Date: 1/16/13

**Title:** Reducing Pain for Children and Adolescents Receiving Injections

**Clinical Question:**

- **P** (Population/Problem): In pediatric patients receiving injections,
- **I** (Intervention): do pharmacological interventions (including topical anesthetic agents), psychological, and physical interventions
- **C** (Comparison): versus no intervention
- **O** (Outcome): reduce pain
- **T** (Time): during injections?

*Definitions for terms marked with * may be found in the Supporting Information section.*

**Target Population for the Recommendation:**

Children ranging from infancy to eighteen years of age, receiving an injection

**Recommendations:** (See Dimensions for Judging the Strength of the Recommendation)

1. It is strongly recommended that age-appropriate interventions with strong evidence, be used to reduce pain during injections* (Chambers, Taddio, Uman, & McCurtry, 2009 [1a]; Shah, Taddio, & Rieder, 2009 [1a]; Taddio et al., 2009 [1a]; Uman, Chambers, McGrath, & Kisely, 2010 [1a]; Kassab, Roydhouse, Fowler, Foureur, & Epi, 2012 [1b]; Harrington et al., 2012 [2a]). See cells marked “Strongly” in Table 1. See Table 2 for intervention-specific citations.
   
   **Note:** Combining an intervention with distraction is more effective than a single intervention (Uman, Chambers, McGrath, & Kisely, 2010 [1a]).

2. It is recommended that, when strongly recommended interventions are not sufficient or feasible to reduce pain during injections, additional age-appropriate consensus-based interventions are used (Local Consensus [5]). See cells marked “Local Consensus” in Table 1. See Table 2 for intervention-specific citations.
   
   **Note:** Combining an intervention with distraction is more effective than a single intervention (Uman, Chambers, McGrath, & Kisely, 2010 [1a]).

### Table 1: Recommendations for Interventions by Developmental Level to Reduce Pain during Injections

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Infants</th>
<th>Toddlers</th>
<th>Preschool-age children</th>
<th>School-age children</th>
<th>Adolescents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose solution*</td>
<td>Strongly</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Breastfeeding</td>
<td>Strongly</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Holding the infant</td>
<td>Strongly</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Distraction*, age-appropriate</td>
<td>Strongly</td>
<td>Strongly</td>
<td>Strongly</td>
<td>Strongly</td>
<td>Strongly</td>
</tr>
<tr>
<td>Topical agent, containing lidocaine/prilocaine*</td>
<td>Strongly</td>
<td>Strongly</td>
<td>Strongly</td>
<td>Strongly</td>
<td>Strongly</td>
</tr>
<tr>
<td>Sequential injection*</td>
<td>Strongly</td>
<td>Strongly</td>
<td>Strongly</td>
<td>Strongly</td>
<td>Strongly</td>
</tr>
<tr>
<td>Rapid combined injection*</td>
<td>Strongly</td>
<td>Strongly</td>
<td>Strongly</td>
<td>Strongly</td>
<td>Strongly</td>
</tr>
<tr>
<td>Preparation*, developmentally appropriate</td>
<td>--</td>
<td>Local consensus</td>
<td>Strongly</td>
<td>Local consensus</td>
<td>Local consensus</td>
</tr>
<tr>
<td>Positioning</td>
<td>--</td>
<td>Local consensus</td>
<td>Strongly</td>
<td>Local consensus</td>
<td>Local consensus</td>
</tr>
<tr>
<td>Breathing exercises**†</td>
<td>--</td>
<td>--</td>
<td>Strongly</td>
<td>Strongly</td>
<td>Local consensus</td>
</tr>
<tr>
<td>Hypnosis*</td>
<td>--</td>
<td>--</td>
<td>Strongly</td>
<td>Strongly</td>
<td>Strongly</td>
</tr>
</tbody>
</table>

*see definitions

†including blowing bubbles, using party blowers, deep breathing, and breathing exercises
Table 2: Citations for Interventions by Developmental Level to Reduce Pain during Injections

