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Educating Parturients on Labor Analgesia


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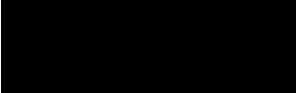
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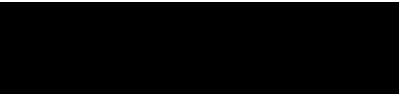
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Due to the impact of the COVID19 Pandemic, 2020 graduates of the Daniel K. Inouye Graduate School of Nursing were deemed critical to the mission of caring for the health of the nation. All phases of the DNP Project were complete and met the standards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

Table of Contents

Abstract	4
Introduction	5
Significance of the Problem	5
Clinical Question	6
Focus Areas	6
Relevance to Military Nursing	7
Organizing Framework	7
Project Design	8
General Approach	8
Procedural Steps	10
HIPAA Concerns	13
Project Results	14
Analysis of Results	15
Organizational Impact	17
Future Directions	17
Conclusion	18
References	19
Appendix A	24
Appendix B	32
Appendix C	33
Appendix D	41
Appendix E	42

Abstract

Background or Problem: Through a needs assessment, stakeholders at Naval Medical Center San Diego (NMCS D) identified the absence of a standardized, evidence-based approach to providing education to parturients regarding epidural analgesia.

Clinical Question: Among parturients at NMCS D, did adjunct video education during the informed consent process increase perception of knowledge about epidural analgesia and satisfaction?

Project Design: An electronic tablet was the selected method for delivering the video after considering all options due to portability, ease of use, and overall practicality. The project team invited 100 parturients over a three-month time frame to view an educational video on an iPad upon admission to the labor and delivery (L&D) unit just before the consenting process. The team then administered a Likert-scale survey to assess perceived knowledge and satisfaction after parturients watched the video.

Analysis of the Results: Results demonstrated the video provided significantly improved epidural analgesia education and NMCS Ds s consenting process. Survey results indicated a statistically significant increase in perceived knowledge with an increase in median score from three to five and a 99% satisfaction rate with the content of the information provided in the video.

Organizational Impact and Implications for Practice: By providing an educational video to improve knowledge and satisfaction, this project addressed NMCS D's "Guiding Principles" and the Military Health System (MHS) Quadruple Aim of providing "Better Care." Viewing the video had a direct correlation with increased knowledge about epidural analgesia, increased satisfaction with the consenting process, and improved patient care.

Introduction

A noteworthy study entitled “Listening to Mothers” employed a retrospective, open-ended survey of a nationally representative sample to investigate what parturients perceived as the best and worst parts of childbirth (Attanasio, Kozhimannil, Jou, McPherson, & Williams, 2015). One of the worst aspects of childbirth was severe pain, which can cause adverse physical, psychological, and emotional effects (Micaglio, Sorbello, & Di Filippo, 2018). Attanasio et al. (2014) found that parturients viewed neuraxial analgesia as a positive experience because it eased the pain of labor while allowing them to remain alert, which helped them enjoy the birthing process. However, Attanasio et al. (2014) also noted that some parturients were not satisfied with the amount of information they received before epidural placement.

Significance of the Problem

Annually, an average of 71% of parturients in the United States receives neuraxial analgesia by way of an epidural catheter, intrathecal injection, or a combined spinal-epidural (Alexander, Wong, & Guo, 2018). A large military treatment facility (MTF) reported in 2015 that 85% of parturients requested neuraxial analgesia for labor (Birkla, Phipps, & Loran, 2017). In order to perform invasive procedures, such as placing epidurals, permission is required from the patient through an informed consenting process. Informed consent entails educating the patient about the planned procedure(s) and informing them about the associated risks and benefits. According to Farrell et al. (2014), the traditional process for obtaining informed consent for invasive procedures is suboptimal for patients because poor information delivery can impair understanding of recommended treatments, reduce satisfaction with care delivery, and have a detrimental impact on treatment adherence. Prior to this project, the standard of practice for obtaining informed consent at NMCS D relied upon the anesthesia provider verbally explaining

the anesthesia plan along with the risk and benefits of neuraxial analgesia. Providers included anesthesiologists, anesthesia residents, Certified Registered Nurse Anesthetists (CRNAs), and Student Registered Nurse Anesthetists (SRNAs). The amount of information presented to patients varied and was not standardized. According to Attanasio et al. (2014), the variability between the provider's informed consent technique on the L&D unit can leave some patients feeling not adequately informed of the adverse effects of neuraxial analgesia before epidural placement. These adverse effects included discomfort during insertion, remaining still during contractions, lower extremity paresthesias, pruritus, and hypotension after epidural placement (Attanasio et al., 2014).

The goal of this project was to implement an evidence-based approach to educating parturients about epidurals to improve their level of knowledge, as well as provide a more comprehensive and informative consenting process. Farrell et al. (2014) reported that audio-visual education provided as an adjunct to the traditional verbal consent process improved patient knowledge and increased satisfaction with the amount of information supplied. Through a literature review, the project team discovered that adults learn best through a multi-modal approach that included audio-visual aids. The addition of an adjunct educational video was presumed to enhance parturients' understanding of labor epidural analgesia.

Clinical Question

Among parturients at NMCSD, did adjunct video education during the informed consent process increase perception of knowledge about epidural analgesia and satisfaction?

Focus Areas

The primary focus area was the implementation of an educational video that served as an adjunct to the consenting process for laboring epidurals. The goal was to improve patient

knowledge, increase satisfaction, and standardize the consent process. The second focus area was to collect surveys from 100 parturients who watched the video after initiation of the project to elicit their feedback. The survey would assess if parturients perceived the video improved their level of knowledge and if they were satisfied with the content of the video. The last area of focus was to disseminate the project findings to the anesthesia and obstetric staff leadership.

Disseminating this information to stakeholders provided an opportunity to examine potential benefits of a standardized educational video and create a plan for sustainability.

