NICU Procedures Are Getting Sweeter: Development of a Sucrose Protocol for Neonatal Procedural Pain

Larisa Mokhnach, RNC *Kristi Diercks, BSN, RN*
Marilyn Anderson, BSN, MS, RN *Maureen Berkan, RNC*
Rachelle Glorioso, BSN, RN *Shwu-Shin Hou, MN, ARNP, NNP-BC*
Katie Loeffler, BSN, RN *April Millar, BSN, RN*
Kelly Shinabarger, BSN, RNC *Karen A. Thomas, PhD, RN*
Lauren Thorngate, PhD(c), RN, CCRN *Wendy Walker, MN, RN*
Marna Yates, RN *Ilona Zbirun, MS*

Abstract

Neonates in the neonatal intensive care nursery experience multiple, painful, tissue-damaging procedures daily. Pain among neonates is often underestimated and untreated, producing untoward consequences. A literature review established strong evidence supporting the use of sucrose as an analgesic for minor procedural pain among neonates. A review of unit practices and nurses' experiential evidence initiated the production of a standardized protocol in our unit at the University of Washington Medical Center NICU in Seattle.

Nursing practices surrounding sucrose use differed widely in dose, timing, and patient application. We carefully evaluated evidence documenting the effectiveness as well as the safety of sucrose administration and wrote a protocol and practice standards for our primarily premature patient population. This article describes the development and execution of a standardized, nurse-implemented, sucrose protocol to reduce procedural pain.

During an average week, an estimated 10,000 infants are born prematurely in the U.S.[1] In one study, premature infants experienced an average of 12 painful procedures per day of hospitalization.[2] Bedside nurses express mounting concern (documented by research) that neonatal pain is often underestimated and undertreated. Advances in technology and medical breakthroughs have significantly improved survivability for premature neonates; however, these advances have multiplied the number of invasive, painful, and tissue-damaging procedures these infants undergo.[3–5] Evidence clearly indicates that untreated procedural pain produces emotional and behavioral consequences, including learning disabilities, that last into adulthood.[6,7] Physiologic effects include altered pain sensitivity and permanent neuroanatomic abnormalities.[8] Additionally, the reduction of pain is a significant ethical concern in neonatal care. Because it is difficult to quantify pain in infants, neonatal nurses are obligated to recognize and reduce the pain of procedures.[9]

Published studies of sucrose administration in the neonatal population demonstrate that "a spoonful of sugar" may prevent or relieve discomfort related to certain medical procedures.[10–14] In addition to primary research, many review articles exist that recommend sucrose and guide clinical use.[15–17] The Cochrane Reviews have consistently supported the use of sucrose for the use of procedural pain in neonates since 1998.[18] This article

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TABLE 1 ■ Selected Sucrose Studies Reviewed

Reference/ Location	Study Design and Sample	Sucrose Dose	Pain-Causing Procedure	Pain Evaluation	Results
Carbajal et al.[27] (2002) Poissy NICU, Poissy-Saint Germain Hospital, Poissy, France	Crossover clinical study Included 40 preterm neonates 24.8–31 and 25.2–32.8 weeks GA in two trials	30% glucose (0.3 mL) vs a placebo 30% glucose (0.3 mL) vs 30% glucose (0.3 mL) followed by NNS	First subcutaneous injection of erythropoietin	DAN: (Douleur Aiguë Nouveau-né) Behavioral Acute Pain Rating Scale for Neonates (0–10)	Pain scores were significantly lower in the group receiving 30% sucrose than in the group receiving a placebo. No statistically significant difference in pain scores was found between the 30% sucrose group and the 30% sucrose-plus-pacifier group.
Ramenghi et al.[12] (2002) University of Leeds, U.K.	RCT 184 healthy infants born between 37 and 42 weeks GA with birth weights of >2,500 g and undergoing immunizations randomized to receive one of four solutions	Four solutions: 1. Sucrose 25% 2. Sucrose 50% 3. Lycasin (Roquette Pharma, Lestrem, France) (40% weight/volume) hydrogenated glucose syrup, maltilol sweetener, used in pediatric oral medications 4. Water/placebo 2 mL of the test solution was syringed for 1 minute onto anterior part of baby's tongue	DTP and HIB immunizations	Duration of the baby's cry during the 3 minutes following injections	25% sucrose had less effect than 50% sucrose. Lycasin appeared to be considerably less effective than either sucrose preparation. Babies in the placebo groups (all immunization times) spent the most time crying.
Johnston et al.[23] (2002) McGill University, Montreal, Quebec, Canada	Double-blind RCT at Level III university-affiliated Canadian NICUs 107 preterm infants <31 weeks PCA were enrolled within 48 hours after birth; 103 completed study	Sucrose or water group (randomly assigned): 0.1 mL 24% sucrose or water Dose given at the beginning and 2 minutes into the procedure; up to 3 doses for prolonged procedures	Invasive: heel lance, IV placement, injection, arterial puncture Uncomfortable: endotracheal tube suctioning, gavage tube insertion, tape/lead removal	Motor development and vigor, and alertness and orientation components of the NAPI were measured at 32, 36, and 40 weeks PCA. The NBRS was measured at 2 weeks of age and at discharge.	No significant differences were found between the groups on any outcomes. Higher number of doses of sucrose predicted lower scores on motor development and vigor and on alertness and orientation at 36 weeks PCA.

