



**Clinical Practice  
Guideline for Pain  
Management during  
Childhood  
Immunizations**

**Technical Report**

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## INTRODUCTION

All Canadian children undergo routine immunizations as part of their medical care.<sup>1</sup> Immunization injections are the most common source of iatrogenic pain in childhood,<sup>2</sup> being administered repeatedly throughout infancy, childhood and adolescence. Pain from vaccine injections is a source of distress for children, their parents and vaccinators, and if not addressed, can lead to pre-procedural anxiety at future procedures, medical fears, and healthcare avoidance behaviours including non-adherence with immunization schedules.<sup>3</sup> It is estimated that up to 25% of adults have needle fears.<sup>4</sup> The majority of people with needle fears develop them in childhood.<sup>5</sup> Efforts aimed at minimizing pain in childhood have the potential to prevent the development of needle fears and promote consumer satisfaction and trust in the health care system because of more positive experiences for children and their families.<sup>3</sup>

The objectives and expected health outcomes from following these guidelines are:

- 1) reduced pain and distress for children undergoing immunization injections,
- 2) reduced distress for parents of children undergoing immunization injections and clinicians performing immunization injections,
- 3) child, parent and clinician satisfaction with the immunization experience,
- 4) child, parent and clinician adherence with immunization schedules,
- 5) prevention of the development of pre-procedural anxiety and needle fears in children undergoing immunization injections.

This guideline is intended for healthcare professionals involved in childhood immunization, although it could be expanded to include others who work with children and child health. It includes resources and tools for healthcare professionals, parents/families, and researchers. It contains recommendations that can be implemented by the intended audience in children aged 0-18 years.

The scope includes acute (immediate) pain at the time of vaccine injection. For the purposes of this guideline, distress and pain are considered together as pain.

### *Funding and Panel Membership*

This project was funded by a knowledge synthesis grant (KRS- 91783) awarded by the Canadian Institutes of Health Research (CIHR) to Dr. Taddio and colleagues. The views and interests of the funding agency have not influenced the recommendations.

The panel included knowledge users from a diverse range of disciplines and positions across Canada that have an interest in immunization pain management in children to ensure that different perspectives and values were captured. They were identified using formal and informal (word-of-mouth) processes.

The panel includes:

- Dr. Anna Taddio (Chair), Paediatric Pain Researcher and Pharmacist, Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto
- Ms. Mary Appleton, CCfV Executive Coordinator, Canadian Centre for Vaccinology (CCfV), IWK Health Centre, Halifax
- Dr. Robert Bortolussi, Paediatric Infectious Diseases Specialist, Chair of the Infection and Immunization Committee, Canadian Paediatric Society, IWK Health Centre, Halifax
- Dr. Christine Chambers, Paediatric Pain Researcher and Clinical Psychologist, IWK Health Centre, Halifax
- Dr. Vinita Dubey, Associate Medical Officer of Health, Toronto Public Health, Toronto
- Dr. Scott Halperin, Paediatric Infectious Diseases Specialist, Director, Canadian Centre for Vaccinology (CCfV), Head, Pediatric Infectious Diseases, IWK Health Centre, Halifax
- Ms. Anita Hanrahan, Public Health Nurse and Director of Communicable Disease Control in the Capital Health Region of Alberta, and member, National Advisory Committee on Immunization (NACI), Edmonton
- Dr. Moshe Ipp, Paediatrician and Clinician Teacher, The Hospital for Sick Children, Toronto
- Dr. Donna Lockett, Knowledge Translation Consultant and Psychotherapist, Milton
- Dr. Noni MacDonald, Paediatric Infectious Diseases Specialist, IWK Health Centre, Head, Health Policy and Translation, Canadian Centre for Vaccinology (CCfV), and Editor, Paediatrics & Child Health, Halifax

- Dr. Deana Midmer, Associate Professor and Research Scholar and Nurse, Department of Family & Community Medicine, University of Toronto, Toronto
- Dr. Patricia Mousmanis, Family Physician and Coordinator of the Healthy Child Development Program, Ontario College of Family Physicians, Toronto
- Ms. Karen Pielak, Nurse-Epidemiologist, BC Centre for Disease Control, Vancouver
- Dr. Rebecca Pillai Riddell, Paediatric Pain Researcher and Clinical Psychologist, York University, Toronto
- Dr. Michael Rieder, Paediatrician and Clinical Pharmacologist, Chair of the Drug Therapy and Hazardous Products Committee, Canadian Paediatric Society, CIHR-GSK Chair in Paediatric Clinical Pharmacology, University of Western Ontario, London
- Dr. Jeffrey Scott, Paediatric Infectious Diseases Specialist, former Chief Medical Officer of Health, IWK Health Centre, Halifax
- Dr. Vibhuti Shah, Neonatologist and Epidemiologist, Mount Sinai Hospital, Toronto

The panel ensured that parent/family perspectives informed the guideline development process. Information was obtained from our stakeholder workshop, and quantitative and qualitative interviews with parents.<sup>6 7 8</sup> The panel felt it important to recognize that while each member represented a formal perspective on the content of the guideline, some members were also parents and had experiences with childhood immunization pain. Their experiences and expectations also informed the development of the guideline.

Participants received letters of appointment and were requested to sign and return the enclosed Confidentiality, Conflict of Interest and Declaration of Potential Conflict of Interest forms (**Appendix A**). One panel member identified a potential conflict of interest. The Chair determined that the apparent conflict did not impact on the member's consideration of the evidence and development of the recommendations. The panel did not feel that their parental experiences with childhood immunization was a conflict of interest, rather they felt it provided added value to ensure that the evidence based recommendations were supported with practical considerations.

## Background to the Recommendations

The clinical questions included in this guideline were primarily derived from systematic reviews of the effectiveness of various interventions for reducing pain during vaccine injections performed in childhood.<sup>9 10 11</sup> The systematic reviews included interventions from 3 domains of pain management strategies: 1) physical, 2) psychological and 3) pharmacological. For each clinical question, our recommendation was based on consideration of: 1) the evidence from the systematic reviews, which included randomized controlled trials (RCTs) and quasi-RCTs, 2) methodologic limitations of included trials, 3) evidence from related contexts, and 4) child and other stakeholder-related factors. Formal criteria for evaluating the evidence and grading recommendations were adapted from the Canadian Task Force on Preventive Health Care (**Appendix B**).

The recommendations included in this guideline are evidence-based responses to the clinical questions. They describe the actions that are to be taken to mitigate pain during vaccine injections. Some recommendations are applicable to children of all ages, and others to a sub-population of children of specific ages. Some judgement about the suitability and feasibility of the recommendations is required - not all of the recommendations may be appropriate in all situations. Issues associated with the implementation of each recommendation are described, as appropriate.

### *Combining Strategies for an integrated approach:*

The goal of immunization pain management is to prevent pain. At present, there is no single pain-relieving intervention that reliably reduces pain to zero (i.e., prevents pain). There is some evidence that combining strategies with different underlying mechanisms of action (multimodal analgesia) is more effective than single interventions.<sup>11</sup> However, the optimal multimodal regimen is not known. This is due to limitations of prior research, including: a relatively small number of studies; examination of a variety of techniques, and inclusion of individual techniques that were not shown to be effective in our systematic reviews. Clinicians and parents are therefore advised to try multimodal approaches that consider the analgesic effectiveness of individual modalities. In addition, clinicians and parents can incorporate their own preferences when choosing among different approaches. Additional research is recommended in order to determine the optimal multimodal approach for individual children.



# RECOMMENDATIONS



## Topical Anesthetics

**Among children receiving intramuscular and subcutaneous immunizations, does application of topical anesthetics on the skin prior to vaccine injection reduce pain at the time of injection?**

### Background:

Topical anesthetic creams and gels reduce acute pain from cutaneous needle procedures.<sup>6-12</sup> At present, they are not routinely used to reduce vaccine injection pain.<sup>6</sup> Identified barriers include: lack of parental and clinician knowledge regarding their effectiveness and inconvenience (they require a 30-60 minute application time, thus, prior planning is required).<sup>6</sup> There are also concerns that topical anesthetics may interfere with vaccine immunogenicity<sup>7</sup> and that the analgesic effects depend on genetic factors.<sup>13</sup> Parents have successfully demonstrated they can apply topical anesthetics in their children prior to medical procedures and report they are willing to accommodate topical anaesthetics in their schedules.<sup>14-15</sup> Parents also report they are willing to pay to reduce immunization pain.<sup>6-16</sup>

Ten randomised controlled trials (RCTs) evaluating 1156 infants and children ( $\leq 15$  years of age) examined the effect of topical anesthetics for intramuscular and subcutaneous vaccine injections. Of the eight studies that compared topical anesthetics to placebo cream or patch, 7 demonstrated effectiveness of these drugs in reducing pain (Dilli 2008,<sup>17</sup> Cassidy 2001,<sup>18</sup> Halperin 2000,<sup>19</sup> Halperin 2002,<sup>20</sup> O'Brien 2004,<sup>21</sup> Taddio 1994,<sup>22</sup> Uhari 1993<sup>23</sup>). In the negative study (Hansen 1993<sup>24</sup>), older children (11-15 years) were enrolled, and certain methodological limitations of the study may explain the results, including: use of an insensitive pain assessment method, and rating performed with the help of the doctor. In 2 RCTs including a 'no treatment' control group (Cohen 1999,<sup>25</sup> Cohen 2006<sup>26</sup>), topical anesthetics were ineffective. Again, some methodological limitations may have explained the results, including: lack of blinding and nurse interactions with the no control group that equalized responses between groups; increased anticipatory anxiety due to a 1-hour application time; and close proximity of peers (children from same classroom) influencing self-reported pain ratings.

No interference with vaccine immunogenicity was observed in 3 trials evaluating 379 infants for measles-mumps-rubella, hepatitis B, and diphtheria-tetanus-acellular pertussis-inactivated poliovirus-*Hemophilus influenzae* type b conjugate

vaccine.<sup>19 20 21</sup> In one study of children undergoing venous cannulation, topical anesthetics were less effective in children with the *EDNRA* TT genotype, a specific gene involved in peripheral nociception at the site of topical local anesthetic action.<sup>27</sup>

## RECOMMENDATION

**Advise parents to use topical anesthetics in children during immunizations in order to reduce pain at the time of injection.**

*Level of Evidence: I*

Grade of Recommendation: A

### **Clinical Considerations:**

Lidocaine-prilocaine 5% is available as a patch or cream. The patch is impregnated with 1 g of lidocaine-prilocaine and applied directly to the skin for 60 minutes prior to immunization. The cream contains lidocaine-prilocaine and approximately 1-2 g is applied directly to the skin for 60 minutes prior to immunization. In order to facilitate absorption through the skin, and prevent accidental removal or ingestion, the cream is covered with an occlusive dressing (e.g., Tegaderm™, Op-Site™).

Amethocaine 4% is available as a gel. Approximately 1g is applied directly to the skin and covered by an occlusive dressing for 30-45 minutes prior to immunization.

Liposomal lidocaine 4% is available as a cream. At present, it has not been evaluated for its effect on vaccine injection pain, however, based on its shared mechanism of action to other anesthetics, and accumulating body of evidence demonstrating similar clinical effectiveness for a variety of painful cutaneous procedures, it is expected to be effective.

There are several alternative methods of administration of local anesthetics<sup>28</sup> that may result in a faster onset of action (e.g., lidocaine iontophoresis, sonophoresis with lidocaine cream). However, there are currently no studies investigating their safety and efficacy in children undergoing immunization and they are not routinely available.