Relevance to Military Nursing

According to the Director of the U. S. Navy Nurse Corps (2018), the goal of Navy nursing is to seize opportunities to educate, lead, and shape policy within Navy healthcare. Navy CRNAs have the opportunity to educate and improve the parturient epidural experience by increasing knowledge prior to the consenting process. In alignment with the MHS goal of providing better care, improving knowledge and satisfaction enhances the birthing experience (Attanasio et al., 2014; Eley, Searles, Donavan, & Walters, 2013). The educational video selected for use was adapted from a pilot project conducted in 2017 at Naval Medical Center Portsmouth (NMCP), and their results indicated parturients reported increased knowledge following the viewing of the laboring analgesia video.

Organizing Framework

The Rosswurm and Larrabee's Model (RLM) for Evidence-Based Practice (EBP) organizing framework guided this project, which utilizes a six-step process. This process included completing a needs assessment, identifying interventions and outcomes, conducting a literature review, and designing, implementing, and sustaining the project. The RLM improves

the quality of care and education through a systematic process for the synthesis of literature and the implementation of a quality improvement project (Rosswurm & Larrabee, 1999).

Stakeholders identified included the anesthesia OB providers and L&D leadership. Data was collected internally to evaluate the current process of epidural education for parturients. Data collected was compared with external data through a literature review to develop a clinical question to address the problem. The literature review revealed that the addition of an audio-visual component could improve patient education as part of the consenting process. The problem, interventions, and outcome goals were established. Implementation required dissemination of an educational video and an evaluation tool to measure outcome indicators. Data analysis determined the efficacy of the laboring analgesia video and modifications potentially necessary for sustainment. Finally, the project members disseminated the results and practice change for sustainment.

Project Design

General Approach

This project was evidence-based and incorporated a post-implementation evaluation survey. The goal was to improve the informed consent process through adjunct education for parturients regarding epidural analgesia. To assess the need for a change in practice, the team conducted an assessment of the current consenting process for epidural placement for parturients. Several areas of concern were identified, including parturient knowledge gaps regarding epidural analgesia and a lack of standardization of information provided during the consenting process. Next, the project team identified the resources required for implementation. Additional site-specific actions included obtaining anesthesia and L&D leadership endorsement

of the proposal and submission to the Institutional Review Board (IRB) for their review and exemption.

Next, the team conducted a literature search of relevant databases, including PubMed, Cumulative Index of Nursing and Allied Health Literature (CINAHL), and Excerpta Medica database (Embase). The search results were limited in all three databases to English only, peer-reviewed, and with a date range from 2000 to present. The date range set was due to the volume of articles generated and to exclude outdated material. The PubMed search strategy and MESH terms used were variations of “pregnant women” or “pregnancy” and “anesthesia” or “anesthesia, epidural” or “anesthesia, obstetrical” and “informed consent.” The search string yielded 309 results. The CINAHL search terms included “labor” and “anesthesia” and “consent.” Variants of these terms yielded 134 results. The Embase search utilized variations of the search terms “parturient” or “pregnancy” or “labor” and “anesthesia” or “analgesics” or “labor pain” or “epidural” and “informed decision” or “informed consent” or “patient education” or “informed choice.” The search terms yielded 525 results.

The three databases searched generated 968 articles. From these articles, 175 did not meet the inclusion criteria of an article date from 2000 to present and 141 were removed due to duplication, resulting in 652 articles for further review. Inclusion criteria based on article title ensured there was mention of pregnancy or parturient patients, educational techniques, informed consent processes, assessment of anesthetic knowledge after education, and satisfaction with these techniques. From inclusion criteria based upon titles, 95 articles were subsequently retained. Each article was evaluated for consistency with the clinical question. Secondly, the title and abstracts were reviewed by two members of the project team for inter-rater reliability. After reviewing abstracts, 16 articles met the requirements for full-text selection.

The 16 articles selected for the final review provided a sufficient quantity of evidence to support the proposed clinical question. The Johns Hopkins Nursing Evidence-Based Practice model was used to evaluate the quality of the articles (Johns Hopkins, 2017). The evidence was level I through III with quality of A through C. Study designs included quantitative, qualitative, and non-experimental studies. Despite the wide range in quality and level of evidence, the results were appropriate to answer the clinical question. Themes regarding common deficiencies in knowledge of parturients included unregulated information sources, anesthetic concerns and anxiety about the process, and inconsistencies in the preferred amount of disclosure of risks. Consistent themes in favor of improving the education process included the benefits of using educational adjuncts, standardization of the process, and implementing education in the antenatal setting.

Setting

This project was conducted at NMCS D, which is a large MTF in southwest California and serves active duty, retirees, and their beneficiaries. Implementation occurred on NMCS Ds 11-bed L&D unit, where approximately 250 labor epidurals are placed for an average of 308 deliveries per month. The project impacted the obstetric staff, anesthesia staff, nursing staff, and parturients.

Procedural Steps

The steps involved in completing this project included conducting a site survey, an evaluation of the literature, the design of an assessment tool, the application for a Tri-Service Nursing Research Program (TSNRP) mini-EBP award to purchase iPads for displaying the video, the implementation of an educational video, and the creation of a sustainability plan.

The outcome measures created determined the efficacy of the intervention and the results evaluated through the use of a survey (Appendix D). The survey design was in the form of Likert-scale questions that assessed patient knowledge and satisfaction with epidural analgesia education. No pre-implementation data was collected. The focus of the survey was on the patient self-reporting their perceived level of knowledge and satisfaction after watching the video. Survey items also included the number of previous epidurals and whether the patient had previously viewed the video. Demographic information was also requested in the survey to include age, education level, gravida, and para.

A TSNRP mini-EBP award was requested to obtain funding for iPads and necessary equipment for parturients to watch the video. The project team completed each of the required documents for the award, including a description of the project, evidence table, budget, timeline, and letters of endorsement. Upon completion of the mini-EBP award, the project team applied to TSNRP in December 2018 and approval for the award was provided in February 2019.

