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Communicable Disease Control Manual

Chapter 2: Immunization

Appendix D - Reducing Immunization Injection Pain

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1. Introduction to Strategies to Increase Child Comfort Before and During the Administration of a Biological Product

Pain associated with vaccine injections is a source of distress for individuals of any age as well as for the immunization provider. If not addressed, the pain and anxiety associated with immunizations can be related to fear of future procedures, medical fears, and avoidance behaviours including non-adherence with immunization schedules. It is estimated that up to 25% of adults have needle fears. The majority of people with needle fears develop them in childhood. Efforts aimed at minimizing pain in childhood have the potential to prevent the development of needle fears and promote consumer satisfaction and trust in health care providers because of more positive experiences for children and their families.

Pain is subjective; each person feels and expresses pain differently. Every individual learns the meaning of pain through experiences early in life. For children, being distressed during a procedure may have a negative impact on the memory of pain.

Research indicates that infants who are exposed to painful experiences develop a sensitization to future pain and may develop altered responses to future pain. For example, studies of infant males who were circumcised as neonates found that those infants exhibited greater pain responses to their 4 and 6 month immunizations than infants who were not circumcised. The effect on their future pain response was attenuated when a topical anesthetic was applied before the circumcision. Neonates who were exposed to repeat painful stimuli such as venipuncture or heel prick demonstrated an anticipatory response to the pain.

Rather than developing a tolerance for pain, if exposed to repeated procedures, children may actually develop a conditioned anxiety response that manifests as “pre-procedural anxiety”. Approximately 10% of the adult population have needle phobia, a condition that develops in childhood following a negative medical experience involving an injection. Over time, the phobia may become generalized to all medical situations. Adults who have needle fears or needle phobia tend to avoid preventive medical care for themselves and may avoid immunizations for their children.

While the immunization experience can be anxiety-provoking for the child and for the parent, it is also an opportunity for parents and the child (of preschool age and older) to learn coping strategies that will be useful in any stressful situation.

There are several evidence-based interventions that can be used before and during the immunization procedure to reduce acute pain and anxiety at the time of vaccine injection. The immunization provider and client or parent should work together to select from the strategies presented in this chapter which will work best for the vaccine recipient. A comprehensive approach includes at a minimum:

- preparation of the child before the procedure
- presence of calm adults who can coach children during the procedure
- a comfortable environment
- use of effective pain management strategies.

2. Psychosocial Considerations and Strategies

Refer to [Appendix B – Administration of Biological Products, 2.3 Client Assessment](#) for techniques to decrease anxiety and the risk of fainting prior to administration of biological products.

Not recommended: Prophylactic oral analgesia (infant acetaminophen or ibuprofen). Advise parents that oral analgesics are only recommended for use in managing adverse events (e.g., fever) if they occur *after* immunization. There is currently no demonstrated benefit of administering oral analgesics for the prevention of immunization injection pain. Prior recommendations for the use of prophylactic analgesics were not related to pain management, but to the prevention of fever and other adverse events following immunization (particularly after the administration of whole-cell pertussis vaccine). Recent studies indicate that, in addition to a lack of reduction in pain, there is a possibility that administration of prophylactic oral analgesics prior to immunization may decrease vaccine immunogenicity.

2.1 Preparation of the Child Before the Procedure

Prior to the appointment:

Provide the child and parent with tools to address pre-appointment anxiety before the visit. Refer parents to HealthLink BC File 50e [“A Better Immunization Experience for your Child”](#).

Give parents realistic information about how much pain is associated with immunization. Partner with them by providing them with techniques they can use to support, distract, and coach their child before, during, and after the immunization.

Advise parents that specific discussion about the immunization procedure is appropriate for children > 2 years of age. In general, toddlers and preschool age children should be informed about the injection as close to the actual administration of the vaccine as possible. For school age children, one day of advance preparation may be appropriate. Older children may benefit from longer preparation time but much depends on individual coping styles.

Inquire about the child's previous experiences with needles or other painful medical procedures. This information can be helpful in planning how to approach the visit as individual responses to stress are influenced by temperament, environment, and past experience.

At the appointment:

When the client presents, describe what you plan to do. Describing what you plan to do demonstrates respect for the child's right to know, confidence in their ability to manage, and your interest in dealing with their concerns. Important elements of information for the child include:

- what will be done (i.e., the steps involved in the procedure);
- how it will feel, using words that evoke as little anxiety as possible (i.e., pressure, squeezing, and poking instead of pain, hurt, sting, or shot). It may be useful to ask the parent what words the child is familiar with (e.g., “owie”); and
- strategies you, the child, and the parent can use to minimize discomfort.

Acknowledge the child's feelings and encourage parents to do the same. For example, consider use of phrases such as "you look worried/scared"; or "let's talk about some of the things we can do to make this better for you".

Do not tell children that "it won't hurt". Use honest statements such as "you may feel it a bit, but I think you can handle it" or "there may be a pinch and some pressure that will last a few seconds".

Use words that are explanatory without evoking anxiety (e.g., use words such as pressure, squeezing, and poking. Avoid words such as shot, pain, and hurt).

