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Anxiety Management for Needle Localization

Jorge Arizpe, Maj, NC, USAF

Keren Stimeling, Capt, NC, USAF

Lonnie Hodges, Lt Col, NC, USAF

Uniformed Services University of the Health Sciences

Daniel K. Inouye Graduate School of Nursing

Eglin Air Force Base Hospital

Copyright Acknowledgement Statement

Jorge Arizpe, BSN, RN, Major, USAF
Student Registered Nurse Anesthetist Program
Daniel K. Inouye Graduate School of Nursing
Uniformed Services University
April 15, 2018

Keren Stimeling, BSN, RN, Captain, USAF
Student Registered Nurse Anesthetist Program
Daniel K. Inouye Graduate School of Nursing
Uniformed Services University
April 15, 2018

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Abstract

Phase II Site: Eglin Air Force Base Hospital

DNP Project Title: Anxiety Management for Needle Localization

Authors: Arizpe, J. A., Stimeling, K. L.

Background or Problem/Issue: Unaddressed anxiety of individuals undergoing needle localized breast biopsy (NLBBx) may lead to delays in follow-up care and changes in anesthetic plans, increasing healthcare costs and adversely impacting patient short and long-term well-being.

Clinical Question or Purpose: The purpose of this project was to improve the patient experience by developing and implementing a process improvement (PI) project for the assessment and management of anxiety in patients undergoing needle localization prior to breast surgery.

Project Design: This was a PI project utilizing a pre- and post-implementation design. All patients undergoing NLBBx between May 2017 and November 2017 completed a patient data questionnaire (PDQ) (Appendix A) prior to discharge to measure patient satisfaction and assess patient experience. The project was implemented on September 2017 to allow patients undergoing NLBBx to receive anxiolysis prior to needle placement in interventional radiology (IR).

Analysis of the Results: After implementation of the project, more patients endorsed the medications given before needle placement as beneficial (60% pre- vs 100% post-implementation) and their experience in IR as discomfort-free (10% pre- vs 37% post-implementation).

Organizational Impact/Implications for Practice: Unrelieved patient anxiety may result in decreased postoperative satisfaction, and potentially increase the financial burden on the health care system through costlier interventions and prolonging treatment. By providing anxiolysis prior to NLBBx in IR, we can improve the patient experience and potentially decrease patient anxiety. By addressing anxiety, we can provide the best anesthetic intervention, achieve better patient outcomes, diminish postoperative recovery time, and decrease overall cost to the health care system.

Introduction

Women with breast cancer experience stress, anxiety, and depression (Kwakkenbos, Coyne, & Thombs, 2014; Shelby, Golden-Kreutz, & Andersen, 2008). Additionally, women undergoing needle-localized breast biopsy to confirm breast cancer experience anxiety and pain during the procedure (van Vlymen, Sá Rêgo, & White, 1999). Anxiolysis is typically not provided during wire localization in Interventional Radiology (IR) due to the procedural consent process involved, and healthcare providers have personally observed untreated anxiety and pain as root causes of poor patient satisfaction (M. Erias, personal communication, November 6, 2015; Murtha Cancer Center Staff, personal communication, October 9, 2015). In addition, patient anxiety may contribute to decreased adherence to follow-up care (S. Van Dyke, personal communication, September 15, 2015).

Follow-on discussions with providers reveal concerns about follow-up care after breast biopsy. It has been suggested that delay in follow-up care may occur with these individuals due to anxiety and discomfort experienced during the initial intervention. Hence, patients avoid follow-up care due to the anxiety of a similar experience occurring again and health concerns go unaddressed (Bugbee, Wellisch, Arnott, Maxwell, Kirsch, Sayre, & Bassett, 2005; Cathy, 2008; S. Vandyke & K. Wofford, personal communication, September 16, 2015; Jane, 2012; van Vlymen, Sá Rêgo, & White, 1999). Elevated anxiety can lead to increased health care costs and heighten patient risks (Fatiregun, Olagunju, Erinfolami, Fatiregun, & Arogunmati, 2016; Miller, O'Hea, Lerner, Moon, & Foran-Tuller, 2011; Pederson, Sawatzky, & Hack, 2010). Therefore, it is suggested that inadequate management of anxiety prior to needle localization has the potential to raise health care costs and adversely impact short and long-term patient well-being.

Significance of the Problem

Based on a 2013 military demographic study, there are approximately 225,000 female active duty members and 400,000 dependent wives of military members (Department of Defense, 2013). According to the Tricare fiscal year 2015 report to Congress, cancer is listed as one of Healthcare Cost and Utilization Project's top ten medical conditions for all inpatient discharges (Medicaid - 1.9%, private insurance - 4.2%, and Tricare - 2.7%). Of those discharges, 2.7% were active duty direct enrollees, 1.3% were family members, and 3% retired family member (Defense Health Agency, 2015, p. 73). In the Surveillance, Epidemiology, and End Results Cancer Statistics Review 12.4% of women (approximately 1 in 8) in the United States will develop breast cancer (Howlader et al., 2012). From 2000-2010, 780 active duty individuals were diagnosed with breast cancer; of those 780, 328 underwent surgical lumpectomy, 390 had mastectomies, and 15 underwent radical mastectomies (Office of the Assistant Secretary of Defense, 2014, p. 30). While the statistics on military medicine only cover active duty females, projecting Howlader's statistic suggests that 12.4% (49,600 women) of the female dependent and retiree populations carry the lifetime risk of breast cancer diagnosis. Whether it is a service member, or a family member, cancer affects military readiness (Manne, et al, 2015; Mantini, et. al, 2007). Lives and outlooks change, especially if treatment is delayed, ultimately raising the risk for a decrease in readiness capabilities of the military system (Manne, et al, 2015).

The MHS quadruple aim outlines strategic mission priorities for the military health system. The four components are "increased readiness, better care, better health, and lower cost" (Defense Health Agency, 2015, p. 2). This strategic framework applies to military outcomes and emphasizes the fulfillment of our duty as nurses to our patients. According to the American Nurses Association (2015), nurses are to "protect, promote, and optimize the health and abilities of our patients by

preventing illness and injury, alleviating suffering, treating human response, and advocating the care of individuals, families, communities, and populations." We fulfill this duty by decreasing procedural pain and anxiety during needle localization for surgical breast procedures, optimizing the outcomes of these patients, and ensuring patient centered care. In the trajectory of surgical care for breast cancer, nurses are optimally positioned to identify and advocate for patients at risk of pain and anxiety during needle localization. Therefore, this problem is relevant to both the military health service and nursing.

Clinical Question

In patients undergoing needle localization in Interventional Radiology (IR), will giving an anxiolytic before the procedure increase patient satisfaction compared to no anxiolysis?

Focus Areas

This project has four focus areas. Focus area 1 is to understand the process of obtaining surgical and anesthetic consent prior to needle localization and surgical breast biopsy at Eglin AFB. Focus area 2 is to develop process improvement plan (PI) and an educational offering to address barriers to offering anxiolysis prior to wire placement in Radiology. Focus area 3 is to provide the educational offering and implement the PI plan. Lastly, focus area 4 is to assess the uptake and impact of project implementation. Patient satisfaction surveys will be obtained prior to discharge.

Project Short & Long-Term Goals

The short-term goals are to increase provider awareness of the possible impact of untreated patient anxiety and pain during needle localization and develop an implementation plan for identifying eligible patients and obtaining surgery, radiology, and anesthesia consents prior to administration of an anxiolytic. The long-term goal is to have the PI project implemented as

hospital protocol for anxiolytic pretreatment of patients undergoing needle localization in interventional radiology. The anticipated global impact is to provide the best anesthetic intervention for patients, achieve better patient outcomes (such as anxiety management, decreased levels of discomfort, and continued follow-up care), diminish postoperative recovery time, decrease patient leakage to civilian purchased care, and decrease overall cost to the Military Health System.

Potential Benefit

Unrelieved patient anxiety can lead to costlier interventions and prolonging medical treatment (Fatiregun, Olagunju, Erinfolami, Fatiregun, & Arogunmati, 2016; Miller, O'Hea, Lerner, Moon, & Foran-Tuller, 2011; Pederson, Sawatzky, and Hack, 2010). By providing anxiolysis to women who desire such care during wire localization, we can decrease patient anxiety and potentially improve the patient experience (Bortolussi et al., 2015; Joo et al., 2012; Shen et al., 2008; Talamo, Liao, Bayerl, Claxton, & Zangari, 2010).

