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Barriers to Remifentanil Use for Labor Analgesia: A Process Improvement Initiative

LT Stephanie Daniels, LT Sharrod Greene, LT Cassy Piela

Uniformed Services University

Naval Medical Center Portsmouth, Virginia

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[redacted]

Stephanie Daniels, BSN, RN, LT, USN, Registered Nurse Anesthesia Program
Daniel K. Inouye Graduate School of Nursing
Uniformed Services University
01Sep2017

[redacted]

Sharrod R. Greene, BSN, RN, LT, USN, Registered Nurse Anesthesia Program
Daniel K. Inouye Graduate School of Nursing
Uniformed Services University
01Sep2017

[redacted]

Cassy A. Piela, BSN, RN, LT, USN, Registered Nurse Anesthesia Program
Daniel K. Inouye Graduate School of Nursing
Uniformed Services University
01Sep2017

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Abstract

Phase II Site: Naval Medical Center, Portsmouth, Virginia

Project Title: Barriers to Remifentanil Use for Labor Analgesia: A Process Improvement Initiative

Authors: Daniels, S., Greene, S., & Piela, C.

Problem/Issue: Neuraxial analgesia is the gold standard for labor analgesia, but is contraindicated in some parturients. Patient-controlled intravenous administration of remifentanil (PCIAR) offers analgesia using an ultra-short acting opioid agonist; however, barriers, including staff knowledge deficits and limited logistical support, limited its use at our facility.

Purpose: The purpose of this project was to remove barriers to the appropriate use of remifentanil at our hospital.

Project Design: A pre- and post-implementation process improvement approach was utilized based on the Plan, Do, Study, Act Model at Naval Medical Center Portsmouth. A systematic literature review was conducted to determine best practices for safe and effective use of remifentanil in laboring parturients and surveys were disseminated to identify barriers. An updated standard operating procedure (SOP), including revised order sets, was developed through collaboration with stakeholders (anesthesia, obstetrics, and pharmacy). It reflected current best practices and addressed barriers identified in the pre-survey. An education plan was designed based on the updated SOP and disseminated to target groups. Pre and post-implementation knowledge assessments were utilized to assess effectiveness of training and removal of barriers through project implementation.

Analysis of the Results: Identified barriers to successful implementation were: staffing and time constraints, knowledge deficits, and equipment concerns. After implementation of the updated SOP and training, anesthesia and obstetrical staff demonstrated substantially improved knowledge about the safe use of PCIAR. Post-implementation knowledge assessments also indicated increase in knowledge of PCIAR, as well as a better understanding of the updated SOP.

Organizational Impact: When utilized properly, PCIAR is a safe and effective alternative for labor pain in women who are ineligible for neuraxial analgesia. In our facility, an evidence-based revision of the SOP combined with staff education and collaboration with key stakeholders was effective in improving staff knowledge about PCIAR and decreasing barriers to its appropriate use.

Introduction

Pain defines labor for many parturients. The severity and duration of pain is patient specific and entails both physiological and psychological characteristics (Rowlands & Permezel, 1998). There are many factors that contribute to labor pain in the parturient: decreased blood supply to the uterus during contractions that causes hypoxia of the uterine muscle; distension of the pelvic floor; along with stretching and pressure of the cervix, vagina, and perineal floor muscles (Kennedy, Ruth, & Martin, 2009). Pain can also be exacerbated by psychological factors including fear, apprehension, anxiety, and enduring the labor experience without the presence of a significant other (Ravishankar, Parthasarathy, & Saravanan, 1999).

Uncontrolled labor pain may have deleterious effects on both mother and fetus. Pain causes increased respiratory rate and catecholamine release, causing constriction of blood vessels, resulting in decreased blood flow to the placenta and fetal acidosis (Kennedy et al., 2009). The release of catecholamines also increases glucose levels, causing a poor insulin response in the mother and fetus. (Kennedy et al., 2009). This leads to an inability of the fetal brain cells to compensate for even short states of hypoxia, as oxygen requirements to compensate for the increased free fatty acids, ketones and lactate are greatly increased (Kulkarni & Tjunan, 2014). Episodes of severe pain can increase cardiac output and blood pressure, change cardiac rhythm and decrease blood flow to the coronary arteries leading to myocardial infarction or stroke (Kennedy et al., 2009). Appropriate pain management can help minimize the deleterious effects of acute labor pain on the mother and child.

Significance of the Problem

The current gold standard for managing labor pain is neuraxial analgesia, including epidural, spinal, or combined spinal epidural analgesia (El-Wahab & Robinson, 2011). Neuraxial analgesia allows for dosing adjustments to achieve pain relief with minimal systemic

effects (Kranke et al., 2013). However, not all women are eligible for or desire to receive neuraxial analgesia and may benefit from an intravenous analgesia option. Contraindications to receiving neuraxial analgesia in the laboring patient include patient refusal, coagulopathy, septicemia, and increased intracranial pressure (Drasner & Larson, 2011). Complications and concerns include postdural puncture headache, backache, infection and hematoma (Stocki et al., 2014). Lastly, neuraxial analgesia requires extensive human and material resources, from skilled providers for initiation and management, to costly supplies that must be introduced under sterile conditions (Kranke, et al., 2013).

Systemic opioids are standard therapy for both acute and chronic pain in the non-pregnant patient. Intravenous and intramuscular opiates are common pain relief measures used during labor, though there are potential adverse effects for the mother and fetus when systemic opioids are used (Evron, 2007). Both decreased fetal heart rate variability and respiratory depression have been reported with systemic opioid use (Lucero & Rollins, 2013). However, newer opioids with favorable pharmacologic profiles now exist. Remifentanil has a rapid onset and short duration of action, as well as a rapid metabolism via red blood cell ester hydrolysis, lending the drug a unique advantage over traditional opioids due to its quick onset, offset, and ability to be titrated (Kranke, et al., 2013).

Remifentanil is an ultra-short acting selective mu one opioid receptor agonist with an onset of 30 to 60 seconds and peak effect after 2.5 minutes when infused intravenously (Schnabel et al., 2012). Its rapid metabolism by blood and tissue esterases, short half-life of 3 to 10 minutes, brief context-sensitive half-life of 3-6 minutes, and lack of teratogenic effects make it a desirable alternative analgesic for use in parturients. Per drug manufacturer Abbott Laboratories, remifentanil does not exhibit a longer duration of action with extended

administration (2001). Remifentanil does undergo placental transfer, but the rapid clearance rate exhibited by full-term neonates, which can be as high as two times as fast as a young adult, translates to short-lived side effects and rapid recovery of the fetus (Abbott Laboratories, 2001). Remifentanil can be administered intravenously via patient controlled analgesia (PCA), continuous infusion, and combination PCA/continuous infusion.

Unfortunately, even with the availability of rapidly metabolized systemic opioids, barriers across nursing, anesthesia, and pharmacy staff still exist preventing appropriate implementation and utilization of these drugs to combat labor pain. Some barriers include infrequent use, leading to an experience deficit; requirement of 1:1 nursing care for patients using remifentanil; the requirement for anesthesia to be present for an extended period of time following implementation; the time and cost of compounding remifentanil by the pharmacy; and lack of knowledge regarding remifentanil on the labor and delivery unit. These barriers must be addressed to ensure women receive appropriate, safe, and timely pain relief.

Military Relevance of the Problem

Annually, the Military Health System (MHS) releases a report comprised of the overview of the Department of Defense's health system and an analysis of previous and upcoming fiscal logistics and budget planning. The four objectives of the MHS include: increased readiness, better population health, better care experience, and lower per capita cost (Military Health System, 2014). Omitting purchased care, individual military treatment facilities assist women in more than 50,000 births per year across the MHS (LaFraniere & Lehren, 2014). As labor, delivery, postpartum, and newborn procedures account for 43% of all hospital admissions and 28% of total hospital costs, providing alternative labor pain relief methods and promoting

maternal satisfaction could positively impact MHS' fiscal status, military readiness, and overall goal achievement (Defense Health Agency, 2015).

Remifentanil's favorable pharmacologic profile and lack of teratogenic effects also make it an ideal agent to administer during labor and in austere environments, where resources are limited. Initiation of a remifentanil PCA is a non-sterile procedure and, at minimum, requires a portable infusion pump and only standard monitoring such as pulse oximetry and heart rate (Kranke et al., 2013). Also, highly skilled providers are not necessary at the bedside for the duration of the infusion, freeing up medical resources and delivering pain relief with fewer complications than those associated with neuraxial analgesia (Kranke et al., 2013).

As reported by the supply team at Naval Medical Center Portsmouth (NMCP), epidural consumables including: epidural kit, epidural bag solution, sterile gloves, tegaderm, and epidural tubing cost $74.52 (Bonnema, 2016). This does not include the cost of local anesthetics, opioids, or adjunct medications injected into the epidural or spinal. Reports in the literature show an average cost of $22.00 for 1mg vial of remifentanil. Minimal additional supplies, such as IV tubing and peripheral intravenous catheters add approximately $8.00 to the total cost per patient (Bonnema, 2016). Considering only materials and medication costs, there is a moderate economic per capita advantage over neuraxial analgesia.

Nursing Relevance of the Problem

A common goal is to promote and enhance the comfort and wellness of the patients and their loved ones. Patient advocacy can encompass a myriad of approaches, including advocating for patient safety, patient rights, and the patient's health (Ecker, 2009). Adopting policies and procedures that provide more access to effective labor analgesia for women could result in

improved patient comfort and safety, a decrease in untoward events, and an overall increase in patient satisfaction (Rosen, 2002).

Potential Benefit of Addressing the Problem

By addressing and overcoming the barriers to remifentanil use for parturients, more women can receive pain relief during labor, minimizing the deleterious psychological and physiological effects associated with labor discomfort (Rowlands & Permezel, 1998). Neuraxial analgesia is unavailable or inappropriate for some laboring women (Shen et al., 2013). While not routinely used, it is important for maternity staff to maintain the skills and competencies for effective delivery of remifentanil. Removing barriers to care will allow staff to become better educated about it, increase the appropriate prescription and utilization of remifentanil, and, over time, become more comfortable with its safe delivery. Decreasing pain and increasing patient satisfaction with labor analgesia is key in creating a better care experience, which is critical to the MHS Quadruple Aim (Military Health System, 2014). By identifying barriers, educating staff, and creating effective solutions, the initiation and administration of remifentanil for labor analgesia can be greatly improved.