Key: DTP = diphtheria, pertussis, tetanus; HIB = *Haemophilus influenzae* type b; GA = gestational age; IV = intravenous; NAPI = Neurobehavioral Assessment for the Preterm Infant; NBRS = Neurobiological Risk Score; NEC = necrotizing enterocolitis; NFCS = neonatal facial coding system; NNS = nonnutritive sucking; NPO = nothing by mouth; PCA = postconceptional age; PIPP = premature infant pain profile; RCT = randomized controlled trial; ROP = retinopathy of prematurity

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Gibbins & Stevens [28] (2003) Sunnybrook and Womens College Health Center, Toronto, Ontario, Canada	Exploratory secondary analysis of larger RCT to stratify for GA 190 infants 27–36 weeks GA to assess safety and efficacy by GA	0.5 mL of 24% sucrose on pacifier, sucrose only, or sterile water on pacifier for control	Heel lance	PIPP	Short-term safety (choking, coughing, vomiting, sustained tachycardia, sustained tachypnea or dyspnea, sustained oxygen desaturation) indications were demonstrated for a single dose. Higher numbers of adverse events were recorded in lowest GA group (27–31 6/7 weeks) than in other groups. Efficacy of NNS + sucrose was significantly better than that of sucrose alone or that of NNS + sterile water. There were significant differences in pain behaviors by GA.
Mitchell et al.[11] (2004) University of Louisiana at Monroe, U.S.	Double-blind RCT 30 preterm infants at Level III university-affiliated NICU without previous exposure to sucrose analgesia	Local-anesthetic eyedrops, a pacifier, plus three 0.1 mL doses of 24% sucrose or water at 2-minute intervals during eye exam	Eye examination for ROP	PIPP	Significant differences in mean PIPP scores were found between the sucrose and the water groups.
Stevens et al.[22] (2005) Hospital for Sick Children, Toronto, Ontario, Canada	Prospective RCT with repeated measures 66 premature infants 26–30 weeks GA at a Level III NICU	2 minutes before procedure: 0.1 mL of 24% sucrose or sterile water with a pacifier or standard care: no pacifier All painful procedures for the first 28 days of life included	Invasive, tissue-damaging cutaneous procedures including, but not limited to, heel lance, IV or arterial line insertion, lumbar puncture, and tape removal	PIPP and NBRS	No significant differences in safety outcomes (choking, tachycardia, tachypnea, oxygen desaturation, hyperglycemia, oral infection, NEC) between groups. No differences in neurologic (NBRS) or clinical outcomes. Sucrose + pacifier showed significant benefit over standard care (lower PIPP scores).
Taddio et al.[30] (2008) Mt. Sinai Hospital, Toronto, Ontario, Canada	Double-blind RCT Newborns (≥36 weeks gestation) of diabetic and nondiabetic mothers	2 mL of a 24% sucrose or placebo solution before all procedures	Intramuscular injection of vitamin K, venipuncture for the newborn screening test, and the first 3 heel lances for glucose monitoring	PIPP	Modest reduction of pain in newborns of both diabetic and nondiabetic mothers when sucrose was used for all medical procedures performed in the first 2 days after birth. With separate analysis by procedure, effectiveness of sucrose was limited to venipuncture for the newborn screening test.
Taddio, Shah, & Katz[13] (2009) Mount Sinai Hospital, Toronto, Ontario, Canada	Double-blind RCT Healthy neonates within two strata (normal infants and infants of diabetic mothers) were randomly assigned to a sucrose or placebo (water) group before all needle procedures after birth.	2 mL of a 24% sucrose solution or sterile water before all procedures	Diaper change performed after venipuncture for the newborn screening test	PIPP	When used to manage pain, sucrose reduces the pain response to a subsequent routine caregiving procedure. Benefits of sucrose analgesia extend beyond the painful event to other aversive and potentially painful procedures.