The Bureau of Medicine and Surgery (BUMED) approved the video for the project initially piloted at NMCP. Approval from BUMED and NMCP was obtained for the use at NMCSO for our proposed project. The video was 4 minutes and 41 seconds in length and discussed general epidural information, timing, positioning, technique, benefits, side effects, and potential complications.

The NMCSO project members provided an in-service and presented L&D and anesthesia staff the video, described the timeline from admission to survey completion, and answered questions. The project team loaded the video onto three 10.5-inch iPad Pro tablets. There was no requirement for Wi-Fi access since the video was downloaded directly into the iPad's internal

storage. Project team members then educated the anesthesia staff and trainees assigned to L&D how to administer the video and provide the project's survey after the video was viewed.

Participants were approached by a member of the L&D anesthesia staff after check-in and admission to L&D and asked if they would be willing to participate in watching the epidural education video and complete a short survey afterward. There were no exclusion criteria other than the patient's refusal. Parturients were also informed no personal identifiers would be collected. If patients were amenable to participation, then they were provided the video regardless of their current pain level or degree of cervical dilation. Patients were allowed to pause and resume the video between contractions if desired.

Following the video, the anesthesia provider issued the post-video survey. After the collection of the survey, the anesthesia staff member assigned to the L&D service performed the informed consent. Data was collected over three-months until 100 parturients had viewed and completed the project's survey. Following data collection, the project team polled the anesthesia staff and L&D nurses for their feedback on perceived knowledge of parturients based on staff-patient interactions. They were also polled on ease of the informed consent process and patient compliance with epidural placement.

A patient survey was comprised of Likert-scale questions used to evaluate laboring analgesia knowledge and satisfaction with the video's content. Survey results were initially entered into Microsoft Excel, then uploaded into the Statistical Package for the Social Sciences program (version 24.0) for final data analysis. All data was maintained on a government computer and double password protected. The team used descriptive statistics to describe the sample and their responses to the survey questions, including mean, mode, and percentages where appropriate.

Dissemination of the project involved presenting the design and findings through an Evidence-Based Practice poster and PowerPoint presentation. The design and results were presented to the NMCSA anesthesia department, including the Departments Chairperson, anesthesia department staff, project leadership, L&D stakeholders, and faculty at the Uniformed Services University of the Health Sciences. An abstract was submitted for consideration to the American Association of Nurse Anesthetists for their 2020 Annual Congress, but due to a high volume of submissions, it was not selected. The sustainability plan included the creation of a Standard Operating Procedure (SOP) based on the results of the survey and input from anesthesia stakeholders. An annual review of the SOP will appraise the status of implementation, compliance with the program, and relevancy of the educational video to ensure the content remains relevant and staff have the means to carry out the program

HIPAA Concerns

This project involved interacting with human subjects and collection of survey data. However, personally identifiable information (PII) and protected health information (PHI) were not collected. To ensure the protection of patient information, the project proposal was submitted for review by the IRB to verify compliance with the Department of Defense (DoD) privacy program, DoD directive 5400.11 and the Health Insurance Portability and Accountability Act (HIPAA). The project was submitted as a health care delivery improvement project and received exemption from IRB review. All non-identified data were obtained via anonymous and voluntary patient surveys. Survey data were compiled into an Excel spreadsheet utilizing assigned numerical values for individual surveys. Physical data were stored in a locked, controlled-access room. Electronic data were saved on a single Controlled Access Card enabled computer housed

in a locked room. At the conclusion of data analysis, physical data were shredded in accordance with DoD and NMCS D policy.

Project Results

A total of 100 parturients participated in the survey and included in the final data analysis. Ninety-two percent of participants spoke English as their first language; however, primary languages for some parturients included Spanish, Tagalog, Japanese, and Mandarin. All participants reported speaking and understanding English and none requested an interpreter. Three percent of participants had less than a high school education, 60% had a high school or equivalent degree, 24% had an undergraduate degree, and 13% had a graduate degree. Forty-eight percent of participants were experiencing their first pregnancy, with a range of results from gravida one to 10. Sixty-four percent of participants were having their first baby, with a range from para zero to four. Sixty-eight percent had never had a previous epidural, while 32% had between one and five prior epidurals.

Dichotomous survey questions of “yes” and “no” asked if participants had received any education about epidurals prior to watching the video, whether they had watched the video prior to their respective L&D admission, and if their understanding about epidurals improved after watching the video. Eighty-four percent of survey participants reported having received previous education about epidural analgesia. Twenty-nine percent of participants reported having seen the video prior to their hospital admission and 98% reported an improved understanding about epidurals after watching the video.

Likert-type survey questions included a self-assessment of knowledge about epidurals prior to and after watching the video, and a satisfaction rating with epidural education after watching the video. Survey participant’s perceived knowledge prior to watching the video were

5% *very poor*, 13% *poor*, 41% *fair*, 29% *good*, and 12% *very good*. After viewing the video parturient's perceived knowledge revealed 0% of participants scored *very poor* or *poor*, 1% *fair*, 40% *good*, and 59% *very good*. A Wilcoxon Signed Rank Test was conducted to compare perceived patient knowledge before and after viewing the laboring epidural video. Final analysis suggested a significant increase in perceived knowledge, $z = -7.931$, and $p < 0.001$. In addition, the median knowledge score after watching the video increased from *fair* to *very good*, and 99% of participants reported they were *satisfied* or *very satisfied* with the educational content provided by the video.

