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Remifentanil for Labor Analgesia: An Evidence Based Practice Project

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Abstract

Phase II Site: Fort Belvoir Community Hospital

DNP Project Title: Remifentanil for Labor Analgesia: an Evidence-Based Practice Project

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Background or Problem/Issue: Neuraxial analgesia is the most common and effective method for pain management during labor due to its minimal maternal and fetal risks (Devabhakthuni, 2013). Contraindications to neuraxial analgesia can limit its availability to some parturients (Balki, Kasodekar, Dhumne, Bernsetin, & Carvalho, 2007). Remifentanil has emerged as a safe and effective alternative for pain management during labor in the parturient (Volmanen, Akural, Raudaskoski, & Alahuta, 2002). Previously at Fort Belvoir Community Hospital (FBCH) there was lack of standardization for the administration and nursing care of parturients receiving remifentanil.

Clinical Question or Purpose: The purpose of this evidence-based practice (EBP) project was to increase knowledge and develop an evidence-based protocol that standardized administration and nursing care for the parturient receiving remifentanil.

Project Design: This project was a pre- and post-implementation performance improvement project. An evidence-based remifentanil protocol was developed that specified patient population, mode of administration, dosage, and nursing care to be implemented on FBCH's labor and delivery unit. An educational intervention (EI) with a vignette was constructed and presented to anesthesia providers (AP), obstetric providers (OB), and labor and delivery nursing staff (NS). The groups were provided the same five-question pre- and post-test that evaluated the effectiveness of the EI. One-month post-implementation the AP were given a modified Evidence-Based Practice Implementation Scale that assessed whether they changed their practice based on the EI.

Analysis of Results: The pre-test illustrated a baseline of limited knowledge on remifentanil. The EI proved to be effective as illustrated from the increase in the pre- and post-test scores. The modified Evidence-Based Practice Implementation Scale demonstrated that the majority of AP discussed the remifentanil project and were using it to change their practice.

Organizational Impact/Implications for Practice: An evidence-based protocol provided the organization with a standardized method for the administration of remifentanil and nursing care of parturients for whom neuraxial analgesia was contraindicated.

Introduction

Inadequately managed pain during childbirth can contribute to psychological and emotional stress (Kwok, Moo, Sia, Razak, & Sng, 2015). Uncontrolled pain during labor can produce physiologic stress due to activation of the sympathetic nervous system (Ohashi, Baghirzada, Sumikara, & Balki, 2016). Parturients experience increased cardiac workload and oxygen consumption (Braveman, Scavone, Blessing, & Wong, 2013). The increase in the sympathetic nervous system activity leads to uteroplacental vasoconstriction which can precipitate fetal distress (Braveman et al., 2013). Adequate pain management in the parturient can attenuate unwanted sequelae.

Significance of the Problem

Neuraxial analgesia is the most common and effective method for pain management during labor due to its minimal maternal and fetal risks (Devabhakthuni, 2013). However, neuraxial analgesia is contraindicated for parturients in whom the risks of a spinal or epidural placement outweigh the benefits. Absolute and relative contraindications include patient refusal, bleeding disorders, prophylactic anticoagulation, spinal abnormalities, difficult placement, and infection (Devabhakthuni, 2013). Parenteral opioids provide an alternative method for pain management in these clinical scenarios.

Parental opioids have comparable pharmacodynamics and side effects, but they may differ in their pharmacokinetics. Nalbuphine and fentanyl are commonly administered parenteral opioids given to parturients. Fentanyl, a short acting opioid agonist, carries an increased risk of drug accumulation with prolonged infusions due to uptake of the drug into tissues (Marwah, Hassan, Carvalho, & Balki, 2011). This has the potential to lead to prolonged maternal respiratory depression and fetal acidosis, as well as neonatal respiratory depression. Nalbuphine,

an opioid agonist-antagonist, has a prolonged half-life of 3-6 hours that can precipitate neonatal respiratory depression (Omoigui, 2013).

Remifentanil, an ultra-short acting opioid agonist, has emerged as a safe and effective alternative for pain management during labor (Volmanen et al., 2002). Remifentanil has a rapid onset of 30-60 seconds and a half-life of less than 10 minutes regardless of infusion time secondary to its unique metabolism by plasma and tissue esterases (Ohashi et al., 2016). Remifentanil's pharmacokinetics makes it suitable for prolonged infusions with no risk of drug accumulation.

The most common maternal adverse effects of remifentanil are sedation and respiratory depression leading to hypoxemia. The rapid metabolism and short duration of action allows for the prompt return of spontaneous respirations (Ohashi et al., 2016). In the event that a parturient experiences problematic sedation or respiratory depression, remifentanil can be turned off while providing airway support and supplemental oxygen. Analgesia can be restored by restarting remifentanil at a lower dose.

Although remifentanil readily crosses the placenta, there have been no reports of serious neonatal or fetal adverse effects (Ohashi et al., 2016). In the event of neonatal respiratory depression, mask ventilation and supplemental oxygen should be supplied until the neonate metabolizes the residual remifentanil.

Despite the advantages of remifentanil, it has not been commonly used at FBCH for parturients who are not candidates for neuraxial analgesia. Two likely reasons for the low rate of remifentanil use at FBCH are unfamiliarity with its use among OB and NS and the absence of a protocol to govern its administration. Historically, the administration of remifentanil was a "one-off" event with dosing range and monitoring orders varying with individual providers. The

EBP protocol increased knowledge and standardized administration and nursing care for the parturient receiving remifentanil at FBCH.

Benefit of Addressing the Problem

Parturients who are not candidates for neuraxial analgesia are at risk for inadequate pain management during delivery. Remifentanil allows providers to offer parturients pain control that is feasible for administration in a cost effective manner. The implementation of an evidence-based protocol for the administration of remifentanil at FBCH addresses one of the four arms of the Military Health Systems (MHS) Quadruple Aim: improving patient experience.

Purpose

The purpose of this EBP project was to increase knowledge and develop an evidence-based protocol that standardized administration and nursing care for the parturient receiving remifentanil.

Focus Areas

There were three focus areas for this project. First, an evidence-based protocol and corresponding standardized order set was developed for the administration of remifentanil to parturients. The protocol outlined the criteria for patient selection, the standards for monitoring the parturient and fetus, the mode of administration, titration of the medication, and interventions to treat potential side effects. This evidence-based protocol and corresponding standardized order set facilitated the use of remifentanil, reduced variation in provider practice, and ensured sustainment of remifentanil administration beyond the conclusion of this EBP project.

The second focus area was an educational intervention (EI) that included a presentation and an accompanying patient vignette. The purpose of the presentation was to enhance knowledge of remifentanil and overcome barriers to its use in parturients. Use of patient

vignettes in education is widely accepted as an effective tool that enhances critical thinking and clinical problem solving (Sandstrom, 2006). The effect of the EI was assessed using a pre- and post-test that was provided to AP, OB and NS.

The third focus area evaluated the level of adoption of the EBP protocol by AP via dissemination of the modified Evidence-Based Practice Implementation Scale. This was completed 30 days following implementation of the remifentanil EBP protocol and EI. The Evidence-Based Practice Implementation Scale has demonstrated validity for the adoption of evidence-based practice principals into registered nursing practice (Melnyk, Fineout-Overholt, & Mays, 2008). In addition, the modified Evidence-Based Practice Implementation Scale has been used on AP and published as part of a quality improvement project that sought to reduce variation in practice regarding administration of neuraxial analgesia (Johnson, Walter, Fugate, & Titch, 2015).

