Reducing Parental Concern for Vaccine-Associated Pain in Infants

Mona Abukhaled, DNP, RN, C-PNP

Chamberlain University

Nikki R. Smith, DNP, RN, FNP-BC

Moncrief Army Health Clinic, Fort Jackson, SC

Susan Cortez, Ph.D., MBA, MHCM, BSN, RN, HIMSS HIT

Chamberlain University

Abstract

Vaccines are the most common source of iatrogenic pain in infants and studies have shown that parental concern for this pain contributes to vaccine hesitancy. Addressing these concerns can encourage parents to consent to infant immunization. The purpose of this evidence-based practice project was to perform non-pharmacological pain relief methods for infants up to six months old and assess the effect on parental concerns for vaccine-associated pain. For this, a pre- and post- method design was performed over eight weeks. A statistically significant reduction in the level of parental concern for infant pain from pre- to post- implementation was observed. Thus, nurses can effectively use non-pharmacological methods of pain management for infants undergoing routine vaccination while reducing parents' concern for vaccine-associated pain. Future recommendations to provide similar EBP initiatives for vaccine pain relief to a wider range of pediatric patients have been formulated.

Keywords: vaccination, non-pharmacological, pain management, infants, vaccine hesitancy, vaccine pain, parental concern for pain

Dedication

I would like to thank my dear friends, Abir Ibrahim, for encouraging me to pursue my DNP degree and Dr. Amy Magra for her unwavering support and professionalism. Additionally, a special thanks to my friend Denise Cortez for helping me overcome times of uncertainty and futility, staying up with me during late nights, and her willingness to watch my children so that I could diligently complete assignments. Finally, I would like to thank my parents, husband, and children for believing in me.

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Executive Summary

Purpose: Vaccines are the most common source of iatrogenic pain in infants (Stevens & Marvicsin, 2016). Parents have expressed concerns about the pain associated with childhood immunization (Taddio et al., 2012; Kennedy et al., 2011). The clinical question that guided the scholarly project was ““For parents of infant patients at the Mendoza Pediatric Clinic, will the use of EB non-pharmacological pain relief methods, compared to current practice, reduce parental concern for vaccine-associated pain in eight weeks?”

Background and Significance: Infants are capable of remembering painful experiences. Unmitigated pain can lead infants to experience more pain and behavioral changes with future procedures (Wilson-Smith, 2011). Furthermore, parental concern for vaccine pain has contributed to vaccine hesitancy (Kennedy, Basket, & Sheedy, 2011; Wallace et al., 2014). Despite a large body of evidence showing effective ways to minimize vaccine pain in infants, pain management strategies are rarely used. The aim of this of this evidence-based practice project was to implement non-pharmacological pain management methods during infant vaccination to reduce parental concerns for pain. The project was conducted at an urban ambulatory care clinic. A convenience sample of participants was used and included parents of infant’s two to six months of age.

Methods and Intervention: The project was conducted using a pre- and post- evidence-based implementation design. Pediatric nurses at a pediatric clinic were given an educational offering that included an overview of the evidence-based practice guideline for effectively managing vaccine-associated pain in infants. Following this review, the nurses were instructed on implementing non-pharmacological methods (breastfeeding or sucrose solution) as well as

physical and psychological strategies (parental holding and presence of calm parents) for pain control during infant vaccination. Additionally, a survey for measuring parental concern for infant vaccine-related pain on a five-point Likert scale (Zhao, Leong, & Watson, 2015) was administered before vaccination and after implementation of the pain relief interventions during vaccination. The level of satisfaction for the selected pain intervention was assessed using a similar five-point Likert scale for qualitative enhancement.

Results: Cross-tabulations of parental concern for pain levels were calculated according to treatment group (breastfeeding or sucrose solution administration) using Fisher's Exact Test. No significant difference in the level of parental concern for pain at baseline (pre) was observed between the two groups. Significant differences in the distribution of parental concern for pain were identified for post-measurement variables and the change in parental concern from pre- to post- between the two groups ($p = 0.479$, 0.0347 respectively). Parents tended to be less concerned about infant pain after pain management interventions were performed. Additionally, first-time parents had a tendency to be more concerned about pain at baseline ($p = 0.0086$) when controlling for first-time parents.

Conclusion: Addressing parental concerns pertaining to infant vaccine-related pain is essential for combating vaccine hesitancy. Non-pharmacological pain relief methods are safe, effective, economical, and readily available. These evidence-based pain-mitigating strategies minimize vaccine-associated discomfort in infants while alleviating parental concerns. Parents who feel that their concerns are addressed are more emotionally available to comfort their children and further promote infant pain regulation. This interdependent relationship between

mother/caregiver and infants is deeply rooted and explained by attachment theory, emotional contagion theory, and the gate control theory of pain.

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CHAPTER 1: INTRODUCTION

Reducing Parental Concern For Vaccine Pain in Infants

In 2004, the World Health Organization (WHO) led a global relief effort that acknowledged pain management as a fundamental human right. Vaccines are the most significant source of iatrogenic pain for infants (Stevens & Marvicsin, 2016). In the first two years of life, the Centers for Disease Control (CDC) recommend that infants receive 24 immunizations (2019). Additionally, infants generally receive three to four intramuscular (IM) injections at one visit, with up to six injections at the 12-month visit. Undoubtedly, this is a significant amount of painful procedures that infants must endure at the cost of preventing morbidity and mortality from communicable diseases. Similarly, parents also become distressed at the thought of inflicting pain onto their infant. The evidence has shown that parental concern for pain has contributed to vaccine hesitancy (Kennedy, Basket, & Sheedy, 2011; Wallace et al., 2014). Infants depend on their parents for consolation and reassurance. Consequently, if parents are anxious, fearful, or reluctant, infants' ability to regulate their emotions is compromised and experience pain more acutely (Atkinson, Gennis, Racine, & Pillai Riddell, 2015; Badovinac, Gennis, Pillai Riddell, Garfield, & Greenberg, 2018).

Infant pain management for minor painful procedures has been largely inconsistent despite the large body of empirical evidence that provides effective pain relief for infants (Shah et al., 2015). Unmitigated pain has deleterious effects of having an intensified reaction to pain with future procedures, increased anxiety and behavioral changes, and a diminished effect of adequate analgesia for painful procedures (Wilson-Smith, 2011). These concerns aligned with

the needs of the organization identified as strategies for improving pain management for patients. As such, the Doctor of Nursing Practice (DNP) scholar formulated an evidence-based practice (EBP) change project to alleviate parental concern for pain during infant vaccination. This proposal will discuss how the project was implemented, as well as the educational offering that facilitated nurses to provide a non-pharmacological pain-relief method, how data was collected and outcomes measured, dissemination of findings, and sustainability of interventions. It is important to note that the terms *vaccination* and *immunization* will be used interchangeably throughout this proposal.

Problem Statement

The American Pain Society has developed a position statement indicating that pain and anxiety should be assessed and managed before and after a medical procedure; furthermore, this should be performed regardless of the procedure's degree of severity (Czarnecki et al., 2011). Several studies have shown that neonates with a history of multiple minor painful procedures without pain management later react with a hyperalgesic response during subsequent venipunctures (Stevens, Yamada, Ohlsson, Haliburton, & Shorkey, 2016). Infants are susceptible to experiencing unmitigated pain because they cannot advocate for themselves; consequently, healthcare providers have a moral and ethical obligation to prevent pain and suffering for this vulnerable population. This is consistent with William Beaumont Army Medical Center's (WBAMC) mission statement of providing optimal pain relief in patients.

The current process for administering routine infant immunizations involves the infant being laid supine on the exam table with a parent restraining hands and vocally reassuring the infant, while the nurse restrains the legs and administers three to four consecutive IM

injections into the anterolateral aspects of the upper thigh. Afterward, the parent is encouraged to pick up the infant for consolation. No pain management techniques are administered. Implementing cost-effective interventions for pain control during infant vaccination has thus drawn considerable attention. As a result, the I judiciously researched evidence to the following question (PICOT): For parents of infant patients at the Mendoza Pediatric Clinic (P), will the use of evidence-based non-pharmacological pain relief methods (I), compared to current practice (C), reduce parental concern for vaccine-associated pain (O) in eight weeks (T)?

Objectives and Aims

The aim of the DNP change project was to decrease parental concern for vaccine-associated pain in infants by employing evidenced-based (EB) non-pharmacological pain management methods. In order to achieve this, the following primary objective was identified, which guided my work during the project: To compare usual vaccination practice with using a non-pharmacological approach to decrease parental concern for pain related to vaccine administration. Secondary objectives include decreasing infant pain, parents' desire to learn about pain management strategies, why previous pain management strategies were not used, satisfaction with pain management intervention, and whether or not parents would recommend the non-pharmacological pain intervention to others.

Significance of the Practice Problem

Immunizations are an important public healthcare endeavor that protects the welfare of all citizens, especially for those in which vaccines are contraindicated. Infants are particularly vulnerable to experiencing severe morbidity or mortality from common diseases that are

vaccine-preventable. Despite public health efforts to improve vaccine coverage in under-served populations, vaccine hesitancy has been steadily rising over the years (Larson, Jarrett, Eckersberger, Smith, & Paterson, 2014; Pannaraj, 2018). The more recent increase in vaccine hesitancy has led to endemic outbreaks of measles and pertussis. Among those who were infected with measles, 59% were unvaccinated, of which 70.6% had non-medical exemptions (Phadke, Bednarczyk, Salmon, & Omer, 2016). These epidemics have led to more discussion about addressing parental concerns regarding childhood immunization especially for parents that exhibit hesitancy. Studies have shown that efforts may not be conducive in parents that strongly oppose vaccines and that dismissing these patients from private practice sends them the message that vaccination is essential for everyone's safety (Edwards & Hackell, 2016). However, for those that are vaccine-hesitant, parents generally turn to their healthcare providers as a trusted source of information and guidance for claims from unverified sources (Dube et al.; 2016; Edwards & Hackell, 2016).

Understanding how infants perceive pain is imperative for intervening and preventing secondary sequela. Infants perceive pain in a similar way and possibly more acutely than adults (Hatfield, Meyers, & Messing, 2013). Moreover, affective and emotional components of painful stimuli are modulated through memories of past experiences with pain (Matthew & Matthew, 2003). The misunderstanding that infants do not perceive pain due to an underdeveloped nervous system may be due to nociceptive stimuli being processed through an unmyelinated pathway; however, this common misnomer indicates that infants' response to pain is slightly slower relative to adults. Additionally, their perception of pain is more exaggerated than adults and older children because they have a lower threshold for the activation of the pain pathway,

relatively higher concentrations of substance P receptors, and fewer inhibitory neurotransmitters (Fitzgerald, 1995). Unmanaged pain can have significant impacts on health behaviors including avoidance of necessary medical care and delaying or refusing vaccination. Implementing pain management methods during vaccination has shown to be an effective strategy for overcoming parental vaccine hesitancy (WHO, 2014).

Studies from the United States and Canada indicate that 24%–45% of parents are concerned about vaccination-associated pain in children (Kennedy, Basket, & Sheedy, 2011; Taddio et al., 2012). Pain is one of the primary sources of anxiety for caregivers of children receiving multiple injections in one visit (WHO, 2015). As a result, some parents have requested alternative vaccine schedules to reduce the number of injections at one time. The problem is that there is no evidence to support the efficacy of alternative vaccine schedules other than the one that is recommended by the CDC (Kennedy et al., 2011).

Since parents are concerned about vaccine pain, nurses need awareness of how it can be managed effortlessly. Many resources have documented that nurses and physicians believe that immunizations cause pain, yet pain management for vaccines has been underutilized (Porter, Wolf, Gold, Lotsoff, & Miller, 1997; Taddio et al., 2009). Pain-relieving strategies for infants and children have been empirically demonstrated and formulated in an evidence-based practice guideline (EBPG) for clinicians including pharmacological, non-pharmacological, physical, and psychological techniques (Taddio et al., 2015). This gap in knowledge and clinical practice was the foundation for this project. More specifically, the project was designed to implement non-pharmacological methods of pain relief for infants undergoing routine immunization. Implementing procedural pain management operationalized the organization's

aim for relieving pain in patient care and parental concern for pain relief.

Synthesis of the Literature

To address the PICOT question, an extensive literature search was conducted using electronic databases including the Cumulative Index of Nursing and Allied Health (CINAHL), Cochrane Database of Systemic Reviews, MEDLINE, PubMed, ProQuest, Joanna Briggs Institute, and Google Scholar. Inclusion criteria of the following search terms were used: decreased pain with vaccination, vaccination pain, pain scale, infants, sucrose solution (SS), breastfeeding, parental vaccine concerns, and vaccine hesitancy. Results were limited to peer-reviewed journals, English language, and publication dates ranging from 2000-2018. The search identified 129 studies, of which 12 met the inclusion criteria. Studies that involved preterm infants, methods of pain control not including breastfeeding or SS, procedures other than vaccination, or studies published more than five years ago were excluded.

Critical appraisal was facilitated using the Appraisal of Guidelines for Research and Evaluation (AGREE II) with the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methods (Brouwers et al., 2010; Guyatt et al., 2008). Ranges between AGREE II levels 1-7 and GRADEs A-D were selected as evidence to support the presented clinical problem. Most evidence included levels 1 and 2 evidence as well as GRADE A - C based on the inclusion of experimental trials and systemic reviews (SRs) with meta-analysis. Six experimental trials were selected due to higher levels of evidence that they carry along with similarities in methodology with the use of IM injections, selected populations, and interventions (Chittaluri & Rani, 2017; Despriee & Langeland, 2016; Gajbhiye, Rao, & Singh, 2018; Kavthekar, Patil, Kurane, & Bharati, 2016; Suhrabi, Taghinejad, Valian, Sayehmiri, & Taheri, 2014; Zurita-Cruz, Rivas-Ruiz,

Gordillo-Álvarez, & Villasis-Keever, 2017). The three SRs selected for this review not only provided the highest quality of evidence (AGREE II level 1) with succinct summaries of clinical recommendations but also provided economic information related to pain-mitigating interventions for infants undergoing vaccinations (Harrison et al., 2016; Shah et al., 2015; Stevens, Yamada, Ohlsson, Haliburton, & Shorkey, 2016). Varying degrees of recommendations were offered in the SRs that were dependent on the quality of evidence from the studies selected for their critical outcomes. Finally, three qualitative surveys were selected to provide a practical perspective of what pain relief interventions are readily used in clinical settings (Russell & Harrison, 2015), the parental role in pain management (McNair et al., 2017), and parental concerns regarding vaccination (Zhao, Leong, & Watson, 2015). While providing lower levels of evidence (AGREE II levels, 7, 6, 6; and GRADE D respectively), these later articles offered a holistic view of pain experienced by infants, parental concerns about infant pain, and pain relief interventions that have been integrated into clinical practice. Appendix A outlines synthesized research findings from randomized control trials (RCT) and qualitative studies and Appendix B summarizes evidence from SRs that collectively provide empirical evidence for the proposed change project. The evidence templates have been intermittently modified with supporting literature published within the last five years. The focus of this literature synthesis will be the research supporting the interventions used in this project.

Experimental Trials and Systemic Reviews

Breastfeeding. Many experimental studies testing the efficacy and safety of breastfeeding as a pain-relief method during infant immunization have been conducted. Chittaluri and Rani (2017) conducted an RCT of 200 infants (100/group) ages six weeks to six

months treated at an urban healthcare center in India. Pain scores and duration of cry (DOC) measured in seconds (s) were obtained for the breastfed and control groups. Pain scores were determined using the modified behavioral pain scale (MBPS) and the visual analog scale (VAS) for comparison. The study demonstrated that infants breastfed during immunization had significantly lower average pain scores (MBPS 6.02; VAS 5.5) and a decreased DOC (77.2 s) compared to the control group (MBPS 8.55; VAS 8.56; and DOC 128.54 s). Significant reductions in pain were observed for breastfed infants according to both measurement scales ($p < 0.01$). This investigation had a large sample size and strongly supports the use of breastfeeding during infant vaccination for the DNP change project.