Analysis of Results

The primary survey results of interest aligned with the project clinical question of whether an adjunct education video would increase perceived knowledge and satisfaction. The plan to implement an educational video was based on a comprehensive literature review on labor analgesia education, which demonstrated a multimodal approach to education was optimal for adult learning (Eley, Searles, Donovan, & Walters, 2013; Gerncher, Grice, Dewan, & Eisenach, 2000; Mahomed, Chin, & Drew, 2015; White, Gorton, Wee, & Mandal, 2003). This project's primary goal was to increase the parturient's knowledge following a standardized laboring analgesia video. The project's results revealed that 99% of participants reported *good* or *very good* perceived knowledge about labor epidurals after watching the video. This result was an expected finding based on the evidence found in the literature review and similar positive findings when initially piloted at NMCP. Likewise, an overwhelming majority of survey respondents reported they were satisfied with the education provided by the video. These results speak to the overall high quality of the video.

Twenty-nine percent of survey participants reported they had already seen the video before admission to L&D. This occurred after a Doctor of Nursing Practice candidate attending a different university had uploaded the same video onto NMCSDe L&D Department's website, which was offered for viewing during the parturient's antepartum obstetrical visit(s). Although this could be considered a limitation to the validity of the project results, the increase from pre to post video perceived knowledge scores indicated that parturients were still reporting higher knowledge scores after viewing the video multiple times. This finding is supported by adult learning theory and provides evidence to support the efficacy of the video as a useful educational tool.

One potential limitation of the results was that some parturients were in active labor at the time they viewed the video or were experiencing severe labor pain when approached about watching the educational video. According to our literature review, the ideal time to implement the video was during the antenatal period around the third-trimester, but before onset of labor (Black & Cyna, 2006; Frohlic, Tan, Walsh, & Carey, 2011; Jackson et. al, 2012; Mahomed, Chin, & Drew, 2015). This was the project group's original plan; however, NMCSDe leadership and anesthesia stakeholders preferred our project be implemented solely on the L&D Unit. Likewise, NMCSDe leadership's decision was supported in the literature by several sources, as it coincides with the timing of obtaining informed consent for anesthesia-related procedures (Saunders, Stein, & Dilger, 2006; Stewart, Sodhi, Harper, & Yentis, 2003). Although data on percentage or rationale for refusing to watch the video were not collected, patients in precipitous labor seemed less inclined to watch the video before delivery.

A second limitation was compliance with showing the video. L&D anesthesia services include anesthesiology residents and SRNAs from multiple anesthesia training programs. There

was a continual need to train new personnel about the project, how to provide the video, and how to collect survey data. Also, when the L&D census was high, anesthesia trainees and staff did not have time to present the video due to the fast-paced nature of needing to consent and provide optimal care. In addition, there were many instances when anesthesia providers were in the operating room for a cesarean section and missed the opportunity to present the video and survey. These limitations could be resolved through the use of the video in the antenatal period in addition to providing the video at the time of admission.

Organizational Impact

Project results and conclusions were disseminated to NMCSOs anesthesia and L&D departments and submitted for consideration at the AANA national conference in August 2020. The L&D department have accepted recommendations to incorporate the labor epidural education video into the antenatal education courses currently offered, the NMCSO L&D webpage, and during the admission process on the labor and delivery unit. The project team purchased three iPads that are kept secure in the L&D Anesthesia Office. The anesthesia staff and L&D nurses have access to the iPads for use after parturient admission to the L&D unit. Additionally, a tracking board was purchased for the L&D Anesthesia Office to track which patients have viewed the video. As part of the sustainment plan, color posters were placed on the walls inside each L&D inpatient room to advertise and promote the video. In addition to posters, business cards with a link to the video were provided to the L&D Clinic to capture the parturients earlier in the antenatal period.

Future Directions

Potential future direction for this project includes expanding the educational program to additional MTFs. This program is already in the process of being implemented at Naval Hospital

Camp Pendleton. By expanding this project to additional sites, this project will standardize patient education regarding epidural analgesia and may have a significant impact within Navy Medicine. Additional goals include expanding the education to cover additional anesthesia modalities, such as general anesthesia, to better inform and educate patients undergoing surgery in areas other than L&D. For example, similar educational videos esoteric to the anesthesia consenting process could be provided to patients at their surgery screening appointment in the Preoperative Assessment Center.

Conclusion

The main goal of this project was to increase parturient knowledge using an educational adjunct before gaining informed consent about the risks, benefits, and process of receiving an epidural for labor analgesia. Our results indicated that the implementation of a standardized educational video resulted in a significant increase in parturient's perceived knowledge about epidural analgesia. By increasing knowledge, the project team found a direct correlation with increased satisfaction with the consenting process, epidural placement, and likely overall patient care. Implementing educational adjuncts, like the use of standardized videos, into anesthesia education encourages anesthesia providers to explore new evidence-based methods of increasing their patient's knowledge, safety, and satisfaction.

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Appendix A

CITI Certificates

**COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS***

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

- **Name:** Gregory Nevenon (ID: 6536376)
- **Institution Affiliation:** Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- **Institution Email:** gregory.nevenon@usuhs.edu
- **Phone:** 7605677991

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

- **Record ID:** 24330836
- **Completion Date:** 27-Aug-2017
- **Expiration Date:** 26-Aug-2020
- **Minimum Passing:** 80
- **Reported Score*:** 84

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	27-Aug-2017	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	27-Aug-2017	4/5 (80%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	27-Aug-2017	5/5 (100%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	27-Aug-2017	No Quiz
History and Ethics of Human Subjects Research (ID: 498)	27-Aug-2017	4/7 (57%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	27-Aug-2017	5/5 (100%)
Informed Consent (ID: 3)	27-Aug-2017	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	27-Aug-2017	4/4 (100%)
Records-Based Research (ID: 5)	27-Aug-2017	2/3 (67%)
Genetic Research in Human Populations (ID: 6)	27-Aug-2017	4/5 (80%)
Research Involving Children (ID: 9)	27-Aug-2017	3/3 (100%)
Research Involving Pregnant Women, Fetuses, and Neonates (ID: 10)	27-Aug-2017	3/3 (100%)
FDA-Regulated Research (ID: 12)	27-Aug-2017	4/5 (80%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	27-Aug-2017	3/5 (60%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	27-Aug-2017	No Quiz
Assessing Risk - SBE (ID: 503)	27-Aug-2017	4/5 (80%)