Telling a child that the immunization won't hurt ("suggestion therapy") has been found to be ineffective at reducing pain during immunization and may lead to a relationship of distrust between the child and health care provider.

Provide limited, realistic choices and let the child decide (e.g., "Would you like to use your right or left arm?" or "Would you like to look at this book or blow the pinwheel while I give you the vaccine?"). Offering realistic choices creates a setting where the child can maintain some personal control and contributes to an atmosphere of mutual respect.

Consider the use of practice dolls with children less than 6 years of age who need additional support. Offer to immunize a stuffed toy or doll, and invite the child to hold the "patient". Use a syringe *without* a needle and go through all the steps, explaining each one as you proceed.

Encourage the child's effort throughout the immunization process. After the immunization, acknowledge the child's effort and perseverance and encourage the parent to comfort their child and acknowledge their efforts. For example, encourage parents to use phrases such as "I know that was hard for you and I'm proud of you, that you did it", or "I really liked how you took lots of deep breaths while the nurse gave you the vaccine". Positive recognition after the procedure will help a child feel good about the skills they learned during the procedure.

2.2 Presence of Calm Adults

Prior to the appointment:

When immunizing infants and children, it is important to recognize that the parent may also be stressed and may have difficulty knowing how to support their child. The immunization experience is an opportunity for health care providers to observe and coach parents in ways to effectively interact with and comfort their child during stressful and painful experiences.

Advise parents that a matter-of-fact, supportive, non-apologetic approach is the most effective. The most helpful parent behaviours have been found to include humour, coaching their child to use coping strategies, distraction, and non-procedural talk with the child (i.e., talking about something other than the immunization).

Advise parents not to use needles or vaccination as a disciplinary threat.

At the appointment:

Coach parents in ways to decrease pain and anxiety in their child during the immunization. Suggest that parents:

- stay calm and speak in a calm and soft tone of voice;
- do not use words that focus the child's attention on the needle such as "It'll be over soon and you'll be okay.";
- answer their child's questions honestly (e.g., "You need the vaccine to stay healthy. The medicine will be put in your arm with a needle. You will feel a quick poke.");
- talk about things that can focus the child's attention on a fun event (e.g., an outing to the park, a fun or interesting activity done at home or school, something the child learned or did that made the parent proud, or an upcoming event the child is excited about);
- use humour when talking with the child;
- re-direct the child's attention to the distraction strategy as needed.

Parental reassurance, empathy, and apologies offered **before** the immunization are associated with increased stress in the child. It is thought these behaviours and the parent's tone of voice focus the child's attention on the procedure and cue them to realize something unpleasant is about to happen with the result that they feel more distress. Advise parents of this phenomenon and coach them to use the above strategies instead.

Researchers believe that it is appropriate for parents to acknowledge the child's pain by saying things such as "it's okay" or "I know it hurts", once or twice, right **after** the needle. However, pain researchers also suspect that parents who verbally reassure too much following a stressful experience tend to do this instead of trying other strategies (e.g., distraction) that help a child regulate more quickly and are using a tone of voice that children only hear in times of distress. After the immunization, encourage parents to calmly cuddle their child, briefly acknowledge their child's pain, and then use a normal voice to talk to their child about mundane things such as describing what is going to happen next with them (e.g., dress them, take them home, etc.).

Parent behaviours that may increase the child's distress include threatening, bribing, shaming, or manipulating the child. If you encounter a parent using these behaviours during an appointment, the most helpful response is to offer empathy to the parent, state a neutral fact or principle and offer hope (e.g., "This must be frustrating for you. Immunizations are important, but are not emergencies. I think we can work this out.").

The situation in which a child is being forcibly restrained in order to deliver an immunization presents an ethical dilemma to the immunization provider.

Immunization providers practice under the guidance of various professional codes of ethics. An element common to these codes of ethics is the provision of safe, compassionate, competent and ethical care. It is not ethical or compassionate, and could at times be unsafe, to force an individual to receive an immunization.

In situations where the immunization provider assesses the child to be extremely distressed and the immunization provider is uncomfortable with the behaviour of the parents towards the child (i.e., the parent is threatening, blaming, or shaming the child), it is the responsibility of the immunization provider to stop the immunization, re-evaluate, and adjust the plan.

This may include:

- assessing the techniques that have been used to this point and determining if any additional/different techniques may be more effective;
- deferring the immunization temporarily;
- making a plan with the parent regarding how/when they will return with the child;
- considering with the parent the option of having another health care provider do the immunizations in a different setting.

If the parent resists the above suggestions and insists upon having the child immunized that day, explain that as a health care provider you are bound by a code of ethics that prohibits you from providing care under these circumstances.

In a setting where a child is being immunized without a parent present (e.g., school) and the child is extremely distressed, it is the immunization provider's responsibility to assess whether the immunization can be safely and ethically administered. If the immunization is to be deferred, the provider should contact the parent and discuss a plan for immunization with the parent present.

