ETHANOL-LOCK THERAPY IN PATIENTS ADMITTED TO PEDIATRIC SERVICES

Purpose:
The purpose of this guideline is to establish and disseminate the standards and guidelines used at C.S. Mott Children’s Hospital to prescribe and administer ethanol-lock therapy (ELT) in the management and prevention of central venous access device (CVAD)-related bloodstream infections.

Definitions:
A. Ethanol-lock therapy (ELT): The filling of a lumen of a central venous access device with a high concentration ethanol solution (70%) and leaving the solution in the lumen for a certain dwelling time. Ethanol’s properties of both bactericidal and fungicidal activity, as well as being without known clinical resistance make ethanol an attractive option for prevention of central venous access device-related bloodstream infection in high risk patients.

B. Central Venous Access Device (CVAD): a long term, central venous catheter including central tunneled venous access device, non-tunneled central venous access devices such as PICC lines, or implanted ports.

C. Limited Venous Access: venous access in patients who will require anticipated long-term (i.e., >6 months) venous access and will be at risk of losing venous access during periods of treatment.

D. Pediatric Patient: Patient managed by a Pediatric primary service

Procedure Actions:
A. Inclusion for ELT:
   1. At least one of the following inclusion criteria must be met for ethanol-lock therapy:
      i. Suspected CVAD-related bloodstream infection with limited venous access in a patient who receives ELT as an outpatient
      ii. Requires CVAD prophylaxis due to extensive history of CVAD-related bloodstream infections
   2. All of the following criteria must be met:
      i. Have a silicone-based CVAD (see table below)
      ii. Must be able to accommodate a minimum of two hours of dwell time for ELT

Examples of Central Venous Access Devices at C.S. Mott Children’s Hospital

<table>
<thead>
<tr>
<th>Type of Central Venous Access Devices</th>
<th>Size</th>
<th>Lumens</th>
<th>Manufacturer</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broviac</td>
<td>2.7Fr</td>
<td>Single</td>
<td>Bard 0600040</td>
<td>Silicone</td>
</tr>
<tr>
<td>Broviac</td>
<td>4.2Fr</td>
<td>Single</td>
<td>Bard 0600520</td>
<td>Silicone</td>
</tr>
<tr>
<td>Broviac</td>
<td>6.6Fr</td>
<td>Single</td>
<td>Bard 0600540</td>
<td>Silicone</td>
</tr>
<tr>
<td>Hickman</td>
<td>7.0Fr</td>
<td>Dual</td>
<td>Bard 0600570</td>
<td>Silicone</td>
</tr>
<tr>
<td>Hickman</td>
<td>9Fr</td>
<td>Dual</td>
<td>Bard 600604</td>
<td>Silicone/Antimicrobial</td>
</tr>
<tr>
<td>Hickman</td>
<td>9.6Fr</td>
<td>Single</td>
<td>Bard 0600560</td>
<td>Silicone</td>
</tr>
<tr>
<td>Leonard</td>
<td>10Fr</td>
<td>Dual</td>
<td>Bard 0600630</td>
<td>Silicone</td>
</tr>
<tr>
<td>Hickman</td>
<td>12.5Fr</td>
<td>Triple</td>
<td>Bard 0600650</td>
<td>Silicone</td>
</tr>
<tr>
<td>PowerLine</td>
<td>6Fr</td>
<td>Dual</td>
<td>Bard 0700615</td>
<td>Polyurethane</td>
</tr>
<tr>
<td>PowerHickman</td>
<td>9.5Fr</td>
<td>Dual</td>
<td>Bard 0805915</td>
<td>Polyurethane</td>
</tr>
<tr>
<td>Repair Kit</td>
<td>6.6Fr</td>
<td>Single</td>
<td>Bard 0601620</td>
<td>Silicone</td>
</tr>
</tbody>
</table>

