

The Comfort Promise

Eliminating (or easing) pain and anxiety caused by needle procedure for children in pediatric healthcare settings

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The logo for Children's Minnesota, featuring a blue star above the word "Children's" in a serif font, with "MINNESOTA" in a blue sans-serif font below it.

The logo for UCSF Benioff Children's Hospitals, featuring a row of five stylized human figures in orange, red, purple, blue, and green above the text "UCSF Benioff Children's Hospitals" in a bold sans-serif font, with "Stad Center for Pediatric Pain, Palliative & Integrative Medicine" in a smaller sans-serif font below it.

The Comfort Promise

Module 2:

Current Evidence. The Why. The What. The How

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Why Change?

(We have always been doing it like this!)





What are children most afraid of when coming to a clinic or hospital ?

Friedrichsdorf S, Eull D, Weidner C: *Children Are Actually Afraid of Needle Pokes. And their Parents, too.* Journal of Things We Already Knew. 2016;(1)1:1-518

Needle Pain: A Call for Action

- **Needle procedures (incl. vaccine injections) performed in childhood are substantial source of distress**
 - By age 2: 14-20 vaccine injections in US
 - Children get behind in vaccination schedule
- **Injection-induced anxiety and pain most frequent adverse effect following immunization**
- **Over 90% of young children exhibit severe distress during immunization**

Taddio A, Chambers CT, Halperin SA, Ipp M, Lockett D, Rieder MJ, et al. Inadequate pain management during routine childhood immunizations: the nerve of it. Clin Ther 2009;31:S152-67.

Jacobson RM, Swan A, Adegbenro A, Ludington SL, Wollan PC, Poland GA, Vaccine Research Group. Making vaccines more acceptable—methods to prevent and minimize pain and other common adverse events associated with vaccines. Vaccine 2001;19:2418-27.



Challenges reported by 883 parents during childhood immunizations

Challenges	Frequency (%)
Crying	752 (85)
Screaming	338 (38)
Flailing	288 (33)
Having to use restraint to carry out procedure	206 (23)
Running away	173 (20)
Kicking	136 (15)
Light headedness	37 (4)
Threatening	31 (4)
Shortness of breath	33 (4)
Soil self	15 (2)
Fainting	14 (2)

- Taddio A, Ipp M, Thivakaran S, Jamal A, Parikh C, Smart S, Sovran J, Stephens D, Katz J. Survey of the prevalence of immunization non-compliance due to needle fears in children and adults. Vaccine 2012;30(32):4807-4812.

Procedural Pain in the Neonate

- Critically ill infant may experience >480 painful procedures during NICU stay Barker DP (1995)

Exposure to invasive procedures in neonatal intensive care unit admissions. Arch Dis Child Fetal Neonatal Ed 72:F47-8; Johnston CC (1997) A cross-sectional survey of pain and pharmacological analgesia in Canadian neonatal intensive care units. Clin J Pain 13:308-12

- Exposure to severe pain on NICU, without adequate treatment, has negative long-term consequences

- ↑ morbidity (hypoxia, coagulopathy, respiratory incoordination, increased intracranial pressure)
- ↑ risk of IVH

- ↑ mortality Anand KJS (1999) Analgesia and sedation in preterm neonates who require ventilatory support: results from the NOPAIN trial. Neonatal Outcome and Prolonged Analgesia in Neonates. Arch Pediatr Adolesc Med 153:331-8

- Combined procedural pain interventions (sucrose, massage, music, nonnutritive sucking, and gentle human touch) during neonatal intensive care improves sleep = correlated with improved cognitive neurodevelopment development at 2 years Gao H, Li M, Gao

H, Xu G, Wang D, Lv H. Effect of combined procedural pain interventions during neonatal intensive care on sleep, cognitive development, and internalizing behavior: a follow-up analysis of a randomized controlled trial. Pain. 2023;164(8):1793-800.



What is the Evidence?

What should we offer to every child. Every time. Everywhere.



