American Society for Parenteral and Enteral Nutrition Guidelines for the Selection and Care of Central Venous Access Devices for Adult Home Parenteral Nutrition Administration

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Abstract
This document represents the American Society for Parenteral and Enteral Nutrition (ASPEN) clinical guidelines to describe best practices in the selection and care of central venous access devices (CVADs) for the infusion of home parenteral nutrition (HPN) admixtures in adult patients. The guidelines targeted adults >18 years of age in which the intervention or exposure had to include HPN that was administered via a CVAD. Case studies, non-English studies, or studies of CVAD no longer available in the United States were excluded. In total, 564 abstract citations, 350 from Medline and 214 from PubMed/non-MEDLINE databases, were scanned for relevance. Of the 564 citations, 13 studies addressed at least 1 of the 6 guideline-related questions, and none of the studies were prospective and randomized. The Grading of Recommendations, Assessment, Development and Evaluation (GRADE) criteria were used to adjust the evidence grade based on assessment of the quality of study design and execution. Recommendations for the CVAD type, composition, or number of lumens to minimize infectious or mechanical complications are based on a limited number of studies and expert opinion of the authors, all very experienced in home infusion therapy. No studies were found that compared best solutions for routine flushing of lumens (eg, heparin versus saline) or for maintaining catheters in situ while treating CVAD mechanical or infectious complications. It is clear that studies to answer these questions are very limited, and further research is needed. These clinical guidelines were approved by the ASPEN Board of Directors. (JPEN J Parenter Enteral Nutr. 2019;43:15–31)

Keywords
adults; antibiotic locks; catheter flushing; catheter related blood stream infection; catheter salvage; central line associated blood stream infection; central venous access device; central venous access device lumens; central venous access device types; central venous access material; ethanol locks; guidelines; home parenteral nutrition

Preliminary Remarks (Intent of Guidelines)
This document represents the American Society for Parenteral and Enteral Nutrition (ASPEN) Clinical Guidelines to describe best practices in the selection and care of central venous access devices (CVADs) for the infusion of home parenteral nutrition (HPN) solutions in the adult patient.

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Financial disclosure: There was no funding or contribution from industry, nor were any industry representatives present at any of the committee meetings.

Conflicts of interest: All authors completed both the ASPEN conflict of interest form for copyright assignment and financial disclosure. The authors of these guidelines have reported all potential conflicts or financial disclosures.

Received for publication September 10, 2018; accepted for publication September 11, 2018.

This article originally appeared online on October 19, 2018.

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The mission of ASPEN is to improve patient care by advancing the science and practice of clinical nutrition and metabolism.

**Guideline Limitations**

These ASPEN Clinical Guidelines are based on general consensus among a group of professionals who, in developing such guidelines, have examined the available literature on the subject and balanced potential benefits of nutrition practices against risks inherent with such therapy. These practice guidelines are not intended as absolute policy statements. Use of these practice guidelines does not in any way guarantee any specific benefit in outcome or survival. The professional judgment of the attending health professional is the primary component of quality medical care delivery. Since guidelines cannot account for every variation in circumstances, practitioners must always exercise professional judgment when applying these recommendations for individual patients. These Clinical Guidelines are intended to supplement, but not replace, professional training and judgment.

The guidelines reflect an exhaustive search of the research literature for evidence about the best practices related to CVADs used in the care of adult HPN patients. Many of the reports excluded from analyses were anecdotal, describing diverse experiences of heterogeneous groups of HPN patients without data to address the guideline questions. Studies addressing the guideline questions were analyzed and used to develop recommendations. Recommendations reflect a review and analysis of the current literature and a blend of expert opinion and clinical practicality. The population of adult home patients receiving parenteral nutrition (PN) is not homogeneous. These guidelines represent a review of published research through September 9, 2017, about the selection and care of CVADs. All of the reviewed studies were observational; no prospective randomized clinical trials were found that addressed questions about CVADs used for HPN.

A comprehensive search of the medical literature yielded 13 prospective or retrospective cohort studies that provided data about CVADs used for HPN administration in adults. Study quality and data were critically reviewed by a group of multidisciplinary experts in clinical nutrition composed of nurses, dietitians, and a biostatistician. These individuals used the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) methodology to develop consensus-derived recommendations.³

**Methods**

The GRADE process was used to develop key questions and plan data acquisition and conflation for these guidelines.³ The task force of experts began by defining language used for the routine care and complications associated with CVADs and keywords to be used for the literature search. This was followed by: 1) development of the key questions that were the focus of this clinical guideline; 2) establishing a time frame that would be used for the literature search; 3) determining the target population (inclusion and exclusion criteria); and 4) establishing the specific outcomes that would be addressed. Ultimately, 6 questions were developed by the guideline experts and approved by the ASPEN Board of Directors. These questions and their recommendations are summarized in Table 1.

All included studies were prospective or retrospective investigations of clinical outcomes tailored to address specific questions. The GRADE criteria were used to adjust the evidence based on assessment of the quality of study design and execution. The GRADE approach separates the evidence compiled from the recommendation statements, enabling independent assessment of the weight of the risks versus (vs) the benefits that occur from adopting the recommendation. All recommendations that were based solely on expert opinion were deemed as very low. Table 2 describes the standard language and rationale for the grade assigned to a recommendation.

The Centers for Disease Control (CDC) and the Infusion Nurses Society (INS) have guidelines and standards that include the insertion, maintenance, care, and surveillance monitoring for CVAD complications (https://www.cdc.gov/infectioncontrol/guidelines/bsi/updates.html). Their recommendations are based on the strength of the study design. They include information regarding some of the questions that were identified in these guidelines. However, the majority of their focus is based heavily on the acute care setting rather than care in the home. Establishing guidelines for use in the home creates unique challenges as care is provided by patients and caregivers with little or no medical background, and the environment, supplies, equipment, and reimbursement are different compared with hospital settings.

**Definition**

Home nutrition support therapy refers specifically to the provision of parenteral PN through a CVAD in a homecare setting.