Clinical Question

Does the implementation of an updated, evidence based, standardized operating procedure, in conjunction with education on best practice of remifentanil administration for obstetric nurses, anesthesia providers, and pharmacy staff, improve clinical knowledge, comfort level, and frequency of appropriate administration of remifentanil in laboring parturients?

Focus areas

This process improvement project has four primary focus areas: barrier identification, protocol revision, educational remediation, and risk management. A survey tool identifies

specific barriers to safe administration of and challenges to remifentanil implementation. Protocol revision provides the opportunity to update the current SOP to reflect current evidence-based best practice in the administration of remifentanil. Educational remediation supports the new SOP by enhancing clinical knowledge and comfort levels of the three key stakeholder groups—anesthesia, pharmacy, and the obstetrics nursing staff. Risk management strategies will aid in ensuring the proper implementation of critical safety measures such as end-tidal carbon dioxide (EtCO2) monitoring and guardrail programming for the utilization of remifentanil throughout the labor and delivery unit.

Project Short and Long Term Goals

The short-term goal of this evidence-based practice project is to provide an updated policy to reflect best practice for remifentanil use on the labor and delivery unit. Short-term goals also include increasing the knowledge of the OB staff in relation to remifentanil administration, as well as training 100% of the labor and delivery, anesthesia, and pharmacy staff on the updated remifentanil policy. The long-term goal of this project is to implement a continuous quality improvement process that will lead to a 50% increase in appropriate and timely remifentanil administration for women who are unable or unwilling to receive neuraxial analgesia, as determined by evidence based practice. Additionally, we would like to increase the comfort level of the staff involved in remifentanil administration.

Anticipated Global Impact

Pain is a prominent characteristic of labor; and after decades of research and differing treatment modalities, it has not been completely eradicated in the laboring parturient. It is our hope to achieve enterprise-wide adoption of the updated remifentanil policy and process improvement model, where applicable, across the military health system. In doing so, we aim to

improve labor analgesia in situations and settings where neuraxial analgesia utilization may not be indicated, impractical or possible. Expanding remifentanil use for parturients in areas where sterile conditions cannot be ensured or in areas where laboratory coagulation testing cannot be performed would provide another viable option of labor analgesia for our military providers to utilize in austere environments. In time, with continued positive impact and lack of untoward events, the remifentanil PCA may be offered to women across the world who desire another mechanism of pain relief and to improve the overall labor experience.

Organizing Framework

The organizational framework for this process improvement project was the Plan, Do, Study, Act (PDSA) model (Nelson, Batalden, & Godfrey, 2007). The PDSA model uses a four-step approach to test new ideas, evaluate data collection, and provide insight into future decision-making that will produce desired outcomes.

The "Plan" phase incorporates a baseline assessment that identifies the current barriers to the safe administration of remifentanil as an effective labor analgesic alternative to the parturient that is either ineligible for, or has an aversion to standard neuraxial analgesia. The general approach to this project incorporates pre- and post-education knowledge assessments to evaluate project outcomes. The "Do" phase involves the remediation of existing barriers and protocol deficiencies that will ensure safe and timely administration and monitoring of remifentanil as a labor analgesic alternative for the parturient that is ineligible for or refuses standard neuraxial analgesia.

The "Study" phase provides the opportunity for reflection and evaluation of key measures such as increasing the knowledge of nursing staff and anesthesia providers on the labor and delivery unit. The study phase can also be used to assess long-term goals of increasing the

appropriate utilization of remifentanil for laboring women with contraindications for receiving neuraxial analgesia. The "Act" phase will be driven by the outcomes and data collected of previously executed phases of the project. Additionally, it will provide insight into future clinical decision-making regarding the utilization of remifentanil, and may lead to additional PDSA cycles. The PDSA model was chosen for this process improvement project because it provides a simplified yet thorough framework for a systematic approach to achieve our desired outcome [Figure 1].

Project Design

General Approach

This project was a pre- and post-implementation process improvement design.

Setting

This project was undertaken in a large military medical center in the eastern United States. The hospital has a labor and delivery unit that averages approximately 3000 deliveries annually. The hospital has 10 labor and delivery (L&D) suites, three operating rooms, four special care rooms, and a four-bed post-surgical recovery room (Naval Medical Center Portsmouth, 2016). It also has a 24-bed level III neonatal intensive care unit (NICU), which has the capacity to facilitate high-risk deliveries. Anesthesia care is provided by both civilian and active duty anesthesiologists and certified registered nurse anesthetists (CRNA). Both active duty and civilian registered nurses provide labor and delivery nursing care. Active duty military members, retired military members, and eligible dependents comprise the patient population.

Procedural Steps

Evidence evaluation: A conceptually analogous search with controlled vocabulary was performed using five databases, including the Cochrane Library, PubMed, CINHAL, EMBASE,

and Web of Science. Key words included: “remifentanil,” “Ultiva,” “patient-controlled analgesia,” “self-controlled analgesia,” “self-administered,” “obstetrical,” “labor,” “women,” “delivery,” “pregnancy”, and “obstetrics,” as well as MeSH terminology. Exclusion criteria were applied and the Johns Hopkins University Evidence Rating Scale (Johns Hopkins Evidence Rating Scale, n.d.) was used to systematically appraise the evidence.

Barrier Identification: In order to identify whether remifentanil was being appropriately utilized on the labor and delivery unit, a third-party Essentris champion from our facility performed a de-identified chart review from 01/01/2016 to 05/26/2017. For the purposes of our chart review, appropriate utilization was considered to be the use of remifentanil in parturients who presented to the labor and delivery unit with potential coagulopathy demonstrated by low platelet counts. While many contraindications to neuraxial anesthesia are difficult to identify in chart reviews, such as patient refusal or increased intracranial pressure, potential coagulopathy can be identified through routine laboratory work. Women admitted to the labor and delivery unit with low or critically low platelet counts, defined by the target facility laboratory as less than 100,000cells/µL and 60,000cells/µL, respectively, were the focus of this review. One hundred nine women were generated in the report showing 278 low platelet counts and 39 critically low platelet counts. These patients were flagged and a more in depth chart review was conducted to identify whether or not remifentanil was offered and/or ordered for labor analgesia, or whether neuraxial analgesia was placed despite thrombocytopenia. Between 01/01/2016 to 05/26/2017, a remifentanil PCA was initiated in 4 out of 109 patients identified with low and critically low platelet counts. Of that group of 109 women, neuraxial analgesia had been initiated in 57.

After confirming the need for training in the appropriate utilization of remifentanil on the labor and delivery unit, our team commenced the development and dissemination of a preliminary survey to clarify barriers to appropriate remifentanil use. Appropriate implementation was defined as the offering and/or administration of remifentanil when neuraxial analgesia was unsuitable or contraindicated, as stated in the introduction of this paper (i.e., coagulopathy or other bleeding diathesis). To help develop the questions of our survey, our team interviewed several key stakeholders with experience in remifentanil administration, as well as a patient who had met the requirements for a remifentanil infusion and subsequently requested it. A paper survey was administered to each key stakeholder group involved: anesthesia, labor and delivery nursing staff, and pharmacy staff [appendix E]. Three basic demographic questions were asked, including occupation, number of years of experience in that respective field, and if trainee or staff. A Likert scale was used to evaluate participants' comfort level in administering remifentanil. Four additional open-ended questions were administered, and results were entered into a database. Qualitative analysis was performed to identify common themes and potential barriers, which included: one-to-one nursing staffing requirements, difficulty understanding or locating the ward policy, time for pharmacy to fill medication, nursing knowledge deficits, time constraints, and equipment concerns.

Process Improvement and Education: The second step of our project was two-fold. First, we presented department leadership with an updated labor and delivery remifentanil SOP that reflects current best practice based on our literature review. Next, we developed and disseminated a targeted staff education and training plan (also based on our literature review), and a revised policy.

Following a systematic review of literature to determine the best and safest method for remifentanil administration in the laboring parturient, an updated labor and delivery remifentanil policy was drafted. The revised policy requires remifentanil to be administered via patient controlled analgesia (PCA) pump with a continuous, titratable background infusion and a fixed dose bolus. This differs from the previous dosing policy, where an escalating bolus dose of medication was given with an optional fixed basal rate in the background. Both values are based on ideal body weight, and the titratable infusion is guided by a tiered system centered on patient comfort level and vital signs [appendix F]. This method of administration was shown to provide the most effective analgesia in combination with the best safety profile in both the mother and fetus (Balki, Kasodekar, Dhumne, Bernstein, & Cavalho, 2007; Ohashi, Baghirzada, Sumikura, & Balki, 2016).

While we could not decrease the amount of time required for pharmacy to fill the medication, our team worked with them to ensure two remifentanil PCA syringes would be filled with each request. This requires less work for both pharmacy and nursing staff by decreasing the number of times an RN has to leave the floor to sign for the medication at the pharmacy, and decreases the risk of delayed labor analgesia. Additional safety measures were also implemented, such as the requirement of a second intravenous line dedicated to the remifentanil infusion. (El-Kerdawy & Farouk, 2010; Stourac et al., 2016). The second intravenous line must be placed within 15 minutes of remifentanil administration, allowing for pain relief and a potentially more controlled setting in which to establish the additional IV. Literature recommends end-tidal carbon dioxide ($EtCO_2$) respiratory monitoring, if available, as an increased safety measure (Ohashi, Baghirzada, Sumikura, & Balki, 2016). This $EtCO_2$ monitoring for apnea detection is now required when a remifentanil PCA is used on our labor

and delivery unit. Adjusting Guardrails™ safety limits to Alaris® infusion pumps for remifentanil is a goal for the near future. The time constraints involved in adjusting hospital-wide pumps will be discussed in our limitations section.

After SOP approval and implementation, we administered follow-up pre- and post-education knowledge assessments to the same key stakeholder groups [appendix I]. This knowledge assessment aimed to assess comprehension of the revised standard operating procedures and to identify new barriers, if present, regarding remifentanil use on the labor and delivery unit.

