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Programmed Intermittent Epidural Bolus for Labor Analgesia in a Critical Access Hospital

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PROGRAMMED INTERMITTENT EPIDURAL BOLUS FOR LABOR ANALGESIA IN A CRITICAL ACCESS HOSPITAL

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ABSTRACT

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With over two-thirds of women in the United States receiving neuraxial analgesia or anesthesia to ease the pain of labor and delivery, advances in epidural technology can potentially influence the childbirth experience. Continuous epidural infusion (CEI) with patient-controlled epidural analgesia (PCEA) has been the mainstay for delivering epidural labor analgesia for the past two decades; however, programmed intermittent epidural bolus (PIEB) is making its debut as a promising new technology to improve labor analgesia. Literature suggests delivery of programmed boluses of dilute local anesthetic with or without opioid at regularly spaced intervals may result in lower local anesthetic utilization while maintaining or improving analgesia quality and maternal satisfaction and minimizing motor blockade.

The purpose of this Doctor of Nursing Practice (DNP) scholarly project was to develop and plan for translation of an evidence-based clinical practice protocol for PIEB for labor analgesia in a critical access hospital. The clinical practice protocol incorporated findings from an integrated literature review. Planning for implementation of the clinical practice protocol consisted of a before-and-after without control design to measure the effect of PIEB with PCEA modality for labor analgesia (*after* group) on analgesia quality, local anesthetic utilization, and prevalence of motor blockade compared to the CEI with PCEA modality (*before* group). The plan for translation includes the provision of staff education about protocol implementation.

Lastly, structure, process, outcomes, and balancing measures were identified to evaluate translation of the practice change. Statistical analysis using SAS software was used where applicable.

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LIST OF ABBREVIATIONS

AANA	American Association of Nurse Anesthetists
ASA	American Society of Anesthesiologists
CEI	Continuous Epidural Infusion
CRNA	Certified Registered Nurse Anesthetist
CSE	Combined Spinal Epidural
DNP	Doctorate of Nursing Practice
JHNEBP	Johns Hopkins Nursing Evidence-Based Practice
PCEA	Patient Controlled Epidural Analgesia
PICOT	Population, Intervention, Comparison, Outcome, Time
PIEB	Programmed Intermittent Epidural Bolus
QRG	Quick Reference Guide
VAS	Visual Analog Scale
VNPS	Visual Numeric Pain Score
VRS	Verbal Rating Scale

CHAPTER I

INTRODUCTION

Pain during labor is a nearly universal phenomenon that warrants consideration during a woman's childbirth experience. Various therapies have been employed to ease labor pain, with epidural analgesia ranking as not only the most widely used pharmacologic technique (Schrock & Harraway-Smith, 2012), but also the modality with the most effective analgesia for labor pain (Capogna et al., 2011). Not surprisingly, the epidural rate in U.S. obstetric patients increased by 10% from 2008 to 2014, with 71% of pregnant women receiving neuraxial analgesia or anesthesia (Butwick et al., 2018). These statistics emphasize the merit of providing effective epidural analgesia focused on improving the quality of analgesia while simultaneously decreasing the degree of motor blockade.

Utilization of programmed intermittent epidural bolus (PIEB) shows promise as a technique theorized to improve the spread of epidural medication compared to continuous infusion, despite using the same hourly volume of solution (Hogan, 2002; Kaynar & Shankar, 1999), thus hypothetically leading to less local anesthetic consumption for similar or improved quality of analgesia. The implications for clinical practice are varied and may include shorter duration of the second stage of labor, higher maternal satisfaction, reduction in instrumented delivery rates, and less need for clinician intervention for breakthrough pain (George et al., 2013). Until recently, technology was not universally available to implement PIEB settings for

laboring mothers (Tien et al., 2016); fortunately, epidural pumps with advanced technology that allows programmable intermittent dosing are becoming more mainstream, allowing translation of evidence into practice to be carried out more readily. As more advanced epidural pumps become available, studies on the optimal epidural solution, bolus dose, and interval timing are up-and-coming (Delgado et al., 2018; Epsztein Kanczuk et al., 2017; Zakus et al., 2018).

Background

In the setting of neuraxial techniques for labor analgesia, the primary goal is to provide adequate pain relief while preserving motor function (American Association of Nurse Anesthetists [AANA], 2017). Epidural analgesia is achieved with administration of low concentrations of local anesthetics (e.g., bupivacaine or ropivacaine) with or without opioids (e.g., fentanyl or sufentanil), which permits lower doses of each agent and mitigates adverse side effects. Epidural analgesia for labor is typically initiated using epidural or combined-spinal epidural (CSE) technique, followed by infusion of a local anesthetic solution via an epidural catheter, oftentimes using a continuous epidural infusion (CEI) with or without patient-controlled epidural analgesia (PCEA).

Gambling et al. (1988) conducted a randomized controlled trial comparing the efficacy of PCEA alone with CEI and found that laboring patients in the PCEA group used significantly less mean hourly bupivacaine (M = 0.85 mg/hr, SD = 11.2 mg vs. M = 0.5 mg/hr, SD = 15.2 mg, $p <$ .01), but had no significant differences in degree of analgesia. In another study, Paech (1992) was the first to investigate the effects of administering PCEA in addition to CEI for labor analgesia. Fifty-two laboring mothers were randomized to receive either PCEA alone or PCEA with CEI of 4 ml/hr of 0.125% bupivacaine plus fentanyl 3 μg/ml. Though the study did not demonstrate a statistically significant difference in pain relief, supplementary boluses, or

maternal satisfaction, it did serve as a springboard for further trials investigating the effects of different background infusion rates (most ranging from 2-10 ml/hr), local anesthetics, drug concentrations, and PCEA bolus volume and lockout intervals. Both of these initial studies represent a pivotal turning point in favor of bolus-based epidural analgesia, which spurred many more studies, and ultimately led to CEI with PCEA becoming arguably the reference standard for labor epidural analgesia (Halpern & Carvalho, 2009; Onuoha, 2017; Sng et al., 2015).

In a systematic review by Halpern and Carvalho (2009), PCEA added to a background infusion improved the quality of analgesia by reducing breakthrough pain and clinician interventions. Halpern and Carvalho's review (2009) included randomized controlled trials that compared PCEA use of the following categories: background infusion versus no background infusion, ropivacaine versus bupivacaine, and high-volume PCEA bolus versus low-volume PCEA bolus and/or longer lockout interval versus shorter lockout interval. Studies comparing background infusions versus no background infusions found that background infusions reduced the need for clinician intervention for breakthrough pain and may have improved analgesia. Moreover, several trials included in the review compared ropivacaine to bupivacaine. Halpern and Carvalho (2009) concluded that ropivacaine and bupivacaine for PCEA boluses are appropriate for use in labor patients; however, they reported increased incidence of motor blockade with bupivacaine use. Motor blockade was especially evident at increased local anesthetic concentrations (e.g., bupivacaine 0.25% or greater, ropivacaine 0.2% or greater). Interestingly, one study found that the ED_{50} of bupivacaine for initiation of epidural analgesia for labor was lower when 0.125% bupivacaine was used compared to 0.25% bupivacaine (Lyons et al., 2007). The postulated rationale for this finding is that the use of more dilute local anesthetic solutions results in increased volume injected into the epidural space, possibly resulting in more

uniform spread in the epidural space (Hogan, 2002). Bolus dose volume and lockout intervals were also reviewed. While various regimens produced effective analgesia, evidence of the ideal dose volume and lockout interval was limited. It was suggested that larger boluses (e.g., 10-12 ml) of dilute local anesthetic provide superior analgesia than smaller boluses (e.g., 4-5 ml) in the absence of a background infusion. Shorter lockout intervals (e.g., 5-8 min) were found to improve the PCEA given:attempted ratio, but this did not reflect better analgesia or improved maternal satisfaction.

While CEI with PCEA is a widely popular modality for delivering epidural analgesia during labor, it is not without limitations. In a meta-analysis of ropivacaine and fentanyl epidural analgesia, the incidence of motor blockade was found to be 18.28% for continuous infusions (Zhang et al., 2018). Motor blockade significantly correlated with instrumental vaginal delivery ($r = .64$, $p = .0001$) (Zhang et al., 2018). The duration of the second stage of labor was also positively associated with the incidence of motor blockade (*OR* 0.23 [95% CI 0.01, 0.44], $p = .043$) (Zhang et al., 2018). Though there was no significant correlation between the incidence of motor blockade and cesarean delivery ($r = .18$, $p = .309$), percent fentanyl concentration and total fentanyl dosage positively correlated with incidence of cesarean delivery (percent fentanyl concentration $b = 25{,}358$, $p = .003$; total fentanyl dosage $r = .45$, $p = .046$). Conversely, fentanyl concentration and total fentanyl dosage was negatively associated with the incidence of instrumental deliveries (percent fentanyl concentration $b = -36{,}809$, $p = .015$; total fentanyl dosage $r = -.48$, $p = .046$).

In an effort to improve labor analgesia and minimize side effects, namely motor blockade, PIEB regimens have been developed. The use of PIEB settings was conceived based largely on cadaveric and experimental studies on the improved spread of liquids within the

epidural space with bolus delivery (Hogan, 2002; Kaynar & Shankar, 1999) and previous studies on manual bolus delivery by the clinician (Bogod et al., 1987; Boutros et al., 1999; Smedstad & Morison, 1988). Studies on the efficacy of single-orifice versus multiorifice epidural catheters are mixed, for which Kaynar and Shankar (1999) attributed to differential flow through the multiorifice catheter. Flow is greatest at the proximal hole, which under low injection pressures, such as with CEI, the catheter essentially acts as single-orifice with no flow observed through the distal ports. Kaynar and Shankar (1999) conducted a study to observe the difference in diffusion of a contrast solution from a multiorifice catheter during continuous infusion (10 ml/hr) or intermittent bolus (3.5 ml boluses over 1 minute every 20 minutes). They found that the continuous infusion flowed mainly through the proximal hole with practically no flow through the distal hole. Conversely, flow from the intermittent boluses was observed through all holes. This resulted in a wider spread of contrast solution in the intermittent bolus compared to continuous infusion (1.4 vs 0.26 in^2) (Kaynar & Shankar, 1999).

Statement of the Problem

The premise of the provision of epidural analgesia for labor is adequate pain relief while supporting maternal and neonatal outcomes. Programmed intermittent epidural bolus modality of analgesia has been shown to improve quality of analgesia, decrease local anesthetic consumption, and improve maternal satisfaction compared to CEI mode of delivery (Sng et al., 2018); however, CEI with PCEA remains a prevalent mode of delivery and was the existing practice at the critical access hospital that was the target of this Doctor of Nursing Practice (DNP) scholarly project. In response to this problem, this project proposed to develop a clinical practice protocol for PIEB for labor and plan for implementation and evaluation of the protocol in a critical access hospital.

Purpose of the Project

The purpose of this DNP scholarly project was to develop, implement, and evaluate an evidence-based clinical practice protocol for PIEB for labor analgesia in a critical access hospital. The project focused on enhancing labor analgesia outcomes by providing stakeholders with an evidence-based clinical practice protocol used to implement the practice change from CEI to PIEB for labor analgesia.

Need for the Project

While studies on the superiority of PIEB compared to CEI are emerging, widespread adoption of PIEB in clinical practice has been limited by the unavailability of epidural pumps with advanced technology capable of PIEB dosing (Tien et al., 2016). As more advanced epidural pumps become available, studies on the optimal epidural solution, bolus dose, and interval timing are transpiring. Considering these studies, the need for translation of the evidence to interventions aimed at improving labor epidural analgesia outcomes was evident in this DNP scholarly project.

Study Questions

This project aimed to answer the following population, intervention, comparison, outcome, and time (PICOT) questions:

Q1 In healthy laboring women in a critical access hospital (patient population) how effective is PIEB with PCEA settings for labor epidural analgesia (intervention of interest) compared to CEI with PCEA (comparison intervention) on quality of analgesia (outcome) during labor and delivery (time)? Quality of analgesia is measured by: (a) visual analog scale (VAS), visual numeric pain score (VNPS), or verbal rating scale (VRS) 30 min after epidural placement and hourly thereafter until delivery by the patient; (b) PCEA given: attempted ratio; (c) time (min) to first PCEA use; (d) time (min) to first certified registered nurse anesthetist (CRNA) intervention (manual bolus of additional epidural medication, adjustments in pump settings, or manipulation of the epidural catheter); and (e) number of top-up doses delivered by manual boluses.