Zurita-Cruz, Rivas-Ruiz, Gordillo-Álvarez, & Villasis-Keeverz (2017) conducted an RCT including 144 infants ages two to six months undergoing Diphtheria, Pertussis, and Tetanus (DPT) vaccination at a primary care clinic in Mexico. The study compared pain levels of infants during vaccination divided into three arms (48/group): ones who received breastfeeding, a milk substitute, or no intervention. Treatment groups received interventions two minutes (min) before injection. The researchers measured pain levels using the University Pediatric Hospital of Wisconsin pain scale (validated for children < three years) at 30, 60, 90, and 120 s after vaccination. Data analysis showed that breastfeeding significantly reduced injection pain levels but only at the 90 ($p < 0.006$) and 120 s ($p = 0.003$) intervals. Breastfed infants also exhibited a significant decreased mean DOC (19 s, $p < 0.1$), compared to infants given the milk substitute (41 s) and the control group (41 s). Components of the milk substitute were not disclosed so it is difficult to relate findings from this investigation to those from other studies that also compared pain relief from breastfeeding to that observed with water, expressed breastmilk, SS,

or formula. DOC was an outcome that was considered for the DNP project, however it was infeasible due to time constraints. Nonetheless, Findings from this trial support the use of breastfeeding during vaccine administration in the DNP change project.

Sucrose solution. Investigational trials have also tested the pain-relief efficacy of SS in infants. Suhrabi, Taghinejad, Valian, Sayehmiri, and Taheri (2014) measured the pain levels of 90 newborn infants during hepatitis B vaccination at a postnatal ward in Iran. The subjects were divided into three groups that received a 25% SS, 25% glucose solution, or no intervention. Both treatment groups were administered two milliliters (ml) of solution via a syringe two min before vaccination. Pain was measured using the Neonatal Infant Pain Scale. Average pain scores for both the SS (2.9) and glucose (3.0) groups were significantly lower ($p < 0.001$) than that of the control group (5.2). No statistical significance was found between the two treatment groups ($p = 0.78$). This evidence supports the use of SS in the DNP change project for infant injection pain relief.

Despriee and Langeland (2016) conducted an RCT to assess the effect of two ml of 30% SS compared to two ml of water (control group) on the DOC of114 infants ages 15 months receiving the Measles, Mumps, and Rubella vaccine. SS or water was administered one to two min before vaccination. The study revealed that infants given SS had a significantly lower DOC of 18 s compared to 33 s for the control group ($p < 0.001$). The high effect and power of these clinically significant results support the use of SS for injection pain relief. Additionally, numerous studies have shown the efficacy of SS in premature infants and newborns while fewer have been conducted with on older infants. Although the investigation included patients

that were older than the population selected for the proposed project, it was included to show that SS can effectively be used for older infants as well.

Stevens, Yamada, Ohlsson, Haliburton, and Shorkey (2016) conducted a meta-analysis to evaluate the use of SS for infant pain relief. The meta-analysis yielded high quality evidence (GRADE A) to support the administration of a 24% SS in two-ml doses for two min prior to venipuncture or IM injection. Non-nutritive sucking (NNS) using a pacifier was shown to provide an added benefit. No adverse effects were found to be associated with this method of pain management.

Combined studies (breastfeeding, sucrose solution, and other interventions). Gajbhiye, Rao, and Singh (2018) conducted an RCT that compared newborn pain levels using the premature infant pain profile scale for patients receiving their first hepatitis B vaccine at a postnatal ward of a hospital in India. A sample of 150 newborns were divided into three groups: breastfeeding, one ml of 25% SS, or no intervention. Breastfeeding was started for two min prior to injection. The SS was also administered two min before the injection. All infants lay in their mothers' laps. The investigators found that breastfeeding provided superior pain relief with a mean pain score of 8.36 compared to those for the SS (11.06) or control (14.26) groups ($p < 0.0001$). SS also provided significant pain relief compared to the control group. The DOC was not significantly different when comparing the breastfeeding and SS groups. This study supports breastfeeding for the intervention in the DNP change project; however, this study only used one ml of SS whereas other investigational studies have shown significant pain relief in infants using two ml of SS. On this basis alone, SS cannot be excluded.

Kavthekar, Patil, Kurane, and Bharati (2016) conducted an RCT investigating pain relief conferred by 24% SS, breastfeeding, or sterile water (50 subjects/group) for 150 infants less than two months of age receiving a DPT injection at an outpatient clinic in India. All interventions were administered to the infants two min prior to vaccination while in their mothers' lap. Outcome variables were total DOC, duration of first cry, change in heart rate, and pain ratings using the modified facial coding system (MFCS); all of these techniques have been validated in previous studies. The mean total DOC was significantly lower for the 24% SS (36.3 s) and breastfeeding (42.1 s) groups compared to the control (137.2 s). Decreased duration of first cry (18.2 s, 25.1 s, and 94.3 s respectively) and lower mean heart rate increase [beats/min] (3, 7.4, and 18.2 beats/min, respectively) were also observed. Furthermore, MCFS pain ratings were significantly less for the 24% SS and breastfeeding groups than the control group at one and three min ($p < 0.05$). Interestingly, maximal reductions for all outcome variables were significantly favorable for the 24% SS group compared to the breastfed group. These findings support the use of both interventions proposed in the DNP change project.

Two Cochrane SRs summarized research findings and quality of evidence for multiple non-pharmacological and pharmacological interventions including breastfeeding and SS. Shah et al. (2015) evaluated the use of pharmacological (topical anesthetics, vapocoolant spray, and oral analgesics), non-pharmacological (breastfeeding, sweet solutions [SS, glucose, dextrose], cuddling, NNS, and holding), and combined interventions for vaccination pain relief in children and adults. Among the studies examined, 1056 infants (0-12 months) were included to measure acute distress relief for breastfed infants during vaccination. The authors concluded that there was a moderate quality of evidence for the efficacy of breastfeeding when performed at least

two min prior to injection (GRADE C). Topical anesthetic application in conjunction with breastfeeding exerted a synergistic effect. The authors strongly encouraged breastfeeding as an intervention due to its natural and cost-neutral properties as well as a lack of adverse effects. Additionally, 2462 infants (0-18 months) were examined to measure the efficacy of 12 to 33% SS. The solutions were also shown to be effective, safe, and inexpensive with most studies using 20 - 33% concentrations administered in two-ml doses two min before IM injection (GRADE B). Neither oral analgesics nor vapocoolant spray relieved pain relief in infants. In summary, this SR supports the use of breastfeeding and SS for pain relief during infant vaccination.

Harrison et al. (2016) conducted an SR to assess the pain relief conferred by breastfeeding in infants beyond the neonatal age. Ten studies were included with a total of 1066 infants, generally less than six months old. Breastfeeding ameliorated behavioral pain responses (DOC and pain scores) during infant vaccination across all studies compared to water, control, glucose, topical anesthetics, vapocoolant spray, massage, and cuddling. Six studies measured DOC (n = 547 infants) with a meta-analysis that revealed a 38 s reduction in DOC among breastfed infants ($p < 0.00001$). Five studies evaluating pain scores for treatment/placebo groups (n = 310 infants) were pooled and showed a 1.7-point reduction in pain ratings among breastfed infants. The authors concluded that there is a moderate degree of evidence (GRADE B) indicating that breastfeeding is a superior method of pain control for infants one to six months old. Of note, the level of evidence was graded as moderate because the investigators were not blinded to breastfeeding in each of the experimental trials.

Non-experimental Trials

Qualitative studies. McNair et al. (2017) conducted an investigation of parental attitudes and use of non-pharmacological pain control methods among four different treatment groups. The first group was the control group; the second watched a video about being calm while supporting, cuddling, and distracting infants; the third group watched the video and were educated about SS administration; and the forth had a video with additional instruction on the use of SS and topical anesthetics. Surveys from the three treatment groups showed that parents readily implemented the techniques portrayed in the video (psychological interventions) and did not feel that SS or topical anesthetics were necessary. This further shows how parental emotions affect infants' pain perception and self-regulation.

Russell and Harrison (2015) discussed the natural analgesic properties of breastfeeding in infants and the fact that this method is rarely used in clinical practice although it does not generate extra costs for stakeholders. Among 62 nurses, only 16 (25%) actually reported that their place of employment had a policy for managing vaccine-associated pain. The most common method was distraction (84%). When asked about breastfeeding practices, only 25% of the nurses reported that they "often" allowed infants to breastfeed during immunization. SS was not administered despite the ease of preparation, and topical anesthetics were not applied due to the associated cost.

Finally, Zhao, Leong, & Watson (2015) described the findings of a survey that identified parental barriers for using pain-relief techniques for children undergoing vaccination. The survey revealed that 36 out of 56 parents were moderately to very concerned about pain associated with vaccination. Among parents of children less than 24 months of age, this percentage was higher (78%). Reported barriers against implementing pain-relief methods

included lack of awareness of pain-relief techniques, clinicians never disclosing related information, or perceptions that pain was merely part of the process. This survey explicates the need for parents to be educated and empowered to advocate for childhood pain management during routine immunization.

Practice Recommendations

The PICOT question "For parents of infant patients at the Mendoza Pediatric Clinic, will the use of EB non-pharmacological pain relief methods, compared to current practice, reduce parental concern for vaccine-associated pain in eight weeks," yielded critical analysis of the most current EBP. As a result, the use of breastfeeding or 24% SS in infants undergoing routine immunization was chosen for this project. The evidence from the two SRs and four RCTs was categorized as AGREE levels 1 and 2 (high quality) with moderate recommendation strengths (GRADE B and C). Moreover, these data indicate that breastfeeding can provide adequate pain relief for infants when performed continuously for two min prior to and during vaccination. Breastfeeding offers three fundamental elements of pain relief for infants: skin-to-skin contact, the act of suckling, and the sweet taste of breastmilk (Russell & Harrison, 2015; Shah et al., 2015). Skin-to-skin contact, in addition to a mother's familiar scent and voice, provides security and warmth for the infant while the mechanical motion of suckling enacts the oral-motor reflex while providing substantial distraction. The sweet taste of breastmilk is satiating and also provides adequate distraction. Furthermore, naturally occurring endorphins are released into breastmilk and ingested. Breastfeeding inherently promotes mother-infant bonding, healing, and provides optimal pain relief for infants. It is a process that cannot be replicated by any other mechanism. Finally, breastmilk (non-expressed) is readily available, does not require the

use of additional resources, and has not been found to cause adverse events during immunization.

Similarly, many experimental trials have been conducted to test the efficacy and safety of SS. Critical analysis of three RCTs and two SRs revealed AGREE levels 1 and 2 (high quality) with moderate recommendation strengths (GRADE B) that indicate SS should provide adequate pain relief for infants when administered two minutes before vaccination and while laying in their mother's lap. SS is an inexpensive non-pharmacological pain-relief intervention that can be easily made by dissolving one teaspoon of sugar in 15 ml of clean or sterile water (Shah et al., 2015). Additionally, this reagent has also been shown to be superior to expressed breastmilk due to the rapid onset of endogenous opioid release that provides pain relief in infants undergoing minor painful procedures.

Evidence Based Intervention: Chosen Option

Breastfeeding and SS were found to be equally efficacious for alleviating injection-associated pain in infants. Both of these non-pharmacological methods are easily administered, readily available, and economical. Previous studies have demonstrated that breastfeeding or SS ingestion while being held by a parent alleviates pain for infants. As such, a similar design was used for the EBP change project: a) infants lay in the mother's lap and began breastfeeding continuously for two minutes, followed by vaccine administration with breastfeeding sustained throughout the entire process or b) infants that were bottle-fed were calmly placed in a parent's lap and given two ml of a 24% SS. A pacifier (NNS) was offered when available and agreeable to the parent, as Stevens et al. (2016) concluded NNS with SS has shown to have a

synergistic effect. Vaccine administration commenced after two min of SS ingestion with parental holding and parental reassurance (similar to the breastfeeding technique).

CHAPTER 2: THEORETICAL FRAMEWORK

Theory unequivocally incorporates the epistemological, ontological, and axiological elements of nursing practice. The theoretical frameworks that underpinned the implementation of the EBP change project included attachment theory, emotional contagion theory, and gate control theory. The emotional relationship between mother and infant is a complex exchange of preverbal interactions of affection, availability, and nurturance. The quality of this inimitable relationship is critical for infant development, that is to say, that both mother and infant are readily available to respond to each other's emotional needs (Biringen & Robinson, 1991). This interdependent emotional exchange is deeply rooted in attachment theory.

Theoretical Framework

Attachment Theory

Attachment theory postulates that mother and infant attachment facilitates the development of emotional regulation and empathy. Positive attachment yields positive emotional regulation and resiliency. Caregivers attend to the physical and psychological needs of the infant. The infant seeks physical proximity of parent to provide security. Secure attachment promotes emotional regulation, and these emotional experiences become encoded into memory.

This theory was developed by the collaborative work of John Bowlby and Mary Ainsworth. Bowlby (1969) was the first to describe how children inherently develop close relationships with their caregivers. Bowlby (1982) conceptualized infant attachment with the caregiver by the act of the infant seeking close proximity of a protective figure under

circumstances of discomfort or danger. Ainsworth expanded on Bowlby's work by further describing the quality of mother and infant attachment and its effect on behavior. Her groundbreaking research provided insight on the effects of secure and insecure attachment on behavior (Ainsworth, Blehar, Waters, & Wall, 1978). As the theory has evolved, Donnelly and Jaaniste (2016) described that the success of the attachment largely influences the patterns of interpersonal relationships, temperament, and pain tolerance. Taking this a step further, Horton, Pollal Riddell, Moran, and Lisi (2016) demonstrated how securely attached infants readily sought the comfort of their parent after experiencing acute pain associated with vaccination. In contrast, Mikulincer and Shaver (2019) described how attachment insecurity can be prompted by traumatic events such as hospitalizations or medical conditions causing unrelieved pain, thereby resulting in increased physical symptoms of pain. Groh and Narayan (2019) conducted a meta-analysis that showed the association between insecure infants and heightened physiological symptoms during stress-related events. In summary, emotional regulation is contingent upon a securely bonded mother-infant attachment. Secure attachment facilitates positive coping strategies in circumstances causing distress or pain, while insecure attachment exhibits emotional dysregulation or avoidance behaviors.

Emotional Contagion Theory

Emotional contagion theory states that people synchronize emotions and behaviors of others, especially with those whom they are close to (Howard & Gengler, 2001). This theory conceptualizes emotions as "contagious transmitters," whereby facial expressions are mimicked by "catchers" and internalized with the emotion that matches the behavior (Hatfield, Cacioppo, & Rapson, 1993). Current theory builds on previous studies showing how infants cry

in response to others' distress and how infants' affective state is related to the emotions of other people (Davidof, Zahn-Waxler, Roth-Hanania, & Knafo, 2013; Decety & Jackson, 2004; Johnston, Stevens, Craig, & Grunau, 1993). Flora (2019) defined emotional contagion as a primitive human function of social interaction that is "copied" by infants with whom they are closely bonded with. Oh, Yeom, and Kim (2019) portrayed emotional transference from parents to children to be "unidirectional," whereby the emotional state of the parent directly affects the emotional regulation of the child. Atkinson et al. (2015) demonstrated the association of parental emotional availability and pain relief in infants during vaccine administration. The authors concluded that parents with higher emotional availability yielded lower pain scores in infants.

Gate Control Theory of Pain

Finally, the gate control theory of pain (GCTP) postulates that pain is modulated through a neural gate in the spinal cord (Melzack & Wall, 1965). Melzack and Wall (1965) explained that noxious stimuli are transmitted through pain fibers in the dorsal horn that transmits signals to the brain. However, these impulses to the brain can only be transmitted if the gate is "open." Physical, emotional, and behavioral factors influence the opening or closing of the gate. Noxious stimuli such as pain, fear, anxiety, and focusing on an injury, open the gate and increase the painful experience. On the other hand, analgesics, methods of distraction, and pleasant thoughts inhibit the pain gate. As a result, the authors of GCT recommended cognitive-behavioral techniques to distract the patient from pain intensity and close the pain pathway. Tansky and Lindberg (2010) applied the GCT to describe how infants experience pain relief through breastfeeding. They described how suckling, the sweet taste of milk, and skin-to-skin

contact with the mother provide quality distraction for the infant to stimulate non-nociceptive nerve fibers that “close” the gate for pain entry. Nerve impulses from the brain regulate this process. Similarly, sucrose solution stimulates receptors in the brain to produce endogenous opioid analgesia (Stevens et al., 2016). This analgesia can work in a similar manner whereby the brain transmits a signal to “close” the gate and decrease pain sensation.

Linking theory to EBP intervention. The intimate relationship of the mother and infant as well as the emotional bond is saliently explicated by these theories. A securely attached infant relies on their mother/caretaker for reassurance and emotional stability during stressful encounters. However, if a parent is anxious, fearful, or concerned about the painful process of vaccination these emotions will yield the infant to feel more distressed before the process even begins. Furthermore, the parent will not be able to adequately provide the emotional support that the infant needs due to the painful injection(s). Providing non-pharmacological pain management and allowing the mother/caretaker to hold the infant during immunization allows parents to feel at ease and promote “emotional availability” for comforting the infant. That is to say that parents will have less concern for pain as a result of administering pain management and thus be able to provide the security that the infant is seeking during painful procedures. Both the pain management and parental comfort decreases the infant’s pain experience during vaccination.