HIPPA Concerns

Collecting and storing patient and provider personally identifiable information (PII) for the purposes of analyzing appropriate remifentanil policy utilization creates potential concerns related to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). To mitigate the risk of improperly handling this information, de-identified patient data was utilized for analysis of appropriate remifentanil policy use. The goal was to track trends and triggers for protocol initiation; thus, accessing patient PII to execute this project was superfluous. Additionally, we did not collect staff members' PII when conducting surveys. The knowledge assessment was created to track the trends of provider knowledge and views toward the remifentanil protocol, as opposed to tracking individual provider behaviors, thus collection and storage of PII was unwarranted.

Project Results

Evidence Evaluation

A total of 620 articles were available for review based on our original literature search. Articles that were not available in English, those regarding the use of PCAs with a medication

other than remifentanil, the use of other modalities of pain control in addition to remifentanil, or the use of remifentanil for anything other than labor pain were excluded.

After removal of duplicates, our team reviewed 366 article titles and abstracts for relevance using the above criteria; an additional 185 were then excluded and 181 were chosen for full text review. Two team members read each article and, using the Johns Hopkins University Evidence Rating Scale (Johns Hopkins Evidence Rating Scale, Baltimore, MD), evaluated each article for strength and quality of evidence. Only articles with an overall quality rating of A (High) or B (Good) were chosen for inclusion in our literature review. If the two team members disagreed on a rating, a third team member was then chosen to also read the study and the article was rated based on the majority rating. Following full text review, 15 articles were chosen for inclusion in our literate review [appendix J].

Survey Results

Results of the preliminary survey showed a wide range of experience in current field of practice, from 0 to 10+ years. Remifentanil administration comfort level also showed significant variation in all stakeholder groups. Response rates of the groups are as follows: 37% of the anesthesia group, 20% of the pharmacy group, and 74% of the obstetric nursing group completed the survey. However, this still yielded over 50 surveys for review by our team. Of those who returned surveys, 26% had <2 years' experience, 22% had 2-5 years' experience, 19% had 5-10 years' experience, and 33% had 10+ years' experience. Thirty percent were on training status and 56% had utilized remifentanil in the obstetric population at some point during their practice. The average comfort level of the anesthesia group surveyed was 5 on a 0-10 scale [figure 2], with 0 being not comfortable at all, and 10 being very comfortable.

All pharmacy staff surveyed had 5-10 years of experience and none were on training status. All providers had utilized remifentanil in the obstetric population at some point during their practice; however, the average comfort level was only 4 [figure 2]. Sixteen percent had <2 years' experience, 20% had 2-5 years' experience, 12% had 5-10 years' experience, and 52% had 10+ years' experience. No obstetric nurses on training status completed the survey and 68% of those who completed the survey had utilized remifentanil in the obstetric population at some point during their career. The average comfort level of the nursing group surveyed was 4 on a 0-10 scale [figure 2], with 0 being not comfortable administering remifentanil at all, and 10 being very comfortable administering remifentanil. Based on the preliminary surveys from the obstetric nursing staff and assessment of barriers, we determined that a special focus should be placed on the labor and delivery nursing stakeholder group.

Barriers were identified by qualitative analysis of open-ended questions. Primary concerns across all stakeholder groups were: one-to-one nursing staffing requirements, difficulty understanding or locating the ward policy, time for pharmacy to fill medication, nursing knowledge deficits, time constraints, and equipment concerns. Overall, nursing knowledge and staffing constraints across all stakeholder groups were the largest concerns. These results were used to guide our policy revision and educational interventions.

Policy Implementation and Educational Intervention

Several experts in the anesthesia and obstetrics field, as well as key stakeholder leaders, reviewed the completed policy. This included the anesthesia department head, labor and delivery CNS, pharmacy department head, and corresponding labor and delivery anesthesiologist. Following a comprehensive review and the agreement of all parties involved, the policy was accepted for practice and educational intervention was conducted. This part of

our project aimed to reduce knowledge deficits identified as a primary barrier to remifentanil administration.

Educational intervention knowledge assessments results demonstrated both an improvement in the understanding of the new labor and delivery remifentanil policy, as well as a better understanding of the pharmacodynamics and pharmacokinetics of remifentanil. Nineteen knowledge assessments from the anesthesia stakeholder group were completed and returned following education. The mean pre-education score was 54% (SD 26) and the mean post-education score was 83% (SD 11) [figure 3]. Twenty knowledge assessments from the obstetrics nursing stakeholder group were completed and returned following education. The mean pre-education score was 52% (SD 16) and the mean post-education score was 94% (SD 12) [figure 3]. Based on the significant involvement of the labor and delivery nurse at the bedside, a supplemental nursing packet was also created by our group to help guide the preparation and implementation of remifentanil for labor analgesia. This supplemental information includes a weight and dosing conversion chart, a supply and equipment checklist, and a safety checklist for assessing parturients with a remifentanil PCA.

We also eliminated barriers to remifentanil administration identified by our preliminary survey. For safety, 1:1 nursing was supported by the overwhelming majority of literature reviewed and was not able to be altered. Our team created a supplemental nursing information packet to help the nursing staff organize equipment [appendix G], initiate the remifentanil orders, and assess patient safety and comfort prior to dose changes [appendix H]. While the original policy recommended anesthesia remain at bedside for 30 minutes following implementation, we reviewed no evidence that supported this requirement. The policy was revised to recommend 10 minutes at the bedside to assess immediate effects of the infusion once started.

While we could not decrease the amount of time required for pharmacy to fill the medication, our team worked with pharmacy to ensure two remifentanil PCA syringes would be filled by from pharmacy with each request. This requires less work for both pharmacy and nursing staff by decreasing the number of time a RN had to leave the floor to sign for the medication at the pharmacy, and decreases the risk of delayed labor analgesia. Additional safety measures were also implemented during our policy implementation such as the requirement of a second intravenous line dedicated to the remifentanil infusion. (El-Kerdawy & Farouk, 2010; Stourac et al., 2016). The second intravenous line needs to be placed within 15 minutes of remifentanil administration, allowing for pain relief and possibly a more controlled setting to establish the additional IV. The application of end-tidal carbon dioxide (EtCO2) is an available bedside monitor on our labor and delivery unit. Literature recommends this supplemental respiratory monitoring, if available, as an increased safety measure (Ohashi, Baghirzada, Sumikura, & Balki, 2016). The use of EtCO2 for apnea detection is now required when a remifentanil PCA is used on the labor and delivery unit. Adjusting Guardrails™ safety limits to Alaris® infusion pumps for remifentanil is a goal for the near future. The time constraints involved in adjusting hospital-wide pumps will be discussed in our limitations section.

After SOP approval and implementation, we administered follow-up pre- and post-education knowledge assessments to the same key stakeholder groups [appendix I]. This knowledge assessment aimed to assess comprehension of the revised standard operating procedures and to identify new barriers, if present, regarding remifentanil use on the labor and delivery unit.

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Analysis of Results

This process improvement process led to an increase in knowledge of remifentanil as a labor analgesic, as well as a better understanding of the labor and delivery remifentanil protocol. There were multiple barriers to implementation of remifentanil in laboring parturients who were unable to received neuraxial analgesia, and the majority of staff involved in the remifentanil administration process on labor and delivery rated their comfort level as <5 on a 0-10 scale. After training, there was an improvement in policy comprehension, safety and assessment guidelines, and the remifentanil administration process on the labor and delivery ward.

Organizational Impact/Implications to Practice & Policy

This evidence-based practice project culminated in a revised labor and delivery remifentanil policy for parturients who are unable to receive neuraxial analgesia. The updated policy is based on the most recent literature regarding remifentanil safety and efficacy in the

pregnant population. As a process improvement initiative, this project also led to significant improvement in knowledge and understanding of key stakeholder groups involved in the implementation of remifentanil for labor analgesia. Unfortunately, due to the infrequent use of remifentanil on the labor and delivery unit, it is impractical to determine if there was a significant change in the number of appropriate parturients being offered or administered remifentanil for labor analgesia within the timeframe of this project.

Observing Change within the Organization

The barriers to utilizing remifentanil and the methods to overcome those barriers are highlighted in two case scenarios: one with the original protocol and the second with the new evidence-based process improvement protocol.

The original protocol was used for a 29 year-old gravida 1 para 0 at 38+5 weeks gestation. Having had a deep vein thrombosis recently, she was undergoing twice daily treatment with Lovenox, rendering her ineligible to receive neuraxial analgesia. After a brief discussion with the patient about analgesia options, the decision was made to use a remifentanil infusion for labor pain management. Barriers to implementation were immediately noted.

The nursing staff was extremely hesitant due to the unfamiliarity with the equipment, unknown charting requirements, methods of assessing the patient, and appropriate dosing parameters. Additionally, a licensed RN would have to leave the floor to pick up the remifentanil to sign for the narcotic filled syringe several times each shift, stressing staffing levels. The anesthesia team was hesitant due to a busy labor deck and felt constrained by the requirement to sit in one patient's room for 30 minutes during the start of the infusion. An additional requirement to wait 4 hours to initiate the infusion after administration of another opioid would cause a significant delay in labor pain management. Ultimately, remifentanil was

used but the staff felt that the process was "broken," stressful, time and resource consuming, and ineffective. All of this stemmed from lack of an updated evidence-based practice protocol demonstrating multiple barriers to effective use.

The second patient, a 39 year-old gravida 1 para 0 at 39 weeks gestation, refused an epidural and requested intravenous remifentanil patient-controlled analgesia due to having an Arnold Chiari Malformation Type I and unpleasant experiences with lumbar punctures during the diagnosis of her condition. The patient researched labor analgesia prior to arrival and requested a remifentanil infusion. The new remifentanil protocol had been initiated and many of the aforementioned barriers were overcome. For example, the new policy contains a supply pull sheet that lists the equipment required to initiate the infusion, a detailed document about the specific assessments, and parameters for dosing changes. These were placed with the protocol and updated in the electronic health record. Training was conducted on infusion dosing parameters and adjustments, and the pharmacy doubled the amount of replenishment remifentanil syringes delivered to the bedside, decreasing the number of trips to the pharmacy for refills. Additionally, the new protocol decreased the amount of time an anesthesia provider had to stay in the room after starting the infusion and reduced the time interval after opioid administration. Adding end-tidal carbon dioxide ($EtCO_2$) respiratory monitoring increased the safety of the infusion. All of these updates to the protocol enhanced the ability of the nursing and anesthesia staff to initiate an infusion, as well as the safety and care experience of the patient.

