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Implementation of a Neuraxial Task Trainer During the Didactic Phase of the Registered Nurse

Anesthetist Program at The Uniformed Services University

Aaron Patterson and Daisha Wilson

Uniformed Services University

Daniel K. Inouye Graduate School of Nursing


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Disclaimer

Due to the impact of the COVID19 Pandemic, 2020, graduates of the Daniel K. Inouye Graduate School of Nursing were deemed critical to the mission of caring for the health of the nation. All phases of the DNP Project were complete and met the standards and rigors of a quality DNP Project with an abbreviated dissemination timeframe.

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Aaron B. Patterson, MBA, RN, LCDR, USPHS, Registered Nurse Anesthetist Program
Daniel K. Inouye Graduate School of Nursing
Uniformed Services University
28 Feb 2020

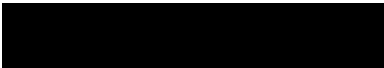

Daisha B. Wilson, BSN, RN, Capt, USAF, Registered Nurse Anesthetist Program
Daniel K. Inouye Graduate School of Nursing
Uniformed Services University
28 Feb 2020

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Abstract

Phase II Site: Walter Reed National Military Medical Center

DNP Project Title: Implementation of a Neuraxial Task Trainer During the Didactic Phase of the Registered Nurse Anesthetist Program at The Uniformed Services University (USU)

Authors: Patterson, A.B, Wilson, D.B

Background or Problem/Issue: Performing neuraxial anesthesia is a high-risk procedure in which a provider obtains specialized skills that have an extensive learning curve. The risks of this procedure increase for novice providers, as most providers acquire their training by practicing on patients in the clinical setting instead of simulation environments. Currently, USU utilizes a training aid (watermelon) to teach this method. Using a neuraxial task trainer can increase the Student Registered Nurse Anesthetist (SRNA's) comfort level and skills with a more accurate representation of the spinal anatomy.

Clinical Question: Does the implementation of a neuraxial task trainer improve skill acquisition and comfort level of SRNAs at USU during the didactic phase of education?

Project Design: This process improvement project assessed neuraxial needle placement skills and comfort levels, both pre and post-implementation, of participant education simulation training with a neuraxial task trainer.

Analysis of the Results: There was a statistical difference in students' comfort level teaching another trainee and attaining the targeted location post-survey after receiving training materials and performing the simulation lab. Pre-survey results showed only 4 of 31 students (13%) felt moderately comfortable training another trainee, and no students felt comfortable attaining the target location. Implementation of this training demonstrated an increase of participants

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successfully attaining the target location from 74% to that of 93%. Additionally, 99% of the students reported that utilizing a task trainer was the preferred method over a watermelon.

Organizational Impact/Implications for Practice: Utilizing a neuraxial task trainer for SRNAs improved their comfort level and aided psychomotor skills to perform this procedure prior to starting their clinical phase. This resulted in increased confidence and safer patient care.

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Introduction

Neuraxial anesthesia refers to epidural, spinal, and combined spinal-epidural procedures and is considered to be a challenging skill to teach novice providers. Epidurals and spinals are commonly used to provide analgesia and anesthesia during childbirth, chronic pain treatment, and surgeries that involve the lower abdomen and lower extremities (Harrison, Daste, McDaniel, Patterson, & Guirguis, 2018). However, neuraxial procedures are considered high-risk and can expose patients to a diverse array of complications such as a post-dural puncture headache (PDPH), vertebral abscess, hematoma, and direct nerve injury (Liu, Brown, Sun...& Kaye, 2019). Patients can experience increased exposure to these complications when interacting with inexperienced providers. Today, neuraxial anesthesia training has expanded from simulation training on fruit to spinal and epidural task trainers to provide a more realistic approach to patient landmarks and vertebral interspaces. Currently, the USU SRNA program utilizes a watermelon training aid to teach neuraxial anesthesia. The use of a watermelon as a training aid, when teaching neuraxial anesthesia, acts as a method trainees can experience a loss of resistance when completing an epidural, spinal, or a combined spinal-epidural procedure (Frank, 2019). However, the simplicity of the current model fails to recreate an accurate tactile sensation of human anatomy to include tissue and bone (Mock, 2016). Task trainers that more accurately reproduce an actual limb or body part have the potential to increase competence, clinical performance, and confidence while improving patient safety (Green, Tariq, & Green, 2016). Therefore, this project aimed to determine if the implementation of a spinal/epidural task trainer simulation program at USU would improve the skills acquisition and comfort level of SRNAs performing neuraxial procedures.

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This project followed a format where the authors introduced the significance of the problem being studied, highlighted the clinical question that guided the project, and provided an overview of both the long and short-term goals. The authors then guided a discussion on the relevance of completing the study, highlighted the overview of the project's design and the associated procedural steps, and outlined the project's results. This project concluded with a robust analysis of the results, combined with a discussion on the organizational impacts and implications to practice and policy, and recommendations for future studies.

Significance of the Problem

Neuraxial anesthesia is a fundamental skill for military Certified Registered Nurse Anesthetists (CRNA). Currently, SRNAs in the didactic phase of their first year of education at USU utilize a watermelon training aid model to learn and practice epidural needle placement. However, this model does not accurately represent anatomical structures of the human body and the incorrect placement of a needle results in patient complications (Lee, Lee, Sim...& Bang, 2016; Rodziewicz & Hipskind, 2019). Researchers have suggested a need for improved alternatives in the training of epidurals and spinals as the placement of the needle into the epidural or subarachnoid space only yields a small margin of error, which can result in potentially life-threatening outcomes for the patient (Nixon, Stariha, Farrer, Wong, Maisels, & Toledo, 2019). Most anesthesia providers place neuraxial needles with a blind technique that relies mostly on the feel of anatomical structures and a loss of resistance as the needle passes through the ligamentum flavum and into the epidural space (Mock, 2016). The spinal/epidural task trainers are designed to recreate every anatomical layer of the human lower back and spine so that students can obtain a realistic feel of the layers during the insertion of the needle (Upshall & Collins, 2018). Therefore, the implementation of a spinal/epidural task trainer, along with an

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education module, will offer the SRNA a more realistic hands-on training evolution in a safe and non-stressful environment.