**Target Patient Population for Guidelines**

The target of these guidelines is to determine the type of CVAD that is associated with the lowest occurrence of infectious and mechanical complications in adult (>18 years of age) patients receiving HPN. Studies that evaluated pediatric HPN and inpatient PN populations were excluded. These guidelines are directed toward generalized outpatient populations but, like any other management strategy, the infusion therapy selected should be tailored to the individual patient.
Table 1. Guidelines for the Selection and Care of CVADs for Adult HPN Administration.

<table>
<thead>
<tr>
<th>Questions and Recommendations</th>
<th>Evidence/GRADE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1. Does the type of CVAD (tunneled, implanted, or PICC) influence CLABSI rates?</td>
<td>Quality of Evidence: low</td>
</tr>
<tr>
<td>R1. Based on observational studies and expert consensus, we suggest tunneled CVADs should be selected for adult patients anticipated to require long-term daily PN infusions. If the duration of HPN is uncertain or of short duration (&lt;30 days), PICCs may be used.</td>
<td>GRADE: weak</td>
</tr>
<tr>
<td>Q2. Does the number of CVAD lumens impact CLABSI rates?</td>
<td>Quality of Evidence: very low</td>
</tr>
<tr>
<td>R2. Based on 1 observational study and expert opinion, we suggest using the fewest number of lumens required for individual patient therapy.</td>
<td>GRADE: weak</td>
</tr>
<tr>
<td>Q3. Does the type of CVAD material influence CLABSI rates?</td>
<td>Quality of Evidence: very low</td>
</tr>
<tr>
<td>R3. We cannot make a recommendation at this time regarding CVAD composition to minimize infection.</td>
<td>GRADE: further research is needed</td>
</tr>
<tr>
<td>Q4. What is the best CVAD for minimizing mechanical complications?</td>
<td>Quality of Evidence: low</td>
</tr>
<tr>
<td>R4. Based upon observational cohort studies, the risk for mechanical complications does not differ by the type of CVAD. The choice of CVAD should be selected based upon length of therapy, patient choice, and the ability of the patient/caregiver to care for the CVAD.</td>
<td>GRADE: low</td>
</tr>
<tr>
<td>Q5. Should antimicrobial/ethanol locks be used versus standard care for treating or preventing CVAD infections?</td>
<td>Quality of Evidence: low</td>
</tr>
<tr>
<td>R5. No recommendation can be made at this time.</td>
<td>GRADE: weak</td>
</tr>
<tr>
<td>Q6. Should saline or heparin locks be used for CVAD maintenance?</td>
<td>Quality of Evidence: very low</td>
</tr>
<tr>
<td>R6. No recommendations can be made as to which flush solution should be used to maintain patency for HPN CVADs due to the lack of studies.</td>
<td>GRADE: expert opinion</td>
</tr>
</tbody>
</table>

CLABSI, central line–associated blood stream infection; CVAD, central venous access device; GRADE, Grading of Recommendations, Assessment, Development and Evaluation; HPN, home parenteral nutrition; PICC, peripherally inserted central catheter; PN, parenteral nutrition.

Table 2. Language for Guidelines Recommendations.

<table>
<thead>
<tr>
<th>Quality of Evidence</th>
<th>Weighing Risks Versus Benefits</th>
<th>Grading of Recommendations, Assessment, Development and Evaluation Recommendations</th>
<th>Clinical Guideline Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>High to very low</td>
<td>Net benefits outweigh harms</td>
<td>Strong</td>
<td>We recommend</td>
</tr>
<tr>
<td>High to very low</td>
<td>Tradeoffs for patient are important</td>
<td>Weak</td>
<td>We suggest</td>
</tr>
<tr>
<td>High to very low</td>
<td>Uncertain tradeoffs</td>
<td>Further research needed</td>
<td>We cannot make a recommendation at this time.</td>
</tr>
</tbody>
</table>

Target Audience

These guidelines are intended for use by all healthcare providers involved in nutrition support of the home patient receiving PN, primarily physicians, nurses, dietitians, and pharmacists. These guidelines may also be helpful to patients and their caregivers to assist them in the selection of a CVAD.

Literature Search Methodology

The PubMed/MEDLINE databases were searched through September 9, 2017, for relevant citations. To be included in our search results, citations had to be indexed in the “Catheters” and “Humans” MeSH folders as well as either the “Parenteral Nutrition, Home” or “Home infusion therapy” MeSH folders. Then, the non-MEDLINE PubMed
devices (VADs), PICCs, and tunneled catheters, each with unique risks (Table 3). The most common complications for HPN therapy are CVAD mechanical complications and central line–associated bloodstream infections (CLABSIs).

Introduction

HPN therapy requires patients to have a CVAD. Data obtained from ASPEN's National Patient Registry for Nutrition Care (Sustain) found the duration of HPN therapy varies from 3 months–34 years for adults. The appropriate CVAD that will accommodate these variable time intervals is essential to minimize complications and frequent access changes. Additionally, prior to selection of the CVAD, the contents of the HPN solution and patient and caregiver preference as well as the ability to care for and monitor for complications all need to be considered. The CVADs used for HPN infusion include implanted infusion venous access devices (VADs), PICCs, and tunneled catheters, each with unique risks (Table 3). The most common complications for HPN therapy are CVAD mechanical complications and central line–associated blood stream infections (CLABSIs).

During the early years of HPN, removal of the CVAD was advocated for mechanical problems, such as clotting due to improper flushing when patency could not be resolved as well as for CLABSI. Treatment following CVAD removal for CLABSI was typically followed by the administration of several days of intravenous antibiotics. Re-insertion of the CVAD was only considered once the infection was resolved.