Future Direction for Research and Practice

Remifentanil use on the labor and delivery unit at our facility is a rare occurrence; however, when needed, safe administration requires an evidence based policy and understanding

by all members of the care team. Its infrequent use proves to be one of the challenges faced when implementing remifentanil policy on the labor and delivery unit. Because of this unique challenge, some long-term analyses must be completed following the conclusion of this project.

After 6 months of new SOP implementation, a third-party Essentris champion will conduct a de-identified chart review to identify patients admitted to the labor and delivery unit with low or critically low platelet counts. The same Essentris champion should assess charts for whether or not remifentanil was offered and/or utilized for each patient. Descriptive statistics will be used to characterize the number of women for whom remifentanil was appropriate and the number of women for whom remifentanil was prescribed and given. These numbers will be compared before and after implementation using McNemar's test to determine if the project has changed the proportion of women who were correctly prescribed remifentanil. Alpha will be set < 0.05 for this two-tailed test. Results of this query can help guide the need for future process improvement. Improvements in appropriate administration of remifentanil should be reflected as part of long-term goal results.

Conclusion

Remifentanil remains an alternative for labor analgesia in parturients who are unable to receive neuraxial analgesia due to issues such as coagulopathy, increases in intracranial pressure, or refusal. This process improvement project is a reflection of best practices from a literature review; in addition, it created a significant amount of change to the policy. These changes required education on both remifentanil as a labor analgesia and the new policy itself. The training of anesthesia, nursing, and pharmacy staff resulted in knowledge improvement, but cannot guarantee an increase in appropriate utilization or comfort level.

Limitations

There were several limitations encountered during our scholarly inquiry project. First, we encountered time constraints when attempting to adjust Guardrails™ safety limits on the Alaris® infusion pumps. While the literature supports remifentanil administration in mcg/kg/min, the infusion pumps were preprogrammed to administer mcg/kg/hr (Ohashi, Baghirzada, Sumikura, & Balki, 2016). Additionally, the dosing should be based on ideal body weight, but the pumps were programmed for 10-kilogram weight ranges. For example, an ideal body weight of 75 kilograms could not be programmed. Instead, a range of 70 to 80 kilograms had to be selected.

Although adjustments can be made, both pharmacy and biomedical device delegates must service the equipment, which can only be completed after approval from the pharmacy and therapeutics committee. This limitation did not significantly alter our project; however, it did limit some of the impact we hoped to make prior to the new policy enactment. In addition, pharmacy staff members were unable to complete educational intervention knowledge assessments without approval of the pharmacy and therapeutics committee. This constraint was unanticipated and thus we were unable to educate pharmacy staff and administer knowledge assessments prior to the on-site completion of our project. Pharmacy represents the smallest of the three stakeholder groups; however, when considering the overall number of staff, this limitation did not significantly alter the implementation of the new evidence-based protocol.

Second, a national shortage of remifentanil is impacting our hospital. While pharmacy is attempting to keep a separate amount of remifentanil available for parturients, there is no anticipated end date to the shortage. Remifentanil may not be available for use for labor analgesia.

Finally, as aforementioned, there are significant limitations in the reassessment of both frequency of appropriate remifentanil on the labor and delivery unit, as well as comfort levels of those involved in patient care of the parturient receiving a remifentanil PCA. Infrequency of use makes these two objectives measurable only via long-term study after the revised policy has been implemented for more patients.

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Figure 1: Plan, Do, Study, Act Model

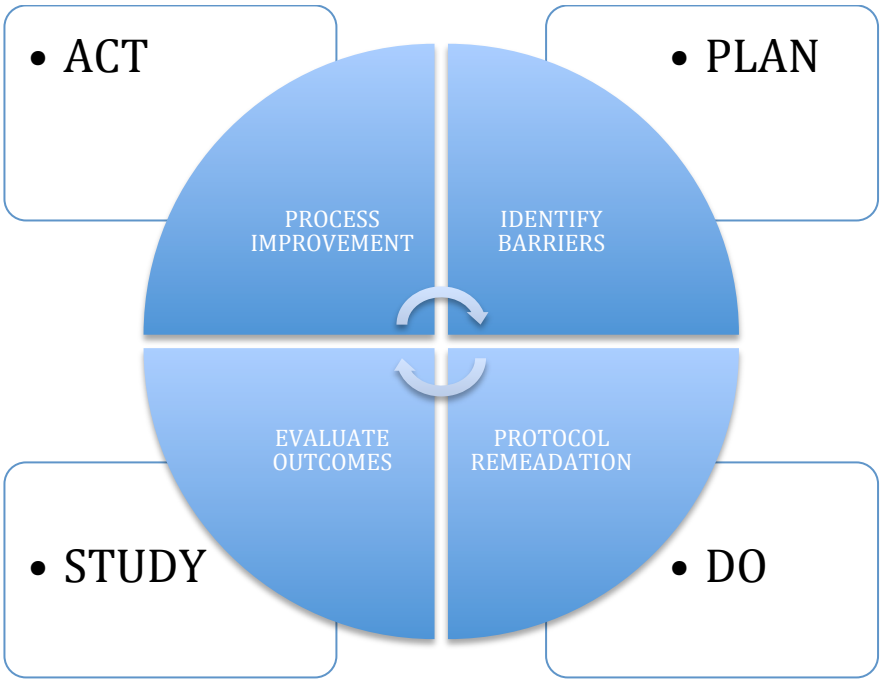


Figure 2: Average years of experience and levels of comfort with remifentanil PCA use among key stakeholder groups (Anesthesia, OB Nursing, and Pharmacy)

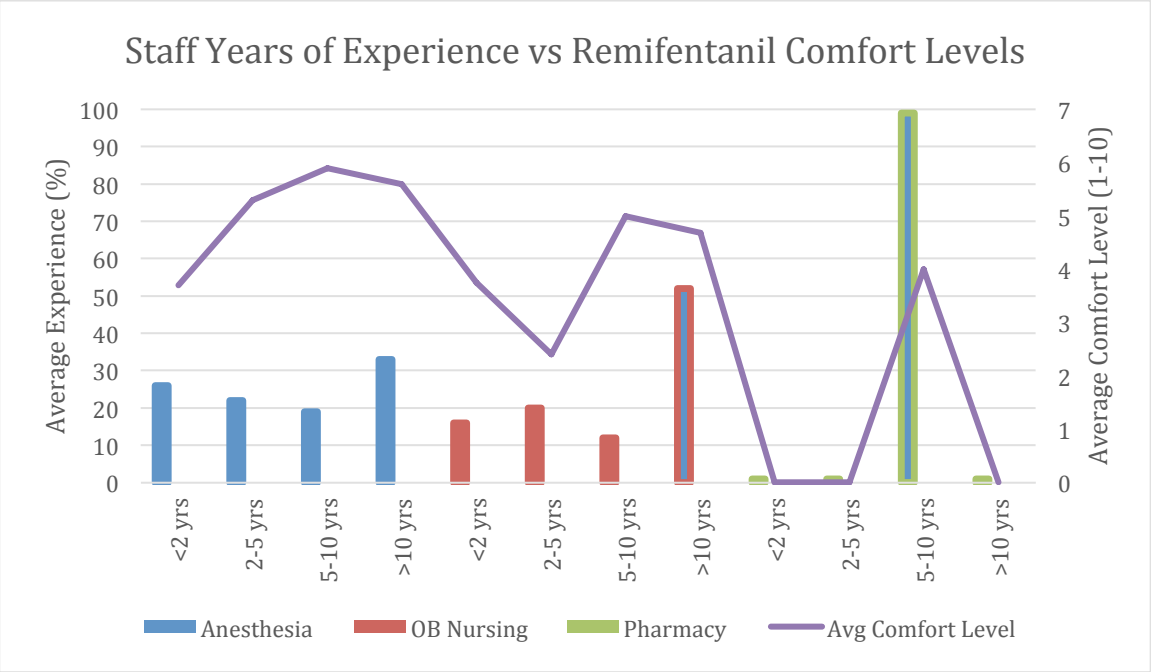
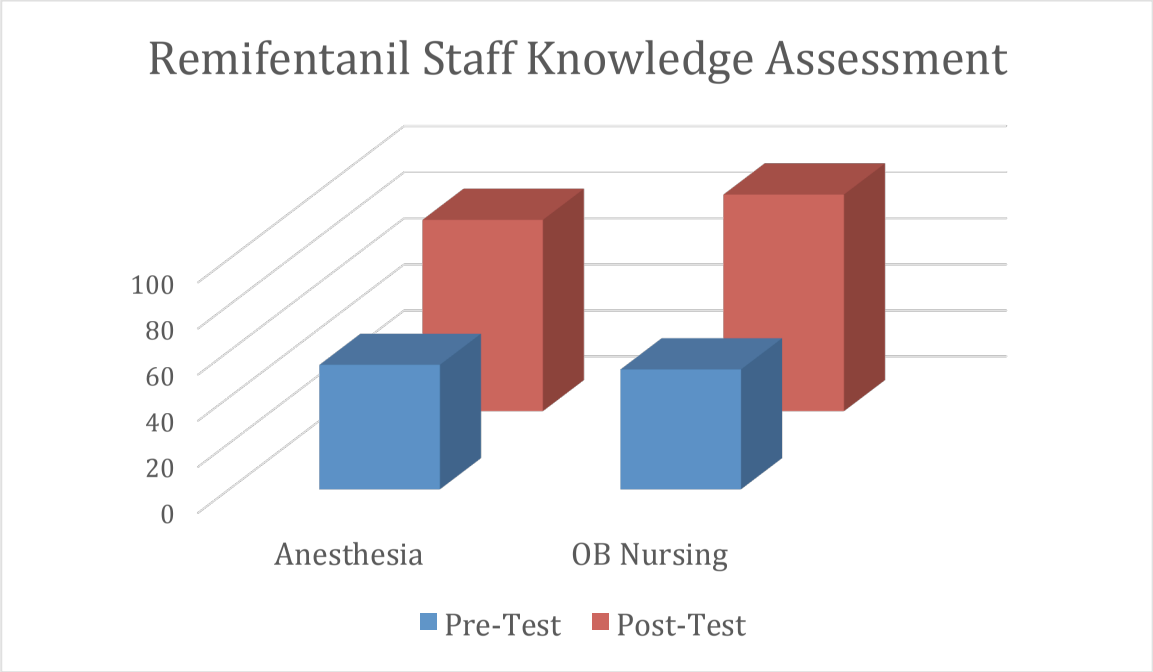