Change Model

Kurt Lewin is considered a founding father of organizational change. His theory of change includes three stages: unfreezing, change, and refreezing (Cummings, Bridgman, & Brown, 2016). Lewin’s change theory was developed in 1947 in the field of social sciences and

has been criticized for its over-simplistic view of organizational change. Other theorists such as Lippitt, Rogers, and Kotter have strived to expand upon his model and form more concrete steps (Mitchell, 2013). However, these newer models still mirror Lewin's original three-step process of change. It has also been noted that the titles of Lewin's stages are slightly paradoxical to the underlying conceptualization described as "quasi-equilibrium." Lewin imagined the changing process as fluid and dynamic. When a change is first introduced (unfreezing), the need for change establishes a disruption of equilibrium (change). Subsequently, all efforts shift during the change process to establish the new norm, thus restoring equilibrium (re-freezing). The subsequent paragraphs will describe Lewin's three stages with a description of how the EBP intervention will be implemented using Lewin's process of change.

Kurt Lewin's Change Theory

Stage 1: Unfreezing. The unfreezing stage of Lewin's theory begins with organizational recognition of the need for change, addresses the needs of the stakeholders, and provides information about the benefit of the change. It is also essential to consider barriers that may cause employees and leaders to resist change and skillfully provide insight into the benefit that the change will facilitate for the organization. This provides more staff recognition and willingness to embrace change (Batras, Duff, & Smith, 2014). Demonstrating the need for the change and benefits will create a disturbance in equilibrium and awareness that the status quo is no longer acceptable. Accordingly, preparations for the process of change can be made (Hussain et al., 2018).

Unfreezing (EBP intervention). WBAMC's mission statement prioritizes the alleviation of pain and suffering. The pain management policy has an overall goal of relieving physical and psychosocial symptoms of pain to promote recovery, healing, and optimal quality of life (WBAMC Regulation no. 40-13-1, 2017). Additionally, all healthcare providers should arrange for pain relief in the best way possible. Since needle-based minor procedures are frequently ordered in the ambulatory care setting for preventative care measures, diagnostic evaluations, or therapeutic medical management, special attention for minimizing pain during these procedures demands careful consideration as these experiences can significantly impact how individuals cope with future medical procedures or treatments (Eden, Macintosh, Luthy, & Beckstrand, 2014). Conscious efforts for pain control will improve the quality of healthcare delivery, improve patient outcomes, and simultaneously align with the organization's goal and mission of optimal pain management. Addressing the benefits that the DNP change project will create for the organization facilitated acceptance and acknowledgement of the need for change.

Stage 2: Change. The second stage of Lewin's theory is implementing the desired change. This stage requires a detailed plan of action to make the change. For this, scholarly evidence is the underpinning for creating a strategy for change (Batras et al., 2014). Employee involvement and knowledge sharing are essential to minimize resistance (Hussain et al., 2018). It is the leader's responsibility to educate, coach, remind, enforce, and provide incentives to successfully implement the change (Hussain et al., 2018). This stage ultimately involves the transitioning process of change. The final step of this stage is evaluating the efficacy of the implemented change and modifying parameters to obtain the desired effect.

Change (EBP intervention). Within the last decade, pediatricians have increasingly encountered parental vaccine refusal, hesitation, or delays with the recommended schedule (Larson, Jarrett, Eckersberger, Smith, & Paterson, 2014). Parents have an innately protective behavior to prevent their child from experiencing pain (Loopstra et al., 2015). Moreover, parental emotional dysregulation negatively affects children's response to painful stimuli and self-regulation (Atkinson, Gennis, Racine, & Pillai Riddell, 2015). Procedural pain that is poorly managed early in life can trigger a decreased tolerance to pain, the development of psychosomatic conditions, or refusal of treatments (Hatfield, Meyers, & Messing, 2013).

Varying levels of quantitative and qualitative empirical evidence have shown the efficacy and safety of non-pharmacological methods of pain relief as described in the previous chapter (Shah et al., 2015; Stevens et al., 2016; Zhao et al., 2015). Non-pharmacological interventions are cost effective and have no reported adverse reactions (Shah et al., 2015). Furthermore, these methods do not require additional clinical competencies, rather modest knowledge acquisition. As a result, an educational offering that included how infants perceive and react to pain as well as EB non-pharmacological pain relief strategies for infants undergoing routine immunization was presented to the staff nurses of the Mendoza pediatric clinic (Appendix C). The presentation was approved for nurses to earn continuing nursing education (CNE) credit that cultivated interest in the subject matter, motivated participation in the change project, and rewarded nurses for acquiring EB knowledge.

Since breastfeeding and SS have been empirically proven to decrease injection pain in infants, the projected outcome for implementing non-pharmacological pain management to infants during vaccine administration included decreased parental psychological symptoms

(anxiety, fear) associated with vaccination. Secondary outcomes included decreased parental vaccine hesitancy, decreased pain for the infant, improved adherence to the recommended vaccine schedule, and overall improved satisfaction with the vaccination process. I implemented skills of project management throughout the implementation phase that monitored progress, integrated necessary modifications, provided guidance and feedback, periodically reported progress to key stakeholders, and evaluated outcomes. Providing scientific evidence promoted understanding of the need for improving standards of care and created motivation for implementing change.

Stage 3: Refreezing. Refreezing is the last stage of Lewin's theory in which a change within an organization is well established and sustained (Cummings et al., 2016). Evaluation and dissemination of findings are critical for project success and sustainability of changed interventions. Methods for embedding the change include disseminating the results of the implemented change to provide evidence of the benefit that the change has created for the organization. Additionally, providing reminders of the implemented change will reaffirm that the new process is being used and well adapted. Formulating new policies and operating procedures will also establish a new level of expectations for employees. This stage involves sustaining momentum for the implemented change.

Refreezing (EBP intervention). Evaluation of the EBP project and outcome parameters will measure the success of non-pharmacological interventions and facilitate the integration of an improved standard of care for vaccine administration (i.e., pain mitigation). Dr. Bader, organizational statistician, and I evaluated the results of the project. A poster presentation was provided to the clinic staff to discuss the results of the project on October 10, 2019. The

findings showed a statistically significant reduction in the level of parental concern for infant pain from pre- to post- implementation. This was vital for the nurses to recognize how the intervention impacted patient care and sustain the practice change during vaccine administration. The results of the project were sent to the Public Affairs Office for final approval before releasing findings to the Chamberlain College of Nursing (CCN) DNP committee.

A new standard operating procedure (SOP) for non-pharmacological pain management during infant immunization was drafted and will provide sustainability of the implemented change in patient care for the pediatric clinic. The charge nurse approved the policy and it was sent to the chief of the clinic for final approval.

CHAPTER 3: PROJECT DESIGN AND METHODS

A needs-based organizational assessment was obtained by interviewing a DNP leader at WBAMC, Lieutenant Colonel (LTC) Nikki R. Smith, DNP, Family Nurse Practitioner (FNP). This interview affirmed an organizational need for improving pain management interventions and documentation hospital wide. Further discussion led to the identification of a DNP change project that could improve infant pain management during routine vaccination in the ambulatory care setting. The following section provides insight into the organizational need, DNP change project identification, organizational support, key stakeholders, a strengths, weaknesses, opportunities, and threats (SWOT) analysis, project management, and sustainability of selected interventions.

Organizational Need

A meeting with LTC Smith was arranged on September 13, 2018, at the Education Division of WBAMC to assess organizational needs and identify a reasonable EBP project to promote optimal patient care. The interview revealed that hospital leaders had delegated priorities for improving Healthcare Effectiveness Data and Information Set (HEDIS) measures, pain management and documentation (inpatient and outpatient), and communication skills among employees. HEDIS measures are quality performance indicators that are managed by the National Committee for Quality Assurance. Since both of our expertise are in primary care, it was mutually decided to organize a change project that would facilitate pain management methods in the ambulatory care setting. Further discussion and collaboration revealed the need for pain management strategies for pediatric patients undergoing minor painful procedures. In

doing so, pain management will reduce parents' concern for physical pain symptoms as well as decrease reluctance for necessary medical procedures.

Additionally, it was noted that the Department of Health Agency recently launched a longitudinal investigation of vaccine rates among children under two years of age. Pain interventions during minor painful procedures could significantly impact this data by increasing vaccination rates among infants due to less parental hesitancy toward vaccination. As a result, infants and their parents were selected as the target population for implementing interventions that will alleviate pain associated with routine vaccination in the Mendoza pediatric primary care clinic. The DNP change project was opportunistic in benefitting the organization's goal (i.e., HEDIS measures) of optimizing vaccination rates among infants and children.

Organizational Support

The interview with LTC Smith was not only fortuitous for assessing organizational need and project identification, but also in securing mentorship for my project. Afterward, it was discovered that Chamberlain University already had a contract in place with WBAMC for graduate nursing clinical hours. Discussion of the project was initiated with leaders in the pediatric clinic. This led to a verbal agreement from the charge nurse to support the implementation of the change project pending approval from the Medical Command of the hospital. As a result, a brief letter of intent was prepared and sent to LTC Lara, the Chief of Education, and Colonel (COL) Scully, the Deputy Chief of Medicine Services (DCMS). COL Scully promptly supported my intent for improving patient care with EBP that was contingent on fully reviewing the DNP proposal and undergoing an Institutional Review Board (IRB) process. Obtaining support from the DCMS was a significant milestone in the project approval process

and facilitated other leadership support. LTC Smith was instrumental in guiding the entire project process and obtaining clinical site approval. She provided me with the forms necessary for formal project approval and gaining access to the clinic and electronic health record (Appendix D). Meetings with the charge nurse and population health nurse of the pediatric clinic solidified the need for pain mitigation for infants undergoing vaccination and were eager to learn about new pain relief strategies.

Project Stakeholders

Infants, their parents, and the nurses caring for them were the obvious stakeholders for the change project. Infants benefited from the pain relief of non-pharmacological interventions that have been empirically proven and free from adverse effects. Parents also benefited from the implementation of non-pharmacological interventions by decreasing their concern for injection pain associated with immunizations. Eliminating concerns of pain allows parents to make more sensible decisions about vaccination. Furthermore, nurses gained knowledge of alternative pain management strategies without apprehension from the adverse reactions that are more commonly associated with pharmacological methods. Delivering effective methods of pain relief for infants embodies the fundamental principles of the nursing profession including compassion, empathy, ethical and moral standards of care, and patient-centered care.

The charge nurse and chief of the pediatric clinic were also key stakeholders that acknowledged the need for the EBP project to enhance pain management strategies for minor procedures in the outpatient setting. Additionally, the leaders of the clinic believed that the change project would improve the vaccine experience for infants and parents that could lead to an increased overall patient satisfaction.

Due to the time limit of the DNP project, cumulative organizational benefit was difficult to accurately assess; however, it was presumed that the organization would benefit from the project as evidenced by improved patient satisfaction scores (i.e., parents) and enhanced quality metrics of HEDIS measures for infant vaccinations. Promoting vaccine adherence could also improve community health, decrease morbidity and mortality rates, and reduce healthcare costs generated by vaccine-preventable illnesses. Finally, the project promoted actions that supported the organizational mission (optimal pain relief).

SWOT Analysis

A SWOT analysis was generated to adequately visualize the strengths, opportunities, weaknesses, and threats of the DNP change project. The SWOT analysis is beneficial for any project to allow the project manager and key stakeholders to identify the benefits that will stem from the change (strengths); secondary outcomes (opportunities); potential barriers of implementation (weaknesses); or threats that need be monitored, minimized, and eliminated if possible. A summary of the DNP change project SWOT analysis is described and can be reviewed in Appendix E.

Strengths

A major strength of the project was that the interventions operationalized WBAMC's mission for optimizing pain control in patients. Additionally, EB non-pharmacologic pain-relief methods are safe, efficacious, and cost-effective. It caused minimal disruption to the standards of care and did not require a physician's order. And most importantly, it facilitated maternal-infant bonding and promoted infant regulation related to pain experienced from vaccine injection(s).

Weaknesses

Weaknesses of the project included implementing pain relief for infant vaccination only. Due to the limited duration of the project, pain management strategies for vaccination had to be limited to a specific population for feasibility and management, thereby excluding benefit to all children of various ages. Since this was an EB implementation project, no control group was available. Additionally, objective pain scale data was not included as an outcome measurement, as the charge nurse in the clinic preferred that the primary change be focused on implementing preventative pain interventions. It was collectively decided that once the nurses became comfortable with implementing pain management techniques with minor painful procedures, documenting pain levels using validated pain scales would easily follow thereafter. Finally, the EBPG by Taddio et al. (2015) suggested that the combination of pharmacologic (i.e., topical anesthetics) and non-pharmacologic methods yielded optimal pain relief for infants and children undergoing intramuscular injection; however, due to the cost and lack of clinic availability, topical anesthetics were excluded.

Opportunities

Opportunities that could be yielded from implementation the project included the promotion of breastfeeding, perceptivity into the natural pain-relieving properties of breastfeeding, as well as policy formation. I drafted a clinic policy that guides nurses on implementing pain relief strategies to infants undergoing routine immunization with the use of non-pharmacological interventions and adequate documentation. Policy formation can promote the use of pain management methods, documentation, and sustainability.

Additional organizational benefits from the project included decreased parental vaccine hesitancy related to alleviating concern for pain, increased parental satisfaction with vaccination, and improved implementation of pain management methods. Decreasing infant pain could facilitate adherence to the recommended vaccine schedule and improve HEDIS measures for the organization. However, these outcomes were not directly evaluated due to the time limit of the project.

Threats

Some threats that impeded implementation included parents that were too anxious and incapable of calmly soothing and supporting their infant. Additionally, some nurses were resistant to changing existing practice of placing infants supine on exam tables, as they perceived that the traditional method facilitated the vaccine process by having full control of the injection site. Establishing inter-rater reliability with using the survey tool also thwarted the validity of survey results. However, the goal of the educational offering was to address these concerns upfront and mitigate the aforementioned barriers to accepting change. Fortunately, the charge nurse and the population health nurse were committed to facilitating success of the project and were available to provide extra support for staff nurses during the implementation phase.

Barriers and Facilitators

Nursing is a profession of caring and providing individualized holistic care. Subsequently, the impetus for accepting change was facilitated by the educational offering whereby nurses learned how infants experience and modulate pain. It grasped their interest in learning about effective pain relief methods. Furthermore, the DNP change project promoted family-centered

care by enabling parents to hold and comfort their infant during vaccine administration while addressing parental concerns for pain. These critical factors facilitated the implementation of the EBP change project.

An informal query directed to some of the nurses in the clinic regarding barriers to accepting the proposed changes was conducted. This query identified that nurses were most reluctant to having parents hold infants during immunization due to the perception of losing control of the injection site. Other nurses verbalized discomfort with having mothers' breastfeed during the injection. It was critical to address these prominent concerns during the educational offering to promote acceptance and participation. For instance, nurses were instructed to educate parents about how their involvement provides crucial support and pain relief for their infant. This information would encourage parents to participate and hold the infant in an optimal manner willingly. Additionally, the in-service emphasized that breastfeeding offers natural analgesia and enhances infant regulation, which facilitated the nurses to incorporate the change into practice. Moreover, WBAMC has a policy that allows mothers to openly breastfeed infants in any manner they choose to promote breastfeeding and minimize shaming. The focal point of this policy was reviewed and enhanced the acceptance of accommodating the practice of breastfeeding during infant vaccine administration.

Project Schedule

Following this project proposal, an application for IRB exemption was completed and submitted to Dr. Larissa Schmersal, WBAMC Human Protections Administrator, as well as to the CCN DNP committee. After obtaining IRB exemption, the pediatric nurses received an education offering on how infants perceive pain, non-pharmacological pain management strategies, and

the implementation of the DNP change project. Upon completion of this in-service, the nurses received CNE credit. The project was implemented over eight weeks during July 8 – August 31, 2019. In September, data findings were evaluated for primary and secondary outcomes. And in October, the data was synthesized and presented to leaders at WBAMC to evaluate the organizational impact and the levels of parental concern for vaccine-associated pain. Project data was also distributed to the public affairs office for approval before releasing findings to the CCN and completing DNP program requirements.