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Lago et al.[15] (2009) Pain Study Group of the Italian Society of Neonatology	A panel of expert neonatologists used systematic review, data synthesis, and open discussion to reach a consensus on the level of evidence supported by the literature or customs in clinical practice and to describe a global analgesic management, considering pharmacologic, nonpharmacologic, behavioral, and environmental measures for each invasive procedure.	Sucrose in doses from 0.2 –0.3 mL orally 2 minutes before procedure in preterm infants and 1–2 mL orally in term infants	Pain control measures used during chest tube placement and removal, screening and treatment for ROP, or for postoperative pain		These guidelines should help improve the health care professional's awareness of the need to manage procedural pain adequately in neonates, based on the strongest evidence currently available.
Harrison et al.[29] (2009) Royal Children's Hospital, Melbourne, Australia	Prospective longitudinal observational study of serial pain assessments during routine heel lancing. Infants were studied for entire hospitalization. 55 infants (33–38 weeks GA at birth) over 11 months; a total of 443 pain assessments in the cohort	0.25 mL or 0.05 mL (if patient was NPO) of 33% sucrose syringed onto anterior tongue 2 minutes before start of procedure. Additional doses immediately before the heel lance and every 2 minutes until procedure was completed. Pacifier offered if usual for that infant and if developmentally appropriate.	Standard heel lance for phlebotomy	Behavioral: crying times (audio-recorded for analysis) and facial expression (4-point subset of NFCS: brow bulge, eye squeeze, nasolabial furrow, open mouth) Physiologic: heart rate and oxygen saturation	Lack of increase in behavioral and most physiologic responses to successive heel lance procedures and persistently low behavioral pain scores in sick infants. Taken together these findings suggest a sustained analgesic effect of oral sucrose.

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describes development of a standardized, nurse-implemented, sucrose protocol for analgesia in neonatal intensive care.

SYNTHESIS OF EVIDENCE

As a first step, NICU practices at the University of Washington Medical Center were reviewed and feedback solicited from nursing staff about sucrose use. Findings showed that sucrose administration practices varied, in dosing and timing, and were influenced by nurses' experience quantifying neonatal pain. A literature review by the unit's Local Practice Council (LPC) established the scientific background supporting sucrose as an analgesic for neonates (Table 1). Key findings included the following:

- Absorption of sucrose occurs more rapidly by oral/buccal administration than by ingestion or enteral instillation. Sucrose administration via nasogastric (NG) tube is not effective. A study comparing intragastric to intraoral administration of sucrose demonstrated no effect when given via NG tube.[19]
- A minimal dose of one to two drops of 24 percent sucrose results in endogenous endorphin release within two minutes of sublingual administration.
- Sucking on a pacifier potentiates the analgesic effect of sucrose and enhances the neonate's comfort.
- Repeating the dose every five minutes enhances analgesia for prolonged procedures.

We evaluated potential hazards to the neonate of sucrose use. Specific risks associated with sucrose administration include choking, coughing, vomiting, and hemoglobin desaturation.[5] Evidence suggests that reasonable precautions during sucrose administration can limit these effects. In our experience, visualizing dispensed drops, practice with use of a dropper-style dispenser, and careful administration to the side (buccal area) or anterior tongue can enhance delivery techniques. Attention to administration details can reduce the risk of coughing and choking. Further, using minimal volume (one to two drops) also reduces such risks. For larger more mature infants, nurses may choose to offer a pacifier dipped in sucrose solution.

