Anti-Infective Lock Therapy – Adult/Pediatric – Inpatient/Ambulatory – Clinical Practice Guideline

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Executive Summary
Guideline Overview
The guideline provides recommendations on the use of anti-infective lock technique (ALT) including: indications for use, ordering, preparing, and monitoring.

Target Population
Patients at risk for developing, and/or diagnosed with a catheter-related bloodstream infection (CRBSI)

Key Practice Recommendations
This guideline provides recommendations on antiinfective lock technique selection and administration for patients receiving antiinfective lock technique.

Companion Documents
1. Flushing/Locking of Venous Access Devices – Adult/Pediatric – Inpatient/Ambulatory – Clinical Practice Guideline
2. Central Venous Access Device Occlusion – Adult/Pediatric/Neonatal – ED/Inpatient/Ambulatory – Clinical Practice Guideline

Pertinent UW Health Policies & Procedures
1. UWHC Policy #13.26: Insertion and Maintenance of Central Venous Catheters for Prevention of Central Line-Associated Bloodstream Infection (CLABSI)
Scope

Disease/Condition(s):
1. Adult and pediatric patients with long-term central venous catheters at-risk for and with central-line-associated bloodstream infections (CLABSI).
2. Low birth weight infants and neonates requiring central venous catheters at-risk for and with CLABSI are **NOT INCLUDED** in the scope of this guideline.

Clinical Specialties/Intended Users
Physicians, Advanced Practice Providers, Nurses, and Pharmacists

CPG objective
To provide an evidence-based resource that will maximize the safe, efficacious and efficient use of anti-infective lock therapy

Target Population:
Patients at risk for developing, and/or diagnosed with a catheter-related bloodstream infection (CRBSI)

Interventions and Practices Considered:
The use of ALT for the prevention or treatment of CRBSI

Major Outcomes Considered:
1. Sterility and stability of anti-infective lock therapy preparations
2. Catheter salvage rates

Guideline Implementation Metrics:
1. Availability of clinical decision support (order sets, medication record) build to promote adherence to the guidelines
2. Adherence of prescribed anti-infective lock regimens to the CPG
Methodology
A modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) developed by the American Heart Association and American College of Cardiology has been used to assess the quality and strength of the evidence in this Clinical Practice Guideline.¹

Definitions
1. Anti-infective lock technique (ALT)²: The installation of a highly concentrated anti-infective solution into a catheter lumen and allowing the solution to dwell for a specified period for the purpose of sterilizing the lumen.

2. Catheter-related bloodstream infection (CRBSI)²: Defines the catheter as the cause of a bloodstream infection. CRBSI is a clinical definition used when diagnosing or treating patients. Criteria for CRBSI include the following: Presence of bacteremia or fungemia in a patient who has an intravascular catheter; AND at least 1 positive blood culture obtained peripherally; AND clinical signs of infection (fever, chills, or hypotension); AND absence of infection at another site; AND one of the following: (a) Positive semiquantitative [≥15 colony forming units (CFU) per catheter segment] or quantitative [≥10² CFU per catheter segment] catheter tip culture, (b) Quantitative blood culture with a ratio ≥3:1 CFU/mL (catheter vs peripheral), (c) Differential time to positivity (blood culture from catheter is detected at least 2 hours before detection of peripheral blood culture).

3. Central-line associated bloodstream infection (CLABSI)³: Describes a bloodstream infection in a patient who had a recent central catheter. Used by the National Healthcare Safety Network (NHSN) for surveillance. Criteria for CLABSI include: Presence of bacteremia or fungemia (a single positive blood culture is required for most organisms, whereas 2 positive blood cultures are required for skin flora organisms), AND presence of central line within 48 hours, AND absence of an infection at a different site.
4. **Catheter volume**: the intraluminal volume of the catheter
   4.1. French (Fr) scale$^4$ - describes the external diameter of the catheter (1Fr = 1/3mm) using an ascending scale (i.e., higher Fr size indicates larger catheter diameter)
   4.2. Gauge - describes both inner and outer diameter using a descending scale (i.e. higher gauge indicates smaller catheter diameter)
5. **Catheter overfill**: a specified volume *in addition to the catheter volume* that ensures that the ALT solution totally fills the catheter, including the portion closest to the blood interface
   5.1. For patient weighing fewer than 15 kg, the overfill volume is 0.1 mL$^5$
   5.2. For patient weighing 15 kg or greater, the overfill volume is 0.2 mL$^5$