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Infants</th>
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<th>Preschool-age children</th>
<th>School-age children</th>
<th>Adolescents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breastfeeding</td>
<td>Shah, Taddio, &amp; Rieder, 2009 [1a]</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Holding the infant</td>
<td>Harrington, Logan, Harwell, Gardner, Swingle, McGuire, &amp; Santos, 2012 [2a]; Taddio et al., 2009 [1a]</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Hypnosis</td>
<td>--</td>
<td>--</td>
<td>Uman, Chambers, McGrath, &amp; Kisely, 2010 [1a]</td>
<td>Uman, Chambers, McGrath, &amp; Kisely, 2010 [1a]</td>
<td>Uman, Chambers, McGrath, &amp; Kisely, 2010 [1a]</td>
</tr>
</tbody>
</table>

*see definitions
†including blowing bubbles, using party blowers, deep breathing, and breathing exercises
Discussion/Synthesis of Evidence related to the recommendations:

Our evidence consisted of five systematic reviews and a clinical guideline which answered our PICO question. Articles addressed psychosocial intervention, pharmacological and physical injection techniques. It has been found that developmentally appropriate preparation, breastfeeding in infants, bubble blowing/deep breathing, age appropriate distraction, hypnosis, sucrose solution for infants, lidocaine/prilocaine, rapid combined injection technique, and sequential injection are effective techniques in reducing pain during injections (Chambers et al., 2009 [1a]; Kassab, Roydhouse, Fowler, Foureur, & Epi, 2012 [1b]; Shah, Taddio, & Rieder, 2009 [1a]; Taddio et al., 2009 [1a]; Uman, Chambers, McGrath, & Kisely, 2010[1a]; Taddio et al, 2010 [5a]).

For the interventions in which evidence was not available, local consensus was obtained. These included: developmentally appropriate preparation for toddlers and adolescents, positioning for toddlers, school aged children, and adolescents, and deep breathing for adolescents (Local Consensus [5]).

In reviewing the evidence for infants, two systematic reviews and one randomized control trial supported the use of sucrose solution as an effective method to reduce pain during injections for infants (Harrington et al., [2a]; Kassab et al., [1b]; Shah, Taddio, & Rieder, 2009 [1a]). In one systematic review and meta-analysis, the use of sucrose solution demonstrated a moderate effect size (-0.56) for infants who received an injection (Shah, Taddio, & Rieder, 2009 [1a]). This same systematic review supported the use of breastfeeding for appropriate infants (Shah, Taddio & Rieder, 2009 [1a]) showing a strong effect size (-2.03) for reducing pain in infants receiving injections. Finally, holding an infant was also supported in the literature by a systematic review as well as a randomized control trial (Taddio et al., 2009 [1a]; Harrington et al., 2012 [2a]). Holding demonstrated a small effect size (-0.22) on the duration of crying during injections (Taddio et al., 2009 [1a]).

