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Implementation of a Pre-procedural Ultrasound-based Neuraxial Navigation Device in Parturients at Risk for Difficult Lumbar Epidural Placement

LT Jeffrey Henderson, LCDR Paul Kuhn, LCDR Kathryn Miller

Uniformed Services University of the Health Sciences

Daniel K. Inouye Graduate School of Nursing

Naval Medical Center Portsmouth

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[redacted]

Registered Nurse Anesthesia Program
Daniel K. Inouye Graduate School of Nursing
Uniformed Services University
Bethesda, MD
Date: 30APR2021

[redacted]

Paul E. Kuhn, BSN, RN, LCDR, USN
Registered Nurse Anesthesia Program
Daniel K. Inouye Graduate School of Nursing
Uniformed Services University
Bethesda, MD
Date: 30APR2021

[redacted]

Kathryn A. Miller, BSN, RN, LCDR, USN
Registered Nurse Anesthesia Program
Daniel K. Inouye Graduate School of Nursing
Uniformed Services University
Bethesda, MD
Date: 30APR2021

Disclaimer Statement

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Abstract

Continuous labor epidural (CLE) analgesia provides the most effective peripartum pain relief (Chestnut et al., 2014). Difficult lumbar epidural placement (DLEP) is resultant when a CLE procedure requires multiple interspace attempts or prolonged procedure time, which is associated with increased patient discomfort, spinal hematoma, post-dural puncture headaches, and nerve trauma (Clark et al., 2015; Faitot et al., 2011). The purpose of this project was to determine if, in parturients that had characteristics that would place them at "high risk" for DLEP, the use of a neuraxial navigation device, specifically the Accuro (Rivanna Medical Inc.), decreased the number of attempts and procedure time for CLE placement.

With the Revised Iowa Model as a guide, we developed a 60-day pre- and post-implementation after performing three literature reviews to explore best practices to mitigate DLEP. In a pre-implementation phase, we deployed a screening questionnaire on the obstetric unit to gather data for baseline rates of DLEP at our facility. The post-implementation phase required a stepwise approach to include the same screening questionnaire coupled with the use of the Accuro device for all patients screened “high risk” or on any subsequent procedure following an initial failed placement.

Our results exhibit no significant difference between the pre- and post-implementation data, including screening compliance (58.4% versus 58.8%), the number of CLEs completed by staff (27.8% versus 26.8%) versus trainee (72.1% versus 76.6%), number of DLEPs (30% versus 30.6%), and the number of parturients that screened "high risk" (8% versus 6.2%). Ultimately, lack of provider compliance (30%) with our stepwise approach to parturients at “high risk” for DLEP led to decreased statistically and clinically significant outcomes. Our analysis did confirm that DLEP is, in fact, a problem that occurs consistent with the rate found in the literature.

Introduction

Analgesia is a priority for most parturients as they enter the active stage of labor. Among the many options, a continuous lumbar epidural (CLE) with an infusion of a long-acting local anesthetic is the most effective method of providing analgesia during the peripartum period (Chestnut et al., 2014). Successful epidural analgesia is predicated upon accurate placement of an indwelling catheter into the epidural space. Parturients can be predisposed to a challenging epidural placement due to tissue edema and weight gain associated with pregnancy; making palpation of the spine and landmark identification difficult (Sahin et al., 2014).

Ultrasonography has been demonstrated to improve first-attempt success in epidural cannulation compared to landmark palpation; however, ultrasonography requires extensive training and practice to be effective (Chin et al., 2018). The advent of emerging neuraxial navigation devices has provided the benefit of ultrasonography to novice ultrasonographers (Caponga et al., 2018). There was no standardized, evidence-based practice (EBP) in place at our MTF to either identify parturients at risk for difficult lumbar epidural placement (DLEP) or mitigate DLEP occurrence. Management of challenging epidural procedures would entail a standard palpation technique by the anesthesia provider with multiple interspace attempts or a change in the anesthesia provider performing the procedure. In the instance of multiple failed attempts, ultimately the procedure would be abandoned, and an inferior mode of analgesia implemented. Our project aimed to identify patients with risk factors associated with DLEP through a screening questionnaire to determine which parturients are at “high risk” and implement a neuraxial navigation device to assist anesthesia providers in the successful placement for those parturients’ CLE.

Problem Significance

The incidence of DLEP nationally is nebulous due to the inconsistency of definitions used throughout the literature; however, published rates have ranged from 7-30% (Clark et al., 2015; Guglielminotti et al. 2013). Historically our facility has averaged 230 deliveries a month, with 85% of parturients receiving neuraxial analgesia (Birkla et al., 2017). Our assigned Military Treatment Facility (MTF) has one of the busiest obstetric units in the Defense Health Agency (DHA) with a large number of parturients requesting neuraxial analgesia for labor (Health.mil, 2019). Multiple CLE placement attempts are associated with significant adverse outcomes such as increased spinal hematomas, post-dural puncture headaches, chronic low back pain, and nerve damage (Chia et al., 2016; Faitot et al., 2011). Furthermore, healthcare costs associated with treating a post-dural puncture headache include as much as $1,500.00 for an epidural blood patch and $1,209.00 daily for neurology inpatient services, if necessary, in the civilian sector (Dakka et al., 2011). While our MTF does not track for itemized billing for each patient, this project can impact inpatient budgeting for our facility. The results of this EBP, if clinically and statistically significant, could proceed to publication to assist other facilities, including civilian facilities, in reducing the financial burden associated with DLEP. The literature does not purport that anesthesia providers with less experience increase the risk for DLEP (Guglielminotti et al., 2013), but, notably, our MTF has an anesthesia department with 29% of staff providers having less than 5 years' experience and more than 40 anesthesia trainees per year.

Relevance to Military Nursing

The DHA has prioritized a medically ready force and ready medical force (Defense Health Agency [DHA], 2019). Mitigating DLEP and its associated adverse sequelae supports DHA's quadruple aims of better care, lower cost, better health, and improved readiness (DHA, 2019; Perna et al., 2017). The project provided an evidence-based solution for anesthesia providers to reinforce success with neuraxial placement in DLEP patients, which can decrease workload for medical and nursing staff caring for parturients that may suffer from complications of DLEP, including anesthesia services, inpatient neurology, and nursing staff. From identifying key characteristics associated with risk for DLEP, anesthesia providers will be better prepared to mitigate DLEP occurrence in neuraxial procedures in a deployed setting.

Military missions that routinely require anesthesia service include humanitarian and forward-based facilities of various echelons of care, supporting operations in times of both war and peace. For humanitarian missions, anesthesia providers may encounter patients including, but not limited to, parturients. Epidural analgesia may be preferred over general anesthesia in certain circumstances in the forward-deployed, resource-constrained environment. A preference for epidural analgesia is related to the ease of mobilizing and transporting patients with less monitoring or eliminating a need for a critical care transport team. Patients transported under general anesthesia necessitate a significant amount of medical assets and specialized equipment for air, sea, or land transportation. These options are most useful in pain control for abdominal and lower extremity injuries often encountered in forward-deployed settings.

Our project also focuses on the DHA's prioritization of better care. Women constitute 20% of the officer and enlisted active-duty component of the United States Navy, with as much as 80% of those women of child-bearing age ranging from 17-44 years old (Council on Foreign Relations, 2020). Chia et al. (2016) attribute chronic low back pain to epidural hematomas that develop during a CLE procedure; it can be inferred that the risk of hematoma increases with multiple procedural interspace attempts. Adverse outcomes associated with traumatic epidural placements could potentially extend the timeline for female service members' return to full duty status. This project prepares anesthesia providers with the tactile sensation of CLE procedures that are difficult, whether in the hospital setting or deployed. By providing better care to our active duty female parturients, we can reduce the incidence of limited duty status from chronic issues that arise from an increased number of attempts during a CLE procedure.

Clinical Question

In parturients that screen high risk for difficult lumbar epidural placement, does the implementation of an ultrasound-based neuraxial navigation device, compared to standard palpation technique reduce the number of attempts and time required for successful placement over a 60-day period?

Literature Review of Solution

Ultrasound Literature Synthesis

Our initial literature search focused on an evidence-based solution to mitigate DLEP. Pre-procedural ultrasonography was the adjunct with the most salient evidence for success (Guglielminotti et al., 2013, Sahin et al., 2014). We refined our search to articles espousing the use of preprocedural US for neuraxial anesthesia. We searched PUBMED and CINAHL databases dating back 10 years from 2018 for English full-text articles and used the following search terms: “obstetric” and “analgesia” and “epidural” and “ultrasonography” and “obstetrics” and “intrapartum” and “parturient” and “epidural catheters” and “spinals” and “combination” and “US intervention.” The search yielded 39 total articles, with four duplicates excluded from the CINAHL database. We appraised 35 articles with 30 articles excluded for the following reasons: study not an RCT (N=7), experimental device not available on the market (n=3), did not include parturients (n =6), and intervention other than preprocedural ultrasound (n=14). Our PRISMA and Evidence Table are attached as Figure 1 appraising 1A-3B articles. The literature review suggested using the pre-procedural US to guide epidural catheter placement to increase successful procedures, by doing so there were a decreased number of interspace attempts, as well as decreased procedure time for CLEs. While the use of an ultrasound adjunct may raise concerns about prolonged procedural time, Tubinis et al. (2019) specifically support that it reduces procedure time by 32% when managing obese parturients.

Our project was completed on a robust obstetric unit at a large MTF. The training environment, frequent staff turnover, and the obstetric unit workload volume made implementing pre-procedural US for all parturients requesting CLE not ideal, especially considering our goal to maximize anesthesia provider workload efficiency.

DLEP Literature Synthesis

The main focus of the follow-up literature review was to identify risk factors associated with DLEP and/or a tool to evaluate for risk, with a secondary focus on determining a standardized definition for DLEP. The definition of a difficult epidural was not consistent in the literature, although a compilation of articles found similar DLEP attributes. We searched PUBMED and CINAHL databases, dating back 10 years from 2018 for English full-text articles, and used the following search terms: "obstetric" and/or "analgesia" and/or "epidural" and/or "difficult placement" and/or "insertion" or "screening tool." This literature search produced a total of 55 articles. We used the following exclusion criteria: studies were not an RCT (n=7), did not define what constitutes a “difficult” epidural (n=15), did not include parturients (n=7), did not define risk factors associated with difficult epidural placement (n=10), which narrowed the results to five articles. After screening abstracts and removing duplicates, we compiled five articles for inclusion. The PRISMA Diagram and Evidence table appraising 1A-2B articles are included in Figure 2.

Lumbar epidural placement is most commonly considered difficult when the time of procedure is prolonged, or the procedure requires multiple attempts. However, inconsistencies throughout the literature compelled our group to composite our working definition based on the most common evidence from multiple articles (Clark et al., 2015; Vallejo et al., 2017). Our definition of DLEP includes any procedure that requires more than one attempt or a procedure time greater than 15 minutes.