Q2 In healthy laboring women in a critical access hospital (patient population) how effective is PIEB with PCEA settings for labor epidural analgesia (intervention of interest) compared to CEI with PCEA (comparison intervention) on incidence of motor blockade (outcome) as measured 30 min after epidural placement and hourly thereafter until delivery (time)? Motor blockade is measured by Bromage scale.

Q3 In healthy laboring women in a critical access hospital (patient population) how effective is PIEB with PCEA settings for labor epidural analgesia (intervention of interest) compared to CEI with PCEA (comparison intervention) on hourly and total local anesthetic utilization (outcome) during labor and delivery (time)?

Objectives of the Project

The objectives of the project are outlined here. Objectives were to:

1. Collect and analyze data and outcome measures (e.g., demographics/maternal characteristics, obstetrical data, analgesia quality, motor blockade, and local anesthetic utilization) and baseline maternal satisfaction scores and untoward epidural complications (e.g., high block level, unilateral block, "hot spot," catheter migration, hypotension requiring intervention, pruritis requiring intervention, nausea/vomiting requiring intervention, etc.) of the existing practice of CEI with PCEA modality of labor analgesia.
2. Develop a clinical practice protocol for PIEB with PCEA modality of labor epidural analgesia based on synthesis of the existing body of literature.
3. Translate the clinical practice protocol for PIEB with PCEA modality of labor epidural analgesia into practice.
4. Evaluate the practice change in terms of: (a) structure measures (i.e., adequate resources); (b) process measures (i.e., measure of fidelity to the protocol); (c) outcome measures (e.g., demographics/maternal characteristics, analgesia quality, local anesthetic utilization, and motor blockade, and obstetrical data); and (d)

balancing measures (e.g., maternal satisfaction scores and untoward epidural complications).

Definitions of Terms

Breakthrough pain: pain requiring intervention from the CRNA, such as manual bolus of additional epidural medication, adjustments in pump settings, or manipulation of the epidural catheter.

Combined-spinal epidural (CSE): a neuraxial technique that employs injection of medication into the intrathecal space, followed by insertion of a catheter into the epidural space for continued analgesia.

Continuous epidural infusion (CEI): infusion modality for delivery of medication to the epidural space via catheter at a constant, or basal, rate; may be combined with PCEA setting.

Epidural analgesia: a neuraxial technique of introducing an analgesic agent into the epidural space (includes both epidural and CSE techniques).

First stage of labor: stage of labor that begins with onset of labor and ends when cervix is 100% effaced and fully dilated to 10cm.

Local anesthetic utilization: combined hourly use of pump delivered (calculated via the pump totals) and CRNA-delivered local anesthetic medications (calculated via documentation in the anesthesia record).

Motor blockade: lower limb motor weakness indicated by Bromage scale grade II-IV.

Patient controlled epidural analgesia (PCEA): an additional top-up dose of supplementary analgesia dose by patient activation of a programmable pump.

Programmed intermittent epidural bolus (PIEB): infusion modality for delivery of medication to the epidural space via catheter an intermittent dose (every now and again); may be combined with PCEA setting.

Second stage of labor: stage of labor that begins when cervix is completely effaced and dilated and ends with delivery of the baby.

Term pregnancy: pregnancy at 37 to 41 weeks' gestation.

CHAPTER II

REVIEW OF THE LITERATURE

In this chapter, the literature review describes the historical background of the problem. Multiple studies are discussed showing the superiority of PIEB compared to CEI with PCEA regimens for maintenance of labor analgesia. Studies examining various epidural solutions and optimal PIEB pump settings are reviewed for their relevance to implementation in a critical access hospital. Stetler's model of research utilization and Donabedian's model are also discussed as the theoretical frameworks that underpin the scholarly project.

Historical Background

Neuraxial anesthesia was first described in 1885 by Leonard James Corning, an American neurologist who initially experimented with spinal anesthesia using cocaine in dogs and later in human subjects (Corning, 1885). Not long after in 1900, Oskar Kreis, a Swiss obstetrician, pioneered the first use of spinal cocaine in six parturients for labor pain (Schneider & Holzgreve, 2001). An early case report using spinal anesthesia with cocaine for cesarean section discussed the perceived benefit of maintained uterine tone during spinal anesthesia versus ether or chloroform anesthesia (Hopkins, 1902). Unfortunately, rare but serious complications of spinal anesthesia (e.g., high spinal, neurologic injuries, and death) were reported and resulted in a decline in its use for a short period of time ("Spinal Anesthesia," 1909). Single-shot caudal epidural techniques were also described in 1909 by German obstetrician Stoeckel in a case series

of 141 obstetric patients. It was not until 1931 that a technique for continuous caudal epidural was described by Eugen Aburel (Chau & Tsen, 2018). Several pivotal advances for epidural analgesia occurred over the next several decades until the 1980s when epidural analgesia became widely available (Meng & Smiley, 2017). Historically, epidural analgesia was achieved with an initial loading dose of local anesthetic and maintained by manual boluses by the provider (Chau & Tsen, 2018). Continuous epidural infusions with PCEA became mainstream with the advent of electronic pumps (Chau & Tsen, 2018). Intermittent bolus methods have also been described, with Kaynar and Shankar (1999) first describing improved spread and block quality with intermittent boluses versus continuous infusions.

Literature Review

Methodology

The literature on PIEB for labor analgesia was searched via PubMed (Medline), Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials (CENTRAL), and the Cumulative Index of Nursing and Allied Health Literature (CINAHL). References within eligible articles were also screened for additional sources. The search was conducted September through March 2019. The Boolean operator "AND" was used to combine search terms "programmed intermittent epidural bolus" or "automated intermittent epidural bolus," and "labor." Results of the search query were further refined to full-text scholarly journal articles in the English language. Studies including non-obstetric patient populations were excluded. Titles and abstracts were reviewed to determine relevance, including exclusion of studies that were not specific to the PIEB method and exclusion of reviews, editorials, and clinical updates.

In total, 22 studies were deemed relevant to the research question and compiled for analysis and synthesis, including 13 randomized controlled trials (Capogna et al., 2011; Ferrer et al., 2017; Fettes et al., 2006; Lange et al., 2018; Leo et al., 2010; Lin et al., 2016; Nunes et al., 2016; Patkar et al., 2015; Rodriguez-Campoo et al., 2018; Sia et al., 2013, 2007; Wong et al., 2011, 2006), 2 biased coin up-and-down sequential allocation trials (Epsztein Kanczuk et al., 2017; Zakus et al., 2018), 3 systematic reviews (George et al., 2013; Sng et al., 2018; Xu et al., 2019), 2 prospective controlled before-and-after cohort studies (Bullingham et al., 2018; Delgado et al., 2018), and 2 retrospective studies (McKenzie et al., 2016; Tien et al., 2016).

Synthesis

Overall

Fifteen of the 22 studies compared CEI with or without PCEA to PIEB with or without PCEA. Of those studies, 11 used randomized controlled trial design (Capogna et al., 2011; Ferrer et al., 2017; Fettes et al., 2006; Leo et al., 2010; Lin et al., 2016; Nunes et al., 2016; Patkar et al., 2015; Rodriguez-Campoo et al., 2018; Sia et al., 2013, 2007; Wong et al., 2006), 2 used prospective before-and-after cohort design (Bullingham et al., 2018; Delgado et al., 2018), and 2 used retrospective designs (McKenzie et al., 2016; Tien et al., 2016). Most of these used the same epidural solution for the CEI group and PIEB groups, except for the Bullingham et al. (2018) and Nunes et al. (2016) studies, both of which utilized a more dilute concentration of local anesthetic for the PIEB groups. Several studies compared various PIEB settings without a CEI comparison group (Delgado et al., 2018; Epsztein Kanczuk et al., 2017; Lange et al., 2018; Tien et al., 2016; Wong et al., 2011; Zakus et al., 2018). Three systematic reviews are also included in the synthesis (George et al., 2013; Sng et al., 2018; Xu et al., 2019).

The measurement outcomes of each study varied, but could be broadly categorized as quality and efficacy of analgesia, local anesthetic consumption, motor blockade, maternal outcomes, and neonatal outcomes. Several studies found significant differences in the presence of motor blockade among women who received PIEB compared to CEI (Bullingham et al., 2018; Epsztein Kanczuk et al., 2017). Using the Bromage scale for assessment of lower limb motor blockade, Bullingham et al. (2018) found that 21.8% of women in the CEI group experienced some degree of motor blockade (Bromage score II-IV) versus only 1.0% of women in the PIEB with PCEA group ($p < .001$). Similarly, in another study comparing the time interval in minutes between PIEB of 10 ml of 0.0625% bupivacaine with fentanyl 2 μg/ml, only 15.4% of women in the 30-minute interval group experienced motor blockade (Bromage II-IV) compared to none in the 40-, 50-, and 60-minute interval groups (Epsztein Kanczuk et al., 2017).

Chen and colleagues (2014) suggested that the presence of motor blockade in nulliparous women receiving CEI analgesia may affect the duration and effectiveness of expulsive efforts in the second stage of labor and, therefore, increases the rates of instrumented delivery, although a systematic review of 11 studies with a total of 1,079 women participants found little or no difference in PIEB compared to CEI in the risk of instrumented delivery (12% and 9%, respectively; *RR* 0.75, 95% *CI* [0.54, 1.06]) nor in the mean difference in duration of labor (*MD* = -10.38 min, 95% *CI* [-26.73, 5.96]) (Sng et al., 2018). Somewhat contrary to these findings, Bullingham et al. (2018) found the duration of the second stage of labor to be significantly shorter in PIEB groups compared to CEI groups of nulliparous women ($M = 79.4$ min, $SD = 55.1$ vs. $M = 108.2$ min, $SD = 61.2$, $p < .002$); however, no significant difference was found in PIEB versus CEI groups among multiparous women ($M = 45.1$ min, $SD = 52.1$ vs. $M = 52.8$ min, $SD = 52.3$, $p = .510$).

Likely related to the decreased prevalence of motor blockade, several studies have shown decreased local anesthetic consumption in PIEB groups compared to CEI groups (Bullingham et al., 2018; Ferrer et al., 2017; Sng et al., 2018). In one study, hourly ropivacaine consumption in the PIEB group was significantly less than the CEI group (M = 7.8 mg, SD = 0.44 vs. M = 13.8 mg, SD = 0.89, $p < .001$) (Bullingham et al., 2018). However, the study used a lower concentration of ropivacaine for the PIEB group than for the CEI group, so the results may be skewed. Ferrer et al. (2017) also showed a decreased utilization of local anesthetic, albeit bupivacaine, with the PIEB group consuming a total drug dose of 24.9 mg (SD = 13.5, 95% CI [21.5, 28.3]) compared to the CEI group consumption of 34.4 mg (SD = 21.4, 95% CI [29.0, 39.7], p = .13). Similarly, a systematic review of 12 studies of 1,121 women suggested a reduction in total hourly consumption of local anesthetic with PIEB compared to CEI (MD = -1.08 mg/hr, 95% CI [-1.78, -0.38]) (Sng et al., 2018). Improved analgesia quality as evidenced by a decrease in the number of women requiring either manual top-up boluses or PCEA boluses for breakthrough pain was also demonstrated in several studies (Delgado et al., 2018; Epsztein Kanczuk et al., 2017; Ferrer et al., 2017). Furthermore, in a systematic review including seven studies of 570 women evaluating maternal satisfaction of labor epidural analgesia, five studies reported an increase in the PIEB groups compared to the CEI groups (Sng et al., 2018).