Figure 3: Results of educational intervention among key stakeholder groups (Anesthesia, OB nursing, and Pharmacy)



Appendix A: Citi Certificates

CITI PROGRAM

Completion Date 22-Aug-2015
Expiration Date 21-Aug-2018
Record ID 16980565

This is to certify that:

Stephanie Daniels

Has completed the following CITI Program course:

OUSD P&R Human Research (Current) (Curriculum Group)
Biomedical Investigators and Research Study Team (Course Learner Group)
1 - Biomedical Investigators (Stage)

Under requirements set by:

Uniformed Services University of The Health Sciences

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?wb9d54915-c6b4-47da-bc0b-960211aba557-16980565

CITI PROGRAM

Completion Date 26-Aug-2015
Expiration Date 25-Aug-2018
Record ID 16986776

This is to certify that:

Sharrod Greene

Has completed the following CITI Program course:

OUSD P&R Human Research (Current) (Curriculum Group)
Biomedical Investigators and Research Study Team (Course Learner Group)
1 - Biomedical Investigators (Stage)

Under requirements set by:

Uniformed Services University of The Health Sciences

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w49116d93-76ce-4825-b245-1657655ea31d-16986776

CITI PROGRAM

Completion Date 23-Aug-2015
Expiration Date 22-Aug-2018
Record ID 16982775

This is to certify that:

Cassy Piela

Has completed the following CITI Program course:

OUSD P&R Human Research (Current) (Curriculum Group)
Social and Behavioral Investigators and Research Study Team (Course Learner Group)
1 - Social and Behavioral In (Stage)

Under requirements set by:

Uniformed Services University of The Health Sciences

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?wd215a19d-971d-46ee-bf5e-6682f449806d-16982775

Appendix B: USU (VPR) Form 3202N

USUHS FORM 3202N
DANIEL K. INOUYE GRADUATE SCHOOL OF NURSING
EVIDENCE-BASED PRACTICE/PERFORMANCE IMPROVEMENT PROPOSAL

VPR Date Stamp

Project Number: TO 61 9343 (VPR will assign)

Project Title: Barriers to Remifentanil Use for Labor Analgesia

SECTION A: STUDENT POC INFORMATION

1. Name (Last, First, MI): Piela, Cassy, A. Student E-mail: Cassy.Piela@usuhs.edu

[redacted]

SECTION B: COMMITTEE CHAIR / SENIOR MENTOR INFORMATION

3. Name (Last, First, MI): Nations, Ryan, L.
4. Telephone: (858)705-4472 Fax: E-mail: Ryan.Nation@usuhs.edu
5. USUHS Building/ Room No.:

SECTION C: PROJECT INFORMATION

6. Attach the Abstract for the proposal, including the following sections: Site Location of the Project, Title, Authors, Background or Problem/Issue, Clinical Question/Purpose, Project Design, Anticipated Organizational Impact/Implications for Practice and also include the Proposed Timeline. Single space the abstract and use Times New Roman font, size 12.
7. Is this proposal related to an active research project of the Chair/Senior Mentor identified in Section B? ☐ Yes ☒ No
   If yes, complete below; if no, proceed to Part 8.
   Project Number: _____
   Project Title:
   Project Start Date: _____ Project End Date: _____
8. Anticipated period of performance: Project Start Date: 4/1/2017 Project End Date: 4/1/2018
9. Performance Site(s): Naval Medical Center, Portsmouth, VA
10. Does this project involve any classified information? (Contact the USUHS Security Office for guidance) ☐ Yes ☒ No
11. Do you have a funding source for this project? ☐ Yes ☒ No ☐ NA
    If yes, specify the funding agency and the amount provided:

SECTION D: SIGNATURES

[redacted]

In light of the above signatures, the project is approved.

USUHS Vice President for Research Date

USUHS Form 3202N (VPR) - Revised Sep 2015 v1.2
Previous versions are obsolete

Appendix C: MTF IRB/PI Letter of Determination

Clinical Investigation Department, Naval Medical Center Portsmouth

620 John Paul Jones Circle, Portsmouth, VA 23708 (757) 953-5939 Fax (757) 953-5298, DSN 377-5939

16 March 2017

From: Head, Clinical Investigation Department
To: LT Cassy Piela, NC, USN

SUBJ: LETTER OF WAIVER OF IRB REVIEW FOR HEALTHCARE DELIVERY IMPROVEMENT PROJECT

1. I am writing to inform you that your project titled, "NMCP.2017.0048: Barriers to Remifentanil Use for Labor Analgesia" does not require IRB review. Navy policy states that these types of healthcare delivery improvement projects are exempt from IRB review.

2. You will still need to obtain publication approval for the project which is required for all works presented outside of NMCP.

3. I remain available and may be reached at (757)953-5939.

[redacted]

T. S. RIEG

"FIRST AND FINEST"

Appendix D: PAO Clearance/Level of Dissemination Classification

IV. THIS SECTION IS TO BE COMPLETED BY THE AUTHOR:

Name (Last, First, MI):		**Corps:**	**Service:**
Daniels, Stephanie D		NC	USN
Rank:	**Position:**	**E-mail:**	
LT	Other	stephanie.d.bonner.mil@mail.mil	
Phone:	**Pager:**	**Publication type:**	
757-953-3204	757-860-5379	**manuscript**	
Department:	**Dept. Head (name and rank):**	**Deadline for NMCP approval (Allow 10 business days):**	
Anesthesia	CDR J. Longwell, MC, USN	21 Apr 2018	
Directorate:	**Director (name and rank):**	**Deadline for BUMED approval (Allow additional 35 business days):**	
DSS	CDR R. Ricca, MC, USN	30 May 2018	
Submission title: Barriers to Remifentanil Use for Labor Analgesia: A Process Improvement Initiative			
OCONUS presentations may require higher level approval. Is conference OCONUS? Yes ☐ No ☒			
Via this request, three conferences or journal articles for this manuscript/abstract/presentation may be approved in the same calendar year. Complete the section below, with today's submission as your first or only conference/journal.			
Conference/Journal/Other 1: TriService Nursing Research Program: 2018 Research and Evidence-Based Practice Dissemination course		**Date:** 30 Apr 2018	
Conference/Journal/Other 2: Uniformed Services University of the Health Sciences 2018 Research Days		**Date:** 14 May 2018	
Conference/Journal/Other 3:		**Date:**	
Previous approval? No			

ANSWER THE FOLLOWING QUESTIONS:	Yes	No
Is it possible that members of the media or the public will be in attendance?	☒	☐
Does your submission include the required identification (name, rank, corps, and command)?	☒	☐
Does it include the required disclaimer?	☒	☐
Does it contain the required copyright statement?	☒	☐
Have you completed the required research integrity training?	☒	☐

IF YOUR TOPIC IS HUMAN RESEARCH RELATED COMPLETE THE FOLLOWING:		
Does the study have IRB Approval?	☐	☐
PI name:		
Study title:		

If approved by another institution, name of institution:		
The protocol number is:		
Have you attached the most recent IRB approval letter or continuing review?	☐	☐
Does it contain the required CIP (IRB approval) statement?	☐	☐

IF YOUR TOPIC IS ANIMAL RESEARCH RELATED COMPLETE THE FOLLOWING:		
Does the study have IACUC approval?	☐	☐
PI name:		
Study title: Click here to enter text.		
If approved by another institution, name of institution:		
The protocol number is:		
Have you attached the most recent IACUC approval letter or continuing review?	☐	☐
Does it include the required CIP (IACUC approval) statement?	☐	☐
Does it include the required animal welfare statement?	☐	☐
If applicable, does it include the required animal tissue use statement?	☐	☐
If hemorrhage or trauma related, does the methods section mention that the animal was anesthetized?	☐	☐

Additional Information
Other DoD agency or command to which this material has been submitted for approval. n/a
Submission Date: n/a
Optional Comments: Approval is requested for abstract, manuscript, PPT presentation, and poster. Approval is also requested for warehousing of submitted documents in the James A. Zimble Learning Resource Center (LRC) at Uniformed Services University of the Health Sciences (USUHS), to include storage of electronic copies of these documents on USUHS's internal database for future reference. Documents will be presented at USUHS Research Days and the TriService Nursing Research Program 2018 Research and Evidence Based Practice Dissemination Course.

V. TO BE COMPLETED BY PUBLICATION OFFICER:

Department Head Recommendation:	**Director Recommendation:**
☒ Approve ☐ Approve with comment ☐ Return to author for revision, discussion ☐ Disapprove ☐ Forward for higher level review Comments: Name/Signature: CDR Jason Longwell Date: 5/9/18	☒ Approve ☐ Approve with comment ☐ Return to author for revision, discussion ☐ Disapprove ☐ Forward for higher level review Comments: Name/Signature: CAPT Robert Ricca Date: 5/3/18

Public Affairs Recommendation:	**CID Recommendation:**
☒ Approve ☐ Approve with comment ☐ Return to author for revision, discussion ☐ Disapprove ☐ Forward for higher level review Comments: Name/Signature: Rebecca Perron Date: 5/2/18	☒ Approve ☐ Approve with comment ☐ Return to author for revision, discussion ☐ Disapprove ☐ Forward for higher level review Comments: Name/Signature: June Brockman Date: 5/10/18

Attending Veterinarian Recommendation: ☒ N/A	**OPSEC Security Recommendation:**
☐ Approve ☐ Approve with comment ☐ Return to author for revision, discussion ☐ Disapprove ☐ Forward for higher level review Comments: Name/Signature: Date:	☒ Approve ☐ Approve with comment ☐ Return to author for revision, discussion ☐ Disapprove ☐ Forward for higher level review Comments: Name/Signature: Monica Larry Date: 5/2/18

NME Recommendation: ☒ N/A	**BUMED Recommendation:**	**Command Action:**
☐ Approve ☐ Approve w/ comment ☐ Return to author for revision ☐ Disapprove ☐ Forward to BUMED Comments: Name/Signature: Date:	☐ Approve ☐ Approve w/ comment ☐ Return to author for revision ☐ Disapprove ☒ Not required Comments: Name/Signature: Date:	☒ Approve ☐ Approve w/ comment ☐ Return to author for revision ☐ Disapprove ☐ Forward for higher level review Comments: Name/Signature: June Brockman by direction Date: 5/10/18

Author Notification Date: 5/10/18 By: SMW

Appendix E: Preliminary Barrier Survey

Student Nurse Anesthetist Class of 2018 DNP Scholarly Inquiry Project:
Barriers to Remifentanil Use for Labor Analgesia

Please complete the following knowledge assessment:

Which profession do you associate with (circle one): Obstetric Anesthesia OB Nursing Pharmacy

How long have you been associated with this profession (circle one)? 0-2 yrs 2-5 yrs 5-10 yrs 10+ yrs

Are you on resident/student/training status (circle one)? YES NO

1. Have you ever prescribed, initiated, or filled remifentanil (Ultiva ©) for an obstetric patient, or provided care for an obstetric patient receiving a remifentanil patient-controlled analgesia (PCA) infusion?