We then extracted the most commonly cited patient characteristics that place parturients at risk for DLEP. According to Guglielminotti et al. (2013), characteristics that make for a difficult epidural placement are the inability for the parturient to flex their back for optimal procedural positioning, difficulty or inability to palpate bony spinous processes, spinal deformity by history or objectively determined by the anesthesia provider, obesity, and novice providers, including anesthesia trainees. Several articles supported these characteristics as predictive of DLEP (Ellinas et al., 2009; Faitot et al., 2011).

Difficult Bony Landmark Palpation and Poor Back Flexion.

Difficult bony landmark palpation was the most significant risk factor for DLEP (Guglielminotti et al., 2013; Ellinas et al., 2009). The ability to palpate bony landmarks was scored in the literature to allocate patients with visible spinous processes to patients that had spinous processes that were neither visible nor palpable (Guglielminotti et al., 2013, Faitot et al., 2012). Difficult bony landmark palpation carried twice the odds of causing DLEP compared to spinal deformity and poor back flexion (Guglielminotti et al., 2013).

Obesity.

According to Tubinis et al. (2019) the United States has an obesity rate among parturients as high as 31.9%. Ellinas et al. (2009) purported that obese body mass index (BMI) was correlated with reduced spinal flexion and difficulty palpating bony landmarks. A standardized definition of obesity in the parturient population did not exist across the articles our team reviewed. The American College of Obstetricians and Gynecologists (2015) recommends measuring pre-pregnancy height and weight for parturient BMI determination. Tubinis et al. (2019) found that BMI greater than 30 kg/m2 was considered obese and associated with technically difficult epidural placement, which led to a difficult epidural rate as high as 42% (Tubinis et al., 2019). Multiple sources concur that there is a high correlation between increased BMI, difficult landmark palpation, and DLEP (Ellinas et al., 2009, Guglielminotti, et al., 2013). Guglielminotti et al. (2013) ultimately recommended eliminating obesity as part of their final recommended screening questionnaire because they found that the overwhelming majority of those parturients would be captured by assessing difficult landmark palpation. Obesity can distort the palpable landmarks the anesthesia providers assess before epidural placement; research supports that non-obese parturients require fewer needle redirections and insertions during epidural placement when pre-procedural ultrasound is utilized (Chin et al., 2018, Tubinis et al., 2019).

Spinal Deformity.

While multiple articles included in our literature syntheses excluded patients with spinal deformities, the studies that included these parturients determined that an alteration in the spine's normal curvature attributed to a higher risk of DLEP (Guglielminotti et al., 2013). Spinal deformities were determined either by patient history or physical assessment by the anesthesia provider before an epidural placement. Faitot et al. (2012) found spinal deformity was the most significant predictor of DLEP and was associated with increased attempts.

Novice Providers.

The definition for novice providers is not synonymous in the literature with an absolute number of epidural placements required for competence (Faitot et al., 2010, Guglielminotti et al., 2013, Kula et al., 2017). Guglielminotti et al. (2013) hypothesized that novice providers would account for an increased risk of DLEP. They defined a novice provider as one with less than 100 epidural placements. Post-analysis of the impact of this risk factor found it was insignificant and it was ultimately removed from the screening tool.

Only one current article developed a risk assessment scoring system to attempt to identify parturients at risk for DLEP (Guglielminotti et al., 2013). Guglielminotti et al. (2013) included difficult landmark palpation, spinal deformity, and inability to flex back as the final parameters to be included in their risk assessment questionnaire. The article assigned 2 points for difficulty in palpating bony landmarks, one point for poor back flexion, and one point for spinal deformity. Furthermore, the article assigned a percentage for DLEP based on the total score; low risk was zero points resulted in less than 10%, intermediate risk 1-2 points more than 25%, and high risk 3-4 points resulting in greater than 60% for DLEP. Duplication of these results has not been attempted. Our group decided to incorporate the Guglielminotti questionnaire risk factors into our screening questionnaire (Figure 4).

Hand-held Neuraxial Navigation Device Literature Synthesis

During our initial literature reviews, we came across several articles that introduced an alternative to standard console ultrasound equipment. Primarily within studies by Vallejo et al. (2010) and Guglielminotti et al. (2013), an experienced anesthesia ultrasonographer was utilized to perform the preprocedural US and reported the depths to the provider placing the epidural (Vallejo et al., 2010). With the presence of over 50 anesthesia trainees over a year, there is varying education given on the utilization of a console ultrasound for spinal anatomy. This extends to our population of anesthesia staff with 29% having less than five years' experience in anesthesia practice with little to no training in pre-procedural ultrasound for neuraxial placement. Tubinis et al. (2019) and Arzola et al. (2015) found that novice providers that had to perform ultrasound guidance themselves required more time to place epidural catheters, as well as had longer procedure times; increased anesthesia workload is contradictory to the goals of this project. Implementing a hand-held spinal navigation device could improve provider compliance and overcome the challenges associated with standard US.

We searched PUBMED and CINAHL, dating back 10 years from 2018 for English full-text articles, to ensure that its performance was equal to that of the known evidence-based practice of standard ultrasound. We used the following search terms: "hand-held ultrasound," "neuraxial." The search yielded six articles with one duplicate excluded from the CINHAL database. We appraised five articles, all with a level of evidence 2B, with one excluded for the following reason: not commercially available technology (n=1). The PRISMA and Evidence table are attached as Figure 3.

Rivanna Medical's Accuro device is a low-profile, hand-held device that uses three-dimensional spinal ultrasound navigational software to give anesthesia providers exact dimensions and visualization of the spinal anatomy (Rivanna Medical, 2019). This device is lightweight, battery-powered, and has a user-friendly interface to assist with depth analysis to the epidural space. It is successfully utilized by novice providers without extensive ultrasonography experience (Seligman, Weiniger, & Carvalho, 2018). Capogna et al. (2018) found that novice providers had the same measured depths as expert providers in both sitting and lateral positions at any intervertebral level. Our proposed solution to close the gap from evidence to clinical implementation of preprocedural US is by using this neuraxial navigation device. Seligman et al. (2018) found an 87% first-pass success rate with the Accuro. Seligman also found comparable results between the Accuro ultrasound and console ultrasound for determining depth from skin to epidural space. Both Accuro and console ultrasound consistently underestimated depth measurements, which provided a potential margin of safety (Tiouririne et al., 2017).

The accuracy of the Accuro has provided greater first-pass success, reduced needle insertions, and decreased needle passes (Singla et al., 2019). The Accuro demonstrated a 26% increase in first-pass success compared to standard palpation techniques. Singla et al. (2019) also found that novice practitioners following didactic and psychomotor training could successfully obtain neuraxial ultrasounds to guide procedures. We synthesized from the review of literature that the Accuro provided comparable epidural depth predictability, had a high first-pass success rate and was a viable tool to assist in mitigating DLEP.

Focus Areas

Our two major areas of focus were identifying patients with risk factors associated with DLEP and implementing the Accuro device on patients identified as high- risk for DLEP.

Organizing Framework

The Revised Iowa Model for Evidence-Based Practice provided the most appropriate organizing framework for developing our project (Figure 4). The Iowa Model provided organization for our project to include; identifying a clinical trigger, developing a clinical question, reviewing the literature, designing a process improvement project, implementing the project on the labor unit, analyze data, and disseminate results (Buckwalter et al., 2017). The problem-focused trigger associated with our project was an anecdotal increase in the rate of difficult epidurals in the previous year at this MTF by staff anesthesia providers, as evidenced by an increase in non-functioning epidurals that required subsequent placements, as well as increases in inadvertent dural punctures and post-dural puncture headaches.

After identifying the trigger and developing our clinical question, we built a team consisting of ourselves, our academic and clinical faculty advisors, and stakeholders within the Anesthesia Department and Labor and Delivery unit to help design this project. The available literature was critiqued and an evidence-based intervention was synthesized as previously discussed. Our project was designed as a pre- and post-implementation process improvement project and we secured an exemption for “not-human research” from our organization's institutional review board. Our implementation consisted of two 60-day periods to include a pre-implementation phase including screening with the risk questionnaire and a post-implementation phase including screening and our proposed intervention, the Accuro. We evaluated and monitored DLEP outcomes and disseminated the results to key stakeholders. Our organizing framework provided an effective strategy to identify and address our clinical question using EBP.

Project Design

General Approach

We developed a pre- and post-implementation process improvement project for anesthesia providers that evaluated processes for identifying characteristics associated with DLEP. Our timeline for our project is presented in Figure 5. In the post-implementation period, we provided the Accuro for anesthesia providers to utilize for parturients that screened "high risk" on the screening questionnaire. Our objective was to identify "high-risk" parturients via a modified evidence-based risk assessment questionnaire then implement an ultrasound-based neuraxial navigation device, the Accuro (Rivanna Medical Inc.), to decrease the incidence of DLEP in this patient population.

Setting and Population

The setting of our project was a large, east-coast academic military treatment facility (MTF) with 202 inpatient beds and 22 operating rooms. This MTF provides care for 180,000 beneficiaries and the obstetrical unit delivers roughly 230 babies per month (Health.mil, 2019). The average age of parturients, nationally, is between 20-24 years old (Stahlman et al., 2016) and over 90% of these deliveries request the consultation of anesthesia services (Birkla, Loran, and Phipps, 2017). The staff anesthesia providers are comprised of 35 physician anesthesiologists and 30 certified registered nurse anesthetists (CRNA). In addition to staff anesthesia providers, there is a residency training program that has 30 anesthesiology residents, as well as over 50 student registered nurse anesthetists (SRNA) from several school of nursing nurse anesthesia programs over a year. The typical day shift obstetrical unit anesthesia staffing is comprised of two anesthesia teams: one physician anesthesiologist and resident team and one CRNA and SRNA team to provide care for four triage rooms, 10 labor rooms, four complicated obstetric rooms, and three operating rooms. An evening shift comprises a primary obstetric team that includes one staff anesthesia provider, accompanied by one anesthesia trainee. There also is an additional anesthesia staff provider within the MTF if the need for simultaneous anesthesia services arises on the obstetric.

Procedural Steps

The timeline for our project is displayed in Figure 5. The pre-implementation phase of our project began by creating our DLEP Screening Questionnaire (Appendix E). We adapted the screening tool from Guglielminotti et al. to include the subjective and objective assessment for each of the following physical characteristics of a parturient and answer “yes” or “no” for each: the difficulty in palpation of a parturient’s lumbar spine, the inability of the parturient to flex her back and the presence or history of a spinal deformity. Each “yes” on the scoring tool was associated with a numerical score. Difficult lumbar palpation was associated with two points as it was the most significant determinant of DLEP (Guglielminotti et al., 2013). The inability to flex back and spinal deformity was associated with one point each. The summative score that determined “high risk” for DLEP was three points or higher. Also included on the screening tool for each parturient was the time of localization, and the test dose time of the procedure, indicating the start and stop times of the procedure respectively. We also elicited the date, time, and location, or obstetric patient room, of each procedure, the total number of attempts, which type of provider, staff versus trainee, conducted each attempt, and years of experience for staff providers.

