



The infant and family experience in neonatal intensive care: management of acute procedural pain

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 **Sponsors**

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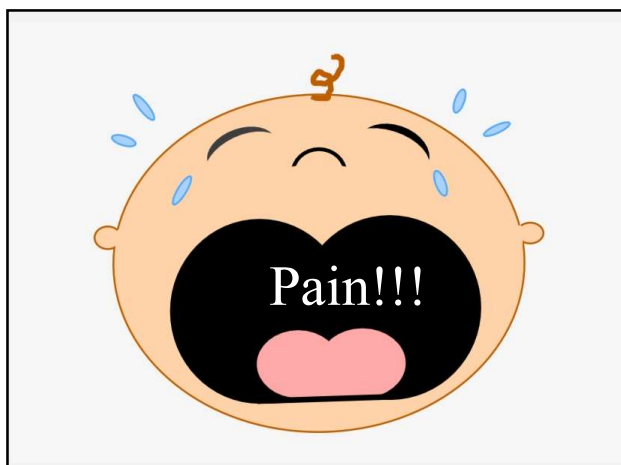
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 **The infant and family experience in neonatal intensive care**

Evidence synthesis for informed decisions and better health including:

1. Management of acute procedural pain;
2. Management of longer-term pain and discomfort associated with mechanical ventilation and surgical procedures; and
3. Impact of the intensive care environment and developmental care practices on infant development.


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Stress in Neonatal Intensive Care

- Although there have been significant strides towards decreasing mortality in preterm infants, many surviving infants experience significant developmental problems, in both motor and intellectual development [Horbar 2012; Stoll 2015; Saigal 2008; Hintz 2011; Santos 2015].
- The stressful environment of neonatal intensive care is a double-edged sword, contributing to both improved survival as well as concerning developmental outcome.


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Stress in Neonatal Intensive Care

The stresses inherent to neonatal intensive care include the need for frequent painful procedures, pain associated mechanical ventilation and major surgical intervention, and the overall environment of neonatal intensive care, so vastly different than the experience of the infant prior to delivery.

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Pain and discomfort

Painful procedures are a perfect example of the stress inflicted on newborn infants while receiving intensive care [Anand 2006].

A study in 2003 found that newborns in intensive care receive an unbelievable 14 painful procedures per day, while almost 40% did not receive any analgesic therapy [Simmons 2003].

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American Academy of Pediatrics 
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Pain and discomfort

In response to such studies, the Committee on Fetus and Newborn of the American Academy of Pediatrics states that preventing or minimizing pain in neonates should be a priority for neonatal caregivers and recommends "written guidelines, based on existing and emerging evidence, for a stepwise pain-prevention and treatment plan" which would include judicious use of procedures, routine assessment of pain, and use of both pharmacologic and nonpharmacologic therapies for the prevention of pain

The pain management strategy suggested by the Committee on Fetus and Newborn and Section on Anesthesiology and Pain Medicines is comprehensive, but acting on each facet is not without challenges.

[Committee on Fetus and Newborn and Section on Anesthesiology and Pain Medicines 2016].


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 **Cochrane Neonatal**

Management of acute procedural pain

Reports from NICUs across the world demonstrate that we have considerable room for improvement.

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Surveys of practice

A variety of surveys from the early 2000s have demonstrated major gaps in staff knowledge and understanding to the diagnosis, implications and treatment of pain in neonates

- Staff underestimated the pain caused by procedures.
- Pain assessment tools were used by a minority of centers
- Respondents reported that analgesia and comfort measures were not usually administered for most procedures:
- Non-nutritive sucking was used by 66% of respondents but other methods of non-pharmacological management were under-utilized.
- Few (21% and 37%) had received training on neonatal pain

Dodds E. Neonatal procedural pain: a survey of nursing staff. Paediatr Nurs.2003;15:18-2

Akuma AO, Jordan S. Pain management in neonates: a survey of nurses and doctors. J Adv Nurs. 2012 Jun;68(6):1288-301. doi: 10.1111/j.1365-2648.2011.05837.x. Epub 2011 Oct 11. PMID: 21988718.

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INTERNATIONAL JOURNAL OF Nursing Studies

Epidemiology and neonatal pain management of heelsticks in intensive care units: EPIPAIN 2

Objectives: To describe the frequency of heelsticks and their analgesic management in newborns in the NICU. To determine the factors associated with the lack of specific preprocedural analgesia for this procedure.

Design: EPIPAIN 2 (Epidemiology of Procedural PAIN In Neonates) is a descriptive prospective epidemiologic study.

Setting: All 16 NICUs in the Paris region in France.

Participants: All newborns in the NICU with a maximum corrected age of 44 weeks +6 days of gestation on admission who had at least one heelstick during the study period were eligible for the study. The study included 562 newborns.

Methods: Data on all heelsticks and their corresponding analgesic therapies were prospectively collected. The inclusion period lasted six weeks, from June 2, 2011 to July 12, 2011. Newborns were followed from their admission to the 14th day of their NICU stay or discharge, whichever occurred first.

Results: **The mean (SD; range) of heelsticks per neonate was 16.0 (14.4; 1-86) during the study period.**

Of the 8995 heelsticks studied, 2379 (26.4%) were performed with continuous analgesia, 5236 (58.2%) with specific preprocedural analgesia.

Overall, 6764 (75.2%) heelsticks were performed with analgesia (continuous and/or specific).

Courtois E, and colleagues. Epidemiology and neonatal pain management of heelsticks in intensive care units: EPIPAIN 2, a prospective observational study. *Int J Nurs Stud.* 2016 Jul;59:79-88. doi: 10.1016/j.ijnurstu.2016.03.014.

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Cochrane Neonatal

Management of acute procedural pain

What are the downstream effects of pain in hospitalized neonates?

It is no longer debated that premature infants have the necessary peripheral and central anatomical architecture required for nociceptive transmission.

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Cochrane Neonatal


Management of acute procedural pain

The prevention and alleviation of pain in neonates, particularly preterm infants, is important **not only because it is ethical** but also because exposure to repeated painful stimuli early in life is **known to have short- and long-term adverse sequelae**.

These sequelae include physiologic instability, altered brain development, and abnormal neurodevelopment, somatosensory, and stress response systems, which can persist into childhood. (e.g., reduced white matter microstructure and subcortical gray matter, dorsal horn central desensitization)

[Committee on Fetus and Newborn and Section on Anesthesiology and Pain Medicines 2016].

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So....
What do we **know** from trials regarding management of acute procedural pain?

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Minimizing procedures

The most effective way of reducing minor procedural pain in the neonate is to **reduce** the number of procedures performed

There currently is a paucity of research regarding effective ways to accomplish this, but strategies for reducing the number of procedures that neonates experience should be developed and their effectiveness should be tested.

Such an approach might include reducing the number of bedside disruptions in care.


Other strategies might include bundling interventions, eliminating unnecessary laboratory or radiographic procedures, using transcutaneous measurements when possible, and minimizing the number of repeat procedures performed after failed attempts.

Gibbins S, Stevens B, Asztalos E. Assessment and management of acute pain in high-risk neonates. *Expert Opin Pharmacother.*2003;4 :475- 483

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Minimizing procedures: POKE



POKE was developed and implemented at Dixie Regional Medical Center's Neonatal Intensive Care Unit (NICU) over the past 10 years to eliminate waste and reduce harm in healthcare.

POKE is a combination of a unique culture and process, with a supporting database, that is designed to guide and inform care decisions while minimizing POKES.

The program utilizes an implementation framework, educational materials, electronic health records (EHR), and decision support analytics.