PORTS
<table>
<thead>
<tr>
<th>Device Type</th>
<th>Fr</th>
<th>Configuration</th>
<th>Manufacturer</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>SlimPort Titanium</td>
<td>6Fr</td>
<td>Single</td>
<td>Bard 0605560</td>
<td>Polyurethane</td>
</tr>
<tr>
<td>SlimPort Ultralow MRI</td>
<td>6Fr</td>
<td>Single</td>
<td>Bard 0605640</td>
<td>Polyurethane</td>
</tr>
<tr>
<td>PowerPort Titanium</td>
<td>6Fr</td>
<td>Single</td>
<td>Bard 1706060</td>
<td>Polyurethane</td>
</tr>
<tr>
<td>BardPort Hickman Titanium</td>
<td>6.6Fr</td>
<td>Single</td>
<td>Bard 0606200</td>
<td>Silicone</td>
</tr>
<tr>
<td>SlimPort Rosenblatt</td>
<td>7Fr</td>
<td>Dual</td>
<td>Bard 0604970</td>
<td>Silicone</td>
</tr>
<tr>
<td>PowerPort Titanium</td>
<td>8Fr</td>
<td>Single</td>
<td>Bard 1708060</td>
<td>Polyurethane</td>
</tr>
<tr>
<td>BardPort Hickman Titanium</td>
<td>9.6Fr</td>
<td>Single</td>
<td>Bard 0602210</td>
<td>Silicone</td>
</tr>
<tr>
<td>BardPort Hickman MRI</td>
<td>10Fr</td>
<td>Dual</td>
<td>Bard 0615460</td>
<td>Silicone</td>
</tr>
<tr>
<td>NeoStar</td>
<td>12.5Fr</td>
<td>Triple</td>
<td>Angio Dynamics CV-332ek</td>
<td>Silicone</td>
</tr>
</tbody>
</table>

**B. Exclusion for ELT:**

1. If any of the following criteria are met, patients are ineligible for ELT:
   
   i. Documented CVAD-related bloodstream infection (patients should be converted to targeted antimicrobial lock therapy if appropriate)
   ii. A polyurethane CVAD
   iii. Patients weighing <5 kg
   iv. Patients receiving heparin or citrate through CVAD where ELT would occur
   v. Patients receiving continuous renal replacement therapy (CRRT) due to the anticoagulant citrate used in this process
   vi. Documented allergy to ethyl alcohol or thrombolytic agents

2. Special consideration should be given to the following populations:
   
   i. Inability to aspirate back the volume infused into the CVAD
   ii. Recovering alcoholics or children of recovering alcoholics
   iii. Caregiver with a history of inability to properly administer IV medications

**C. Prescribing Procedures and Requirements for Ethanol-Lock Therapy**

1. ELT approval must be obtained from the Pediatric Infectious Diseases service or Children’s Intestinal Rehabilitation Program (CHIRP) prior to ordering.

2. An electronic order-set for ethyl alcohol 70% syringe will contain the following:
   
   i. Acknowledgement of ELT requirements (if the statements are not acknowledged by the prescriber, the order will not be processed)
      a. I verify that the patient’s catheter/port is ethanol compatible
      b. I verify that I have reviewed the policy of ethanol lock therapy, that an allergy to heparin and citrate containing compounds has been entered and that the patient is not allergic to ethanol
   ii. Antimicrobial Stewardship, Infectious Diseases Consult, or CHIRP Approver
   iii. Lumen to lock
   iv. Line location

3. When prescribing parenteral nutrition (PN) for patients on ELT, the prescriber will delete the heparin and citrate from the PN to avoid incompatibility issues.

4. An allergy for “Heparin and citrate containing compounds” should be entered into the electronic medical record stating incompatible with ethanol-lock. Once ELT is discontinued, this allergy alert shall be removed provided no true allergy exists.