During the post-implementation phase, we also requested information for each attempt regarding if the Accuro device was used and if the anesthesia staff or trainee had received the Accuro training discussed later in this section. We collected no personal identifiable information (PII) within this screening questionnaire. We used the date, time, and location of the procedure to review electronic health records and monitor overall compliance; comparing how many CLE procedures were conducted vice how many screening questionnaires were collected.

Next, we conducted in-person educational instruction for the anesthesia department to introduce our project, discuss the key steps of the project that would require provider participation on the obstetric unit. We also provided a PowerPoint presentation to the Labor & Delivery nursing staff to introduce the project and discuss expectations for the nurses involved in epidural procedures. We ensured reinforcement of essential data points such as “time out” which was to refer to the time of localization and test dose time as procedure completion time, which would aid in our measurement in the length of the procedure. We further defined an “attempt” as any new puncture of the skin after the initial insertion or when a new provider, whether staff or trainee, assumed control of the Tuohy needle. CLE procedure time was measured from the time of pre-procedural time-out to the time of test dose administration. This was an effort to standardize the front end of our procedure time to adjust for inter-provider variance.

Between July 2020 and September 2020 we conducted the pre-implementation phase, deploying our screening questionnaire for all laboring patients at assigned MTF requesting epidural analgesia (Appendix E). We standardized screening questionnaire form location to clipboards that were coupled with blank admission forms for each labor room. Members of our group were made available to the obstetric unit anesthesia providers at the start of most shifts, to engage the anesthesia providers assigned to the obstetric unit for the day and encourage participation while addressing any questions or concerns. For each epidural requested on the obstetric unit, the anesthesia provider, whether staff or trainee, was expected to conduct the screening before the CLE attempt. Screening questionnaires were collected from the obstetric unit folder at least weekly. At the end of the 60 days, data was transcribed from the paper forms to an electronic spreadsheet in a format designed by the MTF biostatistician. Due to low provider compliance with our project process during the pre-implementation phase, our group met with department leadership, and an email was sent to all providers in the department to reiterate our project goals and encourage participation.

The post-implementation phase of our project began with an in-person education instruction on the use of the Accuro device provided by a sales representative of Rivanna Medical Inc. As part of the agreement associated with the “Train Accuro” program through which we procured two Accuro devices, Rivanna Medical required that providers completed the full orientation and training program which consisted of the in-person lecture, five hands-on live model scans with the device, and completed an online video and quiz. In fulfillment of this requirement, a Rivanna Medical representative spent one eight-hour workday presenting a PowerPoint introducing the Accuro and provided the opportunity for hands-on training every hour, while anesthesia providers and trainees were provided the opportunity to attend the training. Staff anesthesia providers and trainees that were not able to attend this training were presented the same PowerPoint presentation by a member of our group and were instructed on five live model scans for familiarization. We provided education to a total of 30 staff anesthesiologists, 30 CRNAs, 15 resident anesthesiologists, and 14 SRNAs. While these numbers do not reflect our entire anesthesia department, they do encompass the primary providers on the obstetric unit during our project.

The post-implementation phase took place from October 2020 to December 2020. During the post-implementation period, anesthesia providers were to complete the screening questionnaire assessment before each CLE attempt (Appendix E). If the parturient screened "high risk" for DLEP, or a calculated three or more points, the provider was instructed to use the Accuro device on the initial attempt. We also endorsed the Accuro use after a failed attempt at CLE, regardless if the parturient was initially screened at "high-risk." Questionnaires were collected and transcribed to electronic format as in the pre-implementation phase.

Project Results

Provider Type, DLEP, and "High-Risk" Status

There was an identical 58% compliance rate for completing the screening questionnaire in both the pre- and post-implementation phases of the project (p=0.94). Pre- and post-implementation phases were also similar in provider type, the incidence of DLEP, and the number of parturients screened as "high risk." Staff anesthesia providers completed 26.6% and 27.8% of CLE procedures, while trainees completed 68.9% and 72.1% of the total CLE procedures in the pre- and post-implementation phases, respectively. There was no significant difference in provider type between the two groups (p>0.99). Of the CLE procedures that met our criteria for DLEP, 76.6%, and 82.4% were completed by trainees in the pre- and post-implementation phases respectively; with no significant difference between groups. (p=0.67). In the pre-implementation phase, 68 procedures, or 30%, met DLEP criteria, while the post-implementation phase had 64 DLEPs, which accounted for 30.6% of procedures. Again, there was no significant difference between groups related to the number of DLEPs. (p=0.91).

For our screening questionnaire, 8.4% and 6.2%, of parturients screened scored “high-risk” in the pre- and post-implementation phases, respectively (p=0.46). Of all procedures, when the parturient was deemed not “high risk” per the scoring tool, 94.7% of the time the CLE was not difficult for the anesthesia provider, regardless of staff or trainee. When parturients were screened “high risk” per our scoring tool, 11.9% of the CLE procedures were difficult by our definition (p=0.17). This provided data for our group to evaluate the sensitivity (12.12%) and specificity (94.7%) of our DLEP questionnaire.

Post-Implementation Data

Following the implementation of the Accuro, 13 patients were screened as “high-risk” for difficult epidural placement. The Accuro was only utilized on 4 of these 13 patients as the first attempt for CLE, resulting in a 30.7% compliance with our project. One procedure was aborted following multiple attempts with and without the Accuro device and was considered an outlier and ultimately not included in our data analysis. When the Accuro device was utilized for a “high risk” patient as the first attempt, the Accuro provided a 75% first-attempt success rate (3/4). The Accuro device was used for a second attempt on two parturients that screened “high risk.” In both of these attempts, the epidural placement was successful on the first subsequent attempt utilizing the Accuro. The single unsuccessful attempt utilizing the Accuro was successfully placed on the second attempt using the Accuro device. The overall rate for first-pass successful placement utilizing the Accuro device, regardless of whether the parturient was “high risk” or not, was 73.9% (p=0.56).

By comparison, only 50% of the initial placement attempts were successful when not utilizing the Accuro device in parturients who screen “high-risk” for DLEP. Of the four misses in this group, two were successfully placed with one subsequent attempt without the Accuro device and two were ultimately successfully placed on subsequent attempts with the use of the Accuro device. There was no significant difference in the first attempt success rate or overall success rate following the implementation of the Accuro device.

Analysis of the Results

Our primary outcome for this project was to elicit a reduction in the number of attempts and time required for the successful placement of a CLE, which were the two most commonly cited determinants of a difficult placement. Among “high-risk” parturients, we sought to reduce these outcomes through the implementation of the Accuro device. Primarily, Fisher Exact statistical analysis was conducted on the pre- and post-implementation groups for screening compliance ($p=0.94$), number of “high risk” parturients ($p=0.46$), number of DLEP procedures ($p=0.92$), and provider type, whether staff or trainee ($p=0.99$). We identified from the pre and post-implementation data that the local DLEP rate was an average of 30.3% ($p=0.92$). This rate correlated with previously published literature on the scoring tool. Mann-Whitney tests were used to evaluate the primary outcomes in the pre-and post-implementation phases. This included a comparison of the 60 days periods’ procedure time regardless of whether “high risk” or Accuro use in the post-implementation phase, as well as a comparison of procedure time and the number of attempts for “high risk” parturients among the two phases. The average total procedure time for each CLE was 10.8 minutes in the pre-implementation phase with a standard deviation of 0.5 minutes, while in the post-implementation phase the average total procedure time was 10.57 minutes with a standard deviation of 0.78minutes ($p=0.039$); this data is statistically significant but not clinically significant. When the procedure was considered difficult or met the criteria for DLEP, the average time for each attempt increased to 10.8 and 10.23 minutes, in the pre- and post-implementation phases respectively (p=0.289). The total procedure time for these DLEPs was increased to an average of 19.5 and 20.38 minutes in the pre- and post-implementation phases, respectively (p=0.498).

To answer our PICOT to the best of our ability with insufficient data, we found that among "high risk" parturients, there was no significant difference in the number of attempts or procedure time in the pre- and post-implementation phases. Both groups had an average of one attempt (p=0.704). For procedure time in those parturients that screened "high risk," there was no significant difference noted. In the pre-implementation phase, the average CLE procedure required 7.14 minutes in a "high risk" parturient. In the post-implementation phase, with the availability of the Accuro device, the average CLE procedure for a "high risk" parturient required 6.29 minutes (p=0.205). Accuro-specific results could not be evaluated to determine significance, such as if the device specifically decreased the average procedure time or decreased the time of one attempt when utilized; we have identified that low screening compliance, low Accuro utilization, as well as no documented measurement of time for each attempt, could have attributed to the inability to capture statistically significant results. Given that the Accuro had a 75% first-pass success rate in the four parturients it was utilized for, we conclude that future investigations into this evidence-based intervention are necessary to determine whether a difference could be appreciated across our entire parturient population. The success of those future projects would depend greatly on leadership buy-in and provider compliance.

There is no clinically significant data to imply our EBP project decreased the number of attempts or time of the procedure with our interventions. However, the Accuro device did have an impressive performance with a 75% first-time success rate in the four parturients for which it was properly implemented. We would be very interested to see if this performance could be sustained or improved over a larger population with greater provider compliance.

Barriers

Following data analysis, we identified the major barrier to the successful implementation of this project was low provider compliance in both screening patients for DLEP risk status and intervening with the Accuro device on initial attempts when patients do screen “high-risk.” Following the pre-implementation phase data analysis, and upon recognizing low screening compliance, we conferred with department leadership, who encouraged staff to participate fully in our project process. These efforts did not affect the compliance rate after steps to improve compliance was still less than 60% of epidural procedures.

Another barrier that we encountered during the project was difficulty with influencing staff to implement the Accuro in patients that screened “high-risk” for DLEP or requiring more than one attempt for epidural cannulation. In the post-implementation phase, 6.2% of parturients screened as “high-risk;” however, anesthesia providers only used the Accuro in 33.3% of the parturients that screened “high-risk.” A concern was raised by graduate medical education faculty that anesthesia trainees utilizing the Accuro device to mitigate DLEP are not ideal when the device would not be accessible once they are in practice. They expressed concern that this may inhibit the development of palpation skills commonly used to overcome difficult placements. Additionally, it was suggested that military trainees should be educated and encouraged to use standard console ultrasound in the event of difficult neuraxial placements. Members of our group addressed these concerns with both the program directors and department leadership. Arguments were made that trainees were still able to and actually instructed to palpate for landmarks to guide the location of needle insertion, but that the use of the Accuro would simply provide confirmation of their site selection. It was also suggested that the ease of use, relatively low cost, and low profile of the Accuro device may make it a good substitution for standard console US and that forward-deployed military anesthesia providers may soon be seeing these devices if projects like ours are successful in exhibiting their usefulness.