POKE's initial deployment showed extremely promising results for Intermountain, which included: (1) eliminating 11,000 POKEs per year (a 50% reduction in overall POKEs), (2) realizing \$940,000 per year in cost savings (a 28% reduction of overall cost), (3) reducing length of stay by 2 weeks per average stay (a 21% reduction in length of stay), and (4) eliminating Hospital Acquired Infections (i.e., Central-line Associated Bloodstream Infection and Ventilator-associated Pneumonia), translating into 10 lives saved and a \$5.2M savings over a decade.

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Routine assessment of pain

What our babies can't tell us!

No Pain Moderate Pain Worst Pain

0 1 2 3 4 5 6 7 8 9 10

0 2 4 6 8 10

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Routine assessment of pain

Optimal pain management requires competent pain assessment, which can be especially difficult to perform in neonates.

The pain-assessment tool used should be multidimensional, including measurements for both physiologic and behavioral indicators of pain, because neonates cannot self-report

Chiswick ML. Assessment of pain in neonates. *Lancet*.2000;355 :6– 8;

Walden M. Pain Assessment and Management: Guideline for Practice. Glenview, IL: National Association of Neonatal Nurses; 2001. Document 1222

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Routine assessment of pain

Physiologic indicators of pain include changes in:

- heart rate
- respiratory rate
- blood pressure
- oxygen saturation
- vagal tone
- palmar sweating
- plasma cortisol or catecholamine concentrations

Behavioral indicators of pain may include changes in:

- facial expressions
- body movements
- crying

NB: may be absent in some neonates who are neurologically impaired or pharmacologically paralyzed.

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Routine assessment of pain

Facial expressions

Forehead protusion

Contraction of eyelids

Horizontal stretch of the mouth

Tense tongue

Nasionabial groove

From Martínez A, Pujol FA, Mora H. Application of Texture Descriptors to Facial Emotion Recognition in Infants. *Applied Sciences*. 2020; 10(3):1115. <https://doi.org/10.3390/app10031115>

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Routine assessment of pain

Commonly used Neonatal Pain Assessment Scales

Tool	Characteristics	Score	Reliability
Premature Infant Pain Profile Revised (PIPP-R)(44%)	heart rate oxygen saturation facial actions	0-21 for preterm 0-18 for term	Reliable, valid, clinical utility is well established
Neonatal Infant Pain Scale (NIPS)(23%)	facial expression, crying, breathing patterns, arm and leg movements, arousal	0-7	Reliable, valid
Neonatal Facial Coding System Revised (NFCS-R) (9%)	facial movement	0-10	Reliable, valid, clinical utility is well established, high degree of sensitivity to analgesia
Douleur Aigüe Nouveau-né (DAN) (6%)	facial responses limb movements vocal expression of pain	0-10	Reliable, valid
COMFORT neo (4%)	behavioral indicators: state of alertness, agitation, respiratory reaction, crying, general movements, muscle tone and facial expression, and physiological indicators: blood pressure and heart rate.	7-35	Reliable, valid, clinical utility well established
Neonatal Pain, Agitation and Sedation Scale (N-PASS)(3%)	Crying, irritability, facial expression, extremity tone, vital signs	0-13 for preterm 0-10 for term	Reliable, valid. Includes sedation end of scale, does not distinguish pain from agitation

Modified from I. McPherson and colleagues. The influence of pain, agitation, and their management on the immature brain. *Pediatric Research* (2020) 88:168 – 175.2.

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The infant and family experience in neonatal intensive care

Optimal management for procedural pain

1. Venipuncture versus heel lance for blood sampling in term neonates
2. Breastfeeding or breast milk for procedural pain in newborn infants
3. Non-pharmacological management of infant and young child procedural pain
 - Non-nutritive sucking for procedural pain in newborn infants
 - Swaddling or tucking
4. Skin-to-skin care for procedural pain in neonates
5. Sweet solutions for procedural pain in newborn infants
6. Topical anesthesia for procedural pain in newborn infants
7. Non-opioid analgesic agents for procedural pain in newborn infants
8. Opioids for procedural pain in neonates

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Venipuncture versus heel lance for blood sampling in term neonates

Shah VS, Ohlsson A.

Cochrane Database of Systematic Reviews 2011, Issue 10.
Art. No.: CD001452.

DOI: 10.1002/14651858.CD001452.pub4.

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Cochrane Neonatal

Venipuncture versus heel lance for blood sampling in term neonates

Background: Heel lance has been the conventional method of blood sampling in neonates for screening tests. Neonates undergoing heel lance experience pain which cannot be completely alleviated.

Objectives: To determine whether venipuncture or heel lance is less painful and more effective for blood sampling in term neonates.

Selection criteria: Trials comparing pain response to venipuncture versus heel lance with or without the use of a sweet tasting solution as a co-intervention in term neonates.

Shah VS, Ohlsson A. Venipuncture versus heel lance for blood sampling in term neonates. Cochrane Database of Systematic Reviews 2011, Issue 10. Art. No.: CD001452. DOI: 10.1002/14651858.CD001452.pub4.

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Venipuncture versus heel lance for blood sampling in term neonates

6 trials involving 478 infants

Shah VS, Ohlsson A. Venipuncture versus heel lance for blood sampling in term neonates. Cochrane Database of Systematic Reviews 2011, Issue 10. Art. No.: CD001452. DOI: 10.1002/14651858.CD001452.pub4.

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Venipuncture versus heel lance for blood sampling in term neonates

Behavioral pain scores

Intervention/ outcome	Studies	Infants	Results
Pain response to venipuncture versus heel lance in infants who did not receive a sweet tasting solution:			
• Neonatal Infant Pain Scale (NIPS)	2 studies	81 infants	SMD -0.93 lower (95% CI -1.40 lower to -0.47 lower)
• NFCS score	2 studies	147 infants	SMD -0.71 lower (95% CI -1.05 lower to -0.38 lower)
• PIP score	1 study	60 infants	SMD -0.67 lower (95% CI -1.19 lower to -0.15 lower)
• Overall estimate	5 studies		SMD -0.76 lower (95% CI -1.00 lower to -0.52 lower)
Pain response to venipuncture versus heel lance in infants who received a sweet tasting solution			
• Neonatal Infant Pain Scale (NIPS)			Not reported
• NFCS score	2 studies	110 infants	MD -0.48 lower (95% CI -0.87 lower to -0.09 lower)
• PIP score	1 study	60 infants	MD -0.21 lower (95% CI -0.72 lower to 0.30 higher)
• Overall estimate	3 studies	230 infants	MD -0.38 lower (95% CI -0.69 lower to -0.07 lower)

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Venipuncture versus heel lance for blood sampling in term neonates

Need for more than one skin puncture

Study or subgroup	VP n/N	HL n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Eriksson 1999	8/90	13/30		21.8 %	0.62 [0.30, 1.27]
Larsen 1998	7/65	5/67		71.7 %	0.19 [0.09, 0.38]
Qigao 2005	0/25	0/25			Not estimable
Shah 1997	1/13	4/14		6.5 %	0.27 [0.03, 2.11]
Total (95% CI)	118	136		100.0 %	0.29 [0.18, 0.46]

Total events: 11 (VP), 17 (HL)
Heterogeneity: I² = 5.7%; I² = 0.00; P = 0.85
Test for overall effect: Z = 5.95; P < 0.0001
Test for subgroup differences: Not applicable

The RR for requiring more than one skin puncture for venipuncture versus heel lance is 0.29 (95% CI 0.18 to 0.46).

The RD for requiring more than one skin puncture for venipuncture versus heel lance (reported in 4 studies; n = 254) was -0.34 (95% CI -0.43 to -0.25; I² = 97%). The NNT to avoid one repeat skin puncture was 3 (95% CI 2 to 4).