Project Short and Long Term Goals

The short-term goals of this project were to increase the knowledge and minimize variation regarding the use of remifentanil for parturients where neuraxial analgesia is contraindicated. The long-term goal of this project was to change AP practice through expansion of remifentanil as a labor analgesia alternative.

Military Significance

The goals of the MHS Quadruple Aim are to improve population health, improve the patient experience, decrease per capita cost, and support readiness. Remifentanil administration addresses the MHS quadruple aim goal of improving patient experience by providing an alternative pain management modality to parturients who are not candidates for neuraxial

analgesia. This protocol and its educational and assessment tools serve as a resource for the use of remifentanil on labor and delivery units across the MHS.

Organizing Framework

The Iowa Model of Evidence-Based Practice to Promote Quality Care was used to guide the development and implementation of this project (Appendix 1). The model has seven steps and begins with the identification of a problem-focused trigger. In this case, there was no standardized protocol for the use of remifentanil for labor analgesia at FBCH. Developing an evidence-based protocol represents an institutional priority secondary to its potential to improve the experience of care, which is a pillar of the MHS Quadruple Aim. In addition, an evidence-based protocol will reduce variation in provider practice that correlates with the institutional goal of becoming a high reliability organization. A search of the literature was conducted and we determined that there was sufficient evidence to pilot a change in practice. FBCH stakeholders included: the chief of obstetric anesthesia, the chief nurse of the labor and delivery unit and the clinical nurse specialist for the labor and delivery unit.

Project Design

General Approach

We developed a remifentanil EI that presented the medication's pharmacokinetics, pharmacodynamics, adverse reactions with interventions, and introduced our EBP protocol and order set. We then presented our intervention to AP, OB and NS. We assessed effectiveness of our EI with a pre- and post-test (Appendix 2). One month after presentation of our EI, we assessed for change in the anesthesia staff practice by administering the modified Evidence-Based Practice Implementation Scale (Appendix 3).

Setting

This EBP project was conducted at a 120-bed community hospital located in the National Capital Region of Northern Virginia. The labor and delivery unit consists of 7 patient beds and 2 operating rooms providing care for approximately 150 low-risk parturients each month. One AP, an obstetrician, and a family medicine resident and/or a certified nurse midwife are present and immediately available at all times. A neonatal rapid response team, consisting of a pediatrician and/or neonatal nurse practitioner, two neonatal nurses, and a nursing assistant, are available to respond to neonatal compromise.

Procedural Steps

Evidence Evaluation: Embase, PubMed, CINAHL, and Evidence based Medicine (EBM), which included the Cochrane library, were searched to identify articles, abstracts, or studies for inclusion in this review of the literature on the analgesic and adverse effects of remifentanil delivered via patient-controlled analgesia (PCA versus remifentanil delivered via continuous infusion in laboring parturients. The drug “remifentanil” was searched in Embase. Subsequent search terms were separated into categories with corresponding keywords. The following categories were used: laboring parturients, continuous infusion, and patient controlled analgesia. The keywords for parturients were “paturients” and “laboring”. To account for the different spellings of labor, keywords “labouring” and “labor OR labour” were also used. The second category was continuous infusion and had the following keywords: “basal rate”, “infusion”, “continuous infusion” and “continuous rate”. The final category was patient controlled analgesia with keywords “patient controlled analgesia”, “PCA”, and “bolus”. PubMed search terms were remifentanil AND (“patient controlled” OR bolus OR PCA OR patient controlled analgesia) AND (continuous infusion OR basal rate OR infusion) AND (pain OR adverse effects). CINAHL search categories consisted of "pregnancy OR pregnant OR

parturients OR laboring women" OR "Labor" OR "Childbirth" OR "Pregnancy" AND remifentanil. EBM Reviews search categories consisted of remifentanil or ultiva and (labor or laboring women or parturients or childbirth or labour or labouring).

The literature search was limited to articles published in English. There was no constraint on the date of publication of the articles. The literature search generated 174 articles. Fifty-seven articles were eliminated as being duplicates. After reviewing titles and abstracts of the remaining 117 articles, 78 were considered irrelevant to the clinical question and were eliminated. For the remaining 39 articles, the full text was reviewed and articles were eliminated based on inclusion and exclusion criteria. The inclusion criteria were articles describing studies of remifentanil administered via PCA, infusion or in combination. The exclusion criteria were studies of remifentanil administered concurrently with other pain modalities such as other opioids or neuraxial analgesia in a single patient. In total, seven studies remained and were deemed to inform our evidence-based practice project.

The seven studies were organized based on the Joanna Briggs Institute levels of Evidence-Effectiveness (JBL) (Joanna Briggs Institute, 2013). JBL organizes evidence into 5 levels. We determined that there was sufficient evidence to inform our evidence-based practice project. Three articles were level I (randomized control trials), three articles were level III (non-experimental studies consisting of descriptive, retrospective, and prospective articles), and one article was a level IV (case report) (See Table 1).

Our review of the literature revealed a lack of consensus regarding optimal dose of remifentanil and method of administration for labor pain. In addition, there was considerable variation in patient response to this medication. The remifentanil dosing strategy utilized in the FBCH protocol is based on a study by Balki et al. (2007). Their study sought to optimize drug

delivery regimes by comparing a fixed PCA bolus of 0.25 mcg/kg with a variable background infusion of 0.025-0.1 mcg/kg/min to a fixed background infusion 0.025 mcg/kg/min with a variable bolus from 0.25-1 mcg/kg. The results of the study were that parturients who received variable bolus doses experienced greater adverse effects with drowsiness and desaturation being the most common. A possible explanation for this is the sudden increase in plasma concentrations of remifentanil following bolus delivery combined with the unpredictable timing of contraction pain. Increased maternal adverse effects were also seen when a fixed bolus was combined with continuous infusions greater than 0.05 mcg/kg/min, thus we incorporated 0.05 mcg/kg/min as the upper limit of our background infusion with a fixed bolus. For the FBCH remifentanil protocol we decided on a two level dosing strategy. Level one begins with a fixed PCA bolus of 0.25 mcg/kg combined with a background infusion 0.025 mcg/kg/min. If needed, the parturient can be increased to level two, which retains the fixed PCA bolus of 0.25 mcg/kg and increases the background infusion to 0.05 mcg/kg/min. The rational for this dosing strategy is based on the peak effect of remifentanil which is 2.5 minutes combined with variability in contraction duration. The result is that a remifentanil bolus delivered at the onset of contraction may not reach peak effect concurrently with the contraction. This leads to increased sedation and possibly desaturation in the time between contractions. Therefore a variable background infusion providing steady-state plasma concentrations combined with fixed bolus doses for breakthrough pain may provide better analgesia with fewer adverse effects.

This same dosing strategy was used by Marwah et al. (2011) who conducted a five-year retrospective cohort study comparing the analgesic efficacy and adverse effects of IVPCA remifentanil vs. fentanyl. Forty-seven parturients received remifentanil utilizing the same dosing strategy described in the FBCH protocol. Moderate pain relief was seen in both the remifentanil

and fentanyl groups and the most common adverse effects were maternal sedation and desaturation. IVPCA fentanyl was associated with a higher need for neonatal resuscitation. This article demonstrated the superior safety profile of remifentanil compared to fentanyl for labor analgesia. It also provided further support for the safety and efficacy of a small bolus dose of remifentanil (0.25 mcg/kg) combined with a variable background infusion (0.025-0.05 mcg/kg/min) provided that strict patient monitoring requirements are in place including continuous end tidal carbon dioxide ($EtCO_2$) and one to one nursing.

