009) was utilized by the researcher for all post-hoc power analysis. Pain assessments were not documented at regular intervals; therefore, no data were collected on pain scores. Naloxone was not administered to any of the sample participants.

#### Discussion of Results

The sample population for this capstone project was predominantly Caucasian females. Of the 80 subjects, 25 (31.25%) were male, and 55 (68.75%) female. Group T comprised 35% (14) male and 65% (26) female, whereas Group NT contained 27.5%

(11) male and 72.5% (29) female. The Caucasian ethnicity was the most prominent (58 subjects, 72.5%) for the total sample, Group T (29 subjects, 70%), and Group NT (30 subjects, 75%). The majority of the total participants in this study consisted of nonsmokers (59 participants, 73.75%). Both Group T and Group NT were composed primarily of patients categorized as ASA 2 (28 participants, 70%; 29 participants, 73%). See Table 3 for patient demographics.

Table 3

*Patient demographics*

	Group T (n = 40)	Group NT (n=40)	Total (N = 80)
<b>Gender</b>			
Male	14 (35%)	11 (27.5%)	25 (31.25%)
Female	26 (65%)	29 (72.5%)	55 (68.75%)
<b>Ethnicity</b>			
African American	9 (22.5%)	8 (20%)	19 (23.75%)
Caucasian	28 (70%)	30 (75%)	58 (72.5%)
Hispanic	1 (2.5%)	2 (5%)	3 (3.75%)
<b>Smoking status</b>			
Nonsmoker	27 (67.5%)	31 (80%)	59 (73.75%)
Smoker	9 (22.5%)	6 (15%)	15 (18.8%)
Former smoker	4 (10%)	2 (5%)	6 (7.5%)
<b>ASA Classification</b>			



Table 3 (continued).

ASA 1	2 (5%)	4 (10%)	6 (7.5%)
ASA 2	28 (70%)	29 (73%)	57 (71%)
ASA 3	10 (25%)	7 (18%)	17 (21%)

An independent-samples t-test was conducted to compare patient age for Group T and Group NT. There was a significant difference found in the scores for Group T (M=44.93, SD=11.58) and Group NT (M=38.95, SD=11.44);  $t(78) = 2.29, p = 0.03$ . These results suggest that the age of the participating subjects may have an impact on the factors related to other variables.

An independent-samples t-test was conducted to compare the difference in BMI between Group T and Group NT. There was not a significant difference in the BMI for Group T (M=38.49, SD=5.51) and Group NT (M=40.61, SD=7.14);  $t(78) = -1.49, p = 0.19$ . These results suggest that the difference in BMI between Group T and Group NT do not affect the results of other variables between the two groups.

The time from IV acetaminophen to surgical cut in Group T had a wide range, 34 to 484 minutes, with the mean being 137.475 minutes. The manufacturer does not require or suggest a specific administration time for the purpose of possibly reducing the amount of opioid use for postoperative pain. However, the clinician must remember that the onset of analgesia of IV acetaminophen is less than 10 minutes, and the maximum analgesia is attained in 15 minutes (Golembiewski, 2011).

Table 4

*Age, BMI, and IV acetaminophen times*

	Group T	Group NT	Total
	(n = 40)	(n=40)	(N = 80)
<b>Age</b>			
Min	22	19	19
Max	62	60	62
Mean	44.93	38.95	41.94
SD	11.58	11.44	11.89
P value	0.03		
<b>BMI</b>			
Min	30.29	31.42	30.29
Max	56.14	63.08	63.08
Mean	38.49	40.61	39.55
SD	5.44	7.05	6.39
P value	0.19		
<b>Time from IV acetaminophen to surgery start</b>			
Min	34		
Max	484		
Mean	137.48		
SD	94.98		

An independent-samples t-test was conducted to compare total anesthesia time for Group T and Group NT. There was no significant difference in the scores for Group T (M=83.85, SD=12.3) and Group NT (M=90.9, SD=21.54);  $t(78) = -1.78$ ,  $p=0.0965$ . These results suggest that IV acetaminophen has no direct effect on the amount of time that the patient is anesthetized.

An independent-samples t-test was conducted to compare the amount of hydromorphone administered in the PACU for Group T and Group NT. There was a significant difference in the amount of hydromorphone administered for Group T (M=0.63, SD=0.61) and Group NT (M=1.00, SD=0.70);  $t(78) = -2.54$ ,  $p=0.02$ . These results suggest that IV acetaminophen has a direct effect on the amount of hydromorphone the patient receives in PACU for postoperative pain relief.

An independent-samples t-test was performed to compare total PACU time for Group T and Group NT. No significant difference was found in the PACU times for Group T (M=68.93, SD=42.02) and Group NT (M=55.68, SD=23.24);  $t(78) = 1.75$ ,  $p=0.09$ . These results suggest that IV acetaminophen has no direct effect on the amount of time that the patient stays in PACU. However, patients who experienced any adverse side effects were admitted to the medical facility, which affected the total LOS for these patients.

Table 5

*Total anesthesia time, hydromorphone given in PACU, and Total PACU time*

	Group T (n = 40)	Group NT (n=40)	Total (N = 80)
<b>Total anesthesia time</b>			
Min	66	43	43
Max	117	156	156
Mean	83.85	90.9	87.38
SD	12.30	21.54	17.89
P value	0.10		
<b>Hydromorphone given in PACU</b>			
Min	0	0	0
Max	2	3	3
Mean	0.63	1.00	0.81
SD	0.61	0.70	0.68
P value	0.02		
<b>Total PACU time</b>			
Min	27	24	24
Max	163	129	163
Mean	68.93	55.68	62.3
SD	41.49	22.95	34.17
P value	0.09		

Adverse events in the postoperative period can result in an unintended extended LOS, reduction or cessation of reimbursement, and decreased patient satisfaction. The most common adverse event in this study for both Group T and Group NT during and after PACU was nausea. Of the subjects in Group T, 50% did not have any adverse events in the PACU, and 70% did not have any adverse events after PACU. See table 8 for adverse events during and after PACU. Surprisingly, 2 subjects in Group T experienced decreased O<sub>2</sub> saturation in PACU, whereas 0 patients in Group NT encountered this adverse event. Another unexpected discovery in this study was 15% of Group T encountered nausea and vomiting (N/V) during PACU, whereas 2.5% of Group NT encountered N/V in PACU. The incidence of all measured adverse events in both groups decreased after PACU, except nausea and N/V in Group NT.

The most common adverse event in this study was PONV. Similarly, a randomized prospective study by Memis, et. al. (2010) found that administration of IV acetaminophen every 6 hours in addition to meperidine significantly reduced PONV compared to placebo and meperidine. In contrast, Konstantatos, et. al. (2012) did not find a significant difference in the instance of PONV between IV acetaminophen group, oral (PO) acetaminophen group, and placebo. A study that compared IV acetaminophen to placebo in adults undergoing tonsillectomy also found no significant difference in adverse events (Atef & Fawaz, 2008). Additional literature similarly reported no significant difference in ORADEs with the addition of IV acetaminophen compared to placebo (Tzortzopoulou et. al, 2011).

Table 6

*Adverse events during and after PACU*

	Group T (n = 40)	Group NT (n=40)	Total (N = 80)
<b>Adverse events in PACU</b>			
No adverse events	20 (50%)	11 (27.5%)	31 (38.75%)
Decreased O2 Sat	2 (5%)	0	2 (2.5%)
Nausea	11 (27.5%)	28 (70%)	39 (48.75%)
N/V	6 (15%)	1 (2.5%)	7 (8.75%)
Decreased O2 Sat and N/V	1 (2.5%)	0 (0%)	1 (1.25%)
<b>Adverse events after PACU</b>			
No adverse events	28 (70%)	24 (60%)	52 (65%)
Decreased O2 Sat	0	0	0
Nausea	7 (17.5%)	11 (27.5%)	18 (22.5%)
N/V	5 (12.5%)	5 (12.5%)	10 (12.5%)
Decreased O2 Sat and N/V	0	0	0

This retrospective chart review assessed the discharge status of patients in both Group T and Group NT. A majority of the patients in Group T were discharged home (33, 82.5%), whereas only half of the patients in Group NT were discharged home (20, 50%). This discharge status is an important factor in the total cost for the patient and the healthcare facility.