Shah VS, Ohlsson A. Venipuncture versus heel lance for blood sampling in term neonates. Cochrane Database of Systematic Reviews 2011, Issue 10. Art. No.: CD001452. DOI: 10.1002/14651858.CD001452.pub4.

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Cochrane Neonatal

Venipuncture versus heel lance for blood sampling in term neonates


Authors' conclusions

Venipuncture, when performed by a skilled phlebotomist, appears to be the method of choice for blood sampling in term neonates. The use of a sweet tasting solution further reduces the pain.

Further well designed randomized controlled trials should be conducted in settings where several individuals perform the procedures.

Shah VS, Ohlsson A. Venipuncture versus heel lance for blood sampling in term neonates. Cochrane Database of Systematic Reviews 2011, Issue 10. Art. No.: CD001452. DOI: 10.1002/14651858.CD001452.pub4.

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Breastfeeding or breast milk for procedural pain in newborn infants

Shah PS, Torgalkar R, Shah VS.

Cochrane Database of Systematic Reviews 2012, Issue 12. Art. No.: CD004950.
DOI: 10.1002/14651858.CD004950.pub3.

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Breastfeeding or breast milk for procedural pain in newborn infants


Background: Pain in the neonate is associated with acute behavioral and physiological changes. Cumulative pain is associated with morbidities including adverse neurodevelopmental outcomes. Clinical studies have shown reduction in changes in physiological parameters and pain score measurements following pre-emptive analgesic administration in situations where the neonate is experiencing pain or stress. **Non-pharmacological measures (such as holding, swaddling and breastfeeding) and pharmacological measures (such as acetaminophen, sucrose and opioids) have been used for analgesia.**

Objectives: The primary objective was to evaluate the effectiveness of breastfeeding or supplemental breast milk in reducing procedural pain in neonates. The secondary objective was to conduct subgroup analyses based on the type of control intervention, gestational age and the amount of supplemental breast milk given.

Selection criteria: We included randomized controlled trials (RCTs) or quasi-RCTs of breastfeeding or supplemental breast milk versus no treatment/other measures in neonates. We included both term (≥ 37 completed weeks postmenstrual age) and preterm infants (< 37 completed weeks' postmenstrual age) up to maximum of 44 weeks' postmenstrual age.

Shah PS, Torgalkar R, Shah VS. Breastfeeding or breast milk for procedural pain in newborn infants
Cochrane Database of Systematic Reviews 2012, Issue 12. Art. No.: CD004950. DOI: 10.1002/14651858.CD004950.pub3. update 2022


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Breastfeeding for procedural pain in newborn infants

Intervention / outcome	Studies	Infants	Results
Breastfeeding versus no intervention			
• Heart rate	2 studies	166 infants	MD -5.56 bpm lower (95% CI -16.34 lower to 5.22 higher)
• Duration of crying	10 studies	790 infants	MD -36.23 seconds (95% CI -55.57 lower to -16.89 lower)
• Neonatal Infant Pain Scale (NIPS)	5 studies	459 infants	MD -2.53 lower (95% CI -3.46 lower to -1.60 lower)
Breastfeeding versus being held by mother			
• Heart rate	5 studies	295 infants	MD -11.78 bpm lower (95% CI -19.95 lower to -3.60 lower)
• Duration of crying	4 study	260 infants	MD -16.50 seconds (95% CI -29.68 lower to -3.32 lower)
• Neonatal Infant Pain Scale (NIPS)	3 studies	230 infants	MD -0.81 lower (95% CI [-1.57 lower to -0.05 lower])


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Breast milk for procedural pain in newborn infants

Intervention / outcome	Studies	Infants	Results
Breast milk feeding versus no intervention			
• Heart rate	1 study	60 infants	MD -20.00 bpm lower (95% CI -28.74 lower to -11.26 lower)
• Duration of crying	1 study	60 infants	MD 36.70 seconds higher (95% CI 0.60 higher to 72.80 higher)
• Oxygen saturation	2 studies	166 infants	MD -0.90 seconds lower (95% CI -1.40 lower to -0.50 lower)
• Neonatal Infant Pain Scale (NIPS)	1 study	60 infants	MD -0.30 lower (95% CI -1.60 lower to 1.00 higher)

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Breastfeeding or breast milk for procedural pain in newborn infants

Authors' conclusions

Moderate/low certainty of evidence suggest that breastfeeding or supplemental breast milk likely reduce pain in neonates undergoing painful procedure as compared to no intervention/positioning/holding neonates or placebo or non-pharmacological interventions.

Low certainty of evidence suggest that moderate concentration (20% to 33%) of glucose/sucrose may have little or no difference in reducing pain compared to breastfeeding.

The effectiveness of breast milk for painful procedure should be studied in the preterm population, as there are currently a limited number of studies that have assessed its effectiveness in this population.

Shah PS, Torgalkar R, Shah VS. Breastfeeding or breast milk for procedural pain in newborn infants
Cochrane Database of Systematic Reviews 2012, Issue 12. Art. No.: CD004950. DOI: 10.1002/14651858.CD004950.pub3. update 2022

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Non-pharmacological management of infant and young child procedural pain.

Pillai Riddell RR, Racine NM, Gennis HG, Turcotte K, Uman LS, Horton RE, Ahola Kohut S, Hillgrove Stuart J, Stevens B, Lisi DM.

Cochrane Database Syst Rev. 2015 Dec 2;2015(12):CD006275.

doi: 10.1002/14651858.CD006275.pub3.

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Cochrane Neonatal Non-nutritive sucking

What do we mean by “Non-nutritive sucking”

Non-nutritive sucking-related strategies: an object (e.g. pacifier, non-lactating nipple) is placed into an infant's mouth to stimulate oro-tactile or sucking behaviors during a painful event.

This may have involved other adjuvant non-pharmacological interventions that fall under the purvey of the review

Pillai Riddell and colleagues. Non-pharmacological management of infant and young child procedural pain. Cochrane Database Syst Rev. 2015 Dec 2;2015(12):CD006275. doi: 10.1002/14651858.CD006275.pub3.

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Non-pharmacological management of infant and young child procedural pain.

Non-nutritive sucking

28 treatment arms evaluated



Pillai Riddell and colleagues. Non-pharmacological management of infant and young child procedural pain. Cochrane Database Syst Rev. 2015 Dec 2;2015(12):CD006275. doi: 10.1002/14651858.CD006275.pub3.

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Cochrane Neonatal Non-nutritive sucking

Outcome	Studies	Infants	Results
Preterm infants			
• Pain reactivity	6 studies (7 arms)	329 infants	SMD -0.31 lower (95% CI -0.65 lower to 0.04 higher)
• Immediate pain regulation	5 studies (7 arms)	260 infants	SMD -0.43 lower (95% CI -0.63 lower to -0.23 lower)
Term infants			
• Pain reactivity	5 studies	270 infants	SMD -1.20 lower (95% CI -2.01 lower to -0.38 lower)
• Immediate pain regulation	7 studies	325 infants	SMD -0.90 lower (95% CI -1.54 lower to -0.25 lower)

Very low quality evidence

Pillai Riddell and colleagues. Non-pharmacological management of infant and young child procedural pain. Cochrane Database Syst Rev. 2015 Dec 2;2015(12):CD006275. doi: 10.1002/14651858.CD006275.pub3.

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Cochrane Neonatal Swaddling/facilitated tucking

What do we mean by “swaddling/facilitated tucking”

Swaddling is when an infant is securely wrapped in a blanket to prevent the child's limbs from moving around excessively.

