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A comparison of hydrophobic polyurethane and polyurethane peripherally inserted central catheter: results from a feasibility randomized controlled trial

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Abstract

Background: To evaluate the feasibility of an efficacy trial comparing a hydrophobic polyurethane peripherally inserted central catheter (PICC) with a standard polyurethane PICC.

Methods: This pilot randomised controlled trial (RCT) was conducted between May 2017 and February 2018. Adult participants ($n = 111$) were assigned to hydrophobic polyurethane PICC with proximal valve (intervention) or a polyurethane PICC with external clamp (standard care). Primary outcome was trial feasibility including PICC failure. Secondary outcomes were central line-associated bloodstream infection, local infection, occlusion, thrombosis, fracture and dislodgement, phlebitis, local or systemic allergic reaction, and PICC dwell time.

Results: All feasibility outcomes were achieved, apart from eligibility criteria. In total, 338 patients were screened, 138 were eligible (41%), and of these 111 were randomised (80%). Patients received the allocated PICC in 106 (95%) insertions. No patients withdrew from the study and there was no missing data. PICC failure was 24% (13/55) in the intervention group and 22% (12/55) in the standard care group ($p = 0.820$). PICC failure per 1000 PICC days was 16.3 in the intervention group and 18.4 in the control group ($p = 0.755$). The average dwell time was 12 days in the intervention and 8 days in the control group.

Conclusions: This study demonstrates the feasibility of an efficacy trial of PICC materials in an adult population, once adjustments were made to include not only in-patients, but also patients being discharged to the Hospital in the Home service.

Trial registration: Australia and New Zealand Clinical Trials Registry [ACTRN12616001578493](https://www.anzctr.org.au/Trial/Registration/Trial.asp?id=12616001578493). Prospectively registered on 16 November 2016. The trial protocol was published a priori (Kleidon et al., Vasc Access 3:15–21, 2017).

Keywords: Feasibility, Hydrophobic polyurethane, Peripherally inserted central catheter (PICC), PICC failure, Pilot randomised controlled trial, Polyurethane

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Background

Peripherally inserted central catheters (PICCs) are used for intravenous (IV) fluids, medications, and blood products and for blood sampling to prevent frequent phlebotomy [1, 2]. PICCs are the most frequently inserted central venous access device outside of the intensive care unit [3], and their appropriate use [4, 5] enables treatment in diverse settings, including inpatient, outpatient, and community-based [2]. Unfortunately, about one third of PICCs fail prior to completion of treatment [6], often necessitating removal and replacement [7], due to mechanical (blockage, dislodgement, vein thrombosis, rupture) or infective (local or bloodstream infections) complications [6]. PICC complications reduce patient satisfaction, prolong hospitalisation, increase healthcare costs, and risk mortality [8–12].

PICC material and designs have evolved from the first silicone PICCs with external clamps in the 1970s [13] to modern materials and characteristics which include the following: trimmable or un-trimmable catheters, silicone or polyurethane (power injectable and non-power injectable), and anti-microbial or heparin bonding [14]. PICCs are available in various sizes (1 to 6 Fr), configured with single or multiple lumens, open- or closed-ended, with or without external clamps [14]. Despite this abundance of choice, there is a paucity of evidence comparing PICC features. In a recent scoping review [15] of 178 randomised controlled trials (RCTs) in central venous access devices in the past decade, only five studies compared PICC materials [16–20] and two PICC types [21, 22].

A recent addition to the market, BioFlo® is a hydrophobic polyurethane PICC with a surface-modifying macromolecule (Endexo®) that enhances the biocompatibility of medical devices [23]. This durable surface modification occurs during the extrusion moulding manufacturing process. A small amount of polymer/macromolecule is added to the polyurethane/carbothane® to provide hydrophobic properties to the PICC [23, 24]. Earlier unpublished pre-clinical data suggested the Endexo® technology suppressed procoagulant conformation, reduced platelet adhesion, inhibited platelet activation in the presence of blood, and reduced bacteria adhesion and encrustation in the presence of bacteria [23]; however, no anti-infective claim is made by the BioFlo® manufacturers [25]. In addition to surface modification, BioFlo® has a direction-specific pressure-activated safety valve situated at the proximal hub of the PICC, designed to reduce retrograde blood flow into the PICC during normal venous pressures [25]. This technology demonstrates some effectiveness at reducing thrombus accumulation in laboratory settings, but its clinical effectiveness is less established [14].

A recent pilot RCT in paediatric patients [26] compared a polyurethane, power-injected PICC with an

external clamp to a hydrophobic polyurethane PICC (BioFlo®). Failure was halved in the hydrophobic polyurethane group (8/72; 11%) compared to standard care (16/74; 22%) ($p = 0.087$), which when expressed as an incident rate was 12.6 and 7.3 per 1000 PICC days (incident rate ratio 0.58; 95% confidence interval (CI) 0.21–1.43; $p = 0.172$). However, this has not been tested in the adult population. Therefore, the primary aim of our feasibility RCT was to compare the effectiveness of a hydrophobic polyurethane PICC with a standard polyurethane PICC to prevent PICC failure. We hypothesised that conducting an RCT would be feasible.

Methods

Design

This pilot parallel RCT with 1:1 allocation compared a hydrophobic polyurethane PICC with pressure-activated proximal valve to a polyurethane PICC with external clamp.

Study setting

This trial recruited between May 2017 and February 2018 at the Royal Brisbane and Women's Hospital (RBWH) in Brisbane, Australia, a large quaternary hospital. During the study, PICCs at this hospital were inserted in the Department of Medical Imaging, which provided a specialist diagnostic imaging and radiology service, supporting the care and treatment of patients. Patients with a PICC were either be treated in a traditional hospital ward or in the Hospital in the Home (HITH) service, which allowed patients to receive their hospital intravenous treatment in their own homes.

Sample

The target sample size was 110 participants, 50 participants per group plus 10% for potential attrition, as determined by pilot trial sample size recommendations [27]. Patients were consecutively recruited and randomised if they met the inclusion criteria: PICC to be inserted in the Department of Medical Imaging for fluid or medication administration, predicted hospital inpatient admission > 24 h, 18 years or older, and provided informed consent. Due to slow recruitment, the inclusion criteria were expanded to include patients who were transferred to the HITH service within 24 h of PICC insertion. Patients were excluded if they had a current bloodstream infection (classified as a positive blood culture within 48 h prior to PICC insertion); had an allergy to the study product; the PICC was to be inserted through diseased, burned, or scarred skin; the PICC was inserted in other departments or units in the hospital; they could not provide consent without an interpreter; had a previous enrolment in the study; or had an

existing central venous access device including pulmonary artery catheters.

Participants were randomised to receive either (1) standard care—polyurethane, power-injectable PICC with external clamp (Arrow International, Reading, Pennsylvania)—or (2) the intervention—hydrophobic polyurethane PICC with a proximal valve (BioFlo® with Endexo® and PASV®, AngioDynamics Inc., Queensbury).

Outcomes

Primary outcomes

Feasibility The primary outcome was feasibility of conducting a large, definitive RCT comparing hydrophobic polyurethane PICC with simple polyurethane to prevent PICC failure and complications in adults. Feasibility was assessed as a composite analysis of elements [27–29] of the following: (i) eligibility (> 70% of screened patients were eligible), (ii) recruitment (> 70% of eligible patients agreed to enrol), (iii) retention and attrition (< 15% of participants are lost to follow-up or withdrew from the study), (iv) protocol adherence (> 80% of participants received their randomly assigned study product), (v) missing data (< 10% of endpoint data were missed during data collection), and (vi) patient and healthcare professional satisfaction and acceptability. Patient satisfaction with the PICC was collected as pain at removal on an 11-point Likert scale (0 being no pain and 10 being worst imaginable pain). PICC inserters were asked to rate their levels of satisfaction with insertion equipment (0 being very dissatisfied and 10 being very satisfied) and ease of PICC insertion (0 being very difficult and 10 being very easy) on an 11-point Likert scale. For staff satisfaction and acceptability, nurses were asked to rate their difficulty during PICC removal on an 11-point Likert scale (0 being no difficulty and 10 being significant difficulty); and (vii) sample size estimates for a definitive trial.

PICC failure PICC failure was defined as the following complications associated with PICC removal: (i) central line-associated bloodstream infection (CLABSI) [30], (ii) local infection [30], (iii) device occlusion [31, 32], (iv) venous thrombosis [33], and (v) PICC fracture or dislodgement [31, 34]. The outcome of device failure was an objective measure, assigned by clinical staff (not research staff or investigators). The published protocol by Kleidon and colleagues [35] defines PICC failure in further detail.

Secondary outcomes

In addition to individual complications (CLABSI, local infection, occlusion, thrombosis, fracture, and dislodgement), secondary outcomes included the following: (i) phlebitis, defined as any sign of chemical, mechanical, or

infective phlebitis, determined by patient complaint of pain and nurse examining PICC site; (ii) safety endpoints (local or systemic allergic reactions); and (iii) PICC dwell time in days.

Study procedures A research nurse (ReN) screened for eligible patients. Patients who agreed to participate were randomised via computer-generated randomisation immediately before PICC insertion via a web-based service (<https://randomisation.griffith.edu.au/>) to ensure allocation concealment until study entry. Patients were randomly assigned in a 1:1 ratio with randomly varied block sizes of two and four. The ReN provided the randomised study product to the inserting clinician. Data were collected using Research Electronic Data Capture [36]. Demographic and clinical data were collected at recruitment. The ReN visited inpatients twice weekly and the HITH nurse visited daily until the PICC was removed due to treatment completion, PICC failure, or until 4 weeks (maximum follow-up). Primary and secondary outcomes were collected by the ReN from the medical records, clinical staff, and patient assessment. Outcome data were collected at 48 h post PICC removal. The infection control physician (adjudicating infection outcomes), radiologist (adjudicating thrombosis outcomes), and data analyst were blinded to the study allocation. Infection and mortality data were collected at 48 h post PICC removal. Participants were followed for 4 weeks, unless the PICC was removed earlier. It was not possible to blind the PICC inserters, patients, or healthcare professionals caring for the patients enrolled in the study.

PICC procedures Prior to the study, the intervention PICC was not used in the hospital. Pre-study training for PICC inserters, inpatient, and HITH staff was provided by the manufacturer in the month preceding study commencement and for the first month after recruitment of the first patient. The ReN provided ongoing training and support for PICC inserters and clinical staff caring for the PICC.

PICCs were inserted by a registered nurse, radiographer, or medical officer; experience ranged from novice to expert. PICC insertion occurred in either digital fluoroscopy or the angiography suite. Asepsis was maintained using maximal barrier precautions including use of 2% chlorhexidine gluconate in 70% isopropyl alcohol skin preparation (Soluprep; 3M) [37]. Ultrasound was used for all initial venous assessment and initial vein puncture. A modified Seldinger technique was used for the remainder of the PICC insertion. Fluoroscopy was used to confirm optimal catheter tip placement in the lower third of the superior vena cava or cavo-atrial junction. When necessary, 10 mL of iodinated contrast and digital subtraction angiography was used to assist

accurate tip placement during complicated PICC insertion. Dressing and securement were achieved with a chlorhexidine impregnated foam disc (Biopatch®; Ethicon, New Jersey), a sterile semi-permeable, adhesive transparent dressing (IV3000 10 × 12cm; Smith and Nephew; Hull), and a stabilisation device (StatLock® PICC Plus Stabilization Device; Bard, Georgia) [37].

Post insertion care and maintenance was standardised with the PICC dressing and needleless connectors (SmartSite™; BD, Utah) replaced weekly or as required if soiled or lifting [38]. Inpatients who had continuous infusions had their IV administration sets replaced every 72 h, excluding blood products or chemotherapy, which were replaced on completion of the infusion. Intermittent infusions were flushed and locked with 0.9% sodium chloride. Complications were identified and monitored by the treating team. Occlusion was managed with a thrombolytic agent (e.g. urokinase). The decision to take blood cultures and remove PICCs was made by the medical officer treating the patient. HITH patients were visited daily to have their elastomeric device (Infusor™; Baxter, Illinois) and antibiotic replaced. If HITH patients required treatment to manage a PICC complication, such as administration of a thrombolytic agent, they were re-admitted to the ward.

Statistical analyses

Data were exported to Stata 15 for cleaning and analysis. Data cleaning of outlying figures and missing and implausible data were undertaken prior to analysis. Missing data were not imputed. The patient was the unit of measurement, and all randomly assigned patients were analysed on an intention-to-treat basis [39]. Descriptive statistics (frequencies and percentages) were used to ascertain the primary outcome of feasibility for the larger trial. Incidence rates (per 1000 PICC days) and rate ratios, including 95% confidence intervals, were calculated. The comparability of groups at baseline was described across demographic, clinical, and device characteristics. Kaplan-Meier survival curves (with log-rank tests) were used to compare PICC failure between study groups over time. Associations between failure and baseline characteristics were described by calculating hazard ratios. Multivariable Cox regression was not performed due to the relatively low number of outcomes. *p* values of < 0.05 were considered statistically significant.

Results

Participant and PICC characteristics

The participant and PICC characteristics are described in Table 1. Over 90% of patients recruited to this study were medical or surgical patients. Demographic and PICC insertion characteristics were balanced between the groups. The PICC inserters were more experienced

at inserting the standard care PICC: in only 1/52 (2%) PICC insertions had the PICC inserter never inserted a standard care PICC compared to 16/56 (29%) in the intervention group, and three quarters of the PICC inserters (39/52; 75%) had inserted more than 11 standard care PICCs compared to 3/56 (5%) in the intervention group.

Feasibility outcomes

Apart from eligibility criteria, all feasibility outcomes were achieved. In total, 338 patients screened, 138 were eligible (41%), and of these 111 were randomised (80%). Figure 1 outlines the reasons for unsuccessful achievement of the eligibility criteria. Additionally, Fig. 1 displays the flow of patients through the study confirming > 80% participants received their randomly assigned study product. Of the five who did not receive the intervention (106/111 received the allocated treatment, 95%), four received the standard care PICC. No patients withdrew from the study; therefore, the retention and attrition criteria of < 15% were met. Thirteen (12%) patients were censored on transfer to another hospital (seven in the standard care and six in the intervention group). There was no missing data for the primary outcome. The research team did not have ethical approval to request clinical information for these patients transferred to another hospital.

PICC inserter satisfaction with ease of insertion with the insertion equipment was rated higher in the standard care group (10.0 in the standard care group and 7.0 in the intervention) (Table 1). Although the number of insertion attempts was balanced between the groups, there were more difficult insertions in the intervention group (20; 36% in the intervention group compared to 13; 24% in the standard care group). Patient satisfaction and acceptability was collected as pain on PICC removal. Of the twenty-six patients asked, no one reported pain at removal (Table 2).

PICC failure

In total, 25 out of 110 patients (23%) experienced PICC failure: of these, two patients (one in each group) had completed their treatment and 23 had not. Presented as absolute numbers, 13/55 (24%) PICCs failed in the intervention group and 12/55 (22%) in the standard care group (*p* = 0.820). The risk ratio was 1.08 (0.54–2.16), and the risk difference was 1.8% (–13.8–17.5). PICC failure per 1000 PICC days was 16.3 (95% CI 9.5–28.1) in the intervention group and 18.4 (95% CI 10.5–32.5) in the control group (*p* = 0.755). Failure was most commonly due to dislodgement, followed by occlusion. See Tables 2 and 3, also Fig. 2. The average dwell time was 12 days in the intervention and 8 days in the control group (Table 3). During the study, six adverse events

Table 1 Participant and insertion characteristics at insertion

	<i>n</i>	Intervention	Control	Total
Group size ^a	111	56 (50)	55 (50)	111 (100)
Female gender	111	28 (50)	29 (53)	57 (51)
Age (years) ^b	111	59 (15)	62 (16)	61 (16)
Body mass index ^b	111	28 (10)	31 (16)	30 (13)
Comorbidities	111			
None		2 (4)	1 (2)	3 (3)
One		7 (12)	8 (15)	15 (14)
Two		9 (16)	5 (9)	14 (13)
Three		7 (12)	6 (11)	13 (12)
Four or more		31 (55)	35 (64)	66 (59)
History of ^c				
Clot	109	17 (30)	17 (32)	34 (31)
Antithrombotic therapy	108	46 (84)	48 (91)	94 (87)
Diagnosis at admission	111			
Surgical		39 (70)	35 (64)	74 (67)
Medical		12 (21)	15 (27)	27 (24)
Other		5 (9)	5 (9)	10 (9)
Infection at time of recruitment	111	38 (68)	31 (56)	69 (62)
Wound at time of recruitment	111	35 (62)	27 (49)	62 (56)
Side of insertion: non-dominant arm	110	33 (60)	35 (64)	68 (62)
PICC placement:	110			
Basilic		46 (84)	40 (73)	86 (78)
Brachial		8 (15)	12 (22)	20 (18)
Other		1 (2)	3 (5)	4 (4)
Catheter size:	110			
5 Fr		54 (98)	53 (96)	107 (97)
4 Fr		1 (2)	2 (4)	3 (3)
Lumens	110			
Two		54 (98)	53 (96)	107 (97)
One		1 (2)	2 (4)	3 (3)
Difficult insertion	111	20 (36)	13 (24)	33 (30)
Number of attempts	110			
One (first time success)		40 (71)	42 (78)	82 (75)
Two		9 (16)	6 (11)	15 (14)
Three or more		7 (12)	6 (11)	13 (12)
Inserted by	110			
Radiographer		27 (49)	26 (47)	53 (48)
Nurse		21 (38)	21 (38)	42 (38)
Doctor		7 (13)	8 (15)	15 (14)
Ease of insertion ^{d,e}	108	7.5 (5.0–9.0)	10.0 (7.0–10.0)	8.0 (5.0–10.0)
Satisfaction with insertion kit ^{d,e}	108	7.0 (3.0–8.0)	10.0 (10.0–10.0)	9.0 (7.0–10.0)
PICC inserter level of experience	108			
No history of insertion		16 (29)	1 (2)	17 (16)
One to ten devices inserted		37 (66)	12 (23)	49 (45)

Table 1 Participant and insertion characteristics at insertion (*Continued*)

	<i>n</i>	Intervention	Control	Total
11 or more devices inserted		3 (5)	39 (75)	42 (39)

Frequencies and column percentages shown unless noted otherwise

n number of non-missing observations

^aRow percentages shown

^bMean (standard deviation)

^cMultiple responses possible per participant

^dMedian (25–75th percentiles) shown

^eOn a 0 to 10 scale, 0 = worst and 10 = best

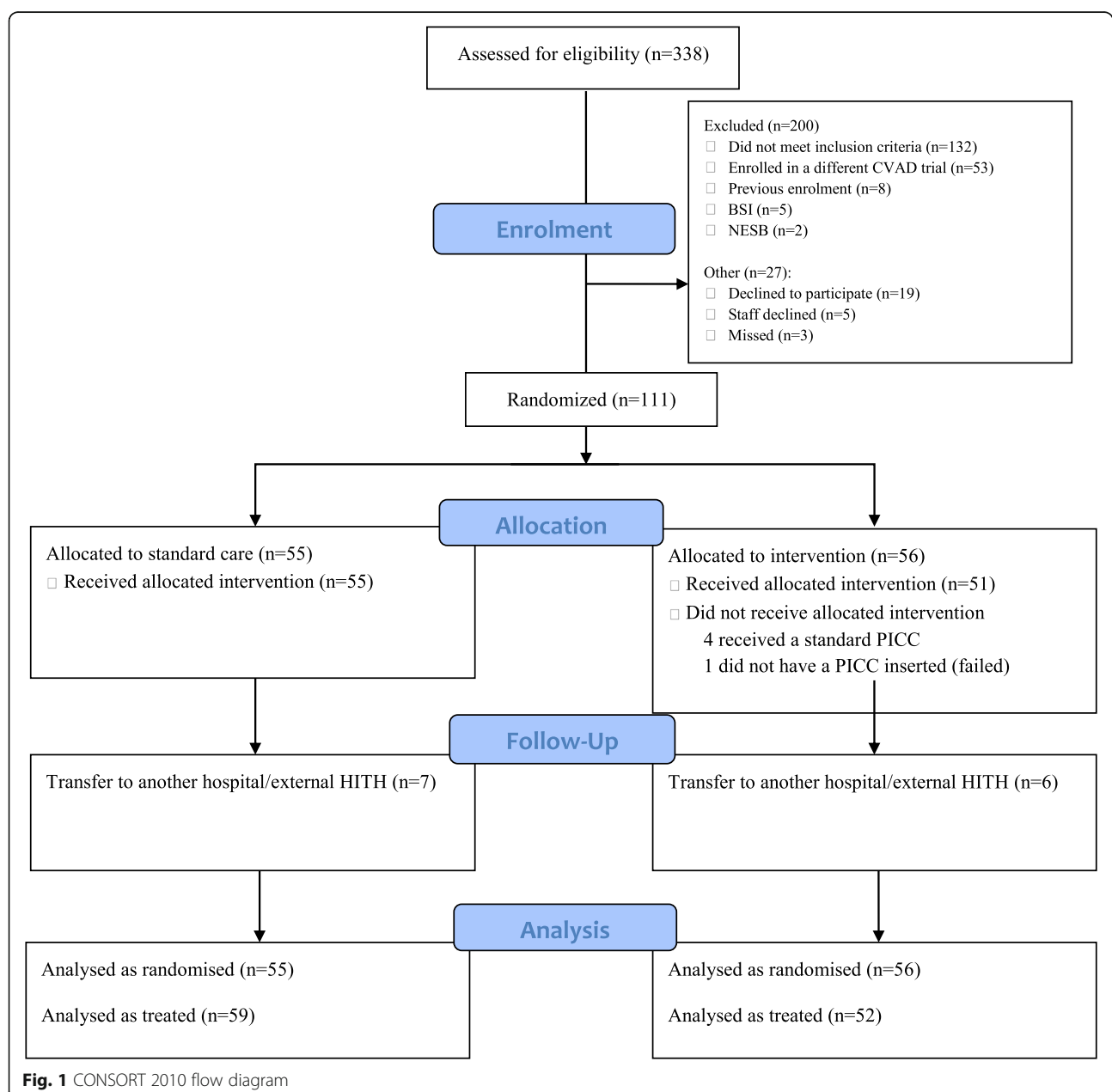


Table 2 End points

	<i>n</i>	Intervention	Control
Group size ^a	111	56 (50)	55 (50)
Reason for study completion	110		
Removed		41 (75)	42 (76)
Patient transferred		6 (11)	7 (13)
4 weeks completed		7 (13)	5 (9)
Patient deceased		1 (2)	1 (2)
Reason for removal ^b	83		
tx completed, no device complications		27 (66)	29 (69)
tx incomplete, device complications		12 (29)	11 (26)
tx completed, device complications		1 (2)	1 (2)
Transferred, no device complications		1 (2)	1 (2)
Complications (resulting in failure) ^c			
Any complication	110	13 (24)	12 (22)
PICC-associated BSI, suspected	25	6 (46)	5 (42)
Dislodgement, full	25	4 (31)	7 (58)
Occlusion	25	3 (23)	1 (8)
Skin reaction	25	1 (8)	0 (0)
Fracture	25	0 (0)	0 (0)
Suspected thrombus	25	0 (0)	0 (0)
Complications (during tx) ^c			
Any complication	110	25 (45)	20 (36)
Occlusion	45	15 (60)	11 (55)
PICC-associated BSI, suspected	45	8 (32)	3 (15)
Dislodgement, partial	45	7 (28)	4 (20)
PICC-associated thrombosis, suspected	45	1 (4)	1 (5)
Other	45	4 (16)	3 (15)
Serious adverse events ^c			
Any type	110	5 (9)	6 (11)
Positive blood culture	11	3 (60)	3 (50)
Unplanned admission to ICU	11	2 (40)	2 (33)
Death	11	1 (20)	2 (33)
Infection (baseline or during tx) ^c			
Any type	110	45 (82)	37 (67)
Wound	82	14 (31)	12 (32)
Urinary	82	8 (18)	9 (24)
Bone	82	4 (9)	7 (19)
Faecal/gastrointestinal	82	7 (16)	3 (8)
Respiratory	82	5 (11)	4 (11)
Skin/cellulitis	82	7 (16)	1 (3)
Other	82	11 (24)	13 (35)
Unknown	82	4 (9)	5 (14)
Confirmed BSI classifications (count) ^c			
LCBI (common commensal)	110	3 (5)	0 (0)
CLABSI	110	0 (0)	2 (4)

Table 2 End points (*Continued*)

	<i>n</i>	Intervention	Control
MBI-LCBI	110	1 (2)	0 (0)
Thrombus, confirmed	110	1 (2)	0 (0)
Pain at removal (0 = worst, 10 = none) ^d	26	0.0 (0–0)	0.0 (0–0)
Outpatient/HITH tx	110	19 (35)	14 (25)

Frequencies and column percentages shown unless noted otherwise

ICU intensive care unit, PICC peripherally inserted central catheter, BSI bloodstream infection, *incl.* including, HITH hospital in the home, CLABSI central line associated bloodstream infection, MBI-LCBI mucosal barrier injury laboratory confirmed bloodstream infection, LCBI laboratory confirmed bloodstream infection, tx treatment

^aRow percentages shown

^bDenominator was the number of observations with device removed

^cMultiple outcomes per device possible

^dMedian (25th/75th percentiles shown)

were recorded: one skin reaction (in the intervention group), four patients were transferred to the intensive care unit (two in each group), and three patients died (one in the intervention and two in the standard care group). In all cases, the patients' deterioration was not related to the PICC.

Discussion

This study demonstrates the feasibility of an efficacy trial of PICC materials in an adult population, once adjustments were made to include patients to be discharged to the HITH service. No lead-in time with the intervention PICC was possible outside of the trial; therefore, PICC inserters were inexperienced with the new device. This study included a broad selection of medical/surgical patients who required a PICC for treatment in the hospital and/or as a HITH patient in their own homes. Patients ranged from being ambulant requiring long-term antibiotics to patients with major surgery, such as pelvic exenterations. To further improve eligibility, future trials might consider surrogate decision maker and telephone consent as 21 out of the 338 (6%) patients approached were too confused to consent. Despite these challenges, it is important that an adequately powered trial comparing

the effectiveness of hydrophobic PICCs to other PICC technologies is conducted, as PICC failure remains unacceptably high. Previous systematic reviews have highlighted that one-third of PICCs fail [6] with comparable incidence seen in our study. Clinicians and policy makers need to take urgent steps to investigate potential improvements in PICC outcomes since failure disrupts patient treatment due to delay in insertion of a new PICC and multiple PICCs can increase patient complications and decrease the quality of a patient's experience [8–12]. PICCs are associated with morbid complications, such as CLABSI and deep vein thrombosis; thus, it is essential researchers generate further evidence to guide clinicians to select the most appropriate PICC materials to reduce these potentially fatal adverse events and improve the overall quality of care provided to patients [14, 40].

This pilot RCT compared a hydrophobic polyurethane PICC with proximal valve with a power-injectable polyurethane PICC with external clamp to reduce PICC failure and complications in an adult population. This study followed the same methodology as the paediatric protocol [35] and published study [26] and was reported in line with the CONSORT guidelines. A quarter of PICCs failed (25/110; 23%) before treatment completion. The

Table 3 Failure rates and survival analysis

	<i>n</i>	Intervention (<i>n</i> = 55)	Control (<i>n</i> = 55)	<i>p</i> value
PICC failure	110	13 (24%)	12 (22%)	0.820 ^a
Dwell time (days) ^b	110	12 (5–21)	8 (5–15)	0.175 ^c
Device days	110	797	651	–
Incidence rate (per 1000 PICC days) ^d		16.3 (9.5–28.1)	18.4 (10.5–32.5)	0.755 ^e
Incidence rate ratio		0.89 (0.37–2.12)	Reference	

hyphen = not calculated

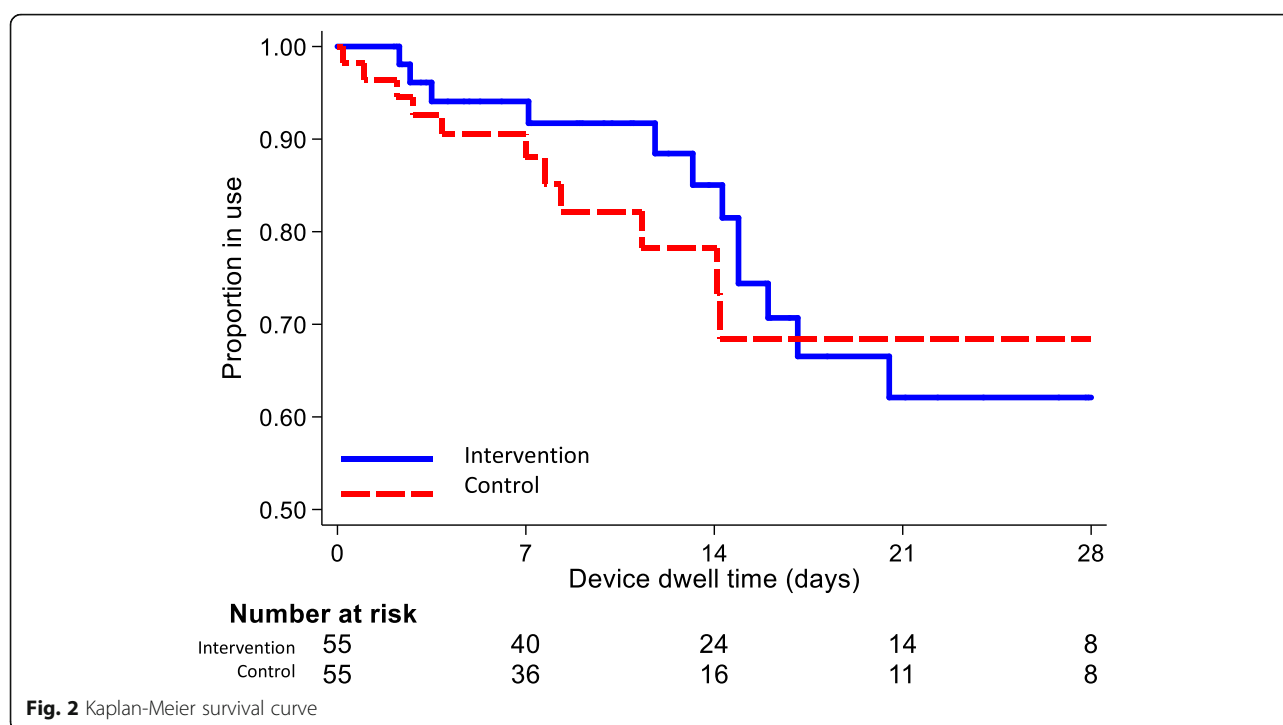
^aChi-squared test

^bMedian (25–75th percentiles) shown

^cWilcoxon rank-sum test

^dRate and 95% confidence interval shown

^eCox univariable regression



primary objective of this study was feasibility (rather than reducing PICC failure); and although the incident rate ratio of 0.89 favoured the intervention, PICC failure was not significantly different between the groups (12/55; 22% in the standard care and 13/55; 24% in the intervention group).

To date, six studies, published in peer reviewed journals and as conference abstracts, have compared the BioFlo® PICC with non-hydrophobic PICCs: one paediatric pilot RCT [26], one adult RCT [41], one quasi-experimental clinical evaluation [42], and three retrospective cohort studies [43–45]. With the exception of the paediatric pilot RCT [26], it is difficult to assess the risk of bias in the other studies published to date as they are conference abstracts. All but one [41] study demonstrated an improvement in PICC-associated thrombosis and occlusion with BioFlo®. Musial and Hamad [43] reported in their economic evaluation that despite the reduction in occlusion with BioFlo® PICC, when the increased cost of BioFlo® was compared to cost savings from reduced use of the thrombolytic treatment alteplase (Cathflo Activase, Genentec Inc., San Francisco, CA), there was no economic benefit, but they did not consider costs of lost treatment time and extended in-patient stay. Currently, there is insufficient clinical data to definitively demonstrate the potentially beneficial hydrophobic properties of BioFlo® PICC in clinical practice, thus further large trials have commenced.

Limitations of this study include the length of follow-up of patients. We followed our patients for up to of 4 weeks

rather than until PICC removal. This might explain why only four incidences of occlusion resulting in PICC failure occurred (see Table 2). Another limitation was that only patients showing clinical symptoms of thrombus were referred for an ultrasound for confirmation. This may explain the low rate of PICC-associated thrombus in this cohort. Future studies should consider routine ultrasounds as approximately two-thirds of PICC-associated thrombi are asymptomatic [46]. Additionally, it was not possible to blind the PICC inserters, patient or other healthcare professionals. Despite these limitations, intervention fidelity was strong and the potential for reproducibility in future trials through the publication of the trial protocol [35] and reporting of the study and PICC procedures, which allows for generalisability of the study results.

The results of this study should be interpreted with caution as it reports the results of a pilot RCT that recruited 110 patients. A full-scale adequately powered efficacy trial is required to test the statistical hypotheses of the efficacy of a hydrophobic polyurethane PICC with proximal valve compared to a plain polyurethane PICC with external clamp to reduce PICC failure and complications. A multi-centre trial recruiting adults and children would ensure these results are generalizable beyond this single centre and demonstrate external validity and safeguarding internal validity with comparable groups at baseline.

Conclusions

In conclusion, this study demonstrated that it is feasible to conduct an RCT comparing the efficacy of

hydrophobic polyurethane PICCs (with pressure-activated proximal valves) with polyurethane PICCs (with external clamps) in an adult population receiving treatment at a large quaternary referral hospital and/or HITH service. It is important that future studies evaluate cost-effectiveness, including inserter and patient acceptability, to robustly evaluate the impact of different PICC materials on failure. Additionally, this study demonstrated the importance of providing a sufficient lead-in time to train PICC inserters before the commencement of data collection as lack of familiarity with an interventional product could impact study results.

Abbreviations

CLABSI: Central line-associated bloodstream infection; HITH: Hospital in the Home; PASV: Pressure-activated safety valve; PICC: Peripherally inserted central catheter; RBWH: Royal Brisbane and Women's Hospital; RCT: Randomised controlled trial; ReN: Research nurse

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Authors' contributions

NG contributed to the acquisition, analysis, and interpretation of data and drafted the first version; TK contributed to the design of the study and the analysis and interpretation of data; EL contributed to the analysis and interpretation of data; COB contributed to the acquisition, analysis, and interpretation of data; AU contributed to the design of the study and the analysis and interpretation of data; SN contributed to the design of the study; GM contributed to the analysis and interpretation of data; NR contributed to the analysis and interpretation of data; NM contributed to the analysis and interpretation of data; CR contributed to the design of the study and the analysis and interpretation of data. All authors substantially revised the publication and have read and approved the submitted version. All authors agree to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

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Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available due to our Human Research and Ethics Committee approval but are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The trial was approved by the Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC/15/QRCH/164) and Griffith University Human Research Ethics Committee (Ref No. 2016/077). Written informed consent was obtained from all participants prior to entry into the study.

Consent for publication

Not applicable

Competing interests

NG: none; TK: related to the submitted project, TK reports an investigator-initiated research grant from Angiodynamics. TK reports investigator-initiated research grants and speaker fees provided to Griffith University from 3M Medical, Angiodynamics, Baxter, Becton Dickinson, Centurion Medical, Cook Medical, Medical Specialties Australia, Smiths Medical, and Vygon (unrelated to the current project); EL: Griffith University has received consultancy payment for an educational lecture from 3M on behalf of EL; an investigator-initiated research grant from Cardinal Health (formerly Medtronic); and a conference scholarship attendance supported by Angiodynamics (unrelated to the submitted work) to support EL's research. EL is a recipient of a Higher Degree Research Scholarship from the Australian Government Research Training Program; COB: none; AU: related to the submitted project, AU reports an investigator-initiated research grant from Angiodynamics. AU reports investigator-initiated research grants and speaker fees provided to Griffith University from 3M Medical, Becton Dickinson and Cardinal Health (unrelated to the current project). AU is currently supported by an Australian Government, National Health and Medical Research Council Fellowship, via Griffith University; SN: related to the submitted project, SN reports an investigator-initiated research grant from Angiodynamics; GM: related to the submitted project, GM reports an investigator-initiated research grant from Angiodynamics. GM is a recipient of a Higher Degree Research Scholarship from the Australian Government Research Training Program; NR: none; NM: NM's previous employer (Griffith University) has received on her behalf: investigator-initiated research grants and unrestricted educational grants from Becton Dickinson and Cardinal Health and a consultancy payment provided to Griffith University from Becton Dickinson for clinical feedback related to catheter placement and maintenance (unrelated to the current project); CM: Griffith University has received unrestricted investigator-initiated research or educational grants on my behalf from product manufacturers (BD-Bard; Cardinal Health). Griffith University has received consultancy payments on my behalf from manufacturers (3M, B Braun, BD-Bard).

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ORIGINAL ARTICLE



Effects of Peripherally inserted Central Catheter (PICC) materials and designs on reduction of PICC-related complications: A systematic review and meta-analysis

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Abstract

Studies showed that integrating coating or valve into Peripherally Inserted Central (PICC) can prevent related complications. However, data regarding efficiency were controversial. Therefore, a systematic review was needed to analyse the effect of PICC materials and designs on reduction of PICC-related complications. We searched PubMed, Cochrane library, EMBASE, grey literature and referent literature from inception to 5 August 2022. Randomized controlled trials (RCTs) and case-control study were included. Two authors extracted data independently, using a predesigned Excel form, and assessed the quality of included RCTs according to the Cochrane Handbook for Systematic Reviews (V5.1.0), case-control study was assessed by the Newcastle-Ottawa Scale. Data were analysed using Review Manager (v5.3.0). A total of 10 RCTs and one case-control study were included. Meta-analysis results showed that PICC designs reduce the incidence of obstruction, and at the critical value of PICC-associated bloodstream infection, but may have no effects on other complications. Based on the literature reviewed, we can only say PICC new materials did not reflect significant reduction on complications, what's more, the result needs more multicentre, large RCTs to support. We suggested clinicians combine descriptive research and cost-effect analysis to select appropriate PICC materials and designs for patients.

KEYWORDS

complication, new design, new material, PICC, valve

Key Messages

- This is the first meta-analysis to compare the effects of Peripherally Inserted Central Catheter (PICC) design on reduction of complications.

- Our study found that PICC designs reduced the incidence of obstruction, and at the critical value of PICC-associated bloodstream infection. However, based on the literature reviewed, we can only say PICC new materials did not reflect significant reduction on complications.

1 | BACKGROUND

Peripherally Inserted Central Catheter (PICC) refers to the catheterization of the catheter through the patient's peripheral venous puncture, so that the tip of the catheter reaches the lower 1/3 of the superior vena cava, or the central venous catheter where the superior vena cava joins the right atrium. PICCs are used for intravenous fluids, medications, blood products and for blood sampling to prevent frequent venipuncture, which can enable treatment in inpatient, outpatient and community-based.¹ The study showed that about one-third of PICCs failed prior to completion of treatment, due to infections, blockage, dislodgement, vein thrombosis, occlusion and so on.² The United States National Healthcare Safety Network reported that Catheter-Related Blood Stream Infection (CRBSI) rates up to 3.5%,³ another study which included France, Germany, Italy and the United Kingdom estimated that CRBSI was associated with costs of between EUR 35.9 and EUR 163.9 million per year in these countries.⁴ It reported that symptomatic thrombosis incidence rate can be up to 3%–20%,^{5–9} asymptomatic thrombosis can be 61.9%,¹⁰ and 25%–30%¹¹ of catheters were occluded.

Integrating antithrombotic and anti-infective technologies into the PICC materials are potential innovations to prevent complications. There are four common antithrombotic materials, which include hydrophilic surfaces, hydrophobic surfaces, biological surfaces and added drugs.¹² Cochrane review¹³ which included 57 studies concluded that impregnation, coating or bonding central venous catheters (CVCs) significantly reduced catheter-associated blood stream Infection (CABSI) risk. An animal experiment¹⁴ demonstrated that Chlorhexidine gluconate (CHG) coating controlled the fibrin sheath development after 30 days in situ, compared with uncoated catheters. Also, a study¹⁵ showed that heparin coating was thought to reduce bacterial growth via a prevention of fibrin deposition and thrombus formation in the catheters. Ullman AJ¹⁶ team conducted a protocol of a multicentre, parallel group, superiority randomized controlled trial, and compared the effect of hydrophobic PICC (with pressure activated valve), chlorhexidine gluconate-impregnated PICC (with external clamp) and conventional polyurethane PICC (with external clamp) on reduction of infections

and clots. An evidence-based study¹⁷ which was published in 2016 suggested that antimicrobial PICCs may reduce CLABSI. However, the team of Ullman AJ conducted¹⁸ an analysis of 42 562 hospitalized patients and concluded that antimicrobial and antithrombogenic PICCs were not associated with a reduction in major catheter complications.

PICC design included valves built into the device to reduce occlusion. It prevents reflux of blood from catheter tip to the distal end of the catheter. One research¹⁹ showed that proximal valve polyurethane PICCs were more durable than distal valve silicone PICCs. However, a randomized controlled trial (RCT) concluded that no differences in device longevity or occlusion rates were observed when three different valve types were compared head to head.²⁰ So, the effects of PICC designs on complications remained elusive.

Overall, Since 2016 several new studies to compare the effect of coating PICC were published, there were also necessary to know the effects of PICC valve design. Therefore, we would update the systematic review of PICC materials published in 2016, and conduct a new systematic review to compare the effect of PICC valve design, to provide evidence for clinical practice.

2 | METHODS

2.1 | Search strategy

PubMed, Cochrane library, Embase, grey literature and referent literature were searched from inception to 5 August 2022. The search strategies were ('PICC' OR 'peripheral catheterization*' OR 'peripherally inserted central catheter*' OR 'peripheral arterial catheterization*' OR 'peripheral venous catheterization*') AND ('Chlorhexidine' OR 'Antithrombogenic' OR 'Antimicrobial' OR 'hydrophobic' OR 'polyurethane' OR 'fluorinated' OR 'Anti-infective' OR 'minocycline-rifampicin' OR 'chlorhexidine gluconate' OR 'CHG' OR 'Distal Valve' OR 'Proximal Valve' OR 'external clamp' OR 'internal valve'). An experienced expert was invited to review the selected search strategy. In addition, we manually searched for the unpublished literature and also tried to contact the authors via email to obtain unreliable literature.

2.2 | Eligibility criteria

2.2.1 | Types of participants

Patients with PICC were included. We did not limit the age, type of diseases, inpatient or outpatient.

2.2.2 | Types of intervention

We considered intervention as any PICC with new materials or designs, included antimicrobial impregnated PICC, hydrophobic PICC, antibiotic impregnated PICC, proximal valved PICC, solo valved PICC, pressure activated safety valved PICC and Groshong valved PICC. Also, both simple intervention and multiple interventions were included.

2.2.3 | Comparators

The control group was the control group set in each study was unified into the traditional PICC.

2.2.4 | Outcome measures

The outcomes were PICC-associated BSI, thrombosis, occlusion and dislodgement.

2.2.5 | Types of study

RCTs and case-control study were included. Conference presentations, thesis and abstracts were excluded.

2.3 | Study selection

All studies were selected in the EndNote X8 which was a literature management software. Two authors independently reviewed the titles and abstracts to screen studies, then reviewed the full-text to include studies for quantitative analysis. A third reviewer would be invited when there were differences between the two authors.

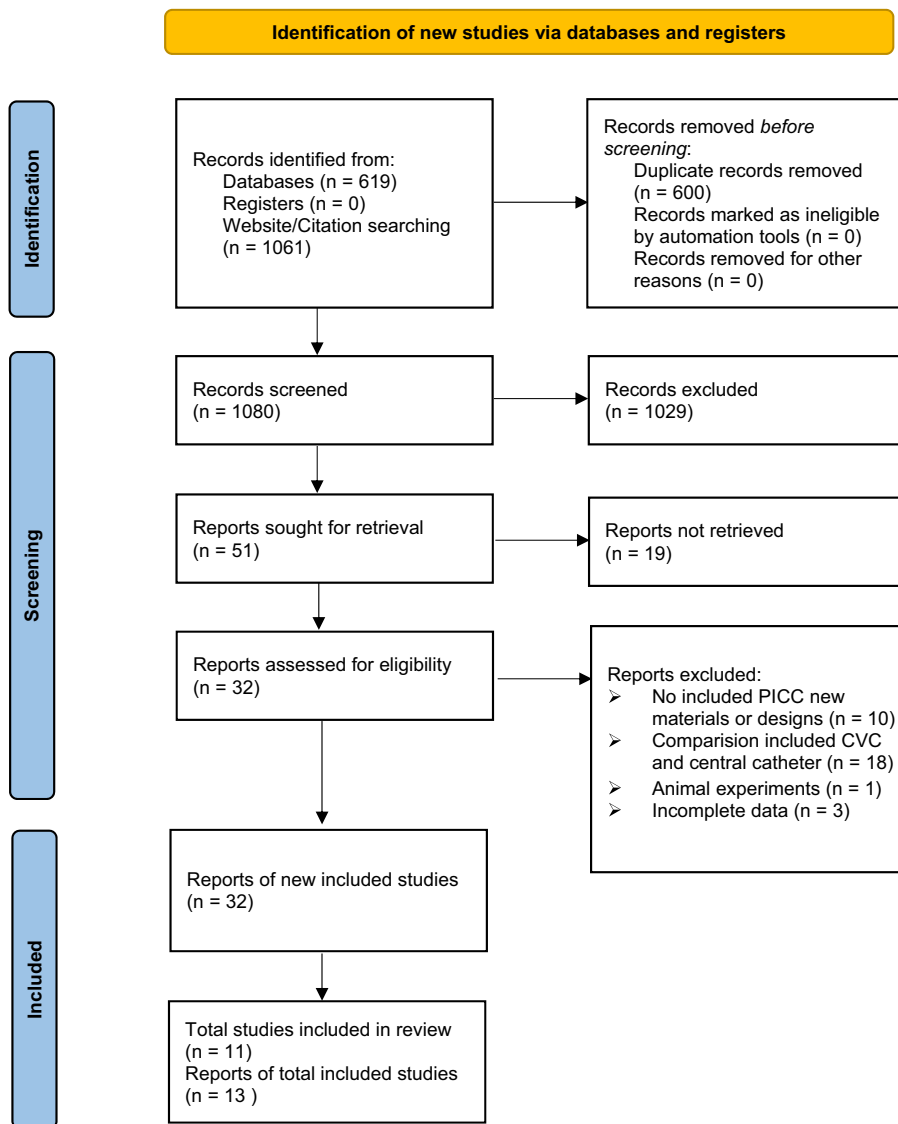


FIGURE 1 Study flow diagram. CVC, Central venous catheter; PICC, Peripherally Inserted Central Catheter.

2.4 | Data extraction

Two authors independently extracted data according to a predesigned form, which included study characteristics (first author, year, country, study type), patient characteristics (sample type, sample size, male/female, age, interventions and controls) and outcomes (incidence of CRSBI, thrombus, occlusion and dislodgement).

2.5 | Quality assessment

Two reviewers independently assessed the risk of bias of RCT using the Cochrane Handbook for Systematic Reviews (V5.1.0),²¹ which included random sequence generation, allocation concealment, participants/personnel blinding, outcome assessor blinding, incomplete outcome data, selective reporting and other bias. Case-control study was assessed by the Newcastle-Ottawa Scale (NOS),²² which includes 'the selection of the study groups', 'the comparability of the groups' and 'the ascertainment of either the exposure or outcome of interest for case-control or cohort studies, respectively'. A third reviewer would be invited when there were differences between the two authors.

2.6 | Data synthesis and statistical methods

We performed meta-analysis of the included trials with Review Manager 5.3 (Revman 5.3). For dichotomous outcomes, we used the OR and 95% CIs to measure treatment effects. For the heterogeneity test, if $p \geq 0.1$, $I^2 < 50\%$, the fixed effects model was used for analysis; otherwise, we will consider there is a large heterogeneity between the studies and sensitivity analysis and subgroup analysis will be performed to find the source of heterogeneity. If data cannot be combined quantitatively, we will perform qualitative analysis.

PROSPERO registration number: CRD42022356087.

3 | RESULTS

3.1 | Study inclusion

The initial literature search retrieved 1680 potentially eligible studies. After screening titles, abstracts and full-text review, 11 studies were included in review, two studies included three comparisons of interventions and split into four studies, so, 13 studies were analysed. The study flow diagram is shown in Figure 1. Among the 11 studies with 2346 patients, 10 studies were RCT, one study was

case-control study, one study was from Asia, 10 studies were from Europe; the details are shown in Table 1.

3.2 | Quality of inclusion study

Ten studies were RCT, the risk of bias assessed by Cochrane Handbook for Systematic Reviews (V5.1.0), the red, yellow and green represented high, unclear and low risk of bias, one study reported no participants and personnel blinding, which was high-risk bias, other studies reported unclear or blind for participants and personnel. One case-control study was included, and was evaluated by NOS. The study population were patients with CLABSI, the origin of infection was PICC, and the diagnosis were made by microbiological laboratory, and data were collected continuously for 4 years, the control group consisted of patients without PICC CLABSI. Also, the study analysed potential risk factors, and the data can be found in the hospital charts, the exposure factors are the same, the quality score was 5 points, the quality of study was medium. Details are shown in Figure 2 and Table 2.

3.3 | Synthesized outcomes

3.3.1 | Occlusion

Seven studies (five studies were new design, two studies were new materials) were included in these outcomes. There was no significant heterogeneity among the studies of new design ($I^2 = 11\%$, $p = 0.34$) and new materials ($I^2 = 0\%$, $p = 0.49$), so we chose the fixed effects model. The results revealed that PICC new designs may reduce incidence of occlusion ($p = 0.02$), but the evidence of new materials was poor ($p = 0.25$). For details see Figure 3.

3.3.2 | Peripherally inserted central catheter-associated bloodstream infection

PICC-associated BSI included nine studies (three studies were new design, six studies were new materials), we selected the fixed effects model because the heterogeneity were not significant of new design ($I^2 = 0\%$, $p = 0.37$) and new materials ($I^2 = 50\%$, $p = 0.07$). The results did not demonstrate reduction of PICC-associated BSI of new designs ($p = 0.05$) and materials ($p = 0.26$), but new designs were at the critical value, which may be small sample size and sample inadequately powered to measure BSIs. For details see Figure 4.

TABLE 1 Characteristics of studies included in the meta-analysis.

Protocol	Author/year	Study type	Country	Sample type	Age		Male/Female		Interventions		Outcomes
					Intervention group	Control group	Intervention group	Control group	Intervention group	Control group	
PICC new materials	Nicole C. Gavin 2020	RCT	Australia	Adult	59 ± 15	62 ± 16	28/56	24/53	Hydrophobic polyurethane PICC with a proximal valve	Traditional PICC	1, 2, 3, 4
	M. Klemme 2019	RCT	Germany , Italy	Neonates	NA	NA	17/37	18/34	Antibiotic-impregnated PICC	Traditional PICC	2, 4
	Susan Storey 2016	RCT	USA	Adult	62	64	NA	NA	Chlorhexidine PICC	Traditional PICC	2, 4
	Evgenia Kagan 2018	Case-control study	USA	Adult	59	55	49/93	117/263	Antimicrobial PICC	Traditional PICC	2
	Hiromichi Miyagaki 2012	RCT	Japan	Adult	64.5 (56 ~ 80)	67 (58 ~ 80)	13/14	11/11	Polyurethane catheter with open-end tip	Traditional PICC	1, 2, 4
PICC new designs	Ruth Gilbert 2019	RCT	England	Neonatal	NA	NA	214/430	225/431	Antimicrobial impregnated PICC	Traditional PICC	2
	Cheng K 2010	RCT	\	Adult	49.0 ± 15.8	51.9 ± 17.9	119/198	128/194	Proximal valve polyurethane PICCs	Traditional PICC	1, 2, 3
	Mauro Pittiruti 2014	RCT	Italy	Adult	64 ± 12.1	62 ± 14.5	22/61	19/59	Solo valve	Traditional PICC	4
	Mauro Pittiruti 2014 ²	RCT	Italy	Adult	61 ± 10.1	62 ± 14.5	22/60	19/59	Pressure activated safety valve	Traditional PICC	4
	Tricia Kleidon 2017	RCT	Australia	Paediatric	7.1 ± 5.1	7.5 ± 4.9	45/75	41/75	PICC with internal valve	Traditional PICC	1, 2, 3, 4
	Eric K 2001	RCT	USA	Adult	47.5 (18 ~ 85)	52.1 (18 ~ 89)	35/52	31/48	Proximal valve	Traditional PICC	1, 2, 3
	Andrew J. Johnston 2012	RCT	UK	Adult	53.7 ± 18.7	60.7 ± 14.9	20/34	12/34	Groshong valve	Traditional PICC	1
	Andrew J. Johnston 2012 ²	RCT	UK	Adult	58.5 ± 16.1	60.7 ± 14.9	22/33	12/34	PICC with pressure activated safety valve	Traditional PICC	1

Note: Outcome 1: Occlusion; outcome 2: PICC-associated BSI; outcome 3: Dislodgement; outcome 4: PICC-associated thrombosis. Abbreviations: NA, Not available; PICC, Peripherally inserted central catheters; RCTs, Randomized controlled trials.

3.3.3 | Dislodgement

Four studies (three studies were new design, one study was new material) were included in dislodgement. There was no significant heterogeneity among the studies of new design ($I^2 = 0\%$, $p = 0.92$), we selected the fixed effects model. The included studies did not fully demonstrate the effectiveness of new materials and designs on dislodgement, which may be due to the small number of included studies. For details see Figure 5.

3.3.4 | PICC-associated thrombosis

Six studies (three studies were new design, three studies were new materials) reported PICC-associated thrombosis, no statistical heterogeneity was observed among the studies of new designs ($I^2 = 11\%$, $p = 0.33$) and new

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Andrew J. Johnston 2012	?	?	?	?	+	+	+
Cheng K 2010	+	+	+	+	+	+	+
Eric K 2001	+	?	?	?	+	+	+
Hiromichi Miyagaki 2012	+	+	?	?	+	+	+
M. Klemme 2019	+	?	?	?	+	+	+
Mauro Pittiruti 2014	?	?	?	?	+	+	+
Nicole C. Gavin 2020	?	?	?	?	+	+	+
Ruth Gilbert 2019	+	+	+	+	+	+	+
Susan Storey 2016	+	+	?	?	+	+	+
Tricia Kleidon 2017	+	+	?	+	+	+	+

FIGURE 2 Risk of bias.

TABLE 2 Risk of bias of included case-control studies.

Study	Representativeness of the exposed cohort	Selection of the non-exposed cohort	Demonstration that outcome of interest was not present at the start of study	Comparability of cohorts on the basis of the design or analysis	Assessment of outcome	Was followed-up long enough for outcomes to occur	Adequacy of follow-up of cohorts	Quality score
Evgenia Kagan 2018	*	*	*	*	*	/	/	5

materials ($I^2 = 0\%$, $p = 0.75$). There were no statistical differences of the results of both designs and materials. For details see Figure 6.

3.3.5 | Sensitivity analysis

We performed sensitivity analysis by sequential culling to test stability. For every outcome, one study was excluded in turn, and the remaining studies were meta-analysed and merged. We found the models of the four outcomes were stable.

4 | DISCUSSION

The result of our meta-analysis showed that new designs of PICC can reduce incidence of occlusion, but it was not statistically significant for other complications, while the new PICC material had no effect on all complications, but the effect of infection was at the cut-off value of statistical variability. Seven studies reported randomized method, four studies did not mention. Five studies reported allocation concealment and is low-risk bias, one study reported no participants and personnel blinding, which were high-risk bias, other studies were unclear or report blind. The quality of the case-control study was medium. Overall, the quality of included studies was reliable, but more studies with large samples are needed to verify.

4.1 | The effect of new materials on PICC-related complications

Fibrin sheath was triggered by the vessel injury during catheter implantation, and covered the entire catheter within a few days.²³ Fibrin sheath was associated with CLABSI pathogens, which enter the bloodstream through both extraluminal and inner luminal wall of implanted catheter, seeding of bacterial pathogens from biofilm also induces CLABSI.²⁴ Bio-passive surface coated to target both thrombosis and infection gradually was a successful approach for medical devices and implants. Gavin et al.²⁵ showed the effectiveness of PICC new materials (hydrophobic polyurethane PICC) in an adult population, not only in-patients, but also patients discharged from hospital. A systematic review¹⁷ suggested that antimicrobial PICCs may reduce CLABSI for the high-risk population. Takezawa et al.²⁶ showed that synthetic polymer-coated PICC is safe and has less catheter complications. However, a prospective cohort study involving 52 hospitals showed that antimicrobial and antithrombogenic PICCs cannot reduce catheter complications, and proposed more attention to balance benefits against cost.¹⁶ Also, antibiotic coated CVCs have limited clinical success in resisting bloodstream infection and may increase the risk of emerging antibiotic resistant strains, and is not widely recommended, except in high-risk patient populations, for example, surgical patients with cancer or infection, immunocompromised, adult burn patients or infants.¹⁷ Therefore, the effect of PICC new materials on complications was still unclear, and need more trials to innovate new materials.

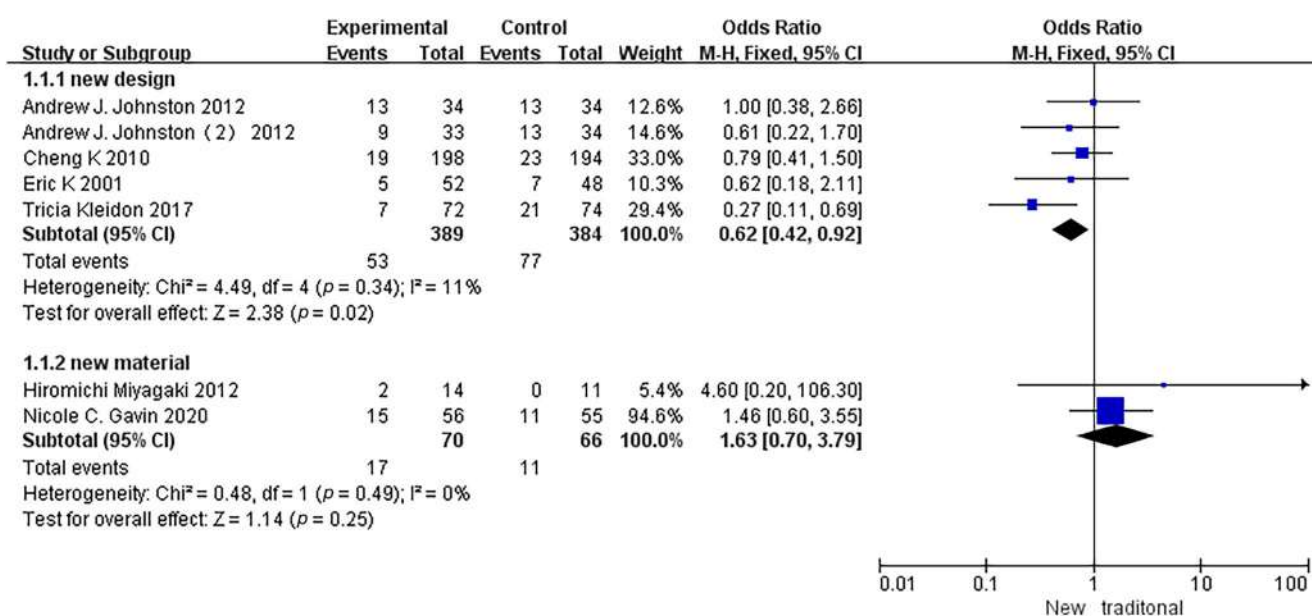


FIGURE 3 Forest of occlusion.

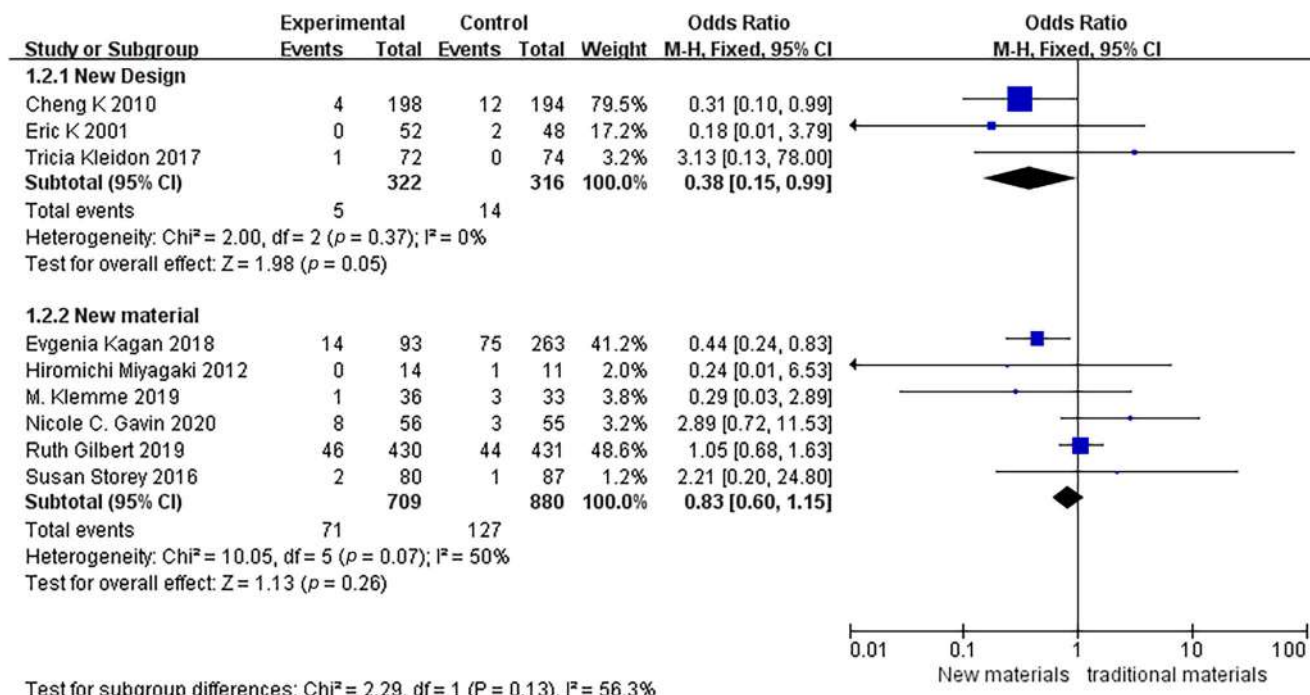


FIGURE 4 Forest of Peripherally Inserted Central Catheter-associated bloodstream infection.

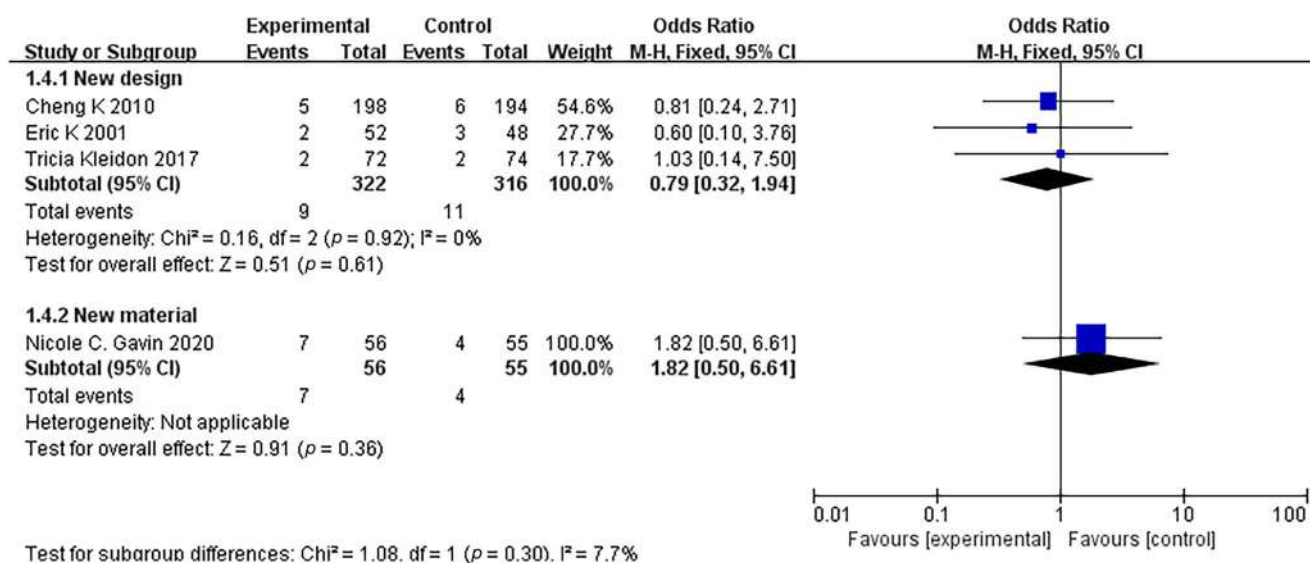


FIGURE 5 Forest of dislodgement.

4.2 | The effect of new designs on PICC-related complications

PICC valves designed can reduce reflux of blood from the catheter tip back into the lumen as a means to prevent occlusion. Significantly lower incidence of complications was found when compared with the open-ended catheters,²⁷ and a study showed that proximal valve

polyurethane PICCs¹⁹ were more durable than traditional PICCs. However, Pittiruti et al.²⁸ showed no clinical advantages of valved versus non-valved PICCs, also, another study²⁰ showed that valved PICCs do not appear to influence PICC occlusion rates. Our study showed that valved PICC may reduce complications, the reasons may be the control group included were not only valved PICC, but also mixed interventions of different PICC materials.

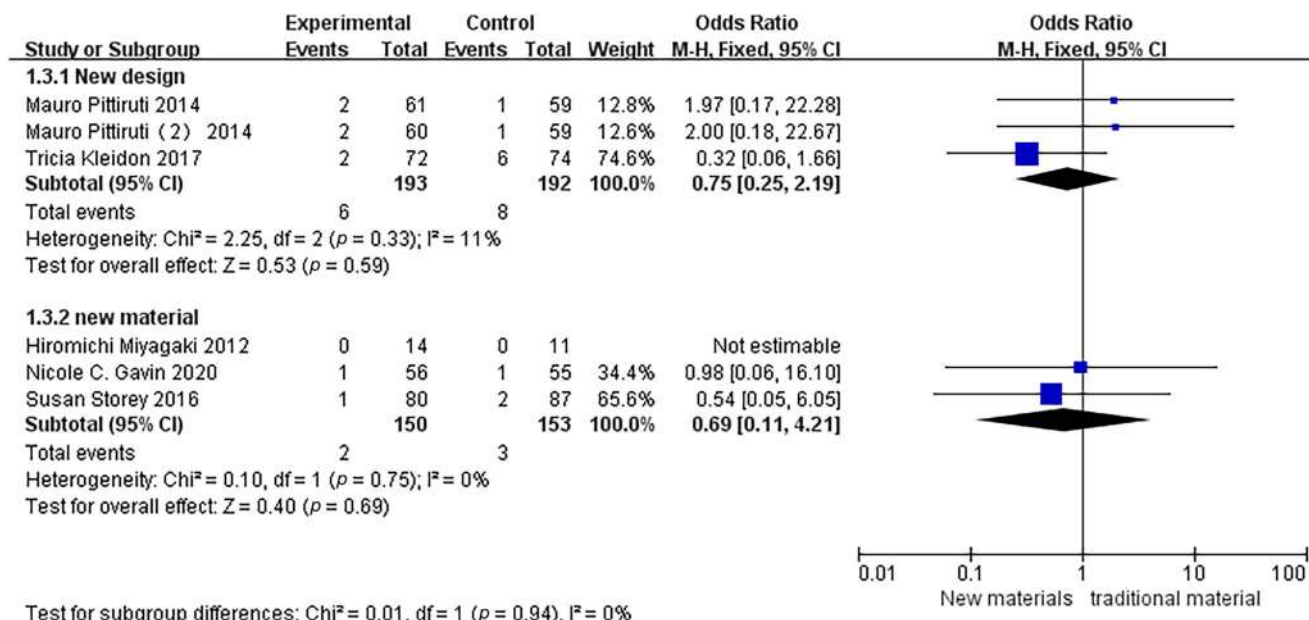


FIGURE 6 Forest of Peripherally Inserted Central Catheter-associated thrombosis.

4.3 | Limitations

This study has several limitations. Firstly, limited number of studies were included, and only one study was from Asia, study representation may not be strong. Secondly, because too few studies were included, we did not limit the population characteristics of the included studies, and clinical heterogeneity may be observed. Thirdly, the control group was not uniform and may have an impact on heterogeneity. Fourthly, studies did not have cost-benefit analyses, could not inform clinicians to choose better. Finally, the quality of the included study was not high, more multi-centre, large-sample RCTs are needed.

5 | CONCLUSION

We concluded that PICC new designs may reduce the incidence of catheter obstruction and PICC-associated BSI. The impact of PICC new materials was inconclusive and may not demonstrate a reduction on complications based on the literature reviewed. We suggested that the clinicians should consider cost-effect analysis to select appropriate PICC materials and designs for patients.

CONFLICT OF INTEREST STATEMENT

All authors disclosed no relevant relationships.

DATA AVAILABILITY STATEMENT

The data that supports the findings of this study are available in the supplementary material of this article

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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CLINICAL TRIAL

Intravenous Line Labels For High-Alert Drugs Administered To Critically Ill Patients: A Simulated Experimental Assessment

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ABSTRACT

Aims and Objectives: Evaluate the effect of IV line labels on nurses' identification of high-alert medications in a simulated scenario of multiple infusions for critically ill patients.

Design: Randomised crossover simulation experimental study.

Methods: A study was conducted on 29 nurses working in intensive care for over 6 months. They were given two critical scenarios in a simulated environment, one with labels and the other without labels, involving multiple intravenous infusions. The nurses had to identify the medications infused into the critical patients' intravenous lines and disconnect a specific line. The data were collected and analysed to evaluate the errors made by the nurses in identifying and disconnecting the medications and the time they spent carrying out the tasks. The Wilcoxon test was used to analyse the variation in outcome before and after the intervention.

Results: Approximately one-third of the study participants incorrectly identified the intravenous lines in both scenarios. There was no significant difference in the average number of errors between the scenarios with and without labels. However, the time taken to perform the tasks in the scenario with labels was 1 min less than in the scenario without labels, suggesting a potential efficiency gain.

Conclusions: The labels on the intravenous lines allowed for quick drug identification and disconnection. The professionals performed similarly in correctly recognising the high-alert medication intravenous lines, in the scenarios with or without labels.

Relevance to Clinical Practice: The label can be used as a technology to prevent misidentification of high-alert medications administered to critically ill patients through intravenous lines, thereby enhancing medication safety in healthcare institutions. No Public Contribution.

1 | Introduction

Medication errors involving high-alert drugs administered intravenously are a significant concern in critically ill patients.

These errors increase the risk of causing significant harm to the patient (Kuitunen et al. 2021). One reason for these errors is intensive care professionals' difficulty identifying these drugs in intravenous (IV) lines (Pinkney, Fan, Chan et al. 2019).

Summary

- What does this paper contribute to the wider global clinical community?
 - Intertwining of intravenous lines of multiple infusions administered to critically ill patients increases the chances of drug administration errors;
 - There is a lack of knowledge regarding the best labelling standards for intravenous lines of high-alert medications administered to critically ill patients and the impact of labelling on patient safety;
 - Our research provides practical insights, revealing that labels with specific characteristics can significantly reduce the time nurses spend identifying drugs in intravenous lines and minimise errors related to identifying high-alert drugs. These characteristics include labels printed on resistant material, with differences in font colour and size, and containing the following information: the name of the drug, its dose, time of preparation, date of line change and expiration date of the drug.

It can be challenging to identify IV lines due to visual clutter and the entwining of lines that occur when multiple medications are used simultaneously. In intensive care settings, a multi-lumen central venous catheter can be used to administer multiple infusions, which can increase the risk of drug administration errors in critically ill patients. This population often requires urgent and frequent changes in medication therapy (Pinkney, Fan, Koczmara, and Trbovich 2019; Smith and Litman 2017; Fan et al. 2019).

Implementing preventive strategies to ensure the safety of critically ill patients with multiple IV infusions is increasingly essential. One such strategy is to use IV line labels with drug information attached to each infusion line. Drug information is typically only found on labels attached to infusion bags. However, IV lines are handled close to the patient's vascular access point during drug administration or when disconnecting infusions. Since the lengths of IV lines are visually similar, proper identification is necessary to avoid medication errors (Pinkney, Fan, Koczmara, and Trbovich 2019; Souza et al. 2019; Rodziewicz, Houseman, and Reduction 2023).

There are no general recommendations or guidelines on using IV line labels in practice. Furthermore, the existing standard for label standardisation—International Organization for Standardization (ISO) number 26825/2021—is limited to single-dose drugs used in the anaesthetic area and for syringe-type devices (International Organization for Standardization 2022).

Given this context, it is relevant to consider the development and integration of technologies aimed at increasing patient safety, especially in light of the Global Action Plan for Patient Safety 2021–2030, proposed by the World Health Organization. This plan aims to achieve the maximum possible reduction in avoidable harm due to unsafe health care worldwide in 2021–2030 (World Health Organization 2021).

2 | Background

Errors with high-alert medications are a problem of significant magnitude. A systematic review of five studies on the prevalence of harm caused by medication errors involving high-risk medications illustrates this. The combined prevalence of harm was 16.3%, and 0.01% of harms resulted in patient death. The highest prevalence of harm occurred following the use of potassium chloride, insulin and epoprostenol (Alves et al. 2021).

A 2015 study analysed medication errors reported in a safety record system at a tertiary hospital in Saudi Arabia. The study found 624 medication errors, with 281 (45%) attributed to high-alert drugs, which were identified as the leading cause of safety failures. Chemotherapeutic agents accounted for the highest percentage, 23.6%, followed by anticoagulants at 7.5% and narcotics at 4.8% (Aseeri et al. 2020).

A study investigated medication errors within intensive care units, specifically focusing on those involving high-alert medications. The study identified 305 incidents of medication errors involving 73 different drugs in 33 classes. High-alert medications were responsible for 37 occurrences (12%), with venous anaesthetics (midazolam and fentanyl) and anticoagulants (heparin) being the main culprits, with a frequency of 43% and 27%, respectively (Bohomol 2014). Another study also found that errors with high-alert drugs in intensive care units ranged from 14% to 50%, with most errors occurring during drug administration (Sessions et al. 2019).

In a simulated scenario, a study found a 7.7% error rate when handling multiple IV infusions, specifically during the screening of IV lines to identify infusions (Pinkney, Fan, Chan, et al. 2019). Another investigation analysed medication error reports from 2004 to 2013 in Pennsylvania, USA, and found 907 errors related to IV line manipulations. These errors occurred mainly during the inclusion of infusion rates in infusion pumps, the manipulation of IV lines with unintended medications and the lack of connection of IV lines to patients. It was observed that high-alert drugs were involved in 71% of the errors associated with IV lines, with heparin being the drug that caused the most frequent errors (Wollitz and Grissinger 2019).

In 2015, the Emergency Care Research Institute listed the top 10 hazards related to health technologies. One of the hazards on the list was errors in handling IV lines for high-alert medications. These errors included connecting the infusion line to the wrong device, administering inappropriate medication to the patient and titrating doses incorrectly or through an inappropriate route. Intertwining lines can make distinguishing one IV line from another difficult, compromising the correct tracing of the line to the bag (Emergency Care Research Institute 2014).

Studies have shown that labelling errors, including non-labelling and incorrect or incomplete intravenous (IV) line labelling, are common in intensive care units. However, no studies have adequately recommended labelling IV lines (Nunes, Campos, and Silva 2022). This highlights the importance of the current study, which aims to evaluate the effectiveness of labels designed for high-alert drug lines in reducing medication errors.

Clinical simulation is a technique that replicates real-life situations to evaluate skills and competencies in a safe environment. It is considered a meaningful learning strategy in which learners actively construct their knowledge (Kim, Park, and Shin 2016). Therefore, simulation can be used to examine the professionals' performance regarding the IV line labels suggested in this study.

3 | Objective

Evaluate the effect of IV line labels on nurses' identification of high-alert medications in a simulated scenario of multiple infusions for critically ill patients.

4 | Method

4.1 | Study Design

It was a randomised, crossover, experimental simulation study. The experiment evaluated the effect of IV line labels on nurses' performance in the identification of high-alert medications. The study took place in two simulated scenarios with multiple IV infusions in critically ill patients. One scenario involved IV line labels, while the other did not. The researchers followed the extended Consolidated Standards of Reporting Trials (CONSORT) checklist, adapted for simulation research, to guide the presentation of the research report (Cheng et al. 2016). As this was a simulated experimental study, there was no requirement for clinical trial registration.

4.2 | Construction of the IV Line Label Prototype

The prototype of the IV line label was constructed based on a scoping review using the Joanna Briggs Institute methodology. According to a prospective protocol registered with the Open Science Framework, the review aimed to identify existing knowledge on labelling devices for administering IV drugs to critically ill patients. The findings were mapped to synthesise the ideal labelling characteristics and standards to prevent medication errors associated with IV line labelling. This review identified 715 scientific articles in various databases and 10 materials from other sources. After the selection process, eight documents specifically addressed intravenous line labels. The primary evidence mapped is presented in Table 1:

The results guided the selection of materials, content and visual structure for the prototype label. The medications chosen were based on the 'High-Alert Medications in Acute Care Settings' list from the Institute for Safe Medication Practices (Institute for Safe Medication Practices 2018). Medications commonly used in critically ill patients, such as vasoactive drugs (noradrenaline/vasopressin), sedatives (midazolam) and analgesics/tranquilisers (fentanyl), were selected from this list. Additionally, heparin was included due to a high error rate identified in a previous study (Wollitz and Grissinger 2019).

The label prototype includes the following key characteristics: (a) Information: It includes the name of the drug and the dose and date of the IV line change. The dose of the drugs is in mg/

ml for midazolam, fentanyl and noradrenaline, and in IU/ml for heparin and vasopressin; (b) Visual structure: The label measures 7 cm in length and 2.5 cm in width. The text is in Times New Roman font, size 12. It uses Tall Man Lettering strategies and colour coding according to ISO 26925:2021; (c) Physical material: The label is made of vinyl due to its good durability, adhesiveness and low cost. It allows the use of marker pens without smudging; (d) Safety features: It adopts acronyms for the drug names on the white part of the label in size 18 to reduce the chance of intra-class medicine errors due to colour. A QR code is used for each drug, redirecting to the websites of the Brazilian National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária—Brasil) and the Brazilian Institute for Safe Medication Practices (Instituto para Práticas Seguras no Uso de Medicamentos ISMP—Brasil), providing technical information on the use of each drug.

A graphic designer used Corel Draw21 software to create the prototype and organise the label template. The templates were then printed and applied to the IV lines for evaluation before the investigation. Feedback from the evaluation led to adjustments, resulting in the final template and prototype evaluation. Figures 1 and 2 display the final prototype:

4.3 | Setting Study

The prototype evaluation was conducted in a Nursing Clinical Simulation Laboratory at a public university in Rio de Janeiro, Brazil. This laboratory was equipped with advanced technological resources that simulated a variety of clinical situations that could occur in a hospital. This mannequin allowed the researchers to perform various nursing procedures, such as administering IV medication, applying dressings and inserting probes. The simulation included multiple IV infusions, and the researchers used various materials to set up the scenario, including infusion pumps, solution bags, IV catheters, connectors and other equipment used for administering medication.

4.4 | Participants, Selection Criteria and Sample

The study included nurses who had at least 6 months of practical experience in intensive care or emergency units, which was considered enough to manage IV therapy for critically ill patients. Nurses who were not currently working in these settings were excluded from the study.

The authors carefully considered the sample size because this was a study that evaluated the use of labels constructed in a simulated environment. They decided not to perform sample calculations because it is difficult to gather large samples of intensive care nurses outside the ICU. Instead, they relied on the literature's recommendation of using a group of 30–40 participants and considered the behaviour of this group as an estimate for the population (Miot 2011).

The participants were intentionally selected from a specialised intensive care nursing course in Rio de Janeiro, which nurses from various health institutions in the city attended. Initially, the postgraduate course had 50 applicants divided into two

TABLE 1 | Evidence mapped in the scoping review.

Year/country	Document types/ Scenarios	Types of labels	Content and structure of labels
2009/USA	Article: experimental study, quantitative, conducted in a simulated environment. Scenario: Simulated ICU	- Colour-coded labels with printed and handwritten content and standardised design for IV lines. - Labels without colour coding, with handwritten and printed contents, standardised design for IV lines. Impacts of labels regarding error prevention: Colour-coded labels provided greater drug administration safety, allowing devices to be labelled correctly in less time and facilitating visual identification, avoiding errors.	-Information on labels: Name of medication; date and time of preparation -Colour coding.
2019/Canada	Article: experimental quantitative study in simulated environment Scenario: Simulated ICU	- Labels without colour coding, printed content, standardised design for IV lines. Impacts of labels regarding error prevention: Labels without colour coding, with printed content, enabled correct and more timely identification.	-Information on labels: Name of the medication.
2017/Chile	Article: quasi-experimental, quantitative study Scenario: ICU	- Labels without colour coding, handwritten, unspecified design for IV lines. - Colour-coded labels, with printed content, standardised design for IV lines. Impacts of labels regarding error prevention: Adopting labels with pre-established colour codes increased drug administration safety. The risk of errors for patients who received drugs without colour coding and in a handwritten format was four times greater.	-Information on labels: Name of the medication; Date and time of preparation; Dose; Patient identification; Identification of who prepared the drug; -Colour coding.
2019/ Brazil	Article: survey, quantitative Scenario: ICU	- Colour-coded labels, with printed content, standardised design for IV lines. Impacts of labels regarding error prevention: Colour-coded labels and printed content helped prevent errors by improving the continuous monitoring of administered infusions, providing greater accuracy in identifying medications in high-stress situations and reducing the average time required to label medications.	-Information on labels: Name of the medication; date and time of preparation; -Colour coding; -Label size (length x width): 5 × 1.5 cm; - Type of font for drug name: Times New Roman; - Different-sized letters
2013/South Korea	Article: controlled, quantitative clinical trial Scenario: Emergency department	- Colour-coded labels, printed, unspecified design for IV lines. Impacts of labels regarding error prevention The colour-coded labels provided faster and more accurate handling of infusions individually and relative to other fluids; greater assertiveness in connecting and disconnecting fluids; and faster administration of medications in emergencies.	-Colour coding.

(Continues)

TABLE 1 | (Continued)

Year/country	Document types/ Scenarios	Types of labels	Content and structure of labels
2017/United Kingdom	Guideline Scenario: Anaesthesia unit	- Labels without colour coding, handwritten, unspecified design for bags, syringes, and IV lines. Impacts of labels regarding error prevention: In the absence of pre-printed labels, handwritten labels can be used, but they must be labelled with permanent markers. Infusion lines should be labelled at both ends near the connectors for easy verification and to reduce erroneous connections.	-Information on labels: Name of the medication; -Labelling method: Permanent marker for handwritten information.
2012/Australia	Guideline Scenario: Anaesthesia unit	- Labels without colour coding, printed, standardised design for IV lines Impacts of labels regarding error prevention: The main means of identifying the route of administration for IV lines is reading the written content containing information about the drug. Strategies such as using capital letters and colours help differentiate drugs.	-Information on labels: Route; -Label size (length × width): 7 × 2.5 cm; -Type of font for drug name: Sans Serif; - Different-sized letters; -Colour coding.
2015/Australia	Guideline Scenario: Anaesthesia unit	-Colour-coded labels, printed, standardised design for IV lines Impacts of labels regarding error prevention: The labels must be pre-printed, and contain the name of the drug and the additive, a capital initial letter for each word, and lowercase for other letters. Uppercase letters interspersed with lowercase letters to differentiate drug names should be used for drugs with similar names.	- Information on labels: Name of the medication; - Dose; Route; -Label size (length × width): 7 × 2.5 cm; -Type of font for drug name: Sans Serif (11–20); - Different-sized letters; -Colour coding.

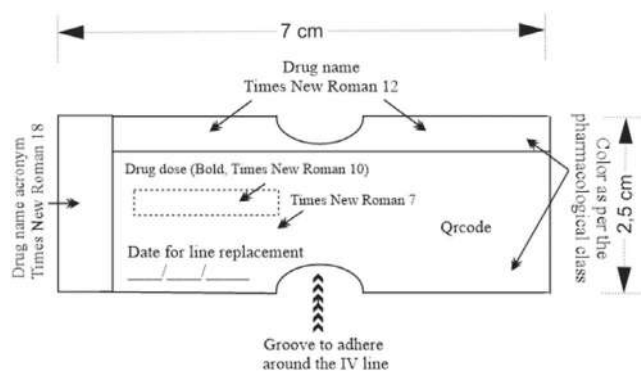


FIGURE 1 | Template used to label IV lines of high-alert medications.

classes of 25 students. After assessing compliance with the selection criteria, 29 participants met the requirements and agreed to participate, forming the final research sample.

4.5 | Intervention

A clinical scenario was set up to develop procedures for managing multiple intravenous infusions. The scenario involved a patient mannequin with a three-lumen central venous access and a two-way peripheral intravenous access. Continuous infusions of

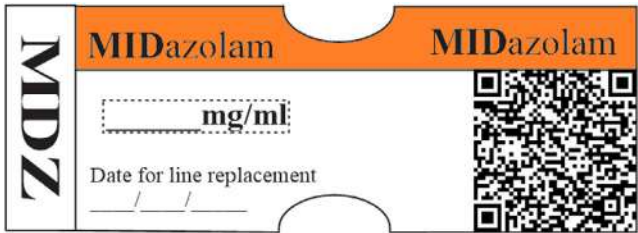


FIGURE 2 | Midazolam IV line label prototype.

drugs commonly used in critically ill patients (such as noradrenaline, vasopressin, midazolam, fentanyl and heparin) were given through the central venous access lumens. Two gravity infusions of simple Ringer's or saline solution were administered through the peripheral intravenous access to simulate a situation where IV lines were tangled. The order in which the drugs were distributed in the infusion lines differed in the two scenarios.