Resources Needed

The selected interventions for this change project required very few resources. A breakdown of the project budget can be viewed in Appendix F. Primary expenditure for the project was for the paper required to print the parental surveys and consent forms. Fortunately, breastfeeding is free, natural, and promotes maternal-infant bonding. The clinic already had 24% SS (Sweet-Ease®, 15 ml) in stock for managing infant pain but was rarely used. Costs for the clinic included $212 for 200-15 ml packets. The evidence shows that two ml of SS is efficacious, leading to 13 ml of solution wasted. However, I discovered that the organization supplied two ml prefilled vials (Sweet-Ease Natural®) that were used on the labor and delivery unit. I subsequently informed the charge nurse that subsequently led the clinic to order the newer formulation. This saved money for the clinic by reducing wasted resources and facilitated nurses to easily administer the single dose bullet to patients.

Since the change project required the administration of pain management during infant vaccination, it required some additional time at first until the nurses became acclimated to the practice change. The nurses were required to incorporate additional education to parents

about how breastfeeding and SS provided adequate pain relief for infants during immunization, and upon parents consent, the selected intervention was initiated. The nurses proceeded to review vaccine information and obtained parental consent for vaccine administration. This sequence of events maximized time efficiency and allowed for the two minutes required for the analgesic effect to take place. Since non-pharmacological methods of pain relief were selected for use in this project, nurses were able to autonomously implement the methods without the need of an order from a physician or mid-level practitioner.

Project Manager Role

I assumed the role of project manager and provided the education for the nurses to ensure implementation success. Knowledge obtained from the educational in-service was assessed collectively and individually. Additionally, I was on site most weekdays during the implementation stage that provided necessary support and monitoring of project progress. The charge nurse was mentored to serve as a practice champion and an expert resource for nurses to consult with for any concerns or assistance especially during times when I was not available. Nurses were familiarized with parental surveys and instructed to avoid transcription of protected health information on the surveys to maintain confidentially. Intermittent evaluation of project implementation was obtained and communicated with key leaders and staff. Appropriate changes were made for unanticipated results and reported to the charge nurse as appropriate. Finally, I collected data, collaborated with a statistician to evaluate outcomes, and communicated findings with staff and leaders of the organization.

Plans for Sustainability

As previously stated, a new standard of care was the first step in adopting new methods of pain management for infant immunization. These evidence-based pain relief methods have also been efficacious for infants undergoing other minor painful procedures such as heel lancet and venipuncture (McNair, Yeo, Johnston, & Taddio, 2013). I collaborated with the charge nurse and chief of the pediatric clinic in drafting a proposal for a new clinic policy that could facilitate the adoption of a new standard of care for childhood vaccination and other minor painful procedures.

Additionally, it would be invaluable to require nurses in ambulatory care to complete an annual online training regarding this competency via Swank Health, an online educational tool for healthcare facilities. Currently, annual online pain management training is required for all healthcare providers, but it is more applicable to patients that are hospitalized and experiencing pain related to more invasive procedures, surgeries, or acute morbidity. An online training targeting common outpatient procedures (i.e. vaccination and minor procedures) would be more suitable for nurses in ambulatory care clinics. The information provided in the educational offering for nurses could be used to in an online training session; however, the adoption for a formal training requirement in Swank Health is not be feasible in the allotted time for the change project. Discussion and collaboration for a new virtual training session was discussed with key stakeholders and will be the next course of action for sustaining the change project.

Project Vision, Mission, and Objectives

The vision for the DNP change project was to create a standard operating procedure (SOP) on pain relief for infants undergoing routine vaccination and other minor painful procedures such as heel lance, venipuncture, and venous cannulation. The setting for this change project was at the Mendoza Pediatric Clinic within the Department of Primary Care and has the potential to slowly be incorporated into routine practice among the other family care clinics at Fort Bliss, as well as the emergency room. Furthermore, other age-appropriate, evidence-based strategies could similarly be adapted into a standard of care to benefit all Department of Defense (DoD) beneficiaries. The non-pharmacological interventions selected for this project have empirically shown to provide pain relief, reduce detrimental effects on neurophysiological development, and reduce parental vaccine hesitancy (Chan, Pielak, McIntyre, Deeter, & Taddio, 2013; Siu & Goubert, 2015). Finally, implementing pain relief methods can promote vaccine adherence to national pediatric immunization guidelines and decrease healthcare costs related to vaccine-related illnesses.

The mission of the DNP project was to provide adequate pain relief for infants undergoing routine immunization. Pain management is imperative for providing high-quality care for patients. Omitting pain management without just cause is against ethical behavior and contrary to the integrity of avoiding intentional harm. The project mission was parallel to the organization's mission of providing optimal pain management for all patients. Moreover, this new intervention improved the quality of patient care delivered at WBAMC.

PICOT Question

The following PICOT question served as the basis for the DNP project "For parents of infant patients at the Mendoza Pediatric Clinic, will the use of EB non-pharmacological pain relief methods, compared to current practice, reduce parental concern for vaccine-associated pain in eight weeks?"

Population

The population of interest was parents of infants two to six months of age whom presented to the pediatric clinic for routine well-baby examination that included the administration of age-appropriate immunizations. As such, parents were asked to participate in the change project during the initial infant screening process. For those that wished to participate, a consent form was handed to parents that explained the objectives of the project and methods of pain control that they could choose from. Additionally, the parents were asked to complete the parental surveys after obtaining consent. No personal identifiable patient information was used for the project, except infant age and an indication if the parent was a first-time parent, and therefore, patient identity was preserved. As a result, subjects were recruited for participation after an IRB exemption was obtained from WBAMC and the CCN.

Inclusion criteria for infants included overall good health and clearance for routine vaccine administration by the primary care provider. Additionally, parents of the selected infant population were required to be fluent in English and willing and able to participate. Exclusion criteria included infants with an acute illness that would contraindicate vaccination, previous adverse reaction to vaccination, parents that were unable to calmly hold the infant during vaccine administration, or parents who refused vaccination.

Intervention

The pediatric nurses received a CNE-approved in-service about infant pain perception, vaccine-associated pain management strategies, and the project implementation plan. Nurses were encouraged to ask questions or share concerns about the implementation process followed by an evaluation of the educational offering.

The nurses educated parents about EB pain relief interventions that can be safely used during immunization. Parents were instructed to calmly hold infants in their lap and provide reassurance with either non-pharmacological intervention used during vaccination to promote infant regulation. Although breastfeeding was encouraged for breastfeeding infants, parents had the choice to breastfeed or use SS to provide pain relief for their infant that promoted family-centered care.

Breastfeeding has shown to be most effective when implemented two minutes before, during, and after vaccination (Shah et al., 2015). Accordingly, a timer was used to ensure that infants' breastfed for two minutes after confirming a coordinated suck and swallow reflex. Vaccine administration commenced while breastfeeding continued during and after vaccination. Similarly, SS has shown to be effective when administered two minutes before vaccination and with concentrations between 20-30%. The additional use of a pacifier (i.e., NNS) has also shown to improve pain relief when used in conjunction with sweet solutions (Stevens et al., 2016). Subsequently, infants in the SS group received two ml of 24% SS (Sweet-Ease Natural® by Phillips Healthcare) orally, followed by the use of NNS upon availability and parental preference. After two minutes passed, vaccines were administered.

Since there were two non-pharmacological options for parents to use within the project, all efforts were made to recruit an equal amount of participants for each intervention. A goal of at least 100 infants total with 50 breastfeeding and 50 using SS was the goal for data collection to yield optimal statistical analyses.

Comparison

The standard of care was laying the infant supine on the examination table, with parents holding arms and attempting to console infant, while the nurse immobilized the legs to administer vaccines. Pain relief strategies were not implemented during previous routine immunization. No comparison data about parental concern was available for project use.

Outcome

The primary outcome for the project was reducing parental concern for vaccine-associated pain related to IM injection. Zhao, Leong, and Watson (2015, Appendix A) developed a questionnaire to assess parental use of and barriers to using pain-relief strategies. In one item, which was key to the project's outcome data, parents were asked to rate their level of concern for pain related to vaccination, measured on a 5-point Likert scale. Additionally, parents rated their child's previous level of anxiety during vaccination (for older children), interest in learning more about pain relief interventions, and the best method of learning.

After obtaining permission for survey use (Appendix G), select questions that were most relevant to the interventions, population of interest, and the primary outcome of the proposed project were adapted for use in the EBP project (Appendix H). Questions regarding previous use of breastfeeding or SS and parental desire to learn about pain relief methods were selected to provide additional insight on implications for future practice. The data was collected with a

paper and pen survey given to parents during nursing triage at the start of the patient encounter. The data was based on the current level of concern for vaccine pain to reduce recall bias.

Time frame

The time frame for the DNP change project was implemented for eight weeks from July 8 – August 31, 2019. An outline of the implementation schedule can be found in Appendix I.

Feasibility

The timeline presented in Appendix I describes the breakdown of activities that were critical for ensuring project success. Accommodations were made as identified throughout the implementation process. It was anticipated that recruiting patients for the SS group would be more difficult because many infants are breastfed. However, the opposite effect was observed, and subject recruitment for the breastfeeding group was more challenging. Fortunately, adequate subjects were recruited by the end of the eight weeks. I was present during most clinic weekdays to ensure that nurses had all resources available and supported with additional assistance that kept a steady flow of subject participation.

Sample and Setting

WBAMC is an academic DoD healthcare system located on Fort Bliss in El Paso, Texas. Medical services are prioritized for active duty soldier members and their beneficiaries. Five outpatient centers provide primary healthcare services for soldiers and their beneficiaries within the organization. With service members deploying to different countries and having foreign military members training at Fort Bliss, vaccination is even more critical for family members to reduce the risk of frequent vaccine-preventable outbreaks.

At the time of project implementation, nurses within the Mendoza Pediatric Clinic consisted of Licensed Vocational Nurses (LVNs) and Registered Nurses (RNs). All of the nurses were educated on pain management strategies for infant vaccination. The RNs were either administrators, team leaders, or provided care in the treatment and immunization rooms. In general, the LVNs administer ordered vaccines in each patient care room if possible; however, some patients are sent to the immunization rooms to receive vaccines to maintain the flow of patient care. Parents are then instructed to remain in the waiting area for at least 15 minutes after immunization to observe for adverse reactions.

Well-baby visits are recommended for infants at two weeks, two months, four months, six months, nine months, and 12-months of age. Vaccines are administered at the two, four, six, and 12-month visits. An audit of well-baby visits demonstrated that approximately 100 well-infant exams were completed each week. Since the EB project included infants receiving vaccines for the two, four, and six-month visits, it was estimated that at least half of the weekly visits contributed to the selected population of interest.

Implementation Plan/Procedures

The first phase of the project implementation was a 60- minute educational in-service for the staff nurses at the Mendoza Pediatric Department. The clinic nurses received instruction about how infants experience pain, secondary effects of untreated pain, interventions that can be used to minimize pain, and how the nurses would implement the selected non-pharmacological interventions for the change project. Following a brief demonstration provided with an infant manikin, the nurses were encouraged to ask questions. The nurses completed an evaluation of the lecture and provided individual feedback. Nurses that were unable to attend

the educational training were provided with a copy of the presentation via email, as the clinic did not allow for additional times to be taken away from patient care. However, I provided individual consultations with the three nurses to ensure that all nurses received adequate training and a chance to ask for clarification or voice concerns.

During the first week, I prepared copies of the parental surveys and handed them out to each nurse personally to provide another opportunity to address individual concerns and review inter-rater reliability. Since patients were given a choice to use breastfeeding or 24% SS to alleviate pain for their infant, nurses were prepared to implement either strategy at the parents' discretion. I continuously stocked the immunization rooms with 24% SS that facilitated use and maximized time efficiency.

Recruitment of subjects started the following week (week two). Completed parental surveys were kept in a locked drawer in each exam room whereby I collected and secured them in a double-locked file. I was available Monday through Thursday 0830 - 1430 to provide education to patient families while nurses prepared vaccines for patients or to answer additional questions that nurses or parents had. This was helpful in maintaining clinic flow and minimizing disruption of clinic operations. Strategies for ensuring inter-rater reliability for using the survey were a primary goal. At the end of week two, I addressed a concern that nurses verbalized regarding the breastfeeding group and administration of the oral vaccine RotaTeq (rotavirus). Originally, I had recommended that nurses use the two-minute interval time to discuss the vaccines to be administered and obtain parental consent. When using this approach, the nurses would have to interrupt the breastfeeding process to administer the oral vaccine. This caused more distress in the infants and disrupted the natural analgesic properties

that the infants experience during breastfeeding. A modified recommendation in the approach was made to review vaccines and obtain consent before initiating breastfeeding. Nurses were encouraged to judiciously use the interval time to coach parents to remain calm to promote infant regulation and minimize pain during vaccination.

During week four, I evaluated the number of subjects recruited in each part of the project. This provided insight into how many more subjects needed to be recruited and facilitated a discussion about the flow of the project with the charge nurse and staff nurses. Valuable information from this assessment was shared during morning huddle to express appreciation for the nurses' contributions and to address surfacing concerns. Subject recruitment continued over the next four weeks with periodic evaluations and accommodating necessary changes.

During the last two weeks of the project, participants for the breastfeeding group were prioritized because the project had already achieved 50 participants in the SS group. At the end of the implementation phase, I queried staff nurses about how the change project would impact future consideration of pain management during vaccination. Barriers to implementation were addressed in small group sessions to facilitate discussions on how to overcome them and to review strategies suggested by evidence-based practice.

Data Collection Procedures

I synthesized the data and evaluated the findings with the collaboration of Dr. Julia Bader, a statistician at WBAMC in the department of clinical investigations. As such, a table of data collection parameters was mutually agreed upon and constructed in an excel workbook. Separate spreadsheets were developed for each group for ease of data analyses. Descriptive

statistics facilitates the interpretation of data findings from a set of quantitative data analysis (Mishra et al., 2019). As such, descriptive statistics were used to describe the results of the data. Since two non-pharmacological interventions were used in the project (breastfeeding and SS) the use of nonparametric testing was more suitable to analyze the data since it cannot be assumed that the two populations were normally distributed.

For the primary outcome designated for this project, parents were asked to rate their current level of concern for pain related to the vaccine injections on a 5-point Likert scale that was used by Zhao et al. (2015). To control for recall bias, the survey sought to capture the current level of concern for pain immediately before and after vaccination. These numerical parameters are associated with ordinal data (Gadermann, Guhn, & Zumbo, 2012). Ratings from the parental surveys (level of concern) were also expressed in terms of central tendency (i.e., median). Furthermore, I compared pre - to - post data distribution of parental concern (before and after vaccination) that assessed impact of the implemented interventions on the levels of parental concern for vaccine-associated pain.

Recruitment and Selection

Subjects were recruited from a convenience sample of patients scheduled for routine well-baby exams (i.e., two, four, and six months). As a result, provider schedules were accessed each weekday afternoon to view the appointments scheduled for well-baby exams for the following day that anticipated future project participants. This also ensured that nurses were adequately prepared with resources and well supported by me, the DNP scholar and project manager.

Parents with infants up to six months of age that were generally in good health and cleared for vaccination by their primary care provider were considered for participation in the project. Parents with infants that had an acute febrile illness, parents that declined vaccination, not able to calmly hold the infant during vaccine administration, or not fluent in English were excluded from participation.

The goal of the project was to obtain at least 50 subjects in the breastfeeding group as well as 50 in the SS group. The pre-and-post implementation design selected for the EBP change project was vital to test a hypothesis that assumes that implementing pain-relief interventions will reduce parental vaccine hesitancy for those that are concerned about injection pain and determine if desired outcomes can be attributed to select interventions.

Data Analysis Plan

Parental surveys were collected on a double-sided sheet of paper that measured the level of parental concern (Appendix H). The pages were labeled with a “pre” on the front side that indicated a baseline (BL) measurement for the level of concern and “post” on the backside that served as the post-intervention rating. This facilitated tracking data for pre - and - post measurement levels from each parent respectively whilst preserving confidentiality. The other two questions on the front side of the survey were also used in Zhao’s et al. (2015, pp. 11-14 and 47) study and provided additional insight for clinicians as to whether parents wanted to learn about pain-relief interventions, whether or not they have used such interventions, and if not, why such interventions have not been used. These emerging themes also contributed qualitative value in the discussion of findings. Each participant was given an envelope to put his

or her completed survey in that allowed parents to report unbiased ratings and preserved confidentiality. I collected the envelopes and placed the responses in a double-locked cabinet.