Facilitated tucking involves firmly containing the infant using a caregiver's hands on both head and lower limbs to maintain a 'folded-in' position. Infant may or may not be wearing clothes.

Pillai Riddell and colleagues. Non-pharmacological management of infant and young child procedural pain. Cochrane Database Syst Rev. 2015 Dec 2;2015(12):CD006275. doi: 10.1002/14651858.CD006275.pub3.

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Non-pharmacological management of infant and young child procedural pain.

Swaddling/facilitated tucking

15 treatment arms



Pillai Riddell and colleagues. Non-pharmacological management of infant and young child procedural pain. Cochrane Database Syst Rev. 2015 Dec 2;2015(12):CD006275. doi: 10.1002/14651858.CD006275.pub3.

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Cochrane Neonatal Swaddling/tucking-related

Outcome	Studies	Infants	Results
Preterm infants			
• Pain reactivity	9 studies	331 infants	SMD -0.89 lower (95% CI -1.37 lower to -0.40 lower)
• Immediate pain regulation	5 studies	119 infants	SMD -0.71 lower (95% CI -1.00 lower to -0.43 lower)
Term infants			
• Pain reactivity	1 study	42 infants	SMD -1.26 lower (95% CI -1.92 lower to -0.60 lower)

Pillai Riddell and colleagues. Non-pharmacological management of infant and young child procedural pain. Cochrane Database Syst Rev. 2015 Dec 2;2015(12):CD006275. doi: 10.1002/14651858.CD006275.pub3.

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Cochrane Neonatal

Skin-to-skin care for procedural pain in neonates

Johnston C, Campbell-Yeo M, Benoit B, Disher T. Skin-to-skin care for procedural pain in neonates.

Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: CD008435. DOI: 10.1002/14651858.CD008435.pub3.

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Cochrane Neonatal Skin-to-skin care for procedural pain in neonates.



Johnston and colleagues. Skin-to-skin care for procedural pain in neonates. Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: CD008435. DOI: 10.1002/14651858.CD008435.pub3.

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Cochrane Neonatal Skin-to-skin care for procedural pain in neonates.

Background : Skin-to-skin care (SSC), often referred to as 'kangaroo care' (KC) due to its similarity with marsupial behavior of ventral maternal-infant contact, is one non-pharmacological intervention for pain control in infants.

Objectives: The primary objectives were to determine the effect of SSC alone on pain from medical or nursing procedures in neonates compared to no intervention, sucrose or other analgesics, or additions to simple SSC such as rocking; and to determine the effects of the amount of SSC (duration in minutes), method of administration (e.g. who provided the SSC) of SSC in reducing pain from medical or nursing procedures in neonates

The secondary objectives were to determine the safety of SSC care for relieving procedural pain in infants; and to compare the SSC effect in different postmenstrual age subgroups of infants.

Selection criteria: Studies with randomization or quasi-randomization, double- or single-blinded, involving term infants (≥ 37 completed weeks' postmenstrual age (PMA) to a maximum of 44 weeks' PMA and preterm infants (< 37 completed weeks PMA) receiving SSC for painful procedures conducted by healthcare professionals.

Johnston and colleagues. Skin-to-skin care for procedural pain in neonates. Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: CD008435. DOI: 10.1002/14651858.CD008435.pub3.

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Skin-to-skin care for procedural pain in neonates.



25 trials
2001 infants

Johnston and colleagues. Skin-to-skin care for procedural pain in neonates. Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: CD008435. DOI: 10.1002/14651858.CD008435.pub3.

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Cochrane Neonatal Skin-to-skin care for procedural pain in neonates

Intervention/outcome	Studies	Infants	Results
Seventeen studies (n = 810) compared skin to skin care (SSC) to a no-treatment control			
• Heart rate during	5 studies	161 infants	MD -10.78 bpm lower (95% CI -13.63 lower to -7.93 lower)
• Heart rate after	4 studies	120 infants	MD 0.08 seconds higher (95% CI -4.39 lower to 4.55 higher)
• Duration of crying	• 2 studies heel lance • 2 studies IM injection	heel lance: 33 infants IM injection: 100 infants	heel lance MD -34.16 seconds lower (95% CI -42.86 lower to -25.45 lower) IM injection (MD -8.83 seconds lower (95% CI -14.63 lower to -3.02 lower)
• Premature Infant Pain Profile (PIPP)	5 studies	267 infants	30 seconds MD -3.21 lower (95% CI -3.94 lower to -2.47 lower)
	3 studies 60 seconds	156 infants	60 seconds MD -1.64 lower (95% CI -2.86 lower to -0.43 lower)
	3 studies 90 seconds	156 infants	90 seconds MD -1.28 lower (95% CI -2.53 lower to -0.04 lower)
	3 studies 120 seconds	156 infants	120 seconds MD 0.07 higher (95% CI -1.11 lower to 1.25 higher).

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Cochrane Neonatal Skin-to-skin care for procedural pain in neonates.


Authors' conclusions

SSC appears to be effective as measured by composite pain indicators with both physiological and behavioral indicators and, independently, using heart rate and crying time; and safe for a single painful procedure.

There is a need for replication studies that use similar, clearly defined outcomes. Studies examining optimal duration of SSC, gestational age groups, repeated use, and long-term effects of SSC are needed. Of interest would be to study synergistic effects of SSC with other interventions.

Johnston and colleagues. Skin-to-skin care for procedural pain in neonates. Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: CD008435. DOI: 10.1002/14651858.CD008435.pub3.

54

 **Cochrane Neonatal**


Sucrose for analgesia in newborn infants undergoing painful procedures.

Stevens B, Yamada J, Ohlsson A, Haliburton S, Shorkey A.

Cochrane Database of Systematic Reviews 2016, Issue 7. Art. No.: CD001069. DOI: 10.1002/14651858.CD001069.pub5.

55


Sucrose for analgesia in newborn infants undergoing painful procedures



74 trials
7049 infants


Stevens and colleagues. Sucrose for analgesia in newborn infants undergoing painful procedures. Cochrane Database of Systematic Reviews 2016, Issue 7. Art. No.: CD001069. DOI: 10.1002/14651858.CD001069.pub5.

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 **Cochrane Neonatal** **Sucrose for analgesia in newborn infants undergoing painful procedures**

Administration of oral sucrose with or without non-nutritive sucking is the most frequently studied non-pharmacological intervention for procedural pain relief in neonates.

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 **Cochrane Neonatal** **Sucrose for analgesia in newborn infants undergoing painful procedures**

Intervention/outcome	Studies	Infants	Results
Heel lance: sucrose (12% to 12.5%) versus water/routine care			
• Duration of crying	1 study	42 infants	MD -48.09 seconds lower (95% CI -93.04 lower to -3.14 lower)
Heel lance: sucrose (20% to 33%) versus water			
• Duration of crying	2 studies	88 infants	MD -22.11 seconds lower (95% CI -32.52 lower to -11.70 lower)
Heel lance: sucrose (50%) versus water			
• Duration of crying (first cry)	2 studies	80 infants	MD -63.20 seconds lower (95% CI -79.20 lower to -47.19 lower)
Heel lance: sucrose (20%) versus human milk			
• Duration of crying	1 study	35 infants	MD -8.00 seconds lower (95% CI -21.07 lower to 5.07 higher)

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 **Cochrane Neonatal**


Topical anaesthesia for needle-related pain in newborn infants.

Foster JP, Taylor C, Spence K, Shaffer Zawahry H, Stefaniv I.

Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: CD010331. DOI: 10.1002/14651858.CD010331.pub2.

