Title: Application of Liposomal lidocaine 4%

This procedure is attached to: Collective order for the administration of Topical Anesthetics to reduce Needle Pain in the Neonatal and Pediatric Population

1. DEFINITION AND PURPOSE
Topical anesthetic application can contribute significantly to preventing and eliminating pain in children with each needle procedure or more rarely in the context of small cutaneous procedure. Topical anesthetic application is standard of care for each needle procedure at the Montreal Children's Hospital. At the Montreal Children's Hospital, first line topical anesthetic: Liposomal lidocaine 4% (Maxilene4®) Tetracaine 4% is to be used only in case of allergic reaction to Liposomal lidocaine 4% or one of its components.

2. CARE GOALS
Decrease or eliminate pain related to needle procedure and/or small cutaneous procedure.

3. PROFESSIONALS INVOLVED
Nurses, licensed practical nurses, physicians.

4. POPULATION
Pediatric patients, 37 weeks gestational age and older.
Liposomal lidocaine 4% can be safely applied to neonates with an individual order
Preterm (33 weeks and more) and neonates in the NICU can receive liposomal lidocaine 4% as per the NICU staff recommendations.

5. INDICATIONS
   - Needle procedure:
     - Venous blood draw
     - Peripheral intravenous (PIV) catheter insertion
     - Implanted port needle insertion
     - Intramuscular injection
     - Subcutaneous and intradermic injection
     - Lumbar puncture
     - Bone marrow aspiration
Minor cutaneous procedure such as wart removal

6. CONTRAINDICATION
   o Allergy to lidocaine or other components of this product
   o Liver impairment (will require an individual evaluation and prescription)

7. PRECAUTION
   o Only apply on intact skin
   o Do not ingest
   o Do not apply on wounds, mucous membranes, eyes, ears, anal or genital region

8. PHARMACOKINETICS
   o Liposomal lidocaine is a liposomal encapsulated formula containing 4% lidocaine. Liposomal encapsulation involves the use of lipid bilayers to rapidly deliver the lidocaine into the dermis of the skin. The liposome protects the lidocaine molecule from metabolic processes and from removal by blood circulation and acts as a depot in the epidermis for prolonged release of the drug.
   o Once the lidocaine reaches the nerve endings, it causes a reversible block to the conduction of impulses along the nerve fibers by preventing the sodium channels from opening.
   o Onset 20-30 minutes
   o Duration of application: 30-60 minutes.
   o Duration of action more than 60 minutes after application time
   o Metabolism: Systemically absorbed lidocaine is rapidly metabolized in the liver
   o Excretion: Excreted principally in urine as metabolites (90%) and small amounts (less than 10%) as unchanged drug

   Keeping the cream in place will not delay pic of action or prolonged duration of action; however it is not contraindicated to keep it in place longer if cares are delayed.

8.1. PREGNANCY RISK
   C: Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. (FDA pregnancy categories)

8.2. MONITORING
   Local skin reaction or allergy to product should be monitored and documented.

8.3. SIDE EFFECTS
   o Local skin reaction or skin color change at the site of cream application such as redness can be observed without consequences
   o Allergic reaction to product should be observed and documented. If allergic reaction remove cream and clean area with mild soap solution

9. EQUIPMENT

Application of Liposomal lidocaine 4%, Clinical Procedure, Final July 31 2017
Liposomal lidocaine 4% (Maxilene4®): No occlusive dressing required. However, for younger children, occlusive dressing or plastic film (saran wrap style) to keep cream in place.

10. PROCEDURE

<table>
<thead>
<tr>
<th>ACTION</th>
<th>RATIONAL</th>
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<tbody>
<tr>
<td>1 Select site(s)</td>
<td>First step when needle procedure is planned is to apply topical anesthetic to ensure patient is ready when it’s the time for the procedure. Selecting more than one site will minimize impact if failure on first attempt.</td>
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<tr>
<td>• For PIV:</td>
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<tr>
<td>o Select one or two sites</td>
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<td>o Determined site(s) with the use of tourniquet if required.</td>
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<tr>
<td>• For blood procurement</td>
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<td>o Select sites if those sites are not available, consult for advice from phlebotomist.</td>
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<tr>
<td>• For other needle procedures such as Subcutaneous and Intramuscular, lumbar puncture, select one site</td>
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<tr>
<td>2) Apply a small amount of cream on intact dry skin, and gently massage into the skin.</td>
<td>Broken skin will affect absorption of product. Acetone and alcohol will impair the penetration of the local anesthetic into the skin.</td>
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<tr>
<td>Do not use acetone or alcohol before applying the cream.</td>
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</table>
3) Squeeze tube to cover dry and intact skin with a thick layer of cream on intact and dry skin. Do not rub. Refer to dosage for total amount recommended. Gloves are suggested to avoid direct contact with anesthetic cream. Broken skin will affect systemic absorption of product.

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<th>e.g. children more then 10kg</th>
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5) Occlusive dressing is not required. However, it is suggested to cover with plastic wrap or dressing like Tegaderm to hold cream in place for young children.

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6) Left over cream can be used for the same patient at another time Decrease waste
11. STORAGE
Room temperature. Stable for three months after open.

12. SUPPLIED
- Liposomal lidocaine 4%: 5 gram tube (multidose)

13. COMPATIBILITY
N/A

14. DOSE
- There is no indication of maximum dosage; however we suggest applying as below.
  - Infant 10 kg and less: 1-1.5 grams (approximately 1/5 of the tube) to one to three sites
    - The cream should cover just sufficiently the selected area, approximately the size of one dime (10 cents) per selected sites
  - Children more than 10 kg: may use up to 2.5 grams (approximately 1/5 to 1/2 tube) to one to three sites
    - The cream should cover sufficiently the selected area, approximately the size of one quarter (25 cents) per selected sites
  - May repeat 3 - 4 times per day with a reasonable delay (2 hours) between applications. Consider context and the total amount used (one site versus three sites) as well as the age of the child; neonate versus children. One should not worry about multiple site application for more than 40kg patients.

15. DOCUMENTATION IN CHART
Document on c-mar
- Date, time, application zone

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16. TEACHING PROGRAM
N/A

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CONSULTANTS:
Eren Alexander, Nursing Practice Consultant for Staff development, MCH
Nursing Practice Development Quality group

17. APPROVAL PROCESS

<table>
<thead>
<tr>
<th>Committees</th>
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<tbody>
<tr>
<td>❑ Clinical Practice Review Committee (if applicable)</td>
<td>2017-06-08</td>
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<tr>
<td>□ Adult Pharmacy and Therapeutics (if applicable)</td>
<td>NA</td>
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<tr>
<td>❑ Pharmacy and Therapeutics Pediatrics (if applicable)</td>
<td>2017-05-01</td>
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<tr>
<td>❑ MUHC Pediatric Medication Administration Policy (PMAP) (if applicable)</td>
<td>2017-04-05</td>
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REVIEW DATE
To be updated in maximum of 4 years or sooner if presence of new evidence or need for practice change.

6. REFERENCES

Application of Liposomal lidocaine 4%, Clinical Procedure, Final July 31 2017

<table>
<thead>
<tr>
<th>Version</th>
<th>Description</th>
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<th>Date</th>
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<tbody>
<tr>
<td>No 1</td>
<td>Development and Approval</td>
<td>Eren Alexander, NPC</td>
<td>2009-11-09</td>
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<tr>
<td>No 2</td>
<td>Revision with modification</td>
<td>Annik Otis, CNS</td>
<td>2017-07-31</td>
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<td>No</td>
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