Does a Dedicated Lumen for Parenteral Nutrition Administration Reduce the Risk of Catheter-Related Bloodstream Infections? A Systematic Literature Review

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ABSTRACT

Guidelines recommend using single-lumen central vascular access devices (CVADs) for the administration of parenteral nutrition (PN) or lipid-based solutions, or a dedicated lumen on a multilumen CVAD. Publications reviewed by the authors reported comparative rates of catheter-related bloodstream infection (CR-BSI) in patients with CVADs who received PN through a dedicated lumen compared with those who had PN administered through multilumen CVADs. Two studies included 650 patients with 1349 CVADs. CR-BSIs were equally distributed between the 2 groups. Both studies were poorly reported and had significant risk of bias. These results should be interpreted with caution.

Key words: catheter-related bloodstream infection, central vascular access device, intravenous administration set, parenteral nutrition, systematic review

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Health care today is unthinkable without vascular access devices for the management of patients with acute and chronic conditions, both in hospitals and at home. Multilumen central vascular access devices (CVADs) allow the concurrent administration of incompatible intravenous (IV) medications through separate lumens of the same device, thus negating the need for multiple devices. This is tempered with the principle to insert CVADs with the minimum number of lumens required for the management of each patient, to minimize infection risk.[1]

Traditionally, CVADs used for parenteral nutrition (PN) delivery, including the IV administration sets, have associated unique maintenance strategies given the perceived heightened infection risk.[2] The European Society for Parenteral and Enteral Nutrition's *Guidelines on Parenteral Nutrition* and the *epic3: National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in National Health Service Hospitals in England* recommend using single-lumen CVADs for the administration of PN or lipid-based solutions, if possible, or a dedicated lumen on a multilumen CVAD.[1,3]

These recommendations can pose logistical challenges to the management of patients with complex drug regimens. Acutely ill patients may require a multitude of IV therapies including fluid resuscitation, vasopressors, dialysis, apheresis, chemotherapy, antiemetics, immune suppression, antimicrobials, analgesia, PN, blood products, and other supportive treatment. Many of these therapies are incompatible when administered concurrently through the same lumen of a CVAD. Clinicians must optimize available vascular access to ensure appropriate and timely administration of all infusions prior to establishing additional access.[4] This may compromise adherence to clinical guidelines that recommend that PN be administered via a dedicated lumen.

Many medications, such as antibiotics, have peak and trough levels that must be maintained to minimize the development of antimicrobial resistance. Physical compatibility and stability of some IV medications with PN has been confirmed over the years.[4-6] Multilumen extension sets are connected between the CVAD and the IV administration set to allow compatible medications to be infused concurrently with the PN. Each time the IV administration set is handled, there is the risk of microbial contamination from inadequate disinfection of the needleless connector, health care workers' hands, or the patients' skin.[7] PN-containing lipids have distinct maintenance practices compared with nonlipid infusions because of the infection risk related to the lipid content of PN. Catheter-related bloodstream infections (CR-BSIs) may be improved if the IV administration set is handled less often.[8,9] A lumen dedicated to PN would suggest that the IV administration set is manipulated less frequently. However, as highlighted above, this may not always be possible in patients with complex needs. This clinical problem is the basis for seeking clarification on the actual effect of PN on microbial growth, CR-BSI, and patient safety. The aim of this paper was to systematically review research-based publications that reported comparative rates of CR-BSI in patients with CVADs who received PN through a dedicated lumen compared with those who had PN administered through a multilumen CVAD.

METHODS

Systematic reviews attempt to collate all the empirical evidence that fits prespecified eligibility criteria to answer a specific research question.[10] Explicit, systematic methods are used to minimize bias to provide reliable findings from which conclusions can be drawn and decisions made.[11,12]

Protocol Registration

The protocol was registered prospectively with the PROSPERO International Prospective Register of Systematic Reviews as CRD42015016438 at http://www.crd.york.ac.uk/PROSPERO/.

Search Strategy

Four electronic databases (Cochrane Central Register of Controlled Trials [CENTRAL] in the Cochrane Library, MEDLINE, CINAHL, and PubMed) were screened for research studies focusing on CR-BSI in patients receiving PN through a CVAD, from inception until June 10, 2016 (Table 1). Search results were imported into the referencing software EndNote X7, and duplicates were removed. First, titles and abstracts were screened by 2 authors independently. Disagreements were resolved by discussion with a third reviewer. Thereafter, the full-text manuscripts were read and the data were extracted. The reference lists of relevant publications were searched for additional studies not identified by the methods outlined. There were no limitations placed on the age of the patients, the location (hospital or home) where the PN was administered, the study methodology, or the language or year of the publication.