The expansive duration of HPN (ranging from months–decades) has shifted the focus of care to salvaging rather than removing the CVAD. Salvaging a long-term catheter is defined as trying to save or keep the catheter in place while treating mechanical or infectious complications. These can range from mechanical repair of a broken tunneled catheter to a full course of IV antibiotics to treat a catheter infection. This salvaging is beneficial to the patient as every CVAD insertion limits the number of remaining viable veins that can be used to reinsert a new CVAD in the future. Infusion of concentrated antibiotics sensitive to the offending organisms into the CVAD lumen was one of the first alternatives used to avoid venous access removal. To limit risks of antibiotic resistance and systemic toxic effects, the CDC Catheter Guidelines recommend prophylactic antibiotic lock solutions only in patients with long-term CVADs who have a history of multiple CLABSIs despite optimal maximum adherence to aseptic technique. However, antibiotics may not adequately infiltrate the biofilm, a substance that allows microbial colonization along CVAD surfaces when in situ. This led to the treatment of CLABSI with concentrated ethanol as it has the ability to penetrate the biofilm and is bactericidal as well as fungicidal. These properties have led many clinicians to use ethanol for treatment as well as prophylaxis in HPN populations.

The goals of HPN care are to 1) teach patients to become independent in their care, 2) keep patients in their home, and 3) maintain their quality of life by avoiding hospitalizations or unnecessary resource utilization needed to treat CVAD complications. To achieve these goals, clinicians must be knowledgeable in regard to the best CVAD on the market and the most effective treatment options that minimize risk of mechanical or infectious complications. Therefore, the recommendations provided in this guideline are tailored to address these issues and provide a science-based starting point for individualized HPN therapy.

**Question 1: Does the type of CVAD (tunneled, implanted, or PICC) influence CLABSI rates? (See Table 4.)**

**Recommendations 1.** Based on observational studies and expert consensus, we suggest tunneled CVADs should be selected for adult patients anticipated to require long-term daily PN infusions. If the duration of HPN is uncertain or of short duration (ie, <31 days), PICCs may be used.

**Quality of Evidence:** Low

**GRADE Recommendation:** Weak

**Rationale 1:** No randomized controlled trials were found that addressed this question. Nine observational studies...
Table 3. Types of Central Vascular Access Devices for HPN.

<table>
<thead>
<tr>
<th>Type</th>
<th>Dwell Time</th>
<th>Therapeutic Applications</th>
<th>PN Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>PICCs</td>
<td>Maximum dwell time is unknown.</td>
<td>Suitable for acute care and short-term and medium-term PN for adults and pediatric patients</td>
<td>Associated with an increased risk for deep vein thrombosis, limiting use for indefinite PN therapy and situations where vessel preservation is a priority. Antecubital location of exit site hinders self-care and activity. Clothing may not always cover insertion site, potentially having a negative impact on body image; may be easily removed when infected or PN is no longer needed.</td>
</tr>
<tr>
<td>Tunneled CVADs</td>
<td>3 months–years</td>
<td>Suitable for long-term PN; the presence of a cuff within the tunnel inhibits microbial migration and decreases risk of dislodgement.</td>
<td>No restrictions on upper extremity activity; position on chest facilitates self-care; VAD can be easily hidden under clothing.</td>
</tr>
<tr>
<td>(Hickman, Broviac, Hohn types)</td>
<td></td>
<td>Primarily intended for low-frequency, intermittent access. Associated with lowest risk for CLABSI due to reduced manipulation.</td>
<td>Suitable for PN in selected circumstances; motivated patients can learn access procedures; body image remains intact; requires no local site care when device is not accessed. PN may increase risk for CLABSI and occlusion in children with cancer.</td>
</tr>
<tr>
<td>Implanted ports</td>
<td>6 months–years</td>
<td></td>
<td></td>
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</table>

Adapted with permission from the American Society for Parenteral and Enteral Nutrition.28 CLABSI, central line–associated blood stream infection; CVAD, central venous access device; HPN, home parenteral nutrition; PICC, peripherally inserted central catheter; PN, parenteral nutrition; VAD, venous access device.

were found that compared CLABSI and types of CVAD.7–13 An observational study of severely ill cancer patients compared CLABSI rates in tunneled, implanted, or PICC CVADs, and found no significant difference between the groups even though implanted ports had a longer dwell time.7 Severity of illness was not controlled for and may have been a factor contributing to the non-significant differences among the catheter groups.

Four studies compared CLABSI rates in patients with tunneled vs implanted CVADs (not PICC).8–10,12 Three reported significantly higher rates of infections in patients with implanted CVADs.8–10 Two of these studies8,9 noted a higher proportion of cancer patients with implanted catheters compared with tunneled catheters, suggesting the higher infection rates observed may be due to the underlying disease, immunosuppression, and/or the use of implanted CVADs. Buchman et al10 found higher rates of infections for implanted CVADs in a cohort of patients that predominantly had intestinal failure (IF) as their primary diagnosis rather than cancer. In a small case-series study of 6 severely ill cancer patients that first received a tunneled CVAD followed by an implanted CVAD, a higher rate of infection was reported in patients with tunneled CVADs.12 Due to the very small sample size and sampling on the dependent variable, it is difficult to draw any conclusion from this study.

In addition to Cotogni et al,7 3 other studies compared CLABSI rates in tunneled vs PICC CVADs.11,13,14 Christenson and associates and Bech and associates appeared to analyze the same dataset of Danish HPN patients, and while different questions were asked, similar results were found. Christensen et al14 reported higher CLABSI rates for PICC compared with tunneled CVADs and a shorter time to first infection (84 ± 94 days vs 297 ± 387 days; P < .05). After controlling for environmental factors, Bech et al11 reported identical time to first infection (83.91 ± 93.8 vs 297.2 ± 386.9 days; P < .001) that was more significant. Toure and associates13 found higher rates of infections for the tunneled vs PICC CVADs; however, shorter median time to first infection occurred in the PICC group (60 vs 134 days; P = .008). Patients in the tunneled group received HPN prior to entry in the study; thus, this “greater unaccounted for exposure time” likely biased these results. Additionally, almost a third of patients in both groups were receiving taurolidine citrate locks, suggesting some or all were at higher risk of infection.

Ross et al15 described CLABSI rates in 1046 HPN patients from a national cohort of patients in the United States of which 13.2% were <18 years of age. They found patients with tunneled or implanted CVADs experienced higher infection rates (0.51 and 0.66/total PN days, respectively) than those with PICCs (0.41/total PN days). Children experienced a higher rate of infection compared with adults; however, their reported infection rates by catheter type include both children and adults, which precluded inclusion of this study in our analyses.
Table 4. Question 1: Does the type of CVAD (tunneled, implanted, or PICC) influence CLABSI rates?