For children of all ages, distraction was effective in reducing pain during injections (Chambers et al., 2009 [1a]; 2009 [1a]; Uman et al., 2010 [1a]). Child (-0.28) in self-reported pain, parent (-0.19 on observer rated pain) (-0.50 with observer rated distress) (-0.12 with parent rated distress) (-0.25 with nurse rated distress), or nurse-led (-0.40) distraction had small effect sizes (Chambers et al., 2009 [1a]). These studies used scales that were both observer reported as well as self-reported scales. Uman (2010, [1a]) determined that on measures of self-reported pain during injections there was a small effect size (-0.24) for distraction. For children of all ages, topical agents reduced pain with a small effect size (0.43) (Shah, Taddio & Rieder, 2009 [1a]). This was determined using Modified Behavioral Pain Scales (Shah, Taddio & Rieder, 2009 [1a]). Two systematic reviews supported the use of developmentally appropriate preparation for school age and preschoolers to reduce pain during injections (Shah, Taddio, & Rieder, 2009 [1a]; Taddio et al., 2009 [1a]; Uman et al., 2010[1a]). For pre-school and school age children receiving developmentally appropriate preparation, Uman found a moderate effect size (-0.77) for observer reported pain scores (Uman et al., 2010[1a]). In pre-school, school age children and adolescents, hypnosis was found to be an effective technique to reduce pain during injections (Uman et al., 2010 [1a]). There was a strong effect size for self-reported pain (-1.77), self-reported distress (-2.20) and behavioral distress (-1.07) in children who participated in hypnosis to reduce pain during injections. There were three systematic reviews that supported the use of breathing to reduce pain during injections for pre-school and school age children (Uman et al., 2010 [1a]; Chambers et al., 2009 [1a]). For pre-school and school age children, breathing was another effective strategy at reducing pain during injections. There was a small effect size (-0.43) found for breathing to reduce pain (Chambers et al., 2009). There were small effect sizes for both behavioral distress and self-reported pain (-0.32, -0.38 respectively) when breathing was used during injections (Uman et al., 2010 [1a]).

Sequential and rapid injection techniques were determined to reduce pain in children of all ages (Taddio et al., 2009 [1a]). There were statistically significant differences in children receiving rapid injections without aspiration on measures of observer modified behavior pain scales, cry duration, parent visual analogue scale difference, and physician visual analogue scale difference. To prevent one infant from crying the number needed to treat was 2.5. It was found that when administering the DPT (diphtheria-polio-tetanus), diphtheria-polio-tetanus -acellular pertussis-Haemophilus influenza type b (DPTaP-Hib) was administered first; the measures of observer modified behavior pain scales, cry duration, parent visual analogue scales were significantly different. To prevent one infant from crying, the number needed to treat was 3.6 in sequential injections (Taddio et al., 2009 [1a]).
Reference List:  (Evidence Level in [ ]; See Table of Evidence Levels)


Local consensus formed during project development. [5].


IMPLEMENTATION

Applicability Issues:

Breastfeeding in infants, developmentally supportive positioning, and injection technique (the use of sequential injection and rapid combined injection) do not require additional funds, resources, or staffing. The use of developmentally appropriate preparation and distraction, deep breathing, and bubble blowing/party blowers can be taught to patients and caregivers. These interventions fall within the scope of practice of a child life specialist. When involved, they can give recommendations to patients and caregivers on which techniques are most appropriate. At that time, the child and family can choose which of these options will best meet their needs. The additional time needed to involve these techniques or a Child Life Specialist may be counterbalanced by more cooperative patients, shorter length of time spent giving an injections, as well as increase family satisfaction. The use of sucrose and lidocaine/prilocaine poses a monetary cost. However, evidence shows the use of these products reduces pain for infants, children, and adolescents (Shah, Taddio, & Rieder, 2009 [1a]; Kassab, Roydhouse, Fowler, Foureur, & Epi, 2012 [1b]; Harrington, Logan, Harwell, Gardner, Swingle, McGuire, & Santos, 2012 [2a]). Use of these products may increase compliance with injections, specifically vaccinations, in turn offsetting costs of pharmacological agents and increasing the overall health and wellbeing of children.

Relevant CCHMC Tools for Implementation:

Cincinnati Children’s Hospital Medical Center, CCHMC Pharmacy & Therapeutics Policy: Use of Sucrose Water in Infants. Policy Number III-115, Effective Date 2/7/2012
Outcome or Process Measures:
After implementing the aforementioned recommendations, outcomes could be measured by comparing the percentage of patients who receive injections while receiving one or more of the psychosocial interventions, pharmacological, and physical injection techniques, pre and post implementation. This would indicate how often each of the interventions was utilized. It would be essential to obtain feedback from patients and staff regarding success of the varying interventions in their clinical setting. It would also be important to evaluate the number of staff present for a patient’s injection. Another helpful piece of information would be to measure the time it takes for vaccination appointments when implementing the recommendations, in order to address productivity.