Comfort Promise 1.0 versus 2.0

Since 2021 the “**Comfort Promise**” lists **6 simple steps to reduce or eliminate needle pain (5 in each age group)**

All age groups:

- Topical anesthesia (numbing cream)
- Comfort positioning
- Distraction
- Choices
- plus Infants only: Sucrose or breast feeding
- plus Children only: Praise & Memory-shaping





Numbing cream

Makes needle procedures less painful



Comfort positions

Helps children feel calm and secure



Distractions

Puts the focus on an entertaining activity



Choices

Provides the patient with some sense of control



Breastfeeding or sugar water

Soothes and reduces babies' pain



Memory-shaping

Frames the experience in a positive way

Comfort Tool Kit

**Plan the
“Before”,
“During”,
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Topical Local Anesthetics

- To reduce pain at time of injection, encourage parents to use **topical anesthetics** during vaccination of children (*grade A recommendation, based on level I evidence*). Taddio A, Appleton M, Bortolussi R, Chambers C, Dubey V, Halperin S, et al. Reducing the pain of childhood vaccination: an evidence-based clinical practice guideline. CMAJ : Canadian Medical Association journal 2010 Dec 14;182(18):E843-55.
- **Topical anesthetics considered safe for children of all ages.** However, administration of excessive doses and/or prolonged application times can lead to serious adverse effects, including irregular heartbeat, seizures and difficulty breathing
www.hc-sc.gc.ca/dhp-mpps/medeff/advisories-avis/public/_2009/empla_ametop_pc-cp-eng.php
- **Use numbing prior to all needle sticks** - incl. for term infants (36 weeks and older)
- **4% lidocaine**
 - Apply 30 minutes prior to needle procedure
 - Cover with plastic wrap or tape to avoid getting in mouth or eyes
 - Wipe off prior to injection, prep skin per protocol
 - Can safely be left in place for 2 hours
 - Effect lasts for at least 1 hour after it is removed
 - Warm pack may be applied to speed up numbing process

Can Numbing Cream be Substituted?

- Some single studies -usually industry-sponsored - show efficacy compared to NO TREATMENT (not compared to numbing cream), however
- **Vapocoolant spray**
 - Moderate-quality evidence indicates that use of a vapocoolant immediately before intravenous cannulation **reduces pain** during the procedure **by only 1.1 on a 0-10 scale** Griffith RJ, Jordan V, Herd D, Reed PW, Dalziel SR. Vapocoolants (cold spray) for pain treatment during intravenous cannulation. Cochrane Database Syst Rev. 2016;4(4):CD009484.
 - Metaanalysis [12 studies, 1266 patients (509 children, 757 adults)] **Vapocoolants ineffective in children** and adults when compared to placebo, and **effective in adults only when compared to no treatment.** Hogan ME, Smart S, Shah V, Taddio A. A systematic review of vapocoolants for reducing pain from venipuncture and venous cannulation in children and adults. J Emerg Med. 2014;47(6):736-49.
 - Metaanalysis (25 studies involving 3,143 participants) **Vapocoolant spray ineffective in children.** Wang L, Fang L, Zhou Y, Fang X, Liu J, Qu G (2023) Efficacy and safety of vapocoolant spray for vascular puncture in children and adults: A systematic review and meta-analysis. PLoS ONE 18(2): e0279463. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0279463>

Can Numbing Cream be Substituted?

- **Buzzy device**
- **Pain and anxiety relief using the Buzzy device is not as effective as EMLA cream in children requiring venipuncture.** Haidar NA, Al Amri MH, Sendad NG, Toaimah FHS. Efficacy of Buzzy Device Versus EMLA Cream for Reducing Pain During Needle-Related Procedures in Children: A Randomized Controlled Trial. *Pediatr Emerg Care*. Mar 1 2024;40(3):180-186.
- **Insufficient evidence** for or against use of **shot-blockers, Buzzy-Bees, skin-cooling techniques** Shah V, Taddio A, Rieder MJ, Team HE. Effectiveness and tolerability of pharmacologic and combined interventions for reducing injection pain during routine childhood immunizations: systematic review and meta-analyses. *Clin Ther*. 2009;31 Suppl 2:S104-51. (vapocoolants spray cause pain/discomfort in children) etc. to reduce pain at time of injection.
- **These tools may be considered in ADDITION to topical anesthetics - NOT INSTEAD of numbing cream!**

Application of Cream



- If removal of transparent adhesive uncomfortable, use adhesive remover spray
- or alternatively...