Thoracic epidural anesthesia is the preferred method when treating thoracic injuries in the deployed setting because it provides adequate analgesia with decreased variability on patient hemodynamics when compared to general anesthesia (Banks, Buckenmaier, & Mahoney, 2015). Neuraxial procedures are also common in obstetric anesthesia. Approximately 60% of women in labor receive epidurals in the United States, and parturients in the military health system are more likely to use epidurals for pain relief compared to private non-profit hospitals or rural areas (Couture, 2016). Therefore, it was relevant and appropriate for the authors of this project to determine if the implementation of a spinal/epidural task trainer simulation program at USU would improve the skills acquisition and comfort level of SRNAs performing neuraxial procedures.

Clinical Question

Clinical Question: Does the implementation of a neuraxial task trainer improve skill acquisition and comfort level of SRNAs at USU during the didactic phase of education?

Focus Areas

This project consisted of three primary focus areas: a robust literature review search, completion of the class of 2021 SRNA's pre-survey and reviewing of the associated training materials, and simulation training. First, the authors completed a literature search that determined the most effective neuraxial training method and materials. This literature review search was comprehensive, as the authors used a variety of databases and search terms to retrieve the most up-to-date-information found in the medical field. Databases that were used in the construction of the literature review included PubMed, PubMed Central, Excerpta Medical Database

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(EMBASE), Cumulative Index of Nursing and Allied Health Literature (CINAHL), and Cochrane Library.

Second, the class of 2021 SRNAs completed a pre-survey and reviewed the training materials provided. The authors collected data from 31 SRNAs via an anonymous survey that utilized a five-point Likert Scale (1= Extremely, 5 = Not at all) (Chen, 2016). The Likert scale survey asked SRNAs to rate their level of comfort with teaching another trainee, placing needles for interventional procedures, maneuvering a spinal needle, and attaining the correct location at the subarachnoid space. Following the pre-survey, the authors provided the SRNAs a 15-minute step-by-step instruction video, a neuraxial Frequently Asked Questions (FAQs) session, and a technique description that was retrieved from the literature (Udani et al., 2014; Tanaka, 2013). The 15-minute step-by-step instruction video and the neuraxial FAQ sessions were interventions that were added by the authors to ensure that all participants were provided appropriate information on exact techniques.

Finally, simulation training was held where students performed neuraxial techniques on both a watermelon and a neuraxial task trainer, and concluded with a post-survey. The post-survey followed a similar Likert-scale design as the pre-survey: it included additional questions that asked SRNAs to compare the differences between the use of a watermelon and a neuraxial task trainer.

Project Short and Long-Term Goals

Both short and long-term goals were considered for this project. The short-term goal of this project was to increase skill acquisition and comfort level of SRNAs during the didactic phase with the use of a neuraxial task trainer for simulation. The long-term goal was the permanent implementation of a neuraxial task trainer into the didactic phase curriculum. Both

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short and long-term goals of the study were in alignment with offering SRNAs a more realistic, hands-on training evolution in a safe and non-stressful environment.

Relevance

The Department of Defense (DoD) recognized that to maintain an effective fighting force, the Defense Health Agency (DHA) needed to increase readiness, improve the health of the military community, providing superior quality of care, and maximizing efficiency (Defense Health Agency, 2013). Newly graduated military CRNAs can find themselves deployed to austere environments upon program completion, and increasing their comfort level performing neuraxial techniques can prove to be beneficial. Implementing the most effective evidence-based tools and methods supports the goals of Quadruple Aim, a framework for the delivery of high-value care, and is a critical element of establishing a culture that delivers safe and reliable care.

Organizing Framework

The organizing framework for this project was the Iowa Model of Evidence-Based Practice. The Iowa Model provides a step-by-step guide to implement evidence-based changes (Brown, 2014). This model involved a multi-step approach to help translate evidence into practice. The first step of the model was to identify either a *problem-focused trigger* or a *knowledge-focused trigger* that warrants the change (Brown, 2014). The problem that this project identified was the low comfort level of neuraxial needle placement by students in the didactic phase of the Registered Nurse Anesthesia program. The second step in the Iowa Model was to determine if the current watermelon training aid was adequate, as depicted in Figure 1.

The Iowa Model of Evidence Based Practice to Promote Quality Care

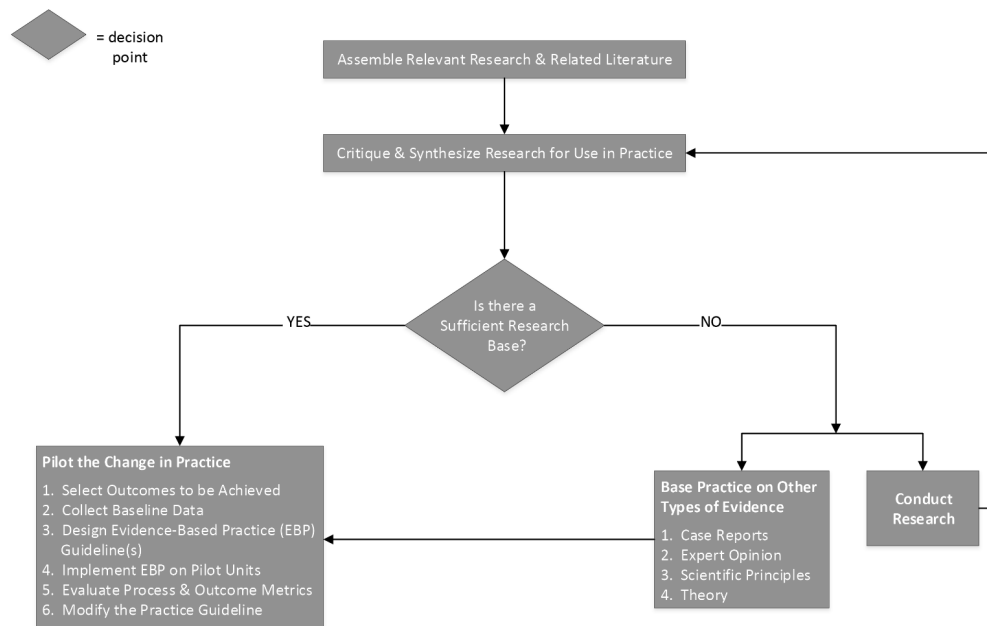


Figure 1. *The Iowa Model*

The Iowa Model has been used in many other improvement projects within the medical field, allowing improved practices and changes to be placed in different healthcare milieus. For example, Lloyd, D’Errico, and Bristol (2016) used the Iowa Model to develop a curriculum framework for a Doctor of Nursing (DNP) practice project. The authors reported developing an infrastructure for the DNP curriculum and final project using the Iowa Model, and were able to strengthen the project’s purpose, ensure competency fulfillment, retention, and timely completion utilizing best practices obtained from the literature. The authors in this study reported that their program had a high completion rate by the participants. This model was beneficial in this project because the authors had similar goals compared to Lloyd, D’Errico, and Bristol (2016). The authors in this current project aimed to ensure competency fulfillment, retention, and timely completion within the use of evidence-based practice.

