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Implementation of an Oral Sucrose Protocol for Advanced Practice Providers

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Implementation of an Oral Sucrose Protocol for Advanced Practice Providers: Review of Literature

BY

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Implementation of Oral Sucrose in Infants

This Doctor of Nursing Practice (DNP) Project is approved as a credible and independent investigation by a candidate for the DNP degree and is acceptable for meeting the project requirements for this degree. Acceptance of this DNP Project does not imply that the conclusions reached by the candidate are necessarily the conclusions of the major department.

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Abstract

Introduction: Pain related to immunization administration in infancy can lead to negative effects on neurodevelopment, needle fear, vaccine hesitancy, and endemic outbreaks of previously eradicated diseases. Pain management in immunization administration may be done safely and effectively through use of oral sucrose.

Methods: Using the keywords oral sucrose, immunizations, infants, sucrose, pain, analgesia, vaccine, intramuscular injection, advanced practice providers, and knowledge, attitudes, and practice survey, a literature search was completed using the databases Cochrane, Wiley, Science Direct, Ovid, and Cumulative Index to Nursing and Allied Health Literature. Full-text, peer-reviewed articles published in English between 2011 and 2023 were included. A total of 17 articles were selected for the literature review and were assigned a level and grade with guidance from the Johns Hopkins Nursing Evidence-Based Practice Model.

Gaps: There is a lack of evidence within the setting of a clinic that administers routine immunizations for infants 6 months of age and younger, as many studies focus on premature infants in a neonatal intensive care setting. There are also gaps in research on simultaneous nonnutritive sucking, minimally effective dose, and maximum number of repeated doses.

Recommendations: Implementation of an oral sucrose protocol for advanced practice providers can improve their knowledge, attitudes, and practice.

Implementation of an Oral Sucrose Protocol for Advanced Practice Providers: Review of Literature

Immunizations are a global health success story and are considered a basic human right. Immunizations reduce risks of both getting and transmitting a disease. Currently, vaccines are available to prevent more than 20 life-threatening diseases, and more are being researched and developed (World Health Organization, n.d.). Immunizations save nearly three million lives each year (Gad et al., 2019). Despite countless benefits, immunizations are among the most common yet unpleasant procedures of childhood. The Centers for Disease Control and Prevention (CDC) recommends 24 immunizations during the first 2 years of life, and it is not uncommon for three or four to be given at one visit (Abukhaled & Cortez, 2020; Kumar et al., 2019; McNair et al., 2019; Yilmaz et al., 2014). Many immunizations are intramuscular injections but there are some that are administered orally. Throughout this paper, any reference to immunizations or vaccines implies those administered by injection.

At birth, an infant's nervous system is mature enough to perceive pain to its full extent (Chang et al., 2020; Kavthekar et al., 2016; Liaw et al., 2011; Uzelli & Gunes, 2014). While pain caused by immunization administration is often short-lived, it can lead to numerous negative effects in neurodevelopment, brain function, and future pain perception. Uncontrolled pain in infancy can also produce negative physiologic, behavioral, hormonal, and metabolic changes (Banga et al., 2016; Harrison, 2020; Kavthekar et al., 2016; Liaw et al., 2011; McNair et al., 2019; Stevens et al., 2016; Uzelli & Gunes, 2014). In addition to negative developmental impacts, immunization-related pain causes distress and anxiety in infants, parents, and healthcare providers. This distress

often leads to parental hesitancy in following vaccination schedules, increasing the number of unvaccinated infants and children. Recently, this hesitancy has resulted in endemic outbreaks of measles and pertussis (Abukhaled & Cortez, 2020; Harrison et al., 2016; Kumar et al., 2019).

Besides preventing endemic outbreaks, an increase in vaccination rates also decreases healthcare costs associated with preventable illnesses. While there are costs associated with vaccination programs, the result of widespread vaccination is decreased morbidity and mortality and decreased costs related to procedures, tests, and treatment of preventable illness. Additionally, the financial status of patients and parents is improved because they are taking less time off work. It has been found that industrialized nations, such as the United States, obtain a net economic benefit of $69 billion as a result of successful vaccination programs (Rodrigues & Plotkin, 2020).

Learning about pain begins at one's first perception of pain. The experience infants have with pain has long-lasting effects on pain perception and response, and often leads to severe fear and avoidance of needles. An estimated two-thirds of children will develop needle fear as a response to repeated painful experiences, and this fear can extend into adulthood. Nearly 25% of adults have a fear of needles that developed in childhood, and nearly 10% of the adult population avoids immunization because of their fear (Gad et al., 2019; Kumar et al., 2019; Yilmaz et al., 2014). The reason for untreated pain in infancy is often due to misconceptions and a lack of understanding by healthcare providers. Opportunity exists to manage pain during routine infant and childhood immunizations.

Oral sucrose has become the most widely studied pain intervention (McNair et al., 2019). Oral sucrose has shown to have analgesic and calming effects in children up to 18 months of age. In addition to reducing pain response safely, administration of oral sucrose has also shown to reduce physiologic indicators, such as crying time and heart rate with no negative impact on neurodevelopment (Banga et al., 2016; Levine, 2017; Matsuda, 2017; Stevens et al., 2018; Valeri et al., 2018). The aim of this literature review is to identify recommendations, safety, and effectiveness of oral sucrose when given to minimize immunization-related pain and utilize the information to develop a protocol for advanced practice providers to implement.

Clinical Question

The population, intervention, comparison, outcome, and time (PICOT) question guiding this literature review is as follows: Among advanced practice providers in a family practice clinic that serves rural communities (P), how does the implementation of an oral sucrose protocol (I), compared to no protocol (C), affect knowledge, attitudes, and practices (KAP) regarding oral sucrose (O), within 8 weeks (T)?

Methods

A literature review was completed through Google Scholar and the Hilton Briggs Library. Cochrane, Wiley, Science Direct, Ovid, and The Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases were used to collect articles. When searching the databases, the following keywords were used: *oral sucrose, immunizations, infants, sucrose, pain, analgesia, vaccine, intramuscular injection, advanced practice providers,* and *knowledge, attitudes, and practice survey.* Inclusion criteria included full text, peer-reviewed articles published between 2011 and 2023 that were written in

English. Exclusion criteria included articles published before 2011, sources not available in full text, and articles not written in English.

Articles produced in the search were chosen based on applicability, and a total of 17 were selected for the literature review. The 17 articles are outlined in an evidence table that can be found in Appendix A. To assist in assigning a level and grade to each article, the Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) Model from 2017 was utilized. The JHNEBP model produced the following results: 11 level I articles, one level II article, and five level III articles. Of those, 10 articles are grade A, and seven articles are grade B. A table showing the levels of evidence can be found in Appendix B.

A search for guidelines to assist in intervention planning was conducted which produced minimal results. Guidelines published by the Royal Children's Hospital (RCH) in Melbourne, Australia were the only easily accessible and publicly published guidelines available to review and reference. Upon review, the guidelines from RCH provided strong, evidence-based recommendations for the use of oral sucrose in infants for painful procedures while including details such as indications, contraindications, methods, dosing, and administration techniques (Kendrick, 2021). To determine the strength and quality of the RCH guidelines, an appraisal of guidelines for research and evaluation II (AGREE II) tool score was calculated. The AGREE II tool assesses the scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence of published guidelines (National Collaborating Centre for Methods and Tools, 2017). Based on the AGREE II tool, the overall quality of the RCH guidelines is 6 out of 7, indicating great quality.