Topical anesthetics are available without a prescription. Parent instruction/demonstration and/or education are required prior to their use (dose, application method), AND preceding the vaccine appointment so that the parent can come to the appointment with the cream already applied; otherwise, a product with a shorter onset of action should be used in order to allow for application at the clinic just prior to immunization.

Prior to using topical local anesthetics, a medical history should be performed to rule out the presence of allergic reactions or sensitivity to the specific agents being used.

Transient skin reactions (changes in skin colour or sensation) are common, occurring in approximately one-third to one-half of individuals.

Children should be monitored for allergic reactions with repeated use of topical anesthetics.

Topical anesthetic creams are considered safe to use in infants and children. Scores of studies have been performed with these agents all over the world and they have been routinely used in Canada to manage pain in children since the early 1990's with few reported adverse effects. Inappropriate use of topical anesthetic creams, however, can lead to serious side effects, including death. There are some cases of serious side effects in children. Health Canada advises that children be closely monitored following their use ([http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/public/2009/emla\\_ametop\\_pc-cp-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/public/2009/emla_ametop_pc-cp-eng.php)). Parents are encouraged to use only commercially available products, and to administer them in recommended doses using approved techniques in order to minimize the risk of side effects.

Two doses of topical anesthetic creams and gels may be required at two separate anatomical sites (for instance in two separate limbs) if  $\geq 2$  vaccines are being injected sequentially at one visit.

The cost of two doses is approximately ~ \$10-15 CAD.

### **Future Research:**

- There are insufficient data on the impact of genetic variability on apparent clinical effectiveness of topical anesthetics and further studies are needed.
- The risk of hypersensitivity following repeated use requires investigation.
- The effectiveness and safety of alternative methods of administration which lead to a faster onset of action is required.

## Skin Cooling Techniques: Vapocoolants and Ice or Cool/Cold Packs

**Among children undergoing immunization,**

**1) does application of vapocoolant sprays on the skin prior to vaccine injection reduce pain at the time of injection?**

**2) does application of ice or cool/cold packs on the skin prior to vaccine injection reduce pain at the time of injection?**

### *Background*

#### *1. Vapocoolants:*

Vapocoolants (skin refrigerants) numb the skin and may prevent the transmission of pain sensation.

Four RCTs examined the effects of vapocoolants in 247 infants and children undergoing immunization (Abbott and Kerry-Fowler 1995,<sup>29</sup> Cohen 2009,<sup>30</sup> Eland 1981,<sup>31</sup> Maikler 1991<sup>32</sup>). In three RCTs the effect of a vapocoolant was compared to a placebo spray (Abbott and Kerry-Fowler 1995,<sup>29</sup> Eland 1981,<sup>31</sup> Maikler 1991<sup>32</sup>). A meta-analysis including data from two of these RCTs (n=100 children aged 4-6 years) showed a beneficial effect on self-reported pain (Abbott and Kerry-Fowler 1995,<sup>29</sup> Eland 1981<sup>29</sup>). In the third RCT, including 60 infants aged 2-6 months, there was no difference in vaccine injection pain (Maikler 1991<sup>32</sup>). Further, in two RCTs that compared vapocoolant spray to typical care (no spray or typical care given by the nurse), there was no difference between groups (Abbott and Kerry-Fowler 1995,<sup>29</sup> Cohen 2009<sup>30</sup>). In the absence of a placebo group, one would have expected positive results. This result further reinforces the negative findings.

#### *2. Ice or Cool/Cold Packs:*

Applying ice to the skin can cause a numbing sensation, and is in-expensive. Cold packs are readily available, can be transported to clinics or stored in clinic freezers.

Two RCTs in 78 children aged 4-18 years old have examined the effects of ice for vaccine injection pain. Neither study showed a beneficial effect on self-reported

pain (Ebner 1996,<sup>33</sup> Gedaly-Duff 1992<sup>34</sup>). The timing of application was variable; in one study ice was applied for 30 seconds while in the other, it was applied for 15 minutes. Effectiveness may be dependent on application technique.

## RECOMMENDATION

**There is insufficient evidence for or against the use of skin cooling techniques (vapocoolants, ice, cool/cold packs) in children during immunizations in order to reduce pain at the time of injection.**

*Level of Evidence: I*

Grade of Recommendation: I

## Clinical Considerations

### 1. Vapocoolants:

The cold sensation of vapocoolant spray may be perceived as painful.

Young children ( $\leq 3$  years old) in particular, do not have the cognitive maturity to understand the role of a cold sensation in reducing pain, and coldness may cause them to focus their attention on the procedure.

Effectiveness is dependent on application technique. Excessive duration of application can result in skin discoloration (hypopigmentation) and frostbite.

Vapocoolants available for clinical use in Canada include: Gebauer ethyl chloride™ and Gebauer Pain Ease™ (1,1,1,3,3-pentafluoropropane and 1,1,1,2-tetrafluoroethane). Gebauer ethyl chloride™ was ineffective in one RCT (Cohen 2009<sup>30</sup>) and there are no studies for Gebauer Pain Ease™ for vaccine injection pain.

The recommended application time for Gebauer Pain Ease™/Ethyl chloride™ vapocoolant is 4 to 10 seconds. The procedure should be performed within 60 seconds of vapocoolant application.

Cost ~ \$70 CAD for 80-100 applications

### 2. Ice or Cool/Cold Packs:

The cold sensation of ice may be perceived as painful.

Young children ( $\leq 3$  years old) in particular, do not have the cognitive maturity to understand the role of a cold sensation in reducing pain, and coldness may cause them to focus their attention on the procedure.

***Future Research:***

- Further research is needed to confirm or refute the effectiveness of skin cooling techniques, particularly for children aged  $\geq 6$  years.

## Acetaminophen or Ibuprofen

**Among children undergoing immunization, does administration of acetaminophen or ibuprofen prior to injection reduce pain at the time of injection?**

### *Background:*

Oral analgesics (acetaminophen and ibuprofen) are currently recommended for use to treat delayed (post-immunization) reactions (e.g., delayed pain, swelling, fever) that develop in the hours to days following immunization. Some clinicians and parents use these medications to reduce acute pain at the time of vaccine injection.<sup>6</sup>

No RCT was identified that evaluated the analgesic effects of oral analgesics on acute vaccine injection pain in children. In two RCTs examining the analgesic effects of sucrose (Lewindon 1998<sup>35</sup>) and amethocaine (O'Brien 2004<sup>21</sup>) during immunization whereby children received acetaminophen concomitantly (at the discretion of parents), authors reported no impact of acetaminophen on pain at the time of injection.

### RECOMMENDATION

**There is currently no demonstrated benefit of acetaminophen or ibuprofen in reducing pain at the time of injection, although they may be effective in reducing post-immunization minor adverse events (delayed pain, swelling, fever).**

*Level of Evidence: III*

Grade of Recommendation: I

### *Clinical Considerations:*

This recommendation refers to the use of acetaminophen or ibuprofen to reduce acute pain at the time of vaccine injection and not to delayed (post-immunization) minor adverse events. There is no evidence of an analgesic effect of acetaminophen or ibuprofen at the time of vaccine injection.



## Breastfeeding

### Among infants receiving immunizations, does breastfeeding during vaccine injection reduce pain at the time of injection?

#### Background:

Breastfeeding is the preferred method of infant feeding in the first year of life.<sup>36</sup> Breastfeeding has been shown to have analgesic effects in infants undergoing medical procedures.<sup>37</sup> Breastfeeding is considered a combined analgesic intervention because it includes different components (i.e., sweet-tasting solution, sucking, and holding/skin-to-skin contact) that may individually attenuate pain responses.

Three RCTs and one quasi-RCT including 478 infants ( $\leq 12$  months) compared breastfeeding infants before, during and after vaccine injections to either no intervention [i.e. mother seated with infant in her arms (Dilli 2008<sup>17</sup>) *or* swaddling infants in bassinets (Efe 2007<sup>38</sup>), *or* routine care (not described, Moddares 2006<sup>39</sup>) *or* restraint of infants by mothers (Razek 2009<sup>40</sup>)]. These studies found that breastfed infants had less pain during vaccine injection. There were no reported adverse effects.

#### RECOMMENDATION

**Encourage breastfeeding mothers to breastfeed their infants during immunizations in order to reduce pain at the time of injection.**

*Level of Evidence: I*

Grade of Recommendation: A

#### Clinical Considerations:

Breastfeeding should be commenced prior to immunization and continue during and after injection(s), for up to several minutes afterward. Some infants may refuse to breastfeed, and some mothers may not wish to breastfeed during immunization. In such situations, alternative pain relieving strategies should be used (for instance, sweet-tasting solutions – discussed in the subsequent recommendation). Offering breast milk or formula via a bottle is not equivalent to breastfeeding and should not be considered a substitute for breastfeeding as a method of reducing pain at the time of injection.<sup>41</sup>

There are no reports of adverse events, such as gagging or spitting up in infants that were breastfed during immunization.

Compared to how often an infant is breastfed, vaccine injections are uncommon/rare. It is therefore unlikely that an infant will associate breastfeeding with painful procedures.

Breastfeeding may add time to the procedure for clinic staff due to the time required to initiate breastfeeding if this is not mentioned to mothers until right before the vaccine injection. Mothers may benefit from a reduction in the amount of time at the clinic due to a reduction in the amount of time required to settle infants after the injection.

## Sweet-Tasting Solutions

**Among children undergoing immunization, does administration of sweet-tasting solutions reduce pain at the time of injection?**

### *Background:*

Oral sweet-tasting solutions may be used in infants that are not breastfed during immunization. Although studies that directly compare the analgesic effects of breastfeeding to sweetening agents have not been performed in infants undergoing immunizations, the steering committee felt that breastfeeding should be recommended over sweetening agents because: 1) breastfeeding is the preferred method of infant feeding in the first year of life and we are advocates of breastfeeding, 2) breastfeeding does not incur cost or training for parents.

Like breastfeeding, sweet-tasting solutions (with and without non-nutritive sucking) are analgesic in infants.<sup>42 43</sup> The proposed mechanism of analgesia involves endogenous opioid release and distraction. They are inexpensive and can be administered immediately prior to medical procedures.

Eleven RCTs including 1452 infants and children compared the effects of sweet tasting solutions with or without non-nutritive sucking [9 evaluated sucrose solutions (sugar water) (Allen 1996,<sup>44</sup> Barr 1995,<sup>45</sup> Dilli 2008,<sup>17</sup> Hatfield 2008a,<sup>46</sup> Hatfield 2008b,<sup>47</sup> Lewindon 1998,<sup>35</sup> Mowrey 2007,<sup>48</sup> Ramenghi 2002,<sup>49</sup> Soriano-Faura 2003,<sup>50</sup> and one each evaluated sweetened gum (Lewkowski 2003<sup>51</sup>) and glucose water (Thyr 2007<sup>52</sup>)] to either no intervention, sterile water, or unsweetened gum. A meta-analysis including data from 6 RCTs involving single or multiple vaccine injections (n=665 infants  $\leq$  12 months) demonstrated that sucrose with or without non-nutritive sucking reduced acute pain (Dilli 2008,<sup>17</sup> Hatfield 2008a,<sup>46</sup> Lewindon 1998,<sup>35</sup> Mowrey 2007,<sup>48</sup> Ramenghi 2002,<sup>49</sup> Soriano-Faura 2003<sup>50</sup>). In 1 RCT that was not included in the meta-analysis, pain scores were lower in the sucrose group (Allen 1996). Three trials evaluated sweet-tasting solutions longitudinally (216 infants); pain scores were lower in the treatment group (Barr 1995,<sup>45</sup> Hatfield 2008b,<sup>47</sup> Thyr 2007<sup>52</sup>). In 1 study of the effects of sweetened gum in children aged 9-11 years, the gum was ineffective for reducing pain (Lewkowski 2003<sup>51</sup>).