Organizing Framework

The Iowa Model of Evidence-Based Practice was utilized to guide and organize the project. The problem-focused trigger of patient anxiety during needle localization was identified as a clinical problem. A thorough review of relevant literature was completed. The articles were critiqued and evaluated for implementation into practice. A gap in the literature was identified in that evidence is lacking related to patients undergoing needle localization in interventional radiology. Similar outpatient procedures were included in the literature search and reviewed providing a base for developing a practice change and process improvement implementation. The project consisted of an evaluation of the current process, education to the providers on the need for anxiolysis prior to procedure, and data analysis of patient reported satisfaction. Data analysis

was completed, and process changes were incorporated as needed to facilitate patient and provider needs. Outcomes were monitored, and ongoing evaluation were completed throughout the implementation phase (Titler et al., 2001).

Project Design

General Approach

This project is a process improvement design with data gathering.

Setting

This project will be undertaken at the Eglin Air Force Base Hospital in the southeast United States. The hospital has a surgery department, oncology department, and a radiology department. Anesthesia staff will include Certified Registered Nurse Anesthetists and anesthesiologists. The population will include active duty military, retired, and eligible dependent women undergoing NLBBx at Eglin Air Force Base Hospital. At this time, there are five or less NLBBx occurring each month in this facility.

Procedural Steps

First, we evaluated the current process of obtaining surgical and anesthetic consent prior to needle localization and surgical breast biopsy at Eglin AFB. This was accomplished by reviewing relevant local and Air Force policy and by tracking patients through the process via patient discharge questionnaires (PDQ). The PDQs were summarized and reviewed to identify potential barriers to offering anxiolysis as well as key staff stakeholders involved in the process. Permission was verbally obtained from patients prior to observing the process, but no potentially identifying information will be collected from the patient or record.

Second, we obtained buy-in from key-stakeholders identified during the patient observation process and from impacted departments.

Third, we met with key stakeholders and developed a process improvement plan to obtain consent prior to needle localization (e.g. surgery, radiology, anesthesia, and preoperative clinic) and administer anxiolysis. PDQs were collected during this implementation period to track patient outcomes and satisfaction with administered anxiolysis.

Fourth, we evaluated the data obtained from the PDQs and disseminate this information to the key stakeholders. This data included capturing the number of NLBBx patients, the number of NLBBx patients who received anxiolysis, and their feedback (PDQs). Data gathering specifically looked at the post-needle localization period prior to surgical intervention and post-surgical intervention. After dissemination of this data, the stakeholders were encouraged to implement the PI project as a standard operating procedure that implements anxiolysis for patients undergoing NLBBX.

Evidence Evaluation: PubMED, CINAHL, and Embase databases were searched to identify evidence-based literature to include in the literature review. PubMed was searched with the key terms: “pain” or “anxiety” or “anxious*” or “discomfort” or “stress” or “distress”. “Analgesia” was implemented as a Medical Subject Heading (MeSH) with MeSH terms “analges*” or “anxiol*” or “antianxiety agents”. “Mastectomy, segmental” was also used as a MeSH with associated terms of “lumpectomy*” or “breast biops*”. CINAHL utilized subject headings (MH), which were broken down as follows: “pain+” or “anxiety+” or “stress+” or “analgesia+” or “antianxiety agents+” or “lumpectomy”. The following terms were included: “pain” or “anxiety” or “anxious” or “distress” or “discomfort” or “analges*” or “anxioly*” or “antianxiety” or “lumpectom*” or “breast biops*”. Embase was searched including these terms: “’pain’/exp” or “’anxiety’/exp” or “’stress’/exp” or “pain” or “anxiety” or “stress” or “distress” or “discomfort” or “anxious*”; “’analgesia’/exp” or “’anxiolytic agent’/exp” or “analges*” or

"anxioly*" or "antianxiety"; "'partial mastectomy'/exp" or "'breast biopsy'/exp" or "lumpect*" or "breast" and "biops*"; "'recovery room'/exp" or "'preoperative period'/exp" or "recovery room" or "preoperative" or "postoperative" or "'pre-operative'" or "'post-operative'".

Our criteria for literature review required English language and publication within 10 years. As of January 28, 2016, the results of the literature review produced 53 records from PubMed, 4 records from CINAHL, and 51 records from EMBASE. The entire review of literature includes articles from searches of three databases, information from the military health system website, and associated reports to Congress. Based upon review of article titles, 34 articles were selected for abstract review. Inclusion criteria were articles describing preoperative, intraoperative, and postoperative management and evaluation of pain and anxiety associated with breast biopsy, lumpectomy, or other outpatient procedures. Exclusion criteria included anticipated hospitalization/overnight stay, implementation of GA, and anesthesia provider present during IR procedure.

Upon reviewing the abstracts, a total of 14 articles were selected for comprehensive full-text review, with four articles included in the final literature review. One article that included overnight hospitalization was retained for its possible applicability to effectively decrease perceived anxiety and pain. The remaining 9 articles were eliminated due to the following reasons: 1 abstract was in English, but article was in French, 3 articles did not meet the level of evidence criteria (level of evidence required - I, II, and III), 1 was an editorial and 2 were poster presentations. Five articles were eliminated based on the previously discussed exclusion criteria. Refer to Appendix B and Appendix C for comprehensive outlines of search methods and broad overview of the literature review.

After reviewing the selected articles, the literature was evaluated on quantity, quality, and

consistency. These three measures provide a foundation for the clinical implications of the literature appraisal. The quantity of directly pertinent literature is extremely limited; of the 108 original articles only 4 articles were included in the final review. Those selected articles included articles about other outpatient procedures such as bone marrow biopsy and central venous catheter placement. Review of the references of the selected articles identified a further two articles that were beyond the 10-year search limit but added valuable evidence specific to anxiolysis for NLBBx. More evidence would give better generalizable information about the issue and possible solutions for this population (Bortolussi et al., 2015; Frank et al., 2007; Shen et al., 2008; Talamo et al., 2010).

Next, articles were assessed for level and quality of evidence Johns Hopkins Nursing Evidence-Based Rating Scale (Johns Hopkins Evidence Rating Scale, n.d.). All papers were read and evaluated separately by two team members. There was agreement between both team members as to the level and quality of evidence, with no need to break ties. There were four randomized control trials (level I) and two quasi-experimental studies (level II). Of the four RCTs, three were level A and one was level B; of the two quasi-experimental studies one was level A and one was level B (Johns Hopkins Evidence Rating Scale, n.d.).

Overall, the sample sizes included in the studies ranged from 65-299 participants. Unfortunately, each article discussed a different intervention, making it impossible to assess the consistency of the findings. These interventions included fentanyl buccal tablet, percocet/lorazepam combination, intravenous tramadol, and active therapeutic touch. Thus, these interventions included different classes of medications and administration routes (Bortolussi et al., 2015; Frank et al., 2007; Shen et al., 2008; Talamo et al., 2010).

Two previous studies were included as foundational precedence to support this process

improvement project. Both articles support the efficacy of benzodiazepine administration for anxiety management during breast biopsy procedures, reiterating the importance of addressing anxiety for this patient population. Preemptive anxiolysis results in improved patient comfort, increased patient satisfaction with procedure and achieved positive patient outcomes. According to the article by van Vlymen, Sá Rêgo, & White (1999), premedication with benzodiazepines resulted in a 36-52% increase in patient satisfaction. Bugbee, Wellisch, Arnott, Maxwell, Kirsch, Sayre, & Bassett (2005), concluded that the medication group reported a decrease in anxiety of 44% from preprocedural levels to intraoperative levels compared to the usual care group of an increase by 15% and relaxation therapy group with a decrease of 8% (Bugbee, Wellisch, Arnott, Maxwell, Kirsch, Sayre, & Bassett, 2005; van Vlymen, Sá Rêgo, & White, 1999).

Educational Intervention: An oral presentation with supporting documentation was offered to all personnel within the affected departments. Implementation guidance of the proposed process improvement project was presented.