Local Anesthetic and Opioid Adjuncts

Various local anesthetic solutions were used, including bupivacaine with fentanyl or sufentanil (Delgado et al. 2018; Epsztein Kanczuk et al., 2017; Ferrer et al., 2017; Lange et al., 2018; McKenzie et al., 2016; Tien et al., 2016; Wong et al., 2011, 2006; Zakus et al., 2018), ropivacaine with fentanyl or sufentanil (Bullingham et al., 2018; Fettes et al., 2006; Leo et al.,

2010; Lin et al., 2016; Nunes et al., 2016; Patkar et al., 2015; Sia et al., 2013, 2007), and levobupivacaine with sufentanil (Capogna et al., 2011; Rodriguez-Campoo et al., 2018).

Bupivacaine. Bupivacaine concentrations ranged from 0.0125% (Tien et al., 2016) to bupivacaine 0.1% (Ferrer et al., 2017), with the majority using 0.0625% bupivacaine. Of the studies using bupivacaine solutions, all but one included fentanyl ranging from 1.95-2 μg/ml. The study that did not use fentanyl used sufentanil 0.4 μg/ml (McKenzie et al., 2016).

Ropivacaine. Ropivacaine concentrations ranged from 0.1% (Bullingham et al., 2018; Leo et al., 2010; Lin et al., 2016; Nunes et al., 2016; Patkar et al., 2015; Sia et al., 2013, 2007) to 0.2% (Bullingham et al., 2018; Fettes et al., 2006). Of the studies using ropivacaine solutions, six included fentanyl 2 μg/ml (Bullingham et al., 2018; Fettes et al., 2006; Leo et al., 2010; Patkar et al., 2015; Sia et al., 2013, 2007), and two included sufentanil ranging from 0.2 μg/ml (Nunes et al., 2016) to 0.3 μg/ml (Lin et al., 2016).

Levobupivacaine. Only two studies used a levobupivacaine solution, with the CEI and PIEB maintenance infusion concentrations of 0.0625% (Capogna et al., 2011; Rodriguez-Campoo et al., 2018). One study included sufentanil 0.5 μg/ml and PCEA boluses of 0.125% levobupivacaine with sufentanil 0.5 μ/ml (Capogna et al., 2011). One study included fentanyl 1 μg/ml (Rodriguez-Campoo et al., 2018).

Epidural Pump Settings

Programmed bolus volumes and time intervals varied among studies. Most studies utilized a PIEB setting of 10 ml every 1 hour with PCEA or provider-dosed boluses for breakthrough pain. Several studies aimed to determine optimal PIEB settings. Wong et al. (2011) compared three bolus regimens: 2.5 ml every 15 minutes, 5 ml every 30 minutes, and 10 ml every 60 minutes. Breakthrough pain was treated with PCEA, followed by manual boluses if

needed. The 10 ml every 60 minutes group decreased bupivacaine consumption most without decreasing patient comfort or satisfaction. While most studies employed a PCEA setting or clinician-delivery bolus for breakthrough pain, Epsztein Kanczuk et al. (2017) aimed to determine the optimal time interval between PIEB of 10 ml of bupivacaine 0.0625% with fentanyl 2 μg/ml. Using biased coin up-down sequential allocation, they found that the optimal time interval was approximately 40 minutes (Epsztein Kanczuk et al., 2017). With this evidence on the optimal time interval, Zakus et al. (2018) sought to determine the optimal PIEB volume at a fixed interval of 40 minutes. The findings suggested that reduction in volume (i.e., less than 10 ml) was not possible without compromising quality of analgesia. Another study compared the effect of PIEB rate of infusion on labor analgesia quality (Lange et al., 2018). Patients were assigned to either high-rate bolus over 2 minutes, or low-rate bolus over 6 minutes. Patient outcomes did not differ with high- versus low-rate bolusing.

Theoretical Frameworks

Stetler's Model of Research Utilization

The Stetler model of research utilization was first developed by Stetler and Marram in 1976. The model was further refined in 1994 and again in 2001 to incorporate emerging trends in evidence-based practice. The primary focus of the Stetler model is utilization of research findings in individual practice or by individuals operating within a group under the premise that critical thinking plays a key role in facilitating safe and effective use of research findings (Stetler, 2001). The model has five phases: preparation, validation, comparative evaluation/decision making, translation/application, and evaluation.

The preparation phase requires the user to clarify the purpose of the research utilization. This phase seeks to answer "why" the research utilization is needed in nursing practice. The

potential significance of influential internal (e.g., personal factors that diminish objectivity) or external factors (e.g., politics, imposed deadlines, or prioritized goals of the organization) is also considered (Stetler, 2001). Measurable outcomes might also be identifiable. Additionally, the user is directed to differentiate sources of relevant research evidence in their literature search and select studies appropriate to the purpose of the research utilization.

In this DNP scholarly project, the preparation phase began with defining the purpose, which was to incorporate the most up-to-date evidence about labor epidural analgesia into practice. Influential factors included the organization's commitment to cost-effective care, patient satisfaction initiatives, as well as the author's own biases about the appeal of new interventions. Relevant evidence from the literature was limited to quantitative studies. Measurable outcomes included pain scores, interventions for break-through pain, amount of local anesthetic used, and motor blockade.

The second phase is validation, which involves a utilization-focused critique of the evidence. This involves appraisal of the findings of the study, rather than simply appraisal of the study itself. The process of critiquing and recording each study involves documentation in both a methodological table and a utilization table (Stetler et al., 1998). The process ends here if there is insufficient evidence. If the evidence is deemed sufficient, progression to the comparative evaluation/decision-making phase ensues where synthesis of the evidence occurs. This phase has four criteria that are used to determine application of the study's finding to practice. The four criteria are fit of setting, feasibility (risk factor, resources, and readiness), current practice, and substantiating evidence. On the basis of the synthesis and the applicability criteria, a decision to use, not use, or consider use is made. To use means to accept and use the findings immediately.

To not use means to reject the findings altogether. To consider use means a delay in use, pending further information.

For this DNP scholarly project, an integrative review process was used to systematically analyze and synthesize findings from research to facilitate decision making regarding protocol recommendations for the practice change. The integrative review process was adapted from Stetler et al.'s (1998) integrative review framework and incorporated the following steps:

1. Form an integrative review group.
2. Outline the problem and review process.
3. Select and evaluate applicable studies, and synthesize findings.
4. Develop recommendations based on synthesis.
5. Disseminate recommendations to the integrative review group for approval.

During synthesis of the findings, the Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) Rating Scale was used to evaluate the strength and quality of the evidence (Dang & Dearholt, 2017).

At this point, the level of application (e.g., individual, group, or organization) needs to be made in order to develop a proposal for practice change. Translation/application is the "how-to" phase of implementation of the evidence from the previous phases. If use goes beyond simple informal use, strategies for formal dissemination and evidence-based change plans are developed. For this DNP scholarly project, the translation/application phase involved key stakeholders, such as fellow CRNAs, obstetric providers, nursing staff, pharmacists, and patients. A clinical practice protocol was developed based on the integrative review. Education on protocol implementation, including pump setup for PIEB settings, was developed as part of the

translation plan. A data collection worksheet was used to collect baseline and can be used to collect post-implementation data.

Evaluation is the fifth and final phase of the Stetler model. Evaluation can be formal or informal. In this case, a high degree of rigor is appropriate because the DNP scholarly project involved pre- and post-intervention comparisons of measures. Stetler (2001) recommended using both formative and summative evaluation of outcomes in order to evaluate if implementation is going as planned and outcome or goal achievement.

Donabedian's Model

Donabedian (2005) is credited as a pioneer in healthcare quality and safety. He proposed that the quality of healthcare can be measured using a 3-prong approach focused on the relationship between structure, process, and outcome within an organization. Balancing measures are also considered alongside contemporary descriptions of the Donabedian model (Fondahn et al., 2016). Measures for structure, process, and outcome are components for evaluation of the degree to which an improvement project results in the desired impact. For this DNP scholarly project, structure measures included the resources available to provide adequate patient care, such as epidural pumps with advanced technology, the presence of competent staff members, staff education resources, and administrative support. Process measures reflect the degree to which the protocol is being followed. Outcome measures determine if the practice change project had the desired outcome of improving the quality of labor epidural analgesia. Lastly, balancing measures evaluated if improvements gained from the practice change negatively impacted another area as a result of the practice change.

CHAPTER III

METHODOLOGY

This chapter details the methods used for the DNP scholarly project. The design of the project, the setting and sample, and the measures used are described. Plans for data analysis are presented along with limitations of the project. The informed consent process and the protection of human subjects are detailed.

Design

The DNP scholarly project included development of an evidence-based clinical practice protocol incorporating findings from an integrated literature review. Implementation of a before-and-after without control design was planned in collaboration with a multidisciplinary team to measure the effect of PIEB with PCEA modality for labor analgesia (*after* group) on analgesia quality, local anesthetic utilization, and prevalence of motor blockade compared to the CEI with PCEA modality (*Before* group).

Setting

The setting was the labor and delivery unit at a midwestern critical access hospital. The number of deliveries per year over the past five years varied from 55 in 2013 to 80 in 2018.

Sample

The sample included all labor patients with term singleton pregnancy who received epidural analgesia in the setting during the pre- and post-measurement period. Women were excluded from participating if they had any of the following conditions: preeclampsia,

gestational diabetes, intrauterine growth restriction, fetal birth defects or chromosomal abnormalities, known placental pathology, and/or poorly controlled systemic disease, and patients who delivered less than two hours after the epidural pump was started.

Project Mission, Vision, and Objectives

The mission of this project was to provide labor epidural analgesia services of the highest quality to give mothers the best possible childbirth experience. The vision of the project was to become leaders in providing innovative anesthesia care for mothers and their families that is patient-centered, evidence-driven, and of the highest quality and safety.

The objectives of this project are outlined here:

Objective 1: The primary researcher collected and analyzed the following data from the existing practice of CEI with PCEA modality of labor epidural analgesia including:

- patient characteristics/demographics (patient age, weight, height, body mass index [BMI], ethnicity, race, physical status classification, comorbidities, prenatal medications);
- obstetric data (parity, gestational age, labor type [spontaneous versus induced], oxytocin administration, fetal presentation, presence of fetal distress/bradycardia, Apgar scores, mode of delivery [vaginal, instrumental, cesarean], length of stages 1 and 2 of labor, estimated blood loss, perineal tear or episiotomy);
- cervical dilation at request for epidural;
- VAS, VNPS, or VRS pain score at time of epidural request;
- outcome measures (analgesia quality, local anesthetic utilization, motor blockade);
- maternal satisfaction survey (completed within 48 hours of delivery);

- detailed narrative of any untoward epidural complications (e.g., high block level, unilateral block, “hot spot,,” catheter migration, hypotension requiring intervention, pruritis requiring intervention, nausea/vomiting requiring intervention, etc.).

This information was gathered from review of patient medical records and review of epidural pump history for 10 patients prior to implementation of the practice protocol for PIEB with PCEA. Data were logged in a spreadsheet with patient information de-identified and securely saved on a computer within the hospital’s network.

Objective 2: The primary researcher, in collaboration with the research committee, developed a practice protocol for implementation of PIEB with PCEA for labor epidural analgesia following complete synthesis of the literature. Part of the protocol development included consultation with a product representative for instructions on setting up pre-programmed pump settings for the Sapphire epidural pump currently used at the clinical site.

Objective 3: The primary researcher, along with the multidisciplinary team, developed an educational plan about protocol implementation for the CRNAs performing epidural analgesia, including an in-service and quick reference guide (QRG). An informational in-service about the practice changes was originally planned for CRNAs, nursing staff, physicians, and pharmacists. A short evaluation was developed to assess participants’ understanding of the materials.

Objective 4: The primary researcher originally planned to collect and analyze the following data following implementation of the PIEB with PCEA practice protocol:

- patient characteristics/demographics (patient age, weight, height, BMI, ethnicity, race, ASA status, comorbidities, and prenatal medications);

- obstetric data (parity, gestational age, presence of singleton or multiple, labor type [spontaneous versus induced], oxytocin administration, fetal presentation, presence of fetal distress/bradycardia, Apgar scores, mode of delivery [vaginal, instrumental, cesarean], length of stages 1 and 2 of labor, estimated blood loss, and perineal tear or episiotomy);
- cervical dilation at request for epidural;
- VAS, VNPS, or VRS pain score at time of epidural request;
- outcome measures (analgesia quality, local anesthetic utilization, and motor blockade);
- maternal satisfaction survey (completed within 48 hours of delivery);
- detailed narrative of any untoward epidural complications (e.g., high block level, unilateral block, "hot spot," catheter migration, hypotension requiring intervention, pruritis requiring intervention, nausea/vomiting requiring intervention, etc.).