Organizational Impact/ Implications to Practice & Policy

Despite poor compliance and insignificant findings related to our proposed evidence-based intervention, we did identify that an average of 7% of our parturient population in both phases were identified as being at high risk for DLEP, and 30% of the epidural procedures documented through our data collection met the definition of DLEP. We can extrapolate our results to infer that for the duration of our project, there would have been 742 parturients screened. Fifty-five parturients would have screened high risk, and potentially 225 parturients would have a DLEP. If the stepwise approach and use of Accuro were completed, we can apply the 73.9% first-attempt success rate to assume we would have mitigated approximately 40 DLEPs. This could be expressed as a cost savings of up to $60,000 to the MTF with the prevention of an inadvertent dural puncture. The emerging trend toward delivering evidence-based healthcare and improving outcomes trending toward a high-reliability organization warranted the need to re-evaluate evidence for mitigating DLEP and instituting it at the point of care. A low-profile, low-cost, easy-to-use device that potentially decreases the time needed for insertion, would produce cost savings for supplies needed for repeat procedures and the adverse outcomes associated with difficult epidural placements. This device may have a place in military medicine where these procedures need to be conducted quickly and in austere environments where time and supplies may be a limitation.

Future Directions for Research and Practice

We have suggestions for future researchers to externally validate the Guglielminotti screening questionnaire; the screening tool has internal validation from the Guglielminotti, et al. initial research, but external validation will strengthen the advocacy for its use (2013). For future EBP projects similar to this, a more stringent focus on provider compliance would be necessary to ensure day-to-day compliance with the process. Identifying champions for your project above and beyond members of your group would be highly recommended. Future research projects may consider looking at additional studies to compare the performance of Accuro with standard US consoles.

Conclusion

This project's primary aim was to assess the effectiveness of implementing a pre-procedural ultrasound-based neuraxial navigation device in mitigating difficult lumbar epidural placements in parturients who screen at high risk for difficult placement. Due to low provider compliance with our implementation process, our results indicate no significant difference in the incidence of DLEP following our implementation. Our results were not statistically significant; however, we could gather baseline information on DLEP prevalence, providing valuable data for future EBP projects at our assigned MTF. The project determined a 30% DLEP rate, which correlated with published literature (Guglielminotti et al., 2013), and the few times the Accuro was used, it had a 75% first-time success rate. Anesthesia providers gained valuable knowledge with risk stratifying parturients for epidural placement and exposed trainees to pre-procedural ultrasonography. Since our project ended, we have had multiple anesthesia providers request and utilize the Accuro device to successfully place epidurals in patients with factors associated with difficult placements.

HIPAA Concerns

Our team did not identify or utilize any Health Insurance Portability and Accountability Act (HIPPA) protected information. The project did not collect or retain any personally identifiable information (PII) from anesthesia providers or patients during the project. Project information was stored on a common access card-protected network with a password-protected shared drive available only to the project team. Electronic Health Records were accessed utilizing the date, time, and location of the procedure and only to elicit data that was left off of the paper screening tool. No patient information was documented or saved during this process. Only members of our group, who have password-protected access to the MTF EHR accessed these records.

Our project design was a process improvement project that did not involve human subjects research on anesthesia staff or patients. We obtained institutional review board exemption before training staff, implementing screening questionnaires, or implementing the Accuro. We adhered to HIPPA regulations and did not collect nor divulge any PII during this process improvement project.

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Appendixes

Appendix A: CITI Certificates


CITI PROGRAM

Completion Date 26-Aug-2018
Expiration Date 25-Aug-2021
Record ID 28312791

This is to certify that:

Paul Kuhn

Has completed the following CITI Program course:

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

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?wf192e0f3-ef92-4759-befe-672ac29ee4fd-28312791


CITI PROGRAM

Completion Date 25-Aug-2018
Expiration Date 24-Aug-2021
Record ID 28289219

This is to certify that:

Kathryn Miller

Has completed the following CITI Program course:

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

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w689f5405-733f-4ee0-93f9-be7dddf06ca5-28289219


CITI PROGRAM

Completion Date 25-Aug-2018
Expiration Date 24-Aug-2021
Record ID 28310878

This is to certify that:

jeffrey henderson

Has completed the following CITI Program course:

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

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?wc5b7c15d-0b1d-4a64-be09-ff1a2492647a-28310878

Appendix B: USU (VPR) Form 3202N

USU
Uniformed Services University

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

NOTICE OF PROJECT APPROVAL

Change Number: Original

VPR Site Number:	GSN-61-11161
Principal Investigator:	Henderson, Jeffrey
Department:	Graduate School of Nursing
Project Type:	Student
Project Title:	Implementation of a Pre-Procedural Ultrasound-based Neuraxial Navigation Device in Parturients at Risk for Difficult Lumbar Epidural Placement
Project Period:	3/18/2020 to 12/31/2020

Assurance and Progress Report Information:

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

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

Questions regarding this approval should be directed to the following person in the Office of Research:
Sharon McIver, (301) 295-9814.

[redacted]

Toya V. Randolph, Ph.D., MSPH Date
Acting Vice President for Research
Uniformed Services University of the Health Sciences

cc: File
Radford, Kennett
Taylor, Laura

Appendix C: MTF IRB/PI Letter of Determination

Clinical Investigation Department, Naval Medical Center Portsmouth

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

June 22, 2020

Thomas S. Rieg, PhD
Research Director

Kersten N. Wheeler, MS
Deputy Director
Division Head,
Research Subjects Protection

June G. Brockman, BA
Division Head,
Research Resources

Joanna E. Fishback, DVM
Major, VC, USA
Division Head,
Laboratory Animal Medicine

From: Deputy, Clinical Investigation Department
To: LT Jeffrey Henderson, NC, USN

SUBJ: LETTER OF WAIVER OF IRB REVIEW FOR PROCESS IMPROVEMENT PROJECT

1. Your project titled NMCP.2020.0065: "Implementation of a Pre-procedural Ultrasound-based Neuraxial Navigation Device in Parturients Screened at Risk for Difficult Lumbar Epidural Placement" has been evaluated by an Exemption Determination Official (EDO). Per Defense Health Agency policy, the EDO determined that your project is not human subject research and does not require IRB review.

2. Projects that do not require IRB approval are not eligible for Clinical Investigation Department travel funds.

3. You will still need to obtain publication approval for the project which is required for all works presented or published outside of your command.

4. I remain available and may be reached at [redacted]

[redacted]

K. N. WHEELER

"FIRST AND FINEST IN RESEARCH SUPPORT"

Appendix D: PAO Clearance/ Level of Dissemination Classification

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

Name (Last, First, MI):		**Corps:**	**Service:**
Henderson, Jeffrey, D		NC	USN
Rank:	**Position:**	**E-mail:**	
LT	Other	jeffrey.henderson@usuhs.edu	
Phone:	**Pager:**	**Publication type:**	
[redacted]		manuscript	
Department:	**Dept. Head (name and rank):**	**Deadline for NMCP approval** (Allow 10 business days):	
Anesthesia	CDR Jason Longwell	16/04/2021	
Directorate:	**Director (name and rank):**	**Deadline for BUMED approval** (Allow additional 35 business days):	
DSS	CDR Mario Cardoso		
Submission title: Implementation of a Pre-procedural Ultrasound-based Neuraxial Navigation Device in Parturients at Risk for Difficult Lumbar Epidural Placement			
OCONUS presentations may require higher level approval. Is conference OCONUS? Yes ☐ No ☒			
Via this request, three conferences or journal articles for this manuscript/abstract/presentation may be approved in the same calendar year. Complete the section below, with today's submission as your first or only conference/journal.			
Conference/Journal/Other 1: Uniformed Services University Research Week			**Date:** 05/11/2021
Conference/Journal/Other 2:			**Date:**
Conference/Journal/Other 3: Click here to enter text.			**Date:**
Previous approval? Select			

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

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

PI name:		
Study title: Click here to enter text.		
If approved by another institution, name of institution:		
The protocol number is:		
Have you attached the most recent IRB approval letter or continuing review?	☐	☐
Does it contain the required CIP (IRB approval) statement?	☐	☐

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

Additional Information
Other DoD agency or command to which this material has been submitted for approval. Uniformed Service University of the Health Sciences
Submission Date: 01/04/2021
Optional Comments: Click here to enter text.

V. TO BE COMPLETED BY PUBLICATION OFFICER:

Department Head Recommendation:	Director Recommendation:
☒ Approve ☐ Approve with comment ☐ Return to author for revision, discussion ☐ Disapprove ☐ Forward for higher level review Comments: Name/Signature: CDR Jason Longwell Date: 4/16/2021	☒ Approve ☐ Approve with comment ☐ Return to author for revision, discussion ☐ Disapprove ☐ Forward for higher level review Comments: Name/Signature: CDR Joseph Kotora Date: 4/6/2021

Public Affairs Recommendation:	CID Recommendation:
☒ Approve ☐ Approve with comment ☐ Return to author for revision, discussion ☐ Disapprove ☐ Forward for higher level review Comments: Name/Signature: PO2 Dylan Kinee Date: 4/6/2021	☒ Approve ☐ Approve with comment ☐ Return to author for revision, discussion ☐ Disapprove ☐ Forward for higher level review Comments: Revisions made Name/Signature: June Brockman Date: 4/7/2021

Attending Veterinarian Recommendation: ☒ N/A	OPSEC Security Recommendation:
☐ Approve ☐ Approve with comment ☐ Return to author for revision, discussion ☐ Disapprove ☐ Forward for higher level review Comments: Name/Signature: Date:	☒ Approve ☐Approve with comment ☐Return to author for revision, discussion ☐Disapprove ☐Forward for higher level review Comments: Name/Signature: Hannah Hilts Date: 4/6/2021

NME Recommendation: ☒ N/A	BUMED Recommendation:	Command Action:
☐ Approve ☐Approve w/ comment ☐Return to author for revision ☐Disapprove ☐Forward to BUMED Comments: Name/Signature: Date:	☐ Approve ☐Approve w/ comment ☐Return to author for revision ☐Disapprove ☒ Not required Comments: Name/Signature: Date:	☒ Approve ☐Approve w/ comment ☐Return to author for revision ☐Disapprove ☐Forward for higher level review Comments: Name/Signature: June Brockman By Direction Date: 4/20/2021

Author Notification Date: 4/20/2021 By: DJO

Appendix E: Forms for Data Collection

Difficult Lumbar Epidural Placement (DLEP) Screening Questionnaire

	CIRCLE ONE	
Is the patient UNABLE to adequately flex the lumbar spine for optimal epidural placement?	Yes 1 pt	No 0 pts
Does the patient have a spinal deformity, either by physical assessment or history of diagnosis?	Yes 1 pt	No 0 pts
Did you have difficulty palpating the neuraxial landmarks associated with epidural placement?	Yes 2 pts	No 0 pts
Calculate Total Points	_______ pts	
Is this patient considered "High Risk" for difficult lumbar epidural placement? (3 or more pts)	Yes / No	

Procedure Date: __________ **Procedure Location:** __________ (Ex. L&D 3, OR 1)

Procedure Times: **Procedural Time Out** __________ **Test Dose** __________

Number of attempts: ______ ****Each new skin insertion and/or each change of proceduralist counts as one attempt****