5. If a patient requires a dose of ethanol-lock to be administered in the clinic setting (i.e., CHIRP clinic), the following procedures for prescribing shall occur:
i. The prescribing clinic will fax the prescription/order to the CW 10th floor inpatient pharmacy (x53285) in advance of medication due time.
ii. The CW 10th floor inpatient pharmacy will process the order and bill the patient for the medication.
iii. A representative from the clinic must pick up the medication once processed from the CW 10th floor pharmacy.

D. Measurement of the line for Ethanol-Lock Administration

1. To estimate the volume of the CVAD:
   i. Prepare a 3 mL syringe filled with 1 mL of Normal Saline
   ii. Attach syringe to needleless hub on the end of the catheter (hub must be connected directly to the end of the venous access device without extension tubing)
   iii. Draw back on plunger until drops of blood enter the syringe
   iv. Subtract 1 mL from the volume on the syringe when blood enters the syringe (for example if the finishing volume on the syringe is 1.2 mL after blood enters the syringe, the catheter volume would be 0.2 mL)
   v. Clamp tubing and record this volume
   vi. Flush tubing
   vii. Document findings in the electronic medical record via the Lines, Drains and Airways section of the chart.
   viii. Communicate volume to ordering prescriber

2. Additional volume will be added to ensure the ELT covers the entire length of the CVAD, with maximum volume of 2 mL.
   i. An order should be written to inform caregivers the estimated volume
   ii. Weight-based additional volume:

<table>
<thead>
<tr>
<th>Weight of patient (kg)</th>
<th>Volume to be Added to Measured Volume</th>
<th>MAXIMUM Volume of Ethanol-Lock: 2 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;15 kg</td>
<td>0.1 mL</td>
<td></td>
</tr>
<tr>
<td>≥15 kg</td>
<td>0.2 mL</td>
<td></td>
</tr>
</tbody>
</table>

3. If unable to determine the volume of the venous access device using the method mentioned above, the following tables can be used if the length of the venous access device is known:

<table>
<thead>
<tr>
<th>Type of venous access device</th>
<th>Catheter size</th>
<th>Number of lumens</th>
<th>Length (cm)</th>
<th>Lock measurement (mL/cm)</th>
<th>Volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broviac</td>
<td>2.7 French</td>
<td>Single</td>
<td>74.87</td>
<td>0.00334</td>
<td>0.25</td>
</tr>
<tr>
<td>Broviac</td>
<td>4.2 French</td>
<td>Single</td>
<td>74.27</td>
<td>0.00512</td>
<td>0.38</td>
</tr>
<tr>
<td>Broviac</td>
<td>6.6 French</td>
<td>Single</td>
<td>95.2</td>
<td>0.00966</td>
<td>0.92</td>
</tr>
</tbody>
</table>

Data constructed by measurements performed by Petrea Cober, PharmD.

4. If still unable to determine the volume of the venous access device (excluding implanted ports) using the methods mentioned above, the following table may be used to estimate the volume of the venous access device:

<table>
<thead>
<tr>
<th>Weight of patient (kg)</th>
<th>Volume of ethanol-lock if unknown venous access device volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-9.9</td>
<td>0.2 mL</td>
</tr>
<tr>
<td>10-14.9</td>
<td>0.3 mL</td>
</tr>
<tr>
<td>15-19.9</td>
<td>0.4 mL</td>
</tr>
<tr>
<td>20-24.9</td>
<td>0.5 mL</td>
</tr>
<tr>
<td>25 or greater</td>
<td>0.7 mL</td>
</tr>
</tbody>
</table>
5. Documentation of lumen volume is completed on the LDA for the CVAD being measured (note, only the volume of the lumen is recorded for dosing an additional 0.1 or 0.2 must be added based on the patient’s weight).