Evidence Summary

This literature search produced results with strong evidence, collected from peer-reviewed articles, and supports the use of oral sucrose prior to immunizations and other painful procedures in infancy and childhood. The studies were completed under a variety of different conditions for varying populations, yet results remain fairly consistent. Consistency in results despite varying studies further supports the development of an oral sucrose protocol for infants receiving immunizations. When completing the literature search, there was no literature on expert opinions surrounding the use of oral sucrose.

Guidelines developed by RCH in Melbourne, Australia were reviewed along with peer-reviewed articles. As mentioned above, these were the only accessible and public guidelines, which resulted in them being the only guidelines reviewed. Despite only reviewing one set of guidelines, those produced by RCH overlap with the information found in the articles reviewed, further supporting the evidence that has been gathered (Kendrick, 2021). The following section will provide specific information about oral sucrose, pain and physiologic responses, parent approval, and provider knowledge, attitudes, and practices.

Oral Sucrose

Sucrose activates the central endogenous opioid system, producing results similar to those of opioids and stimulates the release of endorphins, which bind to opioid receptors and inhibit the feeling of pain (Kavthekar et al., 2016). These effects are attributed to the sweet taste. When given 2 minutes prior to injection, which has been determined as the peak effect, the infant experiences relief from pain as evidenced by decreased pain scores, lower heart rate variability, and reduced crying time (Kavthekar et

al., 2016; Kumar et al., 2019; Liaw et al., 2011; Uzelli & Gunes, 2014). In addition to the analgesic effects, the use of oral sucrose as a nonpharmacologic pain intervention is convenient. Oral sucrose can be used without a prescription and is inexpensive, as opposed to pharmacological interventions, which are not as effective and tend to elicit side effects (Liaw et al., 2011).

Though the research of oral sucrose is becoming more widespread, the concentration and dose of the solution can vary from study to study. Oral sucrose is most commonly studied in concentrations of 20-30% but concentrations as high as 75% have been studied. The American Academy of Pediatrics (AAP) recommends using a 24% concentration of oral sucrose (Chang et al., 2020; Matsuda, 2017). Oral sucrose solution is generally dispensed in 2 mL syringes or droppers. The dose of oral sucrose ranges from 0.5 to 2 mL of solution. It has been proven that 0.1 mL per dose is the minimally effective dose in reducing injection-related pain (Stevens et al., 2018).

Research has also shown that oral sucrose can be used safely in the pediatric population up to 18 months of age (Kumar, 2019; Liaw, 2022; Stevens, 2016). Oral sucrose in older infants and toddlers can be effective in reducing pain response and crying time, but higher sucrose concentrations may be required. In one study, it was found that response to oral sucrose was not as evident when using 12% sucrose, and some children required up to 75% sucrose to produce a significant effect on injection-related pain (Yilmaz, 2014).

Pain Response

Pain can be difficult to determine in infants as they cannot verbally express their pain. There are a variety of pain scales designed for use in infants and children. While

there can be variability among each examiner's interpretation of findings, these pain scores can also be extremely beneficial in providing information on infant pain response. Chang et al. (2020) compared pain scores after a painful procedure among five different intervention groups: (a) breastfeeding, (b) nonnutritive sucking, (c) skin-to-skin, (d) oral sucrose, and (e) a control group. Using the Neonatal Pain, Agitation and Sedation Scale (NPASS), the mean pain score for the oral sucrose group was 1.01 out of 13. Pain scores in the comparison groups were 5.14, 1.88, 1.84, and 3.21 out of 13 in the control, breastfeeding, nonnutritive sucking, and skin-to-skin groups respectively (Chang et al., 2020). In another study comparing the effect of (a) oral sucrose, (b) breastfeeding, and (c) control groups when given to infants receiving intramuscular injection, the Face, Legs, Activity, Cry, Consolability (FLACC) pain scale was used to show the effectiveness of both breastfeeding and oral sucrose, and both groups showed significant improvements in pain scores. In this study, the control group had a mean pain score of 8.9 out of 10, while oral sucrose and breastfeeding groups produced mean pain scores of 3.2 and 2.6 out of 10 respectively (Gad et al., 2019).

Other studies compared oral sucrose to control groups and topical anesthetic solutions while utilizing the Modified Behavior Pain Scale (MBPS) and the Neonatal Infant Pain Scale (NIPS) for data collection (Kumar et al., 2019; Uzelli & Gunes, 2014). When comparing oral sucrose to topical anesthetic, the MBPS found a mean of 5.09 out of 10 for the oral sucrose group (Kumar et al., 2019). The topical anesthetic group had a mean pain score of 5.74, and the control group had a mean of 6.7 out of 10. This data was found to be statistically significant by a chi squared test and *t*-test (Kumar et al., 2019). Additionally, Uzelli and Gunes (2014) utilized NIPS and results showed the control

group had a mean pain score of 5.6 while the oral sucrose group had a mean of 4.2 out of 10. A two-tailed *t*-test found the results to be statistically significant with a *p* value of less than 0.001 (Uzelli & Gunes, 2014). These statistics reflect consistently lower pain scores in the oral sucrose intervention groups and reinforces the efficacy of oral sucrose as a pain management intervention.

Physiologic Indicators

Along with pain scales, physiologic indicators are an effective way to determine the pain and distress an infant is experiencing. In studies analyzing the use of oral sucrose, crying time and heart rate fluctuations were the most commonly assessed physiologic indicators. When assessing heart rate variability, it was found that the oral sucrose group had a smaller increase in heart rate after the painful stimulus. When comparing sterile water, breastmilk, and 24% sucrose, the change in heart rate from baseline was 18.2, 7.4, and 3, respectively (Kavthekar et al., 2016). Additionally, the total duration of crying after injection was significantly reduced in several studies. Chang et al. (2020) provided statistics that showed a mean cry time of 9.6 seconds for the oral sucrose group. Other cry times include 81, 90, 73.2, and 284 seconds for the breastfeeding, skin-to-skin, nonnutritive sucking, and control groups respectively. This was proven to be statistically significant with a *p* value of < 0.01 through analysis with the Kruskal-Wallis test (Chang et al., 2020). Yilmaz et al. (2014) found crying time to range from 85.6 to 154.4 seconds in the control group while the oral sucrose group ranged from 36.2 to 88.2 seconds. This was analyzed with the ANOVA test and produced a *p* value of < 0.001 (Yilmaz et al., 2014). Kavthekar et al. (2016) found the mean crying time to be 36.3 seconds in the oral sucrose group, 42.1 seconds in the breastfeeding group, and 137.2

seconds in the control group. ANOVA analysis was also used in this study which confirmed statistical significance (Kavthekar et al., 2016). Finally, in a study written by Levine (2017), it was specifically noted that the duration of cry in the oral sucrose group was reduced by 12-77 seconds.

When assessing physiologic indicators such as heart rate variation and crying time, Kavthekar et al. (2016) paid specific attention to the duration of the first cry. The first cry is defined in the article as the duration of continuous crying before a quiet interval of 5 seconds. In that study, the duration of first cry was reduced by up to 75 seconds ($p < 0.05$; Kavthekar et al., 2016).

Breastfeeding is often a common comparison group for pain management during immunizations. Breastfeeding has been consistently proven as effective in reducing pain following immunization administration, but studies are inconsistent on whether breastfeeding is more effective than oral sucrose for pain management. Some report oral sucrose being more effective while others report breastfeeding to be more effective (Chang et al., 2020; Gad et al., 2019; Kavthekar et al., 2016). However, despite its effectiveness, it has been reported that while breastfeeding reduced the pain score, it did not affect any physiologic indicators (e.g., crying duration or heart rate reduction; Harrison et al, 2016).