D'Onofrio, Novelli, Mecacci, & Scarselli (2009) conducted one of the largest cohorts studies using remifentanil for labor analgesia. A total of 205 parturients received a remifentanil infusion that was discontinued after delivery. The infusion ranged from 0.025mcg/kg/min to 0.15mcg/kg/min. The authors found a significant decrease in parturient pain. No respiratory depression was noted and oxygen saturation (SpO_2) remained above 95% in all parturients. One minute and five minute Apgar scores were reassuring and 87% of parturients reported satisfaction with their remifentanil experience. The authors recommended variable dose regimes over fixed-dose regimens because flexibility in titration prevented episodes of underdosing and overdosing. The authors postulated that parturients experienced higher rates of respiratory depression when remifentanil was delivered via bolus. This is because the drug can reach peak plasma concentration in the time between contractions when there is an absent of noxious stimuli. This study demonstrated the safety and efficacy of a continuous infusion of remifentanil for labor analgesia. Based on this, we elected to incorporate a continuous infusion option to our two-step dosing strategy. The AP can begin the infusion at 0.025 mcg/kg/min and titrate to a max dose of 0.1 mcg/kg/min.

Shen et al. (2013) compared the neonatal and maternal side effects of remifentanil by administering continuous infusion (0.05 to 0.2mcg/kg/min) or PCA (0.1 to 0.4mcg/kg). This study revealed that, in both groups, there was no difference in maternal side effects. With the exception of decreased fetal heart rate variability, there were no fetal or neonatal adverse events reported. The results of this study reinforced the safety and efficacy of the dosing parameters used in the FBCH protocol.

Stocki et al. (2014) compared the efficacy and respiratory effects of bolus only remifentanil PCA (20 to 60mcg every 2 minutes) and fentanyl epidural PCA. In the remifentanil group, nine parturients experienced 27 apneic events that were not detected by pulse oximetry. In 16 of those events, SpO_2 remained above 94%. One parturient maintained a SpO2 of 96% during an apneic episode that lasted over 30 seconds. However, the time-matched capnography immediately recorded onset of apnea. Ishiwata et al. (2017) demonstrated a delay of 40 to 60 seconds from onset of apnea to recorded change in SpO_2 . This delay obstructs interventions in the event of respiratory depression. Continuous $EtCO_2$ monitoring for early identification of apnea facilitates prompt intervention.

The greatest risk of administering remifentanil for labor analgesia is opioid induced maternal respiratory depression. To mitigate this risk, strict patient monitoring requirements are essential. Tveit, Halvorsen, Seiler, & Roslandb (2013) conducted an observational study of PCA remifentanil administered to 41 parturients in a stepwise approach. Remifentanil was administered as a bolus with a 2-minute lockout. Doses varied from 0.15 mcg/kg to 1.05 mcg/kg with all parturients requiring dose modification as they progressed through labor. Six women in the study experienced respiratory depression and required temporary discontinuation of remifentanil therapy. In all cases, respiratory depression was transient and resolved without

serious adverse effect. Several recommendations were made in this article and incorporated into the FBCH protocol. First, individual variation in dose requirement necessitates a variable dosing strategy. Second, remifentanil doses were calculated using the lean body mass formula "body height (cm) – 100." This calculation reduces body weight by 20% and may mitigate the risk of over sedation and respiratory depression. Third, one to one nursing and the availability of supplemental oxygen are mandatory because of the risk of maternal desaturation.

Parturients who received opioids must wait 2 hours before initiating remifentanil. These recommendations are based on a 2013 case report of cardio-pulmonary arrest in a parturient who received an intramuscular injection of opioid followed by initiation of a remifentanil PCA. The synergistic effect following administration of two potent opioids may have precipitated this event (Marr et al., 2013).

Evidence based protocol and order set: The evidence-based protocol (Appendix 4) established the standard of care, mode of administration, and dosing strategy for the use of remifentanil for labor analgesia. It also served to guide the clinician on the identification and management of potential adverse reactions that may be encountered during administration. Parturients who receive remifentanil PCA require 1:1 nursing care. The risk of respiratory depression and sedation can place the parturient and the fetus at risk; thus, immediate intervention is required if these adverse effects were to occur. In addition, all parturients who receive remifentanil are placed on supplemental oxygen for SpO_2 less than 93%. This was the value the labor and delivery unit at FBCH established as "desaturation".

Based on the literature review, we implemented the following steps: baseline vital signs and fetal heart monitoring (FHM), then vital signs every 10 minutes for the first 30 minutes, then every hour thereafter, and vital signs every 10 minutes for 30 minutes after any rate change. All

parturients are placed on the following continuous monitors: $EtCO_2$, SpO_2, and FHM. Based on the pharmacodynamics of remifentanil, the AP will remain with the patient for the first 10 minutes after the initiation of remifentanil or with any dosage changes.

The anesthesia service will act as a consulting service and will be responsible for placing the remifentanil order set. The anesthesia service is responsible for titrating the remifentanil dose. In the event that a parturient experiences over sedation (sedation score greater than 4), respiratory depression (respiratory rate less than 8), desaturation (SpO2 less than 93%) and/or suspected fetal compromise, any staff member can immediately disconnect the patient from the remifentanil or infusion and provide supplemental oxygen via a face mask or manual resuscitation bag as needed. Anesthesia is immediately notified and following assessment of the patient, the decision can be made to either restart the remifentanil at a lower rate or discontinue the infusion. The protocol also requires adult and neonatal resuscitation equipment in the room.

If pain remains uncontrolled, AP has the choice to either increase the background infusion to 0.05mcg/kg/min and maintain the fixed PCA bolus or initiate a continuous infusion started at 0.025mcg/kg/min and titrated to a maximum of 0.1mcg/kg/min. The AP is to remain at the bedside for 10 minutes following the initiation of remifentanil and with any changes in dose.

Educational intervention: An EI was provided to AP, OB and NS. The EI provided information about the pharmacokinetics and pharmacodynamics of remifentanil, potential adverse effects of this medication and appropriate interventions. Patient selection, absolute and relative contraindications to administration, and the expected effects of remifentanil were addressed. A patient vignette was included in this section. This allowed the audience to connect a real life scenario with the administration of remifentanil. Our presentation concluded with an overview of the EBP protocol and an introduction of a standardized order set.

In order to capture AP, the EI was held on a Tuesday morning during the weekly staff meeting. We presented our intervention to OB and a courtesy presentation to the pharmacy staff during their monthly staff meeting. The NS received the presentation on three occasions during morning turn over.

Due to the low frequency of administration of remifentanil on the labor and delivery unit, a knowledge deficit was presumed to exist regarding its administration and care of parturients receiving remifentanil. Therefore, a pre-and post-test was administered. The same pre-and post-test was administered to AP, OB and NS. The anonymous pre- and post-test consisted of four multiple choice questions and one yes/no question that covered remifentanil pharmacology, monitoring requirements during infusion therapy and critical actions in the event of maternal hypoxemia or other adverse reactions.