**RECOMMENDATION**

**For infants aged up to 12 months that cannot be breastfed during immunizations, administer sweet tasting solutions in order to reduce pain at the time of injection.**

*Level of Evidence: I*

Grade of Recommendation: A

**Clinical Considerations:**

The optimal dose of sucrose solutions is not known. Concentrations of sucrose solutions used in studies ranged from 12-75% (wt/vol) and the volumes used ranged from 0.75 ml to 2 ml (total dose 0.24 to 1.5g). It was given 15 seconds to 2 minutes prior to the procedure. The most commonly used dose was 0.5 g (equivalent to 2 ml of 25%).

The dose of glucose solution in the only trial included in the systematic review was 2 ml of 30% strength (total dose 0.6 g), administered 30 seconds before, during and 10-30 seconds after immunization.

Obtain sweet-tasting solutions from the pharmacy or compound (make) them immediately prior to use; discard the un-used portion to avoid bacterial contamination.

Sucrose solutions of similar strength to those reported in clinical trials can be compounded by mixing one packet/cube of sugar with 10 mL (2 teaspoonfuls) of water in a medicine cup.

Sweet-tasting solutions are placed in the infant's mouth with an oral syringe, medicine cup, or pacifier.

Using sugar water may add time to the procedure for clinic staff due to time required to compound and/or administer them. Parents may administer sweet tasting solutions to their infants rather than clinicians.

Transient adverse events (spitting up) may occur, however, these are relatively uncommon (<1%).

Sweet-tasting solutions are indicated for the management of painful procedures only, not for general comfort or as a food supplement.

There is a theoretical risk of dental caries and it is therefore advised that parents wash/rinse the infant's mouth after the dose.

**Future Research:**

- Dose-ranging studies and studies that compare the effects of single doses vs. multiple doses (when multiple vaccines are injected sequentially at the same visit) are required in order to determine the optimal dosing regimen.

- Additional studies are required for infants aged > 12 months in order to identify the maximum age for reliable analgesia.

## Clinician-Led Distraction

### Among children undergoing immunization, does use of clinician-led distraction result in less pain at the time of injection?

#### *Background:*

Distraction reduces children’s pain and distress from medical procedures.<sup>53</sup> Clinician-led distraction involves using distraction strategies to take a child’s attention away from the procedure. Distraction strategies are relatively simple and easy to use, provided some basic equipment is available or brought by the child and family. Provided age-appropriate distraction strategies are selected, distraction has the advantage of being the only psychological intervention examined in this guideline that can be employed with children of all ages, from infants to adolescents.

Nurse-led distraction was examined in one RCT and three quasi-RCTs (Cohen 1997,<sup>54</sup> Cohen 2002a,<sup>55</sup> Cohen 1999,<sup>56</sup> Cohen 2006a<sup>57</sup>). In these studies, nurses were trained (several studies reported use of a 15 minute training program) to direct the child’s attention to a movie or other age-appropriate toys (e.g., rattles, electric phones, dolls). Children were aged 2 months to 11 years. Nurse-led distraction was effective in reducing observational distress and nurse and parent rated distress. The one study with children old enough to provide self-report of pain found a significant reduction when nurse-led distraction was used.

#### RECOMMENDATION

**Use clinician-led distraction techniques with children during immunizations in order to reduce pain at the time of injection.**

*Level of Evidence: I*

Grade of Recommendation: B

#### *Clinical Considerations:*

The clinician performing the vaccine injection is able to employ distraction techniques themselves, thus, negating the need to involve additional clinic staff.

Using clinician-led distraction may add time to the procedure for clinic staff due to time required to engage children in a distracter. However, this may be offset by a

shorter duration of time required to perform the procedure (due to less distress and struggling) and a faster recovery time.

Using clinician-led distraction may add costs for the clinic related to purchasing distracting items (e.g., books, toys) and clinician training. Clinician training is required prior to the use of distraction. Research studies have typically used a one-time 15 minute training program to train clinicians. The clinician subsequently uses the knowledge gained via the training to distract many different children during immunization.

Clinician training typically includes the following aspects (see also **Appendix I**):

1) Rationale for distraction:

Distraction takes a child's attention away from the procedure. The amount of pain experienced is reduced if the child is focused on something else.

2) Examples of age-appropriate distraction strategies include:

- *Infants*: toys, bubbles, pacifiers, singing, directing the infant's attention to something in the environment that would be of interest for them
- *Toddlers*: toys, bubbles, pop-up books, songs, party blowers, kaleidoscopes, singing, directing the toddler's attention to something in the environment that would be of interest for them, non-procedural talk (talking about something unrelated to the procedure)
- *School-age*: toys, stories, videos, books, joking, counting, non-procedural talk
- *Adolescents*: games, videos, books, joking, music, non-procedural talk

3) Optimizing the effectiveness of distraction strategies:

Ask parents and children about the child's needs and preferences regarding distraction strategies and choose a strategy that incorporates these factors.

Capture the child's attention (that is, engage the child in the distractor) and keep the child's attention on the distractor before and during the painful stimulus.

Maintain a positive attitude throughout, staying focused and interacting with the child.

Re-direct the child's attention back to the distractor if their attention wanders to the procedure. Praise child for distraction behaviours.

## Child-Led Distraction

### Among children undergoing immunization, does use of child-led distraction result in less pain at the time of injection?

#### Background:

Distraction reduces children's pain and distress during medical procedures.<sup>53</sup> Child-led distraction involves using distraction strategies that take a child's attention away from the procedure that do not require an adult to administer or direct. If a clinician or parent is required to assist with the distraction, the intervention is referred to as clinician-led or parent-led distraction. Child-led distraction strategies are relatively simple and easy to use, provided some basic equipment is available or brought by the child and family.

Three RCTs examined child-directed distraction (Cassidy 2002,<sup>58</sup> Fowler-Kerry 1987,<sup>59</sup> Noguchi 2006<sup>60</sup>). They used a range of age-appropriate distraction strategies meant to take children's attention away from the procedure. The trials included children aged 4-6 years and employed a cartoon video or stories/music played on headphones. These trials demonstrated effectiveness of child-led distraction in reducing self-reported pain. We believe that these results can be extrapolated to children  $\geq 3$  years old due to consistency in the results when compared to previous analyses.<sup>10 53</sup>

#### RECOMMENDATION

**Use child-led distraction techniques in children aged  $\geq 3$  years in order to reduce pain at the time of injection.**

*Level of Evidence: I*

Grade of Recommendation: B

#### Clinical Considerations:

Some time will be required to prepare children to perform child-led distraction. Involve and listen to children. Children often have helpful suggestions for the types of distraction strategies that will be effective.

Examples of age-appropriate distraction strategies include:

- *Toddlers:* toys, bubbles, pop-up books, songs, party blowers, kaleidoscopes, singing, directing the toddler's attention to something in the environment that would be of interest for



them, non-procedural talk (talking about something unrelated to the procedure)

- *School-age*: toys, stories, videos, books, joking, counting, non-procedural talk
- *Adolescents*: games, videos, books, joking, music, non-procedural talk

In children aged < 2 years, it is important not to inadvertently encourage parents to use video/television at home.

See also **Appendix H**.

### **Future Research:**

- Are certain types of stimuli (audio versus video versus audio/visual) better for certain age groups?

## Breathing Techniques

**Among children undergoing immunization, does slow deep breathing/blowing performed by the child result in less pain at the time of injection?**

### **Background:**

Breathing exercises are simple psychological strategies that have children engage in deep breathing (“blowing the hurt/pain away”) through a number of different strategies such as the use of a party blower, bubble blowing, or simple direct instruction by an adult to take a deep breath. In addition to serving as a relaxation strategy, breathing exercises (especially those that involve use of bubbles or a party blower) also serve as a distraction (e.g., by focusing attention to the bubbles or party blower). Breathing exercises make use of inexpensive and accessible items that are easy to make available in the clinic or office.

Two RCTs and two quasi-RCTs (Bowen 1999<sup>61</sup>, French 1994,<sup>62</sup> Krauss 1996,<sup>63</sup> Sparks 2001<sup>64</sup>) evaluated the effects of deep breathing (either via use of a party blower, bubble blowing, or with investigator prompting) in children aged 3 to 7 years. These studies also had adults (either parents or the researchers) prompt or remind the child to engage in the deep breathing. There was a significant reduction in pain during immunization if breathing exercises were used.

### **RECOMMENDATION**

**Have children aged  $\geq 3$  years engage in slow deep breathing/blowing during immunizations in order to reduce pain at the time of injection.**

*Level of Evidence: I*

Grade of Recommendation: B

### **Clinical Considerations:**

Slow deep breathing/blowing is facilitated by distracting toys and activities. The specific impact of each component (that is, slow deep breathing and distraction) on child pain response cannot be determined by current scientific evidence. The use of multiple psychological interventions such as slow deep breathing and distraction is discussed in the next recommendation).

Instruct children to take slow deep breaths by taking a deep breath in and blowing it out slowly (i.e., ‘tummy breathing’). Aids to facilitate slow deep breathing in

young children include; party blowers and bubbles. Older children can be instructed to blow a balloon or to imagine they are blowing a balloon.

Adults, either parents or clinicians, must remind or prompt the child to do deep breathing during the procedure.

Using this technique may add costs for the clinic related to the purchasing of aids for slow deep breathing (e.g., bubbles, pinwheels, balloons).

Using this technique may add time to the procedure for clinic staff due to time required to engage children in slow deep breathing. However, this may be offset by a shorter duration of time required to perform the procedure (due to less distress and struggling) and a faster recovery time.

## Combined Cognitive-Behavioural Interventions

**Among children undergoing immunization, does use of combined cognitive-behavioural interventions (i.e., an intervention that includes at least one cognitive and one behavioural intervention) result in less pain and distress at the time of injection?**

### *Background:*

Cognitive-behavioural therapy is an umbrella term for interventions that use methods of change derived from a theoretical base in behavioural learning theory and cognitive psychology and are aimed at modifying emotions, behaviours, and cognitions. For the purposes of summarizing the evidence for the analgesic effects of combined cognitive-behavioural interventions, these interventions were defined as at least two interventions, one of which was cognitive in nature and the other that was behavioural in nature.<sup>10</sup> These interventions are also generally only applicable for use with older children and adolescents who have the cognitive capability to learn and use these more complex interventions.

Two RCTs and two quasi-RCTs examined combined cognitive-behavioural interventions in children aged 3 to 6 years (Blount 1992,<sup>65</sup> Cohen 2002b,<sup>66</sup> Cohen 1997,<sup>54</sup> Fowler-Kerry 1987<sup>67</sup>). There was considerable heterogeneity in regards to the interventions included in this category, ranging from simple combined distraction and suggestion, to more involved interventions that included coping skills training directed towards the child and parent and child training combined with nurse coaching. Interventions were conducted just prior to the procedure and a trained professional provided the intervention. That said, there was good evidence for the efficacy of combined cognitive-behavioural interventions in reducing the pain and distress associated with immunization.