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Topical anaesthesia for procedural pain in newborn infants



8 trials
506 infants

Foster JP, Taylor C, Spence K, Shaffer Zawahry H, Stefaniv I. Topical anaesthesia for needle-related pain in newborn infants. Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: CD010331. DOI: 10.1002/14651858.CD010331.pub2.

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 Topical anesthesia for procedural pain in newborn infants

The review included 8 small randomized controlled trials enrolling 506 infants.


These studies compared either EMLA and placebo or amethocaine and placebo.

No studies compared EMLA and amethocaine.

We were unable to meta-analyze the outcome of pain due to differing outcome measures and methods of reporting.

Foster JP, Taylor C, Spence K, Shaffer Zawahry H, Stefaniv I. Topical anaesthesia for needle-related pain in newborn infants. Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: CD010331. DOI: 10.1002/14651858.CD010331.pub2.

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 Topical anesthesia for procedural pain in newborn infants

For EMLA, two individual studies reported a statistically significant reduction in pain compared to placebo during lumbar puncture and venipuncture. Three studies found no statistical difference between the groups during heel lancing.

For amethocaine, three studies reported a statistically significant reduction in pain compared to placebo during venipuncture and one study reported a statistically significant reduction in pain compared to placebo during cannulation. One study reported no statistical difference between the two groups during intramuscular injection.


Foster JP, Taylor C, Spence K, Shaffer Zawahry H, Stefaniv I. Topical anaesthesia for needle-related pain in newborn infants. Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: CD010331. DOI: 10.1002/14651858.CD010331.pub2.

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 **Topical anesthesia for procedural pain in newborn infants**

Intervention / outcome	Studies	Infants	Results
EMLA versus placebo			
• Pain using Premature Infant Pain Profile (PIPP) score	1 study	38 infants	MD 0.27 higher (95% CI -1.45 lower to 1.99 higher)
• Pain using Neonatal Infant Pain Scale (NIPS) score	2 studies	165 infants	MD -2.69 lower (95% CI -3.11 lower to -2.27 lower)
• Successful venipuncture first attempt	1 study	111 infants	RR 0.98 (95% CI 0.93 to 1.03)
Amethocaine versus placebo			
• Pain using Premature Infant Pain Profile (PIPP) score	1 study	20 infants	MD -0.30 lower (95% CI -2.28 lower to 1.68 higher)
• Pain using Neonatal Infant Pain Scale (NIPS) score	1 study	20 infants	MD -0.30 lower (95% CI -1.62 lower to 1.02 higher)
• Successful venipuncture first attempt	2 studies	98 infants	RR 1.06 (95% CI 0.33 to 1.34)

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 Topical anesthesia for procedural pain in newborn infants

Authors' conclusions

Overall, all the trials were small, and the effects of uncertain clinical significance.

The evidence regarding the effectiveness or safety of the interventions studied is inadequate to support clinical recommendations. There has been no evaluation regarding any long-term effects of topical anesthetics in newborn infants.

High quality studies evaluating the efficacy and safety of topical anesthetics such as amethocaine and EMLA for needle-related pain in newborn term or preterm infants are required. These studies should aim to determine efficacy of these topical anesthetics and on homogenous groups of infants for gestational age.

While there was no methemoglobinemia in the studies that reported methemoglobin, the efficacy and safety of EMLA, especially in very preterm infants, and for repeated application, need to be further evaluated in future studies.

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Non-opioid analgesics for procedural pain in neonates

Persad E, Pizarro AB, Bruschetti M.

Persad E, Pizarro AB, Bruschetti M. Non-opioid analgesics for procedural pain in neonates. Cochrane Database of Systematic Reviews 2022, Issue 7. Art. No.: CD015179. DOI: 10.1002/14651858.CD015179.

65

 Non-opioid analgesics for procedural pain


Background: A wide variety of pain control mechanisms have been developed and implemented to address procedural pain in neonates. This review focused on non-opioid analgesics, specifically nonsteroidal anti-inflammatory drugs (NSAIDs) and N-methyl-D-aspartate (NMDA) receptor antagonists, which alleviate pain through inhibiting cellular pathways to achieve analgesia.

Objectives: To determine the effects of non-opioid analgesics in neonates (term or preterm) exposed to procedural pain compared to placebo or no drug, non-pharmacological intervention, other analgesics, or different routes of administration.

Persad E, Pizarro AB, Bruschetti M. Non-opioid analgesics for procedural pain in neonates. Cochrane Database of Systematic Reviews 2022, Issue 7. Art. No.: CD015179. DOI: 10.1002/14651858.CD015179.

66

Non-opioid analgesics for procedural pain in neonates



2 trials
269 infants

Persad E, Pizarro AB, Bruschetti M. Non-opioid analgesics for procedural pain in neonates. Cochrane Database of Systematic Reviews 2022, Issue 7. Art. No.: CD015179. DOI: 10.1002/14651858.CD015179.

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Cochrane Neonatal

Non-opioid analgesics for procedural pain

Intervention	Studies	Infants	Results
Head-to-head comparison of different analgesics			
Intravenous fentanyl versus intravenous ketamine during laser photocoagulation for retinopathy of prematurity			
Pain score (PIPP-R) up to 10 minutes after the procedure	1 study	124 infants	MD 0.98 higher (95% CI 0.75 higher to 1.25 higher)
Episodes of apnea	1 study	124 infants	RR 0.31 [0.08 to 1.18]
Need for supplemental oxygen	1 study	124 infants	RR 0.33 [0.12 to 0.89]
Hypotension requiring medical therapy	1 study	124 infants	RR 5.53 [0.27 to 112.30]

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Cochrane Neonatal

Non-opioid analgesics for procedural pain

Authors' conclusions

The two small studies included (ketamine versus either placebo or fentanyl) with very low-certainty evidence rendered us unable to draw meaningful conclusions.

The evidence is very uncertain about the effect of ketamine on pain score during the procedure compared with placebo or fentanyl. No evidence was found on NSAIDs or studies comparing different routes of administration.

Future research should prioritize large studies evaluating non-opioid analgesics in this population. As the studies included in this review suggest potential positive effects of ketamine administration, studies evaluating ketamine are of interest.

Further, as no studies on NSAIDs, which are widely used in older infants, or comparing different routes of administration were identified, these should be a priority going forward.

Persad E, Pizarro AB, Bruschetti M. Non-opioid analgesics for procedural pain in neonates. Cochrane Database of Systematic Reviews 2022, Issue 7. Art. No.: CD015179. DOI: 10.1002/14651858.CD015179.

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Cochrane Neonatal

Opioids for procedural pain in neonates.

Kinoshita M, Olsson E, Borys F, Bruschetti M.

Cochrane Database of Systematic Reviews 2021, Issue 12. Art. No.: CD015056. DOI: 10.1002/14651858.CD015056.

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Cochrane Neonatal

Opioids for procedural pain in neonates

Background: Neonates might be exposed to numerous painful procedures due to diagnostic reasons, therapeutic interventions, or surgical procedures.


Options for pain management include opioids, non-pharmacological interventions, and other drugs. Morphine, fentanyl, and remifentanyl are the opioids most often used in neonates. However, negative impact of opioids on the structure and function of the developing brain has been reported.

Objectives: To evaluate the benefits and harms of opioids in term or preterm neonates exposed to procedural pain, compared to placebo or no drug, non-pharmacological intervention, other analgesics or sedatives, other opioids, or the same opioid administered by a different route.

Kinoshita and colleagues. Opioids for procedural pain in neonates. Cochrane Database of Systematic Reviews 2021, Issue 12. Art. No.: CD015056. DOI: 10.1002/14651858.CD015056.