Modified Evidence-Based Practice Implementation Scale: One-month post implementation of the EBP protocol and presentation of the EI, we conducted an assessment of FBCH AP regarding their adoption of the protocol into practice. A one-month delay allowed AP time to discuss and evaluate the educational material. The assessment consisted of seven yes/no questions that addressed change in practice, evaluation of presented remifentanil literature, and dissemination of evidence-based educational material. The modified Evidence-Based Practice Implementation Scale allowed for measurement of the degree to which EBP protocol is being used. It may also be used to inform subsequent EBP projects that aim to improve labor analgesia at FBCH. The tool has been validated among registered nurses by Melnyk et al. (2008) and has been used among AP in a published process improvement project that sought to reduce AP practice variation regarding administration of neuraxial analgesia (Johnson et al., 2015). This post-education assessment (the modified Evidence-Based Practice Implementation Scale) was

disseminated to FBCH AP at two consecutive Tuesday morning staff meetings. This method allowed for wide dissemination of the post-education assessment, prevented duplicate responses and maintained anonymity of respondents. The modified Evidence-Based Practice Implementation Scale was approved by Defense Manpower Data Center Survey Organization for dissemination to Department of Defense employees as a post-education assessment tool in accordance with Department of Defense Instruction (DoDI) 1100.13, "Surveys of DoD Personnel."

Plan for Data Analysis: Descriptive statistics were used to assess the effectiveness of the EI and to evaluate responses to the pre- and post-test and the modified Evidence-Based Practice Implementation Scale.

HIPAA Concerns (IRB)

Personally identifying information was not obtained from parturients or participants at anytime during this project. No personally identifying information was collected in conjunction with the EI pre- and post-test. The Evidence-Based Practice Implementation Scale was administered in paper copy and AP were instructed to not place any identifying information on it. This allowed respondents to remain anonymous. Therefore, there was no concern for violation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) during implementation of this EBP project.

Project Results

Thirty-one participants completed the EI and took the pre-and post-test. The percentages of the participants by stake holder type were as follows: 39% NS (n=12), 19% OB (n=6) and 42% AP (n=13). The scores increased significantly from pre- to post-test, p value < 0.001. Prior to training, the pre-test median score was 80%, IQR 20%. After training, the post-test median

score was 100%, IQR 0, Z = 4.26, p = < 0.001. The NS group demonstrated the greatest increase in knowledge with a mean pre-test score of 58.33% compared to a mean post-test score of 95%.

Thirty-two percent of AP completed the 30-day follow up modified Evidence-Based Practice Implementation Scale to gauge change in practice (See Appendix E). Seventy-five percent of responding AP reported that they had critically appraised and informally discussed with colleagues the evidence presented in the remifentanil EBP project. In addition, 38% of AP reported changing their practice based on the remifentanil EBP project.

Analysis of the Results

Even though many of the AP, NS and OB had heard of or used remifentanil for labor analgesia, at baseline they had limited knowledge about the medications risks, benefits, indications for use, and monitoring requirements. The EI proved to be effective as illustrated from the increase in the pre- and post-test scores. The 30-day follow up of AP using the modified Evidence-Based Practice Implementation Scale demonstrated that the majority of AP discussed the remifentanil project and are using it to change their practice.

Organizational Impact/ Implications to Practice & Policy

Implementation of the remifentanil EBP project moved FBCH closer to becoming a high reliability organization and improving patient experience by standardizing practice. Prior to this project remifentanil had been administered to parturients at FBCH without a protocol to guide and standardize administration. This is an example of variation in practice. In addition, there was a knowledge deficit regarding the potential for complications and required monitoring of parturients receiving PCA opioids. Our project standardized administration of remifentanil and decreased the knowledge deficit among AP, OB and NS.

There were several limitations that existed related to the remifentanil EBP project. Due

to schedule variations, staff turnover and patient care responsibilities it was difficult to present the EI to 100% of AP, OB, and NS. These limitations represent a significant threat to the sustainability of this remifentanil project. A remifentanil binder that includes a printed copy of the EI and additional resources was available at both the nursing station and in the anesthesia office to maintain staff education. Moreover, the EI became a component of NS orientation to the unit. At the time of this writing, the investigators have been notified three times by AP that the protocol had been utilized.

Future Directions for Research and Practice

Although remifentanil has been established as safe to use during labor, the evidence has not established an optimal dosage or mode of administration and more research needs to be done on the administration of remifentanil in parturients. Our dosing strategy is based on the recommendation of Balki et. al 2007 who conducted a randomized control trial. Their findings concur with our own review of the literature on several points. First, dosing regimens that utilized higher bolus doses corresponded with higher incidences of adverse effects. Second, individual variation in response to remifentanil and therapeutic requirement necessitates a variable dosing strategy. Based on these results, we constructed a dosing regimen that preserves patient safety and allows for dosing adjustments in response to individual patient need.

At the time of this writing, our protocol has been used on three separate occasions at FBCH. As per the protocol, these patients were placed on 1:1 nursing care. If there is increase in the use of the remifentanil protocol and staffing constraints become evident, there is potential for the employment of remote EtCO2 monitoring. This will allow more patients who are eligible for remifentanil to receive it without placing additional workload on the staffing.

Conclusion

Remifentanil is a safe and effective technique of providing pain relief to parturients who have a contraindication to neuraxial analgesia provided there is adequate monitoring and staff education. To meet the current standard of utilization of EBP in the health care setting, a remifentanil EBP project was developed and implemented on the labor and delivery unit at FBCH. This led to a reduction in provider practice variation and a potential increase in patient safety. In an effort to increase staff understanding and remove barriers to use, an EI and corresponding pre- and post-test was developed and presented to AP, OB and NS. The results of our pre- and post-test and 30-day modified Evidence-Based Practice Implementation Scale follow-up indicated that this project achieved its goals of increasing staff knowledge and changing practice. The limitations to the project include sustainability of staff education given high staff turnover coupled with the low volume of appropriate patients at FBCH. That said, the standardized order set and protocol resulted in reduced variability in practice.