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

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Collaborative Institutional Training Initiative (CITI Program)

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Phone: 888-529-5929

Web: <https://www.citiprogram.org>

**COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT****

** NOTE: Scores on this [Transcript Report](#) reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Gregory Nevenon (ID: 6536376)
- **Institution Affiliation:** Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- **Institution Email:** gregory.nevenon@usuhs.edu
- **Phone:** 7605677991

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

- **Record ID:** 24330836
- **Report Date:** 22-Nov-2019
- **Current Score**:** 84

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	27-Aug-2017	5/5 (100%)
Informed Consent (ID: 3)	27-Aug-2017	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	27-Aug-2017	4/4 (100%)
Records-Based Research (ID: 5)	27-Aug-2017	2/3 (67%)
Assessing Risk - SBE (ID: 503)	27-Aug-2017	4/5 (80%)
Genetic Research in Human Populations (ID: 6)	27-Aug-2017	4/5 (80%)
Research Involving Children (ID: 9)	27-Aug-2017	3/3 (100%)
Research Involving Pregnant Women, Fetuses, and Neonates (ID: 10)	27-Aug-2017	3/3 (100%)
FDA-Regulated Research (ID: 12)	27-Aug-2017	4/5 (80%)
History and Ethics of Human Subjects Research (ID: 498)	27-Aug-2017	4/7 (57%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	27-Aug-2017	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	27-Aug-2017	4/5 (80%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	27-Aug-2017	No Quiz
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	27-Aug-2017	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	27-Aug-2017	3/5 (60%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	27-Aug-2017	No Quiz

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**COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS***

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

- **Name:** Hannah Parker (ID: 6539641)
- **Institution Affiliation:** Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- **Institution Email:** hannah.parker@usuhs.edu
- **Phone:** 2015728664

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

- **Record ID:** 24339865
- **Completion Date:** 28-Aug-2017
- **Expiration Date:** 27-Aug-2020
- **Minimum Passing:** 80
- **Reported Score*:** 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	28-Aug-2017	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	28-Aug-2017	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	28-Aug-2017	5/5 (100%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	28-Aug-2017	No Quiz
History and Ethics of Human Subjects Research (ID: 498)	28-Aug-2017	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	28-Aug-2017	5/5 (100%)
Informed Consent (ID: 3)	28-Aug-2017	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	28-Aug-2017	4/4 (100%)
Records-Based Research (ID: 5)	28-Aug-2017	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	28-Aug-2017	5/5 (100%)
Research Involving Children (ID: 9)	28-Aug-2017	3/3 (100%)
Research Involving Pregnant Women, Fetuses, and Neonates (ID: 10)	28-Aug-2017	3/3 (100%)
FDA-Regulated Research (ID: 12)	28-Aug-2017	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	28-Aug-2017	5/5 (100%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	28-Aug-2017	No Quiz
Avoiding Group Harms - International Research Perspectives (ID: 14081)	28-Aug-2017	3/3 (100%)

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

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**COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT****

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

- **Name:** Hannah Parker (ID: 6539641)
- **Institution Affiliation:** Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- **Institution Email:** hannah.parker@usuhs.edu
- **Phone:** 2015728664

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

- **Record ID:** 24339865
- **Report Date:** 22-Nov-2019
- **Current Score**:** 100

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	28-Aug-2017	5/5 (100%)
Informed Consent (ID: 3)	28-Aug-2017	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	28-Aug-2017	4/4 (100%)
Records-Based Research (ID: 5)	28-Aug-2017	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	28-Aug-2017	5/5 (100%)
Research Involving Children (ID: 9)	28-Aug-2017	3/3 (100%)
Research Involving Pregnant Women, Fetuses, and Neonates (ID: 10)	28-Aug-2017	3/3 (100%)
FDA-Regulated Research (ID: 12)	28-Aug-2017	5/5 (100%)
History and Ethics of Human Subjects Research (ID: 498)	28-Aug-2017	7/7 (100%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	28-Aug-2017	3/3 (100%)
Avoiding Group Harms - International Research Perspectives (ID: 14081)	28-Aug-2017	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	28-Aug-2017	5/5 (100%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	28-Aug-2017	No Quiz
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	28-Aug-2017	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	28-Aug-2017	5/5 (100%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	28-Aug-2017	No Quiz

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**COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS***

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

- **Name:** Uriah Paul (ID: 6542832)
- **Institution Affiliation:** Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- **Institution Email:** uriah.paul@usuhs.edu
- **Institution Unit:** USUHS
- **Phone:** 2404252138

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

- **Record ID:** 24349049
- **Completion Date:** 29-Aug-2017
- **Expiration Date:** 28-Aug-2020
- **Minimum Passing:** 80
- **Reported Score*:** 97

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	28-Aug-2017	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	28-Aug-2017	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	28-Aug-2017	4/5 (80%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	28-Aug-2017	No Quiz
History and Ethics of Human Subjects Research (ID: 498)	28-Aug-2017	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	28-Aug-2017	5/5 (100%)
Informed Consent (ID: 3)	28-Aug-2017	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	28-Aug-2017	4/4 (100%)
Records-Based Research (ID: 5)	28-Aug-2017	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	28-Aug-2017	4/5 (80%)
Research Involving Children (ID: 9)	29-Aug-2017	3/3 (100%)
Research Involving Pregnant Women, Fetuses, and Neonates (ID: 10)	29-Aug-2017	3/3 (100%)
FDA-Regulated Research (ID: 12)	29-Aug-2017	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	29-Aug-2017	5/5 (100%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	29-Aug-2017	No Quiz
The Federal Regulations - SBE (ID: 502)	29-Aug-2017	5/5 (100%)