### Table 1. Venous access devices (from Flushing/Locking of Venous Access Devices – Adult/Pediatric – Inpatient/Ambulatory Clinical Practice Guideline)$^6$$^8$

<table>
<thead>
<tr>
<th>Type of Device</th>
<th>Common Catheter Length</th>
<th>Insertion Location</th>
<th>When to Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Umbilical Venous and Arterial Catheter (UVC/UAC)</td>
<td>&lt; 5 cm</td>
<td>Inserted through the umbilical vein and joins the left portal vein or umbilical artery and joins arteries either at the thoracic or lumbar vertebral bodies</td>
<td>Short-term access up to 7 days after birth</td>
</tr>
<tr>
<td>Peripheral (PIV)</td>
<td>&lt; 3 in</td>
<td>Terminates in a vein of the forearm or hand; location may vary in pediatric patients</td>
<td>Short-term access &lt; 1 week</td>
</tr>
<tr>
<td>Midline</td>
<td>3 – 8 in</td>
<td>Peripheral device terminating in the basilic, cephalic, or brachial vein distal to the shoulder</td>
<td>Access needed for &lt; 1 month, not appropriate for vesicant administration</td>
</tr>
<tr>
<td>Non-Tunneled Central</td>
<td>≥ 8 cm</td>
<td>Percutaneous device terminating in the superior or inferior vena cava</td>
<td>Short term access when peripheral not suitable, ex. resuscitation and central venous pressure monitoring</td>
</tr>
<tr>
<td>Peripherally Inserted Central (PICC)</td>
<td>≥ 20 cm</td>
<td>Peripheral device terminating in the superior or inferior vena cava</td>
<td>Medium-term (up to 6 months) access</td>
</tr>
<tr>
<td>Tunneled Central</td>
<td>≥ 8 cm</td>
<td>Implanted into the subclavian, internal jugular, or femoral veins</td>
<td>Frequent medium-term (up to 6 months) access and a PICC line is contraindicated</td>
</tr>
<tr>
<td>Implanted Central (Port)</td>
<td>≥ 8 cm</td>
<td>Tunneled under skin with port accessed by needle; implanted in subclavian or internal jugular vein terminating in the superior vena cava</td>
<td>Infrequent long-term (&gt; 6 months) access</td>
</tr>
<tr>
<td>Dialysis and Apheresis</td>
<td>≥ 15 cm</td>
<td>Non-cuffed catheter placed in the neck or chest terminating in the superior or inferior vena cava</td>
<td>Long or short term access for the maintenance of dialysis therapy</td>
</tr>
</tbody>
</table>
Table 2. Central venous catheter type and capacitance (from Central Venous Access Device Occlusion – Adult/Pediatric/Neonatal – ED/Inpatient/Ambulatory – Clinical Practice)

<table>
<thead>
<tr>
<th>Catheter Type</th>
<th>Adult Capacity</th>
<th>Pediatric Capacity</th>
<th>Neonatal Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>PICC</td>
<td>1 mL</td>
<td>1 mL or less</td>
<td>0.1 mL (1.9 Fr)</td>
</tr>
<tr>
<td>Tunneled Cuff Catheter (ex. Hickman)</td>
<td>2 mL</td>
<td>1 mL or less</td>
<td></td>
</tr>
<tr>
<td>Tunneled Cuff Catheter (ex. Groshong)</td>
<td>1 mL</td>
<td>1 mL or less</td>
<td></td>
</tr>
<tr>
<td>Implanted Venous Port</td>
<td>2 mL</td>
<td>1 mL or less</td>
<td></td>
</tr>
<tr>
<td>Dialysis-Pheresis Catheters</td>
<td>Volume on catheter lumen</td>
<td>1 mL or less</td>
<td></td>
</tr>
<tr>
<td>Non-tunneled Triple Lumen (ex. Arrow)</td>
<td>1 mL</td>
<td>1 mL or less</td>
<td></td>
</tr>
<tr>
<td>Umbilical Catheters (Double and Single Lumen 3.5 and 5 Fr)</td>
<td></td>
<td></td>
<td>0.5 mL or less</td>
</tr>
</tbody>
</table>
Introduction
ALT is used for the prevention or treatment of device-related bacteremias or fungemias resulting from the colonization of bacteria or fungi within the lumen of an intravascular device. ALT as developed to allow a concentrated anti-infective solution to dwell within the catheter lumen for an extended period of time in order to eradicate infectious pathogens.