2.3 Structure the Environment

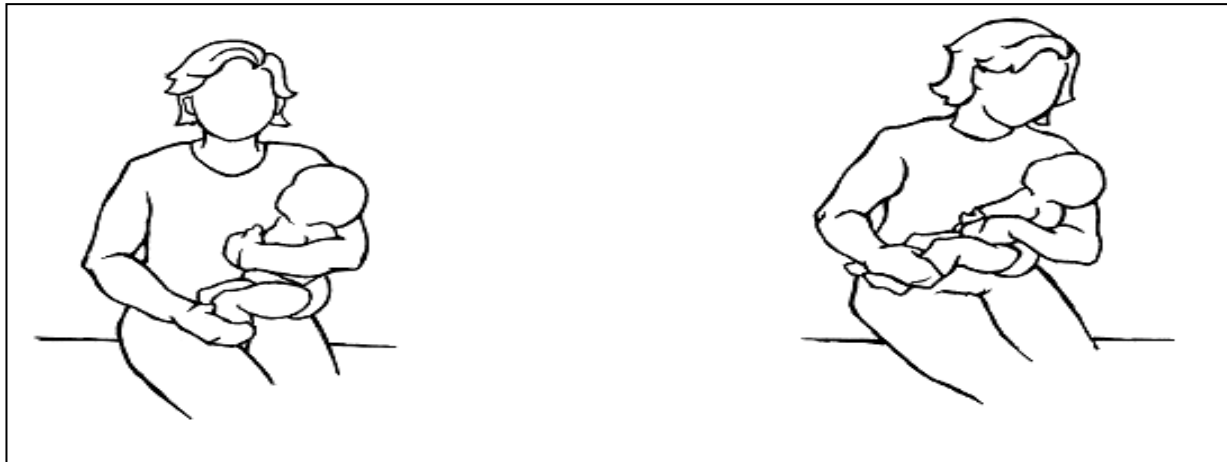
It is the immunization provider's responsibility to establish an environment that fosters trust and mutual respect.

If a parent presents with more than one child, immunize the most anxious one first (usually the eldest). The needle is the focus of the child's fear and watching while someone else is immunized may increase fear and anxiety.

Provide privacy and prepare the immunization out of sight of the child. If the child asks to see the needle, explain you will show it *after* the procedure.

Have parents hold the child in a position that ensures the immunization can be administered without undue risk of needle stick injury to the child or care provider. Restraint should be provided with the goal of assisting the child to remain as still as possible for the procedure, not to overpower the child. Do not restrain the child before you are ready to administer the vaccine. The longer the child is restrained the greater the loss of personal control and hence increased anxiety.

Examples of comforting restraint positioning for injection in the vastus lateralis:



Examples of comforting restraint positioning for injection in the deltoid:



Manage the time and set limits. If the child cannot calm him or herself, or cannot be safely and comfortably restrained, acknowledge their effort and offer a rest period. If there is no other alternative, reschedule the immunization.

The age and developmental stage of the child are important considerations when assessing the immunization environment and the appropriate use of “comforting restraint”. Toddlers are likely to react negatively to being held still but will need to be comfortably restrained by the parent. The preschool or school age child may exhibit signs of extreme distress and verbally express a fear of needles. A discussion of the strategies that will be used to reduce pain during the immunization (see [Section 3. Pharmacologic, Physical and Psychological Strategies](#)) is an important step for anxious children, but children this age may still need assistance to remain still. Encourage parents to use positions of “comforting restraint”.

3. Pharmacologic, Physical and Psychological Strategies

Introduction:

In addition to the psychosocial strategies described in [Section 2. Psychosocial Considerations and Strategies](#), research has shown that there are additional effective pharmacologic, physical and psychological strategies available for use during the immunization procedure. Combining single strategies or using combined strategies (e.g., breastfeeding) has been shown to improve pain relief.

[Section 4. Quick Reference Guide](#) lists strategies most applicable to different age groups of children. The most effective strategies for infants are (in order of effectiveness): breastfeeding or sucrose solution, topical anesthetics, and distraction. The most effective strategies for older children (in order of effectiveness) are topical anesthetics and distraction.

Table 1 outlines the effect sizes (a measure of intervention effectiveness) for these interventions. To determine the effect size of an intervention, multiple studies are reviewed which often use different approaches to delivery of the intervention. To allow comparison between studies, which, for example, may have used different scales (i.e., 1-10 ranking scale or 1-5); the effect sizes are converted to the Standard Mean Deviation (SMD): the difference of the means of the treatments divided by the pooled standard deviation. The SMD is expressed as a negative (-) as the result being measured is a *reduction* in immunization injection pain.