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

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Collaborative Institutional Training Initiative (CITI Program)

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**COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT****

** NOTE: Scores on this [Transcript Report](#) reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Uriah Paul (ID: 6542832)
- **Institution Affiliation:** Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- **Institution Email:** uriah.paul@usuhs.edu
- **Institution Unit:** USUHS
- **Phone:** 2404252138

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

- **Record ID:** 24349049
- **Report Date:** 22-Feb-2020
- **Current Score**:** 97

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	28-Aug-2017	5/5 (100%)
Informed Consent (ID: 3)	28-Aug-2017	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	28-Aug-2017	4/4 (100%)
The Federal Regulations - SBE (ID: 502)	29-Aug-2017	5/5 (100%)
Records-Based Research (ID: 5)	28-Aug-2017	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	28-Aug-2017	4/5 (80%)
Research Involving Children (ID: 9)	29-Aug-2017	3/3 (100%)
Research Involving Pregnant Women, Fetuses, and Neonates (ID: 10)	29-Aug-2017	3/3 (100%)
FDA-Regulated Research (ID: 12)	29-Aug-2017	5/5 (100%)
History and Ethics of Human Subjects Research (ID: 498)	28-Aug-2017	7/7 (100%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	28-Aug-2017	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	28-Aug-2017	5/5 (100%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	29-Aug-2017	No Quiz
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	28-Aug-2017	4/5 (80%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	29-Aug-2017	5/5 (100%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	28-Aug-2017	No Quiz

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Collaborative Institutional Training Initiative (CITI Program)

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2 COURSEWORK REQUIREMENTS*

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

- **Name:** David Sternbaum (ID: 6538537)
- **Institution Affiliation:** Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- **Institution Email:** david.sternbaum@usuhs.edu
- **Phone:** 713-385-9154

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

- **Record ID:** 24335627
- **Completion Date:** 28-Aug-2017
- **Expiration Date:** 27-Aug-2020
- **Minimum Passing:** 80
- **Reported Score*:** 97

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	28-Aug-2017	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	28-Aug-2017	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	28-Aug-2017	5/5 (100%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	28-Aug-2017	No Quiz
History and Ethics of Human Subjects Research (ID: 498)	28-Aug-2017	6/7 (86%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	28-Aug-2017	5/5 (100%)
Informed Consent (ID: 3)	28-Aug-2017	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	28-Aug-2017	4/4 (100%)
Records-Based Research (ID: 5)	28-Aug-2017	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	28-Aug-2017	5/5 (100%)
Research Involving Children (ID: 9)	28-Aug-2017	3/3 (100%)
Research Involving Pregnant Women, Fetuses, and Neonates (ID: 10)	28-Aug-2017	3/3 (100%)
FDA-Regulated Research (ID: 12)	28-Aug-2017	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	28-Aug-2017	4/5 (80%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	28-Aug-2017	No Quiz
The Federal Regulations - SBE (ID: 502)	28-Aug-2017	5/5 (100%)

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**COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT****

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

- **Name:** David Sternbaum (ID: 6538537)
- **Institution Affiliation:** Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- **Institution Email:** david.sternbaum@usuhs.edu
- **Phone:** 713-385-9154

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

- **Record ID:** 24335627
- **Report Date:** 22-Nov-2019
- **Current Score**:** 97

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	28-Aug-2017	5/5 (100%)
Informed Consent (ID: 3)	28-Aug-2017	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	28-Aug-2017	4/4 (100%)
The Federal Regulations - SBE (ID: 502)	28-Aug-2017	5/5 (100%)
Records-Based Research (ID: 5)	28-Aug-2017	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	28-Aug-2017	5/5 (100%)
Research Involving Children (ID: 9)	28-Aug-2017	3/3 (100%)
Research Involving Pregnant Women, Fetuses, and Neonates (ID: 10)	28-Aug-2017	3/3 (100%)
FDA-Regulated Research (ID: 12)	28-Aug-2017	5/5 (100%)
History and Ethics of Human Subjects Research (ID: 498)	28-Aug-2017	6/7 (86%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	28-Aug-2017	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	28-Aug-2017	5/5 (100%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	28-Aug-2017	No Quiz
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	28-Aug-2017	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	28-Aug-2017	4/5 (80%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	28-Aug-2017	No Quiz

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

Verify at: www.citiprogram.org/verify/?k0b66d0f5-1bd1-41fd-87e1-462b5be3c9e6-24335627

Collaborative Institutional Training Initiative (CITI Program)
 Email: support@citiprogram.org
 Phone: 888-529-5929
 Web: <https://www.citiprogram.org>

Appendix B

USU Notice of Project Approval



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-61-10870
Principal Investigator: Parker, Hannah
Department: Graduate School of Nursing
Project Type: Student
Project Title: Educating Parturients on Epidural Labor Analgesia


Project Period: 9/26/2019 to 12/31/2019

Assurance and Progress Report Information:

<u>Name</u>	<u>Sup</u>	<u>Approval Type</u>	<u>Status</u>	<u>Approved On</u>	<u>Forms Received</u>
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.

fo  *9/26/2019*
 Yvonne U Maddox, Ph.D. Date
 Vice President for Research
 Uniformed Services University of the Health Sciences

cc:
 File

 Wanzer, Linda
 Taylor, Laura

Appendix C

MTF IRB/PI Letter of Determination

NMCS D Quality Improvement & Process Improvement Proposal

For CID Use Only
QI Number:

**INTENT TO ENGAGE IN PERFORMANCE IMPROVEMENT
 PROJECT INVOLVING LIVING HUMAN BEINGS OR
 IDENTIFIABLE PATIENT INFORMATION**

Complete and submit this form to [Dr. Elisea Avalos-Reyes](#) when an investigator proposes a performance improvement project involving humans that s/he does not believe constitutes human subject research. The investigator must provide adequate information for the IRB Chair/ Vice Chair and/or delegate to determine whether the project constitutes human subject research. If the reviewer determines that a project is not human subjects research, the IRB will have no on-going involvement with the project. If the project is deemed to meet the definition of human subject research, a complete IRB submission will be required.