Inclusion Criteria

The criteria used for selection of studies were based on participants, interventions, contexts, outcome measures, and types of study as outlined below. Adult or pediatric patients with a CVAD for PN administration in any health care setting (hospital or community) were included. This review considered studies that compared patients with a CVAD with 1 lumen dedicated to PN administration and the other group with PN administered with concurrent compatible IV medications. CR-BSI was the primary outcome. The secondary outcomes were CVAD microbial colonization and identification of clinical isolates (as reported on the blood culture reports). Data needed to be extracted for the primary outcome (CR-BSI), and by patient (preferably) or by the CVAD as the denominator.

TABLE 1

Search Strategy

The following search string was used for MEDLINE and amended for each database accordingly.	
Terms describing parenteral nutrition	(MH "Parenteral Nutrition, Home+") OR (MH "Parenteral Nutrition+") OR (MH "Parenteral Nutrition, Total+") OR (MH "Parenteral Nutrition, Home Total") OR (MH "Infusions, Parenteral+") OR (MH "Parenteral Nutrition Solutions+") OR AB "parenteral nutrition" OR AB parenteral N5[a] feed OR AB parenteral N5 hyperalimentation
	AND
Terms describing central vascular access devices	(MH "Catheterization, Central Venous") OR (MH "Central Venous Catheters") OR (MH "Vascular Access Devices+") OR AB "Central venous catheters" OR AB "Vascular access devices" OR AB central N5 venous OR AB vascular N5 device
	AND
Terms describing infections	(MH "Catheter-Related Infections") OR (MH "Bacteremia+") OR (MH "Fungemia+") OR (MH "Candidemia") OR (MH "Sepsis+") OR (MH "Systemic Inflammatory Response Syndrome+") OR (MH "Infection+") OR (MH "Cross Infection+") OR AB "Catheter related infections" OR AB "Bacteremia" OR AB "Fungemia" OR AB "Sepsis" OR AB "Infection" OR AB Catheter N5 infection OR AB Catheter N5 blood N5 infection OR AB Catheter N5 coloni?ation[b]

Abbreviations: AB, abstract; MH, medical subject headings.
[a]N5 refers to adjacency operator, which searches for terms near each other.
[b]? indicates a search for different spellings (eg, colonization or colonisation).

Exclusion Criteria

Descriptive studies that did not have a comparator group or did not describe PN administration in sufficient detail were not included in this systematic review. Studies of patients with PN infused through peripheral intravenous catheters (PIVCs) were excluded. It is not standard practice to infuse PN through a peripheral vein because of the risk of extravasation and phlebitis, and the incidence of CR-BSI is less frequent in PIVCs compared with CVADs.[3,13-15]

Methodological Risk of Bias

A bias is a systematic error, or deviation from the truth, in results or inferences.[16] Biases can lead to an underestimation or overestimation of the true intervention effect. Two authors independently assessed risk of bias. Disagreements were resolved by discussion with a third reviewer (Table 2).[16,17]

Data Extraction

Two authors independently extracted data using a template. Disagreements were resolved by discussion with a third reviewer. The following data were extracted from each of the included publications:

1. Baseline characteristics of dedicated lumen and multilumen group participants including the number of participants; age; gender; disease; treatment; reason for insertion; profession of inserter (medical officer, radiographer, or nurse); anatomical location of insertion; type of CVAD; insertion care; maintenance care (PN team, ward staff, or patient); dwell time of the CVAD; and existing infection from a secondary site (eg, a wound, current positive blood cultures)
2. Criteria for patient inclusion and exclusion
3. Description of the intervention(s), if relevant, and the number of patients allocated to each intervention (type of PN and non-PN solutions, number of lumens on the CVAD, configuration of IV administration set and infusions, frequency of IV administration set replacement)
4. Health care setting
5. Duration of follow-up and number lost to follow-up
6. Outcomes (CR-BSI, CVAD colonization, and clinical isolates from blood cultures)