An independent-samples t-test was conducted to compare the amount of hydromorphone administered during the total LOS for Group T and Group NT. There was a significant difference in the amount of hydromorphone administered during the total LOS for Group T (M=1.08, SD=0.89) and Group NT (M=2.21, SD=2.19);  $t(78) = -2.98$ ,  $p=0.005$ . These results suggest that one dose of IV acetaminophen in the preoperative period reduces the amount of hydromorphone for postoperative pain relief for the entire LOS.

An independent-samples t-test was conducted to compare the total LOS for Group T and Group NT. There was a significant difference in the total LOS for Group T (M=704.63, SD=768.42) and Group NT (M=1237.90, SD=928.38);  $t(78) = -81.88$ ,  $p=0.007$ . These results suggest that one dose of IV acetaminophen in the preoperative period reduces the average LOS.

Table 7

*Discharge status, total hydromorphone, and total LOS*

	Group T (n = 40)	Group NT (n=40)	Total (N = 80)
<b>Discharge status</b>			
Home	33 (82.5%)	20 (50%)	53 (66.25%)
Inpatient	7 (17.5%)	20 (50%)	27 (33.75%)
<b>Total hydromorphone</b>			
Min	0	0	0
Max	3.8	11	11

Table 7 (continued).

Mean	1.08	2.21	1.65
SD	0.89	2.19	1.77
P value	0.005		
Total LOS			
Min	54	249	54
Max	3673	4071	4071
Mean	704.625	1237.9	971.26
SD	758.75	916.70	882.68
P value	0.007		

#### Cost Analysis

Cost effectiveness is an important aspect of any sustainable business, as well as healthcare facility. Although the price of IV acetaminophen was increased tremendously, this study noted that the total mean cost for Group T is significantly lower than Group NT. This price difference is due to the number of patients that were admitted for inpatient status. Reducing the amount of opioids administered to obese patients in the postoperative period decreases the risk of ORADEs, which increase the total LOS.



Table 8

*Cost analysis*

	Group T (n = 40)	Group NT (n=40)
Cost of PACU	\$950	\$950
Number of Patients	40	40
Total Cost for the group	\$38,000	\$38,000
Cost of Ofirmev	\$34	
Number of Patients	40	
Total Cost for the group	\$1,360	
Discharge status		
Home	33	20
Inpatient	7	20
Cost of Admission	\$912	\$912
Total Cost for the group	\$6,384	\$18,240
Total Cost for the group	\$45,744	\$56,240
Mean Cost for the group	\$1,143.6	\$1,406

## Conclusion

The main goal of this retrospective quantitative study was to determine if IV acetaminophen reduced the amount of opioid administration for postoperative pain in the PACU for obese patients who underwent a laparoscopic cholecystectomy. The subjects that formed Group T were found to use significantly less amounts of opioids in the

PACU period ( $p = 0.02$ ), as well as during the total LOS ( $p = 0.005$ ). Smith and Hoefling (2014) also found that IV acetaminophen did reduce the amount of opioids administered compared to the control group, using morphine equivalents (ME) ( $p=0.015$ ). Another study found that the addition of IV acetaminophen in addition to meperidine reduced the meperidine consumption in the postoperative period ( $76.75 \pm 18.2$  mg) compared to meperidine and placebo ( $198 \pm 66.4$  mg) (Memis, et. al., 2010).

Wininger, et. al. (2010) found that IV acetaminophen provided the patients with statistically significant analgesia during the postoperative period compared to placebo. Atef and Fawaz (2008) also discovered that IV acetaminophen notably decreased the amount of opioid consumption compared to placebo. Another study found that the group that received IV acetaminophen required 30% less opioids over 4 hours when compared to placebo (Tzortzopoulou et. al., 2011). The effectiveness of IV acetaminophen combined with an effective patient-nurse relationship, as indicated by the theory of goal attainment, could reduce postoperative pain in obese patients, and therefore, decrease opioid administration during this period.

Total PACU time was not found to be significant between Group T and Group NT in this capstone project. The facility cost of a PACU stay at the selected medical center is \$950, regardless of the time spent in recovery. However, if the patient must be admitted for overnight stay, the cost to the medical facility is an additional \$912 for a non-telemetry bed. The total LOS between Group T and Group NT was found to be significant ( $p = 0.007$ ). The difference in the total LOS produced a drastic price difference between these two groups, which is the bottom line in all businesses. This study noted a difference between the two groups in the discharge status of the patients.

Thirty-three (82.5%) participants in Group T were discharged home, compared to 20 (50%) in Group NT. Konstantatos, et. al. (2012) did not show a substantial difference in the length of PACU stay or the total LOS with the addition of IV acetaminophen.

## CHAPTER V

### SUMMARY

The purpose of this capstone project was to determine if IV acetaminophen decreased opioid use for postoperative pain in obese patients who underwent a laparoscopic cholecystectomy. Postoperative pain is an anticipated and feared outcome of any surgery. Uncontrolled postoperative pain can impede the healing process, along with other disastrous outcomes. Opioids are commonly used for pain control in the postoperative period. However, opioids have side effects that could be amplified in the obese patient. This capstone project noted that the administration of IV acetaminophen in the preoperative period does reduce the amount of opioids needed for postoperative pain control in obese patients undergoing laparoscopic cholecystectomy. This study also indicated that the addition of IV acetaminophen correlated with a decrease in total LOS and the occurrence of ORADEs.

#### Limitations

There were limitations to this capstone project. The method of this study was a retrospective chart review, which could have more bias than a prospective study. The researcher could not compare pain scores between groups because none were not documented. No physician or nurse's notes were present to explain why the patient was admitted compared to being discharged home.

#### Benefits

There were also benefits of completing a retrospective chart review instead of a prospective study. The information was readily available for the researcher at any time, making data collection less complicated. No funding was needed for this project.

There were also no additional work or resources required from the medical facility. The results of this study show that IV acetaminophen decreases opioid consumption in the postoperative period and the entire LOS. This project also found that IV acetaminophen minimizes the total LOS, which significantly decreases the healthcare costs for this patient population.

#### Future Directions

This capstone project could be expounded upon in the future. Additional studies could be done on a larger scale involving other surgical procedures. A prospective study would provide more complete data for the researcher. Another aspect of IV acetaminophen administration that could be researched is the time of administration compared to the pain scores in the postoperative period. Another avenue pertaining to IV acetaminophen decreasing postoperative pain is to examine the effects of one dose compared to one dose every six hours.

#### Conclusion

Postoperative pain is an unfortunate side effect of any surgery and must be managed for adequate healing. This study examined IV acetaminophen given in the preoperative period compared to opioid use for pain control in the postoperative period, and did find a difference. Opioids are the most common medication administered in the postoperative period for pain control, but can cause adverse occurrences. There was also a difference between the total LOS and the use of IV acetaminophen. In today's economy, healthcare should be patient-centered and cost effective. This capstone project has shown that the administration of IV acetaminophen decreases postoperative pain,

opioid use, and the total LOS. Even with a dramatic price increase, IV acetaminophen should be utilized to provide exceptional, cost-effective care.