Parental Response

Parents ultimately make the decision if their infant will receive all recommended immunizations per CDC guidelines in their first 2 years of life. While pain control is a moral obligation for the infant, it also provides a sense of comfort and satisfaction to parents and increases adherence to the recommended immunization schedule (Yilmaz et

al., 2014). Studies have shown that the distress of the parent and infant during routine immunizations causes vaccine nonadherence at the parent's discretion (Harrison et al., 2016; Kumar et al., 2019). When educated on nonpharmacologic pain interventions and questioned on awareness and approval before and after intervention, there was a great response for satisfaction. In one specific study, 96% of parents would recommend the use of oral sucrose to other parents, and 87% of parents were satisfied with the effects of the pain intervention (Abukhaled & Cortez, 2020).

Knowledge, Attitudes, and Practice

Knowledge, attitudes, and practice surveys are used to collect information, often on health practices. They have many advantages including ease of use, relative generalizability, and cost-effectiveness (Patel, 2022). When completing a literature review, there was no information found on KAP surveys and oral sucrose protocols, specifically. When the search was widened to determine the effect of protocols in general on the KAP of advanced practice providers (APPs), there were still no findings. However, many results populated related to KAP surveys and a variety of protocols, indicating they are commonly used across healthcare settings. As of right now, there is no clear expression of the feelings of healthcare workers administering vaccines to infants before and after pain interventions.

Gaps in the Literature

There are gaps in the literature in relation to the population of infants receiving immunizations in a clinic setting. Many studies reviewing the use of oral sucrose for pain management are set in a neonatal intensive care unit with premature infants as the population of interest. There are also gaps involving the use of nonnutritive sucking as an

aide in pain management. Nonnutritive sucking is often compared to oral sucrose to determine which intervention produces greater results, but evidence is lacking if use of the two simultaneously enhance pain relief. There are gaps in evidence regarding how much sucrose to administer in each dose and how many doses can be given consecutively. Along with the dose of sucrose that should be administered, there is a lack of evidence regarding the long-term effects of sucrose after repeated administration (Stevens, 2018).

Recommendations for Practice

Pain management during infancy, and especially during injections, is helpful to prevent needle fear and vaccine nonadherence. Nonpharmacologic pain interventions have repeatedly proven to be safe and effective, with oral sucrose being recommended from numerous sources, including the AAP (Abukhaled & Cortez, 2020; Chang et al., 2020). In order to improve the KAP of APPs regarding oral sucrose, implementation of a protocol is recommended to provide consistency in oral sucrose indications and administration while allowing APPs to incorporate oral sucrose into their practice in a way they are comfortable with.

Conclusion

Pain management in infancy as a whole is underutilized due to misconceptions in the infant's pain experience and development of the neurologic system (Abukhaled & Cortez, 2020). Painful procedures can have significant negative effects on neurodevelopment and even short-term pain can have detrimental, long-lasting effects (Banga et al., 2016). Various nonpharmacological interventions have been tested, and of those, many have proven effective. Oral sucrose has been found to produce the most

consistent results and is recommended by the AAP (Changa et al., 2020). Despite the evidence, oral sucrose is not yet a well-known, widespread practice. Oral sucrose, when utilized to manage immunization-related pain in infancy, may be beneficial in preventing vaccine nonadherence and needle fear as well as preventing negative impacts on neurodevelopment throughout the first 2 years of the child's life. Educating APPs on oral sucrose and implementing a protocol regarding oral sucrose use prior to immunizations can close the gap in knowledge and promote incorporation into everyday practice.

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Appendix A

Evidence Table

Authors & Date	Study Design	Participants, Sample, Setting	Intervention /Variables Studied	Measure-ment	Data Analysis	Findings/ Recommend ations for Practice	Strengths/ Limitations	Level of Evidence
Abukhaled, M. & Cortez, S. (2020).	Pre- and post-evidence-based implementat ion design	100 infants up to 6 months of age presenting to the clinic for routine well-baby examination and vaccinations	While being held by their parents, infants were either breastfed or given 24% sucrose solution for pain relief.	Pre and post intervention survey with a 5-point Likert scale. The survey studied the level of parental concern for infant vaccine-related pain before and after implementat ion of pain relief intervention s.	Fisher exact test and Wilcoxon-Mann-Whitney test. Both tests revealed significant differences in parental concern when comparing pre- and post-intervention surveys with *p* values of 0.48 and 0.38 respectively.	Both intervention groups showed significant differences in parental concern from pre- to postinterven tion. Pre-intervention surveys showed 43% of parents had a moderate level of concern and 37% had higher levels of concern.	Strengths: minimal cost, ease of use, absence of adverse reactions. Limitations: limited population of 6 months, lack of nurse compliance to the intervention, limited generalizabi lity,	Level III: Quality Grade B

						After observing the pain intervention, 14% of parents reported moderate levels of concern and 2% reported higher levels of concern. Providing pain relief is a moral and ethical obligation and pain relief interventions should be common practice		
Banga, S., Datta, V., Rehan, H. S., &	Randomized Controlled Trial (RCT)	93 clinically stable preterm newborns in the neonatal	Neonates were administered either a 24% sucrose	Motor development and vigor (MDV) and alertness	Unpaired and paired t-tests. The test was not statistically	No difference in neurobehavioral scores in either	Limitations: low likelihood of adverse neurodevelo	Level I: Quality Grade B

Bhakhri, B. K. (2016).		care unit at a tertiary-level teaching hospital.	solution or double-distilled water depending on randomization for every potentially painful procedure over a 7 day period.	and orientation (AO) domains performed at 40 weeks gestational age. Measurement of highest heart rate and lowest SpO2 obtained 30 seconds after the prick.	significant indicating no change in MDV or AO in sucrose groups.	group. No difference in the frequency of adverse effects such as fall in heart rate or oxygen saturation. Recommend using sucrose for single painful events as well as repeated events. Recommend further studies with a longer follow up period to follow neurodevelopmental outcomes.	pmental outcomes.	

Chang, J., Filoteo, L., & Nasr, A. S. (2020).	RCT	226 full-term infants aged 24-48 hours in a California tertiary-level hospital maternity unit.	Infants were given one of four nonpharmacological pain interventions: breastfeeding, sucrose, nonnutritive sucking, and skin-to-skin contact during heel lance procedure.	NPASS pain score	t-test for 2 independent samples with normal distribution and Wilcoxon-Mann-Whitney test for nonparametric distribution. Oral sucrose was shown to be the most effective intervention in reducing pain and shortening crying time with *p* values of <0.01 for both variables.	Mean NPASS scores were 5.14, 1.88, 1.01, 1.84, and 3.21 out of 13 for control, breastfeeding, oral sucrose, nonnutritive sucking, and skin-to-skin contact groups respectively. Oral sucrose was the most effective intervention in shortening the newborn's crying time. Nonpharmacologic pain interventions	Limitations: control arm was not randomized at the same time as the other arms, difficulty recruiting healthy newborns, and lack of resources.	Level I: Quality Grade A