### RECOMMENDATION

**Use combined cognitive-behavioural interventions in children aged  $\geq 3$  years during immunizations in order to reduce pain at the time of injection.**

*Level of Evidence: I*

Grade of Recommendation: B

**Clinical Considerations:**

Examples of combined cognitive-behavioural interventions include:

- *Training and practice:* for child, parent, and clinician; including aspects of slow deep breathing/blowing, distraction, positive statements, role playing/practice

Some of these interventions are quite involved and may not be feasible in terms of time and cost related to purchasing of aids and training and implementation. However, this may be offset by a shorter duration of time required to perform the procedure (due to less distress and struggling) and a faster recovery time.

## Parent-Led Interventions: Distraction and Coaching

Among children undergoing immunization,

- 1) does use of parent-led distraction result in less pain and pain-related distress at the time of injection?
- 2) does use of parent coaching result in less pain and pain-related distress at the time of injection?

### Background

#### 1) Parent-led distraction:

Parent-led distraction typically involves training parents how to deliver age-appropriate distraction strategies that are meant to take children's attention away from the procedure. These types of distraction strategies are relatively simple and easy to administer provided some basic equipment is available or brought by the child and family.

Four RCTs (Cohen 2006b,<sup>68</sup> Cramer-Berness 2005a,<sup>69</sup> Cramer-Berness 2005b,<sup>70</sup> Gonzalez 1993<sup>71</sup>) examined the effects of parent-led distraction on immunization pain and distress in children aged 1 month to 7 years. A meta-analysis of these studies demonstrated that there is insufficient evidence that they reduce vaccine injection pain. There was no difference observed for child self-reported pain, researcher-rated child pain, nurse-reported child distress and parent-reported child distress. The only positive effect was observed for researcher-rated child distress. However, on the grounds that parents are present and that research has shown some benefits on general pain-related distress, clinicians may discuss this option with parents.

#### 2) Parent Coaching:

Certain types of parent behaviours (e.g., non-procedural talk, suggestions on how to cope, humour) are related to decreases in child distress and pain, while others (e.g., use of reassurance, apologies) are related to increases in child distress and pain.<sup>3</sup> It is generally accepted that parents are an important part of children's medical procedures and that involving them formally in the delivery of psychological interventions is helpful in reducing child pain and distress. Parent

coaching involves training in distraction combined with other strategies known to be effective, such as minimizing parental use of reassurance, empathy, and criticism which are known to increase children's pain during procedures.

Two RCTs and one quasi-RCT (Bustos 2008,<sup>72</sup> Cramer-Berness 2005a,<sup>69</sup> Felt 2000<sup>73</sup>) examined parent coaching in children aged 2 months to 2 years. There was insufficient evidence to support parent coaching as a strategy to reduce pain. There were no differences in researcher-rated child pain or parent-rated child distress. The intervention demonstrated efficacy, however, in reducing researcher-rated child distress. On the grounds that parents are present and that research has shown some benefits on pain-related distress, clinicians may discuss this option with parents.

### RECOMMENDATION

**While there is insufficient evidence for or against the use of parent-led distraction or parent coaching during immunizations in children in order to reduce pain at the time of injection, clinicians may offer this intervention to parents in order to reduce pain-related distress.**

*Level of Evidence: I*

Grade of Recommendation: B

### Clinical Considerations

#### 1) Parent-led distraction:

Parents are trained to direct the child's attention age-appropriate strategies (see below). Parents typically receive brief instruction/training on how to appropriately distract their children just prior to the procedure. However, pamphlets and instruction may be disseminated prior to the clinic appointment.

Examples of age-appropriate distraction strategies include:

- *Infants:* toys, bubbles, pacifiers, singing, directing the infant's attention to something in the environment that would be of interest for them
- *Toddlers:* toys, bubbles, pop-up books, songs, party blowers, kaleidoscopes, singing, directing the toddler's attention to something in the environment that would be of interest for them, non-procedural talk (talking about something unrelated to the procedure)
- *School-age:* toys, stories, videos, books, joking, counting, non-procedural talk

- *Adolescents:* games, videos, books, joking, music, non-procedural talk

## 2) Parent coaching:

Parent instruction/demonstration and/or education are required prior to the use of coping promoting behaviours. Parents typically receive brief instruction/training on how to appropriately coach their children just prior to the procedure. However, pamphlets and instruction may be disseminated prior to the clinic appointment.

### **TOOL: Parent Coaching Suggestions**

Information that may be included in parent coaching:

- *Talk to your child about the procedure using age-appropriate words:* In general, young children (< 4 years old) should be told immediately before the procedure. Older children should be told at least 1 day before the procedure, to give them time to think and plan (with you) how they will cope. Involve and listen to your child. Children often have helpful suggestions for how to manage their pain.
  - Tell him or her why the procedure is taking place (“to help you stay healthy”),
  - What will happen (“you will get a medicine called a vaccine in the arm (demonstrate where) using a tube that looks like a straw called a syringe”),
  - How it will feel (“you might feel a pinch and some pushing or pressure that will last a few seconds”),
  - How you will manage any potential discomfort (“some children think it is uncomfortable and some think it is ok. We don’t know how it will feel for you. We are going to do different things so that it does not feel uncomfortable for you” (then tell your child what you will do)),
  - What the child can do to help (“you can help by holding still and ...(suggest other strategies)”)
    - *Stay calm and maintain a positive atmosphere:* Your actions and words can influence your child’s reaction. Children often look to their parents to understand how to act and feel. If you are calm, use your normal voice, and smile, your child will feel that everything is ok.
    - *Take your child’s attention away from the procedure using distraction:* This is effective for children of all ages. Examples of age-appropriate distraction strategies include:



- *Infants*: toys, bubbles, pacifiers, singing, directing the infant’s attention to something in the environment that would be of interest for them
- *Toddlers*: toys, bubbles, pop-up books, songs, party blowers, kaleidoscopes, singing, directing the toddler’s attention to something in the environment that would be of interest for them, non-procedural talk (talking about something unrelated to the procedure)
- *School-age*: toys, stories, videos, books, joking, counting, non-procedural talk
- *Adolescents*: games, videos, books, joking, music, non-procedural talk
- *Give your child suggestions on how to cope* (e.g., prompt child to take deep breaths, count to 10). Deep breaths can be facilitated by using bubbles, pinwheels, or balloons, which also act as distracting techniques.
- *Avoid words that increase distress and focus attention on the procedure*, such as: high anxiety words (“hurt” “pain” or “shot”), reassuring words (“It’ll be over soon”, “You’ll be ok”), apologizing (“I’m sorry you have to go through this”), empathizing (“I know it hurts”).
- Use humour (e.g., tell jokes to child or a funny story) or talk about something unrelated to the procedure (e.g., what you will do or where you will go later)

See also **Appendices F, G and I**.

### **Future Research:**

- Does parental anxiety impact the effectiveness of parent-led distraction and parent coaching?
- What is the influence of age of the child on the parent’s ability to distract or and coach effectively?
- Would increased parental training increase the effectiveness?
- Does familial choice of distraction modality influence effectiveness?

## Suggesting that “it won’t hurt”

### Among children undergoing immunization, does suggesting that “it won’t hurt” result in less pain at the time of injection?

#### **Background:**

Suggestion therapy is a psychological modality that typically involves inducing the patient into a relaxed state and then using words and intonation in order to produce a desired effect or alternative behaviours. Successful application of suggestion depends on first ensuring that children are in a relaxed state. It is often used as part of a more involved imagery or hypnosis experience.

In immunization trials, only simple suggestion (brief use of words or intonation without first using a relaxation induction) has been examined for its effects on pain at the time of injection.

Two RCTs (Eland 1981,<sup>31</sup> Fowler-Kerry 1987<sup>74</sup>) that examined suggestion employed a very simple suggestion intervention in which children aged 4 to 6 years were told that someone (i.e., the experimenter) or something (e.g., a placebo aerosol spray) would make them feel less pain during the procedure. There was no difference in self-reported pain between the group of children that received the suggestion intervention and the control group.

There are ethical concerns raised by this approach because it involves the deception of children. Deceiving children may also lead to a loss of trust between children/families and healthcare workers.

#### **RECOMMENDATION**

**DO NOT tell children that “it won’t hurt” because these types of suggestions alone have been shown to be ineffective in reducing pain at the time of injection**

*Level of Evidence: I*

Grade of Recommendation: D

## Position of Child

**Among children undergoing immunization, does positioning the child in a supine position result in more pain at the time of injection?**

### *Background:*

Children may be immunized in different positions (lying supine, sitting upright/held). Parents instinctively pick up crying children that are lying supine.<sup>75</sup>

Four RCTs including 281 infants (aged newborn to 6 months) and children (aged 4-6 years) have examined the effects of infant/child positioning on pain response during immunization (Hallstrom 1968,<sup>76</sup> Ipp 2004a,<sup>75</sup> Kostandy 2005,<sup>77</sup> Lacey 2008<sup>78</sup>). In 3 studies, lying supine resulted in more pain when compared to sitting upright or being held by a parent. One of these 3 studies involved neonates, and skin-to-skin contact with the mother was provided compared to lying supine in a cot. In the only negative study, parents were able to pick up infants at any time after injection and it is possible that mothers may have preferentially picked up infants that were more distressed, making both groups the same (resulting in no differences between groups) (Ipp 2004a<sup>75</sup>).

### RECOMMENDATION

**In order to reduce pain at the time of injection, DO NOT place children in a supine position during immunizations.**

*Level of Evidence: I*

Grade of Recommendation: E

### *Clinical Considerations:*

The optimal position for children undergoing immunization is not known. Infants should be held by a parent in a position that is most comfortable for them and their parent (e.g., bear hug or holding baby facing outward). Children should be sitting up and may be held by a parent in a position that is most comfortable for both the child and their parent (e.g., held on parent's lap or sitting up on examination table and held by the parent around the trunk). For infants and children, the limb that is to be vaccinated should be exposed to the vaccinator.

The risk for accidental falls is minimized by sitting on a chair or standing against the examination table. Limbs that are to be injected must be exposed for the vaccinator.

Restraint may increase child distress, and parents are encouraged to hold and support children without using excessive force.

## Tactile Stimulation

**Among children undergoing immunization, does rubbing the skin near the injection site before and during injection result in less pain at the time of injection?**

### *Background:*

Parents and vaccinators have opportunities to touch/rub the skin near the injection site prior to and during immunization. Providing tactile stimulation may reduce pain sensation. The proposed mechanism of action of this technique involves the 'Gate Theory of Pain' and the notion that the sensation of touch competes with the sensation of pain for transmission to the brain, resulting in less pain. This technique is often referred to as providing 'white noise'.

One quasi-RCT including 66 children 4-6 years old examined the effect of the vaccinator rubbing the skin near the injection site with moderate intensity before and during intramuscular vaccine injections (Sparks 2001<sup>64</sup>). Rubbing the skin was associated with less pain, as reported by children themselves.

### RECOMMENDATION

**Offer to rub/stroke the skin near the injection site with moderate intensity prior to and during immunizations in children aged  $\geq 4$  years in order to reduce pain at the time of injection.**

*Level of Evidence: II-1*

Grade of Recommendation: B

### *Clinical Considerations:*

Currently, the optimal method for rubbing (frequency, intensity) is not known. The rubbing should be tailored to the individual child's reaction.

In adults, pressure applied to the injection site prior to injection has been demonstrated to reduce pain during injections (Chung 2002,<sup>79</sup> Barnhill 1996<sup>80</sup>).

### *Future Research:*

- Is cutaneous stimulation effective for children aged  $< 4$  years?
- Are parents and vaccinators able to apply this technique effectively?

- What equipment can be used to provide tactile stimulation so that parents/clinicians are not required to do it?