Instrumentation

Zhao et al. (2015, pp. 11-14 and 47, see Appendix G; parental survey in Appendix H) developed a questionnaire that identified parental barriers to using pain management methods for childhood vaccinations. Questions asked parents to rate their level of concern for injection-related pain on a 5-point Liker scale; a similar Likert scale measurement was used for measuring the primary outcome in the DNP change project. Additionally, parents were asked if pain management strategies such as breastfeeding, sugar water, topical anesthetics, or deep breathing exercise have been used during previous vaccinations. Breastfeeding and SS were methods of particular interest for the current project, and thus, permission for the use of pertinent questions for the project was obtained from Dr. Zhao (Appendix G; parental survey in Appendix H). The mean level of concern was examined at baseline and again after undergoing vaccination with the utilization of a pain-relief intervention. The post measurement data was collected during the 15-minute post-vaccination period when parents are required to stay in close proximity of the clinic for observance of vaccine-related adverse reactions. Evaluation for a statistically significant decrease in the degree of concern was analyzed. Other questions used in the parental survey provided clinicians with implications for future practice.

Many investigational studies have strived to identify what parameters influence patients' perception of adequate pain management. Farooq, Khan, and Ahmed (2016) developed a tool to measure patient satisfaction with acute pain management. Their strategy included assessing factors that contribute to the pain experience including the anticipation of

procedural pain versus pain experienced, the quality of pain relief with treatment, healthcare professionalism, overall pain management experience, and whether the pain intervention would be recommended to others. The tool used a 5-point Likert scale to quantify patient ratings for each parameter.

Tickner, Leman, and Woodcock (2010) developed an immunization satisfaction questionnaire that was completed by parents at four outpatient clinics. A 5-point Likert scale was used to quantify the level of satisfaction for each question (1= very dissatisfied; 5=very satisfied). As a result, the pain management satisfaction question used in the DNP parental survey (Appendix H) was developed using these pain management studies that sought to construct a valid and reliable tool to measure patient satisfaction related to pain management experiences.

Instrument Reliability and Validity

Zhao et al. (2015) developed a new questionnaire based on the pain relief strategies identified from a literature search and a previous evidence-based practice guideline for reducing vaccine pain in children (Taddio et al., 2010). Since this is a fairly new audit tool, inter-rater reliability in using the new questions was assessed with individual nurses during the first week of project implementation.

The questionnaire developed by Farooq et al. (2016) was administered by a medical student who was not familiar with the research team or patients. This strategy minimized bias for responders to answer positively. The immunization satisfaction questionnaire developed by Tickner et al. (2010) established validity and reliability by using Cronbach's alpha and Principal Components Analysis. Cognitive interviews with five mothers were completed to assess the

understandability of the questionnaire. Similarly, the participants in this project were provided with an envelope to seal the survey and reduce the rate of responder bias.

A 5-point Likert scale has shown to be a valid scale to allow patients the opportunity to have a neutral opinion regarding satisfaction, i.e., not satisfied, nor dissatisfied (Clark-Carter, 2001). Furthermore, Collins and O'Cathain (2003) reported that patients found value in using a 1-5 rating scale for satisfaction because they attributed significant differences among being "satisfied" (average service) and "very satisfied" (exceeding expectations).

Ethics and Human Subjects Protection

Information collected from this change project was valuable for promoting high-quality family-centered care at WBAMC. Fortunately, the data collected from this project did not contain any patient or family identifiable data and neither carried a risk for a breach of confidentiality nor a risk for physical, social, or psychological harm. The completed surveys from this project were stored in a double-locked file; electronic files that contained relevant data for the project were password protected and maintained by the DNP project manager. Furthermore, data collected for the project were shared with key stakeholders of the organization as well as the DNP faculty members of the CCN. After the project was completed and presented to the CCN, the surveys were dispensed in a locked receptacle designated for proper destruction of health-protected information.

CHAPTER 4: RESULTS AND DISCUSSION OF DNP PROJECT

Summary of Methods and Procedures

The organizational clinical assessment identified that there was a need to improve methods of pain management throughout the institution. The following PICOT question was developed to guide project planning and management: "For parents of infant patients at the Mendoza Pediatric Clinic, will the use of EB non-pharmacological pain relief methods, compared to current practice, reduce parental concern for vaccine-associated pain in eight weeks?" As such, the EBP change project emerged and with the goal of implementing non-pharmacological pain relief methods for infants undergoing routine immunization that would decrease parental concern for pain associated with the procedure. The project was conducted using a pre- and post- EB implementation design.

Although many nurses reported that the in-service was important, relevant, and informative, others simply would not adapt the change intervention into practice. Numerous strategies for overcoming resistance to change were applied to persuade more nurses to participate in the project. The DNP leader made accommodations to encourage nurses to perform pain management methods before vaccination including being available during most clinical hours during the week, actively mentoring nurses how to put the intervention into practice by talking with parents, obtaining consent and survey forms, and showing nurses how to vaccinate infants in the parents' laps and during breastfeeding. Additionally, the charge nurse was very receptive to the changes and eagerly learned the process to become a practice champion. Finally, individual discussions about the new practice and desired outcomes were

conducted with nurses and suggestions for modifying the implementation process were openly accepted.

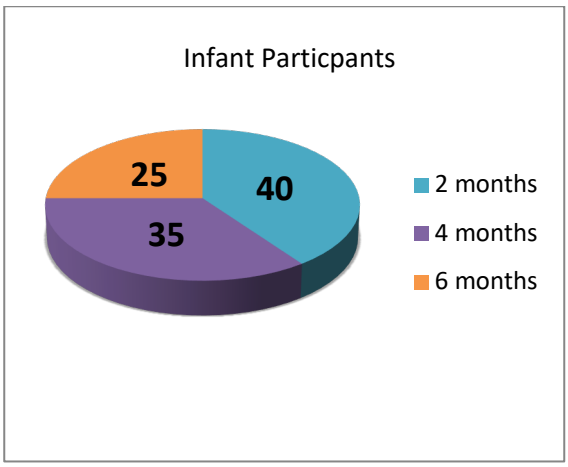
After evaluating responses from surveys showing that some parents indicated a higher level of concern after the intervention whilst expressing a high level of satisfaction with the pain-reduction method, it was obvious that the inter-rater reliability of the survey needed to be re-evaluated. Education was done collectively as a group during morning report and individually with each nurse to ensure that the primary outcome question was being asked appropriately to parents and would accurately reflect efficacy of the intervention. As a result, a better understanding of the survey tool was gained and allowed the staff to appropriately collect data for the project.

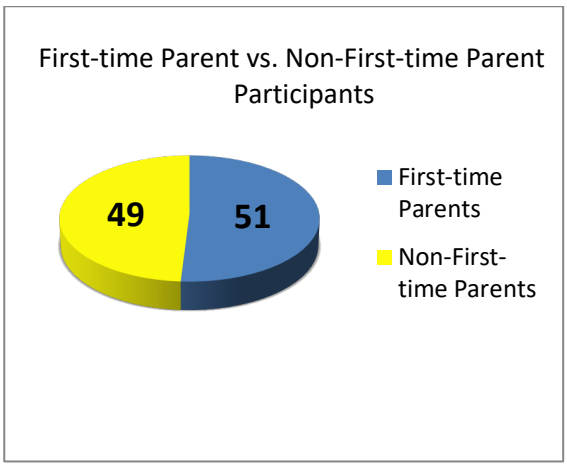
After collaborating with a statistician during week four, data from the completed surveys was recorded in a Microsoft Excel workbook that separated the responses for each project group (breastfeeding or SS). General demographic data that the nurses provided based on the parental surveys ("Administrative Use" section on page 2, Appendix H) included the age of the infant (2, 4, or 6 months), which parent provided the information (mother or father), whether or not the parent was a first-time parent, and the intervention selected for pain management. Additional information collected for analysis included the current baseline (BL) level of concern for vaccine-associated pain (1 = no concern, 5 = very concerned), whether the parent wanted to learn about pain management strategies, why previous pain management strategies were not used, post-intervention levels of concern for pain (1 = no concern, 5 = very concerned), how satisfied the parent was with the method of pain control (1 = not satisfied, 5 = very satisfied), and whether the parent would recommend the pain intervention to others.

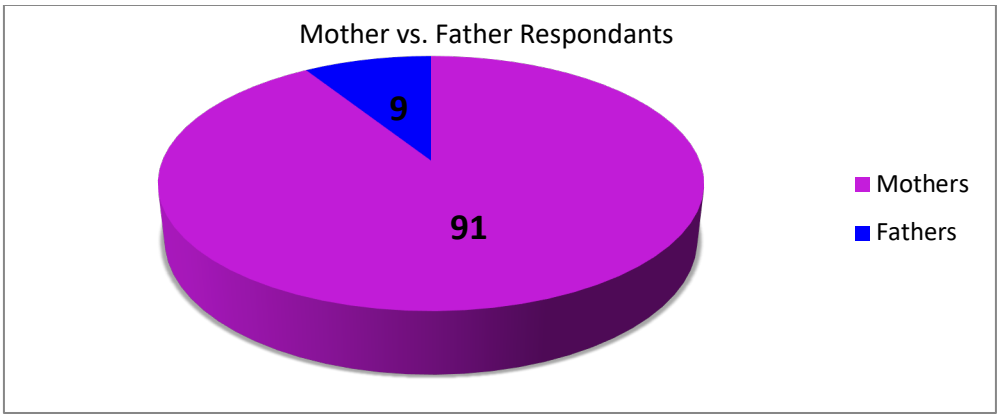
In collaboration with a statistician, a total of 100 participants were recruited with equal representation from each intervention group (breastfeeding or SS). At the start of the project, it was assumed that a chi-square test would be used to analyze the data. However, Fisher's Exact Test more adequately detects statistical differences among small sample sizes using categorical data (UCLA Institute for Digital Research & Education, 2019). A cross-tabulation of parental concern for each group was analyzed at BL (pre) and again after the intervention (post) using Fisher's Exact Test. Statistical significance was observed at alpha ≤ 0.05. Additionally, a Wilcoxon-Mann-Whitney test was used to identify statistical significance for two-paired groups and represents descriptive statistics while assuming that the null hypothesis (no difference between two groups) is true (Nahm, 2016). Thus, the Wilcoxon-Mann-Whitney test can show the distribution of the change in parental concern from pre- to post- for the two groups with no assumption of normality and assuming an ordinal scale.

Summary of Sample and Setting Characteristics

The project was performed at a military healthcare facility that requires more levels of approval for a scholarly project than other institutions. This necessitated the formulation of a plan for patient recruitment that would facilitate organizational acceptance and IRB exemption. Furthermore, confidentiality and improved participation in the project had to be maintained. Therefore, demographic data collected from participants were very limited. Nurses documented demographic data that included which parent answered the survey, infant age in months, whether the parents were first-time parents or not. This data is depicted in the pie charts below (*n* = 100).







By week six of the implementation phase, nearly 80 parents had participated in the EB change intervention. The need to propose an IRB amendment for requesting an increased number of participants was anticipated. As a draft was prepared, subject recruitment significantly decreased by the end of that week. Although this was partially attributed to providers and nurses being out on leave, changes to the daily schedule of the patients could not account for this observation. After reviewing the number of well-infant visits up to six months of age for the eight weeks that the project was conducted, 513 visits were documented in the electronic health record. Although the desired number of participants (n = 100) was obtained, this represented only one-fifth of the visits for the project target population.

Major Findings

The primary outcome of the DNP project was to decrease parental concern for vaccine-related pain. To adequately investigate this objective, a pre- and post- level of concern was analyzed individually according to each intervention group first and then for the entire project population to identify changes in the level of concern from pre- to post- pain intervention. The BL analysis demonstrated that there was no significant difference in the distribution of parental concern for pain between the two groups at BL ($p = 0.3293$), with 43% of overall parents reporting a moderate level of concern and 37% of parents rating higher levels of concern. In contrast, analysis of the post-measurement variables revealed a significant difference in the distribution of parental concern for pain between the two groups ($p = 0.0479$) in which the SS group tended to have a higher post- level of concern (see Figures 1.1 and 1.2).

After combining the pre- and post- levels of concern data for both groups, a cross-tabulation was formulated to assess changes in the level of concern for pain from pre- to post (see Figure 2). A significant difference ($p = 0.0347$) in the distribution of change in parental concern from pre- to post- for the two groups was identified with parents reporting decreased levels of concern after the pain intervention (post). The Wilcoxon-Mann-Whitney Exact Test also showed a significant difference in the distribution of changes in parental concern from pre- to post- intervention for the two groups ($p = 0.0380$).

These results for the two groups demonstrated that the selected non-pharmacological pain relief interventions successfully reduced parental levels of concern for infant vaccine-related pain in line with the main objective of the project. Furthermore, parents indicated that the most common reasons for not using pain management during vaccination were that they

had “never heard of this” (27%) or “the doctor never discussed” (24%) options. In total, 92% of parents reported that they wanted to learn about vaccine pain relief strategies, 96% of parents (92% breastfed, 100% SS) would recommend the non-pharmacological intervention to others, and 87% of parents reporting higher levels of satisfaction (4 and 5) with the pain intervention. The distribution of levels of satisfaction can be viewed in Figure 3.

A secondary analysis was conducted to identify differences in parental concern between first-time parents versus non-first-time parents at pre- and post- data points. Interestingly, 51 first-time parent participants (28 breastfed, 23 SS) and 49 non-first-time parents (22 breastfed, 27 SS) participated in the project. Using Fisher’s Exact Test, no significant difference in the distribution of first-time parents between the two groups ($p = 0.4238$) was observed. Likewise, no significant differences in the distribution of parental concern for pain were observed between the two groups (breastfeeding or SS) among non-first-time parents and first-time parents at BL ($p = 0.8424$; 0.5020), or for post-concern among non-first-time and first-time parents respectively ($p = 0.4772$; 0.1462). Cross-tabulation of parental concern variables for first-time parents and non-first-time parents that included both intervention groups revealed a significant difference in the distribution of BL parental concern for pain ($p = 0.0086$) with first-time parents tending to be more concerned. No other statistical significance was observed among all other similar cross-tabulations when controlling for first-time parents.

Data from this project indicate the strong bond between mother/caregiver and infant (Attachment theory) as well as the interdependent relationship that a mother/caregiver and infant have, which synchronizes expressions of anxiety, pain, and fear (Emotional Contagion Theory). Parents were informed about how non-pharmacological pain interventions have been

empirically proven to reduce vaccine pain in infants and that their emotions further promote infant regulation. This led to decreased levels of parental concern about infant vaccine-related pain and in turn reduced pain experienced by the infant (Gate Control Theory).

CHAPTER 5: IMPLICATIONS IN PRACTICE AND CONCLUSIONS

Implications for Nursing Practice

The DNP project met the objective to decrease parental concern for vaccine-related pain in infants by implementing non-pharmacological pain management techniques. Two non-pharmacological methods of pain relief integrated empirically proven interventions with theoretical underpinnings of EBP. Breastfeeding and SS administration were selected for mitigating vaccine-associated pain in infants. Adjunctive psychological strategies that included parental holding, parental soothing, and the presence of calm-natured parents were based on theoretical aspects of the caregiver-infant bond and significantly impacted the outcomes of these interventions.

Facilitating pain relief for infants is an ethical, moral, and professional obligation of nursing practice. It is also an act of professional advocacy for vulnerable populations that are dependent on caregivers to fulfill basic needs. This holistic approach promoted family-centered, high-quality care for pediatric patients. Furthermore, unmanaged vaccine pain in infants can precipitate hyperalgesia during future painful procedures and negatively impact the efficacy of future pain management approaches (Stevens et al., 2016; Wilson-Smith, 2011). This can lead to patients and/or parents being uncooperative, compromise patients' safety, and delay necessary care.

Barriers that parents primarily reported for not using pain relief methods during vaccination included "never heard of this" and "doctor has not discussed with me." The majority of the participants in this project responded that they wanted to learn about pain

relief strategies for infant vaccination (92%). Both of these findings were also consistent with the findings from Zhao et al. (2015). These prominent barriers for implementation were identified to bring awareness to nurses that patient education for routine vaccination should include pain relief methods that can be readily implemented. Furthermore, the interventions used in this project can be autonomously used in routine practice without having to collaborate with other healthcare professionals.

Recommendations

Breastfeeding and SS are natural modalities of pain control for infants undergoing minor procedures. The DNP EBP change project met the main objective of alleviating parental concern for infant vaccine-associated pain. Furthermore, the parents were satisfied with the pain interventions and stated that they would recommend them to other parents. Nurses have an ethical obligation to provide pain relief to all patients in any manner possible and preferably with EB methods that have minimal adverse effects. Nurses are patient advocates who strive to promote healing and prevent unnecessary injury. When providing care to vulnerable populations, it is essential to provide adequate education to caregivers so they can be empowered to make sound healthcare decisions for minors, and advocate for patient safety and security. This includes conscious efforts to prevent pain and suffering during minor painful procedures.

