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Breastfeeding After Surgery: Influencing Postoperative Recommendations

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Abstract

Phase II Site: U.S. Naval Hospital Jacksonville, Florida

Title: Breastfeeding After Surgery: Influencing Postoperative Recommendations

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Background: Breastfeeding mothers are faced with the dilemma of deciding when to resume breastfeeding after surgery. Interrupting breastfeeding can negatively impact maternal and child health outcomes and healthcare costs. The apprehension experienced by breastfeeding mothers is often compounded by variations in post-anesthetic guidance given by anesthesia providers. For mothers to make an informed decision about resuming breastfeeding, anesthesia providers should deliver consistent, up-to-date information about the risks associated with breastfeeding after surgery.

Purpose: To standardize the education anesthesia providers and post-anesthesia care unit staff provide to breastfeeding mothers in regards to breastfeeding after surgery.

Design: Performance improvement project that assesses provider knowledge, confidence and recommendations before and after an educational intervention.

Results: This evidence-based practice project successfully improved staff knowledge in regard to the transference of anesthetic drugs to breast milk, and also increased staff confidence in the recommendations they provide to breastfeeding mothers. The EBP project also increased the number of staff that would recommend immediate resumption of breastfeeding after surgery. The creation and implementation of a standard operating procedure will serve as a vessel to promote culture change and achieve sustainability.

Implications for Practice: Consistent recommendations will result in a better patient experience secondary to improved patient satisfaction for the mother and potentially better health outcomes for the mother and child which are consistent with three of goals of the Military Health System: improved patient experience, population health, and per capita costs.

Introduction

Exclusive breastfeeding is the recommended source for infant nutrition during the first year of life, since breastmilk and the act of breastfeeding provide both short and long-term health benefits. Breastfeeding mothers experience decreased blood loss and more rapid involution of the uterus postpartum (Eidelman et al, 2012). Each year of breastfeeding provides mothers with a 4 to 12% decrease in risk for developing type II diabetes (Stuebe, Rich-Edwards, Willett, Manson, & Michels, 2005); (Schwarz et al., 2010). Additionally, mothers who breastfeed have a reduced risk for cardiovascular disease (Schwarz et al., 2010; Ray, 2009), along with a decreased risk for developing breast (Bergkvist, 2002) and ovarian cancer (Rosenblatt, Thomas, & The World Health Organization, 1993). Infants who are exclusively breastfed for more than four months have a decreased risk of hospitalization for lower respiratory tract infections (Bachrach, Schwarz, & Bachrach, 2003). Furthermore, breastfed infants have a reduced incidence of nonspecific gastrointestinal infection (Kramer, 2003), and a reduced risk for sudden infant death (Hauck et al., 2003). With obesity identified as one of the top three global social burdens (Gaines, 2015), perhaps the most impactful health benefit is a lowered likelihood of developing obesity in breastfed infants (Owen, Martin, Whincup, Smith, & Cook, 2005).

While some interruptions to breastfeeding postoperatively may be temporary, it is unclear whether there are persistent effects stemming from these interruptions. Bottle feeding and pacifiers may be used as temporary substitutes for breastfeeding but also have disadvantages to their use. For example, pacifier use has been shown to reduce the duration of breastfeeding. This may be particularly troublesome to young mothers who experience frustration with an ineffective breastfeeding technique resulting in a premature cessation of breastfeeding (Kronborg & Vaeth, 2009). Short term substitutes to breastfeeding may indeed have long-term sequelae.

The well-intentioned recommendation to temporarily discontinue breastfeeding after surgery arises from concern that anesthetic agents may be transferred to the infant via breast milk (Dalal, Bosak, Berlin, & Bosenberg, 2014). As a result of the tension between the benefits of early postoperative resumption of breastfeeding and the perceived risks of exposing the infant to transferred anesthetic agents, post-anesthetic guidance is inconsistent for mothers who desire to resume breastfeeding after surgery (Hale, 1999). This project assessed the implementation of an evidence-based standard operating procedure for post-anesthetic guidance delivered by anesthesia providers and post-anesthesia care unit (PACU) staff to breastfeeding mothers undergoing surgery. Knowledge about maternal-infant transfer of anesthetic agents, confidence in delivery of post-anesthetic guidance, and compliance with clinical practice guideline implementation were also measured.

Significance of the Problem

In the U.S., 79% of the nearly 4 million infants born in 2011 were reported having ever been breastfed (Hamilton, Martin, Osterman, Curtin, & Matthews, 2015), which in turn suggests lactating mothers are a large cohort within in the U.S. Healthcare system (Centers for Disease Control and Prevention (CDC), 2014). Although 79 percent of infants are breastfed at some point in their development, breastfeeding appears to decline after birth. The rate of breastfeeding decreases to 49 percent at six months and falls to 27 percent at twelve months. Mothers who exclusively breastfeed represent a smaller portion, 40.7 percent exclusively breastfeed at three months and 18.8 percent at six months (CDC, 2014). Healthy People 2020 objectives for exclusive breastfeeding are 46.2 percent at six months, and 25.5 percent at the one-year mark (Ofiice of Disease Prevention and Health Promotion (ODPHP), 2016). More can be done to assist mothers in achieving this goal.

The breastfeeding mother may encounter a situation where surgical intervention is necessary, and along with the decision to undergo surgery, she must also decide when it will be safe to resume breastfeeding. The mother may decide to postpone breastfeeding for fear that anesthetic drugs may be transferred to the infant. Breastfeeding mothers may also delay breastfeeding if peri-anesthesia providers have advised her that it is not safe to breastfeed immediately. Given the advantages of breastfeeding for both child and mother, any recommendations to interrupt breastfeeding should be limited and grounded in the best possible evidence in order to safeguard the well-being of the child.

Clinical Question

Does the implementation of an evidence-based, local practice guideline influence peri-anesthesia staff recommendations about when breastfeeding should resume after surgery?

Focus Areas

This project encompassed two focus areas. First, we determined current recommendations providers were giving to our breastfeeding mothers. Second, we minimized variance of recommendations by educating staff within the anesthesia department and the post-anesthesia care unit at Naval Hospital Jacksonville on the findings of our literature search.

Project Short- and Long-Term Goals

Short-term goals for this project were to educate providers on transference of anesthetic medications to the infant from mother's milk, and to implement a standard operating procedure that guided provider recommendations about when it is safe for the mother to resume breastfeeding. This project seeks to increase the rate in which breastfeeding is resumed immediately after surgery, decrease the time to the resumption of breast feeding, and allow baby and mother to benefit from long-term, uninterrupted breast-feeding.