Rules for Tables 4–8: Within each question, studies are listed in chronologic order with the newest studies placed first. When there was >1 study in a given year, studies were placed in alphabetic order according to the author’s last name.

<table>
<thead>
<tr>
<th>Reference</th>
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<th>Study Aim(s)</th>
<th>Population, Setting, N</th>
<th>Results/Outcome</th>
<th>Comments</th>
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</table>
| Christensen et al14 | Retrospective cohort | Compared complication rates of tunneled CVADs and PICCs in 1 Danish Center   | 136 adult HPN patients Total of 295 CVADs; 169 tunneled CVADs and 126 PICCs | CLABSI 0.57/1000 catheter days in tunneled CVADs group compared with 1.63 in PICC group \((P = .0001)\)  
Local infection higher in PICC group vs tunneled CVADs \((1.00 vs. 0.24/1,000 CVAD days, \(P = .000)\)  
Mean time to first CLABSI higher in tunneled CVADs than PICCs \((297 \pm 387 \text{ days versus } 84 \pm 94 \text{ days, } P < .05)\) | Unclear if CLABSI was defined for tunneled CVADs at the time of catheter removal or symptoms of infection.  
Unclear that when tunneled CVADs developed infection, was the CVAD treated in situ. This could have resulted in a lower than actual infection rate.  
PICCs were inserted when patient not able to care for the CVAD.  
Patients who had an acute condition, metabolically unstable requiring IV supplementation over limited period of time more often received a PICC.  
There was no mention why 311 patients did not meet the inclusion criteria.  
The authors reported a total of 77 CLABSIs, but only 67 were included in the analysis.  
Patients did not keep a log in the home about if a homecare nurse or the patient performed CVAD care. |
| Bech et al11     | Retrospective cohort | Investigated whether environmental risk factors influenced the time to first CVAD-related infection | Adult HPN patients Total of 295 CVADs in 136 patients | Incidence of infections/1000 CVAD days was significantly increased in the PICC group \((1.43 \pm 0.20)\) compared with \(0.95 \pm 0.39\) in the tunneled CVAD group  
Mean number of days to first infection was significantly decreased in the PICC group vs in the tunneled CVADs group \((297.21 \pm 386.91 \text{ vs } 83.91 \pm 93.754, \text{ respectively})\)  
Environmental factors: the number of infusion days per week, colectomy with stoma, smoking, if a homecare nurse managed the CVAD care, and an elevated C-reactive protein at time of insertion was not statistically significant among the 2 groups  
Mean CLABSI incidence significantly increased in the tunneled CVADs group if the CVAD was managed by a homecare nurse compared with those who were not \((1.45 \pm 0.68 \text{ vs } 0.56 \pm 0.24/1000 \text{ CVAD days})\)  
Time to first infection decreased CLABSI in the PICC group by a factor of 2.47 with 1 additional infusion day/week. | There was no mention why 311 patients did not meet the inclusion criteria.  
The authors reported a total of 77 CLABSIs, but only 67 were included in the analysis.  
Patients did not keep a log in the home about if a homecare nurse or the patient performed CVAD care. |
Table 4. (continued)

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<tbody>
<tr>
<td>Toure et al</td>
<td>Prospective</td>
<td>A comparative study of peripherally inserted and tunneled CVAD complications</td>
<td>196 adult HPN patients; 133 tunneled CVADs and 71 PICCs</td>
<td>CLABSI rate for tunneled CVADs was 1.87/1000 CVAD days and 1.05 for PICCs; Median number of days to first CVAD complication was 134 (16–674) for tunneled CVADs and 60 (25–125) days for PICCs; Taurolidine-citrate locks were used in 35.4% of the tunneled CVADs and 36.62% of the PICCs from the day of insertion.</td>
<td></td>
</tr>
<tr>
<td>Buchanan et al</td>
<td>Retrospective</td>
<td>Determined the risk factors for CLABSI in HPN patients.</td>
<td>Adult (N = 125) and pediatric (N = 18) HPN patients; Total of 331 CVADs; 268 were tunneled and 63 implanted ports</td>
<td>CLABSI significantly higher in the implanted port group than in the tunneled group (0.66 and 0.32/1000 CVAD days, respectively; Pediatric population data was included, but the groups were compared separately and the data were separated for adults versus children.</td>
<td></td>
</tr>
<tr>
<td>Cotogni et al</td>
<td>Prospective,</td>
<td>Investigated CVAD complications in cancer patients with 4 types of VADs (PICC, Hohn, tunneled CVAD, implanted ports)</td>
<td>254 adult HPN patients; 289 CVADs; 65 PICCs, 107 Hohns, 45 tunneled CVADs, 72 implanted ports</td>
<td>No statistical differences between the 4 types of CVADs for local infection, CLABSI/1000 CVAD days or /1000 HPN days; Multivariate analysis demonstrated PICC CLABSI rate significantly lower when compared with Hohn and tunneled CVADs and for implanted ports compared with Hohn and tunneled CVADs; High mortality rate (210 of 289 patients died).</td>
<td></td>
</tr>
</tbody>
</table>

(continued)
Table 4. (continued)