The most commonly reported CLABSI pathogens are coagulase-negative staphylococci, Staphylococcus aureus, enterococci, Candida species, and Gram-negative bacilli. Important pathogenic determinants of CRBSI include: (1) device material; (2) formation of fibrin sheaths around the catheter; (3) intrinsic virulence factors of the infecting organism (extracellular polymeric substance production, biofilm formation). The formation of a biofilm within a catheter lumen limits the penetration of solution. Bacteria within a biofilm require a 100 to 1000 times greater anti-infective concentration to achieve killing versus planktonic bacteria. Standard intravenous therapy does not reach a sufficient concentration in the catheter lumen to reduce microorganism burden within the biofilm of the catheter. One report concluded that, in hemodialysis patients with dialysis catheter-related infection, systemic vancomycin administration produces a therapeutic plasma concentration; however, during the intradialytic period, the diffusion of the vancomycin from the plasma into the catheter lumen was negligible.

Additionally, the success of ALT is dependent on the stability and compatibility of the ALT solution. The stability and compatibility of ALT solutions is dependent on a number of factors including: temperature, dwell time, syringe materials, pH, device materials, and anti-infective concentrations.

Recommendations

1. ALT for the prevention of CRBSI
   1.1. Routine use of ALT in general patient populations is not recommended. (Class III, Level B)
   1.2. Use of ALT is beneficial when vascular access device use is required for a long-term/indefinite duration and cannot easily be replaced in patients with a history of CRBSI despite maximal adherence to aseptic technique. (Class I, Level A)
   1.3. Selection of the ALT solution should consider the following: (Class I, Level C)
      1.3.1. Catheter indication (e.g., hemodialysis, non-hemodialysis)
      1.3.2. Catheter composition and compatibility with ALT solution(s) (e.g., prolonged exposure to ethanol can affect the integrity of certain catheter materials)
      1.3.3. History of CRBSIs and previous culture/sensitivity results
      1.3.4. History of previous ALT use/failure
      1.3.5. Need for anticoagulant as part of ALT therapy
      1.3.6. Medication allergies or adverse drug reactions
      1.3.7. Risk of systemic exposure and adverse effects associated with ALT (e.g. ethanol intoxication in pediatric population)
      1.3.8. Targeted microorganism(s)
      1.3.9. Patient age (neonate, pediatric, adult)
      1.3.10. Risks of adverse effects from ALT systemic exposure
      1.3.11. Regimens available at UW Health (see Appendix 1 and Appendix 2)

2. ALT catheter salvage
   2.1. ALT can be beneficial for patients with CRBSI involving long-term catheters with no signs of exit site or tunnel infection for whom catheter salvage is the goal. (Class IIa, Level B)
2.2. For CRBSI, antibiotic lock should not be used alone; instead, it is reasonable to be used in conjunction with systemic antimicrobial therapy.\(^\text{10}\) (Class IIa, Level B)

2.3. Dwell times for ALT solutions generally should not exceed 48 hours before reinstallation of lock solution. Reinstallation is probably indicated every 24 hours for ambulatory patients with femoral catheters.\(^\text{14}\) (Class IIa, Level B)

2.3.1. For patients who are undergoing hemodialysis, the lock solution can be renewed after every dialysis session.\(^\text{10}\) (Class IIa, Level B)

2.4. Catheter removal is probably recommended for CRBSI due to \textit{S. aureus} and \textit{Candida} species, instead of treatment with ALT and catheter retention, unless there are unusual extenuating circumstances (e.g., no alternative catheter insertion site).\(^\text{10}\) (Class IIa, Level A)