As the prevalence of breastfeeding has increased globally over past decades, evidence for the health advantages of breastfeeding has increased. The World Health Organization (WHO) states in its Global Nutrition Targets 2025 Breastfeeding Policy Brief "exclusive breastfeeding has the single largest potential impact on child mortality of any preventive intervention (WHO, 2014, p.*)." The WHO and United Nations Children's Emergency Fund (UNICEF) launched the *Baby-Friendly Hospital Initiative* to bolster maternity practices to support breastfeeding (WHO, 2016). There are 391certified Baby-Friendly Hospitals in the U.S., and this institution is one of the three hospitals within the Military Health System (MHS) that participate in this initiative. The Joint Commission captures metrics on exclusive breastfeeding across all hospitals, and military hospitals report the rate of exclusive breastfeeding at the time of discharge following delivery. Exclusive breastfeeding at hospitals within the MHS in 2011was 56%, exceeding the national average in the same year by 16% (Buckler, 2011).

Anesthesia providers should be able to support mothers in exclusive breastfeeding, and provide postoperative breastfeeding instructions based on the most current evidence, with the best interest of the infant in mind. Local practice guidelines on breastfeeding after surgery serve as a perpetual framework to inform changes in curriculum for new staff. Standard training will help these new providers deliver a consistent message when advising breastfeeding patients of the risks and benefits of breastfeeding after anesthesia. Consistent recommendations are expected to enhance patient satisfaction for the mother. Exclusive breastfeeding is expected to contribute to achieving better health outcomes for the mother and child, which is consistent with three of the four goals of the MHS quadruple aim: improving patient experience, population health, and per capita costs.

Organizing Framework

The organizing framework utilized for this project is the Iowa Model of Evidence-Based Practice to Promote Quality Care (Figure 1). The Iowa Model provides a framework for practitioners to follow when they have identified a problem within their organization that needs improvement to ensure that patients are receiving the highest quality of care (Cullen & Adams, 2010). In the Iowa Model, the process begins with the identification of a problem or knowledge deficit, and it is determined whether or not this deficit is a priority for the organization. If the deficit is deemed a priority, a team is formed to conduct a thorough review of the literature, and a change in practice is implemented based on the findings of the literature review. Once the change has been implemented, outcomes are evaluated to assess the overall impact on the organization. Based on the evaluation, further changes are recommended or sustainment activities are initiated to maintain the change in practice.

Project Design

General Approach

Formal education provided to perioperative staff regarding the safety of resuming breastfeeding following surgery will lead to a more consistent message to patients and prevent unnecessary interruptions in breastfeeding. The development of a department Standard Operating Procedure will ensure these local practice guidelines will be passed on to future staff and directly contribute to the sustainability of this project.

Setting

The staff of the anesthesia department at Naval Hospital Jacksonville, Florida identified the need for this project. A member of the Military Health System, this medium-sized facility contains a surgical department consisting of six main operating rooms (ORs), two endoscopy

suites and three labor and delivery ORs. The labor and delivery department manages approximately 1,000 live births annually, and the operating room provides anesthesia services to nearly 6,000 patients each year. This facility provides care to active duty and retired military members and their dependents.

Procedural Steps

A search for the most recent evidence related to the transference of anesthetic drugs to mother's milk was conducted using PubMed, CINAHL, and Embase. An additional search of each anesthetic drug of interest was performed in the LactMed database, an NIH affiliated resource that aggregates literature about medications for breastfeeding mothers. Only full-text articles, abstracts, and protocols were included in this review of the literature. The search of each database utilized the keywords "breastfeeding," "breast milk," "breast fed," "colostrum," or "lactation" combined with names of each of the anesthetic drugs of interest. Drugs of interest included commonly used medications from the following drug classes: induction agents, opioids, benzodiazepines, neuromuscular blockers, inhaled anesthetics, and neuromuscular blocker reversal agents. Due to the limited number of experimental studies on this topic, articles were considered from as early as 1985. An evaluation of the quality of each article was conducted using The Johns Hopkins Nursing Evidence-Based Practice Model (JHNEBP). This model rates the level of evidence on a scale of I to V based on standard criteria. The JHNEBP further provides a method of assigning a quality rating for each evidence level by assigning a grade of A (high quality), B (good quality), or C (low quality or major flaws). Inclusion criteria were articles written in the English language, articles that described drug levels in breast milk/colostrum, studies that described the transference of anesthetic drugs and their effect on the breastfed infant, protocols written by reputable organizations, and articles with strength of evidence levels I-IV.

Our search terms initially yielded 1857 potential articles, and after reviewing titles, abstracts, and text, many of these articles were identified as having no relevance to our study. The remaining 259 articles were further evaluated, duplicates were removed, and after applying our inclusion/exclusion criteria, 17 articles remained that were relevant to our project (Figure 2). The majority of the articles were JHNEBP Level II (14), and most of the articles were categorized as either JHNEBP A or B quality (A=6, B=7).

Findings from the Evidence Evaluation

Sedatives/Hypnotics. A search of literature related to three commonly used induction agents for general anesthesia (propofol, etomidate, and ketamine) yielded three articles on propofol, one on etomidate, and no articles specifically addressing ketamine.

Propofol and etomidate. Stuttmann et al. (2010) conducted a study that measured serum concentrations of propofol at 0, 30, 90, and 300 minutes and milk concentrations at 90 and 300 minutes. Maternal serum samples contained propofol levels ranging from 0.48 mg/l immediately upon extubation to 0.12 mg/l at 300 minutes. Propofol levels in the maternal milk samples in this study were undetectable at 2.78 mg/l at 90 minutes, and 0.84 mg/L at 300 minutes. The results in the remaining studies found similar milk/blood concentrations of propofol, and deemed levels to be clinically insignificant to the breastfeeding child (Nitsun et al., 2006; Dailland et al., 1989).

Etomidate concentrations were studied in mothers undergoing elective cesarean section, and blood samples were obtained at 5, 15, 30, 60, and 120 minutes. Milk samples were obtained at 30, 120, and 240 minutes after induction. Mean etomidate concentration in maternal blood samples was 434 ng/ml after 5 min, 64.2 ng/ml after 15 min, 7ng/ml after 30 min, 0.5 ng/ml after 30 min, and undetectable in blood samples at or beyond 120 min. Mean milk concentrations were 79.3 ng/ml at 30 min,16.2 ng/ml at 2 hrs and undetectable at 4 hrs (Esener, Sarihasan,

Guven, & Ustun, 1992). No studies were found on the safety of ketamine in the breastfeeding mother using our current search terms, however, LactMed suggests careful monitoring of the infant after maternal administration (National Institute of Health [NIH], 2016). If zero exposure to these agents were to be a goal, breastfeeding could resume at 120 min following etomidate administration and 90 min after propofol administration; however, the concentrations in breastmilk are so low initially that the risk to the infant from immediate breastfeeding after surgery is nearly zero.

Opioids. Review of the literature identified morphine and fentanyl as the most studied opioids with respect to lactation. Three articles and one case study met inclusion criteria for morphine and one article each for hydromorphone, fentanyl, alfentanil, and sufentanil. One article contained both fentanyl and sufentanil. No studies addressing the safety of remifentanil in breastfeeding and the transference of the drug to the infant were identified.