A second area of concern is the effect of sucrose on blood glucose. Concerns regarding hyperglycemia are theoretical and not supported by evidence. Sucrose is a disaccharide that delivers one equivalent of glucose and one equivalent of fructose. Glucose is a monosaccharide; its structure includes two stereoisomers (mirror images of each other). D-glucose (dextrose) is the biologically active isomer. Sucrose, therefore, is not equal to dextrose; but for the purpose of comparison, we chose to consider how they might relate to each other when considering the issue of hyperglycemia in micropremies.[20,21]

In consultation with our neonatal pharmacist, we compared the amount of glucose in the proposed dose of sucrose with the amount of glucose infants would receive in hyperalimentation (HA). A neonate receiving continuous-drip HA with 10 percent dextrose would receive a minimum of 2 mL/hour delivering 200 mg of dextrose/hour. At the dosage prescribed in the sucrose protocol, neonates receive one to two drops of commercially available 24 percent sucrose. This equates to 0.05 mL/drop delivering 1 mg sucrose/drop, for a total dose of 1–2 mg of sucrose per treatment. This dosage is substantially less than the amount of dextrose a neonate would receive in a continuous HA infusion. We also sought input from our neonatal dietitian regarding the nutritional implications. To control sucrose intake and reduce possible concern about glycemic effect, we elected to standardize administration at one to two drops of sucrose per dose and, additionally, to limit total daily intake to less than 1 mL/day for premature infants ≤1,500 g, with more liberal dosing for larger infants. This limit gives a range of 10–20 doses per 24-hour period for our smallest infants, adequately covering the days when an infant must undergo a high number of invasive procedures.

A third possible risk of sucrose administration is necrotizing enterocolitis (NEC).[22] The hyperosmolarity of sucrose preparations along with fears about early feeding raise concerns about gut integrity.[16] In a comparison of water with nonnutritive sucking (NNS) and sucrose, Stevens and colleagues found no difference in outcomes including NEC and intraventricular hemorrhage.[22] Despite clinicians' fears of NEC, there have been no systematic studies or published case reports showing an association between sublingual, small-volume sucrose administration and NEC. For our protocol, we chose to limit volume and assure sublingual administration, which should alleviate these concerns. We consulted with the neonatology division and our medical director, who agreed with our approach.

The effect of sucrose administration on neurodevelopment is an important—and still unanswered—question. Despite a large body of evidence supporting the efficacy of sucrose in safely decreasing signs of pain, a single study determined that a higher number of sucrose doses among infants <31 weeks gestation predicted lower scores on standard developmental outcome tests.[23] A comparison of outcomes on the Neurobehavioral Assessment for the Preterm Infant (NAPI) test for infants receiving multiple doses of sucrose versus multiple doses of water in the first week of life revealed that an increased number of sucrose doses was predictive of lower scores for motor development and vigor, and also for alertness and orientation, when infants were measured at or near term. Additionally, scores on the Neurobiological Risk Score (NBRS) were higher at two weeks postnatal age for the babies who received more doses of sucrose. The study authors urge caution in widespread, unlimited use of sucrose in very immature infants; however, these worrisome findings have not been replicated by other studies. Sucrose administration in Johnston and colleagues' study involved 0.1 mL of 24 percent sucrose given orally by syringe and repeated up to three times per procedure with no set maximum amount per day. The authors reported wide variability in compliance with the dosing protocol.[23]

TABLE 2 ■ Painful Procedures Appropriate for Treatment with Sucrose[10,15,18]

Arterial puncture
Central venous line insertion (peripherally inserted central catheter)
Endotracheal tube suctioning
Eye exam for ROP
Gavage tube insertion
Heelstick
Intramuscular injection
Lumbar puncture
Peripheral intravenous placement
Subcutaneous injection
Urinary catheterization
Venipuncture

To prevent inconsistencies and to protect our patient population, our group synthesized this and other evidence to develop our own guidelines for effective administration strategies. In our protocol, administration is limited to the sublingual route, and volume is controlled both for each episode and for total dose per day. This was an empiric decision based on the volumes reported by others and on our practical assessment of number of procedures per day.

