GUIDELINES FOR THE USE OF ETHANOL LOCK PROPHYLAXIS IN ADULT PATIENTS

PURPOSE:
The purpose of these guidelines is to provide the standards used at Michigan Medicine to prescribe and administer ethanol-lock therapy in adults for the prevention of central venous access device-related bloodstream infections.

DEFINITIONS:
Adult patient: Patient managed by an Adult primary service
Ethanol lock: Ethanol lock therapy (ELT) is created by filling the lumen of a central venous access device (CVAD) 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 CVAD-related bloodstream infection in high risk patients.
Central Venous Access Device: a long term, central venous catheter including the following:
   1. Central tunneled venous catheter
   2. Implanted port
   3. Non tunneled central venous catheter, including PICC lines
Ethanol compatible central venous access device: a central venous access device that is documented as compatible with ethanol 70% lock solution for the necessary dwelling time, as provided by the manufacturer guidelines (see Attachment A for ethanol compatible adult CVADs that are available in the formulary at Michigan Medicine. For other ethanol compatible CVAD, special ordering is required). Note that polyurethane CVAD that are used at Michigan Medicine are NOT ethanol compatible

PROCEDURE ACTIONS
(Note: Pharmacy preparation instructions available in Attachment B.)
A. Inclusion: Patient Selection for Ethanol-Lock Prophylaxis:
   1. At least one of the following inclusion criteria must be met:
      a. Patient who has a history of recurrent CVAD related bloodstream infections
      b. Patient who is at risk of limited venous access (venous access in patients who require anticipated long-term (i.e., >6 months), has poor vascular access, or is at risk of losing venous access during periods of treatment).
   AND
   2. All of the following criteria must be met:
      a. The patient has an ethanol compatible CVAD (see Attachment A)
      b. A dwell time of a minimum of two hours with the ethanol-lock solution within the patient’s central venous access device is possible
      c. Patient and/or caregiver is capable of performing lock therapy once discharged from Michigan Medicine.
      d. Antimicrobial stewardship team approval was garnered for the use of Ethanol lock prophylaxis

B. Exclusion: Patients Ineligible for Ethanol-Lock Therapy: If any of the following criteria are met, patients are ineligible for ethanol-lock prophylaxis:
   1. The patient has an ethanol incompatible central venous access device, according to manufacturer guidelines and/or Attachment A
   2. Heparin or citrate of any type are injected through, or instilled in, the central venous access device (due to incompatibilities of ethanol with these agents). Heparin may be administered via other routes or access devices if necessary.
      a. A health maintenance modifier will run a Best Practice Alert in MiChart if an order for heparin is placed for a patient receiving ethanol lock therapy. The BPA will state: This patient is receiving ethanol lock therapy. Heparin and citrate containing compounds are incompatible with ethanol lock. Heparin may be administered via other routes or devices not being locked with ethanol if necessary.
   3. Documented allergy to ethyl alcohol or thrombolytic agents
4. Central venous access devices used for hemodialysis treatment are ineligible for ethanol-lock prophylaxis at Michigan Medicine
5. Patient or caregiver objects to the use of ethanol-lock therapy due to social or religious reasons

C. Special considerations: Special consideration are given to the following populations prior to initiating ethanol lock prophylaxis

1. Patients who received drugs with potential interaction with ethanol within 48 hours (Metronidazole, Isoniazid) or within 7 days (disulfiram) of ethanol lock administration should be monitored for adverse reaction
2. For patients with active or past substance abuse, review and discussion should be performed, with case by case decision as to whether benefit outweighs risks of ethanol lock treatment. A statement outlining risks, education provided, and patient/family understanding should be documented in the medical record for all decisions.

D. Special precautions: special precautions are given for the following settings:

1. Patients who are smokers should be advised for the risk of fire in the presence flammable ethanol lock solution.
2. Ethanol concentration of 30% and higher may be associated with protein precipitation and clotting. Close monitoring for clotting of CVAD is required for patients who are treated with ethanol lock prophylaxis.
3. Ethanol lock may be associated with protein precipitation when administered with heparin through the same catheter. Patients who have coagulation disorders and frequently require IV heparin should be evaluated for the risk and benefits of ethanol lock prophylaxis

E. Prescribing Procedures and Requirements for Ethanol-Lock Prophylaxis

Before ordering Ethanol lock prophylaxis, the following steps should be taken:

1. The prescriber is responsible for evaluating the patient’s CVAD compatibility for ethanol lock therapy. Ethanol is incompatible with most CVADs used at Michigan Medicine. If a patient has already been receiving ethanol lock therapy at home through an ethanol-compatible CVAD, proceed to #2 below. If a patient does not have an ethanol-compatible CVAD, then ethanol lock therapy may be utilized if a new, ethanol-compatible CVAD is placed. This decision is made in consultation with Infectious Diseases, and need for a compatible catheter should be documented in the IR Tunneled Catheter order set.
2. Ethanol lock therapy is considered a restricted antimicrobial (see UMHHC Policy 07-01-015 Use of Infectious Diseases Restricted Antimicrobials), and Infectious Diseases consult and approval is mandatory prior to ordering therapy.
   a. For patients continuing on ethanol lock therapy, ID consult is not mandatory if approval was granted in the past 12 months and the indication for prophylaxis remains.
   b. Antimicrobial stewardship team approval is still required for any ethanol lock therapy order.

Ordering Ethanol lock:
A physician enters an order set (“Ethanol lock therapy ADULT”) to begin and maintain a patient’s ethanol lock prophylaxis regimen, which includes the following:

1. Frequency of ethanol lock. Solution must dwell in catheter for a minimum of 2 hours and maximum of 24 hours.
2. Dose (volume) of ethanol lock.
3. Antimicrobial Stewardship Team/ID approver.
4. Management of the central venous access device at the end of each dwelling time and/or prior to venous access device use (Withdraw and discard volume of ethanol lock prior to accessing line, then flush with 10 mL normal saline.). This wording is auto-populated.
5. A check-box that the patient’s central venous access device is ethanol compatible, the prescriber has reviewed the ethanol lock therapy guideline, and that the patient is not allergic to ethanol. If the above statements are not acknowledged by the prescriber, the order will not be processed.

6. A separate order for each lumen must be entered into the order to facilitate appropriate documentation on the Electronic Medication Administration Record (EMAR).

7. Example Order: "ETHANOL-LOCK THERAPY - Instill XXX mL of 70% ethanol solution into the patient's catheter lumen after parenteral nutrition (PN) cycle. Dwell ethanol-lock until lumen is needed for initiation of evening’s PN."

8. When prescribing parenteral nutrition (PN) for patients on ethanol-lock therapy, the prescriber will delete the heparin and citrate from the PN to avoid incompatibility issues.

F. Ethanol lock administration

1. Prepare line for injection following aseptic technique.
2. Assess for blood return with an empty 3 mL syringe, aspirate and discard 3 mL of each lumen content.
3. Attach a 10 mL syringe filled with 10 mL normal saline and gently flush the venous access device lumen.
4. Remove the syringe.
5. Insert lock syringe into the venous device insertion cap. The syringe contains an appropriate lock solution volume according to catheter type and/or measurement (see below section H).
6. Inject Ethanol lock into the lumen using positive pressure technique.
7. Place a new sterile cap.
8. The ethanol-lock is INCOMPATIBLE with heparin and citrate. In order to prevent accidental infusion of heparin or citrate into lines with ethanol-lock, a warning sticker (dispensed with the first syringe by pharmacy) will be placed on the patient’s central venous access device (as close to where the drug is injected as possible) to indicate that the lumen contains an ethanol lock solution (Exhibit B).
9. 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. This poster will print out in the patient’s nursing station at the time the order is placed (auto-checked as part of ethanol lock order set).
10. To avoid heparin or citrate injection through ethanol locked catheter, patients with ELT should carry an identification card (Exhibit C). This will be provided by pharmacy with the first syringe.
11. 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.

G. Removal of Ethanol lock solution at the end of dwelling time and/or prior to venous access use:

After a dwell time of minimum of 2 hours (up to 24 hours), and/or prior to the use of the venous access device, ethanol lock solution is withdrawn from each lumen and discarded, then the lumen(s) is/are flushed with 10 mL of normal saline.

Procedure to remove lock solution:

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. Flush with 10 mL of normal saline once medication is administered or PN administration is complete. (If volume restricted, 5 mL flush volume may be appropriate).
4. Instill the new ethanol-lock solution or leave saline locked until catheter is needed again.
5. Ensure the patient has the ethanol-lock warning label sticker attached to his/her central venous access device.

NOTE: A “Withdraw Ethanol Lock” nursing order will be auto-checked when an ethanol lock is ordered. It will state “Withdraw and discard volume of ethanol lock prior to accessing line, then flush with 10 mL normal saline” and remain in the Nursing Active orders reports. The same instructions will also be present on the MAR.

NOTE: If the caregiver is unable to withdraw the ethanol-lock solution from the venous access device lumen, notify the House Officer on call.
NOTE: In case of inadvertent flushing of the lock into the systemic circulation, the House Officer on call should be notified and the patient should be monitored for the following signs and symptoms: tiredness, headaches, dizziness, nausea, and light-headedness.