Fentanyl and sufentanil. Madej & Strunin (1987) evaluated the concentration of fentanyl and sufentanil in breast milk after epidural administration for cesarean section. Seventeen colostrum samples were collected from participants that received either 100 mcg of fentanyl (n=8) or 50 mcg of sufentanil (n=9). in which 50 patients received varying epidural doses of either fentanyl or sufentanil for cesarean section. None of the eight colostrum samples from mothers who received 50 mcg fentanyl had detectable levels of fentanyl, nor did the nine who received 50 mcg sufentanil demonstrate passage of the drug into colostrum. This demonstrates levels of common lipid-soluble opioids one hour after epidural administration may not even be detectable in colostrum. In the study by Leuschen, Wolf, & Rayburn (1990), ten women received 50 to 100 mcg of fentanyl intravenously per dose as often as every hour on request. Postpartum breastmilk samples of 2-5 ml were collected at four and twenty-four hours. Serum concentrations

ranged from 0.23-0.85 ng/ml at delivery. Milk concentrations ranged from <0.05-0.15 and <0.05-0.14 ng/ml at four hours and twenty-four hours, respectively indicating a lack of substantial excretion in breast milk. The concentration of fentanyl after a 2 mcg/kg intravenous analgesic dose during either cesarean section or postpartum tubal ligation was measured and revealed that colostrum fentanyl concentrations peaked 45 minutes after administration but were undetectable after ten hours (Steer, Biddle, Marley, Lantz, & Sulik, 1992). Transdermal fentanyl was described in a case report of a mother treated with 100 mcg/hr throughout pregnancy and during lactation. Infant serum and maternal milk were analyzed on day 27 of life with undetectable levels of fentanyl in the infant's serum suggesting the viability of a transdermal route during lactation.

Morphine. Morphine was studied in five lactating women undergoing surgery at least one month postpartum. Each donated five 5 ml blood and milk samples at scheduled intervals up to 480 min after single dose administration of 4 mg via epidural or 5 mg intravenously. Based on their findings, if the mother with the highest morphine concentration (500 ng/ml) were to breastfeed, the infant would receive 50 mcg in 100 ml of milk, equivalent to a parental dose of 10 to 20 mcg and clinically insignificant to dissuade resumption of nursing (Feilberg, et al., 1989). From a therapeutic effects perspective, morphine 50mcg orally would be roughly equivalent to 5% of a low oral analgesic dose of 1000 mcg for a 5 kg infant. Despite its extensive history and use in anesthesia, much less is known about the neurobehavioral effects of morphine or its transfer into breastmilk after patient controlled analgesia (PCA).

Wittels, Scott, and Sinatra (1990) assessed neonate alertness after their sample of ten breastfeeding mothers was given morphine or meperidine by PCA. Milk concentrations were measured, and a psychologist evaluated their infants on day 3 using the Brazelton's Neonatal

Behavioral Assessment Scale to determine alertness. There were statistically significant differences between alertness of neonates born to mothers receiving PCA morphine versus meperidine, with less neurobehavioral depression in the morphine group (Wittels, Scott, & Sinatra, 1990). Neonatal implications of PCA morphine and its active metabolite, morphine-6-glucoronide (M6G), were investigated in seven post-cesarean mothers by Baka, Bayoumeu, Boutroy, and Laxenaire (2001). Plasma and colostrum were collected at initiation of PCA and at 12, 24, 36, and 48 hours later. PCA was discontinued at the conclusion of the second postoperative day when morphine, and M6G concentrations were measured in plasma. One patient was not able to donate colostrum. The largest concentrations of morphine and M6G of in colostrum of the remaining patients were 4.8 mcg/100 ml and 100 mcg/100 ml for morphine and M6G respectively. Despite considerably higher M6G levels in colostrum, the oral bioavailability of M6G is only 20-30%, suggesting no clinically significant risks to infants (Baka, Bayoumeu, Boutroy, & Laxenaire, 2001).

One case report challenges the safety of morphine and breastfeeding; however, the quality of this evidence is very low, being limited to a single patient and single infant serum sample. A mother was readmitted for withdrawal syndrome five days after discharge from the maternity unit, and oral morphine was tapered from 50mg every 6 hrs down to 5mg every 6 hrs for ten days. Her infant was admitted for uninterrupted breastfeeding and determined to be symptom-free by a neonatologist and pediatrician. After tapering, one infant serum and three breastmilk samples were obtained on a day the mother had received two 5 mg morphine doses. Infant serum concentration was 4 ng/mL and deemed clinically significant. The infant did not display symptoms, but chronic exposure of the infant in utero may have resulted in tolerance to morphine. Higher morphine levels in chronically exposed infants may be partly attributed to

limited neonatal hepatic elimination, which should be considered when breastfeeding mothers chronically receive doses as high as the 200 mg/day for this case (Robieux, Koren, Vandenbergh, & Schneiderman, 1990). With the exception of this case report, the literature most often aligns with the short-term administration of opioids in the perioperative period.

Hydromorphone. Edwards et al. (2003) administered 2mg hydromorphone intranasally, then measured the levels of hydromorphone in breast milk and maternal serum over 24 hours. They found that the weight-adjusted dose of hydromorphone would be less than 1% (0.67 ± 0.21%) of the original maternal dose. The authors conclude that therapeutic dosing for the mother with hydromorphone would be unlikely to negatively impact the breastfeeding infant (Edwards, et al., 2003).

Alfentanil. Giesecke, Rice, & Lipton (1985) measured alfentanil concentrations in breast milk after mothers were given 50 mcg/kg initially, then in 10 mcg/kg increments intraoperatively for bilateral tubal ligation. The authors of this study did not specify the total amount of alfentanil administered to each patient; however, mean levels of alfentanil in the breastmilk samples were clinically insignificant at 0.88 ng/ml at 4 hrs and 0.05 ng/ml at 28 hrs post-injection (Giesecke, Rice, & Lipton, 1985).

Benzodiazepines. Midazolam is transferred to the mother's breast milk in very small quantities. Koitabashi et al. (1997) showed that after a 6mg intravenous dose of midazolam, the breastmilk contained 25 ng/ml at 30 minutes, 7 ng/ml at 2 hours, and 5 ng/ml at 4 hours. Matheson, et al. (1990) found that midazolam levels were undetectable in breastmilk 7 hours after a single 15 mg oral dose. These clinically insignificant amounts of midazolam should not give cause to interrupt breastfeeding after the administration of midazolam (Montgomery & Hale, 2012; Cobb, et al., 2015).

Other Anesthetic Drug Classes. This systematic review did not yield any articles that discussed drug levels in breast milk for inhaled agents (sevoflurane, isoflurane, & desflurane), neuromuscular blocking drugs (rocuronium, vecuronium, & succinylcholine), or neuromuscular blockade reversal agents (neostigmine, sugammadex, edrophonium, atropine, & glycopyrrolate). United States Department of Health and Human Services published a review suggesting these drugs either do not cross into the breastmilk or are metabolized so rapidly that it is probably safe for the mother to resume breastfeeding immediately (Cobb, et al., 2015). LactMed was also used to search for each of the medications listed above, similarly finding no studies to suggest contraindications for breastfeeding mothers.