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Opioids for procedural pain in neonates



13 trials
823 infants

Kinoshita and colleagues. Opioids for procedural pain in neonates. Cochrane Database of Systematic Reviews 2021, Issue 12. Art. No.: CD015056. DOI: 10.1002/14651858.CD015056.

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Cochrane Neonatal **Opioids for procedural pain**

Intervention	Studies	Infants	Results
Opioids versus no treatment or placebo for procedural pain			
NIPS during procedure	2 studies	102 infants	MD -1.97 lower (95% CI -2.46 lower to -1.48 lower)
Pain score (PIPP/PIPP-R) during the procedure	3 studies	199 infants	MD -2.58 lower (95% CI -3.12 lower to -2.03 lower)
Pain score (PIPP/PIPP-R) up to 30 minutes after procedure	2 studies	123 infants	MD 0.14 higher (95% CI -0.17 lower to 0.45 higher)
PIPP/PIPP-R 1-2 hours after procedure	2 studies	54 infants	MD -0.83 higher (95% CI -2.42 lower to 0.75 higher)
Episodes of bradycardia	3 studies	172 infants	RR 3.19 (95%CI 0.14 to 72.69)
Episodes of desaturation	3 studies	199 infants	RR 1.82 (95% CI 0.72 to 4.58)
Episodes of apnea	3 studies	199 infants	RR 3.15 (95% CI 1.08 to 9.16)
Hypotension	2 studies	88 infants	Not estimable

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Cochrane Neonatal **Opioids for procedural pain in neonates**

Conclusions

Limited evidence is available regarding opioid administration for procedural pain in newborn infants compared to placebo or no drug, non-pharmacological interventions, other opioids or analgesics, or the same opioid by different route of administration.

In comparison to placebo, opioids probably reduce pain score assessed shortly after the procedure.

The evidence is very uncertain about the effect of opioids on episodes of bradycardia or hypotension. Opioids may result in a large increase in episodes of apnea.

No studies reported parent satisfaction with care provided in the NICU.

The evidence is very uncertain about the effect of opioids on any outcome when compared to non-pharmacological interventions or to other analgesics.

Kinoshita and colleagues. Opioids for procedural pain in neonates. Cochrane Database of Systematic Reviews 2021, Issue 12. Art. No.: CD015056. DOI: 10.1002/14651858.CD015056.

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Cochrane Neonatal **Guest Discussants**



Danielle Elvet
Associate Professor of Pediatrics
Asfaw Yemru Green and Gold
Professor in Global Health
University of Vermont



Bill McGuire
Professor,
Hull York Medical School
Coordinating Editor
Cochrane Neonatal



Matteo Bruschetti
Associate Professor, Paediatrics
Lund University, Lund, Sweden
Director, Cochrane Sweden



Kanekal Suresh Gautham
Chair of Pediatrics and
Pediatrician in Chief
Nemours Children's Health System
Professor of Pediatrics
University of Central Florida
College of Medicine

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Cochrane Neonatal **Guest Discussants**



Erick Ridout
Neonatologist/Medical Director
Neonatology Department
Saint George Regional Hospital

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Cochrane Neonatal

Questions regarding minimizing procedural pain...

Where does the evidence take us?

What are best “practices” regarding minimizing procedural pain?

What future research is urgently needed?

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VON Vermont Oxford NETWORK

Worldwide Improvement Community

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Sponsors

Cochrane Neonatal received unrestricted grant support to update reviews on the infant and family experience in neonatal intensive care from the Gerber Foundation

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Guest Discussants

Danielle Ehret Associate Professor of Pediatrics Asfaw Yemru Green and Gold Professor in Global Health University of Vermont	Bill McGuire Professor, Hull York Medical School Coordinating Editor Cochrane Neonatal	Matteo Bruschetti Associate Professor, Paediatrics Lund University, Lund, Sweden Director, Cochrane Sweden	Kanekal Suresh Gautham Chair of Pediatrics and Pediatrician in Chief Nemours Children's Health System Professor of Pediatrics University of Central Florida College of Medicine

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Guest Discussants

Erick Ridout
Neonatologist/Medical Director
Neonatology Department
Saint George Regional Hospital


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The infant and family experience in neonatal intensive care: management of acute procedural pain

To develop an understanding of the strengths and weaknesses of evidence provided by systematic reviews and meta-analyses to inform our practice of neonatal-perinatal medicine.

Today's focus will be on managing acute procedural pain.

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 **Cochrane Neonatal**

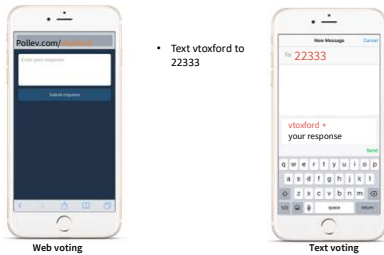
How to Participate in Today's Webinar

- Type questions you have into the chat box at anytime during the presentation.
- Use Poll Everywhere to answer questions posed during the session.

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Three ways to use Poll Everywhere

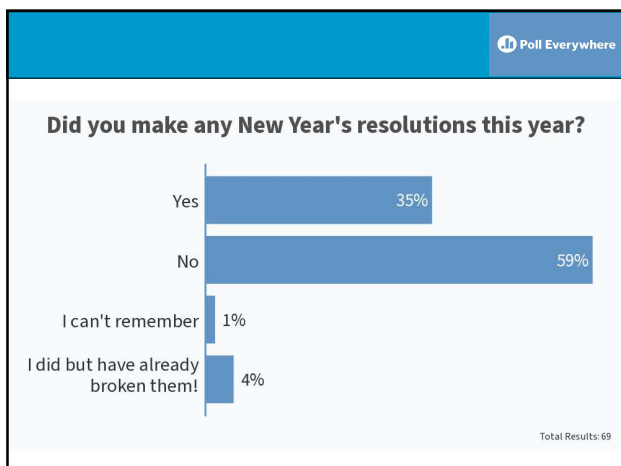
- Open your web browser and type in polllev.com/vtoxford
- Download the app Poll Everywhere on your phone. After it is installed open and select Join Presentation and type in vtoxford
- Text vtoxford to 22333



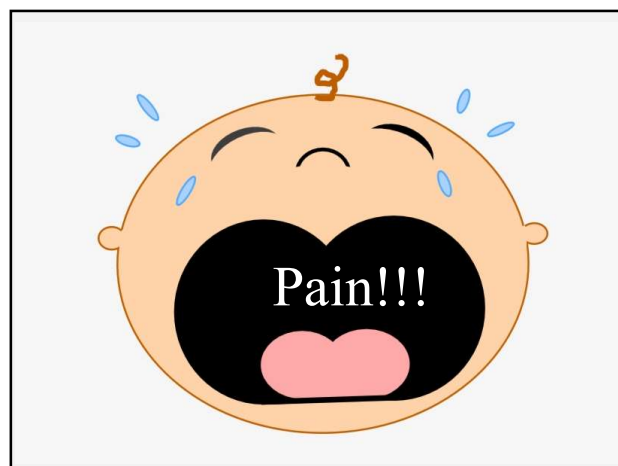
Web voting

Text voting


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 **Cochrane Neonatal**


Questions regarding minimizing procedural pain...

Where does the evidence take us?

What are best “practices” regarding minimizing procedural pain?

What future research is urgently needed?