Background/Purpose of BEST Development:
Child Life Specialists present for immunizations and injections observed high levels of pain, distress, and anxiety. Child Life Specialists noted decreased anxiety and increased cooperation in toddlers, preschoolers, school age children, and adolescents when sitting up for injections, as well as decreased pain, distress, and anxiety with patients receiving topical analgesics with injections. Topical analgesics combined with developmentally appropriate preparation, support and/or distraction appeared to improve outcomes in all age groups. While supporting children and families, Child Life Specialists observed inconsistencies in nursing practice in regards to positioning and care, potentially due to a lack of awareness of best practice techniques. In some situations, when receiving injections, no interventions were offered to patients and families. Caregivers have reported inconsistencies between clinics throughout the medical center. As children grow and develop, they go through a variety of healthcare encounters. As Child Life Specialists, we want to increase patient and family satisfaction and decrease unwarranted variation in care. Through increased satisfaction, there is the potential to keep children healthy through preventative care and improve their self-care.

Definitions:
Breathing Exercises: Focus on deep breathing or breathing from the diaphragm rather than the chest (e.g., using party blowers, blowing bubbles, pretending to inflate or deflate a tire through inhaling/exhaling) (Uman, Chambers, McGrath, & Kisely, 2010 [1a]).

Developmentally Appropriate Preparation: Explaining the steps of the procedures or providing sensory information associated with the procedure, or both. This may include providing instructions about what the child will need to do during the procedure. The intention is to provide information to help the child know what to expect during the procedure (Uman, Chambers, McGrath, & Kisely, 2010 [1a]).

Distraction: Techniques to shift attention away from procedure-related pain to specific counter activities (e.g., counting, listening to music, non-procedure related talk, videotapes, games, interactive books) (Uman, Chambers, McGrath, & Kisely, 2010 [1a]).

Hypnosis: Dissociation from painful experience and distress via hypnotic induction, suggestions, and imagined fantasy; similar to but more involved than imagery (Uman, Chambers, McGrath, & Kisely, 2010 [1a]).
Injection: The act of forcing a liquid into the body by means of a needle and syringe. Injections are designated according to the anatomic site involved; the most common are intra-arterial, intradermal, intramuscular, intravenous, and subcutaneous (Mosby, 2012 [5]).

Rapid combined injection technique: Injection technique utilizing rapid injection without aspiration (Taddio et al., 2010 [1a]).

Sequential Injection: Injecting the least painful vaccine first when 2 vaccines are being administered sequentially during a single office visit (Taddio et al., 2010 [1a]).

Sucrose Solution: An oral solution consisting of a percentage of sucrose which provides quick, non-invasive, non-pharmacologic means to manage pain associated with minor procedures in infants. The percentage of sucrose varies. (CCHMC, 2012 [5]; Harrington et al., 2012 [2a]; Kassab, Roydhouse, Fowler, Foureur, & Epi, 2012 [1b]; Shah, Taddio, & Rieder, 2009 [1a]).

Topical Anesthetic Agent: Surface analgesia produced by application of a topical anesthetic in the form of a solution, gel, or ointment to the skin (Mosby, 2012 [5]).

Search Strategy:
Databases: BMJ, CINAHL, Cochrane Database, ERIC, Nursing Reference Center, Psycho Info, Pubmed
Search Terms: Children, injections, immunization, pain, distress, EMLA, LMX-4, Gebauers Spray and Stretch, Zingo, Paineze, Synera, J-tip, Pediatric, Ice
Limits, Filters, Search Dates: 1992 – January, 2012, Articles in English only

Relevant CCHMC Evidence-Based Documents:
Child Life Support During Medical Procedures Best Evidence Statement (BESt) 120
Subcutaneous Aspiration EBP Project (BESt) 009