This information was to be gathered from review of patient health records, review of epidural pump history, and survey data for at least 10 patients following implementation of the practice protocol for PIEB with PCEA. It was planned for data to be logged in a spreadsheet with patient information de-identified and securely saved on a computer within the hospital's network.

Objective 5: The primary researcher originally planned to evaluate the practice protocol using data analysis to determine clinical and statistical significance. Process measures were assessed in terms of fidelity to the practice protocol.

Project Plan

Key components of this DNP scholarly project included: (a) submission of the University of Northern Colorado Institutional Review Board (IRB) application; (b) assembly of a multidisciplinary team, including a pharmacist, obstetric provider, labor and delivery registered nurse, and quality improvement specialist; (c) development of an evidence-based practice protocol for PIEB with PCEA for labor analgesia based on an integrated literature review; (d) formation of a staff training plan and QRGs; (e) collection and statistical analysis of pre-implementation data to include at least 10 patients in the *before* group; (f) implementation of an evidence-based practice protocol for PIEB with PCEA for labor analgesia; (g) collection and statistical analysis of post-implementation data to include at least 10 patients in the *after* group; (h) evaluation of structure measures, process measures, outcome measures, and balancing measures; and (i) future dissemination of the DNP project results. Because this DNP scholarly project was to develop, implement, and evaluate a practice protocol, submission of the IRB application sought approval to collect and analyze data from the pre-intervention (*before*) group, implement the protocol, collect and analyzed data from the post-intervention (*after*) group, and evaluate outcomes. Application for IRB approval was submitted following presentation of the DNP scholarly project proposal by the primary researcher and approval from the project committee. Staff education materials were developed concurrently as the practice protocol was created, with the goal of a establishing a comprehensive training plan prior to protocol implementation. Collection and statistical analysis of pre-implementation commenced following review by the IRB and determination that the project was exempt from further review (Appendix A) and concluded when a convenience sample of 10 patients was achieved.

Instrumentation

Several instruments were used to measure the outcomes of this DNP project. These instruments are described here.

Analgesia quality was examined in this study. Several measures indexed quality of analgesia, including: (a) patient completion of a VAS, VNPS, or VRS for pain; (b) PCEA given:attempted doses gathered from epidural pump history; (c) time to first PCEA use from epidural pump history; (d) time to first CRNA intervention (manual bolus of additional epidural medication, adjustments in pump settings, or manipulation of the epidural catheter) as documented in medical record or epidural pump history as applicable; and (e) number of top-up doses delivered by manual bolus as documented in medical records.

Local anesthetic utilization was analyzed. Data were gathered from review of epidural pump history and review of the anesthesia record. In the unlikely event of different local anesthetic medications used, the local anesthetic was converted to ropivacaine equivalents as previously described by George et al. (2013).

This DNP project also studied motor blockade. Bromage scores were used as retrieved from the participants' electronic medical records, with motor blockade defined as Bromage score of > 1.

Finally, outcomes were measured by the Maternal Satisfaction Survey. This survey is included in Appendix B.

Analysis

Data Analysis Procedures

Descriptive statistics were used for patient characteristics/demographics, obstetric data, cervical dilation at request for epidural, pain scores at time of request for epidural, and outcome

measures (analgesia quality, motor blockade, and local anesthetic utilization) for the pre-implementation (*before*) group. The same data descriptive statistics analysis procedure for the post-implementation (*after*) group was planned, but not completed due to inability to implement the protocol as discussed above. Comparison of outcome measures between the *before* and *after* groups using the Mann-Whitney U test were originally planned, but was not able to be completed.

Descriptive statistics were used for maternal satisfaction scores from the 5-point Likert scale questionnaire. Comparison of individual survey question mean scores between the pre-implementation group and the post-implementation group using the Mann-Whitney U test were originally planned, but not able to be completed.

Duration of the Project

The project was slated for completion upon data collection from a total of 20 patients, 10 from the pre-implementation group and 10 from the post-implementation group. In the event that data on 20 patients was not collected, the plan was to extend the data collection timeline; however, the timeline was not able to be extended because the protocol implementation date was indeterminate due to the COVID-19 pandemic.

Ethical Considerations

Application for the University of Northern Colorado Institutional Review Board (IRB) approval was submitted prior to initiating the DNP project. The AANA Standards of Care for professional practice and the "Analgesia and Anesthesia for the Obstetric Patient Practice Guidelines" were followed. All participants were protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), thus protecting the privacy of patients' health information. Information collected was evaluated as aggregate data with potential patient

identifiers omitted. Patient confidentiality was assured by coding the participants using individual numerical identification. The data were stored electronically and only accessible by the primary researcher with password-protected access. The risks associated with participating in this project are no different than the risks of receiving the standard labor epidural care. Informed consent from each subject was obtained by the CRNA utilizing the clinical site's existing anesthesia consent form (See Appendix C).

CHAPTER IV

RESULTS AND DATA ANALYSIS

This chapter presents the results and data analysis of the DNP project. Each project objective is examined and the study questions analyzed. Pre-implementation data analysis from the *before* group is presented using descriptive statistics.

Objective 1: Data Analysis of Current Practice

Data from 10 *before* patients who were representative of the current practice were collected. These data were analyzed using descriptive statistics as follows.

Description of the *Before* Sample

Pre-implementation data from a convenience sample of 10 patients in the *before* group were collected and analyzed using descriptive statistics. Patient characteristics and obstetric data are presented in Tables 1 and 2, respectively.

Table 1

Characteristics of Patients in the Before Group (N = 10)

Characteristic	*M* (*SD*)	*n* (%)
Age (years)	26 (4.8)	
Weight (kg)	87.0 (12.8)	
Height (cm)	163.6 (5.7)	
BMI (kg/m^2)	32.6 (4.3)	
Race		
White		10 (100)
Black		0 (0)
Asian		0 (0)
American Indian		0 (0)
Native Hawaiian		0 (0)
Other		0 (0)
Ethnicity		
Hispanic		0 (0)
Not Hispanic		10 (100)
Physical Status		
ASA I		1 (10)
ASA II		8 (80)
ASA III		1 (10)
ASA IV		0 (0)
ASA V		0 (0)
Presence of Comorbidities?		
Yes		7 (70)
No		3 (30)

Note. ASA = American Society of Anesthesiologists; BMI = body mass index; *M* = mean; *SD* = standard deviation.

Table 2

Obstetric Data of Patients in the Before Group (N = 10)

Characteristic	*M (SD)*	*Mdn (IQR)*	*n* (%)
Gestational age (weeks)	39.6 (1.1)		
Gravidity			
1			5 (50)
2			2 (2)
>/= 3			3 (30)
Parity			
0			5 (50)
1			3 (30)
2			2 (20)
>/= 3			0 (0)
Duration 1st stage of labor (min)		561.0 (408.5, 941.25)	
Duration 2nd stage of labor (min)		37 (14.25, 77.0)	
Oxytocin administration?			
Yes			6 (60)
No			3 (30)
Fetal presentation			
Vertex			10 (100)
Breach			0 (0)
Shoulder/transverse			0 (0)
Face			0 (0)
Brow			0 (0)
Labor type			
Spontaneous			7 (70)
Induced			3 (30)
Presence of fetal distress/bradycardia?			
Yes			2 (20)
No			6 (60)
Apgar 1 minute		8.5 (7.75, 9.0)	
Apgar 5 minute		9.0 (9.0, 9.0)	
Apgar 10 minute		9.0 (9.0, 9.5)	

Table 2 (continued)

Characteristic	*M (SD)*	*Mdn (IQR)*	*n* (%)
Mode of delivery			
Vaginal			9 (90)
Instrumental (vacuum-assist, forceps)			1 (10)
Cesarean			0 (0)
EBL (ml)	455.0 (86.4)		
Perineal repair?			
Yes			6 (60)
No			4 (40)

*Note***.** EBL = estimated blood loss; *IQR* = interquartile range; *M* = mean; *Mdn* = median; ml = milliliters; min = minute; *SD* = standard deviation.

Description of Variables

Analgesia quality was evaluated using VAS, VNPS, or VRS pain score at time of epidural request, 30 minutes after epidural placement, and hourly thereafter until delivery (Table 3). The mean pain score on a 0-10 scale at the time of epidural request was 7.8 (*SD* = 1.7). The mean post-epidural maximum score was 2.9 (*SD* = 2.6). The mean post-epidural minimum score was 0.9 (*SD* = 0.9). Eighty percent of patients required at least one PCEA bolus with the mean time to first PCEA use 101.5 minutes (*SD* = 79.9). The ratio of PCEA attempts:given had a median of 1 (0.5, 1). One of 10 patients required an adjustment of the pump settings. No patients required manual top off boluses by the CRNA or manipulation of the epidural catheter. One of 10 patients had a CSE, whereas the other 9 had traditional epidural placement.

Table 3

Quality of Analgesia in the Before Group (N = 10)

Characteristic	*M (SD)*	*Mdn* (*IQR* or range)	*n* (%)
Cervical dilation at time of request		4.0 (*IQR* 2.0, 5.25)	
Pain score at time of request	7.8 (1.7)		
Pre-epidural MAX	7.1 (2.8)		
Post-epidural MAX	2.9 (2.6)		
Post-epidural MIN	0.9 (0.9)		
Patients requiring PCEA boluses			8 (80)
PCEA attempted		2.5 (*IQR* 0.75, 4.0)	
PCEA given		2.0 (*IQR* 0.75, 3.25)	
PCEA attempted/given ratio,		1 (*range* 0.5, 1)	
Time to 1st PCEA use (min)	101.5 (79.9)		

Note. IQR = interquartile range; M = mean; Mdn = median; min = minute; PCEA = patient controlled epidural analgesia; SD = standard deviation.

Motor blockade was evaluated using the Bromage score 30 minutes after epidural placement, and hourly thereafter until delivery (Table 4). The mean post-epidural maximum Bromage score was 1.6 (*SD* = 0.9). Motor blockade, as defined as a Bromage score of >1, was documented in 3 out of 10 patients in the *before* group. Overall compliance with Bromage score documentation was poor, with all 10 records missing at least one data point, and two records with complete omission of documentation of Bromage scores.

Table 4

Motor Blockade of Patients in the Before Group (N = 8)

Characteristic	*M (SD)*	*n* (%)
Incidence of Bromage Score >1		3 (37.5)
Post-epidural MAX Bromage Score	1.6 (0.9)	

Note. M = mean; SD = standard deviation.

Local anesthetic utilization was evaluated by calculating hourly and total local anesthetic consumption in ropivacaine equivalents (Table 5). Hourly and total fentanyl consumption was also collected. The mean hourly ropivacaine utilization was 23.4 mg (*SD* = 7.4). The median total ropivacaine utilization was 92.1 mg (*IQR* = 54.2, 153.6). The mean hourly fentanyl utilization was 23.4 µg (*SD* = 7.4), and the median total fentanyl utilization was 93.8 µg (*IQR* = 56.7, 153.6). Median total epidural pump time in minutes was 225.5 (*IQR* = 103.5, 529.5).

Table 5

Local Anesthetic/Opioid Utilization of Patients in the Before Group (N = 10)

Characteristic	*M (SD)*	*Mdn (IQR)*
LA utilization (mg RE)		
Average hourly	23.4 (7.4)	
Total LA utilization (mg RE)		92.1 (54.2, 153.6)
Opioid utilization (µg FE)		
Average hourly	23.4 (7.4)	
Total fentanyl utilization (µg FE)		93.8 (56.7, 153.6)
Total pump time (min)		225.5 (103.5, 529.5)

Note. FE = fentanyl µg equivalents; *IQR* = interquartile range; LA = local anesthetic; *M* = mean; *Mdn* = median; µg = microgram; mg = milligram; min = minute; RE = ropivacaine mg equivalents.

Maternal satisfaction was surveyed using a Likert scale tool adapted from Clivatti et al. (2013). The survey response rate was 80% (Table 6).