PROTOCOL DEVELOPMENT AND CHANGE IN PRACTICE

The sucrose protocol development occurred as part of the operations of the NICU LPC, which is composed of an assistant nurse manager, a clinical nurse specialist, a neonatal nurse practitioner, a staff development specialist, staff nurses, and a professor from the School of Nursing. The group meets monthly to evaluate care delivery issues, monitor care quality, and develop evidence-based practices. The LPC responded to staff-initiated concern regarding procedural pain management and inconsistent practices related to sucrose administration. The NICU is a 36-bed Level III nursery located in a tertiary academic medical center. Approximately 100 nurses staff the NICU, and the care ratio is one to three patients per nurse. The medical staff comprises attending neonatologists, fellows in training, neonatal nurse practitioners, and pediatric resident physicians.

The lead author of this article served as a champion for change in clinical practice and developed the initial draft of the protocol. The LPC reviewed and modified the work, producing several iterations. We presented a finalized protocol for systematic and informed use of sucrose for procedural pain to the nursing and medical leadership; leadership offered their full approval and support to proceed.

Introduction of the standard protocol to nursery practice involved *forcing functions.* This term from the health care quality literature refers to an aspect of a design or process that prevents an action from being performed (e.g., confusion of dangerous look-alike medications by preemptive removal of them from the stock area) or allows its performance only if another action (e.g., insertion of a key in a lock) is completed first.[24] In this case, preprinted orders forced the availability of sucrose. We incorporated the sucrose protocol in standard preprinted admission medication orders as a nursing PRN order. Retinopathy of prematurity (ROP) examination orders were updated with the addition of sucrose as a PRN comfort measure. Including the sucrose protocol in standard orders streamlined the ordering process and empowered nurses to initiate sucrose treatment for early procedures starting with admission. Sucrose use was limited to a set of procedures that involved mild to moderate pain of short duration. Table 2 contains a comprehensive list of procedures commonly referenced in the literature as appropriate for sucrose administration. Before the protocol was established, nurses offered sucrose for fussiness and irritability. The new protocol does not include use of sucrose for nonprocedural pain because evidence supporting the practice was deemed inadequate. Fussiness and irritability require further clinical investigation to determine their causes, and other possible interventions.

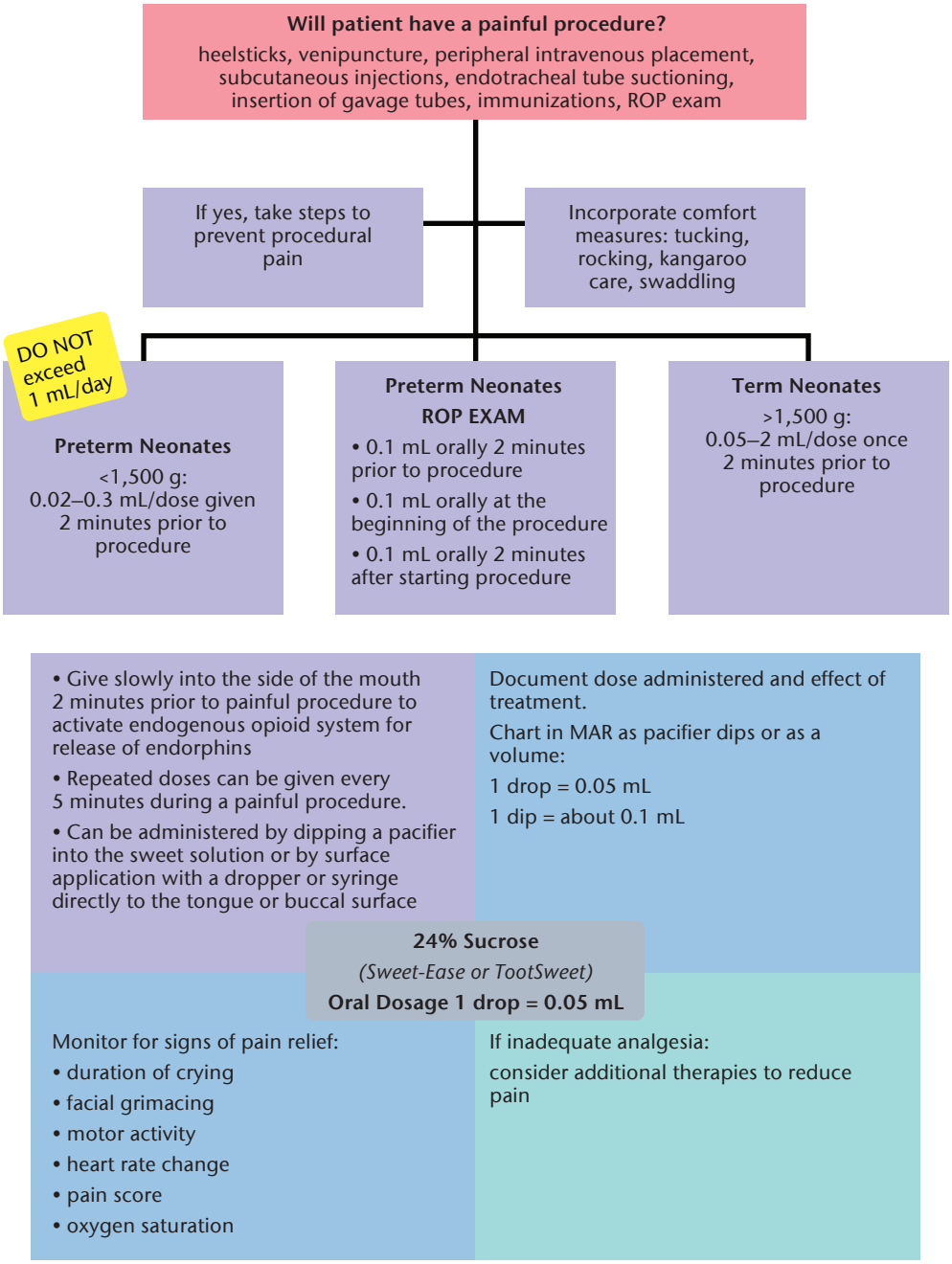
As a second forcing function[24] to regulate volume for the smallest infants, we decided to use body weight–based dosing in two groups with a cutoff at 1,500 g. The total daily sucrose dose for the <1,500 g group is limited to 1 mL/day. For all infants, individual doses are strictly limited to one to two drops per use. Timing of the dose is two minutes prior to the procedure, and the dose may be repeated at five-minute intervals as needed as long as the daily limit is not exceeded for infants in the <1,500 g group. There is no daily limit for the >1,500 g group in this protocol.