The central venous access connections were labelled with proximal, distal and medial lumens to help users identify the drugs infused through each IV line. The infusion pumps were mounted vertically on the supports, and the solution bags of the high-alert drugs were hung on the respective hooks of the support. Each infusion bag had a drug label with the name of the drug, dose and infusion speed. Each solution bag was connected to a channel of the infusion pump, providing the desired scenario for the IV line.

Before the intervention, the nurses received a presentation on the safe use of medications for treating critically ill patients, providing an overview of the research's general context. In the next stage, groups of three potential participants visited the laboratory's anteroom. They were presented with the research proposal and given an informed consent form to sign. Those who agreed to participate completed the proposed scenario individually and only once, as shown in Figure 3.

Scenario without IV line labels (Scenario 1): The researcher instructed the participants to identify the drugs infused into continuous infusion lines for high-alert medications installed in proximal, medial and distal lumens of the patient's central venous access. We asked them to record the identified drug names on a written form in their respective routes. Finally, we instructed them to disconnect the midazolam infusion line from the central venous access inlet connection.

Scenario with IV line labels (Scenario 2): The researcher instructed the participants to identify the drugs infused into continuous infusion lines for high-alert medications installed in the proximal, medial and distal lumens of the patient's central venous access in the presence of IV line labels. We asked them to record the drug names in written form on each lumen. Finally, we instructed them to disconnect the noradrenaline infusion line from the central venous access inlet connection.

The choice of variables for the experiment's design was based on studies that showed that errors in identifying the lines for administering IV drugs and interrupting the infusion, as well as the time spent identifying them, are the main factors that interfere with the safety of professionals' performance in handling continuous infusions (Pinkney, Fan, Koczmara, and Trbovich, 2019; Porat et al. 2009).

4.6 | Randomisation

Upon agreeing to participate, each nurse was assigned a number based on their arrival at the laboratory to receive information about the research. The participants were then divided into two groups—odd and even—and were randomly assigned to either scenario one or two. Odd-numbered participants started with the scenario without labels, while even-numbered participants started

with the scenario containing labels. After completing the first scenario, participants proceeded to the second scenario. This means that both groups were exposed to the two scenarios sequentially.

After receiving the handouts, researchers escorted the participants to the internal area of the laboratory and briefed them about the upcoming activity. They received an overview of the various scenarios and instructions regarding the tasks they needed to complete. Researchers reminded them of the significance of maintaining an authentic and realistic approach while completing the assigned tasks.

4.7 | Data Collection

The study aimed to assess how item labelling affected the participants' performance in scenarios that involved identifying medication infused IV lines, disconnecting a line and completing two additional tasks.

We gathered data from September to October 2022. Each participant received an alphanumeric code based on their selection order. The participants filled out a form provided by the researcher, where they recorded the name of the medication infused in each IV line. The researcher recorded the time taken to complete the tasks and the name of the drug in the disconnected IV line. The form also included a section recording the participants' personal and professional characteristics, such as age, gender, sector of work, time since graduation and length of professional experience.

The evaluation process timer started when the participants indicated they were ready to begin the activity. It ended when they raised their hand, indicating that they had identified all infusions and disconnected the requested line. We used a digital stopwatch on equipment with an iOS operating system for precise and reliable timing measurements.

The researchers closely monitored the participants' completion of tasks in each scenario. These were experienced researchers in managing multiple infusions in intensive care settings. Before data collection, we conducted a pilot test with two nurses with profiles similar to the research participants. This test helped us adjust the process of identifying the infusion route, which



FIGURE 3 | Illustration of the scenarios evaluated in the study.

reduced any potential biases related to the participants' better performance in identifying IV lines through cognitive resources (memory) when moving from one scenario to another.

4.8 | Data Analysis

For this analysis, we compiled and reviewed a database. We performed all analyses using the Statistical Package for the Social Sciences (IBM SPSS, v. 23.0). We used descriptive statistics and measures of central tendency to describe personal and professional variables and the frequency of errors in evaluated scenarios. To assess the results, we compared errors in identifying the IV lines and the time it took to perform the tasks between scenarios using the Wilcoxon test. This test analysed the variation in outcomes before and after the intervention.

We used the Mann–Whitney U-test and Spearman's correlation for bivariate inferential analyses between the study's covariates (personal and professional variables) and the outcomes. The Mann–Whitney U-test was used to evaluate the differences in mean values of participants' performance in outcomes (errors and time) depending on the sectors in which professionals worked. Spearman's correlation analysed the correlation between professionals' performance in scenarios

and their personal and professional characteristics (e.g., age, time since graduation and time of experience). We considered strong correlation (>0.7), moderate correlation (between 0.5 and 0.7), weak correlation (between 0.3 and 0.5) and very weak correlation (<0.3). For all tests, we adopted a 5% significance level.

4.9 | Ethical Considerations

The study followed national ethical standards for research involving human subjects. It was approved by the institution's research ethics committee, where the lead researcher is based, on 21 July 2021. The committee issued an opinion number of 5.656.699 and provided an Ethics Appreciation Certificate with reference number 43137721.9.0000.5238. Before participating, we informed participants about the research objectives and procedures, and they signed an informed consent form. The data were processed numerically to ensure participant anonymity.

5 | Results

Out of the 50 nurses enrolled in an intensive care nursing specialisation course, 31 were excluded from the study because they had less than 6 months of experience in intensive care or were not working in such environments at the time of the study. As a result, the research's methodological procedures were carried out on 29 nurses, as shown in Figure 4.

5.1 | Sample Characteristics

The data in Table 2 indicate that most participants were women (96.6%), young, recent graduates and had limited professional experience in intensive care settings.

In the study, participants identified medications in the IV lines in both scenarios similarly. Seven participants made fewer errors with labels, four made more errors, and 18 showed no significant difference in their performance compared to the scenario without labels.

The overall analysis of the two scenarios revealed that 31% of the participants incorrectly identified the IV lines. Two participants incorrectly identified the five high-alert medications in

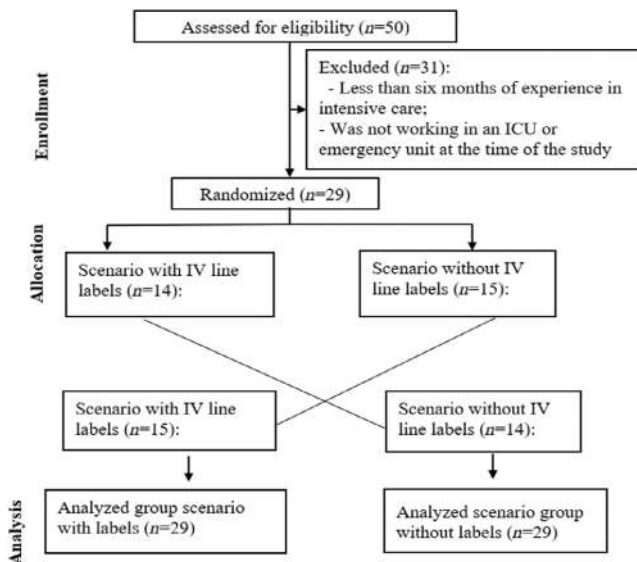


FIGURE 4 | Flowchart of study participants.

TABLE 2 | Characteristics of the study sample.

	N (%)	Average ($\pm$ SD) ^a	Min-Max
Age (years)		29.3 (5.6)	23–47
Department			
ICU	20 (69.0)		
Emergency + ICU	9 (31.0)		
Time since graduation (years)		3.6 ($\pm$ 3.6)	0.7–17.0
Length of professional experience (years)		2.3 ($\pm$ 3.8)	0.5–20.0

Abbreviations: ICU, Intensive care unit; SD, Standard deviation.

the scenario without labels. However, in the scenario with label technology, the maximum number of misidentifications was three, and no participant misidentified all the drugs.

In this study, the highest number of misidentifications occurred with fentanyl (27%) and vasopressin (24%) in the scenario without labels. However, in the scenario with labels, all participants correctly identified midazolam, while fentanyl (20%) and vasopressin (20%) remained the medications with the highest number of misidentifications. The study also found only one error in disconnecting an unintended medication (midazolam) from the multiple infusions underway in the simulated critical patient in the scenario without labels.

Furthermore, as indicated in Table 3, the study's findings confirm no significant difference between the scenarios regarding the number of errors the participants made during the IV lines' drug identification activities.

The time evaluation showed that in the scenario with IV line labels, 24 participants completed the task faster, four took longer, and one had the same time as in the scenario without labels. In the scenario without labels, the fastest completion time was 1 min and 51 s, while the slowest was 9 min and 15 s. In the labelled scenario, the fastest completion time was 49 s, and the slowest was 9 min and 20 s. According to Table 4, the time taken to identify and disconnect the IV line was significantly shorter in the scenario with the label prototype.

According to Table 5, only age was significantly correlated with the time participants took to complete tasks in the labelled scenario. As the participants' age increased, the average time to complete the activity also increased, showing a moderate correlation.

Table 6 compares the average number of errors made by professionals who exclusively worked in the ICU and those who worked in both ICU and emergency departments. The study shows differences in both scenarios. Professionals who worked solely in the ICU made fewer medication identification errors in IV lines.

6 | Discussion

In the evaluation of the label prototype, it was found that the participants in the scenario with labels made similar medication identification errors to those without labels. Interestingly, the average error rate in both scenarios (with and without labels) was 31%. However, using the label designed for the IV lines decreased the time taken to identify the drugs by an average of 1 min compared to the scenario without labels.

Numerous studies have shown the importance of IV line labels in healthcare settings. These studies have consistently demonstrated that implementing standardised medication identification decreases error rates, reduces time spent on labelling tasks and increases professional satisfaction (Pinkney, Fan, Koczmara, and Trbovich, 2019; Souza et al. 2019; Porat et al. 2009; Morales-González and Galiano Gálvez 2017; Stevens et al. 2015; Moreira et al. 2015).

In a study, the impact of interventions in a simulated ICU scenario was evaluated in four different conditions: current practice, with the use of IV line labels and infusion organisers, with smart infusion pumps, and with an infusion path lighting system. Forty participants had to identify and disconnect an infusion in each condition correctly. The study found that participants were able to identify infusions with fewer errors when using labels/line organisers (0%) compared to current practice (7.7%) and smart pump conditions (6.4%) ($p < 0.01$). Moreover, participants were significantly faster at identifying infusions when using line labels/organisers (0:31) compared to current practice (1:20), smart pumps (1:29) and a lighting system (1:22) ($p < 0.001$) (Pinkney, Fan, Koczmara, and Trbovich 2019).

A study compared the effectiveness of a colour-coded label with the current practice of not labelling IV lines for high-alert medications. The study involved 61 participants who performed tasks in a simulated ICU scenario. Participants had to describe all the drugs and lines, estimate the time needed to identify and describe each drug and line, identify errors, and estimate the time needed to identify a mismatch between the

TABLE 3 | Comparison of the total number of errors in the scenarios evaluated.

Scenarios evaluated	Mean of errors ($\pm$ SD)	Median	Interquartile range	Min-Max	Z	p^a
Scenario without labels	0.9 ($\pm$ 1.5)	0	0.0–2.0	2–5	−0.673	0.501
Scenario with labels	0.7 ($\pm$ 1.1)	0	0.0–1.5	1–3		

Abbreviations: SD, Standard deviation; Z, significance test (from the test itself).

^aProbability according to the Wilcoxon test.

TABLE 4 | Comparison of task completion time in the tested scenarios.

Scenarios	Mean time ($\pm$ SD)	Median	Interquartile range	Min-Max	Z	p^a
Scenario without labels	3:55 (1:32)	3:27	2:58–4:34	1:51–9:15	−3.598	<0.001
Scenario with labels	2:40 (1:38)	2:16	1:29–3:32	0:49–9:20		

Abbreviations: SD, Standard deviation; Z, significance test (from the test itself).

^aProbability according to the Wilcoxon test. Bold values indicates $p \leq 0.05$.

TABLE 5 | Comparisons of the characteristics of the sampled studied and task execution time.

Personal and professional characteristics	Time in the scenario without labels		Time in the scenario with labels	
	Correlation Coef. ^b	<i>p</i>	Correlation Coef.	<i>p</i> ^a
Age	0.272	0.154	0.575	0.001
Time since graduation	0.254	0.184	0.335	0.076
Length of experience	−0.124	0.521	0.180	0.350

^aProbability according to the Spearman correlation test. Bold values indicates $p \leq 0.05$.^bSignificance value is $p \leq 0.05$.**TABLE 6** | Comparison of sample characteristics and error count in each simulated scenario.

Department	N	Mean number of errors			
		Scenario without labels		Scenario with labels	
		Mean ($\pm$ SD)	<i>p</i> ^a	Mean ($\pm$ SD)	<i>p</i>
Only ICU	20	0.45 ($\pm$ 0.9)	0.035	0.35 ($\pm$ 0.8)	0.035
Emergency + ICU	9	1.9 ($\pm$ 2.1)		1.3 ($\pm$ 1.3)	

Abbreviations: ICU, Intensive care unit; SD, Standard deviation.

^aMann–Whitney *U*-test. Bold values indicates $p \leq 0.05$.

labelling on the syringe pump and its line. The study found that the use of colour-coded labels reduced the time needed for a general description of drugs and lines ($p=0.04$), improved error identification ($p=0.03$) and reduced the average time taken to perform general tasks ($p=0.0001$) (Morales-González and Galiano Gálvez 2017).

A survey was conducted in Brazil to analyse the opinions of 42 nursing professionals working in a paediatric intensive care unit. The survey aimed to evaluate the design, practicality and usefulness of a standardised colour-coded labelling system implemented for lines, infusion pumps, syringes and serum bottles. The results showed that the labelling technology was highly agreed upon among the participants. They found it to be well-designed and practical for all devices and helpful in preventing medication errors by reducing the time spent on labelling tasks (Souza et al. 2019).

After comparing our results with those of other studies, we observed that the evaluation did not show any differences between the scenarios in the number of errors or correct answers in identifying high-alert drugs. However, it is essential to note that the simulated laboratory environment minimises the influence of other factors that can contribute to errors, such as environmental factors inherent to intensive care. These factors can impact the professionals' daily management of IV therapy.

We allowed the professionals enough time to identify the drugs in the IV lines in two scenarios. This may have improved their performance, especially when there were no labels, which was assumed to be more challenging. This statement is based on the understanding that the intensive care environment is characterised by systemic factors that can lead to errors, including time pressure, high workload, noise, interruptions and distractions. These factors are considered risk factors for medication errors and are highlighted in the

scientific literature (Sasaki, Cucolo, and Perroca 2019; Freitas et al. 2019; Johnson et al. 2017; Raja, Sajid, and Sherali 2019; Bonafide et al. 2020; Schroers 2018).

The absence of certain variables in the laboratory environment may have reduced errors in identifying how multiple infusions are managed in scenarios without labels. Additionally, completing tasks in less time is particularly important in intensive care, where time management directly affects the availability of medical professionals and prioritises certain care activities (Sasaki, Cucolo, and Perroca 2019; Diniz et al. 2021). When multiplied by the frequency of medication administration per critically ill patient, the average difference of 1 min between scenarios can save professional working time. This is a crucial cost indicator that can help to improve care.

This analysis examines the advantages of using labels verified by research on medical devices like infusion bags and syringes. Researchers studied the impact of the design of safety labels in simulated high-stress clinical situations. In the study, anaesthesiologists were asked to select a medication requested by a surgeon during a bleeding emergency from a drawer containing various fluids in two hypothetical situations: one with standardised labels for medication bags and one without. In the scenario with standardised labels, the success rate in choosing the medication was 63%, while in the scenario without identification labels, it was 40% (Estock et al. 2018).

A research study in Switzerland examined the impact of standardised labels on syringe identification in a critical care environment. Intensive care nurses participated in the study and used eye-tracking glasses to assess the Tall Man Lettering feature adoption. The study found that this feature increased visual attention, leading to nurses spending more time looking at the medication names. As a result, the error rate decreased from 5.3% to 0.7% when using the labelled syringes (Lohmeyer et al. 2022).

Understanding the errors that happen in medication systems is crucial. It is essential to see errors as both individual actions and organisational processes. To ensure patient safety, we must systematically consider the active failures and underlying conditions that lead to errors. It is based on the idea that humans make mistakes, so we need to anticipate and prevent errors by understanding how they happen, identifying system weaknesses and implementing safety measures (Seshia et al. 2018).

In patient safety studies, it has been observed that personal factors such as experience, professional training and age can affect the occurrence of errors, especially in intravenous therapy (Porat et al. 2009; Di Fine et al. 2018; Norton et al. 2019; Ribeiro et al. 2023). The results of our study showed that younger professionals were quicker at identifying multiple intravenous lines, similar to findings in another study. Age is a factor that should be explored further in more extensive studies, as time plays a vital role in complications in intensive care. Therefore, quickly identifying multiple intravenous lines for medication administration can improve the effectiveness of interventions during critical moments in the care of severely ill patients. Understanding the identified errors and contributing factors can help in developing safety measures.

6.1 | Limitations

A limitation of the study was the small number of nurses with more than 6 months of experience at the research site. This limited the ability to interpret and apply the findings more broadly. Additionally, the simulation did not account for all variables in the intensive care environment that could affect professionals' performance in identifying drugs in IV lines. This limits the analysis and interpretation of nurses' performance. We suggested that the labels be evaluated in a real environment with a larger sample size of nurses to assess their effectiveness in reducing medication errors and strengthening the findings' validity.

7 | Conclusion

According to the results, IV line labels can help identify and disconnect high-alert drugs in less time. Professionals' performance was similar in correctly recognising intravenous infusion compared to a standard scenario without labels.

Adopting the proposed standards for IV line labels of high-alert drugs is recommended to enhance patient safety and healthcare efficiency. These standards include a pre-established design, printed format, size and fonts suitable for reading, differentiation in the size of the letters, resistant materials in label composition and colour coding. The labels should also include essential information such as the name of the drug, dose and time of preparation, as well as the specification of the date on which the line should be changed and the drug's expiration date.

8 | Relevance To Clinical Practice

Our technology can be used in critical patient care settings based on current knowledge of errors associated with high-alert drugs

administered through IV lines. The research demonstrates that labelling IV lines is effective, and if implemented in routine clinical practice, it can potentially decrease medication errors and save lives. When coupled with an organisational safety culture that prioritises continual education and safety, this approach can improve medication system safety in healthcare institutions and reduce the chances of errors when identifying high-risk IV drugs administered to critically ill patients.

Author Contributions

Made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data: Geovane de Kassio Nunes, Bruna Gonçalves Ribeiro Araújo, Leticia Braga Portes Alves Rentz, Flávia Giron Camerini, and Sabrina da Costa Machado Duarte, Juliana Faria Campos and Rafael Celestino da Silva. Involved in drafting the manuscript or revising it critically for important intellectual content: Geovane de Kassio Nunes, Bruna Gonçalves Ribeiro Araújo, Leticia Braga Portes Alves Rentz, Flávia Giron Camerini, and Sabrina da Costa Machado Duarte, Juliana Faria Campos and Rafael Celestino da Silva. Given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content: Geovane de Kassio Nunes, Bruna Gonçalves Ribeiro Araújo, Leticia Braga Portes Alves Rentz, Flávia Giron Camerini, and Sabrina da Costa Machado Duarte, Juliana Faria Campos and Rafael Celestino da Silva. Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: Geovane de Kassio Nunes, Bruna Gonçalves Ribeiro Araújo, Leticia Braga Portes Alves Rentz, Flávia Giron Camerini, and Sabrina da Costa Machado Duarte, Juliana Faria Campos and Rafael Celestino da Silva.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Peer Review

The peer review history for this article is available at <https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/jan.16529>.

Statistics

The statistics were checked prior to submission by an expert statistician—PhD Luciana Portela—luportela@yahoo.com

Trial Registration

Since this was a simulated experimental study, there was no need for clinical trial registration.

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Retrospective Study

Application value of high-pressure-resistant peripherally inserted central catheters in enhanced computer tomography of diabetic patients with malignant tumors

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Specialty type: Endocrinology and metabolism**Provenance and peer review:** Unsolicited article; Externally peer reviewed.**Peer-review model:** Single blind**Peer-review report's classification****Scientific Quality:** Grade B, Grade B, Grade C, Grade D**Novelty:** Grade B, Grade B**Creativity or Innovation:** Grade B, Grade C**Scientific Significance:** Grade B, Grade C**P-Reviewer:** Daub CD; Mabate B; Papazafropoulou A; Pappachan JM**Received:** July 23, 2024**Revised:** September 3, 2024**Accepted:** October 8, 2024**Published online:** December 15, 2024**Processing time:** 117 Days and 15.3 Hours**Li Zhang**, Department of Comprehensive Interventional, The Second Affiliated Hospital, Jiangxi Medical College, Nanchang University, Nanchang 330006, Jiangxi Province, China**Hui-Feng Yan**, Department of Radiology, The Second Affiliated Hospital, Jiangxi Medical College (Jiangxi Provincial Key Laboratory of Intelligent Medical Imaging), Nanchang University, Nanchang 330006, Jiangxi Province, China**Corresponding author:** Hui-Feng Yan, BMed, Doctor, Department of Radiology, The Second Affiliated Hospital, Jiangxi Medical College (Jiangxi Provincial Key Laboratory of Intelligent Medical Imaging), Nanchang University, No. 1 Minde Road, Nanchang 330006, Jiangxi Province, China. 15879129481@163.com

Abstract

BACKGROUND

Individuals with diabetes mellitus have a higher risk of developing malignant tumors, and diagnosing these tumors can be challenging.

AIM

To confirm the benefits of using peripherally inserted central catheters (PICCs) in contrast-enhanced computerized tomography (CECT) for diagnostic imaging in diabetic patients with malignant tumors and to provide a research basis for follow-up research.

METHODS

This retrospective study analyzed 204 diabetic patients with malignancies treated at The Second Affiliated Hospital, Jiangxi Medical College, Nanchang University, from January 2024 to June 2024. The patients were divided into two groups: A control group ($n = 102$) with indwelling peripheral intravenous catheters and a research group ($n = 102$) with high-pressure-resistant PICC. The study compared baseline data, the incidence of iodine contrast extravasation during CECT, the incidence of adverse events (discomfort, redness and swelling at the puncture site, and blood oozing), imaging quality, nursing time, intubation success rate, number of venipuncture attempts, and catheter maintenance cost.

RESULTS

Male patients accounted for 51.96% in the control group and 55.88% in the

research group; the average age was (59.68 ± 11.82) years in the control group and (61.41 ± 12.92) years in the research group; the proportions of lung cancer, colorectal cancer, and gastric cancer patients in the control group were 42.16%, 38.24%, and 19.61%, respectively, while those in the research group were 34.31%, 37.25%, and 28.43%, respectively. Except for the gender distribution, age, and cancer type mentioned above, other general information such as underlying diseases, puncture location, and long-term chemotherapy shows no significant differences as tested ($P > 0.05$). The results showed that the research group had significantly reduced incidence of iodine contrast extravasation (7 *vs* 1, $P = 0.031$), similar incidence of adverse events (11 *vs* 7, $P = 0.324$), reduced nursing time [(18.50 ± 2.68) minutes *vs* (13.26 ± 3.00) minutes, $P = 0.000$], fewer venipuncture attempts [(2.21 ± 0.78) times *vs* (1.49 ± 0.58) times, $P = 0.000$], lower catheter maintenance cost [(1251.79 ± 205.47) China yuan (CNY) *vs* (1019.25 ± 117.28) CNY, $P = 0.000$], increased intubation success rate (16.67% *vs* 58.82%, $P = 0.000$), and better imaging quality (85.29% *vs* 94.12%, $P = 0.038$).

CONCLUSION

High-pressure-resistant PICCs can lessen the physical burden of diabetic patients during nursing, reduce treatment costs, and improve the efficiency and quality of imaging for diagnosis malignant tumors.

Key Words: Diabetes mellitus complicated with malignant tumors; Contrast-enhanced computerized tomography; High-pressure-resistant peripherally inserted central catheters; The incidence of adverse events; Quality of computer tomography imaging

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Core Tip: For patients with diabetes mellitus complicated by malignant tumors, there is potential for improving the administration of intravenous contrast agents during contrast-enhanced computerized tomography (CECT). High-pressure-resistant peripherally inserted central catheters (PICCs) may be a better option for this improvement. This study has demonstrated the advantages of using high-pressure-resistant PICC in CECT for such patients, including reducing the physical burden during nursing, lowering treatment costs, and enhancing the efficiency and quality of imaging. These novel findings offer a strong research foundation for future research.

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INTRODUCTION

Diabetes mellitus (DM) is a common chronic metabolic disorder, characterized by chronic hyperglycemia caused by insulin resistance or insulin deficiency[1-3]. Diabetic patients are more prone to developing malignancies. It is estimated that DM patients have a significantly higher risk of colorectal, hepatocellular, gallbladder, breast, endometrial, and pancreatic cancers than non-diabetic individuals[4]. However, diagnosing DM complicated by malignancies is challenging, and some antidiabetic agents may mask the symptoms and features of malignancies. Recent advancements in anatomical imaging techniques have significantly improved the detection of malignant diseases. Among these, contrast-enhanced computed tomography (CECT) shows great advantages because of its high sensitivity, high specificity, and higher quality of imaging. In addition, CECT scans are well-tolerated and artifact-free with rapid imaging[5]. Therefore, CECT is expected to be used for early diagnosis and identification of malignancies in DM patients.

During CECT examination, iodine contrast, an intravenous contrast agent, is injected through a scalp steel needle or an intravenous indwelling needle, which may cause adverse reactions in the patient. Moreover, high-pressure injection may increase the risk of iodine contrast extravasation (ICE) and cause symptoms like pain, fever, and vomiting[6,7]. Therefore, there is potential for improvement in how intravenous contrast media is administered. Clinical data suggest that high-pressure-resistant peripherally inserted central catheters (PICCs) are associated with a significantly reduced risk of deep venous thrombosis, accidental catheter removal, and catheter-related infection compared to indwelling central venous catheters[8,9], indicating a wider application prospect of high-pressure-resistant PICCs in clinical imaging.

Previous studies have used high-pressure-resistant PICCs in diagnosing and detecting malignant tumors and obtained high-quality lesion images[10]. However, there is a lack of research on the application of PICCs in CECT examinations for DM patients with malignant tumors. To address this problem, this study intends to select diabetic patients with malignancies as the research subjects, dividing them into a control group and a research group according to the catheter placement method, to compare their differences in terms of safety during CECT, imaging quality, nursing time, catheter maintenance cost, *etc.*, in order to confirm the advantages of using PICCs in CECT examination of such patients and provide a research basis for future research.

MATERIALS AND METHODS

General information

From January to June 2024, patients with type 2 DM (T2DM) complicated by malignant tumors, who were admitted to The Second Affiliated Hospital, Jiangxi Medical College, Nanchang University, and scheduled for CECT scanning were selected.

Inclusion criteria were as follows: Patients were diagnosed with T2DM by biochemical indicators, *etc.*, and met the Chinese Guidelines for the Prevention and Treatment of T2DM (2020 Edition) (I) diagnostic criteria; patients were diagnosed with malignant tumor by histopathological examination, and were to undergo chemotherapy treatment and CECT scanning; patients met the indications for PICC catheterization and peripheral venous catheterization; patients were 18-75 years old and voluntarily participated in this study with informed consent.

Exclusion criteria were as follows: Contraindications to catheter therapy; contraindications to CECT scanning; history of allergies.

A total of 204 patients strictly following the inclusion criteria were enrolled in this study. The flowchart of specific inclusion and exclusion criteria for patients is shown in [Figure 1](#). They were grouped depending on the difference in the catheter type used: A control group ($n = 102$) receiving indwelling peripheral intravenous catheters and a research group ($n = 102$) receiving high-pressure-resistant PICC. The control group consisted of 53 males and 49 females aged (59.68 ± 11.82) years on average, with 43 cases of lung cancer, 39 cases of colorectal cancer, and 20 cases of gastric cancer (imaging results shown in [Figure 2](#)). The research group had a male-to-female ratio of 57:45, an average age of 61.41 ± 12.92 years, and 35 cases of lung cancer, 38 cases of colorectal cancer, and 29 cases of gastric cancer.

Endpoints

Primary outcome measures: (1) Occurrence, specific grade, and definition of ICE during CT scanning ([Table 1](#)). No extravasation, mild extravasation, moderate extravasation, and severe extravasation were rated as grades 0, 1-2, 3, and 4, respectively; (2) Image quality of CECT: [Table 2](#) for specific grades and definitions; and (3) Daily care time: The time spent in daily nursing refers to the total duration of nursing services provided by nurses every day. Nursing services mainly included preoperative assessment, pre-catheterization life care, health education, psychological care, catheterization care, post-catheterization limb care and complication prevention care, dietary care, blood glucose management, medication guidance, *etc.*

Secondary outcome measures: (1) Adverse events: Discomfort, redness and swelling at the puncture site, and blood oozing; (2) Number of venipuncture attempts; (3) First-attempt intubation success rate; and (4) Catheter maintenance cost after 6 months.

Statistical analysis

Statistical analysis was conducted using SPSS software (version 21; IBM Corp., Armonk, NY, United States), while image rendering was performed with GraphPad 9.0 software. Categorical variables, expressed as the number of cases (percentage), were analyzed using χ^2 tests. Continuous variables, represented as the mean $\pm$ variance, were compared using independent samples *t*-tests. The sample size of this study adhered to the inclusion and exclusion criteria for screening, while meeting the minimum requirement of approximately 55 participants for each group, as determined by the binomial proportion sample size estimation formula. All statistical analyses were two-tailed and relied upon a $P < 0.05$ statistical criterion.

RESULTS

Comparison of general data

By independent sample *t*-test or χ^2 test analysis, it was found that the sex distribution ($\chi^2 = 0.316$, $P = 0.574$), age ($t = 0.995$, $P = 0.321$), cancer type ($\chi^2 = 2.487$, $P = 0.288$), hypertension ($\chi^2 = 0.179$, $P = 0.673$), coronary heart disease ($\chi^2 = 0.666$, $P = 0.186$), puncture site ($\chi^2 = 0.766$, $P = 0.682$), and long-term chemotherapy ($\chi^2 = 0.091$, $P = 0.763$) were not statistically different, with comparability between groups ([Table 3](#)).

Comparison of the occurrence of ICE during CT scanning

Regarding the safety of high-pressure-resistant PICCs, this study first counted the ICE of two groups of patients. As shown in [Table 4](#), there were seven cases of ICE in the control group and one case in the research group. The incidence of extravasation was significantly lower in the research group than in the control group ($\chi^2 = 4.684$, $P = 0.031$).

Comparison of the incidence of adverse events

This study further examined the incidence of adverse events to assess the safety of high-pressure-resistant PICCs ([Table 5](#)). In the control group, 5 patients experienced discomfort, 2 redness and swelling at the puncture site, and 4 blood oozing. In the research group, 3 experienced discomfort, 1 redness and swelling at the puncture site, and 3 blood oozing. There was no statistically significant difference in the incidence of adverse events between the research and control groups ($\chi^2 = 0.975$, $P = 0.324$).

Table 1 Symptoms and grades of iodine contrast extravasation

Symptom	Grade
No obvious symptoms	0
Edema diameter < 2.54 cm	1
2.54 cm < edema diameter < 15.24 cm	2
Translucent edema (diameter > 15.24 cm)	3
Edema diameter > 15.24 cm, combined with blood oozing, circulatory disturbance, and moderate to severe pain	4

Table 2 Contrast-enhanced computed tomography imaging quality grading

Image	Grade
Clear vascular display and no artifacts or only a few artifacts, which does not affect the diagnosis	Good
Blurred development of important blood vessels or interrupted display of blood vessels, with a large number or all artifacts in arteries, which cannot be used for diagnosis	Poor

Table 3 Comparison of general information, *n* (%)

	Control group (<i>n</i> = 102)	Research group (<i>n</i> = 102)	χ^2/t	<i>P</i> value
Sex			0.316	0.574
Male	53 (51.96)	57 (55.88)		
Female	49 (48.04)	45 (44.12)		
Age (years)	59.68 ± 11.82	61.41 ± 12.92	0.995	0.321
Cancer type			2.487	0.288
Lung cancer	43 (42.16)	35 (34.31)		
Colorectal cancer	39 (38.24)	38 (37.25)		
Gastric cancer	20 (19.61)	29 (28.43)		
Underlying diseases				
Hypertension			0.179	0.673
With	55 (53.92)	58 (56.86)		
Without	47 (46.08)	44 (43.14)		
Coronary heart disease			0.666	0.186
With	38 (37.25)	41 (40.20)		
Without	64 (62.75)	61 (59.80)		
Puncture site			0.766	0.682
Median cubital vein	14 (13.73)	11 (10.78)		
Basilic vein	84 (82.35)	85 (83.33)		
Cephalic vein	4 (3.92)	6 (5.88)		
Long-term chemotherapy			0.091	0.763
With	69 (67.65)	71 (69.61)		
Without	33 (32.35)	31 (30.39)		

Comparison of CECT imaging quality

In this study, CECT scan quality was assessed to evaluate the benefits of using high-pressure-resistant PICCs. As shown in Table 6, there were 87 cases with good image quality and 15 cases with poor image quality in the control group, and 96 cases with good image quality and six cases with poor image quality in the research group. The research group had significantly higher image quality than the control group ($\chi^2 = 4.300$, $P = 0.038$).

Table 4 Occurrence of iodine contrast extravasation during computed tomography scanning, *n* (%)

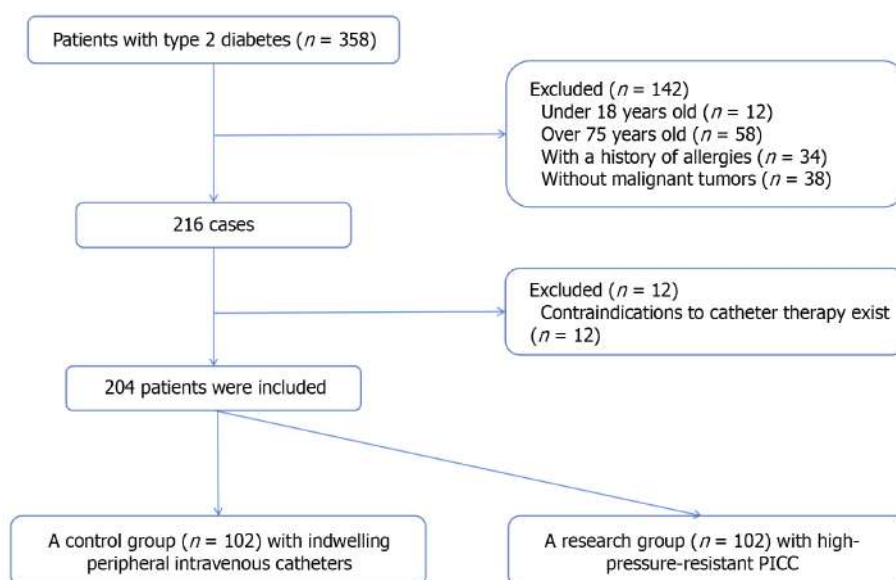
	Control group (<i>n</i> = 102)	Research group (<i>n</i> = 102)	χ^2	<i>P</i> value
No extravasation	95 (93.14)	101 (99.02)		
Mild extravasation	4 (3.92)	1 (0.98)		
Moderate extravasation	1 (0.98)	0 (0.00)		
Severe extravasation	2 (1.96)	0 (0.00)		
Incidence of extravasation	7 (6.86)	1 (0.98)	4.684	0.031

Table 5 Adverse events in the two groups, *n* (%)

	Control group (<i>n</i> = 102)	Research group (<i>n</i> = 102)	χ^2	<i>P</i> value
Discomfort	5 (4.90)	3 (2.94)		
Redness and swelling at the puncture site	2 (1.96)	1 (0.98)		
Blood oozing	4 (3.92)	3 (2.94)		
Incidence rate of adverse events	11 (10.78)	7 (6.86)	0.975	0.324

Table 6 Imaging quality of contrast-enhanced computed tomography scanning, *n* (%)

	Control group (<i>n</i> = 102)	Research group (<i>n</i> = 102)	χ^2	<i>P</i> value
Good	87 (85.29)	96 (94.12)	4.300	0.038
Poor	15 (14.71)	6 (5.88)		

**Figure 1 Flowchart of specific patient inclusion and exclusion criteria.** PICC: Peripherally inserted central catheters.

Comparison of care time

Figure 3 shows the time spent on each nursing session by two patient groups. The duration of each nursing session was 18.50 ± 2.68 minutes in the control group and 13.26 ± 3.00 minutes in the research group. The independent sample *t*-test showed that the research group had significantly less nursing time than the control group ($t = 13.148$, $P = 0.000$).

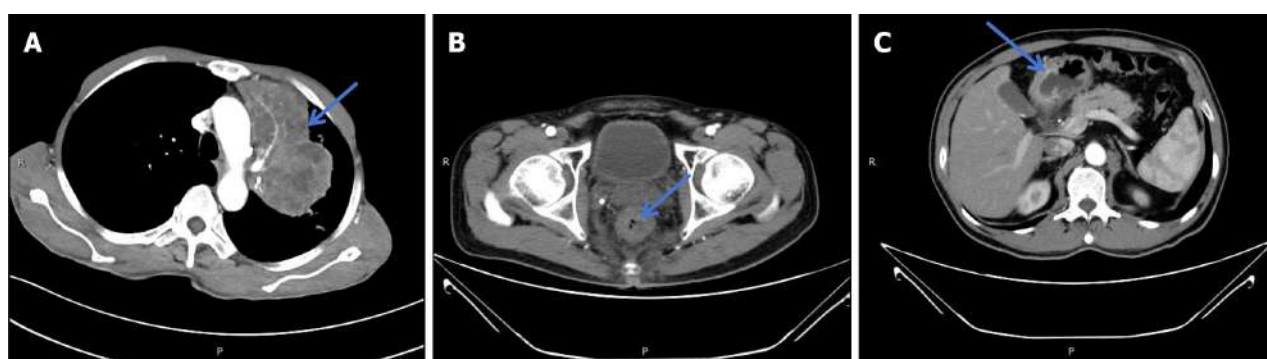


Figure 2 Computerized tomography imaging findings. A: Lung cancer; B: Colorectal cancer; C: Gastric cancer. The arrow indicates the location of the tumor.

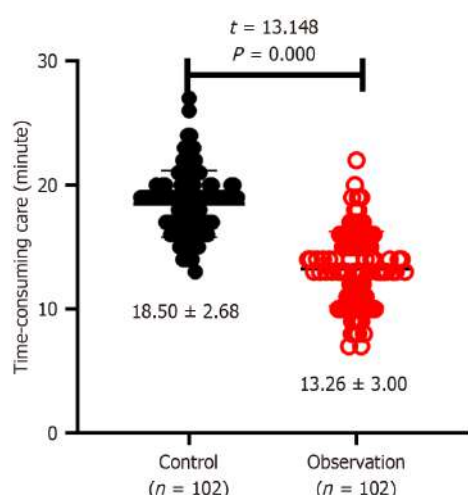


Figure 3 Comparison of nursing time of two groups of patients.

Comparison of the intubation time, number of venipuncture attempts, intubation success rate, and catheter maintenance cost

Table 7 shows the number of venipuncture attempts, intubation success rate, and catheter maintenance cost for the two groups. The intubation success rate was higher in the research group than in the control group ($\chi^2 = 38.570$, $P = 0.000$). The research group had fewer venipuncture attempts ($t = 7.486$, $P = 0.000$) and lower catheter maintenance costs after 6 months ($t = 9.927$, $P = 0.000$) than the control group.

DISCUSSION

DM patients are at significantly increased risk of developing malignancies[11-14]. Meanwhile, the survival rate of diabetic cancer patients is significantly lower compared to non-diabetic cancer patients[15-18]. Early cancer screening can help reduce mortality and prolong survival, but the consistency in cancer screening appears to be lower in DM patients than in non-diabetic patients[19], suggesting that DM can impact the effectiveness of early cancer diagnosis. Advancements in imaging technology offer solutions for improving cancer screening in diabetic patients, in which CECT plays a crucial role.

However, the traditional needle placement method used in CECT be burdensome for patients. Clinical data suggests that continuous and repeated venipunctures may lead to ICE. PICCs, on the conversely, offer an alternative to central venous catheterization *via* the jugular vein, providing central venous access with a reduced risk of intraoperative complications, lower maintenance costs, and fewer catheter-related bloodstream infections[20]. In a retrospective study of 374 cancer patients, PICC was demonstrated to provide simple and easy-to-use intravenous access to enhance out-of-hospital intravenous symptomatic management[21], making it clinically feasible. High-pressure-resistant PICC is further modified on the basis of PICC, with the characteristics of high-pressure resistance and multi-channel, which is suitable for rapid infusion[22]. This type of PICC allows the iodine contrast medium to enter the superior vena cava directly through the catheter, thereby avoiding irritation and damage to the peripheral blood vessels caused by the contrast medium. The results of this study also showed that high-pressure-resistant PICC significantly reduced the incidence of ICE compared

Table 7 The intubation time, number of venipuncture attempts, intubation success rate, and catheter maintenance cost of the two groups, *n* (%)

	Control group (<i>n</i> = 102)	Research group (<i>n</i> = 102)	χ^2/t	<i>P</i> value
Number of venipuncture attempts	2.21 ± 0.78	1.49 ± 0.58	7.486	0.000
Success intubation			38.570	0.000
Yes	17 (16.67)	60 (58.82)		
No	85 (83.33)	42 (41.18)		
Catheter maintenance cost after 6 months (CNY)	1251.79 ± 205.47	1019.25 ± 117.28	9.927	0.000

CNY: China yuan.

to traditional intravenous indwelling needles. This indicates that high-pressure-resistant PICC is associated with a reduced risk of ICE. In addition, there was no statistical difference between the two groups in the incidence of adverse events (including discomfort, redness and swelling at the puncture site, and blood oozing), indicating that the safety of high-pressure-resistant PICC is comparable to that of traditional venous catheters. From the perspective of ICE and adverse events, high-pressure-resistant PICC has a good safety profile, effectively reducing ICE and minimizing serious clinical symptoms in patients. This aligns with findings from Washio *et al*[23], who reported that high-pressure-resistant PICC had a higher safety profile than conventional intravenous indwelling needles, which is mainly due to the absence of complications associated with dynamic injection and significantly lower radiation density values.

This study also explored the impact of high-pressure-resistant PICC on CECT imaging quality. The findings indicate that high-pressure-resistant PICC significantly improved CECT imaging quality compared to conventional catheterization, which may be due to the direct entry of iodine contrast agent into the superior vena cava under high-pressure-resistant PICC, reducing the likelihood of extravasation. Iodine contrast agents contain iodine atoms, which are more susceptible to photoelectric absorption and produce image contrast, making them widely used for intravenous and intra-arterial X-ray imaging[24,25]. The application of high-pressure-resistant PICC significantly reduced ICE, which can greatly meet the injection requirements for iodine contrast agents and ensure the contrast conditions. This allows the iodine contrast agent to quickly reach the target organ and participate in CT imaging, ultimately improving CT imaging quality. These results also indicate the advantages of high-pressure-resistant PICC in CECT diagnosis. By improving imaging quality, high-pressure-resistant PICC enables clinicians to have a clearer understanding of lesion information and make targeted treatment decisions.

This study also found the economic advantages of using high-pressure-resistant PICC. An economic evaluation of PICC compared to other venous access devices pointed out that PICC may be more cost-effective[26]. Based on the results of this study, this type of PICC also helps improve the efficiency of care and reduce catheter maintenance costs. In this study, the use of high-pressure PICC shortened the time spent on each nursing session compared to conventional catheters, thereby reducing the clinical pressure on medical staff. This method also reduced the number of venipuncture attempts and improved the intubation success rate, effectively lessening the physical burden on patients during CECT. The results also showed a reduction in catheter maintenance costs with high-pressure-resistant PICC, suggesting it may help alleviate the economic burden. These findings align with the report by Wang *et al*[27], which also demonstrated that high-pressure-resistant PICC is more cost-effective than totally implanted venous access devices (ports) within a 3-9-month dwell time.

This study has some limitations. First, the sample size is limited because it was conducted at a single trial. Second, more detailed information on the types and severity of adverse events would have provided a better understanding of PICC safety. Third, the lack of long-term follow-up prevented exploration of factors affecting CECT imaging. Finally, for future research, a large-scale, multicenter prospective study and long-term follow-up are necessary to provide a research foundation for follow-up studies, which is crucial for evaluating long-term outcomes such as infection rates, long-term catheter-related complications, and patient satisfaction. The significance of this study lies in confirming the application advantages of high-pressure-resistant PICC in CECT examinations of DM patients complicated by malignant tumors, mainly manifested in minimizing the risk of ICE events to reduce the physical burden on patients and improving the imaging quality of CECT scans while reducing nursing time and catheter maintenance costs over a six-month period, which is of great value for reducing the medical and economic burdens of patients and society.

CONCLUSION

In summary, this study confirms that high-pressure-resistant PICC can reduce the physical burden of patients during nursing, reduce treatment costs, and improve the efficiency and quality of CECT imaging. These findings reveal the value of using high-pressure-resistant PICC in DM patients with malignant tumors, which provides a strong research basis for future research.

FOOTNOTES

Author contributions: Zhang L and Yan HF designed the research and wrote the first manuscript; Zhang L and Yan HF contributed to conceiving the research and analyzing data; Zhang L and Yan HF conducted the analysis and provided guidance for the research; All authors reviewed and approved the final manuscript.

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VASCULAR-INTERVENTIONAL



Safety and effectiveness of tunneled peripherally inserted central catheters versus conventional PICC in adult cancer patients

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Abstract

Objectives This study aimed to compare the safety and effectiveness of tunneled peripherally inserted central catheters (T-PICC) vs. conventional PICCs (C-PICC) in adult cancer patients.

Methods A multicentre randomized controlled trial was conducted between April 2021 and January 2022 in seven hospitals in China. 564 participants were randomly assigned to T-PICC or C-PICC. These data were collected and compared: the baseline characteristics and catheterization-related characteristics, periprocedural complications, and long-term complications.

Results Five-hundred fifty-three participants (aged, 52.6 ± 12.3 years; female, 39.1%) were ultimately analyzed. No significant differences in periprocedural complications were found between the T-PICC and C-PICC groups (all $p > 0.05$). Compared with C-PICC, T-PICC significantly reduced the incidence of long-term complications (26.4% vs. 39.9%, $p < 0.001$). Specifically, reduced complications were found in central line-associated bloodstream infection (1.8% vs. 5.1%, $p = 0.04$), thrombosis (1.1% vs. 4.0%, $p = 0.03$), catheter dislodgement (4.7% vs. 10.1%, $p = 0.01$), non-infectious oozing (17.3% vs. 28.6%, $p = 0.002$), local infection (3.6% vs. 7.6%, $p = 0.04$), skin irritation (6.1% vs. 10.9%, $p = 0.046$), and reduced unplanned catheter removal (2.2% vs. 7.2%, $p = 0.005$). No significant differences were found between T-PICC and C-PICC regarding catheter occlusion (6.5% vs. 5.8%, $p = 0.73$) or skin damage (2.2% vs. 2.9%, $p = 0.58$).

Conclusion T-PICC is safe and effectively reduces long-term complications.

Clinical relevance statement The tunneled technique is effective in reducing PICC-related long-term complications. Thus, it is recommended for cancer patients at high risk of PICC-related complications.

Trial registration The registration number on <https://www.chictr.org.cn/> is ChiCTR2100044632. The name of the trial registry is “A multicenter randomized controlled study of clinical use of tunneled vs. non-tunneled PICC”.

Jia Li, Zeyin Hu, Mengna Luo and Zhenming Wu contributed equally to this work.

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Key Points

- *Catheter-related complications are associated with the technique of catheterization.*
- *Compared with conventional PICC, tunneled PICC reduced catheter-related long-term complications.*
- *Tunneled PICC placement provides an alternative catheterization method for cancer patients.*

Keywords Catheterization (central venous), Tunnel, Complications, Neoplasms, Catheters

Introduction

Peripherally inserted central catheters (PICCs) are widely used vascular access devices in cancer patients [1] and serve as a safe and reliable delivery of systemic anticancer therapy, such as chemotherapy, transfusions, and antibiotic therapy [2, 3]. However, PICC-related complications, such as catheter-related bloodstream infection (CLABSI), catheter-related thrombosis, and catheter dislodgement, develop correspondingly. The overall incidence of complications ranges from 9.9% to 49.4% [4–6], increases the economic burden, affects patients' quality of life, and is associated with an increased hospital mortality rate, lengths of hospital stay, and readmission [7, 8].

With the development of PICC placement techniques, the tunnel technique has gradually been applied in cases requiring PICC placement to prevent PICC-related complications. The use of a tunneled peripherally inserted central catheter (T-PICC) is a catheterization method that adds a subcutaneous tunnel to the puncture site based on conventional peripherally inserted central catheter (C-PICC) insertion and transfers the catheter outlet to a suitable position [9]. Researchers [10–13] found that T-PICC can reduce catheter-related complications. However, there is controversy between studies. For example, T-PICC reduced CLABSI in Kim et al [13], but the incidence of CLABSI did not differ between groups according to Maria et al [10]. Dai et al [12] reported reduced thrombosis and skin injury in the T-PICC group, while significant differences were not found by Li et al [11]. To summarize, a firm conclusion could not be reached on the effect of T-PICC in reducing PICC-related complications. These differences might be associated with the sample size calculation, clinical contexts, tunneling methods, and other factors.

Therefore, a high-quality multicentre randomized controlled trial is needed to further verify the effect of the tunneling technique in PICC placement, and this multicentre randomized controlled trial aimed to compare the incidence of catheter-related complications between T-PICC and C-PICC cases.

Materials and methods**Study design**

This multicentre, randomized controlled trial (clinical trial registration: ChiCTR2100044632) was approved by

the Research Ethics Committee of the Sun Yat-sen University Cancer Center (B2020-320-01). The trial is reported following the guidance of the Consolidated Standards of Reporting Trials (CONSORT) [14].

Study setting

The study sites were seven tertiary A hospitals in China, with 704 to 3294 beds. Four of the study sites were located in Guangdong Province; one, in Gansu Province; one, in Hainan Province; and one, in Fujian Province.

Participants

The target population was all adult oncology patients with indwelling PICCs. The inclusion criteria were as follows: (1) patients aged ≥ 18 years old; (2) patients who underwent PICC catheterization for the first time; (3) patients who did not participate in other clinical studies at the same time and were able to complete PICC maintenance in the study hospitals; and (4) patients who voluntarily participated and signed an informed consent form. The exclusion criteria were as follows: (1) patients with PICCs placed in the lower extremity; and (2) participants with general severe medical conditions, skin damage on the arm, or a history of venous thrombosis, hemodialysis, pacemaker installation, or possible A-V fistula, as determined by the clinical teams.

Sample size

The sample size was calculated by a primary study outcome, the incidence of CLABSI, which was 2.6% and 9.1% in T-PICC and C-PICC cases, respectively [13]. Assuming that the sample sizes of the two groups in the study were equal, a total sample size of at least 402 cases was needed to reach a power of $1 - \beta = 0.8$ at a two-sided type I error of $\alpha = 0.05$. Considering approximately 20% non-evaluable patients, a sample size of at least 483 was needed. Due to the convenience of patient enrollment in these hospitals, 564 participants were ultimately enrolled. Each group included 282 participants.

Randomization, masking, and blinding

Participants were randomly assigned to receive either T-PICC or C-PICC in a 1:1 ratio. Randomization lists were prepared by the Clinical Trials Center of the Sun Yat-sen University Cancer Center. Randomization was

performed using block sizes of four and was stratified by center. The assignment list was generated by a computer program. Allocations were concealed in opaque sealed envelopes. The trial participants and intravenous therapy nurse specialists who placed the PICCs were not blinded to the treatment assignment, as the T-PICC technique would be difficult to implement with the blinding intact. The off-site statistician, who was clinically involved in the trial, was blinded to the treatment assignment. All exit sites of the PICCs were in the green area, and it would be difficult to observe differences after the recovery of the small incisions at the puncture sites. However, because some patients might develop pigmentation at the puncture site, we could not guarantee that the research team carrying out follow-up assessments would be blinded to treatment allocation.

Intervention

PICCs were all placed by PICC nurses with at least five years of experience in PICC placement and were performed using the modified Seldinger technique guided by B-mode ultrasound (Site-Rite 5, Bard). For all participants, 4-Fr silicon single-lumen PICCs (Branden Medical Devices Co., Ltd) were used. This is a Groshong closed-ended valve PICC, which is trimmed and connected to the hub outside the human body. Electrocardiographic guidance during catheter placement and chest X-rays after catheter placement were performed to confirm that the tip of the catheter was located in the lower third of the superior vena cava. Catheter maintenance was performed by the uniformly trained IV team of each hospital. The scheme of catheter maintenance is within 48 h after catheter placement, and then weekly or in situations where the dressing is loosed or PICC-related complications are suspected. All participants were followed up weekly until catheter removal.

According to the Zone Insertion Method [15], the upper arm is divided into three sections, the yellow area (the upper third of the upper arm), the green area (the middle third of the upper arm), and the red area (the lower third of the upper arm). For the T-PICC group, the puncture site was placed in the yellow area, and the exit site was in the green area, for which the puncture site was 5 cm above the catheter exit site (Fig. 1). The intervention of the tunneled technique was based on the principles of the expert consensus on catheterization technology for T-PICCs in China [9]. The procedure for PICC placement in the T-PICC group was as follows: (1) Following the conventional B-ultrasound guidance, the vessel was punctured, and the guide wire was inserted; (2) Local anesthesia was administered, and a 1–2 mm incision was created at the puncture site; (3) The vascular sheath was placed along the guide wire; (4) The catheter was inserted

until it reached the premeasured catheter length, and then the vascular sheath was removed; (5) The location of the tip of the PICC was confirmed by the use of intracardiac electrocardiogram positioning technology; (6) Local anesthesia was administered, and a 1–2 mm incision was created at the catheter exit site (Fig. 1A); (7) A salt water tunnel was established (Fig. 1B) with 10 mL of a 0.9% sodium chloride solution after confirmation (using B-mode ultrasound) that no nerves, blood vessels or lymphangions were present along the tunnel route; (8) The tunnel needle penetrated through the subcutaneous salt water tunnel from the exit site to the puncture site (Fig. 1C); (9) The catheter was guided from the puncture site to the exit site (Fig. 1D); (10) The catheter was trimmed (Fig. 1E) and then further U-like configured by a transparent dressing with a small piece of gauze firmly affixed to the incision sites (Fig. 1F). The C-PICC group received PICC placement for which the puncture site and catheter exit site were at the same position in the green area. The procedure for PICC placement in the C-PICC group was as follows: Steps 1–5 were the same as those for the T-PICC group (Fig. 1G); Step 6 was the same as Step 10 in the T-PICC group (Fig. 1H).

Assessments

Patients' basic characteristics and catheterization-related characteristics

The demographic and disease questionnaire was a structured form for this study to collect patients' characteristics, which included demographic information (sex, age, marital status, etc.) and disease-related data (cancer type, WBC, RBC, PLT, etc.). The catheterization questionnaire was designed by the central venous catheter (CVC) research group to collect catheterization-related characteristics (arm, vein type, the tip of the catheter, vein diameter at the puncture site, vein depth at the puncture site, length of exit site to the cubital crease, first-time puncture success, catheter dwell time, etc.).

Periprocedural complications

Nerve injury was considered to have occurred if, during the process of needle penetration into subcutaneous tissue, sudden electric shock-like pain or numbness, arm weakness, or other symptoms appeared transiently or persistently. Accidental injury to the artery was considered to have occurred if, during the puncture process, blood suddenly gushed out or seeped from the needle inlet, with a faster speed and a bright red color, as confirmed by B-ultrasound. Initial malposition refers to the situation where, during the process of catheter insertion, imaging techniques such as B-ultrasound or chest X-rays indicate that the catheter tip is not in the superior vein

Tunneled PICC key steps:



A local anesthesia at the exit site



B creates a subcutaneous saline tunnel;



C tunnel needle penetrates through the tunnel from the exit site to the puncture site



D guides the catheter from the puncture site to the exit site



E trim the catheter



F secure the catheter

Conventional PICC key steps:



G puncture site is also exit site



H secure the catheter

Fig. 1 Tunneled PICC key steps: **A** Local anesthesia at the exit site. **B** Creates a subcutaneous saline tunnel; **C** Tunnel needle penetrates through the tunnel from the exit site to the puncture site; **D** Guides the catheter from the puncture site to the exit site; **E** Trim the catheter; **F** Secure the catheter. Conventional PICC key steps: **G** Puncture site is also exit site; **H** Secure the catheter

cava [16]. The amount of blood that was absorbed by gauze was measured by an electronic scale that was accurate to 0.01 g. The weight of the blood lost was calculated by the difference in the gauze weight before and after the PICC procedure, based on the gravity of blood of 1.05 g/mL [17]. Pain scores during catheter placement were measured by the Numeric Rating Scale (NRS). This scale has 11 numbers, from 0 to 10; the larger the number is, the more severe the pain is; 0 represents no pain, and 10 represents intolerable pain [18].

Long-term complications

CLABSI refers to the occurrence of bacteremia or mycosis in patients with intravascular catheters or within 48 h after catheter removal, accompanied by signs of infection such as fever ($>38^{\circ}\text{C}$), chills, or hypotension, and no other apparent source of infection other than vascular catheter infection [16]. Thrombosis refers to swelling or pain of the surgical limb, increased skin temperature, and ultrasound examination diagnosed as venous thrombosis [11]. Thrombosis sites were defined as veins occupied by the PICC, including the basilic vein, cephalic vein, brachial vein, axillary vein, subclavian vein, or internal jugular vein (if malposition happened). Catheter occlusion refers to situations where blood cannot be drawn back, the blood reflux is slow, the infusion flow rate slows, the catheter cannot be flushed, or the infusion is not smooth [16]. Catheter dislodgement was recorded when the catheter shifted more than 2 cm [19]. Central venous access device-associated skin impairment (CASI) refers to abnormal skin drainage, erythema, and/or other manifestations, including but not limited to vesicles, blisters, erosion, or tearing cracks that occur in the vascular pathway device area of the underlying area of the dressing, during the removal of continuously present for 30 min or more after removal of dressings, including local infection at the puncture site, skin damage, skin irritation, and a noninfectious exudate [16]. Unplanned catheter removal refers to the early removal of a catheter due to human factors or severe complications that are not retained according to the plan. These complications included severe CLABSI in situations that needed catheter removal [20], severe thrombosis (active anticoagulation but with symptoms still present), catheter dislodgement in cases where the catheter tip was not in the superior vena cava (confirmed by X-rays), catheter occlusion that could not be managed by catheter recanalization successfully, and severe CASI that distressed the participants (requiring catheter removal by the participants themselves).

Training and supervision

The research team was trained in good clinical practice (GCP), data protection and management, research, and

information governance. Data were checked weekly by the researchers to ensure that there were no missing data and that the patients followed the frequency of catheter maintenance. For situations in which there were missing data or patients did not follow the frequency of PICC maintenance, the researchers would telephone them to complete the record or to remind them to complete the catheter maintenance. All PICC nurses received homogenized training, including patient assessments, catheter placement technology, catheter maintenance, and evaluation of catheter complications.

Statistical analysis

All data were entered using the double-entry method and checked. SPSS software (version 23.0; IBM Corp) was used for statistical analysis. (1) Metrological data: Normally distributed data were statistically described using the standard deviation, and comparisons of means were conducted using two independent sample *t*-tests; non-normally distributed econometric data were described using medians and interquartile intervals, and two independent sample rank sum tests were used. (2) Counting data: These are described using the frequencies or percentages and were compared between groups using the chi-square test. Only patients who could be completely analyzed were included in further analysis. Differences were considered statistically significant at $p < 0.05$.

Results

Patients' basic characteristics and catheterization-related characteristics

From April 2021 to January 2022, 733 participants were recruited and randomly allocated to the two study groups (Fig. 2). A total of 564 patients were ultimately analyzed, with 11 participants excluded for the following reasons: five participants experienced unsuccessful PICC placement because of difficulty in catheter propulsion ($N=3$) or puncture failure ($N=2$); six participants were excluded because one was transferred to another hospital for therapy and five failed to follow the scheme for catheter maintenance. The participants ranged from 18 to 75 years, with a mean age of 52.6 (± 12.3). A total of 337 participants were men, and 216 participants were women. The basic patient characteristics, including sex, age, marital status, infusions, body mass index, cancer type, white blood cells, red blood cells, platelets, thrombin time, activated partial thromboplastin time, prothrombin time and fibrinogen, did not differ (all $p > 0.05$) (Table 1). Catheterization-related characteristics of the two groups are shown in Table 2. Compared with those in the C-PICC group, more axillary veins were selected for puncture in the T-PICC group (19, 6.9% vs. 0%, $p < 0.001$). The vein diameter at the puncture site was significantly

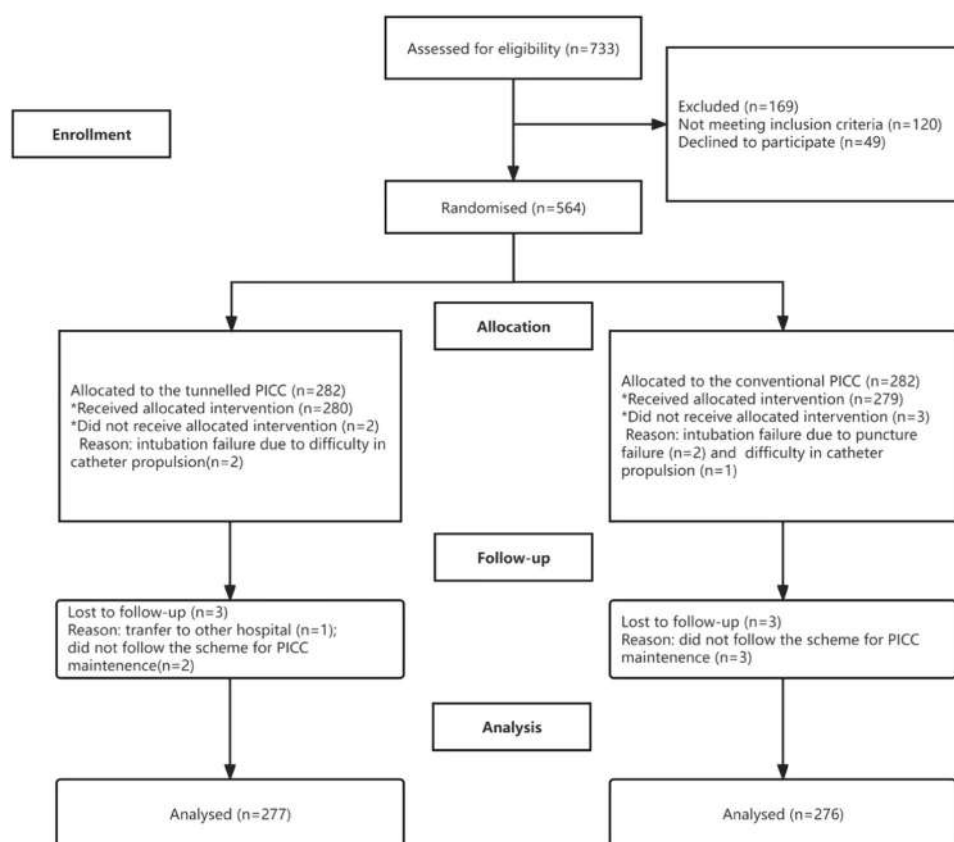


Fig. 2 CONSORT flow diagram of study participants

larger in the T-PICC group (0.6 ± 0.2 cm vs. 0.4 ± 0.1 cm, $p < 0.001$). The catheter dwell time in T-PICC cases was significantly longer (125.9 ± 70.3 days vs. 112.4 ± 54.7 days, $p = 0.01$) than that in C-PICC cases. Other catheter-related characteristics, which included the arm selected for puncture, tip of the catheter, vein depth at the puncture site, length from the exit site to the cubital crease, and first-time puncture success rate did not differ between the two groups (Table 2).

Periprocedural complications

There were 2 (0.7%) cases of arterial or nerve injuries in both groups. Difficulties in catheter or guide wire propulsion were recorded in 11 (4.0%) and 15 (5.4%) in the T-PICC and C-PICC, respectively ($p = 0.42$). Initial malposition occurred in 19 (6.9%) and 15 (5.4%) participants in the T-PICC and C-PICC groups, respectively ($p = 0.49$). There was no significance in the amount of bleeding between T-PICC and C-PICC (3.3 ± 3.1 mL vs. 3.2 ± 3.0 mL, $p = 0.89$). The NRS scores showed no significance between T-PICC and C-PICC groups (1.4 ± 0.9 vs. 1.2 ± 0.8 , $p = 0.09$) (Table 3).

Long-term complications

Significant differences were discovered in overall long-term complications ($p = 0.001$), CLABSI ($p = 0.04$), thrombosis ($p = 0.03$), catheter dislodgement ($p = 0.01$), CASI ($p = 0.001$), and unplanned catheter removal ($p = 0.005$). Overall complications occurred in 73 (26.4%) participants in the T-PICC group and 110 (39.9%) in the C-PICC group. Regarding specific complications, the T-PICC group demonstrated an advantage with fewer CLABSIs (5, 1.8% vs. 14, 5.1%). Thrombosis was observed in 3 (1.1%) and 11 (4.0%) participants in the T-PICC and C-PICC groups, respectively. Catheter dislodgement occurred in 13 (4.7%) participants in the T-PICC group and 28 (10.1%) participants in the C-PICC group. In terms of CASI, T-PICC showed advantages in reducing non-infectious exudate (48, 17.3% vs. 79, 28.6%), local infection (10, 3.6% vs. 21, 7.6%) and skin irritation (17, 6.1% vs. 30, 10.9%), while no significant difference was found in skin damage (6, 2.2% vs. 8, 2.9%). Twenty-six participants experienced unplanned catheter removal: 6 (2.2%) and 20 (7.2%) in the T-PICC and C-PICC groups, respectively. Catheter occlusion rates did not differ between the groups

Table 1 Basic patient characteristics of the two groups (*n* = 553)

Characteristics	Tunneled PICC (<i>n</i> = 277)	Conventional PICC (<i>n</i> = 276)	<i>T</i> / <i>χ</i> ²	<i>p</i>
Gender			0.020 ^a	0.89
Male	168 (60.6)	169 (61.2)		
Female	109 (39.4)	107 (38.8)		
Age (years)	53.3 ± 12.6	52.0 ± 12.0	1.184 ^b	0.24
Infusions				
Vesicants	31 (11.2)	27 (9.8)	0.292 ^a	0.59
Transfusion	10 (3.6)	11 (4.0)	0.053 ^a	0.82
Parenteral nutrition	13 (4.7)	10 (3.6)	0.397 ^a	0.53
BMI			1.172 ^a	0.57
≤ 18.4	37 (13.4)	33 (12.0)		
18.5–24.9	197 (71.1)	191 (69.2)		
≥ 25.0	43 (15.5)	52 (18.8)		
Cancer type			4.017 ^a	0.68
Head and neck tumor	147 (53.0)	141 (51.1)		
Urogenital tumor	40 (14.4)	42 (15.2)		
Hematological malignancy	41 (14.8)	35 (12.7)		
Digestive system tumor	15 (5.4)	20 (7.2)		
Lung cancer	18 (6.5)	21 (7.6)		
Breast cancer	6 (2.2)	11 (4.0)		
Others	10 (3.6)	6 (2.2)		
WBC			0.677 ^a	0.71
Below	31 (11.2)	31 (11.2)		
Normal	214 (77.3)	219 (79.3)		
Above	32 (11.5)	26 (9.4)		
RBC			0.112 ^a	0.95
Below	44 (15.9)	43 (15.6)		
Normal	176 (63.5)	173 (62.7)		
Above	57 (20.6)	60 (21.7)		
PLT			1.006 ^a	0.61
Below	6 (2.2)	9 (3.3)		
Normal	179 (64.6)	183 (66.3)		
Above	92 (33.2)	84 (30.4)		
TT			1.855 ^a	0.40
Below	9 (3.2)	5 (1.8)		
Normal	264 (95.3)	269 (97.5)		
Above	4 (1.5)	2 (0.7)		
APTT			0.827 ^a	0.66
Below	9 (3.2)	9 (3.3)		
Normal	254 (91.7)	248 (89.8)		
Above	14 (5.1)	19 (6.9)		
PT			0.571 ^a	0.75
Below	4 (1.4)	6 (2.2)		

T *T*-test, *C*² Chi-square test, *BMI* body mass index, *WBC* white blood cell, *RBC* red blood cell, *PLT* platelet, *TT* thrombin time, *APTT* activated partial thromboplastin time, *PT* prothrombin time, *FBG* fibrinogen. Data are presented as *n* (%) or mean ± standard deviation

Only patients who could be completely analyzed were included in further analysis

^a*χ*²
^b*t*

Table 2 Catheterization-related characteristics of the two groups (*n* = 553)

Characteristics	Tunneled PICC (<i>n</i> = 277)	Conventional PICC (<i>n</i> = 276)	<i>T</i> / <i>χ</i> ²	<i>p</i>
Arm			1.459 ^a	0.23
Left	84 (30.3)	97 (35.1)		
Right	193 (69.7)	179 (64.9)		
Vein type			19.922 ^a	< 0.001 ^c
Basilic	220 (79.4)	240 (87.0)		
Brachial	38 (13.7)	36 (13.0)		
Axillary	19 (6.9)	0 (0)		
Tip of catheter			0.902 ^a	0.64
T6	44 (15.9)	50 (18.1)		
T7	146 (52.7)	135 (48.9)		
T8	87 (31.4)	91 (33.0)		
Vein diameter at puncture site(cm)	0.6 ± 0.2	0.4 ± 0.1	9.600 ^b	< 0.001 ^c
Vein depth at puncture site (cm)	0.6 ± 0.3	0.6 ± 0.3	0.329 ^b	0.74
First-time puncture success			3.548 ^a	0.06
Yes	264 (95.3)	252 (91.3)		
No	13 (4.7)	24 (8.7)		
Catheter dwell time (days)	125.9 ± 70.3	112.4 ± 54.7	2.512 ^b	0.01 ^c

T *T*-test, *C*² Chi-square test. Data are presented as *n* (%), mean ± standard deviation

Only patients who could be completely analyzed were included in further analysis

^a*χ*²
^b*t*

^cSignificance

(18, 6.5% vs. 16, 5.8%, *p* = 0.73). These results are presented in Table 4.

Discussion

This multicentre study demonstrated that T-PICC placement did not increase the incidence of periprocedural complications. Periprocedural complications including difficulties in catheter or guide wire propulsion and initial malposition did not differ between the two groups, mainly because the catheterization procedure of T-PICC is almost the same as C-PICC except for the addition of a subcutaneous tunnel. Bleeding during placement did not differ between the groups in this study, which contrasted with the results of Dai et al [12]. These different findings might be due to the different instruments used to create subcutaneous tunnels in these two studies. The blunt tunneler and “hydrodissection” technique used in our study could reduce tissue damage, while the trocar and hemostat used in the Dai et al study could cause more tissue damage [12, 21]. The incidence of arterial or nerve injuries and patients’ pain scores did not differ between groups, mainly because, first, the use of ultrasound helped

Table 3 Comparison of periprocedural complications after catheter placement ($n = 553$, n (%))

Characteristics	Tunneled PICC ($n = 277$)	Conventional PICC ($n = 276$)	T/χ^2	p
Arterial or nerve injuries			0 ^a	1.00
Yes	2 (0.7)	2 (0.7)		
No	275 (99.3)	274 (99.3)		
Difficulties in catheter or guide wire propulsion			0.661 ^a	0.42
Yes	11 (4.0)	15 (5.4)		
No	266 (96.0)	261 (94.6)		
Initial malposition			0.486 ^a	0.49
Yes	19 (6.9)	15 (5.4)		
No	258 (93.1)	261 (94.6)		
Amount of bleeding (mL)	3.3 ± 3.1	3.2 ± 3.0	0.133 ^b	0.89
NRS score	1.4 ± 0.9	1.2 ± 0.8	1.693 ^b	0.09

T T-test, χ^2 Chi-square test. Data are presented as n (%), mean ± standard deviation

Only patients who could be completely analyzed were included in further analysis

^a χ^2

^b t

Table 4 Comparison of long-term complications after catheter placement ($n = 553$, n (%))

Characteristics	Tunneled PICC ($n = 277$)	Conventional PICC ($n = 276$)	T/χ^2	p
Overall complications	73 (26.4)	110 (39.9)	11.382	< 0.001 ^a
CLABSI	5 (1.8)	14 (5.1)	4.449	0.04 ^a
Thrombosis	3 (1.1)	11 (4.0)	4.720	0.03 ^a
Catheter occlusion	18 (6.5)	16 (5.8)	0.118	0.73
Catheter dislodgement	13 (4.7)	28 (10.1)	5.986	0.01 ^a
CASI	58 (20.9)	92 (33.3)	10.745	0.001 ^a
Non-infectious oozing	48 (17.3)	79 (28.6)	9.969	0.002 ^a
Local infection	10 (3.6)	21 (7.6)	4.177	0.04 ^a
Skin irritation	17 (6.1)	30 (10.9)	3.981	0.046 ^a
Skin damage	6 (2.2)	8 (2.9)	0.301	0.58
Unplanned catheter removal	6 (2.2)	20 (7.2)	7.964	0.005 ^a

CLABSI central line-associated bloodstream infection, CASI catheter-associated skin injury

Only patients who could be completely analyzed were included in further analysis

^a Significance

identify and avoid the veins and nerves along the tunnel path while avoiding repeated venipuncture [22]. Second, the hydrodissection of subcutaneous tissue limited tissue damage [23].

This study demonstrated that T-PICC placement reduced the incidence of long-term complications. T-PICC significantly reduced CLABSI, perhaps because the distance between the puncture site and exit site helps prevent bacteria from spreading into the vein. These findings are consistent with Kim's multicentre retrospective study [13] but the contrast with Maria et al [10], possibly because the sample size in Maria et al was not powerful enough. T-PICC significantly decreased thrombosis. This could be associated with the larger vein diameter in T-PICC because thrombosis is closely related to a larger catheter-to-vein ratio [24, 25]. T-PICC reduced catheter dislodgement.

The reason might be that the tunnel length increases the stability of the tunnel tract and increases the friction that prevents the PICC from sliding out of the puncture site. This finding is consistent with the study findings of Li et al [11]. T-PICC significantly reduced the risk of CASI. Significant differences were found in the rates of noninfectious exudates, local infection, and skin irritation. The findings regarding noninfectious exudate are consistent with studies revealing that T-PICCs significantly decreased non-infectious wound exudates after PICC placement [11, 12], mainly because of the compression of subcutaneous tissue on the puncture site due to the building of a tunnel. Noninfectious wound exudation may further progress to skin irritation. Blood also provides an environment for bacterial reproduction, which may lead to local infection. Skin damage might be associated with the PICC

maintenance technique used by clinical practitioners [16]. Thus, no significant difference was found in this complication. Along with reductions in overall complications in the T-PICC group, significance was found in unplanned catheter removal. Catheter occlusion rates did not differ between the groups. Catheter occlusion is closely associated with the infusion, flushing, locking technique, and tips of catheters [16, 26], which did not differ between the two groups. T-PICCs might not play a role in catheter occlusion.

The guidelines of the Infusion Nurses Society recommend the use of tunneled catheters based on several studies targeting tunneled CVC [16]. This study provides additional evidence for the effect of T-PICC. For cancer patients at high risk of CLABSI, thrombosis, catheter dislodgement, or unplanned catheter removal, clinicians could consider whether a subcutaneous tunnel is applicable for a lower incidence of complications. Notably, in this study, two PICCs in the T-PICC group were still self-removed by patients during sleep despite the existence of a subcutaneous tunnel. Moreover, T-PICCs may not prevent catheter dislodgement in cases of violence. For unconscious patients, a T-PICC inserted on the arm may not prevent catheter dislodgement. Nevertheless, several cases of T-PICCs inserted in other regions, such as the scapular region and patellar region, have been found to be effective in preventing patients from unconsciously pulling the catheter out [27, 28]. More research is needed in this special population.

This study has several limitations. First, although no significant difference was found in the patients' pain levels during catheter placement, this study failed further to measure the comfort level of patients after PICC placement. Second, this study only recorded the incidence of complications but failed to record the time at which the complications occurred and the detailed grading by Common Terminology Criteria for Adverse Events. Third, all participants were adult cancer patients, and thus, the results cannot be extrapolated to other groups. As the wounds and tunneling method were apparent to the providers and patients, blinding the operators and patients was not achievable. Finally, although T-PICCs showed superiority in reducing PICC-related complications, this study failed to conduct a medical economic analysis between the groups regarding the cost of application of the tunneling technique and the treatment cost of complications.

In conclusion, this multicentre study demonstrated that T-PICCs significantly reduced long-term complications but did not increase periprocedural complications. T-PICCs are recommended for patients at high risk of PICC-related complications. Further research is needed to conduct a medical economic analysis comparing T-PICC and C-PICC placement.

Abbreviations

CLABSI	Catheter-related bloodstream infection
CASI	Central venous access device-associated skin impairment
CVC	Central venous catheter
C-PICC	Conventional peripherally inserted central catheter
PICC	Peripherally inserted central catheter
T-PICC	Tunneled peripherally inserted central catheter

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Guarantor

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Conflict of interest

The authors of this manuscript declare no relationships with any companies, whose products or services may be related to the subject matter of the article.

Statistics and biometry

No complex statistical methods were necessary for this paper.

Informed consent

Written informed consent was obtained from all subjects (patients) in this study.

Ethical approval

Institutional Review Board approval was obtained with reference number B2020-320-01.

Study subjects or cohorts overlap

None.

Methodology

- Prospective/retrospective
- Randomized controlled trial
- Multicenter study

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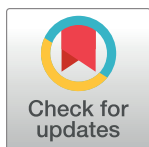
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RESEARCH ARTICLE

Comparison of complications between reverse-tapered and nontapered peripherally inserted central catheters

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Abstract

Purpose of this study was to compare the complication rates between reverse-tapered and nontapered peripherally inserted central catheters (PICCs). In total, 407 patients who had an inpatient clinic-based PICC insertion between September 2019 and November 2019 were retrospectively analyzed. Seven PICC types were used (4 reverse tapered: 4-Fr single-lumen (n = 75), 5-Fr single-lumen (n = 78), 5-Fr double-lumen (n = 62), and 6-Fr triple-lumen (n = 61); 3 nontapered: 4-Fr single-lumen (n = 73), 5-Fr double-lumen (n = 30), and 6-Fr triple-lumen (n = 23)). Complications such as periprocedural bleeding, delayed bleeding, inadvertent removal, catheter obstruction by thrombosis, infection, and leakage were investigated. The overall complication rate was 27.1%. The complication rate was significantly higher for nontapered PICCs than reverse-tapered PICCs (50.0% vs 16.7%, $P < 0.001$). The overall periprocedural bleeding rate was significantly higher for nontapered PICCs than for reverse-tapered PICCs (27.0% vs 6.2%, $P < 0.001$). The overall inadvertent removal rate was significantly higher for nontapered PICCs than for reverse-tapered PICCs (15.1% vs 3.3%, $P < 0.001$). There were no other significant differences in complication rates. Nontapered PICCs were associated with higher rates of periprocedural bleeding and inadvertent removal than reverse-tapered PICCs.

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Introduction

Peripherally inserted central catheters (PICCs) are commonly used for patients in need of long-term intravenous therapy [1, 2]. However, PICC-related complications can adversely affect treatment outcomes. Several studies have reported that the complications could be related to the characteristics of PICCs. For example, increased PICC lumen number has been reported as a strong risk factor for CLABSI (central line associated bloodstream infection) [3–5]. The large diameter of PICCs has been reported to increase the incidence of deep vein thrombosis (DVT), which is another well-known PICC-associated complication [6, 7]. However, a recent randomized controlled trial reported that there was no association between PICC diameter and DVT [8].

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PICCs are divided into two types: reverse-tapered and nontapered. With the reverse-tapered type, the catheter diameter gradually increases toward the hub of the PICC. A large diameter of the catheter at the puncture site might potentially reduce bleeding, but it could also result in the stagnation of blood flow, which could induce DVT. With the nontapered type, the catheter has an equal diameter from the tip toward the hub. The diameter of a nontapered PICC is usually smaller than the peel-away sheath; thus, puncture site bleeding might frequently occur. However, blood flow stagnation could be reduced. There is only one study comparing the two types of PICC. Itkin et al. reported that the catheter-related DVT rate was not significantly different between the two types of PICC [8]. However, only double-lumen catheters were used in their study. Furthermore, complications other than DVT were not evaluated. The aim of this study was to compare complication rates between reverse-tapered and nontapered PICCs.

Materials and methods

Patients

This single-center, retrospective study was approved by the institutional review board. Informed consent was waived by the board because of the retrospective nature of the analysis. Data from September 2019 to November 2019 were reviewed. During this period, a total of 501 PICCs were used in 484 patients. Ninety-nine patients who underwent the procedure at an outpatient clinic were excluded due to limitations in follow-up (Fig 1). Thus, a total of 402 PICC insertions in 387 patients were analyzed in this study. Patients' data are summarized in Table 1. The seven PICC types used in this study were as follows: 4- and 5-Fr single-lumen, 5-Fr double-lumen, and 6-Fr triple-lumen reverse-tapered PICC (Turbo-Ject® Power-Injectable PICC, Cook medical) and 4-Fr single-lumen, 5-Fr double-lumen, and 6-Fr triple-lumen nontapered PICC (Arrow® PICC, Teleflex). The length of reverse tapering was 7 cm in 4- and 5-Fr catheters and was 2 cm in 6-Fr catheters (Fig 2).

PICC insertion procedure and follow-up

After skin sterilization and injection of local anesthetics, the basilic or brachial vein was punctured under ultrasound guidance. A guidewire was used for positioning the catheter tip under fluoroscopy. The preferable location of the catheter tip was the superior vena cava (SVC)–right atrial (RA) junction. The length between the puncture site and the SVC–RA junction was measured, and then the catheter was trimmed accordingly.

With nontapered PICC catheter insertion, the catheter was inserted without trimming, generally. The tip of the catheter was positioned in the SVC–RA junction first, then an external fixator was fitted into the catheter at the puncture site and fixed in the skin by applying suture or StatLock.

After the procedure the PICC insertion site was dressed by applying transparent film. Saline flushing after each use was done during the follow-up period. The follow-up endpoint was the time when the catheter was removed. Complications such as periprocedural bleeding, delayed bleeding, inadvertent removal, catheter obstruction by thrombosis, infection, leakage, and catheter patency were investigated.

Definitions

Periprocedural bleeding was defined as bleeding that requires additional bleeding control such as manual compression at least 2 minutes right after the procedure. Delayed bleeding was defined as the occurrence of bleeding at least 1 hour after the procedure. Catheter obstruction

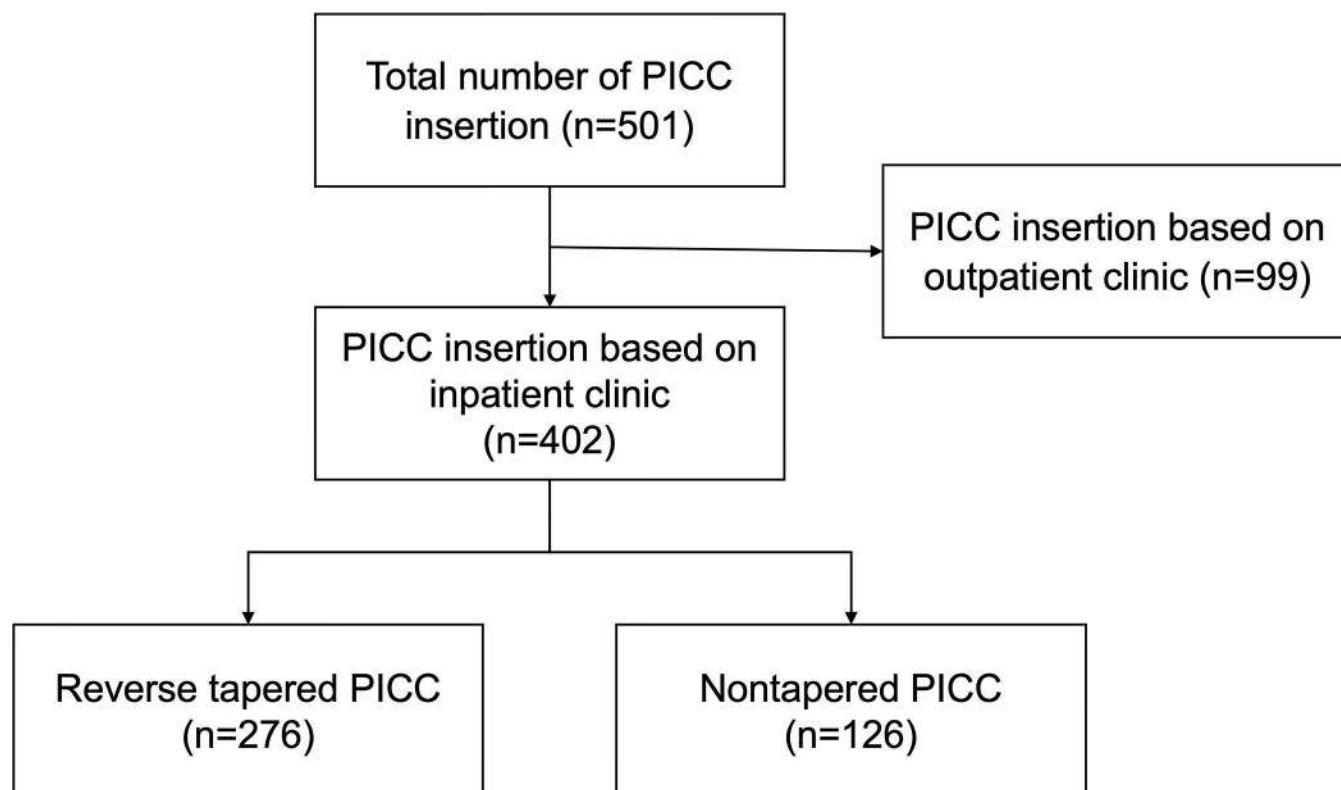


Fig 1. Inclusion and exclusion criteria.