Educational Intervention

The project team synthesized the findings of the literature review into a slide presentation. This presentation was aimed at teaching staff in the anesthesia department and the post-anesthesia care unit about transference of anesthetic drugs into breastmilk and when it is safe to resume breastfeeding after surgery. Peri-anesthesia staff were given a pre-test (Appendix A) just prior to the presentation, and a post-test (Appendix B) immediately following the presentation.

Participating peri-anesthesia staff included nurse anesthetists (n=4), anesthesiologists (n=3), post-anesthesia care nurses (n=10), and an anesthesia technician. The pretest included 17 total multiple-choice questions, with 7 background/demographic questions, 8 knowledge-base questions, a single question that assessed recommendations, and a question that assessed confidence in recommendations. The post-test utilized the same 10 knowledge and confidence questions as were on the pre-test, with the background and demographics questions omitted.

Unit Standard Operating Procedure (SOP). Prior to this project, there had been no existing SOP that addressed recommendations for our breastfeeding patients. The project team developed an anesthesia department SOP that serves as a perpetual resource outlining the department's standardized message to breastfeeding mothers. A similar SOP entry was accepted for the Post-Anesthesia Care Unit, helping to perpetuate a clear and consistent set of recommendations to breastfeeding mothers across multiple departments within the hospital.

Patient Brochure. The project team developed a brochure for breastfeeding mothers that provides information regarding the safety of breastfeeding after anesthesia, including the potential transfer of commonly used anesthetic medications from breastmilk to breastfeeding infants. The brochure lists commonly used anesthetics, provides a space where staff write in specific drugs administered, and lists external resources to help answer additional questions regarding the safety of breastfeeding after surgery.

HIPAA Concerns

The collection of personally identifiable information (PII) from patients or providers was not necessary for the success of this project. Therefore, there was not a conflict with the Health Insurance Portability and Accountability Act of 1996. The team did not collect PII or protected health information from patients or providers. The project was granted exempt status by the institutional review board designee.

Project Results

Primary outcomes included peri-anesthesia staff knowledge scores, confidence scores, and breastfeeding recommendations as assessed before and after the educational intervention.

Analysis of the Results

All 18 participants completed training, including the pre-and post- tests. Four of the seven anesthesia providers had been in practice for less than 5 years and three had been in practice for 6-10 years. Participants endorsed a broad range of sources for recommendations: 5 identified the primary source of their recommendations was their primary training, 5 identified peer recommendations, 4 identified current literature, and 4 identified other or multiple sources. The majority of participants (n = 10) were unaware if NH Jacksonville had a written policy regarding breastfeeding after surgery, while a minority either wrongly believed that a policy existed (n = 6) or correctly identified that NH Jacksonville had no written policy (n = 2). Most of the participants (n = 10) reporting caring for a breastfeeding woman once a month, while the remainder reported caring for a breastfeeding woman once a day (n = 2), once a week (n = 3), or once a year (n = 3). Participants reported to turning to the lactation consultant (n = 8), the pharmacist (n = 4), anesthesia (n = 3), or obstetrics/gynecology (n = 3) to answer questions about the safety of breastfeeding after anesthesia and surgery. The majority of participants (n = 12) reported knowing of additional sources of information about breastfeeding recommendations after anesthesia and surgery, while the remainder either did not know of any other resources (n = 2) or were unaware if any existed or not (n = 4).

Prior to training, the median score was 5 (IQR = 2.5); however, after the training, the median score increased to 7 (IQR = 2.25). This improvement in scores was statistically significant (N = 18, Wilcoxson Signed Rank Test W = 102.5, $p < .00$). After training, the number of staff who recommended resuming breastfeeding immediately increased from n = 8 to n = 16, a statistically significant difference (McNemar test; $p = .01$). Self-reported confidence in ability to give evidence-based recommendations to breastfeeding mothers increased from a

median of 2/4 (IQR 1; representing a response of 'somewhat confident') to a median of 3/4 (IQR 1, representing a response of 'confident'). This increase was statistically significant ($N = 18$, Wilcoxon Signed Rank test $W = 91$, $p < .00$). Overall, providers scored better on knowledge-based questions about breastfeeding after anesthesia and surgery, were more likely to recommend women resume breastfeeding immediately after surgery and anesthesia, and were more confident that the recommendations they supplied were evidence-based.

Organizational Impact/Implications to Practice & Policy

Through education, training, and policy change, our team was able to influence peri-anesthesia staff recommendations and better ensure that providers are giving postoperative breastfeeding mothers a consistent, evidenced-based message. Patient-centered goals were to reduce the confusion and frustration that breastfeeding mothers may experience with varying provider recommendations, and to avoid unnecessary interruptions in breastfeeding. Supporting the mother with breastfeeding during the perioperative period is safe, and is closely aligned with the goal of maintaining a baby-friendly facility.

Future Directions for Practice and Research

Future research is needed to measure transference of common anesthetic drugs through breast milk and the effects these drugs have on breastfeeding infants. Reassessment of peri-anesthesia staff knowledge and confidence should be conducted to determine consistency in staff training. Studies that compare staff recommendations and the resumption of breastfeeding should be conducted to determine rates of patient satisfaction. Repeated measures of staff knowledge and analysis of trends in patient satisfaction will help gauge the long-term impact of this policy implementation.

Conclusions

The implementation of an evidence-based educational tool led to a significant increase in provider knowledge and confidence in the delivery of postoperative breastfeeding recommendations. Providers are willing to change practice at this facility and alter their recommendations if the evidence is presented in a manner that promotes change.

Limitations of this evidence-based practice project include the limited availability of studies regarding categories of anesthetic drugs as well as the small sample sizes of the available studies. Another limitation was currency, since the majority of the studies cited were greater than five years old. Naval Hospital Jacksonville is as a medium-sized hospital with only a small group of peri-anesthesia staff available to participate in the initial phase of the project, which is another limitation. Larger medical treatment facilities may be better suited to capture a larger number of peri-anesthesia staff, and a larger sample will increase both the generalizability and validity of our findings.