H: Measurement of the Lumen for Ethanol-Lock Administration (Applicable when the volume of CVAD is unknown)

To estimate the volume of the venous access device, a practitioner (RN, MD, PA, NP) measures the volume of the catheter:

1. Prepare a 3 mL syringe filled with 1 mL of Normal Saline
2. Attach syringe to hub on the end of the catheter (hub must be connected directly to the end of the venous access device without extension tubing)
3. Draw back on plunger until drops of blood enter the syringe
4. 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 volume would be 0.2 mL)
5. Clamp tubing and record this volume
6. Flush tubing
7. Document findings in the “lines, drains and airway” MiChart tab (‘volume’ space of ‘line’ portion)
8. Communicate volume to ordering prescriber

*NOTE The prescriber will add an additional 0.2 mL to this measured volume to ensure the volume of the ethanol-lock covers the entire length of the venous access device.

*NOTE Interventional Radiology provides the following “approximate” volumes: Hickman catheter 1 mL; port 1.5 mL

I: Other considerations:

1. Pharmacy Preparation and Dispensing
   a. Ethanol lock solution is compounded and dispensed daily
   b. Syringe(s) will be delivered to the patient medication bin.
   c. See Attachment B for Ethanol lock solution compounding information

2. Discharge planning: discharge planners should discuss with HomeMed or other outpatient ELT provider for transition to home. HomeMed does have an Ethanol lock policy.
   a. Service provider is required to notify case management of any patient receiving ethanol lock so that discharge services can be coordinated.
   b. Patients and/or caregivers need to have a plan in place for training and assessment of comprehension on ethanol lock administration prior to discharge. This training will be performed by the ELT provider, not inpatient nursing. The case manager will arrange education.
   c. Upon request information regarding IVAD (e.g., type of catheter, catheter material, and volume of lumens) should be sent with referral (can attach documentation in All Scripts) or faxed. This information should be entered into the home care order. This information will then be attached into All Scripts. This point might not be necessary as long as this information is easily accessible in Michart.
   d. Ethanol lock should be initiated prior to discharge and patient should leave hospital with ethanol lock instilled.
   e. The primary team on-call clinician or team pharmacist on call should be contacted regarding questions.
Attachment A: Ethanol compatible central venous access device available at Michigan Medicine:

1. Hickman catheter 9.6 Fr single lumen ingrowth/4 antimicrobial cuff Silicone (BARD)
2. Broviac 6.6 Fr single lumen ingrowth cuff w/peel stylet Silicone (BARD)
3. Hickman catheter 10 Fr. double lumen ingrowth cuff, Silicone (BARD)
4. Hickman catheter 10 Fr. triple lumen ingrowth cuff, Silicone (BARD)

Notes:

a. Other ethanol compatible catheter venous access devices that are not listed above require special ordering following consultation with the Interventional Radiology service
b. Polyurethane CVAD that are used at Michigan Medicine are NOT ethanol compatible
I. AVAILABLE FROM MANUFACTURER AS: 98% dehydrated alcohol

II. DIRECTIONS FOR DILUTION:
   A. Standard Concentration (70%):
      - Volume of alcohol: 5 mL of 98% dehydrated alcohol
      - Volume of diluent: 2 mL sterile water
      - Total volume: 7 mL of 70% alcohol solution
      - Draw up the correct dose for the ethanol lock from the 7 mL of solution

III. BEYOND USE DATING (BUD) /EXPIRATION DATING:
   A. Bulk:
      a. Room Temp (BUD): 48 hours
      b. Refrigerated (BUD): 9 days
   B. Syringe:
      a. Hang By (BUD): 12 hours
      b. Expiration: 24 hours

IV. DISPENSING CONTAINER: Syringe

V. FILTERING REQUIREMENTS: Must filter when drawing from an ampule

VI. SPECIAL LABELING REQUIREMENTS: None

VII. COMMENTS:
   A. All NEW orders must be approved by the Adult ID attending or fellow AND by antibiotic stewardship team
   B. Continued orders must be approved by antibiotic stewardship team.
   C. A line label sticker (Exhibit B) AND an identification card (Exhibit C) should be dispensed with the 1st dose
Exhibit A: Bedside Poster

Exhibit A: Bedside Poster for Patients Receiving Ethanol-Lock Therapy

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: Line Label

NO HEPARIN or CITRATE

ETHANOL LOCK
Exhibit C: Identification card

I have a central access device which contains an ethanol lock.
WITHDRAW LOCK FIRST, THEN FLUSH WITH NORMAL SALINE ONLY!
NO HEPARIN
NO CITRATES

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.

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