Application of Cream



J-Tip (Lidocaine)

J-tip: single-use, disposable, carbon-dioxide-powered, needle-less lidocaine injector

- J-Tip jet injection of 1% buffered lidocaine provided greater anesthesia than a 30-minute application of ELA-Max according to patient self-assessment of pain for children aged 8 to 15 years undergoing PIV catheter

insertion Spanos S, Booth R, Koenig H, Sikes K, Gracely E, Kim IK. Jet Injection of 1% buffered lidocaine versus topical ELA-Max for anesthesia before peripheral intravenous catheterization in children: a randomized controlled trial. *Pediatr Emerg Care*. Aug 2008;24(8):511-5. doi:10.1097/PEC.0b013e31816a8d5b

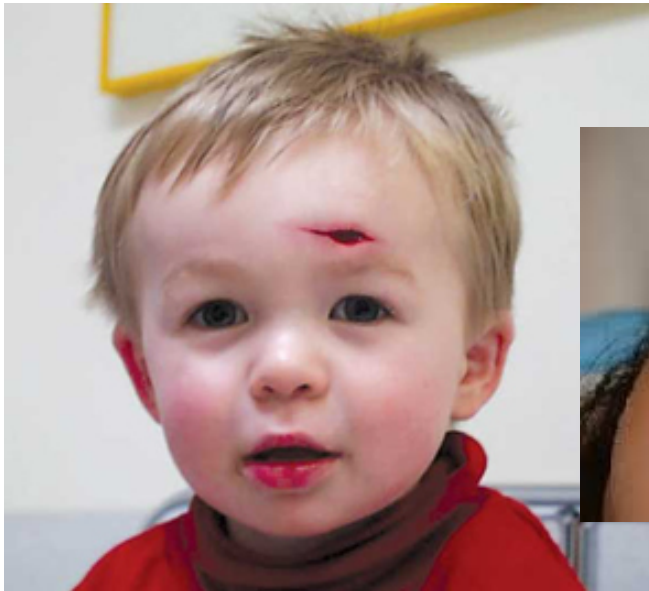
- Use of the J-Tip for children aged 1 to 6 years reduced venipuncture pain compared with vapocoolant spray or sham treatment.

Lunoe MM, Drendel AL, Levas MN, Weisman SJ, Dasgupta M, Hoffmann RG, et al. A Randomized Clinical Trial of Jet-Injected Lidocaine to Reduce Venipuncture Pain for Young Children. *Ann Emerg Med*. 2015;66(5):466-474.



LET Gel

Lidocaine 4% - **E**pinephrine 0.18% - **T**etracaine 0.5%
**On open wounds prior to sutures or painful interventions at
least 30 minutes prior**



MYTH versus REALITY



- **Numbing cream causes vasoconstriction**
 - Incorrect. If blanching, apply warm pack
- **Numbing cream doesn't work as analgesic**
 - Incorrect. Be aware of nocebo-effect; i.e. staff falsely claiming “it doesn't work”
- **We don't have the time to wait 30 (-60) minutes**
 - Incorrect. You may need to change to process - but it actually saved time in healthcare institution, which implemented the Comfort Promise Friedrichsdorf SJ,

Eull D, Weidner C, Postier A. A hospital-wide initiative to eliminate or reduce needle pain in children using lean methodology. Pain Rep. 2018;3(Suppl 1):e671.

WHO Guideline



- **WHO guidelines (2015) state that the lack of analgesic provision for vaccination pain is inexcusable.**

Organization WH. Reducing pain at the time of vaccination:WHO position paper, September 2015-Recommendations.Vaccine. 2016;34(32):3629-30.
<https://www.who.int/publications/i/item/who-wer9039>



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Comfort Tool Kit



Sucrose for Infants 0-12 months

Sucrose

- Reduces pain and cry during painful procedure, such as venipuncture

Stevens B, Yamada J, Ohlsson A, Haliburton S, Shorkey A. Sucrose for analgesia in newborn infants undergoing painful procedures. Cochrane Database Syst Rev. 2016;7:CD001069.

Sucrose (*Does not affect NPO status or Lab Values*)