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was defined as an uncorrectable obliteration of the PICC lumen. In-body length was defined as the length of the catheter between the PICC tip, which is positioned at RA-SVC junction, and the hub of the PICC. Out-body length was defined as the length of the catheter from the hub of the catheter to the puncture site of the skin. Infection was defined as the occurrence of CLABSI according to the definition of The National Healthcare Safety Network surveillance [9, 10].

Statistical analysis

Numerical variables were expressed as mean $\pm$ standard deviation. The Student's t-test was used to compare continuous variables. The Chi-square test was used to compare categorical variables. To identify independent predictors of periprocedural bleeding and inadvertent removal, univariate and multivariate logistic regression analyses were performed. The variables considered were age, sex, history of diabetes, history of cerebrovascular disease, history of anti-coagulants, platelets, prothrombin time (international normalized ratio, INR), type of PICC, number of lumen, diameter at hub, proportion of catheter to target vein diameter, side, punctured vein, diameter of punctured vein, and depth of punctured vein. The diameter and depth of the punctured vein were dichotomized by the cutoff value with the highest Youden index (14). Variables with a P value < 0.1 on univariate analysis were used for multivariate analysis. A two-sided P value < 0.5 was considered statistically significant in the final model. All statistical analyses were performed using MedCalc version 20.109 (Foundation for Statistical Computing, Vienna, Austria).

Table 1. Demographics of patients.

	Reverse-Tapered PICC (n = 276)	Nontapered PICC (n = 126)	P-value
Mean age	68.7 ± 14.0	71.0 ± 14.0	0.128
Sex			0.88
Male	143 (51.8)	63 (50.0)	
Female	133 (48.2)	63 (50.0)	
History of hypertension	152 (55.1)	70 (55.6)	0.986
History of diabetes	75 (27.2)	45 (35.7)	0.106
History of CVD	52 (18.8)	29 (23.0)	0.404
History of stroke	65 (23.6)	18 (14.3)	0.046
History of anticoagulation	60 (21.7)	24 (19.0)	0.629
Platelet (x10 ³)	238.19 ± 137.8	240.53 ± 129.3	0.872
PT (INR)	1.32 ± 0.44	1.26 ± 0.28	0.140
aPTT (seconds)	32.91 ± 7.82	33.80 ± 12.88	0.392
Side			0.858
Right	252 (91.3)	115 (91.3)	
Left	24 (8.7)	11 (8.7)	
Puncture vein			0.353
Basilic	240 (87.0)	109 (86.5)	
Brachial	32 (11.6)	17 (13.5)	
Cephalic	4 (1.4)	0 (0.0)	
PICC lumen			0.678
Single	4-Fr: 75 (27.2) 5-Fr: 78 (28.3)	73 (57.9)	
Double	62 (22.5)	30 (23.8)	
Triple	61 (22.1)	23 (18.3)	

* Numbers in parentheses are percentage

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Results

The overall complication rate was 27.1% (109 of 402 patients). The complication rate was significantly higher for nontapered PICCs (50.0%, 63 of 126 patients) than for reverse-tapered PICCs (16.7%, 46 of 276 patients) ($P < 0.001$). The periprocedural bleeding rate was significantly higher for nontapered PICCs (27.0%, 34 of 126 patients) than for reverse-tapered PICCs (6.2%, 17 of 276 patients) ($P < 0.001$). The inadvertent removal rate was significantly higher for nontapered PICCs (15.1%, 19 of 126 patients) than for reverse-tapered PICCs (3.3%, 9 of 276 patients) ($P < 0.001$). No other complication rates showed significant differences between the PICC types. Data are summarized in Table 2.

Nontapered type, triple lumen, diameter at hub, and more than 50% of catheter diameter to target vein diameter proportion were significant predictors of periprocedural bleeding (Table 3). Among these factors, multivariate analysis indicated that nontapered type (OR, 6.257; 95% CI 3.271–11.968; $P < 0.001$) and triple lumen (OR, 2.929; 95% CI, 1.474–5.822; $P = 0.002$) were independent risk factors for periprocedural bleeding.

History of anticoagulants, nontapered type, diameter at hub, and more than 50% of catheter diameter to target vein diameter proportion were predictors of inadvertent removal (Table 4). Among these factors, multivariate analysis indicated that nontapered type (OR, 5.237; 95% CI 2.283–12.011; $P < 0.001$) was independent risk factors for inadvertent removal.

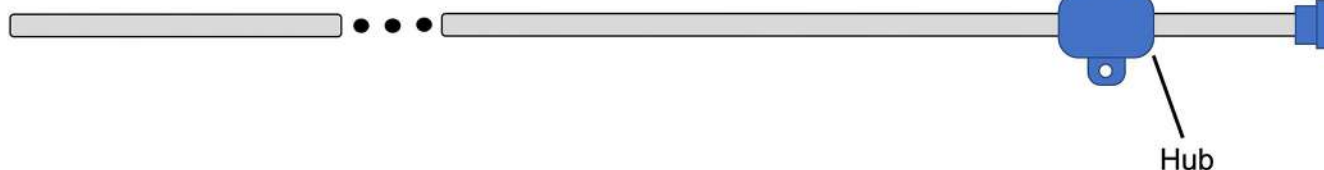
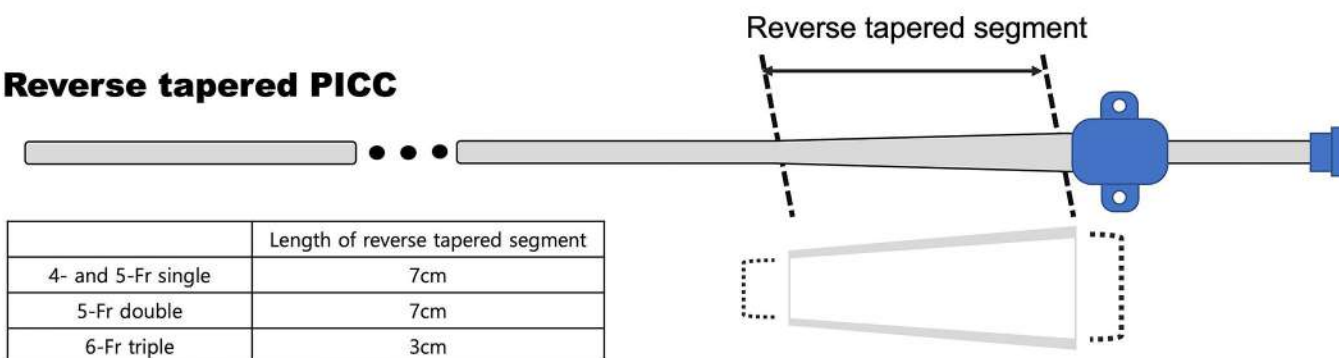
Nontapered PICC**Reverse tapered PICC**

Fig 2. Illustration of nontapered and reverse-tapered PICCs. The diameters of nontapered PICC remain equal throughout the catheter. For a reversed-tapered PICC, the diameter of the catheter gradually increases over a distance of 7 cm or 2 to 3 cm from the hub.

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Multivariate analysis indicated that nontapered type (OR, 6.257; 95% CI 3.271–11.968; $P < 0.001$) and triple lumen (OR, 2.929; 95% CI, 1.474–5.822; $P = 0.002$) were independent risk factors for periprocedural bleeding.

Discussion

Previous reports on the characteristics of PICCs have focused on clinical outcomes. Most of those reports primarily analyzed the risk of DVT. Grove et al. suggested that a catheter should be as small as possible to reduce the incidence of DVT, and Evans et al. reported that a large catheter size was related to an increased risk of DVT [6, 7]. Itkins et al. compared the DVT rate between reversed-tapered and nontapered PICCs in their randomized controlled trial. They reported that there was no significant difference between the two types of PICC [8]. In this study, we showed that PICC type is associated with certain complications. The rates of periprocedural bleeding and inadvertent removal were significantly higher for nontapered PICCs, while other complications were not significantly different between reversed-tapered and nontapered PICCs.

Periprocedural and delayed bleeding rates for PICCs have not been reported in previous studies. In our study, the periprocedural bleeding rate was significantly higher for nontapered PICCs than for reverse-tapered PICCs (27% vs. 6.2%, $p < 0.001$). The factors associated with an increased risk of periprocedural bleeding were nontapered type and triple lumen catheter. Considerable variety in periprocedural bleeding rate was shown among the catheters with a different diameter at the hub (2.9%–33.3%). A catheter to target vein diameter $> 50\%$ was also associated with the decreased risk of periprocedural bleeding in univariate analysis. These results implied that the catheter profile is closely associated with periprocedural bleeding. With nontapered PICCs, the diameter of the peel-away sheath is usually larger than the diameter of the hub. Thus, bleeding could occur through the gap between the PICC catheter and dilated puncture site. Most periprocedural bleeding can be managed simply by manual

Table 2. Complication rates.

	Overall		Single lumen (4 Fr)				Double lumen (5 Fr)				Triple lumen (6 Fr)			
	Tapered (n = 276)	Nontapered (n = 126)	P-value	Tapered (n = 153)	Nontapered (n = 73)	P-value	Tapered (n = 62)	Nontapered (n = 30)	P-value	Tapered (n = 61)	Nontapered (n = 23)	P-value		
Periprocedural bleeding	17 (6.2)	34 (27.0)	<0.001	6 (3.9)	14 (19.2)	<0.001	2 (3.2)	11 (36.7)	<0.001	9 (14.8)	9 (39.1)	0.033		
Inadvertent removal	9 (3.3)	19 (15.1)	<0.001	2 (1.3)	11 (15.1)	<0.001	7 (11.3)	2 (6.7)	0.745	0 (0.0)	6 (26.1)	<0.001		
Catheter obstruction	7 (2.5)	5 (4.0)	0.641	4 (2.6)	4 (5.5)	0.481	3 (4.8)	1 (3.3)	0.831	0 (0.0)	0 (0.0)	-		
Infection	11 (4.0)	5 (4.0)	0.790	4 (2.6)	3 (4.1)	0.845	3 (4.8)	0 (0.0)	0.549	4 (6.6)	2 (8.7)	0.892		
Leakage	1 (0.4)	0 (0.0)	0.687	0 (0.0)	0 (0.0)	-	0 (0.0)	0 (0.0)	-	1 (1.6)	0 (0.0)	0.670		
Delayed bleeding	1 (0.4)	0 (0.0)	0.687	0 (0.0)	0 (0.0)	-	1 (1.6)	0 (0.0)	0.709	0 (0.0)	0 (0.0)	-		

* Data from 5-Fr single lumen PICC (Cook) are omitted in this table. Total of 78 PICCs; periprocedural bleeding, 0 PICCs (0.0%); inadvertent removal, 1 PICCs (1.3%); catheter obstruction, 2 PICCs (2.6%); infection, 4 PICCs (5.1%); leakage, 0 PICCs (0.0%); delayed bleeding, 0 PICCs (0.0%)

* Numbers in parentheses are percentages

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Table 3. Univariate analysis of predictors of periprocedural bleeding.

Variables	Frequency	Periprocedural bleeding		P-value
		Yes	No	
Total number of PICC on inpatient clinic	402	51 (12.7)	351	-
Age ≥ 65	285	40 (14.0)	245	0.208
Male sex	206	23 (11.2)	183	0.348
History of hypertension	222	31 (14.0)	191	0.393
History of diabetes	120	19 (15.8)	101	0.218
History of stroke	81	9 (11.1)	72	0.634
History of anticoagulants taking	84	9 (10.7)	75	0.542
Platelet $< 100,000$	62	8 (12.9)	54	0.956
INR > 1.4	75	10 (13.3)	65	0.852
Nontapered type	126	34 (27.0)	92	< 0.001
Number of lumen				
Single	226	20 (8.8)	206	-
Double	92	13 (14.1)	79	0.165
Triple	84	18 (21.4)	66	0.004
Diameter at hub				0.001
4-Fr (A1)	73	14 (19.2)	59	-
5-Fr (A2)	30	10 (33.3)	20	-
6-Fr (A3 and C1 4-Fr)	98	15 (15.3)	83	-
7-Fr (C2 and C1 5-Fr)	140	4 (2.9)	136	-
8-Fr (C3)	61	8 (13.1)	53	-
Catheter to target vein diameter proportion $> 50\%$	155	12 (7.7)	143	0.021
Left side PICC	35	2 (5.7)	33	0.210
Punctured vein				
Basilic vein	349	40 (11.5)	309	-
Brachial vein	49	11 (22.4)	38	0.035
Cephalic vein	4	0 (0)	4	0.998
Vein diameter $\geq 4.48\text{mm}$	204	25 (12.3)	179	0.792
Vein depth $\geq 5.93\text{mm}$	201	22 (10.9)	179	0.296

* Numbers in parentheses mean percentages

*A1, Arrow single lumen; A2, Arrow double lumen; A3, Arrow triple lumen; C1, Cook single lumen; C2, Cook double lumen; C3, Cook triple lumen

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compression, but an encircling suture around the catheter may be needed if there is persistent bleeding.

Another complication associated with catheter type was inadvertent removal. Our results showed a significantly higher inadvertent removal rate in nontapered PICCs compared to reverse-tapered PICCs (15.1% vs 3.3%, $p < 0.001$). This may be attributable to the difference in the method of PICC fixation. In nontapered PICCs, the catheter is introduced until its tip is in the SVC-RA junction without the trimming of its tip; then, an external skin fixator is assembled to the catheter according to the length inside the body. This method contributed to the reduction of procedure time. However, the external length of the catheter could be longer; consequently, the chance of accidental inadvertent removal may increase. Only simple catheter fixation methods such as StatLock and/or suture were used in this study. Advanced catheter securement system such as SecurAcath (Interrad Medical, Plymouth, MN, USA) might be considered to prevent inadvertent removal when nontapered PICC is used without trimming.

Table 4. Univariate analysis of predictors of inadvertent removal.

Variables	Frequency	inadvertent removal		P-value
		Yes	No	
Total number of PICC on inpatient clinic	402	28 (7.0)	374	-
Age ≥ 65	285	21 (7.4)	264	0.621
Male sex	206	14 (6.8)	192	0.891
History of hypertension	222	15 (6.8)	207	0.855
History of diabetes	120	9 (7.5)	111	0.784
History of stroke	81	5 (6.0)	78	0.426
History of anticoagulants taking	84	1 (1.2)	83	0.047
Platelet $< 100,000$	62	3 (4.8)	59	0.478
INR > 1.4	75	2 (2.7)	73	0.123
Nontapered type	126	19 (15.1)	107	< 0.001
Number of lumen				
Single	226	13 (5.8)	213	-
Double	92	9 (9.8)	83	0.204
Triple	84	6 (7.1)	78	0.651
Diameter at hub				0.009
4-Fr (A1)	73	9 (12.3)	64	
5-Fr (A2)	30	3 (10.0)	27	
6-Fr (A3; C1 4-Fr tip)	98	8 (8.2)	90	
7-Fr (C2; C1 5-Fr tip)	140	7 (5.0)	133	
8-Fr (C3)	61	1 (1.6)	60	
Catheter to target vein diameter proportion $> 50\%$	155	5 (3.2)	150	0.026
Left side PICC	35	0 (0.0)	35	0.998
Punctured vein				
Basilic vein	349	26 (7.4)	323	-
Brachial vein	49	2 (4.1)	47	0.396
Cephalic vein	4	0 (0.0)	4	0.998
Vein diameter $\geq 4.48\text{mm}$	204	14 (6.9)	190	0.935
Vein depth $\geq 5.93\text{mm}$	201	11 (5.5)	190	0.243

* Numbers in parentheses mean percentages

*A1, Arrow single lumen; A2, Arrow double lumen; A3, Arrow triple lumen; C1, Cook single lumen; C2, Cook double lumen; C3, Cook triple lumen

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DVT is a recognized complication of PICCs. There was a concern that the reversed-tapered design hampers blood flow at the insertion site, which can result in DVT. However, a previous RCT showed the tapered design did not increase the number of DVTs, as had been hypothesized [8]. In this study, only DVTs that caused catheter obstruction have been documented due to the retrospective nature of this study. The rate of catheter obstruction was not significantly different between PICC types in this study. Although asymptomatic DVT may be underestimated, our results demonstrated a clinically relevant thrombosis rate causing catheter obstruction.

There were limitations in this study. First, this study was a retrospective, single-center study over a relatively short period of investigation. Second, the procedure was performed by multiple radiologists with different levels of experience. Although all participating radiologists received education about the definition of periprocedural bleeding and used the same technique in PICC insertion, there is inevitable bias from a technical perspective. Third, the hub of

the nontapered PICC catheter was incompletely inserted. This might result in a significantly higher inadvertent removal rate in nontapered PICCs; thus, delayed complications such as infection or catheter obstruction might be underestimated. Fourth, the DVT occurrence rate was not analyzed in this study. As there was a previous RCT on DVT incidence, this study focused on other possible complications of PICCs. A future prospective study to compare complications between reverse-tapered and nontapered PICCs is warranted.

Conclusions

In conclusion, nontapered PICCs were associated with higher rates of periprocedural bleeding and inadvertent removal than reverse-tapered PICCs. The reverse-tapered design does not appear to increase complication rates such as catheter obstruction by thrombosis. Collectively, it appears that nontapered PICCs do not offer specific advantages over reverse-tapered PICCs relative to complications.

Author Contributions

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Reverse tapered versus non-tapered peripherally inserted central catheters: A narrative review

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Sergio Bertoglio 

Abstract

Introduced over 20 years ago, the reverse tapering design for PICC catheters is supposed to have some benefits in terms of both efficacy and safety. In particular, it would ensure less postoperative bleeding at the exit site and greater effectiveness in preventing kinking or twisting of the same. Since its introduction, these hypothesized advantages have never been demonstrated in clinical studies, however very scarce, which have highlighted neither advantages nor disadvantages of reverse tapered catheters when compared to non-reverse tapered ones. This narrative review analyzes some aspects of the use of reverse tapered PICCs, also paying attention to some possible undesirable effects that have arisen from the introduction into clinical practice of new subcutaneous systems of securement of PICCs to the skin. Clinicians should be aware of the fact that reverse tapering design does not represent a sure improvement in terms of safety and efficacy of PICCs and its adoption should be weighed against possible clinical disadvantages.

Keywords

Peripherally inserted central catheters, biomaterials, cyanoacrylate glue, catheter securement

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Peripherally inserted central catheters (PICCs) have been used in clinical practice for more than 30 years. Their use has steadily grown over the years because of the perception of an easy placement procedure with less perioperative complications compared to traditional central venous access and totally implantable port devices.^{1–6} The original configuration of PICCs was a constant outer diameter (from the connection hub to the catheter tip) ranging in size from 3 French (F) to 7F, depending on different clinical needs. Commonly used catheter materials are silicone and new-generation polyurethanes, with a growing prevalence of the latter during the years.

PICCs are associated with a clinically acceptable risk of post-insertion complications such as postoperative bleeding from the exit site, catheter-related venous thrombosis (CRT), central line associated bloodstream infection (CLABSI), occlusion of the catheter lumen, as well as mechanical complications, of which the most frequent are kinking of the extravascular tract of the catheter, dislodgment, or rupture of the catheter. Provided that the clinical efficacy and safety are assessed, there are no specific standards or requirements regarding the design of the catheters. During the last decade of the XX century, some

PICC manufacturers introduced a modification of the catheter design that consisted in a reverse tapering of the proximal portion of the catheter, so that the size of the catheter tract closer to the wing and to the extensions was 2Fr wider (or more) if compared to the rest of the catheter. Thus, in a reverse tapered PICC, though the declared size of the catheter is 4F, the proximal end may be as large as 6F or even more (5–7F). This design feature was mainly originated by the request of some radiologists to obtain an easier manipulation of such thin catheters. Though, reverse tapering rapidly became a successful marketing idea, justified by the theory that a larger proximal tract of the catheter might act as a tamponade on the site of venipuncture, preventing post-insertion bleeding from the site; also, it was assumed that the extravascular tract of the catheter may become less prone to twisting and kinking, because of its greater

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resistance and robustness. These changes of the catheter design were approved by the U.S. Food and Drug Administration (FDA), without any requirement of supplementary research such as clinical trials investigating their safety and effectiveness. In fact, this new design feature did not apparently affect the flow dynamic or the performance of the device. Since then, reverse tapered PICCs have been produced by all main manufacturers.

Since the adoption of reverse tapering for PICCs, some doubts and concerns have been raised inside the scientific community about its actual efficacy in reducing postoperative bleeding from the exit site and/or mechanical complications. It is worth noting that the alleged reduction of postoperative bleeding risk has not been demonstrated in controlled clinical trials, and that there are no bibliographic references available in this regard. Moreover, cyanoacrylate-based glues are increasingly utilized for sealing the exit site after PICC insertion, so that postoperative local bleeding has become infrequent, clinically irrelevant and easily preventable.^{6,7} Similarly, the introduction in clinical practice of new sutureless stabilization devices and the possible option to tunnel catheters with the exit site away from the vein access site has significantly reduced both the risk of mechanical complications (kinking/twisting) of the external tract of PICCs and postoperative insertion bleeding.

In recent years, reverse tapering design has been indicated as a possible risk factor for CRT, considering that a catheter to vein ratio >0.45 or >0.33 (as reported by different guidelines) is currently considered to be predictive for such complication.^{8,9} In fact, for the purpose of reducing CRT risk, a 4F PICC should be preferably inserted in a 4 mm vein; but, if the reverse tapered tract of the catheter (which may be 6F or larger) is located in a 4 mm vein, this will exceed the recommended catheter to vein ratio and could be associated with increased risk of CRT (more specifically, the risk of venous thrombosis at the site of venipuncture). Two recent studies have addressed this issue, in particular for larger triple lumen 6F tapered PICC.^{10,11} In a first prospective study,¹⁰ the incidence of CRT was shown to increase up to 20% if compared to the standard ranges reported in the literature for this complication. It is worth mention that the results of this single center observational study were somehow weak from the statistical point of view and thus considered non-conclusive. This issue has been further addressed in the only randomized clinical trial available in the literature,¹¹ that found no significant differences in post-insertion bleeding or CRT or mechanical complications, when comparing reverse tapered vs. non-tapered PICCs.

Also, interestingly, peel-away introducers of reverse tapered PICCs are somehow greater in size than introducers of non-tapered PICCs of the same size. Thus, although

not yet clinically investigated, the insertion of larger introducers may be probably associated with major trauma to the vein wall and increased risk of CRT.

In summary, though reverse tapering may theoretically have some potential benefits or some potential risks, at this moment there is no available evidence in the literature in favor or against its safety and/or clinical effectiveness.

In our personal experience - more than 20 years of PICC insertions in cancer patients under active treatment, accounting for 200–300 devices per year - we have been using both reverse tapered and non-tapered PICCs. Before 2010, we used mainly non-tapered PICCs and since then mainly tapered PICCs, this switch being based not on clinical ground but the overall conversion of most PICC manufacturers to the reverse tapering design. Data from our continuous monitoring of PICCs outcomes have not shown significant differences of the two different catheter design in terms of safety and efficacy.

It is our perception that all the most relevant improvements in the last decade have mainly been based on the amelioration of the implant procedures, nursing protocols, dressing materials, etc., regardless of the tapered or non-tapered design. Nowadays, the risk of postoperative bleeding can be almost completely avoided by sealing the exit site with cyanoacrylate glue; the risk of CRT can be minimized by using a proper insertion bundle including (a) consideration of the catheter/vein ratio, (b) ultrasound-guided venipuncture with micro-introducer kits, (c) intraprocedural location of the catheter tip by intracavitary ECG, (d) proper sutureless stabilization at the exit site; the risk of dislodgment can be minimized by using the subcutaneously anchored sutureless devices, recently introduced in the clinical practice.

A particular mention should be made about the anchoring devices - strongly recommended by a recent consensus panel of international experts on vascular accesses¹²—which could be somehow affected by the concomitant use of a reverse tapered PICC. In fact, such devices are specifically designed for each catheter size: a 4F anchoring device might not fit the 6F tapered tract of a 4F PICC.

In conclusion, clinicians should be aware of the fact that reverse tapering design does not represents an improvement in terms of safety and efficacy of these devices; the adoption of reverse tapered PICCs should be weighed against their possible disadvantages.

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Guideline Development and Acknowledgments

The following sections document the development, authorship, and review processes that shaped the *Association for Vascular Access (AVA) Clinical Practice Guidelines (CPGs) for Adults*. They recognize the individuals and teams whose collective expertise, diligence, and integrity ensured that each recommendation reflects both scientific rigor and practical clinical relevance. This record of contributors, disclosures, and acknowledgments is presented in the interest of transparency, accountability, and appreciation for the many professionals whose efforts brought these guidelines to completion.

The foundation for this project was established by Blake Hotchkiss, MSN, MBA, RN, VA-BC™, then an AVA staff member, and Andrea Raynak, PhD, RN, a volunteer, who initiated the guideline development process in 2021 and created the original protocol. Their early work provided the framework that allowed guideline development to move forward when the formal editorial team assumed responsibility in late 2023.

I. Editors

The editors of the inaugural AVA CPGs carried responsibility not only for oversight but also for active development. Together, they organized author contributions, standardized format and style, and ensured that recommendations reflected both the evidence base and practical clinical application.

Michelle L. Hawes, DNP, CRNI®, VA-BC™, ACRP-CP

Dr. Hawes has been a nurse for over 30 years, with nearly 3 decades of experience dedicated to vascular access. Her background spans pediatrics, home infusion, emergency medicine, and vascular access team building, with a consistent focus on improving patient safety and outcomes. Today, she works primarily as a researcher, editor, and mentor, supporting evidence-based practice and the next generation of vascular access specialists.

Mickey is nationally certified as a Clinical Research Professional (ACRP-CP) and serves as Editor-in-Chief of the *Journal of the Association for Vascular Access (JAVA)*. She has authored multiple peer-reviewed publications as well as presentations and poster abstracts, which have been presented at national and international conferences. Her work emphasizes appraisal, guideline development, and the translation of research into practical clinical guidance to improve patient outcomes.

Disclosures (past 5 years):

- Access Vascular, Inc.
- Covalon Technologies Ltd.
- Data to Wisdom Research Consulting
- Eloquest Healthcare, Inc.
- Interrad Medical, Inc.
- Mighty Well
- PrevaHex
- Sterile Care

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Antonia “Toni” Sochor began her career as a Hospital Corpsman in the United States Navy before transitioning into civilian health care. She became a Registered Nurse (RN) in 2007 and earned her bachelor’s degree in nursing in 2016. For over 17 years, she has specialized in vascular access across diverse hospital settings, with a focus on advancing safe insertion practices, preventing complications, and delivering patient-centered care.

Toni currently serves as Clinical Education Specialist for the AVA and has played an integral role in the development of these CPGs. She is recognized for her dedication to improving patient outcomes through optimal vascular access and her commitment to supporting clinicians through evidence-informed practice.

Disclosures (past 5 years): None

Lois N. Davis, MSN, RN, VA-BC™

Lois Davis is a nurse and health care consultant with decades of experience in vascular access, infusion therapy, and clinical education. She has served in leadership and educator roles with the Vascular Access Certification Corporation, the AVA, and other professional organizations, helping to shape national and international standards of practice. Lois also served as Editor of the *JAVA*, guiding the publication of peer-reviewed research and clinical innovation. A frequent speaker and published author, she has made significant contributions to advancing best practices, certification, and professional development for clinicians across diverse health care settings.

Disclosures (past 5 years):

- Dynamic Access, Inc.
- H.B. Fuller Medical Adhesive Technologies, LLC
- PICC Excellence

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Warren McGlaufflin has been a nurse for over 25 years, with his early career rooted in emergency medicine before transitioning into vascular access in 2008. He currently serves as a Vascular Access Specialist at Central Maine Medical Center. Since 2015, he has served as a Nurse Leader for the Vascular Access Specialty Team (VAST), where he has contributed to reducing central line-associated bloodstream infections (CLABSI), developed policies, and implemented staff training initiatives. Warren has been an active member of the AVA since 2010, serving on the Board of Directors as Secretary and Director-at-Large as well as chairing the Design Team for the Annual AVA Scientific Meeting (D-Team). He is also recognized for creating mentorship opportunities to support new vascular access clinicians and for leading quality improvement efforts that have advanced the delivery of safe and effective vascular access care.

Disclosures (past 5 years): None

II. Author Recognition and Disclosures

In addition to conducting evidence appraisal, the guideline authors assumed the added responsibility of synthesizing research findings into clear, actionable recommendations. They screened titles and abstracts, evaluated full texts using the Johns Hopkins–Evidence Based Practice (JH-EBP) framework, and translated the evidence into guidance aimed at improving patient safety and outcomes. Their dual roles as appraisers and recommendation writers reflect the depth of expertise and commitment behind these guidelines.

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III. Contributors

Several dedicated colleagues played essential roles in the development of these CPGs, contributing to the foundation on which all recommendations were built. They supported the project through PICO writing, systematic review, and article-level appraisal. Each completed Johns Hopkins Nursing–Evidence-Based Practice (JHN-EBP) training course and participated in screening thousands of titles and abstracts as well as evaluating hundreds of full texts to ensure consistent leveling and grading of the evidence. Although none were available to author recommendations, their expertise and effort were instrumental to the success of this work and are deeply appreciated.

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Phase Six: AVA Board Adoption

Adopted January 12, 2026

Phase Seven: Submission to JAVA

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Phase Eight: JAVA Guest Editor (not a part of the CPG process)

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V. Acknowledgment of the Research Librarian

The editors extend sincere appreciation to Mary Doug Wright, Research Librarian, whose expertise and diligence supported the systematic review process underlying these guidelines. She executed the search strategies within the parameters provided and later repeated the review to ensure the inclusion of the most current evidence available. Her understanding of systematic review methodology and the realities of literature search design greatly informed the foundation of this work.

VI. Special Recognition

Judy Thomson, MSNEd, RN, VA-BC™

Clinical Education Director for AVA, Judy has overseen this project since its inception in 2021. Judy, along with Blake Hotchkiss, secured the grants that supported development costs and provided consistent guidance and leadership across all phases. Her steady support made it possible for the development team to move the CPGs from concept to reality.

Board Liaisons

- Michelle DeVries, MPH, CIC, AL-CIP, VA-BC™, CPHQ, FAPIC—AVA Board Presidential Advisor (2025)
- Christine Vandenhousten, PhD, RN, CPH—AVA Director-at-Large (2024–2025)

Michelle and Christine served as the CPG Board Liaisons, meeting weekly with the CPG Development Team. They brought an essential outside-the-process perspective, represented the Board's view, and consistently offered encouragement that sustained the work through its final phase of development.

Together, Judy, Michelle, and Christine provided support, perspective, and leadership that anchored the development process and ensured the guidelines reached completion.

VII. Special Thanks

The editors extend sincere appreciation to the members of the AVA Board of Directors who served between 2021 and 2025. Their ongoing support, vision, and encouragement sustained the CPGs project through its full development cycle. Board members provided leadership, strategic oversight, and steadfast commitment to advancing vascular access practice, ensuring that the inaugural guidelines reflect both the needs of clinicians and the values of the Association.

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VIII. Credential

Expert Credentials Behind the AVA CPGs

The inaugural AVA CPGs reflect the collective expertise of a uniquely multidisciplinary team. Contributors include nurses, physicians, respiratory therapists, radiologic technologists, paramedics, and researchers whose combined backgrounds span clinical practice, education, administration, and innovation. The credentials listed here represent not only academic degrees and professional certifications but also state licensure and prestigious fellowships awarded by leading professional organizations.

This extraordinary mix of qualifications underscores both the depth of vascular access expertise and the broad commitment across disciplines to advance safe, evidence-based care. The diversity of perspectives and the caliber of contributors are a defining strength of these guidelines.

Credential	Description	Type	Issuing body/region
ACRP-CP	Clinical Research Professional—Certified	Certification	ACRP, US/international
AGACNP-BC	Adult-Gerontology Acute Care Nurse Practitioner—Board Certified	Certification	ANCC, US
AHCP	Advanced Health Care Practitioner	Professional designation	UK/Canada
AOCNS	Advanced Oncology Clinical Nurse Specialist	Certification	ONCC, US
APRN	Advanced Practice Registered Nurse	Licensure	State boards, US
APRN-CNS	Advanced Practice Registered Nurse—Clinical Nurse Specialist	Licensure	State boards, US
ARRT	American Registry of Radiologic Technologists	Licensure	National licensure, ARRT, US
BA	Bachelor of Arts	Academic degree	Accredited university, US/international

Credential	Description	Type	Issuing body/region
BS	Bachelor of Science	Academic degree	Accredited university, US/international
BSIE	Bachelor of Science in Industrial Engineering	Academic degree	Accredited university, US/international
BSN	Bachelor of Science in Nursing	Academic degree	Accredited university, US/international
CCRN	Critical Care Registered Nurse	Certification	AACN, US
CCHN(C)	Certified Community Health Nurse	Certification	CNA, Canada
CEN	Certified Emergency Nurse	Certification	BCEN, US
CIC	Certification in Infection Control	Certification	CBIC, US/international
CIIP	Certified Imaging Informatics Professional	Certification	ABII, US
CPEN	Certified Pediatric Emergency Nurse	Certification	BCEN, US
C-NPT	Certified Neonatal Pediatric Transport	Certification	BCCTPC, US
CPHQ	Certified Professional in Healthcare Quality	Certification	NAHQ, US/international
CPN	Certified Pediatric Nurse	Certification	PNCB, US
CPUI	Certified PICC Ultrasound Inserter	Certification	PICC Excellence, US (industry certification)
CRNI®	Certified Registered Nurse Infusion	Certification	INCC, US
CVAA(C)	Canadian Vascular Access Association–Certified	Certification	CVAA, Canada
DAPWCA	Diplomate, American Professional Wound Care Association	Certification	APWCA, US
DNP	Doctor of Nursing Practice	Academic degree	Accredited university, US
EdD	Doctor of Education	Academic degree	Accredited university, US/international
EMBA	Executive Master of Business Administration	Academic degree	Accredited university, US/international
FAAN	Fellow of the American Academy of Nursing	Honorific	ANA, US
FAARC	Fellow, American Association of Respiratory Care	Honorific	AARC, US
FACS	Fellow, American College of Surgeons	Honorific	ACS, US

Credential	Description	Type	Issuing body/region
FAEN	Fellow of the Academy of Emergency Nurses	Honorific	AEN, US
FAPIC	Fellow of the Association for Professionals in Infection Control and Epidemiology	Honorific	APIC, US
HDip	Higher Diploma (postgraduate qualification)	Academic degree	Accredited university, Ireland/UK
HIN	Health Informatics Nursing	Academic degree	Accredited university, US
JD	Juris Doctor	Academic degree	Accredited university, US
MBA	Master of Business Administration	Academic degree	Accredited university, US/international
MCISc	Master of Clinical Science	Academic degree	Accredited university, Canada
MNA	Master of Nurse Anesthesia	Academic degree	Accredited university, Canada
MNSc	Master of Nursing Science	Academic degree	Accredited university, Canada
MPH	Master of Public Health	Academic degree	Accredited university, US/international
MSc	Master of Science	Academic degree	Accredited university, US/international
MSHI	Master of Science in Health Informatics	Academic degree	Accredited university, US/international
MSN	Master of Science in Nursing	Academic degree	Accredited university, US/international
MSSB	Bachelor of Medicine, Bachelor of Surgery (equivalent to MD in US)	Academic degree	Accredited university, Australia/UK
NEA-BC	Nurse Executive Advanced—Board Certified	Certification	ANCC, US
NE-BC	Nurse Executive—Board Certified	Certification	ANCC, US
NPD-BC	Nursing Professional Development—Board Certified	Certification	ANCC, US
NRP	Nationally Registered Paramedic	Certification	National Registry of EMTs, US
PCCN	Progressive Care Certified Nurse	Certification	AACN, U.S.

Credential	Description	Type	Issuing body/region
PhD	Doctor of Philosophy	Academic degree	Accredited university, US/international
RN	Registered Nurse	Licensure	State boards, US
RNP	Registered Nurse Practitioner	Licensure	State boards, US
RRT	Registered Respiratory Therapist	Licensure	National licensure, NBRC, US
VA-BC™	Vascular Access–Board Certified	Certification	VACC, US

IX. Use of AI Disclosure Statement

The AVA Clinical Practice Guidelines represent the work of 26 section authors whose evidence-based contributions were synthesized into practical recommendations for direct care clinicians involved with vascular access. The early phases of development, including PICO construction, systematic review, and evidence appraisal, were completed by guideline developers, contributors, and the research librarian without the structured use of artificial intelligence.

In the final phase of development, artificial intelligence (AI) was introduced as a tool to support the editorial team. Its pri-

mary role was to assist with organizing content, standardizing language across multiple authors, and maintaining consistency of style and terminology throughout a complex multisection guideline. All interpretation of evidence, appraisal, grading, and recommendation writing were conducted and confirmed by vascular access experts using the Johns Hopkins Evidence-Based Practice framework, with AI serving as a strictly supportive tool.

The editorial team acknowledges the integral role AI played in harmonizing voices and enhancing clarity, while affirming that the clinical judgments, evidence synthesis, and final recommendations reflect the expertise of human clinicians.

Vascular Access is an essential and life-saving tool that is often underappreciated and overlooked as a specialty, yet as we all know, obtaining and maintaining vascular access is a highly complex physical and mental skill that needs to be finely tuned to the clinical situation, patient, and tools or resources available. If you have ever been hospitalized, it is likely that you have had a vascular access device inserted into you, and if you have been a frequent patient, it is likely that you know who is good at putting them in and ask for that person by name. This acutely demonstrates the importance of vascular access to patients. Vascular access is lifesaving; it has the potential to send someone home sooner or land them in the hospital for much longer or, worse yet, even to lose their life. Vascular access should absolutely be treated with the same respect as other clinical specialties and celebrated as a wonder equal to the discovery of penicillin which, by chance, can also be administered through vascular access devices.

Coming back to the field of vascular access, clinical practice guidelines exist for many other aspects of medical care, e.g., for various medicines, surgical procedures, and wound treatment. Vascular access deserves the same level of support for evidence-based clinical decision-making, and this is critical to ensure the best possible patient outcomes (and improved health care efficiency). Add to this the complexity of hospital systems, medical, nursing, and allied health teams that are required to care for increasingly complex patient cohorts, and anything less than care informed by rigorous guidelines and standards of practice would bring unacceptable risk.

We live in a world where science is increasingly questioned in favor of quick and easy soundbites of information. This is not surprising, considering the complexity of the systems and the mental burden this can create. However, we cannot escape the need for deep, science-based knowledge and expertise when it comes to improving people's lives, particularly in our occupations. We have an incredible responsibility to preserve and enhance life, and clinicians rightly deserve comprehensive but digestible information upon which to guide their decision-making.

On this basis, the Association for Vascular Access (AVA) should be congratulated for drafting its inaugural AVA clinical practice guidelines (CPGs). The CPGs are comprehensive and cover all aspects of vascular access (and most invasive device types) in adults across all clinical settings. It is pleasing to see the adoption of a robust methodology, which was used to identify and evaluate current evidence in the respective areas (including the assessment of level and quality of evidence). The holistic approach, considering not just the state of the patient's veins but also his or her personal social and economic conditions, is also admirable. As the Co-Leads of the Alliance for Vascular Access Teaching and Research (AVATAR, avatargroup.org.au), we are proud to note the efforts of AVATAR-trained and affiliated researchers in generating the >50 referenced articles which have helped to shape the CPGs. Without AVA and other specialist groups translating published research studies into digestible, trustworthy guidelines for clinicians, the evidence-to-practice gap would be far greater and

would be delayed for longer. We acknowledge that the AVA CPGs are just the start of a journey, one that will see them expanded and updated routinely. For clinicians, we see value in the CPG approach of providing clinical considerations to contextualize each recommendation, with commentary on benefits, risks, and implementation factors. We invite others to engage with AVA, whether you want to learn more through conference attendance or if you aspire to help the leadership and review teams identify, read, synthesize, debate, and make conclusions regarding the outcomes of published research. The body of evidence will only grow.

As we look to the future, we call upon researchers, clinicians, and industry partners to work together and expand the evidence base of research from which guidelines are developed. It is acknowledged that this will take time, resources, and valuable funds to generate. Equally, we must ensure that research is conducted without bias, always prioritizing valid research findings above all else, in the pursuit of improving outcomes for patients. The breadth of research should be freely accessible and include benchtop or laboratory studies and observational clinical or cohort studies but ideally be prospective in design and in the form of randomized controlled trials (RCTs). Systematic literature reviews with meta-analyses will then coalesce RCTs to assess the effectiveness of interventions across multiple sites. Let us not forget the importance of implementation trials, in which we seek to understand and evaluate the best ways of instigating and maintaining best practices into clinical environments. Finally, we ask all professionals, be they academic researchers, clinicians, industry executives, lawyers, biomedical engineers, data scientists, cleaners, or administrative officers, to be advocates for improving vascular access care, by raising the problems and solutions with their local, state, and federal representatives or policy makers.

We have come a long way and made incredible leaps and bounds in care over the past 50 years, thanks to the efforts of AVA and other advocacy groups. With AVA's increasing engagement with researchers, clinicians, and industry professionals, in addition to the development of training resources and guidelines such as these, now is the time to join the mission and work with our professional societies and governments worldwide to make vascular access complications history.

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Purpose of the Guidelines

The Association for Vascular Access (AVA) is honored to introduce the first edition of the AVA clinical practice guidelines (CPGs) for Adults. These guidelines provide a comprehensive, evidence-informed resource to support the delivery of safe, consistent, and high-quality vascular access care across all health care settings.

Vascular access is essential to modern health care, yet despite decades of research and published recommendations, substantial variation in practice persists worldwide, leading to preventable patient harm, inefficiencies, and inequities in care. The AVA CPGs represent a strategic response to these challenges, offering a standardized framework that integrates the best available evidence, expert consensus, and transparent methodology.

These guidelines are more than a set of clinical recommendations; they reflect AVA's commitment to patients, clinicians, and health systems. Developed through rigorous and transparent processes, they promote interdisciplinary collaboration, enhance clinical reasoning, and strengthen decision-making in practice.

These guidelines are intended to:

- Improve the safety, effectiveness, and consistency of vascular access care.
- Reduce unwarranted variation in practice by addressing both clinical and organizational factors.
- Minimize preventable complications, delays in care, and waste of resources.
- Serve as a trusted reference for clinicians, educators, health care leaders, and policy developers.

By providing a standardized approach to vascular access practice, the AVA CPGs advance excellence in patient care while supporting the professional community dedicated to vascular access. This inaugural edition is both a milestone achievement and a foundation for future updates as research, innovation, and clinical practice continue to evolve.

Scope of the Guidelines

These guidelines address the full life cycle of vascular access devices for adult patients (age ≥ 18 years) across all care environments, including inpatient, ambulatory, long-term postacute care, and home care settings. They provide structured guidance from device planning and selection to insertion, care, complication management, and removal.

The content is organized into 5 major sections:

1. Infrastructure, Teams, and Clinical Foundations
2. Patient Assessment and Planning
3. Device Selection and Procedural Considerations
4. Clinical Considerations for Insertion
5. Ongoing Assessment, Care, and Complication Management

Included Devices

- Peripheral Vascular Access Devices
- Peripheral Intravenous Catheters (PIVCs)
- Peripheral Midlines
- Central Vascular Access Devices
- Peripherally Inserted Central Catheters
- Centrally Inserted Central Catheters (CICCs)
- Tunneled-Cuffed CICCs
- Tunneled Noncuffed CICCs
- Totally Implanted Venous Access Devices (TIVADs)
- Additional Access
- Arterial Catheters
- Interosseous

The guidelines do not include:

- Neonatal and pediatric vascular access
- Advanced cardiovascular devices:
 - Pulmonary artery catheters—inserted via central veins and advanced into the pulmonary artery for hemodynamic monitoring.
 - Intra-aortic balloon pumps—inserted via femoral artery introducers for cardiac support.
 - Extracorporeal Membrane Oxygenation
- Dialysis requiring vascular surgery access:
 - Arteriovenous fistulas and grafts – surgical vascular access created for hemodialysis.
- Neuraxial and Cerebrospinal Access Devices:
 - Epidural catheters—placed in the epidural space for anesthesia or analgesia
 - Intrathecal catheters and ports—access to the cerebrospinal fluid space for medication delivery
 - Intraventricular catheters (e.g., external ventricular drains)—placed into cerebral ventricles for cerebral spinal fluid drainage and pressure monitoring
- Subcutaneous access devices:
 - Subcutaneous fluid ports, injection ports, or insulin delivery systems—devices placed in subcutaneous tissue that do not access the vascular system

Target Audience

These CPGs are intended for a broad, interdisciplinary audience of health professionals engaged in vascular access care. AVA's membership spans across many clinical disciplines, licensure levels, and care environments. These CPGs were developed to reflect that diversity. They are designed for individuals who assess, place, manage, maintain, or remove vascular access devices as well as those who contribute to vascular access policy, education, quality improvement, and research.

The primary users are vascular access specialists. However, these guidelines are relevant to all direct care clinicians,

educators, preceptors, infection preventionists, clinical administrators, quality improvement teams, and policy developers. These guidelines support clinical decision-making across various settings, including hospitals, long-term care facilities, ambulatory clinics, rehabilitation centers, home infusion programs, outpatient oncology units, emergency departments, and transport environments.

As an international organization, AVA recognizes the global need for practical and adaptable vascular access guidance. These guidelines are therefore intended to be broadly applicable while allowing for flexibility based on local scope of practice regulations, resource availability, and care infrastructure. Although every recommendation is grounded in evidence and clinical consensus, implementation must align with each clinician's licensure, regulatory authority, institutional policy, and professional competency.

This inclusive, practice-aware approach is a defining characteristic of the AVA guidelines. It represents a conscious effort to move beyond discipline-specific documents toward a more unified and collaborative model of vascular access care.

Guideline Development Process

The AVA CPGs were developed through a rigorous, multiphase process informed by recognized standards for trustworthy guideline development, including those established by the Institute of Medicine, the Conference on Guideline Standardization, and the Council of Medical Specialty Societies (CMSS). This process was designed to promote transparency, mitigate bias, and ensure the development of practical, evidence-based recommendations relevant to a broad range of healthcare professionals.

Development of the guidelines was led by the AVA Guideline Governance Group (GGG) and supported by multiple Guideline Development Teams (GDTs), composed of multidisciplinary volunteers with expertise in vascular access. The work was organized into 6 sections, later consolidated into 5 thematic content areas to reflect the full life cycle of vascular access devices, from administrative and infrastructure considerations, device planning and insertion through care, maintenance, complication management, and removal. For more information on the protocol, see PROSPERO or Sochor et al. (2024).^{1,2}

Dual Systematic Reviews

Two separate systematic reviews were conducted to support a robust evidence base. The first was initiated early in the project and informed the development of foundational topics. The second review became necessary to include the most up-to-date evidence available. Both systematic reviews were guided by structured population, intervention, comparison, outcome (PICO) questions and search strategies built collaboratively by each GDT. A contracted research librarian conducted a structured search strategy and retrieved titles and abstracts that were uploaded to AVA's collaborative research platform Rayyan.³ Once the articles for inclusion were established, the full texts were obtained for GDT appraisal.

Each article was appraised independently by 2 reviewers using the Johns Hopkins Evidence-Based Practice model.⁴ Scores for both level of evidence (I–V) and quality of evidence (A–C) were recorded, and discrepancies were resolved through expert analysis. A standardized Excel-based scoring system aggregated results to support transparent documentation. A PRISMA flow diagram summarizing identification, screening, and inclusion is provided (Figure 1).

In areas where evidence was limited or inconclusive, AVA elected not to issue consensus-based recommendations without sufficient justification. These topics have been deferred for potential inclusion in a future edition, following structured consensus methods to ensure integrity.

Stakeholder Involvement

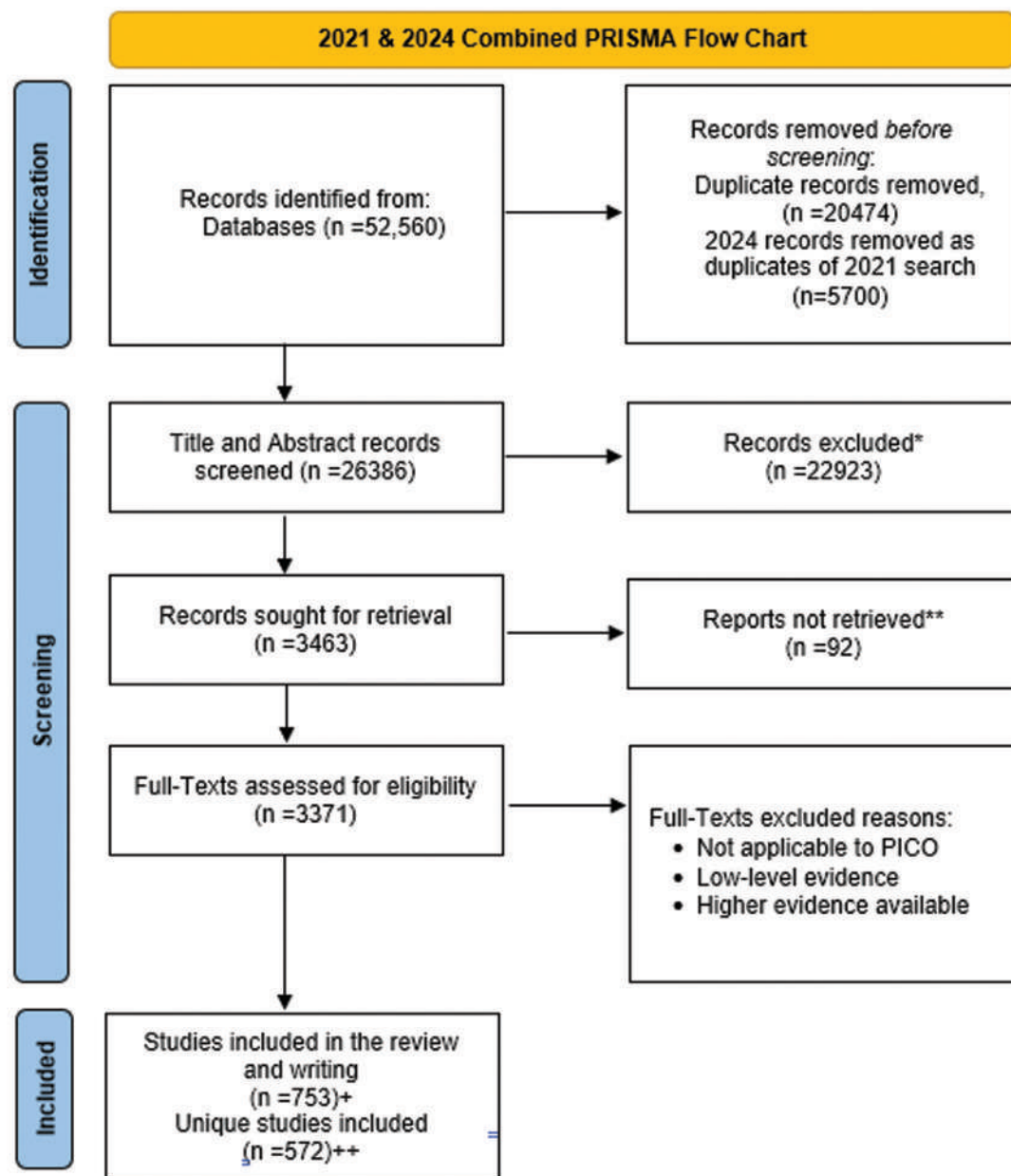
Recommendations were drafted by the GDTs by sections, supported by evidence summaries and structured rationales. These were reviewed internally by the GGG, with extensive feedback. After the consolidation of overlapping information across sections, the final division developed 5 themes. The recommendations were built from the GDT information, GGG feedback, and the included full-text articles. The document was then sent to an AVA internal review by the Clinical Review Team and revised and externally reviewed by independent reviewers and representatives from stakeholder organizations. The review process included advisory committee feedback, a public comment period, and final approval by the AVA Board of Directors before publication. Conflict of interest disclosures were collected and managed throughout the process in accordance with CMSS guidance.⁵

As part of AVA's commitment to transparency and continuous improvement, this inaugural guideline edition reflects both the depth of current evidence and the limitations inherent in real-world implementation. Recommendations requiring further consensus development or newly emerging evidence are being tracked for inclusion in a future update or supplemental publication.

While every effort was made to ensure comprehensive coverage of the evidence, time constraints limited the feasibility of applying formal consensus methods, such as the RAND/UCLA Modified Delphi technique, for all low-evidence topics. Rather than dilute the integrity of this inaugural edition with premature statements, some content areas that require structured expert consensus have been deferred. AVA intends to revisit these unresolved areas in a future supplement or second edition of the CPG, incorporating formal consensus processes to guide safe and clinically relevant recommendations. This iterative approach supports AVA's commitment to methodological rigor, transparency, and continuous improvement.

Conflict of Interest Disclosure and Independence

All authors, editors, and contributors to the AVA guidelines disclosed relevant financial and intellectual interests. Many practicing clinicians engage in research, education, or consulting with health care companies because of their expertise in vascular access. These disclosures are published in full within



* Wrong: population, device, publication type. Non-English translation.

** Bad URL, retracted publications, non-English (other than the abstract).

+ Across all 6 sections.

++ With duplicates across all sections removed.

Figure 1. PRISMA flow chart.

this document. No industry funding was accepted for the development or review of these guidelines.

To uphold independence:

- No single voice or external entity influenced the final recommendations.
- All conflicts of interest were reviewed and managed prior to participation and at the time of this publication.

This approach balances the need for expert input with the responsibility to minimize bias and maintain public trust.

Guideline Users' Responsibilities

These CPGs are intended to support, not replace, professional judgment. While AVA has made every effort to synthesize the best available evidence and present clear, actionable recommendations, applying these recommendations must be guided by the clinician's licensure, training, clinical context, and the resources available in their facility or region.

Ethical Responsibilities

Vascular access practice varies significantly across countries, regulatory frameworks, and health systems. Most AVA mem-

bers practice in the United States, but AVA is an international organization, and these guidelines are designed to be relevant across diverse models of care. Local laws, scope-of-practice regulations, and institutional policies must always be considered when interpreting and applying the recommendations in this document. A strategy that is appropriate and legally permissible for one clinician or setting may be restricted or delegated differently in another setting.

Clinicians are also expected to remain within the bounds of their professional role and training. These guidelines are intended to inform a wide range of users, including advanced practice providers, physicians, direct care clinicians, and specialists in radiology, infusion therapy, or respiratory therapy. No single recommendation should be interpreted as a license to perform procedures beyond one's defined scope of practice. Interprofessional collaboration is essential when scope boundaries are unclear or overlap to ensure patient safety and appropriate care.

Innovation and evidence development continue even as this edition goes to publication. Clinicians are encouraged to critically appraise and responsibly apply emerging practices, particularly when supported by institutional review, expert consensus, or early data. While not all promising techniques may yet meet the evidentiary threshold for inclusion in the guideline, AVA supports the safe, ethical exploration of novel approaches that serve patients well.

Informed Consent

While these guidelines emphasize evidence-based practice, AVA recognizes that many aspects of ethical care extend beyond what can be graded or cited. Actions such as seeking informed consent, maintaining professional integrity, and respecting patient autonomy are core responsibilities that should guide every aspect of vascular access care.

Because legal requirements and documentation expectations vary across regions, licensure types, and health care systems, this guideline does not prescribe a universal consent format. However, clinicians are expected to ensure that patients, or their authorized representatives, are provided with understandable information about the risks, benefits, and available alternatives for vascular access procedures. This process should be culturally sensitive, tailored to the patient's level of understanding, and documented in alignment with institutional policy and applicable regulations.

While a PIVC may not require the same level of formal consent as a TIVAD, the principle remains: Patients have the right to understand and participate in decisions about their care. The form of consent—verbal, implied, or written—should be matched to the procedure's invasiveness, complexity, and the patient's circumstances.

At times, the language used in this guideline, such as “it may be beneficial to...” or “it is advised to...” reflects limitations in the published evidence, not a lack of ethical or professional weight. AVA encourages clinicians to interpret these recommendations considering their training, scope of practice, and obligation to deliver ethically sound, patient-centered care.

Future Updates and Review

As the inaugural edition of the AVA CPGs, this document represents a significant step toward unifying vascular access practice under a transparent, evidence-informed framework. However, as with any guideline, it reflects the best available evidence identified through PICO-informed search strategies conducted from 2021 through February 2024.

These guidelines will be reviewed on a rolling basis, with updates issued in response to significant new evidence, evolving technologies, or shifts in regulatory or clinical practice standards. A formal supplemental publication or compendium is anticipated approximately 12 to 18 months after release to address content areas that were deferred in this edition due to time constraints, particularly those requiring structured consensus processes, including the RAND/UCLA Appropriateness Method, a validated modification of the Delphi technique developed by the RAND Corporation and the University of California, Los Angeles. These deferred topics represent important clinical concerns that lacked sufficient high-level evidence for inclusion at the time of publication but are under continued review.

A full second edition of the guidelines is planned within 3 to 4 years. That future edition will revisit all sections, integrate new findings, and evaluate the uptake and implementation of current recommendations across practice settings.

Clinicians are encouraged not only to use these guidelines but also to actively engage in the critical appraisal of emerging research. Systematic reviews, while rigorous, are inherently selective; they are bound by time frames, search strategies, and inclusion criteria that may exclude promising new or early-stage findings. It is the responsibility of health care professionals to remain attentive to new, credible data, especially when it may address previously unanswerable questions, introduce safer techniques, or refine current practices.

Perhaps most importantly, this inaugural edition highlights the ongoing need for high-quality vascular access research. Randomized controlled trials, quasiexperimental studies, and systematic reviews are in short supply relative to the scope and impact of vascular access on patient outcomes and health care systems. AVA strongly encourages researchers, funders, academic centers, and industry collaborators to prioritize vascular access science to advance the next edition of these guidelines and improve the everyday realities of patient care.

These guidelines are a starting point, not a stopping point. AVA will continue to lead, listen, and evolve with the evidence.

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Section 1: Infrastructure, Teams, & Clinical Foundations

Chapter 1.1—Vascular Access Teams and Roles

Vascular access teams (VATs) are critical in enhancing the safety, efficiency, and cost-effectiveness of vascular access device (VAD) management across health care settings. Through standardized best practices and specialized expertise in insertion and maintenance, VATs reduce complications such as central line–associated bloodstream infections (CLABSIs) and peripheral intravenous (IV) catheter failures. These improvements contribute to improved patient safety, timely care delivery, and lower health care expenditures.

The integration of VATs is supported by consistent evidence demonstrating both clinical and operational value. A growing body of observational and quasiexperimental studies has shown that, in high-acuity environments such as emergency departments and intensive care units (ICUs), VATs improve patient flow, optimize resource use, and reduce the incidence of preventable complications. Their presence enhances procedural accuracy, advances staff education, and aligns with institutional priorities for quality, safety, and value-based care.

Evidence has also shown that ultrasound-trained VATs are more successful during challenging insertions, minimizing patient discomfort and delays. In addition, VATs provide a framework for mentoring and supporting other clinicians, strengthening organizational capacity for safe vascular access.

Recommendation 1: Dedicated VATs

Health care organizations may consider establishing dedicated VATs to reduce complications related to VADs. VATs improve patient safety, reduce unnecessary device use, and contribute to cost-effective care.

Summary of Evidence

Dedicated VATs have been shown to significantly reduce central line use, CLABSI rates, and peripheral IV failure when compared with care provided by general staff.^{1,2(IIIb, IIIb)} Implementation of these teams is associated with measurable cost savings and alignment with infection prevention standards.^{3,4(IIIb, IIIb)} In 1 cost-benefit analysis of a tertiary hospital's VAT, substantial financial benefits were reported.^{3(IIIb)} Authors of 1 study found expert inserters had better insertion outcomes than generalists, while authors of observational studies noted reduced reattempts and complications.^{2,4(IIIb, IIIb)}

Recommendation 2: High-Demand VAT Coverage

It is likely beneficial to prioritize VAT coverage in high-demand departments where streamlined workflows, timely device placement, and optimized resource use are essential for patient safety and throughput.

Summary of Evidence

In high-volume or resource-constrained environments, dedicated VATs have been shown to reduce procedure time, minimize repeat attempts, and improve clinical workflow.^{5–8(IIIa, IIIb, IIa, IIIb)} In 1 emergency department study, VAT implementation reduced IV diagnostic wait times by over 100 minutes.^{5(IIIa)} In middle-resource countries, VATs decreased repeated procedures, improving efficiency.^{6(IIIb)} Ultrasound-trained VATs were also more successful under challenging insertions, minimizing patient discomfort and delays.^{7(IIa)} Authors of a recent US study confirmed these findings and highlighted the workflow optimization VATs provide in large institutions.^{8(IIIb)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Patient safety, reduction in infection rates, and other complications due to VAT expertise.^{1,8}
- Financial savings, decreased costs from fewer complications and reduced hospital stay durations.⁵
- Operational efficiency, improved resource allocation and patient throughput, particularly in high-demand settings.^{7,8}

Risks

- Initial costs, upfront costs for establishing and training VATs, though long-term savings offset these.^{2,5,6}
- Integration challenges, potential resistance to incorporating VATs within existing workflows.⁸

- Strategic departmental deployment, prioritize VAT implementation in high-demand departments, such as emergency and ICU, where procedural efficiency and patient throughput are crucial.^{2,3,5}
- Performance monitoring and quality improvement, regularly track VAT performance, including infection rates, cost savings, and procedural success, to demonstrate return on investment and continuously improve VAT services.^{4,8}

Barriers to Implementation

- Financial barriers, initial training and equipment costs may pose challenges for some institutions, but long-term cost savings outweigh these.^{2,6}
- Resistance to workflow adjustments, integrating VATs into existing workflows may face initial resistance, requiring consistent communication of their value to patient safety and operational efficiency.^{4,7}

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Chapter 1.2—Interprofessional Rounding

Interprofessional rounding is a cornerstone of safe and effective vascular access device (VAD) management. Regular, structured rounds conducted by a multidisciplinary team, including vascular access specialists, direct-care clinicians, physicians, infection preventionists, and pharmacists, enable early recognition of complications and timely intervention to optimize patient outcomes.

These rounds provide a structured forum for collaborative decision-making on catheter necessity, site condition, securement integrity, and adherence to maintenance protocols. They also reinforce infection prevention practices such as insertion bundles, hand hygiene, and maintaining a closed system. When concerns arise, interprofessional rounding facilitates escalation, coordination of catheter removal, and selection of appropriate alternatives.

Embedding vascular access into routine rounding strengthens care coordination, reduces preventable harm, and promotes adherence to evidence-based practices. This proactive, team-based approach ensures that VADs remain appropriate, functional, and safe throughout therapy, while supporting education, accountability, and shared responsibility across disciplines.

Recommendation 1: Composition of Rounding Teams

Organizations should implement interprofessional rounding teams that include vascular access specialists, direct-care clinicians, physicians, pharmacists, and infection preventionists. The diverse expertise of these disciplines facilitates comprehensive catheter assessment, informed decision-making, and the timely identification of vascular access-related concerns.

Summary of Evidence

Collaborative rounding structures support better vascular access outcomes through team-based review of device necessity, site integrity, and maintenance compliance. A systematic review found that central line-associated bloodstream infection (CLABSI) rates are often underreported due to inconsistent surveillance, emphasizing the value of team audits and collaborative oversight.^{1(IIb)} Similarly, a Spanish hospital's infection prevention initiative, combining staff education, team-based surveillance, and creation of a catheter infection team, achieved a multiyear decline in peripheral intravenous catheter (PIVC) bloodstream infection (BSI) rates, particularly for Gram-negative infections.^{2(IIIb)}

Recommendation 2: Rounding Functions and Quality Improvement

Interprofessional rounding teams may use structured tools, audit data, and real-time observation to evaluate catheter condition, ensure protocol compliance, and escalate concerns when necessary. Rounding may serve as an optional strategy to guide targeted education and support quality improvement initiatives to reduce complications and optimize device performance.

Summary of Evidence

Rounding teams that incorporate structured assessment tools and direct observation have demonstrated improved adherence to best practices. A quality improvement project used collaborative rounds and audit-informed education to identify and address unit-specific deficiencies.^{3(Vb)} In intensive care unit settings, Buetti et al. showed that local signs of inflammation at the insertion site during early catheter maintenance were strongly associated with catheter-related BSI (CRBSI), highlighting the importance of routine, structured evaluation to catch early warning signs.^{4(IIIa)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Improved infection outcomes: Multidisciplinary rounds and active surveillance programs significantly reduced peripheral venous catheter-associated BSIs rates over time, particularly for Gram-negative infections.²
- Better data accuracy and benchmarking: Collaborative audits and targeted education improve the accuracy of CRBSI surveillance data, making it more valid for benchmarking and quality improvement.¹

Risks

- Underreporting of CRBSI cases: Nationally reported rates may underestimate the true CRBSI incidence, potentially delaying recognition of systemic issues.¹
- Overreliance on visual cues: CRBSI risk may be underestimated if clinical decisions are based solely on absence of local signs, despite their established association with early infection.^{4,5}

Implementation Considerations

- Use of standardized tools: Incorporating tools like I-DECIDED facilitates structured decision-making for catheter assessments and supports consistent practice across teams.⁶
- Nursing leadership roles: Embedding specialty nursing roles in collaborative rounds enhances consistency in audit feedback and enables unit-specific education.³

Barriers to Implementation

- Resource limitations for audits and rounds: Conducting regular interdisciplinary rounds requires time and personnel, which may not be available in under-resourced settings.⁶
- Variability in adherence across units: Differences in engagement levels or training across departments may limit the consistency and impact of multi-disciplinary rounds.³

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Chapter 1.3—Infection Prevention Infrastructure

A strong infection prevention infrastructure is fundamental to the safe management of vascular access devices (VADs) and the reduction of health care-associated infections. Complications such as central line–associated bloodstream infections (CLABSI), catheter-related bloodstream infections (CRBSIs), and local site infections contribute to increased morbidity, prolonged hospitalization, and higher health care costs.

Effective prevention requires more than adherence to individual clinical practices; it demands a coordinated, system-wide approach. Institutional policies, interdisciplinary collaboration, and environmental readiness must align to create a framework that consistently supports infection prevention.

Embedding infection prevention principles into organizational culture and daily workflow reduces variation, strengthens patient safety, and improves outcomes. A well-structured infrastructure minimizes complications, fosters accountability, and promotes efficiency. In addition, it provides the foundation for sustainable excellence in vascular access practice and supports continuous quality improvement across all care environments.

Recommendation 1: Vascular Access Team to Reduce Infection

Administrators may consider implementing a vascular access specialist team as part of a comprehensive strategy to reduce CLABSI.

Summary of Evidence

Implementing a vascular access team (VAT) using evidence-based insertion and maintenance protocols has significantly reduced CLABSI. In 1 quality improvement initiative, creating a VAT resulted in a 45.2% reduction in central line use and a 90% reduction in CLABSI incidence.^{1(IIIb)} A second hospital-based retrospective analysis showed that, after launching a dedicated vascular access service, CLABSI rates fell from 1.75 to 1.037 infections per 1000 catheter days, a 58% reduction. These findings suggest that VAD specialist teams contribute to decreased device overuse and lower infection risk through protocol adherence and improved insertion and maintenance practices.^{2(IIIa)}

Recommendation 2: Targeted Infection Prevention

Health care organizations may consider implementing vascular access–specific infection surveillance programs and risk prediction tools to proactively identify high-risk patients, reduce complications, and health care costs.

Summary of Evidence

Targeted surveillance and predictive modeling are essential tools for improving vascular access outcomes. In a large cohort study, researchers found a 3.7% incidence of CRBSI following emergency department insertions, with CRBSI independently associated with in-hospital mortality.^{3(IIIb)} Risk increased with total parenteral nutrition and multiple insertion attempts, supporting the need for early identification of high-risk patients.^{3(IIIb)}

Zhu et al. developed a validated predictive model for peripherally inserted central catheter occlusion in critical care patients, identifying factors such as age ≥ 65 , obesity, malignancy, blood transfusion, and parenteral nutrition as independent risks.^{4(IIIa)} Frequent catheter flushing was protective. The model demonstrated strong predictive accuracy, enabling proactive risk stratification at the time of line placement.^{4(IIIa)}

Additionally, Yu et al. showed that expanding surveillance from CLABSI to hospital-onset bacteremia and fungemia (HOB) more effectively captured bloodstream infections that are associated with significantly longer hospital stays, increased costs, and higher mortality.^{5(IIIb)} These findings support broader, risk-adjusted electronic surveillance strategies.

Together, the results of these studies reinforce the value of infection surveillance programs and predictive tools in identifying high-risk patients, guiding preventive interventions, and reducing complications and costs.

Recommendation 3: Hand Hygiene Before All VAD Procedures

Clinicians must perform hand hygiene immediately before, as required during, and after any VAD procedures using either an alcohol-based hand rub (use per the manufacturer's instructions) or antimicrobial soap and water. This requirement is based on universally accepted infection-prevention standards rather than the strength of individual study designs. Hand hygiene is essential even when gloves are worn and is a foundational component of vascular access infection prevention.

Summary of Evidence

Hand hygiene immediately before VAD procedures is essential to reducing extraluminal contamination and subsequent bloodstream infections. The most common mechanism of CLABSI involves microbial transfer from the inserter's hands or the patient's skin at the time of insertion.^{6(Vb)}

Alcohol-based hand rubs are preferred for hand decontamination unless hands are visibly soiled, in which case antimicrobial soap and water are recommended.^{7(IVa)} Authors of multiple implementation studies have shown that improved hand hygiene adherence is consistently associated with reduced CLABSI incidence.^{6(Vb)} As part of a broader insertion protocol, hand hygiene remains a nonnegotiable, evidence-based practice to reduce vascular access complications.

Recommendation 4: Integrate Hand Hygiene into Personal Protective Equipment (PPE) Workflow

Hand hygiene must be performed:

- before donning PPE;
- immediately, if hands become contaminated during PPE removal;
- immediately after removing PPE; and
- before exiting the patient care environment.

Hand hygiene should be explicitly integrated into all vascular access insertion bundles and reinforced as part of routine clinical workflow.

Summary of Evidence

Hand hygiene is a cornerstone of infection prevention and must be embedded within vascular access workflows to minimize transmission of pathogenic organisms. Authors of observational studies and infection surveillance data have consistently shown that missed or improperly timed hand hygiene contributes to contamination and increases the risk of vascular access-related infections.^{6,8(Vb, IIIb)}

Guidelines recommend hand hygiene before donning PPE, when hands are contaminated during PPE removal, immediately after removal, and before exiting the patient care area. These steps are particularly critical during invasive procedures like VAD insertion. Integration into insertion bundles, staff education, and audit-feedback mechanisms has improved compliance and reduced infection rates in intensive care unit (ICU) and non-ICU settings.^{6–8(Vb, IVa, IIIb)}

Recommendation 5: Aseptic Technique with Totally Implanted VADs

Health care providers must follow strict aseptic technique during all needle insertions, maintenance, and needle removal of totally implanted VADs (TIVADs) to reduce the risk of HOB and other serious infections.

Summary of Evidence

Aseptic technique, including proper hand hygiene, sterile field setup, skin antisepsis with alcohol-based chlorhexidine gluconate (CHG) solution, and noncoring needles, is foundational to infection prevention. Evidence has supported dressing and needle changes at 7-day intervals when TIVADs are accessed continuously, aligning with best practices to minimize infection risk.^{9(IIIb)} Implementation of structured care bundles has led to significant improvements in maintenance practices and measurable reductions in port-related infections. For example, in a quality improvement project, the introduction of a TIVAD care bundle reduced CLABSI events from 3 to 0 in the study population, while increasing staff compliance with aseptic steps such as dual verification, nontouch technique, and site monitoring.^{10(IIIb)}

Additional practice guidance from the Oncology Nursing Society (ONS) has emphasized CHG skin prep, appropriate dressing materials, and clinical judgment regarding mask and glove use, while affirming that weekly needle and dressing changes are safe and evidence aligned.^{11(Vb)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Reduction in CRBSIs: Using standardized checklists, procedural bundles, and sterile procedural packs, organi-

zations can reduce contamination and the risk of CRBSIs while promoting consistent adherence to evidence-based practices.^{12–15}

- Improved workflow and clinician adherence: Procedural packs enhance efficiency and adherence to infection control protocols.¹⁶
- Institutional cost savings: Standardized packs reduce complications and unnecessary material use, thereby reducing length of stay and need for additional care.^{12,13,16–21}

Risks

- Initial implementation costs: Implementation of procedural kits and training requires upfront investment.²²
- Resistance to change: Staff may resist changing familiar workflows, while clinician habits may hinder adherence to new infection control practices; the integration of predictive tools and staff training can increase the initial workload, potentially impacting implementation efforts.^{4,6,17,22–24}
- Overdependence on kits: May reduce clinical flexibility in unique cases.¹⁶

Implementation Considerations

- Training and competency validation: Hands-on training, competency assessments with periodic refreshers, and aseptic nontouch technique (ANTT®) education are essential.^{12,13,16}
- Policy development and institutional support: Institutional policies should mandate the use of standardized procedural packs to reduce infection risk, with strong leadership support playing a critical role in ensuring successful implementation, while collaboration across departments ensures consistency and success.^{12,13,16,17,20,24–27}
- Electronic health record integration and surveillance tools: Tracking catheter dwell times, infections, and flush reminders, alongside the use of risk assessment tools for catheter selection and infection risk mitigation, supports data-driven decision-making and enhances patient safety.^{28–34}

Barriers to Implementation

- Limited budget allocation: Institutions may struggle to secure upfront funds for purchasing standardized kits, antimicrobial products, or supporting information technology infrastructure for checklist integration.¹²
- Variability in adherence across different hospital units.^{18,25}
- Resistance to practice change among health care providers.^{18,25,26,35}

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Chapter 1.4—Policies, Procedures & Protocols

Vascular access devices (VADs) are integral to modern health care, providing reliable routes for medications, fluids, nutrition, and blood sampling. However, when improperly selected, placed, or maintained, these devices carry significant risks, including central line–associated bloodstream infections, phlebitis, malposition, and premature device failure. Such complications increase morbidity, lengthen hospital stays, and raise health care costs.

To mitigate these risks, health care organizations must establish and adhere to clear clinical governance which include evidence-based policies, procedures, and protocols. Regularly updated guidance supports clinical competency, standardizes practice, and ensures alignment with evolving research, professional standards, and regulatory requirements.

A structured framework that emphasizes thorough documentation, consistent training, and routine evaluation promotes accountability across teams and fosters a culture of reliability. By embedding policies and protocols into daily workflows, institutions strengthen patient safety, sustain high-quality vascular access practice, and improve system-wide efficiency.

Recommendation 1: Directed Use of Kits

Health care institutions should establish and enforce policies directing the use of standardized kits and procedure trays to improve adherence to aseptic technique and reduce variability in clinical practice.

Summary of Evidence

Standardized kits and procedure trays reduce infection risk and improve adherence to aseptic technique by ensuring essential supplies are consistently available and used correctly. Authors of a quality improvement (QI) study showed that implementing a tailored peripheral cannulation pack aligned with aseptic nontouch technique (ANTT[®]) significantly improved equipment handling, reduced contamination, and enhanced

technique compliance.^{1(Ia)} Similarly, in a mixed-method randomized controlled trial and usability study, Santos-Costa et al. found that implementing a preassembled peripheral intravenous catheter (PIVC) kit significantly reduced procedural time and material omissions while promoting uniformity in practice. When the kit was used, nurses reported increased satisfaction, improved infection control, and greater ease in managing supplies.^{2(Ib)}

Recommendation 2: Clinical Governance for VADs

Health care organizations should develop evidence-based vascular access clinical governance that addresses insertion, maintenance, troubleshooting, and complication prevention. This governance must be interdisciplinary, incorporating input from vascular access specialists, infection preventionists, and direct care clinicians to ensure safe and practical application.

Summary of Evidence

Evidence has supported the development of multidisciplinary, evidence-based vascular access policies to improve clinical consistency and patient outcomes. Clinical governance aligned with national guidelines and built with input from vascular access specialists and infection preventionists improve documentation, standardize procedures, and support competency-based credentialing.^{3–8(Ib, IVb, IIb, IIIb, Vb, Ia)} Authors of studies have shown that such operational management will reduce complications, enhance surveillance, and bridge the gap between best practice and clinical behavior.

Recommendation 3: Structured Audits

It is recommended that health care organizations consider implementing structured audits, checklist-based reviews, and performance feedback loops to assess compliance with vascular access care policies, identify practice gaps, and guide continuous QI efforts.

Summary of Evidence

Routine evaluation strategies such as audits, checklists, and feedback loops have been shown to improve compliance with vascular access protocols and support safer practices. A prospective audit using the Plastic-in-Patient tool improved documentation and early removal of nonindicated PIVCs.^{5(IIIb)} Audit-driven feedback and education significantly increased adherence to peripherally inserted central catheter best practices in a unit specific implementation project.^{9(IIIb)} Similarly, a multidisciplinary QI initiative linked clinician feedback with protocol adherence to support safer peripheral administration of 3% sodium chloride.^{6(IIIb)}

Recommendations 4: Clinical Governance Updating

It is recommended that health care institutions regularly review and update vascular access clinical governance in response to emerging evidence, evolving clinical standards, and new technologies. Involving frontline clinicians in the update process may improve relevance and facilitate implementation.

Summary of Evidence

Ongoing operational management evaluation is essential to ensure alignment with current standards and technologies. A QI project by Hade et al. demonstrated that updating central venous access device insertion checklists improved documentation and reduced malposition rates.^{10(Vb)} Barsuk et al. emphasized that simulation-based mastery standards evolve over time and should inform institutional guidelines and competency policies.^{11(IIIa)} Spina et al. underscored the importance of national alignment with international vascular access standards and recommended incorporating innovations like electrocardiogram navigation and simulation training into policy frameworks.^{12(IVb)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- **Reduced Infection Risks:**
 - Standardized procedural packs support adherence to ANTT, helping reduce catheter-related bloodstream infections and contamination.^{1,13}
 - Evidence-based procedural enhancements, including standardized protocols and accurate documentation practices, help decrease infection rates.^{7,14,15}
- **Improved Workflow and Standardization:**
 - Prepackaged sterile materials eliminate the need to gather individual components, streamline setup, and reduce variability and procedural errors.^{1,13}
 - Protocol-driven site selection, catheter sizing, and documentation reduce variability and improve care consistency.^{5,8}

- **Increased Clinician Confidence and Patient Satisfaction:**
 - Nurses report greater confidence and ease of use with standardized packs, while patients benefit from shorter procedures and fewer complications.²
 - Standardized procedural guidelines enhance adherence to best practices and improve patient outcomes.¹⁰
- **Cost Savings and Resource Optimization:**
 - Standardized packs use only necessary materials, prevent overuse, and reduce complications, resulting in institutional cost savings.^{1,2,13}
 - Fewer complications reduce the need for catheter re-placements and readmissions, translating to lower overall health care costs.^{8,10}

Risks

- **Upfront Costs and Training Requirements:**
 - Transitioning to standardized procedural packs requires initial investment in supplies and clinician training.³
 - Increased documentation and the need for procedural training can raise initial implementation costs.⁵
- **Resistance to Change:**
 - Staff accustomed to previous workflows may resist adopting procedural packs.^{1,13}
 - Clinicians may push back on added administrative tasks or alterations to familiar workflows.^{5,8}
- **Limited Flexibility in Complex Cases:**
 - Overdependence on kits may reduce adaptability; some kits may not suit every clinical scenario.^{1,2}
- **Environmental and Supply Chain Concerns:**
 - Increased use of single-use items contributes to medical waste. Supply chain disruptions could impact kit availability.^{1,2}

Implementation Considerations

- **Staff Education and Competency Validation:**
 - Conduct hands-on training sessions on procedural packs and ANTT principles, with competency assessments to reinforce best practices.^{1,13}
 - Conduct mandatory training on ultrasound-guided vascular access, site selection, and risk-based practices.⁷
- **Institutional Policy Alignment and Leadership Support:**
 - Develop policies mandating procedural packs aligned with infection control standards. Secure leadership and stakeholder support.^{1,2}
 - Establish policies supporting structured documentation and imaging to guide vascular access.^{8,11}
- **Customization and Flexibility:**
 - Ensure packs are adaptable for different patient needs and care settings, such as emergency departments or difficult intravenous access cases.^{2,16}
 - Tailor implementation to unit needs with support from interdisciplinary teams, ensuring flexibility in integration.^{5,17}

- Continuous QI:
 - Monitor adherence and outcomes, gather clinician feedback to refine pack contents, and conduct periodic audits to sustain compliance.^{1,13,16}
 - Leverage electronic health records (EHRs) to track complications, document outcomes, and monitor adherence.¹⁰

Barriers to Implementation

- Lack of Policy Visibility:
 - Staff may be unaware of updated protocols or may not know where to access them.^{1,2}
- Resistance to Standardization:
 - Clinicians may prefer personalized practices over rigid protocols, especially in complex or high-pressure environments.⁷
- Variable Enforcement:
 - Without consistent auditing or leadership oversight, protocol adherence may vary across shifts or units.⁷
- EHR Integration Gaps:
 - Policies not embedded into clinical documentation or decision-making tools may be bypassed during care delivery.¹⁰

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Chapter 1.5—Education & Competency

Safe and effective vascular access procedures depend on clinician knowledge, technical skill, and ongoing competency. Insufficient training or reliance on outdated practices can lead to complications such as infection, occlusion, dislodgement, or device failure, which increases patient risk and health care costs.

Structured education and competency programs are essential for reducing variation in practice and improving outcomes. Simulation-based training, peer-to-peer learning, and formal certification pathways enhance procedural proficiency, support risk-informed decision-making, and reduce complication rates.

Ongoing competency assessment ensures clinicians remain aligned with evolving techniques, technologies, and evidence-based standards. By incorporating multidisciplinary perspectives, competency programs foster collaboration across nursing, medicine, and allied health disciplines. This sustained approach strengthens clinical judgment, supports safe device selection and care, and advances the overall quality of vascular access practice.

Recommendation 1: Initial and Ongoing Competency

It is recommended that vascular access clinicians complete initial and ongoing competency training that incorporates patient-specific factors and promotes individualized, risk-based catheter selection and maintenance strategies.

Summary of Evidence

Ongoing competency training that includes patient-specific considerations is associated with improved catheter outcomes. In a large cohort study, structured ultrasound-guided internal jugular catheter insertion training yielded a 99.3% first-attempt success rate and a low complication rate (3.4%), reinforcing the value of hands-on procedural competency.^{1(IIIb)} Authors of another study reported that adverse event rates were significantly lower with totally implanted vascular access devices (TIVADs) than with peripherally inserted central catheters (PICCs), particularly when clinicians factored in patient comorbidities and anatomy during device selection. This suggests the importance of individualized, evidence-based decision-making in reducing complications.^{2(Ia)}

Recommendation 2: Competency in Complication Recognition

Vascular access clinicians must complete initial and ongoing competency training that includes recognition and management of complications, including catheter-related infections and air embolism, using simulation-based scenarios and structured evaluation.

Summary of Evidence

Simulation-based and structured competency training enhances clinician preparedness for vascular access emergencies. Brull et al. described the lethal consequences of vascular air embolism and advocate for simulation and protocolized team

response to reduce harm.^{3(Vb)} Redstone et al. showed that a structured, system-wide competency framework, including standardized insertion checklists, training refreshers, and peer audits, reduced central line–associated bloodstream infection (CLABSI) rates by over 50% in a multisite health system.^{4(IIIb)} Garcés-Carrasco et al. found that PICC-related complications during stem cell transplantation were no greater in patients treated at home than in the hospital, provided caregivers and patients received structured catheter care education.^{5(IIIb)} These findings support the role of competency-based education as a critical strategy for minimizing vascular access complications.

Recommendation 3: Clinician Insertion Training

Vascular access clinicians should be trained in ultrasound guidance, relevant anatomy, and device selection techniques to ensure accurate placement and reduce insertion-related complications.

Summary of Evidence

Competency in ultrasound guidance and anatomical visualization is essential to safe and effective vascular access. Yu et al. conducted a multicenter study of 433 adult patients receiving ultrasound-guided TIVADs via the brachiocephalic vein, reporting a 94.9% first-attempt success rate and a 6.2% overall complication rate, confirming the technique's reliability and safety.⁶ Redstone et al. demonstrated that clinician training in insertion technique, including ultrasound guidance, contributed to a 51% reduction in CLABSI across a health system.^{4(IIIb)} Appropriate training must include technical use of the ultrasound machine and in-depth knowledge of vascular anatomy, procedural technique, and complications such as inadvertent thoracic duct injury or catheter malposition.^{6(IIIb)} Zhou et al. analyzed over 1500 patients and found that thrombosis risk increases with catheter duration and mechanical vessel injury, which can be minimized through anatomically informed ultrasound-guided access.^{7(IIIb)}

Recommendation 4: National Certification

Organizations should promote initial and ongoing national certification for vascular access clinicians to support clinical proficiency, evidence-based practice, and improved patient outcomes.