Table 1: Effect of Pharmacologic or Psychological Interventions on Child Immunization Injection Pain (all ages)

Intervention	Effect Size	SMD (95%CI; P value)
Breastfeeding	Large	-2.03 (-2.26 to -1.80; $P<0.001$)
Sucrose Solution	Moderate	-0.56 (-0.72 to -0.40; $P<0.001$)
Combined Interventions	Moderate	-0.52 (-0.73 to -0.30; $P=0.001$)
Topical Local Anesthetic	Moderate	-0.43 (-0.60 to -0.26; $P=0.001$)
Nurse-led Distraction	Moderate	-0.40 (-0.68 to -0.12; $P=0.005$)
Child-directed Distraction	Small	-0.28 (-0.54 to -0.03; $P=0.03$)

As can be seen in Table 1, the most effective *single* component intervention is the use of sucrose solution, followed by the use of topical anesthetic. These results have also been the most consistently reported in

pain literature. Breastfeeding and combined interventions are highly effective *multi-component* interventions.

3.1 Pharmacologic Strategies for Use in Infancy

3.1.1 Breastfeeding

Encourage breastfeeding mothers to breastfeed their infants before, during, and after the immunization. Ensure an adequate latch has been achieved before proceeding with the immunization.

Research indicates that breastfeeding during immunization may reduce pain and distress through the combined effect of:

- Presence of a comforting person
- Diversion of attention (sucking and distraction)
- Physical sensation of skin-to-skin contact with mother
- Sweet taste of breast milk and other substances in the milk [e.g., tryptophan (a precursor of melatonin) which has been reported to increase the concentration of β -endorphins, thereby producing analgesia and relaxation].

Offering breast milk or formula via a bottle has not been shown to be equivalent to breastfeeding and should not be considered a substitute for breastfeeding as a method of reducing pain during immunization. Expressed breast milk has not been found to consistently reduce pain in neonates and its effectiveness during immunization injection has not been evaluated. That is, there is no reason to say it wouldn't work, but there are no studies to indicate it does work.

Any theoretical concern that breastfeeding during immunization may cause the infant to associate breastfeeding with pain has not been demonstrated in research. Given that vaccine injections are not common, breastfeeding would not be a reliable cue for the infant of an upcoming painful procedure.

3.1.2 Oral Sucrose Solution

For infants up to and including 12 months of age who cannot be breastfed during immunizations, and who are not receiving oral rotavirus vaccine (ROTARIX®), it is suggested that clinicians discuss with parents the option of administering a sucrose solution 1 to 2 minutes before the immunization. The use of a sucrose solution to prevent pain during minor medical procedures has been endorsed by the Canadian Pediatric Society and the American Pediatric Society. It is suggested that immunizers provide information about the effectiveness of oral sucrose to parents and discuss with parents options for sucrose provision.

There is abundant evidence supporting the effectiveness of sucrose in reducing infant pain. By activating the sweet taste receptors, a sucrose solution is believed to stimulate the release of endogenous opioids and act as a distraction.

The analgesic effect of a sucrose solution has been demonstrated to last for up to 10 minutes following its administration. Due to the duration of its effect, it is expected to mitigate immunization injection pain when multiple injections are administered.

The analgesic effect may be enhanced by having the infant suck on a pacifier following administration of the sucrose solution. If the infant routinely uses a pacifier, encourage the parent to offer the pacifier to the infant after administration of the sucrose solution.

If the use of sucrose is a standard practice in the specific workplace and will be administered by the immunization provider, obtain consent before proceeding. Document the parental consent and the administration of the sucrose solution in the infant's record.

3.1.2.1 Options for the provision of oral sucrose solution

Though the impact of ROTARIX® on immunization pain has not been studied directly, it contains sucrose in amounts known to provide analgesic benefits, and can be used in the same manner as an oral sucrose solution (given 1 to 2 minutes prior to injections) where indicated in the immunization schedule. If ROTARIX® is not indicated at the infant immunization visit, there are a number of options available to providers and parents for providing oral sucrose solutions.

It is a Health Authority and individual provider decision whether pre-packaged sucrose solution is available at the clinic (See [Table 2: Considerations for Use of Oral Sucrose](#)). If pre-packaged oral sucrose will not be made available, parents may be advised regarding the possibility of mixing their own oral sucrose solution and bringing it with them to the clinic. There are several options available to providers who wish to provide information about oral sucrose and/or pre-packaged oral sucrose to infants. Health Authorities and individual providers may review the following options and select as appropriate for their immunization setting. Table 2 outlines some of the considerations specific to each option.

Advise parents who plan to mix their own sucrose solution that the recommended dose is 2 mL of 24% strength (weight/volume) which is equivalent to 1 teaspoon of sugar dissolved in 10 mL (2 teaspoons) of water (only 2 mL of the resulting solution will be administered). Remind them that Health Canada recommends that all water given to infants be sterilized before administration. To ensure water for infants is safe and pathogen-free, advise parent and caregivers to:

- Use cold tap water. Hot tap water may contain more metal contaminants from the pipes such as copper or lead.
- Bring water to a rolling boil.
- Continue to boil for 2 minutes.
- Let cool.

If the parent will be administering the sucrose solution, instruct them to administer it as follows: place a few drops on the infant's tongue, allow them to mouth/suck and swallow the solution, and then repeat the procedure until the recommended dose (i.e., 2 mL) has been administered. If it is assessed that the infant has spit out most of the dose, administer another dose. If the parent administers the oral sucrose solution, consent does not need to be documented in the immunization record, though providers may choose to note that oral sucrose was given for the information of future providers.