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Table 1

Evidence Table

Study	Drugs	Drug Levels	Level of Evidence	Quality of Evidence
Baka, et. al. (2001)	Morphine	Morphine-Mean levels (ng/ml)-0hrs (34), 12hrs (24), 24hrs (7), 36hrs (6.5), 48hrs (21).	II	B
Cobb, et. al. (2015)	Multiple drug classes	N/A	IV	B
Cohen, R (2009)	Fentanyl	6.4ng/ml in mother's milk and baby's blood negative for fentanyl after 24hr period.	II	C
Dailland, et. al. (1989)	Propofol	Propofol- Mean (mcg/ml)-Phase 1: 4hhrs (0.17), 8hrs (0.14). Phase 2: 4hrs (0.54), 6hrs-1 sample-(0.036), 24hrs-1 sample- (0.048).	II	A
Edwards, et. al. (2003)	Hydromorphone	Hydromorphone levels measured over 24hrs. Weight adjusted dose <1% of maternal dose.	II	A
Esener, et. al. (1992)	Etomidate	Etomidate-Mean (ng/ml)-30min (79.3), 2hrs (16.2), 4hrs (0)	II	A
Feilberg, et. al. (1989)	Morphine	Highest concentration of morphine in breast milk was 500ng which translates to approximately 50mcg of morphine per 100ml of milk which is a parenteral dose of 10-20mcg which would likely have no effect on baby.	II	B
Giesecke, et. al. (1985)	Alfentanil	Alfentanil-4hr-Mean 0.88ng/ml. 28 hours-0.05ng/ml	II	B
Leuschen, et. al. (1990)	Fentanyl	Fentanyl-4hr (<0.05-0.14ng/ml). Mean value of 0.09ng/ml	II	B
Koitabashi, et. al. (1997)	Midazolam	Milk samples were obtained at 0.5, 1, 2, 4, 6, and 24 hr intervals. Midazolam in milk ranged from 25ng/ml to <5ng/ml.	II	B
Madej & Strunin (1987)	Sufentanil Fentanyl	No detectable levels of fentanyl or sufentanil after 5 hrs.	I	A

Evidence Table (cont)

Study	Drugs	Drug Levels	Level of Evidence	Quality of Evidence
Matheson, et. al. (1990)	Midazolam	Levels undetectable in breast milk 7 hrs after a single 15mg oral dose.	II	A
Montgomery, et. al. (2012)	Multiple drug classes	N/A (ABM clinical protocol)	IV	B
Nitsun, et. al. (2006)	Propofol Fentanyl Midazolam	Propofol-mean of 26mcg w/in 24 hours Fentanyl-mean of 0.024mcg w/in 24 hours Midazolam - mean of 0.08mcg w/in 24 hours	II	B
Robieux, et. al. (1990)	Morphine	Morphine- Breatmilk (sample 1-100ng/ml), (sample 2-10ng/ml), (sample 3-12ng/ml), Infant serum 4ng/ml	II	C
Steer, et. al. (1992)	Fentanyl	Fentanyl- mean (ng/ml)-0.75 hrs (040), 2hrs(0.22), 4hrs(0.15), 6hrs (0.05), 8hrs (0.07), 10hrs (0.05)	II	A
Stuttmann, et. al. (2010)	Propofol	Propfol (mg/l)-1.5hrs (2.78), 5hrs (0.13 &0.84)	II	B
Wittels, et al. (1990)	Morphine	Morphine-mean (ng/ml), 12 hrs(50), 24hrs(60), 36hrs(50), 48hrs (60), 72hrs (25), 96hrs (20). No effect on infant behavior.	II	A