Table 6

Maternal Satisfaction of Patients in the Before Group

Statement	Strongly Agree (%)	Agree (%)	Neutral (%)	Disagree (%)	Strongly Disagree (%)	Total* (*n*)
The placement of the epidural was comfortable.	25	50.0	25.0	0.0	0.0	8
I felt NO pain from the time I had my epidural until I started pushing.	25.0	37.5	25.0	12.5	0.0	8
I felt NO pain when I was pushing.	62.5	25.0	12.5	0.0	0.0	8
The pain medication received through labor was enough.	87.5	12.5	0.0	0.0	0.0	8
The numbness in my legs bothered me.	0.0	12.5	12.5	62.5	12.5	8
The itchiness from the epidural medication bothered me.	0.0	0.0	37.5	37.5	25.0	8
The shivering from the epidural medication bothered me.	0.0	50.0	12.5	25.0	12.5	8
I could not push well due to the epidural medication.	0.0	0.0	0.0	50.0	50.0	8
Overall, my epidural worked well.	62.5	37.5	0.0	0.0	0.0	8
I would want to receive pain relief with an epidural again if I had another baby.	75.0	25.0	0.0	0.0	0.0	8

*Some parturients did not complete one or more questions.

Despite the small sample size, minor and temporary untoward epidural complications occurred. Patients in the *before* group required intravenous ephedrine for hypotension after

epidural placement (n = 2) or intravenous medications for pruritis (n = 1). There was a unilateral block that corrected with positioning the patient on her side and administering a manual bolus of local anesthetic through the epidural catheter (n = 1). No other complications were reported. Duration of stages 1 and 2 of labor, mode of delivery, prevalence of perineal repair, Apgar scores, and presence of fetal distress/bradycardia are presented in Table 2.

Objective 2: Evidence Evaluation and Protocol Development

An evidence-based clinical practice protocol for PIEB at a critical access hospital was developed utilizing a hybrid approach to Stetler's model for research utilization and the JHNEBP model. The integrative review process detailed by Stetler et al. (1998) was used as a guideline for performing a utilization-focused critique of the literature, which ultimately led to the development of practice recommendations. For the purpose of this scholarly project, the clinical practice protocol represented a cohesive compilation of practice recommendations from the integrative review. The integrative review incorporated the following steps:

1. Form an integrative review group.
2. Outline the problem and review process.
3. Select and evaluate applicable studies, and synthesize findings.
4. Develop recommendations based on synthesis.
5. Disseminate recommendations to the integrative review group for approval.

Members of the integrative review committee were recruited from the pool of key interdisciplinary stakeholders. An OB nurse, an OB physician, the pharmacy manager, the OB nursing manager, a nursing informatics specialist, the hospital's risk manager (who is the Chief Nursing Officer), and the primary researcher (who is a CRNA) comprised the seven-member integrative review committee. The primary researcher was responsible for outlining the problem

and the review process used to select, evaluate, and synthesize evidence from applicable studies. Practice recommendations based on synthesis were disseminated to the integrative review committee for feedback and approval. The purpose of the integrated review was synthesis of research on PIEB for labor analgesia with the goal of development of a clinical practice protocol for a critical access hospital.

The JHNEBP's *Research Evidence Appraisal Tool* was utilized to evaluate the evidence. Each piece of evidence was appraised for evidence level and quality rating by the primary researcher, then collated into an evidence summary table from the JHNEBP toolkit as a concise reference for the integrative review committee. Next, the evidence was synthesized using the JHNEBP *Synthesis Process and Recommendations Tool*. The evidence included multiple studies of JHNEBP Level I and Level II evidence; in fact, 16 of the 22 studies included in the synthesis were Level I evidence, and 3 were Level II evidence. The overall quality rating for each level of evidence was determined. Based on the evidence synthesis, there was a solid indication for practice change as indicated by strong, compelling evidence and consistent results among the studies. Recommendations in the form of a clinical practice protocol were put forth for review by the integrative review committee, and, with minor changes based on feedback from the committee, the clinical practice protocol was finalized for implementation. See appendix D for *Clinical Practice Protocol for Programmed Intermittent Epidural Bolus (PIEB) for Labor Analgesia*.

Real-world applicability of the Stetler and JHNEBP models for evidence-based protocol development proved to be challenging at a critical access hospital. The recruitment pool was limited, and scheduling conflicts posed barriers to interactive discussion. Electronic mail became the primary means of communication with members of the integrative review committee. The

response rate among several members was poor or nonexistent, despite follow-up reminder notifications and in-person requests to respond to e-mails. Input and feedback from the OB nurse, pharmacy manager, and CRNA members were largely employed to finalize the protocol. This lack of engagement within the committee limited the multidisciplinary validity and applicability of the clinical practice protocol. Nonetheless, a clinical practice protocol was developed to meet the objective set forth as a part of this DNP scholarly project.

Objective 3: Translation of the Evidence

Determination of Fit, Feasibility, and Appropriateness to Current Practice

In addition to the external evidence appraisal and synthesis conducted to develop the clinical practice protocol, internal data were examined in anticipation of translation of the evidence into clinical practice. It was determined that identifying change champions within the already formed integrative review committee would be apropos. The change champions were led by the primary researcher, who acted as the project leader. In keeping with Stetler's model and the JHNEBP model, fit, feasibility, and current practice were examined.

Fit

For ease of implementation of the new protocol, the clinical site's existing labor epidural policy was used as a template to compose the new evidence-based clinical practice protocol for PIEB. The document was then directed through appropriate administrative channels in keeping with the clinical site's formal process for approving new or updated guidelines, policies, and procedures. This aided in ensuring a pragmatic fit within the targeted setting.

Feasibility

Feasibility of implementing the substantiated findings was considered by the change champions, including assessment of risks, resources, and readiness. Details regarding these assessments follow.

Risks. The potential risks of implementing the protocol included concerns about providing adequate analgesia in view of effectively reducing the concentration of the current epidural infusion from 0.2% to 0.1% ropivacaine, despite this not being substantiated by the body of evidence. Current practice within the anesthesia practice for providing manual boluses for breakthrough pain varied. Common practice was to deliver a clinical bolus via the epidural pump of 5-10 ml of 0.2% ropivacaine with fentanyl 2 μg/ml or manually bolus 5-10 ml 0.25% bupivacaine with or without fentanyl 50-100 μg. The PIEB clinical practice protocol dictated treatment of breakthrough pain refractory to two PCEA boluses with the administration of 0.2% ropivacaine in 5 ml incremental doses every 10 minutes (up to a maximum of 20 ml) until analgesia is satisfactory. Fentanyl 50 μg may be added if pain score is greater than 3/10 after 10 ml of 0.2% ropivacaine. Research evidence did not explicitly support this recommendation; however, several of the study protocols utilized similar or lower concentration bolus regimens for breakthrough pain (Capogna et al., 2011; Delgado et al., 2018; Ferrer et al., 2017; Fettes et al., 2006; Leo et al., 2010; McKenzie et al., 2016; Nunes et al., 2016; Patkar et al., 2015; Sia et al., 2013, 2007; Wong et al., 2011, 2006).

Theoretical safety concerns, namely high block and catheter migration into the subarachnoid space, were voiced. There were no indications in the literature of an additional risk with PIEB versus CEI to date, although PIEB safety concerns may become evident as use becomes more widespread.

Lastly, there was a perceived risk of delivery of stacked PCEA boluses with PIEB (e.g., a programmed bolus delivered in a short time interval from PCEA bolus). Several studies discussed algorithms designed as part of the study protocol or programmed into the respective epidural pump (Delgado et al., 2018; Leo et al., 2010; Rodriguez-Campoo et al., 2018; Sia et al., 2013, 2007; Tien et al., 2016). The QCore Medical Sapphire epidural infusion pump used at the clinical site allowed for programming of a lockout time between boluses, regardless of PCEA or PIEB. For the purpose of this project, the lockout time was set to 15 minutes. If a PIEB was delivered, the next available PCEA bolus would occur after 15 minutes. Similarly, if a PCEA bolus was delivered within 15 minutes prior to when a programmed intermittent bolus was due to be delivered, it would be delayed until 15 minutes had elapsed between boluses.

Resources. The resources required for implementation of the project were minimal due to the longstanding provision of labor epidural services already in place at the clinical site. There were no anticipated impacts to capital and operational costs. The clinical site owns two epidural pumps with advanced technology capable of PIEB programming. Additionally, the clinical site provides annual in-services for the nursing staff, during which one of the CRNAs lectures about a topic related to obstetric anesthesia. The focus of this year's lecture was aimed at educating the staff on the PIEB clinical practice protocol; however, the annual in-services were postponed until further notice due to COVID-19 concerns.

Readiness. The change champion team included the hospital's risk manager, who was also the Chief Nursing Officer. A culture of leadership support of evidence-based practice is an important factor in engaging stakeholders at all levels and a potential strength for implementation of the PIEB protocol. Unfortunately, the clinical site had minimal exposure to formal evidence-based research utilization in clinical practice, which posed a potential barrier to

implementation. Critical access hospitals encounter several unique challenges when compared to larger medical organizations, one of which is lack of educational preparation regarding the process of research utilization. In an informal inquiry, it was found that the overall attitude toward implementing an evidence-based project was positive, with a few individuals expressing lack of value of evidence-based research utilization compared to longstanding dogma and anecdotal clinical data. These perceived barriers posed real concerns about protocol noncompliance that may result in skewed project outcomes.

Current Practice

The need for change was substantiated by the available evidence. Analysis of the *before* data from the existing labor epidural practice described above served as the basis for comparison of outcome measures following implementation of the PIEB clinical practice protocol.

Action Plan

A pragmatic approach to developing an action plan was deemed necessary for successful implementation of the PIEB clinical protocol. It was decided that the recommendations from the appraisal and synthesis of evidence did not provide all the details required for a complete protocol. This was an expected finding and, thus, the clinical site's extant labor epidural policy was reviewed and used as a template to compose the new evidence-based clinical practice protocol for PIEB. Outdated policy items were updated with the integrative review team's recommendations from the appraisal and synthesis of the evidence. Package dissemination was anticipated with direct instrumental use in the form of protocol roll-out to include nursing staff in-service during the clinical site's annual training sessions and quick reference guides. The protocol was approved for implementation by the clinical site following appropriate administrative channels.

Unfortunately, the COVID-19 pandemic presented as an unforeseen barrier to implementation as staff furloughs impeded the delivery of staff education and training. For this reason, the clinical site personnel made the decision to delay protocol implementation until a new plan for annual staff in-services is developed by the clinical site's nursing education department. Once a definitive implementation date is set by the multidisciplinary team, the epidural pumps will be reprogrammed to allow for the protocol's PIEB pump settings, the electronic labor epidural order sets will be deployed, the pharmacy department will ensure availability of the protocol epidural infusion bags, staff education will be completed, and QRGs will be disseminated.

Objective 4: Evaluation of the Practice Change

The evaluation plan for this evidence-based project comprises formative and summative evaluation, including structure, process, outcome, and balancing measures. This evaluation plan was developed by incorporating Donabedian's (2005) three components of structure, process, outcomes, and balancing measures into the evaluation phase of Stetler's model for research utilization (2001).

Formative Evaluation

Structure Measures

Structural elements of import for this evidence-based project included resources available to support successful protocol implementation. These resources included epidural pumps with advanced technology, competent staff members, staff education resources, and administrative support. The COVID-19 pandemic resulted in delay of staff educational in-services and reallocation of committee members to serve the more immediate needs associated with COVID-19 preparedness, which resulted in postponement of protocol implementation.

Process Measures

During data collection from the *before* group of 10 patients who received continuous epidural infusions, it was determined that documentation in the electronic medical record deviated from the requirements set forth in the clinical site's existing labor epidural policy. For example, the duration of the first and second stages of labor was not easily discernible in the electronic medical record. Additional findings include the lack of hourly pain scores for the duration of the epidural infusion, as well as complete omissions of Bromage scores. Data from the epidural pumps proved to be most reliable in terms of completeness due to the comprehensive pump history. For these reasons, refinements in the staff educational presentations were made to draw greater focus to the nursing assessment and documentation requirements for patients with labor epidurals. Additionally, a template for the CRNAs to use in their procedure notes was created to standardize documentation of the placement of the epidural catheter.