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</tr>
</thead>
<tbody>
<tr>
<td>Guglielmi et al (^9)</td>
<td>Prospective cohort</td>
<td>Described the long-term HPN frequency of complications both in adult cancer and non-cancer patients</td>
<td>270 adult HPN patients</td>
<td>Incidence of sepsis in cancer patients was 0.71/1000 CVAD days who had implanted ports inserted compared with 0.46 in non-cancer patients who had tunneled CVADs. Local skin infections were 0.03/1000 CVAD days in the tunneled CVAD non-cancer group, and 0.01/1000 CVAD days in the cancer implanted port group.</td>
<td>Different CVAD types in cancer and non-cancer patients. CLABSI not defined. HPN protocols were different between the 2 groups. Patient training program was shortened to 3 days in the cancer group compared with 7–14 days; periodic home nurse follow-up visits were not conducted, and the PN solution bag was premixed compared with a personalized mixture. Survival curves between the 2 groups was statistically significant. No definition given for local skin infection or if the results were reported in CVAD or HPN days.</td>
</tr>
<tr>
<td>Santarpia et al (^8)</td>
<td>Retrospective, cohort</td>
<td>CLABSI in oncology vs non-oncology patients, CLABSI by type of CVAD (totally implanted vs partially implanted tunneled CVAD)</td>
<td>Adult HPN patients (N = 296)</td>
<td>Infection rates significantly lower in partially implanted tunneled CVADs compared with totally implanted ports.</td>
<td>CVAD days not available by type of CVAD. More patients with oncology diagnosis than non-oncology.</td>
</tr>
<tr>
<td>Gaggioti et al (^12)</td>
<td>Retrospective HPN crossover</td>
<td>Compared implanted ports and tunneled silicone CVADs</td>
<td>6 adult HPN patients; All 6 previously had a silicone tunneled CVAD and changed to an implanted port</td>
<td>Tunneled CVAD sepsis rate was 3.3/1000 days compared with 0.9/1000 CVAD days in the implanted port.</td>
<td>Authors did not state if the 1000 days were CVAD or HPN days. No statistics given in the paper. Small study group.</td>
</tr>
</tbody>
</table>

CLABSI, central line-associated blood stream infection; CVAD, central venous access device; HPN, home parenteral nutrition; IV, intravenous; PICC, peripherally inserted central catheter; VAD, venous access device; vs, versus.
In summary, 8 studies comparing different CVAD types found lower infection rates in patients with tunneled CVADs compared with implanted or PICC CVADs, and when reported, longer time to first infection suggesting tunneled CVADs may be preferable for patients expected to require HPN over a long period of time. Only 1 study that included both adults and pediatric patients found PICCs to experience lower rates. The impact of the concomitant use of implanted CVADs used for HPN and chemotherapy remains unknown.

**Question 2. Does the number of CVAD lumens influence CLABSI rates? (See Table 5.)**

**Recommendation 2.** Based on 1 observational study and expert opinion, we suggest using the fewest number of lumens required for individual patient therapy.

**Quality of Evidence:** Very Low

**GRADE Recommendation:** Weak

**Rationale 2:** Both the CDC and INS recommend selection of CVADs with the fewest number of lumens. In our more narrow search of adult HPN patients, we found 1 retrospective observational study comparing the number of CVAD lumens for risk of CLABSI. This study compared infection rates in HPN patients from 1 homecare provider in patients with single-lumen, double-lumen, and triple-lumen tunneled CVADs. Significantly lower CLABSI rates occurred in patients with a single-lumen CVAD, followed by the double lumen. Triple-lumen CVADs had the highest CLABSI rate (0.31 vs 0.7 vs 0.87/1000 CVAD days, respectively; \( P = .001 \)).

In summary, insertion of a CVAD with the fewest number of lumens to accommodate the patient’s clinical status reduces the number of manipulations required for flushing pre-HPN and post-HPN and medication administration. CVADs with fewer lumens reduce the number of opportunities for contamination, are more economical, and require less maintenance for patients and caregivers. Further, it is highly unlikely restricting the catheter to the fewest lumens needed to provide care will result in any increase in harm.

**Question 3. Does the type of CVAD material influence CLABSI rates? (See Table 6.)**

**Recommendation 3.** We cannot make a recommendation at this time regarding CVAD composition to minimize infection.

**Quality of Evidence:** Very Low

**GRADE Recommendation:** Further research is needed

**Rationale 3:** Per the information presented in the CDC guidelines, due to their surface irregularities, the type of VAD material plays an important role in the development of CLABSI. These irregularities are thought to heighten the ability of microorganisms to adhere and attach to the surface. VADS manufactured with silicone have been shown to have higher risks of CLABSI compared with polyurethane. In our narrower search, including exclusively adult HPN patients, only 1 study compared the role of CVAD composition with CLABSI. No statistical significance was found in this prospective, non-randomized study of 40 silicone and 13 polyurethane CVADs in 42 patients. Only CVADs manufactured with silicone and polyurethane were included in the study.

To summarize, different CVAD materials may be more susceptible to the development of fibrin sheaths and biofilms that form within the CVAD lumen and the CVAD itself. Tunneled and implanted ports are made of silicone, which may lend itself to increase infection rates compared with PICCS manufactured with polyurethane.

**Question # 4: What is the best CVAD for minimizing mechanical complications? (See Table 7.)**

**Recommendation 4:** Based upon 6 observational cohort studies, the risk for mechanical complications does not differ by the type of CVAD. Therefore, the choice of CVAD should be selected based upon length of therapy, patient choice, and the ability of the patient/caregiver to care for the CVAD.

**Quality of Evidence:** Low

**GRADE Recommendation:** Low

**Rationale 4:** A number of factors related to the CVAD type, size, material, and placement technique are hypothesized to contribute to mechanical complications of CVADs in patients receiving HPN; however, investigations in this area are limited.

When comparing polyurethane vs silicone CVADs, Beau and colleagues found no significant difference in catheter CVAD obstruction or thrombosis among patients with short bowel syndrome (SBS). Additionally, Toure et al. found no significant difference in the incidence of non-infectious CVAD complications/1000 patient days in patients with SBS or Crohn’s disease receiving HPN via a PICC or tunneled CVAD. The first complication occurred later in patients with a tunneled CVAD; however, this difference was not significant (180.2 ± 154.7 days vs 118.1 ± 129.3 days; \( P = .09 \)).