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After the authors identified the problem, they formed a team to assist with their development and implementation. Next, the authors conducted a review of current literature with the assistance of a librarian, and then synthesized and critiqued all gathered evidence. Based on the findings of the literature review, the authors found evidence that supported their clinical question. The final steps of the project included transferring the evidence into practice, and if successful, to institute a permanent simulation training at USU utilizing neuraxial task trainers.

Project Design

General Approach

The project was designed to evaluate the current practice of using a watermelon as the primary method for training student's neuraxial techniques utilizing a pre and post-test survey. The use of a watermelon as a training aid, when teaching neuraxial anesthesia, provides a method where trainees can experience a loss of resistance when performing an epidural, spinal, or a combined spinal-epidural procedure (Frank, 2019). The authors provided training materials to the students in the form of a video, and conducted two separate simulation labs where the students utilized both the watermelon method and the neuraxial task trainer.

Setting

This project took place in the simulation labs at the Uniformed Services University of the Health Sciences, Bethesda, MD. The class of 2021 consisted of a cohort size of 31 SRNAs that comprised the Navy, Army, and Air Force branches. Three CRNA faculty assisted the authors in carrying out this project as evaluators. There were two watermelon stations and two neuraxial task trainer stations that were partitioned off, and students could not see or hear each other. The neuraxial task trainers used were a blue phantom lumbar puncture and spinal/epidural training model (Model BPLP210) and a Genesis epidural and spinal injection simulator.

Procedural Steps

Evidence Evaluation

The authors searched PubMed, PubMed Central, Excerpta Medical Database (EMBASE), Cumulative Index of Nursing and Allied Health Literature (CINAHL), and Cochrane Library from 2000 to 2018. The following words or phrases were used as search terms in all databases: *epidural, spinal, simulation training, regional anesthesia, anatomic models, education, and training*. Database searches were limited to a year range of 2000 to 2018 in the English language, and as of November 27, 2018, the authors retrieved 340 articles. The majority of the articles reviewed were considered recent in nature (2015 to current). Seminal or foundation sources (2014 and older) were used to demonstrate historical sources on the topic being researched.

Each article was appraised for the level of evidence using the evidence pyramid (Murad, Asi, Alsawas, & Alahdab, 2016). Two articles were Level I systematic reviews (Vaughan et al., 2013; Green, Tariq, & Green, 2016), and the remaining 24 were Level IV prospective cohort studies, prospective observational, retrospective cohort, or background information. The Johns Hopkins Nursing Evidence-Based Practice Appendix E: Research Evidence Appraisal Tool was used to evaluate the quality of each of the 22 articles (Johns Hopkins University, 2016). Eight articles were of high quality, 12 were good quality, and two were low quality. All of the articles pertained to the clinical question: does the implementation of a neuraxial task trainer improve skill acquisition and comfort level of SRNAs at USU during the didactic phase of education?

The majority of the articles concluded that simulation training improved skill acquisition of novice anesthesia providers, increased the comfort level of the anesthesia provider and that neuraxial task trainers most accurately represented the human anatomy.

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Implementation

Initial data collection measured the comfort level of SRNAs before neuraxial simulation training. The authors collected data from 31 SRNAs via an anonymous survey utilizing a five-point Likert Scale (1= Extremely, 5 = Not at all) (Chen, 2016). Following the survey, the authors provided the SRNAs a 15-minute step-by-step instruction video, and a neuraxial FAQ and technique description that was retrieved from the literature (Udani et al., 2014; Tanaka, 2013). The neuraxial FAQs and the 15-minute step-by-step description were selected from a robust literature search where multiple studies highlighted specific and proper procedures that must be followed when performing neuraxial techniques.

The following day, SRNAs performed neuraxial techniques (epidural and spinal) on the watermelon training aid followed by the spinal/epidural task trainer. The simulation observers comprised of the USU CRNA faculty and the authors measured skills acquisition through a neuraxial skills checklist obtained from the literature (Udani et al., 2014). The skills checklist was only used for the observation of placing a spinal, with minimal interference and no guidance from the observers. Once the students completed the spinal needle placement, they were allowed to place an epidural, with assistance, on both the watermelon and the neuraxial task trainer without a checklist. During placement of the epidurals, the observers were able to guide and teach the students.

The final data collection consisted of a post-simulation anonymous survey on comfort level with the same five-point Likert Scale questions as the pre-simulation survey plus the additional questions comparing the effectiveness and preference between the watermelon training aid and neuraxial task trainer.

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Plan for Data Analysis

The authors consulted a statistician and utilized quantitative non-parametric and parametric tests as appropriate to compare results. Non-parametric tests aided the authors in not making assumptions regarding the distribution of the samples (Hopkins, Dettori, & Chapman, 2018). Additionally, by using parametric tests, the authors were able to assume any underlying statistical distributions of the dataset. This can be beneficial as parametric tests often have higher levels of power compared to their non-parametric counterparts (Campbell, 2018). It is also important to note that there were additional benefits when completing non-parametric tests. These types of tests frequently appear more robust and allow the authors to ensure validity in a broader range of situations (Fox, 2018). The authors used non-parametric tests alongside parametric tests in this project, as some of the parametric models appeared too restrictive in relation to the fit of the data. Therefore, both parametric and non-parametric tests aided the authors in comparing the watermelon training aid and neuraxial task trainer with respect to student pre and post-implementation comfort levels and device preferences.

When completing the data analysis, the authors were able to clean the data before completing the required statistical tests. When cleaning the data, the authors followed these specific steps:

1. Identified incorrect values for the specific variables that were being evaluated.
2. Checked to ensure that the data represents the inclusion criteria of the project. If the authors found many entries that did not meet the inclusion criteria, they were deleted.
3. Checked and deleted duplicate cases in the dataset.
4. Checked for any missing data and outliers.
5. Identified any skip-patterns or logic breakdowns (Chu, Ilyas, Krishnan, & Wang, 2016).

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When completing non-parametric tests, the authors followed these specific steps:

1. Created the hypothesis and determine a level of significance.
2. Set a test statistic.
3. Set a decision rule.
4. Calculated the test statistic.
5. Compared the test statistic to the decision rule (Verma, 2019).