Group/Team Members:
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Lauren Kathman, BS, CCLS, Complex Airway & Pediatric Primary Care Center
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Mary Ellen Meier, MSN, RN, CPN, Center for Professional Excellence and Business Integration: Research and Evidence Based Practice: Evidence Based Practice Mentor

Conflicts of Interest were declared for each team member and:
☒ No financial or intellectual conflicts of interest were found.
☒ No external funding was received for development of this BESt.
☐ The following conflicts of interest were disclosed:
Note: Full tables of the **LEGEND evidence evaluation system** are available in separate documents:

- [Table of Evidence Levels of Individual Studies by Domain, Study Design, & Quality](#) *(abbreviated table below)*
- [Grading a Body of Evidence to Answer a Clinical Question](#)
- [Judging the Strength of a Recommendation](#) *(dimensions table below)*

### Table of Evidence Levels *(see note above):*

<table>
<thead>
<tr>
<th>Quality level</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a† or 1b†</td>
<td>Systematic review, meta-analysis, or meta-synthesis of multiple studies</td>
</tr>
<tr>
<td>2a or 2b</td>
<td>Best study design for domain</td>
</tr>
<tr>
<td>3a or 3b</td>
<td>Fair study design for domain</td>
</tr>
<tr>
<td>4a or 4b</td>
<td>Weak study design for domain</td>
</tr>
<tr>
<td>5a or 5b</td>
<td>General review, expert opinion, case report, consensus report, or guideline</td>
</tr>
<tr>
<td>5</td>
<td>Local Consensus</td>
</tr>
</tbody>
</table>

†a = good quality study; b = lesser quality study

### Table of Language and Definitions for Recommendation Strength *(see note above):*

<table>
<thead>
<tr>
<th>Language for Strength</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>It is strongly recommended that...</td>
<td>When the dimensions for judging the strength of the evidence are applied, there is high support that benefits clearly outweigh risks and burdens. (or visa-versa for negative recommendations)</td>
</tr>
<tr>
<td>It is recommended that...</td>
<td>When the dimensions for judging the strength of the evidence are applied, there is moderate support that benefits are closely balanced with risks and burdens.</td>
</tr>
<tr>
<td>There is insufficient evidence and a lack of consensus to make a recommendation...</td>
<td></td>
</tr>
</tbody>
</table>

Given the dimensions below and that more answers to the left of the scales indicate support for a stronger recommendation, the recommendation statement above reflects the strength of the recommendation as judged by the development group. (Note that for negative recommendations, the left/right logic may be reversed for one or more dimensions.)

#### Rationale for judgment and selection of each dimension:

1. **Grade of the Body of Evidence**
   - **High**
   - **Moderate**
   - **Low**

   **Rationale:** Our body of evidence contains five systematic reviews with consistent results (Chambers et al., 2009 [1a]; Kassab, Roydhouse, Fowler, Fourre, & Epi, 2012 [1b]; Shah, Taddio, & Rieder, 2009 [1a]; Taddio et al., 2009 [1a]; Uman, Chambers, McGrath, & Kisely, 2010[1a]).

2. **Safety/Harm (Side Effects and Risks)**
   - **Minimal**
   - **Moderate**
   - **Serious**

   **Rationale:** Gagging and coughing were the minimal side effects noted when using the sucrose solution in infants. Lidocaine-prilocaine had minimal transient local skin reaction. Breastfeeding had no side effects (Shah, Taddio, & Rieder, 2009 [1a]).

3. **Health benefit to patient**
   - **Significant**
   - **Moderate**
   - **Minimal**

   **Rationale:**

4. **Burden on patient to adhere to recommendation**
   - **Low**
   - **Unable to determine**
   - **High**

   **Rationale:** There is a time component related to the effectiveness of lidocaine-prilocaine. Non-invasive interventions, such as distraction, deep breathing, bubble blowing, positioning, and hypnosis are activities that also occur outside of a hospital setting.