Guglielmi et al. compared the differences of HPN complications in 270 patients with and without cancer. Cancer patients received HPN via implanted ports; HPN was delivered via tunneled CVADs in the non-cancer participants. No significant difference in incidence rates of mechanical complications occurred between these groups (0.28 vs 0.91/1000 CVAD days; not significant). Christensen et al. also evaluated mechanical complications in IF patients requiring HPN through a PICC or tunneled CVAD. Unfortunately, the material, brand, and size of the PICCs used did not remain constant during the study (silicone 4F Groshong PICC vs 5F polyurethane PICC), limiting interpretation of the findings. Patients with type II IF more often received a PICC, whereas long-term HPN patients with type III IF received tunneled CVADs. The authors defined type II IF as patients who had a prolonged acute condition, metabolically unstable, requiring intravenous therapy over a limited period of time.
Table 5. Question #2: Does the number of CVAD lumens impact CLABSI rates?

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study Design</th>
<th>Study Aim(s)</th>
<th>Population, Setting, N</th>
<th>Results/Outcome</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>Buchman et al[10]</td>
<td>Retrospective cohort</td>
<td>Determined the risk factors for CLABSI in HPN patients.</td>
<td>Adult (N = 125) and pediatric (N = 18) HPN patients Total of 331 CVADs; 268 of which were tunneled and 63 implanted ports</td>
<td>CLABSI significantly higher in the implanted port group than in the tunneled group (0.66 and 0.32/1000 CVAD days, respectively)</td>
<td>Pediatric population data was included but the groups were compared separately for adults versus children.</td>
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</table>

CLABSI, central line–associated blood stream infection; CVAD, central venous access device; HPN, home parenteral nutrition.

Table 6. Question #3: Does the type of CVAD material influence CLABSI rate?

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>Beau et al[17]</td>
<td>Cohort, prospective</td>
<td>Compared experience of long-term complications with polyurethane (LeaderCuff/VYGON) and silicone (Lifevac/VYGON) tunneled, cuffed CVADs</td>
<td>Adult HPN patients N = 53 CVADs in 42 patients</td>
<td>There were no obstructions reported in the polyurethane group and 0.05/patient year of HPN in the silicone group Dislodgement and thrombosis/patient year of HPN not statistically significant Fracture and hub dysfunction higher in the polyurethane group (0.5/patient year of HPN) than the silicone group (0.03/patient year of HPN)</td>
<td>Years of recruitment varied between the 2 groups. Practice may have changed between 1991–1998. More patients in the silicone CVAD group (N = 31) as well as CVADs (N = 40) compared with the polyurethane group with 11 patients and 13 CVADs. Measurement done per patient year of HPN.</td>
</tr>
</tbody>
</table>

Period of time, and type II patients were those with a chronic condition, metabolically stable requiring PN over months to years. Mechanical complications leading to CVAD removal was significantly higher in the PICC group (0.60 vs 1.5; \( P = .0011 \)).

Cotogni and colleagues\[7\] prospectively observed CVAD complications in cancer patients with 4 types of VADs (PICC, Hohn PICC, tunneled, and implanted ports). Mechanical complications were 0.8/1000 catheter days. The Hohn CVAD experienced a significantly higher rate of catheter dislocation than the tunneled or PICC. The Hohn catheter is infrequently used in HPN patients in the United States.

In summary, based on these 6 studies when mechanical complications did occur, it appears to be due to CVAD design. PICCs, without an internal anchoring design, such as the cuff found on tunneled catheters, may be at increased risk for dislodgement. Additionally, PICCs that are not sutured in place, often exit on the distal arm, and require dressing changes that are difficult to perform independently.
Table 7. Question #4: What is the best CVAD for minimizing mechanical complications?

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Christensen et al14</td>
<td>Retrospective cohort</td>
<td>Compared complication rates of tunneled CVADs and PICCs in 1 Danish Center</td>
<td>136 adult HPN patients Total of 295 CVADs; 169 tunneled CVADs and 126 PICCs</td>
<td>If removal was due to a mechanical cause (CVAD fell out, pulled out by mistake, occlusion, broken or other defects) PICC removal was higher (1.5 compared with 0.6/1000 CVAD days)</td>
<td>PICCs were inserted when patient not able to care for the CVAD. Patients who had an acute condition, metabolically unstable requiring IV supplementation over limited period of time more often received a PICC.</td>
</tr>
<tr>
<td>Toure et al13</td>
<td>Prospective cohort</td>
<td>Compared rates of complications associated with peripherally inserted and tunneled CVADs</td>
<td>196 adult HPN patients 133 tunneled CVADs and 71 PICCs</td>
<td>There was no difference in non-infection complications between PICC and tunneled CVADs catheters The mean number of catheter days to non-infection complications was not significant between the 2 CVAD types</td>
<td>Non-infectious complications defined as occlusion, venous thrombosis, pericarditis, breakage, and leakage at the VAD site.</td>
</tr>
<tr>
<td>Cotogni et al7</td>
<td>Prospective, observational</td>
<td>Investigated CVAD complications in cancer patients with 4 types of VADs (PICC, Hohn, tunneled CVADs, implanted ports)</td>
<td>254 adult HPN patients 289 CVADs; 65 PICCs, 107 Hohns, 45 tunneled CVADs, 72 implanted ports</td>
<td>There were no differences in mechanical complications/1000 CVAD days or/1000 HPN days between the 4 CVADs There were 16 catheter dislocations for the Hohn, compared with 4 for the tunneled and 5 for PICCs</td>
<td>High mortality rate (210 of 289 patients died).</td>
</tr>
<tr>
<td>Guglielmi et al9</td>
<td>Prospective cohort</td>
<td>Described the long-term HPN frequency of complications both in adult cancer and non-cancer patients</td>
<td>270 adult HPN patients 139 patients with a cancer diagnosis and 131 without cancer</td>
<td>Overall, incidence of mechanical complications higher in the non-cancer patients with tunneled CVADs compared with the cancer patients with implanted ports (0.91 and 0.82/1000 patient days, respectively)</td>
<td>Different CVAD types in cancer and non-cancer patients HPN protocols were different between the 2 groups. Patient training program was shortened to 3 days in the cancer group compared with 7–14 days; periodic home nurse follow-up visits were not conducted. Lacking mechanical definition.</td>
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<td>Beau et al17</td>
<td>Cohort, prospective</td>
<td>Compared experience of long-term complications with polyurethane (Leader-Cuff/Vygon) and silicone (Lifevac/Vygon) tunneled, cuffed CVADs</td>
<td>Adult HPN patients N = 53 CVADs in 42 patients</td>
<td>There were no obstructions reported in the polyurethane group and 0.05/ patient year of HPN in the silicone group Dislodgement and thrombosis/patient year of HPN was not statistically significant Fracture and hub dysfunction were higher in the polyurethane (0.5/patient year of HPN) than the silicone group (0.03/patient year of HPN)</td>
<td>Years of recruitment varied between the 2 groups. Practice may have changed between 1991 and 1998. More patients were in the silicone catheter group (N = 31) as well as catheters (N = 40) compared with the polyurethane group that had 11 patients with 13 CVADs. Measurement done per patient year of HPN.</td>
</tr>
<tr>
<td>Gaggioti et al12</td>
<td>Retrospective HPN crossover</td>
<td>Compared implanted ports and tunneled silicone CVADs</td>
<td>6 adult HPN patients; All 6 previously had a silicone tunneled CVAD and changed to an implanted port</td>
<td>There were no data on the number of tunneled CVADs, and 3 occlusions occurred in 1 patient</td>
<td>Authors did not state if the 1000 days were CVAD or HPN days. No definition for occlusions. No statistics given in the paper. Small study group.</td>
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</table>