## Brand of Vaccine

**Among children undergoing immunization, does administering one commercial brand of a vaccine rather than another commercial brand of the same vaccine cause less pain at the time of injection?**

### *Background:*

Some vaccines that are marketed by different manufacturers are considered interchangeable. The pharmaceutical formulation for each brand, however, is unique and differences in pain at the time of injection may occur as a result of differences in pharmaceutical factors including; pH, adjuvents, or other excipients.

Four RCTs involving 1027 infants and children (12 months to 6 years) compared two brands of measles-mumps-rubella vaccine: Priorix® and M-M-R II® (or RORVax®, the equivalent of M-M-R II®)\* (Ipp 2004<sup>81</sup>, Ipp 2006<sup>82</sup>, Knutsson 2006<sup>83</sup>, Wood 2004<sup>84</sup>). All four studies reported less pain at the time of injection in children that were administered the Priorix® brand. Pain was assessed by the children themselves, their parents and clinicians performing the injections.

### RECOMMENDATION

**Inject the least painful commercial brand of a vaccine in children during immunizations when more than one interchangeable commercial brand is available in order to reduce pain at the time of injection.**

*Level of Evidence: I*

Grade of Recommendation: A

### *Clinical Considerations:*

Current available evidence is limited to measles-mumps-rubella vaccines.

Clinicians often cannot choose the brand of vaccine that they will use in clinical practice as more than one product may be provided by health authorities to ensure that enough vaccine is available. Vaccine manufacturers and government agencies are encouraged to supply vaccines that are associated with less pain at the time of injection.

***Future Research:***

- The impact of new technologies (e.g., microneedles) and needle-free administration techniques require investigation.

\* TRADEMARKS:

Priorix® (SmithKline Beecham Pharma, Oakville, Ontario, Canada; and GlaxoSmithKline, Brentford, Middlesex, United Kingdom)

M-M-R II® (Merck Frosst Canada & Company, Montreal, Quebec, Canada)

RORVax® (Aventis Pasteur-MSD, Lyon, France)



## Injection Techniques

**Among children undergoing intramuscular vaccine injections, should aspiration and slow injection be avoided in order to reduce pain at the time of injection?**

### Background:

Aspiration prior to intramuscular injection of vaccines is a long-standing practice that has never been subjected to scientific evaluation.<sup>9</sup> It was initially proposed as a safety measure to ensure that a blood vessel was not penetrated during vaccine injection. It involves pulling back on the plunger slowly over a period of 5 to 10 seconds after needle insertion. At present, aspiration is not advocated as a necessary step by authorities involved in developing immunization recommendations. This is because the anatomical sites for vaccine injections involve regions of the body that are devoid of large blood vessels. Recently published data suggest that 1/3 of vaccinators currently do not aspirate prior to vaccine injections.<sup>7</sup> For those that do, most do not appear to wait long enough (5-10 seconds) for aspiration to achieve its desired purpose.<sup>7</sup> A systematic search on this topic has identified no reports of any adverse consequences of not aspirating during immunization injections. Together, these data suggest that for intramuscular vaccine injections, the benefits of aspiration have not been proven and there is minimal risk of harm from not aspirating.

Injecting vaccines slowly is another long-standing practice that has never been subjected to scientific evaluation.<sup>9</sup> It was initially recommended in order to minimize pressure and sudden distension of tissues. The definition of a slow injection, however, is unclear. Some researchers have quantified *slow* to mean between 5 and 10 sec/mL. However, in clinical practice, injection speeds have been observed to be faster. In fact, the slowest observed speed was closer to 4 sec/mL. At present, the influence of injection speed on acute pain during vaccine injections has not been determined.<sup>9</sup>

Together, aspiration and slow injection add pain to vaccine injections due to a longer needle-tissue contact time and lateral movement of the needle within tissue.

One high quality RCT including 113 infants aged 4 to 6 months examined intramuscular injection of DTPaP-Hib using a rapid injection without aspiration (approx. total injection time 1 sec.) vs. slow injection with aspiration (approx. total injection time 9 sec.) technique (Ipp 2007<sup>85</sup>). Pain was significantly reduced using the rapid injection without aspiration technique. We believe that these results are

generalizable to all children due to similarities in the procedure and how pain is processed. There is currently no proven risk of harm for not aspirating prior to intramuscular injection.

**RECOMMENDATION**

**Perform intramuscular injections in children during immunizations using a rapid injection without aspiration technique in order to reduce pain at the time of injection.**

*Level of Evidence: I*

Grade of Recommendation: B

***Clinical Considerations:***

Vaccinators should follow immunization recommendations regarding the appropriate site for injection, needle size, and angle of injection.

## Order of Injections

**Among children receiving multiple vaccine injections at a single immunization visit, does injecting the most painful one last decrease pain at the time of injection?**

### *Background:*

At present, infants and children in Canada routinely receive multiple (2 or more) vaccine injections at the same immunization visit (see provincial and territorial immunization guides). Some vaccines are more painful to administer than others, possibly due to the acidity (lower pH) of the vaccine solution.<sup>9</sup>

A single high quality RCT evaluated sequential injection of Pentacel<sup>®</sup><sup>1</sup> and Prevnar<sup>®</sup> in 120 2-6 month-old infants (Ipp 2009<sup>86</sup>). The study found that giving the more painful vaccine last (i.e., Prevnar<sup>®</sup>) decreased overall pain from both injections. We believe that these results are generalizable to all children due to similarities in the procedure and how pain is processed. There is currently no rationale for providing the more painful vaccine first.

Although RCTs have not examined the pain of other vaccine pairs, we believe it is reasonable to extrapolate these findings to other situations in which the choice of injecting the more painful vaccine last is available to the health care provider.

### RECOMMENDATION

**Inject the most painful vaccine last in children who are being administered multiple vaccine injections sequentially in order to reduce pain at the time of injection.**

*Level of Evidence: I*

Grade of Recommendation: B

### *Clinical Considerations:*

From current available evidence, vaccines known to be more painful are: MMR-II<sup>®</sup> and Prevnar<sup>®</sup>.

<sup>1</sup> Pentacel<sup>®</sup> has now been replaced with Pediacel<sup>®</sup>.

***Future Research:***

- Studies that evaluate the pain caused from other currently available vaccines are warranted so that recommendations can be made about the order of administration.

## Simultaneous Injections

**Among children undergoing immunization, does simultaneous injection in separate limbs by two immunization providers provide less pain at the time of injection than sequential injection by the same provider?**

### Background:

Multiple healthcare providers may be available at the same time, allowing for simultaneous injection of 2 vaccines by 2 healthcare providers rather than sequential injection by 1 provider

One RCT including 46 4-6 year-old children examined the effects of simultaneous versus sequential immunization injections (Horn 1999<sup>87</sup>). No difference in child self-reported pain or observer rated distress was observed between groups.

### RECOMMENDATION

**There is insufficient evidence for or against the use of simultaneous injections rather than sequential injections in separate limbs in children during immunizations in order to reduce pain at the time of injection.**

*Level of Evidence: I*

Grade of Recommendation: I

### Clinical Considerations:

Child preferences (i.e., the empowering choice of having two injections given at the same time), developmental considerations (e.g., school-age children may be more anxious if they see 2 vaccinators on either side of them rather than one), parental preferences (e.g., one study found parents preferred simultaneous injection (Horn 1999<sup>87</sup>)), and availability of providers may influence whether this intervention is offered.

### Future Research:

- Additional research is recommended to determine the impact of simultaneous versus sequential injection of vaccines for infants and children of different ages.

## Routes of Administration:

### Intramuscular and Subcutaneous

**Among children undergoing immunization, does administering vaccines intramuscularly rather than subcutaneously cause less pain at the time of injection?**

#### *Background:*

Some vaccines can be administered intramuscularly or subcutaneously. Manufacturers' instructions, however, generally recommend one route of administration.

Three RCTs including 817 infants and children (14 months to  $\leq 10$  years) investigated the effects of intramuscular injection vs. subcutaneous injection on pain response during immunization (Lafeber 2001,<sup>88</sup> Leung 1989,<sup>89</sup> Mark 1999<sup>90</sup>). No differences were observed for either observer-rated infant pain or child self-reported pain in 2 of the studies (Lafeber 2001,<sup>88</sup> Mark 1999<sup>90</sup>). In 1 study, intramuscular injection caused more pain in infants and children (Leung 1989<sup>89</sup>). However, investigators did not provide detail regarding the injection technique used (if intramuscular injection was performed with aspiration), and this could have a significant effect on perceived pain.

#### RECOMMENDATION

**There is insufficient evidence to recommend for or against the use of a specific route of administration for vaccines that can be administered intramuscularly or subcutaneously in children during immunizations in order to reduce pain at the time of injection.**

*Level of Evidence: I*

Grade of Recommendation: I

#### *Clinical Considerations:*

It is recommended that manufacturers' instructions be followed when injecting vaccines.

**RECOMMENDATION TABLE**

Recommendation	Level of Evidence and Grade of Recommendation	Age of Child	Difficulty of Use
Advise parents to use topical anesthetics in children during immunizations in order to reduce pain at the time of injection.	Level I Grade A	All	++
There is insufficient evidence for or against the use of skin cooling techniques (vapocoolants, ice, cool/cold ice packs) in children during immunizations in order to reduce pain at the time of injection.	Level I Grade I	All	-
There is currently no demonstrated benefit of acetaminophen or ibuprofen in reducing pain at the time of injection, although they may be effective in reducing post-immunization minor adverse events (delayed pain, swelling, fever).	Level III Grade I	All	-
Encourage breastfeeding mothers to breastfeed their infants during immunizations in order to reduce pain at the time of injection.	Level I Grade A	Infants	++
For infants aged up to 12 months that cannot be breastfed during immunizations, administer sweet tasting solutions in order to reduce pain at the time of injection.	Level I Grade A	Infants	++
Use clinician-led distraction techniques with children during immunizations in order to reduce pain at the time of injection.	Level I Grade B	All	+
Use child-led distraction techniques in children aged $\geq 3$ years in order to reduce pain at the time of injection.	Level I Grade B	$\geq 3$ years	+
Have children aged $\geq 3$ years engage in slow deep breathing/blowing during immunizations in order to reduce pain at the time of injection.	Level I Grade B	$\geq 3$ years	+
Use combined cognitive-behavioural interventions in children aged $\geq 3$ years during immunizations in order to reduce pain at the time of injection.	Level I Grade B	$\geq 3$ years	+++
While there is insufficient evidence for or against the use of parent-led distraction or parent coaching during immunizations in children in order to reduce pain at the time of injection, clinicians may offer this intervention to parents in order to reduce pain-related distress.	Level I Grade B	All	+
DO NOT tell children that "it won't hurt" because these types of suggestions alone have been shown to be ineffective in reducing pain at the time of injection	Level I Grade D	All	-

Recommendation	Level of Evidence and Grade of Recommendation	Age of Child	Difficulty of Use
In order to reduce pain at the time of injection, DO NOT place children in a supine position during immunizations.	Level I Grade E	All	+
Offer to rub/stroke the skin near the injection site with moderate intensity prior to and during immunizations in children aged $\geq 4$ years in order to reduce pain at the time of injection.	Level II-1 Grade B	$\geq 4$ years	+
Inject the least painful commercial brand of a vaccine in children during immunizations when more than one interchangeable commercial brand is available in order to reduce pain at the time of injection.	Level I Grade A	All	+++
Perform intramuscular injections in children during immunizations using a rapid injection without aspiration technique in order to reduce pain at the time of injection	Level I Grade B	All	+
Inject the most painful vaccine last in children who are being administered multiple vaccine injections sequentially in order to reduce pain at the time of injection.	Level I Grade B	All	+
There is insufficient evidence for or against the use of simultaneous injections rather than sequential injections in separate limbs in children during immunizations in order to reduce pain at the time of injection.	Level I Grade I	All	-
There is insufficient evidence to recommend for or against the use of a specific route of administration for vaccines that can be administered intramuscularly or subcutaneously in children during immunizations in order to reduce pain at the time of injection.	Level I Grade I	All	-

Ease of use: + = relatively easy to implement, ++ moderately difficult to implement, +++ = relatively difficult to implement.