5. **Cost-effectiveness to healthcare system**
   - **Cost-effective**
   - **Inconclusive**
   - **Not cost-effective**

   **Rationale:** There are costs associated with lidocaine-prilocaine and sucrose solutions. Decreased number of nursing staff involved with individual patients following facilitation of preparation and coping plan.

6. **Directness of the evidence for this target population**
   - **Directly relates**
   - **Some concern of directness**
   - **Indirectly relates**

   **Rationale:** Systematic reviews were included in this recommendation that include infants through adolescents (Chambers et al., 2009 [1a]; Kassab, Roydhouse, Fowler, Fourre, & Epi, 2012 [1b]; Shah, Taddio, & Rieder, 2009 [1a]; Taddio et al., 2009 [1a]; Uman, Chambers, McGrath, & Kisely, 2010[1a]).

7. **Impact on morbidity/mortality or quality of life**
   - **High**
   - **Medium**
   - **Low**

   **Rationale:** Vaccinations are essential to optimal child health and wellbeing.
Injection Technique Recommendation

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<tr>
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Rationale for judgment and selection of each dimension:

1. Grade of the Body of Evidence
   - Rationale: One systematic review provided consistent results [Taddio et al., 2009 [1a]].
   - High
   - Moderate
   - Low

2. Safety/Harm (Side Effects and Risks)
   - Rationale: No adverse events reported.
   - Minimal
   - Moderate
   - Serious

3. Health benefit to patient
   - Rationale:
   - Significant
   - Moderate
   - Minimal

4. Burden on patient to adhere to recommendation
   - Rationale: These techniques are for the health care provider and patient is not burdened by this recommendation.
   - Low
   - Unable to determine
   - High

5. Cost-effectiveness to healthcare system
   - Rationale: This recommendation refers to technique and the cost for vaccines remains the same.
   - Cost-effective
   - Inconclusive
   - Not cost-effective

6. Directness of the evidence for this target population
   - Rationale: Evidence directly relates to children ages 0-18 yrs [Taddio et al., 2009 [1a]].
   - Directly relates
   - Some concern of directness
   - Indirectly relates

7. Impact on morbidity/mortality or quality of life
   - Rationale: These techniques reduce pain for injections.
   - High
   - Medium
   - Low

Copies of this Best Evidence Statement (BEST) and related tools (if applicable, e.g., screening tools, algorithms, etc.) are available online and may be distributed by any organization for the global purpose of improving child health outcomes.


Examples of approved uses of the BEST include the following:
- Copies may be provided to anyone involved in the organization’s process for developing and implementing evidence based care;
- Hyperlinks to the CCHMC website may be placed on the organization’s website;
- The BEST may be adopted or adapted for use within the organization, provided that CCHMC receives appropriate attribution on all written or electronic documents; and
- Copies may be provided to patients and the clinicians who manage their care.

Notification of CCHMC at [EBDMinfo@cchmc.org](mailto:EBDMinfo@cchmc.org) for any BEST adopted, adapted, implemented, or hyperlinked by the organization is appreciated.


This Best Evidence Statement has been reviewed against quality criteria by two independent reviewers from the CCHMC Evidence Collaboration. Conflict of interest declaration forms are filed with the CCHMC EBDM group.

Once the BEST has been in place for five years, the development team reconvenes to explore the continued validity of the guideline. This phase can be initiated at any point that evidence indicates a critical change is needed. CCHMC EBDM staff perform a quarterly search for new evidence in an horizon scanning process. If new evidence arises related to this BEST, authors are contacted to evaluate and revise, if necessary.

For more information about CCHMC Best Evidence Statements and the development process, contact the Evidence Collaboration at [EBDMinfo@cchmc.org](mailto:EBDMinfo@cchmc.org).
Note

This Best Evidence Statement addresses only key points of care for the target population; it is not intended to be a comprehensive practice guideline. These recommendations result from review of literature and practices current at the time of their formulation. This Best Evidence Statement does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this Statement is voluntary. The clinician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.