Summative Evaluation

Outcome Measures

Primary outcome measures were analgesia quality, motor blockade, and local anesthetic utilization. Secondary outcome measures were neonatal outcomes, maternal outcomes, and mode of delivery (Table 2). Data from the *before* group were collected and analyzed for comparison to the post-implementation data from the *after* group.

Analgesia Quality. Several measures indexed quality of analgesia. These measures included VAS, VNPS, or VRS for pain, PCEA given/attempted doses gathered from epidural pump history, time to first PCEA use from epidural pump history, time to first CRNA intervention (manual bolus of additional epidural medication, adjustments in pump settings, or

manipulation of the epidural catheter) as documented in medical record or epidural pump history as applicable, and number of top-up doses delivered by manual bolus as documented in medical record (Table 3).

Motor Blockade. Bromage score was retrieved from the patients' electronic medical records, with motor blockade defined as Bromage score of >1. Motor blockade was assessed 30 minutes after epidural placement and hourly thereafter (Table 4).

Local Anesthetic Utilization. Data were gathered from review of epidural pump history and review of the anesthesia record. In the unlikely event of different local anesthetic medications used, the local anesthetic was converted to ropivacaine equivalents as previously described by George et al. (2013). Several measures were used to evaluate local anesthetic utilization, including hourly and total local anesthetic utilization, and hourly and total fentanyl utilization (Table 5).

Balancing Measures

Balancing measures were assessed to evaluate if improvements gained from the PIEB protocol implementation would negatively impact another area as a result of the practice change. Those measures included maternal satisfaction and any untoward epidural complications.

Analyses of Study Questions

This DNP project aimed to answer three PICOT questions related to the efficacy of PIEB with PCEA settings for labor analgesia compared to CEI with PCEA on quality of analgesia, motor blockade, and local anesthetic utilization when implemented in healthy laboring women in a critical access hospital. Due to unforeseen circumstances related to the COVID-19 pandemic, the PIEB protocol was not implemented and, thus, the study questions remain unanswered. Preliminary data were collected and analyzed, an evidence-based protocol was developed, and

translation and evaluation plans were established for future use at such time as the available evidence can be successfully translated into clinical practice.

CHAPTER V

DISCUSSION

This chapter includes a summary of the scholarly project, including conclusions, limitations, and recommendations for future practice. To close, a reflection on how this scholarly project met the outcomes of the American Association of Colleges of Nursing's (AACN) *The Essentials of Doctoral Education in Advanced Nursing Practice* (2006) using the EC as PIE (enhance, culmination, partnerships, implements, and evaluation) criteria (Waldrop et al., 2014) is imparted.

Conclusions

The purpose of this DNP scholarly project was to develop, implement, and evaluate an evidence-based clinical practice protocol for PIEB for labor analgesia for multidisciplinary use that focused on improving labor epidural analgesia outcomes. The PIEB technique for labor epidural analgesia has been shown in numerous studies to demonstrate advantages over traditional approaches to epidural analgesia, namely improved quality of analgesia, decreased local anesthetic consumption, and improved maternal satisfaction. A number of promising studies were the impetus for developing a clinical practice protocol for translation of the evidence to clinical practice in a critical access hospital. A PIEB clinical practice protocol was developed from extensive review of the research and an integrative review process by a multidisciplinary team to ascertain a cohesive compilation of practice recommendations applicable to the target population of healthy laboring women in a critical access hospital

requesting labor epidural analgesia. Stetler's model for research utilization was combined with the JHNEBP model and was the theoretical frameworks guiding this project.

Healthy laboring women with term singleton pregnancies who received epidural analgesia and met the inclusion criteria were included in the pre-intervention sample (n = 10). The sample size was determined using historical data on the number of newborn deliveries per year at the clinical site and the feasible duration of the project. Data from a convenience sample of 10 patients in the *before* group was collected and analyzed using descriptive statistics. All of the sample participants were White, non-Hispanic, and English speaking. The mean age of participants was 26 years old. Majority of participants were categorized as ASA physical status II, and 70% of the sample had comorbidities documented in their electronic medical record. The average gestational age was 39.6 weeks, with 50% of participants being primigravida. Participants in the *before* group consumed an average hourly ropivacaine equivalent of 23.4 mg with a median epidural pump infusion time of 225.5 minutes. Eighty percent of participants required PCEA boluses and the mean time to first PCEA use was 101.5 minutes after epidural placement. The mean maximum pain score following epidural placement was 2.9 on a 0-10 scale. The incidence of motor blockade defined as a Bromage score >1 was 37.5%; however, interpretation of these findings is cautioned due to the overall insufficiency of documentation of Bromage scores.

Collection and statistical analysis of post-implementation data of a convenience sample of 10 patients was originally planned following protocol implementation, but not completed due to the COVID-19 pandemic. Though project completion as originally planned was curtailed due to the COVID-19 pandemic, the multidisciplinary team achieved protocol finalization, pre-implementation data collection and analysis, development of a staff training plan, logistical

organization of epidural pump reprogramming, and plans for post-implementation data collection. The data collection procedure for the post-implementation group was originally planned to mirror that of the pre-implementation group, but not achieved due to inability to implement the protocol as a result of the COVID-19 pandemic.

Although the project execution did not unfold as originally planned, it did present an opportunity for dynamic evaluation of adherence to the clinical site's existing epidural policy. This allowed for refinement of staff training resources directed not only at PIEB protocol competency, but also at standards of care for patients with labor epidurals, including focused assessment and documentation requirements. The clinical site provides annual in-services for the nursing staff, during which one of the CRNAs lectures was to address a topic related to obstetric anesthesia. Package dissemination of the PIEB clinical practice protocol was anticipated with roll-out to include nursing staff in-service during the clinical site's annual training sessions and quick reference guides; however, the COVID-19 pandemic presented unforeseen barriers to implementation as staff furloughs impeded the delivery of staff education and training. For this reason, the clinical site made the decision to delay protocol implementation until a new plan for annual staff in-services could be developed by the clinical site's nursing education department.

Additionally, analysis of a short evaluation of staff understanding of educational materials to determine readiness for implementation was originally planned, but not completed due to the decision from the clinical site's administration to postpone the annual in-services for the nursing staff. Analysis comparing pre- and post-implementation data to determine clinical and statistical significance was also originally planned, but unable to be achieved due to the project being cut short by the COVID-19 pandemic. Process measures were to be evaluated to

determine degree of fidelity to the protocol following implementation in addition to evaluation of balancing measures to determine impact, but, again, not completed.

A dissemination plan for knowledge gained from this DNP scholarly project was to include a poster presentation at the clinical site displayed in the labor and delivery unit, but will instead be replaced by a poster presentation with project tasks completed to date and future steps. Consideration for collaborative engagement with hospital administration, nursing, and advanced practice providers/physicians will be forthcoming in the form of presentation of the DNP project outcomes at various staff meetings.

Limitations

There were several limitations to this project. During the planning stages of the scholarly project, a sample size of 10 was considered achievable within the project timeframe due to the clinical site's past annual newborn delivery rate. Upon commencement of data collection for the *before* group, it was determined that reaching a sample size of 10 was going to take longer than originally anticipated. It is postulated that seasonal fluctuations in the local birth rate may have been a factor.

Inadequate documentation in the electronic medical record was also a limitation to data collection. The clinical site had recently transitioned to a new electronic medical record system, and while data collection for the *before* group occurred after training and implementation of the new system, clinical documentation in the electronic medical record was scant compared to previous paper-based clinical documentation. It is likely that mastery of the functionality of the new electronic medical record system among the users had not yet occurred. Another consideration was that nursing staff were not familiar with the clinical site's existing labor epidural policy, which led to non-compliance with assessment and documentation requirements.

Critical access facilities face unique challenges and often lag behind in regard to the implementation of evidence-based practice. The barriers to research utilization in a rural setting were underestimated and presented limitations even in the first steps of the project plan. Assembling an integrative review team to develop a multidisciplinary clinical practice protocol was challenging due to lack of time, lack of availability, and lack of confidence in judging the quality of research. Stetler et al. (1998) advised that recruiting individuals knowledgeable about research utilization for the integrative review group permits translation of the research for the group in a user-friendly fashion, which, unfortunately, was not easily attainable in a small rural healthcare setting. Lack of time and other work commitments were often cited as reasons for not being able to fulfil the tasks of the integrative review process. An asynchronous schedule was utilized to allow members to review the available literature and develop recommendations. The integrative review process was largely unilateral due to a lack of engagement by the members of the group. This limited the multidisciplinary validity and applicability of the clinical practice protocol.

Lastly, the COVID-19 pandemic was a substantial limitation to this DNP scholarly project. While great strides were made to develop a PIEB clinical practice protocol and implement it in clinical practice, the actual implementation remained theoretical due to obstacles posed by the COVID-19 pandemic. The clinical site continues to work toward overcoming the setbacks resulting from the COVID-19 pandemic and is hopeful that 2021 is a year of rebuilding and growth. As of early 2021, the clinical site has no definitive plans on when they will be able to resume the annual nursing in-services, which is a determining factor for providing the necessary staff training for the clinical practice protocol.

Recommendations for Future Practice

Considering that this DNP scholarly project was cut short as a repercussion of the COVID-19 pandemic, the recommendations for future practice include completion of the objectives as originally projected. This would include translating the clinical practice protocol for PIEB into practice. Package dissemination remains appropriate with direct instrumental use in the form of protocol roll-out to include nursing staff in-service during the clinical site's annual training sessions upon their resumption and quick reference guides. This would include assessment of knowledge of the learning objectives.

Prior to implementation of the PIEB clinical practice protocol, reassessment of the resources and readiness of the clinical site may need to be conducted to ensure as smooth an implementation as possible. Following implementation of the PIEB clinical practice protocol, collection of data from the *after* group to include a convenience sample of at least 10 patients is recommended. Descriptive statistical analysis would mirror that of the *before* group analysis. At this point, inferential statistical analysis using the Mann-Whitney U test would be completed to compare outcome measures and maternal satisfaction scores between the pre- and post-implementation groups.

In situ evaluation of the practice change could then be carried out to include both formative and summative evaluation. Donabedian's (2005) model remains applicable in evaluating structure, process, outcome, and balancing measures for this scholarly project. The PICOT questions put forth could then be answered to determine the effectiveness of PIEB with PCEA settings for labor analgesia compared to CEI with PCEA on quality of analgesia, the incidence of motor blockade, and hourly and total local anesthetic utilization.

Reflections on Executing a Successful Doctor of Nursing Practice Project

The EC as PIE acronym (enhance, culmination, partnerships, implements, and evaluation) put forth by Waldrop and colleagues (2014) represents five criteria that must be met in order to display the rigor and excellence necessary to meet the outcomes of the AACN essentials and execute a successful DNP project. A reflection on how this DNP scholarly project met the EC as PIE criteria is outlined in the following section.

- E = *Enhance* health outcomes, practice outcomes, or health care policy. This DNP scholarly project involved evaluating a current practice for labor epidural analgesia in a critical access hospital. The project focused on enhancing labor analgesia outcomes by providing stakeholders with an evidence-based clinical practice protocol used to implement the practice change from CEI to PIEB for labor analgesia. Implementing clinical protocols in the provision of labor epidural analgesia has the potential to improve outcomes by helping practitioners provide the best evidence-based care to their patients.
- C = Reflect a *culmination* of practice inquiry. A culmination of practice inquiry was evidenced by both a focused and broad understanding of how to enact change in the clinical setting. An extensive literature review and synthesis was utilized to develop a multidisciplinary protocol for PIEB for labor analgesia. Theoretical frameworks, including the Stetler model for research utilization and the JHNEBP model, were used to evaluate the literature and use knowledge gained to effect change in the clinical setting.
- Partnerships = Require engagement in *partnerships*. Several key partnerships were evident during the execution of this DNP scholarly project. The project involved

recruitment of and coordination with key stakeholders to form an integrative review group in order to engage in meaningful discourse during the development of the clinical practice protocol. Additionally, a multidisciplinary team with stakeholders from diverse backgrounds was responsible for the development of staff education about the clinical practice protocol. Although collaborative partnerships were challenging to coordinate during this DNP project, their importance should not be discounted as change would not be possible without the involvement of the entire team in the process.