Summary of Evidence

Knowledge-based national certification in vascular access is associated with improved clinical performance, reduced complication rates, and greater adherence to evidence-based practices. Certified clinicians report more experience, are more likely to hold leadership roles, and consistently apply best practices such as ultrasound-guided insertion and catheter-to-vessel ratio assessment.^{8,9(IIIb, IIIb)}

Structured competency-based programs incorporating simulation and hands-on deliberate practice improve procedural skills and reduce errors. Corvetto et al. found that residents who completed simulation-based training had significantly

improved technical performance and reduced catheter insertion time.^{10,11(IIb, IIb)} Ongoing certification and recertification also play a critical role in maintaining proficiency. Clinical assessment requirements and recent practice directly influenced competency in vascular access procedures.^{12,13(IIIb, Ia)}

Recommendation 5: Periodic Competency Assessments

Structured competency evaluations must be conducted at least annually for all clinicians involved in vascular access care, and semiannually for those performing high-risk procedures such as central venous catheter insertion. These assessments should incorporate validated tools, simulation-based methods, and performance feedback mechanisms to ensure ongoing proficiency and patient safety.

Summary of Evidence

Evidence demonstrates that periodic competency assessments, especially those using simulation and video-based feedback, help maintain clinician proficiency, improve adherence to aseptic technique, and reduce procedural complications. Authors of 1 study emphasized that procedural exposure alone does not guarantee competence, highlighting the need for structured evaluations.^{14(IIa)} Authors of another study showed video-enhanced feedback supports long-term skill retention, while those of a third study reported that repeated assessment improves procedural success during ultrasound-guided catheter placement.^{15,16(IIa, IIa)}

Recommendation 6: Multidisciplinary Competency Program Development

Facilities should implement vascular access competency programs developed through multidisciplinary collaboration among licensed independent practitioners, direct care clinicians, and educators. These programs must address insertion, care, and maintenance competencies across disciplines to reduce complications, enhance decision-making, and promote standardized best practices.

Summary of Evidence

A multidisciplinary approach to vascular access education and competency development has been associated with improved adherence to guidelines, greater standardization of care, and reduced complications. Keogh et al. demonstrated improved outcomes following the implementation of guideline-based vascular access practices.^{13(Ia)} Authors of another study emphasized that the roles and collaboration of direct care clinicians, physicians, and educators influence appropriate vascular access device use.^{9(IIIb)} Survey data have also revealed gaps in clinician awareness and training regarding catheter dislodgement risks and securement strategies, reinforcing the need for interprofessional education and structured monitoring processes.^{17–19(IIIb, IIIb, IIIb)}

Recommendation 7: Comprehensive Competency Program

Vascular access competency programs should incorporate simulation-based training, peer-assisted learning, structured

video feedback, and performance-tracking systems to ensure clinician readiness, promote skill retention, and address performance deficiencies. These components form the foundation of a rigorous, evidence-informed approach to vascular access education.

Summary of Evidence

Simulation-based training has consistently demonstrated improvements in procedural success and complication reduction, including up to an 85% decrease in CLABSI and arterial punctures.^{14,20(IIa, Ia)} Researchers have confirmed that peer-assisted learning methods are equally effective as instructor-led formats, enhancing procedural confidence and technical skill acquisition.^{21–23(IIa, IIa, IIa)} Video-based feedback further accelerates learning and improves performance consistency, making it a valuable adjunct to simulation in structured training programs.^{24(IIa)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- **Reduced infection risks:** Comprehensive training, including aseptic technique, catheter care, and standardized procedures, has been shown to reduce catheter-related bloodstream infections, while simulation-based education enhances adherence to evidence-based protocols and infection prevention standards. Additionally, instruction in securement and maintenance techniques supports reductions in dislodgement, malposition, and infection risk.^{10,25–29}
- **Improved access and safety:** Early difficult intravenous access recognition and ultrasound-guided training reduce delays and access attempts, while standardized documentation and maintenance minimize complications and enhance safety.^{30–37}
- **Support for accreditation and regulatory compliance:** Training supports institutional alignment with infection prevention guidelines and accreditation requirements, and consistent documentation practices improve quality reporting and legal defensibility.^{25,26,38,39}
- **Leadership development and professional growth:** Certification pathways and continuing education foster clinical leadership and mentorship roles.^{8,9}

Risks

- **Training fatigue or burnout:** Mandatory training and frequent reassessments may cause frustration or disengagement among clinicians.^{14,40}
- **Resistance to change:** Staff may be reluctant to shift from established practices or adopt new documentation and assessment protocols.^{13,25,26,41}

- Workflow disruptions: Time spent on training may temporarily reduce staffing availability or delay care delivery.^{14,15,36}

Implementation Considerations

- Staff education and competency: Implement structured training on aseptic nontouch technique, ultrasound guidance, catheter care, and documentation.^{1,13,25,26,30,32,35,42–47}
- Policy alignment and support: Align training with infection control policies, secure leadership support, and designate clinical champions to reinforce best practices.^{25,48,49}
- Sustained competency: Allocate funds for training, equipment, and certification, and establish regular recertification to maintain proficiency.^{25,48,49}
- Cross-disciplinary collaboration: Engage infection prevention, nursing, vascular access teams, radiology, and administration to co-develop and deliver training.^{38,39,45}

Barriers to Implementation

- Resource limitations: Simulation equipment, educator capacity, and physical training space may not be readily available.^{13,49}
- Time constraints: Competing clinical demands often limit staff availability for training or reassessment.^{14,15}
- Resistance to reassessment: Experienced clinicians may push back against mandatory competency validation.^{14,40}

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Chapter 1.6—Documentation

Documentation extends beyond regulatory compliance; it serves as the clinical narrative that guides decision-making, safeguards patient safety, and demonstrates the quality of care delivered. In vascular access, where risks are significant and outcomes hinge on precision, the written record is essential for continuity, accountability, and safety.

Clear, consistent documentation provides a roadmap for all members of the care team, detailing device selection, insertion site, function, and ongoing assessment. These records enable early recognition of complications, timely intervention, and seamless transitions across care settings.

At the organizational level, structured documentation supports quality improvement, adverse event reporting, and policy development. When performed thoroughly, it generates the data needed for institutional learning and system-wide safety initiatives. By embedding documentation standards into daily workflow, institutions strengthen patient care, advance infection prevention, and reinforce professional accountability.

Recommendation 1: Align Documentation Practices

Organizations are encouraged to standardize documentation for vascular access procedures and maintenance to reflect current evidence-based research and clinical guidelines, supporting consistency in care delivery, accurate data collection, and adherence to best practices across teams.

Summary of Evidence

Variations in procedural documentation can undermine clarity, introduce safety risks, and limit alignment with current standards.^{1(IIIa)} Researchers have shown that standardizing documentation based on best available evidence improves care consistency and enhances team learning.^{2,3(Vb, Va)} Patient-reported outcome frameworks and safety education models like quality and safety education for nurses further support documentation as a driver of quality improvement and safer infusion therapy.^{3(Va)}

Recommendation 2: Integrate Documentation into the Electronic Health Record

Electronic health records (EHRs) should include standardized documentation templates for vascular access procedures. These templates must be developed with input from vascular access specialists to ensure relevant data fields are consistently captured.

Summary of Evidence

Standardized EHR templates improve the completeness and clarity of documentation, promote interdisciplinary communication, and support quality monitoring. Authors of a study of central venous catheter templates demonstrated an increase in documentation completeness from 38% to 93%.^{4(IIa)} Templates developed without input from vascular access clinicians often lack critical data fields such as procedural technique, tip verification, or post-procedural care, limiting their value for tracking complications and evaluating performance.

Recommendation 3: Documentation of Adverse Events

Health care institutions are encouraged to implement structured templates and protocols for documenting adverse events related to vascular access devices (VADs). Documentation should include event details, immediate response, corrective actions, and any care plan modifications.

Summary of Evidence

Underreporting of catheter-related complications is common: Authors of 1 study found that only 1.6% were captured in formal adverse event systems.^{5(IIIb)} Standardized documentation can uncover the true incidence of complications and help prevent recurrence.^{3,6(Va, IIIb)} Well-documented events also support system-wide learning, root cause analysis, and quality improvement. Including patient-reported experiences enhances the accuracy and utility of adverse event records.^{2(Vb)}

Recommendation 4: Standardized Documentation Tools

Health care organizations may consider using standardized tools to document vascular access outcomes to promote consistency, support data analysis, and reduce variability across patient records, research studies, and quality-improvement initiatives.

Summary of Evidence

Structured documentation improves consistency in reporting and facilitates retrospective analysis for quality improvement and patient safety. Authors of 1 study demonstrated the benefit of using a central venous access device checklist to improve accuracy and reduce complications associated with malpositioned tips.^{7(Vb)}

Recommendation 5: Continuously Evaluate Documentation Protocols

Health care organizations are encouraged to conduct periodic audits and solicit staff feedback to maintain accurate, up-to-date vascular access documentation and promote continuous quality improvement.

Summary of Evidence

Regular evaluation of documentation protocols is essential to maintain accuracy, ensure alignment with current standards, and promote safe practices. Thate et al. emphasized how effective documentation supports collaborative decision-making and infection prevention strategies.^{8(IIIb)} Laan et al. revealed that failure to audit catheter-related documentation led to major underreporting, with only 1.6% of complications recorded.^{5(IIIb)} Field et al. found that integrating patient experiences into documentation reviews helped tailor tools to real-world needs.^{2(Vb)} Sherwood and Nickel reported that staff feedback in process reviews promotes a culture of safety and improves infusion therapy outcomes.^{3(Va)}

Recommendation 6: Postinsertion Documentation

Following VAD insertion, clinicians are encouraged to document external catheter length and trim length, when applicable, to enable detection of catheter migration and ensure safe ongoing assessment.

Summary of Evidence

Recording external and trim catheter length is critical for detecting migration and supporting safe device monitoring. Authors of a prospective study found documentation of insertion variables was highly compliant (93.3%), but removal-related data were often missing or unreliable, limiting the detection of complications.^{9(IIIb)} Current clinical standards also recommend capturing catheter characteristics at insertion to guide safe ongoing care.^{10(IVa)}

Recommendation 7: Documentation of VAD Assessment

Each vascular access assessment should be documented and include:

- justification for continued or discontinued use of the VAD,

- assessment findings (site condition, dressing integrity, patency, and securement),
- details of interventions performed (e.g., dressing changes or device adjustments), and
- any patient-reported symptoms (e.g., pain, swelling, or discomfort near the site).

Summary of Evidence

Comprehensive and structured documentation supports clinical decision-making, helps detect complications early, and improves communication across care teams. Failure to document line necessity may result in idle catheters that increase infection risk. Daily audits and EHR-based prompts have been shown to reduce central line days and associated CLABSI rates.^{11(Vb)} Additionally, documentation of symptoms and interventions helps prevent complications such as extravasation and medical adhesive injury. Bahl et al. also highlighted the consequences of unreliable documentation for catheter-related complications and outcomes.^{9,12,13(IIIb, Vb, Vb)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Reduced infection risks: Routine documentation of catheter care, including securement, flushing, and dressing changes, supports early identification of complications and reduces infection risk, while ongoing monitoring for catheter migration and dislodgement ensures adherence to evidence-based infection prevention protocols.^{14–16}
- Improved workflow and standardization: Structured documentation templates and EHR-based prompts streamline clinical entries, promote consistent language among providers, and enhance EHR efficiency, reducing missed steps in catheter care documentation and improving continuity of care.^{4,6,17}
- Support for accreditation and regulatory compliance: Detailed documentation supports compliance with infection prevention standards and is auditable during quality inspections or legal reviews.^{4,8}

Risks

- Training fatigue or workflow disruption: Repeated updates to documentation protocols may require frequent training and temporarily disrupt clinical workflows.¹⁷
- Resistance to change: Staff may be reluctant to adopt new documentation templates, especially if perceived as increasing workload.^{4,8}
- Incomplete or inaccurate documentation: Poorly completed entries or missing data may impair clinical decision-making and hinder infection prevention efforts.¹⁴

- Overdocumentation or redundancy: Excessive or repetitive fields may obscure critical information or delay entry completion.⁴

Implementation Considerations

- Staff education and competency validation: Provide regular training on documentation standards, focusing on infection prevention, device tracking, and structured EHR templates.^{6,14,17}
- Tailored documentation tools and templates design: EHR templates specific to VADs, accounting for device type, patient acuity, and care setting while allowing flexibility to document adverse events such as dislodgement, infiltration, or infection.^{4,6,18,19}
- Measurement and feedback loops: Audit documentation for completeness, timeliness, and alignment with clinical outcomes.^{4,14}

Barriers to Implementation

- System limitations: EHR systems may not be optimized for vascular access documentation or lack customizable templates.¹⁹
- Staff resistance to new workflows: Clinicians may resist additional documentation burdens or prefer unstructured charting.^{8,4}
- Overdocumentation fatigue: Excessive fields or prompts may result in superficial compliance or bypassing critical steps.^{8,4}

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Chapter 1.7—Data Collection

Accurate, systematic data collection is fundamental to safe and effective vascular access care. Capturing key metrics on device use, complications, and outcomes enables health care organizations to identify trends, benchmark performance, and drive continuous quality improvement.

These data are critical for monitoring adverse events such as hospital-onset bloodstream infections and for evaluating the effectiveness of interventions to reduce risk. Structured data collection also advances broader institutional goals, including regulatory compliance, patient safety, financial stewardship, and operational efficiency.

A robust framework for data collection incorporates both technical outcomes and patient experiences, supporting product evaluation, procedural benchmarking, and adaptation to evolving standards. By assigning responsibility to trained personnel and ensuring clinical oversight, organizations improve data integrity, strengthen accountability, and enable timely intervention. Well-structured systems ultimately enhance safety, optimize resource use, and improve outcomes for patients and health systems alike.

Recommendation 1: Product Evaluations Before Implementation

Before implementing new vascular access devices, organizations should conduct structured product evaluations that include data collection on device performance, patient experience, and clinical outcomes.

Summary of Evidence

Effective product evaluation requires both objective outcome data and qualitative feedback from end users and patients. Thate et al. emphasized that standardized data collection and interdisciplinary documentation are critical for identifying device-related risks and informing collaborative decision-making.^{1(IIIb)} Larsen et al. found that patient experiences with peripheral intravenous catheter insertion varied significantly based on inserter skill, communication, and device placement, supporting the need for human-centered evaluation during product trials.^{2(IIIb)} These findings reinforce the value of collecting technical and experiential real-world data before widespread device adoption.

Recommendation 2: Ongoing Evaluation of Products in Use

Facilities should implement ongoing evaluation of vascular access products currently in use to monitor complications, ensure continued effectiveness, and guide quality improvement initiatives.

Summary of Evidence

Ongoing product surveillance is essential to identify device-related complications, ensure clinical effectiveness, and capture the evolving patient and staff experience. Thate et al. highlighted the importance of integrated data collection and

standardized documentation to support collaborative decision-making and identified risks related to catheter management.^{1(IIIb)} Larsen et al. demonstrated how patient feedback reveals critical insights that may not be captured through clinical metrics alone, such as pain, insertion site complications, and device inconvenience.^{2(IIIb)} These findings underscore the importance of clinical data and human experience in continuous product evaluation.

Recommendation 3: Assignment of Data Entry to Trained Personnel

Personnel with appropriate computer skills, familiarity with vascular access terminology, and demonstrated commitment to data accuracy and clinical relevance should be assigned to vascular access data entry.

Summary of Evidence

Accurate vascular access data are foundational for quality improvement and infection surveillance. Assigning this responsibility to trained personnel has improved data integrity, reduced reporting errors, and strengthened accountability.^{3(IIIb)} In a national survey, Chopra et al. found that vascular access specialists with formal training reported greater adherence to best practices and documentation protocols.^{3(IIIb)} Authors of quality improvement studies have further demonstrated that structured, multidisciplinary documentation processes lead to sustained reductions in catheter-related complications and more reliable reporting of infection rates.^{4,5(IIIa, IIIb)}

Recommendation 4: Assignment of Ongoing Data Monitoring

It is recommended that responsibility for ongoing data monitoring be assigned to personnel with relevant clinical expertise who can identify concerning trends, interpret findings in context, and initiate appropriate interventions as needed.

Summary of Evidence

Ongoing data monitoring by clinically experienced personnel enables early detection of complications, facilitates contextual interpretation of findings, and supports timely intervention. Thate et al. emphasized the need for clear and accessible documentation to support collaborative decision-making across care teams.^{1(IIIb)} Li et al. demonstrated how continuous surveillance and root cause analysis can drive targeted infection prevention strategies.^{6(IIIa)} Monitoring catheter-related outcomes, as seen in a study by McGuire and Coronado on peripheral vascular access device removal timing, can improve safety and reduce unnecessary device days.^{7(IIIa)}

Recommendation 5: Establish Monitoring Intervals

It is recommended that data monitoring intervals be established that support the timely detection of clinically significant trends and enable prompt response to critical changes.

Summary of Evidence

Timely and routine data monitoring supports early identification of complications and enables proactive intervention. In the Keystone ICU project, routine implementation of daily safety huddles and checklists significantly reduced catheter-related infections by fostering consistent interdisciplinary review.^{8(IIIb)} Similarly, Mena Lora et al. demonstrated that hospital-wide daily huddles improved device utilization practices and decreased infection rates, highlighting the value of structured, time-based monitoring.^{5(IIIb)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Patient safety: Enhanced data collection supports patient safety by enabling trend analysis and facilitating adaptability to evolving institutional priorities.^{6,9,10}
- Adoption of a standardized dataset ensures consistent terminology and outcome definitions, reducing variability in reporting and enabling valid comparisons across studies and institutions.
- Enhanced research and quality improvement: Standardized metrics facilitate meta-analyses, increase sample size and statistical power, and support evidence synthesis to guide practice.
- Benchmarking and learning: Consistent reporting enables tracking of institutional performance, identification of best practices, and contribution to global vascular access learning systems.

Risks

- Additional resources: Increased data collection may disrupt workflows and necessitate additional resources for training and management.^{6,11}

Implementation Considerations

- Standardization: Use electronic health record templates to standardize data entry and ensure real-time data access for clinical teams.^{1,5}
- Barriers to Implementation
- Resistance to change: Regular training and demonstrating the impact on patient safety can mitigate resistance.^{1,6,12}

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Chapter 1.8—Products, Bundles, & Checklists

Standardized products, insertion bundles, and procedural checklists are essential tools for improving the safety, efficiency, and consistency of vascular access care. Their use minimizes variability, supports adherence to evidence-based practice, and ensures that essential supplies and steps are not overlooked during high-risk procedures.

Preassembled kits and trays designed with evidence-based components streamline workflow, reduce contamination risk, and help prevent complications such as catheter-related bloodstream infections. When combined with structured checklists and documentation protocols, these tools reinforce procedural accuracy, enhance accountability, and sustain reliable practice across care teams.

Care bundles that incorporate elements such as skin antisepsis, maximal sterile barriers, and evidence-guided device selection are strongly associated with improved outcomes and reduced infection rates. As part of a systems-based approach, standardized products and bundles support quality improvement initiatives, align with infection prevention priorities, and optimize vascular access care across all settings.

Recommendation 1: Procedural Packs and Kits

It is recommended that health care facilities implement procedural packs and kits to enhance efficiency and consistency while also promoting adherence to proper technique.

Summary of Evidence

Standardized procedural packs have been shown to improve efficiency and reduce variation in vascular access technique. Rowley and Clare reported that using an aseptic nontouch technique (ANTT®) peripheral intravenous catheter (PIVC) pack ensured all necessary materials were present, reducing set-up time and supporting consistent adherence to aseptic technique.^{1(IIa)} In a mixed-methods study, researchers found that involving nurses in designing and usability testing a PIVC pack led to high satisfaction and perceived improvements in workflow and infection prevention practices.^{2(Ib)} These findings support the role of standardized kits in promoting safer and more efficient vascular access procedures.

Recommendation 2: Sterile Pack Design and Clinician Involvement

It is recommended that all procedural packs and clinical trays be designed to maintain sterility during procedures. Clinicians should also be involved in developing and evaluating these products to ensure usability, clinical relevance, and alignment with best practice guidelines.

Summary of Evidence

Procedural packs support ANTT principles, such as protecting key parts and fields, to improve adherence to infection prevention protocols and reduce contamination risk. Rowley and Clare reported that ANTT-aligned PIVC packs increased clinician compliance and procedural consistency while facilitating

safe, aseptic technique.^{1(IIa)} In earlier work, they emphasized that ANTT is a critical competency for vascular access safety and that product design should explicitly support aseptic workflows.^{3(Va)} Involving clinicians in the development and usability evaluation of procedural kits ensures clinical relevance, enhances uptake, and aligns product design with evidence-based practice.

Recommendation 3: Procurement and Inventory Management

Health care organizations should consider implementing robust procurement and inventory management systems to minimize the risk of device and drug shortages, which can increase complications related to vascular access.

Summary of Evidence

Shortages of essential devices and medications are associated with increased infection risk and mechanical failure. Researchers have demonstrated that proactive inventory systems and preventive maintenance protocols help reduce these complications and ensure continuity of vascular access care.^{4–6(IIIb, IIIb, IVa)}

Recommendation 4: Use of Alternative Devices and Medications

When primary vascular access devices or medications are unavailable, health care providers may consider appropriate alternative products to ensure uninterrupted patient care. Clinicians must be involved in substitution decisions to ensure clinical safety and procedural continuity.

Summary of Evidence

Moderate-quality evidence has supported the use of alternative vascular access products during periods of shortage, with clinician oversight playing a key role in ensuring safe transitions. Researchers have shown that well-chosen substitutions can maintain functionality while avoiding procedural delays or increased complications.^{5,6(IIIb, IVa)}

Recommendation 5: Removal and Reporting of Expired or Defective Products

Expired or defective vascular access products should be immediately removed from patient-use areas, clearly labeled, and a detailed report submitted to the appropriate institutional, manufacturer, or regulatory authorities in accordance with facility policy.

Summary of Evidence

A substantial body of literature has supported the clinical and ethical obligation to report defective vascular access devices. Inconsistent product integrity has been linked to serious complications, including rupture, embolization, and infection. Timely removal and transparent reporting are critical for patient safety, product surveillance, and regulatory oversight.^{7–9(Vb, IIIb, IIIb)}

Recommendation 6: Checklist Implementation for Vascular Access Procedures

It is recommended that health care providers implement standardized checklists for vascular access procedures to promote procedural compliance, reduce variability, and support quality improvement initiatives.

Summary of Evidence

Checklists have been shown to improve adherence to aseptic technique and reduce infection rates during central venous access device (CVAD) insertions. In a randomized intensive care unit (ICU) study, introducing an insertion checklist significantly reduced central line–associated bloodstream infections (CLAB-SIs).^{10(IIb)} Standardized checklist use supports procedural consistency and improves documentation accuracy, both of which are critical for infection prevention and quality assurance.^{11–13(Vb, IIb, IIIa)} Authors of additional studies have highlighted that structured checklists assist in tracking key vascular access metrics, enabling data-driven decision-making and early identification of risk trends.^{12–14(IIIb, IIIa, IIIa)}

Recommendation 7: Standardized Insertion Checklist

All CVAD insertions should be performed using a standardized insertion checklist, ideally with an independent observer, to ensure compliance with aseptic technique and maximal sterile barrier precautions.

Summary of Evidence

In a randomized ICU study, introducing an insertion checklist significantly reduced CLABSI rates by improving compliance with hygiene standards and procedural safety.^{10(IIb)} While using checklists and independent observers is mandated in some health care systems (e.g., CDC/Joint Commission in the US), it is an evidence-based best practice internationally. It should be considered a core infection prevention strategy in all settings.^{10(IIb)}

Recommendation 8: Implementation of Standardized Vascular Access Care Bundles

Health care organizations must implement standardized, evidence-based care bundles for vascular access device insertion and maintenance, including both central and peripheral devices. Bundles should be designed to ensure compliance with key infection prevention practices before, during, and after procedures, reducing variability, improving outcomes, and supporting ongoing quality improvement initiatives.

Summary of Evidence

Substantial evidence has supported the use of insertion and maintenance bundles to reduce vascular access device–related infections and complications. Authors of systematic reviews and meta-analyses have demonstrated that standardized bundles significantly reduce CLABSI and PIVC-associated bacteremia rates across ICU and non-ICU settings, with reported reductions ranging from 12% to over 60%.^{15–19(Vb, IIb, IIb, IIb, IIb)}

Effective bundles typically include core elements such as:

- hand hygiene,
- aseptic technique with maximal or partial sterile barriers,

- skin antisepsis with an appropriate agent and dry time,
- optimal site and device selection, and
- structured documentation and follow-up.

Authors of multiple implementation studies have also shown that incorporating checklists and team-based safety programs into bundle deployment improves fidelity and leads to better patient outcomes.^{11,15,20,21} Though variations in local protocols may exist, the consistency, structure, and monitoring enabled by standardized bundles are key to improving safety and procedural outcomes in vascular access care.^{15,16,22(Vb, IIb, IIIa)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Reduced infection risk: Bundles that include flushing protocols, securement, and chlorhexidine dressings help prevent infection and catheter complications.^{11,19,23,24}
- Improved workflow and standardization: Preassembled kits streamline preparation and promote adherence to best practices by reducing procedural variability.^{1,3,27} Checklists support task completion in a consistent, stepwise manner and enhance inter-provider consistency.²⁸
- Cost savings and resource optimization: Bundles reduce waste and prevent overuse of materials by including only necessary components.^{1,3,27}
- Procedural consistency reduces the rate of complications and catheter replacements, resulting in financial savings.^{29,30}
- Improved quality improvement and surveillance: Embedded checklists and bundles support real-time monitoring and structured auditing for infection and procedural quality.^{23,28}

Risks

- Upfront costs and product investment: Initial expenses may be incurred when implementing standardized packs, chlorhexidine dressings, or tunneled catheters.^{1,25}
- Training burden and workflow disruption: Staff must be trained to correctly use new kits and checklists, which may temporarily reduce productivity.^{1,31}

Implementation Considerations

- Staff education and competency validation training of clinicians in the correct use of standardized kits, product bundles, and checklists with hands-on and simulation-based learning.^{11,32}

- Tailored tools and product selection customize kits and checklists for high-acuity areas, difficult intravenous access patients, or settings like ICU and oncology.^{2,11}
- Checklist design and iteration: Involve frontline staff in designing concise, role-specific checklists that match the workflow and avoid duplication.¹¹
- Technology and EHR integration: Embed checklists into electronic health records with automated reminders and structured fields to promote real-time documentation.¹¹

Barriers

- Limited budget allocation: Many facilities may lack the funds to support the initial investment in standardized kits, antimicrobial devices, and IT tools for checklist integration.^{2,33}
- Supply chain variability: Disruptions in the supply of bundled kits or catheters can hinder sustained implementation, especially in resource-constrained or high-volume settings.^{2,6}
- Workflow incompatibility: If bundles or checklists are not designed to align with department-specific workflows (e.g., emergency department versus ICU), clinicians may find them cumbersome or impractical.¹¹

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Section 2: Patient Assessment & Planning

Chapter 2.1—Anatomical & Physiological Conditions

Patient-specific conditions are critical in the risk profile and management of vascular access devices (VADs). Complications such as infection, thrombosis, and mechanical failure are significantly influenced by factors including age, comorbidities (e.g., malignancy, diabetes, chronic kidney disease), immune status, vascular anatomy, prior history of thrombosis, and patient mobility. High-risk populations, such as oncology and intensive care unit (ICU) patients, face unique challenges, where catheter-related complications can lead to treatment delays, increased morbidity, prolonged hospitalization, and elevated health care costs.

Given the complexity and variability of these factors, vascular access planning must rely on a tailored, risk-based approach. Integrating comprehensive assessments into decision-making allows clinicians to proactively mitigate risks through appropriate device selection, insertion techniques, and surveillance protocols.

An informed approach to vascular access supports better clinical outcomes, minimizes complications, and promotes more efficient use of health care resources by aligning device management strategies with individual patient needs.

Recommendation 1: Anatomical and Device Considerations

Clinicians should assess anatomical factors and prior venous access history before catheter insertion to guide device selection and reduce procedural complications.

Summary of Evidence

Anatomical and device-related factors play a critical role in vascular access planning and must be assessed before catheter insertion. Structural considerations, such as previous central VAD (CVAD) placements, known central venous stenosis, surgical alterations (e.g., mastectomy, arteriovenous fistula), or presence of indwelling implants, can influence catheter tip positioning, risk of malposition, and the feasibility of using specific sites or vessel pathways. Authors of 1 study have described a malpositioned CVAD in the accessory hemiazygos vein due to prior catheterizations and underlying vascular stenosis, underscoring the need for preprocedure anatomical review.^{1(Vb)}

Evidence has also suggested that device selection and placement success are affected by vascular patency and prior complications. In a comparison study, totally implantable venous access devices were associated with a lower risk of venous thromboembolism (VTE) than peripherally inserted central catheters (PICCs) in cancer patients, reinforcing the value of individualized vascular risk assessment.^{2(IIa)} Moss et al. further demonstrated that anatomic and historical factors, including cancer type, vascular access history, and patient-specific vessel

characteristics, directly influence optimal device selection and outcomes.^{3(Ia)} Infection risk also varies by insertion site, with subclavian access showing a lower colonization risk than internal jugular or femoral access.^{4(IIa)} Collectively, these findings support a thorough anatomical and device-related history as essential to improving patient safety and procedural success.

Recommendation 2: Physiological Risk Factors

Clinicians should consider evaluating patient-specific physiological risk factors, including comorbidities, coagulation status, and immune function, to inform safe vascular access planning and device selection.

Summary of Evidence

A growing body of evidence supports the inclusion of physiological risk factors during vascular access planning. Authors of multiple retrospective cohort studies and meta-analyses have identified prior history of VTE, active malignancy, immunosuppression, and renal dysfunction as significant contributors to catheter-related complications such as catheter-related VTE (CR-VTE), bloodstream infections, and thrombosis. For example, authors of 2 studies found that patients with a prior history of thrombosis were at significantly higher risk for CR-VTE following PICC insertion.^{5,6(IIIb, IIIa)} Others identified malignancy, diabetes, and elevated body mass index as contributing factors to thrombosis in breast cancer patients receiving PICCs.^{7(IIIa)}

Authors of 2 similar studies revealed that, while peripheral midlines (PMLs) are generally safe, patients with a history of thrombosis may still be at increased risk, with PMLs associated with higher rates of superficial vein thrombosis than PICCs in some studies.^{8,9(IIIa, IIIb)} Similarly, researchers have shown that prolonged dwell time, catheter diameter, and repeated access increase thrombosis risk, particularly in patients with hypercoagulable conditions.⁷ These findings underscore the importance of individualized physiological risk review as a standard part of vascular access planning to support safer insertion and improve patient outcomes.^{8,9(IIIa, IIIb)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Early identification of thrombosis history reduces CR-VTE risk and improves device selection and prophylaxis.^{5,6,9}

- Supports multidisciplinary management: Encourages collaboration with oncology, nephrology, and hematology for patients with complex comorbidities.^{10,11}

Risks

- Complications: Incomplete clinical assessments may raise the risk of CR-VTE and other complications.⁸
- Investment: Implementation of advanced protocols requires upfront investments, training, and may temporarily increase workload.^{10–15}

Implementation Considerations

- Clinical guidelines: Use clinical guidelines and high-risk medication references to guide appropriate intravenous device selection.^{16,17}
- Training: Train staff on securement, surveillance, flushing, and maintenance using best practices and monitoring systems.^{10–12,14,18–21}
- Barriers to Implementation
- Treatment plans: Barriers include delayed orders due to unclear treatment plans, limited staff awareness, or vein accessibility.^{16,17,22,23}
- Resistance to change: Challenges such as resistance to change, budget limitations, and unit-level adherence variability affect widespread adoption of preventive measures.^{13,19,20,24–27}

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Chapter 2.2—Behavioral, Psychosocial, and Environmental

Safe vascular access requires more than choosing the right vein or device. A person's behavior, mental health, and living environment all influence whether a catheter can be maintained safely over time. Patients struggling with substance use or cognitive decline may be less able to protect their device or participate in care, which increases the risk of complications. Likewise, unstable housing, limited caregiver support, or fragmented health services can make it difficult to manage vascular access outside the hospital.

These factors are not easily measured, but their impact is real. Outcomes vary not only because of anatomy or therapy but also because of the environments patients return to and the support systems they can rely on. Recognizing these influences early and planning around them with input from a multidisciplinary team allows clinicians to anticipate challenges and reduce preventable harm. A holistic assessment that considers the person, their circumstances, and the health care resources available is essential to providing safe and equitable vascular access across all settings.

Recommendation 1: Behavioral Risk Factors

Assess behavioral history, including substance use and potential for catheter misuse, when planning vascular access.

Summary of Evidence

In patients with a known history of injection drug use, intentional catheter manipulation, or line misuse may increase the risk of infection, overdose, or therapy failure. Planning

should involve interprofessional consultation, risk stratification, and consideration of harm reduction strategies such as securement methods, tamper-evident technology, or supervised therapy.^{1(IIIb)}

Behavioral risk factors, including a history of substance use or intentional catheter misuse, warrant careful evaluation during vascular access planning. Although concerns persist about the safety of providing vascular access devices to persons who inject drugs (PWIDs), emerging evidence has challenged blanket exclusions. In a retrospective review by D'Couto et al., PWIDs discharged on outpatient parenteral antimicrobial therapy (OPAT) had similar rates of treatment completion, line complications, and readmissions to those discharged to supervised facilities, suggesting that outpatient intravenous (IV) therapy may be a viable option for select patients.^{1(IIIb)} Similarly, in a multicenter analysis, Levin et al. found that PWIDs had no significant increase in infection, reintervention, or mortality at 1 year following arteriovenous access creation. However, they were more likely to have prosthetic grafts and social vulnerabilities such as homelessness.^{2(Va)} These findings support individualized behavioral risk assessments and highlight the importance of securement strategies, education, and care planning in this population.

Recommendation 2: Psychosocial and Cognitive Considerations

Consider cognitive and psychosocial status when selecting vascular access devices.

Summary of Evidence

Cognitive and psychosocial factors, such as dementia, delirium, traumatic brain injury, or psychiatric illness, can compromise the safety of vascular access by increasing the risk of unintentional catheter dislodgement or poor self-management. Nakano et al. evaluated peripherally inserted central catheter (PICC) use in elderly patients with dementia and found favorable outcomes, with a median catheter dwell of 42 days, a catheter-related bloodstream infection rate of just 0.22 per 1000 PICC days, and only 3 cases of self-removal, none after securement strategies were enhanced.^{3(IIIb)} These results suggest that, with thoughtful placement and securement, even cognitively impaired patients can safely receive vascular access therapy. In a 2018 cross-sectional survey, Moureau further reinforced that patient confusion is a leading contributor to catheter dislodgement, highlighting the need for tailored site selection, concealed dressing techniques, and robust staff training to reduce unintentional removal. Psychosocial complexity should not preclude access but should guide planning.^{4(Vb)}

Recommendation 3: Environmental and Socioeconomic Considerations

Evaluate environmental stability, social support, and discharge feasibility when planning vascular access.

Summary of Evidence

Environmental and socioeconomic conditions, including housing instability, lack of caregiver support, or limited access to outpatient services, can significantly affect the safety and success of vascular access care, particularly for patients discharged with central catheters.^{5(IIIb)} In a cohort study by Ryan et al., homelessness was independently associated with higher rates of tunneled dialysis catheter use at the time of arteriovenous access creation, suggesting that inadequate preoperative care coordination and social support may lead to suboptimal access strategies.^{6(IIIb)} D'Couto et al. also noted that patients discharged on OPAT without strong support systems or addiction counseling had higher risks of complications, regardless of whether they went home or to skilled facilities.¹ These findings underscore the importance of environmental assessments and multidisciplinary discharge planning in determining whether a long-term device can be safely managed outside the hospital setting.

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Improved safety and outcomes: Assessing behavioral, cognitive, and environmental risks supports individualized access planning, reducing infection, dislodgement, and misuse.^{1,4}

- Fewer device complications: Securement strategies like tamper-evident connectors and concealed dressings reduce self-removal in cognitively or behaviorally complex patients.²
- Equitable care access: Patients with substance use or social vulnerabilities can achieve comparable outcomes when provided with appropriate support and monitoring.²

Risks

- Increased costs: Accidental dislodgment of vascular devices leads to treatment interruption and increased health care costs.⁴
- Infection and misuse: Behavioral instability and substance use increase risks of contamination, overdose, and line tampering.¹
- Device dislodgement: Cognitive impairment or psychiatric illness can lead to unintentional removal or poor device care.²

Implementation Considerations

- Multidisciplinary collaboration: Engage addiction medicine, vascular access, nursing, social work, and behavioral health for comprehensive risk assessment.¹
- Harm reduction practices: Use tamper-evident securement, reinforced dressings, and observation protocols to prevent manipulation or accidental removal.²
- Structured discharge planning: Assess social support, home environment, and outpatient resources early to ensure safe transition and follow-up.¹

Barriers to Implementation

- Limited access to support services: Gaps in addiction, behavioral health, and follow-up care hinder safe outpatient management.²
- Institutional bias and policy barriers: Exclusionary practices toward PWIDs or unstable housing populations limit equitable vascular access.¹
- Fragmented care coordination: Poor linkage between inpatient, outpatient, and community teams leads to inconsistent monitoring and outcomes.²

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Chapter 2.3—Special Patient Considerations

Vascular access planning is never one size fits all. Each patient brings a distinct set of circumstances, medical, anatomical, psychosocial, and environmental elements that shape the safety and success of device use. No 2 veins, skin types, prognoses, or personal preferences are alike, and clinicians must approach every patient as a unique case requiring thoughtful assessment and tailored planning.

This chapter highlights 4 populations: those with difficult intravenous access (DIVA), risk for medical adhesive–related skin injury (MARS), catheter-related venous thromboembolism (CR-VTE), and chronic kidney disease (CKD) because these conditions are supported by a body of evidence strong enough to inform specific recommendations. They do not represent the full spectrum of patient variation, rather they illustrate how focused research can guide practice when unique risks are present.

Beyond these examples, clinicians must remain attentive to the nuances of each patient encounter. The true principle of special considerations lies not in categorizing patients by diagnosis or risk factor but in recognizing that all patients require individualized planning. By applying this perspective, balancing evidence-based guidance with patient-specific needs, clinicians can deliver safer, more equitable, and more sustainable vascular access across all settings.

Recommendation 1: DIVA

Clinicians should proactively identify patients at risk for DIVA during the planning phase of vascular access.

Summary of Evidence

DIVA is a common clinical challenge that may increase patient discomfort, delay therapy, and raise the risk of complications. Over 60 predictive factors have been identified, including advanced age, obesity, edema, chronic disease, and history of intravenous drug use.^{1(IIIb)} Early recognition of these risks allows clinicians to adapt their approach before repeated failed attempts occur. Systematic reviews and meta-analyses consistently show that ultrasound (US) guidance improves first-attempt success in DIVA cases, reduces complications, and minimizes the need for central line placement.^{2,3(Ia, IIIb)} Researchers have also shown that patients not classified as DIVA generally do well with conventional landmark-based methods, highlighting the value of early risk stratification.^{4,5(IIb, IIIb)} Early consultation with an US-trained

clinician has been associated with tripled success rates and reduced unnecessary central catheter use by as much as 85%.^{3,6(IIIb, IIb)}

Note: DIVA should be used cautiously, emphasizing it refers to challenging veins rather than the patient, to avoid unintended stigma.

Recommendation 2: MARS

Clinicians should assess patient-specific risk factors for MARS as part of vascular access planning.

Summary of Evidence

MARS affects patients across all care settings and device types, particularly those with fragile or compromised skin. Age, dermatologic history, comorbidities, and skin fragility should inform dressing and securement choices. Early risk identification enables preventive interventions that improve patient comfort and reduce complications.

While no universal MARS risk scale exists, authors of multiple high-quality studies have identified well-established risk factors such as female sex, extremes of age, critical illness, malnutrition, and anti-neoplastic therapy.^{7(IIIa)} Several tools, including predictive nomograms, have been validated in oncology patients with peripherally inserted central catheters (PICCs) but are not generalizable to all populations or devices.^{8,9(IIb, IVb)} Effective MARS prevention begins with preinsertion assessment and continues with tailored product selection, reduce dressing change frequency, and skin-protective strategies.

Recommendation 3: CR-VTE

Evaluate CR-VTE risk factors before device selection. Avoid high-risk devices in predisposed patients and coordinate anticoagulation and device planning with the multidisciplinary team.

Summary of Evidence

CR-VTE is a well-established complication associated with PICCs and midlines. Patients with cancer, elevated body mass index, or prior thrombosis are at significantly higher risk. In a retrospective analysis, a 22.8% VTE incidence in anticoagulated patients was shown compared with 77.2% without, though results were not statistically significant in matched controls.^{10(IIIb)} Authors of multiple systematic reviews have confirmed that PICCs and midlines can contribute to thrombosis, with catheter

characteristics and anatomical placement further influencing outcomes.^{11,12(IIb, IIIb)} In the 2019 kidney disease outcomes quality initiative (KDOQI) guidelines and subsequent reviews, avoiding high-risk device types in patients predisposed to thrombosis and encourage individualized planning have been recommended.^{13(IVa)}

Recommendation 4: CKD Preservation

In patients with CKD, especially stage 3b or higher (Glomerular filtration rate < 45 mL/min), clinicians should avoid vascular access devices (VADs) that may compromise future dialysis options. Planning should include vein preservation, coordination with nephrology, and alternative strategies to support long-term vascular integrity.

Summary of Evidence

PICC use in CKD patients is consistently linked to increased rates of central vein stenosis and reduced likelihood of transitioning to a functioning arteriovenous fistula (AVF).^{14(IIIb)} In the 2019 KDOQI guidelines, PICC placement in this population is discouraged, and caution is advised with midlines unless no alternative exists.^{13(IVa)} While authors of 1 cohort study have suggested midlines may be safe in selected CKD patients, in most of the literature, comprehensive vein preservation protocols are supported as standard care.^{15(IIIa)} Researchers have also confirmed that patients with a history of PICC use have lower AVF success rates after dialysis initiation.^{16(IVb)}

Recommendation 5: Match Dialysis Access Type to Indication and Duration

In patients requiring dialysis, nontunneled centrally inserted central catheters may be used temporarily in emergency or inpatient settings. For long-term access, AVFs remain the gold standard due to lower rates of infection, thrombosis, and mortality than tunneled catheters.

Summary of Evidence

AVFs are associated with improved survival and fewer infections in chronic hemodialysis patients.^{17–20(IIIa, IIIb, IIIb, IIIb)} Long-term tunneled dialysis catheters (TDCs) are linked with increased complications when AVFs are not pursued or delayed. In intensive care unit patients, non-TDCs carry a higher risk of early infection and should be promptly replaced with permanent access when feasible.^{18,21(IIIb, IIIb)} Avoiding PICCs in this population reduces cumulative venous injury and aligns with nephrology best practice guidelines.^{22,23(IIIb, Va)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Adverse event minimization: Appropriate device selection minimizes adverse events and supports optimal treatment outcomes.²⁴

- Vessel health and preservation: Minimizes the need for multiple PIVC starts and preserves vessel health.^{25,26}
- Costs and satisfaction: Early DIVA identification and US access reduce unsuccessful insertions, costs, and improve satisfaction and safety.^{1,3,6,27–29}
- Reduced incidence of MARS: Implementing evidence-based strategies—such as selecting appropriate adhesives, using barrier films, and practicing gentle removal—can significantly lower MARS rates.^{30–32}
- Improved patient outcomes: Prevention of MARS supports skin integrity, reduces pain, and may lower the risk of secondary infections, promoting faster healing and recovery.^{7,33}
- Cost savings: Reducing MARS incidence minimizes the need for advanced wound care, shortens hospital stays, and decreases complications, resulting in lower overall costs.³⁴
- Early identification of patients with a history of thrombosis reduces the risk of CR-VTE and optimizes VAD selection and anticoagulation prophylaxis.^{10,35,36}
- Improved patient outcomes and procedural safety with US-guided vascular access and risk-based strategies.^{37,38}
- Enhanced maintenance and monitoring through standardized protocols and staff education.^{39,40}

Risks

- Complications: Inappropriate device selection may lead to vascular complications.⁴¹
- Decrease productivity: Initial implementation and training can reduce productivity.^{1,3,6,27}
- Increased workload: Thorough assessments for MARS risk require additional clinician time, particularly during VAD planning and dressing changes.^{42,43}
- Resistance to change: Staff may resist implementing new procedures or guidelines if perceived as cumbersome or not evidence based.⁴⁴
- Added direct costs: Incorporating skin barrier products and silicone-based adhesive removers into routine care increases material costs and may require additional staff training.^{30,32}
- Increased risk: Incomplete clinical assessment may increase the risk of CR-VTE and other VAD-related complications.⁴⁵
- Bleeding: Bleeding complications from prophylactic anticoagulation, requiring careful selection and dose management.^{46,47}
- Resources: Resource use required for US, prophylaxis, and staff training.^{48,49}

Implementation Considerations

- Team-based care: Incorporate vascular access teams and embed decision support tools within electronic health record (EHR) systems to standardize practices and support timely, evidence-based decision-making.^{50–52}

- Device selection: Optimize outcomes by ensuring appropriate device selection based on patient needs, vessel health, and therapy duration.²⁶
- Screening tools: Implement DIVA screening tools and supportive policies to enable early recognition.²
- Complex risk factor profile: Numerous patient-related factors, including age, dermatologic history, nutritional status, comorbidities, and frequency of dressing changes, must be considered in VAD and adhesive planning.^{7,30,42,44,53}
- Clinical tools: Algorithms such as catheter-associated skin injury provide structured approaches to managing catheter-related skin impairment and boost clinician confidence in treating MARSI.^{31,54}
- Education: Ensure staff education and competency validation in modified Seldinger technique-guided puncture, electrocardiogram tip positioning, and VAD management.^{45,55,56}
- Documentation: Integrate EHR tools for catheter documentation and complication tracking.^{49,57}
- Team approach: Engage multidisciplinary teams across departments for CR-VTE prevention and workflow improvement.^{39,58}

Barriers to Implementation

- Resources: Limited access to skilled staff and resources to implement device selection strategies.²⁴
- Resistance to change: Clinician hesitancy and training demands may reduce capacity temporarily.^{1,3,6,28,59}
- Absence of a validated universal risk tool: No current MARSI risk assessment scale is applicable across all patient populations and VAD types. Existing models (e.g., nomograms for oncology patients) are limited in scope.^{8,9,60}
- Organizational barriers: Common issues include a lack of administrative support, insufficient funding for necessary supplies, time constraints, and inconsistent institutional policies.³⁴
- Provider-level barriers: Barriers may involve limited clinician awareness, resistance to guideline adherence, or discomfort with altering established routines.⁶¹
- Patient-level barriers: Fragile skin, allergic sensitivities, and non-compliance with care instructions may complicate adherence to MARSI protocols.⁴³
- Evidence variability: Inconsistent guidelines for evidence on anticoagulation therapy before and after PICC insertion may hinder standardized practice adoption.^{10,11}
- Framework deficiency: Lack of structured frameworks to support midline catheter device selection limits consistency and informed decision-making.¹⁰
- Staff resistance: Resistance to adopting new protocols and anticoagulation practices may delay implementation and reduce compliance.^{58,62}

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Section 3: Vascular Access Device Selection

Chapter 3.1—Device Type Overview

Vascular access devices (VADs) are categorized as peripheral or central based on the catheter tip location rather than the insertion site. This classification informs clinical decisions regarding infusate type, therapy duration, and patient risk factors.

- Peripheral VADs (PVADs), including peripheral intravenous catheters (PIVCs) and peripheral midlines (PMLs), terminate in peripheral veins. They are used for short- to intermediate-term therapy with peripheral infusates.
- Central VADs (CVADs), such as peripherally inserted central catheters (PICCs), centrally inserted central catheters (CICCs), tunneled catheters, and totally implanted venous access devices (TIVAD), terminate in the central vasculature and are used when prolonged therapy vesicants are required.

Understanding the indications and limitations of each device is crucial for selecting a safe and appropriate VAD and achieving optimal patient outcomes. This chapter serves as a general guide, but individual patient considerations supersede recommended time frames.¹

Peripheral Intravenous Catheter (PIVC)

PIVCs are the most commonly used VADs for short-term therapy (typically ≤5 days) with peripherally compatible infusates. They are associated with high failure rates due to dislodgement, phlebitis, and infiltration, especially in patients with difficult access.² Integrated PIVCs and those with blood-control features have shown improved outcomes, including lower complication rates and occupational safety benefits.^{2,3}

Peripheral Midline (PML)

PMLs are upper arm catheters terminating in peripheral veins (not central vasculature), appropriate for intermediate-duration therapy (~1–4 weeks) involving peripherally compatible infusates.^{4,5}

Peripherally Inserted Central Catheter (PICC)

PICCs are CVADs inserted through peripheral veins with tips in the superior vena cava. Suitable for long-term use and

central infusates, they carry increased risks of thrombosis and catheter-related complications, particularly in patients with cancer or CKD.^{6–8}

Centrally Inserted Central Catheter (CICC)

CICCs are centrally inserted CVADs, commonly used in critical care. While effective for rapid or high-volume infusion, especially in short-term intensive care unit (ICU) settings, they pose higher infection risks than TIVADs or tunneled catheters.^{9,10}

Tunneled Noncuffed and Cuffed CICCs (Tnc-/Tc-CICC)

Tnc-CICCs are sometimes used for when intermediate access is needed or to reach an adequate vein diameter that may not be in an appropriate site for care and maintenance. Tc-CICCs are long-term devices with a tissue-ingrowth cuff and are often used for parenteral nutrition (PN), oncology, or dialysis.^{11,12}

Totally Implantable Venous Access Device (TIVAD)

TIVADs, sometimes referred to as ports, are fully implanted under the skin and usually placed in the chest or arm for long-term intermittent therapy such as chemotherapy. They are associated with fewer infections and thrombotic complications than PICCs and offer better patient quality of life for long-term access needs.^{13–15}

Intraosseous (IO) Catheters

Intraosseous (IO) devices provide emergency vascular access via bone marrow, ideal when intravenous (IV) access is unobtainable. They support medication, fluid, and blood product administration but are limited to short-term use.^{16,17}

Arterial Catheters

Primarily used for continuous blood pressure monitoring or frequent arterial blood sampling, these devices are not used for drug or fluid infusion due to the risk of ischemic complications.^{18–20} In rare cases, some arterial catheters are used for chemotherapy.

Device type	Key characteristics	Typical duration	Special considerations
Peripheral IV catheter (PIVC)	Short catheter in superficial vein; for short-term use (≤ 5 d); high failure rate; avoid vesicants.	Hours to ≤ 5 d	High failure rate; dislodgement and infiltration are possible.
Intraosseous (IO) access	Emergency access via bone marrow; rapid, temporary; for resuscitation without IV access.	24–48 h (emergent use only)	Short-term only; risks include infection and extravasation.
Peripheral midline (PML)	Intermediate-length catheter in deep peripheral vein; 1–4 wk use; not central; avoid vesicants.	1–4 wk	Lower infection rates versus PICC; mechanical failure possible.
Peripherally inserted central catheter (PICC)	Central tip; long-term use; for vesicants, PN; avoid in chronic kidney disease (CKD) Stage 3b+; not ideal for ≤ 5 d.	>5 d to months	Avoid in CKD; complications increase with short-term use.
Centrally inserted central catheter (CICC)	Inserted in subclavian, jugular, and femoral veins; central tip; used for acute or critical care access.	Days to weeks	Risk varies by insertion site; higher infection or thrombosis in femoral area.
Tunneled noncuffed catheter (Tnc)	Tunneled under skin, no cuff; intermediate- or long-term use. Can be used with PML, PICC, or CICC.	Weeks to months	Used when the adequate vein diameter versus the exit site is a distance apart.
Tunneled cuffed catheter (Tc-CICC)	Tunneling and a cuff reduce infection risk; ideal for continuous long-term infusion like PN.	Months to years	Preferred for extremely long-term PN or continuous infusions; requires surgical placement.
Totally implantable venous access device (TIVAD)	Fully implanted under skin; accessed via noncoring needle; optimal for long-term intermittent therapy.	Months to years (intermittent use)	Requires needle access.
Arterial catheters	Inserted into an artery; used for continuous blood pressure monitoring or frequent arterial blood sampling; not used for drug or fluid infusion. (except for rare chemotherapy)	Hours to days (short-term use)	High risk of ischemic complications and infection.

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Chapter 3.2—Material and Design

Catheter material and design features are fundamental to vascular access device (VAD) performance, durability, and complication risk. While insertion technique and care practices are essential to long-term outcomes, intrinsic device properties also determine how catheters interact with the vasculature and infusates. A well-matched design can reduce the

incidence of infection, thrombosis, occlusion, dislodgement, and mechanical failure. Device selection must therefore consider multiple design factors, including material composition, number of lumens, surface coatings, valve mechanisms, and other structural attributes, based on patient-specific risk and therapy goals.

Overview

Catheter Material Composition

Two primary catheter materials dominate the market: polyurethane and silicone. Both are biocompatible but differ in mechanical properties:

- Polyurethane: Stiffer, pressure-tolerant (supports power injection), but may be more thrombogenic and cause vessel irritation. Newer technologies allow these catheters to soften as they reach body temperature.
- Silicone: Softer, more flexible, may kink or be harder to advance, but associated with lower rates of thrombosis in high-risk patients.

Material properties influence patient safety. In a meta-analysis, Wildgruber et al. found a significantly higher thrombosis rate in polyurethane ports than in silicone ports (35.6% versus 2.0%). Silicone catheters may be especially beneficial in oncology and hypercoagulable populations.¹

Design Features

Key design elements include:

- Number of lumens: Single-lumen catheters are preferred when clinically feasible, as they reduce the risk of central line-associated bloodstream infection, catheter-related thrombosis, and occlusion. Multilumen catheters should be reserved for patients requiring multiple simultaneous infusions.²⁻⁴
- Catheter diameter: A larger diameter in French or gauge size increases the risk of thrombosis. Selection should balance required flow rates with vessel size and patient risk.^{1,5}
- Pressure capacity: Power-injectable catheters must be labeled for high pressure contrast media injection protocols.^{6,7}
- Valve technology: Pressure-activated safety valves (integrated or add-on) and blood control features may improve safety, reduce blood exposure, and minimize occlusion risk.⁸
- Integrated peripheral intravenous catheters (PIVCs): Design enhancements such as integrated PIVCs (with extension tubing and stabilization features) have demonstrated longer dwell times and reduced failure rates compared to nonintegrated systems.^{8,9}

Antimicrobial and Antithrombotic Surface Technologies

Catheters may be modified or manufactured with antimicrobial or antithrombotic coatings to reduce colonization and fibrin adherence:

- Antimicrobial: Chlorhexidine-silver sulfadiazine, silver ions, and minocycline-rifampin reduce bacterial proliferation. These may be helpful in patients with prolonged dwell times or a higher risk of infection.^{10,11}
- Antithrombotic: Heparin bonding, hydrogel coatings, or hydrophilic surfaces reduce platelet adhesion and fibrin

sheath formation. Evidence of benefit is strongest in select, high-risk populations.¹²⁻¹⁴

While authors of studies have suggested these technologies may reduce complications in some settings, their routine use remains a matter of debate. They must be paired with stringent adherence to infection prevention and catheter care practices.¹⁰⁻¹⁴

Recommendation 1: PIVC Design Recommendation

Use integrated PIVCs and those with blood control features when available. These devices are associated with reduced dislodgement, longer dwell time, and improved clinician safety.

Summary of Evidence

Authors of 1 large, randomized controlled trial demonstrated significantly reduced failure rates for integrated PIVCs compared with nonintegrated designs. Blood control technology also improves occupational safety by reducing exposure and helps maintain dressing integrity.^{8,9(Ia, IIb)}

Recommendations 2: Catheter Material Selection Recommendation

Clinicians should consider catheter material (silicone versus polyurethane) when selecting a central venous access device, particularly for patients at elevated thrombotic risk.

Summary of Evidence

In a retrospective analysis, Wildgruber et al. showed silicone catheters had significantly lower thrombosis rates than polyurethane (2.0% versus 35.6%, $P < 0.0001$) in central venous ports.^{1(IIIb)} Authors of additional studies have confirmed that silicone catheters are structurally more durable and less thrombogenic in high-risk populations such as oncology patients.^{1,15,16(IIIb, Ib, IIIb)}

Recommendation 3: Lumen Number Recommendation

Use the fewest number of lumens required to meet therapeutic needs.

Summary of Evidence

Authors of multiple studies have linked multilumen catheters with increased risks of bloodstream infection, catheter-related venous thrombosis, and occlusion. In a modeling study, Ratz et al. and, in observational work, Chopra et al. showed that increasing single-lumen use can reduce complications and hospital costs.^{2-4,17(Vb, IIIa, IIa, IIb)} Multilumen catheters should be reserved for patients requiring multiple simultaneous infusions. These complex intravenous (IV) therapies may require dedicated lumens (i.e., not mixed with other infusions) or the option to allow bolus infusions during intermittent infusions.^{2,3(Vb, IIIa)}

Recommendation 4: Coated Catheters in High-Risk Patients Recommendation

Antimicrobial or antithrombotic catheters may be considered in adults with anticipated catheter dwell times of greater

than 7 days and elevated risk for catheter-related bloodstream infection (CRBSI) or thrombosis. Product selection should reflect patient risk profile, institutional data, and cost-benefit analysis.

Summary of Evidence

In a prospective-observational study, Winkler et al. showed a trend toward reduced thrombosis with chlorhexidine-coated peripherally inserted central catheters (PICCs) despite their original labeling of antimicrobial.^{11(IIIa)} Authors of other studies have suggested mixed outcomes and emphasized appropriate patient selection.^{18,19(Ia, IIb)}

Cautionary Note: Coated catheters are not a substitute for good technique. Antimicrobial and antithrombotic surfaces must complement, not replace, adherence to aseptic insertion, maintenance, and surveillance protocols. Inappropriate use may increase costs without reducing complications.

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- **Reduced complications:** Integrated PIVCs with integrated extension sets are associated with fewer complications, such as dislodgement and site contamination, improving overall device stability.⁸
- **Enhanced safety:** Blood control technology reduces blood exposure during insertion and access, promoting clinician safety and minimizing site contamination.⁹
- **Tailored risk reduction:** Selecting catheter materials based on patient-specific risk factors, such as higher thrombotic risk, may lower the incidence of catheter-related venous thrombosis.^{1,16,20}
- **Patient safety:** Reduced risk of thrombotic complications enhances patient safety and may lower morbidity.^{12,14,21}
- **Reduced adverse events:** Using single-lumen PICCs and midlines by default, unless multiple lumens are clearly indicated, may lower the risk of device-related complications.^{7,24}

Risks

- **Material sensitivity:** Some patients may experience adverse reactions to specific catheter materials, although both polyurethane and silicone are generally safe.^{1,16,20}
- **Device failure:** Inadequate flushing or improper handling may lead to catheter damage, occlusion, or premature failure.⁹
- **False security:** Reliance on blood control features or integrated designs may lead to lapses in aseptic technique or handling vigilance.⁹

- **Anticoagulant interaction:** Potential adverse interactions with anticoagulant therapies may complicate patient management.^{12,14,21}
- **Insufficient access capacity:** Patients requiring concurrent or incompatible infusions may need additional or replacement devices to meet their therapy needs.²⁵
- **Adverse events from nonadherence:** Failure to follow device selection recommendations may increase the risk of CRBSI, catheter-related venous thromboembolism, and catheter occlusion.^{26–28}

Implementation Considerations

- **Device selection protocols:** Institutions should incorporate catheter material, integration, and safety features into standardized device selection protocols based on clinical indication and patient risk.⁹
- **Staff education:** Clinicians must be trained on appropriate handling techniques, flushing protocols, and the clinical advantages of integrated and blood control technologies.⁹
- **Antithrombotic PICCs:** Consider use of antithrombotic-impregnated central VADs (CVADs) in high-risk patients, with attention to cost-effectiveness given the variability in clinical benefit.^{11,14}
- **Training:** Staff training and adherence to infection control protocols are essential for the effective use of antimicrobial-impregnated catheters.^{22,23}
- **Preinsertion planning:** Collaborate with pharmacists and vascular access specialists to assess vascular access needs and determine the appropriate catheter lumen number before ordering a VAD.^{7,24,25}

Barriers to Implementation

- **Limited availability:** Integrated or blood control PIVCs and CVAD silicone-based catheters may not be available in all clinical settings or for all patient populations.⁹
- **Cost concerns:** Advanced catheter designs and safety features may incur higher upfront costs, which can limit routine use in resource-constrained environments.⁹
- **Inconsistent adoption:** Variability in clinician awareness or institutional protocols may hinder consistent use of integrated designs or tailored material selection.⁹
- **Limited data:** Limited long-term efficacy data, variability in clinical benefits, and high device costs complicate widespread adoption of antithrombotic CVADs.^{14,22}
- **Overestimation of access needs:** Clinicians may request multilumen catheters unnecessarily, for example, to separate blood draws from infusions or to maintain a backup lumen, thereby increasing patient risk.²⁵

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Chapter 3.3—Indications & Contraindications

Selecting the right vascular access device (VAD) depends on where the catheter tip terminates and the clinical purpose it must serve. Peripheral devices such as peripheral intravenous catheters (PIVCs) and peripheral midlines (PMLs) are suited for short to intermediate therapies with nonvesicant, nonirritant solutions of lower osmolality. Central VADs (CVADs), with tips positioned in the superior or inferior vena cava, are indicated for long-term therapy, vesicants or irritants, infusates with high osmolality or extreme pH, and when reliable access is needed for monitoring or rapid infusion.

Safe use of VADs also requires recognition of contraindications. Inappropriate device or tip placement increases the risk of infiltration, thrombosis, arrhythmia, or treatment delays. Understanding when not to use a device is as important as knowing when to use it correctly. Therapy type, anticipated duration, vessel health, and patient-specific factors should always guide device choice, ensuring that the benefits outweigh potential risks and that vascular integrity is preserved over time.

Recommendation 1: Device Selection Protocols

Clinicians are advised to implement structured, evidence-based protocols for the selection and maintenance of VADs. These protocols should consider incorporating therapy type, duration, vessel health, and patient-specific factors to ensure device appropriateness, prevent complications, and support high-value care.

Summary of Evidence

Implementing standardized device selection frameworks, such as the Michigan Appropriateness Guide for Intravenous Catheters (MAGIC), improves catheter appropriateness and reduces complications. Authors of a quasiexperimental study across 52 Michigan hospitals found that improved peripherally inserted central catheter (PICC) selection was associated with lower central line–associated bloodstream infection (CLABSI) rates.^{1(IIa)} Predictors of short-term PICCs use included difficult venous access, use of multilumen devices, and care in teaching hospitals.^{2(IIIa)} MAGIC guidelines discourage short-term PICC

use (<5 days), recommending PMLs or ultrasound-guided PIVCs instead.^{3,4(Va,Vb)}

Avoiding unnecessary VADs is a core strategy in CLABSI prevention. In a scoping review on central venous catheter complications, avoiding unnecessary catheterization was the only strategy that eliminated the risk of catheter-related bloodstream infection and other complications.^{5(IIa)} In a meta-analysis, Bahl et al. found that smaller-diameter PICCs were associated with reduced rates of symptomatic deep vein thrombosis (DVT).^{6(IIIa)} Midlines and ultrasound-guided long peripheral catheters further reduced DVT risk and hospital costs.^{6-9(IIIa, IIIb, IIIb, IVb)} The introduction of vascular access teams and structured protocols has shown additional cost savings and improved patient outcomes.^{7-10(IIIb, IIIb, IVb, IIIb)}

Recommendation 2: VAD Selection for Postacute Care

Clinicians should assess therapy type, duration, patient capacity, and available support systems when selecting VADs for patients discharged to postacute care settings, including home infusion.

Summary of Evidence

In a systematic review of hospital-in-the-home and outpatient antibiotic therapy programs, high treatment success rates were reported. Still, the authors of this study noted vascular access–related complications occurred in up to 29% of cases, particularly in older adults and those lacking caregiver support.^{11(IIIb)} Device-specific risks vary by therapy type and patient capacity: Authors of 1 large cohort study found that 28% of home infusion patients experienced catheter occlusions, many within a week of discharge.^{12(IIIb)}

Risks increase with therapy complexity. For long-term therapies like parenteral nutrition, additional risks include dwell time, cyclic infusion, and compounded formulations.^{13(IIIb)} Careful patient selection, standardized discharge education, and access to follow-up support are key strategies to improve outcomes and reduce complications across the continuum of postacute care.^{11-13(IIIb, IIIb, IIIb)}

Recommendation 3: VAD for High-Flow Contrast Injection

Device choice considerations should be based on the required flow rate, therapy duration, vessel size and depth, and the injection parameters specified by the imaging protocol. Clinicians should select VADs labeled for high-flow contrast injections.

Summary of Evidence

Power-injectable devices, including PIVCs, PMLs, and CVADs, are designed to withstand high-pressure contrast delivery. In 1 study, optimized high-flow contrast injection through power-rated totally implanted VADs (TIVADs) improved contrast delivery without increasing complications.^{14(IIb)} Polyurethane power-injectable PMLs safely achieve flow rates up to 283 mL/min, supporting their use in diagnostic imaging.^{3(Va)} The manufacturer lists flow rates for PIVCs on each package.^{15(Vb)}

Recommendation 4: Vasopressor Administration via Peripheral VADs

Vasopressors may be administered through peripheral VADs (PVADs) when central access is not immediately available, provided the infusion is closely monitored for early signs of extravasation. Central access should be obtained as soon as feasible for ongoing therapy.

Summary of Evidence

Vasopressors are traditionally administered via central venous access due to the risk of tissue necrosis from extravasation. However, peripheral administration may be necessary to prevent treatment delays in urgent or emergent situations where central access is not immediately available. Authors have shown that the risk of serious complications is low with proper catheter selection.^{16,17(Vb, IIIb)} The standard of care supports infusing peripheral vasopressors under these conditions, emphasizing frequent reassessment and early transition to central access when appropriate.^{18(IVa)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Improved patient outcomes: Optimized catheter management reduces unplanned removals, lowers infection and thrombosis risks, and decreases adverse events and mortality.^{10,19–27}
- Cost efficiency: Fewer complications and better care coordination through specialist teams and evidence-based practices lead to more efficient resource use and cost savings.^{10,23,25,26}
- Reduced length of stay: Proactive complication prevention and improved catheter dwell time management

support shorter hospital stays and reduced health care costs.^{10,20,22–24,26}

Risks

- Integrating predictive modeling and surveillance tools into clinical practice necessitates staff training, Electronic health record adaptation, and continuous compliance monitoring, which may temporarily increase workload during implementation.^{8,10}
- Learning curve for clinical staff when transitioning to new protocols.^{10,21,28}
- Possible mechanical failure under high-pressure injections if catheter integrity is compromised.²⁹
- Extravasation of vesicant medications into the tissues can lead to tissue damage, nerve injury, necrosis, and in severe cases, necessitate surgical intervention.^{30,31}

Implementation Considerations

- Train staff in proper catheter selection to enhance compliance with best practices.^{10,27,28}
- Lower costs through better vascular access management.^{10,23}
- Prioritize smaller catheter-to-vein ratios to lower thrombosis risks.²⁹
- Using algorithms and frequently educating clinical staff to select the most appropriate intravenous device for the patient may result in longer catheter dwell time without complications, supporting patient safety.^{30,32}

Barriers to Implementation

- Resistance to practice change among health care providers.^{19–21,27}
- Variability in adherence across different hospital units.^{19,20}
- Treatment needs, patient vein options, and clinical staff understanding are often barriers to receiving timely orders for the most appropriate VAD and establishing consistent policy applications.^{30,32–34}

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Chapter 3.4—Infusate Characteristics

The physical and chemical properties of intravenous infusates are critical determinants in vascular access device (VAD) selection. Medications and solutions administered intravenously carry inherent risks, and incongruities between infusate characteristics and device type can result in serious complications, including phlebitis, thrombophlebitis, and premature catheter failure.

Key infusate characteristics such as pH, osmolality, and vesicant or irritant potential must be carefully evaluated. Solutions with extreme pH, high osmolality, or known tissue-damaging effects increase the risk of vessel irritation, inflammation, infiltration, extravasation, and vein sclerosis. These risks are amplified with prolonged therapy or rapid infusion rates.

For high-risk infusates, the use of central venous access devices (CVADs) is recommended. The greater blood flow in central veins enables rapid dilution of harsh infusates, reducing the potential for endothelial injury and systemic complications.

Establishing clear, evidence-based guidelines that match infusate properties to specific VAD types is essential to maintain device integrity, prevent complications, and ensure uninterrupted therapy. Tailoring VAD selection to the infusate improves patient safety, protects vascular health, and promotes optimal clinical outcomes.

Recommendation 1: Irritant and Vesicant Administration

Clinicians should evaluate the characteristics of all infusates for their vesicant or irritant potential, pH, osmolality, and particle content when determining the appropriate VAD.

Summary of Evidence

Infusate characteristics should always be considered in the broader context of vein health, therapy duration, and patient-specific risk factors. Infusates with properties that in-

crease the risk of vessel irritation, such as extreme pH, high or low osmolality (the concentration of dissolved particles per kilogram of solvent), or vesicant potential, are associated with complications including phlebitis, infiltration, and extravasation when delivered through peripheral veins. Standards recommend using CVADs for vesicant drugs whenever possible to reduce the risk of tissue injury.^{1(IVa)} Similarly, clinical alerts and authors of observational studies have emphasized that vesicants and irritants, especially in older adults or patients with vascular impairment, can lead to necrosis, compartment syndrome, or loss of function if extravasation occurs.^{2,3(Va, IIb)}

High particulate content (undissolved or suspended particles $\geq 10\text{--}25\ \mu\text{m}$) can also provoke phlebitis, microvascular obstruction, and tissue injury when infused intravenously.^{2,4(Va, IIb)} In a large prospective cohort study of over 5000 patients, a significantly higher rate of catheter failure was found in those receiving irritant fluids through peripheral devices, with phlebitis and extravasation accounting for nearly one-third of failures.^{4(IIb)} While many infiltration injuries today are managed conservatively, central access remains the safer option for infusates with a high risk of tissue injury or prolonged duration of therapy.^{1,5(IVa, IIb)} Evidence has supported tailoring device selection not only to the infusate characteristics but also to the patient's vascular health, therapy duration, and likelihood of complications.^{5(IIIb)}

Recommendation 2: Peripheral Administration of Infusates

When administering infusates through peripheral VADs (PVADs), clinicians should consider a combination of factors, including pH, osmolality, particle content, infusion rate, therapy duration, and vein condition.

Summary of Evidence

In extensive literature, the concept has been supported that infusates with extreme pH or high osmolality are associated with increased risks of phlebitis, thrombophlebitis, and infiltration when administered peripherally.^{1,6,7(IVa, IVa, IIIb)} However, complications have also been observed with infusates within normal ranges, particularly in patients with fragile veins or prolonged therapy.^{8,9(IIIb, IIIb)} Hemodilution strategies, such as using larger veins, slower infusion rates, or more dilute solutions, have been shown to reduce complications and improve catheter longevity.^{8,9(IIIb, IIIb)}

Authors of studies evaluating peripheral administration of hypertonic or concentrated solutions have emphasized the importance of site selection and infusion monitoring.^{7,9(IIIb, IIIb)} Wu et al. and others have demonstrated that proper dilution protocols reduce local tissue injury and catheter failure rates.^{8,9(IIIb, IIIb)} Clinicians should avoid relying on a single infusate characteristic or numeric thresholds alone and instead assess infusate compatibility within the full context of patient factors, the access site, and infusion goals.

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Fewer complications: Selecting devices based on therapy duration optimizes access and reduces device-related adverse events.¹⁰
- Targeted therapy support: Anticipating access needs and tailoring device selection enhances efficiency and supports effective therapy delivery.^{10–12}

Risks

- Tissue injury: Infiltration of vesicant medications into peripheral sites may cause necrosis, nerve damage, or require surgical intervention.^{13,14}
- Device overload: Inadequate assessment of infusion needs may lead to use of multiple devices, increasing complication risk.¹⁰

Implementation Considerations

- Ongoing clinician education: Use updated drug references, clinical algorithms, and case-based learning to guide device selection and support longer catheter dwell times.^{8,13}
- Vascular access teams: Engage trained teams across care settings to ensure appropriate device selection and insertion.¹⁵
- Electronic health record (EHR) integration: Incorporate decision support tools, such as physician order entry

prompts, into the EHR to standardize catheter selection and reinforce best practices.^{11,12}

Barriers to Implementation

- Staffing limitations: Lack of trained staff or vascular access specialists may impede implementation of best practices.¹⁰
- Clinical variability: Practice deviations may persist despite awareness of evidence, due to inconsistent adherence to guidelines.¹⁶
- Inappropriate device use: Overestimating access needs, such as ordering multilumen catheters without a clear indication, can expose patients to unnecessary risk.¹⁷

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Chapter 3.5—Anticipated Duration

The anticipated duration of therapy is a key determinant in selecting a vascular access device (VAD). Matching the device type to the expected treatment length supports continuity of care, reduces the need for repeated insertions, and minimizes complications such as infection, thrombosis, or mechanical failure.

Short-term therapies are generally suited for peripheral intravenous catheters (PIVCs), provided the infusate is compatible with peripheral administration. For intermediate durations, peripheral midlines (PMLs) may offer improved vessel preservation and greater patient comfort while reducing the need for frequent replacements. Long-term therapies often require central venous access devices (CVADs), such as peripherally inserted central catheters (PICCs), tunneled catheters, or totally implanted VADs (TIVADs), selected according to the regimen and individual patient factors.

Considering therapy duration during initial device planning enhances treatment efficiency, patient satisfaction, and cost-effectiveness. It also helps ensure the device remains functional throughout the intended course of care, reducing the risk of premature failure or unplanned interruptions. Integrating therapy duration with other clinical factors, including vein quality, infusate characteristics, and patient preferences, promotes safe, individualized, and patient-centered vascular access management.

Recommendation 1: Use of PIVCs for Short-Term Therapy

PIVCs are appropriate for intravenous (IV) therapies expected to last 5 days or fewer, provided the infusate is compatible with peripheral administration.

Summary of Evidence

In randomized controlled trials (RCTs) and cohort studies, PIVCs can reliably provide access for short courses of therapy, with average dwell times around 2.5 days.^{1,2(Ib, IIb)} Expert consensus recommends escalation to a longer-term device if therapy is expected to exceed 5 days or involve infusates that pose a higher risk to peripheral veins.^{3(Va)}

Note: PIVCs may remain viable for more than 5 days. The recommendation is asking the clinician to consider how long the patient is expected to need vascular access prior to choosing an appropriate device.

Recommendation 2: Use of PML for Intermediate Duration Therapy

PMLs are appropriate for IV therapy, lasting approximately 1–4 weeks when the infusate is peripherally compatible and central access is not required.

Summary of Evidence

In systematic reviews and multicenter cohort studies, PMLs have provided effective access for intermediate-duration therapy, with lower rates of bloodstream infection and occlusion than PICCs.^{4,5(IIIb, IIIa)} They are especially beneficial in patients with difficult IV access or when frequent replacement of PIVCs would be burdensome. Mechanical complications such as catheter-related venous thromboembolism remain a concern.^{6,7(IIa, IIIa)}

Recommendation 3: Avoid PICCs for Therapy ≤5 Days

PICCs should be avoided when the anticipated duration of IV therapy is 5 days or fewer, unless no other safe or reliable access is available.

Summary of Evidence

Authors of an extensive multicenter cohort study found that nearly 25% of PICCs were removed within 5 days, with a notable rate of complications, including venous thromboembolism (VTE).^{8(IIIa)} Expert consensus recommends avoiding PICC placement in these cases to reduce unnecessary central line risks.^{3(Va)}

Recommendation 4: PICC Use for Short or Long-Term Therapy

PICCs may be considered for short-term therapy when peripheral access is not feasible and for long-term therapy when other CVAD options are contraindicated or unavailable.

Summary of Evidence

In RCTs and cohort studies, PICCs can safely deliver centrally compatible infusates, including vesicants and parenteral nutrition, when peripheral options are inadequate or contraindicated.^{9,10(IVa, Ib)} In leukemia patients undergoing intensive chemotherapy, PICCs demonstrated lower infection and thrombosis rates than centrally inserted central catheters (CICCs).^{9,10(IVa, Ib)} However, PICCs are associated with higher risks of thrombotic events in patients with chronic kidney disease or high VTE risk and are not preferred for patients requiring central access for less than 14 days.^{3,11(Va, IVb)}

Recommendation 5: Long-Term Access Device Selection

For patients requiring long-term vascular access, clinicians should strongly consider tunneled-cuffed (Tc) catheters, tunneled noncuffed catheters, or TIVADs, as these options are associated with a lower risk of thrombosis compared to PICCs.

Summary of Evidence

Authors of multiple studies have supported the use of TIVADs over PICCs in patients with long-term vascular access needs, especially those at high risk for VTE. In a meta-analysis, Jiang et al. found that TIVADs were associated with a significantly lower risk of VTE in cancer patients than PICCs.^{12(IIa)} Similarly, Lin et al. reported reduced rates of catheter-related thrombosis with ports compared with PICCs in oncology populations.^{13(IIIb)}

Bertoglio et al. evaluated PICC ports (fully implanted devices inserted via peripheral veins). They found that, while they offer some advantages over external catheters, thrombosis rates remained higher than chest ports.^{14(IIIa)} Collectively, these findings support prioritizing tunneled or implanted chest ports over PICCs for long-term therapies in patients with elevated thrombotic risk, such as those receiving chemotherapy or prolonged infusions.

Recommendation 6: Thrombosis Risk and Device Selection

When selecting a VAD, clinicians should evaluate individual thrombosis risk factors, such as age >60, history of VTE, malignancy, obesity, critical illness, reduced mobility, and certain chemotherapies.

Summary of Evidence

Catheter-related deep vein thrombosis (CR-DVT) is a significant complication influenced by both patient-specific and device-related factors. Authors of numerous studies have identified older age, malignancy, body mass index ≥ 25 , critical illness, hyperglycemia, and certain chemotherapies as contributors to increased CR-DVT risk.^{15–17(IIIb, IVb, IIIb)} Device type also plays a critical role: in a meta-analysis by Lin et al. and a multicenter study by Haggstrom et al., TIVADs had significantly lower thrombosis rates than PICCs in cancer patients receiving long-term therapy.^{13,18(IIIb, IIIb)}

Recommendation 7: TIVAD Use

A TIVAD is strongly recommended for patients requiring long-term intermittent IV therapy. When continuous infusion is not required, TIVADs are associated with fewer complications and greater patient satisfaction than externalized CVADs.

Summary of Evidence

TIVADs offer a practical and durable option for patients requiring long-term intermittent IV therapy, such as chemotherapy. Compared with PICCs and external tunneled CVADs, TIVADs have resulted in lower infection rates, occlusion, and thrombosis.^{19–23(Ia, Ia, Ib, IIIb, IIIb)} They are generally associated with better patient quality of life and reduced disruption to daily activities.^{20,21(Ia, Ib)} In a large RCT (CAVA) and a systematic review by Yeow et al., TIVADs were more cost-effective than PICCs over time, especially when therapy extended beyond 6 to 12 months.^{19,20(Ia, Ia)}

TIVADs are best suited for long-term intermittent use. For patients requiring long-term continuous therapy (e.g., parenteral nutrition or 24-hour infusion), external Tc-CICC lines may be more appropriate. They allow stable, continuous access without the need for repeated needle access or the risk of dislodgement during daily activity or sleep.^{24(IIIb)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Optimal vascular access: Selecting the appropriate device based on therapy duration supports treatment needs while minimizing device-related complications.³
- Vessel preservation: Reduces the need for multiple PIVC insertions, supporting vessel health and lowering risks associated with improper device use.^{25,26}
- Fewer complications: Decreases bloodstream infection rates, enhances quality of life, and reduces overall complication rates.^{19,27}

- Vascular injury: Inappropriate device selection may increase the likelihood of inadvertent vascular complications.²⁸
- Access-related complications: Alternative catheter choices may raise the risk of thrombosis and infection during insertion or maintenance.²⁴
- Implementation burden: High costs, training demands, and staff learning curves may challenge early implementation.^{29–34}

Implementation Considerations

- Standardized care delivery: Use vascular access teams and integrate decision support tools within the electronic health record (EHR) to standardize care and improve outcomes.^{35–37}
- TIVAD use: Encourage use of implanted ports for long-term therapy, emphasizing their physical and emotional benefits.¹⁹
- Staff training and monitoring: Provide education on catheter use and management, implement EHR-based reminders, and establish surveillance systems for high-risk patients.^{29,31,32,34,38–41}

Barriers to Implementation

- Availability: Requires trained personnel and resource availability.³
- Inconsistencies: Evidence exists, but practices are inconsistently applied.²⁸
- Resistance: Provider resistance; budget constraints; unit variability in adherence.^{30,39,40,42–45}

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Chapter 3.6—Emergent vs Planned Access

The clinical setting in which vascular access is established, whether emergent or planned, significantly impacts device selection, insertion technique, and risk of complications. In true emergencies, rapid vascular access takes precedence over optimization. Peripheral intravenous catheters (PIVCs) and centrally inserted central catheters are often selected in these settings due to their speed and availability, even if conditions are less than ideal. Site sterility, catheter dwell time, and long-term complications must be weighed against immediate patient survival and stabilization.

Planned vascular access allows for careful assessment of patient-specific factors, including vein condition, anticipated duration of therapy, and compatibility of the infusate with peripheral administration. This approach supports using ultrasound guidance, optimal catheter selection, and improved insertion outcomes.

The goal in emergency care is not perfection but best clinical judgment. Once the patient is stabilized, transition to an appropriate long-term device should follow, reducing the cumulative risk of infection, thrombosis, and mechanical failure.

Recommendation 1: Use of PIVCs for Emergency Access

In emergency situations, PIVCs should be the first-line vascular access, provided that access can be achieved promptly. If ultrasound is readily available and can be used without delay, it should be considered to improve insertion success.

Summary of Evidence

Authors of studies have shown that PIVCs remain the most expedient and reliable initial emergency access, with first-pass success rates ranging from 46% to 79% depending on patient and operator factors. Ultrasound guidance improves outcomes, particularly in patients with difficult venous access, but may not be practical in time-critical situations. In emergent cases, up to 2 blind-stick attempts are considered acceptable before escalating to alternate access strategies.^{1–3(Ia, Ib, Ib)}

Recommendation 2: Intraosseous (IO) Access

When PIVC placement is not feasible in an emergency, IO access is the preferred alternative.

Summary of Evidence

IO access provides rapid and effective delivery of fluids and medications in life-threatening situations. Emergency guidelines endorse it as a primary alternative when peripheral access cannot be obtained quickly. If IO is not an option, escalation to central access may be necessary depending on clinical urgency and provider skill.^{4–6(Vb, Vb, Ia)}

Recommendation 3: Vasopressor Administration Through Peripheral Vascular Access Devices in Emergencies

Vasopressors may be administered via peripheral vascular access devices when central access is not immediately available, provided that infusion is closely monitored for signs of extravasation. For ongoing therapy, central access should be obtained as soon as feasible.

Summary of Evidence

Although central access is generally preferred for vasopressor administration due to the risk of tissue injury, authors of several studies have supported the short-term use of vasopressors through peripheral lines in emergencies. Complication rates remain low when appropriate monitoring and rescue protocols (e.g., antidotes) are in place. Authors of 1 systematic review reported a 3.4% complication rate, with no cases of tissue necrosis.^{7,8(Vb, IIb)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Immediate use: Successful PIVC or IO insertions can be used immediately.^{1–3,6}

Risks

- Extravasation or infiltration: Leakage of vesicants or irritants into tissue may cause necrosis, nerve injury, and potentially require surgical intervention.^{9,10}

Implementation Considerations

- Staff education: Using references with listings of high-risk solutions and medications that may indicate CVAD placement, using algorithms, and frequently educating clinical staff to select the most appropriate intravenous device for the patient may result in longer catheter dwell time without complications, supporting patient safety.^{10,11}

Barriers to Implementation:

- Timely implementation: Treatment needs, patient vein options, and clinical staff understanding are often barriers to receiving timely orders for the most appropriate vascular access device and establishing consistent policy applications.^{10–13}

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Section 4: Clinical Considerations for Insertion

Chapter 4.1—Preinsertion: Chart and Imaging Review

A thorough review of the patient's medical chart and available imaging is an essential preparatory step in vascular access planning. This process provides critical insights into patient-specific risk factors, such as coagulopathy, history of venous thromboembolism (VTE), prior access complications, and anatomical variations, that influence safe and effective device placement. This chapter is an overview of key elements to assess prior to insertion.

Key elements of the preinsertion chart review include current medications, known allergies, recent or planned surgeries, and relevant laboratory values. Reviewing prior vascular access history, including previous catheter types, insertion sites, and documented complications, supports vessel preservation and prevents repeated trauma to compromised sites.

Preprocedural imaging may reveal thrombosed or stenosed vessels, aberrant anatomy, or retained or embedded devices. These findings inform insertion strategy, reduce the risk of malposition or vascular injury, and help avoid procedural delays.

Standardizing chart and imaging review as a routine step enhances procedural safety, supports informed decision-making, and enables personalized care for vascular access. By prioritizing this foundational assessment, clinicians can proactively mitigate risks and improve outcomes across all vascular access device types.

This section of the guideline addresses clinical considerations relevant to the planning and insertion of vascular access devices. Topics include the selection of insertion sites, the use of imaging and tunneling techniques, strategies for avoiding complications, and procedural best practices across multiple anatomic sites and care settings.

Preinsertion chart and imaging review is a critical safety step before vascular access device placement. The following checklist summarizes key considerations to guide clinicians in identifying bleeding and thrombosis risks, assessing skin and anatomy, and reviewing the chart and imaging findings. It is intended as a quick reference; institutions may have additional requirements based on local policy or patient population.