						(breastfeeding, oral sucrose, nonnutritive sucking, and skin-to-skin contact) have analgesic effects and should be used to decrease the amount of pain newborn's experience.		
Gad, R. F., Dowling, D. A., Abusaad, F. E., Bassiouny, M. R., & Abd El Aziz, M. A. (2019).	Randomized Controlled Experimental Study	120 healthy, breastfed infants aged 2, 4, and 6 months attending the immunization clinic for routine immunizations.	The infant's mother randomly chose a card that assigned them to group A (sucrose), B (breastfeeding), or C (control) indicating the	FLACC pain scale to measure pain before, during, and after injection.	Repeated measures ANOVA and post hoc tests with Bonferroni adjustment. There were significant differences in pain scores during and after	Mean pain scores, crying time, and heart rate changes of the sucrose and breastfeeding groups were lower when compared with the control	Limitations: lack of blinding because of the breastfeeding intervention, using manual methods to measure heart rate, and	Level I: Quality Grade A

			intervention to be used prior to intramuscular injection. All injections were in the left vastus lateralis muscle with a 23G needle.		injection between groups (*p* value <0.001) and breastfeeding and oral sucrose groups produced lower pain scores than the control group (*p* value <0.001).	group. Pain scores and crying time were lower in the breastfeeding group when compared to the oral sucrose group. Pain scores after injection were 3.2, 2.6, and 8.9 out of 10 for the sucrose, breastfeeding, and control groups respectively. There was no difference in heart rate changes between the breastfeeding and	accuracy of mothers estimating the last feeding time.	

						sucrose groups. Recommendations: new mothers should be encouraged to breastfeed to manage immunization-related pain, but oral sucrose is a strong alternative.		
Harrison, D., Reszel, J., Bueno, M., Sampson, M., Shah, V. S., Taddio, A., Larocque, C., & Turner, L. (2016).	Systematic Review of RCTs and quasi-RCTs.	N/A	Study the effect of breastfeeding on procedural pain in infants between age 28 days and 1 year compared to no intervention, placebo, parental	N/A	N/A	Breastfeeding reduced behavioral pain responses and crying time but did not reduce changes in physiologic indicators (heart rate). Crying time was reduced by 38	Limitation: all studies were high risk of bias for blinding of participants and personnel and high risk for blinding of outcome assessment.	Level II: Quality Grade A

			holding, skin-to-skin contact, expressed breast milk, formula milk, bottle feeding, distraction, or sucrose solution.			seconds and standardized pain scores were reduced by 1.7 points. Recommend breastfeeding for pain management during injections when available, but dextrose also significantly reduced pain scores.		
Harrison, D. (2020).	Non-experimental	N/A	N/A	N/A	N/A	Use of pain interventions are underused due to a variety of myths and misconceptions and other barriers. Painful	Non-experimental	Level III: Quality Grade A

						procedures have been cited as having a strong association with poor neurobehavioral outcomes, and it has been proven that sucrose solutions do not have a negative effect on neurobehavioral outcomes. Oral sucrose should be used as a pain intervention, but it should be treated as a medication and doses		

						should be tracked.		
Kavthekar, S., Patil, R., Kurane, A., & Bharati, H. (2016).	Double-Blind RCT	150 healthy, exclusively breastfed infants less than 2 months of age presenting to the clinic for their first DPT vaccine.	Infants were randomized into 3 groups of 50 for interventions of sterile water, 24% sucrose, or breastmilk.. Duration of cry, first cry, change in heart rate, and modified facial coding score (MFCS) were assessed and compared to other interventions.	Assessment of crying time, first cry, heart rate change, and MFCS immediately, after 1 minute, and after 3 minutes.	ANOVA to assess crying time and heart rate changes. Kruskal Wallis test to analyze MFCS. Crying time and MFCS analysis produced *p* values of 0.000 indicating statistical significance.	Total duration of cry, first cry, and change in heart rate were all significantly lower in breastfed and sucrose groups. Mean duration of total cry was 36.3 seconds, 42.1 seconds, and 137.2 seconds for sucrose, breastfeeding, and control groups respectively. Duration of first cry was	Strengths: comparable postnatal age, weight, sex, and time since last fed in all babies. Limitations: only half the face is visible for MFCS in the breastfed group.	Level I: Quality Grade A

						18.2 seconds, 25.1 seconds, and 94.3 seconds respectively. Change in MFCS was significantly lower in breastfed and sucrose groups. Maximum reduction was more significant in the sucrose group when compared to the breastfed group. Sucrose had a better effect than breastmilk, but both could be		

						used simultaneously to enhance analgesia.		
Kumar, A., Narang, G. S., Singh, G., & Kaur, J. (2019).	Case control study	210 healthy infants coming to a clinic for immunizations	Response to pain was recorded in three intervention groups: oral sucrose solution, topical anesthetic, and control.	Modified Behavior Pain Scale (MBPS) before injection, 15 seconds after injection, and 60 seconds after injection.	Chi square test and t test. *p* values at 15 and 60 seconds after injection were 0.00 indicating statistical significance.	At 15 seconds after injection, mean pain scores were 5.09, 5.74, and 6.7 out of 10 for oral sucrose, topical anesthetic, and control groups respectively. At 60 seconds, scores were 6.43, 7.17, and 8.33 out of 10. Administration of sucrose before injection	Strengths: random division into groups, close range of age. Limitations: similar studies have shown variable results.	Level III: Quality Grade B

						showed greater reduction in pain.		
Levine, H. (2017).	Systematic Review of RCTs	N/A	Provide an evidence-based answer to "does giving a sweet-tasting solution before vaccine injection reduce infant crying?"	N/A	N/A	Oral administration of sucrose before intramuscular injection reduces crying duration by 12-77 seconds as shown by RCTs.	Potential bias in RCTs used for the review is not clear.	Level I: Quality Grade A
Liaw, J., Zeng, W., Yang, L., Yug, Y., Yin, T., & Yang, M. (2011).	RCT	165 full term newborns receiving intramuscular injection.	Measure pain in infants receiving injection based on treatment group: nonnutritive sucking, oral sucrose, or routine	Neonatal Facial Coding System, heart rate and respiratory rate measurement. All measures were collected for	Kruskal-Wallis test and Mann-Whitney U test. Pain scores were significantly lower in the sucrose group with a *p* values of <0.001. Cry duration	Sucrose and nonnutritive sucking lowered pain after vaccine administration. When given 2 minutes before injection, sucrose	Infant facial and physiologic responses could have been influenced by hunger, discomfort, temperament, sleep/wake state, or	Level I: Quality Grade A

			care (control).	5 minutes: baseline, during injection, and minutes 1-5 after injection.	was significantly shorter in the oral sucrose group with a *p* value of <0.001. Both values are statistically significant.	more effectively reduced the newborns pain. Recommend a study that analyzes the effect of sucrose and nonnutritive sucking simultaneously.	prior experiences.	
Matsuda, E. (2017).	Systematic review of RCT.	N/A	Analyze if administering sucrose to hospitalized newborns undergoing painful procedures is safe.	N/A	N/A	Sucrose in concentration of 20-30% reduced pain scores in infants undergoing heel lance. High-quality evidence also suggests it is effective in intramuscular injection.		Level I: Quality Grade A