The approach of providing parents with the information required to mix and administer oral sucrose solution has been in use in Toronto Public Health since June 2010. Staff from the Toronto Public Health Department indicated that they have not received feedback indicating that parents are using this strategy inappropriately.

Table 2: Considerations for Use of Oral Sucrose

Option	Cost and Directions	Pros	Cons
<p>Advising parents on mixing sucrose to bring to the clinic</p>	<ul style="list-style-type: none"> • Free to very low cost <p>Directions for parents:</p> <ul style="list-style-type: none"> – mix 1 teaspoon of sugar with 10 mL (2 teaspoons) of sterile water – 2 mL of the resulting solution will be administered 	<ul style="list-style-type: none"> • Free to very low cost • Parents can mix this prior to coming to appointment and can administer it to their child 	<ul style="list-style-type: none"> • Potentially non-standardized concentration, quantity and quality of sucrose solution • Potential contamination due to non-medical grade products • Initially time consuming to educate parents about this strategy
<p>Providing Ora-sweet® at the clinic^A</p> <p>Contact: Amerisource Bergen Canada 604-279-2520, use HA account # to place order</p>	<ul style="list-style-type: none"> • \$27/bottle • After dilution to 24%, \$27/1226 mL = \$0.04/2 mL dose (+ cost of dropper and medicine cup) <p>Directions for staff:</p> <ul style="list-style-type: none"> – mix 1.6 mL of sterile water per 1 mL of Ora-sweet® to achieve a 24% concentration 	<ul style="list-style-type: none"> • Ready to mix • Medical grade product • Safely preserved • Low cost • 60 day expiry after bottle has been opened • 24 hour expiry once mixed with sterile water 	<ul style="list-style-type: none"> • Immunization provider time required to mix product • Requires other tools to prepare and deliver (clean medicine cup and dropper/syringe)
<p>Providing Toot-sweet™ at the clinic^A</p> <p>Contact: Equinox Specialty Products Inc. 1-888-808-8695</p>	<ul style="list-style-type: none"> • \$0.90/dose • 24% sucrose solution • 2 mL/dose 	<ul style="list-style-type: none"> • Pre-mixed ready to use • Standardized concentration, quantity and quality • Long shelf life – up to 2 years • No additional cost of materials or staff time 	<ul style="list-style-type: none"> • Higher cost than other options

^A Ora-sweet® and Toot-sweet™ are not available commercially for individual purchase by parents and must be purchased in bulk by the Health Authority through the contacts listed above.

3.1.2.2 Potential issues and contraindications related to the provision of a sucrose solution

A sucrose solution is specifically indicated as an analgesic for the management of acutely painful medical interventions. It is considered to be a medication that prevents pain only when given *prior* to a painful procedure. *Discuss with parents that sucrose solutions are appropriate for acute procedural pain only, and would not be effective or appropriate for use at home as a comfort measure for their infant.*

The use of a sucrose solution as an analgesic does not conflict with the World Health Organization/UNICEF definition of exclusive breastfeeding (i.e., “giving a baby no other food or drink, including no water, in addition to breastfeeding (except medicines and vitamins or mineral drops; expressed breast milk is also permitted”). Reference: World Health Organization (1993). [Breastfeeding Counselling: A Training Course, Trainer’s Guide](#).

There is no evidence to support the theoretical concern that the use of a sucrose solution to prevent pain during minor procedures contributes to childhood obesity, dental caries, or parental misuse of the solution. There is proof that not managing pain causes hypersensitivity to pain. This hypersensitivity may lead to vaccine non-compliance, needle fear, and phobia.

To place the amount of sucrose babies are exposed to with oral sucrose solutions in perspective, there are 480 mg of sucrose in 2 mL of a 24% sucrose solution. To compare with the products listed below, this equates to 1200 mg of sucrose in 5 mL of a 24% sucrose solution. This is considerably less than the amount of sucrose ingested by infants when given several commonly used antibiotics, oral vaccines or oral analgesics. See the following examples:

- Advil Pediatric drops 200 mg/5 mL (Dye Free, Grape and Fruit Flavour) made by Pfizer: contains 3000 mg of sucrose/sorbitol per 5 mL
- Apo-amoxicillin 125 mg/5 mL made by Apotex: contains 2300-2400 mg of sucrose/5 mL
- Teva-amoxicillin 125 mg/5 mL made by Teva: contains 3074.69 mg total carbohydrates (= sucrose) per 5 mL
- Teva-cephalexin 125 mg/5 mL made by Teva: contains 2969.75 mg of sucrose per 5 mL
- Oral rotavirus vaccine (ROTARIX®): contains 1073 mg sucrose per 1.5 mL, would contain 3573 mg per 5 mL

The following are *contraindications* to the provision of sucrose solutions:

- Infants with known fructose or sucrose intolerance
- Critically ill infants receiving intravenous analgesia or sedation
- Infants with necrotizing enterocolitis
- Infants with gastric/bowel dysfunction.