- I = *Implement/*apply/translate evidence into practice. Evidence was gathered through the literature review process and synthesized into practice recommendations. The recommendations were then disseminated to the integrative review committee for feedback and approval. A PIEB clinical practice protocol was developed to meet the needs of the target population, and a recommended translation plan was formulated.
- E = Requires *evaluation* of health care, practice, or policy outcomes. This DNP scholarly project included formative and summative evaluation as recommended by Stetler (2001). Structure and process measures as described by Donabedian (2005) were evaluated to determine the degree to which the clinical site's infrastructure and resources would support the project and how processes of care could be improved to support successful translation of the evidence into clinical practice. Summative evaluation of outcome and balancing measures has been proposed as a method of ongoing evaluation once the clinical practice protocol is implemented. Outcome measures specific to this DNP scholarly project examined the effect of implementing PIEB for labor analgesia on quality of analgesia, motor blockade, and local anesthetic

utilization compared to the current practice of CEI for labor analgesia. This involved data collection and analysis from the *before* group prior to implementation of the protocol. Balancing measures include tracking of untoward epidural complications and surveying of maternal satisfaction with a 5-point Likert scale questionnaire.

Summary

Delivery of PIEB is a novel modality for providing effective pain relief to laboring women. Up until recently, epidural pumps with advanced technology capable of PIEB dosing were not readily available. Fortunately, epidural pumps with these capabilities are becoming more widespread, and studies on optimal epidural solutions, dosing, and interval timing have garnered promising support in favor of PIEB settings. This DNP project sought to develop, implement, and evaluate an evidence-based clinical practice protocol for PIEB for labor analgesia in a critical access hospital. Due to obstacles encountered as a result of the COVID-19 pandemic, the project did not come to complete fruition as envisioned. Implementation and subsequent evaluation of the PIEB clinical practice protocol was not achieved.

Despite these obstacles, a multidisciplinary team was able to finalize an evidence-based clinical practice protocol for PIEB, collect and analyze pre-implementation data, develop a staff training plan, organize the logistical aspects of epidural pump reprogramming, and plan eventual protocol implementation and evaluation. Future recommendations include completion of the project as originally planned and continued organizational support for implementation of additional evidence-based practice improvement projects.

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APPENDIX A

INSTITUTIONAL REVIEW BOARD APPROVAL

UNIVERSITY OF
NORTHERN COLORADO

Institutional Review Board

DATE:	September 20, 2019
TO:	Laraine Klunder
FROM:	University of Northern Colorado (UNCO) IRB
PROJECT TITLE:	[1450823-1] Programmed Intermittent Epidural Bolus for Labor Analgesia in a Critical Access Hospital Doctor of Nursing Practice Scholarly Project
SUBMISSION TYPE:	New Project
ACTION:	NOT RESEARCH
DECISION DATE:	September 20, 2019
REVIEW TYPE:	Administrative Review

Thank you for your submission of New Project materials for this project. The University of Northern Colorado (UNCO) IRB has reviewed your submission and determined that the proposed activity does not meet the federal definition of research. Therefore, IRB oversight and approval is not required.

This determiniation applies only to the activities described in the IRBNet submission and does not apply should any changes be made. If changes are being considered and there are questions about whether IRB review is needed, please contact the IRB for a determination.

If you have any questions, please contact Nicole Morse at 970-351-1910 or nicole.morse@unco.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Northern Colorado (UNCO) IRB's records.

APPENDIX B

MATERNAL SATISFACTION SURVEY

United Hospital District
Maternal Satisfaction Survey

Please fill in the number that represents how you feel about your epidural experience.

The placement of the epidural was comfortable.

①	②	③	④	⑤
Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree

I felt <u>NO pain</u> from the time I had my epidural until I started pushing.

①	②	③	④	⑤
Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree

I felt <u>NO pain</u> when I was pushing.

①	②	③	④	⑤
Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree

The pain medication received throughout labor was enough.

①	②	③	④	⑤
Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree

The numbness in my legs bothered me.

①	②	③	④	⑤
Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree

The itchiness from the epidural medication bothered me.

①	②	③	④	⑤
Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree

The shivering from the epidural medication bothered me.

①	②	③	④	⑤
Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree

I could not push well due to the epidural medication.

①	②	③	④	⑤
Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree

Overall, my epidural worked well.

①	②	③	④	⑤
Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree

I would want to receive pain relief with an epidural again if I had another baby.

①	②	③	④	⑤
Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree

Comments: _____
_____
_____
_____
_____

Thank you for completing this survey. Your feedback will help us continue to provide exceptional care.

Adapted from Clivatti et al. (2013) Maternal Satisfaction Questionnaire.

APPENDIX C

INFORMED CONSENT FORM

5H

UHD

UNITED HOSPITAL DISTRICT

CONSENT FOR ANESTHESIA SERVICES

I acknowledge that my doctor has explained to me that I will have an operation, diagnostic or treatment procedure. My doctor has explained the risks of the procedure, advised me of alternative treatments and told me about the expected outcome and what could happen if my condition remains untreated. I also understand that anesthesia services are needed so that my doctor can perform the operation or procedure.

It has been explained to me that **all** forms of anesthesia involve some **risks** and no guarantees or promises can be made concerning the results of my procedure or treatment. Although rare, unexpected *severe complications* with anesthesia can occur and include the remote possibility of *infection, bleeding, drug reactions, loss of sensation, loss of limb function, paralysis, blindness, stroke, brain damage, memory loss, heart attack or death.* I understand that these risks apply to all forms of anesthesia and that additional or specific risks have been identified below as they may apply to a specific type of anesthesia. I understand that the type(s) of anesthesia service checked below will be used for my procedure and that the anesthetic technique to be used is determined by many factors including my physical condition, the type of procedure my doctor is to do, his or her preference, as well as my own desire. If has been explained to me that sometimes an anesthesia technique which involves the use of local anesthetics, with or without sedation, may not succeed completely and therefore another technique may have to be used including general anesthesia.

☐ General Anesthesia ☐ With airway ☐ Without airway	Expected Result	Total unconscious state, possible placement of a tube into the windpipe.
	Technique	Drug injected into the bloodstream, breathed into the lungs, or by other routes.
	Risks	Mouth or throat pain, hoarseness, injury to mouth or teeth, awareness under anesthesia, injury to blood vessels, aspiration, pneumonia.
☐ Spinal or Epidural Analgesia/ Anesthesia ☐ With sedation ☐ Without sedation	Expected Result	Temporary decreased or loss of feeling and/or movement to lower part of the body.
	Technique	Drug injected through a needle/catheter placed either directly into the spinal canal or immediately outside the spinal canal.
	Risks	Headache, backache, buzzing in the ears, convulsions, infection, persistent weakness numbness, residual pain, injury to blood vessels, "total spinal", nerve damage.
☐ Major / Minor Nerve Block ☐ Intravenous Regional Anesthesia ☐ With sedation ☐ Without sedation	Expected Result	Temporary loss of feeling and/or movement of a specific limb or area.
	Technique	Drug injected near nerves or into the veins of an arm or leg while using a tourniquet providing loss of sensation to the area of the operation.
	Risks	Infection, convulsions, weakness, persistent numbness, residual pain, injury to blood vessels, headache, pneumothorax, total spinal, nerve damage.
☐ Monitored Anesthesia Care	Expected Result	Reduced anxiety and pain, partial or total amnesia.
	Technique	Drug injected into the bloodstream, producing a semi-conscious state.
	Risks	An unconscious state, depressed breathing, injury to blood vessels.
☐ Spinal Opiate Injection for Control of Labor Pain	Expected Result	Dramatic decrease in labor pain.
	Technique	Drug injected through needle directly into spinal canal.
	Risks	Headache, nausea, vomiting, backache, urine retention, and itching.

I hereby consent to the anesthesia service checked above and authorize that it be administered by the Certified Registered Nurse Anesthetist at United Hospital District. I also consent to an alternative type of anesthesia, if necessary, as deemed appropriate by the CRNA. Any additional risks that have been discussed with me are listed below.

I certify and acknowledge that I have read this form or had it read to me, that I understand the risks, alternatives and expected results of the anesthesia service and that I have ample time to ask questions and to consider my decision.

_____ _____

Patient's Signature *Date and Time*

_____ _____

Signature of Patient's Legally Authorized Representative/Relationship *Date and Time*

_____ _____

Witness *Date and Time*

_____ _____

Signature of Person Providing Information *Date and Time*

United Hospital District, Blue Earth, MN
S-ANES Forms # 7857 (Rev. 2/16)

CON SUR

APPENDIX D

CLINICAL PRACTICE PROTOCOL

Clinical Practice Protocol for Programmed Intermittent Epidural Bolus (PIEB) for Labor Analgesia

Laraine Klunder, APRN, CRNA
Nurse Anesthetist, United Hospital District

INTRODUCTION

This protocol is intended for use by certified registered nurse anesthetists (CRNAs), obstetrical registered nurses (OB RNs), and obstetrical providers for healthy women, regardless of parity status, with singleton term pregnancy in active labor requesting epidural analgesia at United Hospital District (Blue Earth, Minnesota). Active labor includes spontaneous or induced labor during which contractions are regular and result in dilation of the cervix.

This protocol does not apply to women presenting in preterm labor (< 38 weeks' gestation), or those with multiple pregnancy, preeclampsia, gestational diabetes, intrauterine growth restriction, fetal birth defects or chromosomal abnormalities, known placental pathology, and/or poorly controlled systemic disease. Refer to UHD Epidural Policy on J drive.

The premise of the provision of epidural analgesia for labor is adequate pain relief while supporting maternal and neonatal outcomes. Programmed intermittent epidural bolus (PIEB) modality of analgesia has been shown to improve quality of analgesia, decrease local anesthetic consumption, minimize motor blockade, and improve maternal satisfaction compared to continuous epidural infusion (CEI) mode of delivery (Sng et al., 2018). Other potential benefits of a PIEB modality may include reduced cesarean delivery rate, reduced instrumental vaginal delivery rate, less provider rescue boluses, and shorter second stage of labor. This document provides a detailed description for use of PIEB modality for labor analgesia.

POLICY

The CRNA is responsible for placing and managing the epidural, which includes:

- Obtaining consent for epidural catheter placement and labor analgesia
- Inserting the epidural catheter
- Administering test dose and bolus injections
- Topping off catheters as needed
- Entering orders for nursing care

The OB RN* is responsible for maintaining the epidural infusion, which includes:

- Monitoring vital signs, fetal heart tones (FHTs), sensory block level, degree of motor block, and sedation level
- Monitoring for side effects
- Changing empty epidural infusion bags, with a co signature by another RN or CRNA required

- Stopping infusion for emergencies or after delivery
- Discontinuing epidural catheter with appropriate documentation after delivery

*The OB RN is required to complete competency for maintaining epidural infusions, including the infusion pump and removal of epidural catheters.

EQUIPMENT

- Sapphire epidural pump
- Epidural infusion bags premixed by Pharmacy or manufacturer
- Yellow epidural tubing

PROCEDURE/RESPONSIBILITES

I. ANESTHESIA PROVIDER
   A. The Department of Anesthesia assumes the responsibility for the epidural infusions and side effects, or complications associated with this technique. The CRNA will:
      1. Select appropriate patient based on relative and absolute contraindications as follows:
         a. Absolute contraindications to the placement of an epidural catheter include:
            - Patient refusal
            - Intrinsic coagulation disorder or pharmacologically anticoagulated
            - Active skin infection at the catheter insertion site
            - Increased intracranial pressure
         b. Relative contraindications to the placement of an epidural catheter include:
            - Pre-existing neurological disease
            - Allergies to local anesthetics and opioids
            - Hypovolemia
            - Central nervous system disease
            - Chronic low back pain
         c. Assess pharmacologic anticoagulation of the patient as this affects both the placement and removal of epidural catheters. Follow American Society of Regional Anesthesia (ASRA) guidelines.
      2. Obtain consent, including risks, benefits, and alternatives to treatment.
      3. Perform and document a pre-anesthesia evaluation, including pre-epidural pain score.
         a. Pain score will be assessed on a 0-10 scale as visual analog scale (VAS), visual numeric pain score (VNPS), or verbal rating scale (VRS)
      4. Participate in “Time Out” procedure.
      5. Insert epidural catheter.
         a. Epidural analgesia will be initiated with the patient in sitting position at the L3-4 or L4-5 interspace. The epidural space will be identified using loss of resistance to saline technique with a 17-gauge Tuohy epidural needle, bevel cephalad. A 20-gauge closed-end, multi-orifice epidural catheter will be inserted 3-5 cm into the epidural space.