Preinsertion assessment	Key elements
Bleeding risk ^{1,2}	• Coagulopathy • Thrombocytopenia • Anticoagulation or antiplatelet therapy
Thrombosis risk ^{3,4}	• History of venous thromboembolism, including: ◦ Catheter-related deep vein thrombosis ◦ Catheter-related venous thromboembolism ◦ Superficial vein thrombosis ◦ Pulmonary embolism ◦ Prior catheter occlusion or unexplained catheter dysfunction
Skin and tissue integrity ^{2,5}	• Fragile or aging skin • Medical adhesive–related skin injury • Catheter-associated skin injury • Dermatitis, eczema, or psoriasis • Burns, scars, grafts, or radiation injury • Genetic disorders affecting skin (e.g., epidermolysis bullosa, Ehlers-Danlos) • Chronic wounds or compromised healing
Anatomical challenges ^{6–8}	• Obesity or limited landmarks • Surgical alterations (e.g., mastectomy, axillary dissection) • Difficult intravenous access • Prior vascular surgery or device placement affecting access • Contractures

Chart review^{9–12}

- Current medications (anticoagulants, antiplatelets, immunosuppressants, chemotherapy)
- Allergies (chlorhexidine, latex, adhesives, medications)
- Recent or planned surgeries near the proposed site
- Relevant labs (e.g., INR, platelet count, creatinine)
- Comorbid conditions (e.g., chronic kidney disease, malignancy, diabetes, lymphedema)

Imaging and devices^{13,14}

- Prior vascular access history (device type, insertion site, complications)
- Vessel patency (stenosis, thrombosis, occlusion)
- Retained or embedded hardware (catheters, ports, stents, pacemakers)
- Aberrant anatomy (e.g., dextrocardia, persistent or duplicated superior vena cava)

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Chapter 4.2—Site Selection

Optimal site selection is a critical component of safe and effective vascular access. The insertion site directly influences the risk of complications, including phlebitis, endothelial injury, thrombosis, catheter malposition, and mechanical failure. Areas of flexion (e.g., antecubital fossa, wrist) are associated with higher rates of dislodgement, occlusion, and patient discomfort.

A thorough evaluation of vessel condition, depth, diameter, and adjacent anatomy supports successful placement and improved outcomes.

All vascular access devices (VADs) require careful site selection to mitigate risks, including catheter-related bloodstream infection (CRBSI), thrombotic events, bleeding, and nerve injury.

Clinical decision-making must be grounded in a comprehensive, patient-specific assessment that integrates therapy indication, duration, vessel health, and anatomic risk. Evidence-based insertion practices enable clinicians to reduce complications, prolong catheter dwell time, and optimize device function.

Recommendation 1: Catheter-to-Vessel Ratio

Health care providers should consider selecting the smallest gauge or French size catheter that meets the prescribed therapy requirements while ensuring adequate blood flow within and around the catheter.

Summary of Evidence

A low catheter-to-vessel ratio (CVR) reduces the risk of mechanical phlebitis, endothelial trauma, and thrombus formation. Catheter flow through an internal lumen is necessary for infusate delivery and blood sampling, but flow around the outer diameter of the catheter is equally critical to preserving vessel health.^{1(Vb)} Excessive catheter outer diameters compared with vessel diameter ratios have been linked to endothelial irritation, thrombotic events, and early catheter failure.^{1,2(Vb, IVa)}

Authors of multiple studies have supported the use of smaller diameter catheters to reduce phlebitis, especially when the CVR remains below the 33%–45% threshold. Larger catheters or poor site selection significantly increase the risk of thrombosis, particularly in peripheral veins and low-flow central vessels.^{1,3,4(Vb, IIIb,)}

Recommendation 2: Structured Assessment Using Rapid Assessment of Vascular Exit Site and Tunneling Options

Clinicians may consider using a structured decision-making tool, such as Rapid Assessment of Vascular Exit Site and Tunneling Options (RAVESTO), to guide the selection of insertion sites and exit sites. This approach supports individualized care planning, especially in complex cases or vulnerable populations.

Summary of Evidence

In a 2021 publication, the authors introduced RAVESTO as a decision tool for complex vascular access.^{5(Va)} The RAVESTO protocol provides a structured framework for evaluating

insertion and exit site alignment, particularly in patients with cognitive impairment, skin integrity issues, limited mobility, or a high risk of infection.^{5(Va)}

Recommendation 3: Chest-to-Arm Tunneling

Chest-to-arm (CTA) tunneling may be considered for patients requiring medium- to long-term central venous access when standard percutaneous catheter insertion results in suboptimal exit site location.

Summary of Evidence

The CTA technique offers an alternative for patients with challenging central access anatomy or skin integrity concerns, such as tracheostomy presence, breast surgery, or chest wall deformities. In a case series, CTA was successfully performed in patients requiring a low-profile exit site away from the chest. No intraprocedural complications (e.g., bleeding, misplacement, infection) were observed.^{6(IIIb)} The technique allows for improved exit site location while maintaining central venous tip positioning, reducing risks of dressing disruption, dislodgement, and patient discomfort. While larger prospective studies are needed, the CTA method presents a promising option for complex cases.

Recommendation 4: Blunt Tunneler Technique

Clinicians may consider using the blunt tunneler technique during peripherally inserted central catheter (PICC) or centrally inserted central catheter (CICC) insertion when repositioning the exit site improves dressing care, patient comfort, or securement.

Summary of Evidence

The blunt tunneler technique enables clinicians to relocate the exit site of the catheter without compromising access to a deeper or larger-diameter vessel. This approach is beneficial when the direct percutaneous site would result in:

- Poor dressing adherence (e.g., groin, axilla)
- Excessive movement or flexion (e.g., wrist, antecubital)
- Skin integrity issues (e.g., scarring, moisture, ostomies)

Authors of 1 study demonstrated the successful use of blunt tunneling for PICC and CICC placements, including femoral vein access, with no early complications reported.^{7(IIIb)} The technique enhanced flexibility in exit site selection and supported patient-specific care planning, including nontraditional femoral applications, such as midhigh tunneling, in access-limited patients.^{7,8(IIIb, Vb)}

Recommendation 5: Subcutaneous Track

Subcutaneous track techniques may be used during peripheral midline or PICC insertion to access a larger-diameter vein while maintaining a single skin puncture and placing the dressing in a more stable and manageable location.

Summary of Evidence

This approach involves using a longer needle at a low angle to extend the distance between the skin entry site and the venous insertion site. In contrast with blunt tunneling, which redirects the catheter after venous access is achieved, the subcutaneous track technique adjusts the angle and depth of initial needle entry to reach an optimal vessel while preserving an appropriate external exit site.

This method is practical when:

- The ideal vein is further from the optimal skin entry point.
- The direct path would place the dressing in an undesirable location.
- Vein selection is limited by previous access, thrombosis, or scarring.

Authors have reported reduced rates of^{9–12(IIIb, Ia, IIIb, Ib)}:

- Central line–associated bloodstream infection (CLABSI)
- Catheter dislodgement
- Thrombosis

Additionally, authors of 1 study demonstrated that tunnel lengths of 4–6 cm struck the optimal balance between dwell time, comfort, and stability in oncology patients.^{12(Ia)}

Recommendation 6: Prioritize Axillary/Subclavian for CICC

When a CICC is required, clinicians should prioritize the axillary/subclavian vein region over the internal jugular and femoral veins when anatomically and clinically feasible. This site is associated with lower risks of catheter-related thrombosis (CRT) and CRBSI, and it offers advantages for long-term function, dressing integrity, and patient comfort.

Summary of Evidence

The axillary/subclavian vein region offers a favorable balance of accessibility, vessel diameter, and low complication rates for CICCs.

Authors of numerous studies and meta-analyses have supported^{13–16(IIa, IIIb, Ib, IIIa)}:

- Lower colonization and CLABSI rates compared with internal jugular vein (IJV) and femoral veins.
- Reduced CRT, particularly in high-risk populations.
- Greater anatomical stability for long-term tunneled and implanted devices.

While some clinicians distinguish between ultrasound-guided axillary and landmark-guided subclavian, for the purpose of insertion outcomes, this anatomical segment is best treated as a single, functionally unified access site. The collective evidence supports axillary/subclavian access as the preferred first-line option for CICC placement in stable adult patients, especially when minimizing risks of infection and thrombosis is crucial.^{13,14(IIa, IIIb)}

Recommendation 7: Avoid Femoral Vein Access

The femoral vein should generally be avoided for short-term, nontunneled central venous access in adult patients when other sites are available.

Summary of Evidence

The femoral site presents the highest risk of infection among common central access locations. In a systematic review of intensive care unit (ICU) patients, femoral vein insertion was associated with higher CLABSI rates than axillary/subclavian and IJV access and with a greater risk of colonization by multidrug-resistant organisms such as *Pseudomonas aeruginosa* and *Escherichia coli*.^{13,17(IIa, IIIb)} Authors of another study noted increased local inflammation and bloodstream infection rates with femoral access in hematologic malignancy patients.^{14(IIIb)} Authors of a third study further reported that nonfermenting gram-negative bacilli were disproportionately isolated from femoral site-related infections.^{18(IIIa)} While femoral access remains useful in emergent or contraindicated upper body scenarios, it should be re-evaluated for replacement as soon as safer alternatives become available.

Recommendation 8: Central VADs Favor Right-Sided Venous Access

When placing central VADs (CVADs) that terminate in the superior vena cava (SVC), clinicians should favor right-sided access when anatomically and clinically feasible. This approach enhances tip trajectory, reduces the risk of malposition, and minimizes the likelihood of thoracic duct injury.

Summary of Evidence

Right-sided venous access is preferred for CVADs that terminate in the SVC, including PICCs, CICCs, tunneled catheters, and totally implanted VADs. The right innominate vein provides a straighter path to the SVC, improving tip accuracy and reducing malposition risk. In contrast, left-sided access traverses the longer, more angulated left brachiocephalic vein, increasing the chance of tip deviation into the azygos vein or other unintended vessels.^{19,20(IIb, IIIb)}

Left-sided access also carries a higher risk of thoracic duct injury, particularly in neck or chest insertions.^{2(IVa)}

Recommendation 9: Avoid Injury to High-Risk Structures

Clinicians should avoid vascular access insertion sites near major nerves, arteries, and lymph nodes whenever possible. Real-time ultrasound guidance is recommended to reduce the risk of incidental anatomical injury, particularly when working in high-risk anatomical regions.

Summary of Evidence

Anatomical regions containing major neurovascular structures pose a higher risk of injury during vascular access procedures. These include the brachial plexus, femoral nerve, and carotid or subclavian arteries. Injury to these structures can result in severe complications such as hematoma, thrombosis, ischemia, stroke, or neuropathy.^{21,22(IIIb, IIIb)}

Ultrasound guidance is the only commonly available bedside imaging modality that allows for real-time visualization of adjacent nerves and arteries, enabling clinicians to avoid high-risk zones.^{23(IVa)} Routine ultrasound guidance during catheter insertion has been associated with dramatically reduced complication rates, including near elimination of pneumothorax and arterial injury during tunneled dialysis catheter placements.^{22(IIIb)} Although nerve bundles and lymph nodes are not always visible with ultrasound, their avoidance should be prioritized when possible, especially in immunocompromised or oncology patients.^{22(IIIb)}

Recommendation 10: Radial Artery Site

The radial artery is the preferred site for arterial catheterization in adult patients due to its superficial location, robust collateral circulation, and lower risk of complications compared with femoral or brachial sites.

Summary of Evidence

Radial artery access is associated with fewer major complications (e.g., hematoma, ischemia, and infection) than femoral or brachial sites. Its anatomic location allows for easy palpation, real-time ultrasound guidance, and lower risk of limb ischemia due to the collateral support of the ulnar artery.^{24–26(Va, Ib, Ib)}

Authors of meta-analyses and randomized clinical trials comparing radial versus femoral or brachial approaches have shown:

- Lower risk of major bleeding and limb-threatening ischemia with radial access.^{26,27(Ib, Ib)}
- Higher first-attempt success rates and fewer complications when ultrasound guidance is used.^{25,28,29(Ib, Ia, IIIa)}
- Improved patient comfort and mobility, particularly in awake, nonsedated patients.^{30(Vb)}
- The superficial and accessible position of the radial artery also enables better infection control, easier dressing maintenance, and securement in most cases.^{31,32(IVa, IVb)}

Recommendation 11: Avoid Flexion Zones for Radial Artery Catheter Insertion

Radial artery catheters should be placed outside of areas of flexion (e.g., wrist crease) to reduce the risk of catheter kinking, occlusion, and dysfunction. Site selection should account for individual anatomical variability and support stable dressing and catheter function.

Summary of Evidence

Radial artery anatomy varies significantly between individuals. Cannulation sites in or near high-flexion zones, such as the wrist, are associated with higher rates of catheter dysfunction, including kinking, occlusion, and waveform loss.^{29,32(IIIa, IVb)} These areas are also more prone to dressing disruption, increased motion, and long-term complications such as localized vessel injury or CRT.^{33(Ib)}

Ultrasound imaging enables better assessment of radial artery depth and trajectory, facilitating placement in regions with

less movement and more stable tissue planes, which improves device performance and patient comfort.^{25,26(Ib, Ib)}

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Clinical Considerations

Benefits

- Reduced thrombosis risk with axillary/subclavian access: Selecting the axillary/subclavian vein over the internal jugular or femoral veins can reduce the risk of catheter-related deep vein thrombosis.^{15,34–37}
- Lower infection risk with appropriate site selection: Subclavian vein access has the lowest colonization risk compared to internal jugular and femoral veins, reducing the risk of CRBSIs.^{13,14,38}
- Decreased dislodgement and infection risk with tunneling tools: Use of the RAVESTO tool helps identify optimal exit sites for tunneling, lowering the risk of infection and dislodgement, particularly in high-risk patients.⁵

Risks

- Higher malposition with left-sided access: Left-sided central lines, especially via the left IJV, are more prone to malposition due to anatomic challenges.^{2,20}
- Increased nerve injury near dense nerve areas: Insertion near high-risk anatomical regions (e.g., brachial plexus or femoral nerve) increases the risk of nerve damage.^{39,40}
- CRBSI variability by patient population: Although subclavian access reduces CRBSI risk in hematologic malignancy patients, it may not offer additional benefit over internal jugular access in transplant populations.^{14,38}

Implementation Considerations

- Use smallest effective gauge: Using the smallest catheter gauge necessary helps maintain flow while reducing complications.⁴¹
- Conduct risk stratification before placement: Assess risk factors such as age, malignancy, body mass index, and infusion characteristics when selecting the access site and device.^{42–44}
- Prefer right-sided CVAD insertion: Right-sided CVAD placement is preferred to reduce malposition risk, unless contraindicated.^{2,20}

Barriers to Implementation

- Inconsistent application of CVAD tunneling protocols: Limited familiarity with the RAVESTO tool or tunneling best practices may reduce clinician confidence in individualized exit site selection.⁵

- Conflicting infection risk data in select populations: Conflicting findings regarding subclavian versus internal jugular access in specific populations (e.g., transplant patients) may complicate decision-making.^{14,38}

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Chapter 4.3—Vessel Preservation Considerations

Preserving vessel health is a core priority in vascular access practice, especially for patients requiring multiple or long-term therapies. Repeated cannulation attempts can lead to thrombosis, infiltration, endothelial damage, and eventual loss of viable access sites, compromising both treatment delivery and patient outcomes.

Common causes of failed cannulation include inadequate assessment, poor technique, inaccurate vessel identification, and suboptimal site selection. These risks are amplified in patients

with difficult intravenous access (DIVA), where unsuccessful attempts increase discomfort, delay therapy, and jeopardize future access options.

Although insertion-related complications are addressed in a separate section, this chapter focuses on preserving vessel integrity through the selection of appropriate devices, real-time imaging guidance, and timely escalation when challenges arise. These strategies support safer insertions, reduced complication rates, and the preservation of vessel health.

Recommendation 1: Escalation in DIVA patients

In patients with DIVA, clinicians should escalate to the use of advanced insertion techniques, a vascular access specialist, or both before failed attempts.

Summary of Evidence

DIVA is associated with increased risk of multiple failed insertion attempts, vessel trauma, and early catheter failure. Authors of studies have shown that repeated blind or unsuccessful insertions contribute to loss of viable access sites, increased infection risk, and delays in care delivery.^{1,2(IIa, Ib)}

Escalation to trained clinicians using ultrasound-guided or advanced insertion techniques improves first-attempt success and preserves vessel health, especially in high-risk patients.^{3–5(Ib, Ib, Ib)} Proactive escalation may reduce the need for premature central access and improves patient satisfaction.^{6(Ib)}

Recommendation 2: Ensure Adequate In-Vessel Catheter Length for All Peripheral Insertions

For all peripheral vascular access device (PVAD) insertions, clinicians should select an appropriate device length for the target vessel and ensure that a sufficient portion of the catheter resides within the vessel to promote stability and reduce the risk of infiltration, dislodgement, and early catheter failure. Clinical guidance suggests that, when feasible, at least two-thirds of the catheter should reside within the vein lumen.

Summary of Evidence

Adequate in-vessel catheter length is a key determinant of secure device placement and long-term function. Clinical guidelines and vascular access literature recommend that at least two-thirds of the catheter length reside within the vessel lumen to reduce the risk of complications such as infiltration, dislodgement, or mechanical failure.^{7(IVa)}

This principle applies to all patient populations but is especially critical for patients with deep, mobile, or difficult-to-access veins or arteries, where standard-length devices may not provide sufficient purchase. Longer peripheral catheters (5–6 cm) have been shown to reduce failure rates, especially in settings where ultrasound guidance is used to reach deeper vessels.^{2(Ib)}

Tailoring device length to vessel characteristics improves both clinical outcomes and patient experience.

Recommendation 3: Catheter-to-Vessel Ratio for Thrombosis Risk Reduction

Clinicians should ensure that the catheter-to-vessel ratio (CVR) does not exceed 45%, with a preferred target of <33%, to reduce the risk of catheter-related thrombosis.

Summary of Evidence

CVR quantifies the percentage of the vein lumen occupied by the catheter. Authors of studies have shown that a CVR >45% doubles the risk of thrombosis, particularly in patients with malignancy or hypercoagulable states.^{8,9(IIIb, Vb)}

Maintaining a CVR <33% reduces stasis, improves hemodilution, and supports long-term catheter function. Special caution is required in patients receiving chemotherapy, with

reverse taper catheters, or known vascular compromise. Device choice and vein selection must be made concurrently to minimize risk.^{8,10(IIIb, IIb)}

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Clinical Considerations

Benefits

- Improved safety and satisfaction: Ultrasound guidance improves needle accuracy, reduces complications and delays, and increases first-attempt success, leading to better outcomes and greater patient comfort.^{5,11,12}
- Economic efficiency: Despite initial costs, ultrasound use results in long-term savings through reduced complications, more efficient clinician time use, and decreased waste of supplies from failed attempts.^{5,11–13}

Risks

- Financial and operational burden: The initial purchase of ultrasound equipment, ongoing maintenance, and associated supply costs (e.g., gel, probe covers) represent a significant investment.¹⁴ Additionally, the setup, use, and cleanup of ultrasound machines can extend procedure time.^{15,16}
- Training burden and skill loss: Ultrasound-guided access requires ongoing training, and reliance on ultrasound may reduce landmark-based skills needed in some settings.^{11,13,15,17}
- Visualization limitations: Certain anatomical areas, such as the subclavian region, may be more difficult to visualize with ultrasound, potentially complicating catheter placement.¹¹

Implementation Considerations

- Competency and training: Ongoing training and competency validation in ultrasound-guided vascular access are essential to ensure safe and effective use.^{11,13,15,17}
- Implementation consideration—equipment availability and support: High-quality, functional ultrasound machines must be consistently available. Institutions should establish regular maintenance schedules, ensure adequate supplies (e.g., probes, gel, disposable covers), and have protocols for prompt repair or replacement.^{10,13}

Barriers to Implementation

- Cost and revenue impact: Upfront costs for ultrasound equipment and training may temporarily reduce revenue. The need for ongoing investment in maintenance and training further challenges implementation, particularly in resource-limited settings.^{14,18}

- Cultural resistance and perceived skill loss: Clinician resistance to change and reliance on traditional landmark-based techniques can hinder adoption. Some also fear that increasing ultrasound use may erode their manual skills.^{12,14}
- Limited device access and planning gaps: Inadequate availability of alternative vascular access devices and lack of care plans for patients with limited options may complicate efforts to avoid high-risk placements, such as catheters with a CVR >45%.^{14,18}

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Patient positioning is a critical but often underappreciated component of successful vascular access insertion for all vascular access devices (VADs). It affects vein visualization, catheter trajectory, procedural efficiency, and patient comfort. While certain positions, like supine or Trendelenburg, are often used as defaults, many patients cannot tolerate these postures due to clinical or anatomical limitations.

Unlike other insertion elements that lend themselves to standardized workflows, positioning must remain highly individualized, shaped by the patient's condition, body habitus, care environment, and the provider's experience. Across surgical, home care, and emergency settings, clinicians must tailor positioning strategies to the unique needs of each patient. This chapter offers practical guidance and evidence-based positioning strategies across common scenarios but emphasizes a core truth: No one-size-fits-all approach exists. Successful access requires flexibility, clinical judgment, and a willingness to think beyond the supine.

General Principles of Positioning for Vascular Access Success

- Promote vein visibility and needle trajectory without causing discomfort or harm.
- Consider neutral limb positioning to avoid tension or compression.
- Prioritize anatomical alignment (e.g., shoulder retraction for axillary access).
- Avoid high-flexion joints.
- Adapt to the care environment (hospital bed to kitchen table).
- Never compromise airway, perfusion, or patient stability for access convenience.

Recommendation 1: Comfortable Arm Position for Peripherally Inserted Catheters

A stable, comfortable patient arm position should be maintained during insertion of all peripherally inserted catheters to support vein access, facilitate catheter advancement, and reduce the risk of malposition or mechanical complications.

Summary of Evidence

Arm positioning influences cannulation success, catheter stability, and tip location, particularly for peripheral midline (PML) and peripherally inserted central catheter (PICC) insertions. Changes in limb position can alter catheter trajectory and cause tip migration, particularly a cephalad shift in PICCs.^{1,2(IIIb, IIIb)} Maintaining a comfortable, stable arm position during and after insertion improves catheter trajectory and reduces the likelihood of kinking, malposition, or migration.^{3(Ia)}

In addition, supine positioning has been shown to increase vein diameter, visibility, and palpability compared with seated positioning, improving access success rates, even in difficult intravenous access patients. In a prospective trial of healthy adults,

researchers found a statistically significant increase in forearm vein cross-sectional area and visibility when patients were supine with a tourniquet, supporting this as a preferred position for peripheral intravenous catheter insertion when possible.^{4(IIIb)}

Recommendation 2: Trendelenburg Position for Internal Jugular Vein Access

Trendelenburg positioning may be used to improve success rates during internal jugular vein (IJV) catheterization by enhancing venous distension and reducing air embolism risk.

Summary of Evidence

Trendelenburg positioning increases venous filling and cross-sectional vein diameter, which improves the likelihood of successful IJV cannulation.^{5(IIa)} However, many critically ill patients do not tolerate this position due to cardiorespiratory compromise or increased intracranial pressure, limiting its application.^{6(IVb)}

Recommendation 3: Positioning Considerations for Obese Patients Requiring Axillary/Subclavian Access

For obese patients undergoing axillary/subclavian vein catheterization, a neutral or slightly extended head position with gentle midshoulder retraction may enhance vessel accessibility and procedural success.

Summary of Evidence

In patients with increased body habitus, excess soft tissue can obscure vascular landmarks. Adjusting head and shoulder position improves thoracic inlet alignment, increases axillary/subclavian vein cross-sectional area, and improves ultrasound visualization and cannulation success.^{7(IIa)}

Recommendation 4: Upright Insertion for Patients Unable to Lie Flat

For patients unable to tolerate a supine position due to respiratory compromise, musculoskeletal limitations, or other clinical factors, clinicians may consider performing catheter insertion in a seated or semiupright position when feasible and safe to do so.

Summary of Evidence

In patients with orthopnea, dyspnea, or spinal deformities, upright positioning allows safe and effective insertion of PICCs, PMLs, or totally implanted VADs. Authors of studies have demonstrated that insertions in a seated position are feasible and safe when supine positioning is contraindicated.^{8(IIIb)}

Recommendation 5: Prone-Dependent PICC Insertions

PICC insertion may be safely performed in the prone position when repositioning is not feasible due to patient condition (e.g., spinal injury, severe respiratory failure, or prone ventilation). Procedural success requires specific technique modifications and team coordination.

Summary of Evidence

Prone insertion of PICCs has been successfully described in case studies involving critically ill patients. Safe performance requires modification of technique, including lateral or posterior probe positioning, secure arm stabilization, and team-based coordination.^{9(vb)} Imaging and tip confirmation may require alternate workflows.

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Clinical Considerations

Benefits

- Improved access in high-risk patients: Alternative positioning strategies, such as PICC-PORT placement in the sitting position or prone PICC insertion, offer safe and effective access for patients who cannot tolerate the supine position.^{8,9}
- Increased procedural success: Techniques such as Trendelenburg positioning for IJV access and head/shoulder adjustment in obese patients improve vein accessibility and increase catheterization success rates.^{5,7}
- Reduced malposition risk: Maintaining a neutral arm position and using real-time ultrasound with post-insertion imaging helps prevent catheter tip migration and malposition.^{1,2,10}

Risks

- Contraindications to standard positioning: Critically ill patients may be unable to tolerate positions like Trendelenburg due to respiratory distress, hemodynamic instability, or increased intracranial pressure.⁶
- Catheter migration due to patient movement: Body position changes post-insertion (e.g., sitting to supine) can result in catheter tip displacement, potentially compromising function or safety.¹
- Procedural complexity: Techniques like prone PICC insertion require significant procedural adjustments and specialized skill, which may increase difficulty and error risk.⁹

Implementation Considerations

- Patient assessment: Evaluate individual tolerance for positioning (e.g., Trendelenburg, supine, prone) prior to catheter placement to minimize complications.^{5,6,8}
- Use of imaging and guidance: Employ real-time ultrasound and confirmatory imaging to ensure correct tip placement, especially in patients with altered body positions.¹
- Staff training on modified techniques: Clinicians should be trained in alternative positioning methods (e.g., prone or sitting PICC placement) and how to adapt procedures accordingly.⁹

Barriers to Implementation

- Limited expertise in nonstandard techniques: Lack of familiarity or training in prone or sitting-position catheter placements may limit adoption of these safe alternatives.⁹
- Equipment and imaging constraints: Access to real-time ultrasound and postplacement imaging may be limited in some settings, affecting catheter tip verification.¹
- Variability in patient cooperation: Patients unable to maintain steady or neutral positioning (due to agitation, discomfort, or physical limitations) may increase the risk of malposition or procedural failure.^{1,2,10}

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Chapter 4.5—Pain Management Strategies

Pain during vascular access device (VAD) insertion is often underestimated, especially in adult patients. While pediatric protocols routinely integrate analgesia and comfort techniques, pain management in adult vascular access remains inconsistent, frequently dismissed, or bypassed altogether.

For patients who require repeated access, such as those receiving chemotherapy, dialysis, or critical care, this oversight is more than discomfort; it is cumulative harm. Poorly managed pain leads to vasoconstriction, increased insertion attempts, elevated anxiety, and in many cases, mistrust and trauma that follow patients across care episodes.

Effective pain control is not optional. It improves procedural success, supports patient cooperation, and demonstrates respect for the patient's experience. Pharmacologic options can be paired with nonpharmacologic techniques. These interventions are simple, evidence-based, and cost-effective.

However, barriers remain, such as time pressure, lack of protocols, and clinician bias, all of which contribute to undertreatment. Standardizing preprocedural pain strategies as part of routine VAD insertion planning reinforces the values of safety, dignity, and patient-centered care. Everyone deserves vascular access that is skilled and compassionate.

Recommendation 1: Use of Topical Anesthetics for Peripheral Access

Topical anesthetics, such as lidocaine sprays, vapocoolants, or anesthetic creams, may be applied aseptically before peripheral intravenous catheter (PIVC) insertion to reduce pain associated with skin puncture.

Summary of Evidence

A variety of topical agents are commercially available in both spray and cream formulations. Selection should be guided by local availability, regulatory approval, and clinical context. A Cochrane review of 12 randomized controlled trials found that vapocoolant spray reduced insertion pain by an average of 12.5 points on a 100-point visual analog scale compared with placebo or no treatment.^{1(1a)} A second systematic review and network meta-analysis identified 2% lidocaine cream as the most effective topical agent, with pain score reductions of approximately 13% without compromising sterility or procedural success.^{2(IIIa)}

Recommendation 2: Use of Intradermal and Subcutaneous Local Anesthetic

Intradermal and subcutaneous lidocaine may be administered before the insertion of peripheral midlines, central VADs, and arterial catheters. It may also be used for PIVC insertions.

Summary of Evidence

Intradermal and subcutaneous infiltration with 1%–2% lidocaine provides deeper anesthesia than topical agents, particularly for insertions involving larger-bore needles or longer procedural duration. Authors of multiple trials have supported

lower pain scores, improved patient satisfaction, and no increase in insertion difficulty or complications.^{2,3(IIIa, 1b)}

Intradermal or subcutaneous infiltration is based on the clinician's assessment of the depth of the vessel, possible tunneling, or totally implanted VAD placement.^{2,3(IIIa, 1b)} In comparative studies, intradermal lidocaine was found to be as effective as topical anesthetic creams and more effective than a placebo for venous cannulation discomfort.^{3,4(1b, 1b)}

Recommendation 3: Use of Nonpharmacologic Interventions

Clinicians may use nonpharmacologic interventions, such as distraction techniques, guided imagery, aromatherapy, or virtual reality (VR), as adjuncts to reduce anxiety and perceived pain during vascular access insertion.

Summary of Evidence

In a randomized trial, VR distraction combined with visual stimuli reduced insertion-related pain by 28% compared with standard care. A follow-up study combining VR, rose oil aromatherapy, and handholding reduced pain by 48%, with no workflow delays or complications.^{5,6(1a, 11b)} These methods help modulate pain perception and improve patient experience.⁵

Recommendation 4: Assess and Confirm Adequate Anesthesia

Clinicians should assess and confirm adequate local anesthesia before proceeding with catheter insertion. If the patient experiences significant discomfort, pause to reassess the effectiveness or dosage of the anesthetic before continuing.

Summary of Evidence

Inadequate anesthesia leads to increased patient movement, distress, and procedure-related complications. Failure to address visible discomfort has been associated with higher rates of malposition, infiltration, and negative patient recall. Reinforcing anesthetic verification as a standard procedural checkpoint improves both clinical outcomes and trust in care.^{1,2(1a, IIIa)}

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Clinical Considerations

Benefits

- Reduced procedural pain: Nonpharmacological methods such as VR, aromatherapy, and handholding significantly reduce pain during intravenous (IV) insertion, with up to a 48% decrease in pain scores reported.^{5,6}
- Topical anesthetics, including vapocoolant sprays and 2% lidocaine, also effectively lower pain scores by 12.5%–13% on standardized scales.^{1,2}

- Higher patient satisfaction: Both VR-based and topical anesthetic interventions are associated with improved patient comfort and satisfaction without interfering with procedural success.^{1,2,5,6}
- Rapid onset and workflow compatibility: Topical agents like vapocoolants act quickly (within seconds to 2 minutes) and do not delay IV placement or compromise aseptic technique.^{1,2}

Risks

- Limited generalizability: Evidence supporting VR and aromatherapy is promising but based on small studies; broader replication is needed before widespread adoption.^{5,6}
- Potential allergic or skin reactions: Though rare, patients may experience skin irritation or allergic responses to topical anesthetics like lidocaine.^{1,2}
- Distraction-related limitations: Some patients may find VR equipment uncomfortable or distracting in ways that interfere with cooperation during the procedure.⁵

Implementation Considerations

- Training and protocols: Staff should be trained in the application of VR systems, topical anesthetics, and distraction techniques to ensure consistent use and patient safety.^{1,2,5,6}
- Patient selection: Not all patients may be suitable for VR or aromatherapy (e.g., those with sensory sensitivities or respiratory issues); interventions should be tailored accordingly.^{5,6}
- Integration into workflow: Both nonpharmacological and pharmacological interventions must be integrated into clinical routines without delaying IV insertion; authors of existing studies have reported compatibility.^{1,2,5,6}

Barriers to Implementation

- Equipment availability and cost: VR headsets, optical illusion tools, and aromatherapy supplies may not be readily

available in all settings, especially those with limited budgets.^{5,6}

- Limited evidence for VR strategies: While initial findings are positive, the lack of large-scale studies may limit institutional buy-in or formal guideline endorsement.^{5,6}
- Variable clinician adoption: Differences in provider familiarity, confidence, or perceived value of pain management adjuncts may hinder consistent use of these strategies.^{1,2}

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Chapter 4.6—Vein Visualization

Vein visualization is a foundational skill in vascular access practice, encompassing both technology-assisted techniques and manual assessment strategies. While ultrasound has transformed modern insertion practices by improving accuracy, safety, and first-attempt success, not all care settings or clinicians have access to this technology. For many patients and providers, especially those in ambulatory, home, or underresourced settings, reliance on visual, tactile, and positioning-based methods remains essential to identifying viable veins. When available and appropriately applied, ultrasound guidance is the gold standard for vascular access in patients with difficult intravenous access (DIVA), deep vessels, or high-risk

anatomy. However, vein visualization should not be considered an ultrasound-or-nothing practice. Tools such as near-infrared (NIR) imaging, transillumination, and even simple moist heat and limb dependency techniques can enhance visibility and support successful cannulation. Success does not come from the tool alone but from the clinical judgment behind it.

Recommendation 1: Use Visualization Before All Vascular Access Insertions

Clinicians should assess and visualize the target vein before vascular access device insertion, using the most appropriate method available in their care setting. Visualization may in-

clude direct inspection, palpation, or technology-assisted modalities such as ultrasound or NIR imaging.

Summary of Evidence

Vein visualization before insertion improves first-attempt success and reduces procedural complications. Authors of multiple systematic reviews and randomized controlled trials have demonstrated that ultrasound guidance significantly increases the success of cannulation, especially in patients with DIVA.^{1-3(IIb, Ia, Ib)}

While visualization methods vary across clinical settings, all vascular access insertions should begin with an assessment of vein location, depth, and patency using the best available visualization technique, whether visual, tactile, or technology-assisted.^{1-4(IIb, Ia, Ib, IVa)}

Recommendation 2: Dynamic Ultrasound Guidance for Peripheral Intravenous Catheter Insertion

Clinicians should use dynamic (real-time) ultrasound guidance during vascular access insertion, particularly for patients with challenging intravenous (IV) access, deep vessels, or non-palpable veins, to enhance cannulation success and minimize complications.

Summary of Evidence

Dynamic ultrasound guidance enhances first-attempt success, reduces the number of attempts, and lowers the risk of mechanical complications, including infiltration, arterial puncture, and catheter malposition. In a meta-analysis, van Loon et al. confirmed that dynamic ultrasound significantly outperformed palpation or landmark-based methods for PIVC insertion.^{1(IIb)}

Static ultrasound (where the vessel is located and marked but not actively visualized during cannulation) is less effective, especially in high-risk patients.^{3(IIb)} Dynamic use of ultrasound allows the clinician to continuously visualize the needle tip, vessel trajectory, and insertion angle, resulting in improved accuracy and patient safety.^{1-4(IIb, Ia, Ib, IVa)}

Authors of multiple studies have recommended assessing depth (<1.5 cm), nonthrombosed status, and straight trajectory prior to PIVC insertion. Preprocedural mapping also supports appropriate catheter length planning and optimizes the catheter-to-vein ratio, reducing thrombosis risk.^{5,6(IIIb, Vb)}

Recommendation 3: Dynamic Needle Tip Positioning

When using ultrasound to guide vascular access insertion, clinicians should employ dynamic needle tip positioning (DNTP) to enhance procedural accuracy and minimize the risk of mechanical complications.

Summary of Evidence

DNTP techniques are preferred over static or blind insertion approaches and should be used by trained personnel. DNTP refers to the continuous tracking of the needle tip under real-time ultrasound as it advances toward and enters the vessel. Compared with static techniques or short-axis scanning with out-of-plane insertions, DNTP improves tip visibility, trajectory control, and first-attempt success, especially for deep or difficult-to-access vessels.^{2,4(Ia, IVa)}

In a randomized controlled trial, Privitera et al. demonstrated that DNTP techniques, using either short- or long-axis guidance, significantly improved success rates and reduced complications in patients with difficult access.^{7(IIb)} This technique is increasingly promoted in vascular access literature as the preferred method for ultrasound-guided insertion.^{1-4,7(IIb, Ia, Ib, IVa, Ib)}

Recommendation 4: Ultrasound-Guided Insertion for Central Venous Access Devices

Clinicians should use dynamic ultrasound guidance during insertion of centrally inserted catheters and peripherally inserted central catheters (PICCs) to reduce insertion-related complications and improve procedural success.

Summary of Evidence

Ultrasound guidance significantly reduces the risk of arterial puncture, nerve injury, pneumothorax, and failed cannulation during central venous access procedures. It is the standard of care for internal jugular vein and axillary/subclavian vein access, as recommended by major guidelines and standards.^{1-4,7(IIb, Ia, Ib, IVa, Ib)}

Real-time visualization of vessel anatomy and needle advancement enables safer and more accurate cannulation, particularly in patients with altered anatomy, coagulopathies, or poor landmarks. DNTP techniques further enhance safety by minimizing misplacement and vessel trauma.⁷ For PICCs, ultrasound supports vein mapping, trajectory alignment, and selection of vessels with appropriate diameter and depth, especially in the upper arm.^{1-4,7(IIb, Ia, Ib, IVa, Ib)}

Recommendation 5: Ultrasound Guidance for Radial Artery Catheterization

Clinicians should use dynamic ultrasound guidance during radial artery catheter insertion to improve first-attempt success and reduce complications.

Summary of Evidence

Ultrasound guidance improves first-pass success, shortens procedure time, and reduces the risk of complications, including hematoma, posterior wall puncture, and vasospasm.^{1-3,7(IIb, Ia, Ib, Ib)} However, the radial artery is surrounded by nerves and sensitive tissues, and arterial puncture is consistently rated as more painful than other venous cannulation.^{1-4,7(IIb, Ia, Ib, IVa, Ib)}

Pain management is often overlooked in arterial procedures. The use of local anesthetic (e.g., lidocaine infiltration) prior to radial cannulation has been shown to reduce pain without impairing visualization or success.^{8(IIb)} Insertion near the wrist crease should be avoided when possible to reduce movement-related failure, improve dressing adherence, and enhance catheter stability.^{9,10(Vb, IVa)}

Recommendation 6: Use Ultrasound for Vessel Selection During PICC and Peripheral Midline Placement

Clinicians should use ultrasound to assess and select the optimal vein prior to peripheral midline (PML) or PICC placement. Vein selection should be based on vessel depth, diameter, compressibility, and trajectory, with preference given to sites

that support catheter-to-vessel ratio, securement, and long-term function.

Summary of Evidence

Ultrasound provides a comprehensive assessment of the upper-arm vasculature before insertion. Proper mapping improves vein selection, minimizes insertion attempts, and reduces mechanical complications.^{4,6(IVa, Vb)} Authors of multiple studies have recommended assessing diameter (≥ 3 mm) and nonthrombosed status before PICC or PML insertion. Preprocedural mapping also supports appropriate catheter planning and optimizes the catheter-to-vein ratio, reducing thrombosis risk.^{5,6(IIIb, Vb)}

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Clinical Consideration

Benefits

- Increased insertion success: Ultrasound-guided IV catheterization improves first-attempt success rates and reduces the number of attempts, especially in DIVA patients.^{7,11}
- Fewer mechanical complications: Ultrasound guidance reduces risks of arterial puncture, hematoma, and malposition, decreasing the need for postprocedural imaging.^{7,12–14}
- Enhanced patient satisfaction: Ultrasound-guided catheterization is associated with higher satisfaction, particularly among patients with difficult access.¹¹

Risks

- Increased catheter failure in high-risk patients: Ultrasound-guided PIVCs may have higher failure rates, possibly due to catheter length or placement in patients with poor vascular status.¹⁵
- Longer procedure time: Ultrasound guidance slightly increases the time required for catheter placement (7.89 versus 5.1 minutes; $P = 0.045$).¹¹
- No significant pain reduction: Despite fewer attempts, authors of studies have shown no statistically significant difference in pain scores between ultrasound and traditional methods.¹¹

Implementation Considerations

- Training is essential: Successful outcomes depend on nurses being trained and competent in ultrasound-guided insertion techniques.¹¹
- Catheter selection: Optimal catheter length improves dwell time and reduces failure.^{11,15}

Barriers to Implementation

- Equipment and resource limitations: Lack of immediate access to ultrasound requires reliance on landmark methods.^{1,3}

- Limited benefit in non-DIVA patients: In patients with easily accessible veins, landmark techniques may be faster and equally effective for PIVCs.^{1,3,16,17}
- Increased failure in certain placements: Ultrasound-guided PIVCs may be more prone to failure when inserted in less favorable anatomical sites or in sicker patients.¹⁵

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Chapter 4.7—Tip Navigation and Confirmation

Tip navigation is a critical safeguard in every central vascular access procedure. Accurate catheter tip navigation and confirmation are essential to the safety and effectiveness of central vascular access device (CVAD) insertion. Proper placement within the cavoatrial junction (CAJ) or lower third of the superior vena cava (SVC; in the case of femoral approaches, the inferior vena cava), supports reliable infusion, minimizes complications, and ensures long-term device function.

When catheter tips are malpositioned, whether too proximal, too distal, or outside the target vessel, the risks of dysfunction and serious complications increase substantially. These events not only compromise therapy but also contribute to patient harm and additional health care burden.

Due to these consequences, the consistent use of reliable navigation and confirmation methods has become a cornerstone of best practice in vascular access. Multiple technologies are available, and their appropriate application enhances procedural safety, optimizes outcomes, and builds patient and clinician confidence in the device.

Recommendation 1: Confirm CVAD Tip Location Prior to Use

Clinicians must verify and document the final catheter tip location before initiating infusion therapy. Confirmation should be performed using appropriate technology based on the clinical setting.

Summary of Evidence

Proper catheter tip location, at the CAJ or lower third of the SVC, minimizes the risk of malfunction, arrhythmias, vessel erosion, and catheter-related ventricular tachycardia (CRVT). In a meta-analysis of 13 studies involving 4988 patients, intracavitary electrocardiogram (IC-ECG) guidance demonstrated greater accuracy and safety than landmark-based techniques, followed by chest x-ray (CXR).^{1(IIIb)} In another randomized

controlled trial, Glauser et al. showed that 53.3% of peripherally inserted central catheters (PICCs) placed without imaging guidance required repositioning due to suboptimal tip location compared with only 6.7% in the fluoroscopy group.^{2(Ia)}

Recommendation 2: Intracavitary ECG for Tip Confirmation

When available, IC-ECG may be considered to confirm the central catheter tip location during insertion.

Summary of Evidence

IC-ECG is associated with higher tip positioning accuracy, lower malposition rates, and a reduced risk of CRVT compared with other techniques.^{3–5(Ib, Va, Ia)} Authors of multiple studies and meta-analyses have confirmed the ability of IC-ECG to detect the optimal tip position, especially at the CAJ.^{3–6(Ib, Va, Ia, Vb)}

Recommendation 3: Use Tip Navigation Systems

When available, clinicians should use real-time catheter navigation systems to guide catheter tip placement during insertion.

Summary of Evidence

Tip confirmation systems have been evaluated and endorsed by national health organizations for their ability to improve insertion accuracy and reduce reliance on postprocedure imaging.^{4,7,8(Va, IVa, IIIb)} When used in combination with IC-ECG, these systems improve tip location consistency and may eliminate the need for fluoroscopy or chest radiography for many CVADs.^{4(Va)}

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Improved tip accuracy: IC-ECG technology offers greater accuracy for catheter tip placement than CXR, with authors of a meta-analysis having shown better positioning accuracy (odds ratio: 2.88, $P < 0.0001$).⁹
- Reduced need for imaging and repositioning: IC-ECG and navigation systems minimize the need for confirmatory chest radiographs, reduce repositioning, and allow for faster therapy initiation.^{4-6,10}
- Enhanced safety and fewer complications: Real-time tip confirmation reduces malpositioning, which helps prevent cardiac complications such as arrhythmias and perforation.¹¹⁻¹⁵

Risks

- Suboptimal outcomes without tip confirmation: In a randomized controlled trial, blind bedside PICC placement led to 53.3% of tips being suboptimal or nonoptimal compared with only 6.7% in the fluoroscopy-guided group.²
- Reliance on additional imaging if the ECG signal is unclear: If a P wave is not detected with IC-ECG, clinicians must revert to chest radiography for tip verification, which may delay treatment.^{6,16}

Implementation Considerations

- Combine with navigation systems: Use of IC-ECG in combination with navigation systems has been shown to improve ease and accuracy of CVAD placement.^{7,8,17,18}
- Standardize postinsertion documentation: Accurate documentation of tip confirmation method, external catheter length, and technique supports long-term device safety and monitoring.¹⁹
- Use real-time confirmation: Real-time IC-ECG confirmation should be the preferred method for bedside use when available, allowing for immediate therapy initiation.^{4,10}

Barriers to Implementation

- Equipment cost and access limitations: Access to IC-ECG or navigation systems may be limited by cost or resource availability in some institutions.^{4,7}
- Training and adoption lag: Proper use of IC-ECG and navigation systems requires training, and inconsistent adoption may lead to variable outcomes.^{3,6}
- Dependence on alternate methods when ECG signal fails: When ECG signal cannot be obtained, reliance on CXR may be necessary, which introduces delay and radiation exposure.^{16,20}

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Chapter 4.8—Skin Antisepsis and Sterility

Preventing infection during vascular access device (VAD) insertion is a cornerstone of safe practice. Catheter-related bloodstream infections (CRBSIs) and insertion-site infections are serious complications that increase patient morbidity, extend hospital stays, and escalate healthcare costs.

Because vascular access involves direct entry into the bloodstream, skin antisepsis and aseptic technique are critical defenses against microbial transfer. Although skin cannot be sterilized, standardized antisepsis and sterile insertion practices consistently reduce the risk of infection and reinforce patient safety. These infection-prevention principles form the foundation of all insertion workflows and underpin the recommendations that follow.

Recommendation 1: Perform Hand Hygiene Before Insertion

Clinicians must perform hand hygiene immediately before inserting a VAD, using an alcohol-based hand rub or antimicrobial soap and water. Hand hygiene is essential even when gloves are worn.

Summary of Evidence

Hand hygiene is a cornerstone of infection prevention, with substantial evidence supporting its role in reducing CRBSIs. Alcohol-based hand rub is preferred unless hands are visibly soiled, in which case soap and water are recommended. Meta-analyses and clinical guidelines consistently affirm their efficacy in reducing microbial burden and protecting both patient and provider.^{1–3(IIb, IIb, IVa)}

Recommendation 2: Use Chlorhexidine-Alcohol as First-Line Skin Antiseptic

Unless contraindicated, clinicians should use at least 2% chlorhexidine gluconate (CHG) in 70% isopropyl alcohol for skin antisepsis prior to VAD insertion. The antiseptic should be applied with gentle friction in all directions and allowed to dry completely.

Summary of Evidence

Single-use CHG in alcohol has been supported as the preferred skin antiseptic in multiple systematic reviews and clinical trials. Authors of an early study found CHG-alcohol superior to povidone-iodine (PVP-I) in reducing CRBSI and catheter colonization.^{4(la)} In a large randomized controlled trial, it was confirmed that CHG-alcohol led to significantly fewer local and catheter-related infections compared with PVP-I.^{5(lb)} Gupta et al. found similar reductions in insertion-site complications in peripheral access. Combined, these findings reinforce CHG-alcohol as first-line unless contraindicated.^{6(lb)} Authors of another study emphasized broad-spectrum activity and persistence on skin of CHG, which contributes to its superiority.^{7(IVa)}

Recommendation 3: Consider Alternatives for Sensitive or Damaged Skin

For patients with CHG sensitivity or compromised skin, clinicians may consider alternatives such as PVP-I, alcohol-free CHG, octenidine (OCT), or sodium bicarbonate-based cleansings agents.

Summary of Evidence

While CHG is widely used, it may not be suitable for all patients. Authors of early CHG studies noted that alternatives like PVP-I remain viable options, particularly in patients with known sensitivity.^{4(la)} In a pediatric study, lower infection rates were found when PVP-I was used in alcohol-intolerant populations.^{8(IIIb)} For patients with fragile or damaged skin, a cyanoacrylate seal provided similar control of exit-site colonization as chlorhexidine-releasing dressings, offering a CHG-free alternative for exit-site protection.^{9(IIb)} Authors of a comparative study of OCT and CHG regimens concluded that OCT may be equally effective with fewer skin reactions.^{10(lb)}

Recommendation 4: Use Aseptic Nontouch Technique

Clinicians must use an aseptic nontouch technique (ANTT) during VAD insertion. ANTT requires protection of key sites

and key parts by minimizing direct contact, using sterile fields, and adhering to either standard or surgical ANTT depending on procedure complexity.

Summary of Evidence

ANTT is endorsed as a global standard for safe aseptic technique. ANTT creators distinguish standard ANTT for peripheral insertion and surgical ANTT for complex insertions like peripherally inserted central catheter or centrally inserted central catheter.^{11,12(IIIb, Vb)} ANTT further emphasizes that consistent adherence to the principles reduces insertion-related infections and improves provider technique.^{12,13(IIIb, IIa)} In a pragmatic evaluation, researchers found sustained compliance with critical aseptic behaviors over 4 years postimplementation.^{11(IIIb)}

Recommendation 5: Apply Maximal Sterile Barrier for Central VAD Insertion

Clinicians must use maximal sterile barrier (MSB) precautions for all central VAD (CVAD) insertions. This includes a sterile gown, gloves, mask, cap, and full-body drape.

Summary of Evidence

MSBs are consistently linked with reduced CRBSI rates. Authors of an early study demonstrated that the use of full sterile precautions during central line insertion significantly reduced the risk of infection, especially in high-acuity settings.^{14(Vb)} The choice between full or partial barriers should be guided by insertion technique and clinical judgment, but full MSBs remain best practice for CVADs.^{3(IVa)}

Recommendation 6: Maintain Sterility During Ultrasound-Guided Insertion

During ultrasound-guided VAD insertion, clinicians must use sterile probe covers and sterile gel and disinfect probes between patients according to manufacturer and institutional protocols.

Summary of Evidence

Ultrasound probes and gel are recognized sources of contamination if not properly managed. Saugel et al. emphasized the use of sterile probe covers and gel as standards for real-time ultrasound-guided CVAD insertion.^{15(Vb)} Thompson and Garrett (2018) provided best-practice guidelines for probe disinfection and sheathing for vascular access teams.^{16(IVb)} Authors of another study demonstrated variability in disinfection practices across intensive care units, reinforcing the need for standardized approaches to reduce cross-contamination risk.^{17(IIIb)}

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Clinical Considerations

Benefits

- Reduced infection risk with CHG: Use of 2% chlorhexidine in 70% isopropyl alcohol significantly reduces

CRBSIs and bacterial colonization due to its broad-spectrum activity and residual effect.^{18–21}

- Lower phlebitis incidence with proper asepsis: Proper use of ANTT and skin antisepsis significantly reduces the risk of phlebitis and other insertion-related infections.^{12,22–29}
- Flexible antiseptic options: Alternatives like PVP-I or OCT dihydrochloride offer effective skin antisepsis for patients with sensitivities to CHG or alcohol-based solutions.^{8–10,21}

Risks

- CHG sensitivity and irritation: Some patients may develop allergic reactions or skin irritation to CHG or alcohol-based preparations, necessitating alternative agents.⁸
- Medical adhesive-related skin injury from improper dry time: Failure to allow CHG to fully dry before applying dressings may increase the risk of medical adhesive-related skin injury.²¹
- Inadequate skin disinfection: Incomplete adherence to antiseptic protocols (e.g., inadequate scrub or dry time) may lead to thrombophlebitis or infection.^{5,6,21}

Implementation Considerations

- Agent selection based on patient condition: Clinicians should consider skin condition and allergy history when selecting antiseptic agents. CHG is preferred, but PVP-I, OCT, or even sodium bicarbonate solutions may be appropriate alternatives.^{8–10,21}
- Appropriate barrier precautions: The choice between maximal and partial sterile barriers should be based on the invasiveness of the procedure and insertion technique used (e.g., Seldinger versus accelerated Seldinger).^{3,14}
- Standardized application technique: Antiseptic agents should be applied using back-and-forth strokes for at least 30 seconds and allowed to dry completely to maximize efficacy and minimize complications.²¹

Barriers to Implementation

- Variability in practice: Inconsistent use of ANTT or antiseptic protocols among clinicians can undermine infection prevention efforts.^{12,22–29}
- Limited access to alternative agents: Facilities may not routinely stock alternatives like OCT or sodium bicarbonate-based solutions, limiting options for patients with sensitivities.^{8–10,21}
- Misapplication of sterile field standards: Uncertainty or variability in when to use maximal versus partial barriers may lead to underprotection in higher-risk insertions.^{3,14}

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Chapter 4.9—Stabilization and Vessel Enhancement

Achieving reliable vascular access requires more than good technique; it also depends on preparing the vein and supporting the surrounding anatomy. Joint stabilization and vessel enhancement are 2 often overlooked strategies that improve first-attempt success and preserve vascular integrity.

Avoiding flexion areas is sometimes unavoidable; insertion in these areas requires special attention. Without stabilization, catheter movement at flexion points can lead to phlebitis, dislodgement, or infiltration. Stabilization options may include splints, securement devices, and dressing techniques that maintain catheter integrity while preserving comfort, circulation, and visibility.

Similarly, vessel enhancement techniques, like moist heat, hydration, or limb positioning, can improve vein palpability and visibility, especially in patients with poor perfusion, deep veins, or fragile vasculature. These strategies are beneficial in patients with difficult intravenous access (DIVA) and should be individualized based on clinical context. Integrating both stabilization and enhancement techniques into preinsertion planning supports safer, more efficient, and more compassionate vascular access.

Recommendation 1: Joint Stabilization for Catheters Near Flexion Sites

When vascular access devices are placed near areas of flexion, clinicians should implement stabilization strategies to minimize catheter motion and prevent mechanical complications. Stabilization techniques must maintain patient comfort, ensure adequate circulation, allow for visualization of the insertion site, and minimize the risk of pressure injuries.

Summary of Evidence

In a prospective ultrasound study, Hebbard et al. found that 95% of peripheral intravenous catheters placed in the dorsum of the hand failed during wrist dorsiflexion, with an average tip displacement of 12.5 mm due to anatomical impingement.^{1(IIIb)}

Authors of another study reported that radial arterial catheters placed too close to the wrist crease are prone to securement failure and dislodgement, recommending a proximal insertion site for stability.

These findings support the role of stabilization, when placement near a joint is unavoidable, in preserving catheter function.^{2,3(Vb, IVa)}

Recommendation 2: Avoid Tourniquet Use with Fragile Veins

When cannulating fragile veins, clinicians may consider avoiding a tourniquet to prevent overdistension and reduce the risk of vein rupture.

Summary of Evidence

In patients with vessel fragility or thin subcutaneous tissue, the use of a tourniquet may overdistend superficial veins, thereby increasing the risk of rupture, infiltration, and phlebitis. In a pilot study of older adults, avoiding the tourniquet and using a lower insertion angle improved first-attempt success, reduced postinsertion complications, and preserved vessel integrity.^{4(IIIb)}

Recommendation 3: Manual Traction for Vein Stabilization

For mobile superficial veins, clinicians may apply gentle manual traction below the insertion site to stabilize the vein and reduce lateral movement during needle entry. Excessive tension should be avoided to prevent vein collapse.

Summary of Evidence

Palpable superficial veins may shift during cannulation, leading to failed attempts or injury to the vein. Gentle manual traction, including thumb anchoring and skin tensioning, stabilizes the target vessel and improves needle control.^{4(IIIb)} When paired with proper insertion angle, this technique enhances success and minimizes unnecessary trauma, particularly in mobile dorsal hand or cephalic veins.

Recommendation 4: Vein Enhancement Techniques

Clinicians may use vessel enhancement strategies, such as warm compresses, limb positioning, or gravity-assisted filling, to improve vein visibility and palpability before vascular access insertion.

Summary of Evidence

Vein enhancement methods improve vascular distension and are associated with higher first-attempt success rates, especially in patients with DIVA. While evidence quality is mixed, authors of observational and small interventional studies have supported the use of moist heat, dependent limb positioning,

and hydration as safe, low-risk interventions that improve vein visibility.^{3,4} These techniques should be adapted to the patient's condition, insertion site, and care setting. Combining vein enhancement with ultrasound or infrared imaging may further optimize access.

Note: Heat should be applied cautiously to avoid patient injury. Commercially prepared warm packs or controlled warming devices are preferred. Improvised methods, such as heating wet towels in a microwave, must not be used due to the risk of burns and uneven heat distribution.

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Clinical Considerations

Benefits

- Reduced complications: Avoiding tourniquet use and manually stabilizing the vein reduces the risk of phlebitis and vein trauma in older patients.⁴
- Improved first-attempt success: Manual stabilization techniques improve insertion accuracy, particularly in fragile, superficial veins, increasing the likelihood of first-attempt success.⁴
- Increased catheter dwell time: Forearm site selection and low-angle insertion contribute to longer catheter dwell time and greater patient comfort.⁴

Risks

- Technique variability: Manual stabilization and low-angle insertion may be inconsistently applied, leading to variation in outcomes or inadvertent vein trauma.⁴
- Limited vein accessibility: In some older patients, suitable veins may not be accessible without a tourniquet, potentially complicating insertion.⁴
- Operator dependency: Effectiveness of this approach depends heavily on the skill and technique of the individual clinician performing the insertion.⁴

Implementation Considerations

- Training in stabilization techniques: Clinicians should be trained in manual vein stabilization, proper angle of insertion, and forearm site selection to reduce trauma and increase success.⁴
- Patient-specific assessment: Individual vein characteristics and patient comfort should guide decisions around tourniquet use, insertion site, and technique.⁴
- Monitoring protocols: Regular assessment for signs of phlebitis and documentation of catheter dwell time are necessary to ensure ongoing patient safety.⁴

Barriers to Implementation

- Habitual reliance on tourniquets: Clinicians may be accustomed to standard tourniquet use and may resist adopting manual-only vein stabilization techniques.⁴
- Limited experience with low-angle insertion: Some providers may lack confidence or training in low-angle insertion methods, especially for challenging older adult veins.⁴
- Time and staffing pressures: Manual stabilization can be more time-consuming, which may be a challenge in high-volume or understaffed settings.⁴

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Chapter 4.10—Insertion Complication Management

Vascular access procedures, while routine, are not without risk. A range of insertion-related complications can occur, each with the potential to delay therapy and compromise vascular integrity and safety. These complications include, but are not limited to, arterial puncture, hematoma formation, vasospasm, lymphatic injury, nerve injury, and insertion-related arrhythmias, all of which require prompt identification and intervention. Proper insertion technique, awareness of anatomical

landmarks, and real-time imaging guidance can substantially reduce the likelihood of these adverse events.

Though uncommon, these complications may result in lasting morbidity if not promptly addressed. Nerve injury, for example, may present as immediate or delayed pain, paresthesia, or even loss of motor or sensory function. Air embolism can lead to cardiovascular, pulmonary, and neurological consequences, and even death. Complications are influenced by catheter size,

insertion site, depth, and proximity to surrounding anatomy. Authors of studies have emphasized the importance of skillful technique, preprocedural anatomical assessment, and the use of image guidance to minimize risk.

Effective management of insertion-related complications requires early recognition, adherence to evidence-based intervention protocols, and ongoing staff education. By integrating preventive strategies into standard practice, including proper patient positioning, vein visualization technologies, and escalation pathways, clinicians can reduce complication rates, enhance procedural safety, and optimize outcomes in vascular access care.

Recommendation 1: Insertion Site Bleeding

To reduce postinsertion bleeding and minimize unplanned dressing changes, clinicians should apply direct digital pressure until hemostasis is achieved.

Summary of Evidence

Bleeding following vascular access device (VAD) insertion can compromise dressing adherence, increase the risk of infection, and lead to early dressing disruption or device replacement. After hemostasis is achieved, cyanoacrylate tissue adhesive has demonstrated benefit in controlling minor postinsertion bleeding, improving dressing stability, and reducing the need for unplanned dressing changes. In a review, Zhang et al. confirmed improved hemostasis and dressing integrity using cyanoacrylate in vascular access procedures.^{1(IIb)} In a retrospective analysis, Buetti et al. linked dressing disruption to an increased risk of infection, particularly in patients with an elevated body mass index.^{2(IIb)}

Recommendation 2: Monitor for Bleeding and Hematoma Postinsertion

Following insertion, vascular access sites should be closely monitored for bleeding and hematoma. The surveillance frequency should be tailored to the device type, insertion technique, and patient-specific factors.

Summary of Evidence

Postinsertion bleeding and hematoma formation can go unrecognized without routine monitoring. In a secondary analysis involving over 10,000 VADs, Ullman et al. found that timely documentation and assessment doubled the likelihood of early detection and intervention for skin and insertion site complications.^{3(IIIb)} Standardizing surveillance frequency, especially during the first hours postinsertion, enhances patient safety and supports early escalation if needed.

Recommendation 3: Respond to Unintended Arterial Puncture Immediately

If an artery is inadvertently punctured during insertion, withdraw the needle immediately and apply direct pressure for 5–10 minutes or until hemostasis is achieved.

Summary of Evidence

Unintended arterial puncture during vascular access insertion can result in hematoma, pseudoaneurysm, or severe

hemorrhage. Prompt needle withdrawal and application of direct pressure are recommended to prevent progression of injury. Manual compression as the primary intervention for inadvertent arterial entry, avoiding catheter dilation or advancement into an artery unless intentional arterial access is indicated.^{4(IVa)}

Recommendation 4: Prevent Air Embolism During Insertion

Implement strategies to prevent air embolism during central vascular access insertion. These include Trendelenburg positioning (when safe), minimizing open lumens, using closed-system devices, and ensuring all connections are secure.

Summary of Evidence

Air embolism is a potentially fatal but preventable complication during central catheter insertion. Techniques such as Trendelenburg positioning, occlusion of open lumens, use of closed catheter systems, and vigilance during catheter handling have been shown to reduce risk. Brull et al. emphasized minimizing air entry risk during access procedures, while Pinho et al. described the effectiveness of closed ports and tip position control.^{5,6(Va, IIb)}

Recommendation 5: Respond to Guidewire Resistance Promptly

Maintain continuous control of the guidewire during insertion. If resistance is encountered or the wire cannot be withdrawn easily, stop the procedure and assess for kinking, looping, or entrapment.

Summary of Evidence

Guidewire-related complications are uncommon but potentially serious. Entrapment, embolization, or vessel trauma may result from excessive force or failure to recognize resistance. Maintaining constant control of the guidewire and pausing the procedure when resistance is met are essential safety measures. Evidence supports that guidewire looping, and vascular injury can be avoided by using gentle technique and stopping immediately when unexpected tension or binding occurs.^{4,7(IVa, Vb)}

Recommendation 6: Insertion-Related Arrhythmias

Monitor cardiac rhythm during central catheter insertion. If arrhythmias occur, withdraw the guidewire or catheter slightly and reassess tip position.

Summary of Evidence

Arrhythmias during central venous access insertion typically occur when the catheter or guidewire enters the right atrium. These are usually transient but can progress if unrecognized. Real-time monitoring and immediate withdrawal of the device are associated with the resolution of rhythm disturbances. Authors of several studies have confirmed that repositioning resolves most insertion-related arrhythmias, while persistent events may require catheter removal.^{8–10(IIIa, Ib, IIIb)}

Recommendation 7: Nerve Injury Recognition and Response

If the patient reports sharp, radiating pain or involuntary movement during insertion, stop immediately and reassess. Do not advance the needle until anatomical safety is confirmed.

Summary of Evidence

Nerve contact during insertion may present as sharp pain, tingling, or involuntary movement. Proceeding after these signs can result in serious damage. Evidence supports halting needle advancement immediately and reassessing anatomical landmarks or using ultrasound. Early recognition and appropriate response reduce the likelihood of long-term sensory or motor dysfunction.^{11–13(IIIb, IIIb, Vb)}

Recommendation 8: Venospasm During Insertion

If venospasm occurs during insertion, consider warming the limb, reassessing the technique, or using vasodilators when clinically appropriate.

Summary of Evidence

Venospasm is a recognized contributor to insertion failure and catheter malfunction, often triggered by mechanical stimulation during placement or limb movement after insertion. In an ultrasound imaging study of 83 intravascular catheters (62 venous and 21 arterial), researchers observed that catheter-related obstruction was frequently due to impingement on the vessel wall or localized vessel spasm, particularly in areas of tortuosity or branching.^{14(IIIb)}

Recommendation 9: Lymphatic Injury During Insertion

If lymphatic fluid is observed during device insertion, remove the device immediately. Avoid attempts to flush or reposition and monitor the site for signs of infection or prolonged leakage.

Summary of Evidence

Lymphatic injury during central catheter insertion is rare but underreported. Accidental entry into a lymphatic vessel may cause persistent leakage, local swelling, or infection. Authors of studies have suggested that immediate device removal and site reassessment are essential, especially in high-risk anatomic regions. Early recognition reduces risk of delayed healing and lymphatic fistula.^{4(IVb)}

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Clinical Considerations

Benefits

- Early identification improves outcomes: Early recognition and intervention for nerve injuries postinsertion can prevent long-term disability and improve outcomes.^{11–13}

- Ultrasound reduces complications: Preprocedural and intraprocedural ultrasound guidance improves accuracy, reduces complication rates, and avoids inadvertent puncture of critical structures.^{15–17}
- Arrhythmia detection allows timely intervention: Continuous electrocardiography (ECG) monitoring during and after catheter insertion helps identify catheter-induced arrhythmias early, allowing timely repositioning or removal.^{8–10,16}

Risks

- Nerve injury during insertion: Inadvertent nerve damage may result in sensory or motor deficits if not identified and managed promptly.^{11–13}
- Lymphatic injury: Accidental puncture of lymphatic structures, such as the thoracic duct, may lead to persistent leakage, infection, or hospitalization.^{16–18}
- Catheter-related arrhythmias: Catheter tip malposition may induce arrhythmias, which may resolve with repositioning but can persist and require catheter removal.^{8–10,16}

Implementation Considerations

- Use ultrasound consistently: Preprocedural and intraprocedural ultrasound use enhances visualization and minimizes complications, especially in high-risk areas.^{15,16}
- Clinician training: Ensure operators are trained in ultrasound, lymphatic anatomy, and arrhythmia recognition to improve procedural safety.^{15,16}

Barriers to Implementation

- Variable access to ultrasound and ECG monitoring: Limited availability of imaging and cardiac monitoring equipment may hinder optimal insertion practices.^{15–17}
- Inconsistent provider training: Lack of training in lymphatic anatomy and advanced ultrasound techniques can increase complication risk.^{15,16}

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Section 5: Ongoing Assessment, Care, & Complication Management

Chapter 5.1—Assessment of Vascular Access Device Necessity

Regular assessment of the necessity of vascular access devices (VADs) is essential for safe and effective care. In inpatient settings, daily reviews help prevent prolonged catheter dwell times and reduce the risks of catheter-related bloodstream infections (CRBSIs), thrombosis, and mechanical complications. In outpatient and home care environments, VADs should be reassessed at each encounter to ensure ongoing need, especially for devices like totally implanted VADs (TIVADs) that may remain in place despite extended periods without use.

Incorporating device assessment into daily workflows and encounter-based evaluations supports infection prevention, minimizes device burden, and aligns with stewardship principles. Clear criteria for discontinuing or removing unused devices promote safety and optimize vascular access resources across care settings.

Recommendation 1: Inpatient Daily VAD Assessment

All VADs in inpatient settings should be assessed daily to determine continued necessity. Devices that are no longer required for therapy should be promptly removed.

Summary of Evidence

Prolonged catheter dwell without indication increases the risk of CRBSI, thrombosis, and mechanical failure. In a retrospective study of hospitalized patients, duration of centrally inserted central catheter (CICC) placement remained a significant risk factor for CRBSI even after prevention bundles were adopted.^{1(IIIb)} Authors of another study demonstrated that daily automated catheter day notifications significantly reduced total CICC days and CRBSI rates in the intensive care unit. These findings support embedding daily necessity checks into standard inpatient care.^{2(IIIb)} Peripheral VADs, arterial catheters, and interosseous catheters all require ongoing assessment of need and removal when no longer required.^{3–6(Va, IVa, IVa, IIb)}

Recommendation 2: Encounter-Based VAD Assessment

At each outpatient or home care encounter, VADs should be evaluated for continued clinical indication. Devices without a current therapeutic need, including dormant TIVADs, should be reviewed for removal to prevent unnecessary risk.

Summary of Evidence

Although specific studies on outpatient TIVAD removal are limited, principles of device stewardship and infection prevention apply across care settings. Alanazi et al. reviewed VAD manage-

ment strategies and highlighted that comprehensive bundles, including necessity review, effectively reduce CRBSI across multiple environments.^{7(IIIa)} Educational and audit-based interventions have been shown to promote timely removal and appropriate use of VADs, reducing unnecessary exposure and complications.^{8(IIIb)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Reduces infection and complications: Regular assessment and timely removal of VADs reduce risks of blood stream infection, thrombosis, and device failure.^{7,9}
- Supports infection prevention strategies: Daily audits and removal of unnecessary devices are effective components of CLABSI prevention bundles.¹

Risks

- Extended dwell time increases CRBSI risk: Prolonged catheter duration is associated with higher infection risk, even with prevention bundles in place.¹
- Missed assessments in outpatient/home care: Without consistent review at each encounter, unnecessary device retention may lead to preventable complications.⁹

Implementation Considerations

- Use automated tracking tools: Interventions like automatic catheter day notifications support timely reviews and reduce catheter duration.^{2,10}
- Provider education on risk-based maintenance: Educating clinicians about patient-specific risk factors and device maintenance improves outcomes and reduces complications.^{8,11,12}

Barriers to Implementation

- Inconsistent documentation or workflow gaps: Lack of integrated systems for catheter-day tracking may delay assessment or device removal.²

- Variable adherence across care settings: Outpatient and home care environments may lack standardized protocols for daily VAD need review.^{7,9}

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Chapter 5.2—Postinsertion Monitoring

Postinsertion monitoring is a critical component of vascular access care. The hours, days, and weeks following device placement are marked by the highest risk for early complications, including bleeding, hematoma, infiltration, extravasation, and tip migration. Vigilant daily assessments help detect subtle changes before they become serious problems. This chapter outlines essential postinsertion surveillance strategies for all vascular access devices (VADs), emphasizing dressing condition, securement integrity, external length, and signs of malfunction or malposition. A structured approach to monitoring supports early intervention, minimizes patient harm, and promotes safe, uninterrupted therapy across all care settings.

Recommendation 1: Routine Postinsertion Monitoring

Direct-care clinicians must perform and document vascular access site, dressing integrity, and skin assessments at least once per shift in inpatient settings and at each encounter in am-

bulatory or home care sites. Monitoring should be based on patient risk, infusate, and the VAD.

Summary of Evidence

Routine assessment of vascular access sites is essential to prevent complications such as phlebitis, infiltration, extravasation, migration, and catheter-related bloodstream infections. In a retrospective cohort of 1,502 centrally inserted central catheter placements, structured clinician education and insertion protocols significantly reduced infection rates by 22% following implementation, with additional risk reduction tied to use of ultrasound and fewer puncture attempts.^{1(IIIb)} Similarly, Gohil et al. demonstrated that daily documentation of site condition using a standardized central line insertion site assessment (CLISA) scoring tool reduced early signs of inflammation and led to faster line removal decisions, reinforcing the value of frequent, structured assessments.^{2(IIIb)} Authors of another study

emphasized that nurse-led evaluations improve catheter patency and reduce the need for unplanned device replacements.^{3(IIIb)}

Recommendation 2: Core Components of VAD Site Evaluation

Each vascular access site assessment should include the following components:

- Visual inspection of the insertion site, surrounding skin, limb comparison for edema;
- Palpation (if not contraindicated) for tenderness, warmth, or subcutaneous edema;
- Evaluation of dressing condition, including moisture, integrity, and visibility of the site;
- Assessment of securement stability and changes in catheter external length;
- Inquiry about patient-reported symptoms, such as pain, pulling, burning, or tightness;
- Observation of catheter function, including flow resistance, backflow, or alarms.

Summary of Evidence

Complications are frequently preceded by subtle site changes, such as erythema, localized swelling, or dressing disruption, that may be overlooked without a structured assessment protocol.^{4(IIIa)} In a prospective observational study of 849 peripheral intravenous catheter in patients over 70, nurses performed site checks 3 times daily and identified local complication rates of 50.5 per 1000 catheter-days. Risk factors included hematoma, dressing disruption, and vancomycin administration, reinforcing the need for close inspection and consistent site care. The presence of local signs was also associated with a statistically significant increase in hospital stay duration, further validating the impact of structured site surveillance on patient outcomes.^{5(IIb)}

Recommendation 3: Monitoring External Length and Tip Position

Direct-care clinicians should monitor catheter external length and tip stability at regular intervals, particularly after insertion, patient repositioning, or clinical events that increase movement risk (e.g., seizures, transfers, pressure injection, or high-flow flushes). External length should be clearly documented using standardized methods, and any measurable change must prompt immediate assessment for possible migration, malposition, dislodgement, or mechanical dysfunction.

Summary of Evidence

Monitoring catheter external length and tip position is a critical component of postinsertion surveillance for all VADs. Changes often indicate migration, dislodgement, or kinking. These mechanical complications can lead to infusion into unintended vascular territory, thrombosis, endothelial injury, or device failure. In a prospective study of intensive care unit patients, Singh et al. reported malposition in 3% of central venous catheters, often triggered by manipulation or patient movement.^{6(IIa)} Similarly, Gohil et al. demonstrated that structured documentation of

external length and site condition improved clinician response times and reduced dwell time of compromised catheters, thereby preventing sequelae such as bloodstream infections and infiltration.^{2(IIb)} Standards and guidelines, including those from the Infusion Nurses Society, recommend routine length monitoring, especially for peripherally inserted central catheters (PICCs), which are more susceptible to migration due to limb movement and longer catheter pathways.^{2,7(IIb, IVa)}

Evidence also highlights the clinical consequences of even small shifts in tip position. In a retrospective study of 177 central venous catheters, Smith et al. found that catheters with more than 2 cm of cranial migration were over 7 times more likely to become dysfunctional, with left-sided catheters migrating farther on average than right-sided catheters.^{8(IIIb)} Routine documentation of external length, coupled with site inspection and prompt escalation when changes are detected, allows early recognition of malposition or dysfunction. Structured protocols for reassessment following patient repositioning, seizures, transfers, or high-pressure infusions (e.g., pressure injection, high-flow flushes) further reduce the risk of unrecognized migration and support safe therapy delivery.^{1,2(IIIb, IIb)}

Recommendation 4: Monitoring for Bleeding, Hematoma, or Lymphatic Leak

Clinicians must routinely inspect vascular access sites for bleeding, hematoma formation, or evidence of lymphatic leak, especially during the first 24 hours after insertion and following interventions such as pressure injection or catheter manipulation. Any signs of swelling, ecchymosis, or persistent moisture beneath the dressing should prompt immediate investigation and intervention.

Summary of Evidence

While overt bleeding is often identified and managed promptly after VAD insertion, other forms of postprocedural fluid accumulation, such as hematoma and lymphatic leak, may be underrecognized. Hematomas can track into dependent tissue planes, particularly in older adults with fragile or lax skin, where discoloration and swelling may be masked beneath the limb. In a prospective study by Velioglu et al., early hematoma occurred in over 10% of central venous catheter insertions and was associated with coagulopathy, large-bore devices, and suboptimal compression technique.^{9(IIIb)}

Lymphatic leak, though less frequently documented, has been reported in cases involving deep tunneling, femoral access, and patients with low subcutaneous tissue. This complication may present as persistent dampness under the dressing without overt bleeding. Routine inspection, palpation, and securement reassessment, especially within the first 24–48 hours, support early identification and appropriate intervention to preserve site integrity and prevent device failure.^{2,5(IIa, IIb)}

Recommendation 5: Monitoring Tunneled Devices and Totally Implanted VADs

Clinicians must monitor the full course of tunneled VADs and totally implanted VADs (TIVADs) during each assessment, with specific attention to insertion site condition, tunnel tract

integrity, needle stability (if applicable), and signs of infection or skin breakdown along the entire subcutaneous path. Long-term devices require ongoing evaluation even in the absence of recent use.

Summary of Evidence

Tunneled VADs and TIVADs require full-pathway evaluation during routine monitoring, not just visual inspection of the insertion site or needle hub. Complications such as tunnel tract inflammation, catheter migration, fibrin sheath formation, and pocket infections may develop insidiously, particularly when the device is not actively in use. In a retrospective study of 138 patients with tunneled catheters, Chouhani et al. reported a 46.7% overall complication rate, including tunnelitis, orifice infections, and sepsis.^{10(IIIb)} Delayed complications were significantly associated with longer catheter dwell times, prior tunneled catheter use, and comorbidities such as anemia or heart disease.^{5(IIb)}

Smith et al. further demonstrated that spontaneous tip migration, especially with left-sided TIVADs and tunneled catheters, was associated with an increased risk of catheter dysfunction and thrombosis. In their cohort, devices with more than 2 cm of cranial migration were over 7 times more likely to malfunction. These findings underscore the importance of ongoing monitoring of external length, tunnel tract condition, and subcutaneous pocket integrity.^{8(IIIb)} Even dormant ports require visual and tactile assessment for swelling, discoloration, or tenderness along the tract, as early detection prevents progression to more severe complications.

Recommendation 6: Postpressure Injection Monitoring

Clinicians should assess VAD function and insertion site condition immediately following any pressure injection procedure. Postpressure injection monitoring should include evaluation for signs of infiltration, dislodgement, tip migration, catheter rupture, and dressing disruption. Patients should also be asked about any pain, pressure, or unusual sensations they experience during and after the injection.

Summary of Evidence

Pressure injection of contrast media places significant mechanical stress on all VADs, particularly PICCs and TIVADs. High-pressure flow can cause complications, including catheter rupture, infiltration, tip displacement, and dressing lift, especially if the device is not properly stabilized or rated for injection. In a case series reviewed by Wang et al., pressure injection-related complications included pain, resistance to injection, swelling at the site, and suspected device migration, reinforcing the need for immediate postprocedure evaluation.^{11(IIIb)}

Manufacturers specify maximum flow rates and pressure limits for pressure-injectable devices; however, real-world complications still occur due to improper flushing, the use of inappropriate TIVAD noncoring needles (noncoring needles and extensions not rated for pressure injection), or anatomical resistance. Prompt assessment following injection helps identify subtle signs of compromise that may not be apparent during the procedure. Monitoring should include both subjective

symptoms (pain, pressure, and flushing difficulty) and objective findings (swelling, dressing disruption, and catheter length change), with escalation to imaging or device replacement as indicated.^{2,3(IIa, IIIb)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Reduced complications through routine monitoring: Routine assessments of dressing integrity, securement, and insertion sites help detect early signs of infection, occlusion, or mechanical issues, improving outcomes.^{12–14}
- Improved skin injury management: Use of the central VAD-associated skin impairment (CASI) algorithm improves provider confidence in identifying and managing insertion site complications.^{7,15}
- Early intervention from real-time documentation: Documentation protocols postinsertion increase early detection and management of complications such as bleeding and hematoma.^{4,16}

Risks

- Catheter dislodgement or migration: Without routine assessment, dislodgement or malposition may go unnoticed, compromising therapy.^{12–14}
- Delayed skin complication recognition: Failure to assess for signs of skin impairment or exit site infections may increase the risk of worsening tissue damage.^{7,15}
- Infection risk from poor incision care: Inadequate postinsertion wound care can raise the risk of catheter-related infections, especially for TIVADs with suboptimal tunnel length.^{16–22}

Implementation Considerations

- Training in imaging and lymphatic anatomy: Staff education in ultrasound guidance and anatomic knowledge reduces error rates and enhances outcomes.^{23,24}
- Standardized dressing and securement assessments: Regular checks during dressing changes ensure catheter stability and patient comfort.^{12–14}

Barriers to Implementation

- Limited use of tools like CASI: Despite their benefits, tools like the CASI algorithm may be underused due to lack of awareness or training.^{7,15}
- Documentation burden: Real-time documentation improves care but may strain clinician workload, especially in high-volume settings.^{4,16}

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Chapter 5.3—Postinsertion Complication Identification & Management

Timely intervention and clear escalation pathways are critical components of safe and effective vascular access management. Early recognition of complications, such as signs of infection, catheter malfunction, occlusion, infiltration, or phlebitis, can significantly reduce the risk of progression to more severe outcomes. Prompt, evidence-based responses preserve vascular access integrity, minimize patient harm, and support therapeutic continuity.

Adequate postprocedural care and regular monitoring are crucial for identifying emerging issues and initiating timely interventions. This includes thorough assessments, accurate documentation, and adherence to maintenance protocols. Standardized escalation pathways provide clinicians with defined steps for managing complications at the bedside, including criteria for consulting vascular access specialists, infectious disease specialists, or interventional radiology when indicated.

Escalation protocols should be tailored to facility resources and patient acuity, with built-in flexibility to address complex scenarios. For example, escalating from peripheral to central access or initiating diagnostic imaging for suspected deep vein thrombosis must be informed by clinical findings and individual patient risk. A structured response framework reduces treatment delays, ensures appropriate care transitions, and supports multidisciplinary collaboration.

By embedding escalation protocols into routine practice and education, health care teams can strengthen their ability to respond efficiently to complications. This proactive, systems-based approach enhances patient safety, preserves vascular access longevity, and improves patient outcomes.

Recommendation 1: Identify and Assess Infiltration of a Vascular Access Device

Clinicians must assess for infiltration during every vascular access device (VAD) evaluation. Common signs include localized swelling, coolness, blanching, discomfort, decreased infusion rate, and damp dressings. When infiltration is suspected, clinicians must assess the severity, stabilize the site, and escalate appropriately using institutional protocols and severity grading tools.

Summary of Evidence

Identification: Infiltration occurs when a nonvesicant solution leaks from the VAD into the surrounding tissue. Early signs include localized swelling, pallor, coolness, and a slowed infusion rate; however, symptoms may vary depending on infusion pressure, site location, and patient awareness. Mild infiltrations may be resolved with conservative measures, while severe cases can lead to tissue damage, pain, and functional impairment.^{1–3(IIIb, Va, IVb)} Structured grading tools, such as the Infusion Nurses Society (INS) infiltration scale, support consistent assessment and guide escalation pathways.^{4(IVa)}

In a large observational study of peripheral intravenous catheter complications, infiltration was one of the most frequently documented issues, particularly with catheters in place be-

yond 72 hours or without securement.¹ The use of transparent dressings, tape-only securement, and high-pressure infusions increased the risk. Early identification and consistent severity grading improve intervention timing and reduce the escalation to more severe tissue injury or catheter replacement.^{1,2,4,5(IIIb, Va, IVa, IIIa)}

Recommendation 1a: Immediate Actions for Suspected Infiltration

Clinicians must immediately stop the infusion if infiltration is suspected. The VAD should be assessed for function. If infiltration is confirmed, the device should be discontinued unless required for aspiration, and the site stabilized.

Recommendation 1b: Supportive Management of Infiltration

Following infiltration, clinicians should elevate the affected limb, assess for pain and circulation, and apply warm or cold compresses based on institutional guidance, infusate characteristics, and patient preference. The site should be monitored for changes in swelling, capillary refill, and skin integrity. Suspected compartment syndrome or worsening symptoms must prompt immediate escalation to a licensed independent practitioner.

Summary of Evidence

Management: Immediate cessation of infusion is the critical first step in managing infiltration, regardless of severity.^{3(IVb)} Continuing to infuse fluid into extravascular tissue increases the risk of skin and soft tissue damage. Structured response protocols consistently recommend stopping the infusion, assessing the affected limb, and stabilizing the site before proceeding with interventions. Guidelines also recommend avoiding flushing the catheter if infiltration is suspected, as this may worsen tissue injury.^{2,3(Va, IVb)}

Supportive interventions include elevating the affected limb, applying warm or cold compresses depending on the type of solution infused, and conducting circulatory and neurological assessments to detect early signs of compartment syndrome.⁴ Authors of one study have emphasized the importance of reassessment and escalation, especially when swelling is extensive, pain is severe, or symptoms worsen over time. Infiltration severity grading tools, such as the INS infiltration scale, support consistent clinical decisions regarding escalation, monitoring frequency, and documentation.^{2,4(Va, IVa)}

In a systematic review, infiltration was identified as one of the most common complications across peripheral VADs, reinforcing the need for preventative education and timely intervention when symptoms appear.^{1(IIIb)} Early stabilization and appropriate monitoring reduce the risk of progression to tissue injury, helping to preserve vessel integrity for future access.^{1–4(IIIb, Va, IVb, IVa)}

Recommendation 2: Identification of Extravasation Injury

Clinicians must assess for extravasation with every vascular access evaluation when administering vesicants. Signs of

extravasation include localized swelling, burning, tightness, blanching, erythema, pain, or damp dressings. High-risk drugs may cause tissue damage even with small volumes. Early identification, symptom grading, and clinical context must guide escalation and management.

Summary of Evidence

Identification: Extravasation refers to the leakage of vesicants and irritating infusates into surrounding tissues, which can potentially cause inflammation, tissue damage, or necrosis. This risk is especially significant with vasopressors, hypertonic saline, contrast media, chemotherapeutic agents, and other noncytotoxic irritants. Even small-volume extravasation of certain agents can result in compartment syndrome or long-term soft tissue injury if not recognized and managed promptly.^{6(IIa)}

Common signs include localized swelling, burning pain, blanching, and altered dressing integrity. Although some extravasations may initially be painless, particularly in patients with sensory impairment or under sedation, these signs are often present. According to multiple reviews and observational studies, female gender, advanced age, catheter placement outside the antecubital fossa, small-gauge catheters, and power injection techniques increase the risk of extravasation.^{6–8(IIa, IVa, Ib)}

Regular site evaluation, especially in patients receiving vesicant or irritant infusions, is crucial. In the Atay study, many direct-care clinicians lacked formal training in extravasation recognition, emphasizing the importance of education and severity grading systems to improve early identification.^{8(Ib)}

Recommendation 2a: Antidote Awareness of High-Risk Infusates

Clinicians who prescribe, prepare, or administer high-risk medications through VADs must be aware of the appropriate antidotes, countermeasures, and protocols for those agents. Facilities should ensure that clinicians have access to these agents (e.g., hyaluronidase, phentolamine) and the education necessary for their timely and accurate use.