Process Implementation: Prior to day of surgery (DOS), patients completed their preoperative evaluation in the surgical pre-op clinic. Radiology procedural consent was completed at least 30 minutes prior to the procedure to allow for oral anxiolytic medication to be administered and take effect prior to procedure. The admission orders for these patients included an order for diazepam 5-10 milligrams by mouth (PO) prior to surgery. Patients arrived on their DOS to the ambulatory surgical unit (ASU). Radiology was notified of patient's presence in ASU and availability for consent. After completing all required consents, the diazepam was administered and noted in the patient's chart. Patients received a PDQ (Appendix A) to complete after NLBBx (questions 1-6) and prior to hospital discharge (questions 7-11). The survey included questions directed at anxiety, anxiolysis, and patient satisfaction with experience. (Bugbee, Wellisch, Arnott,

Maxwell, Kirsch, Sayre, Bassett, 2005; van Vlymen, Sá Rêgo, & White, 1999). Inclusion criteria was any individual receiving a needle localized breast biopsy. Exclusion criteria was any individual with an allergy to the prescribed medication and patient refusal.

Directly prior to project implementation educational briefings were provided to the anesthesia, ASU, PACU, and radiology/mammography staff describing the process and impact it would have on each individual department. Staff roles were defined and discussed for active involvement with implementation. The patients were identified prior to DOS. An order was placed for 5-10 mg diazepam PO after all consents were completed, specifically radiology. On DOS, one project investigator facilitated communication amongst the departments and staff to maintain process efficiency. The patient was followed from time of arrival to time of discharge postoperatively evaluating the process, identifying areas for improvement, and educating staff as needed. Open communication was maintained with the staff during the implementation phase in order to encourage feedback.

HIPAA Concerns

No personally identified patient information (PII) was obtained from data gathered during this project. Patient discharge questionnaires were given to patients and collected prior to discharge and did not contain any patient PII. In order to identify this patient population, we reviewed OR schedule in advance to ensure that all patients were provided the opportunity to participate in this process improvement project, this posed a minimal risk HIPAA concern for this project.

Project Results

Evidence Evaluation

A total of ten patients were surveyed prior to implementation of the process improvement project. Pre-implementation statistics from patient surveys demonstrated a 60% satisfaction rate

with the needle localized breast biopsy experience. Eight patients received 5-10mg diazepam prior to NLBBx and surveyed during the implementation phase of this project. Analysis of the post-implementation data reflected a 40% increase in patient satisfaction specifically in relation to question #3. There was also a 15% decrease in discomfort associated with the needle localization procedure from “moderate” to “mild”: and “none” in question #4. Refer to Appendix E for a table comparing these pre and post-implementation results.

Provider Knowledge & Confidence

Post-implementation evaluation of the process and data analysis identified pros and cons of the PI project. This data was collected via field notes and post-brief feedback from key stakeholders from the different departments. Pros included: increased patient satisfaction, decreased patient anxiety level, minimal impact to radiology staff routine (with change to consenting in ASU versus in mammography directly prior to NLBBx). Cons identified include: potentially cumbersome process without direct project investigator facilitation of communication and direction to staff; staff variance and limited number of NLBBx’s at this facility to maintain process familiarity across departments; an OR delay due to unknown lag in radiology consent.

Organizational Impact / Implications to Practice & Policy

Changing the practice of consenting the patient for needle localization from the mammography clinic to the ASU resulted in minimal impact to practice. It positively impacted the patient’s perspective on the needle localization. One hundred percent patient satisfaction when patients are given an anxiolytic prior to needle localization is a notable difference from the 60% baseline satisfaction rate. As discussed previously, the use of an anxiolytic prior to needle localization does not impact consenting for surgery, anesthesia, or radiology. What it can impact is nurse and medical technician flow from time of radiology consent given to time arriving in

mammography—a thirty-minute window was given to allow onset of anxiolytic between administration of diazepam and transport to mammography suite. The ASU nurse must be aware that the radiology consent is signed by the patient, and the anxiolytic must be given with the understanding that a minimum 30-minute wait time before needle localization must take place to allow onset of oral medication. Then, the staff must ensure that an individual is available to transport patient to the mammography clinic in a timely manner. Another issue is that military health care members only work at a military treatment facility (MTF) for a limited time. The high staff turnover rate can create a disruption in clinical practice for this setting if there is not a protocol or practice guideline for the MTF.

Future Directions for Research and Practice

While there was an increase in satisfaction with patients receiving an anxiolytic compared to those who did not receive an anxiolytic, the number of NLBBx's at this facility limited the investigators to only 8 cases over four months. This project should be replicated at a facility with a greater number of NLBBx surgeries to determine if it is feasible on a larger scale and if similar positive impacts are observed.

Conclusion

Administration of anxiolytic prior to NLBBx improved patient satisfaction from 60% to 100%. This supports the findings of the literature review completed during development of this process improvement project. We recommend facility implementation of this PI project as protocol for patients undergoing NLBBx. A written, easily accessible protocol is ideal to sustain the required interdepartmental coordination needed for success and the high staff turnover within these departments. At this point project implementation as standard operating procedure is on hold due to departmental reservations from radiology.

References

American Association of Anesthesiologists. (2014). ASA physical status classification system. Retrieved from https://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system.

American Nurses Association, Inc. (2015). What is nursing? Retrieved from http://www.nursingworld.org/EspeciallyForYou/What-is-Nursing.

Bortolussi, R., Zotti, P., Matovic, M., Morabito, A., Bertuzzi, C., Caserta, M., . . . Fantin, D. (2015). A phase II study on the efficacy and safety of procedural analgesia with fentanyl buccal tablet in cancer patients for the placement of indwelling central venous access systems. *Supportive Care in Cancer*, 1-7. doi:10.1007/s00520-015-2939-7

Bugbee, M. E., Wellsich, D. K., Maxwell, J. R., Kirsch, D. L., Sayre, J. W., & Bassett, L. W. (2005). Breast core-needle biopsy: Clinical trial of relaxation technique versus medication versus no intervention for anxiety reduction. *Radiology*, 234, 73-78.

Cathy. (2008). My breast biopsy: Wire localization and patient empowerment. Retrieved on November 20, 2016 from http://cancerguide.org/cathy_story.html

Defense Health Agency (2015). *Evaluation of the Tricare Program: Access, Cost, and Quality*. *Fiscal Year 2015 Report to* Congress. Retrieved from http://www.health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Health-Care-Program-Evaluation/Annual-Evaluation-of-the-TRICARE-Program.

Department of Defense (2013). *2013 Demographics profile of the military community*. Office of the Deputy Assistant Secretary of Defense (Military Community and Family Policy). Retrieved from http://download.militaryonesource.mil/12038/MOS/Reports/2013-Demographics-Report.pdf.

Fatiregun, O. A., Olagunju, A. T., Erinfolami, A. R., Fatiregun, O. A., Arogunmati, O. A., & Adeyemi, J. D. (2016). Anxiety disorders in breast cancer: Prevalence, types, and determinants. *Journal of Psychosocial Oncology, 34*(5), 432.

Frank, L. S., Frank, J. L., March, D., Makari-Judson, G., Barham, R. B., Mertens, W. C. (2007). Does therapeutic touch ease the discomfort or distress of patients undergoing stereotactic core breast biopsy? A randomized clinical trial. *Pain Med*. 2007 Jul-Aug; 8(5): 419-24.

Howlader, N., Noone, A.M., Krapcho M., Neyman, N., Aminou, R., Waldron, W., Altekruse, S.F., Kosary, C.L., Ruhl, J., Tatalovich, Z., Cho, H., Mariotto, A., Eisner, M.P., Lewis, D.R., Chen, H.S., Feuer, E.J., Cronin, K.A. (eds). (2012). SEER cancer statistics review, 1975-2009 (Vintage 2009 Populations), *National Cancer Institute*. Bethesda, MD. Retrieved from http://seer.cancer.gov/archive/csr/1975_2009_pops09/results_merged/topic_delaygraphs_overview.pdf.

Jane. (2012). Help for painful wire localization. Retrieved on November 20, 2016 from https://www.cancerguide.org/jane_story.html.

Jacox, A. (1994). Management of cancer pain-adults. *American Family Physician*, 49(8), 1853-1868.

Joo, J.D., In, J. H., Kim, D.-W., Jung, H. S., Kang, J. H., Yeom, J. H., & Choi, J. W. (2012). The comparison of sedation quality, side effect and recovery profiles on different dosage of remifentanil patient-controlled sedation during breast biopsy surgery. *Korean Journal of Anesthesiology, 63*(5), 431-435. doi:10.4097/kjae.2012.63.5.431

Kwakkenbos, L., Coyne, J.C., Thombs, B.D. (2014, March). Prevalence of posttraumatic stress disorder (PTSD) in women with breast cancer [Letter to the Editor]. *Journal of Psychosomatic Research*, 76, 485-486.