TABLE 2

Methodological Risk of Bias

Cochrane Collaboration Tools for Assessing Risk of Bias		
Domain	Randomized controlled trials (each domain rated as high risk, low risk, or uncertain risk of bias)[a]	Nonrandomized studies of interventions (each domain rated as low, moderate, serious, or critical risk, or inadequate information to assess risk)[b]
1	Sequence generation	Confounding
2	Allocation concealment	Selection of participation into study
3	Blinding of participants and personnel	Classification of interventions
4	Blinding of outcome assessors	Departures from intended interventions
5	Incomplete outcome data	Missing data
6	Selective outcome reporting	Measurements of outcomes
7	Other sources of bias	Selection of the reported result

[a]Data from Higgins et al.[16]
[b]Data from Sterne et al.[17]

Definition and Terminology

Primary outcome

- Gold standard definition of CR-BSI; 1 of the following: (1) Primary bacteremia/fungemia with ≥1 positive blood culture from a peripheral vein with no other identifiable source for the bloodstream infection other than the CVAD, plus 1 of: a positive semiquantitative (>15 colony-forming units) or quantitative ($>10^3$ colony-forming units) CVAD culture with the same organism (species and antibiogram) isolated from the CVAD and blood[13,18]; or (2) 2 blood cultures (1 from a CVAD hub and 1 from a peripheral vein) that both meet the CR-BSI criteria for quantitative blood cultures (3-fold greater colony count of growth for the same organism as from the peripheral blood), or differential time to positivity (growth of the same organism from hub-drawn blood at least 2 hours before growth from the peripheral blood); or (3) 2 quantitative blood cultures of samples obtained through 2 CVAD lumens in which the colony count for the blood sample drawn through 1 lumen is at least 3-fold greater than the colony count for the blood sample from the second lumen.[19]
  Note: Category (1) is generally used for diagnosis in short-term catheters where the device is commonly removed and cultured when infection is suspected. Categories (2) and (3) are generally used for diagnosis in long-term CVADs where the CVAD is often left in situ when infection is suspected, and may be treated with the CVAD in situ, even when infection is diagnosed.

Secondary outcomes

- CVAD colonization (CVAD tip or positive blood culture drawn through the CVAD): as defined by the trial investigators
- Clinical isolates (pathogen isolated from blood cultures): as described by the trial investigators

Data Analysis

Meta-analysis

It was planned to use data from randomized controlled trials (RCTs) in a meta-analysis if the study population and interventions studied were sufficiently similar. Qualitative summaries were planned for nonrandomized studies or if inadequate RCTs were available for meta-analysis.

Analysis of CR-BSI

Per patient (not per CVAD) analysis was planned as preferable to protect the independence of measures.

Analysis of the incidence of CR-BSI

It was planned to express CR-BSI as the number of episodes per 1000 CVAD days. The most precise measure of incidence is the incidence density, or incidence rate, which is the number of (first) infections that occur over the number of days that the CVAD is in place.[20]

Analysis of the incidence of CVAD colonization

This was calculated as the incidence of CVADs colonized per 1000 CVAD days.

Analysis of clinical isolates (blood) causing CR-BSI

The pathogens that cause CR-BSI were described and categorized according to their morphology (ie, Gram-positive cocci, Gram-positive bacilli, Gram-negative cocci, Gram-negative bacilli, fungi/yeast and polymicrobial infection).

RESULTS

Results of the Search Strategy

The search was conducted on June 10, 2016. A total of 2286 citations were found and imported into EndNote X7 (Clarivate Analytics; Philadelphia, PA). One additional record was identified from hand searching the reference lists. In total, 1295 titles were screened once 992 duplicates were removed, and 1261 were excluded. Thirty-four full-text articles were retrieved. Thirty-two were excluded because they did not meet the inclusion criteria.[21-52] Two studies were included in the analysis: 1 RCT and 1 prospective study (conference abstract).[53,54] The PRISMA 2009 flowchart was used to describe the identification, screening, and eligibility of included studies in this process (Figure 1).[55]

Characteristics of Included Studies

Characteristics of studies

The studies were published in 1988 and 1996 and were carried out in the United States (n = 1) and Spain (n = 1).[53,54] Both studies reported the number of patients and CVADs enrolled. The total number of patients included in this systematic review was 650, and the total number of CVADs was 1349. One study only recruited 1 CVAD per patient, while the other study included patients with multiple CVADs.[53,54] Characteristics of the 2 studies are summarized in Table 3.