Recommendation 2b: Immediate Management of Extravasation

When extravasation is suspected or confirmed, clinicians must immediately stop the infusion, disconnect the tubing, and aspirate any residual drug through the catheter, if permitted by the protocol. The catheter should be left in place to permit administration of a pharmacologic antidote into the affected tissue if indicated. Use of the same catheter to deliver the antidote may reduce additional tissue trauma.

Recommendation 2c: Supportive Management of Extravasation

Following immediate stabilization, the affected limb should be elevated and monitored closely. Warm or cold compresses should be applied based on the physicochemical properties of the infused agent. Clinicians should assess for changes in pain, perfusion, swelling, and skin integrity. Pharmacologic treatments should be administered as indicated, and wound care or

surgical consultation obtained for moderate-to-severe cases or signs of tissue compromise.

Summary of Evidence:

Management: Extravasation injury management requires the rapid identification of the agent, a response tailored to the specific agent, and interdisciplinary collaboration. Although often viewed as a direct-care clinician's responsibility, a safe and effective response begins before the infusion, with the clinician being aware of the antidotes, treatments, and protocols appropriate for high-risk medications. As Stefanos et al. have emphasized, timely access to agents such as phentolamine, hyaluronidase, and terbutaline can significantly reduce the severity of tissue damage, but this requires proactive preparation and staff education.^{7(IVa)}

When extravasation is suspected, infusion must be stopped immediately, and aspiration of residual drug through the catheter should be attempted when permitted. The catheter may be left in place to administer the antidote, a strategy that reduces the risk of additional tissue trauma and delays. Compresses, warm or cold, depending on the physicochemical properties of the infusate, should be applied promptly to limit local injury progression.^{7,9(IVa, Va)}

Ongoing care includes limb elevation, frequent reassessment, and escalation to wound or surgical services in the case of moderate-to-severe injury. In a 2020 integrative review, Taibi et al. found that protocolized multidisciplinary response, combined with timely pharmacological treatment administration, improved healing and reduced the incidence of long-term complications.^{10(IIIb)} Additional risk factors, such as high osmolality, vasoconstrictive agents, and deep tissue penetration, warrant closer observation and early pharmacologic intervention.^{4,7,9(IVa, IVa, Va)} Garcia-Urbe et al. similarly found that local supportive measures plus timely antidote use prevented surgical intervention in patients with vasopressor extravasation.^{4,7,9(IVa, IVa, Va)}

Recommendation 3: Identification and Differentiation of Occlusion

Clinicians must assess all VADs for signs of occlusion, differentiating between complete and partial loss of flow. Occlusions should be further categorized as mechanical, thrombotic, or chemical based on clinical presentation and resistance pattern. Accurate identification supports timely intervention, appropriate escalation, and preservation of the device.

Summary of Evidence

Identification: Occlusion is a leading cause of VAD failure, with clinical presentations ranging from minor withdrawal resistance to complete flow obstruction. Differentiating between partial occlusion (e.g., sluggish flow, inability to aspirate) and complete occlusion (no infusion or aspiration) helps guide intervention. Authors of one study reported that 40% of occlusions in double-lumen peripherally inserted central catheters (PICCs) were partial, and many required pharmacologic or mechanical correction.^{11(IIIb)}

Occlusions should be further assessed for their likely etiology:

- Mechanical occlusion is often positional or product-related (e.g., kinked tubing, tight dressings, end-cap malfunction, pinch-off syndrome).
- Thrombotic occlusion may involve intraluminal clots, mural thrombus, or fibroblastic sleeve formation, often identified by resistance during flush or inability to withdraw blood.^{12(Va)}
- Chemical occlusion typically results from medication or solution incompatibilities, especially with lipid-based or alkaline agents, and may present with visible precipitate or sudden onset of dysfunction.

Matey and Camp-Sorrell outlined a structured algorithm for evaluating occlusion cause based on clinical cues, flow behavior, and catheter history. Correctly identifying the type and extent of occlusion supports early troubleshooting and can prevent premature catheter replacement.^{13(IVa)}

Recommendation 3a: Mechanical Occlusion Management

Clinicians should evaluate for mechanical causes of occlusion, including clamp position, tubing kinks, tight securement, endcaps, or malposition. Repositioning the patient or limb, visualizing the entire external segment, and replacing the needleless connectors (NCs) should be attempted before escalating to pharmacologic or imaging interventions.

Recommendation 3b: Thrombotic Occlusion and Thrombolytic Use

If thrombotic occlusion is suspected, thrombolytic instillation must be initiated per protocol. If function is not restored after 2 doses, clinicians should suspect another cause of occlusion.

Recommendation 3c: Chemical Occlusion (Precipitate Management)

When chemical occlusion is suspected and the causal agents can be identified, clinicians must consult the pharmacy and select appropriate disintegration agents. Antidotes must be administered in collaboration with licensed independent practitioners and pharmacists' guidance to avoid catheter damage or patient harm.

Recommendation 3d: Imaging for Persistent Occlusion

If occlusion is unresolved after mechanical and pharmacologic interventions, imaging must be obtained to evaluate for pinch-off syndrome, catheter fracture, or tip migration.

Summary of Evidence

Management: Occlusion is a leading cause of VAD failure and must be systematically evaluated to prevent unnecessary catheter removal or patient harm. Identification of occlusion type, mechanical, thrombotic, or chemical, guides appropriate intervention. A structured algorithm for troubleshooting occlusions emphasizing initial mechanical checks, catheter repositioning, and escalation based on resistance pattern and clinical history.^{13(IVa)}

Mechanical occlusion is frequently positional and reversible with conservative maneuvers. Thrombotic occlusions require pharmacologic treatment, typically with alteplase, which restores function in the majority of cases with 1 or 2 doses.^{14(Va)}

Hawes (2020) and others caution that repeated use of thrombolytics may indicate biofilm buildup, not thrombus, especially in long-term central devices.^{15(IIIb)}

Chemical occlusions, often underrecognized, require pharmacy collaboration to identify the incompatible agents and select the appropriate countermeasure. Mismanagement can damage the catheter or cause further obstruction. When catheter function cannot be restored, imaging such as chest x-ray, fluoroscopy, or ultrasound is essential to rule out structural or vascular complications.^{13(IVa)}

Recommendation 4: Identification of Dislodgement or Malposition

Direct-care clinicians are encouraged to assess for signs of catheter dislodgement and tip malposition routinely. Indicators include changes in external catheter length, securement malfunction, dressing disruption, pain or swelling, inability to aspirate blood, or altered flow rates during infusion. Assessment should include physical inspection, patient report, and comparison with baseline measurements or imaging when available.

Summary of Evidence

Identification: Catheter dislodgement and tip malposition can occur with any VAD and may present with subtle or nonspecific signs. External catheter length change, especially when not documented at insertion, is one of the most under-recognized indicators. In one study, visible migration was reported as a leading cause of accidental removal and tip displacement.^{16(Vb)} Authors of another study emphasized that PICC tip migration often goes undetected unless catheter length is routinely measured and recorded.^{17(Vb)}

Common symptoms of tip malposition include neck, jaw, or shoulder pain, ear gurgling during flush, or sudden loss of blood return or flow rate changes, especially in PICCs. In central lines, migration into the azygous, jugular, or contralateral subclavian veins can occur due to high intrathoracic pressures, coughing, or poor securement. These complications are more likely to be detected when securement is weak or breakaway connectors are absent.^{15(Vb)}

Recommendation 4a: External Length Change Evaluation

Any change in external catheter length from baseline should prompt immediate reassessment. Marking catheter length at insertion and documenting the baseline serves as a reference point for detecting potential displacement.

Recommendation 4b: Clinical Signs of Tip Migration

When tip migration is suspected, such as new onset of neck or shoulder discomfort (PICC), ipsilateral ear gurgling, or altered function, clinical signs should be documented, and the device should not be used until evaluated. Confirmatory imaging may be warranted.

Recommendation 4c: Imaging Assessment for Suspected Malposition

If clinical or external signs suggest malposition and no other cause is identified, diagnostic imaging must be obtained to

confirm tip location. The catheter should remain unused until evaluation is complete.

Summary of Evidence

Management: When dislodgement is suspected, use of the device should be suspended until full assessment is completed. This includes physical inspection, patient report, and flow testing with non-forceful aspiration or flush. If these steps do not confirm patency, imaging must be obtained. Authors of two studies have outlined protocols recommending chest radiograph, fluoroscopy, or ultrasound to verify catheter tip position following any suspected malposition.^{13,18(IVa, IIb)}

Devices that have migrated but are still functional may be salvaged depending on tip location, device type, and patient risk factors. Otherwise, replacement should be considered. Authors of studies have supported the use of engineered securement devices and breakaway connectors to reduce dislodgement and need for reinsertion.^{16(Vb)} Ongoing education and routine documentation of baseline catheter length also reduce the risk of undetected displacement.

Recommendation 5: Identify Lymphatic Complications

Clinicians must assess for signs of lymphatic leak during routine vascular access site evaluations, particularly in patients with femoral access, tunneled catheters, or deep subcutaneous tissue. Persistent dampness beneath the dressing, accompanied by the absence of overt bleeding, may indicate lymphatic disruption. Early identification and supportive management are crucial to maintaining site integrity and preventing further complications.

Summary of Evidence

Identification: Lymphatic leak is a rare but underrecognized complication of VAD placement, particularly when deep tissue disruption occurs during tunneling or in anatomically complex regions such as the femoral triangle. Although overt bleeding is usually noted and addressed promptly, persistent moisture beneath the dressing, without visible blood, may reflect a serous lymphatic fluid leak rather than hematoma or exudate from infection.^{19(IIIb)}

This complication is most frequently reported following tunneling of central venous catheters, subcutaneous port placement, or femoral vein access, especially in patients with low body fat, altered lymphatic drainage, or prior instrumentation. It may be confused with dressing saturation from sweat, poor securement, or minor bleeding, delaying appropriate intervention. In their discussion of site surveillance, Gohil et al. emphasized that damp dressings and nonvisible site changes require prompt investigation to distinguish emerging complications.^{20(IIa)}

Recommendation 5a: Supportive Management of Suspected Lymphatic Leak

When lymphatic leak is suspected, clinicians should reinforce dressing integrity, consider light compression if not contraindicate, and elevate the limb when feasible. Persistent or worsening leakage must prompt site reassessment and consideration of catheter relocation if securement or skin integrity is compromised.

Summary of Evidence

Management: The phenomenon of lymphatic leak is most often reported in the early postinsertion period, especially following catheter manipulation, power injection, or use of large-bore devices. Gras et al. noted that fluid accumulation beneath the dressing, when not attributed to blood, should raise concern for lymphatic leak, particularly in older adults or patients with fragile skin.^{19(IIIb)} Structured site assessment, including inspection and palpation, improves recognition of such complications before secondary issues such as dislodgement or localized infection occur.^{20(IIa)}

While no protocols specific to lymphatic leak management have been established, the principles of site protection and supportive care apply. Elevation may reduce lymphatic pressure, and conservative compression can support sealing of disrupted vessels when not contraindicated.^{20(IIa)} Reinforcing securement and maintaining a dry, intact dressings are essential to avoid further site compromise. If leakage persists beyond initial conservative efforts, catheter reassessment or relocation may be necessary to prevent downstream complications.^{4(IVa)}

Recommendation 6: Identification of Totally Implanted VAD Complications

Clinicians should routinely assess totally implanted VADs (TIVADs) for signs of complication or failure. Core elements of assessment include:

- Palpation to identify tenderness, pain, or chamber instability;
- Observation for site changes or leakage;
- Performance testing flush resistance or poor blood return;
- Patient-reported symptoms discomfort, burning, pressure.

Complications may be subtle or atypical, particularly in patients receiving chemotherapy, corticosteroids, or prolonged vascular access. Early identification enables intervention before more severe outcomes occur.

Summary of Evidence

Identification: TIVAD-related complications are uncommon but potentially severe. Early detection depends on routine clinical assessments, particularly in high-risk patients such as those undergoing chemotherapy, receiving corticosteroids, or experiencing tissue fragility due to cachexia or prior surgeries.^{21,22(IIIa, IIIa)}

Authors of several studies have emphasized the importance of direct palpation, performance testing, and patient-reported symptoms as key tools for early recognition. In a large single-center study, Mori et al. identified rotation, dislocation, and skin dehiscence as TIVAD-specific risks often detected during flushing or dressing changes.^{23(IIIb)} Tom et al. reported that education and assessment bundles improved detection of early infiltration, extravasation, leakage, and skin injury.^{24(IIIb)}

Particularly, TIVAD portal body (i.e., housing, reservoir, and chamber) rotation (flipping), portal body depth issues, and skin degradation were recognized more frequently when structured assessments, including palpation, inspection, and patient queries, were incorporated into routine care. These findings

support the importance of comprehensive bedside evaluation in preventing complications such as infiltration, extravasation, infection, and tissue breakdown.^{4,21,22(IVa, IIIa, IIIa)}

Recommendation 6a: Infiltration or Extravasation

Clinicians must evaluate signs of infiltration or extravasation during each TIVAD access and infusion, especially when resistance, swelling, or patient discomfort is reported. Potential causes include dislodged or improperly placed needles, catheter fractures, or disconnection of the catheter from the portal body. Prompt cessation of infusion and diagnostic assessment are warranted if infiltration or extravasation is suspected.

Recommendation 6b: Malpositioned or Deep Chamber

Clinicians should suspect portal body malposition when the TIVAD septum is difficult to locate, access attempts are repeatedly unsuccessful, or flushing is impaired. Contributing factors may include deep implantation in obese patients, rotation (flipping), or migration of the TIVAD portal body. Imaging confirmation and specialty consultation should be pursued when access is unreliable.

Recommendation 6c: Skin Breakdown Over and Around the TIVAD Portal Body

Clinicians should assess the skin overlying the TIVAD portal body for signs of breakdown, thinning, infection, or ulceration. Progressive tissue erosion may expose the septum, increasing the risk of infection. Contributing factors include frequent access, steroid use, fragile skin, or infection. If skin breakdown is observed, port use must be discontinued, site care implemented, and surgical evaluation considered.

Summary of Evidence

Management: Effective management strategies must be tailored to the specific etiology, whether mechanical, physiological, or infectious in nature, and depend on early recognition, appropriate imaging, and multidisciplinary intervention. Though infrequent, these events can lead to treatment delays, tissue injury, or infection if not recognized and addressed early. Observational studies and retrospective reviews consistently report low but meaningful rates of catheter dislocation, portal body rotation, and skin breakdown requiring intervention.^{23,25(IIIb, IIIb)}

Effective management strategies rely on timely device reassessment, imaging when needed, and the appropriate discontinuation or replacement of the device. Multidisciplinary care, including surgical or radiologic consultation, is often required when structural failure or tissue compromise is confirmed. Education and access protocols may help reduce the severity of complications when they occur.^{24(IIIb)}

Recommendation 7: Identification of Persistent Pain or Altered Sensation

Clinicians should assess for persistent or atypical pain, numbness, burning, or altered sensation associated with any VAD. These symptoms may indicate nerve irritation, device malposition, circulation issues, or early signs of infection.

Evaluation should include functional assessment of the device, inspection of the site, and inquiry into the quality, location, and duration of symptoms.

Recommendation 7a: Management of Pain or Altered Sensation

When pain or altered sensation persists beyond the expected postinsertion period or presents atypically, clinicians must escalate to appropriate specialty services for diagnostic imaging and further evaluation.

Concerning findings include dermatomal distribution, functional impairment, escalating pain, or symptoms that interfere with device use. Referral may include interventional radiology, neurology, or surgical consultation, depending on presentation and suspected etiology.

Summary of Evidence

While mild postprocedural discomfort is common after VAD insertion, persistent or atypical pain may signal underlying complications, including nerve impingement, mechanical irritation, or early infection. Observational data and surveillance guidelines emphasize the need for structured monitoring to detect these less visible issues before more severe complications emerge.^{26,27(IIb, IIIb)}

Protocols that incorporate patient-reported outcomes and standardized follow-up assessments support earlier identification of pain-related complications and facilitate timely escalation to specialty care. Persistent pain or altered sensation, especially when dermatomal, focal, or interfering with function, warrants clinical investigation and device reassessment.^{28(IIIa)}

Recommendation 8: Insertion Site Infection

Clinicians are encouraged to assess the vascular access insertion site for local signs of infection during every evaluation. Redness, tenderness, swelling, drainage, or localized warmth should prompt immediate investigation and intervention. Dressing materials and antiseptic agents should be adjusted based on skin integrity, and infectious disease consultation should be considered if the condition fails to improve.

Summary of Evidence

Localized infection at the vascular access site often presents with nonspecific symptoms, such as erythema, tenderness, or dressing saturation, but may progress to more serious complications if unrecognized. In a pooled analysis of 4 randomized controlled trials, Buetti et al. found that pain, redness, and discharge within the first 7 days were reliable early indicators of catheter-related infection, independent of dressing type or antiseptic used.^{4,29(IVa, IIIa)} Persistent moisture, poorly adherent dressings, and fragile skin further elevate infection risk.

Best practices recommend immediate evaluation of any new or worsening local symptoms. Adjustments may include switching to non-chlorhexidine gluconate antiseptics, applying absorptive or antimicrobial dressings, and escalating to wound care or infectious disease specialists. Structured documentation and frequent reassessment improve early identification and outcomes.^{4,19(IVa, IIIb)}

Recommendation 9: Recognize and Respond to Systemic Signs of VAD-Related Infection

Clinicians must assess all VADs as potential sources of infection when patients present with systemic signs such as fever, chills, rigors, hypotension, or elevated white blood cell count without an identifiable source. Evaluation should include site inspection, blood cultures (preferably paired), and prompt infectious disease consultation when catheter-related bloodstream infection (CRBSI) is suspected.

Summary of Evidence

CRBSIs can present subtly and progress rapidly, especially in immunocompromised patients or those with long-term central access. Systemic signs such as fever, chills, rigors, or hypotension often represent the first and only indication of infection. In a multicenter randomized trial of neutropenic patients, Biehl et al. found that chlorhexidine dressings significantly reduced probable CRBSI rates (10.4% versus 17.3%, $P = 0.014$), reinforcing the importance of preventive strategies and early identification of systemic signs.^{30(Ia)}

Accurate diagnosis is essential for both clinical safety and infection surveillance. In a systematic review, Larsen et al. found that publicly reported central line–associated bloodstream infection (CLABSI) rates underestimate true incidence by up to 4.4%, potentially delaying recognition and treatment. Guidelines recommend obtaining paired blood cultures (central and peripheral), prompt evaluation of the insertion site, and early involvement of infectious disease specialists when CRBSI is suspected. Failure to promptly address these signs can increase sepsis risk, hospitalization, and mortality.^{31(IIb)}

Recommendation 10: Isolated Fever With Indwelling Central VAD

Clinicians should not automatically remove a central VAD (CVAD) based solely on the presence of fever or suspected infection, without first conducting a comprehensive clinical assessment.

Summary of Evidence

Routine removal of a CVAD at the onset of fever, without further evaluation, may lead to unnecessary device loss, increased procedural risk, and disruption of therapy. In a comprehensive literature review, Patel et al. reported that high-performing interventions emphasized a staged approach to CVAD use, beginning with the appropriateness of placement, continuing through maintenance, and concluding with timely removal. The most effective CLABSI reduction strategies combined clinical assessment with consistent auditing and avoidance of default removal triggers such as fever alone.^{32(Vb)} Updated guidance from Society for Healthcare Epidemiology of America/Infectious Diseases Society of America/Association for Professionals in Infection Control and Epidemiology reinforces this patient-centered strategy, urging daily assessment of line necessity and emphasizing that CVADs should not be removed unless clinically indicated, such as when infection is confirmed or the device is no longer needed.^{33(Va)}

Recommendation 11: Recognize and Respond to Signs of Catheter-Related Thrombosis

Clinicians should assess catheter-related thrombosis (CRT) when patients with a VAD present with unilateral swelling, limb pain, erythema, engorged superficial veins, or catheter dysfunction. Suspicion of CRT should prompt confirmatory imaging (e.g., duplex ultrasound) and consultation with vascular medicine or hematology. Catheter removal may not be required and should be determined based on clinical stability, device functionality, and thrombosis severity.

Summary of Evidence

CRT is a common complication of peripherally and centrally inserted catheters, especially in oncology and critically ill populations. Signs include ipsilateral swelling, discomfort, venous distension, erythema, or loss of catheter function. In a single-center retrospective study, multiple risk factors for CRT were identified, including cancer, prior thrombosis, multiple insertion attempts, and a high catheter-to-vein ratio.^{34(IIIb)}

Authors of another study reported a 22.8% incidence of venous thromboembolism in nonanticoagulated patients with PICCs or midlines, and multiple systematic reviews confirming CRT risk across device types and care settings.^{35(IIIb)} The 2019 Kidney Disease Outcomes Quality Initiative guidelines and subsequent meta-analyses recommend individualized device selection and careful insertion planning for patients at risk of thrombosis. Confirmatory ultrasound and early hematology or vascular consult are essential for diagnosis and risk-aligned intervention.^{36(IVa)} Most cases are managed with anticoagulation, while catheter removal is considered based on clinical needs and device status.

Recommendation 12: Early Recognition of Cardiac Complications

It is strongly recommended to develop and implement standardized protocols to support early recognition and immediate management of cardiac complications, including arrhythmias and cardiac tamponade, in patients with central VADs.

Summary of Evidence

Cardiac complications related to CVADs, including tamponade, arrhythmias, and catheter migration, are rare but potentially fatal. In a multicenter retrospective study of over 400 adults receiving totally implantable VADs via the brachiocephalic vein, a low incidence of serious complications was reported, including cardiac tamponade, arterial puncture, pneumothorax, and post-insertion thrombosis. Early identification and structured follow-up were found to reduce unplanned removals.^{37(IIIb)} Authors of other retrospective reviews have emphasized the value of protocol-driven care in identifying and managing early signs of deterioration, including chest pain, hypotension, or infusion disturbance.

Structured training and competency assessments enhance insertion accuracy and minimize complications resulting from catheter malposition or migration.^{38(IIb)} Ultrasound guidance is highlighted across the literature as a key strategy to reduce

mechanical injury during insertion, while prompt clinical recognition and imaging are essential to address postprocedural events. Infection-related complications may also signal catheter dysfunction and should be evaluated with cardiac complications in mind.^{39(IIIb)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Reduced phlebitis risk: Regular assessment for phlebitis—using validated scales—allows for early intervention, reducing severity and complications.^{27,40–45}
- Improved outcomes in malposition: Timely evaluation of internal catheter malposition allows for spontaneous or assisted correction, improving catheter function and reducing need for replacement.^{46,47}
- Enhanced patient safety: Routine assessment of catheter sites—including inspection for signs of phlebitis, infiltration, or malposition—allows for early recognition of complications and prompt intervention, reducing adverse outcomes.^{27,40–45}
- Enhanced skin injury management: The catheter-associated skin impairment algorithm improves provider confidence and consistency in managing skin damage.^{4,48}

Risks

- Missed signs of dislodgement: Failure to assess catheter stability and securement during dressing changes may result in unnoticed migration or malposition.^{49–52}
- Cardiac tamponade: Delayed recognition of signs like hypotension and jugular venous distension in CVAD patients may lead to life-threatening complications.^{37–39,53,54}
- Underrecognized CRBSI: Inconsistent assessment for bloodstream infection symptoms, such as fever and drainage, may delay diagnosis of catheter-related bloodstream infections.³²
- Topical therapy failure: Exit site infections may worsen if systemic antibiotics are delayed after failed topical treatment.^{4,55}

Implementation Considerations

- Validated tools improve reliability: Use of standardized scales (e.g., for phlebitis) ensures consistent documentation and early recognition of complications.^{27,40–44}
- Power flush utility: High-flow flush techniques have been shown to reposition malpositioned catheters with high first-attempt success rates.^{46,47}

- Routine tip verification: Internal malpositions may not show external signs—requiring protocols for imaging confirmation based on clinical suspicion.^{46,47}
- Use of site cultures and blood cultures: When an exit site infection is suspected, cultures help guide appropriate treatment and catheter management decisions.⁴
- Skin protection protocols: Recommendations include barrier films, nonalcohol antiseptics, and dressing changes based on skin condition severity.⁴

Barriers to Implementation

- Limited imaging access: Internal malpositions may go undetected in settings without access to timely imaging or experienced interpretation.^{46,47}
- Competency gaps: Providers may lack training in recognizing early cardiac, reducing timely intervention.^{38,39,53,54,56–58}
- Documentation variability: Without standardized assessment intervals and scales, symptom tracking (e.g., phlebitis or infiltration) may be inconsistent across providers.^{27,40–44}
- Clinical workload and documentation burden: Standardized assessments (e.g., for phlebitis) and frequent reassessments may be time intensive.^{27,40–44}

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Chapter 5.4—Management of Skin, Dressings & Securement

Maintaining dressing integrity and catheter securement requires thoughtful coordination of skin protection, product selection, and site assessment. This chapter integrates strategies for at risk skin, managing compromised skin, including medical adhesive–related skin injury (MARSI), catheter-associated skin injury (CASI), dermatitis, and tissue breakdown. Skin damage significantly affects patient comfort, dressing adherence, reliability of securement, and the risk of infection.

Dressing and securement of the vascular access device (VAD) are foundational elements of maintenance. Their effectiveness directly influences dwell time, infection risk, device stability, and patient comfort. Maintaining an intact dressing and securement system is not simply a matter of aesthetics; it is a core infection prevention strategy and a defense against complications such as dislodgement, thrombosis, and CASI.

By standardizing practices and matching products to clinical need, clinicians can reduce the frequency of unplanned dressing changes, support device function, and protect skin integrity. Optimizing dressing and securement is a critical component of safe and effective vascular access care across all settings.

Recommendation 1: Identify and Manage CASI

Clinicians must assess for skin injury, including CASI, MARSI, and contact dermatitis, during every vascular access site evaluation.

Summary of Evidence

Skin injury related to VADs is a frequent and preventable complication across all device types, including peripheral intravenous catheters (PIVCs), peripheral midlines (PMLs), and central venous access devices (CVADs). CASI, MARSI, and contact dermatitis may result from chemical irritation, adhesive trauma, pressure, or moisture trapped beneath dressings.^{1(IIIa)} These complications impair dressing adherence, increase infection risk, and can result in premature catheter removal. In a large-scale quality improvement (QI) initiative involving over 30,000 PIVCs, DeVries et al. demonstrated near elimination of MARSI and dressing disruption when clinicians used a bundle of sterile barrier film, adhesive enhancer, and staff education.^{2(Va)} Authors of 1 study emphasized that skin damage is most often related to dressing material, frequency of dressing change, antiseptic exposure, and removal technique.^{3(IIIb)}

Structured assessment tools such as the CASI algorithm support early recognition and guide product selection, escalation, and documentation (Appendix C).^{1(IIIa)} These frameworks improve consistency between providers and reduce the likelihood of delayed referral. When used alongside targeted education and product substitution (e.g., suspending chlorhexidine gluconate [CHG], switching to silicone-based dressings, or nonadhesive based securement), structured response protocols help preserve skin integrity and device function. Patients with fragile skin, repeated adhesive exposure, or chemical sensitivities

are especially vulnerable to skin injury and may require early wound care consultation for healing and continued catheter use.^{1,3–(IIIa,IIIb,IVa,IIIa)}

Recommendation 2: Intervention Strategies for Skin Compromise at the VAD Site

When skin impairment is present at or near the vascular access site, including weeping, oozing, granulation tissue, inflammation, or visible breakdown, clinicians must initiate a structured skin response protocol.

Summary of Evidence

Persistent moisture or exudate at the catheter insertion site increases the risk of skin maceration, dressing disruption, and microbial colonization. Granulation tissue, often caused by mechanical friction, chronic inflammation, or chemical irritation, is a sign of impaired tissue recovery and may reflect biofilm activity along the catheter tract. Inappropriate product selection, such as continued CHG use on broken or moist skin, can exacerbate tissue damage and interfere with healing.^{1,4(IIIa,IVa)}

Wound ostomy, and continence, nursing guidelines recommend immediate suspension of CHG products and transparent occlusive dressings when weeping or granulation is present, especially in patients with impaired skin integrity. Alternative dressings such as nonalcohol barrier films, non-CHG sterile gauze, or foam-based absorbent products may help manage exudate while protecting the catheter.^{1(IIIa)} Using a subcutaneous anchor securement system (SASS) for CVADs and PML will keep the catheter secure without the use of additional adhesive.^{5(IIIa)} In 1 observational study, delayed wound consults were associated with extended dwell times of compromised catheters, leading to unplanned removals and higher infection risk. Structured assessment tools, such as the CASI algorithm, help guide escalation and product substitution while preserving vascular access.^{1,3(IIIa,IIIb)}

Recommendation 3: Routine Dressing Change Intervals

Clinicians should adhere to standardized dressing change intervals to reduce infection risk and maintain dressing integrity:

- Transparent dressings: every 7 days or sooner if compromised.
- Gauze dressings: every 48 hours.
- CHG-impregnated dressings: 7 days if intact.
- Totally implantable VAD (TIVAD) dressing and noncoring needles: every 7 days or sooner if displaced.

Summary of Evidence

Authors of multiple studies and systematic reviews have supported the use of standardized intervals to minimize contamination and dressing disruption.^{6,7(Ia,IVb)} Variation in frequency was associated with increased skin injury and a higher risk of microbial colonization, reinforcing the need for interval-based protocols.^{8(Ia)}

Recommendation 4: Aseptic Technique for Dressing Changes

Dressing changes must employ appropriate aseptic nontouch technique (ANTT) based on device type and patient risk.

Summary of Evidence

The principle of ANTT emphasizes protecting key parts and key sites during all invasive procedures, including routine dressing changes.^{9,10(Va,IIa)} This structured approach is designed to minimize the risk of contamination, improve consistency across providers, and ensure safety without unnecessary use of full sterile fields.^{11(IIIb)} In foundational work, Rowley and Clare have established ANTT as a globally recognized standard for both insertion and maintenance procedures, with evidence supporting its role in reducing catheter-related infections and improving compliance with aseptic protocols.

Further support for ANTT is found in studies in which authors demonstrated that combining a structured technique with staff education and appropriate securement reduces dressing disruption and catheter dislodgement.^{12(Va)} McParlan et al. reported that adhesive and securement protocols built on ANTT principles significantly improved dressing integrity.^{13(IIa)} Schmutz et al. demonstrated that specific securement strategies effectively minimized accidental PIVC removal, highlighting the interdependence of technique and materials.^{14(Ib)}

Recommendation 5: Use of Antimicrobial Dressings and Discs

Antimicrobial dressings and discs should be used for:

- All VADs.
- Immunocompromised patients or those at increased infection risk.
- TIVAD needle insertion sites in immunocompromised patients.

Summary of Evidence

Sustained-release chlorhexidine at the catheter insertion site reduces colonization and infection risk. While authors of most studies have focused on CHG-impregnated dressings (e.g., sponge or gel matrix), adjunctive use of CHG discs placed beneath standard dressings is also a widely adopted method of antimicrobial site protection.^{15,16(IIIb,IIa)}

Authors of systematic reviews and randomized trials have supported the infection prevention benefits of CHG dressings, particularly in high-risk populations such as intensive care unit, oncology, and immunocompromised patients. These products have been shown to reduce catheter-related bloodstream infections (CRBSIs) and extend dressing dwell time.^{16–18(IIa,IIb, Ia)}

Although head-to-head evidence comparing CHG discs and CHG-impregnated dressings is limited, both methods provide similar antimicrobial action and are endorsed in practice guidelines as part of infection prevention bundles. Authors of 2 studies looked at the advantages of CHG dressings for PIVCs showing a reduction in PIVC-BSI.^{19,20(Va, Ia)} Karlnoski et al. discussed the use of silver-plated dressings

as an option to reduce central line–associated bloodstream infections.^{21(IIIb)}

Recommendation 6: Use of Adhesive Enhancers

To improve dressing adherence and reduce the frequency of unplanned dressing changes:

- Use adhesive enhancers (e.g., gum mastic liquid adhesive) for patients at risk for dressing lift due to moisture, skin oils, movement, or high friction areas.
- Apply enhancers in accordance with manufacturer guidance and allow them to dry fully before dressing application.
- Weigh the risk versus the benefit of tackifiers in patients with fragile skin.

Summary of Evidence

Dressing lift and unplanned changes increase the risk of contamination and catheter dislodgement.^{2,22,23(Va, IIIb, IIIb)} Adhesive enhancers such as gum mastic have been shown to significantly improve dressing adherence, especially in high-moisture environments or during prolonged dwell times.^{2(Va)} In a large-scale QI project, authors demonstrated that pairing adhesive enhancers with education and standardized products led to >96% dressing integrity and eliminated MARSI events in >30,000.^{2(Va)} These interventions reduce both cost and complication risk, supporting their inclusion in VAD maintenance protocols.^{2,22,23(Va, IIIb, IIIb)}

Recommendation 7: Skin Protection with Dressings

To decrease the risk of MARSI:

- Apply a sterile barrier film (skin protectant) prior to dressing application.
- Avoid nonsterile gauze, tape, or compression wraps that impair visualization or damage skin.
- Direct-care clinicians should be trained in dressing application and removal techniques to minimize skin trauma.

Summary of Evidence

MARSI is a common complication of vascular access care, especially in older adults and patients requiring frequent dressing changes.^{24–27(Ib, IIb, Va, IIIb)} Evidence supports the use of sterile barrier films to protect the stratum corneum, reduce removal trauma, and maintain dressing adherence.^{25(IIIb)} Authors of clinical studies and consensus documents have shown that barrier film use results in fewer disruptions and less pain during removal, while preserving skin integrity. Training staff in correct dressing removal techniques, such as horizontal pull, skin support, and slow removal, also reduces the likelihood of skin tears and inflammation.^{24,26(Ib, Va)} Together, these practices promote safe, skin-friendly care.^{24–26(Ib, IIb, Va)}

Recommendation 8: Use of Engineered Securement Devices

All VADs should be secured using an appropriate securement device to minimize catheter movement, migration, and

dislodgement. Engineered securement devices (ESDs) should be assessed for their ability to provide securement without introducing additional patient risk, such as skin injury or dressing disruption. Selection should be based on patient-specific factors, anticipated dwell time, and institutional outcome data.

Summary of Evidence

Securement is a critical component of vascular access care, directly impacting dressing integrity, catheter migration, and unplanned dislodgement. In a comparative study of adhesive versus subcutaneous anchor securement systems, researchers found that SASSs improved dressing integrity and significantly reduced catheter migration, supporting their role in securing CVADs without reliance on sutures.^{5,13,28(IIIa, IIa, IIIb)} Authors of another study demonstrated that the force required to dislodge a catheter varied significantly across securement methods, highlighting the mechanical impact of ESD selection on catheter stability.^{14(Ib)}

DeVries et al. reported improved dressing integrity and reduced device disruption following a large-scale QI initiative involving adhesive enhancers, an integrated securement device (ISD), and standardization of securement protocols, further supporting the role of ESDs as part of bundled care.^{2(Va)} In a 2024 meta-analysis, Xu et al. added moderate-certainty evidence that tissue adhesives prolong dressing durability but are associated with increased risk of skin damage, reinforcing the need for patient-specific assessment.^{29(Ia)}

Engineered securement device (ESD) type	Description
Adhesive securement device (ASD)	Adhesive-backed baseplate with strap or clip mechanism.
Integrated securement device (ISD)	Dressing with a built-in securement component (e.g., securing through adhesive).
Subcutaneous anchor securement system (SASS)	Small flexible anchors placed subcutaneously to stabilize the catheter.
Tissue adhesive (TA)	Medical-grade cyanoacrylate glue applied to the insertion site, stabilization platform, or both.

Recommendation 8: Outcome-Driven Securement Strategies

Clinicians should routinely evaluate the effectiveness of VAD securement and adjust the securement strategy if repeated dressing disruptions, catheter migration, or device failure occur. Securement selection should reflect patient-specific factors, such as anatomical site, skin condition, expected dwell time, and history of adhesive-related complications.

Summary of Evidence

Securement-related complications, including migration, dislodgement, and dressing failure, are commonly associated with unplanned catheter removal and therapy interruption. Authors of multiple studies have demonstrated that securement strategies are not universally effective across all patient populations or settings. Structured protocols improve consistency, but individual response to securement products can vary substantially.^{30(Vb)}

Securement failure may be influenced by patient factors such as perspiration, mobility, or skin sensitivity. In a large QI initiative, DeVries et al. demonstrated reduced disruption and dressing failure after tailoring securement approaches to observed outcomes and incorporating adhesive enhancers.^{2(Va)} In a systematic review, Xu et al. found that tissue adhesive, while effective in neonates and some pediatric populations, carries a higher risk of skin injury in adults and does not offer consistent securement for CVADs on its own.^{29(Ia)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Reduced CRBSI risk: Routine dressing care, securement, and needle changes help minimize contamination and infection risk, particularly CRBSI.^{31–39}
- Improved securement and dressing integrity: Routine care and assessment of dressing integrity, securement stability, and timely needle replacement enhance patient comfort, reduce the risk of dislodgement or migration, and support safe, continuous access.^{13,40–46}
- Skin integrity and comfort: Routine dressing care with the use of silicone adhesive removers, barrier films, and sutureless securement devices helps preserve skin integrity by reducing MARSIs, minimizing pain and anxiety during dressing changes, lowering the risk of infection, and protecting against skin breakdown from secretions or bodily fluids.^{2,25,26,31,34–37,47}

Risks

- Skin damage: Repeated or aggressive dressing changes, particularly when using improper adhesive removal techniques, can cause MARSIs, inflammatory reactions, and skin tears, compromise of the skin barrier, and increase the risk of infection.^{1,2,22,26,47–49}
- CRBSI from contamination: Lack of dressing integrity and poor technique with care compromises the antimicrobial barrier, increasing the risk of CRBSI and external contamination.^{16,31–36,50}
- Dislodgement and migration: Poor dressing integrity and inadequate securement can lead to catheter dislodgement

or migration, which increases the risk of infection, device failure and therapy delays.^{30,40–42,44,51–64}

Implementation Considerations

- Use of ANTT: Surgical ANTT should be used for CVADs, midlines, or immunocompromised patients, while standard ANTT may be appropriate for PIVCs and low-risk patients, with all dressings applied aseptically to ensure protection and minimize infection risk.^{16,31–36,65–69}
- Tailored intervals by device type: Protocols should specify dressing and defined intervals while allowing for earlier changes if contamination or malfunction occurs.^{70–72}
- Select appropriate securement method: Tailor use of ESDs in accordance with manufacturer guidelines and patient-specific factors such as mobility, skin integrity, and anatomical site.^{30,44,51–62,64}
- Routine site checks: Frequent checks of securement stability, dressing integrity, and patient comfort should be part of routine maintenance protocols.^{40–42}

Barriers to Implementation

- Inconsistent adherence: Suboptimal dressing adherence and inconsistent compliance with dressing or needle change schedules can compromise dressing integrity and increase infection risk.^{13,73}
- Resource constraints: Implementation of specialized dressing materials and advanced devices may be hindered by cost, limited reimbursement, procurement challenges, and staffing or inventory constraints, making it difficult for resource-constrained facilities to maintain routine care schedules.^{31,32,34–37,41,42,46,68,74}
- Training requirements: Effective use of adhesive dressings and securement devices requires proper training, but limited clinician familiarity with newer products and lack of ongoing education or protocol reinforcement can lead to inconsistent application, increased risk of MARSI or dislodgement, and reduced adoption.^{1,13,26,61,65,66,75}
- Variable outcomes: Standardizing care practices can be challenging due to variability in product performance, differences in patient skin condition and dressing frequency, and potential sensitivities to adhesive materials or CHG, all of which require site-specific outcome tracking and individualized dressing strategies.^{14,26,47}
- Resource and time demands: Adherence to individualized dressing change frequencies, CHG bathing protocols, and aseptic technique can place significant demands on staffing and supply resources.^{2,6,48}

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Chapter 5.5—Flushing, Locking, & Blood Sampling

Routine flushing, catheter locking, and blood sampling are fundamental aspects of vascular access device (VAD) care. These practices support safe medication administration, reduce the risk of catheter-related bloodstream infections (CRBSIs), and promote consistent device function. When performed correctly, they also contribute to accurate laboratory diagnostics and minimize unnecessary device manipulation or replacement.

Evidence-based flushing and locking protocols should be tailored to the type of device, patient population, and clinical setting. Techniques such as pulsatile flushing, appropriate lock solutions, and postdraw saline flushing help reduce the risk of contamination and maintain line functionality. Similarly, blood sampling from VADs, when clinically appropriate, requires strict aseptic nontouch technique, adherence to discard volume guidance, and thoughtful coordination with flushing practices.

Integrating these procedures into routine workflows, supported by clinician education and institutional standardization, enhances care consistency and patient safety. A well-designed flushing and locking protocol, coupled with standardized blood sampling practices, is a critical component of any vascular access maintenance strategy.

Recommendation 1: Flushing Technique

Clinicians should use a pulsatile (push-pause) flushing technique followed by positive pressure to reduce the risk of occlusion, contamination, intraluminal fibrin buildup, and infusate residue.

Summary of Evidence

Pulsatile flushing (push-pause) generates turbulent flow within the catheter lumen, which helps to dislodge medication

residues, prevent fibrin sheath development, and reduce the risk of occlusion or biofilm formation.^{1–3(IIIb, Ib, IIb)} Positive pressure techniques should be used to help prevent retrograde blood reflux.^{3(IIIb)} (Note: The direct care clinician needs to understand the specific catheter and needleless connector engineering to best prevent reflux.)

Standardizing flushing technique across clinical settings enhances care consistency and safety. Authors of several studies have supported the use of single-use prefilled, preservative-free 0.9% saline syringes with a barrel diameter of 10 mL or greater, which are recommended to standardize practice and minimize the risk of infection.^{3,4(IIb, IIIb)} Prefilled syringes with the appropriate volumes reduce the potential for dosing errors and improve workflow efficiency. Institutions should consider these techniques as a core component of their vascular access maintenance protocols.^{4(IIIb)}

Recommendation 2: Flushing Frequency and Volume

Flushing frequency and volume should be tailored to the type of VAD and its pattern of use. Clinicians should follow standardized protocols that specify minimum flushing volumes and appropriate intervals for continuous and intermittent device use.

Summary of Evidence

The frequency and volume of flushing play a critical role in maintaining catheter function and preventing complications such as occlusion or drug residue buildup. Regular flushing after medication administration or at defined intervals has been shown to support VAD patency. Recommended volumes differ by device type, with ≥10 mL of preservative-free saline used for CVADs and 3–5 mL for peripheral intravenous catheters (PIVCs).^{5,6(IIIb, IIIb)}

Table 1. Flushing Frequency and Volume by Device Type^a

Device type	Use pattern	Flush frequency	Minimum volume
Peripheral intravenous catheter (PIVC)	Intermittent	After each medication or every 24 h if not accessed	3–5 mL saline
Peripheral midline (PML)	Daily, continuous, or intermittent	After each medication or at least every 24 h	≥10 mL saline
Peripherally inserted central catheter (PICC)	Daily or continuous	After each medication or at least every 24 h	≥10 mL saline
	Intermittent	Daily to weekly (depending on catheter instructions for use)	≥10 mL saline
Centrally inserted central catheter (CICC)	Daily or continuous	After each medication or at least every 24 h	≥10 mL saline
	Intermittent	Daily to weekly (depending on catheter instructions for use)	≥10 mL saline
Totally implantable venous access device (TIVAD; port)	Daily or continuous (accessed)	After each medication, at least every 24 h, and before de-access	≥10 mL saline
	Dormant (not accessed)	Every 1–3 mo (will require a locking solution)	≥10 mL saline
Hemodialysis catheter	Intermittent, specialized use	Per dialysis protocol	Prescribed volume per lumen

^aNote: The flush volume should exceed the internal volume of the catheter lumen, plus any extension sets. Flushing volumes and frequencies are dependent on several factors, including the number of infusates administered in 24 h, catheter instructions for use, and patient-specific issues.^{4,6–10}

In a mixed-methods study, Norton et al. reported that nurses most frequently used 10 mL flushes for PIVCs and that higher flush volumes and frequencies were positively associated with end-of-shift catheter patency. This supports protocol-driven minimum volumes and highlights the need for continued education on flush timing, especially in the context of maintenance versus medication administration (see Table 1).^{4(IIIb)}

Recommendation 3: Flushing Solutions

Use preservative-free 0.9% normal saline as the standard flushing solution for all peripheral and central VADs unless otherwise indicated by device type, therapy, or patient condition.

Summary of Evidence

Flushing with 0.9% normal saline serves to clear the lumen of residual infusates, reduce intraluminal drug interaction, and confirm patency before or following therapy.^{3(IIIb)} (Some medications are incompatible with saline flush [e.g. Diazepam, Amphotericin B]; check with your pharmacist for specific flush solution.)

This is distinct from locking, which is performed after the final flush when the device is not in active use and requires an indwelling solution to maintain patency over time.^{7,10(IIb, Ib)}

Authors of multiple studies have shown that 0.9% saline is effective for routine flushing of both peripheral VADs and central VADs, reducing the need for heparin and minimizing the risk of drug interaction, hypersensitivity, and heparin-induced thrombocytopenia.^{8,11–13(IIIb, IIb, Ib, IIa)} The use of preservative-free, single-use prefilled saline syringes is recommended to ensure accurate dosing and reduce the risk of contamination.^{14(IIb)}

Recommendation 4: Locking Solutions

Select locking solutions based on patient-specific risks, catheter type, clinical setting, and institutional protocols. Locking technique should follow a complete final saline flush, including sufficient volume to fill the entire lumen, and avoid reflux of blood. Locking solutions must be evidence-based and concentration-specific (see Table 2).

Summary of Evidence

Locking solutions are used to maintain catheter patency and reduce the risk of infection between catheter uses, particularly in long-term or intermittently accessed devices. Saline locks are suitable for most short-term devices. Still, patients with prolonged catheter dwell times or a history of complications may benefit from adjunct locking agents with antimicrobial, antibiofilm, or antithrombotic properties.^{8,11–13,17(IIIb, IIb, Ib, IIa, Vb)}

Table 2. Locking Solutions by Type, Concentration, and Supporting Study

Locking solution	Typical concentration	Authors (Year)
Normal saline	0.9%	Wu et al. (2021) ^{13(IIa)}
Heparin	10–100 units/mL (device-specific)	Han et al. (2016) ^{15(IIa)}
Citrate	4%	Huang (2019) ^{16(IIb)}
Tetrasodium ethylenediaminetetraacetic acid (T-EDTA)	4%	Hill and Garner (2021) ^{17(Vb)}
Taurolidine	1.35%–2% ± citrate	Wouters et al. (2020) ^{18(IIa)}
Ethanol	70%	Zhao et al. (2018) ^{19(IIb)}
Gentamicin-citrate	Gent 5 mg/mL + citrate 4%	Hussein et al. (2021) ^{20(IIIb)}
Vancomycin	2.5–5 mg/mL	Lafaurie et al. (2023) ^{21(IIb)}

While heparin has historically been used for this purpose, authors of studies have shown no clear advantage over saline for routine locking and highlight bleeding risks at higher concentrations.^{22(IIa)} Citrate (4%) is a lower-risk alternative in patients with coagulopathy or high bleeding risk.^{16(IIb)} T-EDTA has emerged as a biofilm-disrupting option with the potential to reduce both infection and occlusion rates in long-term CVADs, especially in home parenteral nutrition populations.^{17(Va)}

Antimicrobial locks, such as taurolidine, gentamicin-citrate, vancomycin, or ethanol, may be appropriate in high-risk or salvage scenarios; however, their use should be guided by real-world outcome data, local protocols, and patient-specific factors, rather than routine preference.^{18–21(IIb, IIb, IIIb)} Regardless of the lock solution used, accurate volume calculation (to fill the entire catheter and extension set), adherence to aseptic technique, and elimination of reflux are critical to achieving safe and effective locking.

Recommendation 5: Blood Sampling from VADs

When feasible, use peripheral venipuncture rather than VADs for blood sampling to reduce the risk of infection, occlusion, and sample contamination.

Summary of Evidence

Using VADs for blood sampling increases the risk of infection, intraluminal thrombus formation, and sample dilution or hemolysis, particularly when discard protocols are not followed.^{23–25(IIa, IIb, IIIb)} Authors of a systematic review found that limiting VAD-based draws reduced adverse events and was associated with improved test accuracy when peripheral venipuncture was used instead.^{13,26(IIa, IIb)}

When blood draws through VADs are necessary, evidence supports using discard volumes tailored to the device (minimum discard equal to twice the fill volume):

- CICC: 5 mL.
- PICC: 3–5 mL.
- TIVAD: 5–7 mL.

- Hemodialysis catheter: 8–10 mL.
- PML/PIVC: 2–3 mL.

Authors of studies have also supported push-pull techniques and saline-only protocols in select cases, with some evidence suggesting 2 mL may be sufficient for certain labs when paired with a 10 mL flush.^{27,28(IIb, IIIb)}

Following any blood sampling, a postdraw flush of 10–20 mL saline is advised to remove residual blood and maintain catheter patency. This step supports clinical alignment between this recommendation and flushing/patency practices.^{9(IVa)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Decreased CRBSI Risk via antimicrobial locks: Ethanol, taurolidine, and T-EDTA locking solution (per IFU) significantly reduce CRBSI rates in patients with tunneled catheters and those on home parenteral nutrition.^{17–20,29,30}
- Improved patency with pulsatile flushing: Use of the pulsatile technique improves flushing effectiveness and reduces biofilm formation.^{1–3}

Risks

- Bleeding with heparin use: Even low-dose heparin carries bleeding risk; alternatives like citrate may be safer for at-risk patients.^{15,31}
- Resistance with antibiotic locks: Prolonged or inappropriate use of antibiotic locks (e.g., vancomycin, gentamicin) may contribute to antimicrobial resistance.²⁰

- Tailored flushing based on catheter type: Flushing frequency and lock solutions should be catheter specific.^{5,23,32}
- Standardized protocols and training: Implement flushing protocols and regular training to ensure consistency and reduce catheter-related deep vein thrombosis by up to 67%.^{33–35}
- Multidisciplinary involvement: Engage nursing, vascular access teams, radiology, and pharmacy in flushing/locking strategies.^{34–38}

Barriers to Implementation

- Cost and access to antimicrobial locks: Advanced locking solutions like taurolidine and gentamicin-citrate may be cost-prohibitive or unavailable in some settings.^{17,29,30}
- Protocol adherence: Inconsistent training or lack of standardized protocols can compromise flushing or locking effectiveness.^{33–35}
- Lack of familiarity with emerging products: Clinicians may be unaware of or untrained in using novel lock agents like T-EDTA or taurolidine.^{17,30}

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Chapter 5.6—Connector & Safety Devices

Accessory devices such as needleless connectors (NCs), antiseptic barrier caps, and breakaway devices enhance the safety and function of vascular access systems. These components support closed systems, reduce the risk of contamination, and protect catheter integrity across various care settings.

NCs provide a protective interface at the hub, reducing manipulation and contamination risk when paired with standardized disinfection practices. Antiseptic barrier caps extend this protection by offering passive, continuous disinfection between accesses. Additionally, antireflux connectors help maintain unidirectional flow, thereby reducing occlusion and blood reflux events.

Breakaway devices protect against catheter damage and dislodgement by releasing under strain. Collectively, these products contribute to comprehensive vascular access care by reducing complications and supporting safe, consistent practice.

Recommendation 1: Use of Blood Culture Diversion Devices

It is reasonable to use blood culture diversion devices (BCDDs) during specimen collection when contamination is possible.

Summary of Evidence

Authors of a prospective, quasi-experimental study assessed contamination rates among intensive care unit (ICU) and non-ICU patients where phlebotomists used either traditional venipuncture or a BCDD. Use of the BCDD resulted in a 0% contamination rate across 11,202 samples compared with a 2.3% contamination rate from 4,759 traditional samples. The authors also reported a significant reduction in false-positive central line-associated bloodstream infection (CLABSI) diagnoses when BCDD were used, supporting their utility in improving diagnostic accuracy and avoiding unnecessary treatment.^{1(IIIa)}

Recommendation 2: Use of Breakaway Connection Systems

It is reasonable to consider the use of breakaway connector systems for patients who are confused, agitated, or ambulatory, to reduce the risk of mechanical complications.

Summary of Evidence

Breakaway devices are engineered to detach when subjected to a specific amount of tension, limiting catheter dislodgement or vascular injury. Authors of both a 2022 product review and 2024 pilot study demonstrated that breakaway systems reduce mechanical stress on peripheral catheters and mitigate external force transmission. While these findings support the theoretical benefit, more robust clinical studies are needed.^{2,3(Vb, IIb)}

Recommendation 3: Evaluation and Selection of NCs

Health care organizations should evaluate and select NCs based on available evidence, clinical performance, and practice alignment. Selection should include consideration of displacement type, occlusion risk, and contamination rates.

Summary of Evidence

Authors of a comparative study at a cardiac center found that neutral or positive-pressure NCs reduced occlusion and catheter-related bloodstream infection (CRBSI) rates relative to negative-pressure devices. Authors of additional studies have reported increased blood reflux and clot formation with negative-pressure models. Authors of a multicenter analysis showed that positive-pressure NCs significantly lowered CRBSI rates in ICU settings. However, labeling of displacement type does not always reflect real-world performance, and outcomes may vary between brands. Ongoing evaluation at the institutional level is essential for sustained product effectiveness.^{4-6(IIb, IIb)}

Recommendation 4: Manual Disinfection of NCs

Clinicians should disinfect NCs before each access using an alcohol-based antiseptic, applying sufficient friction for 10–15 seconds and allowing the surface to dry completely before use.

Summary of Evidence

Effective disinfection of NCs is essential to preventing intraluminal contamination and CRBSI. Authors of a randomized controlled trial found no significant difference between 70% isopropyl alcohol (IPA) and 2% chlorhexidine gluconate (CHG) in 70% IPA for surface decontamination, supporting the continued use of 70% IPA as a viable, efficient option.^{7(Ia)} Further researchers confirmed that 10–15 seconds of scrubbing with alcohol significantly reduces surface colonization, even under high bacterial loads, and mechanical friction is critical to disrupting biofilm on the connector surface.^{8,9(IIb, IIIb)} Drying time for 70% IPA was consistently shorter than that of CHG-alcohol combinations, offering practical advantages in clinical workflows.

Routine, standardized scrubbing of NCs remains a cornerstone of infection prevention, particularly in settings where antiseptic barrier caps are not feasible or not used consistently.^{8,9(IIb, IIIb)}

Note: Verify manufacturer guidelines in the use and availability of CHG to disinfect NCs.

Recommendation 4: Passive Disinfection of NCs

Clinicians should consider the use of antiseptic barrier caps for passive disinfection of NCs. (Note: Follow specific IFU for active disinfection requirement.)

Summary of Evidence

Antiseptic barrier caps are designed to provide continuous passive disinfection of the NC surface between uses. Authors of a systematic review and meta-analysis found that their use significantly reduced CLABSI rates, with a pooled risk ratio of 0.65 (95% confidence interval = 0.55, 0.76) across nearly 550,000 catheter days.^{10(IIa)} Authors of multiple randomized controlled trials demonstrated additional benefits, including lower bloodstream infection rates in hemodialysis and acute care populations and improved adherence to disinfection protocols.^{11-13(Ia, Ia, Ib)}

Clinical Considerations

The points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Lower reflux and clotting risk: Negative-pressure NCs are associated with increased reflux and higher clot formation, contributing to occlusions.⁴
- Reduction in CRBSI: Use of neutral and positive-pressure NCs and antiseptic barrier caps has been associated with a significant reduction in CRBSI rates.^{5,10-12,14}

- Passive disinfection: Antiseptic caps provide passive adjunct disinfection at the NC hub, outperforming manual scrubbing alone in infection prevention.¹⁵
- Prevents catheter dislodgement to preserve vascular access: Breakaway connectors reduce the risk of mechanical complications in confused, agitated, or ambulatory patients by releasing under controlled tension, thus avoiding the need for reinsertion.^{2,3}

Risks

- Displacement terminology variability: Product labels (e.g., positive, neutral, or negative) do not always match clinical performance, complicating product selection.^{4,5,14}
- Inconsistent disinfection technique: Suboptimal inadequate scrub duration or technique as well as inconsistent use of barrier caps may reduce the effectiveness of contamination prevention on connector surfaces thus increasing the risk of CLABSI.^{7–10}

Implementation Considerations

- Product-specific evaluation: Facilities should assess adjunct product performance at the institutional level to guide product selection based on clinical evidence and ensure staff are educated on proper application and replacement.^{11,12,14}
- Monitor compliance: Adjunct product usage offers visual confirmation to support compliance monitoring and quality assurance.^{3,10}

Barriers to Implementation

- Variable device performance: Brand-to-brand variation limits the ability to standardize expectations.^{4,7,14}
- Transition and compliance: Sustaining staff compliance may be challenging, as implementing new practices often requires cultural change and updates to existing protocols.^{7,10,16}
- Cost and availability: In resource-limited settings, adjunct devices may be perceived as non-essential due to initial cost concerns, limited availability, or lack of institutional funding.^{2,17}

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Chapter 5.7—Removal Criteria & Procedures

The safe and timely removal of vascular access devices (VADs) is a critical component of vascular access management. While appropriate device selection and maintenance are essential to achieving positive outcomes, removal decisions must be guided by clear clinical criteria, procedural competency, and patient-centered planning. Unnecessary retention increases the risk of infection, thrombosis, mechanical failure, and other complications.

Removal may be indicated when therapy is complete, complications arise, or the device is no longer necessary for care. Conversely, removal may need to be delayed when the patient is clinically unstable or alternative access is not feasible. Understanding these contextual nuances is essential for risk-balanced decision-making.

Best practices in removal technique are essential for minimizing complications during the final stage of vascular access. Even the removal of a peripheral intravenous catheter (PIVC) can pose risks if done carelessly, including patient complications and occupational exposure for the clinician. Competency in removal supports patient safety, protects the direct-care clinician (DCC), and ensures the overall process of vascular access management is completed safely and effectively.

Recommendation 1: Indications for VAD Removal

Remove VADs when no longer clinically necessary or when the risk of complications outweighs the benefit of continued use. Prompt removal supports infection prevention, reduces thrombotic risk, and promotes vascular preservation.

Indications include:

- Completion of prescribed therapy;
- Suspected or confirmed catheter-related bloodstream infection (CRBSI);
- Symptomatic extensive thrombosis associated with the catheter:
 - Exceptions based on patient-specific factors;
- Occlusion or malfunction unresponsive to appropriate interventions;
- Catheter damage, fracture, or external or internal migration;
- Loss of access site integrity or complications.

Summary of Evidence

Early removal of malfunctioning or infected VADs is associated with a lower incidence of systemic complications such as CRBSI and catheter-related thrombosis.^{1–3(IIa, IIb, Ia)} Delayed

removal in the presence of occlusion or malfunction has been linked to an increased risk of infusion failure, reinsertion delays, and vascular damage.^{4,5(IIIa, IIIb)}

Authors of several studies have supported an interdisciplinary approach when clinical necessity is unclear or when immediate removal may be unsafe due to patient acuity or lack of alternative access. This allows for individualized decisions that prioritize both immediate clinical needs and long-term vascular access planning.^{2,5(IIIb, IIIb)} Prompt removal following resolution of critical illness or completion of therapy helps avoid unnecessary dwell time, a known contributor to infectious and thrombotic events.^{1,3(IIa, Ia)}

Recommendation 2: Remove the VAD When Resolution Fails

When persistent occlusion, suspected or confirmed malposition, or catheter damage cannot be resolved through appropriate troubleshooting or salvage techniques, the VAD should be removed. Continued use of a nonfunctional or compromised catheter increases the risk of infection, thrombosis, infiltration, catheter embolism, and treatment failure.

Summary of Evidence

Unresolved catheter occlusion, despite thrombolytic therapy or mechanical clearing, signals a high likelihood of non-thrombotic occlusion or internal damage. In these cases, device removal is recommended to prevent escalation to bloodstream infection or catheter embolism.^{6,7(Vb, IIIb)}

Malposition, whether external (catheter migration) or internal (tip misdirection), cannot be assumed safe without verification. Use should be withheld until imaging or ultrasound confirms proper placement. If tip location cannot be confidently established or functionality remains impaired, device replacement is the safer course.^{8,9(IVb, IIIb)}

Visible or suspected catheter damage, such as fractures, leaks, or totally implanted VAD defects, compromises the integrity of the vascular system and poses risks for embolism or extravasation.^{10(Vb)} Salvage may be feasible for tunneled silicone catheters in select settings, but the default response should be prompt removal unless clinical conditions warrant a carefully considered exception.^{11,12(IIIa, IIIa)}

Recommendation 3: Ensure Clinician Competency in VAD Removal

Clinicians responsible for VAD removal must demonstrate competency in removal techniques specific to device type.

Adherence to safety, standardized procedures, including positioning, site preparation, hemostasis, and postremoval monitoring, is essential to minimize complications and ensure optimal outcomes.

Summary of Evidence

The safe removal of VADs requires procedural proficiency and consistent adherence to established clinical protocols. Complications such as air embolism, bleeding, infection, and vessel trauma are preventable with correct technique and proper patient positioning.^{13–15(Vb, IVb, IVb)}

Key elements of safe removal include:

- Positioning: Supine or Trendelenburg for central VADs; supine or semi-Fowler for peripherally inserted central catheters; no specific positioning for PIVCs or peripheral midlines.
- Site preparation: Cleanse with chlorhexidine-alcohol unless contraindicated.
- Hemostasis: Apply firm, controlled pressure to achieve hemostasis while protecting tissue integrity.
- Clinician safety: Use techniques that minimize risk of blood exposure to the DCC.
- Site protection: Use occlusive dressing after hemostasis is achieved.
- Patient education: Provide clear instructions on post-removal care and signs of complications.

Competency-based training and periodic skills refreshers have been shown to reduce complication rates and improve consistency in practice. Postremoval protocols, including observation for bleeding, air embolism, or infection, should be followed in all care settings. In the event of suspected air embolism, immediate actions include left lateral Trendelenburg positioning and administration of high-flow oxygen, with activation of emergency protocols as indicated.^{13(Vb)}

Recommendation 4: Delay VAD Removal When Clinically Justified

VAD removal may be delayed when clinical circumstances demand continued access or present heightened procedural risks. In these situations, decisions should be guided by interdisciplinary collaboration, careful risk-benefit analysis, and proactive planning for future access needs.

Summary of Evidence

Immediate removal of a VAD may not be appropriate in specific scenarios, even if minor clinical complications are present (i.e., withdraw occlusion, change in external segment). These include patients with:

- Hemodynamic instability or critical illness, where ongoing vascular access is essential for life-sustaining therapy;
- No alternative access options, particularly in patients with vascular depletion or fragile anatomy;
- Coagulopathy or thrombocytopenia, where the bleeding risk outweighs the benefit of immediate removal.

In such cases, VAD retention may be cautiously continued with close clinical surveillance, therapeutic management, and coordination with vascular access specialists.

Proactive access planning is key. For patients with complex comorbidities (e.g., renal disease, history of chest radiation, prior central venous depletion), decisions regarding timing and method of removal must be balanced against future access needs. Collaboration among providers, including oncology, nephrology, interventional radiology, and direct care clinicians, ensures the right VAD is in place at the right time, and for the right reason.^{1,2,5(IIa, IIIb, IIIb)}

Recommendation 5: Align PIVC Removal with Clinical Indication

PIVCs should be removed when clinically indicated, not solely based on routine dwell time. Institutions that adopt a clinically indicated replacement strategy must ensure robust site monitoring, trained staff, and protocols that support the early detection of complications and the timely removal of PIVCs.

Summary of Evidence

Routine PIVC replacement every 72–96 hours has historically been used to reduce risk of phlebitis, infiltration, and infection. However, in a Cochrane review of 7,000+ patients, no significant differences were found in CRBSI, phlebitis, or mortality between routine and clinically indicated removal strategies.^{3(Ia)}

Clinically indicated removal likely reduces unnecessary catheter insertions, device-related costs, and patient discomfort, but only when supported by strong systems for monitoring and staff education. The I-DECIDED® tool is one structured assessment approach that has been shown to reduce idle lines, insertion site complications, and substandard dressing care (Appendix D).^{16(Va)}

Caution is warranted: Without clear institutional policies and daily site evaluations, clinically indicated replacement may lead to delayed recognition of local complications. Staff should be trained to remove PIVCs promptly if they are no longer needed or show signs of infiltration, extravasation, occlusion, phlebitis, pain, or infection.^{17(Vb)}

Clinical Considerations

The following points summarize potential benefits, risks, and implementation factors identified in the literature and practice experience. They are intended to guide clinical reflection and local adaptation rather than serve as prescriptive recommendations.

Benefits

- Reduced complication risk: Timely removal of malfunctioning or infected VADs based on patient-specific removal decisions, significantly reduces the risk of occlusion, thrombosis, and bloodstream infections.^{1,2,18,19}
- Improved patient outcomes: Interdisciplinary planning for VAD removal, combined with early detection of

complications such as infection, bleeding, or air embolism, enhances patient safety and supports optimal outcomes when immediate removal is not feasible.^{1,2,5,20}

- Device longevity and function: Clear flushing protocols based on device function and patient status can preserve patency over time.^{1,2,18,19}
- Preservation of vascular health: Proactive planning for VAD placement and timely removal preserves vascular integrity, especially in patients with chronic conditions.^{21,22}

Risks

- Delayed removal consequences: Prolonged retention of dormant, nonfunctional or infected devices can lead to increased rates of infection, thrombosis, or systemic complications.^{1–3,18,23}
- Delayed complication recognition: Without clear monitoring or education, patients may miss signs of serious complications such as air embolism or infection.²⁰
- Procedural complications: Inadequate training or technique during removal can increase the risk of bleeding, air embolism, or catheter fracture.²⁰
- Inadequate assessment: Failing to evaluate underlying conditions (e.g., thrombosis) before removal may worsen clinical outcomes or result in unnecessary removal.^{1,2,5}

Implementation Considerations

- Use of clinical decision tools: Removal decision tools help standardize removal criteria and reduce idle catheters, site complications, and dressing failures.¹⁶
- Competency-based training: Ensuring staff are trained in safe removal procedures improves compliance with safety protocols and reduces complication rates.²⁰
- Patient education: Provide clear postremoval instructions regarding signs of infection, bleeding, and when to seek help.^{2,24}
- Interdisciplinary decision-making: Collaborate with the care team and patient to evaluate ongoing need for VADs and develop a maintenance or removal plan.^{18,23}

Barriers to Implementation

- Lack of proactive access planning: Reactive decision-making delays timely removal and increases the risk of inappropriate device use in vulnerable patients.^{21,22}
- Variability in practice: Inconsistent application of removal criteria and variability in clinician adherence to removal protocols, particularly in the absence of standardized guidelines, can lead to premature or delayed device removal and increased complication rates.^{3,18,23}
- Resource and staffing constraints: Insufficient interdisciplinary coordination and limited time for comprehensive assessment may hinder timely decision-making.^{1,2,5}

- Lack of standardized follow-up: Institutions may not have consistent processes for postremoval monitoring or patient follow-up.²⁰

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ACRONYMS

ABHR	alcohol-based hand rub	EPA	Environmental Protection Agency
ANTT®	aseptic nontouch technique	ESD	Engineered Securement Device
AP	anteroposterior	ESRD	end-stage renal disease
APRN	advanced practice registered nurse	FDA	U.S. Food and Drug Administration
ASD	adhesive securement device	Fr	French
AST	accelerated Seldinger technique	GFR	glomerular filtration rate
AVF	arteriovenous fistula	HAI	hospital-associated infection
AVG	arteriovenous graft	HFMEA	Healthcare Failure Mode and Effect Analysis
BCDD	blood culture diversion device	Hg	mercury
BMI	body mass index	HIPAA	Health Insurance Portability and Accountability Act
BSI	bloodstream infection	HIT	heparin-induced thrombocytopenia
BUD	beyond-use date	HITT	heparin-induced thrombocytopenia and thrombosis
CABSI	catheter-associated bloodstream infection	HLA	human leukocyte antigen
CA-DVT	catheter-associated deep vein thrombosis	HOB	hospital onset bacteremia and fungemia
CAJ	cavoatrial junction	IC-ECG	intercavitary electrocardiogram
CASI	catheter-associated skin injury	ICU	intensive care unit
CDC	Centers for Disease Control and Prevention	I-DECIDED®	see glossary entry
CFU	colony-forming unit	IDU	injectable drug use
CHG	chlorhexidine gluconate	IJV	internal jugular vein
CICC	centrally inserted central catheter	INS	Infusion Nurses Society
CKD	chronic kidney disease	IO	intraosseous
CLABSI	central line–associated bloodstream infection	IPA	isopropyl alcohol
CLISA	central line insertion site assessment	IRB	Institutional Review Board
CMV	cytomegalovirus	ISD	integrated securement device
CNA	certified nursing assistant	IV	intravenous
CNLP	clinical nonlicensed personnel	IVC	inferior vena cava
C-PEC	containment primary engineering control	KDOQI	Kidney Disease Outcomes Quality Initiative
CPOE	computerized prescriber order entry	LIP	licensed independent practitioner
CQI	continuous quality improvement	LMWH	low molecular weight heparin
CR-BSI	catheter-related bloodstream infection	MARSI	medical adhesive-related skin injury
CRS	cytokine release syndrome	MDRO	multidrug-resistant organism
CR-VTE	catheter-related venous thromboembolism	MRI	magnetic resonance imaging
CRVT	catheter-related ventricular tachycardia	MSB	maximal sterile barriers
CSTD	closed system transfer device	MST	modified Seldinger technique
CT	computed tomography	NICE	National Institute for Clinical Excellence
CTA	chest to arm	NIOSH	National Institute for Occupational Safety and Health
CVAD	central vascular access device	NIR	near infrared
CVP	central venous pressure	NP	nurse practitioner
CVR	catheter-to-vein ratio	OCT	octenidine
DCC	direct-care clinician	OPAT	outpatient antibiotic therapy
DIVA	difficult intravenous access	PA	physician assistant
DME	durable medical equipment	PBM	patient blood management
DMSO	dimethyl sulfoxide	PICC	peripherally inserted central catheter
DNTP	dynamic needle tip positioning	PIP	plastic in patient (tool)
DTP	differential time to positivity	PIVC	peripheral intravenous catheter
DVT	deep vein thrombosis	PN	parenteral nutrition
EBP	evidence-based practice	PML	peripheral midline
ECG	electrocardiogram	PPE	personal protective equipment
ED	emergency department	PRN	as needed
EDTA	ethylenediaminetetraacetic acid		
EHR	electronic health record		
EMS	emergency medical services		

PVP-I	povidone-iodine	Tc-CVAD	tunneled-cuffed central vascular access device
PWID	people who inject drugs	TIVAD	totally implanted vascular access device
QI	quality improvement	TNA	total nutrient admixture
QSEN	quality and safety education for nurses	Tnc-CVAD	tunneled noncuffed central vascular access device
RAVESTO	rapid assessment of vascular exit site and tunneling options	tPA	tissue plasminogen activator
RBC	red blood cell	TSM	transparent semipermeable membrane
RCA	root cause analysis	US	ultrasound
RCT	randomized controlled trial	USG	ultrasound guidance
REMS	risk evaluation and mitigation strategies	VAD	vascular access device
RN	registered nurse	VAT	vascular access team
SASS	subcutaneous anchor securement system	VIP	visual infusion phlebitis
SBML	simulation-based mastery learning	VHP	vessel health and preservation
SIRS	systemic inflammatory response syndrome	VR	virtual reality
SVC	superior vena cava	VTE	venous thromboembolism
SVT	superficial venous thrombus	WOCN	wound, ostomy, and continence nursing
TA	tissue adhesive		

Adhesive Securement Device (ASD)

An engineered securement device that secures a vascular access catheter to the skin using an adhesive base combined with a molded feature that engages the catheter's stabilization platform. ASDs reduce catheter movement, dislodgement, and accidental removal, and are always used in combination with a sterile dressing. Replaced with each dressing change.

Adhesive Enhancer

A product applied to the skin to improve dressing adherence, particularly in high-moisture or high-movement areas. Examples include gum mastic liquid adhesive.

Air Embolism

The entry of air into the vascular system, which may obstruct blood flow and cause cardiovascular, pulmonary, or neurological complications. A preventable but potentially fatal catheter-related event.

Alcohol-Based Hand Rub (ABHR)

A fast-acting hand antiseptic used for routine decontamination of hands when not visibly soiled.

Antiseptic Barrier Cap

A cap containing an antiseptic agent (commonly alcohol or chlorhexidine-alcohol) is placed on a needle-free connector between uses to provide continuous passive disinfection of the connector surface. Must be replaced per manufacturer's instructions for use.

Arterial Catheter

A catheter is inserted into an artery, primarily for continuous blood pressure monitoring and arterial blood sampling. Not used for infusion of medications or fluids due to the risk of ischemic injury.

Aseptic Nontouch Technique (ANTT®)

A standardized practice framework for aseptic technique that prevents contamination of key parts and key sites during vascular access insertion. ANTT® distinguishes between standard ANTT® (vital but lower-risk procedures, such as peripheral intravenous catheter insertion) and surgical ANTT® (for complex procedures, such as central vascular access device placement).

Practical Note: Placement of peripheral midlines (PMLs) often falls between standard ANTT® and surgical ANTT®. Facilities and clinicians vary in practice, with some treating PML insertion as an advanced peripheral procedure (standard ANTT®) and others applying the higher sterility safeguards of surgical ANTT®.

- **Key Part**—Any sterile component of equipment or device that must remain aseptic to prevent contamination.

- **Key Site**—Any patient site where a vascular access device enters the body or where the bloodstream is directly accessed.

Barrier Film (Skin Protectant)

A sterile protective coating applied to the skin prior to dressing application. Barrier films reduce the risk of medical adhesive-related skin injury, minimize skin trauma on removal, and support dressing adherence.

Body Mass Index (BMI)

A measure of body fat calculated from height and weight; used as a risk factor for vascular access complications, particularly thrombosis.

Blood Control Technology

A safety feature in peripheral intravenous catheters that prevents blood leakage during insertion, reducing occupational exposure and contamination risk.

Bloodstream Infection (BSI)

A laboratory-confirmed infection of the bloodstream, regardless of source. BSIs may be related to vascular access devices, other intravascular devices, or distant infections with hematogenous spread.

Practical Note: The term BSI is the broadest descriptor and does not imply a vascular access association unless otherwise specified (e.g., catheter-related BSI, central line-associated BSI).

Blunt Tunneler Technique

A method of creating a short subcutaneous tunnel for a vascular access device using a blunt instrument after venous access has been achieved. This technique requires 2 skin punctures: one for vessel entry and another for the exit site. The catheter is then redirected through the tunnel to emerge at a new location.

Breakaway Connector or Breakaway Device

A safety device placed in-line with a vascular access catheter that disconnects under controlled tension to prevent catheter dislodgement, damage, or patient injury.

Catheter-Associated Skin Injury (CASI)

Skin damage resulting from the presence of a vascular access device or its securement, dressing, or stabilization products.

Catheter-Related Bloodstream Infection (CR-BSI)

A clinical and microbiologic diagnosis of a bloodstream infection directly attributed to a vascular access device. CR-BSI requires strict evidence, such as identical organisms isolated from catheter and blood cultures or differential time to positivity. Unlike central line-associated BSI, CR-BSI can apply to

any intravascular catheter (peripheral or central) and establish the catheter as the confirmed infection source.

Practical Note: CR-BSI is rarely used for surveillance reporting but is essential in clinical practice and research to confirm causality between the device and infection.

Catheter-Related Deep Vein Thrombosis (CR-DVT)

A thrombus involving a deep vein where a vascular access device is present. CR-DVT is the most common form of catheter-related thrombosis and may present with limb swelling, pain, or catheter dysfunction.

Practical Note: Whether labeled CR-DVT or catheter-related thrombosis, the management approach is usually the same: assess for extension, risk of embolization, and need for anticoagulation.

Catheter-Related Pulmonary Embolism (CR-PE)

A pulmonary embolism that develops secondary to a thrombus originating from a catheter-related venous clot. CR-PE is less common than catheter-related deep vein thrombosis but clinically significant due to higher morbidity and mortality.

Practical Note: CR-PE is rarely tracked separately; most events are counted under catheter-related venous thromboembolism in research reports.

Catheter-Related Thrombosis (CRT)

A blood clot that forms in association with a vascular access device (peripheral or central). CRT is a broad clinical descriptor and may involve superficial or deep veins. Diagnosis is typically confirmed by imaging (e.g., ultrasound, venography). CRT is widely used in clinical documentation and research but is not a formal surveillance category.

Practical Note: At the bedside, CRT is often the most useful shorthand for any catheter-related clot, regardless of depth or risk of embolization.

Catheter-Related Venous Thromboembolism (CR-VTE)

An umbrella term that includes catheter-related deep vein thrombosis and catheter-related pulmonary embolism. In research, CR-VTE is frequently used as the broadest category when reporting catheter-associated clot events.

Practical Note: In everyday clinical care, CR-VTE and catheter-related thrombosis are often used interchangeably, though technically VTE implies the potential for embolization.

Catheter-Related Ventricular Tachycardia (CRVT)

A potentially life-threatening arrhythmia that occurs when a central catheter tip is positioned too deeply within the right atrium or ventricle, leading to irritation of cardiac tissue. Proper tip placement and confirmation reduce this risk.

Catheter-to-Vessel Ratio (CVR)

The ratio of a catheter's external diameter to the diameter of the vessel in which it is placed. Higher CVRs (>33–45%) are associated with endothelial trauma, phlebitis, and catheter-related thrombosis.

Cavo-Atrial Junction (CAJ)

The anatomical junction where the superior vena cava meets the right atrium. The CAJ is the recommended target for central vascular access device catheter tip placement, as it optimizes infusion dynamics while minimizing risks of arrhythmia, thrombosis, and vessel erosion.

Central Line–Associated Bloodstream Infection (CLABSI)

A surveillance definition used primarily by the Centers for Disease Control and Prevention or National Healthcare Safety Network. CLABSI is diagnosed when a patient develops a laboratory-confirmed bloodstream infection and had a central vascular access device in place within the 48 hours prior, with no other identifiable infection source.

Practical Note: CLABSI reflects association rather than causation. It is used for surveillance, benchmarking, quality metrics, and regulatory reporting, not for guiding individual patient management.

Central Line Insertion Site Assessment (CLISA)

A structured tool used to assess and document central line insertion sites for infection risk and complications.

Centrally Inserted Central Catheter (CICC)

A central vascular access device inserted directly into a central vein (e.g., internal jugular, subclavian, femoral).

- Tunneled, cuffed CICC: A CICC placed through a subcutaneous tunnel and secured with a cuff.
- Tunneled, noncuffed CICC: A CICC placed with a subcutaneous tunnel but without a cuff.

Cephalad

In anatomy, cephalad means “toward the head” or upper part of the body. In vascular access, cephalad migration most often refers to unintended upward movement of a catheter tip (e.g., a peripherally inserted center catheter) into the internal jugular vein, away from its intended position in the superior vena cava.

Chest-to-Arm (CTA) Tunneling

A technique in which a catheter is tunneled from a chest insertion site to exit in the upper arm. This creates a low-profile exit site away from the chest while maintaining a central venous tip location.

Practical Note: CTA tunneling may be helpful in patients with tracheostomies, chest wall deformities, or breast surgery where a chest exit site is not feasible.

Chlorhexidine Gluconate (CHG)

A broad-spectrum antiseptic, which is actually chlorhexidine digluconate, commonly used in combination with alcohol for skin preparation prior to vascular access insertion. CHG provides rapid antimicrobial activity and residual effect on the skin surface, making it the preferred first-line agent for infection prevention during vascular access procedures.

Chronic Kidney Disease (CKD)

A progressive decline in kidney function that influences vascular access planning; requires vessel preservation to support future dialysis access.

Clinically Indicated Replacement

A device removal and replacement strategy in which vascular access devices are removed only when clinically necessary (e.g., completion of therapy, signs of complication, or device malfunction), rather than on a fixed schedule.

Practical Note: This approach reduces unnecessary insertions and patient discomfort but requires robust monitoring systems and trained staff to ensure early recognition of complications.

Clinical Nonlicensed Personnel (CNLP)

Unlicensed health care personnel who assist in vascular access care under supervision.

Compartment Syndrome

A limb-threatening condition caused by increased pressure within a closed fascial compartment, leading to reduced tissue perfusion and potential ischemic injury. In vascular access, compartment syndrome may occur as a severe complication of infiltration or extravasation, particularly when large volumes or vesicant solutions enter surrounding tissue.

Practical Note: Early signs include severe pain, swelling, tightness, diminished capillary refill, and sensory changes. Immediate recognition and escalation to surgical consultation are essential to prevent permanent functional loss.

Computerized Prescriber Order Entry (CPOE)

Electronic system for entering and managing medication and infusion therapy orders.

Deep Vein Thrombosis (DVT)

Formation of a thrombus in the deep venous system (e.g., axillary, subclavian, brachiocephalic, femoral, iliac). DVTs are clinically significant due to their risk of extension and subsequent pulmonary embolism.

Device Compatibility

The ability of a vascular access device and its adjunct components to function safely and effectively together without compromising performance or integrity.

Device Stewardship

A clinical framework emphasizing the ongoing evaluation of vascular access devices to ensure necessity, appropriateness, and timely removal when no longer required. Stewardship reduces infection risk, minimizes unnecessary exposure, preserves vessel health, and promotes optimal use of vascular access resources.

Difficult Intravenous Access (DIVA)

A clinical condition in which patients present challenges to successful peripheral vascular access due to anatomical, pathological, or historical factors.

Note: While DIVA is widely used in research and clinical shorthand, it should not be used in patient-facing communication due to negative connotations.

Direct-Care Clinician (DCC)

A licensed health care professional who provides hands-on patient care at the point of service. This term encompasses all disciplines engaged in direct patient contact, including but not limited to nurses, respiratory therapists, and radiology technologists.

Practical Note: The term DCC is used in this guideline in place of role-specific titles (e.g., bedside nurse, frontline clinician) to recognize the multidisciplinary team members responsible for vascular access assessment, insertion, and maintenance.

Dislodgement

Unintended external or internal migration of a vascular access device from its original secure position. Dislodgement may present as changes in external catheter length, securement failure, dressing disruption, or altered catheter function.

Practical Note: Tip migration or malposition is a form of internal dislodgement. Use of engineered securement devices and breakaway connectors reduces risk. Documentation of baseline external length at insertion supports early detection of displacement.

Distal

In anatomy, distal means farther from the point of origin or farther from the heart. In vascular access, distal describes a location further away from central circulation, usually out toward the extremities.

Dynamic Needle Tip Positioning (DNTP)

An ultrasound-guided insertion technique that emphasizes continuous visualization of the needle tip in real time as it advances toward and enters the vessel. DNTP improves accuracy, enhances safety, and reduces complications compared to static or blind approaches. Both short-axis/out-of-plane and long-axis/in-plane methods may be used, but DNTP ensures the needle tip (rather than only the shaft) is tracked throughout the procedure.

End-Stage Renal Disease (ESRD)

The most advanced stage of chronic kidney disease, requiring renal replacement therapy such as dialysis or transplantation.

Engineered Securement Device (ESD)

An umbrella category of securement devices designed to stabilize vascular access catheters without sutures. Types include adhesive securement devices, integrated securement devices, subcutaneous anchor securement systems, and tissue adhesives.

Ethylene Diamine Tetra-Acetic Acid (EDTA)

A chelating agent used in some catheter lock solutions to disrupt biofilm and reduce catheter-related complications.

External Length

The visible catheter length measured from the skin exit site to a reference point on the catheter (commonly either the stabilization platform or the zero mark). Because many catheters have a gap of ~1 cm between the zero mark and the stabilization platform, documentation must specify which reference point was used.

Practical Note: Baseline external length should be recorded at insertion and reassessed during routine monitoring. An increase may indicate catheter migration outward; a decrease may suggest internal migration.

Extravasation

The leakage of a vesicant or irritant solution from a vascular access device into surrounding tissue, with potential to cause inflammation, tissue necrosis, or long-term functional impairment. High-risk agents include vasopressors, hypertonic saline, contrast media, and many chemotherapeutic drugs.

Practical Note: Extravasation is distinguished from infiltration by the nature of the infusate. Even small volumes of vesicant leakage may result in severe injury. Immediate intervention, including drug aspiration, antidote administration when indicated, and supportive care, is required.

Flexion Zones

Anatomical regions near major joints with high mobility, such as the antecubital fossa or wrist. Catheters placed in flexion zones are at increased risk for kinking, occlusion, dislodgement, and dressing disruption.

Flushing

The routine instillation of preservative-free 0.9% normal saline into a vascular access device to clear residual medications, blood, or infusates. Flushing is performed before, between medications, after drug administration, after blood sampling, or at defined intervals to maintain patency.

Practical Note: Sufficient post-blood draw flushing is essential to remove residual blood, reduce clot formation, and support continued device function.

Guidewire Entrapment

A complication during vascular access insertion where the guidewire becomes kinked, looped, or stuck in surrounding structures. Recognition of resistance and immediate cessation of advancement are essential to prevent vascular injury.

Gum Mastic Liquid Adhesive

A resin-based liquid that forms a tacky, flexible interface to increase dressing or securement adhesion to the skin without creating a polymerized film.