## APPENDIX A

### LITERATURE REVIEW TABLE

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, and Setting	Results	Strengths	Weaknesses	Implications for Practice
1. Memis, Inal, Kavalci, Sezer, and Sut, 2010	To assess pain relief effectiveness, side effects, and time to extubation of ICU patients after major surgery receiving IV paracetamol (acetaminophen) in addition to IV meperidine	Quantitative-single randomized controlled trial  Level of Evidence: 2	40 adult ICU patients after major abdominal or pelvic surgery, who were anticipated to need 24-hour postoperative sedation and ventilation. Pts were randomized into 2 groups using sealed envelopes. Group 1 received IV meperidine only, and group 2 received IV paracetamol and IV meperidine.	BPS and pain scores are notably lower in group 2 at 24 hours (P<0.5). In group 2, postoperative meperidine requirements (76.75 +/- 18.2 mg vs. 198 +/- 66.4 mg) and extubation time (64.3 +/- 40.6 min vs. 204.5 +/- 112.7 min) were lower than in group 1 (P<0.1). PONV and sedation scores were also considerably lower in group 2 when compared with group 1 (P<0.5).	The findings were consistent with various other studies regarding the use of acetaminophen in combination with morphine in the management of postoperative analgesia and decreasing the amount of morphine required.	No similar clinical studies were found of meperidine/ paracetamol IV regarding extubation time after major surgery when the patients were in ICU. The factors that cause PONV cannot be controlled in order to achieve significant results.	IV acetaminophen, in addition to meperidine enhances postop pain relief, sedation, and time to extubation in adult ICU patients after major abdominal or pelvic surgery when compared with meperidine only.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, and Setting	Results	Strengths	Weaknesses	Implications for Practice
2. Winger, Miller, Minkowitz, Royal, Ang, Breitmeyer, and Singla, 2010	To assess the safety and analgesic efficiency of 2 doses of IV acetaminophen in patients after laparoscopic abdominal procedures in a 24 hour period, when compared to placebo.	Double-blind, placebo-controlled, parallel-group study  Level of evidence: 2	244 adult post surgical patients from 17 sites randomized into 4 different groups: IV acetaminophen 1000 mg [100 mL] q6h; IV acetaminophen 650 mg [65 mL] q4h; IV placebo 100 mL q6h; or IV placebo 65 mL q4h), over a 24 hour period.	Both groups of IV acetaminophen showed significantly lower pain scores when compared to placebo.	Multiple sites in the US participated in this study. The results of this study are consistent with similar studies.	There was an allocation error after subject 109 (of 244 enrolled) that affected randomization.  Many patients had to remain inpatients, unnecessarily to participate in the study.  There were study design errors that may have contributed to the lack of statistical significance for time to rescue and opioid consumption.	IV acetaminophen is effective for controlling postoperative pain in this patient population. This study showed no significant difference in the safety profile of IV acetaminophen and placebo.



Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, and Setting	Results	Strengths	Weaknesses	Implications for Practice
3. Konstantatos, Smith, and Angliss, 2012	This article investigated whether intraoperative IV acetaminophen has the potential to reduce pain after ambulatory surgery and reduce time to discharge from the PACU and hospital.	Prospective randomized, double-blind clinical trial  Level of evidence: 2	A total of 142 patients undergoing ambulatory surgery were randomized to pre and postoperative placebo (50), IV operative and postoperative oral acetaminophen (49), and pre and postoperative oral acetaminophen (48)	The primary end point; visual analogue scale mean pain intensity over 24 hours after completion of surgery, was not considerably different between the 3 groups, control group 2.0 (1.6), mean (SD), (IV) acetaminophen group 2.1 (1.9) and oral acetaminophen group 2.1 (1.6); (p=0.93). Time to fitness for discharge from the postoperative care unit (p=0.77) and time to fitness for discharge from hospital (p=0.27) also did not vary significantly between the three groups.	142 total patients participated 3 arm study Baseline patient and clinical characteristics were similar in the three groups	Anesthetists had the option of combining fentanyl with morphine for analgesia and surgeons allowed to use local anesthetic infiltration if desired. The study was limited to one ambulatory surgery center with a study population of predominantly young healthy males.	In this setting, IV acetaminophen administered intraoperative did not provide significant pain relief or a reduction in discharge times compared to oral acetaminophen or placebo.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, and Setting	Results	Strengths	Weaknesses	Implications for Practice
4. Atef and Fawaz, 2008)	To assess the analgesic efficacy, safety, and the opioid sparing effect of IV paracetamol (Perfalgan) after elective tonsillectomy in adults.	Prospective randomized, double-blind placebo-controlled study  Level of evidence: 1	76 adult patients, ages 16-40 at Ain Shams University hospital who underwent an elective tonsillectomy.  Patients were randomized into 2 groups using a computer program randomization to either the acetaminophen (Perfalgan) or the placebo group. A nurse not involved in the study prepared the infusion for administration to ensure blindness.	In the paracetamol group, 29% of patients received rescue analgesics compared to the placebo group, 100% of patients.  Pain scores were significantly higher in the placebo group.	Baseline patient and clinical characteristics were similar in both groups Induction medications were the same for all patients and based on mg/kg basis.	The study was limited to one medical facility. The setting was not described for those wanting to duplicate the study.	IV paracetamol given every 6 hours on postoperative day 1 provided greater pain relief compared to placebo for these patients. IV paracetamol produced no significant adverse events.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, and Setting	Results	Strengths	Weaknesses	Implications for Practice
5. Anand et al. (2013)	To compare the effectiveness of pain relief after administration of 1g IV acetaminophen or 30mg IV ketorolac for patients who underwent a parathyroidectomy	Parallel, randomized, double blind, comparative study  Level of evidence: 1	180 patients, 18 years and older scheduled for outpatient parathyroidectomy. Setting: level 1 trauma hospital.  Patients were randomized to a blinded administration of either IV acetaminophen 1 g or ketorolac 30 mg intra-operatively. Upon arrival and before premedication, baseline pain scores were documented in all patients. VAS scores were assessed every 15 minutes in the PACU until discharge by blinded personnel.	Overall mean postoperative VAS scores were not significantly different between the 2 treatment groups (p=0.07). Rescue opioids were required by 3 patients in the ketorolac group compared to 9 patients in the acetaminophen group. However, total opioid consumption was not significant between groups (p = 0.13). The overall incidence of rescue opioid administration, vomiting, headache, muscular pain, dizziness, and drowsiness were not significantly different between the 2 groups.	Induction medications were the same for all patients and based on mg/kg basis. Large sample size – 180 patients, 90 in each group. Patient demographics and surgical time were similar in both groups	The study was limited to one medical facility. Acetaminophen 1 g IV was administered at the beginning of the procedure or 30 mg IV ketorolac 15 minutes before the end of the surgery. The peak onset of acetaminophen is <30 minutes and duration of action is 4-6 hours. The peak onset of ketorolac is 10 minutes and duration of action is 6-8 hours.	Both groups provided adequate pain relief. However, the IV ketorolac group had significantly lower pain scores at later time intervals (at 45, 60, and 75 minutes) and also had lower occurrences of PONV.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, and Setting	Results	Strengths	Weaknesses	Implications for Practice
6. Smith and Hoefling (2014)	To evaluate pain scores, opioid consumption, and ORADEs in spinal surgery patients after receiving IV acetaminophen.	Retrospective analysis  Level of Evidence: 3	The EMR of 68 spinal surgery patients were assessed. The acetaminophen group (n=34) received at least 1 dose pre or postoperatively of IV acetaminophen and the control group (n=34) did not receive acetaminophen but had similar characteristics as group A.	The acetaminophen group (11.3 mg ME) used significantly less opioids than the control group (20.6 mg ME) (p=0.015). There was no significant difference between the 2 groups in pain scores and ORADEs. Respiratory depression that required naloxone administration occurred in 1 patient in the control group.	The mean patient demographics were similar in both groups	Retrospective analysis – cannot control variables.  The setting was not described for those wanting to duplicate the study.  The average surgery time was longer in the acetaminophen group (216.0, SD 114.4) compared to the control group (187.5, SD 93.9) (P=0.264).  Inconsistent documentation of pain scores.  Possible bias in the selection process, of the matched control group	IV acetaminophen can be administered as an effective adjunct analgesic in this patient population to reduce opioid use, but not necessarily reduce the prevalence of ORADEs or pain scores.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, and Setting	Results	Strengths	Weaknesses	Implications for Practice
7. Tzortzopoulou et al., 2011	The purpose of this study was to assess the efficacy and safety of IV propacetamol for the treatment of postoperative pain in adults and children.	Systemic review  Level of Evidence: 1	36 Randomized, double-blind, controlled single dose clinical trials (3896 participants) of IV propacetamol for acute postoperative pain in adults or children were included. Two addition reviews evaluated the risk of bias and extracted data.	Of the 3896 patients, 37% of those receiving IV propacetamol had at least 50% pain relief over 4 hours compared to 16% in the placebo group. The proportion of participants in IV propacetamol group experiencing at least 50% pain relief diminished over 6 hours. Participants that received IV propacetamol required 30% less opioid over 4 hours than the placebo group. No significant difference was found in ORADEs between the 2 groups.	The 2 reviewers impartially evaluated the risk of bias of all included studies, using a domain-based assessment.  Only randomized studies were included, which reduced the potential for bias.  Large number of studies (36) and therefore participants (3896)	All age groups were included.  The results included different surgical procedures.  The possibility of bias using unpublished trials showing no benefit of IV propacetamol or IV paracetamol over placebo may exist.	Both formulations were showed to be associated with fewer ORADEs.  IV propacetamol had a higher occurrence of pain on infusion than both placebo and IV paracetamol.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, and Setting	Results	Strengths	Weaknesses	Implications for Practice
8. Singla et al. (2014)	This study determined the efficacy of postoperative pain control and safety of IV acetaminophen for patients who underwent arthroplasty	Evaluation of 2 double-blind, parallel-group, multicenter, randomized, placebo-controlled clinical trials  Level of Evidence: 2	Total 130 modified intent-to-treat (mITT) patients, November 2003-September 2004. Study 1: single-dose efficacy, n=69, 11 medical sites in the U.S. (IV acetaminophen, n=35; placebo, n=34) undergoing total hip arthroplasty. Study 2: repeated-dose efficacy, n=61 (IV acetaminophen, n=30; placebo, n=31). 21 days preop – screening w/ consent, H&P, labs, and education on using a PCA and pain scales. All pts were anesthetized using either general, spinal, or epidural anesthesia. A PCA was started in PACU. Morphine 2mg was available for rescue analgesia. PCA was interrupted 16 hours after surgery. Once the pt's VAS was at least 45mm, either IV acetaminophen or IV placebo was administered (T0). Pts were asked to wait 30 mins after receiving the infusion before using PCA. Pain responses were assessed in regular increments	Mean pain intensity differences (PID) of IV acetaminophen were significantly higher than the control group (P<0.5). VAS scores were consistently lower in IV acetaminophen than the control group. IV acetaminophen decreased rescue opioid requirements for up to 6 hours in study 1 and up to 4 hours in study 2. Mean time for rescue analgesia for IV acetaminophen was 4.72 compared to placebo 1.4 in study 1, and >4 and 1.25, respectively in study 2.	Both studies had similar patient populations, study design, and methodologies.  These 2 studies provided administration of IV acetaminophen postop day 1 to reduce variability that may have been present due to the type of anesthetic.	Particulate matter and altered pH found in the placebo caused early termination of both studies.  Converted to modified intent-to-treat (mITT)  Study 1: n reduced from 140 to 69.  Study 2: n reduced from 230 to 61.  Patients did not receive the same type of anesthesia.  IV acetaminophen was not initiated until after surgery.  Limited collection of samples.	Both studies showed that IV acetaminophen is effective and safe for postoperative pain relief when used in this patient population  IV acetaminophen significantly improved analgesia, and decreased opioid consumption in more than 50% of patients when compared with placebo.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, and Setting	Results	Strengths	Weaknesses	Implications for Practice
9. Ong, Seymour, Lirk, and Merry, 2010	This study assessed the effectiveness of combining paracetamol and an NSAID versus either drug alone in different acute pain models.	Qualitative Systematic Review  Level of Evidence: 5	A systematic literature search of Medline, Embase, Cumulative Index to Nursing and Allied Health Literature, and PubMed covering the period from January 1988 to June 2009 was performed to identify randomized controlled trials in humans that specifically compared combinations of paracetamol with various NSAIDs versus at least 1 of these constituent drugs. Identified studies were stratified into 2 groups: paracetamol/NSAID combinations versus paracetamol or NSAIDs. We analyzed pain intensity scores and supplemental analgesic requirements as primary outcome measures. In addition, each study was graded for quality using a validated scale.	Twenty-one human studies enrolling 1909 patients were analyzed. The NSAIDs used were ibuprofen ( $n=6$ ), diclofenac ( $n=8$ ), ketoprofen ( $n=3$ ), ketorolac ( $n=1$ ), aspirin ( $n=1$ ), tenoxicam ( $n=1$ ), and rofecoxib ( $n=1$ ). The combination of paracetamol and NSAID was more effective than paracetamol or NSAID alone in 85% and 64% of relevant studies, respectively. The pain intensity and analgesic supplementation was 35.0% +/- 10.9% and 38.8% +/- 13.1% lesser, respectively, in the positive studies for the combination versus paracetamol group, and 37.7% +/- 26.6% and 31.3% +/- 13.4% lesser, respectively, in the positive studies for the combination versus the NSAID group. No statistical difference in median quality scores was found between experimental groups.	The subgroup analysis by surgical model and NSAID type confirms the overall results and further strengthens the conclusion. This conclusion is consistent with many previous expert reviews that recommend the use of combination analgesics	Limitations of our study include its qualitative approach and the wide range of acute pain models included in the studies reviewed.	This review suggests that combining paracetamol and an NSAID confers additional analgesic efficacy over either drug alone.  There are some potential disadvantages in combining NSAIDs and paracetamol. A combination may be disadvantageous when individual drugs are specifically suited to a patient's symptoms (e.g., when only the antipyretic action of paracetamol is required for fever). Combining analgesics may increase the incidence of adverse effects.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, and Setting	Results	Strengths	Weaknesses	Implications for Practice
10. Macario and Royal, 2010	To evaluate analgesic outcomes in the postoperative period after administration of IV acetaminophen in adults	Systematic review Level of evidence: 1	The authors investigated prospective, randomized, controlled trials (RCTs) from January 2000 to January 2010 in Medline and the Cochrane library databases to compare IV acetaminophen and an active comparator or placebo. 22 studies were included for a total of 1,464 subjects.	7 of 8 comparative studies, including IV parecoxib [ $n = 3$ studies], IV metamizol [ $n = 4$ ], oral ibuprofen [ $n = 1$ ], IV acetaminophen had no significant difference in postoperative pain relief. 12 of 14 studies found a significant difference in analgesia from the administration of IV acetaminophen compared to placebo. 10 of 14 studies found patients who received IV acetaminophen required less opioids, a lower percentage of patients needing rescue opioids, or a longer period of time to the first rescue needed.  In aggregate, these data suggest that IV acetaminophen is an efficient analgesic for a assortment of patients and a variety of surgeries.	This study's findings were consistent with other related articles.	Small participant size in the majority of the studies. There were various analgesic interventions among the studies, including nerve blocks. The studies used various systems for documenting the variables. Publication bias also cannot be discounted.	The IV acetaminophen has a faster onset than the oral or rectal administration; therefore, the IV formulation would be preferred for treating acute pain in surgical patients.  The selected RCTs in this study indicated that IV acetaminophen is an efficient postoperative analgesic for a variety of surgical procedures.



Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, and Setting	Results	Strengths	Weaknesses	Implications for Practice
11. Lewis, Gunta, Mitchell, and Bobay, 2012	The purpose of this study was to evaluate different analgesic approaches, group 1 included patients receiving a multimodal approach and group 2 did not.	Retrospective chart review  Level of evidence: 3	A convenience sample of patients undergoing TKA from 2009-2010 was obtained. The control group included 45 patients from 2009 and the multimodal group included 66 patients from 2010. A data collection tool, developed by the researchers was used to gather data. A staff RN was trained by the researchers and gathered data using the data collection form. The multimodal protocol included the use of oxycontin 20mg PO, acetaminophen 1g PO, celecoxib 400mg PO, gabapentin 600mg PO, ondansetron 4mg PO, naropin 0.2% of femoral continuous PNB, oxycodone 5mg, 10mg and 20mg PO, and ketorolac 15mg IV.	The researchers discovered lower PACU pain scores, a decreased probability of PONV, and shorter LOS in the multimodal group versus the control group.	The multimodal and control group subjects were of similar age and the samples were not statistically different based on gender.	Retrospective analysis – cannot control variables and cannot determine causal relationships.  The setting was not described for those wanting to duplicate the study.  Limited to 1 medical facility and 1 surgeon.  Retrospective study	Well-controlled postoperative pain provides more favorable outcomes and possibly a reduction in LOS for this patient population.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, and Setting	Results	Strengths	Weaknesses	Implications for Practice
12. Xiromeritis, Kalogiannidis , Papadopoulos , Prapas, and Prapas, 2011	The purpose of this study is to assess postoperative pain when using a set of multimodal guidelines for females undergoing uterine fibroid surgery.	Prospective, randomized trail  Level of evidence: 1	92 patients undergoing laparoscopic myomectomy and laparoscopic assisted myomectomy were randomized into 2 groups using sealed envelopes: group 1 received the multimodal analgesic protocol and group 2 did not. The VAS scale was used to assess postoperative pain 2 and 8 hours postoperative. The multimodal protocol included the following medications: dexamethasone 8 mg IV, local anesthetic injected at the trocar sites, ondansetron 4 mg IV, a mixture of diclofenac 75 mg and paracetamol 600 mg IM. In the postoperative period, both groups received paracetamol 1 g q 8 hours, diclofenac 50 mg suppository BID PRN.	The mean VAS at 2 and 8 h postoperatively was significantly lower in the multimodal group compared to the control group (2 h postoperatively: $4.7 \pm 0.7$ vs $7.1 \pm 0.9$ , $P < 0.0001$ ; 8 h postoperatively: $2 \pm 0.6$ vs $4.5 \pm 0.8$ , $P < 0.0001$ ). Peristalsis returned earlier in the multimodal group compared to the control group ( $10.1 \pm 2.7$ vs $23 \pm 1.6$ h, $P < 0.0001$ ). The multimodal group compared to the control group had reduced hours in the hospital, indicating a faster recovery time ( $11 \pm 5$ vs $26.8 \pm 5.8$ h, $P < 0.0001$ ). All but 1 woman in the multimodal group were discharged between 6 and 16 h postoperatively. One woman in the multimodal group was discharged 44 h postoperatively, due to a mild fever and late return of bowel peristalsis. All patients in the control group were discharged at least 20 h after surgery. No significant difference was found in the amount of time for return of full activity between the 2 groups. Either group had no ORADEs.	The patient's characteristics in the two groups were similar, except for the mean age.  The LOS, pain scores, incidences of PONV, and ORADEs were all assessed by physicians who were not aware of the study. The physicians used the PADSS discharge criteria, which limited possible bias.	A significant difference in mean age was found ( $35.7 \pm 5.7$ vs $33.4 \pm 4.7$ , $P < 0.04$ ).	A multimodal approach, including different nonopioid analgesics and peripheral nerve blocks are generally safe and can assist with postoperative pain control in this patient population.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, and Setting	Results	Strengths	Weaknesses	Implications for Practice
13. Minkowitz, Gruschkus, Shah, and Raiu, 2014	The purpose of this study is to evaluate the opioid-related adverse drug events (ORADEs) that were reported within a large healthcare facility.	Retrospective cohort study  Level of evidence: 3	The EMRs from 11 hospitals were analyzed with a total of 6,285 patients, 18 years and older, that had an inpatient surgical procedure in 2010. The EMRs were examined from admission date to postdischarge day 30. The amount of opioids administered and the frequency of adverse drug events (ADEs) were documented. Outcomes after	Of the 6,285 patients, 99.8% were administered opioids in the postoperative period, 11.0% (n=689) of those patients experienced ORADE, including GI ADEs (6.3%, n=396), Respiratory (2.9%, n=182), GU (1.5%, n=94), CNS (0.6%, n=38), and other (0.9%, n=57). In the overall population, patients 65 years of age or older were twice as likely to have an ADE compared with younger patients. In the overall population, postoperative opioid use was significantly associated with ADE risk. The mean healthcare cost for those that experienced an ADE compared to those who did not were \$29,782 vs \$16,045. The LOS was higher in those patients who experienced an ADE than those that did not (10.0, 5.5 days). Thirty day readmission rates in patients who experienced an ADE were 71%. The mortality rates of patients who experienced an ADE (3.4%) was higher than those who did not (1.5%).	Described setting adequately.  Identified risk factors associated with ADEs, along with healthcare costs associated with ADEs.	Retrospective analysis – cannot control variables and can not determine causal relationships.  Of the final study population 72.1% (n=4,522) were female. The frequency of ADEs may have been higher than reported if documentation was not adequate.  The study lacks data regarding BMI, opioid dosages and morphine equivalences, home medications, the duration of surgery, and the need for mechanical ventilation.  The examined database only captured 11 hospitals, therefore the readmission rates could be under estimated.	This study found that patients with multiple risk factors for ORADEs were more likely to have higher hospital costs due to the extended LOS, and higher readmission rates compared to patients with fewer risk factors. Results of this study demonstrate that postoperative opioid use occurred in nearly all patient cases evaluated and that approximately 11% of the patients experienced an ADE, with GI events being the most common.  Factors found to be associated with increased ADE risk included demographic characteristics, such as older age and male sex, and clinical factors, such as prior opioid use, COPD, cardiac dysrhythmia, regional enteritis, diverticulitis, and ulcerative colitis.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, and Setting	Results	Strengths	Weaknesses	Implications for Practice
14. Oderda et al., 2007	The purpose of this study was to research the impact of ORADEs on hospital LOS in adult surgical patients.	Retrospective matched cohort study  Level of evidence: 3	Surgical patients treated at LDS Hospital in Salt Lake City from January 1, 1998, to December 31, 2003, were included. The ORADE group included 741 participants, 17 years and older. Each ORADE participant was matched with 15 control cases with similar demographics and characteristics (n=10,116).	Patients experiencing ORADEs had significantly increased total mean hospital costs (7.4% increase, $p < 0.001$ ) and increased median LOS (10.3% increase, $p < 0.001$ ) when compared to the control group.	The ORADE and the control group had statistically similar demographics and characteristics	Retrospective analysis – cannot control variables and can not determine causal relationships. The study did not use morphine-equivalent doses.  ORADEs may have been underestimated due to using a computer-prompted method of surveillance, and bias was not controlled.  Cost data may not be generalizable due to the small geographic area of the study	Postoperative ADEs were found to increase LOS and therefore increase cost.  These ADEs were found to transpire more frequently in patients who require more opioids for postoperative pain control.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, and Setting	Results	Strengths	Weaknesses	Implications for Practice
15. Pizzi et al., 2012	This study examined if ORADEs had an impact on postoperative hospital LOS.	Retrospective chart review  Level of evidence: 3	A stratified, random sample of 402 patients, age 18 or older who underwent orthopedic spine, hip, knee, or shoulder surgery during 2007. The EMRs were reviewed and data collected by 3 trained abstractors. The data collected included patient demographics, LOS, drug therapy, and ORADEs. The dose of all opioids were converted to MEs	Over half (54.2%) of the participants experienced at least 1 adverse effect. Nearly 1:5 (18.4%) of the patients experienced 2 adverse effects and 7.2% experienced 3 or more. There was no significant difference between surgery types and the incidence of adverse events. N/V was the most common adverse effect (36.1%).	Included 4 different procedures – spine, hip, knee, and shoulder surgery.	Retrospective analysis – cannot control variables and cannot determine causal relationships.  Limited to 2 academic medical facilities.  The frequency of ADEs may have been higher than reported if documentation was not adequate.	ORADEs, such as Constipation, PONV, and disorientation resulted in increased in LOS.  There is a need for further examination of risk factors of ORADEs, which effects LOS.