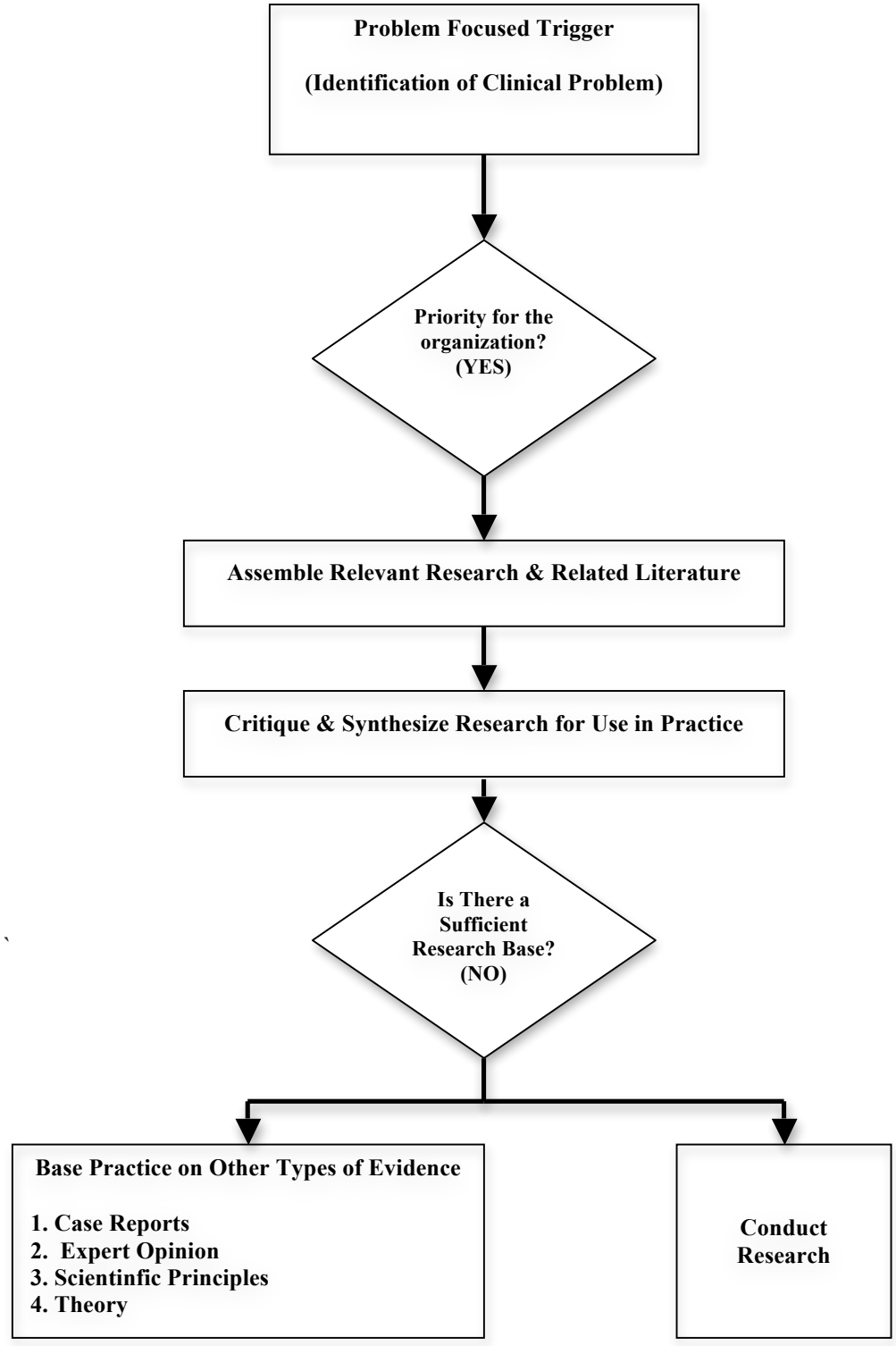


Figure 1: Iowa Model

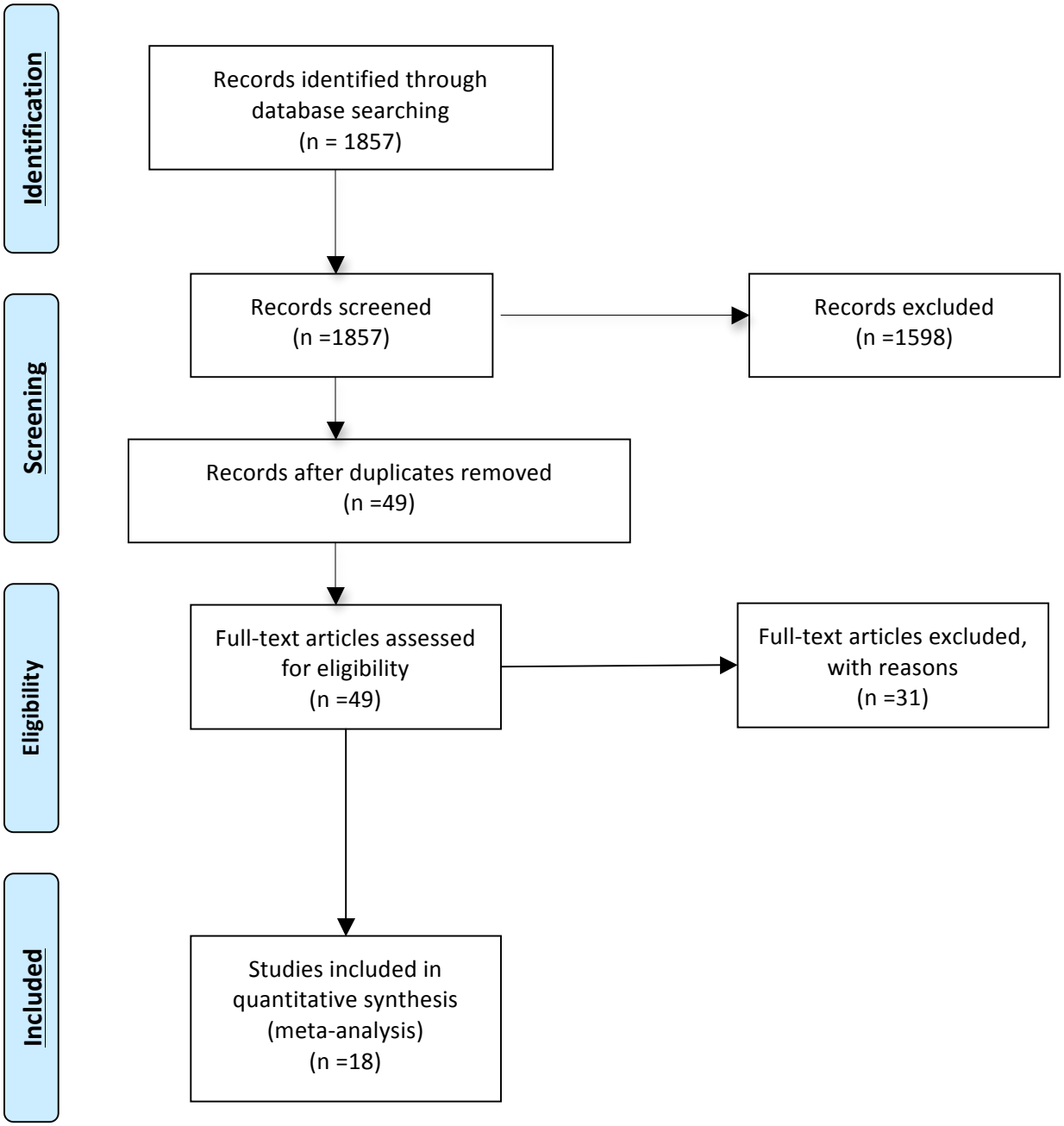
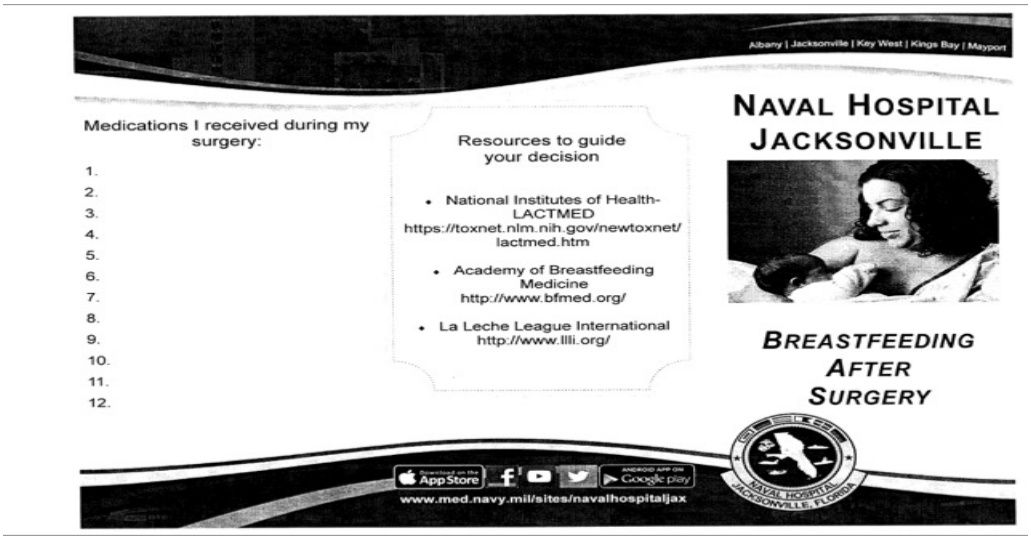


Figure 2. PRISMA Flowsheet



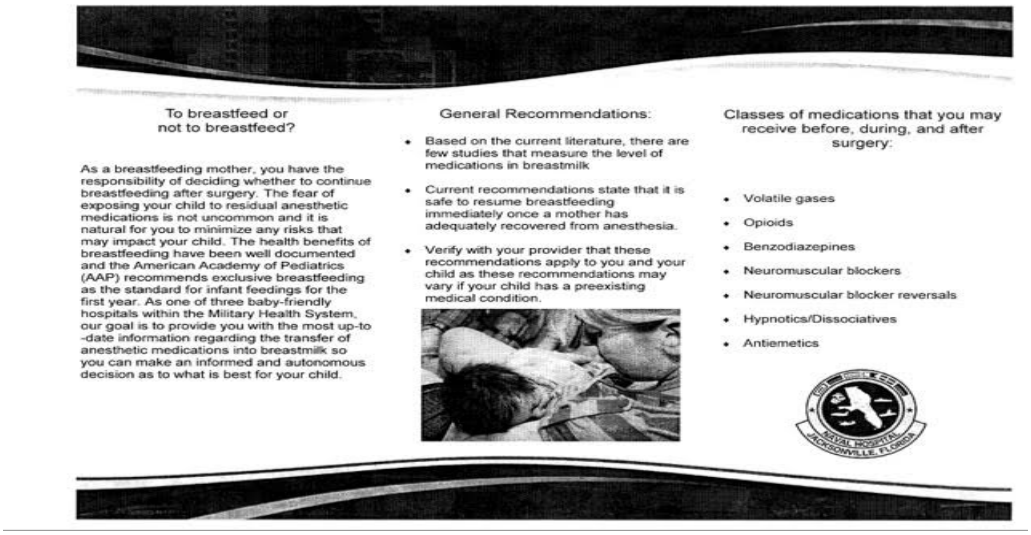


Figure 3: Patient Brochure.