2.5. For patients with multiple positive catheter-drawn blood cultures that grow coagulase-negative staphylococci or Gram-negative bacilli and concurrent negative peripheral blood cultures, antibiotic lock therapy may be considered without systemic therapy for ten to fourteen days.\(^\text{10}\) (Class IIb, Level B)

2.6. Long-term catheter removal is probably indicated in patients with CRBSI associated with any of the following conditions: severe sepsis; suppurative thrombophlebitis; endocarditis; bloodstream infection that continues despite 72 hours of antimicrobial therapy to which the infecting microbes are susceptible; or infections due to \textit{S. aureus}, \textit{P. aeruginosa}, fungi, or mycobacteria.\(^\text{10}\) (Class IIa, Level A)

2.7. Short-term catheter removal is probably indicated in patients with CRBSI due to Gram-negative bacilli, \textit{S. aureus}, enterococci, fungi, or mycobacteria.\(^\text{10}\) (Class IIa, Level A)

2.8. In patients with CRBSI for whom catheter salvage is attempted, additional blood cultures are reasonable. Catheter removal is probably indicated if peripheral blood culture results (e.g., two sets of blood cultures obtained on a given day;) remain positive when blood samples are obtained 72 hours after the initiation of appropriate therapy.\(^\text{10}\) (Class IIa, Level B)

3. \textbf{ALT pathogen-specific salvage recommendations.}

3.1. An infectious diseases consult should be considered for the determination of CRBSI catheter-salvage recommendations. (Class IIb, Level C)

4. \textbf{ALT dwell times}

4.1. Dwell times should be specified as part of the ALT orders.\(^\text{10}\) (Class I, Level C)

4.2. Dwell times for ALT solutions generally should not exceed 48 hours before reinstallation of lock solution. Reinstallation is probably indicated every 24 hours for ambulatory patients with femoral catheters.\(^\text{10}\) (Class IIa, Level B)

4.2.1. For patients who are undergoing hemodialysis, the lock solution can be renewed after every dialysis session.\(^\text{10}\) (Class IIa, Level B)

4.3. Flushing of the instilled ALT solution through the catheter into the systemic circulation is not recommended as to reduce the risk adverse effects and the emergence of microorganism resistance. (Class III, Level C)

5. \textbf{Determining catheter volume}

5.1. The volumes of common catheters currently used at UW Health are specified in the Flushing/Locking of Venous Access Devices – Adult/Pediatric – Inpatient/Ambulatory Clinical Practice Guideline and Central Venous Access Device Occlusion – Adult/Pediatric/Neonatal – ED/Inpatient/Ambulatory – Clinical Practice Guideline.

6. \textbf{ALT solution-specific precautions and considerations}

6.1. Stability and compatibility
6.1.1. The stability and compatibility of the ALT solution should be considered when ordering ALT for prophylaxis or treatment. ALT solutions without documented stability or compatibility should not be used.\(^2\)\(^,\)\(^12\) (Class III, Level B)

6.1.2. Temperature, dwell time, and solution concentration can influence stability and compatibility. Also, stability may be altered by manufacturer changes that are not reflected in the published stability studies. ALT solutions should be examined for evidence of physical incompatibility (discoloration or precipitation) prior to instillation into the catheter. (Class I, Level C)

6.1.3. ALT solutions may be stable for short durations and require admixture in the clinical care area instead of the pharmacy. In these scenarios, it is reasonable for the pharmacy servicing the ambulatory site to supply the necessary supplies and instructions for admixture of the ALT solution. (Class III, Level C)

6.2. Ciprofloxacin

6.2.1. In clinical trials, admixed solution was allowed to dwell for at least 12 hours and was changed daily.\(^15\) Some references cite ciprofloxacin is compatible with heparin, however, experience at UWHealth has shown ciprofloxacin and heparin have variable compatibility. Therefore, ciprofloxacin lock solutions should not include heparin. (Class III, Level C)

6.3. Daptomycin

6.3.1. Daptomycin has a unique mechanism of action involving a calcium-dependent dissipation of membrane potential, leading to the release of intracellular ions from the cell and the killing of bacteria. Daptomycin ALT solution requires the addition of calcium for antimicrobial activity. The addition of Lactated Ringer’s to the daptomycin ALT provides 3.6 mEq/L of calcium ions.\(^16\)