HIPAA Concerns (IRB)

This project involved the collection of skills evaluation data from students at the Uniformed Services University of the Health Sciences. The authors did not collect personal identifiable information (PII) or protected health information (PHI) during the course of this project. To ensure the protection of student participants, the authors submitted their evidenced-based practice (EBP) project for a review by the USU Institutional Review Board (IRB) to also verify compliance with the DoD privacy program (DoD Directive 5400.11) and the Health Insurance Portability and Accountability Act (HIPAA). All anonymous data (de-identified) was stored on a CAC enabled computer that was stored in a locked room. All physical data (surveys) were stored in a locked file cabinet in a locked room. All physical data was shredded at the conclusion of this project. Only the authors had direct access to confidential information and the dataset.

Project Results

All of the 31 students who participated in this project were in the 2021 graduating class and in the didactic phase of the program. None of the participants had practiced neuraxial techniques up until this project implementation. The pre-survey was disseminated two days before the simulation lab and there was a 100% completion rate. The training materials were

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disseminated two days before the simulation lab as well, but there was not a way to ensure the students reviewed the information. There was a 100% completion rate of the post-survey on site after the simulation lab.

A comparative analysis was performed using the Fishers Exact Test for pre- and post-sample scores for the four questions included in both surveys, as depicted in Figures 2 and 3 below. The data was dichotomized in which responses of *Extremely*, *Very*, and *Moderately* were combined, and *Slightly* and *Not at All* were combined. Questions one and four were significant with the P-value set at 0.05, and questions two and three were not significant. *Student's comfort with teaching another trainee* differed significantly between the pre and post-survey ($P < 0.01$). Overall, students indicated higher levels of comfort in the post-survey, with 30 of the 31 respondents reporting that they were at least *moderately* comfortable in the post-survey compared with only four respondents in the pretest. In regards to the *students' level of comfort attaining the target location*, 29 of the 30 students reported they are at least *moderately* comfortable in the post-survey compared with only two in the pre-survey.

t-Test: Paired Two Sample for Means

| | Variable 1 | Variable 2 |
|------------------------------|------------|------------|
| Mean | 6.2 | 6.2 |
| Variance | 39.7 | 49.2 |
| Observations | 5 | 5 |
| Pearson Correlation | -0.28397 | |
| Hypothesized Mean Difference | 0 | |
| df | 4 | |
| t Stat | 0 | |
| P(T<=t) one-tail | 0.5 | |
| t Critical one-tail | 2.131847 | |
| P(T<=t) two-tail | 1 | |
| t Critical two-tail | 2.776445 | |

Figure 2. T-Test: Paired Two Sample for Means

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t-Test: Two-Sample Assuming Unequal Variances

| | <i>Variable 1</i> | <i>Variable 2</i> |
|------------------------------|-------------------|-------------------|
| Mean | 6.2 | 6.2 |
| Variance | 68.2 | 96.7 |
| Observations | 5 | 5 |
| Hypothesized Mean Difference | 0 | |
| df | 8 | |
| t Stat | 0 | |
| P(T<=t) one-tail | 0.5 | |
| t Critical one-tail | 1.859548 | |
| P(T<=t) two-tail | 1 | |
| t Critical two-tail | 2.306004 | |

Figure 3. *T-Test: Two-Sample Assuming Unequal Variances*

The post-survey revealed that 99% of the students reported the task trainer provided better identification of the landmarks, better feedback, reinforced the didactic training, and was the preferred method over the watermelon method.

Analysis of Results

Although the students received some neuraxial didactic training in other classes such as Advanced Anatomy and Principles of Anesthesia II, students reported not feeling comfortable teaching another trainee based on this knowledge or being able to attain the target location. These classes only provided mental imagery to perform the skill. The data indicates that the implementation of training materials reinforced their previous didactic training and significantly increased the level of comfort performing these procedures, as well as teaching another trainee. Not having performed the physical skill prior to the simulation lab, the students selected the task trainer as the best method to learn these skills. Reasons stated were better feedback of loss of resistance when entering the different layers and provided the realistic landmarks that the watermelon could not provide.

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It is essential to view these results in relation to the literature that has been completed in the field. For example, Chen et al. (2016) completed a study that focused on improving the comfort level and competency of 40 anesthesia residents by designing an intervention program. The intervention program included having the residents complete a survey, review a skills checklist, watch a 15-minute video, and review a FAQ sheet alongside the completion of a simulated regional lab. With the purpose of their study determined whether simulation training may improve both trainee comfort level and competency with needle driving, it was concluded that the residents who completed this intervention and program demonstrated a significantly improved level of comfort and competency. Chen et al.'s (2016) study highlighted a direct alignment with this current project, as the students reported the task trainer provided better identification of the landmarks, better feedback, reinforced the didactic training, and was the preferred method over the watermelon method.

Additionally, Udani et al. (2014) also completed a study that focused on how simulated-based training significantly increases performance by completing a project where 21 anesthesia residents in the operating room perform spinal anesthesia. The results of the study highlighted that the participants who were exposed to the teaching curriculum significantly improved resident performance. This also aligned with this current project where students also increased their comfort levels and performance.

Limitations of the study. This study had limitations that need to be identified. First, the authors utilized two different task trainers due to the availability of task trainers on hand. Both models provided the same haptic feedback; however, one provided better anatomy. The author's rationale for using two different models was that they both were task trainers and still provided the same advantages over the watermelon. Another potential limitation was that the students only

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performed a spinal procedure without assistance that was observed with a checklist. The epidural procedure was more of a teaching moment and observers were able to assist the students.

The difference between the watermelon and the task trainer was still present regardless of which procedure was performed (i.e., the watermelon did not provide anatomy, landmarks and layers for loss of resistance). Due to the post-survey including four additional questions related to the difference between two methods, the authors could not compare that data. Additionally, the authors were unable to match up the paired responses in their data set. By assuming that the pre and post-survey responses from the same students were independent, this allowed the authors to dichotomize the data so that they could complete a Fisher's exact test.

Organizational Impact/Implications to Practice and Policy

The EBP project concluded that a training program that encompasses mental imagery, or practices in the form of didactic training and visual training (video), combined with a simulation lab is effective in increasing a student's level of comfort prior to practicing in the clinical arena. The use of a neuraxial task trainer proved to be the preferred method of learning, as identified by the SRNAs, and this skill enhanced the didactic training that was received prior to the simulation. The cost of a neuraxial task trainer is approximately five thousand dollars. The watermelon method may be cost-effective, but the USU Nurse Anesthesia Program, based on data collected by this project, should consider utilizing a realistic task trainer.