Figure 4: Knowledge, confidence, and recommendation data. Significantly improved scores from pretest (median score 5, IQR = 2.5) to posttest (median = 7, IQR = 2.25) assessments. (N = 18, Wilcoxson Signed Rank Test W = 102.5, p < .00). Self-reported confidence in ability to provide evidence-based recommendations increased from a median of 2/4 (IQR 1; representing a response of 'somewhat confident') to a median of ¾ (IQR 1, representing a response of 'confident). Post-training, the number of staff recommending immediate resumption of breastfeeding: increased from n = 8 to n = 16, a significant difference (McNemar test; p = .01)

Appendix A

Provider Breastfeeding Recommendations Pre-test

1.) What is your current/primary profession?

a. Anesthesiologist
b. CRNA
c. Nurse
d. Obstetrician
e. Other

2.) How long have you been practicing Anesthesia?

a. 0-5 years
b. 6-10 years
c. >10 years
d. I am not an anesthesia provider

3.) Your current recommendations are primarily based on (choose only one):

a. Training received in school/residency.
b. Peer recommendations.
c. Current literature.
d. Other

4.) Does NH Jacksonville have a written policy/guideline providing recommendations for postop breastfeeding mothers?

a. Yes
b. No
c. I don't know

5.) How often do you encounter a breastfeeding patient?

a. Daily
b. At least once a week
c. At least once a month
d. At least once a year
e. Rarely or less than once a year.

6.) If you were unable to answer a question regarding when to resume breastfeeding postoperatively from a breastfeeding mother, which service would you consult to find the answer?

a. Obstetrics
b. Anesthesia
c. Pharmacy
d. Lactation Specialist

7.) Are you aware of any additional resources you could utilize to provide recommendations to a breastfeeding patient?

a. Yes
b. No
c. I don't know

8.) According to the NIH LACTMED database, when should a mother resume breastfeeding after receiving sevoflurane, isoflurane, or desflurane?

a. There is no waiting period and breastmilk does not need to be discarded. The mother may resume breastfeeding as soon as she has recovered from anesthesia.
b. The mother should discard all breast milk for a four hour period and then resume breastfeeding
c. The mother should discard all breast milk for a 24-hour period and then resume breastfeeding.
d. The mother may resume breastfeeding after she has discarded breast milk at least once.

9.) Current evidence suggests that _____ quantities of midazolam cross into the breast milk and it is _____ to resume breastfeeding immediately after recovery from anesthesia.

a. moderate, probably not safe
b. large, not safe
c. low, safe
d. moderate, safe

10.) Based on the current literature presented, when is it safe for a mother to resume breastfeeding after receiving etomidate?

a. 4 hours after receiving the medication
b. Immediately after the mother has recovered from anesthesia
c. Etomidate should be avoided in the breastfeeding mother
d. There is no current literature that discusses etomidate in relation to breastfeeding.

11.) Which resource provides information about the safety of drugs in regards to breastfeeding, and also allows the provider to search for individual medications?

a. AANA
b. La Leche League
c. LACTMED
d. CDC lactation guide

12.) Per the Academy of Breastfeeding Medicine, which opioid/opiate is considered the ideal analgesic for breastfeeding mothers due to its limited transport to milk and its poor oral bioavailability?

a. Meperidine
b. Fentanyl
c. Hydromorphone
d. Morphine

13.) Studies report that fentanyl levels in breastmilk are extremely low and generally below the limit of detection approximately _____ postoperatively.

a. 1 hour
b. 2 hours
c. 6 hours
d. 24 hours

14.) Of the commonly used anesthetic agents, which are unreported in the literature?

a. propofol and ketamine
b. ketamine and etomidate
c. etomidate and remifentanil
d. remifentanil and ketamine

15.) Per Department of Health and Human services, which of the following anesthetic agents are not expected to cross into milk ducts? Select all that apply.

a. glycopyrrolate
b. morphine
c. rocuronium
d. neostigmine

16.) If giving teaching to a breastfeeding mother, which best describes your recommendations?

a. Continue breastfeeding immediately postoperatively
b. Discard breast milk for a period of time less than 24 hours
c. Discard breast milk for at least 24 hours
d. My recommendation is not listed

17.) How confident are you that the recommendations you give to breastfeeding mothers in regards to when it safe to resume breastfeeding, are in-line with current evidence?

a. not confident at all
b. somewhat confident
c. confident
d. very confident

Appendix B

Provider Breastfeeding Recommendations Post-test

1.) According to the NIH LACTMED database, when should a mother resume breastfeeding after receiving sevoflurane, isoflurane, or desflurane?

e. There is no waiting period and breastmilk does not need to be discarded. The mother may resume breastfeeding as soon as she has recovered from anesthesia.
f. The mother should discard all breast milk for a four hour period and then resume breastfeeding
g. The mother should discard all breast milk for a 24-hour period and then resume breastfeeding.
h. The mother may resume breastfeeding after she has discarded breast milk at least once.

2.) Current evidence suggests that _____ quantities of midazolam cross into the breast milk and it is _____ to resume breastfeeding immediately after recovery from anesthesia.

e. moderate, probably not safe
f. large, not safe
g. low, safe
h. moderate, safe

3.) Based on the current literature presented, when is it safe for a mother to resume breastfeeding after receiving etomidate?

e. 4 hours after receiving the medication
f. Immediately after the mother has recovered from anesthesia
g. Etomidate should be avoided in the breastfeeding mother
h. There is no current literature that discusses etomidate in relation to breastfeeding.

4.) Which resource provides information about the safety of drugs in regards to breastfeeding, and also allows the provider to search for individual medications?

e. AANA
f. La Leche League
g. LACTMED
h. CDC lactation guide

5.) Per the Academy of Breastfeeding Medicine, which opioid/opiate is considered the ideal analgesic for breastfeeding mothers due to its limited transport to milk and its poor oral bioavailability?

e. Meperidine
f. Fentanyl
g. Hydromorphone
h. Morphine

6.) Studies report that fentanyl levels in breastmilk are extremely low and generally below the limit of detection approximately _____ postoperatively.

e. 1 hour
f. 2 hours
g. 6 hours
h. 24 hours

7.) Of the commonly used anesthetic agents, which are unreported in the literature?

e. propofol and ketamine
f. ketamine and etomidate
g. etomidate and remifentanil
h. remifentanil and ketamine

8.) Per Department of Health and Human services, which of the following anesthetic agents are not expected to cross into milk ducts? Select all that apply.

e. glycopyrrolate
f. morphine
g. rocuronium
h. neostigmine

9.) If giving teaching to a breastfeeding mother, which best describes your recommendations?

e. Continue breastfeeding immediately potoperatively
f. Discard breast milk for a period of time less than 24 hours
g. Discard breast milk for at least 24 hours
h. My recommendation is not listed

10.) How confident are you that the recommendations you give to breastfeeding mothers in regards to when it safe to resume breastfeeding, are in-line with current evidence?