## OTHER CONSIDERATIONS

### Pain Assessment and Documentation:

Assessing pain is an important aspect of providing analgesia as it allows for determination of the effectiveness of the strategy used to decrease pain. If there is sub-optimal analgesia, improvements should be made in analgesic therapies for future procedures. Many different methods of pain assessment are available for infants and children of different ages. In preverbal children, behavioral cues are usually used to signal the presence of pain. These include: crying, facial grimacing, and writhing body movements. In older, verbal children ( $\geq 3$  years of age), pain may be exhibited with similar behaviors; however, children can usually supplement behaviors with a self-report, which is considered the primary source for pain assessment. In all age groups, pain may be accompanied by physiologic changes (eg, increases in heart rate, blood pressure, respiratory rate). Monitoring of these responses, however, is generally unnecessary and limited to research settings.

In order to maintain a record of the effectiveness of interventions and inform the use of pain-reducing strategies at future immunizations, clinicians are encouraged to document the interventions used to reduce acute pain at the time of vaccine injection and the child's pain response. (**Appendix C**)

Behavioural pain tools can be used by adult observers to rate vaccine injection pain in infants and children  $\leq 6$  years. Validated and commonly used tools include:

- Neonatal/Infant Pain Scale (NIPS) (newborn – 1 year)<sup>91</sup>
- Modified behavioural Pain Scale (2 months – 1 year)<sup>92,93</sup>
- Crying ( $\leq 6$  years)
- Visual Analog Scale ( $\leq 6$  years)<sup>93</sup>

Self-report pain tools can be used by children to rate their own pain.<sup>94</sup> Validated and commonly used tools include:

- Poker Chips/Pieces of Hurt (3-6 years)<sup>95</sup>
- Faces scales ( $\geq 4$  years)<sup>96,97,98</sup>
- Visual analog scales ( $\geq 6$  years)
- Numeric rating scales ( $\geq 8$  years)<sup>99 100</sup>.

Some of the tools are available on-line

([http://www.anes.ucla.edu/pain/assessment\\_tool-nips.htm](http://www.anes.ucla.edu/pain/assessment_tool-nips.htm),

<http://painsourcebook.ca/pdfs/pps92.pdf>,

[http://www.painknowledge.org/physiciantools/opioid\\_toolkit/components/Wong-Baker\\_Scale.pdf](http://www.painknowledge.org/physiciantools/opioid_toolkit/components/Wong-Baker_Scale.pdf),

<http://www.ouche.org>,  
<http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat6.section.32536>).

## Barriers to Implementation:

Implementation of the strategies recommended in this guideline requires planning, training and communication among individuals involved in immunization in various practice settings.

Organizational barriers must be identified and supports put in place to allow healthcare providers to implement the guidelines into practice.

In some cases, implementation of pain management interventions may be associated with additional costs due to; additional time required for clinic staff to practice pain management, and acquisition costs for required aids/resources. For the most part, these costs are relatively modest. Upfront, some time is also needed for clinic staff to learn how to use and incorporate the various strategies in their own practice settings.

Several tools have been included in this guideline in order to begin to facilitate this implementation process. Use of the recommended strategies on a routine basis is expected to lead to: reduced pain for children, reduced distress for children, parents and healthcare providers, and improved satisfaction with the immunization process.

## METHODS

### *Identifying and Evaluating the Evidence*

In exploring how to manage pain during routine immunization, 3 domains of intervention were considered (physical, pharmacological, and psychological), and systematic reviews were conducted for each.

Searches were conducted by the chief librarian at The Hospital for Sick Children (Ms. Elizabeth Uleryk). Searches were performed using the OVID search platform in the following databases where appropriate: MEDLINE (1950-October, 2008), EMBASE (1980 to 2008 Week 43), CINAHL (1982 to October Week 3-4 2008), EBM Reviews - Cochrane Central Register of Controlled Trials (3rd-4th Quarter 2008), and PsychINFO (1967 to October Week 3 2008). No language restrictions were imposed. Complimentary and alternative therapies were excluded.

RCTs and quasi-RCTs were included for consideration. The quality of included studies was determined using the Cochrane Risk of Bias Tool. Full description of search strategies, as well as lists of articles reviewed, retrieved and studies included or excluded are reported in the three systematic reviews.<sup>9 10 11</sup>

Published literature, key informant interviews and discussions with panel members and stakeholder partners, including parents, were used to identify important clinical questions for inclusion in this guideline.<sup>2 6 7 8</sup> The Key Clinical Questions that were included in this guideline can be found at the beginning of each recommendation and in **Appendix D**.

### *Recommendation Development and Approval*

The guideline development process was facilitated by the Guidelines Advisory Committee at the Centre for Effective Practice. Formal criteria for evaluating the evidence and grading recommendations were adapted from the Canadian Task Force on Preventive Health Care, definitions of each level and grade may be found in **Appendix D**. Team leaders for each of the 3 domains of intervention (physical, pharmacological, and psychological) prepared draft key questions and recommendations based on the quality of the published evidence, which were reviewed by at least 2 or 3 other team members prior to dissemination to the entire panel. The draft recommendations were then presented and discussed at an in-person meeting held on June 20, 2009 at the University of Toronto (Leslie Dan Faculty of Pharmacy). The recommendations were revised to reflect the comments made by panel members and electronically disseminated to the group for additional

comments. For each clinical question, our recommendation was based on consideration of: 1) the evidence from the systematic reviews, which included randomized controlled trials (RCTs) and quasi-RCTs, 2) methodologic limitations of included trials, 3) evidence from related contexts, and 4) child and other stakeholder-related factors. A consensus process was used to arrive at the final wording for each recommendation.

### *External Review*

In September-October, 2009 a draft guideline was circulated for review and feedback from relevant stakeholders and experts identified by the panel members. Concurrently, a draft was evaluated by three trained Guidelines Advisory Committee (GAC) guideline reviewers who are also practicing physicians in Ontario. External reviewers evaluated the guideline using the AGREE Instrument ([www.agreetrust.org](http://www.agreetrust.org)) and were also asked to provide specific feedback on the individual recommendations. It is important to note that none of the comments disputed any of the guideline recommendations. Most comments related to the identification of potential barriers to adoption, piloting and suggestions for teaching aids. Comments were brought to the panel for discussion and the guideline was revised where necessary.

The external reviewers included:

- Ms. Kristen Christie, parent representative
- Ms. Terri Fergus, Nurse Consultant, BC Centre for Disease Control (BC CDC rep)
- Ms. Alexandra Henteleff, Nurse Consultant, Winnipeg Public Health
- Dr. Inese Grava-Gubins, Family Practice Physician, CFPC Professional Affairs (CFPC rep)
- Ms. Diane Gwartz, Advance Practice Nurse, Board Member, Nurse Practitioners' Association of Ontario (NPAO rep)
- Dr. David J. Kenny, Pediatric Dentist, The Hospital for Sick Children
- Ms. Cheryl McIntyre, Associate Nurse Epidemiologist, BC Centre for Disease Control
- Ms. Lori Palozzi, Advanced Practice Nurse, Acute Pain Service, The Hospital for Sick Children
- Dr. Barry Power, Pharmacist, Canadian Pharmacists' Association (CPhA rep)
- Ms. Judie Surridge, Family Practice Nurse, President, Ontario Family Practice Nurses (OFPN rep)
- Dr. Gary A. Walco, Psychologist, Director of Pain Medicine, Seattle Children's Hospital
- Dr. Carl L von Baeyer, Psychologist, Professor Emeritus, University of Saskatchewan
- Dr. William T. Zempsky, Pediatrician, Associate Director, Pain Relief Program, Connecticut Children's Medical Center

### *Piloting the Guideline*

Recommendations within this guideline have been piloted at: 1) a two-physician outpatient pediatric clinic, and 2) a private school. Questionnaires administered to parents and clinicians in those settings were used to provide feedback to inform clinical considerations for each specific recommendation. The panel plans to identify additional opportunities to pilot this guideline in the future.

### *Guideline Updates*

The panel received additional funding from CIHR to host a collaborative meeting of stakeholders, in 2010, to review initial feedback from users of the guideline, to consider results from additional pilot testing and to identify further opportunities for tool development. At that time, the panel will review whether additional information or revisions are necessary to enhance the guideline.

A process for updating the guideline (including literature search, evidence review and recommendations) will be confirmed within 5 years of publication.

***Not Addressed/Future Research:***

The recommendations included in this guideline are limited by the published evidence that was available at the time of publication of our 3 systematic reviews.

The guideline panel did not consider ethnicity in the recommendations; however, it is acknowledged that the experience of pain may be mediated by ethnic factors. Moreover, ethnicity may influence the pain-relieving strategies that parents and children choose to employ.

This guideline did not include complementary and alternative medicines, and the effectiveness of such therapies should be determined in future studies.

Our literature search did not identify studies that examined the impact of aspects of the needle (gauge, length, angle of injection) or body region (buttock, thigh, arm) on vaccine injection pain. We recommend that future studies examine the effect of these factors on pain at the time of injection.

## APPENDICES



## *Appendix A – Conflict of Interest*

### **Conflict of Interest Disclosure Statement**

As an expert panel member in the development of guidelines for the HELPinKIDS project, it is the responsibility of the Panel/Committee to ensure conflicts of interest are identified and that a policy is confirmed to address any potential issues.

#### **What is a Conflict of Interest?**

Conflict of interest is a situation that arises where your involvement/interest may be incompatible or in conflict with the mandate or work being undertaken to deliver evidence-based guideline recommendations that are free from bias. Such conflicts may arise as a result of past or current involvements, and may be either actual conflicts or potential conflicts. They may not be readily apparent. Not all potential conflicts are problematic for the purposes of reviewing evidence, developing and/or assessing guidelines.

#### **Examples of Potential Conflicts**

You have been involved as a member of a guideline development group for asthma care and are asked to evaluate the guideline you have produced **OR** you are asked to evaluate other guidelines in this area that may “compete” with the one you produced.

You are a member of a task force that is examining policy for OHIP’s schedule of benefits regarding cardiac diagnostic testing and are asked to assess guidelines and/or make recommendations in this area.

You have received payment from a pharmaceutical company for expert advice in a particular clinical area relevant to this project.

You are involved in research that is sponsored by a pharmaceutical company in a particular clinical area.

Each author/member **MUST** complete and sign this form.

#### **I. Personal Potential Financial Conflicts of Interest**

<p><b>Category of Potential Conflict</b></p>	<p>If you have had any of the listed relationships with an entity that has a financial interest in the subject matter discussed in this guideline, check the appropriate “yes” box below. If you do not have a listed relationship, check the appropriate “no” box. Please consider the past 5 years through the present when answering the</p>
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	question.		
	No	Yes	Please describe potential conflicts of interest below and provide additional detail in cover letter if necessary.
Employment			
Consultant Agencies/Companies			
Honoraria			
Stock Ownership (other than mutual funds)			
Expert testimony			
Grants received			
Grants pending			
Patents received			
Patents pending			
Royalties			
Receipt of payment for involvement in the preparation of this manuscript			
Other			

**2. Institutional Conflicts of Interest**

Are you aware that your academic institution or employer has any financial interest in or a financial conflict with the subject matter or materials discussed in this manuscript?