2. How comfortable are you in your role with the preparation, management, and/or administration of remifentanil for obstetric patients? (With 0 being NOT comfortable at all and 10 being very comfortable)

0 1 2 3 4 5 6 7 8 9 10

Not comfortable Very comfortable

Please answer the following as they apply to remifentanil use on the Labor and Delivery Unit:

3. Were there any policy and/or staffing issues associated with the remifentanil PCA administration process?

4. Were there any challenges or untoward outcomes directly related to the remifentanil PCA administration?

5. Were there any delays in the remifentanil PCA process or implementation? If so, please describe the approximate time delay and any significant factors relating to that delay.

6. What, if any, in your profession are the barriers to prescribing, filling, or administering a remifentanil PCA infusion to an obstetric patient?

(Please return to folder by the anesthesia mailboxes labeled "remifentanil knowledge assessment")

Appendix F: Remifentanil Tiered Dosing Protocol

ANESTHESIA LABOR & DELIVERY REMIFENTANIL PATIENT CONTROLLED ANALGESIA (PCA) DOSE TIERING PROTOCOL

Remifentanil will be ordered ONLY via the L&D Remifentanil PCA Essentris order set. Concentration is 20mcg/mL and will come premixed from pharmacy. Dosing should be based on ideal body weight (IBW).

Tier	Background Infusion	Bolus	Interval	Max Dose for PCA only
1 (start here)	0.025mcg/kg/min	0.25mcg/kg	Q2min	0.5mg/hr
2	0.05mcg/kg/min	0.25mcg/kg	Q2min	0.5mg/hr
3*	0.075mcg/kg/min	0.25mcg/kg	Q2min	0.5mg/hr

(Modified from Ohashi, Baghirzada, Sumikura, & Balki, 2016; Balki, Kasodekar, Dhumne, Bernstein, & Carvalho, 2007)

*Lower doses may be utilized, however if the anesthesia provider determines that a higher dosing regimen or a dosing regimen not provided in this policy is required, an anesthesia staff member must remain at the bedside during use.

Approximate calculation for ideal body weight (IBW): IBW=height in cm- 105
(i.e. 165cm-105=60kg IBW)

Appendix G: Nursing Equipment Checklist

Remifentanil PCA Setup Supply List

- € Second peripheral IV
- € Alaris Infusion Pump (with infusion channel and PCA channel with PCA button)
- € Alaris End-tidal CO_2 monitoring module
- € End-tidal CO2 sample line
- € PCA pump key
- € PCA pump tubing
- € Primary IV tubing
- € Normal Saline/LR IV infusion bag
- € Nasal cannula
- € Remifentanil medication syringe (from pharmacy)
- € Ambu Bag
- € Naloxone (Narcan)
- € Supplemental Remifentanil PCA dose conversion chart
- € Second RN/anesthesia provider verifier

Appendix H: Remifentanil PCA Dose Increase Checklist

LABOR & DELIVERY REMIFENTANIL PCA DOSE INCREASE CHECK LIST

The following checklist is not a vital signs assessment sheet, but should be utilized in conjunction with the Pasero Opioid-Induced Sedation Score (POSS) to assess laboring women on a remifentanil PCA who are still in pain. The patient should be assessed and meet all criteria prior to requesting an increase in dose by the anesthesia provider.

- ☐ Respiratory rate ≥8 breaths/minute
- ☐ Heart rate ≥50 bpm
- ☐ Oxygen Saturation (SpO2) ≥ 92% on room air*
- ☐ Fetal Heart Rate >110bpm
- ☐ Blood pressure within 25% of baseline, MAP >60
- ☐ POSS score <3
- ☐ Pain score >4

If all of the above criteria are met, the Labor and Delivery nurse should notify the anesthesia provider to have the patient's PCA increased to the next level per protocol. If all of the criteria are not met, the patient should be assessed to determine if a decrease in dose is warranted.

*Unless the patient is receiving supplemental oxygen for the benefit of the fetus as deemed appropriate by the obstetrics provider and not in relation to the remifentanil PCA.

Appendix I: Pre-Implementation and Post-Implementation Knowledge Assessment

1) When utilized on the labor and delivery unit, the concentration of remifentanil should be:
A) 10mcg/mL
B) 20mcg/mL
C) 30mcg/mL

2) When used on the labor and delivery unit, remifentanil should be dosed based on:
A) Pre-pregnancy weight
B) Actual body weight
C) Ideal body weight

3) How many remifentanil PCA syringes should be prepared with each nursing request?
A) 1
B) 2
C) 4

4) Intravenous or oral opioids may be used concurrently with Remifentanil PCA.
A) True
B) False

5) Remifentanil PCA orders can be transferred to postpartum wards (C4K, C4L).
A) True
B) False

6) The Remifentanil protocol states that you must have:
A) 1:2 Nurse:Patient Ratio
B) No other opioids administered in the previous 90 minutes
C) One good working 18g IV in place
D) A qualified ACLS provider immediately available

7) Anesthesia should remain at the bedside how long post implementation of remifentanil PCA?
A) No current requirement
B) At least 10 minutes after initiation
C) At least 30 minutes after initiation

8) How often should vital signs (BP, HR, SpO2, RR, & Sedation Score) be assessed and documented?
A) q5 x 3, then q15 thereafter
B) q10 x 3, then q30 thereafter
C) q15 x 4, then q1h thereafter
D) Q1H

9) During which scenario should the OB RN notify an anesthesia provider?
A) RR < 12
B) Sedation Score = 2
C) Maternal HR < 60
D) SpO2 < 95% for > 15 seconds

10) A second, dedicated remifentanil IV line should be established within 15minutes of starting the PCA to allow for administration with a set rate carrier fluid and minimize risk of incidental bolus administration of drug.
A) True
B) False

Appendix J: Remifentanil for Labor Analgesia Evidence Table

Title	Author(s)	Year Published	Journal	Purpose	# of subjects analyzed	Inclusion criteria	Exclusion criteria	study design	Independent/ Subject Variable(s)	Dependent variables/ measures collected	Findings	F/U; Themes	Link	Pyramid Rating	Evidence Rating
Patient-controlled analgesia for labour using remifentanil: a feasibility study	Blair, J.M., Hill, D.A, & Fee, J.P. H.	2001	British Journal of Anaesthesia (87)3	To assess the feasibility of PCA remifentanil as an effective and safe alternative to edural analgesia	21 (6 nullparous, 15 multiparous)	ASA I or I, in established labour with the cervix at a minimum of 3 cm	Pts that had already received pethidine or had requested an epidural, twin pregnancy, pre-eclampsia, allergy to an agent under investigation, failure to obtain informed consent.	Feasibility study/Quasi-Experimental Study	Remifentanil levels I - III (basals + boluses), see article.	VAS, subjective comments, APGARs, SpO2, respiratory rate, sedation score, vomiting, dizziness, and HR	Most women (19/21) had decreased pain @ level I dose range (just bolus), All adverse events occurred @ level II or III. Conclusion: All women have pulse oximetry, and adding a background infusion does not reduce pain scores but serves only to increase respiratory depression and sedation.			Level II	C (sample size/study limitations)
Remifentanil for labor analgesia: A double-blinded randomized controlled trial of maternal and neonatal effects of patient-controlled analgesia versus continuous infusion	Shen, M. K., Wu, Z. F., Zhu, A. B., He, L. L., Shen, X. F., Yang, J. J., & Feng, S. W.	2013	Anesthesia and Analgesia	Compare maternal and neonatal effects of remifentanil administered as a continuous infusion or patient-controlled analgesia (PCA)	60 (30 for PCA, 30 for continuous infusion)	Not stated	Not stated	Prospective double blind RCT	Remifentanil PCA (initial settings 0.1 mcg/kg over 30 seconds with 2-min lockout with stepwise increases in 0.1mg increments up to 0.4 mcg/kg); Remifentanil continuous infusion (0.05mcg/kg up to a dose of 0.2 mcg/kg/min)	VAS; Ramsay sedation score; Neurologic Capacity Score; arterial saturation/VS	Arterial saturations values were significantly higher in the PCA group. Pain scores were lower and pain relief scores were higher in the PCA group. Maternal adverse effects were similar in both groups. Fetal outcomes were both satisfactory (no resuscitation or naloxone necessary) and APGAR scores did not differ between groups.	**Method of delivery:** PCA may be superior to continuous infusion	Shen_PCAvsCon tinuousInfusion	Level I	B
The analgesia efficacy of remifentanil for labour, systematic review of recent literature	Stourac, P., Kosinova, M., Harazim, H., Huser, M., Janku, P., Palacky University Olomouc, Czechoslovakia Jarkovsky, J.	2016	Biomedical Papers of the Medical Faculty of the University Palacky, Olomouc, Czechoslovakia	Meta-analysis of RCTs re efficacy of remifentanil for labor analgesia is primary outcome; secondary outcomes: mode of administration, concentration, comparison to other analgesia, safety in mother and neonate, dosing	15 RCTs for meta-analysis; 17 RCTs, 7 reviews, 5 national surveys, 2 meta-analyses, 5 observational studies, 4 initial trials of remifentanil in labor, and 2 case reports for systematic review	For meta-analysis: RCT, VAS at 0min and 60min. Full text available	For meta-analysis: not an RCT, missing full article, missing clinical data or VAS	Meta-analysis and systematic review	Remifentanil vs comparison	VAS change at t=0 (0min) and t=1 (60min after initiation of remifentanil)	Statistically significant decrease in VAS in the remifentanil group from t=0 to t=1; Efficacious, especially in the first stage of labour; preferred dedicated IV; Concentration 20 or 50mcg/mL; Effective dose 0.25-0.5mcg/kg for bolus with 0.7mcg/kg or more potentially causing desaturation; continuous infusion ranges 0.025 mcg/kg/min to 0.15 mcg/kg/min, potential lower side effects with variable basal and fixed bolus group, as well as lower conversion to epidural; no significant timing of bolus except in long, regular contraction	Efficacious; **concentration; effective dose; variable basal with fixed bolus; dedicated IV line**	Stourac_Efficac yMetaanalysis	Level I	B
Efficacy and side effects of intravenous remifentanil patient-controlled analgesia used in a stepwise approach for labour: An observational study	Tveit, T. O., Halvorsen, A., Seiler, S., Rosland, J. H.	2013	International Journal of Obstetric Anesthesia	Prospective observational study of stepwise boluses doses without background infusion during first and second stages of labour	41	ASA I or II, uncomplicated pregnancy at 37-40wks, ongoing uterine contractions, cervical dilatation >3cm, expected vaginal delivery, normal fetus in cephalic presentation, and normal toco	Contraindications to remifentanil use, pethidine given within 8hrs, request for epidural	Prospective observational study	remifentanil boluses via PCA with stepwise increases (start 0.015 mcg/kg with increases by 0.15 mcg/kg with 2min lockout	Pain reduction, maternal satisfaction, maternal and neonatal side effects, and remifentanil metabolism in the neonate (Neonatal exam: APGAR, cord gas, naloxone use, clinical exam, and resuscitation; Maternal exam: VS, SpO2, VAS, RR, maternal sedation)	Statistically significant decrease in VAS after 1 hr with slowly increase thereafter but still below baseline; >50% required dose of 0.7mcg/kg or more; pump stopped in 6 women for side effects; lowest SpO2 91% and lowest RR 9bpm. 4 NRFHTs, but reassuring outcome and all APGARS WNL Greatest risk for sedation between contractions. Supplemental O2 only when needed.	Variable intravenous stepwise dosing (via PCA without background in this study); **PCA dosing; timing; * criteria required to allow for increased bolus dosing Q15min* criteria to STOP PCA pump and administer O2; concentration; PCA administered until delivery (not stopped)**; medications recommendations and BLS support aveiable at all times; **continuous monitoring warranted for sedation with 1:1; Calculatin on LBW**	Tveit_Stepwise ApproachtoPC Adosing	Level III	B
Remifentanil for labor analgesia: An evidence-based narrative review	Van de Velde, M. & Carvalho, B.	2015	International Journal of Obstetric Anesthesia	Narrative Review	4 basic research, 13 case reports, 18 reviews and meta-analyses, 22 editorials and letters, 6 surveys/audits, 1 trial protocol publication, 38 original clinical studies	Literature search with no language restriction on PubMed with key terms "remifentanil" and "labor" or "PCIA remifentanil and labor analgesia.".	33 excluded for not being related to topic of remifentnial safety and efficacy in labor	Qualitative narrative review	Remifentanil	Varied	PCA only most common modality; more efficacious compared to N2O and pethidine, but less than neuraxial; studies vary on whether or not delayed or modified timing decreases pain scores; remifentanil has less effective on the fetus than other parenteral opioids; continuous patient monitoring is necessary for maternal safety because it significantly increases the risk of respiratory depression compared to neuraxial analgesia (1:1 nursing recommended).	**1:1 nursing and etCO2 or apnea monitors and SpO2; dosing; mode of administration**; safety and efficacy, timing	VandeVelde_Evi denceBasedNar rativeReview	Level III	B