E. Ethanol-Lock Administration Procedures
1. ELT will be administered once a day during the longest period of time the patient is off IV medications and PN.
   i. Minimum dwell time of 2 hours, and for a maximum dwell time of 24 hours.
   ii. Inpatients will have a task on the MAR for installation, removal, or flushing at 24 hours of dwell time.
2. If the patient has a CVAD with more than one lumen, ELT will be alternated between each of the lumens.
   i. A separate order for each lumen must be entered into Epic.
   ii. When ELT is not instilled in the other lumen(s), the lumen(s) should contain a saline lock or other administered fluid as decided by the primary team.
3. Flush CVAD with 10 mL of normal saline prior to instilling ELT.
4. Withdraw ELT and flush with 10 mL of normal saline prior to medication or PN administration.
5. The ethanol-lock is INCOMPATIBLE with heparin and citrate. A warning label sticker provided by pharmacy will be placed on the patient’s CVAD (see Exhibit F).
   i. NOTE: if heparin is accidentally co-infused with ethanol-lock: immediately aspirate the heparin from the central venous catheter. Then, flush with normal saline. Additionally, contact the prescriber immediately.
6. A thrombolytic agent (alteplase), with volume dependent on the measured volume of the CVAD, should be instilled prior to ELT if:
   i. First dose of ELT and line has been in place for >7 days.
   ii. No ELT in previous 7 days and CVAD has not been used for >7 days.
7. Document instillation of Ethanol Lock in Medication Administration Record.

F. Procedure for the Removal of ELT:
1. Withdraw the ethanol-lock solution (equal to the volume initially instilled in the venous access device until a blood return is observed).
2. Flush with 10 mL of normal saline (if volume restricted, 5 mL flush volume may be appropriate).
3. Administer the ordered medication or parenteral nutrition, if indicated.
4. Flush with 10 mL of normal saline (if volume restricted, 5 mL flush volume may be appropriate).
5. Instill the new ethanol-lock solution or leave saline locked until catheter is needed again.
6. Ensure the patient has the ethanol-lock warning label sticker attached to his/her central venous access device.

G. Procedure for Flushing of ELT:
1. Verify the patient meets one of the following criteria:
   i. The caregiver is unable to withdraw the ELT from the CVAD
      a. If the caregiver is unable to withdraw fluid, blood or ELT from the CVAD, notify the House Officer on-call. The House Officer on-call will inform the ordering attending/fellow of the inability to withdraw from the CVAD and receive further instructions for the management of the patient’s CVAD. If a line does not draw back, an update to the active medication list in Epic should be made. In a patient whose order includes withdrawing the ELT, whose line will not draw, it is appropriate to flush the ELT in.
      ii. Flushing ELT is the prescribed route of removing the ELT from the CVAD for this patient.
   2. Flush with 10 mL of normal saline (if volume restricted, 5 mL flush volume may be appropriate).
   3. Administer the ordered medication or parenteral nutrition, if indicated.
   4. Flush with 10 mL of normal saline (if volume restricted, 5 mL flush volume may be appropriate).
   5. Instill the new ethanol-lock solution or leave saline locked until catheter is needed again.
6. Ensure the patient has the ethanol-lock warning label sticker attached to his/her central venous access device.

Displays:
A. A poster indicating that the patient is on ethanol-lock therapy (Exhibit A) will be placed above the patient’s bed for all inpatients receiving ethanol-lock therapy.

Patient Education:
A. Patient education materials for outpatient use of ethanol-lock therapy and an instruction sheet are located in Exhibit B and Exhibit D.

Exhibits:
A. Bedside Poster Indicating Patient is on Ethanol-Lock Therapy
B. Patient Education Materials for Outpatient Use of Ethanol-Lock Therapy and Instruction Sheet
C. Health-Care Provider Information Sheet for Ethanol-Lock Therapy
D. Home Instruction Sheet for Ethanol-Lock Therapy
E. Patient Identification Card
F. Labels for Inpatient Use

References:

Authors:
A. Katie Hughes, PharmD (2017)
B. Rebecca Pehovic, MS, RN 12 East Mott (2013, 2018)
C. Allison Blackmer, PharmD, BCPS (2013)
D. Daniel Teitelbaum, MD, Pediatric Surgery (2008, 2013)
F. Petrea Cober, PharmD (2008)