CVAD, central venous access device; HPN, home parenteral nutrition; IV, intravenous; PICC, peripherally inserted central catheter; VAD, venous access device.
(compared with a tunneled catheter exiting the chest) may also lend themselves to be accidently becoming dislodged. Tunneled VADs would have increased rates of malfunction compared with implanted ports due to cracking of the VAD hub and weakening of the lumen from repeated VAD clamping during and after flushing.

**Question 5:** Should antimicrobial or ethanol locks be used vs standard care for treating or preventing CVAD infections? (See Table 8.)

**Recommendation 5:** Based upon 2 studies, ethanol and antimicrobial lock instillations should be considered when used to prevent recurrent infection. Tunneled CVADs instilled with concentrated vancomycin demonstrated a decrease in CLABSI in 1 study. One study showed that there was no difference in removing an infected CVAD vs using a concentrated antibiotic lock followed by ethanol locks for several days.

**Quality of Evidence:** Low

**GRADE Recommendation:** Weak

**Rationale 5:** The CDC recommends that prophylactic antimicrobial locks be used only for long-term VADs with repeated CLABSI episodes following an in-depth review to insure that aseptic techniques are being followed and adhered to. In this narrower literature search of adult HPN patients, no randomized trials in adult HPN patients assessed the impact of antimicrobial or ethanol locks to treat or use prophylactically to prevent CLABSI. Three observational studies explored this question. Lawinski et al retrospectively compared differences in outcome in HPN patients (N = 428) with CVAD removal vs those treated first with ethanol locks followed by antibiotic lock therapy. Of the 331 episodes of CLABSI, the majority (231 of the CVADs) were automatically removed for specific criteria (eg, colonization with fungi or specific bacterial strain which were resistant to most antimicrobials, etc) without using a lock therapy. Of the 100 CVADs that remained in situ, a 95% ethanol solution was instilled daily for 4 days, followed by an antibiotic lock solution which was selected based upon the patient’s blood culture results. There were no differences in the recurrence of CLABSI episodes with the same organism between the 2 groups over a period of 120 days.

The use of a prophylaxis lock of either a highly concentrated antibiotic or a 70% ethanol solution was studied in 59 patients who experienced a total of 313 CLABSI episodes: 264 before and 49 following initiation of the lock solution. There were statistically significant differences in the prelocking groups (10.97 ± 25.92 infections/1000 CVAD days) and postlocking groups (1.09 ± 2.53 infections/1000 CVAD days) as well as for the CVADs that instilled vancomycin (11.59 days prelocking and 1.04 days postlocking/1000 CVAD days; \( P < .001 \)).

John et al also examined the impact of CLABSI-related hospital admission using a 70% ethanol lock solution in adult HPN patients before and after ethanol lock using a quasi-crossover study design. Overall, 31 patients experienced 273 CLABSI-related admissions prior to ethanol lock treatment (10.04/1000 CVAD days) compared with 47 CLABSI after ethanol lock (6.48/1000 CVAD days; \( P = .005 \)). When data were adjusted to include only tunneled CVADs, a significant decrease in CLABSI from 10.1 to 2.9/1000 VAD days before and after ethanol lock use remained.

In summary, while few studies have demonstrated the benefits of ethanol and antimicrobial locks in the adult population, a larger body of research exists for the pediatric HPN population. This research has consistently reported decreased rates of CLABSI. However, increased VAD breakage and thrombosis rates with the use of ethanol have also been cited with the use of silicone CVADs. It should be noted that ethanol locks can only be used if the CVAD material is silicone because a 70% ethanol lock solution has the potential to weaken CVADs constructed of polyurethane. The effect of different dwell times and frequency, as well as concentrations of ethanol, on VAD integrity all are areas that require further investigation. Antimicrobial lock solutions also present difficulties due to the potential to develop antimicrobial resistance as well as risks due to side effects and allergic reactions. Additionally, studies investigating antimicrobial locks differ on the medication used, dose, and CVAD dwell times.

**Question #6:** Should saline or heparin locks be used for CVAD maintenance?

**Recommendation 6:** No recommendations can be made as to which flush solution should be used to maintain patency for HPN CVADs due to the lack of studies.

**Quality of Evidence:** Very Low

**GRADE Recommendation:** Expert opinion

**Rationale 6:** No studies have examined the impact of flushing with normal saline vs heparinized saline to reduce intraluminal clotting for adult patients infusing HPN. Manufacturer guidelines are generally followed regarding the use and frequency of heparin flush in open-ended CVADs. For valved or closed-tip CVADs, manufacturers recommend normal saline flushes. Home infusion providers most often follow standards of practice developed by the INS who recommend flushing CVADs before and after medication administration with preservative-free 0.9% sodium chloride, followed by either heparin 10 U/mL or preservative-free 0.9% sodium chloride. Manufacturer guidelines and the type of needleless connector used also guides the clinician in making an informed decision as to flushing.