Author(s), Date	Purpose or Research Question(s)	Research Design/ Level of Evidence	Sampling Method, Size, and Setting	Results	Strengths	Weaknesses	Implications for Practice
16. Eckstrand et al., 2009	This study examined the opioid-related over-sedation and respiratory depression after naloxone administration	Retrospective, cross-sectional study  Level of evidence: 3	Patients that were administered naloxone (n=419) in the perioperative period were identified using computerized surveillance. The participants were of those that had surgery at Duke University Hospital from 10/15/2007-10/15/2008.	419 cases of perioperative naloxone administration were found, of which, 101 were given postoperatively and 69 were documented as ADEs yielding a rate of 1.89 ADEs/1000. The ADEs increased by 22.7% when the surveillance was expanded into perioperative period. The researchers found that 11 of the participants had a history of over-sedation. Out of those 11, 9 received intraoperative naloxone, and 2 received naloxone in the PACU.	Described setting adequately.	Retrospective analysis – cannot control variables and can not determine causal relationships.  The computerized surveillance system could only detect naloxone administration if it was properly documented into the EMR.  This computerized surveillance system is not readily available for other medical facilities.  The administration of naloxone during the intraoperative period was not examined.	Computerized surveillance systems may be a very useful tool to any medical facility to detect rare, but fatal ADEs.

APPENDIX B  
SWOT ANALYSIS

Strengths	Weaknesses
<ul style="list-style-type: none"> <li>• Retrospective chart review</li> <li>• No additional costs or added workload for the selected clinical site</li> </ul>	<ul style="list-style-type: none"> <li>• Incomplete or inadequate documentation</li> <li>• Cannot control variables as with a prospective study</li> </ul>
Opportunities	Threats
<ul style="list-style-type: none"> <li>• Change in practice within the selected medical facility</li> <li>• Change in practice in other medical facilities after dissemination</li> </ul>	<ul style="list-style-type: none"> <li>• IV acetaminophen does not reduce postoperative pain in the selected patient population</li> <li>• The costs outweighs the benefits of IV acetaminophen</li> </ul>

## APPENDIX C

### DNP ESSENTIALS

DNP Essentials	Clinical Implications
DNP Essentials I – Scientific underpinnings for practice	King’s Theory of Goal Attainment utilizes the communication and interactions between the patient and the nurse in order for the patient to achieve their healthcare goals. The utilization of pathophysiology, pharmacology, anatomy, and physiology is essential to providing excellent patient care.
DNP Essentials II – Organizational and systems leadership for quality improvement and systems thinking	The administration of IV acetaminophen may improve postoperative pain without the negative side effects of multiple doses of opioids. A practice change will likely be established to improve patient safety and satisfaction.
DNP Essentials III – Clinical scholarship and analytical methods for evidence-based practice	This capstone project assesses the methods currently used to prevent postoperative pain in obese patients. After these methods are critiqued, new guidelines for postoperative pain prevention will be established for the obese patient.
DNP Essentials IV – Information systems or technology and patient care technology for the improvement and transformation of health care	Performing a retrospective chart review, patient data will be extracted from their EMR and protected to avoid ethical and legal issues. Other electronic databases will be utilized for the review of literature, industry standards, and other pertinent information dealing with laparoscopic cholecystectomy in the obese patient, postoperative pain in the obese patient, opioid administration in the obese patient, and IV acetaminophen for the reduction of postoperative pain.
DNP Essentials V – Healthcare policy for advocacy in healthcare	If the assumptions of this capstone project prove true, advocacy for a practice change will be implemented for the reduction in postoperative pain in the obese patient after a laparoscopic cholecystectomy, and the reduction of opioids in this population. This will improve patient safety and patient satisfaction, as well as patient outcomes.
DNP Essentials VI – Interprofessional collaboration for improving patient and population health outcomes	Interdisciplinary collaboration can be developed by respecting the knowledge and expertise of other team members; asking



	<p>for input from other team members; and communicating effectively by utilizing active listening, compassion, and empathy. For effective collaboration to take place, one must learn to value and manage diversity, cultivate constructive conflict resolution skills, and understand that collaboration is a journey. Communication is also an essential component between the nurse and the patient in order to achieve the patient's health and wellness goals.</p>
<p>DNP Essentials VII – Clinical prevention and population health for improving the nation's health</p>	<p>The administration of excessive opioids produces harmful side effects, especially in the obese patient. These adverse side effects could cause respiratory depression and detrimental effects on the patient's health and postoperative recovery. This project will evaluate the use of IV acetaminophen and if opioid administration is reduced in the postoperative period, which could potentially improve the outcomes for this population.</p>
<p>DNP Essentials VIII – Advanced nursing practice</p>	<p>Communication throughout the perioperative period is crucial for any surgical procedure in order to provide the desired outcomes for that patient. This communication should be continued during the postoperative period so that the patient receives optimal care. Minimizing the use of opioids in PACU in a patient, who has a low tolerance to these medications as evidence by their reaction during induction of anesthesia, is vital to their recovery. This information should always be communicated to the PACU nurse that will be caring for that patient. The use of IV acetaminophen will reduce postoperative pain and the quantity of opioids required to manage pain. This will improve patient outcomes and decrease the number of adverse events during the postoperative period.</p>

## APPENDIX D

## LOGIC MODEL

Inputs	Outputs		Outcomes -- Impact		
	Activities	Participation	Short	Medium	Long
Time Technology	Review and assess records	CRNAs Anesthesiologists Hospitals Outpatient surgery centers	The incidence of postoperative pain will decrease in obese patients undergoing laparoscopic cholecystectomy when given IV acetaminophen  Learning  Attitudes  Awareness  Opinions	The need for opioid use will be reduced in obese patients undergoing laparoscopic cholecystectomy with the reduction of IV acetaminophen.  Action  Practice  Decision-making  Policies	The time to ambulation and to discharge will be reduced in obese patients undergoing laparoscopic cholecystectomy with the reduction of IV acetaminophen.  Conditions  Social  Economic

**Assumptions**

The administration of IV acetaminophen will decrease postoperative pain in obese patients undergoing laparoscopic cholecystectomy.

**External Factors**

Improper documentation of administration time of IV acetaminophen, pain score, and opioid administration.

## APPENDIX E

## CITI TRAINING

## COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)

SBR FACULTY, STUDENTS AND STAFF AT THE UNIVERSITY OF SOUTHERN MISSISSIPPI (BASIC COURSE)  
CURRICULUM COMPLETION REPORT

Printed on 01/30/2014

**LEARNER** Kimberly Burks (ID: 3985544)  
December 2015  
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**DEPARTMENT** Nurse Anesthesia Program

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**INSTITUTION** University of Southern Mississippi

**EXPIRATION DATE** 01/29/2019

SBR : Faculty, Students and Staff at the University of Southern Mississippi (Basic Course)

**COURSE/STAGE:** Stage 1/1

**PASSED ON:** 01/30/2014

**REFERENCE ID:** 12233563

REQUIRED MODULES	DATE COMPLETED	SCORE
Belmont Report and CITI Course Introduction	01/30/14	3/3 (100%)
Students in Research	01/30/14	10/10 (100%)
History and Ethical Principles - SBE	01/30/14	5/5 (100%)
Defining Research with Human Subjects - SBE	01/30/14	5/5 (100%)
The Regulations - SBE	01/30/14	4/5 (80%)
Assessing Risk - SBE	01/30/14	5/5 (100%)
Informed Consent - SBE	01/30/14	5/5 (100%)
Privacy and Confidentiality - SBE	01/30/14	5/5 (100%)
Internet Research - SBE	01/30/14	5/5 (100%)
The University of Southern Mississippi	01/30/14	No Quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI Program participating institution or be a paid Independent Learner. Falsified information and unauthorized use of the CITI Program course site is unethical, and may be considered research misconduct by your institution.