Manne, S. L., Siegel, S., Heckman, C. J., & Kashy, D. A. (2015). Psychological distress as a mediator of the association between disease severity and occupational functioning among employed spouses of women recently diagnosed with breast cancer. *Psycho-oncology, 24*(11), 1560-1568. doi:10.1002/pon.3767

Mantani, T., Saeki, T., Inoue, S., Okamura, H., Daino, M., Kataoka, T., & Yamawaki, S. (2007). Factors related to anxiety and depression in women with breast cancer and their husbands: Role of alexithymia and family functioning. *Supportive Care in Cancer, 15*(7), 859-868. doi:10.1007/s00520-006-0209-4

Miller, S. J., O'Hea, E. L., Lerner, J. B., Moon, S., & Foran-Tuller, K. A. (2011). The relationship between breast cancer anxiety and mammography: experiential avoidance as a moderator. *Behavioral Medicine*, *37*(4), 113-118. doi: 10,1080/08964289.2011.614291

Office of the Assistant Secretary of Defense (Health Affairs) (2014). *Report to congress. National defense authorization act for fiscal year 2013 (HR 4310), section 737: Study on incidence of breast cancer among members of armed forces serving on active duty.* Retrieved from

http://www.health.mil/Reference-Center/Reports/2014/05/29/Study-on-Incedence-of-Breast-Cancer-Among-Active-Duty-Service-Members.

Pedersen, A., Sawatzky, J., & Hack, T. (2010). The sequelae of anxiety in breast cancer: A human response to illness model. *Oncology Nursing Forum, 37*(4), 469-475. doi:10.1188/10.ONF.469-475

Shelby, R.A., Golden-Kreutz, D.M., Andersen, B.L. (2008). PTSD diagnoses, subsyndromal symptoms, and comorbidities contribute to impairments for breast cancer survivors. *Journal of Traumatic Stress*, 21(2), 165-172.

Shen, X. F., Wang, F. Z., Xu, S. Q., Ma, L., Liu, Y. S., Feng, S. W., . . . Grp, B. (2008). Comparison of the analgesic efficacy of preemptive and preventive tramadol after lumpectomy. *Pharmacological Reports, 60*(3), 415-421.

Talamo, G., Liao, J., Bayerl, M. G., Claxton, D. F., & Zangari, M. (2010). Oral administration of analgesia and anxiolysis for pain associated with bone marrow biopsy. *Supportive Care in Cancer, 18*(3), 301-305. doi:10.1007/s00520-009-0652-0

Titler, M.G., Kleiber, C., Steelman, V. J., Rakel, B. A., Budreau, G., Everett, L. Q., Buckwalter, K. C., Tripp-Reimer, T., Goode, C. J. (2001). The Iowa model of evidence-based practice to promote quality care. *Critical Care Nursing Clinics of North America* 13(4), 497-509.

Van Vlymen, J. M., Sá Rêgo, M. M., White, P. F. (1999). Benzodiazepine premedication: Can it improve outcomes in patients undergoing breast biopsy procedures? *Anesthesiology*, 90(3), 740-747.

Appendix A

Patient Discharge Questionnaire

In an effort to improve the care of patients undergoing breast biopsy procedures, we would appreciate your responses to the following. Please mark all boxes which apply (X).

1. The preoperative registration process was:

( ) Smooth and efficient

( ) Acceptable but rather lengthy

( ) Disorganized and inefficient

2. The preoperative preparation in the Day Surgery Unit was:

( ) Better than expected

( ) Acceptable

( ) Below expectations

3. Did you feel that the sedative medication you received before the needle localization procedure was beneficial?

( ) Yes

( ) No

( ) Uncertain

4. Please indicate the degree of discomfort you experienced during the needle localization procedure in the x-ray *department*:

( ) None

( ) Mild

( ) Moderate

( ) Severe

5. What was the cause of the discomfort?

( ) Position

( ) Needle

6. Overall, how satisfied are you with the drugs that were used to make you comfortable during the actual operating itself?

( ) Extremely satisfied

( ) Satisfied

( ) Somewhat satisfied

( ) Neither satisfied nor dissatisfied (ambivalent)

( ) Somewhat dissatisfied

( ) Dissatisfied

( ) Extremely dissatisfied

7. What is the main reason for your dissatisfaction with the drugs used to make you comfortable during your operation (check all that apply)?

( ) Drugs did not provide adequate comfort

( ) Didn't' like the way the drugs made you feel

( ) The medication did not provide adequate relief of your anxiety in the operating room

( ) The medication did not provide adequate sedation (sleepiness) during the operation

( ) The medication did not provide adequate pain relief

8. If you were to have the same operation performed again, would you want to receive the same medications *before the operation*?

( ) Yes, would prefer the same drugs

( ) Not sure, may or may not prefer the same drugs

( ) No, would ask for something different

9. If you were to have the same operation performed again, would you want to receive the same medications *during the operation*?

( ) Yes, would prefer the same drugs

( ) Not sure, may or may not prefer the same drugs

( ) No, would ask for something different

10. If you were to have the same operation performed again, would you want to receive the same medications *during the operation (Needle localization)*?*