Hand Hygiene (HH)

The act of cleaning hands using soap and water or alcohol-based hand rub. A cornerstone of infection prevention for all vascular access care.

Hemostasis

The process of stopping bleeding at a vascular access insertion or removal site through physiologic or mechanical means. Hemostasis is achieved primarily by direct pressure to compress the vessel and promote clot formation, followed by sealing of the site with an appropriate dressing or hemostatic product if needed. Achieving complete hemostasis before dressing application reduces the risk of hematoma formation and failure of dressing adhesion.

Hospital-Associated Infection (HAI)

An infection acquired during healthcare delivery that was not present or incubating at admission. HAIs include catheter-related infections (e.g., central line-associated bloodstream infection, catheter-related bloodstream infection), as well as other hospital-acquired infections such as surgical site infections, ventilator-associated pneumonia, and urinary tract infections.

Practical Note: HAI is an umbrella term for surveillance and quality monitoring, not specific to bloodstream infections.

Hospital-Onset Bacteremia and Fungemia (HOB)

A surveillance metric that includes all laboratory-confirmed bloodstream infections acquired during hospitalization, regardless of source. HOB captures bacteremia and fungemia events beyond vascular access, providing a broader measure of hospital-associated infection burden.

Practical Note: HOB is increasingly used alongside or in place of central line-associated bloodstream infection for hospital quality reporting because it captures a wider range of bloodstream infection events.

Hydrogel or Hydrophilic Coating

Surface modifications applied to catheters to reduce friction, platelet adhesion, and fibrin sheath formation. Designed to lower the risk of thrombosis and improve catheter performance, particularly in high-risk populations.

I-DECIDED® Tool

A validated decision-making framework for vascular access device assessment and management. Each element of the acronym represents a step in evaluating device necessity, function, safety, and care:

- I—Identify if a device is present.
- D—Does the patient need the device?
- E—Effective function?
- C—Complication-free?
- I—Infection prevention.
- D—Dressing and securement.
- E—Evaluate and educate.
- D—Document your decision.

The I-DECIDED tool guides clinicians in determining whether a vascular access device should remain in place, be maintained, or be removed, thereby supporting timely device removal, patient safety, and vascular preservation.

Practical Note: Although presented as an acronym, I-DE-CIDED functions as a structured clinical tool rather than a simple abbreviation.

Inferior Vena Cava (IVC)

The large vein that returns deoxygenated blood from the lower body to the heart. In femoral central venous access, the IVC is the appropriate target vessel for catheter tip placement.

Infiltration

The inadvertent leakage of a nonvesicant solution or medication from a vascular access device into the surrounding tissue. Signs include localized swelling, pallor, coolness, discomfort, slowed infusion rate, and damp dressings.

Practical Note: Infiltration differs from extravasation because the infused solution is nonvesicant and typically causes less severe tissue damage. However, if unrecognized, infiltration can still result in pain, functional impairment, or compromised vascular access.

Injection Drug Use (IDU)

Use of drugs by injection. See also: People Who Inject Drugs.

Integrated Peripheral Intravenous Catheter (Integrated PIVC)

A PIVC with preattached extension tubing and stabilization features that reduce dislodgement, contamination, and mechanical complications. Associated with longer dwell times compared with nonintegrated designs.

Integrated Securement Dressing (ISD)

An engineered securement device that combines a sterile adhesive dressing with a molded feature that engages the catheter's stabilization platform. ISDs provide securement and site protection in a single device, reducing the risk of dislodgement and simplifying dressing changes. Replaced with each dressing change.

Intracavitary Electrocardiography (IC-ECG)

A technique used for real-time confirmation of the central venous catheter tip position. By monitoring changes in P-wave amplitude as the catheter advances, IC-ECG identifies when the tip is at the cavoatrial junction. This method improves accuracy and may reduce reliance on post-procedural chest radiography.

Intravenous (IV)

Administration of fluids, blood products, or medications directly into a vein.

In-Vessel Catheter Length

The portion of a peripheral catheter that resides inside the vessel lumen. Adequate in-vessel length promotes stability, reduces infiltration and dislodgement, and supports longer dwell times. Clinical guidance suggests that, when feasible, at least two-thirds of the catheter should reside within the vessel.

Practical Note: The *two-thirds rule* assumes that the device length matches vessel depth. Selecting an appropriate catheter length first is essential; short catheters may remain unstable even if two-thirds of the device is intravascular.

Isopropyl Alcohol (IPA)

A commonly used antiseptic agent, typically at a 70% concentration, applied to disinfect skin or device surfaces. IPA provides rapid bactericidal activity and short drying time, making it suitable for hub and needleless connector disinfection.

Licensed Independent Practitioner (LIP)

A health care professional legally authorized and credentialed to independently evaluate, diagnose, prescribe, and manage patient care. LIPs may also provide hands-on care but are distinguished by their authority to write and direct orders. This group typically includes physicians, nurse practitioners, physician assistants, and other licensed providers as defined by state or national regulation.

Practical Note: In this guideline, licensed independent practitioner is used to distinguish order-writers from direct-care clinicians, recognizing that both groups may participate in vascular access care but with different scopes of responsibility.

Locking

The instillation of a solution into a vascular access device lumen after final flushing, when the device is not in active use. The locking solution remains within the lumen to maintain patency and, in some cases, to provide antimicrobial, antibiofilm, or antithrombotic protection. Locking solutions should be device- and patient-specific.

Practical Note: Locking differs from flushing in that the solution remains in the lumen for an extended period. Accurate calculation of lumen volume, complete flushing before lock, and aseptic technique are essential to effectiveness and safety.

Long Peripheral Intravenous Catheter (Long-PIVC)

A peripheral catheter designed for intermediate-duration therapy (1–4 weeks), placed in deeper veins than short PIVCs. Preferred term over *extended dwell catheter*.

Lymphatic Injury

Inadvertent cannulation or trauma of a lymphatic vessel during vascular access insertion. May present with lymphatic fluid leakage, local swelling, or risk of infection.

Malposition

Catheter tip location outside the intended vessel or prescribed anatomical position, occurring at insertion or due to postinsertion migration.

Maximal Sterile Barriers (MSB)

A set of full sterile precautions is required for the insertion of a central vascular access device. MSBs include a sterile gown, sterile gloves, a cap, a mask, and a large sterile drape covering

the patient. Their use is consistently associated with a reduction in catheter-related bloodstream infections.

Medical Adhesive-Related Skin Injury (MARSI)

Skin damage caused by medical adhesives is common at vascular access dressing and securement sites.

Medical Liquid Adhesives

Medical liquid adhesive is an umbrella term encompassing tissue adhesive and gum mastic liquid adhesive, used to augment dressing or securement adherence.

Modified Seldinger Technique (MST)

A variation of the Seldinger technique for vascular access insertion, involving the use of a dilator over a guidewire.

Near-Infrared (NIR) Imaging

A vein visualization technology that uses NIR light to detect hemoglobin and project an image of superficial veins onto the skin surface. NIR imaging can improve vein identification, particularly in patients with difficult intravenous access.

Needle-free Connector (NC)

A device affixed to the end of a vascular access catheter to enable needle-free access for infusion or aspiration.

Occlusion

Partial or complete blockage of a vascular access device lumen, resulting in reduced or absent flow. Occlusions are categorized by etiology:

- Mechanical Occlusion—Positional or device-related obstruction (e.g., kinked tubing, clamp closure, tight securement, pinch-off syndrome).
- Thrombotic Occlusion—Intraluminal clot, fibrin sheath formation, or mural thrombus causing resistance to infusion or aspiration.
- Chemical Occlusion—Precipitate formation or medication incompatibility leading to blockage within the catheter.

Practical Note: Differentiating occlusion type is essential for safe and effective intervention.

Octenidine (OCT)

A cationic antiseptic with broad-spectrum antimicrobial activity. In vascular access, OCT is considered a potential alternative to chlorhexidine for patients with sensitivity or skin irritation, with evidence suggesting comparable efficacy in reducing bacterial colonization.

Outpatient Parenteral Antimicrobial Therapy (OPAT)

Administration of intravenous antimicrobial therapy in the outpatient setting, including at home, infusion centers, or skilled nursing facilities. OPAT allows patients to complete extended antimicrobial regimens outside the hospital while reducing inpatient stays and associated costs.

Patency

The state of a vascular access device being open, unobstructed, and capable of fluid flow and aspiration as intended.

Peripheral Midline (PML)

A peripheral vascular access device is inserted into the upper arm veins with the tip dwelling below the axilla. Preferred term over *midline catheter*.

Peripheral Intravenous Catheter (PIVC)

A short peripheral catheter inserted into a superficial vein, typically for therapy for less than 7 days.

People Who Inject Drugs (PWID)

A patient-centered term describing individuals who inject drugs. Preferred over *injection drug use* when referring to patients.

Peripherally Inserted Central Catheter (PICC)

A central vascular access device inserted via peripheral veins (e.g., basilic, brachial, cephalic) with the tip terminating in a central vein.

- Tunneled, noncuffed PICC: A PICC inserted with subcutaneous tunneling but no cuff.

Peripheral Vascular Access Device (PVAD)

An umbrella category that includes peripheral intravenous catheters, long peripheral intravenous catheters, peripheral midlines, and peripheral arterial catheters.

Pistoning

Visible movement of a vascular access device at the insertion site, characterized by repeated retraction and advancement of the external catheter segment through the skin surface.

Pistoning can occur during patient movement, inadequate securement, or dressing changes when the catheter is not secured. This motion may permit migration of skin flora along the external catheter segment into the insertion tract, thereby increasing the risk of infection. Micromovement below the threshold of visible motion may still contribute to irritation or microtrauma but cannot be reliably detected during clinical observation.

Port (see also: Totally Implanted Vascular Access Device)

Colloquial term for a totally implantable venous access device. Ports are placed under the skin, typically in the chest or arm, and accessed with a non-coring needle for long-term intermittent therapy.

Povidone-Iodine (PVP-I)

An iodine-based antiseptic used for skin preparation in patients with sensitivity to chlorhexidine or alcohol. PVP-I has broad antimicrobial activity but lacks the residual antiseptic effect of Chlorhexidine Gluconate (CHG). Often used as an alternative when CHG is contraindicated.

Pressure-Rated Components

Device or accessory elements (e.g., extension sets, connectors, valves) tested and labeled for maximum allowable injection or infusion pressure.

Proximal

In anatomy, proximal means closer to the point of origin or to the heart. In vascular access, proximal describes a location nearer to central circulation compared with a more distal location in the same vessel.

Pulmonary Embolism (PE)

An obstruction of the pulmonary arteries by thrombus, most often originating from a deep vein thrombosis. Catheter-related pulmonary emboli are included under catheter-related venous thromboembolism in research but are not tracked as a distinct category in most surveillance systems.

Practical Note: Any patient with catheter-related thrombosis who develops chest pain, dyspnea, or hypoxia should be evaluated for PE, regardless of whether the original clot was labeled superficial or deep.

Rapid Assessment of Vascular Exit Site and Tunneling Options (RAVESTO)

A structured clinical decision-making tool for selecting vascular access insertion and exit sites. RAVESTO guides assessment of patient-specific factors such as skin integrity, infection risk, and mobility to optimize site selection and catheter care.

Routine Replacement

A device removal and replacement strategy in which vascular access devices are exchanged at predetermined time intervals (e.g., every 72–96 hours for peripheral intravenous catheters), regardless of clinical indication.

Practical Note: Once considered standard practice, routine replacement has been shown in systematic reviews to provide no significant advantage over clinically indicated replacement when strong monitoring protocols are in place.

Simulation-Based Mastery Learning (SBML)

A structured training approach that emphasizes deliberate practice and assessment until predefined competency standards are achieved.

Stabilization Platform

A molded extension of a vascular access catheter located at the catheter hub junction, designed to rest against the skin and provide a surface for securement. The stabilization platform helps reduce catheter movement and dislodgement by allowing adhesive or subcutaneous anchor securement devices to engage the catheter securely.

Practical Note: Stabilization platforms were historically referred to as *suture wings*, but sutures should not be used as a securement method for vascular access devices.

Subcutaneous Anchor Securement System (SASS)

A securement device that has a small subcutaneous anchor deployed beneath the skin, attached to an external base. The base engages the catheter lumen in a soft channel, providing strong and durable fixation that reduces the risk of dislodgement and extends dwell time. This device remains attached to the catheter throughout the entire therapy period.

Subcutaneous Lidocaine

A local anesthetic administered by infiltration into the subcutaneous tissue prior to vascular access insertion. Commonly used in concentrations of 1%–2%, subcutaneous lidocaine provides deeper anesthesia than topical agents, particularly for central vascular access device and arterial line placement.

Subcutaneous Track Technique

A method of adjusting the angle and depth of the initial needle entry during vascular access insertion to create a longer subcutaneous course before reaching the vessel. Unlike blunt tunneling, this approach uses a single skin puncture.

Superficial Vein Thrombosis (SVT)

Formation of a thrombus in a superficial vein (e.g., cephalic, basilic, saphenous). SVT is generally considered lower risk for embolization than deep vein thrombosis, but in the upper extremity, superficial veins often connect directly to the deep system.

Practical Note: In vascular access, the distinction between SVT and deep vein thrombosis is often less meaningful; both can impair device function and cause complications.

Sutures

A wound closure device made of sterile thread or material used to approximate tissue edges, ligate vessels, or secure surgical repairs. Sutures may be absorbable or nonabsorbable, and are selected based on tissue type, healing requirements, and procedural needs.

Practical Note: Per manufacturer instructions, sutures are not intended to secure external devices such as vascular access catheters. Engineered securement devices (sutureless securement systems) are recommended for device stabilization to reduce infection risk and prevent catheter-associated complications.

Tip Navigation Systems

Technologies that provide real-time catheter guidance during insertion often integrate intracavitary electrocardiography or magnetic tracking to improve the accuracy of tip placement. These systems can reduce malposition rates and may eliminate the need for fluoroscopy or chest radiography in selected patients.

Tissue Adhesive (cyanoacrylate)

An engineered securement device that polymerizes on contact with skin, forming a protective barrier. In vascular access, it may be applied at the insertion site to achieve hemostasis, reduce dressing disruption, aid in securement, and lower infection risk. Reapplied with each dressing change.

Topical Anesthetics

Medications applied to the skin surface to numb the underlying tissue. Formulations include sprays (e.g., vapocoolants) and creams (e.g., lidocaine-based). Used to reduce pain associated with venipuncture and vascular access insertion; onset and efficacy vary by formulation and concentration.

Totally Implanted Venous Access Device (TIVAD)

A surgically implanted central vascular access device placed entirely under the skin, accessed via a noncoring needle. TIVAD components:

1. Portal Body (Housing or Reservoir)
 - a) The implanted chamber that sits subcutaneously, typically in the upper chest or upper arm.
 - b) Constructed from biocompatible materials such as titanium, stainless steel, or medical-grade polymer.
 - c) Houses the internal reservoir that receives infusate from the noncoring needle.
2. Septum (Self-Sealing Membrane)
 - a) A silicone or polyurethane elastomer membrane that covers the reservoir.
 - b) Designed to be punctured repeatedly by a noncoring needle without tearing or leaking.
 - c) Provides a sterile barrier between the internal chamber and the external environment.
3. Catheter
 - a) A radiopaque, flexible tube connected to the portal body, tunneled subcutaneously, and terminating in the central venous circulation (typically lower superior vena cava). Note: Some totally implanted vascular access devices are placed in the arterial system for specialized therapy.
 - b) Constructed of silicone or polyurethane may include antimicrobial or antithrombotic coatings.
 - c) The internal lumen is continuous with the portal body, allowing infusion or withdrawal of fluids.
4. Connection Mechanism (Catheter–Portal Body Junction)
 - a) The junction securing the catheter to the portal body, usually via a compression ring, locking collar, or crimp sleeve.
 - b) Must be leakproof and pressure-rated for intended therapies.
 - c) A critical site for manufacturing integrity and risk of detachment or leakage if damaged.

Transparent Semipermeable Membrane (TSM)

A dressing that allows moisture vapor transmission while maintaining a barrier to external contaminants.

Trim Length

The length of a trimmable catheter that is cut at insertion to achieve correct tip position while minimizing the external segment. Trim length must be documented at insertion and con-

firmed at removal; discrepancies may indicate catheter fracture or embolization.

Practical Note: Not all catheters are trimmable (e.g., valve-tipped or specialized atraumatic designs). Always follow manufacturer guidance. Document trim length in addition to external length for accurate monitoring and safe removal.

Tunneled Dialysis Catheter (TDC)

A tunneled central venous catheter used for dialysis access, generally considered temporary compared with arteriovenous fistulas or grafts.

Ultrasound (US)

An imaging modality that uses high-frequency sound waves for real-time visualization during vascular access insertion or assessment. US enables identification of vessels, guidance of needle and catheter placement, and confirmation of catheter position. It is also used diagnostically to assess for complications such as thrombosis, stenosis, or vessel patency, and to evaluate surrounding structures. In post-insertion care, US may help identify pneumothorax, pericardial effusion, or cardiac abnormalities related to central venous access.

Ultrasound (US) Guidance

The use of real-time ultrasound imaging to aid vascular access device insertion, including vein identification, puncture, and tip guidance. US guidance improves first-attempt success, reduces complications, and helps preserve vessel health by minimizing failed attempts.

Vascular Access Device (VAD)

Any device inserted into a blood vessel for the purpose of delivering fluids, medications, or nutrition, or for monitoring blood pressure and other hemodynamic parameters.

- Peripheral VADs: Peripheral intravenous catheter, long-peripheral intravenous catheter, peripheral midline, peripheral arterial catheters.
- Central VADs: Peripherally inserted central catheter; centrally inserted central catheter (tunneled centrally inserted central catheter); tunneled, noncuffed centrally inserted central catheter; tunneled, noncuffed-peripherally inserted central catheter; totally implanted VAD.

Vascular Access Team (VAT)

A team of specialized clinicians responsible for insertion, management, and maintenance of vascular access devices.

Vein Visualization

The process of identifying suitable veins for vascular access using inspection, palpation, positioning, or technology-assisted methods. Techniques include near-infrared imaging, transillumination, ultrasound, and simple strategies such as limb dependency or moist heat. Effective vein visualization supports appropriate device selection, reduces insertion attempts, and enhances patient safety.

Venospasm

Sudden constriction of a vein in response to mechanical or chemical irritation. Venospasm may impede catheter advancement, contribute to insertion failure, or reduce flow through an indwelling catheter.

Vessel Health and Preservation (VHP)

A clinical framework emphasizing early vessel assessment and selection of the least invasive device needed to preserve vascular integrity over a patient's lifetime.

Virtual Reality (VR)

A computer-generated simulation of a 3-dimensional environment that can be interacted with using special electronic equipment such as a headset. In vascular access, VR distraction

has been studied as a nonpharmacologic intervention to reduce patient anxiety and perceived pain during catheter insertion.

Visual Infusion Phlebitis (VIP) Score

A validated scoring tool used to assess and document signs of phlebitis at a peripheral intravenous site.

Venous Thromboembolism (VTE)

A collective term that includes both deep vein thrombosis and pulmonary embolism. VTE emphasizes the risk of thrombus propagation or embolization.

Practical Note: VTE is a population and research term; clinicians often use catheter-related thrombosis or deep vein thrombosis more directly when documenting patient care.

Johns Hopkins Evidence-Based Practice Model for Nursing and Health Care Professionals Hierarchy of Evidence Guide (Leveling)

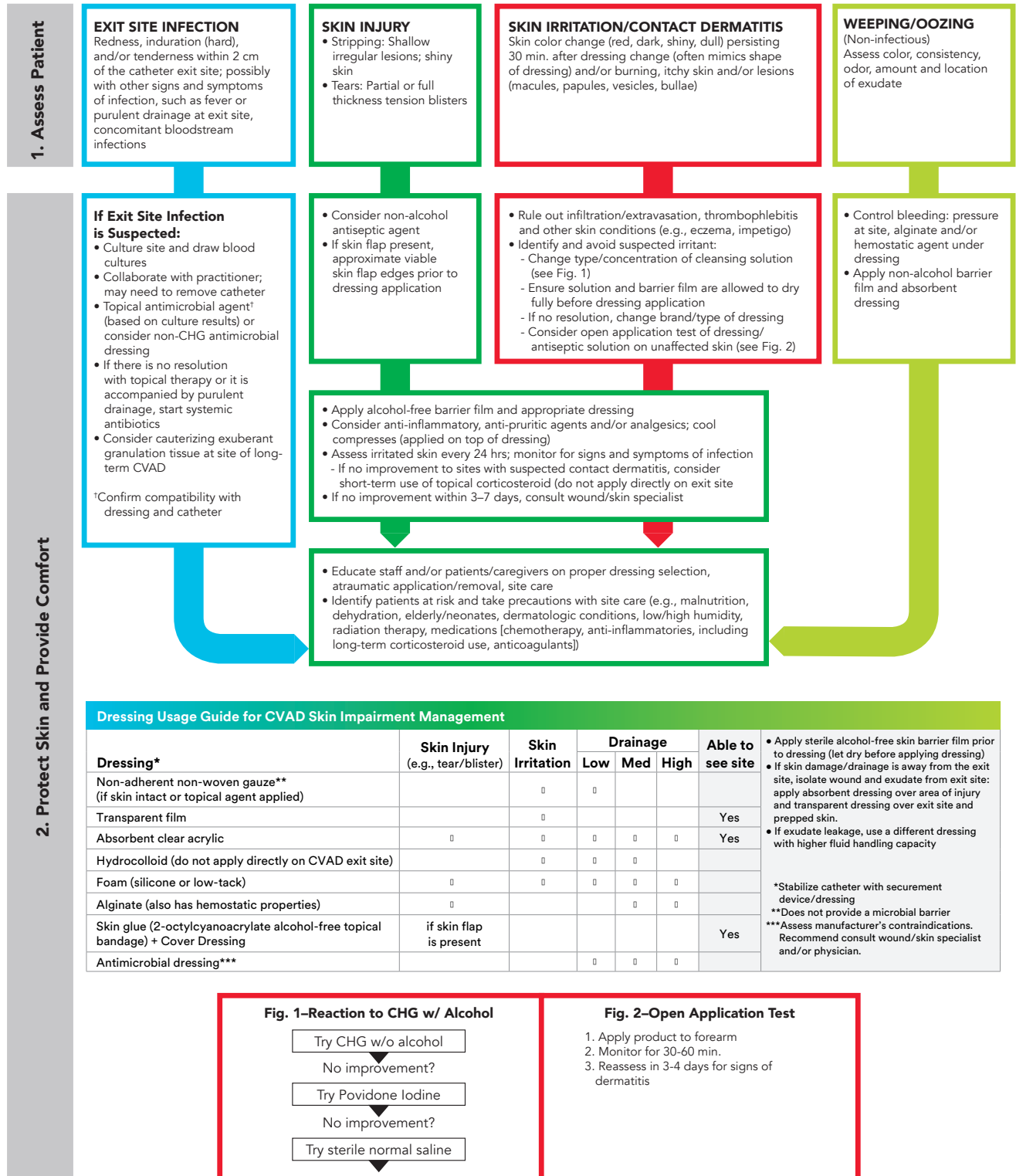
Evidence Level	Types of Evidence
Research evidence	
Level I	• Experimental study, randomized controlled trial (RCT) • Explanatory mixed methods design that includes only a Level I quantitative study • Systematic review of RCTs with or without meta-analysis
Level II	• Quasiexperimental study • Explanatory missed methods design that includes only Level II quantitative study • Systematic review of a combination of RCTs and quasiexperimental studies, or quasiexperimental studies only, with or without meta-analysis
Level III	• Nonexperimental study • Systematic review of a combination of RCTs, quasiexperimental and nonexperimental studies, or nonexperimental studies only, with or without meta-analysis • Exploratory, convergent, or multiphasic mixed methods studies • Explanatory mixed methods design that includes only a Level III quantitative study • Qualitative study • Systematic review of qualitative studies with or without meta-synthesis
Nonresearch evidence	
Level IV	• Opinion of respected authorities, nationally recognized expert committees or consensus panels, or both, based on scientific evidence. Includes: Clinical practice guidelines • Consensus panels or position statements
Level V	• Based on experiential and nonresearch evidence. Includes: Scoping reviews • Integrative reviews • Literature reviews • Quality improvement, program, or financial evaluation • Case reports • Opinion of nationally recognized expert(s) based on experiential evidence

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Johns Hopkins Evidence-Based Practice Model for Nursing and Health Care Professionals Hierarchy of Evidence Guide (Quality)

Quality of the Evidence	
(a) High	
Research	Consistent results with sufficient sample size, adequate control, and definitive conclusions; consistent recommendations based on extensive literature review that includes thoughtful reference to scientific evidence
Summative reviews	Well-defined, reproducible search strategies; consistent results with sufficient numbers of well-defined studies; criteria-based evaluation of overall scientific strength and quality of included studies; definitive conclusions
Organizational	Well-defined methods using a rigorous approach; consistent results with sufficient sample size; use of reliable and valid measures
Expert opinion	Expertise is clearly evident
(b) Good	
Research	Reasonably consistent results, sufficient sample size, some control, with fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence
Summative reviews	Reasonably thorough and appropriate search; reasonably consistent results with sufficient numbers of well-defined studies; evaluation of strengths and limitations of included studies; fairly definitive conclusions
Organizational	Well-defined methods; reasonably consistent results with sufficient numbers; use of reliable and valid measures; reasonably consistent recommendations
Expert opinion	Expertise appears to be credible
(c) Low quality or major flaws	
Research, summative reviews	Little evidence with inconsistent results, insufficient sample size, conclusions cannot be drawn undefined, poorly defined, or limited search strategies; insufficient evidence with inconsistent results; conclusions cannot be drawn
Organizational	Undefined, or poorly defined methods; insufficient sample size; inconsistent results; undefined, poorly defined or measures that lack adequate reliability or validity
Expert opinion	Expertise is not discernable or is dubious

CVAD– Associated Skin Impairment (CASI) Algorithm



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- I IDENTIFY if a device is present**
- D DOES the patient need the device?**
If no longer in active use, consider device removal.
- E EFFECTIVE function?**
Is the device functioning as intended?
If not, troubleshoot as per policy or remove device.
- C COMPLICATION-FREE?**
If complications are noted, troubleshoot or remove device.
- I INFECTION prevention**
Hand hygiene before and after patient and device care.
Careful handling and disinfection of device access points.
- D DRESSING & securement**
Ensure dressings are clean, dry and intact.
Secure devices to prevent tugging or patient injury.
- E EVALUATE & EDUCATE**
Discuss device plan with patient & family. Educate as needed.
- D DOCUMENT your decision**
Continue, troubleshoot, change dressing, or remove device.

*Always consider local policy,
and consult with team & patient as required.*



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Flushing efficacy of high concentration iodinated contrast agent in power-injectable peripherally inserted central catheters: Evaluating different flush volumes in vitro

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Mary Ann Liebert

A Part of Sage

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and Haomiao Qing¹ 

Abstract

Aim: To test the optimum flushing volume for power-injectable peripherally inserted central catheters after the injection of iodinated contrast agents.

Background: Pulsed infusion with saline solution was recommended for peripherally inserted central catheters flushing. However, evidence of flushing volume for power-injectable peripherally inserted central catheters after the injection of iodinated contrast agent was lacking.

Design: Empirical quantitative research in vitro experiment.

Methods: Single lumen power-injectable peripherally inserted central catheters were filled with an iodinated contrast agent. Sixty catheters were randomized into four groups: 10 ml flushing volume of 0.9% sodium chloride (Group A), 15 ml flushing volume of normal saline (Group B), 20 ml flushing volume of 0.9% sodium chloride (Group C), and 25 ml flushing volume of 0.9% sodium chloride (Group D). The same pulsatile flushing technique was performed for all four groups. Efficacy was measured based on the amount of iodine recovered from the lumen of the tested catheters.

Results: The iodine average recovery proportion was $98.5\% \pm 2.1\%$ in Group A, $99.3\% \pm 1.4\%$ in Group B, $98.4\% \pm 1.8\%$ in Group C, and $97.2\% \pm 3.2\%$ in Group D. The difference in proportion of iodine recovery between the control group (Group A) and the three experimental groups (Groups B, C, and D) was not significant.

Conclusion: We concluded that pulsed flushing with 10 ml normal saline immediately after the contrast agent injection was sufficient. Higher flushing volumes did not lead to a better flushing effect; rather, they would only bring unnecessary fluid burden and cost to patients.

Patient or public contribution: No patient or public contribution.

Keywords

Iodinated contrast agent, power-injectable PICC, flush volume, flushing efficacy, in vitro experiment

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Implications for the profession and/or patient care

Impact:

- What problem did the study address?
This study addresses the lack of evidence-based flushing volume for power-injectable peripherally inserted central catheters after the injection of iodinated contrast agents which are highly viscous liquid. The impact of this is that it highlights the need for comparing the effect among different flushing volume with the same pulsatile flushing technique.
- What were the main findings?
Ten ml conventional flush volume was enough for power-injectable peripherally inserted central catheters after the injection of iodinated contrast agents. Higher flushing volumes did not lead to a better flushing effect.
- Where and on whom will the research have an impact?
This study has the potential to impact imaging department nurses and patient care. It highlights that the optimum flushing methods for viscous iodinated contrast agents in power-injectable PICC based both on the nursing quality and patient benefit.

Patient or public contribution: It was vitro experiment. No patient or public contribution.

What does this paper contribute to the wider global clinical community?:

- Ten ml and above normal saline with pulsatile flushing technique can flushing away the vast majority of iodinated contrast agents in power-injectable PICC after power injection.
- Pulsed flushing with 10ml normal saline immediately after the contrast agent injection was sufficient and cost-effective.
- Higher flushing volumes did not lead to a better flushing effect, rather, they would only bring unnecessary fluid burden and cost to patients.

Introduction

Power-injectable peripherally inserted central catheters (PICCs) are widely used for medium and long term intravenous therapy, chemotherapy,^{1–3} central venous pressure monitoring,⁴ and high-pressure injection of an iodine contrast agent.^{5–7} However, PICCs carry the risk of complications such as catheter occlusion, catheter-related venous thrombosis, catheter-related infection, catheter ectopic, and

catheter rupture.⁸ The reported incidence of catheter occlusion is as high as 12%–27.7%.^{9–12} Typically, catheter lumen is flushed with 0.9% sodium chloride with sufficient volume and appropriate rate at the end of infusion to ensure the catheter is unimpeded and to avoid drug incompatibility. The recommended minimum volume is equal to double the internal volume of the catheter system; for central venous access devices, 10ml is the recommended volume.⁸ However, the optimal flush volume also depends on the type of infusion properties. High hyperosmotic or the high viscosity solutions may require larger flush volumes.¹³

Background

Gerard Guiffant explored the best methods of flushing a protein-containing liquid from 6.5 F central venous catheters with a length of 16 cm through in vitro experiments.¹⁴ They found that 90% of the protein was removed after a pulsatile flush with a 10 ml volume. Godelieve Goossens suggested that a 10 ml flushing volume after blood sampling was appropriate, and after a blood transfusion a flush of 20 ml was more effective to eliminate the deposited fibrin that was in contact with the catheter wall for a prolonged time.¹³ The osmotic pressure and viscosity of most iodine contrast agents used in enhanced CT examinations are higher than plasma, however the contrast agent's contact with the catheter wall is limited to tens of seconds or some minutes. There is no study reporting whether more flushing volume is needed after injection of iodine contrast agents in PICCs that are longer than central venous catheters. The description in the iodine contrast agent manual only mentions the necessity of flushing, but does not recommend a specific method.

The study

Aim

This in vitro experimental study aims to determine the optimum flushing volume for power-injectable PICCs after the injection of a high concentration iodinated contrast agent.

Methodology

Design

Empirical research—quantitative, in vitro experiment.

Materials

The tested iodinated contrast agent: iohexol, 370 g (I)/100 ml; osmotic pressure, 796 mmol/l, viscosity (37 °C), 9.4 mPa·s.

The tested catheters: Bard, 4 Fr (1.44 mm OD) Single-Lumen PowerPICC, Polyurethane material. The maximum pressure was 300 psi and the maximum flow rate was

Table 1. HPLC elution gradient.

Time (min)	Solution A (%)	Solution B (%)	Elution method
0–18	100	0	Equimetric
18–40	100–62	0–38	Gradient
40–45	62–50	38–50	Gradient
45–50	50–100	50–0	Gradient
50–60	100	0	Equimetric

5 ml/s. The maximum viscosity limit of the contrast agent used for power injection was 11.8 mPa.s. All 60 catheters were trimmed to a length of 37 cm, which was consistent with the normal length of placement. Their intracavity volume of one catheter without connector was 0.55 ml.

Ten-ml injection syringes and 0.9% normal saline were used to flush the catheters. Sixty 50-ml test tubes were used to collect the recovered flush liquid.

Methods

Sixty catheters, each 37 cm long, were flushed with normal injection saline and aspirated using 10-ml syringes to confirm that the catheters were unobstructed, functioning properly, and intact. The catheters were cleaned with a multi-enzyme cleaning agent, disinfected with acidic oxidized potential water, dried with compressed air and medical hot air drying cabinet, and sterilized with ethylene oxide for use. We checked the intracavity volume of one catheter without connector for use was 0.55 ml which was equal to the same brand and size new catheter.

Subsequently, the catheters were divided into four groups according to a random number table method: Group A (the control group), Groups B, C, and D, with 15 catheters in each group. The catheters were filled with an iodinated contrast agent stored at 37°C thermostat for more than 24 h. After each catheter was filled up, the tube was then flushed with an intermittent, pulsatile technique of 10 short boluses of 1-ml solution interrupted by brief pauses. The flushing volume of Group A was 10 ml, Group B was 15 ml, Group C was 20 ml, and Group D was 25 ml. The injected iodinated contrast agent and the flushed normal saline of each catheter was collected in a separate tube. All operations were performed by one investigator in an identical manner. The recovered amount of the iodine content was tested by high performance liquid chromatography (HPLC) in an iodine contrast agent product testing institution.

In this experiment, the determination method was used, that is, the test solution and the control solution were precisely measured, injected into the liquid chromatograph, after which the chromatogram was recorded according to the external standard method to calculate the peak area, and the recovery rate of iodohydrin was obtained. The chromatographic conditions were as follows: phenylsilane-bonded silica gel was used as the filler (two phenyl

columns in series), water was used as mobile phase A, and acetonitrile-water (50:50) was used as mobile phase B. Gradient elution was performed as shown in Table 1. The detection wave length was 240 nm, the column temperature was 60°C, the flow rate was 2.0 ml/min, and the sample volume was 20 µl.

Statistical analysis

Data were analyzed using Software Package Statistical Analysis (SPSS) version 20.0. The mean $\pm$ SD was used to present the proportion of iodine recovery. Difference between the control group (Group A) and the other three experimental groups (Groups B, C, and D) was tested using Dunnett's analysis of variance (ANOVA). The $p < 0.05$ was considered statistically significant.

Results

The iodine recovery proportion range for the four groups were 92.6%–100% in Group A (10 ml), 94.8%–100% in Group B (15 ml), 95.1%–100% in Group C (20 ml), and 89.0%–100% in Group D (25 ml; Table 2). The results of Levene test for homogeneity of variance show homogeneity of variance ($F=2.173$; $p=0.101$). According to Dunnett's test for proportions, there was no significant difference ($p > 0.05$) in iodine recovery between the control group (Group A) and the three experimental groups (Groups B, C, and D; see Table 3).

Discussion

Vascular access devices should be flushed after each medication administration with 0.9% sodium chloride to avoid medication residue in the catheter lumen and to reduce the risk of contact between incompatible medications.^{8,15–17} The guidelines recommend a minimum flushing volume equal to double the internal volume of the catheter system based on consensus.⁸ Taking the Bard 4Fr Single-Lumen PowerPICC, for example, the total intracavity volume of one 37-cm catheter without a heparin connector or needle free connector is 0.55 ml, which is <1 ml. Both the catheters and their components used for power injection must be resistant to high pressure.¹⁸ In this study, for clinical practice considerations, the connector was removed and the

Table 2. Proportions of iodine recovery (N=60%).

Group	N	Mean	SD	SE	95% CI		Minimum	Maximum
					Lower bound	Upper bound		
Group A	15	98.5	2.1	0.5	97.3	99.7	92.6	100
Group B	15	99.3	1.4	0.4	98.5	100	94.8	100
Group C	15	98.4	1.8	0.5	97.4	99.4	95.1	100
Group D	15	97.2	3.2	0.8	95.4	99.0	89.0	100

Table 3. Differences observed in iodine recovery volumes in Dunnett's test for proportions.

I	J	I-J	SE	p	95% CI	
					Lower bound	Upper bound
Group B	Group A	0.008	0.008	0.642	-0.012	0.028
Group C	Group A	-0.001	0.008	1.000	-0.020	0.019
Group D	Group A	-0.013	0.008	0.290	-0.032	0.007

flushing syringe was directly connected to the catheter interface. That is, ≥ 2 ml was enough for one 37-cm catheter 4Fr Single-Lumen PowerPICC system. A routine 10-ml flush volume, which is more than ten times the internal volume of the catheter system, is widely used in clinics. A volume of 20 ml for high viscosity or high concentration liquids is used to increase the flushing effect during infusion, after infusion, or other situations requiring catheter flush. Several studies have focused on the type of flushing liquid, flushing time, and technique but not the flush volume.^{15,16,19} Gerard Guiffant tested the efficacy of pulsed and continuous infusions on 16-cm 6.5 Fr central venous catheters filled with a mixture of fibronectin and bovine albumin.¹⁴ The outcome measure was the percentage of recovered protein. He concluded that 10 successive boluses of 1 ml flushed in 0.5 s each with "flush-pause" sequences technique had the best flushing effect.

Enhanced CT requires high pressure injection of iodine contrast with a flow rate of 2–6 ml/s,²⁰ and PowerPICC catheters were the main type of central venous catheter used for iodine contrast administration. The viscosity of iodine contrast agents at 37°C is twice that of blood, and the resistance of flushing tube is obvious. On the other side, the total duration of the injection is only about a few tens of seconds, far less than the duration of continuous infusion. There is a lack of clinic studies supporting the necessity of using a larger amount of flush volume, that is, more than 10 ml, after a short-duration injection of an iodine contrast agent. With an aim to improve patient safety and reduce the cost burden, this study sought to determine whether the catheters were overflushed or non-therapeutic fluids were over infused. This is the first study to evaluate the flushing effect of different flush volumes with Gerard Guiffant's pulse flushing method on PowerPICC catheters after iodine contrast injection.

The results of the present study show that the average recovery of 97%–99% of iodine contrast agent could be achieved with a flushing volume of 10 ml and above. There is no statistical difference in the recovery rate of iodine contrast agents between the 10 ml flushing volume group and the 15, 20, and 25 ml groups. In the experiment, it was found that the resistance caused by the highly viscous liquid is still felt at the beginning of the flushing, and this resistance is reduced obviously just after the first two pulses of flushing with 2 ml 0.9% sodium chloride. Although iodine contrast is a highly viscous liquid, it had a short duration contact with the catheter and did not easily adhere to the cavity of the catheter. This was different from other slower high concentration liquid infusions through the catheters with prolonged contact. Horbett TA's study shows that fibronectin adheres to biomaterials easily and strongly.²¹ Pulse flushing is effective to make the liquid easily adhere to the catheter.¹⁴

In the present study, we found that pulsed flushing with 10 ml normal saline immediately after the contrast agent injection is sufficient. Furthermore, it is more cost-effective compared to flushing with higher volumes. Higher flushing volumes do not lead to a better flushing effect; rather, they would only bring unnecessary fluid burden and cost to patients. Of course, considering the design differences among various products, it is recommended to follow the product manual simultaneously.

Limitations

In consideration of the cost of materials, the catheters used in this study were those removed from power-injectable PICCs at the end of treatment. For concerns regarding infection risk and ethical reasons, each catheter was rinsed, inspected, disinfected, and dried. The catheters' condition were different

from those in use. The effect of factors such as different use durations and catheter type need further study. A small sample size and the possibility of operating errors during measurements were other limitations of this study.

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Declaration of conflicting interests

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Ethical approval

This study in vitro did not involve human or animal subjects, and no ethical approval was required.

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The *Journal of Infusion Nursing* is a member benefit of the Infusion Nurses Society (INS). INS is a professional association dedicated to enhancing infusion practices that will improve patient outcomes. Through its many member benefits, INS offers access to the latest infusion research, technology, and education. For more information about the benefits of INS membership, visit www.ins1.org.

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Foreword

Infusion therapy is ubiquitous regardless of the care setting, transcends all patient populations, and connects with other specialty practices. Clinicians navigate the continuum of care to ensure their patients' best interests are addressed over the course of treatment that could last a few hours, days, or a lifetime. The comprehensive nature of the specialty practice of infusion therapy demands that clinicians demonstrate competency. While not well understood, the public's expectation is that once post-secondary education is completed, health care professionals are competent in their practice.

Infusion nurses are key members of the health care team and are recognized for their critical thinking abilities, assessment skills, and technical expertise. Due to its invasive nature, the risks associated with infusion therapy and the need to mitigate them is imperative in order to provide safe, quality patient care. Preventing complications, promoting vein preservation, monitoring outcomes, implementing quality improvement measures while ensuring patient satisfaction and cost-effective care delivery are factors vital for achieving optimal outcomes. Hence, the necessity for a well-respected, reliable reference to guide practice, the *Infusion Therapy Standards of Practice (the Standards)*.

For over 40 years, the evolution of the *Standards* has been impressive. In 1981, the first published standard was the 3-page "Hyperalimentation Standard of Practice" compiled by the Special Interest Group on Hyperalimentation. The document outlined the purpose of six hyperalimentation practices, offered recommendations of practice; however, no references were cited that supported the document's content. Compare that to the 2024 *Standards* written by a committee of clinical experts that is a 285-page publication with 66 standards, including more than 2500 references to support the standard statements and practice recommendations.

Beginning with the 3rd edition of the *Standards* in 1998, I've had the honor to be involved with the revisions of the *Standards* and appreciate the process and the necessity that it reflects current evidence. By 2006, the *Standards* were being revised every 5 years. In 2011, to further enhance the document, the Standards of Practice Committee began rating the strength of the body of evidence. A title change occurred with the 7th edition, when "nursing" was replaced by "therapy," as it was recognized that not one single discipline owned this practice, and providing safe infusion care is the responsibility of all clinicians involved with the practice. With global recognition and use worldwide, since the release of the 2021 *Standards*, the committee has included clinical experts and peer reviewers from outside the United States. With more infusion- and vascular access-related research being published, the revision cycle has been shortened to every 3 years.

The credibility and expertise of the Standards of Practice Committee are unsurpassed. The authors, practicing clinicians with many years of experience in the specialty, represent diverse areas of expertise from multiple practice settings, ensuring a global perspective is provided. This collective with their collaborative spirit, spent countless hours searching, reviewing, synthesizing the literature, and rating the published evidence and research, while coordinating meetings across international time zones. While actions matter, so do words. This committee was hypervigilant as they wrote this document, knowing that implementation of the *Standards* into clinical practice rests on its accuracy. Their dedication to the revision process is unmatched.

While the primary focus of the *Standards* is patient safety, it also supports the clinician's practice and well-being. Infusion-related adverse events have an impact on patients, but also on the clinician involved, resulting in second victim syndrome. Applying the

Standards with its guidance and practice recommendations establishes consistency and confidence in one's practice.

Where is the evidence taking us? Are the *Standards* supporting existing practice or leading to changes by setting aside traditional practices not supported by evidence? I contend it is a combination of both. Scope of practice has expanded based on education, training, and validated competency. Technological advancements are enhancing practice as well as the patient experience. As the specialty evolves, so too must the practice and the *Standards* that clinicians rely on.

I applaud INS for its commitment to "Setting the Standard for Infusion Care" and taking the lead in developing and disseminating standards of practice with a global approach. While there are differences in languages, customs, cultures, practices, and resources, a common goal is to provide safe infusion care to all patients. The *Infusion Therapy Standards of Practice* is a trusted source that informs practice. It is an invaluable reference that provides an evidence-based framework to guide the clinician in providing safe infusion and vascular access care. Our patients deserve nothing less.

Mary Alexander, MA, RN, CRNI®, CAE, FAAN
INS Chief Executive Officer Emerita



About the Standards of Practice Committee

Barb Nickel, APRN-CNS, CCRN, CRNI®—Chair

Clinical Nurse Specialist in Omaha, Nebraska

Ms Nickel works for a large health system and is responsible for staff development, competency assessment, and process improvement to optimize outcomes in multiple areas of clinical practice, including critical care, infusion therapy, sepsis, and new graduate transition to practice. Ms Nickel has presented nationally on infusion-related topics, was coauthor of the 2021 *INS Infusion Therapy Standards of Practice*, and is chair of the 2024, 9th edition of the *Standards*. Ms Nickel has authored several publications on infusion therapy in the critical care setting and also serves as faculty in a BSN program.

Lisa Gorski, MS, RN, HHCNS-BC, CRNI®, FAAN—Co-chair

Clinical Education Specialist/Clinical Nurse Specialist, Ascension at Home

Ms Gorski has worked for more than 35 years as a clinical nurse specialist (CNS) and educator for Wheaton Franciscan Home Health and Hospice, now Ascension at Home. As a CNS, she developed and continues to provide infusion-related education for home care nurses as well as direct patient care. She is the author of several books and more than 70 book chapters and journal articles, is an INS past president (2007-2008), is a past chair of the INCC Board of Directors, and has served as the chair of the INS Standards of Practice Committee for the 2011, 2016, and 2021 editions. She was inducted as a fellow into the American Academy of Nursing in 2006, named the CRNI® of the year by INCC, and named the 2011 CNS of the Year by the National Association of Clinical Nurse Specialists. Ms Gorski speaks nationally and internationally on standards development, infusion therapy/vascular access, and home health care.

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Ms Kleidon is a nurse practitioner in paediatric vascular assessment and management at Queensland Children's Hospital and a research fellow at University of Queensland. Her dual role between clinical and research provides unique opportunities to improve vascular access outcomes for children and promotes a collaborative approach to planning and managing vascular access to ensure best practice. She is currently enrolled in a PhD program of research entitled "Techniques and technologies to improve PIVC first time insertion success and reduce complications and failure."

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Senior Adjunct Research Fellow, AVATAR

Ms DeVries has been involved in infection prevention and hospital epidemiology for 30 years, spanning community, university, and federal health care facilities as well as post-acute care settings. She is passionate about raising awareness around vascular access device complications and devotes her time to education on this topic with an emphasis on data collection and analysis. She was a reviewer for the 2016 and 2021 *Infusion Therapy Standards of Practice*, and was a committee member for the 9th edition of the *Infusion Therapy Standards of Practice*. Ms DeVries is a senior adjunct research fellow with the Alliance for Vascular Access Teaching and Research (AVATAR), a past director-at-large with Vascular Access Certification Corporation (VACC), and the president of the Association for Vascular Access (AVA) for 2024.

Samantha Keogh, PhD, RN, FACN

Joint Professor of Acute and Critical Care Nursing, Queensland University of Technology (QUT) and Metro North Health in Brisbane, Australia;

Senior Researcher, QUT's Centre for Healthcare Transformation and the Alliance for Vascular Access Teaching and Research (AVATAR)

Dr Keogh's clinical background is in intensive care (adult and paediatric), so she understands the importance of vascular access to deliver essential medication, fluids, and blood products, as well as facilitate vital monitoring and sampling. Dr Keogh is a fellow of the Australian College of Nursing (ACN) as well as a member of several other specialty-based colleges, societies, and networks, including the Australasian Nursing and Midwifery Clinical Trials Network (ANMCTN), a network developed to support, mentor, and accelerate growth in nursing and midwifery clinical trials capability and capacity across Australia.

Britt Meyer, PhD, RN, CRNI®, VA-BC, NE-BC

Chair, Infusion Nurses Certification Corporation

Dr Meyer leads the vascular access team at Duke University Hospital and presents nationally and internationally on a variety of infusion and vascular access topics. She is well-published in the specialty and is passionate about empowering clinicians to provide safe and effective care. She also serves as an adjunct faculty member for the East Carolina University School of Nursing.

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Oncology Clinical Nurse Specialist, Swedish Cancer Institute in Seattle, Washington

Dr Crickman has over 23 years of experience as an oncology nurse working in direct patient care and as a clinical nurse specialist. She is a staunch advocate for both staff and patient safety and has published manuscripts on hazardous drug control measures, interventions to promote safety, and central venous catheter blood draws. Her expertise

includes chemotherapy administration, cellular therapies, and CLABSI prevention measures. Outside of work, Dr Crickman enjoys hiking and camping in the Pacific Northwest with her family.

Jennie Ong, PharmD

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Research and Development Director, The Association for Safe Aseptic Practice (ASAP)

Mr Clare's background is in high-risk oncology and haematopoietic stem cell transplantation (HSCT). He is currently the practice development lead for haematology at University College Hospital in London (UCLH) and has previously worked at the Myeloma Institute at the University of Arkansas for Medical Sciences (UAMS) in Little Rock, Arkansas. A former visiting lecturer and module leader at City University in London, Mr Clare received his undergraduate degree from the University of Arkansas at Little Rock (UALR) and a master's degree in health care research from King's College London (KCL). He is a former member of The European Society for Blood and Marrow Transplantation Nursing Group (EBMT-NG) Research Sub-committee (2004-2008), a 2012 runner-up in the Nursing Standard Awards: The Robert Tiffany International Award, and a joint winner of the 2008 Nursing Times Award for Infection Control Nursing. He has worked with several expert panels and is a current member of the Improving Device-Related Infection Prevention Practice (DRIPP) IV Group. He has authored or coauthored numerous papers and journal articles on infection prevention and control, aseptic technique, patient nutrition, and bone marrow transplantation donor issues. For the past fifteen years, he has been working with the ANTT® program, developing resources, teaching, and presenting both in the UK and around the world.

Mary Hagle, PhD, RN, NPD-BC, FAAN

Nurse Scientist and Codirector, Interprofessional Advanced Fellowship Program in Patient Safety at the Clement J. Zablocki Virigina Medical Center in Milwaukee, Wisconsin

Dr Hagle served as a committee member for the 2011, 2016, 2021, and 2024 revisions of the *Standards* and has extensive experience as a researcher and as an oncology clinical nurse specialist. She continues as a mentor and consultant for research, quality improvement, and evidence-based practice teams.

STANDARDS OF PRACTICE COMMITTEE

CONFLICTS OF INTEREST AND OTHER DISCLOSURES

Barb Nickel is a consultant on the advisory board for Baxter Healthcare, is a consultant and part of the speaker's bureau for Becton Dickinson Medical, and is a consultant for Kendle Healthcare. **Lisa Gorski** is on the advisory board for and receives presentation fees from BD, 3M, and Nexus Medical; owns stock in ivWatch; and receives royalties/revenue share from FA Davis, Springer Publishing, and Medbridge. **Tricia Kleidon's** employer UQ has received monies on her behalf from 3M, BD Medical, BBraun, Medical Specialties Australia, and Smiths Medical. **Amy E. Kyes** is the owner/president of A. Kyes Consulting Inc., and consults with INS as an educator. **Samantha Keogh's** employer (QUT) has received monies on her behalf from BD Medical and ITL Biomedical for educational consultancies unrelated to this work. **Britt Meyer** is an HMP Global education consultant, a 3M consultant, on the Teleflex advisory panel, and a Bard paid researcher. **Mary Jo Sarver** is a Regeneron speaker, a G1 Therapeutics speaker, CEO of Sarver Better Living, and a consultant for the Oncology Nursing Society; and she has received a publication stipend for authoring a chapter in the upcoming new edition of vascular access guidelines. **Michelle DeVries** has been on advisory boards and speaker's bureaus for Baxter, B Braun, Becton Dickinson, Eloquest, Ethicon, ICU Medical, Teleflex, Kurin, and 3M. **Rachael Crickman, Jenny Ong, Simon Clare, and Mary Hagle** have no conflicts of interest to report.

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The Standards of Practice Committee, Barb Nickel, chair, Lisa Gorski, cochair, Tricia Kleidon, Amy Kyes, Michelle DeVries, Samantha Keogh, Britt Meyer, Mary Jo Sarver, Rachael Crickman, Jennie Ong, Simon Clare, and Mary Hagle for their commitment and dedication during the 9th edition revision process. The professional and personal commitment required to spend countless hours appraising literature and synthesizing research, labor over each word and language aspect for each standard statement and practice recommendation, ensure that each citation/reference informed clinical practice, and participate in regular committee meetings across different time zones to discuss the evidence and reviewer feedback to ensure the *Standards* were revised/written for clinical application on a global scale demands devotion and expertise in the specialty practice. INS commends the excellence of character and selfless contribution of this committee of the *Infusion Therapy Standards of Practice* 9th Edition.

Mary Alexander, MA, RN, CRNI®, CAE, FAAN, INS CEO emerita, for 26 years of exemplary service to the Infusion Nurses Society and for being a dedicated leader and visionary for the *Infusion Therapy Standards of Practice* and Editor of the *Journal of Infusion Nursing*. Her commitment to excellence is imprinted on this 9th edition of the *Standards* and will continue to impact the practice of infusion therapy for many, many years to come.

The INS Publications Department: Donna Knauss, Managing Editor, for her industrious and businesslike approach to editing and fact-checking. Her dedication to timeliness, attention to detail, and respect for the importance of the *Standards* was imperative to the publication process and is highly commendable. Rachel King, Editorial Production Coordinator, for her thoughtful, reflective recommendations, her willingness and ability to accept additional assignments, and her editorial excellence in all contributions. INS extends generous appreciation to each for her commitment.

Amy Nadell, MA, MSLIS, AHIP-D, Librarian, for conducting extensive literature searches for each of the 66 *Standards*. Her expertise and contribution to the 9th edition revisions is remarkable and greatly appreciated.

Medical librarians who supported committee members locally by assisting in literature retrieval and recommending alternative search strategies: Caralee Witteveen-Lane, Regional Manager Medical Library Services, Trinity Health, Grand Rapids; Lauren Jackson, Regional Medical Librarian, Trinity Health, Grand Rapids; Frances Chu, PhD, MLIS, MSN, RN, Medical Librarian, Providence Regional Medical Center, Everett; and Michele Matucheski, MLIS, AHIP, Medical Librarian, Ascension, Wisconsin. INS would also like to offer a special thank you to the University of Nebraska Medical Center, McGooghan Library for their invaluable assistance in document retrieval.

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Preface

The specialty of infusion therapy encompasses a broad spectrum of patient care that is singularly focused on patient safety, demonstrated through the comprehensive management of all patient infusion needs, including 1) planning for the intended therapy, vascular access device (VAD) and site selection, and skillful VAD insertion; 2) administration, management, and monitoring of the patient's therapeutic regimen; 3) monitoring for and recognition of complications and readily intervening and mitigating patient harm; 4) designing an ongoing plan of care for long-term patient needs or concluding treatment, and performing VAD discontinuation.

The role of infusion therapy specialists is vastly important in achieving consistency and standardization in patient care. These individuals are knowledgeable and skilled in infection prevention and control; medication and solution administration management (infusate properties, mechanism of action, indications for use); and promotion of vein preservation. This specialty care is delivered in all health care settings, across the continuum of care to all age groups and patient populations.

Organizationally, infusion therapy specialists are essential in orchestrating patient care in collaboration with the interprofessional health care team. As an integral part of the health care team, infusion clinicians remain dedicated to evidence-based practice and improving patient outcomes. These professionals are responsible for organizing and defining infusion services/vascular access specialty teams (VASTs) and are significantly involved in policy development and governance of practice within the organization. They are devoted to maintaining clinical competency for themselves and contributing to the competency and professional growth of others through the development of educational programs that promote knowledge and skill acquisition. They are active in quality improvement programs that incorporate surveillance, data aggregation and analysis, and reporting of patient quality indicators, taking action as needed to improve practice, processes, and/or systems.

Professionally, infusion specialists are leaders dedicated to ongoing growth and professional development. They are actively involved in establishing and promoting this specialty practice not only in their local environment, but also on a national, and even international level. They pursue certification that validates their knowledge and expertise within the specialty and their background of clinical experience.

Accordingly, the *Infusion Therapy Standards of Practice (Standards)* are written and designed specifically to direct and support the professional practice of infusion therapy clinicians of many disciplines who practice in various care settings throughout the world. Given the comprehensive nature of the specialty of infusion therapy and expectations of those who have chosen this role, it is imperative that each clinician's practice is informed and guided by standards that provide evidence-based guidance for clinical decision-making.

This edition of the *Standards* was written and developed by an international group of clinical experts who are entrenched in the altruistic pursuit of excellence in infusion therapy. Their work, exhibited on the following pages, is the culmination of expertise, passion, and dedication. The rigor applied to the revision and authorship of this edition is exceptional. Additional content addresses 3 emerging practice challenges/trends in infusion therapy through the inclusion of new standards: Standard 13, *Drug Diversion in Infusion Therapy*; Standard 64, *Vasopressor Administration*; and Standard 66, *Home Infusion Therapy*. Also new in this edition is the redistribution of content formerly presented as individual standards. The Standards of Practice Committee determined it was

prudent to join practice pieces that complemented a similar area of practice. Therefore, Site Selection was combined with VAD planning to become Standard 25, *Vascular Access Device Planning and Site Selection*. Joint Stabilization was combined with Site Protection to become Standard 37, *Site Protection and Joint Stabilization*. Content from Medication Verification was incorporated into Standard 56, *Compounding and Preparation of Parenteral Solutions and Medications*. As usual, the *Standards* statements are declarative and straightforward, establishing the practice expectations of each clinician by which the quality of practice, service, or education is judged. An additional description of this edition's revisions is outlined in *Methodology for Developing the Standards of Practice*.

As stated in INS' Mission ethics, "We are dedicated to advancing the delivery of quality infusion therapy to patients, enhancing the specialty through stringent Standards of Practice and professional ethics, and promoting research and education in the infusion nursing practice." Remaining true to that commitment, INS is proud to present the 9th edition of the *Infusion Therapy Standards of Practice*.

Dawn Berndt, DNP, RN, CRNI®

Editor, *Journal of Infusion Nursing*

Infusion Nurses Society Director of Publications and Educational Design



Methodology for Developing the Standards of Practice

STANDARDS OF PRACTICE REVISION CYCLE

As infusion- and vascular access-related research continues to be published at a rapid pace, it is imperative to update the Standards more frequently. For the 8th edition of the *Standards*, committee members reviewed more than 2500 sources of literature; for this 9th edition of the *Standards*, again in numbers greater than the previous, thousands of publications were reviewed and appraised. As this practice specialty continues to expand and change, it is incumbent upon INS to ensure that these changes are reflected in the *Standards* as quickly as possible. As a result, INS has determined that the *Infusion Therapy Standards of Practice* must undergo revisions every 3 years.

In an effort to support and enhance the goals of the *Standards of Practice* Committee, INS implemented supportive resources and technologies to assist committee members in accomplishing this important work. This *Standards* review and revision process was assisted by the work of a contracted health sciences librarian, Ovid® Synthesis Clinical Evidence Manager (Wolters Kluwer), EndNote Reference Manager (Clarivate), and SharePoint (Microsoft 365). Each of these supportive systems was selected for the express purpose of 1) developing a standardized approach to literature retrieval, evaluation, and appraisal, 2) creating an archival record of review/revision processes, and 3) utilizing a secure document control system. The committee members were introduced to the health sciences librarian and new technology software programs at the initial in-person meeting held in Boston in January 2022.

STANDARDS OF PRACTICE COMMITTEE

INS seated the 9th edition Standards of Practice Committee on January 25, 2022. The committee is comprised of an international group of nurses and clinicians who possess a wealth of clinical knowledge and expertise in the domains of infusion therapy and vascular access device (VAD) planning, placement, use, and management. The committee is charged with identifying and authoring new content and revising existing content as informed by published literature and other sources of information (eg, The Joint Commission, the US Department of Health and Human

Services, Centers for Disease Control and Prevention). In addition to reviewing and synthesizing research, appraising the evidence, and drafting revisions, committee members also commit to participation/attendance in regularly scheduled meetings to discuss new evidence, reviewer feedback, and engage in consensus determination.

LITERATURE SEARCH

A health sciences librarian (HSL) was employed to conduct comprehensive literature searches for each of the 66 existing standards and 3 additional standards slated for inclusion. The HSL collaborated with each committee member to develop and refine search terms and strategies to ensure published literature in each topic area was adequately surveyed. All references were stored, labeled, and categorized on a reference citation platform. This structural approach improved consistency in process and secured a repository of evaluation data for future editions of the *Standards*. Searches were limited to mainly English-language, peer-reviewed journal articles published between January 2017 and March 2023. Additional, but narrow, literature searches were conducted through July 2023 when addressing reviewers' comments or suggestions.

Databases searched included, but were not limited to, Cochrane Library, Cumulative Index to Nursing and Allied Health Literature (CINAHL), EMBASE, Google Scholar, Ingenta Connect, MEDLINE, PubMed, ScienceDirect, Scopus, UpToDate, and Web of Science. References of retrieved articles and select journal titles were reviewed for relevant literature.

Additional sources of evidence included, but were not limited to, the websites of professional organizations, manufacturers, pharmaceutical organizations, and the United States Pharmacopeia (USP). Clinical practice guidelines, publications, and websites of health care and professional organizations from select countries were reviewed; these were used as needed. Evidence was also included from the Association for the Advancement of Medical Instrumentation (AAMI), Institute for Safe Medication Practices, The Joint Commission, the US Department of Health and Human Services, Centers for Disease Control and Prevention, US Food and Drug Administration, National Quality Forum, and the US Department of Labor (eg, Occupational Safety and Health Administration). Other

evidence came from health care-related agencies in Ireland, United Kingdom, Australia, and Canada. Classic papers were included as needed. On occasion, textbooks served as sources of evidence when clinical research and scholarship are widely accepted, such as for anatomy and physiology. Because the *Standards* is written for all health care settings and all populations, evidence was included for each of these areas, as available.

COMMITTEE AUTHORIZING AND REVISION PROCESSES

Once literature searches were conducted and transferred to EndNote, committee subject-matter experts who were assigned to author/co-author specific standards reviewed each reference according to the scope of that Standard. Studies that did not have relevance to the topic were deleted from the EndNote folder. Studies with relevance were reviewed further. If found to be supportive of the Standard content, the article and reference were populated into the Ovid® Synthesis project. After further evaluation, the reference was either “included,” and full critical appraisal and level of evidence was assigned, or it was “excluded.” Once critical appraisals were completed, the research findings were incorporated into the Standard statement, by revising existing content with the most current evidence and/or by supporting/raising the level of evidence of that statement or Practice Recommendation.

After the authors reviewed and appraised all references, initial revisions were written into the master document in SharePoint. Reference citations and bibliographies were generated using “Cite While You Write,” an EndNote application. All written content was reviewed during weekly virtual committee meetings to ensure consensus was reached on all statements and verbiage.

APPRAISING AND EVALUATING EVIDENCE

As noted, Ovid® Synthesis Clinical Evidence Manager was utilized by the Standards of Practice Committee to appraise each source of evidence. The standardized template in Ovid® Synthesis helped facilitate literature appraisal and ranking of level of evidence. Each item of evidence was evaluated from many perspectives, and the highest, most robust evidence relating to the Practice Recommendation was used. Research evidence was preferred over nonresearch evidence. For research evidence, the study design was the initial means for ranking. Other aspects of evaluation of quality include sufficient sample size based on a power analysis, appropriate statistical analysis, examination of the negative cases, and consideration of threats to internal and external validity.

Research on research, such as meta-analyses and systematic reviews, is the highest level of evidence.

Meta-analysis uses statistical analysis and only specific study designs to produce the most robust type of evidence. Single studies with strong research designs, such as randomized controlled trials (RCTs), form the basis for research on research or a strong body of evidence when there are several RCTs with similar findings. Other research designs are needed as well for a developing area of science and often before an RCT can be conducted. A necessary and foundational study for learning about a question or a population is the descriptive research study, but because of its lack of research controls, it is ranked at a low level of evidence for clinical practice.

Lastly, nonresearch is often the only available evidence. Nonresearch includes quality improvement projects, clinical articles, case reports, or position papers, as well as manufacturers’ instructions for use and consensus guidelines. Nonresearch evidence can be extremely valuable for certain aspects of practice when it is unethical to conduct research on a particular topic, or research is impractical. Many times, quality improvement projects lead to a research question and subsequent study.

Evidence tables were generated from Ovid® Synthesis and were sometimes used to synthesize multiple pieces and types of evidence for a Practice Recommendation, while some literature searches yielded very little usable evidence, and evidence table generation was unnecessary. Every effort was made to be consistent throughout the *Standards* when referring to the same action (eg, disinfecting a needleless connector or measuring the circumference of an extremity).

The *Standards* are designed to be a compilation and summary of the highest level and most current evidence on a topic. It is not, however, a systematic review or an exhaustive list of all available published references on these topics.

RATING THE STRENGTH OF THE BODY OF EVIDENCE

The Standards of Practice Committee utilized the Strength of the Body of Evidence rating scale to determine the level of evidence for each referenced item cited in the *Standards*. The literature appraisal template in Ovid® Synthesis was modified to include the INS rating scale. In preparation for a more global approach to the *Standards*, the rating scale was modified for the 8th edition; no additional modifications or revisions were made to the scale for the 9th edition of the *Infusion Therapy Standards of Practice*.

The rating scale provides guidance for clinicians when implementing these *Standards*. This guidance can reflect a range of evidence, from a preponderance of evidence with highly recommended specific clinician actions, to minimal evidence with actions directed by evidence from case studies, organizational preference, clinician judgment, or principles of anatomy.

The rating scale ranges from the highest ranking of “I,” representing research evaluating aggregated research findings (eg, meta-analysis) to the lowest level of “V” (eg, case

study). For a standard of practice with a single item of evidence, such as a meta-analysis with its accepted methods, the body of evidence is within the meta-analysis and the strength of this body of evidence is I. When studies are cited within the larger work of a meta-analysis or systematic review, the individual studies are not cited separately unless they add to the Practice Recommendation content specifically. However, for large research-based guidelines, the level of evidence may vary based on what is cited: the whole guideline or a specific part of the guideline with its related evidence.

The A/P (Anatomy/Physiology) identification may be based on textbooks as well as published case studies. This evaluation is used in a Practice Recommendation to stop an unsafe action, such as preventing an air embolism through body positioning. It may also be used to prevent harm to the patient, such as avoiding venipuncture around dense areas of nerves, when there is a lack of literature or very low levels of evidence with conflicting findings. In these instances, the Standards of Practice Committee reviewed the evidence, discussed the practice, and agreed to a Practice Recommendation using the designation of Committee Consensus. This rating was used infrequently in the Practice Recommendations.

STANDARDS CONTENT ORGANIZATION

Standards Statements. All Standards statements were carefully reviewed and were revised only when new evidence informed clinical practice. New Standard statements were added when additional practice elements were validated in recently published literature or when new Standards of Practice were added (eg, Drug Diversion in Infusion Therapy, Vasopressor Administration, Home Infusion Therapy).

Practice Recommendations. When there is a large body of evidence based on robust research with consistent findings, the strength of the body of evidence reflects a high rating, such as a I or II, and the Practice Recommendation is strong. There is also occasion when a systematic review with a robust research design yields findings that are inconclusive. Thus, there is a strong body of evidence indicating a high rating for the type of evidence cited, but there is insufficient evidence to draw conclusions. In this instance, a term is used such as “consider,” in which the clinician is advised to use this evidence along with her or his expertise and clinical judgment. As previously described, “Committee Consensus” is assigned as the level of evidence when there are minimal or low-rated conflicting studies but guidance is needed for clinicians to provide safe care without harm.

Level of Evidence Note: In systematic reviews and systematic reviews/meta-analysis, the level of evidence may reflect the overall document if used to support a main finding in the study, or may be different from the overall document based on the level of evidence for a particular statement (eg, one of the findings in the systematic review or

systematic review/meta-analysis is noted to have a lower level of evidence, supported by lower quality studies). These statements will be used to adjust the Practice Recommendation Level of Evidence.

When cited literature supports a Practice Recommendation and each of the subsequent supportive statements listed below, (eg, a list of items), the reference citations were placed with the Practice Recommendation. If a sub-point under a Practice Recommendation was informed by findings of a specific study or studies, the reference citations were noted along with that statement.

In an effort to control repetition and enhance clarity throughout the *Standards*, the committee included cross-reference guidance to direct attention to specific Standards for additional reference. Statements that use “see” (eg, see Standard 19, *Aseptic Non Touch Technique [ANTT®]*) means the statement agrees with a statement in another Standard as listed, but there are references specific to the current standard that should be cited. Conversely, statements that use “refer” (eg, refer to Standard 38, *Flushing and Locking*) indicate that the statement agrees fully with a statement in the cited Standard (typically the most relevant source of that information) and related references can be found in the cited Standard.

References. Complete bibliographical information was included at the end of each Standard of Practice and prepared using American Medical Association (AMA) formatting style.

Appendices. Supplemental content was provided as a clinical reference for these topic areas: Aseptic Non Touch Technique (ANTT®), Catheter-Associated Skin Injury, and Assessment Scales/Tools for Infiltration, Extravasation, and Phlebitis.

Glossary. Some clinical definitions are included at the beginning of specific Standards, where it seemed prudent to include this information to enhance readability and understanding. However, a comprehensive glossary has also been prepared and is published in the later pages of this edition.

FIRST DRAFT PUBLIC REVIEW

Throughout the *Standards* review and revision process, the committee met regularly via virtual technology, reviewed each standard in detail, and came to consensus on the final strength of the body of evidence rating for the first draft of the *Infusion Therapy Standards of Practice*, 9th edition.

Upon completion of the first draft, more than 200 international, interdisciplinary reviewers who are experts in the field, comprising all aspects of infusion therapy and VAD management, were invited to submit a blind review via Editorial Manager. A total of 144 reviewers returned critiques, of whom 117 were from the United States and 28 were international. Including the United States, 12 countries were represented. Reviewers provided comments,

suggestions, references, and questions, which were compiled by specific standard into a comprehensive Excel document.

SECOND DRAFT REVISIONS

Second draft revisions were completed during a 6-week period, where again, weekly committee virtual meetings were held to discuss these recommendations, supporting evidence, and appropriate revisions. The committee addressed every comment, revised practice recommendations, and sought additional evidence as needed. While all references suggested by public review were carefully considered for inclusion, references were only included if they strengthened the level of evidence of a Practice Recommendation or provided new information for the statement/recommendation. The feedback provided helped to further strengthen the recommendations outlined in this revision. Each Standard had a final review by the committee for consensus on the content, evidence, recommendation, and rating.

COMPREHENSIVE COMMITTEE REVIEW

Once the second draft revision process was completed, the committee then conducted individual cover-to-cover

reviews of the documents for flow and consistency. This comprehensive committee review ensured that all terminology was consistent throughout this edition, allowed committee members to consider all standards within the context of the whole, and to achieve final committee consensus.

PUBLISHING

The Infusion Therapy Standards of Practice is published as a supplement to the *Journal of Infusion Nursing*, the official publication of INS, now in its 47th year of publication. The *Journal of Infusion Nursing* is cited in Clarivate Web of Science Core Collection ESCI, *Cumulative Index to Nursing & Allied Health Literature* (CINAHL), EBSCO A-Z, EMBASE, HINARI, JournalGuide, MEDLINE, ProQuest, PubMed, Scopus, and TDNet.

The *Standards* is written for clinicians of many disciplines who practice infusion therapy around the world in a variety of settings with various educational backgrounds, training, certifications, and licensing. As INS continues to “Set the Standard for Infusion Care,” our focus is optimal patient-centered infusion care, consistency in practice, enhanced competency development and assessment, and evidence-based guidance for infusion therapy clinical decision-making around the globe.



Strength of the Body of Evidence

Evidence that is research-based is preferred; however, it may come from a variety of sources as needed. The strength of evidence in this document reflects the body of evidence available and retrievable at the time of review, and thus is titled *Strength of the Body of Evidence*. The strength of the body of evidence is only as robust as the highest level of a single item of evidence. Studies and other evidence comprise similar patient populations unless otherwise noted.

Evidence Rating	Evidence Description ^a
I	Meta-analysis, systematic literature review, guideline based on randomized controlled trials (RCTs), or at least 3 well-designed RCTs.
II	Two well-designed RCTs, 2 or more well-designed, multicenter clinical trials without randomization, or systematic literature review of varied prospective study designs.
III	One well-designed RCT, several well-designed clinical trials without randomization, or several studies with quasi-experimental designs focused on the same question. Includes 2 or more well-designed laboratory studies.
IV	Well-designed quasi-experimental study, case control study, cohort study, correlational study, time series study, systematic literature review of descriptive and qualitative studies, narrative literature review, or psychometric study. Includes 1 well-designed laboratory study.
V	Clinical article, clinical/professional book, consensus report, case report, guideline based on consensus, descriptive study, well-designed quality improvement project, theoretical basis, recommendations by accrediting bodies and professional organizations, or manufacturer recommendations for products or services. This also includes a standard of practice that is generally accepted but does not have a research basis (eg, patient identification).
A/P	Evidence from anatomy, physiology, and pathophysiology as understood at the time of writing.
Committee Consensus	Review of evidence, discussion, and committee agreement for a Practice Recommendation. Used when there is insufficient or low-quality evidence to draw a conclusion.
^a Sufficient sample size is needed with preference for power analysis adding to the strength of the evidence.	

Abbreviations and Acronyms

AABB	Association for the Advancement of Blood & Biotherapies	CKD	chronic kidney disease
AACA	authorized agent-controlled analgesia	CLABSI	central line-associated bloodstream infection
ABHR	alcohol-based hand rub	CMV	cytomegalovirus
ACD	automated dispensing cabinet	CNA	certified nursing assistant
ACD	allergic contact dermatitis	COE	computerized order entry
ACF	antecubital fossa	CPAP	continuous positive airway pressure
ACHC	Accreditation Commission for Health Care	C-PEC	containment primary engineering control
ACR	American College of Radiology	CPOE	computerized prescriber order entry
ADF	abuse-deterrent formulations	CQI	continuous quality improvement
ADR	adverse drug reaction	CR-BSI	catheter-related bloodstream infection
ANTT®	Aseptic Non Touch Technique	CRNI®	Certified Registered Nurse Infusion
ANVISA	Brazilian Health Regulatory Agency	CRPS	complex regional pain syndrome
AP	anteroposterior	CRS	cytokine release syndrome
APN	advanced practice nurse	CRT	catheter-related thrombosis
APRN	advanced practice registered nurse	CS	controlled substance
ARA-C	cytosine arabinoside	CSA	Controlled Substances Act
ARRT	American Registry of Radiologic Technologists	CSDP	Controlled Substance Diversion Prevention
ASA	American Society of Anesthesiology	CSTD	closed system transfer device
ASD	adhesive securement device	CT	computed tomography
ASPEN	American Society for Parenteral and Enteral Nutrition	CTA	computed tomography angiogram
ASRT	American Society of Radiologic Technologists	CVAD	central vascular access device
AVF	arteriovenous fistula	CVC	central venous catheter
AVG	arteriovenous graft	DEA	Drug Enforcement Administration
BfArM	Federal Institute for Drugs and Medical Devices	DEHP	Di[2-ethylhexyl]phthalate
BIS	bispectral index	DERS	dose error reduction system
BMCA	barcode medication administration	DMSO	dimethyl sulfoxide
BMI	body mass index	DIVA	difficult IV access
BSC	biological safety cabinet	DME	durable medical equipment
BSI	bloodstream infection	DNV	Det Norske Veritas
BUD	beyond-use date	DTP	differential time to positivity
CABSI	catheter-associated bloodstream infection	DVT	deep vein thrombosis
CA-DVT	catheter-associated deep vein thrombosis	EBP	evidence-based practice
CAJ	cavoatrial junction	ECG	electrocardiogram
CASI	catheter-associated skin injury	ECOG	Eastern Oncology Cooperative Group
CAT	catheter-associated thrombosis	ED	emergency department
CBER	Center for Biologics Evaluation and Research	EDTA	ethylenediaminetetraacetic acid
CDC	Centers for Disease Control and Prevention	EHR	electronic health record
CFU	colony forming unit	ELBW	extremely low-birthweight
CHAP	Community Health Accreditation Partner	EMR	electronic medical record
CHG	chlorhexidine gluconate	EMS	emergency medical service
		EPA	Environmental Protection Agency

ERAS	enhanced recovery after surgery	MAUDE	manufacturer and user facility device experience
FDA	US Food and Drug Administration	MBPS	Modified Behavioral Pain Scale
FLACC	Face, Legs, Activity, Cry, Consolability [scale]	MDRO	multidrug-resistant organism
FMEA	failure mode and effects analysis	MHRA	Medicines and Healthcare Products Regulatory Agency
Fr	French	MIC	minimum inhibitory concentration
FT	facilitated tucking	ML	midline catheter
GFR	glomerular filtration rate	mLs	milliliters
HBP	Health Protection Branch of the Canada Department of National Health and Welfare	mOsm	milliosmole
HCl	hydrochloric acid	MRI	magnetic resonance imaging
HCW	health care worker	MRSA	methicillin-resistant <i>Staphylococcus aureus</i>
HD	hazardous drug	MST	modified Seldinger technique
HEPA	high-efficiency particulate air [filter]	NCBS	Newborn Comfort Behavior Scale
HF	heart failure	NHSN	National Healthcare Safety Network
HFAP	Healthcare Facilities Accreditation Program	NICA	National Infusion Center Association
HFMEA	Healthcare Failure Mode and Effect Analysis	NICE	National Institute for Clinical Excellence
Hgb	hemoglobin	NICU	newborn intensive care unit
HIT	heparin-induced thrombocytopenia	NIOSH	National Institute for Occupational Safety and Health
HITT	heparin-induced thrombocytopenia and thrombosis	NIPS	Neonatal Infant Pain Scale
HLA	human leukocyte antigen	NPASS	Neonatal Pain Agitation and Sedation Scale
HPN	home parenteral nutrition	nIR	near infrared
ICD	irritant contact dermatitis	OIRD	opioid-induced respiratory depression
ICU	intensive care unit	OPAT	outpatient antimicrobial therapy
ID	infectious disease	OSA	obstructive sleep apnea
IEC	Independent Ethics Committee	OTC	over-the-counter
IFU	instruction for use	PA	physician assistant
Ig	immunoglobulin	PADSS	post-anesthesia discharge scoring system
IgE	immunoglobulin E	PAINAD	Pain in Advanced Dementia [scale]
IgG	immunoglobulin gamma	PAPR	powered air purifying respirator
ILE	lipid injectable emulsion	PBM	patient blood management
INS	Infusion Nurses Society	PCA	patient-controlled analgesia
IRB	institutional review board	PCEA	patient-controlled epidural analgesia
ISD	integrated securement device	PCT	patient care technician
ISMP	Institute for Safe Medication Practices	PEG	percutaneous endoscopic gastronomy
ITDD	implanted intrathecal drug delivery [system]	PICC	peripherally inserted central catheter
IVC	inferior vena cava	PIPP	Premature Infant Pain Profile
IO	intraosseous	PIVC	peripheral intravenous catheter
IV	intravenous	PLR	passive leg raise
IVIg	intravenous immunoglobulin	PLSVC	persistent left superior vena cava
IWS	iatrogenic withdrawal syndrome	PN	parenteral nutrition
JCI	Joint Commission International	PNCA	patient/nurse-controlled analgesia
LBW	low-birthweight	PPE	personal protective equipment
LPN	licensed practical nurse	PPN	peripheral PN
LVN	licensed vocational nurse	PSI	pounds per square inch
Long PIVC	long peripheral intravenous catheter	PTS	post-thrombotic syndrome
MA	medical assistant	PVC	polyvinyl chloride
MARSI	medical adhesive-related skin injury	PWID	persons who inject drugs
		QI	quality improvement

QOL	quality of life	tPA	tissue plasminogen activator
RA	right atrium/atrial	TNA	total nutrient admixture
RBC	red blood cell	TRALI	transfusion-related acute lung injury
RCA	root cause analysis	TSM	transparent semipermeable membrane
RCT	randomized controlled trial	UAC	umbilical arterial catheter
REMS	risk evaluation and mitigation strategies	UAP	unlicensed assistive personnel
RN	registered nurse	UE-DVT	upper extremity DVT
ROTEM	rotational thromboelastometry	ULPA	ultra-low particulate air [filter]
SASS	subcutaneous anchor securement system	USG-PIVC	ultrasound-guided peripheral intravenous catheter
SCIg	subcutaneous immunoglobulin	UVC	umbilical venous catheter
Short PIVC	short peripheral intravenous catheter	VAD	vascular access device
SIRS	systemic inflammatory response syndrome	VAST	vascular access specialist team
SVC	superior vena cava	VIP	visual infusion phlebitis
SVT	supra-ventricular tachycardia	VR	virtual reality
SVT	superficial vein thrombosis	VRE	vancomycin-resistant enterococci
TA	tissue adhesive	VTE	venous thromboembolism
TACO	transfusion-associated circulatory overload	WFWB	warm fresh whole blood
TJC	The Joint Commission	WHO	World Health Organization

Section One: Infusion Therapy Practice

1. PATIENT CARE

Standard

1.1 The *Infusion Therapy Standards of Practice* is applicable to any patient population and any setting in which vascular, intraosseous (IO), subcutaneous, and epidural/intrathecal access devices are inserted and/or managed and where infusion therapies are administered.

1.2 Infusion therapy is provided in accordance with laws, rules, and regulations established by regulatory and accrediting bodies in each jurisdiction (eg, countries, states, provinces).

1.3 Infusion therapy practice is established in organizational policies, procedures, practice guidelines, and/or standardized written protocols/orders that describe the acceptable course of action, including performance and accountability, and provides a basis for clinical decision-making.

1.4 Infusion therapy is provided with attention to quality and patient/health care provider safety. Care is individualized, collaborative, evidence-based, culturally sensitive, and appropriate to patient/caregiver age and level of cognition.

1.5 Ethical principles are used as a foundation for decision-making. The clinician acts as a patient advocate; maintains patient confidentiality, safety, and security; and respects, promotes, and preserves human autonomy, dignity, rights, diversity, equity, inclusion, and accessibility.

1.6 Clinician decisions related to infusion therapy practice, including device and/or product selection, are influenced by clinical evidence of positive patient outcomes and not by commercial and/or conflicts of interest.

2. SPECIAL PATIENT POPULATIONS

Standard

2.1 The needs and characteristics of special patient populations, including physiologic, developmental, socioeconomic, sociocultural, communication/cognitive ability, and/or safety requirements, are identified and addressed in the planning, insertion, removal, care and management, and monitoring of vascular access devices (VADs), and with administration of infusion therapy.

Practice Recommendations

A. Considerations for neonatal and pediatric patients:

1. Recognize physiologic characteristics and their effect on drug, fluids, and nutrient selection; device selection, administration set selection (eg, free of Di[2-ethylhexyl]phthalate [DEHP]); electronic infusion pump selection; dosage, rate, and volume limitations with reference to age, height, weight, or body surface area; pharmacologic actions, interactions, side effects, and adverse effects; monitoring parameters; and response to infusion therapy (see Standard 40, *Administration Set Management*).¹⁻⁴ (III)
2. Recognize the vulnerability of the preterm infant's skin and monitor for potential skin injury, absorption, and side effects of various skin antiseptics (see Standard 52, *Catheter-Associated Skin Injury*).⁵ (II)
3. Provide vascular access with attention to the child's anatomy, physiology, and developmental level.⁶⁻¹⁰ (III)
 - a. Use nonpharmacologic measures to promote comfort and reduce pain and anxiety associated with infusion therapy procedures (refer to Standard 30, *Pain Management for Venipuncture and Vascular Access Procedures*).
 - b. Identify pediatric patients with difficult intravenous access (DIVA); utilize technology (eg, ultrasound, near infrared light) and ensure skill of clinicians to improve insertion success (see Standard 5, *Competency and Competency Assessment*; Standard 21, *Vascular Visualization*; Standard 25, *Vascular Access Device Planning and Site Selection*).^{1,8,11,12} (I)
 - c. Consider novel insertion sites and techniques such as ultrasound-guided supraclavicular approach to the brachiocephalic vein or subcutaneously tunneled femoral vein cannulation in preterm infants and term infants when traditional intravenous insertion sites are compromised or not suitable for the infusion needs of the individual patient.^{6,13} (IV)
4. Consider psychosocial, sociocultural, and socioeconomic considerations that may affect the plan for infusion therapy.^{1,14,15} (IV)
5. Identify and involve family and caregivers as members of the patient's health care team, including provision of

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- patient education, with attention to age, developmental level, health literacy, culture, and language preferences (see Standard 8, *Patient Education*).^{1,2} (IV)
6. Obtain assent from school-aged or adolescent patients as appropriate (refer to Standard 9, *Informed Consent*).
- B. Considerations in pregnancy:
1. Recognize physiologic changes related to pregnancy and its effect on drug dosage, volume limitations, and potential impact on the fetus; pharmacologic actions, interactions, side effects, adverse effects; monitoring parameters; and response to infusion therapy.¹⁶ (IV, A/P)
 2. Educate the pregnant individual and/or their guardian(s) regarding the potential impact, risks, and benefits of each medication used during pregnancy.¹⁶ (V)
 3. Consider indication-only peripheral intravenous catheter (PIVC) insertion in lieu of “just in case” PIVCs in pregnant patients at low risk for adverse outcomes during labor or birth. Indication-only PIVC insertion should be reserved for hospital or facilities with resources to support emergent PIVC insertion in low-risk patients. Policies to define low-risk patients and the resources/process for emergent PIVC insertion are important for patient safety.¹⁷⁻¹⁹ (IV)
 4. Recognize potential risks of peripherally inserted central catheter (PICC) complications (eg, infection and thrombosis) during pregnancy.²⁰ (I)
 - a. Enteral feeding (eg, nasogastric or nasoduodenal) is the first-line treatment to provide nutritional support to the woman with hyperemesis gravidarum, previously unresponsive to medical therapy and unable to maintain weight.²¹ (IV)
 - i. Potential infusion therapy needs for patients with hyperemesis gravidarum include subcutaneous antiemetics, intravenous (IV) hydration solutions, and parenteral nutrition (PN).²² (IV)
- C. Considerations for the older adult patients:
1. Recognize physiologic changes associated with the aging process and its effect on immunity, device selection, drug dosage and volume limitations, pharmacologic actions, interactions, side effects, monitoring parameters, and response to infusion therapy. Anatomical changes, including loss of thickness of the dermal skin layer, thickening of the tunica intima/media, and loss of connective tissue contribute to vessel and skin fragility and present challenges in vascular access.²³⁻²⁷ (IV)
 2. Assess for changes in cognitive abilities, dexterity, and ability to communicate or learn, and psychosocial and socioeconomic changes that may affect the patient’s ability to communicate symptoms of potential complications. These factors may impact the plan for infusion therapy.²⁸⁻³¹ (IV)
 - a. Assess the older adult’s cognition, mobility, dexterity, and ability to communicate with the health care team prior to initiating home antimicrobial therapy (see Standard 66, *Home Infusion Therapy*).³² (IV)
3. Assess for ability to safely manage medication regimens and VADs in the presence of cognitive impairment and dexterity issues and for the presence of unsafe practices in the storage of medications in the home setting (see Standard 66, *Home Infusion Therapy*).³³ (V)
 4. Identify and interact with appropriate family members, caregivers, or surrogates as members of the patient’s health care team, with consent of the patient, or as necessary due to mental status.³⁴⁻³⁸ (IV)
 5. Identify potential for adverse events and significant drug interactions in older adults who may be prescribed multiple medications; work with the health care team to resolve medication issues and reduce risks.³⁹⁻⁴² (IV)
 6. Identify potential for vascular access complications and early mortality in elderly adults who require hemodialysis. Arteriovenous fistulas (AVFs) are the preferred vascular access in most hemodialysis patients. Age-related frailty and chronic disease may contribute to device-related complications and early mortality. Use a patient-centered approach, including patient preference, when considering risk/benefits associated with AVF, arteriovenous graft (AVG), and central vascular access device (CVAD) to determine the most appropriate vascular access device (see Standard 27, *Vascular Access and Hemodialysis*).⁴³⁻⁴⁷ (IV)

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3. SCOPE OF PRACTICE

Standard

3.1 Clinicians prescribing and/or administering infusion therapy and performing vascular access insertion and management are qualified and competent to perform these services based on their licensure and certification and practice within the boundaries of their identified scope of practice.