Many organizations have formulated pain management policies for medical procedures. However, policies on managing pain during minor painful procedures are often lacking. Although many clinicians find this insignificant, evidence clearly demonstrates that providing adequate pain relief during minor painful procedures minimizes the development of future

sequela such as lower thresholds of pain tolerance, increased anxiety and fear, and diminished analgesic effects with more complex procedures (Wilson-Smith, 2011). Poor pain management can also lead patients to delay necessary medical care due to fear of procedural pain and delay or refuse vaccination. Nurses must remember that non-pharmacological and behavioral methods of pain management can be efficacious and economical when used appropriately or consider using these modalities in conjunction with pharmacological strategies for optimal pain relief. Policies that guide clinicians on effective strategies will thus improve the knowledge and utilization of pain management during minor painful procedures.

Breastfeeding and SS are EB pain-mitigating interventions that are safe, economical, and readily available. These techniques do not require extensive knowledge acquisition for application into routine practice. Nursing is a profession in which patients' needs and discomforts are regularly evaluated. Not meeting patients' needs can significantly impact healthcare quality. The EB methods of pain control used for this project require only a few extra minutes to perform and can put parents more at ease, thereby allowing them to better provide reassurance to the infant as a focal point of pain management. This collaborative approach will help parents understand their critical role in managing vaccine-related pain in infants, forge trusting relationships with clinicians, and improve healthcare quality.

Since this was an EBP project, the objective was to improve standards of care using a translational scientific approach at a military outpatient clinic. As such, I collaborated with the clinic nurses to encourage parental participation and employ pain management methods. Parents of infant patients were not called ahead of time to explain the objectives of the project. This approach may have increased the number of participants and provided a larger data set for

analysis. Alerting parents in advance may also have prompted them to abstain from breastfeeding for at least two hours prior to the appointment time for regularly breastfed children. The infants would have been hungry and eagerly anticipating a feeding, thereby making breastfeeding a stronger distraction for the infants and more therapeutic during vaccination as observed in other clinical investigations (Chittaluri & Rani, 2017; Gajbhiye et al., 2018; Kavthekar et al., 2016; Zurita-Cruz et al., 2017). Additionally, parents could have also been more prepared to assume the critical role of a calm-natured and soothing caregiver for the infant. Alerting parents in advance about participating in these pain management techniques with future EBP projects should be explored.

Discussion

Cross-tabulations of parental concern variables according to first-time parents and non-first time parents that included both intervention groups revealed a significant difference in the distribution of BL parental concern for pain was observed with first-time parents tending to be more concerned. This finding is consistent with the data generated by Zhao et al. (2015) and is an important factor for clinicians to consider when encountering first-time parents who may require more reassurance and time to express concerns, especially during their child's first vaccination. Increasing the knowledge of first-time parents will help these individuals make sound medical decisions for their children and help develop a trusting relationship with their primary care provider.

Assessing patient satisfaction in healthcare organizations is an important quality indicator that can facilitate opportunities for improving the quality of healthcare services delivered to patients. Pain management satisfaction is often difficult to interpret because

patient expectations can significantly impact the level of satisfaction with a pain management experience (Fizzah, Khan, & Ahmed, 2016). This poses challenges in establishing a valid and reliable tool that can adequately capture pain management satisfaction.

The Hospital Consumer Assessment of Healthcare Providers and Services (HCAHPS) survey was designed by the Centers of Medicare and Medicaid Services (CMS) to measure the quality of healthcare delivery to patients as a way to generate reimbursement for hospital services (i.e., value-based purchasing). The American Hospital Association (2016) pleaded with the Centers for Medicare and Medicaid Services (CMS) to reconsider three pain management questions on HCAHPS. The main reason was related to the likelihood of influencing patients that medication must be prescribed to manage pain adequately, thereby contributing to the ongoing opioid crisis. The CMS acknowledged that the questions on the HCAHPS could be negatively influencing patients, but felt that questions related to pain management were still critical in evaluating a patient's overall care experience. As a result, the HCAHPS pain management questions were modified to reflect if patients experienced pain during their hospital stay and if strategies to treat pain were discussed by healthcare providers (Mahoney, 2017). This approach broadens pain management to include a wide variety of aspects, including non-pharmacological, psychological, or behavioral strategies. I also value assessing the level of satisfaction with pain management strategies, and thus, this qualitative variable was included in the project's evaluation. Additionally, the DNP project used EB non-pharmacological methods of pain relief that reinforce natural methods of analgesia.

Strengths of the techniques used for this project include minimal cost (i.e., SS), ease of use, and no adverse reactions. The pain control methods were effortless and only two minutes

were required to implement therapeutic pain modulation. Additionally, infant-maternal/caregiver bonding, breastfeeding, and infant regulation for future minor painful procedures were promoted.

Another important strength of the project was that discussions about vaccine hesitancy related to parental concern for pain were facilitated. For example, the mother of a breastfed two-month-old infant informed the nurse that she wanted her child to receive only one injection at a time because she believed multiple injections would cause too much pain. When the nurse reported this, I went into the room and discussed the mother's concerns about pain associated with vaccination. The mother had a master's degree in a healthcare field and requested additional scientific information about the EBP pain relief methods. She was under the impression that breastfeeding her infant afterward would be the "reward and comfort" that the infant needed after immunization. I explained the theoretical mechanisms of pain relief that breastfeeding provides to infants including skin-to-skin contact, the act of suckling, and the sweet taste of milk. It was then explained to the parent that not only does the breastfeeding provide distraction and comfort, but the mother's calm state and soothing nature were equally important for optimal infant regulation. Finally, the parent was informed that breastfeeding should start at least two minutes before vaccination and continue during and after the injection(s). The mother appreciated the dialogue and consented to the infant to receiving all recommended vaccines. She was confident that she could provide her child with superior pain control by engaging in the simple, routine act of breastfeeding.

Despite numerous positive results, several limitations of this project were noted. First, there was a short duration of implementation. The population of interest was therefore limited

to allow ample time for implementation and thorough evaluation of project results. Future studies should expand pain management methodologies to include a larger population of pediatric patients. Additionally, nurses at the Mendoza Pediatric Clinic were already hard-pressed for time to complete many essential interventions for each encounter. They found my availability invaluable for saving time during patient encounters. I was able to educate parents about EBP while encouraging parents to be calm and relaxed so they could help the infant achieve a similar tranquil state. This allowed nurses to incorporate the EB techniques without adding more “tasks” to their regular practice routine. It would be beneficial to provide a small buffer of time in between patients when implementing new changes into routine practice to allow the nurses to familiarize themselves with the process and establish a new routine. This approach would help nurses to more readily accept the proposed changes. However, this would not benefit any healthcare organization from a business-related point of view.

Another limitation was the use of non-pharmacological methods alone. Previous studies have demonstrated the efficacy of EMLA during vaccination that is enhanced when used with breastfeeding (Gupta et al., 2013; Shah et al., 2015). However, EMLA is not a regularly stocked item in the ambulatory care setting of the current organization. Doing so would incur a significant financial burden especially when other modalities are available and empirically proven to work. EMLA use also necessitates additional planning for application time, obtaining a provider’s order, and monitoring for adverse reactions.

Finally, the sample size for this project was small and thus generalizability may be limited. Given that the participants were recruited from a convenience sample at a military health care facility, most participants were not residents of El Paso, Texas, as many families

resided in the area only for limited military assignments. Furthermore, neither residential nor ethnic demographic data were collected for this project and cannot be evaluated objectively.

Plans for Dissemination

I created a poster that outlined the project and results was displayed in the pediatric clinic for others to observe. This may have encouraged employees from other clinics to consider improving their clinical practice especially for the infant population. Additionally, it displayed faith in the medical organization's ability to continually strive to improve the standard of care. A formal presentation was given to the staff of the pediatric clinic staff as well as prominent leaders of the healthcare organization including LTC Smith (Preceptor), Dr. Schmersal (Clinical Investigations), Dr. Bader (Statistician), COL Scully (DCMS), the chief of primary care, and the chief nursing office for WBAMC. This further disseminated knowledge about the EBP change project design, the project's methods, and the evaluation process.

I also submitted an abstract for a podium poster presentation at the annual National Association of Pediatric Nurse Practitioners' (NAPNAP) conference in Long Beach, California on March 25-28, 2020. NAPNAP selects one submission from the practice innovation group for an award and recognition at the conference. Furthermore, I prepared a manuscript for publication and submitted it to the *Journal of Pediatric Health Care* (*JPHC*), which is also sponsored by NAPNAP. This journal was selected because of the relevance of primary care topics that pertain to the project and the fact that I am a current NAPNAP member. The second journal of interest may be the *Journal of Pediatric Nursing* (*JPN*) since the DNP project applied EB nursing interventions that can be implemented independently. Given that the pain control methods used for the project are non-pharmacological, nurses can readily employ these strategies

without having to undergo a formal change process or require a provider order. The key findings from this project can promote knowledge uptake and provide a detailed method of implementation to nursing professionals for immediately incorporation into practice. Finally, these pain management strategies can improve the standard of care for infants in ambulatory and acute care settings.

Conclusions and Contributions to the Profession of Nursing

Pain management during immunization is underutilized despite the abundance of scientific evidence and clinical practice guidelines that provide effective strategies for minimizing vaccine-associated pain. This gap between knowledge and clinical practice can be attributed to several factors that include misconceptions of how infants experience pain, belief that vaccinations are quickly administered and do not require pain management, and concerns for time and adverse reactions that are associated with pharmacological pain management methods. It is essential for nurses to remember that vaccines are the most common source of iatrogenic pain for infants (Stevens & Marvicsin, 2016), and that parental vaccine hesitancy has been linked to parental concern about infant pain (Dube et al., 2016; Kennedy et al., 2011). Urgency of this issue is underscored by the fact that vaccine hesitancy has led to endemic outbreaks of measles and pertussis (Bortz, 2018; Phadke et al., 2016). Breastfeeding and SS administration provide adequate pain relief during vaccination and therapeutic pain modulation can be achieved in just two minutes. These two minutes can be spent encouraging parents to remain calm and soothe their infant in any manner they choose to yield optimal results for minimizing infant pain during injection.

This project addressed misconceptions about infant pain perception, clinical concerns about implementing pain management, and therapeutic discussions with parents with concerns about vaccine-related pain. I formulated a plan and implemented EBP methods of pain management that met organizational needs, educated nurses about effective non-pharmacological pain management techniques, and successfully alleviated parental concerns about infant vaccine-associated pain. Previous studies have also demonstrated the benefit of educating parents about effectively managing vaccine-associated pain (McNair et al., 2017; Taddio et al., 2013); educating nurses about EBP pain-relief methods (Taddio et al., 2015); and helping parents to view their primary care provider as a trusted source of information (Dube et al., 2016; Kennedy et al., 2011). Nurses in primary healthcare settings can advocate for vaccine pain relief in infants that will minimize parental concern about pain and improve vaccine acceptance. In summary, non-pharmacological and behavioral methods of pain control encourage parental-infant bonding and provide natural analgesia for infants with a minimal risk of adverse reactions.

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Appendix A

Primary Research

Source and Database	Variables of Interest (Keywords)	Literature Type and Research Tools	Research Design and Sample Size	Theoretical Foundation	# References and SWOT Critique	Key Findings
(Chittaluri & Rani, 2017), India, MEDLINE	-breastfeeding (BF) -vaccination (Pentavalent vaccine) -pain perception -infants 6wks-6 mos	AGREE Level= 2 Modified behavioral pain scale (Taddio, et al, 1995) Visual analog scale (Wong & Baker, 1988)	RCT (*N*=200, *n*= 100 BF group *n*=100 Control)	None	#9 S=Performed a pilot study to prove tool reliability; all infants received the same kind and number of vaccine; large sample size; compared 2 pain scales W=Does not state what researcher(s) collected data for pain scale in main or pilot study; VAS was completed by mothers of infants'; a highly subjective test for pain and can have a varied response O=None stated T=Failed to provide a detailed description of methodology in context of paper,	BF group has significantly lower pain score: 10 mild pain, 74 mod pain, 16 severe pain; Control results: 1 mild pain, 21 moderate pain, 78 severe pain. Similar results recorded from VAS scores: BF group: 6 mild pain, 84 moderate pain, 10 severe pain; Control group: 1 mild pain, 25 moderate pain, 74 severe pain. BF group was found to have significant pain reduction in both MBPS ,VAS, and cry duration with a significance of P<0.01.

					difficult for replication. GRADE=**B**	
(Despriee & Langeland, 2016) Norway, Consumer Health Complete	-30% SS -SW (control) 15 month old infants -vaccine pain relief	AGREE Level=2 Duration of cry (DOC) (Allen et al., 2006)	RCT (*N*=114, *N=59 SS* *N= 55 Control*	None	#33 S=double blind study; pacifier use was compared and statistically analyzed to decrease result bias. W=only used DOC as measurement of pain; SS/SW given 1-2 min (no exact same time) O=None stated T=Did not mention use if parental holding/soothing was implemented which may have influenced results and make study difficult to replicate. Grade=**C**	Toddlers administered SS had a significantly decreased DOC; 18sec vs 33 sec.
(Gajbhiye, Rao, & Singh, 2018), India, CINAHL	-breastfeeding -25% SS (1ml) -control -newborn term infants	AGREE Level= 2 PIPP score (premature infant pain	RCT (*N* = 150; *n*=50 BF, *n*=50 SS,	None	#24 S=compared two previously known efficacious pain relievers with	BF superior pain relief as indicated by statistically significant lower pain score (PIPP).

	-Hepatitis B vaccine -duration of cry defined parameters	profile) (Stevens, Johnston, Petryshen, & Taddio, 1996)	*n*=50 control)		control; pilot study conducted; power analysis showed that groups needed #51 subjects/arm W=Could not randomize BF group O=none stated T=This is a high quality that defined all parameters, used valid/reliable instrument, and used equal technique among all subjects. Only no randomization for BF. However, 1 ml of SS used; previous studies have shown efficacy using 2 ml of at least 24% SS. Grade=**B**	BF and SS decrease mod-severe pain with injection to mild-mod pain levels. No statistical difference b/w BF and SS in cry duration.
(Kavthekar, Patil, Kurane, & Bharati, 2016) India, Google Scholar	-DOC -Change in HR from BL -MCFS (pain) -infants (<2mos) -Hep B vaccine -24% SS	AGREE level=2 DOC (Allen et al., 2006), Modified facial coding system (MFCS)	RCT-double blind (*N*=150, *n*=50 breastfed, *n*=50 24% SS, *n*=50 water)	None	#24 S= good sample size; multiple parameters used to assess efficacy of interventions; tools are valid	Infants that had 24% SS and BF had significantly lower total DOC, lower duration of first cry, lower rise in HR @ 3 min, lower pain score

	-BF	(Upadhyay, 2004)			W=state that the difference in outcome parameters b/w SS and BF was significant, but did not show or discuss how this was observed. O=none stated T=Quality study advocating for use of both BF and SS (in conjunction even). GRADE**: B**	@ 1 min and 3 min compared to placebo. The difference in these parameters were sig better in SS than in BF.
(McNair, Fung, Taddio, Ipp, Moss, Baker, & ... Pillai Riddell, 2017), Canada, MEDLINE	-infant pain -vaccination -parent-led interventions -video instruction	AGREE level=6 No tools used	Descriptive survey (*N*=130 parents) a) standard care, b) parent-led educational video (being calm, cuddling and distracting infants), c) video and SS, d) video, SS, and TA	None	#8 S=parents were able to answer open-ended questions W= no control group O=None stated T= some parents that participated in longitudinal RCT were excluded (possible sampling bias) GRADE=**D**	Parents commonly used non-pharmacologic interventions (more feasible and preferred). Parents that were given TA or taught how to use SS did not do so as they did not think it was necessary.