The rationale for the above contraindications is as follows:

In infants receiving intravenous analgesia or sedation, a sucrose solution is not indicated as the infant is already receiving analgesia. In addition, intravenous opioid analgesic agents would compete to bind with the same opioid receptor sites as the endogenous opioids produced by the sweet taste of the sucrose solution, rendering the sucrose solution ineffective.

Infants with necrotizing enterocolitis or who have gastric or bowel dysfunction may experience gut trauma relating to the osmolarity of sucrose solutions. This can cause damage and may initiate a pathological

process that could lead to necrotizing enterocolitis in susceptible infants. Necrotizing enterocolitis is almost exclusively a disease process that affects premature or seriously ill infants and is unlikely to affect infants seen in the public health setting.

A large proportion of the research on sucrose and related contraindications comes from the neonatal intensive care settings, where clients are likely to be getting multiple medications and are at risk of necrotizing enterocolitis. These contraindications have been extrapolated to the public health setting, but are much less likely to be relevant to a non-hospitalized infant seen in the clinician's office.

3.2 Other Pharmacologic Strategies

3.2.1 Topical Anaesthetics

Advise parents about the option of using topical anaesthetics prior to immunization.

Topical local anaesthetics act by inhibiting the generation and transmission of pain impulses across nerve endings located in the dermis. They decrease the pain as the needle penetrates the skin and reduce the underlying muscle spasm associated with this pain. Given that there is a cumulative effect when infants or children are exposed to sequential painful stimuli; prevention of the initial painful stimulus (needle puncture through the skin) decreases the overall pain experience. Topical anaesthetics have been well-studied and found to be effective in reducing vaccine injection pain in infants and children.

Topical anaesthetics are safe and effective for infants and children. Examples are:

- EMLA® (eutectic mixture of local anaesthesia – 2.5% lidocaine and 2.5% prilocaine) cream or patch
- Ametop™ gel (4% tetracaine)
- Maxilene 4™ or Maxilene 5™ cream (4% and 5% lidocaine respectively)

Studies have demonstrated that topical local anaesthetics do not interfere with the immune response to several vaccines [i.e., DTaP-IPV-Hib (Pentacel®), hepatitis B (Recombivax®) and MMR]. In light of this body of research, there is no reason to suspect there would be a risk of decreased immune response to other antigens.

Topical local anaesthetics may be more effective in some individuals than others. Factors that may influence effectiveness include the level of anxiety, age, temperament, and genetic variability.

Topical local anaesthetics have been found to cause transient local skin reactions (e.g., pallor and/or erythema). The presence of a transient local skin reaction does not affect the effectiveness of the topical local anaesthetic. Discuss this possibility to assist parents in distinguishing between this reaction and a local reaction to the vaccine.

Research has shown that parents are able to apply topical local anaesthetics correctly when trained to do so and would pay the additional cost of the agents to reduce their infant/child's pain.

Advise parents to apply the topical anaesthetic according to the manufacturer's instructions found on the product label or the product insert. After application, parents should use a pen to trace the edges of the product. This will let the immunizer see where the product was applied.

The inappropriate use of topical local anaesthetics (e.g., applying more than the recommended amount, leaving the product in place for longer than the recommended time, or applying the product to non-intact skin) can lead to serious side effects such as methemoglobinemia, seizures, irregular heartbeat and difficulty breathing. Very rarely, these reactions have occurred even after correct application of these products.

Neonates are at increased risk of methemoglobinemia as a result of exposure to prilocaine. Methemoglobinemia is a clinical condition in which more than 1% of hemoglobin in blood has been oxidized to the ferric form. The principal sign is cyanosis because the oxidized hemoglobin is incapable of transporting oxygen.

This risk is very small; a systematic review of 11 studies demonstrated that the risk of methemoglobinemia is low after single-dose application of EMLA®. In full term neonates, single doses ranging from 0.5 to 2.0 grams applied for 30 to 180 minutes have not been reported to cause methemoglobinemia (Taddio et al., 1998, Weise et al., 2005). However, due to reports of rare serious adverse events related to the use of topical local anaesthetics, Health Canada advises that children be monitored closely following their application. For more information, refer to <http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php>.

Whenever a topical anaesthetic is applied, it must be removed before proceeding with the immunization.