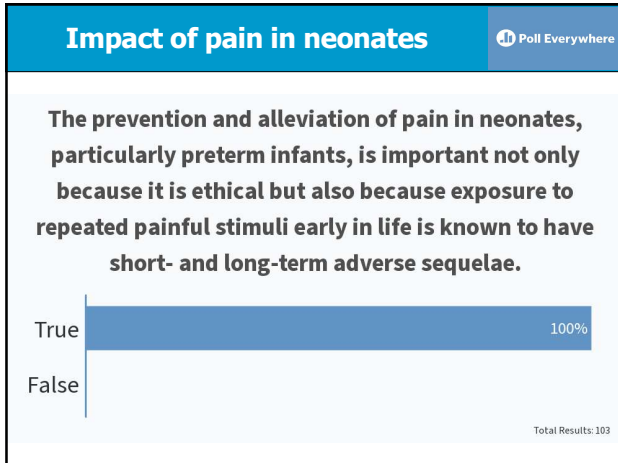
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 **Cochrane Neonatal**

Management of acute procedural pain

- Impact of pain on neonates
- Guidelines for pain management
- Policies and procedures to minimize painful procedures
- Assessment of pain
- Treatment(s) for procedural pain

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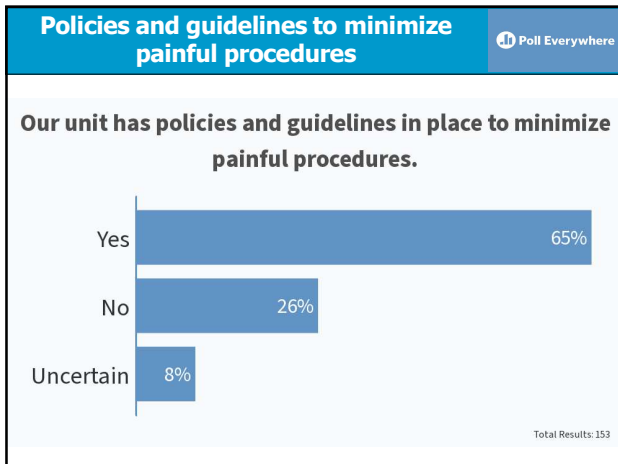
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Management of acute procedural pain

Short- and long-term adverse sequelae including:

- physiologic instability
- altered brain development
- abnormal neurodevelopment, somatosensory, and stress response systems, which can persist into childhood. (e.g., reduced white matter microstructure and subcortical gray matter, dorsal horn central desensitization)

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Cochrane Neonatal

Guest Discussants

Tell us more about POKE!

Erick Ridout
Neonatologist/Medical Director
Neonatology Department
Saint George Regional Hospital

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Cochrane Neonatal **Minimizing procedures: POKE**

DO FOR THE PATIENT...NEVER TO THE PATIENT

There are two main definitions for POKE:
 1) Any clinical experience that has the potential to harm the patient or fails to add value
 2) Team-based, patient-centered ecosystem where all are empowered to actively contribute, surface safety concerns, experience deep respect, relentlessly eliminate waste, and help patients, their families, and caregivers feel valued, safe, and loved.

HOW: Truly thoughtful (evidence and pretest probability driven), (VOICE OF) PATIENT DRIVEN, team-based, value-added care.

The program utilizes an implementation framework: Culture, Leadership, and Tools -> all to "Leverage the Genius at the Bedside."

<p>My NICU:</p> <ul style="list-style-type: none"> - 50% reduction in POKEs (11,000/yr) - Reduction in length of stay (~248 hours) - CLABSI (1/15 years) Last 4211 days ago - Press Ganey Engagement: 4.64 - RN Turnover <3% 	<p>Multi-Hospital Deployment of POKE (1 year):</p> <ul style="list-style-type: none"> - 150,000 POKEs eliminated - POKEs per patient: 5.1/day -> 3.1/day - \$1.2 Million Cost Avoided - \$50 Million Net Revenue Decrease
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Cochrane Neonatal **Minimizing procedures: POKE**

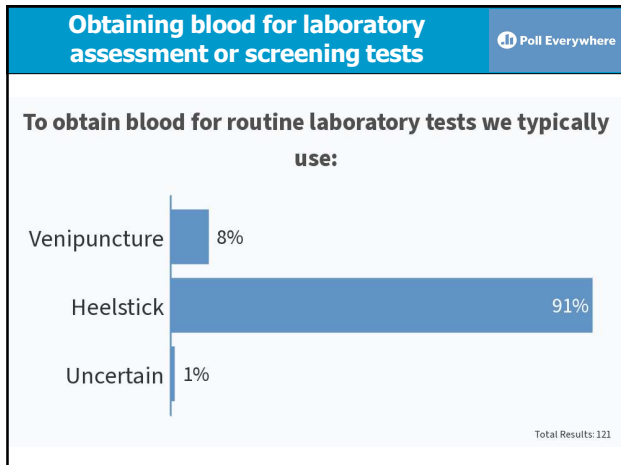
DO FOR THE PATIENT...NEVER TO THE PATIENT

HARM (Hierarchy, Burn Out, Ego)

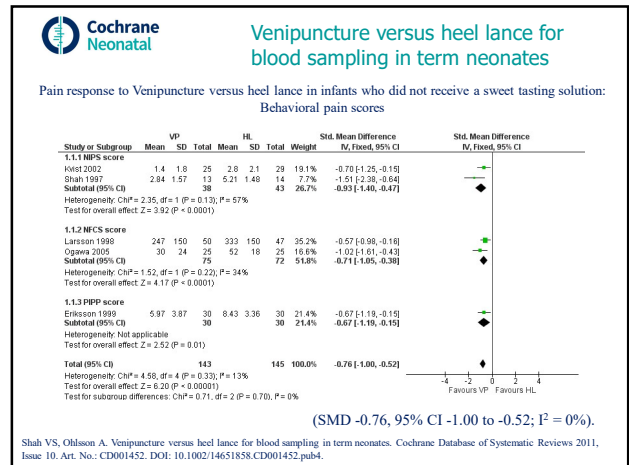
JUST CULTURE

Health Policy, Financial Incentives, Hospital & Health System Quality Alignment, Psychological Safety, Family, Team-Based Care, HUDDles, Leadership: Humility, Accountability, Value-Added, Respectful Care, Patient, Family, M.D., Nurse, Respiratory Care, Pharmacist, APP, NP, What are YOU going to do keep babies safe today?, Safety Culture, We are YOU going to do keep babies safe today!

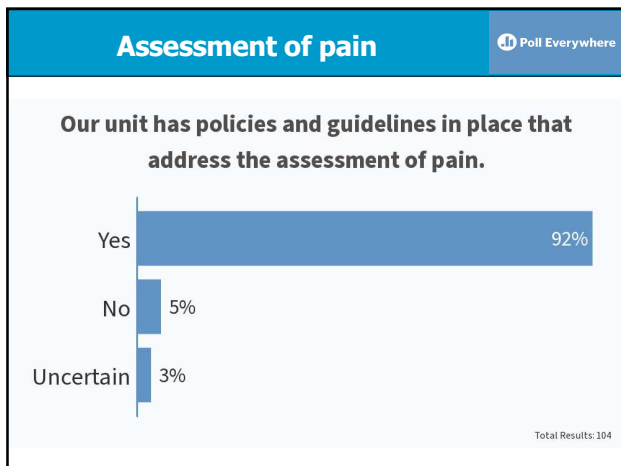
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Cochrane Neonatal: Routine assessment of pain

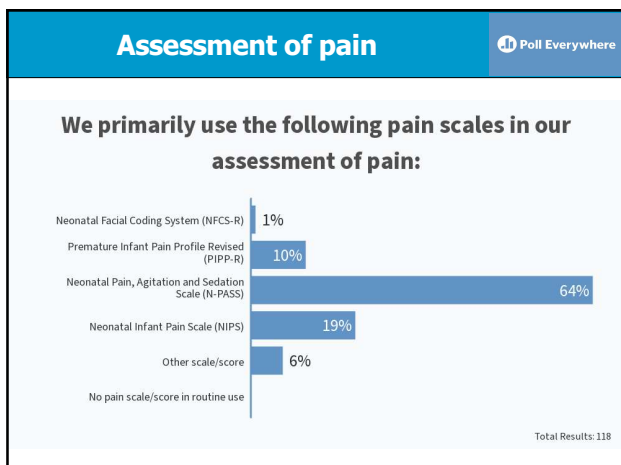
Optimal pain management requires competent pain assessment, which can be especially difficult to perform in neonates.