						Units should establish protocols regarding the use of oral sucrose for painful procedures such as heel lance, venipuncture, and intramuscular injection.		
McNair, C., Yeo, M. C., Johnston, C., & Taddio, A. (2019).	Systematic Review	N/A	Evaluate use of various nonpharmacologic pain interventions for common needle punctures in infants.	N/A	N/A	Evidence supports the use of nonpharmacologic interventions, particularly breastfeeding, sweet tasting solutions, and skin-to-skin care. These three interventions are	Limited understanding of mechanism of action of nonpharmacologic interventions. Various limitations in studies used for this review.	Level III: Quality Grade A

						encouraged for managing pain and distress during common needle procedures in infants.		
Stevens, B., Yamada, J., Ohlsson, A., Haliburton, S., & Shorkey, A. (2016).	Systematic Review of RCTs	N/A	Determine efficacy, effect of dose, method of administration and safety of sucrose for relieving procedural pain in neonates.	N/A	N/A	Sucrose is effective for reducing procedural pain from single events with no serious side effects or harms documented.	Inconsistency of effective sucrose dosage among studies.	Level I: Quality Grade A
Stevens, B., Yamada, J., Campbell-Yeo, M., Gibbins, S., Harrison, D., Dionne, K., Taddio,	Single-Blind RCT	245 neonates in a NICU born between 24 and 42 weeks gestation	Determine pain scores in infants receiving one of three doses of 24% sucrose: 0.1	Premature Infant Pain Profile-Revised (PIPP-R) 30 and 60 seconds	Analysis of covariance models. *p* value at 30 seconds was 0.97 and at 60 seconds was 0.93.	No difference in pain intensity was shown among the three doses. Mean pain	Limitation of 30 and 60 seconds after injection may have different results than	Level I: Quality Grade B

A., McNair, C., Willan, A., Ballantyne, M., Widger, K., Sidani, S., Estabrooks, C., Synnes, A., Squires, J., Victor, C., & Riahi, S. (2018).		and less than 30 days old at the time of intervention.	mL, 0.5 mL, or 1.0 mL.	after heel lance.	there is no significant change in pain related to dose of oral sucrose administered.	scores 30 seconds after heel lance were 6.8, 6.8, and 6,7 for the three groups, indicating that 0.1 mL is the minimally effective dose of sucrose that can be used for pain management in infants.	longer intervals. No gold standard for measuring pain in infants- different pain score may produce different results.	
Uzelli, D. & Gunes, U. Y. (2014).	Unblinded RCT	80 medically stable infants receiving intramuscular Synagis injection.	40 infants were given 5% glucose and 40 infants were not given anything prior to intramuscular injection to assess	Neonatal Infant Pain Scale (NIPS)	Two-tailed Student's t test. Infants in the intervention group had lower pain scores, less crying time, higher oxygen saturation,	Mean NIPS score and mean crying time was significantly longer in the control group when compared to the sweet solutions group. NIPS	Strengths: even distribution of males and females, no significant difference in age, gestational age, and weight.	Level I: Quality Grade B

			pain response.		and lower heart rate than the control group (*p* values <0.001, <0.001, <0.001, and 0.02 respectively).	scores were 4.2 and 5.6 in the glucose and control groups respectively. Crying time had a mean of 10.9 seconds in the glucose group and 16.9 seconds in the control group. Recommend glucose be given 2 minutes before injection as part of routine practice if no other solution is available.	Limitations: investigators were not blinded, producing a risk of bias. Limited generalizability.	

Valeri, B. O., Gaspardo, C. M., Martinez, F. E., & Linhares, M. B. M. (2018).	Nonrandomized controlled clinical trial	104 preterm, very low birth weight neonates in a level 3 NICU.	Assess pain response in high and low clinical risk neonates using sucrose intervention and comparing it to the control group.	Neonatal Facial Coding System (NFCS) taken in four stages: baseline, puncture, and two recover phases.	Repeated measure ANOVA with mixed design. There is a significant effect on NFCS scores and facial activity. This is proven with *p* values of <0.0001 and 0.002 respectively.	Sucrose interventions for pain relief during acute painful procedures is effective in reducing pain intensity and increasing biobehavioral regulation, regardless of clinical risk status. Pain scores in the high risk group were 4 and 6.5 for sucrose and control groups respectively. In low risk groups, pain scores were	Study was not randomized and blinded. Amount of sucrose was estimated as there was not prescription or routine documentation.	Level III: Quality Grade B

						3.4 and 15 for sucrose and control groups.		
Yilmaz, G., Caylan, N., Oguz, M., & Karacan, C. D. (2014).	RCT	537 healthy, 16 to 19 month old infants receiving routine intramuscular injections.	Infants were randomized into groups to receive 2 mL of 75% sucrose, 25% sucrose, or sterile water before injections. Crying time and pain scores were measured.	Crying time and Children's Hospital of Eastern Ontario Pain Scale (CHEOPS)	Analysis of variance (ANOVA). There was a significant difference in pain and crying time when comparing the control group with both intervention groups. *p* value was <0.001 for both variables.	Both sucrose groups showed reduced crying time and CHEOPS scores. The 75% sucrose group had a greater reduction in crying and pain when compared to the 25% sucrose group. Crying time was 120 seconds, 62.2 seconds, and 43.4 seconds in the control,	Previous pain experience and use of intraoral sugar in the home environment can impact pain scores. Sucrose is inexpensive and easily administered.	Level I: Quality Grade B

						25% sucrose, and 75% sucrose groups respectively. The control group had 152 infants, out of 179, with CHEOPS scores greater than 4. In the 25% and 75% sucrose groups, a majority of the group had CHEOPS scores less than 4.		

Appendix B

Levels of Evidence

Evidence Level	Quality	Number of sources
Level I	A	7
	B	4
	C	0
Level II	A	1
	B	0
	C	0
Level III	A	2
	B	3
	C	0
Level V	A	0
	B	0
	C	0

Implementation of an Oral Sucrose Protocol for Advanced Practice Providers: Methodology

BY

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Abstract

Background/Purpose: Pain in infancy due to immunization administration often goes untreated. The pain infants experience leads to negative effects on neurodevelopment and pain response. Needle fear develops in infancy and can extend into adulthood, leading to vaccine avoidance and endemic outbreaks.

Methods: In a family practice clinic in an upper Midwest state, an oral sucrose protocol was implemented for use by advanced practice providers (APPs). Prior to education on the protocol, a survey was administered to assess the providers' knowledge, attitudes, and practice (KAP) in relation to oral sucrose. The providers were educated on the benefits and intended use of oral sucrose prior to the oral sucrose protocol being implemented throughout the clinic. After 8 weeks, the survey was repeated, and the two KAP surveys were compared and analyzed statistically.

Results: A statistically significant improvement was found in the knowledge, attitudes, and practices of clinic APPs.

Discussion: Due to statistical significance upon analysis, this quality improvement project has the potential to become sustainable practice. It is difficult to make this a regular practice in a rural area due to patient population. Recommendations would be to implement in a large family practice or pediatric clinic to confirm sustainability.

Implications for Practice: Oral sucrose has a quick onset and is cost-effective. Implementing an oral sucrose protocol can block pain response in infants receiving immunizations, which may promote adherence to vaccine schedules, improve the health of the population, and decrease healthcare costs related to preventable illness.

Implementation of an Oral Sucrose Protocol for Advanced Practice Providers: Methodology

Background and Purpose

Current immunizations prevent more than 20 life-threatening diseases and save nearly three million lives each year (Gad et al., 2019; World Health Organization [WHO], n.d.). While immunizations are extremely beneficial, they are one of the most unpleasant procedures of childhood. Children receive up to 24 immunizations during their first 2 years of life when following guidelines set by the Centers for Disease Control and Prevention [CDC]; Abukhaled & Cortez, 2020; CDC, 2022). Many immunizations are intramuscular injections but some are administered orally. Throughout this paper, any reference to immunizations or vaccines implies those administered by injection.