Reviewed by:
A. Dana Steien, MD (2018)
B. Kristin Klein, PharmD (2013, 2018)
C. Roland Blackwood, MD (2013)
D. Sue Roebuck, RN (2013)
Patient Receiving Ethanol-Lock Therapy

No HEPARIN OR CITRATE to be infused or flushed into Catheter

For use in approved silicone central venous access devices only
Exhibit B: Patient/Parent Information Sheet – Ethanol-Lock Therapy

1. **What is ethanol-lock therapy?**
The ethanol-lock is a solution that can be placed in your child’s IV catheter to prevent or treat an IV catheter infection.

2. **How is ethanol-lock therapy given to my child?**
The ethanol-lock is placed in your child’s IV catheter and is allowed to sit in the catheter while your child is not receiving other IV medications or Parenteral Nutrition (PN) in order to kill any bacteria in the catheter. The ethanol solution will be taken out of your child’s IV catheter prior to giving other IV medicines or PN.

3. **What happens if the ethanol-lock is accidentally pushed into my child’s IV catheter?**
If the ethanol-lock solution cannot be taken out of your child’s IV catheter or if you have been directed by your providers to flush with the ethanol-lock, it will have to be given to your child. Your child should be watched for the following signs and symptoms: tiredness, headaches, dizziness, nausea, and light-headedness. If you see a change in your child’s behavior or activity level, call your doctor’s office immediately.

4. **What are adverse effects of the ethanol-lock therapy?**
As with the use of all IV medicines, entering your child’s IV catheter does increase the risk of infection. However, if this is done under clean conditions, the risk is lowered. If the ethanol-lock is infused into your child, watch for the following signs and symptoms: tiredness, headaches, dizziness, nausea, and light-headedness.

5. **Can the ethanol-lock therapy be used at home?**
Yes. You will be trained on how to give and remove the ethanol-lock, storage of the ethanol-lock, and possible side effects.

6. **How do I store the ethanol-lock therapy at home?**
The ethanol-lock is flammable so it should be treated like any other flammable item. You should store your child’s ethanol-lock supply in the same refrigerator you store IV medicine or home PN solutions. No one should smoke around the ethanol-lock.

7. **Are there any restrictions in my child’s activity while on ethanol-lock therapy?**
If your child is old enough to drive, he/she should not drive while taking the ethanol-lock therapy.
Exhibit C: Health-care Provider Information Sheet – Ethanol-Lock Therapy

1. **What is ethanol-lock therapy?**
   Ethanol-lock is a solution that can be instilled in an IV catheter to prevent or treat an IV catheter related infection. It is similar to an antibiotic lock (an antibiotic solution placed in the IV catheter) but does not have the problem of antibiotic resistance for the particular infection.

2. **How is ethanol-lock therapy given to a patient?**
   Ethanol-lock is injected into the end cap of an IV catheter. It is allowed to dwell in the catheter when not receiving other IV medications or parenteral nutrition (PN) in order to kill any bacteria present in the catheter. The ethanol solution will be withdrawn from the IV catheter prior to administration of other IV medications or PN. To be sure the ethanol-lock solution can be withdrawn from the IV catheter, each patient prior to using ethanol-lock therapy needs to receive a medication that removes any clots from the catheter. Ethanol-lock therapy can only be used with IV catheters made of silicone (e.g., Broviac, Hickman).

3. **Are there compatibility and stability issues with the ethanol-lock?**
   Ethanol is INCOMPATIBLE with heparin and citrate, so DO NOT use heparin flushes or citrate if you are on ethanol-lock therapy. Ethanol-lock solutions are stable for 14 days at room temperature.

4. **What happens if the ethanol-lock is accidentally flushed into a patient’s catheter?**
   Ethanol infusions are fairly safe. Studies have shown that the use of the ethanol-lock had no significant adverse effects to infants and children. If you are unable to withdraw the ethanol, you will need to flush it through the catheter. This may cause: tiredness, headaches, dizziness, nausea, and light-headedness.