Paul Braunschweiger Ph.D.  
Professor, University of Miami  
Director Office of Research Education  
CITI Program Course Coordinator

Collaborative Institutional  
Training Initiative  
at the University of Miami

**COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)**  
**COMMON COURSE FOR USM GRADUATE STUDENTS CURRICULUM COMPLETION REPORT**  
 Printed on 01/30/2014

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**EXPIRATION DATE** 01/29/2019

**COMMON COURSE FOR USM GRADUATE STUDENTS :**

**COURSE/STAGE:** RCR/1  
**PASSED ON:** 01/30/2014  
**REFERENCE ID:** 12233561

REQUIRED MODULES	DATE COMPLETED	SCORE
Introduction to the Responsible Conduct of Research	01/29/14	No Quiz
Research Misconduct (RCR-Biomed)	01/29/14	5/5 (100%)
Case Study Plagiarism (RCR-Biomed)	01/30/14	2/2 (100%)
Data Management (RCR-Biomed)	01/30/14	5/5 (100%)
Authorship (RCR-Biomed)	01/30/14	5/5 (100%)
Mentoring (RCR-Interdisciplinary)	01/30/14	5/5 (100%)
Conflicts of Interest (RCR-Biomed)	01/30/14	6/6 (100%)
Collaborative Research (RCR-Biomed)	01/30/14	5/5 (100%)
Internet Research - SBE	01/30/14	5/5 (100%)
Privacy and Confidentiality - SBE	01/30/14	5/5 (100%)
The University of Southern Mississippi	01/30/14	No Quiz

**For this Completion Report to be valid, the learner listed above must be affiliated with a CITI Program participating institution or be a paid Independent Learner. Falsified information and unauthorized use of the CITI Program course site is unethical, and may be considered research misconduct by your institution.**

Paul Braunschweiger Ph.D.  
 Professor, University of Miami  
 Director Office of Research Education  
 CITI Program Course Coordinator

Collaborative Institutional  
 Training Initiative  
 at the University of Miami

**COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)**  
**CONFLICT OF INTEREST MINI-COURSE CURRICULUM COMPLETION REPORT**  
 Printed on 01/30/2014

**LEARNER** Kimberly Burks (ID: 3985544)  
 December 2015  
 12 Tuckahoe  
 Hattiesburg  
 MS 39402

**DEPARTMENT** Nurse Anesthesia Program

**EMAIL** kimberly.s.burks@eagles.usm.edu

**INSTITUTION** University of Southern Mississippi

**EXPIRATION DATE** 01/29/2019

**CONFLICT OF INTEREST**

**COURSE/STAGE:** Stage 1/1

**PASSED ON:** 01/30/2014

**REFERENCE ID:** 12233564

REQUIRED MODULES	DATE COMPLETED	SCORE
Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules	01/30/14	5/5 (100%)
Institutional Responsibilities as They Affect Investigators	01/30/14	4/5 (80%)

**For this Completion Report to be valid, the learner listed above must be affiliated with a CITI Program participating institution or be a paid Independent Learner. Falsified information and unauthorized use of the CITI Program course site is unethical, and may be considered research misconduct by your institution.**

Paul Braunschweiger Ph.D.  
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 Training Initiative  
 at the University of Miami

**COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)**  
**RESEARCHERS, FACULTY, STUDENTS AND IRB MEMBER'S CURRICULUM COMPLETION REPORT**  
 Printed on 01/30/2014

**LEARNER** Kimberly Burks (ID: 3985544)  
 December 2015  
 12 Tuckahoe  
 Hattiesburg  
 MS 39402

**DEPARTMENT** Nurse Anesthesia Program

**EMAIL** kimberly.s.burks@eagles.usm.edu

**INSTITUTION** University of Southern Mississippi

**EXPIRATION DATE** 01/29/2019

**RESEARCHERS, FACULTY, STUDENTS AND IRB MEMBERS ENGAGING IN RESEARCH INVOLVING HUMAN SUBJECTS RCR :**  
 Researchers, Faculty, Students

**COURSE/STAGE:** Stage 1/1  
**PASSED ON:** 01/30/2014  
**REFERENCE ID:** 12233562

REQUIRED MODULES	DATE COMPLETED	SCORE
The University of Southern Mississippi	01/30/14	No Quiz
Belmont Report and CITI Course Introduction	01/30/14	3/3 (100%)
Students in Research	01/30/14	10/10 (100%)
History and Ethical Principles - SBE	01/30/14	5/5 (100%)
Defining Research with Human Subjects - SBE	01/30/14	5/5 (100%)
The Regulations - SBE	01/30/14	4/5 (80%)
Assessing Risk - SBE	01/30/14	5/5 (100%)
Informed Consent - SBE	01/30/14	5/5 (100%)
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research	01/30/14	3/3 (100%)

**For this Completion Report to be valid, the learner listed above must be affiliated with a CITI Program participating institution or be a paid Independent Learner. Falsified information and unauthorized use of the CITI Program course site is unethical, and may be considered research misconduct by your institution.**

Paul Braunschweiger Ph.D.  
 Professor, University of Miami  
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 Training Initiative  
 at the University of Miami

## APPENDIX G

## LETTER OF SUPPORT FROM MEDICAL FACILITY



December 12, 2014

University of Southern Mississippi  
Office of Research Integrity, Institutional Review Board  
118 College Drive #5147  
Hattiesburg, MS 39406-0001

RE: Kimberly Burks' Capstone Project

To Whom It May Concern:


This is a letter of support for Kimberly Burks to preform her capstone project titled, "Intravenous Acetaminophen Reduces Opioid Use for Postoperative Pain in Obese Patients Undergoing Laparoscopic Cholecystectomy" at Forrest General Hospital. I give her permission to examine charts during January to May, 2015, for patients who underwent elective laparoscopic cholecystectomy between January 1, 2012 to December 31, 2014. I understand that the inclusion criteria also specifies the patients to be between the ages of 18 to 65 and a BMI greater than 30.

Mrs. Burks will gather the following information on each record:

- Procedure date and Surgeon
- Age, Gender, and Ethnicity
- Height, Weight, and Body mass index
- Current medications and Personal medical history
- Previous surgeries and any anesthetic complications
- ASA classification and Mallampati classification
- Any medications that were administered during the perioperative period, along with the dosage, and time
- Results of the chest radiograph and electrocardiogram
- Anesthesia start and end time, Surgery start and end time, and Time in the PACU
- Intubation information, including number of direct laryngoscopies, airway grade, size of the endotracheal tube, and what laryngoscope blade was used
- Intraoperative vital signs and any intraoperative adverse events
- Type and amount of IV fluids administered, and Estimated blood loss
- If extubation was awake, deep, or not available
- PACU vital signs, Pain score, and Time to ambulation
- If the patient is discharged home or transferred to an inpatient floor
- Any abnormal finding in the perioperative period

I am aware that the data Mrs. Burks gathers will be de-identified and kept confidential using a password-protected computer and a locked box for the data collection forms. I also understand that this data will be used for her Doctor of Nursing Practice capstone project, white paper proposals, and future publications and presentations.