Research shows that an infant's nervous system is mature enough to perceive pain which can lead to negative developmental effects when untreated (Chang et al., 2020; Kavthekar et al., 2016; Liaw et al., 2011; Uzelli & Gunes, 2014). An infant's experience with pain has permanent effects on pain perception and response, often leading to severe fear and avoidance of needles. Nearly two-thirds of children develop needle fear, which can extend into adulthood. It is estimated that 25% of adults have a needle fear that developed in childhood (Gad et al., 2019; Kumar et al., 2019; Yilmaz et al., 2014). There continues to be an increasing number of unvaccinated infants, children, and adults. Nearly 10% of adults avoid immunizations because of their fear, and many parents are hesitant to follow vaccine schedules due to the distress injections cause both themselves and their child. Hesitancy to receive recommended immunizations has recently resulted

in endemic outbreaks of measles and pertussis (Abukhaled & Cortez, 2020; Kumar et al., 2019; Yilmaz et al., 2014).

Pain management during infancy and childhood is widely underutilized due to misconceptions and lack of understanding by providers. Through education, advanced practice providers (APPs) can improve their knowledge and attitudes on infant pain management and confidently incorporate interventions into their practice. With more utilization of infant pain management during painful procedures, there is potential to have a positive impact on vaccination rates and needle fear development. Treating pain during immunization is a basic human right and should be routinely included in pediatric care (Gad et al., 2019).

PICOT Question

The population, intervention, comparison, outcome, and time (PICOT) question used for this quality improvement project is: Among advanced practice providers in a family practice clinic that serves rural communities (P), how does the implementation of an oral sucrose protocol (I), compared to no protocol (C), affect knowledge, attitudes, and practice (KAP) regarding oral sucrose (O) within 8 weeks (T)?

Evidence Findings

The American Academy of Pediatrics (AAP) recommends using 24% sucrose concentrations for painful procedures (Chang et al., 2020; Committee on Fetus and Newborn & Section on Anesthesiology and Pain Medicine, 2016; Matsuda, 2017). A variety of studies have compared the use of sucrose solutions to breastfeeding, nonnutritive sucking, skin-to-skin contact, and control groups in different settings and populations. Oral sucrose consistently produced lower pain scores, smaller heart rate

increases, and shorter durations of crying that proved to be statistically significant through a variety of analytical methods (Chang et al., 2020; Gad et al., 2019; Kavthekar et al., 2016; Kumar et al., 2019; Uzelli & Gunes, 2014; Yilmaz et al., 2014). Additionally, oral sucrose is convenient and inexpensive (Liaw et al., 2011).

Many parents are unaware of pain management options for their infants. After education on the benefits of oral sucrose with immunization administration, 96% of parents would recommend oral sucrose to other parents, and 87% of parents were satisfied with the effects of pain management for their infant (Abukhaled & Cortez, 2020). When conducting research about APPs and oral sucrose protocols specifically, there is no published evidence. There is also no published evidence regarding APP KAP related to protocols. Through further research, there was a wide population of results related to KAP surveys and a variety of protocols, indicating KAP surveys are commonly used across healthcare settings. An oral sucrose protocol based on guidelines produced by Royal Children's Hospital (RCH) in Melbourne, Australia and independent research can provide consistency in the use of oral sucrose in clinic settings. The protocol also gives APPs the opportunity to directly impact the pain experienced by infants receiving immunizations, in turn providing a more positive experience and promoting immunization compliance.

Recommendations for Practice

Nonpharmacologic pain interventions have proven to be safe and effective in reducing pain response in infants and have gained support from credible sources such as the AAP (Chang et al., 2020). With a peak response of 2 minutes and a duration of up to 10 minutes, oral sucrose should be administered 2 minutes before the injection for

maximum efficacy (Abukhaled & Cortez, 2020; Kavthekar et al., 2016; Levine, 2017; Liaw et al., 2011; McNair et al., 2019). Pain management during infancy is necessary to prevent needle fear and vaccine nonadherence; routine administration of oral sucrose prior to immunizations should become a common practice (Abukhaled & Cortez, 2020). APPs in a primary care role should take the time to educate parents on the use and benefits of oral sucrose and encourage use prior to routine immunizations.

Gaps

Gaps in the literature make it difficult to fully grasp the impact of oral sucrose in infants up to 6 months of age as much of the current research is focused on premature infants as the population of interest. Additionally, current research compares nonnutritive sucking to oral sucrose to determine which produces greater pain reduction as a nonpharmacologic intervention, but there is limited evidence regarding whether it is beneficial to use both nonnutritive sucking and oral sucrose together. Finally, evidence is limited on how much sucrose to administer in each dose and how many doses can be given consecutively. There is also a lack of evidence related to long-term and potential negative effects of sucrose after consecutive administration (Stevens, 2018).

Methods

Framework, Theories, and Models

The Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) Model and Guidelines was utilized to help guide this project (Dang et al., 2022). The Knowledge-to-Action theoretical framework helped guide the planning and implementation of the oral sucrose intervention (WHO, n.d.-a). The Awareness, Desire, Knowledge, Ability, and

Reinforcement (ADKAR) model change theory was used to aid in reaching goals and promoting adherence to the protocol (Prosci, n.d.).

Setting and Sample

This project was implemented in a primary care clinic that serves rural communities in an upper Midwest state. The town has an estimated population of 23,577 with 5.4% of the population being 5 years old and younger. Of the population, 89.1% is Caucasian, followed by 4.4% Asian, 1.8% American Indian, and 1.7% African American (United States Census Bureau, 2021). The clinic employs eight APPs: six nurse practitioners (NPs) and two physician assistants [PA-Cs] ([redacted], personal communication, August 26, 2022).

The APPs at the clinic see a variety of pediatric patients with well-child checks and routine immunizations being common appointments. Prior to project implementation, there were no pain management protocols in place to promote comfort for infants 6 months of age and younger receiving routine immunizations ([redacted], personal communication, August 26, 2022).

Intervention Tools

Oral Sucrose Protocol

Oral Sucrose Protocol Guidelines developed by RCH were used as a guide for planning the Doctor of Nursing Practice (DNP) Project implementation (Kendrick, 2021). These guidelines are published publicly and permission for their use is not required. The guidelines note that oral sucrose should be used for reduction of pain during minor procedures, and the benefits have been demonstrated in older infants. Intramuscular injections are listed as one of the approved procedures in which oral sucrose is

recommended (Kendrick, 2021). No other guidelines were found during the literature search. After completing an appraisal of guidelines for research and evaluation II (AGREE II) tool, it was found these guidelines score an overall quality rating of 6 out of 7, indicating great quality.

The RCH oral sucrose guidelines encourage administration of oral sucrose 2 minutes prior to the painful procedure, with or without use of nonnutritive sucking. It is also specified that oral sucrose should be administered on the anterior aspect of the tongue. Infants older than 1 month of age can receive 1-2 mL of oral sucrose (Kendrick, 2021).

The oral sucrose protocol was created to reflect those published by RCH. The protocol highlights administering oral sucrose prior to injections with consideration to timing, onset of action, and location of administration on the tongue. Based on the population of this DNP Project, the protocol was limited to infants 6 months old and younger in a clinic setting, while RCH guidelines do not specify an age limit and are written to be used in an inpatient setting. A copy of the oral sucrose protocol can be found in Appendix C.

Knowledge, Attitudes, and Practice Survey

A knowledge, attitudes, and practice (KAP) survey is a cost effective and readily available tool used to assess the feasibility of an intervention in a healthcare setting (Patel, 2022). There is widespread use of KAP surveys to determine the impact of a variety of different interventions and protocols. For this DNP Project, a KAP survey was administered pre- and post-implementation.