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Table 1

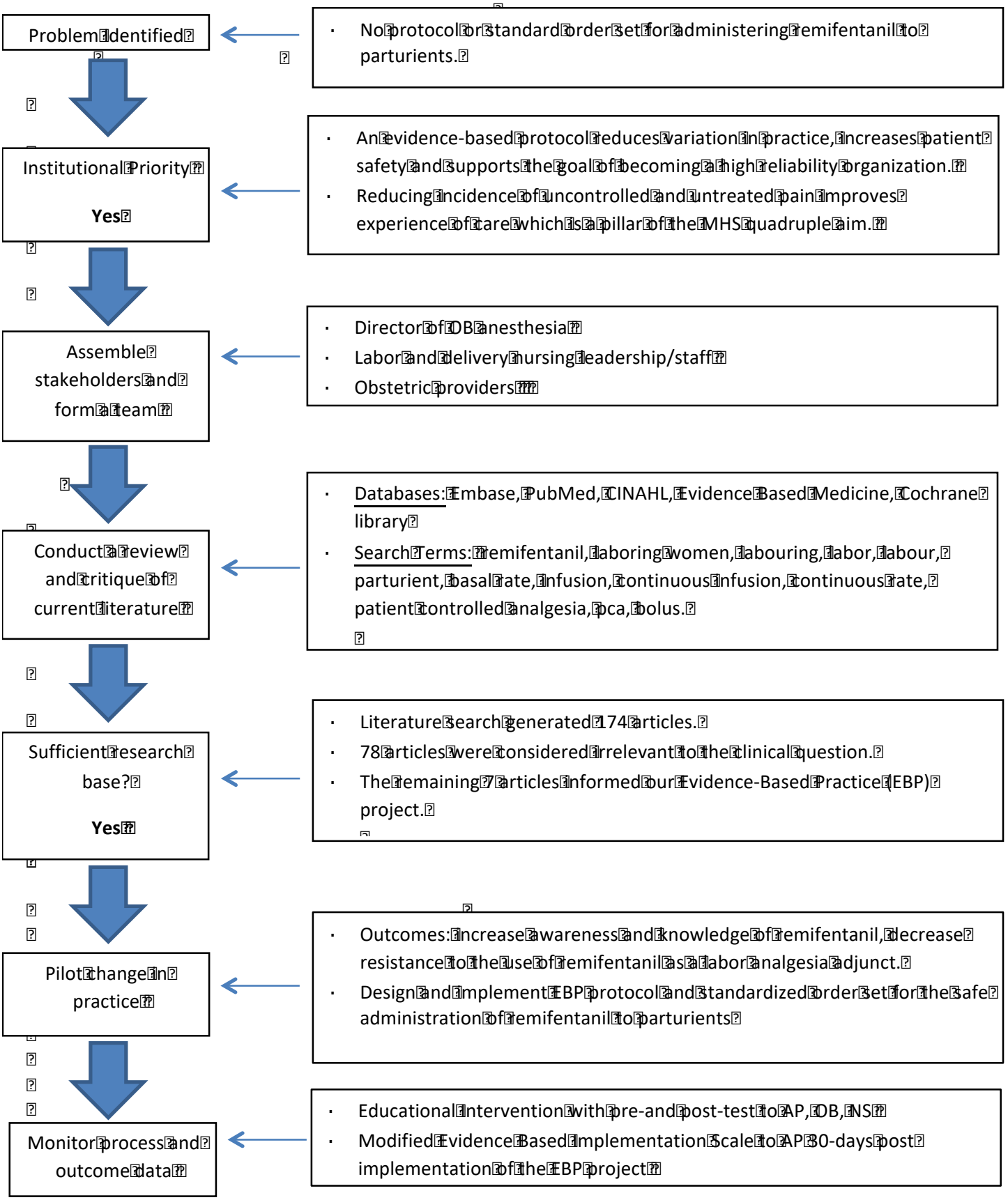
Overview of Articles

Author	Study Design	Sample Size	Remifertenil Dose(dose-lockout)	Compared to	Maternal side effects	Neonatal side effects	Pain Score (0-10VAS)	Findings
Balki et al. (2007)	RCT Level 1	20	0.25 to 1 mcg/kg-2 min-3mg; 0.025 to 0.1 mcg/kg/min, Gr 1: variable infusion, consistent bolus; Gr 2: variable bolus, consistent infusion	Group 1 to Group 2	Desaturation: 3, nausea: 8, Drowsiness: 13	Non-reassuring FHR: 3 (no intervention required) 1 (meconium aspiration)	Gr 1: 6.09 and Gr 2: 5.51	Gr 1 (variable infusion with fixed bolus) had fewer maternal adverse events, similar pain scores compared to Gr 2.
D'Onofrio et al. (2009)	Prospective observational study Level 3	205	0.025 to 0.15 mcg/kg/min	NA	Nausea	NA	Baseline score: 9.4 (SD 1.2) Decreased to 5.1 (SD .04) after 5 mins. And further decreased to 3.6 (SD1.5) after 30 min	High satisfaction scores and a reduction in pain with no maternal/fetal/neonatal side effects.

(Marr et al., 2013)	Case Report Level 4	1	Bolus: 40mcg-2min-5mg max (4 hrs)	NA	Cardio pulmonary arrest	NA	NA	Parturient received opioids prior to remifentanil PCA and suffered cardiopulmonary arrest
Marwah et al. (2011)	Retrospective observational study Level 3	47	Bolus:0.25 mcg/kg-2 min infusion 0.025-0.05 mcg/kg/min	Fentanyl PCA	Desaturation: 6, Nausea: 3, Drowsiness: 4	25%v received supplemental oxygen	Max decrease pain score 7.6 to 4.1	Moderate pain relief and few maternal and neonatal adverse effects compared to fentanyl PCA
Shen et al. (2013)	RCT Level 1	53	GR 1: 0.1mcg/kg -2min-0.4mcg/kg	GR 2: 0.05 to 0.2mcg/kg/min	Ramsay sedation score of 4 (brisk response to stimulus):8/53 . Nausea: 14/53, Vomiting: 2/53, Itching: 3/53. Desaturation: <95%: 8/53.	Transient Fetal bradycardia: 9/53	Lower pain scores and higher satisfaction in GR 1. GR 1 Required faster escalation in doses compared to GR 1 to reach relief	Identified doses that would provide pain relief without adverse side effects. No difference in maternal/fetal/neonatal side effects. No difference in Apgar scores. No cases of respiratory depression, use of naloxone or resuscitation.

Stocki et al. (2014)	RCT Level 1	19	20 mcg-2min-60mcg	PCA epidural 0.1% bupivicaine with Fentanyl 2mcg/ml Bolus:15 ml CI:10ml Lo:2min CI:5ml	4-point sedation scale (easily arouseable) 6/19 Nausea: 3/19. Sedation: 13/19. Apnea occurred 27 times in 9 women.	1 required stimulation and supplemental oxygen. 1 required stimulation and manual ventilation using bag and mask with recovery within 30 secs. Apgar scores after 1 min and 5 minute: 7/6 & 8/10.	Scores significantly lower at 30 mins in both groups. Over 6 hours, remifentanil was significantly less effective than epidural analgesia.	Data revealed from ETCO2 report that apnea had occurred without desaturation. SPO2 remained above 94% in 16/27 apnea events suggesting pulse oximetry is inadequate as an early alert to apnea.
Tveit et al. (2012)	Prospective observational study Level 3	41	0.15 mcg/kg-2min (increments 0.15 mcg/kg)	NA	Respiratory depression: 6	NA	Pain scores reduced from 7.6 to 4.6	Wide variation in dose requirement for adequate analgesia. Respiratory depression is common, recommend 1:1 nursing, ETCO2 monitoring and dose based on ideal body weight

Appendix A **Remifentanil for Labor Analgesia**



*Project flowchart modified from the Iowa Model of Evidence-Based Practice to Promote Quality Care.

Appendix B

Pretest/Posttest

1. What is the duration of action of a remifentanil infusion?
    a) <1min
    b) <10min
    c) <30min
    d) <1hour

2. Remifentanil can cause the following adverse reactions? (Select all that apply)
    a) Maternal respiratory depression
    b) Decreased fetal HR variability
    c) Neonatal respiratory depression
    d) Maternal/Neonatal bradycardia
    e) Maternal sedation

3. According to the FBCH protocol, remifentanil requires 1:1 nursing care?
    a) True
    b) False

4. Which patient is not a candidate for remifentanil?
    a) Received fentanyl 1 hour ago
    b) Received fentanyl 6 hours ago
    c) Platelet count of 50,000
    d) Spinal deformity

5. If you suspect that a parturient is experiencing an adverse reaction to remifentanil, the most appropriate initial action is to?
    a) Stop PCA disconnect tubing from patient
    b) Administer naloxone
    c) Prompt the parturient to breath with physical and verbal stimulation
    d) Call rapid response

Appendix C

Modified Evidence-Based Practice Implementation Scale

Survey Question	Yes	No
1. I changed my clinical practice as a result of the remifentanil labor analgesia project.	☐	☐
2. I critically appraised the evidence presented for the remifentanil labor analgesia project.	☐	☐
3. I informally discussed evidence related to the remifentanil labor analgesia project with a colleague.	☐	☐
4. I shared the evidence presented for the remifentanil labor analgesia project with more than two colleagues.	☐	☐
5. I shared the remifentanil labor analgesia standard operating procedure with a colleague.	☐	☐
6. I shared the evidence for the remifentanil labor analgesia project with a patient/family member.	☐	☐
7. I shared evidence from the remifentanil labor analgesia project with a staff/team member from another department or service.	☐	☐

Appendix D

Standard Operating Procedure

Fort Belvoir Community Hospital
Anesthesia Department
9300 DeWitt Loop
Fort Belvoir VA, 22060

DCSS-DOS-AS

SUBJECT: Standard Operating Procedure for remifentanil labor analgesia

1. PURPOSE. This SOP establishes standards of care, mode of administration, and dosing strategy for the use of remifentanil for labor analgesia.