6. Perform test dose to confirm placement in the epidural space.
    a. A test dose of 3 mL of 1.5% lidocaine with 1:200,000 epinephrine will be administered.
7. Administer loading dose to obtain appropriate sensory block.
    a. After verification of a negative test, an additional 2 mL of 1.5% lidocaine with 1:200,000 epinephrine and a loading dose of up to 10 mL of 0.1% ropivacaine with 2mcg/ml fentanyl will be administered.
    b. If bilateral sensory block at the T10 level is not achieved 30 minutes after the loading dose and the patient is still in pain, an additional 5 mL of 0.1% ropivacaine with 2mcg/ml fentanyl will be administered.
    c. If bilateral sensory block at the T10 level is not achieved after 45 minutes and the patient is still in pain, the epidural catheter will be re-sited, and the patient withdrawn from the protocol.
8. After loading dose, assess and document pain score, sensory level, and motor blockade in procedure note.
    a. Pain score is measured on a 0-10 scale as VAS, VNPS, or VRS
    b. Sensory level is measured by cold perception bilaterally with dermatome levels as follows:
        - S1: Back of calf
        - L1: Pelvic/iliac crest
        - T10: Umbilicus
        - T8: Lower ribs/between umbilicus and xyphoid process
        - T6: Xyphoid process
        - T4: Nipple line
    c. Motor blockade is measured using Bromage as follows:
        - 1 = Free movement of legs and feet
        - 2 = Just able to flex knees with free movement of feet
        - 3 = Unable to flex knees, but with free movement of feet
        - 4 = Unable to move legs or feet
9. Initiate the epidural infusion.
    a. Epidural infusion bag: 0.1% ropivacaine with 2mcg/ml fentanyl 100ml
    b. Pump settings will be as follows:
        QCore Medical Sapphire epidural infusion pump
        PIEB 10 mL every 40 minutes starting 30 minutes after loading dose
        PCEA 5 mL, lockout 15 minutes (max 4 PCEA boluses per hour)
10. Troubleshoot the epidural catheter for any possible complications (e.g., unsatisfactory sensory block, disconnected or leaking catheter)
    a. If the patient has breakthrough pain at any time during labor for which two consecutive PCEA doses within 30 minutes are ineffective, administer manual bolus as follows:
        - 0.2% ropivacaine in 5 ml incremental doses every 10 minutes (up to a maximum of 20ml) until analgesia is satisfactory.

- Fentanyl 50mcg if pain score greater than or equal to 3/10 after 10ml of 0.2% ropivacaine.
- If inadequate analgesia persists after 20ml of manual bolus and fentanyl 50mcg, it is considered failed epidural and the patient is excluded from the protocol. Epidural re-siting recommended with infusion per departmental policy.

11. Electronically enter order set UHD ANE OB PIEB FOR LABOR AND DELIVERY - CRNA.
12. Change epidural dressing as necessary.
13. In the event of cesarean section, epidural catheter may be used per anesthesia provider's clinical judgment.
14. Review and approve orders for anticoagulation when ordered by other providers when alerted by Pharmacy or Nursing for patients currently with epidural catheters or recently discontinued epidural catheters.
15. Enter an order as to when to initiate anticoagulant therapy after catheter removal.
16. Be immediately available via telephone for consultation.

II. OB PROVIDER
   A. May request consultation from the Anesthesia Department
   B. Manage continuing analgesia after discontinuation of epidural infusion.
   C. Permit nursing to implement orders from UHD ANE OB PIEB FOR LABOR AND DELIVERY – CRNA order set and contact CRNA with any questions regarding orders.

III. PHARMACY
   A. Review and provide the ordered epidural formulation of 0.1% ropivacaine with 2mcg/ml fentanyl.
   B. Verify that medications are preservative free.
   C. Verify that the patient has no recorded allergy to the ordered medications.
   D. Ensure that Intralipid and resuscitation drugs are available on each unit on which epidural infusions are infused.
   E. Alert the ordering, CRNA, and nursing when anticoagulant drugs are ordered for patients receiving epidural medications prior to dispensing anticoagulants.
   F. Verify the label on the epidural bag states "preservative free" and for "epidural use".

IV. NURSING
   A. Conduct a patient assessment prior to the procedure, including, but not limited to, history, vital signs, pain, FHTs, and labor progress.
   B. Obtain intravenous (IV) access and administer IV fluid bolus as directed by the CRNA.
   C. Retrieve epidural infusion bag and emergency OB tray from Pyxis to be at bedside.
   D. Assist the CRNA with placement of the epidural catheter as required, including witnessing consent and conducting "Time Out".
   E. Review and verify epidural pump settings, epidural medication in the bag to the drug ordered with another RN or independent practitioner in the following situations:

1. Initial programming of the pump
2. Changes in pump settings or medications as ordered by the CRNA
3. Replacement of empty epidural infusion bag with new epidural infusion bag.

F. Adhere to UHD ANE OB PIEB FOR LABOR AND DELIVERY – CRNA order set for management of breakthrough pain and side effects. Enforce strict bedrest and place Foley catheter as ordered.

G. Reinforce and document patient education in the electronic health record.
   1. Patient education is a shared responsibility between Nursing, Anesthesia, and OB provider. Topics include:
      a. Use of PCEA button. The family is educated that only the patient is allowed to push the button.
      b. Pain rating scale
      c. Bolus interval and safety parameters of PCEA
      d. Adverse side effects and what patient should report to RN
      e. Other interventions for pain control, both pharmacologic and nonpharmacologic.
      f. Patients are cautioned to be careful when turning and to wait for assistance while catheter is in place.
      g. Ambulation is not permitted during epidural analgesia.

H. Assessment and Monitoring
   1. Nursing will monitor vital signs, FHTs, tocodynametry, pain score, sensory level, and motor blockade.
      a. Vital signs will be assessed and documented as follows:
         - NIBP, HR, RR, and SpO_2 Q5min x3, Q15min x3, then hourly
      b. FHTs and tocodynametry will be assessed and documented per nursing policy.
      c. Pain score is measured on a 0-10 scale as VAS, VNPS, or VRS, and documented 30 minutes after loading dose, then hourly for duration of epidural analgesia.
      d. Sensory level is measured by cold perception bilaterally with dermatome levels, and documented Q5min x3, Q15min x3, then hourly for duration of epidural analgesia, as follows:
         - S1: Back of calf
         - L1: Pelvic/iliac crest
         - T10: Umbilicus
         - T8: Lower ribs/between umbilicus and xyphoid process
         - T6: Xyphoid process
         - T4: Nipple line
      e. Motor blockade is measured using Bromage, and documented 30 minutes after loading dose, then hourly for duration of epidural analgesia, as follows:
         - 1 = Free movement of legs and feet
         - 2 = Just able to flex knees with free movement of feet

- 3 = Unable to flex knees, but with free movement of feet
- 4 = Unable to move legs or feet

I. Documentation
1. The OB RN will document vital signs in the electronic health record (EHR) during placement of the epidural catheter, including NIBP and HR Q5min and continuous SpO_2. FHTs and tocodynametry will be documented per nursing policy.
2. Post-epidural documentation for the OB RN is outlined in bullet point H.1.
3. Additional OB RN documentation includes, but is not limited to:
    a. Co-signature with another RN or CRNA in the medication administration record (MAR) upon initiation of the epidural infusion verifying medication and pump settings match the order,
    b. Epidural catheter site assessment,
    c. Cumulative shift totals,
    d. Presence of side effects,
    e. Patient education, and
    f. Discontinuation of the epidural catheter upon delivery.
4. The CRNA will document a pre-procedure evaluation and procedure note in the EHR. The dot phrase .UHDLABORPIEB will be used in the procedure note.

J. Fluid, Catheter, and Dressing Change Issues
1. Epidural infusion bag is changed every 48 hours
2. Epidural pump tubing is changed every 72 hours
3. In the event of accidental disconnection of the epidural catheter from the connector, **DO NOT RECONNECT THE CATHETER**. Wrap the patient end in a sterile dressing and notify anesthesia provider.
4. Dressing changes are to be done by the anesthesia provider as needed. If the dressing is no longer intact, reinforce the edges with tape and notify the anesthesia provider.
5. Assess catheter insertion site every shift. Notify anesthesia provider of site pain, excessive back pain, redness, bleeding, edema, or drainage at catheter site.

K. Nursing Management for Side Effects and Complications
1. **In case of emergency, the RN will stop the infusion, call for help, and notify anesthesia immediately.** Emergencies include, but are not limited to:
    a. Cardiac or respiratory arrest, or RR < 10
    b. Decreased level of consciousness
        - If patient is somnolent or has minimal to no response to physical stimulation, administer naloxone 0.1mg IV push while awaiting physician and/or CRNA; may repeat every 5 minutes until adequate ventilation and alertness is achieved without significant pain.
    c. Signs of local anesthetic toxicity (e.g., confusion, tinnitus, circumoral tingling/numbness, blurred vision, dizziness, metallic taste, altered speech, or seizures)
    d. Sensory level above the T6 (xyphoid process)
    e. Excessive motor block of Bromage 3 or 4

f. Signs of epidural hematoma or abscess, such as new significant backache or new or increasing lower extremity weakness
g. Signs and symptoms of infection at the catheter site, such as fever, pain, warmth, drainage, or redness
h. Epidural catheter disconnection

2. **Conditions requiring notification of anesthesia provider**
   a. Inadequate pain relief after assessment by the OB RN to include:
      - Pain score
      - PCEA utilization (if patient has not been using PCEA, encourage use for 30 minutes prior to calling CRNA)
      - Consider repositioning patient
      - Assessment for bladder distension
      - Assessment of cervical dilation and progress of labor
   b. Unrelieved nausea and vomiting
   c. Unrelieved itching
   d. Decrease in SBP less than 90mmHg or drop of >20% of baseline SBP
      - Administer ephedrine or phenylephrine per UHD ANE OB PIEB FOR LABOR AND DELIVERY - CRNA order set
   e. Decreased level of consciousness or change in mental status
   f. Anticoagulation orders (except subcutaneous heparin, NSAIDS, or low dose aspirin **unless other anticoagulants or antiplatelets are also ordered**)

L. Discontinuation of the epidural catheter

1. Policy
   a. RNs must complete competency packet in order to become qualified to remove epidural catheters.
   b. There must be an order in the HER to remove epidural catheter.
   c. If there is any concern about safe epidural removal, the RN will notify the anesthesia provider.
2. Stopping the infusion
   a. The epidural infusion should be discontinued at the time of delivery unless extensive repair or other complication is anticipated.
   b. If a tubal ligation is planned, consult anesthesia provider for an order to retain or remove epidural catheter.
   c. To stop the infusion press STOP, then press OFF.
3. Removal of the epidural catheter
   a. Explain the procedure to the patient.
   b. Don nonsterile gloves.
   c. Assist the patient into a sitting or lateral position with the back flexed.
   d. Disconnect the epidural catheter from the infusion tubing.
   e. Remove the tape and sterile dressing from the patient's back starting at the shoulder.

f. Grasp the catheter at the skin and pull with a constant gentle pressure at a 90-degree angle to the skin. If any resistance if felt, STOP, place a sterile dressing over the site and call anesthesia provider immediately. **Never forcefully remove an epidural catheter.**
g. Assess the insertion site for bleeding, bruising, swelling, redness, or discharge.
h. Inspect the catheter to ensure the tip in intact.
i. Document catheter removal in the EHR, noting that the tip was intact upon removal.
j. Waste the remaining epidural medication per Pharmacy Medication Management Policy on J drive.
k. Clean the epidural pump per current infection control guidelines.