Attempt 1 Provider (circle one):	Trainee	Staff	(If staff, # years in practice: ______)
Accuro Device Used:	Yes	No	Completed Accuro Training: Yes No
Inadvertent Dural Puncture:	Yes	No	- Training includes both (web-based and hands on)
Attempt 2 Provider (circle one):	Trainee	Staff	(If staff, # years in practice: ______)
Accuro Device Used:	Yes	No	Completed Accuro Training: Yes No
Inadvertent Dural Puncture:	Yes	No	- Training includes both (web-based and hands on)
Attempt 3 Provider (circle one):	Trainee	Staff	(If staff, # years in practice: ______)
Accuro Device Used:	Yes	No	Completed Accuro Training: Yes No
Inadvertent Dural Puncture:	Yes	No	- Training includes both (web-based and hands on)
Attempt 4 Provider (circle one):	Trainee	Staff	(If staff, # years in practice: ______)
Accuro Device Used:	Yes	No	Completed Accuro Training: Yes No
Inadvertent Dural Puncture:	Yes	No	- Training includes both (web-based and hands on)
Attempt 5 Provider (circle one):	Trainee	Staff	(If staff, # years in practice: ______)
Accuro Device Used:	Yes	No	Completed Accuro Training: Yes No
Inadvertent Dural Puncture:	Yes	No	- Training includes both (web-based and hands on)

Appendix F: DNP Project Completion Verification Form

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

DOCTOR OF NURSING PRACTICE PROJECT
Completion Verification Form

The DNP Project titled: Implementation of a Pre-procedural Ultrasound-based Neuraxial Navigation Device in Parturients at Risk for Difficult Lumbar Epidural Placement was completed at Naval Medical Center Portsmouth by the following student(s):

LT Jeffrey Henderson	Jeffrey henderson	04/01/2021
LCDR Paul Kuhn	Paul Kuhn	04/01/2021
LCDR Kathryn Miller	[redacted]	04/01/2021

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

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

Verified by:

LCDR Michael Rucker	Michael T Rucker	04/01/2021	Senior Mentor
LCDR Katherine Kidde	Katherine Kidde	04/01/2021	Phase II Site Director

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

CDR Ken Radford RNA Project Director	[redacted] *(Signature)*	Apr 1, 2021 *(Date)*

Signatur[redacted]
Email: kathryn.miller@usuhs.edu

Form Version: 26 Aug 2017

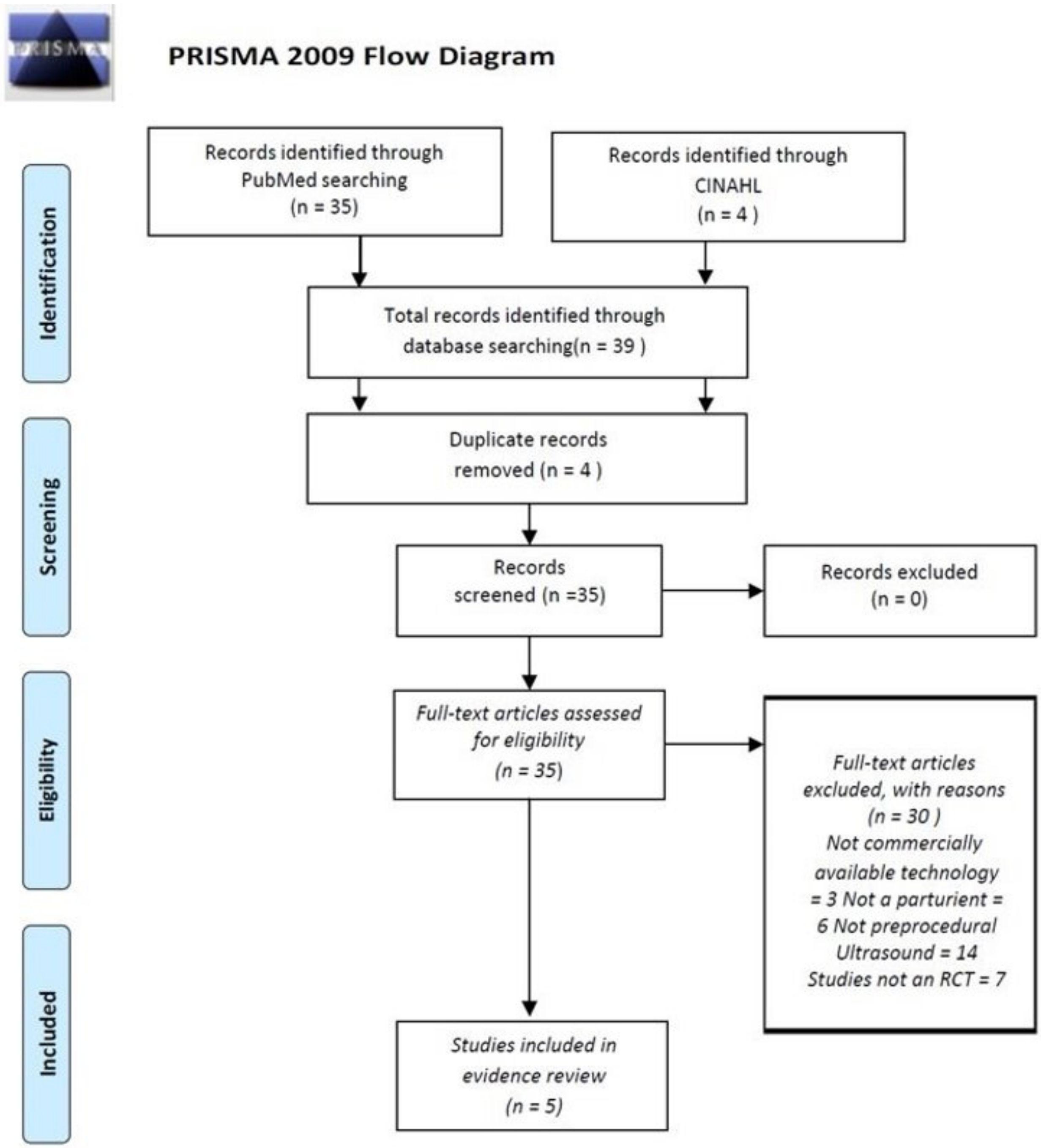
Signature: [redacted] Jeffrey Henderson (Apr 1, 2021 12:50 EDT)
Email: jeffrey.henderson@usuhs.edu

Signature: [redacted] Paul Kuhn (Apr 1, 2021 18:14 EDT)
Email: paul.kuhn@usuhs.edu

Signature: [redacted] Michael T Rucker (Apr 1, 2021 18:27 EDT)
Email: michael.rucker@usuhs.edu

Signature: [redacted] Katherine Kidde (Apr 1, 2021 22:00 EDT)
Email: katherine.kidde@usuhs.edu