Table 3: Considerations for Use of Topical Anaesthetics

Topical Local Anaesthetic	Considerations
<p>EMLA® (2.5% lidocaine and 2.5% prilocaine) cream or patch</p>	<ul style="list-style-type: none"> • Should be applied at least 60 minutes before immunization. Local analgesia is achieved after a 60 minute application under an occlusive dressing. • EMLA® cream should be covered with an occlusive dressing. • Depth of analgesia is 3 mm after 1 hour of application. • Local analgesia persists for at least 2 hours after removal of cream. • Neonates are at increased risk of methemoglobinemia as a result of exposure to prilocaine. Methemoglobinemia is a clinical condition in which more than 1% of hemoglobin in blood has been oxidized to the ferric form. The principal sign is cyanosis because the oxidized hemoglobin is incapable of transporting oxygen. Studies have found that the risk of methemoglobinemia is low in infants exposed to recommended dosages of prilocaine. Children should be monitored during product use. • The safety of EMLA® during pregnancy has not been established. • Contraindicated for: <ul style="list-style-type: none"> ○ Individuals who are sensitive to local anaesthetics of the amide type or to any ingredients of EMLA® ○ Individuals with congenital or idiopathic methemoglobinemia ○ Infants ≤ 12 months of age who require treatment with methemoglobin-inducing agents (e.g., sulphonamides) ○ Preterm infants (i.e., < 37 weeks gestational age) ○ Care should be used when applying EMLA® to individuals with atopic dermatitis (eczema) or other skin conditions. A more rapid and greater absorption through the skin may occur. A shorter application time should be used.
<p>Ametop™ gel (4% tetracaine)</p>	<ul style="list-style-type: none"> • Should be applied 30-45 minutes before immunization. • Local analgesia persists for 4-6 hours. • Contraindicated for: <ul style="list-style-type: none"> ○ Infants < 1 month of age and premature infants ○ Individuals who are allergic to local anaesthetics of the ester type • Do not use on broken skin, mucous membranes, eyes, or ears.
<p>Maxilene cream (available in 4% and 5% lidocaine)</p>	<ul style="list-style-type: none"> • Should be applied 30-60 minutes before immunization. • It is recommended that the cream be covered with an occlusive substance (e.g., clear, plastic wrap) to prevent children from ingesting it orally. • Consult a physician regarding use in children < 2 years of age.

3.3 Physical Strategies and Injection Procedure

3.3.1 Seated Position

Advise parents to hold their infant on their lap during immunization. Infants should be held in a seated or semi-seated position that is comfortable for the infant and the parent and ensures the limb to be immunized is in an appropriate position for the immunization provider. Do not place infants and children in a supine position during immunization. To view examples of comforting restraint, refer to [Appendix B – Administration of Biological Products, Injection Sites, Needle Size and Positioning](#).

Children and adults should be sitting up during immunization (unless the client has indicated a history of fainting during or following immunization, in which case they should be supine).

Studies have demonstrated that compared to a supine position, parental holding (for infants) and sitting up (for all other ages) are associated with reduced pain during immunization. This may be because parental holding and sitting up are associated with a greater sense of personal control and reduced anxiety which in turn reduces the perception of pain.

Advise the parent to not restrain the child until you are ready to administer the vaccine. The goal of restraint is to assist the child to remain as still as possible for the procedure, rather than to overpower the child.

3.3.2 Rapid Injection without Aspiration

Perform injections using rapid injection without aspiration technique.

Aspiration is not recommended as there are no data to document its necessity prior to subcutaneous or intramuscular injection of biological products. There are no large blood vessels at the recommended injection sites. Not aspirating before injection has been demonstrated to reduce pain at the injection site because there is less contact time between the needle and tissue and less lateral movement of the needle. For more information, refer to [Appendix B - Administration of Biological Products, 9.3 Intramuscular \(IM\) Injection Technique](#).

3.3.3 Injecting Most Painful Vaccine Last

Inject the most painful vaccine last when administering multiple vaccine injections sequentially (e.g., give INFANRIX hexa® and NEISVAC-C® before PREVNAR® 13; when PREVNAR® 13 and MMR II® are given at the same visit, give MMR II® last, if it is in inventory).

Studies have indicated that when 2 vaccines were injected sequentially, injection of the least painful vaccine first not only reduced pain from the first injection, but also reduced pain from both injections. This finding is consistent with other pain research which has found a relationship between increased pain perception and repeated painful stimulation.

3.3.4 Rubbing/Stroking the Skin Near the Injection Site

In children ≥ 4 years of age, rub/stroke the skin near the injection site with moderate intensity prior to and during immunizations. Alternatively, coach the parent to do so. Tailor the intensity of the rubbing to the individual child's reaction. Ensure the rubbing/stroking action does not contaminate the injection site once it has been cleansed with alcohol.

In adults, pressure applied to the injection site prior to injection has been demonstrated to reduce pain during injections.

This strategy has only been studied in children ≥ 4 years of age and is not recommended for use in children less than 4 years of age due to the absence of data, the potential this intervention might focus the child's attention on the injection site, or that the procedure or excessive rubbing might cause discomfort.

It is believed that touch may decrease pain perception by stimulating large diameter (touch) neurons that compete with small diameter (pain) neurons activated during painful procedures, resulting in reduced "pain" input transmission to the brain. This is also referred to as the "Gate Control Theory of Pain".

It is important to distinguish between rubbing the area near the injection site prior to and during immunization from rubbing/massaging the site after injection. Rubbing the injection site after immunization is not recommended.

3.4 Psychological Strategies

3.4.1 Distraction

Distraction is the only strategy that can be used with all age groups during immunization (provided an age-appropriate distraction strategy is utilized). There are many theories about why distraction is effective (e.g., the gate-control theory that suggests the parts of the brain that process painful stimuli are less active when the person is distracted; and the limited-attention capacity theory which suggests that when some attention is directed to a distracting task, there are less resources available within the brain to pay attention to the pain).