6.4. Ethanol and other alcohol-containing solutions

6.4.1. Ethanol compatibility with heparin and trisodium citrate is variable.\(^12\) Ethanol should not be considered compatible with heparin or trisodium citrate and neither heparin nor trisodium citrate should be used with ethanol in ALT. (Class III, Level C)

6.4.2. When ethanol lock solutions are considered, the effect of ethanol on the mechanical and structural integrity of the catheter should be considered.\(^13\) (Class IIa, Level B)

6.4.3. It is reasonable to restrict use of ethanol ALT to silicone and carbachane catheters until sufficient data are available to ensure that ethanol has no effect on catheter integrity of non-silicone catheters (e.g. polyurethane catheters).\(^13\),\(^17\) (Class IIa, Level C)

6.4.4. It is reasonable to aspirate and discard ethanol ALT from the catheter lumen and at the end of the dwell, and catheter should be flushed with 0.9% sodium chloride.\(^13\),\(^17\) (Class IIa, Level C)

6.5. Gentamicin

6.5.1. Gentamicin precipitates at a concentration of 10mg/mL or higher when mixed with heparin.\(^18\)

6.6. Vancomycin

6.6.1. In vancomycin ALT solution, it is reasonable that the vancomycin concentration be at least 1000 times greater than the MIC of the microorganism involved.\(^10\) (Class IIa, Level B)

7. ALT Preparation
7.1. To maximize the sterility and stability of the ALT, it is reasonable to prepare all ALT aseptically in a pharmacy when feasible.\textsuperscript{10} (Class IIa, Level A)

**Benefits/Harms of Implementation**

1. Potential benefits of use of anti-infective lock therapy in appropriately selected patients include improved patient outcomes and decreased healthcare costs by reducing infectious complications associated with intravascular catheter use and the need to for catheter replacement.\textsuperscript{9,10}

2. Potential harms include the potential for adverse drug events and the emergence of microbial resistance.\textsuperscript{9,10}

**Implementation Tools/Plan**

1. Development and build of medication records (ERx) and an order set to facilitate ordering, dispensing and administration for common ALT regimens.

2. CPG will be hyperlinked to ALT solution medication records (ERx).

**Disclaimer**

This Clinical Practice Guideline provides an evidence-based approach for use of anti-infective lock therapy for the prevention and treatment of catheter-related infections. It is understood that occasionally patients will not match the conditions considered in the guideline.

**References**


Appendix 1. Non-hemodialysis ALT preparations available at UWHC

<table>
<thead>
<tr>
<th>Lock</th>
<th>Base Solution</th>
<th>Record Number in HealthLink</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ciprofloxacin 2 mg/mL(^{15, A})</td>
<td>D5W</td>
<td>760332</td>
<td></td>
</tr>
<tr>
<td>Ceftazidime 2 mg/mL and heparin 100 units/mL(^{12,19})</td>
<td>Normal saline</td>
<td>760299</td>
<td></td>
</tr>
<tr>
<td>Daptomycin 1 mg/mL and heparin 100 units/mL(^{20, A})</td>
<td>Lactated Ringers</td>
<td>760356</td>
<td>• Not available at UWHC&lt;br&gt;• Available for ambulatory through Chartwell Midwest Wisconsin</td>
</tr>
<tr>
<td>Daptomycin 5 mg/mL(^{16,21})</td>
<td>Lactated Ringers</td>
<td>N/A</td>
<td>• Do not use with polyurethane catheters&lt;br&gt;• Incompatible with heparin and sodium citrate</td>
</tr>
<tr>
<td>Ethanol 50% (v/v)(^{5,17,22-28})</td>
<td>Sterile water</td>
<td>760301</td>
<td></td>
</tr>
<tr>
<td>Ethanol 70% (v/v)(^{5,17,22-28})</td>
<td>Sterile water</td>
<td>760352</td>
<td></td>
</tr>
<tr>
<td>Vancomycin 2 mg/mL and heparin 100 units/mL(^{15})</td>
<td>Normal saline</td>
<td>760303</td>
<td></td>
</tr>
<tr>
<td>Vancomycin 2 mg/mL and heparin 20 units/mL(^{15})</td>
<td>Normal saline</td>
<td>760304</td>
<td></td>
</tr>
</tbody>
</table>