( ) Yes, would prefer the same drugs

( ) Not sure, may or may not prefer the same drugs

( ) No, would ask for something different

11. What was the worst aspect of the day of surgery?

( ) Waiting for the procedure

( ) Needle localization procedure

( ) Operating room activities

a. before surgery
b. during surgery
c. after surgery

( ) Postoperative recovery period

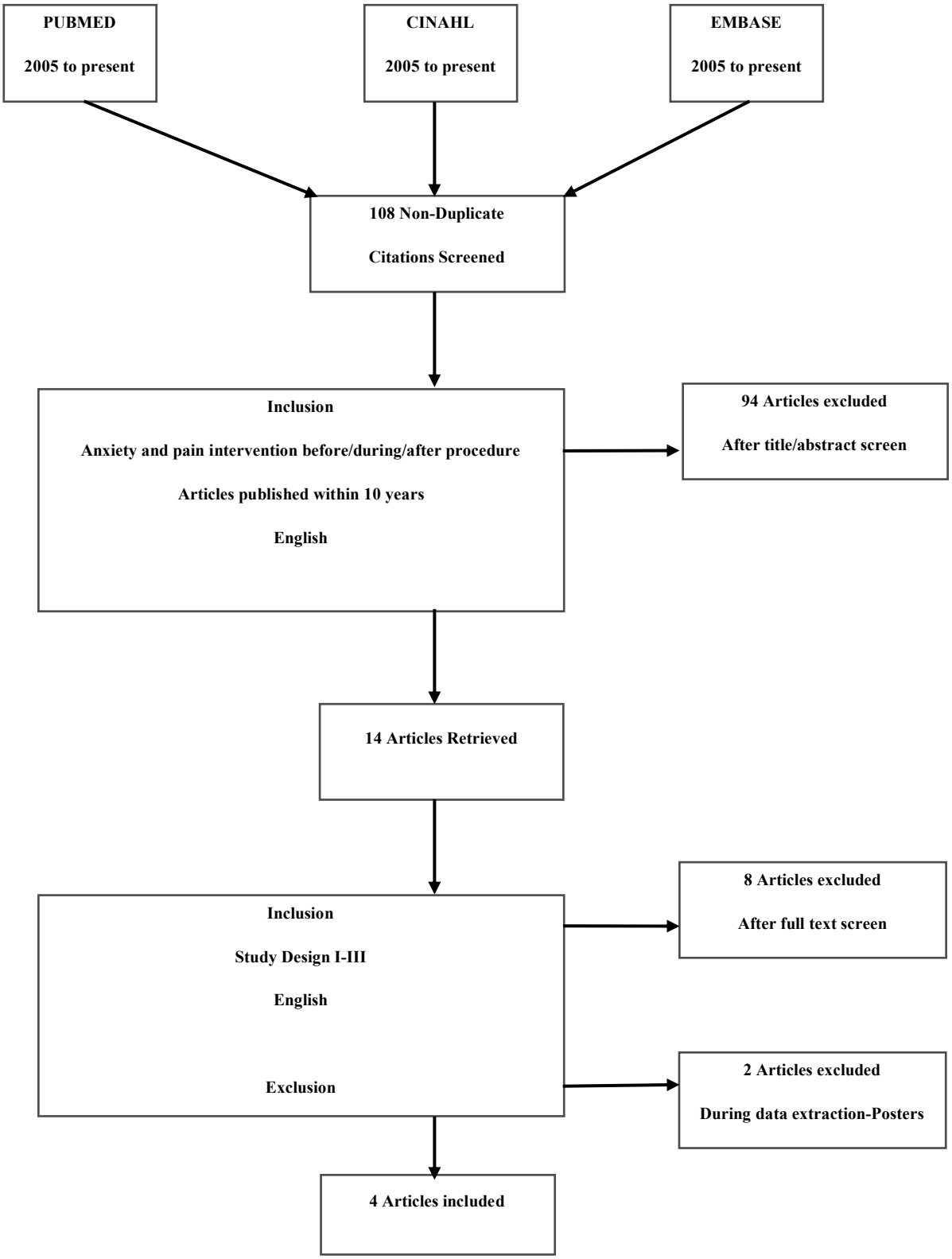
a. pain

b. nausea
c. drowsiness/tiredness

( ) None of the above

Appendix B

***Figure 1*: PRISMA flowchart. Outline of search methods and selected article**



Appendix C

Table 1

Broad Overview of the Literature

Search Engine	Article Title	Author(s)	Year	Journal	Purpose	Keywords	Target Population	Sample Size	Study design	Inclusion criteria	Exclusion criteria	Independent Variable(s)	Dependent variables/ measures collected	Statistical Tests	Relevant Results	Level of Evidence	Quality of Study/ Article
PubMed	A phase II study on the efficacy and safety of procedural analgesia with fentanyl buccal tablet in cancer patients for the placement of indwelling central venous access systems.	Bortolussi, R., Zotti, P., Matovic, M., Bertuzzi, C., Caserta, M., Fabiani, F., Fracasso, A., Santantonio, C., Zanier, C., Roscetti, A., Polesel, J., Gusseti, D., Bedin, S., Colussi, A. M., Fantin, D.	2015	Support Care Cancer 16Sep2015 (Epub ahead of print)	Pts undergoing central venous catheter placement (CVC), pain management with 100 mcg Fentanyl buccal tablet	Pain, cancer, anesthesia	Pt having CVC placement	65	Convenience sample, quasi-experimental study	(1) Patient aged over 18 years, (2) Histologically confirmed cancer diagnosis, (3) Indication for the placement of the indwelling central venous catheter connected to the subcutaneous port as an inpatient, (4) Unimpaired cognitive capacity, (5) Written informed consent	(1) Xerostomy or any other condition that does not make it possible to take effervescent tablets, (2) Patients already being treated with opioids for chronic cancer pain, (3) A documented history of significant nausea and vomiting related to the administration of opioids, (4) A history of intolerance to intravenous fentanyl or FBT, (5) Severe or moderate chronic respiratory insufficiency, (6) Patients with renal or hepatic function impairment	100 mcg Fentanyl buccal tablet	Preop pain & anxiety, intraop pain, postop pain	Fisher test, ANOVA	Statistically significant reduction in pain perception compared to pain assessment of patients not treated with FBT in the years 2010–2011 (Fisher test p = 0.0018)	II	A
PubMed	Oral administration of analgesia and anxiolysis for pain associated with bone marrow biopsy	Talamo, G., Liao, J., Bayerl, M. G., Claxton, D. F., Zangari, M.	2010	Support Care Cancer 2010 Mar; 18(3): 301-5. DOI: 10.1007/s00520-009-0652	Bone marrow aspiration & biopsy (BMAB) and pain	Bone marrow biopsy, pain, analgesia, anxiolysis, benzodiazepines	Individuals undergoing bone marrow aspiration and biopsy	84	Convenience sample, quasi-experimental study	Adult patients seen at the hematology clinic in 2007 underwent BMAB	Not discussed	Percocet PO x1 tab (10/650) & lorazepam 2 mg PO x1	Post-op pain via Wong Baker faces scale	*t test, chi square, proportional odds model for the event of pain level smaller or equal to level k, for k=0, multivariate regression analysis for predictors of pain (3 identified - analgesia/anxiolysis group, male sex, older age), p value of <0.05 was considered statistically significant*	Statistical significance with p values of 0.004 (Group B vs A), 0.0240 (age in years), and 0.0261 (sex, M vs F), ultimate findings statistical significance but not clinically significant	II	B
PubMed	Comparison of the analgesic efficacy of preemptive and preventive tramadol after lumpectomy	Shen, X., Wang, F., Xu, S., Ma, L., Liu, Y., Feng, S., Wang, W., Zhao, Q., Li, X., Zhao, L., Yao, X., Qu, J., Xie, B., Wang, H., Yuan, H., Cao, Y., Sun, Y., Wang, W., Guo, L., Song, Z., Wang, Z., Guan, X.	2008	Pharmacol Rep. 2008 May-Jun; 60(3): 415-21	Evaluate analgesic efficacy of tramadol administrated preemptively or preventively in the earlier period of lumpectomy	Postoperative pain, postoperative analgesia, opioids, tramadol, lumpectomy	Lumpectomy	317, 299 completed study, no discussion of what happened to the 18 participants who did not complete the study	RCT	400 ASA physical status I–II patients who underwent elective lumpectomy at the facility	(1) Allergy to opioids, a history of the use of centrally-acting drugs of any sort, chronic pain and psychiatric disease records, (2) Participants younger than 18 years or older than 65 years or pregnancy, (3) Those who were not willing to or could not finish the whole study at any time, (4) The post-anesthetic care unit (PACU) assessing score was under 6 on a scale of 10 (measuring somnolence, respiration, movement, color, and blood pressure on 0–2 scales), and arterial oxygen saturation measured by pulse oximetry (SaO_2) was 92% or lower (supplemental oxygen was permitted), (5) Using or used in the past 14 days of the monoamine oxidase inhibitors, (6) Alcohol addictive or narcotinum dependent patients were excluded for their influence on the analgesic efficacy of the study substances	IVP 100 mg Tramadol 15 min prior to procedure (preemptive group), IVP 100 mg Tramadol prior to end of procedure (preventive group)	Pain intensity at rest, overall satisfaction score, morphine consumption and side effects were recorded	Demographic data and background characteristics (age, wt, ht), ASA physical status & morphine consumption - compared with two-way ANOVA, effects of the study drugs on patient's self-rated VAS of pain & satisfaction were analyzed by two-way ANOVA with repeated measures, ANOVA tests were always followed by the Bonferroni post-hoc tests, a Chi-square t-test was performed to compare side effects among groups, statistical significance was accepted at the level of $p \leq 0.05$	Preemptive and preventive delivery of tramadol expressed analgesia of similar efficacy up to 24 h after lumpectomy, no statistical significance in side effects, pt satisfaction, and additional morphine requirements between the preemptive and preventive groups	I	B
PubMed	Does therapeutic touch ease the discomfort or distress of patients undergoing stereotactic core breast biopsy? A randomized clinical trial.	Frank, L. S., Frank, J. L., March, D., Makari-Judson, G., Barham, R. B., Mertens, W. C.	2007	Pain Med. 2007 Jul-Aug; 8(5): 419-24	Does therapeutic touch decrease anxiety & pain in individuals undergoing stereotactic core biopsy of suspicious breast lesions?	Therapeutic touch, pain, percutaneous, breast biopsy, anxiety	Pts undergoing stereotactic breast biopsy	82 participants, all female	RCT	Patients were eligible for this study if they were recommended for SCB for a nonpalpable lesion found on mammography	Not discussed	Active therapeutic touch (TT) vs sham TT	Pain & anxiety	Continuous variables were analyzed by t-tests or Pearson correlation, categorical variables or outcomes were compared by contingency table analysis (chi-square or Fisher exact tests), Spearman correlation, or simple logistic regression, all P values reported are two-sided	TT may be shown to be effective in other clinical settings, we do not feel—given these results—that TT is an effective intervention to reduce pain & other forms of distress resulting from acute percutaneous procedures, such as SCB performed on conscious patients	I	A
PubMed	Benzodiazepine Predeciation: Can it improve outcome in patients undergoing breast biopsy procedures?	Van Vlymen, J.M., Sá Rêgo, M.M., White, P.F.	1999	Anesthesiology. 2007 Mar; 90(3): 740-747	Use of benzodiazepines (anxiolytic) decreases discomfort of needle localization, decreases anxiety of surgical procedure, and does not affect discharge times.	Diazepam; monitored anesthesia care; preanesthetic medication	Patients undergoing needle localization and breast biopsies	90 participants, all female: 29 received saline; 30 received midazolam; 31 received diazepam	RCT, convenience	Anesthesiologist physical status I-III, age 18-79, scheduled for a needle localization and breast biopsy	Pregnancy, breastfeeding, long-term use of benzodiazepines, allergy to any of the medications	Saline, midazolam, diazepam	Pain, anxiety, satisfaction	Power analysis; Type I error (α)—0.05; Type II error (β)—0.2; One-way analysis of variance (continuous variables); Analysis of variance (significant difference); Newman-Keuls test (*post hoc* intergroup comparisons); chi-square and Kruskal-Wallis tests (categorical variables—median values or percentages)	Diazepam group: 90% found medication helpful, 97% would choose the same medication again, 6% experienced discomfort. Midazolam group: 74% found medication helpful, 83% would choose the same medication again, 20% experienced discomfort. Saline group: 38% found medication helpful, 55% would choose it again, 70% experienced discomfort.	I	A
	Breast core-needle biopsy: Clinical trials of relaxation technique versus medication versus no intervention for anxiety reduction	Bugbee, M.E. Wellisch, D.K., Arnott, I.M., Maxell, J.R., Kirsch, D.L., Sayre, J.W., Bassett, L.W.	2005	Radiology. 2005 Jan; 234: 73-78	Effectiveness in relieving anxiety: anxiolytics versus relaxation techniques	Core-needle biopsy, anxiety, relaxation therapy, relaxation technique, alprazolam	Women scheduled for breast core-needle biopsy	143 participants, all women	RCT, convenience	Subjects had to be willing to be randomized to any of the three treatment arms, speak English, accompanies by a person who was able to drive them home	Taking anxiety reduction medications prior to arriving for appointment	Relaxation therapy, alprazolam, usual care	Post-procedural anxiety assessment (State-Trait Anxiety Inventory)	Analysis of variance (group differences), Bonferroni multiple comparison procedure (differences in mean values), chi-square statistic (categorical demographic differences)	Medication group reported a decrease in anxiety of 44% from preprocedural levels to intraoperative levels compared to the usual care group of an increase by 15% and relaxation therapy group with a decrease of 8%; no significant difference 24 hours post-procedure in anxiety scores of the three groups	I	A