5. **What are adverse effects of the ethanol-lock therapy?**
   As with the use of all IV medications, entering an IV catheter does increase the risk of infection. However, if this is done under clean conditions, the risk is greatly reduced and the ethanol-lock is actually used to prevent and treat infections. If the ethanol-lock is infused into the catheter, observe for tiredness, headaches, dizziness, nausea, and light-headedness. If there are changes in behavior or activity level, the caregiver should be instructed to contact their doctor immediately.

6. **Can ethanol-lock therapy be used at home?**
   Yes. Parents/caregivers need to be trained on proper administration and removal of the ethanol-lock, storage of the ethanol-lock, and possible adverse effects that need to be monitored. Prior to using in the home, the patient’s home infusion provider and visiting nurse agency should be contacted to determine if they provide ethanol-lock therapy.

7. **How should the ethanol-lock therapy be stored in the hospital or at home?**
   The ethanol-lock is flammable so it should be treated like any other flammable item. The current recommendation is to store in the refrigerator. No smoking should be permitted around the ethanol-lock.

8. **Are there any restrictions in a patient’s activity while on ethanol-lock therapy?**
   If the child is old enough to drive, he/she should not drive while taking the ethanol-lock therapy.
Exhibit D:

Home Instruction Sheet for Ethanol-Lock Therapy

1. After finishing other IV medications/PN, flush the patient’s line with ____ mL of normal saline. **(DO NOT USE HEPARIN or CITRATE)**

2. Inject ____ mL of 70% ethanol-lock into the patient’s IV catheter.

3. Allow the ethanol-lock to dwell in the patient’s line for 2 to 24 hours.

4. Prior to administration of other IV medications/PN, withdraw ____ mL of ethanol from the patient’s catheter. (You should draw back enough volume to begin to see the first drops of blood in the syringe.)

5. Flush the patient’s line with ____ mL of normal saline. **(DO NOT USE HEPARIN or CITRATE)**

6. Administer other IV medications/PN.
## Exhibit E: Patient Identification Card

<table>
<thead>
<tr>
<th>I have a central access device which contains an ethanol lock.</th>
<th>I have a central access device which contains an ethanol lock.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FLUSH WITH NORMAL SALINE ONLY!</strong></td>
<td><strong>FLUSH WITH NORMAL SALINE ONLY!</strong></td>
</tr>
<tr>
<td><img src="no_heparin.png" alt="No Heparin" /> <img src="no_citrates.png" alt="No Citrates" /></td>
<td><img src="no_heparin.png" alt="No Heparin" /> <img src="no_citrates.png" alt="No Citrates" /></td>
</tr>
<tr>
<td>Please contact the Vascular Access Department</td>
<td>Please contact the Vascular Access Department</td>
</tr>
<tr>
<td>Michigan Medicine</td>
<td>Michigan Medicine</td>
</tr>
<tr>
<td>Phone: (734) 936-9786</td>
<td>Phone: (734) 936-9786</td>
</tr>
<tr>
<td>Pager: (734) 936-6266 (X2957)</td>
<td>Pager: (734) 936-6266 (X2957)</td>
</tr>
</tbody>
</table>
Exhibit F: Ethanol-Lock Labels

The recommendations in this guide are meant to serve as treatment guidelines for use at Michigan Medicine facilities. If you are an individual experiencing a medical emergency, call 911 immediately. These guidelines should not replace a provider's professional medical advice based on clinical judgment, or be used in lieu of an Infectious Diseases consultation when necessary. As a result of ongoing research, practice guidelines may from time to time change. The authors of these guidelines have made all attempts to ensure the accuracy based on current information, however, due to ongoing research, users of these guidelines are strongly encouraged to confirm the information contained within them through an independent source.

If obtained from a source other than med.umich.edu/asp, please visit the webpage for the most up-to-date document.