Figure 1: Prisma for Ultrasound

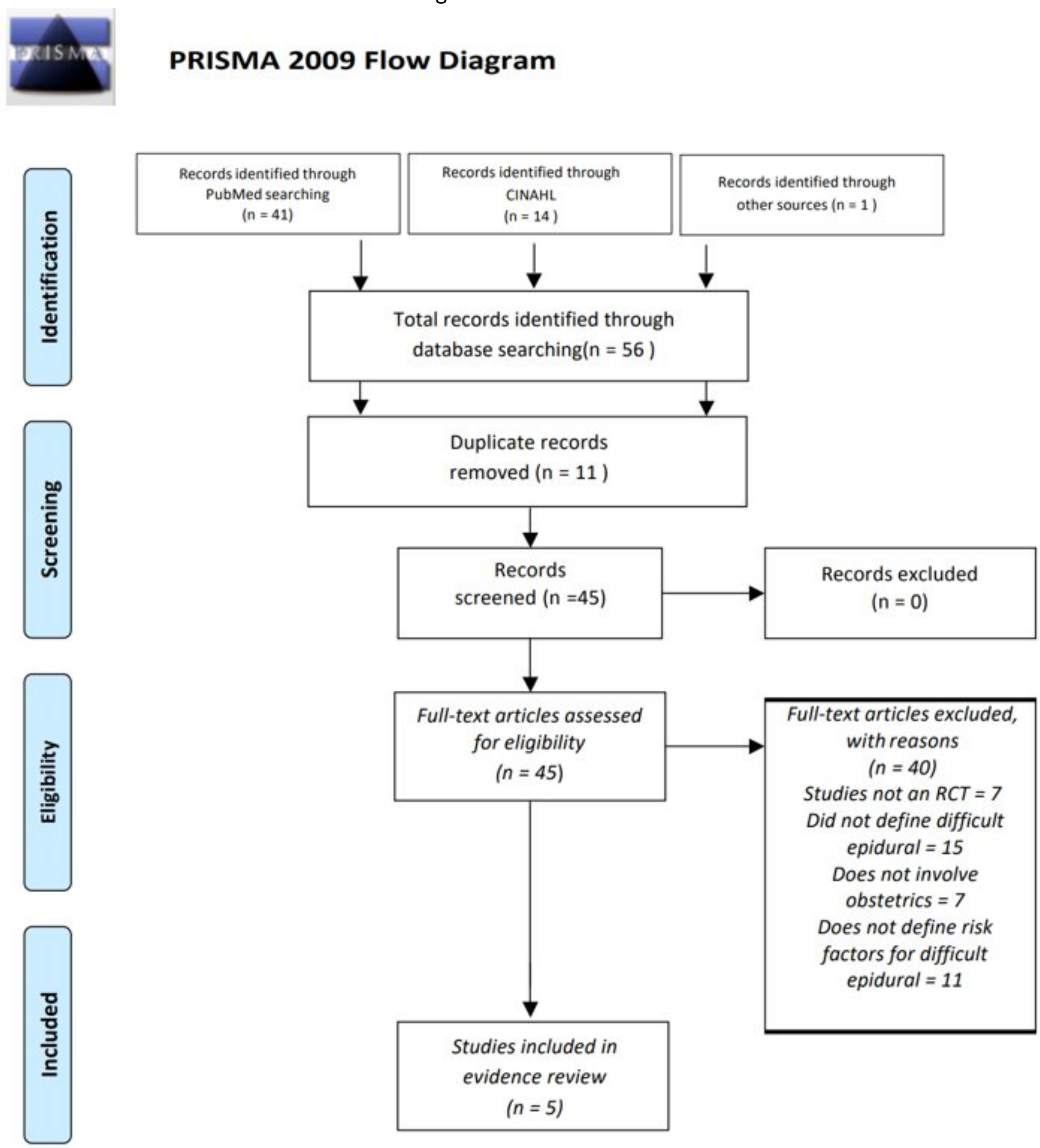


1st Author Name (Publication Yr)	Title	Study Purpose/Aims	Research Questions/Hypotheses	Study Design	Total Sample Size	Sampling Plan	Independent Variables	Dependent Variables	Statistical Analyses	Results	LEVEL OF EVIDENCE — using JHNEBP tool
Chin (2018)	A randomized controlled trial comparing needle movements during combined spinal-epidural anaesthesia with and without ultrasound assistance	Investigate the efficacy of neuraxial ultrasound in women having caesarean section with combined spinal-epidural anesthesia and to identify factors associated with improved technical performance	Does preprocedural neuraxial ultrasound in a general obstetric population increase the efficacy of needle movements and procedural difficulty to identify factors associated with difficult combined spinal-epidural anesthesia compared to landmark palpation?	Prospective randomized controlled trial conducted between May 2013 and December 2014	317 assessed for eligibility, 218 included in random allocation, 215 completed the study and were analyzed	Recruited women aged > 18 years and > 37 weeks gestation who were scheduled for elective caesarean section under CSE anesthesia Simple non-block randomization with surplus allocations to account for dropouts	Preprocedural ultrasound scanning, landmark palpation,	First pass success with CSE placement Block quality, patient pain, procedural complications, patient satisfaction	Categorical data Chi squared, Fisher exact test for data that did not meet assumptions of Chi squared, student t-tests for continuous parametric data Mann Whitney U for continuous non-parametric data Analyzing multiple outcomes, Benjamini–Yekutieli [14] method (four tests) Binary logistic regression was used to model first-pass	First-pass success was achieved in 67 (63 8%) and 42 (38 2%) women in the ultrasound and control groups, respectively (adjusted p = 0 001; Table 2) Combined spinal-epidural was difficult in 19 (18 1%) and 33 (30 0%) women in the ultrasound and control groups, respectively, Fewer women in the ultrasound group needed additional needle insertions (20 women (19 0%) vs 42 women (38 2%) in the control group; adjusted (p = 0 005) and needle redirections (36 women (34 3%) vs 64 women (58 2%) in the control group; adjusted p = 0 002)	1B
Xiaohu (2017)	Risk assessment of morbidly obese parturient in cesarean section delivery: a prospective, cohort, single-center study	Study aimed to explore the safety and risk of perioperative anesthesia in obese pregnant women undergoing CS with general anesthesia, epidural anesthesia, or epidural anesthesia combined with spinal anesthesia	Does various perioperative anesthetic methods impact safety and risk of CS delivery in obese women	Prospective randomized controlled trial	790	Divided into 3 groups morbid obesity (>40BMI) Severe obesity (40-30 BMI), non-obesity (<30 BMI)	Obesity, anesthetic technique	Pregnancy outcomes, heart rat, ecg, SAP, DAP, MAP SpO2	Chi squared, Fisher exact test	Significantly more fetal distress and higher BMI in morbid obesity group, morbid obesity group had more GA and EA, more proportion of PACU patients in morbid obese and severe obese group	2B
Kula (2017)	Increasing body mass index predicts increasing difficulty, failure rate, and time to discovery of failure of epidural anesthesia in laboring patients	To define difficult or failure of neuraxial anesthesia in obese parturients and define difficult and failure	Does increasing BMI would be associated with increased neuraxial analgesic failure and difficulty as well as time needed for epidural placement	Retrospective chart review	2485	Review QA and anesthesia records over 12-month period	BMI	Catheter failure, placement time, difficulty	Unpaired student t-tests, Mann-Whitney U and Chi squared	Placement duration increased by 20 minutes when placement was difficult vs non difficult, placement was difficult in patients with higher BMI	1B
Sahin (2014)	A randomized controlled trial of preinsertion ultrasound guidance for spinal anaesthesia in pregnancy: outcomes among obese and lean parturients: ultrasound for spinal anesthesia in pregnancy	Examine if pre-insertion lumbar ultrasound scanning helps with performance of spinal puncture as a tool for decreasing the number of puncture attempts and spinal procedure time and increasing success rate; Secondary outcome was to determine if L4-L5 interspace identified by	Ultrasound can facilitate neuraxial blockade, particularly in pregnant women with difficult topographic anatomy	Prospective study	100 (50 obese, 50 non-obese)	Four groups (1) preprocedural US in lean patients (2) preprocedural US in obese (3) no ultrasound lean patients (4) no ultrasound obese patients ** BMI of 30 was considered obese	BMI, US examination (US examination was performed by same individual with extensive expertise--evaluated up from sacral and then US depth from ligamentum flavum via paramedian approach)	Number of puncture attempts, number of puncture levels, duration of procedure	Shapiro-Wilk test, ANOVA,Tukey for post hoc, Kruskal-Wallis, sample t test, chi square test, pearson correlation analysis	Edema was more frequent and more difficult landmark palpation was in obese parturients Correlation of (p< 0 001 that US matched needle depth requirements) Landmark identification was more difficult in obese parturients, higher correlation between US depth and needle depth compared to control, fewer puncture attempts and levels in US group, duration was shorter in US group Fewer puncture	1B

		physical examination also correlated with US								attempts and fewer levels with US (p< 0 001) Success with US first attempt was 92% with US and only 44% in obese conventional methods Duration of procedure was shorter in US group (p=0 031)	
Guglielminotti (2013)	Development and evaluation of a score to predict difficult epidural placement during labor	Aimed to identify risk factors for DLEP and build a prediction score	Test the five risk factors for difficult neuraxial placement reported in the literature are also risk factors for DLEP during labor and that a score predicting the risk of DLEP could be used to inform appropriate clinical decisions	Prospective cross-sectional study	330 epidurals analyzed	Split population into training set and validation set	Five risk factors for DLEP	Dural puncture, DLEP	Fisher exact test (frequency of dural punctures), Wilcoxon test (continuous variables), Fisher exact test (discrete variables), univariate logistic regression (odds ratio of DLEP), C-statistic (discrimination of DLEP)	Dural punctures were higher in patients with DLEP than without, prevalence of DLEP was 32% in training set, difficult palpation of landmarks, spinal deformity, and poor back flexion were independent risk factors for DLEP	1B
Faitot (2011),	An observational study of factors leading to difficulty in resident anaesthesiologists identifying the epidural space in obstetric patients	To identify the factors leading to difficult epidural space cannulation in obstetric patients for resident anesthesiologist with no prior experience in obstetric anesthesia	N/A	Prospective, observation	4 first semester residents, during 3 months of training with no experience in OB	Convenience sampling	Spinal abnormalities, Body Mass Index, abdominal circumference, inability to palpate anatomic landmarks	Difficulty of epidural placement	Univariate analysis Chi squared Significant univariant factors were included in multivariate logistic regression models	In the univariate analysis, factors associated with a difficult epidural were BMI >30 kg/m2, abdominal circumference >105 cm, anatomical landmarks grade 3 or 4 and the presence of a spine abnormality All these factors, with the exception of abdominal circumference >105 cm, were independent predictive factors in the multivariate analysis	2B
Ellinas (2009)	The effect of obesity on neuraxial technique difficulty in pregnant patients: a prospective, observational study	To determine which factors, if any, predicted technically difficult neuraxial anesthetics in pregnant patients	Hypothesized that Obesity, defined by current BMI, would be the best predictor of neuraxial technique difficult for neuraxial anesthetics	Prospective observational	427 subjects, 14 rejected due to inconsistent data or not meeting inclusion criteria 413 analyzed	Convenience	Age, height, weight, BMI, ethnicity, patient position, spinal deformity, palpation of spinous processes, back flexion, experience of the practitioner, and procedure type	Number of needle passes and neuraxial placement time	Univariate analysis was performed on single predictors, association between predictors of anesthetic technique difficulty and "Passes," including negative binomial and Poisson error models on all predictors Linear model was used to assess the relationship between the difficulty predictors and log of placement time Binary logistic regression was used to test the association between BMI and the significant predictors of neuraxial technique difficulty	Based on our negative binomial model, the only significant predictors of increased passes were palpation (P = 0 002) and back flexion (P = 0 001) BMI was not a predictor of difficulty, whether considered a continuous (P = 0 50) or categorical variable (P = 0 19) The negative binomial model predicted the passes required for successful neuraxial procedures in pregnant patients with varying palpation and flexion	2B
Clinkscales CP (2007)	An observational study of the relationship between	The aim of this study was to characterize the		Retrospective chart review	2009	convenience	body mass index as the independent variable, adjusted for maternal age,	Centimeter Depth from skin to lumbar epidural space	multilinear regression model	When maternal age, gestational age and vertebral interspace are	3B

	lumbar epidural space depth and body mass index in Michigan parturients	relationship between lumbar epidural space depth and body mass index in United States parturients from Michigan					gestational age and vertebral interspace				controlled for, increasing body mass index is associated with increasing Depth, while increasing maternal age is associated with decreasing depth	