Characteristics of patients and their CVADs

Gastroenterology patients were recruited from medical and surgical inpatient units in 1 study and were unreported in the other.[53,54] Gender and age were not reported in either study. One study reported that polyurethane CVADs were used but did not state the number of lumens.[54] The other study compared a multiple-use single-lumen CVAD with a dedicated lumen on a triple-lumen CVAD.[53] The average CVAD dwell time was 8.5 days.[53] Neither study identified the specific type of CVAD used. The average duration of PN was 12 days (range, 3-44 days).[54] Follow-up duration was not reported in either study.

Characteristics of CVAD insertion and maintenance care

The care for CVAD insertion and maintenance was described in 1 study.[54] Maximal sterile procedures were

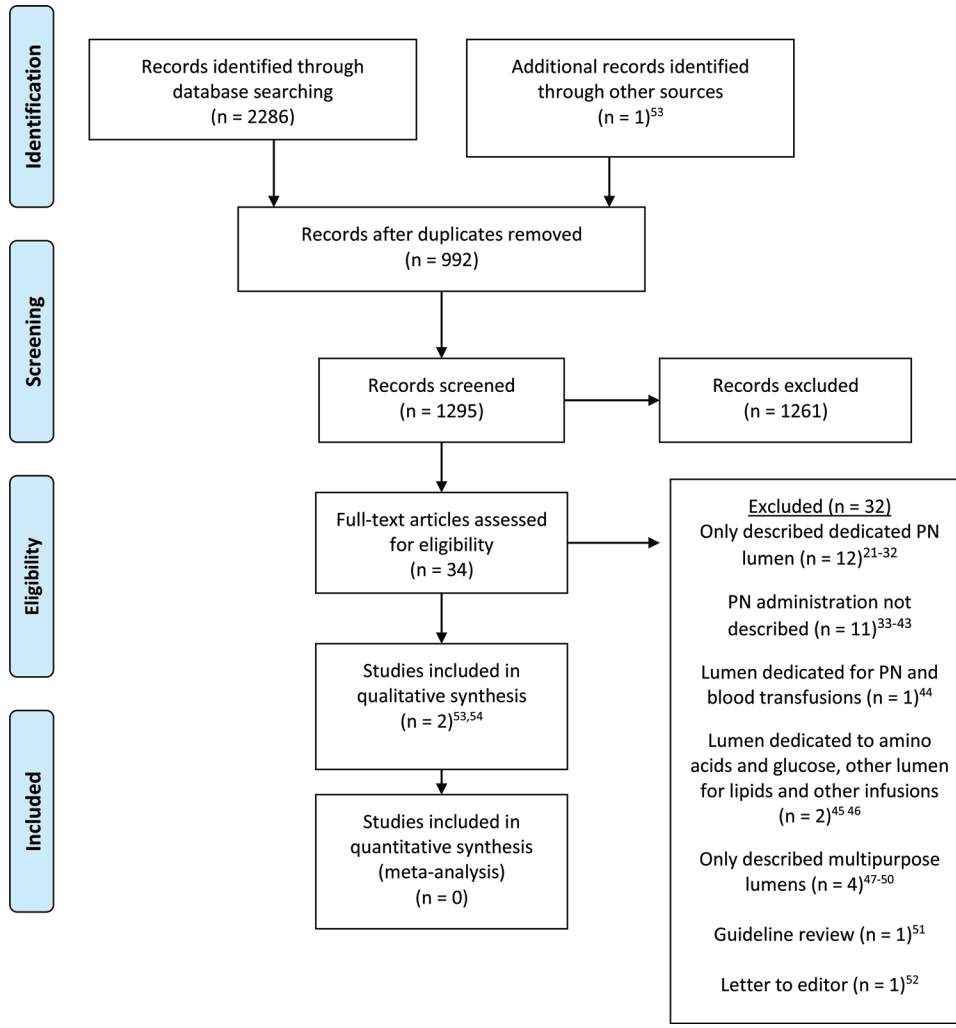

Figure 1 PRISMA flow diagram. Figure borrowed with permission from the PRISMA Group.[55]

used for CVAD insertion. Acetone, povidone-iodine, and 70% alcohol were used for skin disinfection insertion and maintenance. CVAD insertion sites were dressed with gauze and tape, which was replaced every 2 to 3 days. Flushing was not described, nor was the person responsible for maintaining the dressings (ie, PN team, ward staff, or patient).

Characteristics of IV administration set and PN maintenance

The maintenance of the IV administration set and PN was not described in either study. In the dedicated PN lumen group, Gómez Palomar and colleagues[54] did not describe whether the patients received IV antibiotics through another device or whether these patients did not require this treatment.