Implementation of the task trainer and supplemental training materials can prove beneficial for students entering into the clinical phase of their training (Phase II) by increasing their comfort level prior to interacting with a real patient. Additionally, with a student's increase in comfort and increased skills, they are better aligned with the MHS quadruple aim to provide better care.

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Future Direction for Research and Practice

Future projects should consider measuring secondary outcomes such as knowledge retention and competency. A measurement of comfort level could be measured when students place their first few spinal and epidurals in the clinical phase of their training. This information would demonstrate if the training affected students' comfort and skill levels when performing techniques on actual patients. Another consideration would be to compare the use of high-fidelity simulation training such as computer-based simulators versus low fidelity training such as the task trainer. Other projects could also take on the role of following a more qualitative methodology, where students can complete semi-structured interviews and provide their perceptions and lived experiences regarding different training programs (Creswell & Creswell, 2017). Qualitative methodologies can aid researchers by having participants answer questions in any manner that they seem fit, providing a more robust and personal review of their experiences when it comes to knowledge retention and competency in the arena of utilizing neuraxial techniques (Glesne, 2016).

Conclusion

This project aimed to identify and implement a training program that encompassed checklist and visual training (video), combined with a task trainer simulation lab, in the didactic phase of an anesthesia program to effectively increase a student's level of comfort prior to practicing in the clinical setting. Some research has demonstrated that there is no difference between task trainers and fruit, and that fruit did indeed represent the different layers in neuraxial placement (Frank, 2019). However, there were suggestions that mental practice, prior to physical practice, for new skills can be more effective than the mental practice or physical practice alone (Lim et al., 2016). The authors in this project demonstrated that a combination of training

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materials with a task trainer was the preferred method rather than utilizing a watermelon. Despite the limitations of the project, it would be a beneficial to the students, prior to starting the clinical phase of their training, to utilize a neuraxial task trainer to improve comfort and skills.

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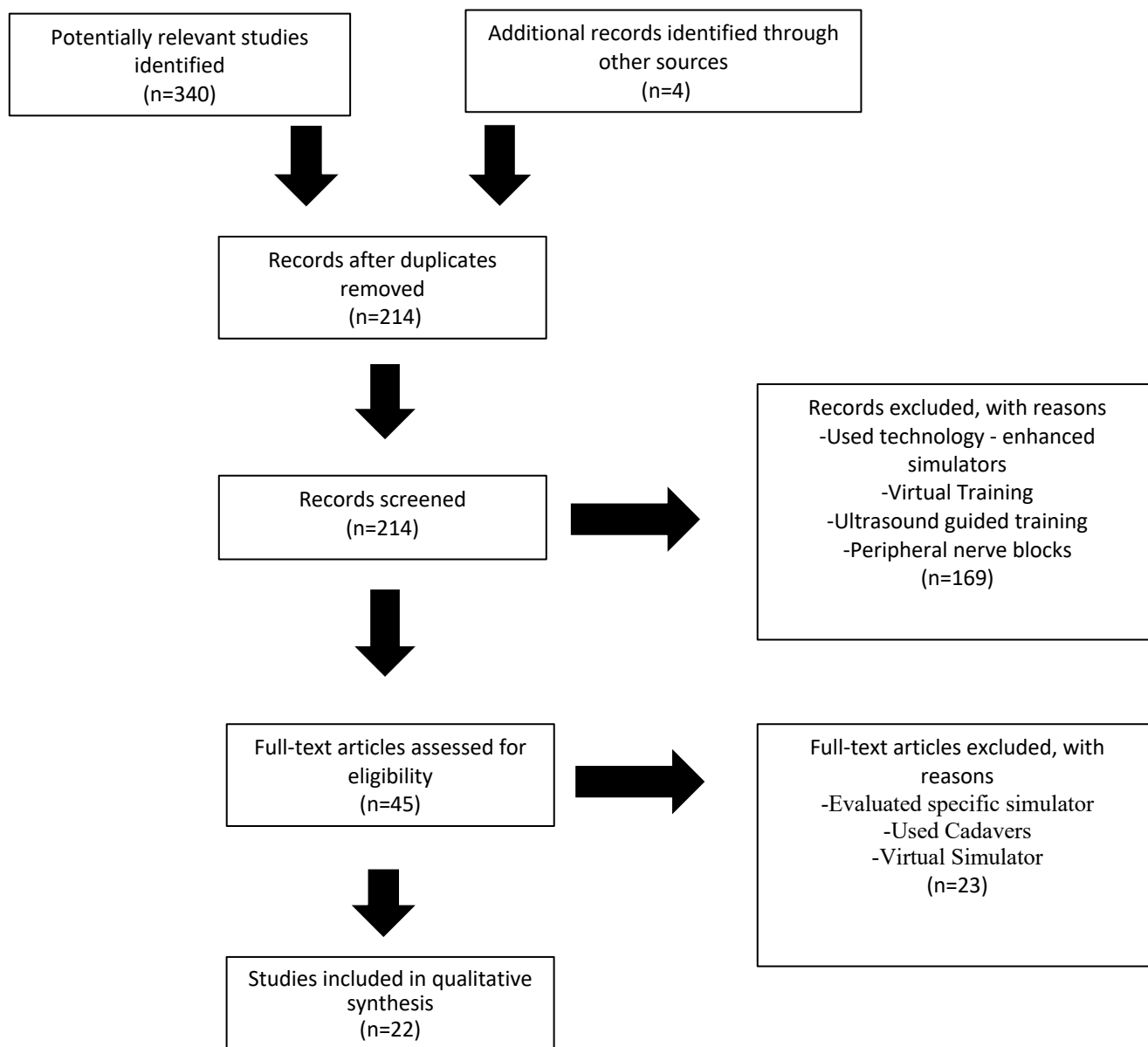
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Appendix A – PRISMA Diagram