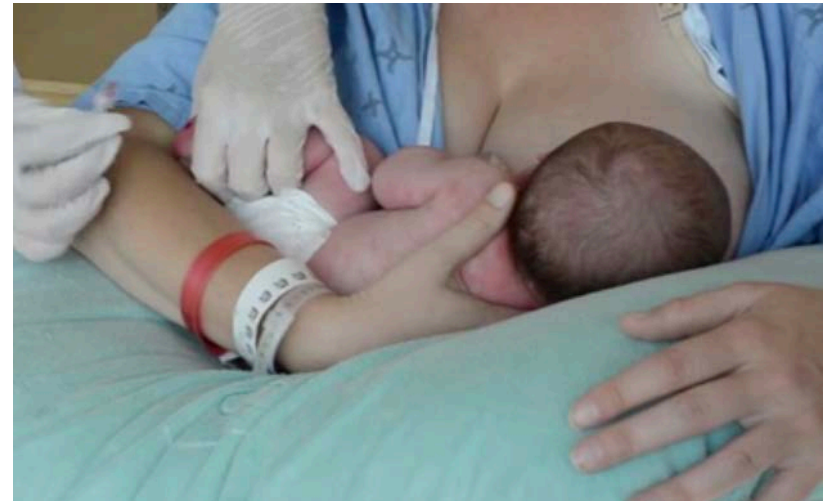
- Give solution 2 minutes prior to procedure (on pacifier, parents' finger, side of cheek)
- Just drops are needed (taste triggers the effect)
- Effect lasts for 4 minutes
- Re-administer as needed during and after the procedure
- Role of endogenous opioids - naloxone blunts effect
 - Effective dose (24%): Just a drop (0.1 ml) Stevens B, Yamada J, Campbell-Yeo M, Gibbins S, Harrison D, Dionne K, et al. The minimally effective dose of sucrose for procedural pain relief in neonates: a randomized controlled trial. BMC pediatrics. 2018;18(1):85.
 - Administration 2 minutes prior to mild - moderately painful procedure
 - Duration ~ 4 min
- Evidence for 0-12 months, may offer beyond



Breastfeeding for Infants 0-12 months

Breastfeeding

- Start 2-5 minutes before the procedure
- Continue throughout
- Evidence for 0-12 months, may offer beyond
- Effective in term infants (superior to sweetening agents - likely due to skin-to-skin?) (1) Shah PS, Herbozo C, Aliwalas LL, Shah VS. Breastfeeding or breast milk for procedural pain in neonates. Cochrane Database Syst Rev. 2012;12:CD004950. (2) Gray L, Miller LVW, Philipp BL, Blass EM. Breastfeeding is analgesic in healthy newborns. Pediatrics. 2002 Apr;109(4):590-3. (3) Weissman A, Aranovitch M, Blazer S, Zimmer EZ. Heel-lancing in newborns: behavioral and spectral analysis assessment of pain control methods. Pediatrics. 2009 Nov;124(5):e921-6.
- Ineffective in preterm infants? Holsti L, Oberlander TF, Brant R. Does breastfeeding reduce acute procedural pain in preterm infants in the neonatal intensive care unit? A randomized clinical trial. Pain. 2011 Nov;152(11):2575-81.





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Comfort Promise Tool Box

Comfort Positioning

For Children <6 months of age

- Swaddle, warmth
- Skin to skin (kangaroo care)
- Facilitated tucking
- Parent to hold

Johnston C, Campbell-Yeo M, Disher T, Benoit B, Fernandes A, Streiner D, Inglis D, Zee R. (2017) Skin-to-skin care for procedural pain in neonates. Cochrane Database of Systematic Reviews, Issue 2. Art. No.: CD008435.; Campbell-Yeo M, Johnston CC, Benoit B, Disher T, Caddell K, Vincer M, Walker CD, Latimer M, Streiner DL, Inglis D. Sustained efficacy of kangaroo care for repeated painful procedures over neonatal intensive care unit hospitalization: a single-blind randomized controlled trial. Pain 2019.



Comfort Positioning

- For Children > 6 months **Upright position is best**

- **Use of Restraint Never Supportive:**
Restraining children with cancer for procedures makes them feel ashamed, humiliated, powerless; report having lost right to control his/her own

body Karlson K, Darcy L, Enskär K: The Use of Restraint is Never Supportive (Poster) Nordic Society of Pediatric Hematology/Oncology (NOPHO) 34th Annual meeting 2016 and 11th Biannual Meeting of Nordic Society of Pediatric Oncology Nurses (NOBOS). May 27 - 31, 2016, Reykjavik, Iceland

- **Give children school age and older a choice**

- Whenever feasible, offer choice to child (“Would you like to sit on daddy’s lap?” Next to caregiver?)
- Parents are not “partners in crime” - their job is to comfort / comfortably hold, NOT to restrain





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Distraction for Needle Procedures

- 59 trials (20 new for this update) with 5550 children 2-19 years: Evidence supporting the efficacy of **distraction**, **hypnosis**, combined **CBT**, and **breathing interventions** for reducing children's needle-related pain or distress, or both Birnie KA, Noel M, Chambers CT, Uman LS, Parker JA. Psychological interventions for needle-related procedural pain and distress in children and adolescents. Cochrane Database Syst Rev. 2018;10(10):CD005179.