(Russell & Harrison, 2015), New Zealand, CINAHL	-immunization -pain -infants	AGREE Level= 6 No tools used	Descriptive survey (*N*=62 nurses)	None	#24 S=Survey allowed participants to answer open-ended questions; good clinical recommendations W=Small sample; no parental perspectives O=Study on Pain relief with Rota-Teq compared to sucrose solution; develop training techniques T= Recommended use of Rota-Teq in place of sucrose soln without empirical evidence GRADE=**D**	16 nurses (25%) reported pain mgmt. policies in their clinic. 52 (84%) reported using distraction methods (i.e. blowing bubbles). 16 reported using BF for infants <6 months often, occasionally by 28 surveys, and never in 12. SS not reported although shown to be effective. No use of topical anesthetics (costly). 60% used rapid injection; 4 used needle aspiration (non-necessary). 5 (8%) used "Buzzy" vibrator and ice pack device. BF and providing distraction does not require additional use of resources. Sucrose soln and topical anesthetics require resources and organizational support; EMLA could

						add $20 to vaccine cost. Rota-Teq oral vaccine has 50% sucrose solution and recommended to be given first. More education needed for clinicians and parents about intervention effectiveness.
(Suhrabi, Taghinejad, Valian, Sayehmiri, & Taheri, 2014), Iran, MEDLINE	-pain level -newborn infants -Hepatitis B vaccine -25% SS -25% Glucose	AGREE level= 2 Neonatal Infant Pain Scale (NIPS) (Lawrence et al., 1993)	RCT-double blind (N=90, N=30 SS, N=30 Glucose, N=30 control)	None	#12 S=Comparison of two sweet solutions; detailed description of tool validity/reliability W=Methods do not disclose how many nurses performed injections; no mention of position of infant (in mother's lap?), NNS; were nurses/researchers blinded to treatment groups O=None stated T=Did not mention who obtained NIPS	Avg pain scores in SS and glucose grps statistically lower than control ($p<0.001$). No difference b/w treatment grps.

					pain ratings; blinding? GRADE=**C**	
(Zhao, Leong, & Watson, 2015), Canada, Complimentary Index	-pain -pain reduction strategies -pain education -vaccinations	AGREE Level=_6 No tools used Survey developed based on lit review and CPG.	Descriptive Survey (*N*=62 parental surveys)	None	#=18 S=Good reflection of parental concerns about children and immunization W=Small sample size, making it difficult to generalize finding.s O=None stated T=Survey did not include open-ended questions to assess what parents are most concerned about regarding vaccinating their child. GRADE=**D**	Parents moderately to significantly concerned about vaccine pain in children < 24 mos. Barriers to implementing pain measures=parents were not aware of pain-relieving interventions, "doctor's never mentioned it"—EDUCATION NEEDED. Parents assumed pain was a "normal" part of vaccination process.
(Zurita-Cruz, Rivas-Ruiz, Gordillo-Álvarez, & Villasis-Keever, 2017) Mexico, MEDLINE	-infants 2-6 mos -vaccination pain -BF: indidicated as LM in study -MS (milk substitute)	AGREE level= 2 Duration of cry (Fort & Mafredi, 1998; Corwin, Lester, & Golub, 1996)	RCT, single-blind. (*N=144, 48 BF, 48 MS, 48 C)*	None	#39 S=observers were blinded to treatment groups (only heard voice	BF significantly reduced pain rating after vaccination and duration of cry.

	-control	University Pediatic Hospital of Wisoncsin (HUPW) pain scale (Soetenga, Frank, Pellino, & Hayes, 1999)			to assess cry duration). W=did not have O=studies comparing BF vs expressed breast milk in a similar single blind trial T=generalizes MS to be the same as SS in discussion and compares findings in other SR such as Shah et al. (2015). Does not specify what the milk substitute is (SS or type of formula)? GRADE=**B**	BF is effective for pain mgmt. during vaccination

Note. Manuscripts reviewed total 12, which incorporated the review of an additional 107 citations.

Legend: Developed from Davidson, J. U. (2003). Example knowledgebase development template. In Rankin, S. H., Dumas, M. A., & Reavis, C. (Eds.), *Grantsmanship: Developing a program of research, Appendix B* (pp. 77-78). Washington, DC: National Organization of Nurse Practitioner Faculties.

Appendix B

Summary of Systematic Review

Citation	Question	Search Strategy	Inclusion/ Exclusion Criteria	Data Extraction and Analysis	Key Findings	Recommendation / Implications	Level of Evidence
(Harrison, Reszel, Bueno, Sampson, Shah, Taddio, Larocque, & Turner, 2016), Canada, The Cochrane Database Of Systematic Reviews	Determine the effect of breastfeeding on procedural pain in infants beyond the neonatal period (first 28 days of life) up to one year of age compared to no intervention, placebo, parental holding, skin-to-skin contact, expressed breastmilk, formulamilk, bottle feeding, sweet-tasting solutions (e.g. sucrose or glucose), distraction, or other interventions.	Cochrane Central Register of Controlled Trials (CENTRAL) (the Cochrane Library), MEDLINE including In-Process & OtherNon-Indexed Citations (OVID), Embase (OVID), PsycINFO (OVID), and CINAHL (EBSCO); the metaRegister of Controlled Trials (mRCT), ClinicalTrials.gov (clinicaltrials.gov), and the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) (apps.who.int/trial	RCTs and quasi-RCTs involving infants 0 to 12months and receiving breastfeeding while undergoing a painful procedure. Efficacy compared to water, sweet solutions, expressed breast or formula milk, no intervention, use of pacifiers, positioning, cuddling, distraction, topical anaesthetics, and skin-to-skin care. Procedures included, but were not limited to: subcutaneous or intramuscular	Two reviewers evaluated trials for inclusion, assessed risk of bias, and extracted data. The main outcome measures were behavioral or physiological indicators and composite pain scores. Pooled data for most comparable outcomes and where data from at least two studies could be included. Mean difference (MD) with 95% CI, employing a random-effects model for continuous outcomes measured on the	BF consistently showed a decrease in cry duration and lower pain scores across studies compared to other methods of pain control (dextrose, topical analgesics, VCS, massage, cuddling) or no treatment groups. No adverse reactions are reported with BF Most studies were on infants' ages 1-6 months. Benefits of BF is in consensus of previous SR (Moderate quality of evidence).	Breastfeeding provides pain relief beyond neonatal period. Breastfeeding reduces behavioral responses of DOC and pain scores during and after vaccinations.	AGREE level= 1

		search/) for ongoing trials.	injection, venipuncture, intravenous line insertion, heel lance, and finger lance.	same scales. For continuous outcomes measured on different scales, data was pooled via standardized mean differences (SMDs) and associated 95% CIs. For dichotomous outcomes pooled events between groups across studies using risk ratios (RRs) and 95% CIs. Quality of evidence was rated using GRADE.			
Shah, Taddio, McCurtry, Halperin, Noel, Pillai Riddell, & Chambers, 2015), Canada, MEDLINE	Should breastfeeding be used during vaccine injections in children 0-2 y? If breastfeeding is not used during vaccine injections, should breastfeeding be used before vaccine injections in children	EMBASE, Mediline, PsycINFO, CINAHL, ProQuest dissertations & Theses Global. No language restrictions. 2 reviewers assessed eligibility.	Inclusion: children and adults undergoing routine vaccination in all clinical settings and any needle related procedures (venipuncture, venous	Data abstraction on a form and verified by 2 reviewers. Meta-analysis of prioritized outcomes, with validated tools. Pain and/or distress were	*BF is cost-neutral * Analgesic effects of BF also promote BF as choice of nutrition in infants! SS showed decreased distress in infants in acute	BF shown to be effective for infants undergoing minor painful procedures via comfort (close to mother), distraction, stimulation of oral	AGREE level= 1

	0-2 y? Should topical anesthetics be applied before vaccine injections in children 0-12 y? Should topical anesthetics be applied before vaccine injections in adolescents >12y and adults? Should topical anesthetics be used before vaccine injections in combination with breastfeeding during vaccine injections (rather than topical anesthetics or breastfeeding alone) in children 0-2 y? Should sucrose solution be given before vaccine injections in children 0-2 y? Should glucose solution be given before vaccine injections in children 0-2 y?		cannulation; sub-Q port access) and RCTs or quasi-randomized study designs. All published studies in full/short reports and academic theses. Exclusion: unclear outcomes or analegesic interventions; published abstracts, letters, commentaries, and editorials.	analyzed according to the phase of the procedures (i.e., pre-procedure phase, acute procedure phase, and the recovery phase. Bias reduced by including all studies with similar outcomes to be included in meta-analysis. Authors were contacted for more information is not clearly identified in study. Statistical analysis performed using Review Manager 5.2 (software by Cochrane collaboration. Results reported as SMD or RR and 95% CI. Risk of Bias tool used if necessary in a sensitivity analysis. Separate analyses made for :	and recovery phases; majority of studies used concentrations ranges from 20-33%; administered 2 minutes before and used 2ml volume. Inexpensive; can be made in pharmacy/clinic: mix 1 tsp sugar with 15ml of sterile water, yields 25% solution. TA shown to be an effective analgesia for infants and children; however COSTLY. ~$12 single patch, $50 for 60g tube; individual must self-pay, not available OTC; questionable effects on immunogenicity effect. OA did not show pain relief during vaccination	suck and sweet taste. Breastfeeding, topical anesthetics, sweet-tasting solutions, and combination of topical anesthetics and breastfeeding demonstrated evidence of benefit for reducing vaccine injection pain in infants and children.	

	Should sweet-tasting solutions (sucrose, glucose) be used before vaccine injections in combination with non-nutritive sucking (finger/thumb, pacifier) during vaccine injections (rather than sweet-tasting solutions or non-nutritive sucking alone) in children 0-2 y? Should breastfeeding and sweet-tasting solutions (sucrose, glucose) be combined together before vaccine injections (rather than breastfeeding or sweet-tasting solutions alone) in children 0-2 y? Should vapocoolants be applied before vaccine injections in children 0-3 y? Should vapocoolants be applied before vaccine injections in2			BF (0-2y); TA (ages 0-12, 12y-adults); SS (0-2y); VCS (0-3 y; children 3-17y, and adults). SS concentrations were analyzed for < 20%, 20-50%, and > 50%. Post-hoc analyses conducted to examine effects of methodology, heterogeneity or both. H	and has shown to reduce		

	children >3-17 y? Should vapocoolants be applied before vaccine injections in adults? Should acetaminophen be given before vaccine injections in individuals of all ages?						
(Stevens, Yamada, Ohlsson, Haliburton, & Shorkey, 2016), Canada, The Cochrane Database Of Systematic Reviews	How well does SS alleviate pain in newborns undergoing painful prcoedures (IM inj, heel lance, venipuncture or eye exam).?	Lit search for sucrose pain-relief for minor procedures in pre-term and term neonates up to Feb 2016.	Inclusion: RCT only. Identified 74 studeis with more than 700 infants. 38 full term infants; 31 pre-term, 5 included both.		High-quality evidence for support of using 2ml of 24% sucrose prior to heel lance, and venipuncture and IM inj. **(GRADE A).** High quality evidence for 24% sucrose with NNS (or 0.5ml) during heel lance (**GRADE A/B).** Moderate quality evidence of SS + NNS=more efficacious. No adverse reactions documented.	**S**S has a rapid onset of endogenous opioid release. Higher concentrations of SS yields more pain relief.	AGREE level= 1

Legend: Developed from Davidson, J. U. (2003). Example knowledgebase development template. In Rankin, S. H., Dumas, M. A., & Reavis, C. (Eds.), *Grantsmanship: Developing a program of research, Appendix B* (pp. 77-78). Washington, DC: National Organization of Nurse Practitioner Faculties.

Appendix C

Plan for Educational Offering

The purpose of this presentation is to increase knowledge and awareness of nurses regarding how infants experience pain and how to implement infant pain management during routine vaccination/minor painful procedures. Committee members: Nikki Smith, DNP, FNP-BC (MAJ, USA) & Mona Abukhaled, MSN, C-PNP				
OBJECTIVES	**CONTENT (Topics)**	**TIMEFRAME (minutes)**	**PRESENTER**	**TEACHING METHODS**
1. Discuss how infants experience pain	a. Anatomical, physiological, and biochemical factors for pain perception is present during intrauterine development b. Nociceptive stimuli processed via unmyelinated pathway c. Lower threshold to activate pain pathway d. Relatively higher concentration of P receptors e. Fewer inhibitory neurotransmitters f. Parental's emotions affect infant's response to pain	15	Mona Abukhaled, MSN, C-PNP	Power point presentation Roundtable discussion Facilitator led
2. Review CPG for infant pain relief during vaccine administration	a. Non-pharmacological b. Psychological c. Pharmacological	15		Power point presentation Roundtable discussion Facilitator led

3. Discuss procedure of implementation pertaining to DNP project	a. Breastfeeding b. 24% sucrose solution c. Parental survey pre/post intervention d. Demonstration	20		Power point presentation Roundtable discussion Facilitator led
4. Q and A		10		Audience participation

References:

1. **Czarnecki, M. L., Turner, H. N., Collins, P. M., Doellman, D., Wrona, S., and Reynolds, J. (2011). Procedural pain management: A position statement with clinical practice recommendations. *Pain Management Nursing, 12*(2), 95-111. doi:10.1016/j.pmn.2011.02.003**
2. **Fitzgerald M. (1995). Developmental biology of inflammatory pain. *Br J Anaesth, 75,* 177–85. doi:10.1093/bja/75.2.177**
3. **Hatfield, L. A., Meyers, M. A., Messing, T. M. (2013). A systematic review of the effects of repeated painful procedures in infants: Is there a potential to mitigate future pain responsivity? *Journal of Nursing Education and Practice, 3*(8), 99-112. doi:10.5430/jnep.v3n8p99**
4. **Mathew, P. J., & Mathew, J. L. (2003). Assessment and management of pain in infants. *Postgrad Med J, 79,* 438-443. doi:10.1136/pmj.79.934.438**
5. **Stevens, B., Yamada, J., Ohlsson, A., Haliburton, S., & Shorkey, A. (2016). Sucrose for analgesia in newborn infants undergoing painful procedures. *Cochrane Database Syst Rev, 7*(7):CD001069.**
6. **Taddio, A., McMurtry, C. M., Shah, V., Riddell, R. P., Chambers, C. T., Noel, M., … Votta Bleeker, E. (2015). Reducing pain during vaccine injections: Clinical practice guideline. *CMAJ: Canadian Medical Association Journal, 187*(13), 975-982. doi:10.1503/cmaj.150391**
7. **Taddio, A., Shah, V., Wang, J., Parikh, C., Smart, S., Ipp, M., … Franck, L. S. (2015). Usability and knowledge testing of educational tools about infant vaccination pain management directed to postnatal nurses. *BMC Medical Education*, *15*, 45. doi:10.1186/s12909-015-0305-6**
8. **WHO: SAGE working group on vaccine hesitancy. (2015). Report to SAGE on reducing pain and distress at the time of vaccination. Retrieved from: http://www.who.int/immunization/sage/meetings/2015/april/1_SAGE_latest_pain_guidelines_March_24_Final.pdf?ua=1**

Appendix D

Letter of Support

William Beaumont Army Medical Center
5005 N. Piedras Street
El Paso, TX 79920-5001

9 January 2019

To Whom It May Concern,
Mona Abukhaled and I have discussed her proposed DNP Project focusing on improving pain management for infants undergoing routine immunization. I am providing assistance with obtaining full authorization for Mona Abukhaled to implement her project within William Beaumont Army Medical Center. Additionally, Mona Abukhaled is requesting authorization to access electronic / physical medical records in order to collect primary and secondary data relevant to her DNP Project.

The process for obtaining IRB approval or exemption for any DNP projects is initiating contact with Dr. Larissa A. Schmersal, Ph.D, WBAMC Human Research Protections Office, Human Protections Administrator at Larissa.a.schmersal.civ@mail.mil. The new submission requirements are in the process of being revised and should be available on or around 21 January 2019. I have attached a copy of the current process to this email.

Please do not hesitate to contact me at (915) 742-4435 or nikki.r.smith3.mil@mail.mil if I can be of further assistance.

Nikki R. Smith, DNP, FNP-BC
MAJ, AN,
USU DNP Phase II Site Director

Appendix E

SWOT Analysis

Strengths	Weaknesses
• Congruent mission statement: Mission statement states that pain management is a priority. • Once nurses are aware of non-pharmacological methods, it can quickly be administered while obtaining vaccine consent and reviewing vaccine effects. • Natural: Breastfeeding is a natural pain-alleviating measure that mothers can provide for their infant. • Non-pharmacologic: Sucrose solution is another safe, non-pharmacological method of pain control. • Safe: No side effects have been reported with these pain strategies. • Implementing these non-pharmacological methods are cost neutral or most cost effective compared to pharmacological methods of pain management. • No physician order required. • Promote maternal-infant bonding and infant regulation of pain experience.	• Time constraints: project will only be conducted over 8 weeks and is limited to infants ages 2-6 months old. Only information from project surveys can be used to measure satisfaction and feedback data. • Optimal pain management has shown that optimal pain relief was established with a combination of pharmacological and non-pharmacological measures such as topical anesthetics, however, it was omitted due to organizational cost and lack of leadership support. • Pain assessment scale will not be used to adequately obtain objective infant pain levels, nor will there be a comparative group.