\(^{A}\) Note: not available through Chartwell Midwest Wisconsin home infusion services
## Appendix 2. Hemodialysis (HD) ALT preparations available at UWHC A, B

<table>
<thead>
<tr>
<th>Lock</th>
<th>Base Solution</th>
<th>Record Number in HealthLink</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftazidime 10 mg/mL and heparin 5000 units/mL (HD)(^{12,31})</td>
<td>Normal saline</td>
<td>760298</td>
</tr>
<tr>
<td>Daptomycin 1 mg/mL and heparin 1000 units/mL (HD)(^{20})</td>
<td>Lactated Ringers</td>
<td>760355</td>
</tr>
<tr>
<td>Gentamicin 1 mg/mL and heparin 2500 units/mL (HD)(^{18})</td>
<td>Normal Saline</td>
<td>760302</td>
</tr>
<tr>
<td>Gentamicin 2.5 mg/mL and 4% sodium citrate (40 mg/mL) (HD)(^{32})</td>
<td>No base</td>
<td>760334</td>
</tr>
<tr>
<td>Vancomycin 2.5 mg/mL and heparin 2500 units/mL (HD)(^{18})</td>
<td>Normal Saline</td>
<td>760305</td>
</tr>
<tr>
<td>Vancomycin 3 mg/mL and 4% mg sodium citrate(40 mg/mL) (HD)(^{33})</td>
<td>No base</td>
<td>760336</td>
</tr>
</tbody>
</table>

A Note: Chartwell Midwest Wisconsin does not provide any HD ALT preparations

B ALT for HD include anticoagulant of high-dose heparin (1000 units/mL or greater) or sodium citrate (40 mg/mL)
### Appendix 3. ALT preparations available from Chartwell Midwest Wisconsin home infusion services for central lines (May 2015)

<table>
<thead>
<tr>
<th>Lock</th>
<th>Base Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefazolin 0.5 mg/mL and heparin 100 units/mL</td>
<td>Normal saline</td>
</tr>
<tr>
<td>Cefazolin 10 mg/mL and heparin 10 units/mL</td>
<td>Normal saline</td>
</tr>
<tr>
<td>Ceftazidime 0.5 mg/mL and heparin 100 units/mL</td>
<td>Normal saline</td>
</tr>
<tr>
<td>Ceftazidime 2 mg/mL and heparin 100 units/mL</td>
<td>Normal saline</td>
</tr>
<tr>
<td>Ciprofloxacin 0.125 mg/mL and heparin 100 units/mL</td>
<td>Normal saline</td>
</tr>
<tr>
<td>Daptomycin 5 mg/mL</td>
<td>Lactated Ringers</td>
</tr>
<tr>
<td>Daptomycin 5 mg/mL and heparin 100 units/mL or heparin 10 units/mL</td>
<td>Lactated Ringers</td>
</tr>
<tr>
<td>Ethanol 50%</td>
<td>Sterile water</td>
</tr>
<tr>
<td>Ethanol 70%</td>
<td>Sterile water</td>
</tr>
<tr>
<td>Vancomycin 25 mcg/mL, ciprofloxacin 0.002 mg/mL and heparin 10 units/mL</td>
<td>Normal saline</td>
</tr>
<tr>
<td>Vancomycin 50 mcg/mL, ciprofloxacin 0.002 mg/mL and heparin 10 units/mL</td>
<td>Normal saline</td>
</tr>
<tr>
<td>Vancomycin 0.5 mg/mL and heparin 100 units/mL</td>
<td>0.45% saline</td>
</tr>
<tr>
<td>Vancomycin 25 mcg/mL and heparin 10 units/mL</td>
<td>Normal saline</td>
</tr>
<tr>
<td>Vancomycin 2 mg/mL and heparin 10 units/mL</td>
<td>Normal saline</td>
</tr>
<tr>
<td>Vancomycin 2 mg/mL and heparin 100 units/mL</td>
<td>Normal saline</td>
</tr>
<tr>
<td>Vancomycin 2 mg/mL and heparin 20 units/mL</td>
<td>Normal saline</td>
</tr>
</tbody>
</table>