Characteristics of IV administration set and non-PN maintenance

The maintenance of an IV administration set was not described in either study.

Risk of Bias and Quality of Included Studies

The randomization in Gómez Palomar and colleagues' study[54] was not described. Therefore, it is unknown how the random sequence was generated or groups allocated, or whether allocation was concealed until study entry for each patient. One group received only PN through a dedicated lumen, and the other 2 groups received other IV medications through a single lumen. It is not clear whether the PN-only group received IV antibiotics. This lack of clarification raises serious questions of potential confounders and bias in the interpretation of the study results. If this study had been published after the Consolidated Standards of Reporting Trials (CONSORT) statement, it may have alleviated the problems arising from inadequate reporting of RCTs.[56] Baseline patient characteristics were not reported, and there was no flow diagram provided to ascertain whether all randomized patients were followed up and included in the primary analysis. The main source of potential bias for this domain is postrandomization exclusions as the number of patients assessed as eligible or excluded was not described (Table 4a).

TABLE 3

Characteristics of Included Studies

Author; Year	Study Design	Country	Population	Number of CVAD Lumens	CVAD Insertion Location	Number of Patients Enrolled	Number of CVADs	Incidence of CR-BSI	Incidence of CVAD Colonization
						N [PN; ML]	N [PN; ML]	n (%) [PN (%); ML (%)]	n (%) [PN (%); ML (%)]
Gómez Palomar et al; 1996[a]	Randomized controlled trial	Spain	Medical surgical	Not reported	Subclavian internal jugular basilic	70 [23; 47]	70 [23; 47]	3 (4.3) [1 (4.3); 2 (4.3)]	8 (11.4) [3 (13.0); 5 (10.6)]
Kovacevich et al; 1988[b]	Prospective	USA	Not reported	Single triple	Not reported	580 [258; 322]	1279 [523; 756]	0 [0; 0]	Not reported

Abbreviations: CR-BSI, catheter-related bloodstream infection; CVAD, central vascular access device; ML, multilumen; PN, parenteral nutrition.
[a]Data from Gómez Palomar et al.[54]
[b]Data from Kovacevich et al.[53]

It was challenging to ascertain risk of bias in the study by Kovacevich et al[53] because it was limited to a conference abstract, which does not appear to have been subsequently published. One attempt was made to contact the lead author by email, but no reply was received. It was not reported why patients received a single- or a triple-lumen CVAD. If it was based on clinical need, this is a potential selection bias. The authors stated that "care of the 2 catheters was identical based on protocols,"[53(p23S)] but no mention was made of potential deviations from the protocol or who carried out CVAD insertion and maintenance care. Overall, the risk of bias of this study was rated as serious, indicating a limitation in the study design. Results should, therefore, be interpreted with caution (Table 4b).

Neither study reported whether ethical approval was sought or provided inclusion and exclusion criteria. Neither study reported sample size calculations.

Primary Outcome

Both studies provided incidence of CR-BSI per patient.[53,54] Gómez Palomar and colleagues[54] reported 1 CR-BSI case in the multilumen group (1/23; 4.3%) and 2 cases in the dedicated lumen group (2/47; 4.3%). No CR-BSIs were reported in either group in Kovacevich and colleagues' study.[53]

TABLE 4a

Risk of Bias Ratings in Randomized Controlled Trials for CR-BSI Outcome

Study; Year	Sequence Generation	Allocation Concealment	Blinding of Participants, Personnel, and Outcome Assessors	Incomplete Outcome Data	Selective Outcome Reporting	Other Sources of Bias
Gómez Palomar et al; 1996[a]	Unclear	Unclear	Unclear	Unclear	Low	Low

TABLE 4b

Risk of Bias Ratings in Nonrandomized Studies of Interventions for CR-BSI Outcome

Study; Year	Bias Due to Confounding	Bias in Selection of Participation Into the Study	Bias in Classification of Interventions	Bias Due to Departures From Intended Interventions	Bias Due to Missing Data	Bias in Measurement of Outcomes	Bias in Selection of the Reported Result	Overall
Kovacevich et al; 1988[b]	Critical	Moderate	Serious	Serious	Serious	Moderate	Moderate	Serious

Abbreviation: CR-BSI, catheter-related bloodstream infection.
[a]Data from Gómez Palomar et al.[54]
[b]Data from Kovacevich et al.[53]

Incidence of CR-BSI per 1000 CVAD Days

It was not possible to calculate the incidence of CR-BSI per 1000 CVAD days because the denominator was not reported in either study.