To promote survey completion and provide a survey that is easily accessible to the APPs, a web-based platform, QuestionPro, was used to record the responses. Because the survey was assessing the KAP of APPs, there was no patient protected health information included in the survey. The survey was developed based on previous KAP surveys utilized in healthcare. A copy of the pre- and post-intervention surveys that were used can be found in Appendix D and Appendix E.

Procedure

The DNP Project began with APPs completing a survey at the beginning of a monthly staff meeting to assess their KAP regarding oral sucrose and its use and benefits. After all surveys were completed, the DNP Project Manager presented an educational PowerPoint presentation. The presentation was developed utilizing RCH guidelines combined with independent research and covered oral sucrose risks and benefits, correct administration, the developed oral sucrose protocol, and general project information (Appendix F). Following the educational presentation, all questions were addressed to ensure understanding and promote adherence to the intervention.

After the educational presentation, the oral sucrose protocol was implemented for 8 weeks. The APPs then completed a post-intervention survey. The survey remained open with weekly reminders via the clinic director until all responses were received.

To maintain confidentiality during survey completion, the APPs entered a unique identification code so pre- and post-survey answers could be compared. Only the APP knew their unique code as they developed their own ID based on a prompt from the DNP Project Manager. The prompt was a four-digit ID code with their birth month plus the number of years they have worked in their current position.

Ethical Considerations

Approval was obtained from the facility's Nursing Research Council prior to project implementation. Additionally, an application for approval from the facility and university institutional review board (IRB) was submitted. The DNP Project was deemed a non-human subjects quality improvement project by the facility. The university accepted the facility's determination. Copies of IRB approval can be found in Appendix A and B. Electronic surveys were used for data collection, which helped ensure no data was lost. The DNP Project Manager is the only person with access to the results of completed surveys. The results are accessible to the DNP Project Manager on a password protected QuestionPro account on a password protected computer.

Results

Demographics

Six APPs completed the pre- and post-intervention KAP survey with all of them being female. The age of the sample ranged from 25-49 with a mean age of 40. The years of experience of this group of participants are distributed evenly between one and 15 years of experience. Of the APPs in the sample, one of them had prior experience administering oral sucrose for pain management in the pediatric population.

KAP Survey

The KAP of the APPs were assessed in the format of a 5-point Likert scale with 1 being very unlikely or very unfamiliar and 5 being very likely or very familiar. The KAP sections were all scored individually to assess changes in each aspect of the survey. The data of the pre- and post-intervention surveys were analyzed statistically using the

Wilcoxon signed-rank test for paired data. Appendix G shows significant data related to the KAP of APPs.

Knowledge. On a 5-point scale, the mean response regarding knowledge for the pre-intervention group was 2.06. The post-intervention mean increased to 4. With a *p* value of 0.027, this is a statistically significant increase in knowledge.

Attitudes. When assessing attitudes, the pre-intervention survey mean score was 3.67. The mean increased to 4.5 in the post-intervention survey, indicating the providers find pain management important and beneficial in the pediatric population. The *p* value was 0.026, indicating a statistically significant increase in APP attitudes.

Practice. When starting the intervention, none of the APPs participating in the survey regularly offered oral sucrose to pediatric patients for the purpose of pain management. Over the course of the intervention, four APPs reported seeing 6-10 infants aged 6 months and younger. Two APPs reported seeing 0-5 infants aged 6 months and younger. Oral sucrose was offered to 0-5 infants over the course of 8 weeks by 5 of the APPs, while one APP offered it to 6-10 infants. When assessing how likely the APPs would be to offer oral sucrose on a regular basis, the pre-intervention mean was 1.83, and the post-intervention mean was 3.5. With a *p* value of 0.041, this is statistically significant.

Discussion

Significance of Findings

This project showed a statistically significant increase in APP KAP with the implementation of an oral sucrose protocol, and response to the protocol was positive throughout. In free text comments provided at the end of the post-intervention survey,

two APPs reported the desire to offer oral sucrose to more patients. Two APPs also reported that parents were very receptive to the protocol and one APP is looking forward to receiving more in-depth feedback from the parents whose infants received oral sucrose. Knowing that an improvement in KAP at this clinic was found suggests that an oral sucrose protocol for infants prior to immunizations could become a sustainable practice that can reduce immediate pain response in infants. Implementing the routine use of oral sucrose as an analgesic for immunizations may translate to improved vaccine adherence throughout childhood and into adulthood.

The family practice clinic where the oral sucrose protocol was implemented is going to keep oral sucrose in stock so APPs can continue offering this intervention to their patients receiving immunizations. At this time, they are not expanding the age range in which it is offered. However, the number of patients they see that are eligible for oral sucrose administration is relatively low.

The APPs were receptive to the oral sucrose protocol implementation and reported it was easy to use and understand. Overall, it is a sustainable protocol, but the setting in which it was implemented makes it challenging to continue utilizing it on a regular basis. Widespread research on oral sucrose outlines larger age groups and purposes other than immunizations in which oral sucrose can be used. It would be recommended to introduce the oral sucrose protocol at a larger family practice or pediatric clinic to determine if the protocol is sustainable within the defined population on a larger scale. Determining sustainability in other similar settings will be helpful in widespread adoption of an oral sucrose protocol, which must be done prior to expanding use based on age and indication.

Barriers

One barrier was a small sample size due to a small team of APPs. Another barrier was difficulty obtaining the supply of oral sucrose. The oral sucrose was on backorder but arrived in time for protocol implementation. Finally, the location proved to be a barrier for implementation of the oral protocol. APPs were excited about the intervention, and parents were receptive to the oral sucrose. However, due to the location serving rural communities, there was a small number of infants that were eligible to be offered oral sucrose over the course of implementation.

Implications for Practice

Administering oral sucrose is a quick, cost-effective intervention that has the potential to make a large impact. The cost per unit of 1 mL oral sucrose droppers is $0.51 ([redacted], personal communication, July 12, 2023). Infants are one of the most vulnerable populations that often do not receive healthcare services to the extent that they deserve, such as pain control (Gad, 2019). Successful implementation of an oral sucrose protocol can manage vaccine-related pain and may promote adherence to future vaccines and improve the health of the population. Improved population health related to increased immunization rates would greatly decrease healthcare costs and reduce clinic visits for preventable illnesses (Infectious Diseases Society of America, 2019).

Conclusion

Immunizations are essential and lifesaving, but untreated pain related to frequent injections during infancy can lead to negative neurodevelopmental effects and alter future pain response (Chang et al., 2020; Kavthekar et al., 2016; Liaw et al., 2011 Uzelli & Gunes, 2014). The untreated pain related to immunizations can lead to needle fear that

extends into adulthood and contributes to the growing number of unvaccinated individuals (Gad et al., 2019; Kumar et al., 2019; Yilmaz et al., 2014). Oral sucrose has continuously proven to be effective in reducing pain response throughout a variety of studies (Chang et al., 2020; Gad et al., 2019; Kumar et al., 2019; Uzelli & Gunes, 2014). Through education to clinic APPs and implementation of the oral sucrose protocol, a statistically significant increase in KAP was found among the APPs. The long-term potential for reduction in infant pain and increase in vaccine compliance may lead to improvements in the health of the entire population, which would reduce healthcare costs related to preventable illness.