2. APPLICABILITY. This SOP is applicable to all labor and delivery staff and anesthesia providers.

3. RESONSIBITIES.

    a. The following delineates the responsibilities of the delivering physician, labor nurse, and anesthesia provider.
        i. Delivering obstetric provider will:
            1. Decide if the patient is a candidate for remifentanil analgesia, and that the patients, both mother and fetus, will not be adversely affected by the administration of intravenous remifentanil. The delivering physician will contact: (1) the charge nurse for Labor & Delivery to assure that adequate staffing is available for the required one to one nursing care involved, (2) the anesthesia provider to request remifentanil infusion.
            2. Be present on the Labor & Delivery unit during the procedure to attend to any urgency that may arise and will remain until which time the anesthesia provider and labor nurse all agree that the patient is stable. After this time, the delivering physician will be immediately available by pager to the labor nurse and anesthesia provider.
            3. Continue to be responsible for monitoring the progress of labor.
            4. Notify Anesthesia provider of any medications ordered while patient is on the remifentanil infusion.
    c. Labor and Delivery
        i. Labor nurse will be required to remain in the room during the remifentanil infusion.
        ii. Labor nurse will instruct the patient in the necessary nursing care. Specifically: 1) 1:1 nursing will be required for remifentanil infusion 2) The patient will require assistance with ambulation. 3) Need for continuous monitoring of the fetus (FMR) and the patient's blood pressure (NIBP),end

tidal CO2 ($EtCO_2$) and oxygen saturation (SpO_2). 4) If an emergency arises, the family member/coach may be asked to exit quickly.

iii. The labor nurse will assure that a supplemental oxygen delivery system and a oral suction device are present and functional. In addition, (NIBP) should be on the patient, $EtCO_2$, SpO_2, and the FHM and toco-dynamometer are functioning.

iv. The labor nurse will assure that a second (dedicated) functioning intravenous line (IV) is present. Lactated Ringers (LR) or Normal Saline (NS) should be infused as a carrier for remifentanil infusion.

v. The labor nurse documents on the external FHM strip the doses and times of medications given by the anesthesia provider.

vi. After obtaining baseline vital signs, the labor nurse will record vital signs every 10 minutes for 30 minutes, then hourly thereafter. For every change in dosage, the labor nurse will record vital signs for every10 minutes for 30 minutes.

vii. The labor nurse alerts the anesthesia provider to the need to discontinue infusion

viii. The labor nurse will be aware of possible complications of remifentanil infusion and will immediately disconnect PCA tubing from the patient as well as alert anesthesia provider for any questions or problems. These complications include the following:

1. Blood pressure drop > 20% of pre-remifentanil values, or systolic blood pressure < 90 mm Hg or diastolic blood pressure <60
2. Pulse <60 bpm
3. Respiratory rate < 8 or sedation score >4
4. SpO2 <93%
5. Abnormal fetal heart rate tracing
6. Nurse judgement

d. Anesthesia Provider

I. The anesthesia provider completes a history and physical exam to establish the patient is a suitable candidate for remifentanil infusion.

ii. The anesthesia provider will verify that supplemental oxygen, suction, and resuscitation equipment is present and functioning.

iii. Anesthesia Provider will fully counsel patient as to risks and benefits of remifentanil labor analgesia to include:

1. Risk of respiratory depression for the patient and neonate
2. Risk of hypotension to patient and neonate.
3. Idiosyncratic reaction to medications administered
4. Continuous $EtCO_2$, SpO_2, NIBP, and FHR monitoring.
5. Possibility of ineffective or incomplete analgesia.
6. The anesthesia provider is responsible for assuring that consent for the procedure is signed by the patient and witnessed.
7. Anesthesia provider will order the Essentris “Anesthesia OB Remifentanil” order set and notify pharmacy for bag preparation.

8. After assuring that all necessary equipment, monitors are present, and baseline vital signs have been assessed and obtained the anesthesia provider will initiate the remifentanil infusion.
9. Anesthesia Provider will remain at the bedside for the first ten minutes after the initiation of remifentanil infusion.
10. The anesthesia provider will program the PCA infusion pump, and initiate the infusion. The anesthesia provider will control the rate of the infusion.
11. The anesthesia provider will remain in the hospital and be immediately available. Presence at the delivery is not required unless requested by the delivering physician.
12. The anesthesia provider will follow-up in 24 to 48 hours to assure that there are no post procedure complications and document as above.

6. PROCEDURES.

1. Anesthesia provider will consent patient for remifentanil administration.
2. Assure patient has not received opioid or sedating medication within the last 2 hours
3. The anesthesia provider will notify nurse of anesthesia orders and 1:1 nursing will be put into place once the administration of remifentanil has been initiated.
4. Patient will be assigned to a room with $EtCO_2$ capabilities.
5. Initiate a second IV line specifically for remifentanil line.
6. Obtain complete set of maternal vital signs, sedation score, pain assessment and FHM assessment prior to the administration of remifentanil and report to anesthesia provider.
7. Ensure continuous SPO_2, $EtCO_2$, and FHR is initiated
8. Once patient is receiving remifentanil, assess Vital signs and sedation score every 10 minutes for the first 30 minutes, than every 1 hour thereafter.
9. Assess pain every hour.
10. Educate patient family and friends that only the patient is able to utilize the PCA demand button. Document education.
11. Immediately disconnect intravenous PCA tubing from the patient and notify anesthesia if any of the following adverse events occur:
    a. Sedation Score >4
    b. Respiratory rate <8 breaths per minute
    c. Sa02 <93%
    d. Any indication of fetal compromise
    e. Bradycardia/SBP <90 or DBP <60
    f. Provider and Nursing judgment
12. Based on the clinical judgment, the anesthesia provider can restart remifentanil at a lower dose or discontinue it.

If the patient is not responding to verbal and physical stimulation, disconnect remifentanil infusion, call OB rapid response and administer oxygen via non-rebreather. If respiratory arrest occurs, call code Blue administer oxygen via a self-inflating resuscitation bag at a rate of 1 breath every 6 seconds

REMIFENTANIL Order Set

1. Obtain informed consent from patient for remifentanil administration
2. Patient becomes 1:1 RN supervision
3. L&D RN will obtain PCA module for implementation
4. Patient will require a dedicated IV for infusion with carrier solution.
5. In Essentris, utilize "Anesthesia OB Remifentanil orders".
6. Remifentanil concentration of 25mcg/ml will be prepared by pharmacy (5mg remifentanil in 200ml of NS). This will be stable for 24 hours at room temperature after reconstitution. Remifentanil is to be attached to carrier infusion at 20ml//hr.
7. Dosages will be based on Ideal Body weight for obese women. Height in cm – 100. Example: 65in (65 x 2.54)→ 165 cm-100=65kg (add a conversion for height in inches since this is what the patient will report)
8. LEVEL 1: Remifentanil started as a PCA bolus at 0.25mcg/kg Lock out time: 2min, and continuous infusion at the rate of 0.025mcg/kg/min
    a. Any change in dose requires V/S q10min x3 and anesthesia provider at bedside for first 10minutes
9. LEVEL 2: Pain is uncontrolled
    a. Increase continuous infusion to 0.05mcg/kg/min with PCA 0.25mcg/kg

OR

Continuous infusion at the rate of 0.025mcg/kg/min to a maximum of 0.1mcg/kg/min. Increase dose by increments of 0.025mcg/kg/min. **NO PCA BOLUS**.