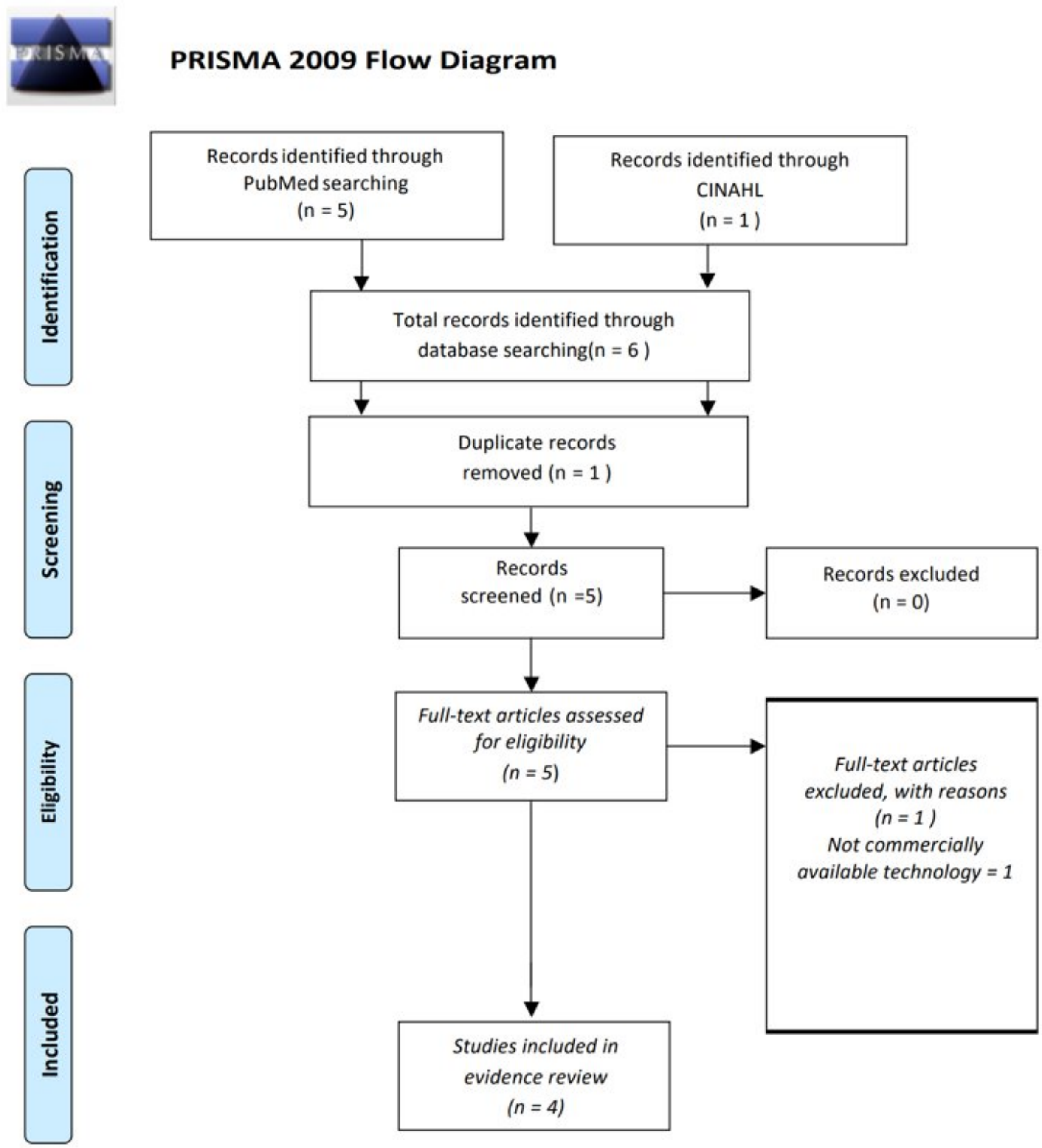
Figure 2: Prisma DLEP



1st Author Name (Publication Yr)	Title	Study Purpose/Aims	Research Questions/Hypotheses	Study Design	Total Sample Size	Sampling Plan	Independent Variables	Dependent Variables	Statistical Analyses	Results	LEVEL OF EVIDENCE — using JHNEBP tool
Tubinis (2019)	Utility of ultrasonography in identification of midline and epidural placement in severely obese parturients	Does performing an abbreviated ultrasound exam of the lumbar spine to determine midline by locating spinous process could facilitate lumbar epidural placement in severely obese parturients	Does use of abbreviated ultrasound to identify the midline on obese parturients lead to significantly shorter times in epidural placement when compared to locating the midline by palpation	prospective observational study	150 parturients with >35% BMI randomized into two equal groups	convenience sampling	Ultrasound exam to identify midline of spinous process, landmark palpation	procedure time, epidural placement time, number of needle passes	two sample t-test to compare U/S and palpation primary endpoints Linear regression used to compare midline identification method and time Chi square test used to compare epidural fail rates between the two groups	BMI was similar in the U and P groups (43 3 vs 44 4 kg/m2, P=0 359) Time for epidural placement (6 2 vs 9 0 minutes, P<0 01) and total procedure time (6 9 vs 9 5 minutes, P<0 01) were significantly less in the U group The number of needle passes (2 1 vs 2 8, P=0 02) was also less in the U group	2B
Chin (2018)	A randomised controlled trial comparing needle movements during combined spinal-epidural anaesthesia with and without ultrasound assistance	Primary: Aimed to investigate the efficacy of neuraxial ultrasound in women having caesarean section with combined spinal-epidural anesthesia Secondary: to identify factors associated with improved technical performance	Ultrasound assistance would not improve technical performance in women with easily palpable surface landmarks (Surprised that it increased performance significantly)	Randomized controlled trial: Experienced anesthetists performing ultrasound and trainees performing neuraxial anesthesia Prospective blinded for patient not operator	215, calculated by 5% significance level, 90% power, and SD 0 69	Convenience sample of all women in antenatal clinic, >18yrs old and >37weeks gestation simple non block randomization	Ultrasound group with markings place or ultrasound group with no markings placed (land marks) LOM: Nominal	Primary: First pass success and block difficulty Secondary: Block quality (satisfied/not satisfied), pain (Likert 5-point scale) Primary LOM: Nominal/Nominal Secondary LOM: Nominal/Ordinal	Descriptive statistics used Pearson Chi-squared test of association and Fischer's exact test when assumptions for Chi squared not met Student's t-test used to show differences between groups for parametric continuous variables Mann-Whitney used for non-parametric continuous variables	1 First pass success was achieved in 63 8% of ultrasound group and 38 2% in control group (adjusted p = 0 001) 2 Difficulty (defined as >5 contacts with bone, >2 needle insertions at same space, insertion at different space and no CSF return) 18 1% vs 30% in control 3 Fewer needle insertions 19% vs 38 2% control (adjusted p = 0 005), needle redirections 34 3% vs 58 2% in control (adjusted p = 0 002) NO significant difference in secondary outcome of block quality (please report your actual statistical results too This is all descriptive statistics	1B
Perna (2017)	Can pre-procedure neuraxial ultrasound improve the identification of the potential epidural space when compared with anatomical landmarks? A prospective randomized study	Primary: Verification of preprocedural neuraxial US, in comparison with palpation of anatomical landmarks, might improve the identification of the potential epidural space by reducing the number of attempts necessary to place an epidural catheter Secondary: Evaluate the precision of the transverse echo-graphic approach for the definition of	Will use of the US before epidural insertion aid the anesthesia provider more than palpation and loss of resistance technique in reducing the number of attempts needed	Prospective randomized controlled study between Feb 2014 and June 2014	60 parturients	Convenience sampling with closed envelope technique	**Primary:** Utilization of US preprocedural **LOM:** Nominal Secondary: US usage and depth LOM: Interval	**Primary:** Epidural Success (**LOM:** Nominal) Total number of puncture attempt, which encompassed: Number of attempts, number of redirections, total number of puncture attempts **LOM:** Interval Secondary: Real depth of the Tuohy needle as it entered the skin LOM: Interval	X2 and Student T tests; nonparametric K sample test on the equality of means; Bland-Altman analysis to compare two different measurements; Pearson's correlation coefficient was used to estimate the precision	Primary: Control group (without US) resulted in more mean number of attempts (3 43+/-3 8) as opposed to US group which was 1 7+/-0 87; US group the number of repositions <1 for 100% of parturients, Control group <1 repositions was 76 7%; Secondary: The average RD was 5 08+/- 0 62cm and UD was 4 94+/-0 60cm (95% precision with Blant Altman analysis) (need statistical results)	2b

		the desired epidural space									
Arzola (2015)	Spinal ultrasound versus palpation for epidural catheter insertion in labour: A randomised controlled trial	Primary: ease of insertion of epidural catheter composed of the time taken to insert epidural catheter, number of interspace levels attempted and number of needle passes Secondary: total procedural time (assessment and insertion); first pass success rate; number of attempts required to thread the epidural catheter; failure of epidural analgesia and patient satisfaction determine the impact of ultrasound usage on the ease of insertion of labor epidurals by a group of trainees after a comprehensive teaching program in US assessment of the spine	Does the use of preprocedural spinal ultrasound improve the ease of insertion of labor epidural catheters when compared with the conventional palpation techniques in full-term parturients with easily palpable spines?	A randomized controlled trial	1 17 residents and 5 fellows 2 128 parturients (84 by second year anesthesia residents and 44 by anesthesia fellows)	Convenience- inclusion: full-term parturients with easily palpable lumbar spines requiring labor analgesia	1 Fellows and residents received didactic teaching in form of reading material and educational video on US facilitated spinals and epidurals, 15m demonstration on live model with 2 h hands on workshop in small group setting 2 Ultrasound usage (5 to 2 MHz curved array probe)	1 Ease of insertion (duration of epidural procedure) 2 total duration of the procedure: using both US & success rate	Students T test or Wilcoxon Rank Sum Test and Pearson's Chi square or Fisher's exact test for continuous and categorical data Normal distribution assumed with Shapiro-Wilk test	There was no difference in the median epidural insertion time between US and palpation groups No significant differences even after adjustment for the trainees level; the preprocedural assessment in the US group was clinically short (70 to 135 seconds), the total duration of the procedure was longer in the US group (261 vs 180) The residents showed shorter epidural procedure time, but residents had longer procedure times No significant different between palpation & US group for first pass success rate (50% vs 50% [p=0 26]), the number of interspace levels (4/68 vs 2/60) [p=0 68]; the number of needle passes at the first level (p=0 43); There were no failures in epidural labor analgesia and patient satisfaction was same among groups Preprocedural US spinal assessment by trainees specifically trained in spinal epidural ultrasound assessment with women with easily palpable lumbar spines does not improve the ease of insertion	2A
Vallejo (2010)	Ultrasound decreases the failed labor epidural rate in resident trainees	Primary: Determine if US measurement of epidural space depth before labor epidural placement by residents decreases the replacement rate of epidural catheters for failed analgesia Secondary: Correlate the US estimated depth of the epidural space with the actual needle depth at the time of placement	that by utilizing ultrasound to determine epidural depth before labor epidural catheter insertion, the rate of failed epidural techniques would be reduced from 8% to 2%, a failure rate similar to techniques performed by experienced practitioners	Prospective, randomized, non-blinded trial	370 laboring parturients	370 laboring parturients, were randomized consecutively by a computerized schema 189 in the US Group and 181 in the Control Group	Primary: US measurement of epidural space depth before labor epidural placement by residents LOM: nominal Secondary: US estimated depth of the epidural space LOM: Interval	Primary: Replacement rate of epidural catheters for failed analgesia based on VAS > 3/10 LOM: Interval Secondary: Actual needle depth at the time of placement LOM: Interval	Interval data was analyzed using t-test and reported as mean (±SD), nominal data was analyzed using chi-squared, ordinal data using Mann-Whitney test Fisher's Exact test for fewer than five events Pearson's Coefficient for correlation between the depth to the epidural space	US measurement decreased epidural failure rate (1 6%) compared without ultrasound scanning (5 5%) Insertion attempts were decreased in ultrasound group (1) compared with control (2) (need statistical results) Pearson's correlation coefficients for longitudinal median and transverse ultrasound planes were 0 914 and 0 909, respectively	1A: consistent, generalizable results, sufficient sample size with power analysis, adequate control, definitive conclusions, consistent recommendations based on comprehensive literature review