Distraction for Needle Procedures

Encourage parents to actively distract their child with age appropriate options

- Favorite toy, comfort item
- Music, singing
- Breathing exercises, i.e., bubbles, pinwheels, tissues
- Books, find-it sheets, stories

* Note this will look different in neonates (e.g. spinning light toy)





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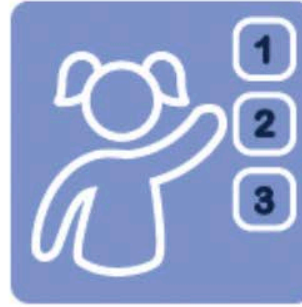
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Choices: Allow Control

Offer CHOICES where to place cream, how to position, whether they want to look or be distracted by bubbles or app etc.





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**Plan the
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Pain Memories Predict Future Pain & Distress

- **Role of narrative** in development of children's pain memories

Noel M, Pavlova M, Lund T, et al.

The role of narrative in the development of children's pain memories: influences of father- and mother-child reminiscing on children's recall of pain. *Pain*. 2019;160(8):1866-1875.

- Greater parental use of pain words = more negatively biased pain memories
- More elaborative parental reminiscing style & greater use of emotional words = more accurate/positively biased pain memories



Reframe the Pain

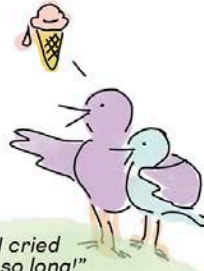
USE POSITIVE TALK

Don't talk about pain or scary feelings. Focus on the positive.



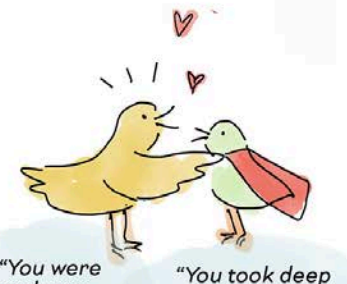
KEEP IT REAL

Catch exaggerations and remind your child what really happened.



BUILD THEM UP

Tell your child that they were brave, and why. Celebrate.



“Do I get a shot...?”

- We are **honest** with kids (Do. Not. Lie!)
- **Reframe** e.g. “at the end there will be a super-short vaccination AND this time we will use magic cream and bubbles...and you get a sticker”
- **Focus** the conversation on all of the **awesome strategies** we can use to make the procedure go well!
- **Set Expectation** (aka Self-Fulfilling Prophecy) “Many kids told me that they didn’t feel anything, and others told me they only felt a little... I wonder what you will feel...”

How to Implement



Map the Process

- Current state vs desired state
- Identify opportunities (tasks)

Type Opportunity (gap) here



Homework - Next Steps

Prior to assembling work group:

- Perform observations (watch, listen, poke around...no pun intended...)
- Engage formal and informal leaders and build trust
- List barriers (myth-based and reality)
- Collect ideas for addressing both types of barriers (gaps)



#1 Numb the skin

Tasks for topical anesthetic

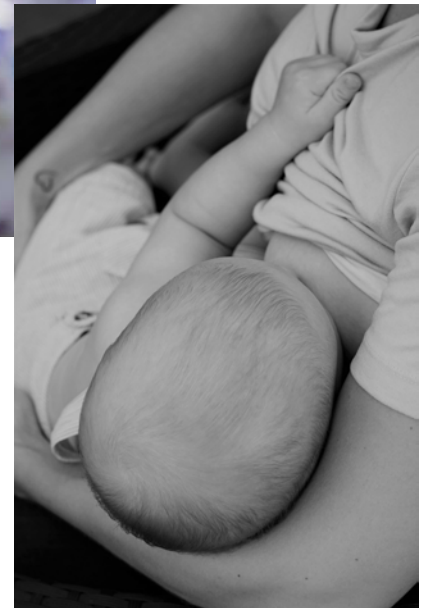
- Who applies
 - For labs
 - For IV starts
 - For injections
- Process for families and staff for each
 - Where to obtain
 - How, when, and where to place
 - How to keep in place
 - Educational resources



#2 Sucrose or Breastfeeding

Tasks for sucrose and breastfeeding

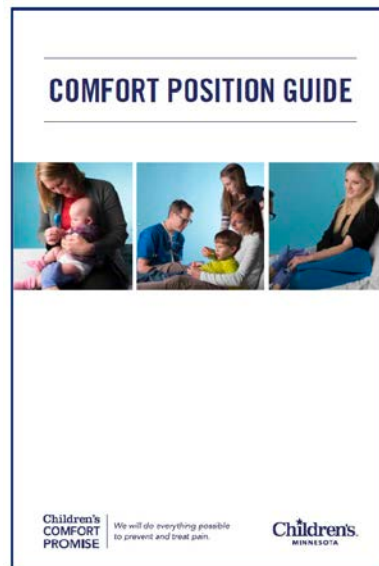
- Sucrose
 - How to stock and replenish
 - Where to keep
 - How to give (educational resources)
- Breastfeeding
 - Look at ergonomics for staff (need medical stool on wheels?)
 - Provide education to staff
 - Education for parents