Appendix B – Evidence Table

| Source | Related to EBP | Design Type | Study Design & Study Outcome Measures | Study Setting & Study Population | Study Intervention | Key Findings |
|--|---|------------------------------|--|---|--|--|
| Sujatta, S. & Oberarztin (2015) | It is ethical to practice on patients | Systematic Literature Review | Outcomes – Reviews current simulators and educational processes | Residents | Interventions were educational materials, different simulators | Four major components – 1. Acquiring cognitive knowledge about the specific procedure, including the steps of the procedure, the function and operation of the equipment; 2. Receiving instruction on basic enabling skills required for the procedure; 3. Simulation-based education with deliberate practice in achieving specific clinical skills with feedback during training; and 4. Continued access to this practice for continued improvement |
| Udani, A. D., Kim, T. E., Howard, S. K. & Mariano, E. R.. 2015 | Simulation training for regional anesthesia education and its effectiveness | Systematic Literature Review | Outcomes – Simulation based training effective in anesthesia | 79 Articles, 14 articles solely descriptions of simulators; 14 articles published study the effect on learners who underwent a simulation-based educational intervention in regional anesthesia; 18 articles describe the design of a novel regional anesthesia simulator; 11 articles present a new medical device or evaluate an established nerve block technique in a simulated environment; The remaining articles span a broad range of topics, and none test the effectiveness or efficacy of simulation-based teaching in regional anesthesia | Interventions were simulation based, simulator designs; simulated environment as an experimental setting | As technology advances in regional anesthesia, training needs to as well. The simulated environment is ideal for training; however, the topic needs further research. |
| Smith, T. S., Johannsson, H. E. & Sadler, C.. 2005 | Can simulation training make a difference | Systematic Literature Review | Outcome measures – Does simulation training enhance the skills of the OB anesthesia provider | | Course surveys, integration of simulation training into obstetric training | Today's trainers of anesthetists have a responsibility to adapt the current training programs. Simulation has much to offer obstetric anesthesia and should be part of the solution |
| Jeong, S. M., Choi, J. M., Kim, J. H., Yoo, H., Lee, S., Seo, H., Kim, S. & Kim, S. H.. 2016 | Simulator as an educational tool over the greengrocer method training novices | Controlled Trial | Survey methods Outcomes – Assess lumbar epidural simulator as a possible training tool. | Setting – Simulation Population – 89 Anesthesiologist | Simple 3 syringe simulator versus the greengrocer method | Epidural anesthesia depends greatly on haptic feedback. The greengrocer method has drawbacks such as a lack of uniformity in the different fruits |
| Chen, H., Kim, R., Perret, D., Hata, J., Rinehart, J. & Chang, E.. 2016 | Improving comfort level and competency using simulation training | Prospective, observational | Outcomes – Measure level of comfort and competency after simulation training | 40 Anesthesia residents | Surveys and skills checklist, 15-minute video, FAQ sheet, simulated regional lab | Simulation training may improve both trainee comfort level and competency with needle driving. After a brief lecture and a 30-minute training session with the simulator, subjective comfort measures and competency were significantly improved compared to before. |

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|--|--|------------------------------|--|---|--|--|
| Udani, A. D., Macario, A., Nandagopal, K., Tanaka, M. A. & Tanaka, P. 2014 | Simulation based training improves performance | RCT | Simulation training with deliberate practice improve clinical performance in spinal anesthesia | 21 anesthesia residents in the OR for 3 neuraxial procedures, and in the simulated environment. | After baseline assessment of SAB on a task-trainer, all residents participated in a base curriculum. Half the residents received additional deliberate practice including repetition and expert-guided, real-time feedback. All residents were then retested for technique. SABs on all residents' next three patients were evaluated in the operating room (OR) | The curriculum significantly improved resident SAB performance. Deliberate practice training added a significant, independent, incremental benefit |
| Vaughan, N., Dubey, V. N., Wee, M. Y. K. & Isaacs, R. 2013 | Type of simulator | Meta- analysis | Detailed evaluation of the need of epidural and spinal simulators in the first instance and then draws comparisons between computer-based and manikin-based simulators | 31 simulators reviewed | | Manikin models are easier to set up, more portable, easier to clean and are often less expensive. Manikins are physical rather than virtual, and since a clinician uses his/her hands to perform the epidural insertion, a physical simulator may be a closer analogy to a patient from the tactile point of view. The user can see the physical body and choose where to insert the needle. |
| Chang, C. H. 2013 | Simulation training and patient safety | Review | Simulation training after "traditional" training is more effective for training technical skills such as epidural and spinal procedures | Residents after anesthesia traditional training | Anesthesia Training with Simulators, Simulation Training Process, Simulation in Technical Skill Teaching, Anesthesia Non-technical Skills | Technical skills and non-technical skills can be learned by anesthesiology residents through a standardized and organized simulation program |
| Green, M., Tariq, R. & Green, P. 2016 | Simulation training in anesthesia | Systematic Literature Review | History and evolution of use of simulation in anesthesiology and highlights some of the more recent studies that have advanced simulation-based training | Articles with different types of simulation training in anesthesia, that is, simulation of airway management, simulation of ultrasound guided regional anesthesia, use of simulation in obstetric anesthesia, and cardiothoracic anesthesia training. | Review of simulation training in the three different settings and its effectiveness through review of the literature | The use of simulation in an anesthesiology department requires considerable faculty development, yet such programs are poorly defined. Over the last few years there has been an increased interest in team-based simulation training particularly interdisciplinary simulation training. the use of simulation in anesthesiology is evolving rapidly and integrating deeply into the anesthesia curricula, and it seems likely it will continue to do so. |

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|--|--|--------------------------------|---|---|--|--|
| Allen, Meincke, Ramirez, Watts, Marienau, 2003 | Develop and evaluate a new model for teaching spinal anesthesia to SRNAs | Randomized Control Trial (RCT) | 6 groups, 6 stations, 2 models (spinal & traditional) Difference in the number of success rates? Amount of time taken for the spinal attempts? The number of participants who reached 90% proficiency? | Mayo School of Health Science laboratory & 26 SRNAs w/15 months in the program and no prior regional anesthesia experience or experience w/ the models. | Performing spinal placement on newly designed model | Significant difference b/w students who used both visual & haptic sense (spinal model) and who used primarily the haptic sense (traditional) |
| Capogna, G. | Evaluation of a new training device for neuraxial anesthesia techniques | Cross-sectional study | Each experienced anesthetist performed an epidural and a lumbar puncture and then scored their likeness to a real pt. using a Likert scale | Simulation lab & 20 expert obstetric anesthetists who are instructors | | The device may be a promising tool for training neuraxial procedures |
| Del Buono, R | A simple & cheap simulator for training in spinal anesthesia | Case study | One group received a 25 min training & then performed at least 20 punctures before touching a real pt | Simulation lab 25 residents | | The approach improved residents' confidence towards spinal anesthesia & could reduce the adverse effects on the pts. |
| Friedman, Z. | High-versus low-fidelity model training | RCT | 72 sessions by 24 residents were recorded. Manual skill checklist & global rating scale total scores were compared using independent-samples t tests. | 24 second-year anesthesia residents | Performing epidural placements on either low or high-fidelity models | A simple model can be as useful for learning how to place an epidural catheter as an expensive anatomically correct simulator |
| Lee, R. | Evaluation of the Mediseus epidural simulator | Cross-sectional study | 3 groups of 15 anesthesia trainees & scored on 20 simulated epidural needle insertions on time, success of the insertion & bone collisions | 45 anesthesia trainees | | The simulator seems to be an appropriate training device for an introduction to epidural needle insertion |