Although there are no studies in adult HPN patients that evaluated the efficacy of various flush solutions a priori, the prospective study by Lyons et al of 90 homecare patients that included 7 HPN patients infusing various therapy types via a PICC were randomized into 3 different flushing protocols. The flushing protocols compared were saline alone, saline with heparin 10 U/mL, and saline with...
<table>
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<tbody>
<tr>
<td>Davidson et al</td>
<td>Retrospective, cohort</td>
<td>Rate of CLABSI before and after antibiotic or ethanol lock</td>
<td>59 eligible patients</td>
<td>Total of 313 CLABSI; before the use of a locking solution, the CLABSI rate was 10.97 ± 25.92/1000 CVAD days; following locking 1.09 ± 2.53/1000 CVAD days (P &lt; .001)</td>
<td>No statistical significance in the reduction of VAD infection rates when antimicrobial locking was used compared with ethanol locking. Decision as to which lock solution used was made depending upon clinical evaluation and was not controlled. Patients could have used both an antimicrobial and ethanol lock, thus being included in both groups. The type of lock reported and use in the analyses was the lock that the patient was using the majority of the time. The appropriate antimicrobial lock solution was based upon previous CLABSI episodes and the general incidence, not on an organism obtained from a blood culture. No mention as to how often a patient was instilling the lock technique. Small sample sizes in both groups.</td>
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<td>51 patients instilled their CVADs with antibiotic lock</td>
<td>For patients who instilled with ethanol lock; CLABSI rate was 4.18/1000 CVAD days before locking and 0.47/1000 CVAD days after locking</td>
<td>No statistical differences in the 2 groups. CLABSI not defined. Ethanol lock used for 4 days followed by antimicrobial lock for 4 days; HPN restarted after last antimicrobial lock and if asymptomatic and repeat blood culture negative, patient sent home.</td>
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<td>8 patients instilled their CVADs with ethanol lock</td>
<td>For patients who instilled antimicrobial lock CLABSI rate was 12.03/1000 CVAD days and 1.19 after locking Pre-vancomycin locks: rate was 11.59/1000 CVAD days, and post-vancomycin locks decreased to 1.04/1000 CVAD days</td>
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<tr>
<td>Lawinski et al</td>
<td>Retrospective, cohort</td>
<td>Compare antimicrobial (according to blood culture results) with 95% ethanol lock therapy versus CVAD removal</td>
<td>428 adult patients receiving HPN</td>
<td>181 patients developed 352 episodes of CLABSI 48 patients treated with ethanol/antimicrobial lock versus 133 treated with CVAD removal and replacement of a new catheter Median numbers to CVAD infection complication after treatment 1053 ± 748 days in antimicrobial/ethanol group and 952 ± 709 days in the CVAD removal/replacement group Average time of catheter use after a CLABSI to next episode of infection: 436 ± 436 days antimicrobial/ethanol group; 468 ± 411 days CVAD removal/replacement group Re-infection in tunneled CVADs after treatment for CLABSI: 431 ± 437 days in antimicrobial/ethanol group; 565 ± 443 CVAD removal/replacement group</td>
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</thead>
<tbody>
<tr>
<td><em>John et al</em>&lt;sup&gt;18&lt;/sup&gt;</td>
<td>Retrospective, cohort Patients served as their own control</td>
<td>Investigated the efficacy of ethanol lock installation (3 mL of 70% ethanol followed by 10 mL normal saline) in reducing the incidence of CLABSIs</td>
<td>31 adult HPN patients</td>
<td>273 CLABSI-related admissions pre-ethanol lock and 47 admissions post-ethanol lock/1000 CVAD days</td>
<td>Small sample size. No reported side effects or complications from ethanol lock. Only patients with silicone catheters received ethanol lock. In the pre-ethanol lock population, 16 patients had PICCs for at least some of the infusion days. Number of catheter days in prelock group was 27,210 and 7201 in tunneled group with ethanol lock. Ethanol lock started on existing CVADs in which the presence of a biofilm could affect results.</td>
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</table>

CLABSI, central line–associated blood stream infection; CVAD, central venous access device; HPN, home parenteral nutrition; VAD, venous access device.
heparin 100 U/mL. Results indicated that the saline-only group required additional home RN visits to assess for sluggishness/occlusions (32.1% compared with 15.6% for the 100 U/mL and 13.3% for the 10 U/mL; \( P = .150 \)). This group also experienced the highest percentage of patients requiring tissue plasminogen activator (tPA) to restore PICC patency (25% vs 9.4% and 10% in the 100 U/mL and 10 U/mL, respectively; \( P = .160 \)). Both of these results trended toward significance, likely reflecting the small sample sizes. The impact of additional home visits by a registered nurse and the use of tPA needs to be considered when evaluating the benefits of the type of flushing solution.

In summary, there is no strong evidence to support the use of heparin vs saline flush solutions to maintain CVAD patency. This challenges the homecare clinician to further study the use of saline flush solutions due to the increased cost to provide heparin flushes as well as the potential for the development of heparin-induced thrombocytopenia.

**Summary**

These guidelines are tailored to assist clinicians to use best practices in the selection and care of CVADs for the infusion of HPN solutions in the adult patient. Due to the absence of randomized control studies, our recommendations to answer these questions are based upon observational cohort studies and expert opinion. For all of our questions, the quality of evidence was either low or very low. It is our hope that this systematic search strategy, followed by meticulous data abstraction, will provide clinicians with the most current scientific evidence to integrate with their clinical expertise and enable them to optimize catheter care for their HPN patients and to underscore the need for research in the homecare population.

These recommendations serve only as a beginning point to stimulate interest in developing the next generation of studies to provide optimal care to our HPN population. We selected key questions, but are aware that these as well as other questions remain unanswered. It is clear that further multidisciplinary research is needed to continue the quest to decrease or eliminate complications for our HPN patients.

**References**