** Patient needs to be 1:1 nursing, on continuous: SPO_2, $ETCO_2$, FHR with resuscitation equipment immediately available. Anesthesia to order, initiate, and titrate remifentanil.

7. RELEASABILITY. UNLIMITED. This Manual is approved for public release and is available on the internet from the JTF CAPMED Web Site at http://www.jtfcapmed.mil.

8. EFFECTIVE DATE. This is effective immediately.

Appendix E

Modified EBP Implementation Scale Results

Survey Question	**Yes**
1. I changed my clinical practice as a result of the remifentanil labor analgesia project.	**38%**
2. I critically appraised the evidence presented for the remifentanil labor analgesia project.	**75%**
3. I informally discussed evidence related to the 75% remifentanil labor analgesia project with a colleague.	**75%**
4. I shared the evidence presented for the remifentanil labor analgesia project with more than two colleagues.	**0%**
5. I shared the remifentanil labor analgesia protocol with a colleague.	**38%**
6. I shared the evidence for the remifentanil labor analgesia project with a patient/family member.	**25%**
7. I shared evidence from the remifentanil labor analgesia project with a staff/team member from another department or service.	**13%**

Timeline

Project Year 1 (2016)												
Activity/Month	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**
Upload DNP Project Team Mentors			X									
Oral Presentation: Background and Literature Review			X									
Project Planning			X	X	X	X	X	X	X	X	X	
Survey Submission											X	
Submit Final DNP Proposal												X

Project Year 2 (2017)												
Activity/Month	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**
SITE IRB Submission and Approval	X											
Educational Interventions		X										
Project Implementation			X									
Anesthesia Data Collection			X									
Data Analysis			X									
Register to Present at AANA Conference					X							
Project Year 3 (2018)												
Activity/Month	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**
Senior Mentor Discussion	X											
Upload Oral Presentation Given to FBCH Leadership			X									
Upload Oral Presentation Given to DNP project Team			X									
Upload Completed Milestone Checklist			X									
Upload Signed DNP Project Senior Mentor Approved Abstract/impact Statement form				X								
Upload Electronic Version of the Final Senior Mentor Approved Poster				X								
Print Final Approval Poster				X								
15 Minute Oral PPT Presentation Given to GSN/USU				X								

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

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- **Email:** Marylou.proano@usuhs.edu
- **Institution Affiliation:** Uniformed Services University of The Health Sciences (ID: 395)
- **Institution Unit:** GSN
- **Phone:** 9177161208

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

- **Report ID:** 16982730
- **Completion Date:** 08/22/2015
- **Expiration Date:** 08/21/2018
- **Minimum Passing:** 80
- **Reported Score*:** 83

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED
Records-Based Research (ID: 5)	08/22/15
Vulnerable Subjects - Research Involving Children (ID: 9)	08/22/15
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	08/22/15
FDA-Regulated Research (ID: 12)	08/22/15
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	08/22/15
Informed Consent (ID: 3)	08/22/15
History and Ethics of Human Subjects Research (ID: 498)	08/22/15
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	08/22/15
Genetic Research in Human Populations (ID: 6)	08/22/15
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	08/22/15
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	08/22/15
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	08/22/15
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	08/22/15
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	08/22/15
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	08/22/15
Cultural Competence in Research (ID: 15166)	08/22/15

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COURSEWORK TRANSCRIPT REPORT**

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- **Report ID:** 16982730
- **Report Date:** 08/22/2015
- **Current Score**:** 83

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT
History and Ethics of Human Subjects Research (ID: 498)	08/22/15
Informed Consent (ID: 3)	08/22/15
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	08/22/15
Records-Based Research (ID: 5)	08/22/15
Genetic Research in Human Populations (ID: 6)	08/22/15
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	08/22/15
Vulnerable Subjects - Research Involving Children (ID: 9)	08/22/15
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	08/22/15
FDA-Regulated Research (ID: 12)	08/22/15
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	08/22/15
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	08/22/15
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	08/22/15
Cultural Competence in Research (ID: 15166)	08/22/15
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	08/22/15
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	08/22/15
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	08/22/15
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	08/22/15

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- **Institution Unit:** nursing
- **Phone:** 7078497629

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

- **Report ID:** 16981968
- **Report Date:** 08/23/2015
- **Current Score**:** 89

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT
History and Ethics of Human Subjects Research (ID: 498)	08/23/15
Informed Consent (ID: 3)	08/23/15
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	08/23/15
Records-Based Research (ID: 5)	08/22/15
Genetic Research in Human Populations (ID: 6)	08/23/15
Vulnerable Subjects - Research Involving Children (ID: 9)	08/22/15
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	08/23/15
FDA-Regulated Research (ID: 12)	08/23/15
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	08/23/15
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	08/23/15
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	08/23/15
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	08/23/15
Stem Cell Research Oversight (Part I) (ID: 13882)	08/23/15
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	08/23/15
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	08/23/15
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	08/23/15

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- **Phone:** 7078497629

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

- **Report ID:** 16981968
- **Completion Date:** 08/23/2015
- **Expiration Date:** 08/22/2018
- **Minimum Passing:** 80
- **Reported Score*:** 89

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED
Records-Based Research (ID: 5)	08/22/15
Vulnerable Subjects - Research Involving Children (ID: 9)	08/22/15
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	08/23/15
FDA-Regulated Research (ID: 12)	08/23/15
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	08/23/15
Informed Consent (ID: 3)	08/23/15
History and Ethics of Human Subjects Research (ID: 498)	08/23/15
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	08/23/15
Genetic Research in Human Populations (ID: 6)	08/23/15
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	08/23/15
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	08/23/15
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	08/23/15
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	08/23/15
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	08/23/15
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	08/23/15
Stem Cell Research Oversight (Part I) (ID: 13882)	08/23/15

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

CITI Program
Email: citisupport@miami.edu
Phone: 305-243-7970
Web: https://www.citiprogram.org

UNIFORMED SERVICES UNIVERSITY
of the Health Sciences

.L TITLE

OFFICE OF RESEARCH
4301 JONES BRIDGE ROAD
BETHESDA, MAYLAND 20814
PHONE: (301) 295-3303; FAX: (301) 295-6771

NOTICE OF PROJECT APPROVAL

Change Number: Original

VPR Site Number: T0-GSN-61-8981-01

Principal Investigator: Tranberg, John (GSN-61)

Department: Graduate School of Nursing

Project Type: Student

Project Title: Remifentanil for Labor Analgesia an Evidence-based Practice Project

Project Period: 4/4/2017 to 6/30/2017

Assurance and Progress Report Information:

Name	Sup	Approval Type	Status	Approved On	Forms Received
Progress Report	0			To be Submitted	N/A

Remarks:
This Notice of Project Approval has been reviewed and approved. Please remember that you must submit a final Progress Report (Form 3210) upon completion of this project.

Questions regarding this approval should be directed to the following person in the Office of Research:
Ronda Dudley, (301) 295-9818.