A data sharing agreement checklist must also be included in this submission. Contact the Clinical Investigation Department or Dr. Elisea Avalos-Reyes for the most recent version.

Be as specific as possible when answering the below questions.

<p>Investigator Name (LAST, FIRST):</p> <input style="width: 100%; height: 20px;" type="text" value="TOZER, KIMBERLY"/>	<p>Rank, Designation and/or Degree:</p> <input style="width: 100%; height: 20px;" type="text" value="LCDR"/>
<p>E-mail:</p> <input style="width: 100%; height: 20px;" type="text" value="kimberly.a.tozer.mil@mail.mil"/>	<p>Phone Number:</p> <input style="width: 100%; height: 20px;" type="text" value="262-308-2627"/>
<p>Command:</p> <input style="width: 100%; height: 20px;" type="text" value="Naval Medical Center San Diego"/>	<p>Department:</p> <input style="width: 100%; height: 20px;" type="text" value="Anesthesia"/>
<p>Project Title:</p> <input style="width: 100%; height: 60px;" type="text" value="Educating Parturients on Labor Analgesia"/>	

1. Describe the problem that this project will identify and improve. Specifically mention the population/program and provide the background, evaluation, and method of implementation.

Problem: Naval Medical Center San Diego (NMCS D) provides the majority of labor analgesia for Navy Medicine West. Currently, there is no standardized, evidence-based approach at NMCS D to provide education to pregnant laboring patients regarding epidural analgesia. Much of the information on labor analgesia comes from sources other than the anesthesia provider in the form of verbal communication. This quality improvement project will provide standardized education in the form of a video, with the goal to improve the patient's level of knowledge and satisfaction.

Population: Patients checking into the labor and delivery ward in active labor.

Background: The evidence suggests that audio-visual education provided as an adjunct to verbal education may improve patient knowledge and increase satisfaction. Providing an epidural education video to laboring patients has the potential to enhance understanding and standardize the education process at NMCS D. The goal of this quality improvement project is to utilize an evidence-based approach to educate laboring women on epidurals and improve the quality and consistency of information provided.

Program & Implementation: A BUMED educational video about epidural analgesia was developed by student nurse anesthetists at Naval Medical Center Portsmouth (NMCP) in 2017 for a quality improvement project. Permission has been obtained by BUMED and the group from NMCP for use at NMCS D. A mini-EBP award from the TriService Nursing Research Program (TSNRP) will be submitted in Feb 2019. If granted, the mini-EBP award would provide \$10,000 of funding to help implement the project. The majority of the funds will be allocated for iPads that patients will utilize to view

2. Do you have intentions to publish and/or present the outcome/findings of this project?

- YES
- NO

If YES, please indicate the forum in which you primarily plan to disseminate the information (e.g. local conference, international conference, peer-reviewed manuscript)

We are student nurse anesthetists doing our clinical training at NMCS D in the Graduate School of Nursing at the Uniformed Services University of the Health (USUHS) Sciences. This quality improvement project is part of the doctoral project required for graduation. Part of that requirement is to present project findings at USUHS in the form of a podium and poster presentation. The plan is to also submit to two other conferences for a poster and podium presentation at (TSNRP and American Society of PeriAnesthesia Nurses).

3. Does the project include testing the safety and efficacy of a drug or device in a human subject?

- YES
- NO

If YES, please explain:

No medications will be administered in this project. Only the viewing of an educational video.

4. Do you PRIMARILY intend the information you learn from this project to be generalizable beyond your institution?

Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which are designed to contribute "generalizable knowledge" would be those whose original intent is to make public via oral presentation, poster, or journal publication outside of the Command at which the activity occurs, or outside of an Educational program (PhD program, for example) for which the activity was done.

- YES
- NO

If Yes, please explain:

This project is intended to improve the epidural analgesia education process at NMCS D and is not intended for large generalization beyond this institution.

5. Do you PRIMARILY intend the information you learn to provide immediate and continuous improvement and feedback at your institution?

- YES
- NO

If Yes, please explain:

Yes, this educational video is meant as an adjunct to our current process for educating patients on labor analgesia at NMCS D. If survey results show that the video increases knowledge and satisfaction, this will provide immediate feedback for patients to continue to view the video. The information will also guide the creation of a sustainment plan.

6. Are the activities or interventions considered standard of care?

- YES
- NO

If Yes, please explain:

Yes, patients already receive education on epidural analgesia in the form of verbal communication only. This project will only augment the current process and standard of care already in place.

7. Are participants expected to benefit directly from these activities?

- YES
- NO

If Yes, please explain:

Yes, the goal is to increase patient's knowledge and satisfaction regarding epidural analgesia upon admission to the labor and delivery ward.

8. Will you collect data from living individuals through some type of intervention?

- YES
- NO

If Yes, please explain:

No, Personally Identifiable Information (PII) will be collected at anytime during this project.

We will be collecting basic non-identifiable demographic data from a survey: age, highest level of education, language, # of pregnancies, # of births

We will be collecting satisfaction and level of knowledge through survey questions

9. Will you interact in ANY way with a living individual?

- YES
- NO

If Yes, please explain:

Yes, we will interact with approximately 100 patients on the Labor & Delivery Ward over an estimated 60 day period (our estimated time for project implementation). The interaction includes introducing ourselves to the patient, explaining our project including the education video and post-video survey. The video and survey are completely voluntary. Estimated time spent with each patient is approximately 10 minutes.

10. Will you have access to individually identifiable information?

- YES
- NO

If Yes, please explain:

No PII will be collected at anytime. Surveys will be collected and stored in a 2 locked system (behind a locked door, in a locked cabinet). Survey information will be compiled in an excel database without PII on a locked CAC computer. Surverys will be delineated by number and date (no PII information will be collected).