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|--------------------------------------|--|--------------------------------------|---|---|--|--|
| Murray D.J. | Overview of recent studies that expand the simulation curriculum | Literature Review | | | | Using recent literature can help guide a simulation curriculum to improve clinical training |
| Pratt, S.D. | Task simulators for epidural placement | Literature Review/ Focused Review | | | | Simulation training is beneficial to obstetric anesthesia. |
| Rabago, J. L. | Evaluation of a simulation-based introductory course to anesthesia | Prospective Study | Checklist of 28 skills and behaviors was used to assess & satisfactory survey | Simulation lab & 12 first year anesthesiology residents | | >83% of participants reported a high level of self-efficacy in placing epidural catheter |
| Schornack, L.A. | Low and high fidelity simulation devices | Qualitative Study/Review | | | | Simulation allows for practice of tasks and teamwork in a controlled manner |
| Wiggins, L. L. | Develop and improve a regional anesthesia training course | Cross-sectional survey | Quality improvement project | 49 experienced CRNAs completed course components including skills training & checklists | | Knowledge & confidence levels demonstrated significant gains |
| Yunoki, K., 2018 | The efficacy of simulation training in anesthesia education | Literature Review | | | | To provide an overview of the status of simulation training, encourage more simulation education and stimulate future research |
| Lawrand Ltd Medical Publishing, 2014 | To improve the patient experience & reduce risk of harm | Literature Review | | | | To implement an epidural simulator in anesthesia training |

NEURAXIAL TRAINING

Appendix C – Neuraxial Procedure Comfort Level Pre Survey

Name: _____

Date:

Please answer the following questions regarding your comfort performing neuraxial procedures

1. If you had to teach another trainee, how comfortable would you be?
 - a. Extremely
 - b. Very
 - c. Moderately
 - d. Slightly
 - e. Not at all

2. What is your level of comfort in placing needles for interventional procedures?
 - a. Extremely
 - b. Very
 - c. Moderately
 - d. Slightly
 - e. Not at all

3. What is your level of comfort maneuvering a spinal needle?
 - a. Extremely
 - b. Very
 - c. Moderately
 - d. Slightly
 - e. Not at all

4. What is your level of comfort attaining the target location?
 - a. Extremely
 - b. Very
 - c. Moderately
 - d. Slightly
 - e. Not at all

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Appendix D – Neuraxial Procedure Comfort Level Survey Post Survey

Name: _____

Date:

Please answer the following questions regarding your comfort performing neuraxial procedures

5. If you had to teach another trainee, how comfortable would you be?
 - a. Extremely
 - b. Very
 - c. Moderately
 - d. Slightly
 - e. Not at all

6. What is your level of comfort in placing needles for interventional procedures?
 - a. Extremely
 - b. Very
 - c. Moderately
 - d. Slightly
 - e. Not at all

7. What is your level of comfort maneuvering a spinal needle?
 - a. Extremely
 - b. Very
 - c. Moderately
 - d. Slightly
 - e. Not at all

8. What is your level of comfort attaining the target location?
 - a. Extremely
 - b. Very
 - c. Moderately
 - d. Slightly
 - e. Not at all

NEURAXIAL TRAINING

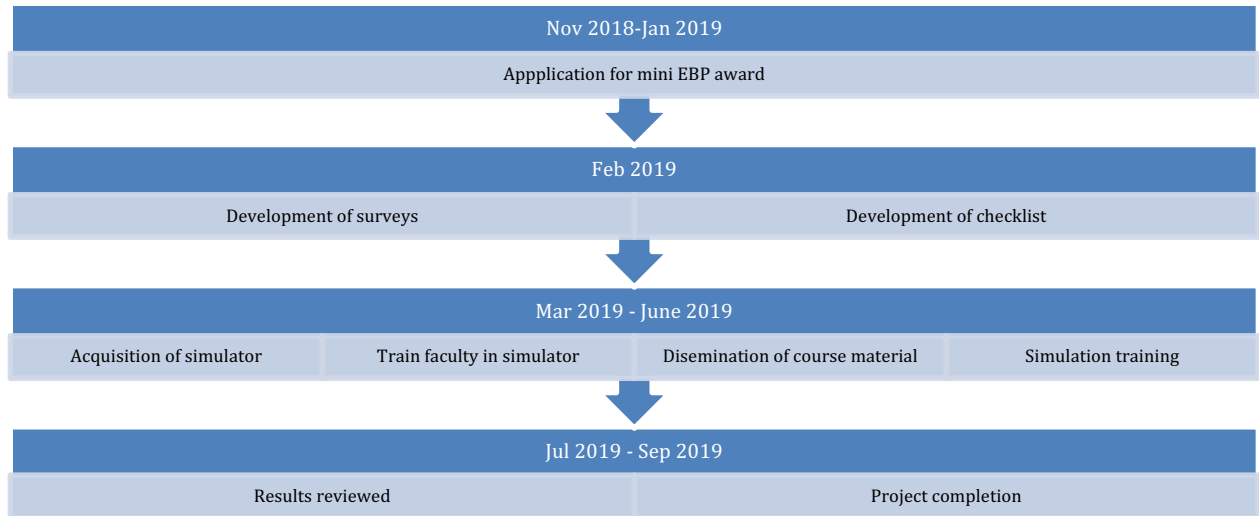
9. Which method provided better identification of landmarks? Watermelon_____ Task Trainer_____
- Extremely
 - Very
 - Moderately
 - Slightly
 - Not at all
10. Which method provided better feedback (Loss of resistance)? Watermelon_____ Task Trainer_____
- Extremely
 - Very
 - Moderately
 - Slightly
 - Not at all
11. Which method do you prefer? Watermelon_____ Task Trainer_____
- Extremely
 - Very
 - Moderately
 - Slightly
 - Not at all
12. Which method was more effective in reinforcing your didactic training? Watermelon_____ Task Trainer_____
- Extremely
 - Very
 - Moderately
 - Slightly
 - Not at all