Appendix D

Table 2

Project Timeline: Anxiety Management for Needle Localization

Project Year 1 (2017)												
Activity/Month	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
USUHS VPR Submission and Approval			X									
Site IRB Submission and Approval			X									
Project Implementation/Data Collection									X	X	X	X
Data Analysis									X	X	X	X
Dissemination												
Project Year 2 (2018)												
Activity/Month	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
USUHS VPR Submission and Approval												
Site IRB Submission and Approval												
Project Implementation/Data Collection	X	X										
Data Analysis	X	X										
Dissemination			X	X	X							

Appendix E

Table 3

Comparison of Pre and Post-Implementation Data

PDQ Questions: 1-12	Pre-Implementation Data (10 patients)	Post-Implementation Data (8 patients)
1. The preoperative registration process was:	90% - smooth and efficient; 10% - no answer	100% - smooth and efficient
2. The preoperative preparation in the Day Surgery Unit was:	70% - better than expected; 20% - acceptable; 10% - no answer	100% - better than expected
3. Did you feel that the sedative medication you received before the needle localization procedure was beneficial?	60% - yes; 30% - I did not receive medication prior to needle localization; 10% - no answer	100% - yes
4. Please indicate the degree of discomfort you experienced during the needle localization procedure in the x-ray department:	80% - mild discomfort; 10% - no answer; 10% - none	25% - moderate discomfort; 37.5% - mild discomfort; 37.5% - none
5. What was the cause of the discomfort?	60% - needle discomfort; 20% - position; 10% - N/A; 10% - no answer	50% - needle discomfort; 12.5% - position; 37.5% - no answer
6. How satisfied are you with the drugs that were used in the operating room to make you feel comfortable while the surgeon was injecting the numbing medication?	50% - extremely satisfied; 10% - satisfied; 10% - "no recall"; 10% - neither satisfied no dissatisfied; 20% - no answer	37.5% - extremely satisfied; 62.5% - satisfied
7. Overall, how satisfied are you with the drugs that were used to make you comfortable during the actual operation itself?	80% - extremely satisfied; 20% - no answer	37.5% - extremely satisfied; 62.5% - satisfied
8. What is the main reason for your dissatisfaction with the drugs used to make you comfortable during your operation (check all that apply)?	20% - N/A; 80% - no answer	25% - drugs did not provide adequate comfort; 25% - N/A; 50% - no answer
9. If you were to have the same operation performed again, would you want to receive the same medications before the operation?	80% - yes; 20% - no answer	75% - yes; 25% - not sure, may or may not prefer the same drugs
10. If you were to have the same operation performed again, would you want to receive the same medications during the operation?	80% - yes; 20% - no answer	75% - yes; 25% - not sure, may or may not prefer the same drugs
11. What was the worst aspect of the day of surgery?	40% - waiting for the procedure; 10% - needle localization procedure; 10% - postoperative recovery period: drowsiness/tiredness; 20% - none of the above; 20% - no answer	62.5% - waiting for the procedure; 12.5% - postoperative recovery period: pain; 12.5% postoperative recovery period: headache; 12.5% - "no dissatisfaction with any part today"

Appendix F

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

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

- **Name:** Jorge Arizpe (ID: 2015093)
- **Email:** jorge.arizpe@usuhs.mil
- **Institution Affiliation:** Uniformed Services University of The Health Sciences (ID: 395)
- **Institution Unit:** Graduate School of Nursing
- **Phone:** 713-377-4574

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

- **Report ID:** 16983122
- **Completion Date:** 08/22/2015
- **Expiration Date:** 08/21/2018
- **Minimum Passing:** 80
- **Reported Score*:** 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED
Records-Based Research (ID: 5)	08/22/15
Vulnerable Subjects - Research Involving Children (ID: 9)	08/22/15
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	08/22/15
FDA-Regulated Research (ID: 12)	08/22/15
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	08/22/15
Informed Consent (ID: 3)	08/22/15
History and Ethics of Human Subjects Research (ID: 498)	08/22/15
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	08/22/15
Genetic Research in Human Populations (ID: 6)	08/22/15
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	08/22/15
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	08/22/15
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	08/22/15
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	08/22/15
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	04/19/12
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	08/22/15
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	08/22/15

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

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

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

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

- **Name:** Keren Stimeling (ID: 4990657)
- **Email:** keren.stimeling@usuhs.edu
- **Institution Affiliation:** Uniformed Services University of The Health Sciences (ID: 395)
- **Institution Unit:** GSN
- **Phone:** 717-490-0130

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

- **Report ID:** 16987188
- **Completion Date:** 08/23/2015
- **Expiration Date:** 08/22/2018
- **Minimum Passing:** 80
- **Reported Score*:** 97

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED
Records-Based Research (ID: 5)	08/23/15
Vulnerable Subjects - Research Involving Children (ID: 9)	08/23/15
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	08/23/15
FDA-Regulated Research (ID: 12)	08/23/15
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	08/23/15
Informed Consent (ID: 3)	08/23/15
History and Ethics of Human Subjects Research (ID: 498)	08/23/15
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	08/23/15
Genetic Research in Human Populations (ID: 6)	08/23/15
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	08/23/15
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	08/23/15
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	08/23/15
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	08/23/15
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	08/23/15
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	08/23/15
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	08/23/15

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

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

Appendix G

UNIFORMED SERVICES UNIVERSITY
of the Health Sciences

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:	T0-GSN-61-9342-01
Principal Investigator:	Arizpe, Jorge (GSN-61)
Department:	Graduate School of Nursing
Project Type:	Student
Project Title:	Anxiety Management for Needle Localization
Project Period:	10/5/2017 to 5/31/2018

Assurance and Progress Report Information:

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

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

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

[redacted]

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

cc: Arizpe, Jorge (GSN-61)
Vernell Shaw
File
Lonnie Hodges
Linda Wanzer

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

VPR Date Stamp

Project Number: T0619342 (VPR will assign)
Project Title: Anxiety Management for Needle Localization