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Appendix A

Facility IRB Approval

NOT HUMAN RESEARCH

August 29, 2023

Dear [redacted]

The IRB reviewed the following submission:

Type of Review:	Initial Study via Non-Committee Review
Title of Study:	Oral Sucrose Protocol for APPs: Implementation of an Oral Sucrose Protocol for Advanced Practice Providers
Investigator:	[redacted]
IRB ID:	STUDY00003341
Special Determinations:	

The IRB determined, on 8/29/2023, that the proposed activity is not human research. [redacted] IRB review and approval is not required.

This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are being considered and there are questions about whether IRB review is needed, please submit a study modification to the IRB for a determination. You can create a modification by clicking **Create Modification / CR** within the study.

For questions please contact the IRB Office: [redacted]

Appendix B

University IRB Approval

RE: Shatto DNP Project- Non-Human Subjects

SDSU IRB <SDSU.IRB@sdstate.edu>
Wed 9/6/2023 10:47 AM
To: Shatto, Cori A - SDSU Student [redacted]; SDSU IRB <SDSU.IRB@sdstate.edu>
Cc: Callies, Dannica [redacted] Varilek, Brandon [redacted]
Good morning Cori,

SDSU will rely on [redacted] determination of not human subjects research. No further action is needed as this time.

Best, [redacted]

Appendix C

Oral Sucrose Protocol

Cori Shatto- SDSU, DNP-FNP Program

1. **PURPOSE**
    a. Immunizations reduce the risk of getting and transmitting diseases but they are the most common painful procedure throughout infancy and childhood. Oral sucrose is a cheap, effective non-pharmacologic intervention to reduce injection related pain in infants.
2. **CHARACTERISTICS OF THE PATIENT POPULATION**
    a. Infants aged 6 months old and younger.
    b. Infants attending a well-child appointment and receiving routine immunizations.
3. **PROCEDURES**
    a. Sucrose is recommended to be given before immunizations.
    b. The onset of action of oral sucrose is 2 minutes. After administration, wait 2 minutes before administering any ordered injections.
    c. Use of other comfort measures (swaddling, nonnutritive sucking, etc.) can be used as needed in conjunction with oral sucrose.
    d. Prefilled 1 mL syringes will be used for oral sucrose administration. Sweet receptors are found on the tip of the tongue; place 3-5 drops of oral sucrose on the tip of the tongue.
    e. Sucrose should not be used to calm fussy babies or after the administration of injections.

Appendix D

Pre-intervention KAP Survey

* Enter a four digit ID code that will be used for future surveys.
Prompt: Birth month + number of years in your current position.

What is your gender?

- ◯ Female
- ◯ Male
- ◯ Other (specify)

What is your age?

- ◯ 25-29
- ◯ 30-39
- ◯ 40-49
- ◯ 50-59
- ◯ 60+

How many years have you been in your current position?

- ◯ Less than 1 year
- ◯ 1-5 years
- ◯ 6-10 years
- ◯ 11-15 years
- ◯ More than 15 years

Do you have any experience with oral sucrose for pain management in the pediatric population?

- ◯ Yes
- ◯ No

Knowledge

	Very Unfamiliar	Unfamiliar	Somewhat Familiar	Familiar	Very Familiar
How familiar are you with oral sucrose and its intended use?	◯	◯	◯	◯	◯
How familiar are you with the benefits of oral sucrose?	◯	◯	◯	◯	◯
How familiar are you with correct administration of oral sucrose?	◯	◯	◯	◯	◯

Attitudes

	None	Low	Medium	High	Very High
How would you rate the importance of pain management in infants?	○	○	○	○	○
To what extent is there a need for pain management interventions for infants?	○	○	○	○	○
In your opinion, how beneficial would oral sucrose be for the infant population at your clinic?	○	○	○	○	○

Practice

	Yes	No
Do you regularly offer oral sucrose to any patients?	○	○

Practice

	Very Unlikely	Unlikely	Somewhat Likely	Likely	Very Likely
How likely are you to offer oral sucrose to infants receiving routine immunizations?	○	○	○	○	○

Appendix E

Post-intervention KAP Survey

Enter your four digit ID code.
Prompt: Birth month + number of years in your current position.

Over the past 8 weeks, how many infants 6-months old and younger did you see that received routine immunizations?

- ◯ 0-5 infants
- ◯ 6-10 infants
- ◯ 11-15 infants
- ◯ 16+ infants

Over the past 8 weeks, how many times did you offer oral sucrose to infants receiving routine immunizations?

- ◯ 0-5 times
- ◯ 6-10 times
- ◯ 11-15 times
- ◯ More than 15 times

Knowledge

	Very Unfamiliar	Unfamiliar	Somewhat Familiar	Familiar	Very Familiar
How familiar are you with oral sucrose and its intended use?	◯	◯	◯	◯	◯
How familiar are you with the benefits of oral sucrose?	◯	◯	◯	◯	◯
How familiar are you with correct administration of oral sucrose?	◯	◯	◯	◯	◯

Attitudes

	None	Low	Medium	High	Very High
How would you rate the importance of pain management in infants?	◯	◯	◯	◯	◯
To what extent is there a need for pain management interventions for infants?	◯	◯	◯	◯	◯
In your opinion, how beneficial would oral sucrose be for the infant population at your clinic?	◯	◯	◯	◯	◯

Practice

	Yes	No
Do you regularly offer oral sucrose to any patients?	◯	◯

Practice

	Very Unlikely	Unlikely	Somewhat Likely	Likely	Very Likely
How likely are you to offer oral sucrose to infants receiving routine immunizations?	◯	◯	◯	◯	◯

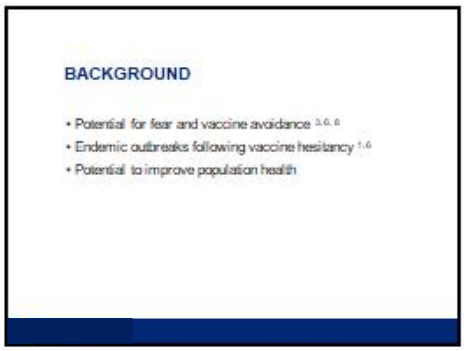
Please include any feedback you have on the oral sucrose protocol and administration of oral sucrose.

Appendix F

Clinic Provider Education

1

2



3

4

SUPPORTING EVIDENCE

- Reduction in physiologic indicators [6]
  - Heart rate variability and crying time
- Parents would recommend sucrose to others [1]
- Safe, effective, and inexpensive

5

PROJECT PLAN

- Sample: Brookings clinic APPs
- Oral sucrose education session
- Oral sucrose protocol implementation
- Statistical analysis to assess knowledge and attitudes

6

ORAL SUCROSE PROTOCOL

7

CONCLUSION

- Immunizations are lifesaving
- Prevent negative neurodevelopmental effects
- Oral sucrose effective for pain management
- Anticipated findings:
  - Reduction in FLACC pain scores
- May improve vaccine compliance
- May improve population health

8

Appendix G

Table 1

Table 1

KAP of APPs Before and After Implementation of an Oral Sucrose Protocol

Knowledge

	Pre-intervention mean	Post-intervention mean	*p* value
Use	2.33	4.17	
Benefits	2.33	4.17	
Administration	1.5	3.67	
Total	2.06	4	0.027

Attitudes

	Pre-intervention mean	Post-intervention mean	*p* value
Importance of pain management	4.17	4.67	
Need for pain intervention	3.67	4.5	
Benefit for infants	3.17	4.33	
Total	3.67	4.5	0.026

Practice

	Pre-intervention mean	Post-intervention mean	*p* value
Likely to offer oral sucrose regularly	1.83	3.5	0.041