#3 Comfort Positioning

Tasks for Comfort Positioning

- Education/training for staff
- Education for families
- Quick resources for rooms



#4 Distraction

Tasks for Distraction

- Select options
- Set up plan for ordering and restocking
- Set up cleaning and cues
- Staff education/training



#5 Choices

Tasks for Choices

- Staff education/training
- Education for families

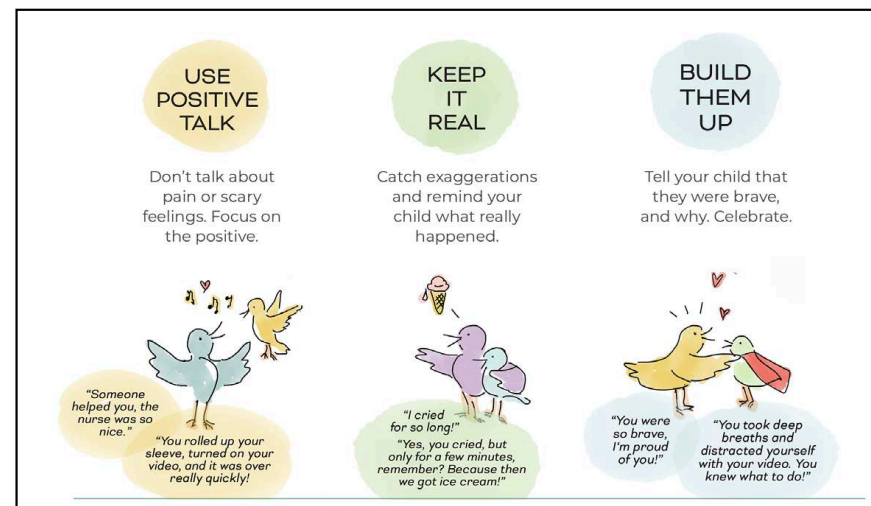
Offer CHOICES where to place cream, how to position, whether they want to look or be distracted by bubbles or app etc.



#6 Praise & Reframe Memory

Tasks for Praise & Reframe Memory

- Staff education/training
- Education for families



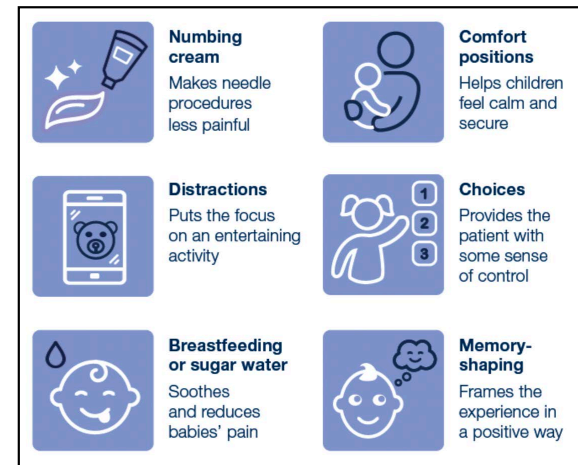
Summary

- Parents and children expect we will do everything possible to reduce or prevent pain
- There is strong evidence for 6 simple steps to eliminate or reduce needle pain

All age groups:

- Topical anesthesia (numbing cream)
- Comfort positioning
- Distraction
- Choices
- plus Infants only: Sucrose or breast feeding
- plus Children only: Praise & Memory-shaping

- Map the process
- Each step presents opportunities (gaps) which requires logistics



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The Comfort Promise

Eliminating (or easing) pain and anxiety caused by needle procedure for children in pediatric healthcare settings

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The logo for Children's Minnesota, featuring a blue star above the word "Children's" in a serif font, with "MINNESOTA" in a blue sans-serif font below it.

The logo for UCSF Benioff Children's Hospitals, featuring a row of five stylized human figures in orange, red, purple, blue, and green above the text "UCSF Benioff Children's Hospitals" in a bold sans-serif font, with "Stad Center for Pediatric Pain, Palliative & Integrative Medicine" in a smaller sans-serif font below it.