The pain-assessment tool used should be multidimensional, including measurements for both physiologic and behavioral indicators of pain, because neonates cannot self-report

Chiswick ML. Assessment of pain in neonates. Lancet.2000;355 :6- 8;

Walden M. Pain Assessment and Management: Guideline for Practice. Glenview, IL: National Association of Neonatal Nurses; 2001. Document 1222

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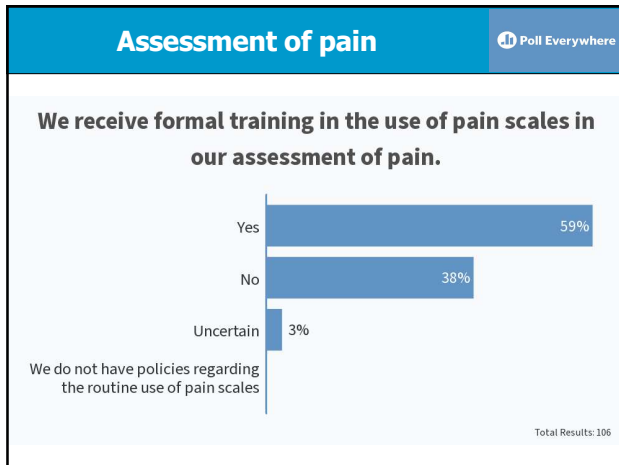
Cochrane Neonatal: Routine assessment of pain

Commonly used Neonatal Pain Assessment Scales

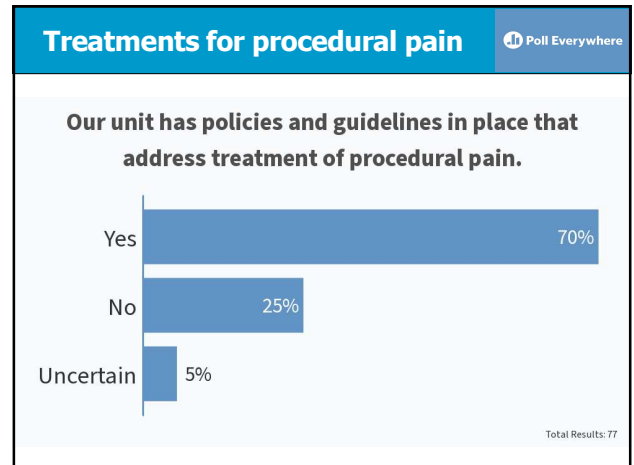
Tool	Characteristics	Score	Reliability
Neonatal Facial Coding System Revised (NFCS-R)	Five domains of facial movement	0-5	High inter-rater and construct validity
Premature Infant Pain Profile Revised (PIPP-R)	Two physiological, three behavioral two contextual items	0-18	Moderate consistency Good validity
Neonatal Pain, Agitation and Sedation Scale (N-PASS)	Five items: (1) crying; (2) behavior state; (3) facial expression; (4) tone of extremities; (5) vital sign changes (choice between HR, blood pressure, pulse, and oxygen saturation)	0-13 for preterm 0-10 for term	High consistency High validity Treatment recommended with score >3
Neonatal Infant Pain Scale (NIPS)	Six behavioral indicators	0-7	High consistency Limited validity data
Bernese Pain Scale Neonates (BPSN)	Three physiological and six behavioral indicators	0-27	High consistency High validity

Modified from McPherson and colleagues. The influence of pain, agitation, and their management on the immature brain. Pediatric Research (2020) 88:168 - 175

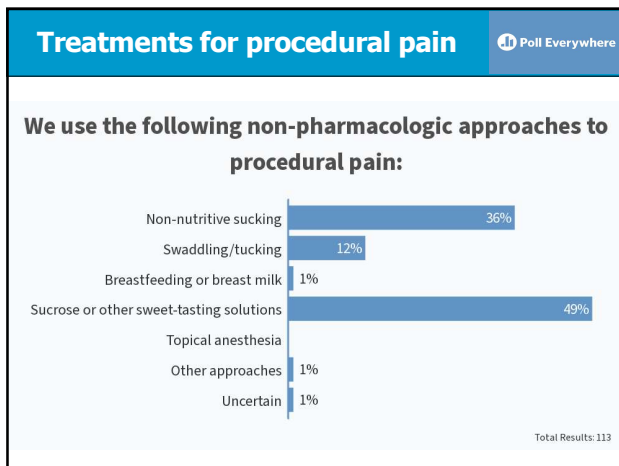
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American Academy of Pediatrics
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Pain and discomfort

The Committee on Fetus and Newborn of the American Academy of Pediatrics states that preventing or minimizing pain in neonates should be a priority for neonatal caregivers and recommends "written guidelines, based on existing and emerging evidence, for a stepwise pain-prevention and treatment plan" which would include judicious use of procedures, routine assessment of pain, and use of both pharmacologic and nonpharmacologic therapies for the prevention of pain

The pain management strategy suggested by the Committee on Fetus and Newborn and Section on Anesthesiology and Pain Medicines is comprehensive, but acting on each facet is not without challenges.

[Committee on Fetus and Newborn and Section on Anesthesiology and Pain Medicines 2016].

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American Academy of Pediatrics
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Pain and discomfort


Although there are major gaps in knowledge regarding the most effective way to prevent and relieve pain in neonates, proven and safe therapies are currently underused for routine minor, yet painful procedures.

Therefore, every health care facility caring for neonates should implement

- (1) a pain-prevention program that includes strategies for minimizing the number of painful procedures performed and
- (2) a pain assessment and management plan that includes routine assessment of pain, pharmacologic and nonpharmacologic therapies for the prevention of pain associated with routine minor procedures, and measures for minimizing pain associated with surgery and other major procedures


Committee on Fetus and Newborn and Section on Anesthesiology and Pain Medicines Prevention and Management of Procedural Pain in the Neonate: An Update. Pediatrics 2016

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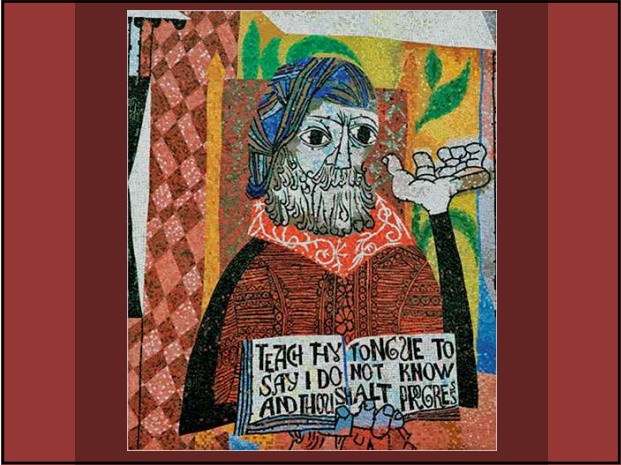
 **Cochrane**
Neonatal

Future programs for 2023:

- Plans for safe care – NAS
- Translating evidence to practice: The use of CPAP in diverse settings
- Translating evidence to practice: Care of the developing brain



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