Yvonne T. Maddox, Ph.D. Date
Vice President for Research
Uniformed Services University of the Health Sciences

cc: Tranberg, John (GSN-61)
Vernell Shaw
File
Paul Johnson
Linda Wanzer

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

VPR Date Stamp

Project Number: TO 61 8981 (VPR will assign)

Project Title: Remifentanil for Labor Analgesia an Evidence-Based Practice Project

SECTION A: STUDENT POC INFORMATION

1. Name (Last, First, MI): **Tranberg, John, W** Student E-mail: **john.tranberg@usuhs.edu**

[redacted]

SECTION B: COMMITTEE CHAIR / SENIOR MENTOR INFORMATION

3. Name (Last, First, MI): **Johnson, Paul**
4. Telephone: **9129804922** Fax: E-mail: **paul.johnson@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: **04/01/2017** Project End Date: **5/30/2017**
9. Performance Site(s): **Fort Belvoir Community Hospital**
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

The following signatures attest to the validity of the above information:

[redacted]

Student (Project Point of Contact for the Group) (Signature and Date)

Chair/Senior Mentor (Signature and Date)

[redacted]

Chair/Program Director (Signature and Date)

Chair/Program Director (Signature and Date)

[redacted]

Associate Dean for Research, GSN (Signature and Date)

Dean, DKI Graduate School of Nursing (Signature and Date)

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

[redacted]

USUHS Vice President for Research

4/11/17
Date

DEFENSE HEALTH AGENCY
FORT BELVOIR COMMUNITY HOSPITAL
9300 DEWITT LOOP
FORT BELVOIR, VIRGINIA 22060-5901

FBCH-RPCI Date: 29 March 2017

FROM: Fort Belvoir Community Hospital (FBCH) Department of Research Programs (DRP) Determinations

TO: John W. Tranberg, LT, NC, USN

SUBJECT: FBCH DRP Determinations Review of Project #900020; Reference #880710

PROJECT TITLE: "Remifentanil for Labor Analgesia an Evidence-Based-Practice Project"

SUBMISSION TYPE: New Project

ACTION: Determination of Not Research—Evidence Based Practice (EBP)

DECISION DATE: 29 March 2017

1. Thank you for your submission of the plan and supporting materials for this project. A FBCH DRP Determinations Official has determined the activity as described is an EBP Project and does not meet the full definition of research as defined in 32 Code of Federal Regulations 219.102(d). Submission of an IRB research application is not required.

2. This project is a local FBCH Anesthesia Service initiative evaluating evidence along a continuum and identifying the strongest, or best, evidence to guide clinical practice within an organizational setting and with a specific patient population (parturients with contraindications to neuraxial analgesia, including patient refusal).

3. Your Departmental support is noted.

4. Any changes to your project must be reviewed by a FBCH DRP Determinations Official to ensure that the changes do not impact this Determination.

5. Any publication(s) or manuscripts arising from this work must be submitted and cleared through the publication clearance process. Many journals are interested in publishing EBP projects. If you do decide to publish your EBP findings, please use paragraph headings such as "issue", "procedures for collecting and evaluating information", "information found", "lessons learned", etc. and avoid using terminology such as "research questions", "methods", "results", "study limitations", etc.

6. This is not an approval to receive extramural resources (i.e. personnel, drugs, supplies, equipment, money, and gifts from any source outside of FBCH). You must coordinate

extramural resource approvals with the Office of Research and Technology Applications (ORTA) at (301) 295-8239/8219. If any extramural resources are received without DOD or MEDCOM approval, the individual who receives them may be found in ethics violation and prosecuted for criminal misconduct.

7. You may begin your project pursuant to any appropriate FBCH Committee and/or Command approvals. At the completion of your project, you are required to submit a Closure Form in EIRB. Please remember that project data remain the property of FBCH and may not be removed without prior Command authorization.

8. If you have any questions or concerns, the POC is Ms. Kristin Beltz at 571-231-2748. Please include your project title and reference number in all correspondence with this committee.

[redacted]

KRISTIN BELTZ
DOD CIV
Determinations Official
DRP, FBCH

REQUEST FOR PUBLIC RELEASE

(This form is to be used at Fort Belvoir Community Hospital in requesting review and clearance of DoD information for public release in accordance with DoDD 5230.09)

1. DOCUMENT DESCRIPTION

a. TYPE	b. TITLE	
Manuscript, Abstract and Poster	Remifentanil for Labor Analgesia: An Evidence-Based Project	
c. DATE OF SUBMISSION 16MARCH2018	d. PAGE COUNT 3	e. RESEARCH OR PUBLIC CLEARANCE? NA
f. CLEARANCE REQUESTED BY *(YYYYMMDD) (All submissions require a minimum of 10 days for review)* 31MARCH2018		

2. AUTHOR/SPEAKER *(If more than one author, include names of additional authors on separate sheet.)*

a. NAME *(Last, First, Middle Initial)*	b. AFFILIATION *(Armed service, civilian, contractor)*	c. RANK
Tranberg, John, W	Navy	LT
d. DEPARTMENT/CLINIC Anesthesia		

3. PRESENTATION/PUBLICATION DATA *(Date, Place, Event)*

May 15, Bethesda MD, Uniformed Services University of the Health Sciences, Graduate School of Nursing DNP project presentation

project # 900020

4. POINT OF CONTACT

a. NAME *(Last, First, Middle Initial)*	b. EMAIL	c. TELEPHONE NO.
Tranberg, John, W	john.tranberg@usuhs.edu	7078497629

5. STAFF JUDGE ADVOCATE (SJA) COORDINATION

a. NAME *(Last, First, Middle Initial)*

b. REMARKS

This manuscript, abstract and poster are consistent with an Evidence-Based Practice project submitted to DRP, Project #900020, reference number 880710.
The publication clearance request is cleared by DRP and forwarded for final PAO clearance.
VR,
Erica Reid, CIP
Chief, Department of Research Programs

c. SUBMISSION IS: (●) APPROVED ( ) APPROVED WITH QUALIFICATIONS *(See REMARKS, block 5b)* ( ) NOT APPROVED

d. SIGNATURE | e. DATE SIGNED *(YYYYMMDD)*

6. PUBLIC AFFAIRS OFFICER (PAO) COORDINATION

a. NAME *(Last, First, Middle Initial)*

b. REMARKS

This project is approved

V/R
Chris Walz
Strategic Communications, Fort Belvoir Community Hospital, Office: 571.231.3214, E-mail: christopher.d.walz.civ@mail.mil

c. SUBMISSION IS: (●) APPROVED ( ) APPROVED WITH QUALIFICATIONS *(See REMARKS, block 6b)* ( ) NOT APPROVED

d. SIGNATURE | e. DATE SIGNED *(YYYYMMDD)*

Submitted documents require both Staff Judge Advocate (SJA) and Public Affairs Officer (PAO) approval in blocks 5c and 6c above before public release. Please note any qualifications for approval, which will be included in the REMARKS block (if applicable). If approved by both SJA and PAO, the material is approved for public release and clearance for open publication is recommended under the provisions of DoDD 5230.09

FBCH STRATCOM FORM 1910, OCT 2015

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: Remifentanil for Labor Analgesia: An Evidence-Based Practice Project
was completed at Fort Belvoir Community Hospital by the following student(s):

(type student name)	*(signature)*	*(date)*
Marylou Proano	[redacted]	4-13-2018
John Tranberg		4-13-2018

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)*	
Sandra Bruner	[redacted]	4-13-2018	Senior Mentor
Paul Johnson		4·12·2018	Team Mentor
Williams Sellers		4-13-2018	Team Mentor & Phase II Site Director

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

Kenneth A. Wofford	[redacted]	23APR18
RNA Project Director *(type name)*		*(Date)*

Form Version: 26 Aug 2017