We developed a specific set of dosing instructions for ROP eye exams that calls for 0.1 mL or two drops two minutes before the procedure, 0.1 mL at the beginning of the procedure, and an additional 0.1 mL two minutes after starting the procedure. This schema should provide four to six minutes of effective coverage.

We opted to use a commercial 24 percent sucrose preparation (TootSweet, Hawaii Medical/Natus, Inc., San Carlos, California). This product is available as a 1 mL unit-dose vial, consistent with our protocol, and can be dispensed in single drops. The sucrose vials are purple, which differentiates them visually from other products such as normal saline solution and prevents application errors. Sucrose is routinely available in the unit electronic medication dispensing system. In our system, the standardized order for sucrose generates an entry into the medication administration record (MAR). The pharmacy supply system electronically tracks each sucrose vial to manage inventory. The nurse documents administered doses in the MAR and the effect of the treatment in the patient medical record.

We designed the protocol to integrate with unit standards for additional comfort measures. The lead author created an algorithm (Figure 1) summarizing the protocol as a

FIGURE 1 ■ Sucrose algorithm.



supportive document. The algorithm serves to enhance decision making and promote consistent application among nurses. It is available on the unit website, and printed copies are accessible for bedside use.

IMPLEMENTATION OF AN ORAL SUCROSE PROTOCOL

We introduced the protocol to nursing and medical staff using an evidence-based slide show presented during staff meetings. Posters about the sucrose protocol were developed and

displayed in the staff room. We sent frequent e-mail reminders encouraging use of the protocol to all staff nurses. The educational content and the sucrose protocol are now part of new nursing staff orientation. In education of the staff, we emphasized ethical expectations, short-term and long-term consequences of pain prevention, and the caregiver's role in maximizing the effect of sucrose for procedural pain by careful timing and repeated dosing. Following the educational offerings, we established a start date to legitimize the new practice. All LPC members served as resources for questions or concerns related to the protocol.