Secondary Outcomes

One study described using the Cleri qualitative and Maki quantitative methods for culturing CVADs.[54,57,58] The second study reported secondary sites of infection, not CVAD colonization.[53]

CVAD Colonization

One study reported colonization.[54] There were 8 episodes of CVAD colonization reported: 3 in the dedicated lumen group (3/23; 13%) and 5 in the multilumen group (5/47; 10.6%).

Clinical Isolates (Blood)

This information was not reported in either study.

DISCUSSION

The findings of this review demonstrate that there is a paucity of literature in this area, with only 2 studies meeting inclusion criteria, 1 of which was a conference abstract. The results from the 2 studies included in this systematic review suggest that there is no difference in rates of CR-BSI when PN is administered through a dedicated lumen or a multilumen catheter. However, both studies were poorly reported and had significant risk of bias; therefore, these results should be interpreted with caution.

Future studies should clearly describe CVAD insertion and IV administration set and PN maintenance procedures. Future studies should report baseline characteristics or endeavor to control for confounding variables, such as differences in insertion and maintenance practices; ensure blinding of investigators diagnosing CR-BSI; state a priori research aims and statistical methods on a clinical trials registry; calculate sample size; and ensure good quality and transparent reporting in compliance with the CONSORT and the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.[56,59]

The American Society for Parenteral and Enteral Nutrition Safe Practices for Parenteral Nutrition special report states that "the infectious complications of PN administration are also reduced when catheter access devices are dedicated solely to PN usage (or the designation of one port solely for PN administration if a multilumen catheter is used) and catheter manipulations are minimized."[14(pS66)] This recommendation is based on the Centers for Disease Control and Prevention Guidelines for the Prevention of Intravascular Catheter-Related Infections published in 2002.[18] These guidelines were updated in 2011 and state that "no recommendation can be made regarding the use of a designated lumen for PN" and that the practice is an "unresolved issue."[60(pe164)]

To the authors' knowledge, this is the first systematic review reporting comparative rates of CR-BSI in patients with CVADs who received PN through a dedicated lumen compared with those who were administered PN through a multilumen catheter. This review has used a rigorous approach to study selection, data extraction, and quality assessment. Because of the small numbers of included studies and the serious risk of bias, it was not possible to pool the data for meta-analysis; the studies were therefore reported descriptively. From the available data, no conclusions can be made about the effect of a dedicated lumen for PN administration on CR-BSI. However, this review identifies a significant gap in the literature and provides a strong platform for further research to lead to definitive results.

Currently, there are insufficient data on which to establish whether patients receiving PN through a multilumen catheter are more at risk of developing CR-BSI than those who have a dedicated lumen for PN. In the absence of good-quality evidence, it remains essential to rely on guideline recommendations for clinical practice. However, no data are available on how consistently PN is delivered through a single lumen in current clinical practice. Are acutely ill patients in our hospitals who require multiple lifesaving IV therapies receiving PN through a dedicated lumen?

As this systematic review has highlighted the lack of high-quality data on this topic, clinicians could also consider the need for CVAD registries. Clinical registries collect a defined minimum data set from patients undergoing a procedure, diagnosed with a disease, or using a health care resource.[61,62] Data are captured systematically from existing medical records and databases. A CVAD registry would do much to identify variations in practice and provide feedback on performance. This would allow for improvements in patient outcomes by reducing adverse events such as CR-BSIs.

The belief that PN requires a dedicated lumen to prevent infection must be weighed against the increased risk of infection risk if multilumen devices, or additional concurrently sited devices, are chosen to achieve this goal.[4] Patient acuity can fluctuate during the dwell time of a CVAD, and this makes it difficult for clinicians to accurately predict the number of lumens required at CVAD insertion. Multiple concurrent devices may place patients at risk for infection, venous thromboembolism, and falls.[63-66] Clinicians should be aware of the safety of physical compatibility and stability of IV medications with PN when coinfusing these products.[4-6] In 2008, the National Confidential Enquiry into Patient Outcomes and Death conducted an observational study of patients receiving PN in National Health Service hospitals.[2] Retrospectively, patients were identified randomly by hospital pharmacies dispensing PN. The report states that there is evidence that approximately one-third (68/191) of CVADs for PN were being used for other reasons.[2] This study demonstrated the inherent risks associated with multilumen CVADs and the need for high-quality evidence to guide practice.

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