	No
	Yes, please describe and provide additional detail in cover letter if necessary

Author:

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

## Appendix B – Criteria for Evaluating Evidence and Grading Recommendations

### Levels of Evidence

<b>I</b>	Evidence from randomized controlled trial(s)
<b>II-1</b>	Evidence from controlled trial(s) without randomization
<b>II-2</b>	Evidence from cohort or case-control analytic studies, preferably From more than one centre or research group
<b>II-3</b>	Evidence from comparisons between times or places with or without the intervention; dramatic results in uncontrolled experiments could be included here
<b>III</b>	Opinions of respected authorities, based on clinical experience; descriptive studies or reports of expert committees

### Grades of Recommendation

<b>A</b>	There is good evidence to recommend the action
<b>B</b>	There is fair evidence to recommend the action
<b>C</b>	The existing evidence is conflicting and does not allow making a recommendation for or against the use of the action, however other factors may influence decision-making
<b>D</b>	There is fair evidence to recommend against the action
<b>E</b>	There is good evidence to recommend against action
<b>I</b>	There is insufficient evidence (in quantity and/or quality) to make a recommendation, however other factors may influence decision-making

Adapted from: Definitions of levels of evidence and grades of recommendations of the Canadian Task Force on Preventive Health Care.

<http://www.cmaj.ca/cgi/content/full/170/6/976/DC1>

*Appendix C – Evaluation and Measures (Audit Tool)*

There are many recommendations that can be used by clinicians and parents to assist in reducing pain at the time of injection of vaccines. The HELPinKIDS Guideline Panel has reviewed the evidence from the literature, documented specific recommendations and provided parent information tools to assist clinicians to implement these suggestions.

**Try identifying what you are currently doing in practice and what you would consider trying. This table could also be used to initiate dialogue with other members of your team to help determine a strategy for managing pain during immunization in your practice. The results from this exercise can begin to form an audit mechanism for your practice to ensure adherence to the guideline recommendations.**

Recommendation	Do you currently use this strategy in your practice?		Would you be willing to try it?	
	Yes	No	Yes	No
Advise parents to use topical anesthetics in children during immunizations in order to reduce pain at the time of injection.				
There is insufficient evidence for or against the use of skin cooling techniques (vapocoolants, ice, cool/cold ice packs) in children during immunizations in order to reduce pain at the time of injection.				
There is currently no demonstrated benefit of acetaminophen or ibuprofen in reducing pain at the time of injection, although they may be effective in reducing post-immunization minor adverse events (delayed pain, swelling, fever).				
Encourage breastfeeding mothers to breastfeed their infants during immunizations in order to reduce pain at the time of injection.				
For infants aged up to 12 months that cannot be breastfed during immunizations, administer sweet tasting solutions in order to reduce pain at the time of injection.				
Use clinician-led distraction techniques with children during immunizations in order to reduce pain at the time of injection.				

Recommendation	Do you currently use this strategy in your practice?		Would you be willing to try it?	
	Yes	No	Yes	No
Use child-led distraction techniques in children aged $\geq 3$ years in order to reduce pain at the time of injection.				
Have children aged $\geq 3$ years engage in slow deep breathing/blowing during immunizations in order to reduce pain at the time of injection.				
Use combined cognitive-behavioural interventions in children aged $\geq 3$ years during immunizations in order to reduce pain at the time of injection.				
While there is insufficient evidence for or against the use of parent-led distraction or parent coaching during immunizations in children in order to reduce pain at the time of injection, clinicians may offer this intervention to parents in order to reduce pain-related distress.				
DO NOT tell children that “it won’t hurt” because these types of suggestions alone have been shown to be ineffective in reducing pain at the time of injection				
In order to reduce pain at the time of injection, DO NOT place children in a supine position during immunizations.				
Offer to rub/stroke the skin near the injection site with moderate intensity prior to and during immunizations in children aged $\geq 4$ years in order to reduce pain at the time of injection.				
Perform intramuscular injections in children during immunizations using a rapid injection without aspiration technique in order to reduce pain at the time of injection				
Inject the most painful vaccine last in children who are being administered multiple vaccine injections sequentially in order to reduce pain at the time of injection.				
There is insufficient evidence for or against the use of simultaneous injections rather than sequential injections in separate limbs in children during immunizations in order to reduce pain at the time of injection.				
There is insufficient evidence to recommend for or against the use of a specific route of administration for vaccines that can be administered intramuscularly or subcutaneously in children during immunizations in order to reduce pain at the time of injection.				

Recommendation	Do you currently use this strategy in your practice?		Would you be willing to try it?	
	Yes	No	Yes	No
Inject the least painful commercial brand of a vaccine in children during immunizations when more than one interchangeable commercial brand is available in order to reduce pain at the time of injection.				

## *Appendix D – Key Clinical Questions*

1. Among children receiving intramuscular and subcutaneous immunizations, does application of topical anesthetics on the skin prior to vaccine injection reduce pain at the time of injection?
2. Among children undergoing immunization,
  - 1) does application of vapocoolant sprays on the skin prior to vaccine injection reduce pain at the time of injection?
  - 2) does application of ice or cool/cold packs on the skin prior to vaccine injection reduce pain at the time of injection?
3. Among children undergoing immunization, does administration of acetaminophen or ibuprofen prior to injection reduce pain at the time of injection?
4. Among infants receiving immunizations, does breastfeeding during vaccine injection reduce pain at the time of injection?
5. Among children undergoing immunization, does administration of sweet-tasting solutions reduce pain at the time of injection?
6. Among children undergoing immunization, does use of clinician-led distraction result in less pain at the time of injection?
7. Among children undergoing immunization, does use of child-led distraction result in less pain at the time of injection?
8. Among children undergoing immunization, does slow deep breathing/blowing performed by the child result in less pain at the time of injection?
9. Among children undergoing immunization, does use of combined cognitive-behavioural interventions (i.e., an intervention that includes at least one cognitive and one behavioural intervention) result in less pain and distress at the time of injection?
10. Among children undergoing immunization,
  - 1) does use of parent-led distraction result in less pain and pain-related distress at the time of injection?

- 2) does use of parent coaching result in less pain and pain-related distress at the time of injection?
11. Among children undergoing immunization, does suggesting that “it won’t hurt” result in less pain at the time of injection?
12. Among children undergoing immunization, does positioning the child in a supine position result in more pain at the time of injection?
13. Among children undergoing immunization, does rubbing the skin near the injection site before and during injection result in less pain at the time of injection?
14. Among children undergoing immunization, does administering one commercial brand of a vaccine rather than another commercial brand of the same vaccine cause less pain at the time of injection?
15. Among children undergoing intramuscular vaccine injections, should aspiration and slow injection be avoided in order to reduce pain at the time of injection?
16. Among children receiving multiple vaccine injections at a single immunization visit, does injecting the most painful one last decrease pain at the time of injection?
17. Among children undergoing immunization, does simultaneous injection in separate limbs by two immunization providers provide less pain at the time of injection than sequential injection by the same provider?
18. Among children undergoing immunization, does administering vaccines intramuscularly rather than subcutaneously cause less pain at the time of injection?



## *Appendix E – Health Care Workers Quick Reference*

Chambers CT, Taddio A, Uman LS, BA, & McMurtry CM for the HELPinKIDS Team. Psychological interventions for reducing pain and distress during routine childhood immunizations: A systematic review. *Clinical Therapeutics* 2009;31(B):S77-S103.

Shah V, Taddio A, & Rieder MJ for the HELPinKIDS Team. Effectiveness and tolerability of pharmacologic and combined interventions for reducing injection pain during routine childhood immunizations: Systematic review and meta-analyses. *Clinical Therapeutics* 2009;31(B):S104-S151

Taddio A, Ilersich AL, Ipp M, Kikuta A, & Shah V, for the HELPinKIDS Team. Physical interventions and injection techniques for reducing injection pain during routine childhood immunizations: Systematic review of randomized controlled trials and quasi-randomized controlled trials. *Clinical Therapeutics* 2009;31(B):S48-S76.

Schechter N, Zempsky WT, Cohen LL, et al. Pain reduction during pediatric immunizations: Evidence-based review and recommendations. *Pediatrics*. 2007;119:e1184–e1198.

## Appendix F – Fact Sheets for Parents

### Long version

#### PAIN MANAGEMENT DURING CHILDHOOD IMMUNIZATION

Vaccines are medicines that protect against infectious diseases. Vaccines are given with a needle, which is painful. Children, their families, and the health care providers performing vaccine injections are concerned about pain during vaccine injections. This fact sheet summarizes ways to minimize pain from vaccine injections in children.

#### What can you do to reduce vaccine injection pain in your child?

##### 1. Prepare yourself:

- *Stay calm:*  
Your actions and words can influence your child’s reaction. Children often look to their parents to understand how to act and feel. If you are calm, use your normal voice, and smile, your child will feel that everything is ok.
- *Take your child’s attention away from the procedure using distraction:*  
This is effective for children of all ages. Examples of age-appropriate distraction strategies include:
  - *Infants:* toys, bubbles, pacifiers, singing, directing the infant’s attention to something in the environment that would be of interest for them
  - *Toddlers:* toys, bubbles, pop-up books, songs, party blowers, kaleidoscopes, singing, directing the toddler’s attention to something in the environment that would be of interest for them, non-procedural talk (talking about something unrelated to the procedure)
  - *School-age:* toys, stories, videos, books, joking, counting, non-procedural talk
  - *Adolescents:* games, videos, books, joking, music, non-procedural talk
- *Prompt your child to take slow deep breaths.* Deep breaths can be facilitated by using bubbles, pinwheels, or balloons, which also act as distracting techniques.

- *Avoid words that increase distress and focus attention on the procedure, such as: high anxiety words (“hurt” “pain” or “shot”), reassuring words (“It’ll be over soon”, “You’ll be ok”), apologizing (“I’m sorry you have to go through this”), empathizing (“I know it hurts”).*
- *Provide physical comfort:*  
Have your child sit up-right. Infants and young children should be held by a parent in a position that is most comfortable for them and their parent (for example, on parent’s lap in a bear hug). Hugging feels comfortable and helps children to stay still. Sit on a chair or stand against the examination table to minimize the risk for accidental falls. Keep limbs exposed for the vaccinator. Secure your child if necessary but do not use undue force- this increases child distress. In older children, hold hands or offer to stroke/rub their arm before and during vaccine injections.
- *Plan to use other pain-relieving interventions:*
  - *Breastfeed your infant.* You can breastfeed your infant before, during, and after vaccine injections.
  - *Give sugar water to your infant.* If your infant cannot be breastfed, then consider giving sugar water. Sugar water can be made by mixing one packet of sugar (the kind you put in your coffee or tea) with 2 teaspoonfuls (10 mL) of water. Put some in your baby’s mouth with a cup, syringe or pacifier right before the vaccine injection. It is important not to use sucrose at home to calm upset or crying babies. It is only recommended for managing pain from medical procedures.
  - *Give topical anesthetics.* Topical anaesthetics can be used in children of all ages. They are particularly useful for school-age children that are anxious. Several products are available in Canada without a prescription, including: EMLA (lidocaine-prilocaine) and Ametop (amethocaine). They must be applied ahead of time (30-60 minutes beforehand) so require some planning. Before using them, make sure your child is not allergic to any of the ingredients. Follow the instructions carefully, being careful to apply them to the correct location and for the correct amount of time. You may want to talk to your health care professional about how and where to apply them. Topical anaesthetics can cause temporary discoloration of the skin where they are applied. If you notice a rash, it could be a sign of an allergic reaction. Tell your healthcare professional.