We learned many lessons during the process of implementation. The first was a simple one, but it had the potential to derail the project in its early stages. Because use of sucrose increased, the supply of sucrose on hand was inadequate, and we ran out of it. This indicated a need to work collaboratively with pharmacy staff to project supply needs more accurately. Some more complicated lessons revolved around behavioral changes. Changes in nursing practices and behavior related to implementation of the protocol included anticipating painful procedures, standardizing administration, and dealing with additional documentation.

Nurses' responses to the protocol varied. Some nurses enthusiastically embraced the use of sucrose for procedural pain; time constraints due to obtaining the product, planning for administration before the prodedure, and documentation requirements were barriers for others. Some nurses were reluctant to abandon the use of sucrose for fussiness and irritability. We found that offering nurses suggestions and tools for enhancing infant comfort was a good way to change the behavior of those who had used sucrose for reasons not associated with pain. Nurses were reminded of the benefits of developmental care strategies for comforting irritable or fussy infants. For example, we are promoting earlier dressing and swaddling, we evaluated and purchased better pacifiers for micropreemies and more comfortable bilirubin masks, and we post "Quiet Zone" signs at the bedsides of infants who are particularly sensitive to noise. Staffing ratio, physical layout of the unit, and the medication dispensing system are obstacles that can interfere with timely access to the sucrose product. Nurses need to prioritize the use of sucrose and value its benefits in order to overcome barriers to its use, make behavior changes, and integrate the new practices. Practice changes that support use of the sucrose algorithm and new protocol require consistent reinforcement and education. Innovation literature describes practice change as a *process* of adopting new actions rather than as a single event.[25] Adoption of change is most successful when a clear set of criteria is developed to accompany the proposed change. If an innovation is valued by the adopter, is simple and unambiguous, is compatible with existing unit processes, and is reinforced until it becomes the norm, the likelihood of its being adopted and sustained increases.[26]

EVALUATION

The sucrose protocol provides a standardized approach for this form of analgesia, increases nursing and medical staff awareness of procedural pain relief, and improves pain management. LPC members' initial reports show improved infant tolerance of painful procedures and positive unsolicited feedback from other NICU staff. Although they have not yet been formally measured, family responses are positive. This project demonstrates how a multidisciplinary team's integration of literature reports and evidence into NICU practice can improve patient care.

In order to evaluate the adoption of our protocol, we plan to use a chart review to track patients who receive sucrose, along with information about dosing and frequency of administration. We will determine the extent of compliance with the protocol as a first measure of change. Nurse and physician knowledge surveys, pain scale values, and family experience of painful procedures are possible outcomes we may explore as secondary evaluations of the outcome of the project.

As a result of our experiences with protocol development and integration of the new protocol into practice, we are seeing a shift in the culture of pain management in our NICU. Removing access barriers, simplifying documentation, and providing a standard order by which a nurse can decide when to administer sucrose has resulted in its being administered more consistently to our tiny patients. Our sucrose protocol is part of the orientation for new RNs in our NICU. As these and other nurses make sucrose administration a part of their nursing practice, the late adopters are embracing the protocol as well. Nurses are now actively involved in teaching the medical staff about the effects of sucrose. Proactive use of sucrose is becoming the norm. Nurses advocate for use of sucrose at the bedside prior to painful procedures and incorporate time for sucrose administration into the infant's care.

We focused on limited volumes and specific doses of sucrose to leverage the physiologic benefits of its use while reducing the theoretical risks. Development of an algorithm, designed by nurses for nurses, reinforces prevention of the consequences of procedural pain and successfully translates the scientific evidence base into routine practice. A simple, old-fashioned remedy, a spoonful of sugar, is proving its value in the pharmacologically enhanced world of neonatal care.

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About the Authors

Larisa Mokhnach is a staff nurse in neonatal intensive care at the University of Washington Medical Center in Seattle and an active member of the Local Practice Council. She graduated from nursing school in Riga, Latvia, and had an opportunity to work with premature infants in Latvia and Ukraine before moving to the United States.

Kristi Diercks graduated from the University of Washington School of Nursing. Kristi has 18 years of neonatal experience and is an active member of the Local Practice Council.

Lauren Thorngate is a predoctoral research trainee.

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For further information, please contact:
Larisa Mokhnach, RNC
Box 356077
University of Washington Medical Center
Seattle, WA 98195-6153
E-mail: mokhnach@u.washington.edu