SECTION A: STUDENT/POC INFORMATION

1. Name (Last, First, MI): Arizpe, Jorge Student E [redacted]
2. Home Address: [redacted]

SECTION B: COMMITTEE CHAIR/SENIOR MENTOR INFORMATION

3. Name (Last, First, MI): Hodges, Lonnie
4. Telephone: Fax: E-mail: lonnie.hodges@usuhs.edu
5. USUHS Building/Room No.:

SECTION C: PROJECT INFORMATION

6. Attach the Abstract for the proposal, including the following sections: Site Location of the Project, Title, Authors, Background or Problem/Issue, Clinical Question/Purpose, Project Design, Anticipated Organizational Impact/Implications for Practice and also include the Proposed Timeline. Single space the abstract and use Times New Roman font, size 12.
7. Is this proposal related to an active research project of the Chair/Senior Mentor identified in Section B? Yes ✓ No
   If yes, complete below; if no, proceed to Part 8.
   Project Number:
   Project Title:
   Project Start Date: Project End Date:
8. Anticipated period of performance: Project Start Date: 01APR17 Project End Date: 15May2018
9. Performance Site(s): Eglin Air Force Base Regional Hospital, Eglin AFB, FL
10. Does this project involve any classified information? (Contact the USUHS Security Office for guidance) Yes ✓ No
11. Do you have a funding source for this project? Yes No ✓ NA
    If yes, specify the funding agency and the amount provided:

SECTION D: SIGNATURES

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

[redacted] 27MAR2017 (Signature and Date)
13Apr2017 (Signature and Date)
13Sep2017 (Signature and Date)
19Sept2017 (Signature and Date)

[redacted] 3Apr 2017 (Signature and Date)
(Signature and Date)
21 Sep 2017 (Signature and Date)
Sept 2017 (Signature and Date)

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

USUHS Vice President for Research Date

USUHS Form 3202N (VPR) - Revised Sep 2015 v1.2
Previous versions are obsolete

Appendix H

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS 88TH AIR BASE WING (AFMC)
WRIGHT-PATTERSON AIR FORCE BASE OHIO

17 August 2017

MEMORANDUM FOR 96 SGC/SGCJ
ATTN: MAJ JORGE ARIZPE

FROM: WPMC INSTITUTIONAL REVIEW BOARD
88 MDG/SGNE
4881 Sugar Maple Drive
Wright-Patterson AFB OH 45433-5219

SUBJECT: Institutional Review Board (IRB) Research Determination

1. Your project proposal entitled "Anxiety Management for Needle Localization" has been reviewed by the Wright-Patterson Medical Center (WPMC) IRB.

DoD Assurance: F50005
DHHS FWA: 00000609
DHHS IRB: 00001357

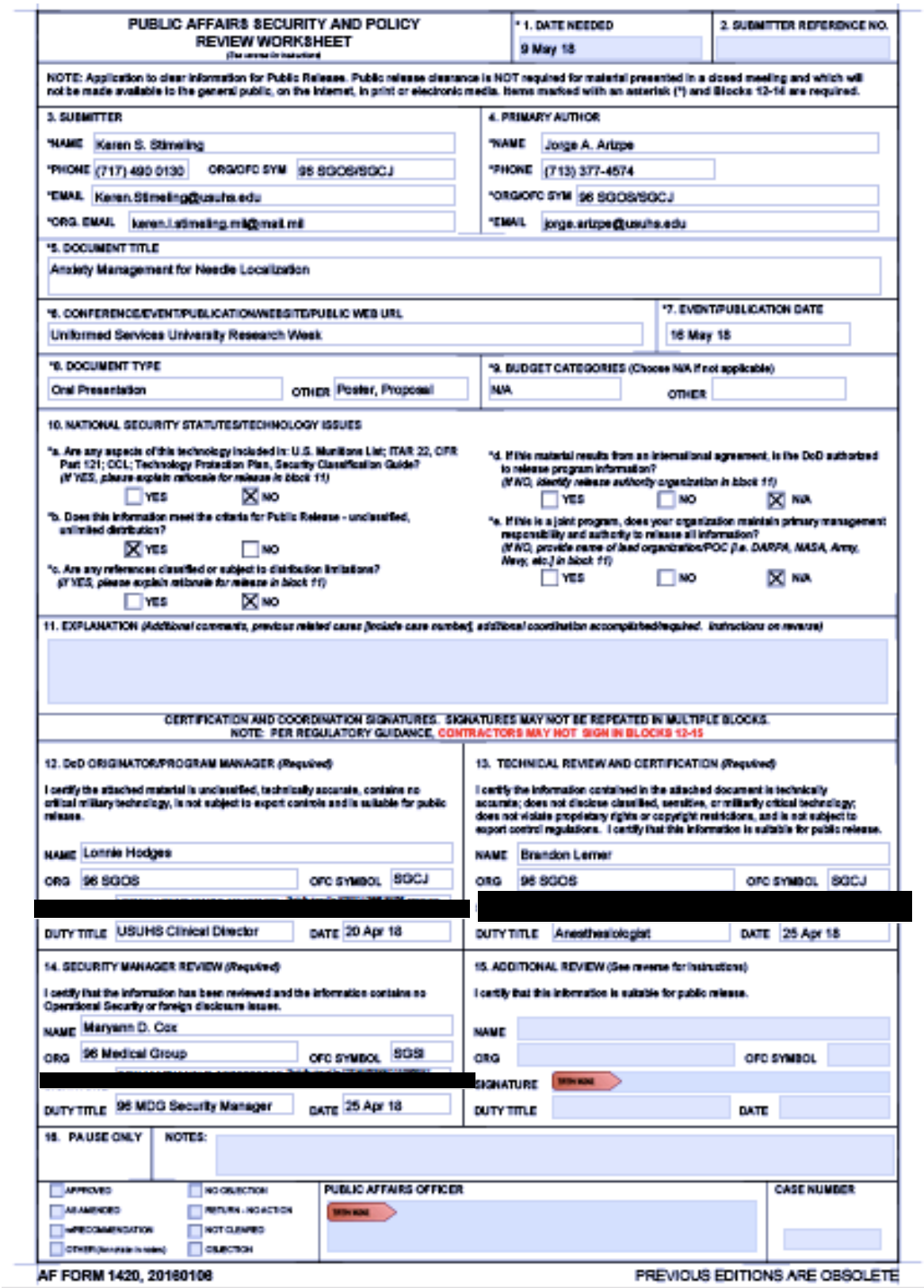
2. As a designated expedited review member of the WPMC IRB, I have determined that this project does not meet the criteria to be considered research involving human subjects in accordance with 32 CFR § 219.102. The design and intent of this project is to implement and evaluate evidence-based practice change at the 96th Medical Group involving anxiolytic pretreatment of patients undergoing needle localization in interventional radiology. This project is a local practice change at the 96th Medical Group that is not intended to contribute to generalizable knowledge, does not impose risks to patients beyond the standard of practice, and is designed to result in immediate improvement at the institution. Therefore, research protocol approval and oversight by an IRB is not required. *Any changes to the activity may affect the study status and must be reviewed by the WPMC IRB.*

3. This determination does not grant permission to conduct this project; this authority lies with 96th Medical Group Leadership. Questions or concerns should be addressed to me at (937) 257-4242, or e-mail frederick.funke@us.af.mil.

FREDERICK H. FUNKE, Civ, DAF, CIP
WPMC IRB Administrator

Atch
Human Subject Research Checklist

Appendix I



PUBLIC AFFAIRS SECURITY AND POLICY REVIEW WORKSHEET

*1. DATE NEEDED: 9 May 18

2. SUBMITTER REFERENCE NO.:

NOTE: Application to clear information for Public Release. Public release clearance is NOT required for material presented in a closed meeting and which will not be made available to the general public, on the Internet, in print or electronic media. Items marked with an asterisk (*) and Blocks 12-15 are required.