Remifentanil in obstetric analgesia: A dose-finding study	Volmanen, P., Akural, E. I., Raudaskoski, T., & Alahuhta, S.	2002	Anesthesia and Analgesia	Determine dose required for effective analgesia without causing serious side effects; study completed over 60min	20	Healthy term parturient; singleton pregnancy; first stage of labor (<7cm); fetus in normal cephalic position	Prior administration of regional of opioid analgesia; entry into second stage of labor during study	Quasi Experimental	Remifentanil PCA (0.2 mcg/kg over 1min with a lockout of 1min) with increasing boluses in 0.2mcg/kg increments Q10min as requested to a maximum dose of 0.8 mcg/kg or until there were was a sign of serious side effects (SaO2 <92%, RR <8, FHR <80) for a total of 60min only	SaO2, RR, FHR, VAS (0-10), BP Q5, HR, pt satisfaction, APGAR, sedation (4 pt scale), umbilical artery pH, nausea, itching	Median effective consumption was 0.066 mcg/kg/min (no different in primiparous or multiparous) with a range of 0.027 mcg/kg/min0. 207mcg/kg/min). Respiratory depression most common between contractions with O2 sat <94% in 10/17 women. 4/17 episodes of reduced variability.	Dedicated line with NS infusion 100mL/hr, recommend longer duration of bolus; **continuous monitoring of respiratory function**, supplemental O2.	Volmanen_DoseFindingStudy	Level II	C (sample size/study limitations)
Timing of intravenous patient-controlled remifentanil bolus during early labor	Volmanen, P., Akural, E. I., Raudaskoski, T., Ranta, P., Ohtonen, P., & Alahuhta, S.	2011	Acta Anaesthesiologica Scandinavica	Determine if administering a remifentanil bolus during contraction pause would improve analgesia in early labour	50	Uncomplicated singleton pregnancy (8/15/04-10/9/08); first stage of labor (<7cm), fetus in normal cephalic position	Prior administration of opioids in the previous 4hrs or administration of regional blocks.	Double blind cross-over study (computer generated assignments)	Group 1 (n=25) Instant remi and delayed placebo for 6-8 contractions, then instant placebo and delayed remi for 6-8 contractions; Group 2 (n=25) Delayed remi and instant placebo for 6-8 contractions, then instant remi and delayed placebo for 6-8 contractions; remi bolus was 0.4mcg/kg over 1min; delay time was 140seconds. Dedicated IV line for infusions with NS at 100mL/hr. Lockout 1min.	Numeric pain scale (0-11) with every contraction; pain relief (5 point scale); side effects on 4 point scale (nausea, sedation) after every other uterine contraction; overall desire to continue with medication at teh end of the time period; HR, SaO2, NIBP Q10, FHR, APGAR, umbilical artery pH	No difference in pain scores or the variables related to the analgesic effect. No difference between duration of study period or the average contractio interval between the two dosing regimens. The first study period was preferred by both groups (the instant remi and the delayed remi). No difference in nausea/vomiting. No differences in APGAR. *Timing of administration of remifentanil bolus during the uterine contraction cycle has no significance when a 1min PCA bolus was given.	Concentration (20mcg/mL); **timing of bolus does not affect pain scores; dedicated IV line**	Volmanen_TimingofPCA	Level I	B
Neuraxial analgesia versus intravenous remifentanil for pain relief in early labor in nulliparous women	Ismail, M. T., & Hassanin, M. Z.	2012	Archives of Gynecology and Obstetrics (286) 6	To assess if there is a difference in duration of labor, the mode of delivery, average VAS pain scores, maternal overall satisfaction with analgesia, side effects and neonatal outcomes in nulliparous women who received early labor analgesia with either epidural, PCIA with remifentanil, or CSE technique	1140	Nulliparous, singleton pregnancy, spontaneously went into labor (at least 2 painful contractions in 10 mins, cervix at least 80% effaced, and up to 3 cm dilated) and requesting labor analgesia	Allergy to opioids, a history of the use of centrally acting drugs of any sort, chronic pain, psychiatric disease; age <18 or >40; those not willing or able to complete entire study; alcohol- or opioid-dependent patients (were excluded for their influence on the analgesic efficiay of epidural analgesics); pts with non-vertex presentation or scheduled for induction of labor; pts with DM or PIH; twin gestation and breech presentation; any contraindication to neuraxial or systemic opioid analgesia; cervical dilation of 4cm or more; estimated fetal weight >4,000 g and abnormal fetal heart rate tracing on admission	Randomized interventional study	CLE with PCEA, CSE with PCEA, Remifentanil PCIA with bolus dose escalation scheme (bolus only), see article	Rate of cesarean delivery (primary), rate of instrumental vaginal delivery, duration of active phase of first stage labor, second stage labor, VAS pain scores, maternal satisfaction, oxytocin requirement, nausea, vomiting, puritis, neonatal outcomes (measured with Apgar scores at 1 and 5 mins, umbilical cord blood gases/umbilical artery pH)	No statistically significant difference between the three groups with regard to the rate of cesarean delivery, rate of instrumental vaginal delivery, or the percentage of subjects who were treated with oxytocin infusion after analgesia. N/V and puritis similar across the groups. No patients required O2 supplementation or naloxone administration. Neonatal outcomes were not statistically different across the groups. CSE showed a statistically highly significant short duration of labor, active + latent phases of first stage, and second stage of labor.	Bolus-only PCA dosing with dose escalation scheme	Ismail_Neuraxialanalgesia	Level I	C. No evaluation of strengths/weaknesses of the study
Remifentanil for labor analgesia: A comprehensive review	Ohashi, Y., Baghirzada, L., Sumikura, H., & Balki, M.	2016	Japanese Society of Anesthesiologists (30) 6	To provide an overview of knowledge and principles of using remifentanil IVPCA for labor analgesia and introduce its potential usage in Japan	3 double-blind RCTs; 5 RCTs; 7 prospective observational studies; 3 case reports; 1 dose-finding study	Not stated	Not stated	Qualitative narrative review	Remifentanil	Maternal safety, neonatal safety	Greater analgesic efficacy with remifentail when compared with other opioids or N2O, but less than with epidural analgesia. Dedicated IV line for PCA recommended. *Standard monitoring for remifentanil PCA use should include BP , HR, pulse ox, RR, and verbal pain score q10 mins for the first 30 minutes, then q1hr or more frequently if clinically indicated. O2 sat should be maintained >95%. Capnography should be utilized if available. If unable to maintain O2 sat >95% with supplemental O2, D/C PCA and notify anesthesia. Notify anesthesia of hypotension (SBP<90 OR >20% drop from baseline). Maintain continuous FHT monitoring	Maternal monitoring guidlines during remifentanil PCA use. Remifentail PCA dosing regimens, including recs on bolus-only, continuous-only, and continuous+PCA regimens	Ohashi_Remifentanil for labor	Level III	C. No article inclusion/exclusion criteria