Sincerely,



Joe Campbell,  
Chairman of Anesthesiology and Chief Medical Officer

P.O. Box 16389 • Hattiesburg, MS 39404-6389  
6051 Highway 49 • Hattiesburg, MS 39401-7243  
(601) 288-7000 • forrestgeneral.com

APPENDIX H  
LETTER OF SUPPORT FROM USM



THE UNIVERSITY OF  
SOUTHERN MISSISSIPPI

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COLLEGE OF NURSING

118 College Drive #5095 | Hattiesburg, MS 39406-0001  
Phone: 601.266.5445 | Fax: 601.266.5927 | [nursing@usm.edu](mailto:nursing@usm.edu) | [www.usm.edu/nursing](http://www.usm.edu/nursing)

January 13, 2015

Dear Dr. Lewis E. Hatten:

I have reviewed Kim Burks's research plan for her Doctorate of Nursing Practice Capstone Project entitled, *Intravenous Acetaminophen Reduces Opioid Use for Postoperative Pain in Obese Patients Undergoing Laparoscopic Cholecystectomy*. I understand that she plans to conduct a retrospective chart review of obese patients who underwent laparoscopic cholecystectomy. She will be gathering body mass index, age, the amount and time of pain medication during and after the procedure, and compare these amount to the patients who received Ofirmev and those who did not. Mrs. Burks' project has been approved by her capstone committee and is under review by The University of Southern Mississippi Institutional Review Board. The data collection will begin once approval is granted.

The College of Nursing supports Mrs. Burks's project. This project is sound and has merit to future practice. Please let me know if you need anything further as you move forward. Your support for her project is greatly appreciated.

Sincerely,

A handwritten signature in cursive script that reads "Lachel Story".

Lachel Story, PhD, RN  
Assistant Dean for Research and Evaluation  
PhD Program Director  
Assistant Professor  
The University of Southern Mississippi  
College of Nursing



## APPENDIX I

## MEDICAL FACILITY IRB APPROVAL LETTER



**DATE:** February 5, 2015

**TO:** Kimberly Burks, SRNA, BSN, RN  
**FROM:** Forrest General Hospital Institutional Review Board

**STUDY TITLE:** [713003-1] Intravenous Acetaminophen Reduces Opioid Use for Postoperative Pain In Obese Patients Undergoing Laparoscopic Cholecystectomy

**IRB REFERENCE #:**  
**SUBMISSION TYPE:** New Project

**ACTION:** DETERMINATION OF EXEMPT STATUS  
**DECISION DATE:** January 28, 2015

Thank you for your submission of New Project materials for this research study. Forrest General Hospital Institutional Review Board has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations.

We will put a copy of this correspondence on file in our office.

If you have any questions, please contact Michele Stanley at 601-288-4324 or [mstanley@forrestgeneral.com](mailto:mstanley@forrestgeneral.com). Please include your study title and reference number in all correspondence with this office.

## APPENDIX J

## USM IRB APPROVAL LETTER

**INSTITUTIONAL REVIEW BOARD**

118 College Drive #5147 | Hattiesburg, MS 39406-0001

Phone: 601.266.5997 | Fax: 601.266.4377 | [www.usm.edu/research/institutional.review.board](http://www.usm.edu/research/institutional.review.board)**NOTICE OF COMMITTEE ACTION**

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

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

PROTOCOL NUMBER: 15012803

PROJECT TITLE: Intravenous Acetaminophen Reduces Opioid use for Postoperative Pain in Obese Patients Undergoing Laparoscopic Cholecystectomy

PROJECT TYPE: New Project

RESEARCHER(S): Kimberly Shae Burks

COLLEGE/DIVISION: College of Nursing

DEPARTMENT: Advanced Practice, Nurse Anesthesia

FUNDING AGENCY/SPONSOR: N/A

IRB COMMITTEE ACTION: Exempt Review Approval

PERIOD OF APPROVAL: 04/02/2015 to 04/01/2016

**Lawrence A. Hosman, Ph.D.****Institutional Review Board**



## APPENDIX L

## PROJECTED TIMETABLE

Capstone proposal to chair/committee	November 30, 2014
Defend Capstone proposal	December 10, 2014
IRB Submission	December 20, 2014
IRB Approval	January 30, 2015
Review charts for patients who underwent an elective laparoscopic cholecystectomy between May 1, 2013 to December 31, 2014	February 1, 2015 to May 15, 2015
Rough draft on final document	July 15, 2015
Oral defense of Capstone	September 1, 2015
Submit hard copy of Capstone to Graduate reader for proofing	September 2015
Submit final copy to Graduate reader	October 2015

## APPENDIX M

## WHITE PAPER PROPOSAL

**BACKGROUND:** The management of postoperative pain is essential to many aspects of the healing process after an invasive surgical procedure. The opioid class of pain medication has and continues to be the drug of choice for the relief of pain in the perioperative setting due to their effectiveness, but these medications have numerous side effects that could cause morbidity or even mortality (Casati & Putzu, 2004). In addition to the potential adverse pharmacodynamic effects of opioid consumption, the physiological and pathophysiological alterations associated with obesity, pose an increased risk for developing adverse events in the postoperative period in the presence of opioid administration (Nagelhout, 2014b).

**PURPOSE:** The purpose of this capstone project was to determine if intravenous (IV) acetaminophen reduces the amount of opioid administration for postoperative pain in the post anesthesia care unit (PACU) in obese patients who underwent a laparoscopic cholecystectomy.

**METHODS:** This retrospective study consisted of 80 chart reviews and examined if IV acetaminophen reduced opioid consumption in the postoperative period in obese patients who underwent a laparoscopic cholecystectomy. The inclusion criterion comprised patients within the ages of 18 to 65, a body mass index (BMI) greater than 30, and that underwent a laparoscopic cholecystectomy at the designated medical facility. Exclusion criteria included patients with a known allergy to acetaminophen; severe hepatic impairment, chronic alcoholism or use of opioids, and malnutrition; severe hypovolemia, or renal impairment.

RESULTS OF DATA: Independent-samples t-tests were conducted to conclude the following:

- IV acetaminophen decreases the amount of hydromorphone the patient receives in PACU for postoperative pain relief; Group T (M=0.63, SD=0.61) and Group NT (M=1.00, SD=0.70);  $t(78) = -2.54, p=0.02$ . The amount of hydromorphone dispensed for the total LOS was also decreased by the administration of IV acetaminophen; Group T (M=1.08, SD=0.89) and Group NT (M=2.21, SD=2.19);  $t(78) = -2.98, p=0.005$ .
- The majority of the patients in Group T were discharged (d/c) home (33, 82.5%), whereas only half of the patients in Group NT were discharged home (20, 50%). This discharge status is an important factor in the total cost for the patient and the healthcare facility.
- The average LOS is reduced with the administration of 1 dose of IV acetaminophen in the preoperative period; Group T (M=704.63, SD=768.42) and Group NT (M=1237.90, SD=928.38);  $t(78) = -81.88, p=0.007$ .
- Although the price of IV acetaminophen was increased tremendously, this study shows that the total mean cost for Group T is significantly lower than Group NT. This price difference is due to the number of patients that were admitted for inpatient status. See cost analysis table.
- There was no significant difference between Group T and Group NT in the:
  - Total anesthesia time
  - Total PACU time.

## Cost analysis

	Group T (n = 40)	Group NT (n=40)
Cost of PACU	\$950	\$950
Number of Patients	40	40
Total Cost for the group	\$38,000	\$38,000
Cost of Ofirmev	\$34	
Number of Patients	40	
Total Cost for the group	\$1,360	
Discharge status		
Home	33	20
Inpatient	7	20
Cost of Admission	\$912	\$912
Total Cost for the group	\$6,384	\$18,240
Total Cost for the group	\$45,744	\$56,240
Mean Cost for the group	\$1,143.6	\$1,406

CHANGE PROPOSAL: In order to improve patient safety and reduce healthcare costs, we propose all obese patients undergoing a laparoscopic cholecystectomy receive IV acetaminophen in the preoperative period unless contraindicated. Also, limit the amount of narcotics administered to this patient population as much as possible to help reduce the incidence of adverse events and increased LOS caused by excessive opioids.

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