3. SUBMITTER
*NAME: Karen S. Stimeling
*PHONE: (717) 490 0130 ORG/OFC SYM: 96 SGOS/SGCJ
*EMAIL: Karen.Stimeling@usuhs.edu
*ORG. EMAIL: karen.l.stimeling.mil@mail.mil

4. PRIMARY AUTHOR
*NAME: Jorge A. Artpe
*PHONE: (713) 377-4574
*ORG/OFC SYM: 96 SGOS/SGCJ
*EMAIL: jorge.artpe@usuhs.edu

*5. DOCUMENT TITLE: Anxiety Management for Needle Localization

*6. CONFERENCE/EVENT/PUBLICATION/WEBSITE/PUBLIC WEB URL: Uniformed Services University Research Week

*7. EVENT/PUBLICATION DATE: 16 May 18

*8. DOCUMENT TYPE: Oral Presentation OTHER: Poster, Proposal

*9. BUDGET CATEGORIES (Choose N/A if not applicable): N/A OTHER:

10. NATIONAL SECURITY STATUTES/TECHNOLOGY ISSUES

*a. Are any aspects of this technology included in: U.S. Munitions List; ITAR 22, CFR Part 121; CCL; Technology Protection Plan, Security Classification Guide? (If YES, please explain rationale for release in block 11) ☐ YES ☒ NO

*b. Does this information meet the criteria for Public Release - unclassified, unlimited distribution? ☒ YES ☐ NO

*c. Are any references classified or subject to distribution limitations? (If YES, please explain rationale for release in block 11) ☐ YES ☒ NO

*d. If this material results from an international agreement, is the DoD authorized to release program information? (If NO, identify release authority organization in block 11) ☐ YES ☐ NO ☒ N/A

*e. If this is a joint program, does your organization maintain primary management responsibility and authority to release all information? (If NO, provide name of lead organization/POC (i.e. DARPA, NASA, Army, Navy, etc.) in block 11) ☐ YES ☐ NO ☒ N/A

11. EXPLANATION (Additional comments, previous related cases [include case number], additional coordination accomplished/required. Instructions on reverse)

CERTIFICATION AND COORDINATION SIGNATURES. SIGNATURES MAY NOT BE REPEATED IN MULTIPLE BLOCKS.
NOTE: PER REGULATORY GUIDANCE, CONTRACTORS MAY NOT SIGN IN BLOCKS 12-15

12. DoD ORIGINATOR/PROGRAM MANAGER (Required)
I certify the attached material is unclassified, technically accurate, contains no critical military technology, is not subject to export controls and is suitable for public release.
NAME: Lonnie Hodges
ORG: 96 SGOS OFC SYMBOL: SGCJ
[redacted]
DUTY TITLE: USUHS Clinical Director DATE: 20 Apr 18

13. TECHNICAL REVIEW AND CERTIFICATION (Required)
I certify the information contained in the attached document is technically accurate; does not disclose classified, sensitive, or militarily critical technology; does not violate proprietary rights or copyright restrictions, and is not subject to export control regulations. I certify that this information is suitable for public release.
NAME: Brandon Lerner
ORG: 96 SGOS OFC SYMBOL: SGCJ
[redacted]
DUTY TITLE: Anesthesiologist DATE: 25 Apr 18

14. SECURITY MANAGER REVIEW (Required)
I certify that the information has been reviewed and the information contains no Operational Security or foreign disclosure issues.
NAME: Maryann D. Cox
ORG: 96 Medical Group OFC SYMBOL: SGS
[redacted]
DUTY TITLE: 96 MDG Security Manager DATE: 25 Apr 18

15. ADDITIONAL REVIEW (See reverse for instructions)
I certify that this information is suitable for public release.
NAME:
ORG: OFC SYMBOL:
SIGNATURE:
DUTY TITLE: DATE:

16. PA USE ONLY
NOTES:
☐ APPROVED ☐ NO OBJECTION
☐ AS AMENDED ☐ RETURN - NO ACTION
☐ NOT RECOMMENDATION ☐ NOT CLEARED
☐ OTHER (See note in notes) ☐ OBJECTION
PUBLIC AFFAIRS OFFICER:
CASE NUMBER:

AF FORM 1420, 20160108 PREVIOUS EDITIONS ARE OBSOLETE

Block 11 - Explanation (Continued):

INSTRUCTIONS FOR COMPLETING THE SECURITY AND POLICY REVIEW WORKSHEET

NOTE: Items marked with an asterisk (*) and Blocks 12-14 are required. If all required information is not provided, case will be returned with no action taken and must be resubmitted.

1. Date Needed: Allow at least 10 working days *(not including day of submission)* for PA review. Additional time may be required for unit processing.
   - Requests for less than 10 working days require a justification letter as to why the submission does not fall within the required time frame signed by a Directorate-Level Director or Commander. More information including a justification letter template is available on the S&PR SharePoint Site.
   - Depending on complexity or requirements for other coordination, items can take longer to process. You will be notified of any issues with processing.
   - Items already publicly presented will not be reviewed.

2. Include your organizational reference/tracking number (optional). Tracking numbers will not be added by PA.

3. Submitter information: Self explanatory. *These e-mail addresses receive notification when case is assigned and completed.*

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6. Conference/Event/Publication Name/Website URL. Identify date of event/name of publication where submission will be published, or web site where cleared material will be posted.

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8. Document type: Indicate the type of information to be reviewed from the pull down menu, or choose Other and fill in that blank.

9. Identify the budget category or program element code associated with the weapon system from pull down menu, or choose NA.

10. National Security Statutes/Technology Issues:
   a. References:
      - Electronic Code of Federal Regulations: http://www.ecfr.gov
      - Export Administration Regulations Database: http://www.bis.doc.gov
      - U.S. Munitions List (Part 121) and International Traffic in Arms Regulations http://fas.org/spp/starwars/offdocs/itar/p120.htm
      - The Commerce Control List http://www.bis.doc.gov
   b. Materials that must be/are marked FOUO or Distribution B or higher will not be cleared.
   c. Identify whether classified references are used. Annotate in Block 11 (Explanation) exact references and why it is necessary to use them.

11. Explanation. Include additional comments from other blocks (list previous related cases), clearly identify coordination with agencies already accomplished. If additional coordination with other command agencies is required, provide POC information (use back of form, as necessary).

CERTIFICATION AND COORDINATION SIGNATURES. PER REGULATORY GUIDANCE, **CONTRACTORS MAY NOT SIGN IN BLOCKS 12-15**

12. Originator/Program Manager/Author Certification. Signature certifies that the U.S. Government originator, program manager, or author concurs that the information is appropriate for public release based on regulations, classification guides, and any other pertinent guidance.

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15. Additional review. Used to document coordination with outside agencies/program offices, or organizations may have an internal process that requires an additional signature, such as director or commander. Required only when external coordination needs to be documented, or internal processes dictate additional review.

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CASE NUMBER: 96TW-2018-0151
SOURCE:
SUBJECT: Uniformed Services University Research Week - Anxiety Management for Needle Localization
STATUS: Closed

CASE SUMMARY

Case Number:	96TW-2018-0151	**Case Reviewer:**	Williams, Kevin
Type of Case:	Regular	**Document Type:**	Graphics - Poster
Date Received:	01 May 2018	**Date Last Modified:**	01 May 2018
Subject:	Uniformed Services University Research Week - Anxiety Management for Needle Localization		
Description:	2018 AF Form 1420 ArtzpeStimeling 25Apr-Signed; ArtzpeJ_StimelingK_DNP_posterKW3; ArtzpeJ_StimelingK_DNP_posterKW3		
Suspense Date:	10 May 2018		
Extended Suspense Date:		**Funding Level:**	
Originator Reference Number:			

ORIGINATOR

Originator:		**Originator Name:**	
Originator Commercial Phone:		**Originator DSN:**	
Originator Email:			
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MEDIA

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E-file	6647.00	1

REVIEW

Disposition Date:	01 May 2018	**Business Days to Clear:**	1
DAF Initiated:	Cleared		

ORIGINAL/COORDINATION

COORDINATION

External Review / Coordination Note	Date Sent	Review Suspense Date	Response Date	Response	Response Comment

Printed by Kevin, Williams on 01 May 2018 1107

Appendix J

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

DOCTOR OF NURSING PRACTICE PROJECT
Completion Verification Form

The DNP Project titled: Anxiety Management for Needle Localization

was completed at Eglin Air Force Base Hospital, Egling AFB, Florida by the following student(s):

(type student name)	*(signature)*	*(date)*
Jorge A. Arizpe	[redacted]	15 Apr 2018
Keren L. Stimeling		15 Apr 2018

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

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

Verified by:

(type name)	*(signature)*	*(date)*	
Lonnie Hodges	[redacted]	18 Apr 18	Senior Mentor
Ken Wofford		18APR18	Team Mentor
Kathy Algu		18 Apr 18	Team Mentor
			Team Mentor & Phase II Site Director

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

Kenneth Wofford	[redacted]	18APR18
RNA Project Director *(type name)*	*(Signature)*	*(Date)*

Form Version: 26 Aug 2017