NEURAXIAL TRAINING

Appendix E - Procedural Checklist for Subarachnoid Block

- | Task | Satisfactory (S) | Unsatisfactory (U) |
|------|---|--------------------|
| (1) | Performs a “time-out” and places monitors on patient (pulse oximetry and NIBP). | S U |
| (2) | Verifies that spinal kit tray, nonsterile and sterile gloves (correct size), and cleansing solution are present. | S U |
| (3) | Palpates the superior aspects of the iliac crests and identifies the intersection at the L4 spinous process with nonsterile gloves on. Marks position at the L3/L4 or L4/L5 interspace. | S U |
| (4) | Cleans the overlying skin with chlorhexidine. | S U |
| (5) | Opens the spinal tray before placing sterile gloves on. | S U |
| (6) | Puts on sterile gloves with proper technique. | S U |
| (7) | Applies sterile drapes. | S U |
| (8) | Draws up lidocaine in the 3cc syringe and bupivacaine in the 5cc syringe. Administers local anesthesia in a wheal at the previously marked site. | S U |
| (9) | Injects more anesthetic in the correct location and angle. | S U |
| (10) | Inserts the introducer needle in the middle of the interspace with a slight cephalad angulation of 10 to 15 degrees. The bevel of the spinal needle should be in the sagittal plane. | S U |
| (11) | Advances spinal needle through anatomic structures until the subarachnoid space is reached. May experience a popping sensation as the ligamentum flavum is crossed. | S U |
| (12) | Withdraws the stylet each time a pop is felt to assess for CSF flow. | S U |
| (13) | Confirms CSF flow by aspiration before and after injecting anesthetic. | S U |
| (14) | Removes the spinal and introducer needle together once completed. | S U |
| (15) | Applies pressure with the provided 2 × 2 gauze and assesses good hemostasis. | S U |
| (16) | Removes the drape, lays the patient, and observes vitals. Disposes of all sharps and biohazard material appropriately. | S U |

Appendix F - Timeline



Appendix G - CITI Certificates



Completion Date 28-Aug-2017
Expiration Date 27-Aug-2020
Record ID [REDACTED]

This is to certify that:

Aaron Patterson

Has completed the following CITI Program course:

Responsible Conduct of Research (RCR) (Curriculum Group)
Responsible Conduct of Research (RCR) (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

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



Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w528cb090-36eb-4a55-b57d-d662fed396e5-24343581



Completion Date 28-Aug-2017
Expiration Date 27-Aug-2020
Record ID [REDACTED]

This is to certify that:

Aaron Patterson

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)



Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w9ced3d95-aff4-4745-a4b3-cba52cbcf45e-24343580

NEURAXIAL TRAINING



Completion Date 30-Aug-2017
Expiration Date 29-Aug-2020
Record ID [REDACTED]

This is to certify that:

DAISHA WILSON

Has completed the following CITI Program course:

Responsible Conduct of Research (RCR) (Curriculum Group)
Responsible Conduct of Research (RCR) (Course Learner Group)
1 - Basic Course (Stage)



Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness) National Training Initiative

Verify at www.citiprogram.org/verify/?w41cac209-a627-4a3e-a58c-8faca329e3d3-24376449



Completion Date 30-Aug-2017
Expiration Date 29-Aug-2020
Record ID [REDACTED]

This is to certify that:

DAISHA WILSON

Has completed the following CITI Program course:

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



Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness) National Training Initiative

Verify at www.citiprogram.org/verify/?w23d86f4d-3f8b-43c9-8a65-9b21cfe22c87-24302268

Appendix H – Notice of Project Approval Letter



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

NOTICE OF PROJECT APPROVAL

Change Number: Original


VPR Site Number: GSN-61-10699
Principal Investigator: Patterson, Aaron
Department: Graduate School of Nursing
Project Type: Student
Project Title: A Comparison Between Two Low-Fidelity Neuraxial Simulation Techniques
Project Period: 1/1/2019 to 4/1/2020

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.


Yvonne T. Maddox, Ph.D.
Vice President for Research
Uniformed Services University of the Health Sciences
Date: 2 July 2019

cc: Patterson, Aaron
File

NEURAXIAL TRAINING

Appendix I – IRB/PI Letter of Determination



UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

4301 JONES BRIDGE ROAD
 BETHESDA, MARYLAND
 20814-4799
 www.usuhs.edu



18 July 2019

MEMORANDUM FOR LCDR DOUGLAS T. JOHNSON, NC, USN, GRADUATE SCHOOL OF NURSING

SUBJECT: Uniformed Services University (USU) Human Research Protections Program (HRPP) Determination of Not Research for Protocol Neuraxial Spinal/Epidural Task Trainer (eIRB Ref# 914873)

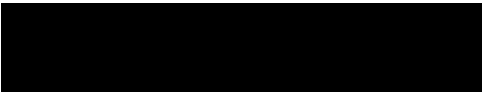
Protocol Neuraxial Spinal/Epidural Task Trainer (eIRB Ref# 914873), entitled “Implementation of a Neuraxial Spinal/Epidural Task Trainer: A Quality Improvement Project” was reviewed by the Uniformed Services University’s Human Research Protections Program Office and determined not to meet the criteria of research as defined at 32 CFR 219.102(l), and applicable DoD policy guidance. As such, this protocol does not require Institutional Review Board (IRB) review.

The purpose of this quality improvement project is to implement a spinal/epidural task trainer, increase skill acquisition and comfort level of 31 Student Registered Nurse Anesthetists (SRNA), and create a sustainability plan for enhanced education in the didactic phase. USU nursing students will be performing spinal and epidural procedures comparing a watermelon vs. the task trainer. This activity will collect data from surveys of experience.

As a reminder, it is your responsibility to ensure all necessary approvals have been obtained prior to initiating activities associated with this project.

Should your project data sources, personnel, or methodology change, please contact this office before you implement any changes to your work so that we may review it with you. Otherwise, we cannot ensure you will be in compliance with all applicable human subjects research regulations. The IRB/HRPPO staff is a key resource that is available to assist you to ensure you are in compliance with applicable human research regulations.

If you have questions regarding this action, or questions of a more general nature concerning human participation in research, please contact Elizabeth Thammasuvimol at 301-295-0704 or elizabeth.tham.ctr@usuhs.edu.


 Petrice B. Longenecker, PhD, MA, CIP
 Exemption Determination Official
 Human Protection Administrator

*Learning to Care for Those in Harm's
 Way*