11. Will you be utilizing the electronic medical record in any way?

- YES
- NO

Please use this space to include any other information you would like considered in the determination of this review:

No, we will not be utilizing the EMR to collect information at anytime. Upon admission to the labor ward, we will be informed by the nursing or anesthesia staff that a patient needs to view the video.

Project Lead and Department Head

The information provided clearly states the intention and plan for this project. All responsibilities and resources needed in conducting this project lies with the project lead and their respective department.

Project Lead
Signature and Date:

TOZER.KIMBERLY
.ANN. [REDACTED]

Department Head
Signature and Date:

WALLACE.SCOTT.CHR
ISTOPHER. [REDACTED]



CID DETERMINATION
(CID USE ONLY)

More information is required to complete review, specifically:

This is a Performance Improvement / Quality Assurance project.

NOTES:

NMCS.D.QI.2019.02271

This appears to be a human subject research project and warrants full submission to the IRB

NOTES:

Reviewer Signature and
Date:

COOK.WEN
DY.ANNE.10


DO NOT COMPLETE THIS PAGE, CID USE ONLY

***Reviewer Checklist: Human Subject Research-vs.-
Quality Improvement/Process Improvement***

Each Assessed Element must meet criteria for Quality Improvement in order for this project to be conducted without IRB review and approval. This form must accompany the signed QI checklist submitted by the POC of the project.

Assessed Element	Human Subject Research	Quality Improvement	Notes
Intent	<input type="checkbox"/> Contribute to “generalizable” knowledge	<input checked="" type="checkbox"/> Improve a program or service or ensure it conforms with expected norms	
Design	<input type="checkbox"/> Develop or contribute to “generalizable” knowledge, may involve randomization of individuals to different treatment regimens or processes.	<input checked="" type="checkbox"/> Not intended to develop or contribute to “generalizable” knowledge, does not involve randomization of individuals, but may involve comparison of variations in programs	
Effect on Program or Practice Evaluated	<input type="checkbox"/> It is not the specific intent that findings of the activity will directly affect institutional or programmatic practice; however, they may influence future policies	<input checked="" type="checkbox"/> Findings of the activity are expected to directly affect institutional practice and may identify corrective action(s) needed	
Population	<input type="checkbox"/> Usually involves a subset of individuals; generally, statistical justification for sample size is used to ensure endpoints are met	<input checked="" type="checkbox"/> Includes all or most receiving a particular treatment or process; exclusion of information from some individuals significantly affects conclusions	
Benefits	<input type="checkbox"/> Participants may or may not benefit directly; benefit, if any, to individuals is incidental or delayed	<input checked="" type="checkbox"/> Participants are expected to benefit directly from the activities	
Dissemination of Results	<input checked="" type="checkbox"/> The intent to publish or present the findings is generally presumed at the outset; dissemination of information usually occurs in research/scientific publications or other research/scientific fora; results expected to develop or contribute to “generalizable” knowledge	<input type="checkbox"/> The intent to publish or present is generally NOT presumed at the outset; dissemination of information does not occur beyond the institution evaluated; dissemination of information may occur in quality improvement publications; when published or presented to a wider audience, the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks or base rates rather than to develop or contribute to “generalizable” knowledge.	Intend to present/publish as EBP

Appendix D

All Forms Used in Data Collection

Anesthesia Epidural Video Survey				
Age: <input style="width: 100px;" type="text"/>				
Number of pregnancies: <input style="width: 100px;" type="text"/>				
Number of previous deliveries: <input style="width: 100px;" type="text"/>				
Number of previous epidurals: <input style="width: 100px;" type="text"/>				
Primary language: <input style="width: 100px;" type="text"/>				
Highest level of education (check one):				
<input type="checkbox"/> Less than a high school diploma				
<input type="checkbox"/> High school degree or equivalent				
<input type="checkbox"/> Undergraduate degree				
<input type="checkbox"/> Graduate degree				
Did you receive any education about epidurals prior to watching this video? Yes / No				
Have you watched this epidural video before today? Yes / No				
How would you rate your knowledge about epidurals <u>PRIOR</u> to watching the video?				
1 Very Poor	2 Poor	3 Fair	4 Good	5 Very Good
How would you rate your knowledge about epidurals <u>AFTER</u> watching the video?				
1 Very Poor	2 Poor	3 Fair	4 Good	5 Very Good
How would you rate your satisfaction with epidural education <u>AFTER</u> watching the video?				
1 Very Unsatisfied	2 Unsatisfied	3 Neither	4 Satisfied	5 Very Satisfied
Did your understanding about epidurals improve after watching the video? Yes / No				

Appendix E

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: Educating Parturients on Labor Analgesia
was completed at Naval Medical Center San Diego, CA by the following student(s):

<i>(type student name)</i>	<i>(signature)</i>	<i>(date)</i>
<u>LT Greg Nevenon</u>		<u>22 March 2020</u>
<u>LT Hannah Parker</u>		<u>22 March 2020</u>
<u>LT Uriah Paul</u>		<u>22 March 2020</u>
<u>LT David Sternbaum</u>		<u>22 March 2020</u>

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:

<i>(type name)</i>	<i>(signature)</i>	<i>(date)</i>	
<u>CDR Danielle Cuevas</u>		<u>03/24/2020</u>	Senior Mentor
<u>CDR Eric Bopp</u>		<u>3/24/2020</u>	Team Mentor
<u>CDR Tiffany Uranga</u>		<u>3/24/2020</u>	Team Mentor & Phase II Site Director

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

<u>CDR Kenneth Radford</u>	<u>RADFORD, KENNETH D ARREL II.</u>	<u>30Mar2020</u>
<i>RNA Project Director (type name)</i>	<i>(Signature)</i>	<i>(Date)</i>