## **2. Prepare your child:**

- *Talk to your child about the procedure using age-appropriate words:*  
In general, young children (< 4 years old) should be told immediately before the procedure. Older children should be told at least 1 day

before the procedure, to give them time to think and plan with you how they will cope. Involve and listen to your child. Children often have helpful suggestions for how to manage their pain.

- Tell him or her why the procedure is taking place (“to help you stay healthy”),
- What will happen (“you will get a medicine called a vaccine in the arm (demonstrate where) using a tube that looks like a straw called a syringe”),
- How it will feel (“you might feel a pinch and some pushing or pressure that will last a few seconds”),
- How you will manage any potential discomfort (“some children think it is uncomfortable and some think it is ok. We don’t know how it will feel for you. We are going to do different things so that it does not feel uncomfortable for you” (then tell your child what you will do)),
- What the child can do to help (“you can help by holding still and ...(suggest other strategies)”)

### **3. Prepare your healthcare professional:**

- Let your doctor or nurse know what pain management strategies you are planning for your child’s vaccine injections and try to enlist their support. Show them this information sheet.
- Ask them to make vaccine injections less painful by using the following techniques:
  - Administer intramuscular vaccines quickly without aspiration. Authorities involved in developing immunization recommendations say that aspiration is not a necessary step in vaccine injections.
  - Administer the most painful vaccine last when more than one vaccine is administered in the same visit. There is no rationale for injecting the more painful vaccine first and it increases overall pain.

### **4. Reward your child:**

- After the procedure, provide praise to your child to reinforce their accomplishment of getting through the procedure

## Short version

### What is the best way to minimize the pain my child may have during vaccinations?

Try using some of the strategies described in this pamphlet. They will help your child feel less pain and help you to stay calm.

**1) Take your child's attention away from the procedure.**

This is effective for children of all ages. You can sing, talk about something that is not related to the procedure, tell jokes, or direct your child's attention to something interesting to them (picture, toy, book, game). Prompting children to take deep breaths with bubbles, pinwheels or balloons is also effective. Tell your child why the procedure is taking place (*to keep you healthy*), what will happen (*you will get a medicine called a vaccine in the arm*), how it will feel (*there may be a pinch and some pushing or pressure that will last a few seconds*), and how you will manage potential discomfort. Involve children in your planning (for example, let them choose a comfort item or toy to bring).

**2) Provide physical comfort.**

Hold your infant or young child, and offer to hold hands or stroke/rub the arm of older children before and during vaccination. It feels comfortable and helps children to reduce pain.

**3) Use other pain-relieving interventions like breastfeeding, sugar water, or topical anesthetics.**

Mothers can breastfeed infants during vaccine injections. Alternatively, infants can be given sugar water right before the injection. Sugar water is made by mixing one packet of sugar (the same as you put in coffee) with 2 teaspoonfuls (10 mL) of water. Put some in the baby's mouth with a syringe or pacifier right before the vaccine injection. You can use topical anesthetics in children of all ages. These are medications that temporarily numb the skin so that there is less feeling from the needle. They are particularly useful for school-age children that are anxious. They must be applied ahead of time (30-60 minutes beforehand) so require some planning.

**4) Tell your doctor or nurse.**

Show them this information sheet. Ask them to make vaccine injections less painful by giving them quickly and without aspiration. Authorities involved in developing immunization recommendations say that aspiration is not a necessary step in vaccine injections.

## Appendix G – Sample Quick Reference Chart for Parents and Children

### Template for Ontario

#### Childhood Immunizations in Ontario and Recommended Pain-Management Strategies (Anna Taddio for HELPinKIDS Team)

Age	Vaccines to be injected (according to Ontario immunization schedule)		Recommended pain-management strategies
2,4, 6 months	Diphtheria, Tetanus and Acellular Pertussis/ Inactivated Poliovirus and Haemophilus influenzae type b (DTaP-IPV-Hib)	Pneumococcal conjugate (PCV)	<ul style="list-style-type: none"> <li>• Topical anaesthetics</li> <li>• Breastfeeding or sugar water</li> <li>• Adult-led distraction</li> <li>• Physical comfort/holding</li> <li>• Inject PCV after DTaP-IPV-Hib</li> <li>• Inject vaccines rapidly without aspiration</li> </ul>
12 months	Meningococcal C Conjugate (Men-C)	Measles, Mumps, Rubella (MMR)	<ul style="list-style-type: none"> <li>• Topical anaesthetics</li> <li>• Breastfeeding or sugar water</li> <li>• Adult-led distraction</li> <li>• Physical comfort/holding</li> <li>• Inject Men-C rapidly without aspiration</li> <li>• Inject MMR* after Men-C</li> </ul>
15 months	Varicella/Chicken Pox (Var)	Pneumococcal conjugate (PCV)	<ul style="list-style-type: none"> <li>• Topical anaesthetics</li> <li>• Adult-led distraction</li> <li>• Physical comfort/holding</li> <li>• Inject PCV rapidly without aspiration</li> <li>• Inject PCV after Var</li> </ul>
18 months	Diphtheria, Tetanus and Acellular Pertussis/ Inactivated Poliovirus and Haemophilus influenzae type b (DTaP-IPV-Hib)	Measles, Mumps, Rubella (MMR)	<ul style="list-style-type: none"> <li>• Topical anaesthetics</li> <li>• Adult-led distraction</li> <li>• Physical comfort/holding</li> <li>• Inject DTaP-IPV-Hib rapidly without aspiration</li> <li>• Inject MMR* after DTaP-IPV-Hib</li> </ul>
4-6 years	Diphtheria, Tetanus and Acellular Pertussis/Inactivated Poliovirus (DTaP-IPV)		<ul style="list-style-type: none"> <li>• Topical anaesthetics</li> <li>• Self-distraction/Adult-led distraction</li> <li>• Deep breathing (facilitated with bubbles, pinwheel, balloon)</li> <li>• Physical comfort/holding</li> <li>• Inject vaccine rapidly without aspiration</li> </ul>
Grade 7	Meningococcal C Conjugate (Men-C)	Hepatitis B (HB)	<ul style="list-style-type: none"> <li>• Topical anaesthetics</li> <li>• Self-distraction/Adult-led distraction</li> </ul>

			<ul style="list-style-type: none"> <li>• Deep breathing</li> <li>• Physical comfort/holding</li> <li>• Inject vaccines rapidly without aspiration</li> </ul>
Grade 8	Human Papillomavirus (HPV)		<ul style="list-style-type: none"> <li>• Topical anaesthetics</li> <li>• Self-distraction/Adult-led distraction</li> <li>• Deep breathing</li> <li>• Physical comfort/holding</li> <li>• Inject vaccine rapidly without aspiration</li> </ul>
Every 10 years thereafter	Tetanus and Diphtheria (Td)		<ul style="list-style-type: none"> <li>• Topical anesthetics</li> <li>• Self-distraction/Adult-led distraction</li> <li>• Deep breathing</li> <li>• Physical comfort/holding</li> <li>• Inject vaccine rapidly without aspiration</li> </ul>
Every year (in fall)	Influenza (Inf)		<ul style="list-style-type: none"> <li>• Topical anaesthetics</li> <li>• Self-distraction/Adult-led distraction</li> <li>• Deep breathing</li> <li>• Physical comfort/holding</li> <li>• Inject vaccine rapidly without aspiration</li> </ul>

\* If using trade name MMR-II

Posted on AboutKidsHealth.ca website

## *Appendix H – Resources for Children*

### ***Books for Young Children About Getting an Injection***

A child in pain: How to help, what to do by Leora Kuttner

Be the Boss of Your Pain: Self-Care for Kids by Timothy Culbert and Rebecca Kajander

My Friend the Doctor by Joanna Cole, illustrated by Maxie Chambliss

The Berenstain Bears go to the Doctor by Stan and Jan Berenstain

Tom and Ally Visit the Doctor! by Beth Robbins, illustrated by Jon Stuart

### ***Books for Young Children about Visiting the Doctor***

Lions aren't scared of shots: a story for children about visiting the doctor by Howard J. Bennett

Felix Feels Better by Rosemary Wells

Corduroy Goes to the Doctor by Lisa McCue

Time to See the Doctor by Heather Maisner, illustrated by Kristina Stephenson

I Am Sick by Patricia Jensen, illustrated by Johanna Hantel

Next Please by Ernst Jandl and Norman Junge



## Appendix I - Clinician-led Distraction Fact Sheet

### Clinician-led distraction notes for procedural pain management in children

1. Involve parents and children in helping to select the best distractor for the child and involve parents in helping to keep the child distracted during the procedure.
2. Choose an age-appropriate distraction strategy. Effective distraction aids are neither expensive nor time-consuming. Examples of age-appropriate distraction strategies include:
  - *Infants*: toys, bubbles, pacifiers, singing, directing the infant's attention to something in the environment that would be of interest for them
  - *Toddlers*: toys, bubbles, pop-up books, songs, party blowers, kaleidoscopes, singing, directing the toddler's attention to something in the environment that would be of interest for them, non-procedural talk (talking about something unrelated to the procedure)
  - *School-age*: toys, stories, videos, books, joking, counting, non-procedural talk (for example, ask about what the child is doing in school right now, what their favourite tv shows are and what their favourite movie is).
  - *Adolescents*: games, videos, books, joking, music, non-procedural talk.
3. Capture the child's attention (that is, engage the child in the distractor) and keep the child's attention on the distractor before and during the painful stimulus.
4. Maintain a positive attitude, stay focused on the child and interact with the child throughout. Be sensitive to the child and respond to the child's questions and cues.
5. Provide verbal and physical (e.g., pointing) reminders for the child to continue to pay attention to the distractor. You can help the child stay distracted by asking questions about the distractor (e.g., "What colour is the bird on the poster?")
6. Re-direct the child's attention back to the distractor if their attention wanders to the procedure. Vary distractors and methods if necessary. Use multisensorial stimulation.
7. Praise the child for engaging in distraction behaviours.

## *Appendix J - School Based Information*

*The following is provided as possible language to use by school administration/public health when sending consent forms home to parents.*

Dear Parent,

*(insert name)* Public Health will be conducting a school-based vaccination clinic for *(insert date)*. *(insert name)* Public Health will be offering routine vaccination with *(insert vaccine name)* and *(insert vaccine name)*.

We will be planning activities that will minimize distress from the vaccine injection(s).

We ask parents to assist us by informing their child about the upcoming vaccination, taking care not to imply that the procedure will definitely hurt. Let your child know that he/she will receive two injections (one in each arm) and that he/she may bring comfort items (e.g., small toy, i-pod, electronic game, book) in order to serve as a distraction during the procedure. Distraction is a proven effective pain management strategy.

With your permission, we will offer to apply a topical local anesthetic cream. Topical anesthetics creams are medicines that numb the skin in order to reduce feeling at the procedure site. The topical anesthetic will be applied at school before immunization. People who are allergic to local anesthetic medications such as lidocaine, should not receive them. If you agree to let your child receive the topical anesthetic, please sign below:

\_\_\_\_\_  
Signature of parent or substitute decision maker

\_\_\_\_\_  
Date and Time

If you would like to have more information, please contact *(insert name and contact information)*.

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