Opportunities	Threats
• Improve patient/parental satisfaction: attention to pain management strategies may improve parental satisfaction with vaccine process and/or clinic visit. • Decrease vaccine hesitancy: Implementing pain management to infants can promote adherence to prescribed vaccine schedule and decrease vaccine hesitancy related to concerns of pain. • Policy development: Success may influence new policy development in pediatric clinic, and other outpatient clinics to adopt similar policies/procedures for pain management methods in infants undergoing routine vaccination. • Other institutions: Similar pain management policies may be adapted at other military institutions. • Promote breastfeeding: using breastfeeding for pain management during vaccination can further promote mothers to continue breastfeeding infants due to its natural analgesic effects.	• May be difficult to obtain objective information from parents that are unable to be calm and participate in holding their infant. • Nurses are used to having infant on exam table for stability and are not used to having parents holding the infant. This will be difficult to diminish and may cause confounding results. • Minor procedures are not perceived as a concern, and it may be difficult to influence staff about how important it is to implement simple pain mgmt. strategies. • Work disruption: Staff nurses may view this as “extra tasks” that are unnecessary and disrupt their workflow.

• Pain policy for vaccination or all children undergoing minor procedures may follow the results of the project.	

Appendix F

Budget for DNP Evidence-Based Project

Expenses	Amount Requested	Total
• **Personnel Expenses** o Clinical Resources ▪ DNP project manager ▪ Pediatric Charge nurse ▪ Pediatric Clinical Nurses o Analysis Resource ▪ Statistician	No additional personnel needed No cost	0
• **Operating Expenses** o Printed Surveys ▪ Paper ▪ Ink cartridge o Intervention Supplies ▪ 24% Sucrose Solution	$ 17.99 In kind In kind (regular clinic supply)	
Total Expenses	$17.99	$17.99

Appendix G

Permission for Survey Use

Zhao, A., Leong, R., & Watson, W. (2015). A survey of parental barriers to using pain-reduction strategies during childhood immunizations. *UBC Medical Journal*, *6*(2), 11–14. Retrieved from http://med-fom-ubcmj.sites.olt.ubc.ca/files/2015/02/ubcmj-v6i2-web.pdf#page=11

On Fri, 4 Jan 2019 at 10:44, Mona Abukhaled <monanp1@yahoo.com> wrote:
Dear Dr. Zhao,
I read your article "A Survey of Parental Barriers to Using Pain-Reduction Strategies During Childhood Immunizations." I thoroughly enjoyed the article as well as the results learned from this investigation. Additionally, I have used the article as a scholarly reference to support the development of my capstone project for a qualitative improvement project as a doctoral nursing student. I would like to request permission to use the survey developed for this qualitative study for my capstone project. I am a Pediatric Nurse Practitioner working in a primary care pediatric clinic, DNP student at Chamberlain University. I appreciate your consideration for this valuable project that I would like to implement in my studies and organization. Adequate credit will be given if consent is granted.

Kind Regards,
Mona Abukhaled, MSN, C-PNP
Doctoral Nursing Student

From: Alex Zhao <alex.zhao@mail.utoronto.ca>
Subject: Re: Permission for survey use
Date: January 6, 2019 at 6:55:08 PM MST
To: Mona Abukhaled <monanp1@yahoo.com>

Hi Mona,

Sure, you're welcome to use them for your project.

Best,
Alex

Appendix H

Parental Survey

Parental Concern for Pain (Pre)

1. Please rate your level of concern about pain regarding your child's current vaccination:

1	2	3	4	5

Not concerned Moderate Very concerned

2. Are you interested in learning about strategies to decrease pain during your child's vaccinations?

YES or NO

3. Below is a list of ways to reduce pain. Please select if you have tried any. If yes, go down to the next row. If no, go across to the right column.

Strategy	Yes, I've tried	Tried but didn't work	No, I haven't tried	If No, please select all reasons that apply (you may choose more than one)
Breastfeeding the infant during injection (skip for men)	☐	☐	☐	☐Doctor has not discussed with me ☐I'm not comfortable with this ☐It won't work ☐Never heard of this ☐Not enough time for this ☐Pain is okay ☐This is our first vaccination ☐Other (please specify)
For children up to 12 months, feeding them	☐	☐	☐	☐Doctor has not discussed with me

sugar water during the injection				☐I'm not comfortable with this ☐It won't work ☐Never heard of this ☐Not enough time for this ☐Pain is okay ☐This is our first vaccination ☐Other (please specify)

Parental Concern for Pain (Post)

Please rate your level of concern about pain during your child's most recent vaccination:

1 2 3 4 5

Not concerned Moderate Very concerned

Would you recommend this form of pain management to others?

YES or NO

Are you satisfied with your method of pain management today?

1 2 3 4 5

Not satisfied Moderate Very satisfied

Adapted with permission from:

Zhao, A., Leong, R., & Watson, W. (2015). *Appendix A: What are the parental barriers to applying pain reduction strategies for their child during routine vaccination? UBC Medical Journal*, *6*(2), 47. Retrieved from http://med-fom-ubcmj.sites.olt.ubc.ca/files/2015/02/ubcmj-v6i2-web.pdf

For Administrative Use Only:
Parent answering survey: Mother/Father/Caretaker
Infant age:
First-time parent? Yes or No
First-time vaccination? Yes or No

Appendix I

Timeline for Project Implementation

Week/Date	Objectives to complete
1: July 8-12	Begin implementation with educational offering for nurses; review DNP procedure and obtain pre/post nursing knowledge survey. Prepare for implementation and ensure that SS is in stock and available. Prepare copies of parental surveys and distribute to each nurse for data collection. Meet with nurses individually to ensure that process is understood and answer questions.
2: July 15-19	Recruit subjects for breastfeeding and SS groups; provide staff support
3: July 22-26	Recruit subjects for breastfeeding and SS groups; provide staff support. Intermittent project evaluation to assess progress and address concerns.
4: July 29-Aug 2	Midway evaluation of project implementation phase; make any necessary changes; meet with nurses if needed
5: Aug 5-9	Continue recruiting subjects for both groups.
6: Aug 12-16	Recruit subjects for each group. Intermittent project evaluation to assess progress and address concerns.
7: Aug 19-23	Recruit additional subjects for either arm if goal of 50/grp was not met.
8: Aug 26-30	End of implementation phase; thank you staff commencement and lunch. Collect final data pieces. Assess staff feedback and generate a post project report.

Figures

Figure 1.1. Frequency of Parental Level of Concern (Pre and Post): Breastfeeding Group

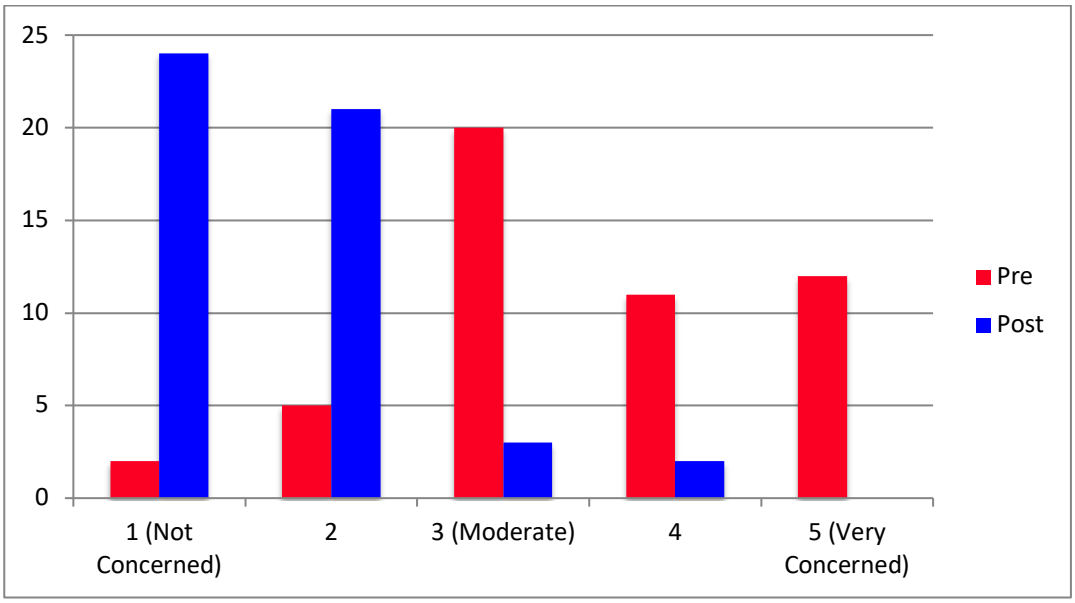

Figure 1.2 Frequency of Parental Level of Concern (Pre and Post): Sucrose Group

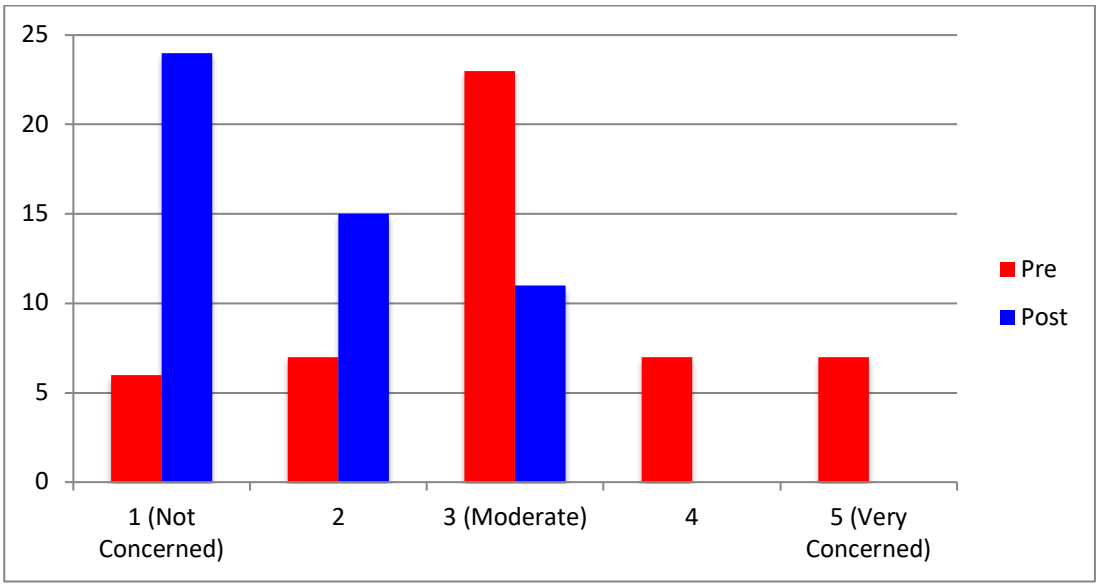

Figure 1.1 and 1.2. Distribution of pre- and post- parental levels of concern for pain by intervention group. The figure shows how the levels of parental concern decreased after intervention (post).

Figure 2. Parental Concern for Pain (Combined Data)

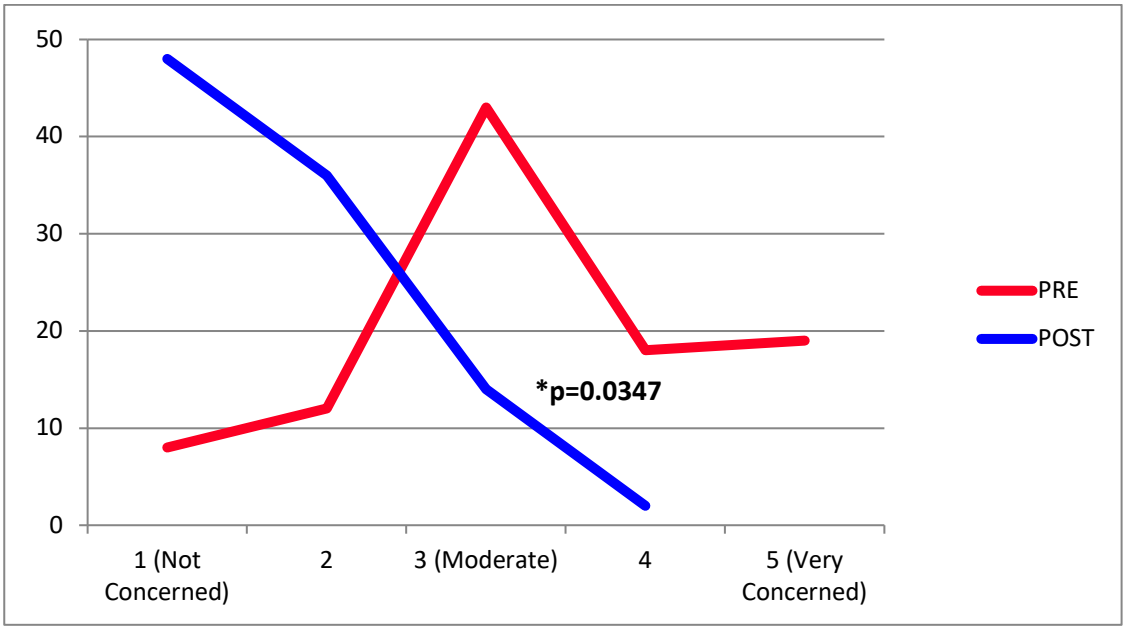

Figure 2. After analyzing data from both interventions, this figure depicts how parental levels of concern for pain is decreased after the implementation of non-pharmacological interventions. The Fisher's Exact Test showed a significant difference in the distribution of change in parental concern from pre- to post- ($p = 0.0347$).

Figure 3. Level of Satisfaction with Non-pharmacological Intervention

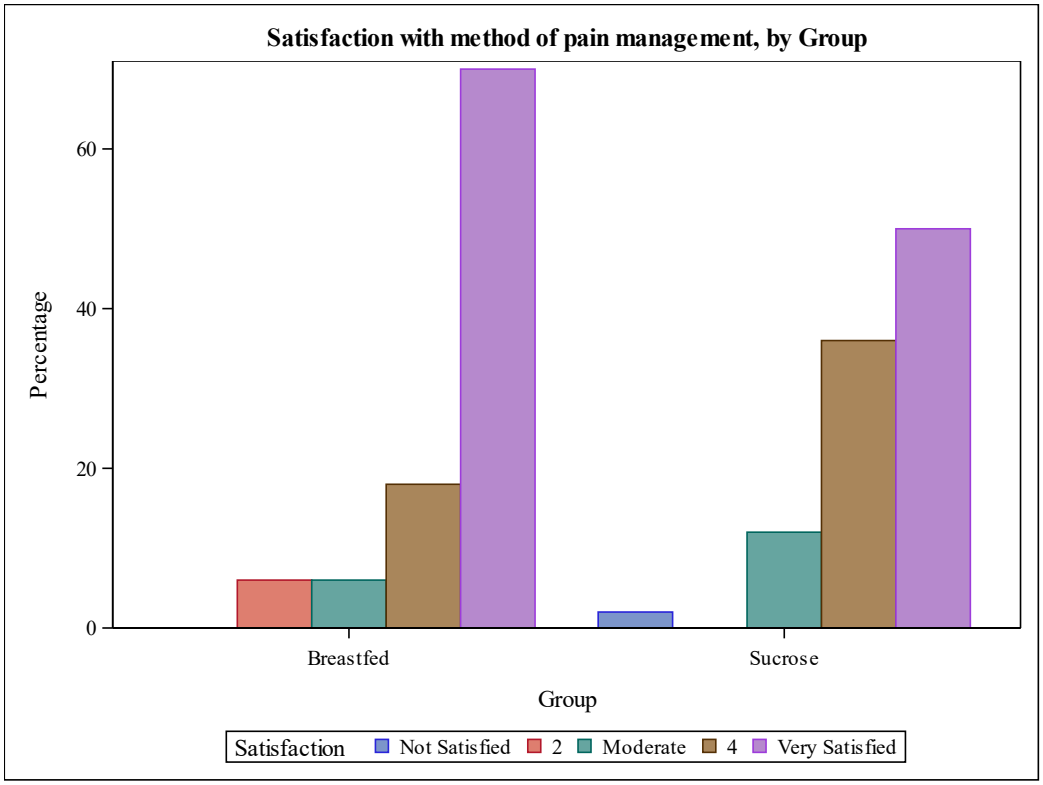

Figure 3. Distribution of parental levels of satisfaction with non-pharmacological pain relief method by intervention group. Majority of parents reported higher levels of satisfaction (4 &5).