e. not confident at all
f. somewhat confident
g. confident
h. very confident

Appendix C

CITI Certificates

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:** Jeremiah Bond (ID: 5070682)
- **Email:** jeremiah.bond@usuhs.edu
- **Institution Affiliation:** Uniformed Services University of The Health Sciences (ID: 395)
- **Institution Unit:** GSN
- **Phone:** 904-651-7007

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

- **Report ID:** 17262975
- **Completion Date:** 09/13/2015
- **Expiration Date:** 09/12/2018
- **Minimum Passing:** 80
- **Reported Score*:** 94

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED
Records-Based Research (ID: 5)	09/12/15
Vulnerable Subjects - Research Involving Children (ID: 9)	09/12/15
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	09/12/15
FDA-Regulated Research (ID: 12)	09/12/15
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	09/12/15
Informed Consent (ID: 3)	09/12/15
History and Ethics of Human Subjects Research (ID: 498)	09/12/15
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	09/12/15
Genetic Research in Human Populations (ID: 6)	09/12/15
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	09/12/15
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	09/12/15
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	09/13/15
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	09/13/15
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	09/13/15
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	09/13/15
Cultural Competence in Research (ID: 15166)	09/13/15

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:** Craig Wilkins (ID: 5003371)
- **Email:** craig.wilkins@usuhs.edu
- **Institution Affiliation:** Uniformed Services University of The Health Sciences (ID: 395)
- **Institution Unit:** ICU
- **Phone:** 3012959004

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

- **Report ID:** 17032181
- **Completion Date:** 08/26/2015
- **Expiration Date:** 08/25/2018
- **Minimum Passing:** 80
- **Reported Score*:** 98

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED
Records-Based Research (ID: 5)	08/26/15
Vulnerable Subjects - Research Involving Children (ID: 9)	08/26/15
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	08/26/15
FDA-Regulated Research (ID: 12)	08/26/15
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	08/26/15
Informed Consent (ID: 3)	08/26/15
History and Ethics of Human Subjects Research (ID: 498)	08/26/15
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	08/26/15
Genetic Research in Human Populations (ID: 6)	08/26/15
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	08/26/15
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	08/26/15
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	08/26/15
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	08/26/15
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	08/26/15
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	08/26/15
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	08/26/15

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 D

USU Form 3202N

UNIFORMED SERVICES UNIVERSITY
of the Health Sciences

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

NOTICE OF PROJECT APPROVAL
Change Number: Original

VPR Site Number:	T0-GSN-61-9008-01
Principal Investigator:	Bundoc, Eliseo (GSN-61)
Department:	Graduate School of Nursing
Project Type:	Student
Project Title:	Standardization of Anesthesia Provider Postoperative Breastfeeding Recommendations
Project Period:	4/4/2017 to 6/30/2017

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: Bundoc, Eliseo (GSN-61)
Vernell Shaw
File
Chad Moore
Linda Wanzer

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

VPR Date Stamp

Project Number: T0619008 (VPR will assign)

Project Title: Standardization of Anesthesia Provider Postoperative Breastfeeding Recommendations

SECTION A: STUDENT POC INFORMATION

1. Name (Last, First, MI): Bundoc, Eliseo G. Student E-mail: eliseo.bundoc@usuhs.edu

[redacted]

SECTION B: COMMITTEE CHAIR / SENIOR MENTOR INFORMATION

3. Name (Last, First, MI): MOORE, CHAD B
4. Telephone: 9048645321 Fax: N/A E-mail: chad.moore@usuhs.edu
5. USUHS Building/ Room No.: Remote Site: Anesthesia Dept, Naval Hospital Jacksonville, 2080 Child St, Jacksonville, FL 32073

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: 1/17/2017 Project End Date: 2/17/2017
9. Performance Site(s): Naval Hospital Jacksonville
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]

Associate Dean for Research, GSN (Signature and Date) Dean, DKI Graduate School of Nursing (Signature and Date)

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

[redacted]

USUHS Vice President for Research Date 4/11/17

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

Appendix E

MTF IRB/PI Letter of Determination

Clinical Investigation Department, Naval Medical Center Portsmouth
620 John Paul Jones Circle, Portsmouth, VA 23708 (757) 953-5939 Fax (757) 953-5298, DSN 377-5939

19 December 2016

From: Head, Clinical Investigation Department
To: LCDR Chad Moore, NC, USN

SUBJ: LETTER OF WAIVER OF IRB REVIEW FOR PROGRAM EVALUATION/QUALITY IMPROVEMENT PROJECT

1. I am writing to inform you that your project titled, "NHJX.2017.0003: Postoperative Breastfeeding for Mothers Having Surgery" does not require IRB review. Navy policy states that these types of program evaluation/quality improvement projects are exempt from IRB review.

2. You will still need to obtain publication approval for the project which is required for all works presented outside of your Command.

3. I remain available and may be reached at (757)953-5939. [redacted]

T. S. RIEG /

"FIRST AND FINEST"

Appendix F

PAO Clearance

MEMORANDUM FOR THE RECORD

Date: 7-Mar-2018

Subj: Request for Approval for Manuscript and Abstract for USU Research Days, Poster and PowerPoint entitled, "Medication transfer into breastmilk after surgery: An integrated review of the literature", Dissemination for the poster/presentation at USUHS Research Days, and indefinite and publicly accessible warehousing of the report in the library at USUHS.

Author: LCDR Chad Moore

On April 9, 2017 a Manuscript and Abstract entitled, "Medication transfer into breastmilk after surgery: An integrated review of the literature." was approved for presentation at the Tri-Service Nursing Research Program (TSNRP) for the American Association of Nurse Anesthetist (AANA) Conference by Commanding Officer CAPT. David Collins on April 9, 2017. At this time, LCDR Moore is requesting to present the same Manuscript and abstract with no substantive changes to the Uniformed Services University Research Days. There is no need to re-submit this request as the poster and PowerPoint has not been edited and will only be presented at a different conference.

Clinical Investigations Department
Naval Hospital Jacksonville

[redacted]

Aimer Mendoza
Sr. Clinical Research, Assistant

cc: CAPT. Brenda R. Hamilton, DMD, MS, FAGD
Research Director, Clinical Investigations Department
Naval Hospital Jacksonville

Enclosed: RPPA approval with CO signature on April 9, 2017.

Appendix G

DNP Project Completion Verification Form

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: Breastfeeding after Surgery: Influencing Postoperative Recommendations was completed at Naval Hospital Jacksonville by the following student(s):

(type student name)		*(date)*
LT Jeremiah Bond, BSN, NC, USN	[redacted]	02FEB2018
LCDR Craig Wilkins, BSN, NC, US	[redacted]	02FEB2018

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)*	
LCDR Chad Moore	[redacted]		Senior Mentor
CDR Raymond Bonds		02Feb2018	Team Member & Phase II Site Director
CDR Kenneth Wofford	[redacted]		RNA Project Director
(type name)	*(Signature)*	*(Date)*	

Form Version: 26 Aug 2017