Remifentanil patient-controlled analgesia for labour: optimizing drug delivery regimens	Balki, M., Kasodekar, S., Dhumne, S., Bernstein, P., & Carvalho, J.C.	2007	Canada Journal of Anesthesia (54) 8	To compare two regimens of intravenous remifentanil PCA, along with continuous background infusion, for labour analgesia	20 term parturients	Term pregnancy, ASA I and II patients in active labour, who requested systemic analgesia w/ or without contraindications to epidural analgesia.	Allergy or hypersensitivity to remifentanil, opioid dependence or addiction, consumption of narcotics within 24 hr of the study period, FHR abnormalities, fetal compromise and/or language barrier.	Prospective RCT	(Group A) - Remifentanil constant PC boluses w/ a stepwise increase in the infusion rate; (Group B) - Remifentanil constant infusion rate w/ a stepwise increase in the PCA bolus dose	Maternal pain, satisfaction, and sedation scores, remifentanil requirement, and side effects	Mean pain and patient satisfaction scores, and cumulative doses of remifentanil were similar in both groups. Overall incidence of side effects greater in Group B. Conclusion: Remi PCA is efficacious for labour analgesia as a bolus of 0.25 mcg/kg with a lockout interval of 2 mins and continuous infusion of 0.025-0.1mcg/kg/min. Close respiratory monitoring mandated.	Dosing regimen; pain and satisfaction scores		Level I	C (small sample size)
Remifentanil patient-controlled analgesia for labour: a complete audit cycle	Buehner, U., Broadbent, J.R., & Chesterfield, B.	2011	Anaesthesia and Intensive Care (39) 4	Presents the results of an audit cycle, designed to ensure that weaknesses in the provision of Remifentanil PCA were identified and corrected through appropriate changes. Also provided reassurance to the midwifery community about the efficacy and safety of remifentanil PCA and therefore encouraged its wider uptake	244 remifentanil PCA users (82% primiparous women) and 153 completed satisfaction questionnaires obtained.			2-stage audit	"Procedural changes and midwifery training in the competent and safe use of remifentanil PCA"	A comparison of both audits against four standards of care: Standard 1: Commencement of remifentanil PCA within 30 minutes of prescription; Standard 2: Recordings of remifentanil-specific observations as per PCA protocol; Standard 3: Provision of effective labour analgesia; Standard 4: No maternal and fetal side-effects.	The PCA bolus dose options and lockout increments were prescribed together and on the reverse side of the prescription, a flowchart provided guidance on patient selection, indications, process of administration and observations required prior to and during remifentanil PCA. Regular midwifery teaching sessions on the safe use of remifentanil PCA reinforced the importance of stringent monitoring and 1:1 supervision of the parturient. These sessions included pre-training reading material and case scenarios, w/ emphasis on respiratory rate and sedation score monitoring, and a quiz to test understanding. No side effects were experienced by 20% of parturient in audit 1 versus 13% in audit 2. The three most common side effects were drowsiness, pruritus, and nausea.	Maternal satisfaction, dosing regimen, PCA commencement times, midwifery training, side effect profile (maternal & fetal), remifentanil partogram		Level V (non-research)	B
Labor Analgesia in Preeclampsia: Remifentanil Patient Controlled Intravenous Analgesia Versus Epidural Analgesia	El-Kerdawy, H. & Farouk, A.	2010	Middle East Journal of Anesthesiology 20 (4)	Compare the use of Remifentanil PCA intravenous analgesia to epidural bupivacaine plus fentanyl for labor analgesia in preeclamptic patients	30 Preeclamptic patients	≥ 32 WGA, normal cephalic presentation, < 5 cm cervical dilatation, clinical diagnosis of preeclampsia (which required at least one of the three criteria listed in the article)	Remifentanil allergy, progression to eclampsia, evidence of increased intracranial pressure or focal neurologic deficity, platelet count of less than 80 x 10^9/L, or evidence of pulmonary edema, NRFHR tracing requiring imminent delivery.	RCT	Epidural Group (initial bolus of 10-15mL of 0.25% bupivacaine + 1 mcg/kg Fentanyl, followed by continuous infusion of 0.125% bupivacaine + 2 mcg/ml Fentanyl @ 10-12 ml/hr); Remifentanil Group (0.5 mcg/kg loading bolus over 20 seconds, lockout time of 5 mins, PCA bolus of 0.25 mcg/kg, basal infusion of 0.05 mcg/kg/min, max dose of 3mg in 4 hrs)	VAS, sedation, post-delivery patient satisfaction, maternal side effects and neonatal side effects	All women demonstrated a significant decrease in VAS score in the first hour after administration of analgesia. Analgesic quality was comparable in both groups (P > 0.05), PCA remifentanil infusion until time of delivery produce no observable maternal, fetal or neonatl side effects (P < 0.05)	Our purpose for keeping this article was as a reference to when to discontinue the remifentanil. As stated in the article, "The continuous remifentanil infusion until the time of delivery produced no observable fetal or neonatal side effects compared to the epidural group. This was indicated by the normal APGAR score, reassuring FHR tracing, normal umbilical cord gases, the absence of need for naloxone, or mechanical ventilation for the neonates".		Level I	C (sample size/study limitations)
The Efficacy & Safety of Continuous Intravenous Administration of Remifentanil for Birth Pain Relief: An Open Study of 205 Parturients	D'Onofrio, P., Novelli, A.M., Mecacci, F. & Scarselli, G.	2009	Anesthesia & Analgesia	To examine the maternal and neonatal safety of a continuous IV infusion of remifentanil during labor and to evaluate the analgesic effects and patient satisfaction.	205 parturients	Term, singleton pregnancy and ASA physical status I and II patients in active labor with cephalic presentation	Allergy or hypersensitivity to remifentanil or other opioid analgesia during the same labor	Prospective Observational Study/Quasi-Experimental	Remifentanil initial infusion @ 0.025 mcg/kg/min, increased after 3 min 0.025 mcg/kg/min, to a maximum dose of 0.15mcg/kg/min.	maternal pain (VAPS), satisfaction, respiratory depression (QAA/S scale), maternal HR, ABP, and SpO2, side effects (nausa/vomiting/dizziness/pruritis/confusion) FHR/Variability & APGAR's	High degree of satisfaction (87%), mean SpO2 of 98% +/- 1%, No O2 supplementation or administration of narcan, minimal sedation scores. No changes in FHR variability, median APGAR's were 9 and 9.	the data collected in this observational study show that continuous IV remifentanil titrated to VAPS score may be a valid option for labor analgesia w/ few side effects.		Level II	B

Patient-controlled intravenous analgesia with remifentanil in nulliparous subjects in labor	Balcioglu, O., Akin, S., Demir, S. & Aribogan, A.	2007	Expert Opinion on Pharmacotherapy	to assess and compare the efficiency and safety of patient-controlled use of remifentanil combine with two different supplementary background infusions during labor in nulliparous women	60 subjects	Nulliparous women, ASA I or II, cervix dilated to atleast 3cm, single, healthy fetus (36-41 wks of gestation) with a vertex presentation and a normal FHR pattern	Hx of twin pregnancy, pre-eclampsia, drug abuse, allergy to any agent and/or conditions of inability to understand PCA, ASA physical classification > 3, age < 18 and/or failure to obtain informed consent	Quasi-Experimental	Group r (30) - background infusion @ 0.1mcg/kg/min; Group R (30) - background infusion @ 0.15 mcg/kg/min	Pain relief (VAS), HR, BP, SpO2, RR, FHR(@ 5th, 10th, 20th, & 30th min of the study & continued q15 until deliver), sedation scores	Mean VAS scores were lower in the increased infusion group. No significant differences in hemodynamics and resp parameters, no brady, hypotention, resp depression or pruritis in either group. Satisfaction scores were high and about the same for both. No difference in total remi consumption, lower infusion rate had increased bolus demands.	Showed that PCA, low bolus administration of Remi w/ low continuous background infusion is an effective and safe alternative for labor pain.*did not specify any limitations in the study*		Level II	B
Remifentanil: A Novel Systemic Analgesic for Labor Pain	Evron, S., Glezerman, M., Sadan, O., Boaz, M., & Ezri, T.	2004	Anesthesia & Analgesia	The main objective of this investigation was to compare the analgesic effect of remifentanil administered as patient-controlled IV analgesia (PCIA) with the effect of an IV infusion of meperidine for labor pain. Additionally, effects of treatment methods on labor, delivery, and fetal outcomes were assessed.	88 parturients	all term parturients with singleton cephalic presentation neonates requesting systemic analgesia, ASA I or II, in active labor (cervical dilation of 3-6cm)	ASA of III or more, obesity (more than 100kg or BMI >40), hx of drug or alcohol abuse, smoking more than 10 cigarettes/day, and abnormal liver, renal, or hematologic function.	Double-Blind RCT	Control group - 75mg of meperidine in 100mL of NS over 30 mins; Experimental Group - PCIA 20mcg bolus, and a 3 minute lockout interval without basal. Increased every 15-20 mins by 5mcg increments to a max dose of 1500mcg/h.	VAS, patient satisfaction, sedation, hemoglobin saturation, analgesia failure, neonatal outcome (APGARs, FHR patterns)	an intermittent incremental regimen with repeated small-dose PCIA boluses of remifentanil provided effect and reliable analgesia during labor and delivery	Dosing regimen; pain and satisfaction scores		Level I	A

Appendix K: DNP Project Completion Verification

Appendix J: Daniel K. Inouye Graduate School of Nursing
DNP Project Completion Verification Form

DOCTOR OF NURSING PRACTICE PROJECT
Completion Verification Form

The DNP Project titled: Barriers to Remifentanil Use for Labor Analgesia: A Process Improvement Initiative was completed at Naval Medical Center Portsmouth, VA by the following student(s):

(type student name)	*(signature)*	*(date)*
Stephanie Daniels	[redacted]	01 Sep 2017
Sharrod Greene		01Sep2017
Cassy Piela		9/1/17

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

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

Verified by:

(type name)	*(signature)*	*(date)*	
Ryan Nations	[redacted]	9/1/17	Senior Mentor
Lauren Suszan		9/1/17	Team Mentor
Reginald Middlebro		9/1/17	Team Mentor & Phase II Site Director

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

Kenneth Wofford [redacted] 9-22-17
RNA Project Director *(type name)* *(Signature)* *(Date)*

Form Version: 26 Aug 2017

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