Figure 3: Prisma Accuro



Accuro Device Literature Review

1st Author Name (Publication Yr)	Title	Study Purpose/Aims	Research Questions/Hypotheses	Study Design	Total Sample Size	Sampling Plan	Independent Variables	Dependent Variables	Statistical Analyses	Results	Strengths (how promoted internal/external validity)	Weaknesses (biases; poorly controlled threats to internal/external validity)	LEVEL OF EVIDENCE - using JHNEBP tool
PUBMED													
Carvalho, 2019 (this is a republish of the Seligman, 2018 article)	The comparative accuracy of a handheld and console ultrasound device for neuraxial depth and landmark assessment	To assess the ultrasound-estimated depth to the epidural space for the AU, compared to a console ultrasound (GU) device Secondary distance between the midpoint of the interspace as marked by the AU versus GU in both the horizontal and the vertical plane, and the differences between ultrasound and Tuohy ND measurements	Does the accuracy of epidural depth estimation of a handheld ultrasound device, with an integrated algorithm that estimates epidural depth to that of a console ultrasound machine have comparative depth accuracy	prospective cohort study	50, 3 lost from study withdrawal, 47 total completed study	convenience	Ultrasound scanning with AU, ultrasound scanning with GU	ultrasound estimated depth, actual epidural depth	mean depth between AU and GU paired t-tests, Bland Altman for agreement between AU and GU depth measurements, Kolmogorov-Smirnov test and Q-Q plots were used to assess for normal distribution	The AU assessment of the L3–4 interspace matched the GU assessment in 94% of patients The key finding of this study is that the AU and GU provided comparable and accurate epidural depth estimates	Anesthesia provider placing epidurals was blinded to AU and GU One observed was present to ensure protocol that was not involved in management	AU and GU measurement was not blinded to measurer The order of AU and GU measurement was not randomized BMI of sample was 29, which did not meet WHO definition of obesity, accuracy in morbidly obese patients cannot be determined	2B
Seligman, 2018	The Accuracy of a Handheld Ultrasound Device for Neuraxial Depth and Landmark Assessment: A Prospective Cohort Trial	to assess the accuracy of the Accuro in estimating the epidural space depth compared to the needle depth using labor epidural insertion	Does the accuracy of epidural depth estimation of a handheld ultrasound device, with an integrated algorithm that estimates epidural depth to that of a console ultrasound machine have comparative depth accuracy	prospective cohort study	50, 3 lost from study withdrawal, 47 total completed study	convenience	Ultrasound scanning with AU	estimated AU depth compared to actual epidural depth secondary: tuohy redirects, tuohy needle passes, and # of interspaces attempted	Pearson correlation coefficient between AU and ND is presented together with its 95% CI, Bland-Altman plot of the mean versus the difference Descriptive statistics used to summarize discrete data	Primary: The AU underestimates the needle depth by a mean of 0 61 cm With a 95% CI of 0 44-0 79, meaning the anesthesia provider can anticipate loss of resistance within 0 8cm, comparable to standard ultrasound Secondary: Placed epidural first pass 87% vs 59% standard ultrasound	anesthesia provider placing epidurals was blinded to AU depth and palpation, instructed to use markings alone	Small sample size, most were done in non-obese paturients	2B
Capogna, 2018	Accuracy of the SpineNav3DTM Technology to Measure the Depth of Epidural Space: A Comparison with the Standard Ultrasound Technique in	"Primary end point to validate the ability of the Accuro ultrasound scanner to detect the distance from skin to epidural space by comparing it to the gold	Does the accuracy of epidural depth estimation with a 3d ultrasound device differ from that of the gold standard ultrasound?	prospective semi blind study	96 parturients at term	convenience	Accuro Ultrasound vs Standard Ultrasound	Primary: Epidural space depth with Accuro, Secondary: Epidural space measurement by expert and novice anesthesia provider	"Shapiro-Wilk and Lilliefors test, T-test was used to compare the results of the Accuro and standard ultrasound Bland-Altman plot was used to compare the	No difference between the experts measurement with the ultrasound and Accuro, compared to the novice's measurements with the Accuro	Investigators were blind to each others results	Healthy parturients with BMI 27+/- 4 35 Only 2 participants, one expert and one novice investigator, novice may be more skilled then most	2B

	Pregnant Volunteers	standard (the standard ultrasound) The secondary end-point was the inter-rater agreement between an expert anesthesiologist and a novice trainee in determining the epidural space depth with the Accuro device "							standard ultrasound vs Accuro and the expert's vs the novice's measurements performed with the Accuro	alone Results within 0 25cm of each other			
Tiouririne, M (2017)	Imaging performance of a handheld ultrasound system with real-time computer-aided detection of lumbar spine anatomy: a feasibility study	to evaluate the accuracy, sensitivity, and specificity of the CAD algorithm for the automated detection of neuraxial landmarks in human subjects	Does the imaging performance of a handheld ultrasound system and the accuracy of an automated lumbar spine computer-aided detection (CAD) algorithm correlate with the spines in human subjects?	observational, imaging only study	80 (in the first 12 volunteers could not be analyzed due to inconsistencies in image acquisition techniques) 68 participants remained	convenience	Obesity, anatomic landmarks,	accuracy, sensitivity, and specificity of CAD algorithm	two-sided t-tests for p-values and statistical significance, Gaussian-distributed random variable for confidence intervals, Bland Altman for CAD algorithm measurements to radiologist measurements	A total of eighty volunteers with BMI between 18 5 and 48 kg/m2 were recruited, first 12 lost to inconsistencies in image acquisition techniques	sample of 68 parturients, a homogeneous group other than BMI and weight, which supports generalizability If radiologist could manually detect the epidural space or spinous processes, CAD algorithm recognized with a sensitivity and specificity between 85 – 95% Accuracy was preserved in BMIs up to 48% Correlation between CAD and radiologist readings for epidural depth were within ± 0 5 cm	Only recognizes images in transverse plane The deepest epidural space measured was 6 9cm, which does not account for more distal epidural spaces in more challenging parturients Measured depth was not confirmed with actual needle insertion and depth measurement	2B
Singla, P (2019)	Feasibility of Spinal Anesthesia Placement Using Automated Interpretation of Lumbar Ultrasound Images: A Prospective Randomized Controlled Trial	Evaluate the feasibility of implementing neuraxial ultrasound as a means of identifying the needle insertion location prior to needle placement in a cohort of resident physicians with minimal ultrasonography training	"Assumed expected first attempt success rate of 40% in palpation group and 73% in the ultrasound groups"	Prospective RCT	150	Convenience: Delivered Jan2016-Oct2017 but SCHEDULED delivery	Palpation group, US group, vs Palpation/US group [so ultrasound or not]	Success rate for Spinal Anesthesia	Chi-squared, Wilcoxon-Mann-Whitney, Poisson regression model	First insertion success rates increased with use of US (p=0 431) [not significant], 59% first insertion success rate in Group Palpation and 66% in Group US (0 13); US resulted in 15% reduction in needle insertions (p=0 052), a 26% decrease in needle passes (p=0 110), 33% reduction in needle insertion time (0 07)	We had hypothesized that the combination of palpation and ultrasound in the PU group may have resulted in improved outcomes, but an improvement was not observed, again suggesting functional equivalence between the two landmark identification techniques in the context of this study		

										Took longer to identify landmarks with Accuro, but length of procedure was not different; Post-Hoc analysis of spinal placement in Obese--> first insertion rates were 26% higher in US group than palpation, US resulted in 21% decrease in insertions, 38% decrease in needle passes and 58% reduction in a difficult spinal ** defined by requiring more than TEN passes, 75% reduction in patient satisfaction <			

Figure 4: Iowa Model

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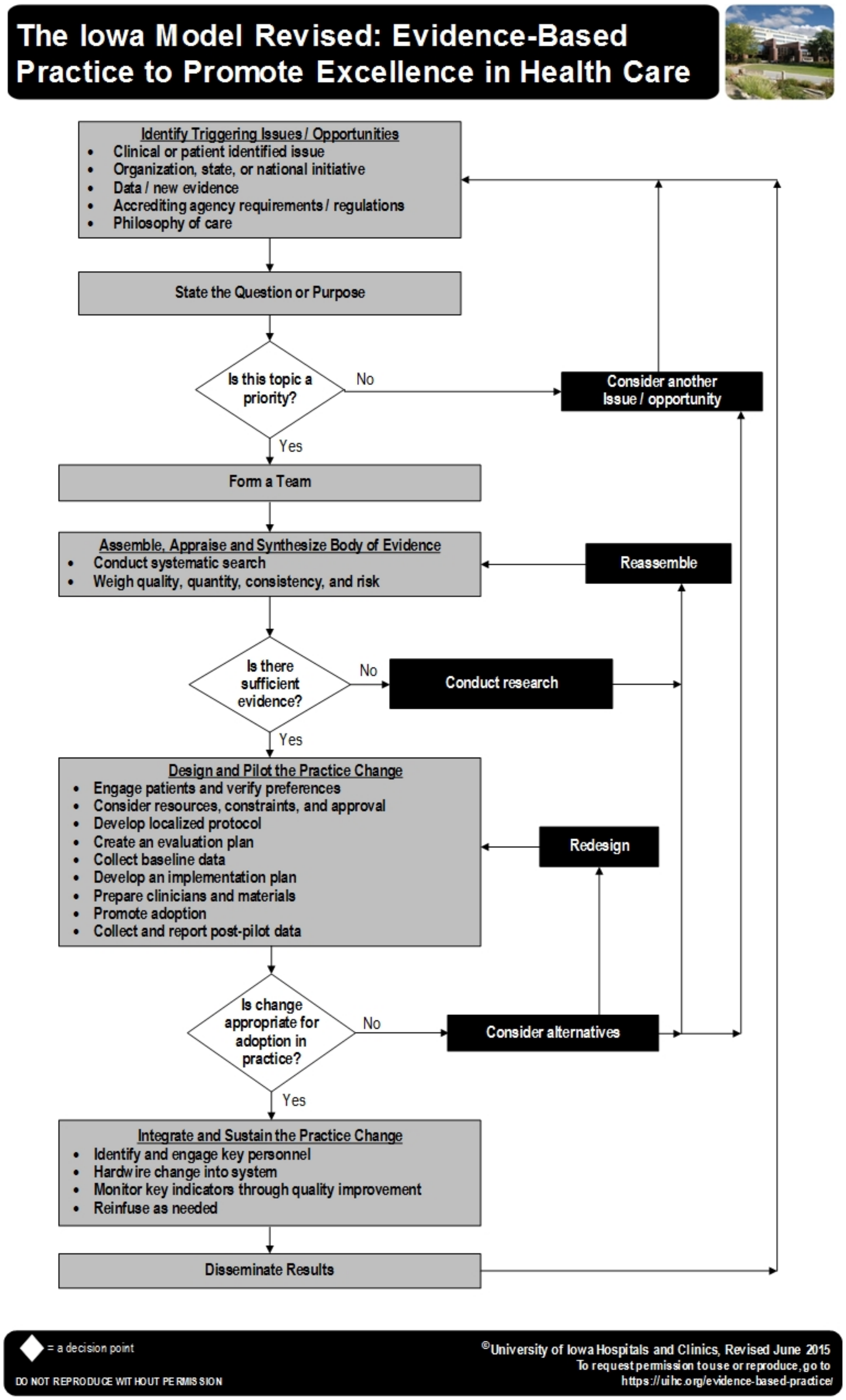

Figure 5: Timeline

	DEC 2019	**FEB 2020**	**APR 2020**	**JUL 2020**	**SEP 2020**	**OCT 2020**	**DEC 2020**	**JAN 2020**	**FEB 2020**	**MAR 2020**
Project approval from USU										
QI Proposal										
NMCP BioMed Department approval										
Start project data collection Phase I										
Complete project data collection Phase I										
Start project data collection Phase II										
Complete project data collection Phase II										
Analyze Survey results										
VANA Presentation										
DNP EBP project completion										