Studies have demonstrated that distraction is most effective when it is interactive and when the child is actively engaged in the distraction strategy.

3.4.1.1 Immunization provider-led distraction

Use immunization provider-led distraction techniques with individuals of all ages during immunizations. Involve parents and children in selecting the best distraction strategy.

Research has shown that distraction led by the immunization provider effectively reduces pain and distress during immunization.

Choose an age-appropriate distraction strategy. Examples include:

- **Infant** – toys, bubbles, singing, directing the infant’s attention to something in the environment that may be of interest to them
- **Toddler** – toys, bubbles, pinwheels, pop-up books, singing, party-blowers, kaleidoscopes, directing the toddler’s attention to something in the environment that may be of interest to them, non-procedural talk
- **School-age** – toys, stories, videos, books, joking, music, counting, non-procedural talk, directing the child’s attention to something in the environment
- **Adolescents** – games, videos, joking, music (personal headphones), non-procedural talk.

Capture the child’s attention before the immunization and keep the child’s attention on the distraction strategy during the immunization. Provide verbal and physical (i.e., pointing) reminders for the child to assist them with continuing to pay attention to the distraction strategy. Re-direct the child’s attention back to the distraction strategy if their attention wanders to the immunization.

Maintain a positive attitude, stay focused on the child, and interact with the child throughout. When engaging in non-procedural talk with the child, attempt to discuss something of interest and enjoyment for the child (e.g., favorite toy, funny thing their pet did, favorite superhero). Acknowledge the child’s effort in engaging in distraction behaviours.

3.4.1.2 Child-led distraction

Use child-led distraction techniques in children ≥ 3 years of age.

Many children who are ≥ 3 years of age are developmentally capable of engaging in the distraction strategy without adult intervention. For children who are not developmentally able to engage in and stay involved in the child-led distraction, use clinician-led distraction strategies.

Child-led distraction techniques involve the use of distraction strategies by the child without the aid or direction of an adult. Examples include: cartoon video, handheld game, or stories/music played on headphones.

Encourage parents and children to come prepared with their own distraction tool to the immunization appointment.

3.4.1.3 Slow, deep breathing/blowing

Have children ≥ 3 years of age engage in slow, deep breathing/blowing out during immunizations.

Simple breathing exercises are effective at significantly reducing immunization pain and distress. Examples include:

- Advise children to take a deep breath at the time of the injection
- Have the child blow a party blower, pinwheel, or bubbles
- Ask the child to “show me how you blow out candles on a birthday cake”
- Instruct children to blow the hurt/pain away.

3.4.1.3 Parent-led distraction

Engage parents in selecting a distraction strategy for their child.

Distraction led by a parent has been found to be less effective than distraction led by the immunization provider or the child. This may be because the parent finds it difficult to provide distraction when he/she is also distressed. Studies have shown that parents often know what will interest their child and parental anxiety may be decreased if they have an active role during the immunization experience.

4. Quick Reference Guide

Age of Child	Pain Management Strategies
2 months to ≤ 12 months	<ul style="list-style-type: none"> • Breastfeeding • Oral sucrose solution • Topical anaesthetics • Clinician-led distraction (e.g., toys, bubbles, singing, re-directing infant's attention) • Seated upright in adult's lap using comforting restraint • Rapid injection of biological without aspiration • Inject most painful vaccine last (e.g., MMR II® or PREVNAR® 13)
> 12 months to ≤ 2 years	<ul style="list-style-type: none"> • Breastfeeding • Topical anaesthetics • Clinician-led distraction (e.g., toys, bubbles, singing, books, kaleidoscopes, party blowers, re-direct child's attention) • Seated upright in adult's lap using comforting restraint • Rapid injection of biological without aspiration • Inject most painful vaccine last (e.g., MMR II® or PREVNAR® 13) • Do not tell children "it won't hurt"
3 to 6 years	<ul style="list-style-type: none"> • Topical anaesthetics • Clinician-led or parent-led distraction (e.g., toys, books, counting, re-directing child's attention) • Child-led distraction (e.g., handheld video games, music with personal headphones) • Slow, deep breathing and/or blowing (e.g., pinwheels, bubbles) • Seated upright in adults lap using comforting restraint • Rapid injection of biological without aspiration • Inject most painful vaccine last (e.g., MMR II® or PREVNAR® 13) • If child is ≥ 4 years, rubbing or stroking at immunization site before injection • Do not tell children "it won't hurt"
School-age	<ul style="list-style-type: none"> • Topical anaesthetics • Child-led distraction (e.g., toys, stories, videos, music) • Clinician-led or parent-led distraction (e.g., non-procedural talk, re-directing child's attention) • Slow, deep breathing • Comfortable seated position • Rapid injection of biological without aspiration • Inject most painful vaccine last • Rubbing or stroking immunization site before injection • Do not tell children "it won't hurt"

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