3.2 The role, responsibilities, and accountability for each type of clinician involved with infusion therapy prescription and administration and vascular access insertion and management are clearly defined in organizational policy according to the applicable regulatory agencies or boards.

3.3 Members of the health care team collaborate to achieve the universal goal of safe, effective, and appropriate infusion therapy.

3.4 Infusion therapy and vascular access activities, skills, or procedures are delegated from a licensed professional to others in accordance with rules and regulations established by the appropriate regulatory agency (eg, state board of nursing) and within the policies and procedures of the organization.

Practice Recommendations

A. Recognize that many clinical roles require licensure (eg, registered nurse [RN], advanced practice registered nurse [APRN], Advanced Practice Nurse [APN]), whereas others do not have licensure requirements (eg, unlicensed assistive personnel [UAP]), and still others have variable credential requirements based on the applicable regulatory agencies or boards (eg, radiologic technologists).

1. Know and act within the defined scope of practice for one's licensure(s) in the jurisdiction of the practice venue. The defined "scope of practice" for licensed clinicians varies by jurisdiction (eg, countries, states, provinces); practice beyond or outside the defined scope is unsafe.¹⁻⁶ (IV)

a. Clinicians who do not require licensure may have their scope of practice defined through certification programs established by the respective

professional organizations (eg, American Society of Radiologic Technologists [ASRT]).⁷ (V)

b. Educational requirements and services provided by UAP vary among countries, states, and health care organizations. UAPs usually do not have a regulated legal scope of practice, and the roles of this group vary extensively.⁸⁻¹⁰ (V)

2. Apply the 5 types of regulations that impact scope of practice, including the following¹¹: (V)

- a. Transnational agreements across countries
- b. Laws, ordinances, or statutes authorized by the appropriate legislative body for each jurisdiction
- c. Rules and regulations created by the responsible board or council in each jurisdiction
- d. Interpretation and implementation to apply the laws as specific guidelines
- e. Standards, guidelines, position statements, and/or competency frameworks written by professional organizations.

3. Accept responsibility and accountability for one's actions or inactions and those of others who are supervised by or receiving delegation from the licensed clinician.¹¹ (V)

B. Know the process for defining the scope of practice for one's profession and the appropriate framework for making scope of practice decisions.

1. Recognize that, in some jurisdictions, governments define the scope of practice through legislation, but in others, professional organizations have the authority to define scope of practice.

a. While establishing parameters and boundaries, the scope of nursing practice should be sufficiently broad and flexible and focus on a combination of knowledge, judgment, and skills of direct patient care, patient advocacy, supervision, and delegation to others, as well as leadership, management, research, and health care policy development.^{1,2,12} (IV)

b. Identify changing needs that require the scope of practice to evolve. Expansion or extension of the scope of practice should be accompanied by rigorous educational and competency requirements to ensure health care tasks are performed by qualified personnel. Examples of appropriate expansions occurring in some jurisdictions include RN insertion of a central vascular access device (CVAD), medication prescribing by an APRN, and insertion of a short peripheral intravenous catheter (PIVC) by UAP (see Standard 5, *Competency and Competency Assessment*).^{1,2,4,13-21} (V)

C. Use scope of practice decision-making frameworks when available to determine if a task is within scope of practice. For example, in the United States, decision-making frameworks commonly include the following criteria^{4,11,22}: (V)

1. Is in accordance with laws, regulations, and policies of the governing regulatory body.
 2. Aligns with evidence-based practice (EBP) and other published resources.
 3. Is supported by established policies and procedures.
 4. All educational requirements have been completed by the individual.
 5. Competency assessment and documentation have occurred.
 6. Appropriate resources are readily available in the setting.
 7. The individual is prepared to accept accountability for the outcome of the activity/intervention.
- D. Identify and understand the roles of all team members to best collaborate and optimize performance for all clinicians.^{23,24} (IV)
1. Where scopes of practice overlap, the most skilled team member should perform a skill or intervention, considering safety, efficacy, outcomes, and costs. For example, better patient outcomes are achieved when the RN is accountable for assessment, care planning, evaluation of care, and the supervisory role of the licensed practical/vocational nurses (LPN/LVN) and UAPs.^{23,25} (IV)
 2. In some jurisdictions, clinical personnel identified as providers (eg, physician, APRN) may need to be granted privileges in order to practice at a venue of care. Their scope of practice may further be limited by which privileges are granted to them.²⁶⁻²⁸ (V)
- E. Follow the *Five Rights of Delegation*, including the right task, under the right circumstances, to the right person, with the right direction and communication, and under the right supervision and evaluation. Specific guidelines for the nursing profession may be applied to other professions.²⁹ (V)
1. Delegation, as permitted by applicable regulations, may occur from a clinician (delegator) to another individual whose scope of practice is encompassed within the delegator's scope of practice. For example, APRNs can delegate to RNs, LPN/LVNs, and UAP, but an RN cannot delegate to an APRN because the APRN has a broader scope of practice than the RN.²⁹ (V)
 2. Medical assistants (MAs) are typically UAP who may have tasks delegated to them (eg, insertion of a short PIVC or administration of blood or intravenous medication). The scope of which tasks can be delegated to the MA and which clinicians (eg, physician versus nurse) can delegate tasks to the MA vary according to jurisdictional regulations.¹⁵ (V)
 3. Policies and procedures regarding which infusion and vascular access activities can and cannot be delegated should be developed in collaboration with the designated organizational leader on delegation activities.²⁹ (V)
 4. An activity requiring clinical reasoning (eg, nursing judgment, critical decision-making) cannot be delegated.²⁹ (V)
 5. Delegators should develop delegation skills based on rules and regulations articulated by the applicable regulatory agency or board.^{29,30} (V)
 6. Those accepting delegated responsibilities should only accept assignments for which they have documented competency (see Standard 5, *Competency and Competency Assessment*).²⁹ (V)
- F. Nursing Personnel
1. Registered Nurse (RN)
 - a. Perform independent nursing interventions using appropriate clinical reasoning, nursing judgment, and critical decision-making skills.^{31,32} (V)
 - b. Advocate for practice at the top of licensure and identify opportunities to remove barriers that prevent practice at the top of licensure.^{1,23,33-36} (IV)
 2. LPN/LVN
 - a. Practice for LPN/LVN varies greatly across the globe but may include a broad range of infusion/vascular access-related tasks (eg, venipuncture, management of CVADs); monitoring of intravenous (IV) flow rates, transfusions, and pain control devices; and administration of some IV medications.³⁷⁻³⁹ (V)
 3. Infusion Nurse (eg, Certified Registered Nurse Infusion [CRNI®])
 - a. Enhance professional growth and empowerment through specialization in infusion nursing, designated by earning board certification.^{31,40,41} (V)
 - b. Participate in quality improvement (QI) activities and clinical research in infusion therapy (refer to Standard 6, *Quality Improvement*; Standard 7, *Evidence-Based Practice and Research*).
 - c. Serve as the educator, leader, manager, consultant, and primary resource to guide policy and procedure development of infusion therapy and vascular access derived from best evidence.^{42,43} (V)
 4. APRN
 - a. APRN scope of practice differs across the globe, ranging from independent to restricted with and without prescriptive authority, or with requirements for collaboration with the interprofessional team.⁴⁴⁻⁴⁷ (IV)
 - b. In the United States (US), hospitals credential APRNs and grant privileges to practice according to the policies of the organization, which may differ from their legal scope of practice.^{45,48-51} (IV)
 - i. Advocate for the highest level of autonomy in practice decisions: organizational bylaws (eg, hospital admitting privileges) and payer policies (eg, billing under physician's billing number) impact APRN practice.^{45,52-54} (IV)

TABLE 1

Additional Clinical Disciplines Involved with Infusion Therapy and Vascular Access

Discipline	Roles/responsibilities for infusion therapy and vascular access
EMS personnel ³	Advanced emergency medical technicians may: • Insert and access short PIVCs and IO devices • Administer IV and IO solutions without added medication(s) • Administer certain medications by the IV route. • Perform venous blood sampling. Paramedics may: • Insert and access short PIVCs and IO devices • Administer IV and IO solutions with and without added medications • Administer IV medications • Perform venous blood sampling • Access and monitor indwelling CVADs • Manage infusions of blood and blood products.
Physician ⁶⁶	• Establishes the medical plan of care • Prescribes and may administer infusion solutions or medications • Prescribes the insertion, management, or removal of infusion devices • May insert, access, manage, or remove all types of VADs, IO devices, and epidural/intrathecal catheters • Interprets radiology studies and documents final tip location for CVADs.
Physician assistant, Physician Associate ⁶⁷	• A dependent practitioner who practices under the license of and within the scope of practice of the supervising physician • May prescribe infusion solutions and medications • May insert and access all types of VADs and IO devices • May insert, manage, access, or remove other infusion devices (eg, epidural or intra-articular anesthetic infusions) • May administer infusion solutions or medications.
Registered radiology assistant ⁶⁸	• A dependent practitioner who practices under the license of and within the scope of practice of the supervising radiologist • May insert, manage access, and remove all types of VADs • May administer infusion solutions and medications.
Medical imaging and radiologic technologist (licensed or certified) ⁶⁸	• May insert, manage access, and remove all types of VADs • May administer infusion solutions and medications.
Respiratory care practitioner ⁶⁹	• May insert, access, manage, and remove all VADs, including arterial catheters • May administer infusion solutions or medications related to respiratory function • May manage cardiopulmonary systems (eg, extracorporeal life support).
Registered pharmacist ^{70,71}	Depending on jurisdictional protocols, authorization of independent prescribing, collaborative practice agreements or institutional protocols, pharmacists may have the authority to: • Prescribe or modify medication prescriptions • Administer medications and vaccines.

Abbreviations: ACR, American College of Radiology; ARRT, American Registry of Radiologic Technologists; ASRT, American Society of Radiologic Technologists; CVAD, central vascular access device; EMS, emergency medical services; IO, intraosseous; IV, intravenous; PA, physician assistant; PICC, peripherally inserted central catheter; PIVC, peripheral intravenous catheter; VAD, vascular access device.

- c. Provide leadership and opportunities in education, conducting research, and application of EBP according to the needs of the employing organization and/or patient populations served. (eg, APRN use of point of care ultrasound technology).^{5,36,46,55-58} (IV)

G. UAP

1. UAP encompass medical assistants (MAs), certified nursing assistants (CNAs), patient care technicians (PCTs), and additional roles (eg, nurse extern) working under the supervision of a licensed health care professional.⁵⁹ (IV)
 - a. An unofficial scope of practice for certified nursing assistants (CNAs) is derived from the US law

that applies to care for residents of nursing facilities. No tasks related to vascular access device (VAD) insertion, care, or management, or to the administration of any IV solution or medications are included.^{8,60} (V)

- b. Regulations for UAP vary greatly across jurisdictions, with very few identifying any form of scope of practice.^{39,61-63} (IV)
- c. Managing equipment and supplies, gathering data, and assisting licensed clinicians with invasive procedures are infusion-related tasks that may be assigned to UAP. Although UAPs might not perform infusion therapy-related activities, the care provided must involve knowing how to

protect the VAD dressing and attached administration sets and infusion pumps while performing other patient care activities (eg, bathing, mobility).^{9,15,64} (IV)

- d. There is much variation among jurisdictions regarding what is allowed for UAP working with dialysis patients (ie, patient care technicians) who manage CVADs for hemodialysis and IV administration of medications, such as heparin and 0.9% sodium chloride.^{38,65} (V)

H. Other clinical disciplines involved with infusion therapy and vascular access

1. Refer to Table 1, which is based on local and regional (eg, state/ province) rules, regulations, and laws.
2. Unless otherwise noted, the content is about scope of practice in the US, as comparable information for other countries is not readily found or available.
3. The Infusion Nurses Society (INS) recognizes that there is great variation among countries in titles, licensure requirements, and scope of practice relative to infusion therapy and vascular access.

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4. INFUSION AND VASCULAR ACCESS SERVICES

Standard

- 4.1 Infusion and vascular access services require interprofessional collaboration and clinical experts to advance patient and organizational outcomes of care.
- 4.2 The scope of services provided by infusion and vascular access specialist teams (VAST) is structured to meet patient and organizational needs for safe delivery/administration of quality infusion therapy.
- 4.3 Infusion and vascular access services follow regulations applicable to each jurisdiction.

Practice Recommendations

A. General

1. Identify opportunities, challenges, clinical outcomes, and costs associated with delivery of infusion and vascular access services within the organization.
 - a. While some health care organizations have eliminated infusion/VASTs to conserve resources, the use of VASTs is recognized for reduction in health care-acquired complications associated with central vascular access devices (CVADs), including pneumothorax and arterial puncture, and as essential to prevention of catheter-associated bloodstream infections (CABSI) in acute care hospitals.¹⁻¹⁸ (II)
 - b. Specialty teams reduce the need to escalate from use of peripheral VADs to more invasive CVADs through clinical consultation; reduce costs associated with device-related complications, labor resources, and vascular access supplies and equipment; and improve patient satisfaction with greater first-attempt insertion success and lower rates of complications.^{2,4,9,10,19-25} (II)

B. Team Leadership and Organization

1. Provide interprofessional leadership for infusion/VAST services to advance evidence-based standards and improve patient care outcomes (eg, clinical nurse specialist, infection preventionist, quality/

patient safety roles, and physician champions). Keys to the success of interprofessional teams are clarity of purpose, communication, adoption of best practices, and optimization of efficiencies to achieve patient-centered outcomes.^{4,13,19,26-34} (IV)

- a. Identify the most appropriate subject matter expert to organize and lead the team. Leadership responsibilities include promotion of evidence-based practice, clinical governance, staff development, and quality improvement (QI) activities.^{4,11,13,18,26,27,30,32-34} (IV)
2. Choose the name for the designated team of clinicians that reflects procedural services, QI, and education services provided to advance safe patient care. Contemporary team names are used synonymously, including, but not limited to, vascular access specialist team, vascular access team, vascular access resource team, and infusion team.^{2,4,10,15,24,35,36} (IV)
3. Plan the process required for financial management of the infusion/VAST within the health care system in each jurisdiction. Establish the budgetary process, including operational costs, and sources of operational revenue (eg, placement of outpatient peripherally inserted central catheters (PICCs), productivity capture as a variance to the budget).
 - a. Establish as a revenue and cost center in acute care hospitals, allowing the team to track and analyze services provided and document financial contributions to the organization, showing revenue to offset costs.³⁷ (V)
4. Promote participation in interprofessional safety programs to reduce the incidence, risk, and costs of adverse events related to infusion/vascular access, including³⁸⁻⁴⁸: (IV)
 - a. Antimicrobial stewardship programs
 - b. Infection prevention committees in analysis of CABSI
 - c. Analysis of IV-associated medication errors
 - d. Analysis of systemic adverse drug reactions (eg, vancomycin flushing syndrome) and VAD-associated complications
 - e. Collaboration with acute pain teams to reduce lapses in analgesia
 - f. Extravasation prevention
 - g. Collaboration with multiple disciplines and departments (eg, pharmacy infusion pump safety committee) to reduce errors related to dose error reduction systems (DERS) in electronic infusion pumps (refer to Standard 23, *Flow-Control Devices*)
 - h. Coordination of product evaluation, QI, staff development, and standardized evidence-based practice (EBP), within and between health care organizations (refer to Standard 6, *Quality Improvement*; Standard 5, *Competency & Competency Assessment*).

5. Use QI methods such as failure mode and effects analysis (FMEA) and Lean Six Sigma for evaluation of patient care delivery and workflow processes toward the goals of risk reduction and improvement of infusion and vascular access services (see Standard 6, *Quality Improvement*).^{19,49-55} (IV)
 6. Encourage and support team membership with professional organizations and board certification to advance specialized knowledge of vascular access and infusion therapies (see Standard 3, *Scope of Practice*).⁵⁶ (V)
- C. Team Care Delivery Model
1. Design the infusion/VAST services to include clinicians dedicated exclusively to vascular access and infusion practice. The team provides holistic evidence-based interventions and advances quality of care outcomes in inpatient and outpatient settings. Contemporary teams should provide expertise in procedural tasks (eg, vascular access for patients with difficult intravenous access (DIVA) and perform clinical rounding to assess staff adherence to care and maintenance practices, assess central line necessity, and provide education to staff regarding infusion/vascular access best practices.^{1-9,11,15,25,57-60} (II)
 2. Identify services to meet organizational and patient needs; examples include:
 - a. Placement of peripheral intravenous catheters (PIVCs), peripherally inserted central catheters (PICCs), and other CVADs; VAD dressing changes, medication administration (eg, blood products, chemotherapeutic agents), and support services to specialty departments (eg, emergency department) on an as-needed basis. Combining small specialty groups with the hospital VAST into a centralized service may improve patient outcomes.^{11,13,22,35,61} (II)
 - b. Proactive assessment of patient needs and selection of the most appropriate VAD, using evidence-based insertion techniques, managing infusion methods and vascular access care, along with evaluation of clinical outcomes.^{28,34,62,63} (IV)
 - c. Urgent venipuncture services in emergency departments (EDs) and dedicated DIVA teams to insert PIVCs and draw blood samples in patients using near infrared light or ultrasound technology. Failure to successfully perform venipuncture causes significant delays in diagnostic and therapeutic infusions.^{21,64-69} (IV)
 3. Assess the needs of the organization to determine appropriate hours of service to meet patient needs. Comprehensive infusion/VASTs provide services on a 24-hour basis, 7 days/week, assess patient and caregiver needs, and select the most appropriate VAD using skillful insertion techniques, managing infusion methods and vascular access care, and evaluating clinical outcomes.^{2,4,13,35,61} (IV)
4. Promote the consultative role rather than viewing team members solely as task performers. This approach facilitates interprofessional communication and shared decision-making about central and peripheral VAD appropriateness and provides consultation regarding clinical practice guidelines for vascular access management and appropriate removal. Infusion/VASTs functioning as valued consultants have a better relationship with physicians and other nursing staff.^{25,28,58-60,70-72} (IV)
 - a. Consider using an electronic communication tool to facilitate shared decision-making between the patient's health care team and the infusion/VAST (eg, line necessity checklist embedded in electronic medical record [EMR]).⁵⁷ (II)
 - b. Consider expanding the scope and services to include placement of all types of CVADs, use of appropriate technologies, and insertion of arterial catheters as needed in each facility. Collaborate with members of other disciplines as needed to accomplish the required steps for this expansion (see Standard 3, *Scope of Practice*).⁷³⁻⁷⁶ (V)
- D. Alternative Care Settings
1. Recognize variations in the types of infusion therapies, organizational structure, and regulatory requirements for delivery in the home, outpatient, or skilled nursing facility.
 - a. Adhere to the minimum threshold for operational and clinical aspects of patient safety for in-office infusion as identified by the National Infusion Center Association (NICA).⁷⁷ (V)
 2. Establish methods to communicate between acute care and community care organizations. Provide details of the specific type and management of VADs and the type and methods of delivery for the infusion therapy required to enhance care by alternative care organizations. Standardizing practices across all organizations and sharing outcome data result in decreased central line-associated bloodstream infection (CLABSI).^{78,79} (IV)
 3. Establish clear methods of communication among all disciplines (eg, nurses, pharmacists, physicians, laboratory staff) involved in patient care, as services may be geographically separated.^{80,81} (V)
 4. Provide ultrasound-guided peripheral intravenous catheter (USG-PIVC) services, including USG-PIVC training to infusion clinic clinicians to improve patient satisfaction and reduce infusion delays in outpatient procedure centers.⁸²⁻⁸⁴ (V)
 5. Include the expertise of infusion/VAST to develop and manage alternate site infusion services (eg, nurse-run infusion centers, community monoclonal antibody therapy). Nurses with advanced knowledge in infusion therapy are critical to the success of alternate site infusion during global emergencies.^{85,86} (V)

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Note: All electronic references in this section were accessed between March 1, 2023, and August 10, 2023.

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5. COMPETENCY AND COMPETENCY ASSESSMENT

Standard

- 5.1 To ensure patient safety and public protection, clinicians meet licensing requirements and core competencies according to their specific profession.
- 5.2 Due to the invasive, high-risk nature of infusion therapy, the clinician with responsibility for the safe delivery of infusion therapy and vascular access device (VAD) insertion and/or management demonstrates competency with this role.
- 5.3 Initial competency is assessed and documented before the task or skill is performed without supervision.
- 5.4 Ongoing competency assessment and documentation is a continuous process driven by accreditation bodies and patient and organizational outcomes.

Practice Recommendations

- A. Provide infusion therapy education and skill development opportunities for newly graduated clinicians (eg, nurse residency programs) to promote best practice and improve confidence.¹⁻⁵ (IV)
 1. Recognize that every clinician has a unique set of prelicensure education, experience, and method for assessing individual competence. Support and feedback of coworkers should support the transition to practice.^{2,6-11} (III)
 2. Although some regulatory organizations require competence with certain procedures (eg, central vascular access device [CVAD] insertion), there are no consistent guidelines to provide training or to measure outcomes.^{5,8,9,12-16} (III)
- B. Accept individual responsibility for developing and maintaining clinical competency with infusion therapy and vascular access practices as defined by the clinician's legal scope of practice and the requirements of the specific clinical practice venue and/or patient population.^{9,13,17-20} (IV)
- C. Plan interprofessional competency assessment programs as appropriate due to the need for a high level of interprofessional collaboration with infusion and vascular access practices.^{1,4,8,9,15,16,21-24} (IV)
- D. Promote professional growth and development. Options include participation in continuing professional education, achieving and maintaining board certification, serving as faculty at seminars and conferences, conducting clinical research, publishing in a scholarly journal, and completion of an accredited academic study program in a related field.^{1,10,13,22} (IV)
- E. Collaborate with staff development personnel to identify infusion and vascular access knowledge, skills, and attitudes that require competency assessment, including technical and nontechnical skills. Use standards, guidelines, and published evidence to create the competency assessment process.^{1,3,4,6,7,9,20,25} (III)

1. Incorporate adult learning principles and practices by using appropriate teaching methods for adults as learners, their motivations and characteristics as learners, and methods to overcome obstacles to adult learning.^{1,13,26} (V)
2. Identify the services provided by the infusion/VAST (Vascular Access Specialty Team) versus those provided by other clinicians and define the competencies associated with each role. Some skills may apply to all (eg, monitoring outcome data, use of information technology, interprofessional teamwork), whereas some may be very specific for the team members based on organization resources (eg, use of ultrasound, insertion of midline catheters and CVADs, catheter clearance procedures).^{4,20,23,24,27,28} (IV)
3. Employ a systems-based approach to infusion and vascular access competencies centered on standardized policies and procedures applied across the entire organization (eg, hospital, ambulatory infusion centers, radiology, outpatient, home infusion, and emergency services).^{10,13,15,29} (IV)
4. Consider implementing assessment methods to identify the clinical skills specific to individual nursing units or a specialty. This method is reported to produce greater clinician satisfaction, improve confidence, and increase independence.^{1,3,15,30} (IV)
5. Consider implementing skills fairs for learning needs assessment and identify additional interventions for competency development. Skills fairs may be better designed for systemwide core competencies.^{10,20,31} (V)
- F. Manage competency assessment and validation in 2 phases: initial and ongoing competency.¹³ (V)
 1. Perform initial competency assessment when:
 - a. Orienting newly hired clinicians, both new graduates and clinicians re-entering the workforce.^{3,5,32} (IV)
 - b. An experienced clinician moves into a position requiring infusion/vascular access skills.^{19,33,34} (V)
 - c. Practice expansion occurs (eg, insertion of CVADs, administration of hazardous drugs).^{19,20,24} (V)
 - d. Introducing new policies, practices, and products.^{24,35} (V)
 2. Perform ongoing or continuing competency assessment and validation as directed by regulatory and accreditation requirements and organizational safety and quality indicators.^{15,18,19,32} (V)
 - a. Follow regulatory and accreditation standards to create a competency assessment plan. Periodic competency assessment is required by accreditation organizations, but the frequency of ongoing assessments is defined by the organization.^{14,32,36} (IV)
 - b. Identify interventions, actions, and skills requiring ongoing assessment by using clinical outcome data; safety and quality indicators, safety events, and sentinel events; changing patient populations served; and patient satisfaction data.^{20,30,34,36-38} (IV)
- c. Determine the root cause and appropriate methods for improvement of identified practice gaps through a learning needs assessment.^{14,36,39} (IV)
- d. Build alliances with all stakeholders (eg, staff, clinical nurse specialist, professional development specialists/educators, or management, infection preventionist) to increase their interest and participation in the needs assessment process.^{9,14,39} (IV)
- G. Employ a blended learning approach by combining a variety of methods to deliver education and training. This will improve learning outcomes, maximize use of resources, and allow flexibility.^{1,9,20,26,40,41} (I)
 1. For knowledge acquisition and critical thinking skills, choose instructor-led delivery or electronic-based delivery of content. Assigned reading, self-directed study, large and small group discussions, and lectures are additional teaching strategies for knowledge acquisition.^{1,9,19,28,37,42} (IV)
 2. For psychomotor skill acquisition, employ simulation that encompasses the procedural aspects of the selected skill to assist in the process of learning to complete a technical skill(s).^{6,30,43-48} (II)
 3. For patient assessment skills, use web-based, multimedia technology for simulation of scenarios or standardized patients.^{30,45,49} (IV)
- H. Use learner-centered, experiential methods to assess competency for psychomotor skills development in 4 consecutive phases, including knowledge acquisition, observation, simulation, and clinical performance. Choose the most appropriate teaching and evaluation strategies for each phase.^{6,26,42,43,50} (III)
- I. Use simulation method(s) most suitable to develop and refine technical and nontechnical skills using methods with the greatest degree of realism possible.⁴⁴⁻⁴⁶ (IV)
- J. VAD insertion education and competency development:
 1. Develop competency through repetitive practice until the skill can be successfully performed on patients under supervision.^{21,45,51,52} (IV)
 2. Practice noninvasive steps of a skill on human volunteers, including tourniquet application and removal, vein palpation, and vascular visualization using electronic devices such as near infrared light and ultrasound.⁵³ (III)
 - a. Do not perform invasive procedures (eg, venipuncture, catheter insertion) on live human volunteers for training purposes.^{54,55} (II)
 - i. The risk of performing invasive procedures on live human volunteers outweighs the benefits. This method may require higher levels of supervision from the instructor to protect the volunteer. The volunteer would be exposed to physical health risk for

- infection, thrombosis, and vessel/tissue damage, plus emotional stress.^{56,57} (III)
3. Use anatomical models, task trainers, or virtual reality to allow for repetitive practice in invasive procedures.^{26,44,45,54} (IV)
 - a. Simulation on anatomical models is learner-centered and associated with a greater number of learning actions taken (eg, checking available printed guidelines, repetitive skill performance) and a higher level of learner engagement.^{54,58,59} (II)
 - K. Measure competency by performance and not by a time or a predetermined number of procedures. There is no established number of procedures performed that will ensure competency for any skill.^{4,15,36} (IV)
 1. Repetition of the skill in the simulation phase demonstrates that the learner can show how the skill is performed. Repetition in clinical practice demonstrates that the learner can perform the skill from initial patient assessment through documentation.^{26,36,43,58,60} (II)
 2. Performing greater numbers of CVAD insertion procedures is associated with lower rates of complications; however, the number of procedures performed is not an adequate surrogate for competency.^{23,51,60} (V)
 3. Success rates with ultrasound-guided peripheral intravenous catheter (PIVC) and/or CVAD insertions have been shown to improve with greater number of procedures performed.^{43,51} (V)
 4. Consider establishing a mastery learning process for simulation and insertion training that allows the learner to repeat training steps if the mastery rating score is less than a level established by institutional policy.^{3,52,54,61} (IV)
 - L. Employ a variety of perspectives to assess competency, including self-assessment, peer-assisted learning, and assessment by others, such as an instructor or preceptor.^{7,11,28,37,62} (III)
 - M. Designate qualified, competent instructors and assessors to develop and implement all phases of the competency assessment process for infusion and vascular access competencies in an unbiased, objective manner.^{1,4,7,9,32,34,37,42} (IV)
 - N. Identify low-frequency and/or high-risk skills required in an organization and address ongoing competency by using realistic simulation to practice these skills on a frequent basis.^{15,47,63,64} (V)
 - O. Use a validated skills checklist with a minimum passing or performance scale, a global rating scale, or both to assess and document performance in an objective, measurable manner. The tool should reflect real clinical practice and be tested for reliability and validity in the planning process.^{6,26,30,43,47,49,54,58,60,65-67} (I)
 - P. Establish a process to revise education and competency assessment for clinicians with all levels of experience based on current evidence-based practice guidelines.

Competency assessment aligned with evidence-based practices promotes improved outcomes. Recognize that length of clinical experience and/or recurrent performance of a skill (without updated and ongoing competency assessment) may not be accurate measurements of an experienced clinician's clinical knowledge or procedural competence.^{1,4,7,10,15,43,68} (IV)

- Q. Use a consistent process to manage and monitor outcomes produced by contracted consultants (eg, VAD insertion). Performance expectations for competency for all contracted clinicians include documentation of licensure, competency, and compliance with the organization's requirements for staff qualifications, personnel practices, and clinical policies and procedures. When contractors are acquiring initial competency of a new skill, the organization's management should be knowledgeable of the status of these contractors; that these contracted clinicians are adequately supervised while obtaining competency; and that final documentation of competency is provided to the organization.^{19,38,69,70} (V)
- R. Identify and address the needs of diverse patient populations by enhancing clinician competency to meet those needs (eg, anatomical models with different skin tones). Incorporate respect for all racial, ethnic, and linguistic groups, as well as geographical, religious/spiritual, and sociological characteristics, into infusion and vascular access practices.^{20,71,72} (III)
- S. Evaluate the competency assessment program based on learner satisfaction, degree of knowledge acquisition, behavioral changes, changes in patient indicators, and the program's return on investment.^{6,17,43,71} (III)

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6. QUALITY IMPROVEMENT

Standard

6.1 Quality improvement (QI) activities are implemented to advance safety and excellence in infusion therapy and vascular access device (VAD) insertion and management.

6.2 QI programs incorporate surveillance, aggregation, analysis, and reporting of patient quality indicators and adverse events with clinicians taking action as needed to improve practice, processes, and/or systems.

Practice Recommendations

- A. Foster a just culture and individual accountability through improvement of systems and processes by clinicians and leaders.¹⁻³ (IV)
- B. Identify and prioritize organizational objectives for QI initiatives and incorporate a variety of strategies as part of a QI program.
 - 1. Engage the interprofessional team in development of a QI plan; include leadership and local champions (eg, infusion/vascular access specialist team [VAST]), infection preventionists, quality and patient safety clinicians, contracted specialists, and other staff) (see Standard 4, *Infusion and Vascular Access Services*).⁴⁻¹⁰ (II)
 - 2. Assess current gaps in practice and identify, minimize, and/or eliminate barriers to change and improvement. Consider potential barriers, including attitudes, time, and financial and physical resources.⁹ (V)
 - 3. Identify areas for improvement through evaluating safety and quality indicators, including close calls, errors, and adverse events (refer to Standard 11, *Adverse and Serious Adverse Events*).
 - 4. Use systematic methods and tools to guide activities such as Model for Improvement (Plan-Do-Check-Act), Lean Six Sigma, continuous quality improvement (CQI), root cause analysis (RCA), and Healthcare Failure Mode and Effect Analysis (HFMEA) (see Standard 11, *Adverse and Serious Adverse Events*).^{5,11-21} (I)
 - a. Use an implementation science framework to guide study design, implementation, and evaluation.²² (II)
 - 5. Clearly define the aims of the quality improvement project and the metrics for success (refer to Standard 12, *Product Management*).
 - 6. Plan for sustainability of QI at the onset; integrate changes into the organization through staff engagement, education, and leadership, as well as through organizational infrastructure (including regular audit and feedback) and culture. Consider issues such as transparency, simplicity, and actionability of the plan.^{5,19,23} (III)
 - 7. Evaluate the use of electronic health record (EHR) decision support and reporting structures to improve compliance with quality improvement activities.^{16,24,25} (IV)
 - 8. Use audit and real-time feedback when implementing changes in practice.
 - a. Include rationale for practice changes and audit activities; ensure there is a link between audit criteria and patient outcomes (eg, disinfection of needleless connector and catheter-associated bloodstream infection [CABSI]). Provide both written and verbal feedback; translate feedback into goals and action plans.^{14,26-34} (I)
 - 9. Provide education as part of a QI strategy.^{7-9,16,17,39-41} (II)
 - a. Recognize that education alone is insufficient to improve clinical outcomes and clinical practice.
 - b. Employ a blended learning approach by combining various methods to deliver education and training (see Standard 5, *Competency and Competency Assessment*).
 - c. Comprehensive process improvement, including updated policies, broad education, and product changes, contribute to improved outcomes and financial savings.
 - 10. Utilize patient education to improve professional practice by increasing clinician adherence to recommended clinical practice and improve patient outcomes (see Standard 8, *Patient Education*).⁴² (I)
 - 11. Share improvements gained through QI programs both internally and externally.^{7-10,29-33,43} (II)
- C. Evaluate adverse events from all vascular or other infusion access devices (eg, epidural) for complications (eg, CABSI, reasons for removal, unnecessary central vascular access device [CVAD] placements, occlusions, venous thrombosis, infiltrations, phlebitis).^{6,8,13,14,36,39,44-53} (I)
 - 1. Use surveillance methods and definitions that are consistent across the continuum of care and allow comparison to benchmark data, as well as reviewing for root cause (eg, CABSI).
 - 2. Collect data; analyze and evaluate outcomes against benchmarks for areas of improvement.
 - 3. Compare rates to historical internal data and external data (eg, publicly reported outcomes).
 - 4. Use a standard formula to calculate complication rates.
 - 5. Report adverse events as mandated by jurisdictional requirements to external quality initiatives or programs.
- D. Consider expanding surveillance to include hospital-onset bacteremia as a broad-quality metric.^{54,55} (IV)
- E. Monitor and evaluate medication adverse reactions and errors according to organizational practice.
 - 1. Establish a strong just culture that strengthens safety and creates an environment that raises the level

of transparency and encourages reporting of medication errors (see Standard 11, *Adverse and Serious Adverse Events*).^{2,56-59} (IV)

2. Establish a system that supports the reporting of close calls.^{60,61} (IV)
3. Identify infusion medication safety risk factors.^{62,63} (III)
4. Analyze technology analytics, such as smart pumps and barcode medication administration, for errors, overrides, and other alerts so that improvements may be made (see Standard 57, *Infusion Medication and Solution Administration*).⁶⁴⁻⁷² (IV)

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Note: All electronic references in this section were accessed between February 25, 2023, and August 11, 2023.

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7. EVIDENCE-BASED PRACTICE AND RESEARCH

Standard

- 7.1 The clinician integrates evidence-based knowledge with clinical expertise and patient preferences and values in the current context when providing safe, effective, and patient-centered infusion therapy.
- 7.2 The clinician uses the highest level of research findings and current best evidence to expand knowledge in infusion therapy, validate and improve practice, advance professional accountability, and enhance evidence-based decision-making.
- 7.3 The clinician conducts or participates in research studies that generate new knowledge about the environment and processes of, products for, or the care of patients receiving infusion therapy.
- 7.4 The clinician shares innovations, knowledge gained, and outcomes about infusion therapy with other clinicians internally and externally to improve care globally.
- 7.5 Organizational policies, procedures, and/or practice guidelines are based on current research findings and best evidence with regular review and revisions as needed and when new guidelines/findings are published.

- 7.6 The clinician obtains approval for research activities in accordance with local/national laws and organizational policy.

Practice Recommendations

- A. Promote a culture of evidence-based practice (EBP) and research that advances safe and effective infusion therapy in collaboration with patients, families, clinicians, leadership, and consultants.¹⁻¹² (I)
- B. Participate in critical evaluation, interpretation, and synthesis of the body of evidence, including research findings and current best evidence, into practice through sustainable implementation, including regular audits or clinical outcome monitoring for sustainment, and a collaborative decision-making framework. This includes, but is not limited to, policy and procedure development or revision; product technology selection; practice guideline implementation; standard of care; and evidence-based quality improvement (QI).¹³⁻³¹ (I)
- C. Provide support, education, and other opportunities to engage clinicians in, and increase their knowledge and skills of, EBP synthesis and implementation. Activities for engagement and learning may include participation in the organization's EBP education or EBP team/committee/council; a university online EBP education program; a professional organization's EBP education program and/or guideline development committee; or mentorship with the organization's librarian, clinical nurse specialist, EBP coordinator, or nurse scientist.³²⁻³⁹ (II)
- D. Participate in infusion therapy research activities that advance knowledge. This includes activities such as participating in or leading a journal club discussion, participating in or leading a research team to pilot new products, or answering clinical questions using a research framework with appropriate approval for the protection of human research subjects (eg, Institutional Review Board [IRB] or Independent Ethics Committee [IEC]).³⁷⁻⁵⁵ (III)
- E. Provide support, education, and opportunities to clinicians for increasing their knowledge and skills of presenting and publishing (internally and externally) their EBP project outcomes and research results that add to the body of evidence. Activities may include mentorship, workshops, or other programs that address abstract writing and the process of abstract submission, poster and presentation development, and manuscript writing and the process of peer review and publication.^{39,40,56-61} (IV)

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8. PATIENT EDUCATION

Standard

- 8.1 The patient/caregiver is educated in all relevant aspects of the prescribed infusion therapy and plan of care to support shared decision-making and positive outcomes.
- 8.2 Teaching strategies and learning materials are congruent with health literacy and with the knowledge and skills being taught and encompass patient/caregiver learning needs, abilities, and resources.

Practice Recommendations

- A. Develop an effective and mutually agreed upon educational plan based on identified goals to ensure the safe delivery of infusion therapy and reduce the risk of infusion therapy and vascular access-related complications.¹⁻³ (II)
 1. Establish specific, achievable, and measurable goals.⁴⁻⁹ (II)
 2. Engage the patient/caregiver in the development of and commitment to these goals.³⁻¹¹ (II)
 3. Select effective ways to validate appropriate knowledge and skill acquisition for all aspects of infusion therapy that the patient/caregiver will be performing.^{6,10-16} (II)
 4. Communicate the educational plan and the patient's progress as the patient transitions to other health care settings.^{3,5-7,9,10,17,18} (II)

- B. Select teaching methods based on an assessment of age, developmental and cognitive level, health literacy, access to educational resources and technology, preferred learning style, cultural influences, language preference, and readiness to learn. Also assess additional factors affecting readiness of the patient/caregiver to learn (eg, current stressors, sensory deficits, functional limitations, and relationship with the clinician).^{4,7,18-25} (II)
 1. Employ strategies to address issues relative to health literacy when conducting patient teaching to ensure communication is simplified, comprehension is confirmed, and misinformation is minimized.^{5,6,11,20,26-30} (I)
 - a. Recognize populations at higher risk of low health literacy or low digital literacy, including older adults or those who are culturally or linguistically diverse. Use teaching strategies (eg, simplified communication, encourage questions, and provide resources) that acknowledge the varied comprehension of health-related information and ongoing learning needs.^{6,11,19,24,27,30,31} (IV)
 - b. Improve effectiveness of patient education through utilization of resources to evaluate and address variations in health literacy, cultural needs, accessibility/usability, and the impact of the clinician/patient relationship.^{3-5,10,12,19-21,27,31-39} (II)
 - c. Use educational resources that are understandable and actionable. These elements include consideration of health literacy levels (written, verbal, and numeracy), cultural congruence, primary language, and instructional methods. Avoid medical jargon and use plain language.^{11,19,20,23,27,28,40-42} (IV)
 - d. Use active learning strategies to prompt the learner to connect previous and new knowledge. Examples include pausing to ask for reflection or quick recall on what was just taught and the inclusion of case scenarios.^{3,4,11,15,28,29} (IV)
 - e. Consider sensory modalities of learning: visual, auditory, reading (or writing), and kinesthetic. Whenever possible, and if patient states a preference, adapt teaching to the patient's preferred learning style to improve uptake of education.^{5,11,19,32,37,42-45} (II)
 2. Evaluate the impact of home infusion therapy upon caregivers who are required to learn or participate in infusion administration and vascular access care; caregivers as well as patients may experience anxiety, depression, and social restrictions when participating in more complex home infusion therapy such as parenteral nutrition (PN), analgesic infusions, and chemotherapy (see Standard 66, *Home Infusion Therapy*).^{26,42} (I)
 3. Ensure that websites that are used/available for patient/caregiver education are reputable, usable, and accessible to the learner and incorporate national accessibility standards (eg, meets regional accessibility and usability guidelines, if applicable), such as effective use of text and page layout, clear navigation, user experience optimization, and accessibility statement.^{5,20,27,46-50} (II)
 4. Use well-designed printed information and technology (eg, electronic tablets and educational videos) to enable self-paced and repetitive learning in the patient's home environment and to enhance retention of self-care practices.^{5,15,20,26,27,43,46,51-54} (I)
 5. Consider providing a bundled approach to patient teaching at home, using printed and audio/visual materials.^{4,27,28,44,55} (IV)
- C. Advise the patient/caregiver about the benefits and challenges associated with the use of social media (ie, YouTube, Twitter, Facebook, blogs) to seek health advice or information and to seek social support. Limited research has shown benefits of patient engagement; however, there are challenges that include safety, privacy, and risk of misinformation.^{26,46,48} (I)
- D. Evaluate patient/caregiver learning outcomes with methods that directly measure knowledge (eg, demonstration/return demonstration for psychomotor skills), verbal feedback for cognitive knowledge (eg, teach-back), and reports of feelings and beliefs (eg, affective domain).^{4,6,15-17,32,46,51,56-59} (I)
- E. Educate all patients/caregivers about all aspects of infusion therapy as applicable to their clinical needs.^{2,5,6,13,17,20,44,46,51,57,60-69} (I)
 1. The right for information should include the risks and benefits of therapy, the risks and benefits of foregoing therapy, and consideration for alternative treatment options, if available.
 2. Vascular access device (VAD) options, expected duration of therapy, and proper care of the VAD.
 3. Precautions for preventing infection and other complications and adherence to the principles of Aseptic Non Touch Technique (ANTT®).
 4. Self-monitoring for signs and symptoms of VAD or infusion-related complications, adverse reactions, and side effects, including those that may occur after the infusion device is removed or after the patient leaves the health care setting (eg, signs of postinfusion phlebitis, fever) and how/where to report them.
 5. For outpatients and those receiving home infusion therapy, include additional education and evaluation as appropriate (see Standard 66, *Home Infusion Therapy*).
 - a. Regular evaluation of patient/caregiver comprehension and performance of infusion therapy at established intervals.
 - b. Safe storage, maintenance, and disposal of solutions, supplies, and equipment.
 - c. Hazardous medication handling, storage, and management of hazardous spill, if applicable (See Standard 15, *Hazardous Drugs and Waste*; See Standard 66, *Home Infusion Therapy*).

- d. Infusion administration procedures required for safe administration specific to VAD, infusion device, and infusate.
- e. Lifestyle adjustments required due to presence of the VAD and infusion-related devices, including activity limitations, and protecting the device during activities of daily living.
- f. Symptoms of adverse events related to the VAD or infusate that should be reported and contact information to access emergency assistance, if required.

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9. INFORMED CONSENT

Standard

9.1 Informed consent is obtained for all infusion/vascular access-related procedures and treatments in accordance with jurisdictional laws, rules and regulations, and organizational policy.

9.2 The clinician performing any invasive procedure (eg, central vascular access device [CVAD] insertion) facilitates the process and ensures informed consent is obtained.

9.3 The patient or surrogate has the right to accept or refuse treatment.

9.4 Informed consent is required for human subject participation in research in accordance with jurisdictional laws, rules and regulations, and organizational policy.

Practice Recommendations

- A. Recognize that obtaining informed consent is a collaborative educational process involving the patient/surrogate in shared decision-making.¹⁻⁵ (IV)
1. The process begins with dialogue between the patient/surrogate and the provider or qualified clinician performing the procedure; however, other clinicians have a significant role in the complete process.
 2. The process concludes with the patient/surrogate signing a consent document or providing verbal consent according to organizational policy (eg, via phone conversation).
 3. Develop an organizational process for identifying surrogate decision-makers.
 4. Continued confirmation of informed consent may be necessary for ongoing treatments (eg, blood administration, hemodialysis, or antineoplastic administration).
- B. Follow requirements for obtaining informed consent from the patient/surrogate, as regulations vary across jurisdictions. Differences include documentation, the professional performing the consent process, procedures/treatments requiring informed consent, and variations in the legal approach to evaluation of informed consent.⁶ (V)
1. Adhere to organizational policy for managing exceptions to usual informed consent requirements (eg, emergency/life-threatening situations, patient incapacitation without surrogate decision-maker).^{7,8} (I)
2. Define circumstances (eg, emergent and time-sensitive situations) when exemption from obtaining informed consent is allowed. Document details of information provided, method of discussion (eg, telephone), to whom it was given, and the patient or surrogate response in the patient's health record.^{1,6} (V)
- C. Ensure that the process for informed consent includes the following precepts:
1. Consent is voluntarily given and is free from coercion, persuasion, or undue influence.^{9,10} (V)
 2. The patient/surrogate has received the necessary information to understand the procedure/treatment, its purpose, common risks, potential benefits, alternative procedures/treatments, common complications, and potentially serious or irreversible risks.^{1,4,11} (V)
 - a. When possible, include information related to vascular access device (VAD) insertion regarding site location or number of allowable cannulation attempts to ensure the patient/surrogate's consent spans most common potentialities and scope of the proposed procedure.¹² (IV)
 3. The patient/surrogate can comprehend the information, appreciates the situation and its consequences, and is able to make choices.¹³⁻¹⁷ (II)
 4. Formal interpreter services are used to ensure understanding when a language difference exists.⁴ (V)
 5. The decision is authorized by the patient/surrogate and documented on the signed form, as appropriate.¹⁸ (V)
- D. Facilitate the informed consent process by choosing learning methods most appropriate for the patient's age, relational abilities, and level of health literacy (refer to Standard 8, *Patient Education*).
1. Use multimedia tools (eg, videos, digital programs, 3-D virtual reality) to support patient understanding and comprehension during the informed consent process.^{2,13,19-27} (I)
 2. Employ interactive communication methods that facilitate shared decision-making and improve understanding and retention of information.²⁸⁻³⁰ (IV)
- E. Document the informed consent process by serving as a witness to the patient/surrogate signature on an informed consent document, if written consent is required.^{4,31} (V)
- F. For research-informed consent, provide a clear, concise, and accurate explanation of the research purpose(s). Allow the participant an opportunity to ask questions and have time to consider participation. In addition to the standard components of informed consent, the research-informed consent should include items listed below.^{3,32-36} (I)
1. The anticipated length of participation in the research.
 2. Identification of procedures that are experimental.

3. Management processes for confidential patient information and their identity.
4. Compensation for participation, if any.
5. Risks and benefits of participation.
6. Availability of medical treatments if injury occurs.
- G. Obtain informed consent for photographs and/or videotaping of patients according to your institutional policy.^{37,38} (V)
- H. Recognize cultural differences that may affect the process of informed consent. The foundation of informed consent is self-determination, which may not fit with cultures where medical treatment choices are a family decision rather than an individual decision.^{4,39-43} (V)
- I. Assess patients with age-, trauma-, or disease-related alterations in cognitive capacity for their ability to consent. Use tools to evaluate decisional capacity or ask probing questions to evaluate language comprehension, memory, and ability to reason. When the patient does not have the necessary cognitive capacity, obtain informed consent from a surrogate.^{5,7,8,16-18,44,45} (I)
- J. Verify that informed consent for neonatal, pediatric, and adolescent patients is obtained for the procedure/treatment from the parent or legal guardian. From the patient, verify assent (ie, agreement) to the procedure/treatment using language and learning methods appropriate for the age and/or cognitive stage of the individual. While there is a lack of consensus over the age of assent, it is generally considered 7 years old or school age (see Standard 2, *Special Patient Populations*).^{1,19,46-50} (V)

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10. DOCUMENTATION IN THE HEALTH RECORD

Standard

- 10.1 Clinicians record their initial and ongoing assessments or collection of data, diagnosis or problem, intervention and monitoring, the patient’s response to that intervention, and plan of care for infusion therapy and vascular access in a patient-specific physical (ie, paper) or electronic/digital document.
- 10.2 Documentation contains accurate, complete, chronological, and objective information in the patient’s health record regarding the patient’s infusion therapy and vascular access with the clinician’s name, licensure or credential to practice, date, and time.
- 10.3 Documentation is legible, timely, accessible to authorized personnel, efficiently retrievable, and promotes communication with the health care team.
- 10.4 Documentation reflects the continuity, quality, and safety of care for all patient interactions.
- 10.5 Documentation guidelines and the policies for confidentiality and privacy of the patient’s health care information and personal data are established in organizational policies, procedures, and/or practice guidelines according to the scope of practice for individuals with specific licensure or credentials, standards of care, accrediting bodies, and local/national laws.

Practice Recommendations

- A. Document the patient, caregiver, or surrogate’s consent or assent to vascular access device (VAD) insertion, as

appropriate, and their participation in or understanding of VAD-related procedures including, but not limited to, the following (see Standard 8, *Patient Education*; Standard 9, *Informed Consent*)¹⁻⁵: (I)

1. Patient responses to VAD insertion and removal procedures
 2. Patient responses to VAD access and/or infusion therapy, including symptoms, side effects, or adverse events
 3. Patient, caregiver, or surrogate education and understanding of VAD- and infusion therapy-related education or barriers to that education.
- B. Incorporate standardized elements for VAD/infusion-related documentation into the electronic medical record (EMR).⁶⁻¹³ (I)
- C. Document the following upon VAD insertion^{11,12,14-17}: (IV)
1. Indication for use
 2. Date and time of insertion
 3. Number of attempts
 4. Insertion technique (eg, visualization technology, landmark technique)
 5. Type of VAD/number of lumens/length and gauge/French size
 6. Insertion site identification using anatomical descriptors (laterality, landmarks, or appropriately marked drawings)
 7. Lot number, if included with product
 8. Pain management intervention(s)
 9. VAD tip location
 10. VAD patency/function
 11. Dressing type and VAD securement method
 12. For peripherally inserted central catheters (PICCs) and midline peripheral catheters (ML):
 - a. Circumference of the extremity at time of insertion and when clinically indicated to assess the presence of edema and possible catheter-associated thrombosis. Note presence of pitting or nonpitting edema (refer to *Standard 50, Catheter-Associated Thrombosis*).
 - b. Catheter-to-vein ratio with placement (refer to *Standard 50, Catheter-Associated Thrombosis*) (see *Standard 21, Vascular Visualization*; *Standard 30, Pain Management for Venipuncture and Vascular Access Procedures*; *Standard 32, Vascular Access Device Insertion*).
- D. Document ongoing assessment of dressing and securement integrity, external catheter length (noting any discrepancy between the length documented at insertion), dressing change, site care, patient report of discomfort/pain, and any changes related to the VAD or access site.^{5,17} (IV)
- E. Document VAD-related complications using a standardized assessment for signs and symptoms, including but not limited to: phlebitis, infiltration, and extravasation appropriate for the specific patient (eg, age or cognitive ability), with photography as appropriate and in accordance with organizational policy (see *Standard 9, Informed Consent*; *Standard 43, Phlebitis*; *Standard 44, Infiltration and Extravasation*).^{3,5,15-19} (IV)
- F. Document type of therapy, including flushing or locking, drug, dose, rate, time, route, and method of administration, including vital signs and laboratory test results as appropriate; condition of the venipuncture or VAD site prior to and after infusion therapy.^{2,11} (V)
1. Avoid the practice of documenting administration of multiple intravenous (IV) medications as a single time occurrence. Failure to document actual administration times for medications administered sequentially may result in inaccurate dosing of medications requiring therapeutic drug monitoring.²⁰ (V)
 2. Clearly indicate which solutions and medications are being infused through each device or lumen when multiple VADs or catheter lumens are used. (Committee Consensus)
 3. Consider the potential benefit of integrated documentation from smart pumps data to improve accuracy of documentation on infusions (see *Standard 57, Infusion Medication and Solution Administration*).²¹⁻²³ (IV)
 4. Use barcode medication administration, if available, to scan infusion medications/solutions prior to administration to capture documentation of the right dose and formulation administered to the patient at the right time (see *Standard 57, Infusion Medication and Solution Administration*).²⁴ (V)
- G. Document type of equipment used for infusion therapy administration; depending on the venue of care, accountability for maintenance and replacement of administration sets/add-on devices, as well as identification of caregiver or surrogate for patient support and their ability to provide this care.²⁵ (V)
- H. Assess and document the ongoing need for the VAD (see *Standard 39, Vascular Access Device Post-Insertion Care*)^{5,13,14,26,27}: (I)
1. Daily for acute inpatient settings
 2. During regular assessment visits in other settings, such as in the home, outpatient facility, or skilled nursing facility.
- I. Document upon removal: condition of site; length of VAD compared to length documented at insertion; reason for device removal, interventions during removal, dressing applied, date/time of removal; any necessary continuing management for complications; and, if cultures are obtained, source of culture(s) (see *Standard 42, Vascular Access Device Removal*).^{5,11,16} (IV)
- J. Document required elements of care using standardized templates or tools (eg, for VAD insertion and infusion therapy), without limiting further description, as needed.^{3,18,28} (V)
- K. Complete all documentation in an electronic health record (EHR) or other electronic health information system, if available, using standardized terminology.^{1,29-32} (I)

1. Electronic entries should reflect current patient status, even when an entry is pulled from another location in the health record.^{3,33} (V)
 - a. Consider EHR compatible technology (eg, mobile applications, portable devices, or speech recognition) to enhance real-time documentation of assessment data to improve timeliness of documentation, improve communication between the care team, and decrease potential for transcription errors.³⁴⁻³⁶ (II)
 - b. Configure the EHR to capture data for quality improvement (QI) of patient vascular access without additional documentation from clinicians.^{3,37-43} (II)
- L. Conduct routine audits of documentation to identify patient safety risks associated with missed care and related outcomes.⁴⁴⁻⁴⁸ (IV)
- M. Consider integration of EHR technologies to capture posttreatment patient-reported symptoms and guide appropriate interventions. Autogenerated text messages or surveys set to trigger provider follow-up may enhance patient outcomes of care.⁴⁹ (V)

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Section Two: Patient and Clinician Safety

11. ADVERSE AND SERIOUS ADVERSE EVENTS

Standard

11.1 Adverse events, serious adverse events (eg, sentinel events), or close calls (near misses) associated with infusion therapy and/or vascular access devices (VADs) are documented and reported within the patient's health record, health care organization reporting system, and to the appropriate regulatory body when required.

11.2 The science of safety, which includes human errors and system failures, along with reporting of adverse events and serious adverse events, is defined in organizational policies, procedures, and/or practice guidelines.

Practice Recommendations

- A. Use standardized tools to identify, document, and track adverse events in accordance with organization policy. Use documents and tools providing objective and specific facts about the adverse event.¹⁻⁷ (II)
- B. Educate the patient and caregivers about signs and symptoms of complications, reactions, or any untoward event that could be an adverse event and how to contact the appropriate clinician (eg, home care nurse, ambulatory clinic staff) for timely management (see Standard 8, *Patient Education*).⁸⁻¹¹ (I)
- C. Report adverse events or serious adverse events or the risk thereof (ie, close calls) associated with VADs and/or infusion products/devices and the administration of drugs, biologics, and/or infusates to the appropriate individuals and organizations in the time frame defined by organizational and regulatory requirements^{1-3,12-16}. (V)
 1. Provider and other essential health care team members.
 2. Organization's designated management personnel.
 3. Organizational department(s) (eg, risk management, quality improvement [QI]).
 4. Advisory organization (eg, Institute for Safe Medication Practices [ISMP]).
 5. Regulatory organization (eg, US Food and Drug Administration [FDA]/Manufacturer and User

Facility Device Experience [MAUDE] database, Health Protection Branch of the Canada Department of National Health and Welfare [HPB], Federal Institute for Drugs and Medical Devices [BfArM], Medicines and Healthcare Products Regulatory Agency [MHRA], Swissmedic, and Brazilian Health Regulatory Agency [Anvisa]).

6. Accreditation organization (eg, The Joint Commission [TJC], Joint Commission International [JCI], Healthcare Facilities Accreditation Program [HFAP], Det Norske Veritas [DNV], Community Health Accreditation Partner [CHAP], and Accreditation Commission for Health Care [ACHC]) in accordance with institutional policy and accreditation standards.
7. Drug and/or device manufacturer (when possible, retain defective device and return to manufacturer as part of the product incident report).^{4,13-16} (V)
- D. Investigate serious adverse events to ensure prompt action and improve safety. The process includes a systematic investigation and analysis to improve quality and safety. Organizations must have a process to determine which serious events require root cause analysis (RCA).^{1-3,13,17-22} (IV)
 1. Describe and analyze the event and contributing factors to discern the cause(s) of the event.¹⁹⁻²² (V)
 2. Implement specific strategies and/or actions for improvements that protect patients. An interprofessional approach to patient safety is comprehensive and focuses on systems issues, procedures, human resources, peer and/or clinical review, products/equipment, processes, and training gaps. Domains of patient safety likely to be associated with improved outcomes include 8 identified domains: transformational leadership (leadership style to encourage positive change), patient engagement, human resources management quality, innovation technology, skill competency, education in patient safety, teamwork, and effective communication.^{1,19,22-24} (IV)
 3. Participate in the development, implementation, and evaluation of the improvement plan.^{1,13} (V)
 4. Use a systematic investigation or analysis for complex and/or recurrent problems and for near misses.^{18,20-22} (IV)

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5. Consider aggregate analysis of serious events to identify organization-specific trends impacting multiple events.^{19,21,25} (IV)
- E. Improve safety within the organization through a prevention-focused approach:
 1. Develop a culture of safety, shared learning, and high reliability.^{7,26-32} (IV)
 2. Focus on correction of the system(s) and processes rather than blaming the clinician.^{27-29,33} (V)
 3. Examine at-risk behaviors and coach individuals to make safe behavioral choices according to the precepts of a just culture.^{27,29} (V)
 4. Advocate for teamwork interventions, including training and education (eg, focus on communication and leadership), work redesign (eg, change interactions such as interprofessional rounds or local team “huddles”), use of structured tools and protocols (eg, handoff communication tools and checklists), and management support.^{31,32,34,35} (IV)
 5. Standardize and simplify the reporting processes throughout the organization, as practicable.³⁶ (IV)
 6. Use a systematic method to guide safety initiatives, such as Healthcare Failure Mode and Effect Analysis (HFMEA) (see Standard 6, *Quality Improvement*).³⁷⁻⁴² (IV)
 7. Monitor recommendations from investigations for implementation and effectiveness.^{6,22,25,43-45} (II)
 8. Remind clinicians to include patient safety in rounds to identify and report adverse events.⁴⁶ (IV)
- F. Establish a culture that promotes safety transparency, shared learning, encourages reporting, and empowers the clinician to identify and implement appropriate actions to prevent adverse events and close calls (see Standard 6, *Quality Improvement*).^{6,27-29,33,35,47,48} (II)
- G. Promote organizational learning and communicate necessary practice changes to staff at all levels.^{19,24,49-51} (IV)
- H. Ensure responsible disclosure of errors to the patient/caregiver or surrogate; promote interprofessional collaboration in planning and discussing information with the team responsible for disclosing information about the adverse event.^{13,21,52} (IV)
- I. Include the patient/caregiver or surrogate in adverse event review when appropriate.^{7,11,12,25,53-55} (II)
- J. Identify levels of clinical knowledge and skills necessary to reduce adverse events. Fewer adverse events are documented when there is adequate staffing.^{13,24,56-58} (IV)
- K. Support health care clinicians who may be considered second victims as a result of involvement in an adverse patient event or injury or unintentional health care error.^{21,59-63} (IV)

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12. PRODUCT MANAGEMENT

Standard

12.1 Clinician end users are involved in the evaluation of vascular access device (VAD) and infusion products, equipment, and technologies, including clinical application, performance, infection/complication prevention, safety, efficacy, ease of use, acceptability, reliability, and cost.

12.2 Clinician end users attain and maintain knowledge about developments and technologies relating to VADs, infusion products, and equipment to meet evidence-based recommendations.

12.3 Infusion and vascular access equipment and supplies are inspected for product integrity and function before, during, and after use; products are visually inspected for damage before use to ensure that the packaging is clean, dry, and intact and the product expiration date is verified.

12.4 Expired/defective products are removed from patient use and labeled as such; the defect is reported to the appropriate department within the organization, to the manufacturer, and/or to authoritative reporting organizations as required.

12.5 Clinical experts participate with product substitution decisions as required during supply chain disruptions and ensure that there is a plan for communication, education, and outcome monitoring.

Practice Recommendations

- A. Select VADs and infusion-related products/equipment for evaluation based upon factors including, but not limited to, organizational quality indicators, internally and externally reported incident/occurrence/adverse event reports, availability of new/safer products, current/new evidence, and emerging technology.

1. Include an interprofessional group of direct and indirect clinician end users (eg, nurses, infection preventionists, physicians, biomedical engineers, information technologists, pharmacists, and patient representatives) in the product evaluation process.¹ (V)
2. Select devices appropriate to the setting in which they will be used as part of the value analysis process. Assess factors including the following^{2,3}: (II)
 - a. Is the device designed for the unique environment (eg, the home)?
 - b. For reusable equipment, can it be cleaned/disinfected properly between each use?
 - c. Does it provide feedback to assist the patient/caregiver in identifying and troubleshooting problems?
 - d. Will the product/technology improve communication between the home care patient and the health care team?
3. Establish clear goals of what is to be measured and evaluated during the process of product evaluation (eg, enhance continuity of care, reduce a complication, improve clinician compliance, save time, and standardize use) and define in advance the minimum parameters that must be met for evaluation to be considered successful.¹ (V)
4. Consider the risk/benefit (eg, patient risk for injury) in the selection of products against indications for use.^{4,5} (II)
 - a. Understand the intended organizational use of the product (eg, reduction of infection, occlusion, or thrombosis) compared to the manufacturer's directions for use and indications for the product.
 - b. Develop data collection tools for analysis and ongoing monitoring.
 - c. Provide education and training for use of the product/equipment selected for evaluation; consider support/involvement by the manufacturer in product education.
- B. Report problems associated with the use of any product; remove the product from use and follow organizational policies and procedures for reporting.
 1. Monitor for product recalls and hazard alerts.⁶ (V)
 2. Use a structured and objective approach when investigating problems associated with medical devices, which may include issues such as device malfunction, user error, and surrounding infrastructure. Identify the need for additional clinician education versus review of compliance and accountability.⁷ (V)
 3. Develop an organizational environment conducive to reporting.
 - a. Recognize that clinicians may switch to different devices or develop work-around strategies to continue to use problematic products and may be uncertain regarding what to report and be fearful of incident reporting.⁸ (IV)

- b. Explore systems to facilitate the ease of reporting, including electronic error reporting. Contribute to medical device surveillance programs to increase patient safety and promote manufacturer accountability.^{4,9} (II)
4. Report adverse events or serious adverse events (eg, sentinel events), or the risk thereof (ie, close calls) associated with VADs and/or infusion products/equipment to the appropriate department(s) within the organization (eg, risk management, quality improvement [QI]) and authoritative reporting organizations as required (refer to Standard 11, *Adverse and Serious Adverse Events*).

13.3 Members of the health care team with access to CSs are trained and are competent in role-specific processes related to CS handling and use.

13.4 Each CS administration is accompanied by a valid order from an authorized prescriber.

Practice Recommendations

- A. Implement a program for prevention of diversion to optimize patient safety during procurement, dispensing, handling, and/or administration of CSs (eg, Controlled Substance Diversion Prevention [CSDP]).¹⁻⁴ (IV)
 1. Empower health care workers and leadership to implement strategies to create a safe, healthy work environment.^{3,5} (IV)
 2. Establish expectations within the organization for professional behaviors and norms that discourage abuse of CSs.^{4,6-9} (V)
 3. Establish policies and procedures that accurately reflect local and regional regulatory requirements in all aspects of CS management, including consistent monitoring of CS procurement, storage, dispensing, handling, administration, and waste processes, and a clear communication structure.^{1-4,6-16} (IV)
 4. Collaborate with key stakeholders (eg, pharmacy, providers, nursing, local law enforcement officials, vendors, health care leaders, infection prevention, contracted services, risk management, human resources, bio-med) to ensure that the CSDP is comprehensive and effective.^{1,4,6} (V)
 - a. Use a secure chain of custody of CSs throughout the medication pathway.^{1,4,10,11,13} (IV)
 - i. Consider use of a locked device when transporting CS from pharmacy to unit-based storage unit.^{12,13} (V)
 - b. Establish consistent surveillance processes:
 - i. Collaborate with an interprofessional team in selection and effective utilization of technology for CS (eg, medication-related automated systems, automated dispensing cabinets), including initial and ongoing staff training and competency, regular validation of proper user access, regular review of override list, ongoing system maintenance, and downtime procedures.^{1,3,4,6,10-13,17-23} (IV)
 - a) Consider establishing interoperability between medication storage unit and the electronic health record to improve system support.
 5. Develop an interprofessional process to conduct a thorough investigation of each suspected or confirmed diversion event to determine potential for system improvements.^{1,4,7,10,15,16,24,25} (IV)
 - a. Consider use of Failure Modes and Effects Analysis (FMEA) to identify vulnerabilities through the entire medication pathway.^{3,12,20} (IV)

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13. DRUG DIVERSION IN INFUSION THERAPY

Standard

13.1 Organizations that procure, dispense, handle, and/or administer controlled substances (CSs) establish policies, procedures, and processes that ensure proper management of CSs throughout the medication pathway.

13.2 An organizational culture of safety is fostered to promote prompt reporting and confidential, nonpunitive investigation of suspected diversion of CSs.

6. Ensure that infusion devices operate according to manufacturer specifications.¹⁵ (V)
- B. Diversion Prevention
1. Establish an opioid stewardship program to optimize dosing, provide multimodal pain relief, and provide patient/caregiver education on diversion prevention.^{7,26-30} (III)
 - a. Develop processes to prevent diversion in home care and hospice programs, including proper CS waste procedures and screening of patient/caregivers for history of addiction or risk of misuse where CS is in use.^{29,31} (IV)
 - b. Recognize the risk of immediate release opioids that may be converted to non-oral routes.
 - i. Investigate abuse-deterrent formulation (ADF) preparations of oral opioids.^{32,33} (V)
 2. Implement pre-employment background checks for health care workers (HCWs) with access to CS.^{4,11,29,34,35} (IV)
 3. Review orders for CS carefully for accuracy and appropriateness for the individual patient.⁴ (V)
 4. Use electronic prescribing of CS and minimize use of paper prescriptions. When paper prescriptions are required, secure prescription pads to ensure that only authorized individuals have access.^{4,7,8,10} (V)
 5. Limit access to CS through restricted access to storage (eg, key, biometrics, badge access).⁴ (V)
 - a. Identify high-risk and high-volume areas where diversion may occur to facilitate increased surveillance and control of the medication pathway.^{4,8,36} (V)
 - i. Consider camera surveillance for high-risk areas.^{4,6,10,14,20,37} (V)
 6. Ensure chain of custody of CS is always maintained throughout the medication management process.^{1,4,8,29,36} (IV)
 - a. Store a CS that is removed from main medication storage in a secured, locked receptacle, accessible only to authorized staff.
 - b. Ensure a process to maintain chain of custody of keys when used to access and administer CS (eg, locked box, refrigerated storage, infusion pumps).
 - c. Ensure that authorized staff do not delegate their access to CS in a way that alters chain of custody.
 - d. Ensure security of CS that a patient brings into a facility or arrives with a patient transferred from another facility.
 7. Conduct CS diversion education (including unlicensed and contracted personnel) at initial orientation and regularly. Information should include, but is not limited to, the following^{2-5,7,8,10-12,16,21,24,25,29,34,35,37-50}: (IV)
 - a. Responsibility to protect public safety.
 - b. Risk factors for substance use disorder, addiction, and diversion (eg, work-related injuries, workplace trauma, burnout, work role strain, personal/family history of addiction, childhood adverse events, illicit drug use).
 - c. Signs, symptoms, and patterns of behavior that may indicate diversion.
 - d. Medications at high risk for diversion (eg, opioids, sedatives).
 - e. Preventative measures in place in the organization (eg, auditing, reporting structure).
 - f. Proper documentation processes for all CS transactions.
 - g. Processes used to conduct a diversion investigation.
 - h. Potential for civil and/or criminal penalties if diversion is confirmed.
 - i. Potential for disciplinary actions for failure to report.
 8. Integrate curriculum within health care education programs (eg, provider, pharmacy, nursing) regarding prevention and recognition of CS diversion.^{41,42,46,51} (IV)
 9. Ensure compliance with approved CS administration processes, including, but not limited to:
 - a. Consider stocking CSs in a “ready-to-administer” form in the lowest available units typically prescribed to patients to limit volume required to be wasted.^{4,10,21,52} (IV)
 - b. Prepare CSs as close to administration time as possible.
 - i. Identify optimal time allowed from CS removal to administration.^{1,4,10} (V)
 - c. Limit dose preparation to single dose when possible.
 - i. If sequential dosing is delivered from a single syringe, ensure a method exists to accurately track and document delivery.^{4,11,21} (IV)
 - d. Maintain chain of custody when there is a delay between preparation and administration.^{4,10,15} (V)
 - i. Label syringe containing CS per organization policy, if not immediately used, and maintain control of the medication at all times.
 - ii. Administer continuous infusions or patient-controlled CS through a secure device that does not allow access/tampering (see Standard 60, *Patient- Controlled Analgesia*).
 10. Ensure proper adherence to CS waste processes for unused CSs.^{1,4,7,10,11,20,21,40,53-55} (IV)
 - a. Ensure that waste occurs at medication removal or promptly after administration (within an established time frame).
 - b. Use an independent witness to physically watch and validate the accuracy of volume/dose of the medication to be wasted.
 - c. Secure and track all waste receptacles.
 - d. Dispose of CS in a manner that renders it irretrievable and unusable.

- i. Consider utilization of a waste product that converts the CS to a nonretrievable state and is allowable for landfill waste.
 - e. Establish processes for CS tracking, with prompt resolution of CSs that are expired, unusable, returned, or subject to loss of chain of custody.^{4,8-13,29,36} (IV)
- C. Diversion Recognition
1. Establish a culture that communicates each employee's obligation to recognize and promptly, anonymously report behaviors that may be associated with diversion.^{8,10,16,25,34,38,46,50} (IV)
 2. Implement drug testing as appropriate to detect potential diversion and impaired practice according to local jurisdiction and governing boards.^{4,7,11,16,25,29,40} (IV)
 - a. Consider implementation of waste-testing technology to detect saline replacement of CS as a diversion tactic.² (V)
 3. Promptly investigate and resolve controlled substance discrepancies.^{4,6-8,10,56} (IV)
 4. Conduct routine audits of aspects of the medication pathway to detect potential for diversion, including reports listed below.^{1,4,8,10,20,21,35,40,57-59} (IV)
 - a. Review prescribing practices for patterns that may indicate potential diversion.
 - b. Identify system-generated reports and processes to investigate patterns and trends of medication retrieval as allowed by technology (eg, blind narcotic count, override list review, CS removal per staff).
 - i. False-positive reports may occur in system-generated reports and should be investigated carefully. One retrospective study indicated that medication administration timing discrepancies may be more accurate than reports based on standard deviation.⁵⁹ (IV)
 - c. Review documentation for accuracy and unusual patterns.
 - d. Review patient response to documented medication delivery and to pain management trends to identify potential deviations in actual medication delivery compared to documented administration.
 - e. Consider monitoring the pathway of high-risk medications (eg, propofol) that have an increased risk of diversion but do not have a controlled substance designation.
 5. Implement a process to rapidly remove an HCW suspected of being impaired from patient care delivery, preventing access to CS while investigation is conducted.^{4,38} (V)
 6. Report confirmed diversion and unaccounted loss of CS to the proper entities in accordance with licensing, local laws, and regulations.^{1,4,7,16,34,35,50} (IV)
 7. Establish systems and processes to rapidly identify and manage infectious outbreaks that may be due to CS diversion.^{1,4,35,60,61} (IV)
- D. Diversion Recovery Program
1. Establish a process to support the confidentiality and recovery of an HCW substance abuse disorder.^{4,16,34,43,46,47} (IV)
 - a. Alternative-to-discipline programs that implement evidence-based strategies have been associated with increased success.^{40,42,43,51,62} (IV)
 2. Establish a culture that regards substance use/addiction as a chronic illness, with clear goals of retention, rehabilitation, and reentry into practice.^{5,7,16,34,38,41-43,47,63} (IV)
 3. Establish a process to monitor the practice of health care workers returning to the workforce after recovery to assure that patient safety is protected.^{25,38,42,43,51} (IV)

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14. LATEX SENSITIVITY OR ALLERGY

Standard

- 14.1 Exposure to latex in the environment is minimized.
- 14.2 Personal protective equipment (PPE), patient care equipment, and other supplies where natural rubber latex is not a part of the material formulation are provided to latex-sensitive or latex-allergic clinicians and patients and are used during patient care.

Practice Recommendations

- A. Identify health care providers with latex allergy/sensitivity. Exposure to latex gloves is the most common cause of latex allergy/sensitivity.¹⁻⁸ (IV)
- B. Identify patients at increased risk for or with known latex allergy/sensitivity.^{1-3,6,7,9-11} (IV)
 1. Children with birth defects, neurologic and genitourinary disorders/populations with diseases requiring multiple surgical procedures and indwelling urinary catheters, history of atopy.
 2. Patients with myelomeningocele; an important risk factor for these patients is having more than 5 surgical procedures.
 3. Patients with allergy to tropical fruits and some vegetables (eg, avocado, banana, chestnut, kiwi, tomato) have a high cross-reactivity to latex, as such fruits and vegetables contain proteins with allergenic similarities to latex. Fifty percent of patients with latex allergies will have reactions to one or more fruits and vegetables that contain similar proteins.
- C. Document and communicate the positive screen for latex sensitivity or allergy in the patient's health record so all health care providers involved in the patient's care can incorporate precautions into the patient's plan of care.^{12,13} (V)
- D. Distinguish between the signs and symptoms associated with latex sensitivity versus latex allergy; educate clinicians in recognition and treatment.^{6,14-16} (IV)
 1. Latex sensitivity/allergic contact dermatitis: type IV immunologic reaction/delayed T cell-mediated reaction to chemicals used in latex manufacturing; begins with an acute eczema-like skin rash, vesicles, and pruritus, erythema, or hives. With continued exposure to latex, sensitivity can become latex allergy.
 2. Latex allergy: type I immunoglobulin E (IgE)-mediated hypersensitivity reactions occur within minutes of exposure to latex. Reactions range from mild (eg, urticaria, rhino conjunctivitis) to severe (eg, bronchospasm, hypotension, anaphylaxis).
 3. Sublingual immunotherapy has been shown to be effective in decreasing severity of reactions in sensitized individuals.
- E. Recognize potential exposure routes to latex, including direct skin contact, airborne exposure (largely reduced with powder-free gloves), and food/medicine contamination (eg, medical devices, vials).^{3,5,7,12,17-19} (V)
- F. Use nonpowdered, nonlatex gloves; a change to non-powdered latex and synthetic gloves has resulted in dramatic reduction in sensitization.^{2,6,20} (IV)
 1. The U.S. Food and Drug Administration (FDA) has banned the use of powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove.
- G. Minimize exposure to latex for those at risk or with known latex allergy/sensitivity, as frequent exposure to

latex remains the primary cause of sensitization.^{2,5,6,18,21} (IV)

1. Review the label on medical devices, equipment, and supplies prior to use for the presence of latex, which is a component of product labeling required by the FDA.
 2. Remove latex-containing products from the patient care setting to reduce exposure to latex.
 3. Recognize that latex products are ubiquitous and that prevention of contact with latex is challenging; examples of items within homes include balloons, condoms, adhesives, gloves, baby bottle nipples/pacifiers, and toys. Refer to available lists of products that contain latex.
 4. Access medication vials with latex stoppers only once; most multidose vials no longer contain latex; the Centers for Disease Control and Prevention (CDC) provides a list of vaccines indicating presence or absence of latex in the packaging (eg, syringe/vial).
 5. Provide patient education about how to avoid latex exposure.
- H. Consider involving an allergist in formation of interprofessional procurement committees within health care organizations.^{1,2} (V)
- I. Instruct patients/clinicians with latex allergy in recognizing signs/symptoms of anaphylaxis; to wear a medical alert bracelet/necklace; to inform all health care providers and caregivers (eg, teachers, babysitters) about latex allergies; to carry two (2) epinephrine auto-injectors (20% of patients will require a second dose), and to ensure patient/caregivers receive education on proper use.^{1,2} (V)

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15. HAZARDOUS DRUGS AND WASTE

Standard

15.1 Safe handling of hazardous drugs (HDs), appropriate use of personal protective equipment (PPE), exposure risk reduction, and safe handling of waste, including spills, is addressed in accordance with jurisdictional laws, rules, and regulations, as well as organizational policies, procedures, and/or practice guidelines.

15.2 Safe handling practices are used at all times, including, but not limited to, during transportation, preparation, administration, and disposal of all hazardous drugs.

15.3 All hazardous waste is discarded in appropriate containers and disposed of according to jurisdictional regulations.

Practice Recommendations

- A. Follow guidelines for handling hazardous drugs to protect clinicians and nonclinicians from unintentional exposure. Compliance may be voluntary or mandatory based upon the jurisdiction.^{1,2} (II)
- B. Prepare and distribute a list of HDs used in the organization. Review and update the HD list annually and as needed, including before use of a drug begins.³⁻⁶ (V)
 1. Compile the HD list in accordance with the current National Institute for Occupational Safety and Health (NIOSH) list of HDs. Additionally, consult other trustworthy sources to identify HDs that are excluded from the NIOSH list, such as radiopharmaceuticals, veterinary drugs, or biologic products approved through the US Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER). Until enough safety data is available to determine whether a new drug is hazardous or not, first-in-class drugs with a mechanism of action suggestive of harm from incidental exposure should be treated as hazardous.^{4,5,7-10} (II)
 2. Categorize HDs according to hazardous potential to delineate appropriate handling precautions. Consider utilizing the following NIOSH risk categories¹⁰: (V)
 - a. Group 1: known to be or probably carcinogenic to humans (may or may not pose other toxicity risks).
 - b. Group 2: meets NIOSH criteria for HD but is not categorized as known to be or probably carcinogenic to humans.
- C. Ensure HDs are physically labeled at all times with the drug identity and the appropriate hazard warning; where possible, also distinguish HDs electronically (eg, in the electronic health record, electronic medication administration record, infusion pump library).^{3,4,7,11} (II)
- D. Identify risk points for HD exposure and implement a comprehensive HD exposure control program. For many HDs, there is no established safe threshold of exposure. Exposure can occur in any venue of care at any point in the HD chain of custody, including, but not limited to, receipt of drug shipments, storage, compounding, preparation, transportation, administration, waste handling, contaminated bodily fluid contact, cleaning, spill response, and through environmental contamination.^{5,7,12} (II)
 1. Recognize that HDs are not limited to oncology settings, as many nonantineoplastic drugs are hazardous and certain antineoplastic drugs are administered for nononcology disease states. Personnel in all settings who handle hazardous drugs and waste should be provided appropriate PPE and engineering controls to reduce exposure (see Standard 58, *Antineoplastic Therapy*).^{4,7} (II)
- E. Use multiple levels of controls to decrease HD exposure risk. From most effective to least effective, the hierarchy of controls includes^{5,13}: (V)
 1. Elimination: removing the hazard (eg, avoiding unnecessary doses by selecting an appropriate duration of therapy)
 2. Substitution: replacing the hazard with a nonhazard or a lesser hazard (eg, switching from intravenous [IV] administration to oral administration)
 3. Engineering: isolating from the hazard (eg, compounding in a biological safety cabinet [BSC])
 4. Administrative: changing the way people interact with HDs (eg, through organizational policies and procedures)
 5. Personal protective equipment (PPE): wearing a physical barrier to prevent transmission.
- F. Wear PPE both to protect the user from the anticipated route(s) of exposure and to protect others from environmental exposure due to transmission of HDs. Remove PPE upon leaving the HD handling area.
 1. Include instructions for appropriate PPE donning and doffing in organizational policies and procedures, including goggles, face shields, head covers, fit-tested respirators, gloves, and gowns.^{3,11,13,14} (IV)
 2. Assess and document competency in donning and doffing for all employees who may experience environmental exposure and monitor compliance.^{3,13} (V)
 3. Improve compliance with appropriate use of PPE by identifying and removing barriers to compliance.^{3,7,11} (II)
- G. Allow clinicians who are actively trying to conceive, are pregnant, or are breastfeeding to refrain from exposure to HDs and waste. Guidelines from some countries suggest that avoidance of handling chemotherapy drugs is needed only for those trying to conceive and during the first trimester of pregnancy.^{11,13,15} (II)
- H. Participate in environmental wipe sampling at least every 6 months to identify surface residue of HDs in the areas where compounding/preparation and administration are conducted.^{3,7,11,15-19} (II)
 1. Identify, document, and contain the cause of contamination. This could include a thorough deactivation and decontamination, along with adjustments in engineering controls or administrative controls to prevent recontamination.
- I. Participate in a program of medical surveillance if handling of HDs is a regular part of the job assignment.^{3,5,7,11,20} (II)
 1. Monitor individuals who have experienced an acute exposure (eg, spill).
- J. Document that training and assessment of competency for clinicians who handle HDs is completed prior to handling HDs.^{3,7,11} (II)

1. Include the list of HDs and their associated risk, review of all policies and procedures, appropriate use of PPE and other equipment or devices, management of known or suspected exposure, spill management, and proper disposal.
 2. Reassess and document competency at least every 12 months (United States).
- K. Sterile HD compounding (see Standard 56, *Compounding and Preparation of Parenteral Solutions and Medications*):
1. Where possible, use closed-system drug transfer devices (CSTDs) to further reduce the risk of HD exposure.^{3,5,7,13,15,19,20} (II)
- L. Administration of HDs:
1. Use protective devices such as needleless connectors and CSTDs for administration of all HDs when dosage form allows.^{3,7,11,13,21} (II)
 - a. Select CSTDs with containment reduction demonstrated by independent, peer-reviewed studies.
 2. Utilize the protection of the containment primary engineering control (C-PEC) to perform preadministration activities, such as spiking the bag and priming the administration set.^{3,6,11,15,21} (V)
 - a. Spiking the bag and priming the administration set with a compatible fluid prior to addition of HD to the IV bag further reduces exposure risk since leaking that could occur when the administration set is first connected to the vascular access device (VAD) would be fluid that does not contain the HD.
 3. Dispose of the HD container with the administration set still attached; do not disconnect them. This requires a new administration set to be used for each HD dose (see Standard 40, *Administration Set Management*).^{6,11,15,21} (V)
 4. If spiking and priming must be done outside the C-PEC, attach the unprimed set to the primary (non-HD) solution and back-prime to move the air into the secondary (HD) container. This method should only be used with CSTDs that have proven capability to produce a dry connection.^{3,6,11} (V)
 5. To prevent spills, perform a visual inspection of solution container, administration set, and VAD connections before starting the infusion.²² (IV)
- M. Protect staff, visitors, and patients from HD exposure by preparing for and appropriately responding to spills.
1. Ensure that a spill kit containing all the materials needed is available wherever HDs are prepared, transported, and administered. The spill kit should include a sign to restrict access to the contaminated area.^{3,11,23} (IV)
 2. Establish appropriate spill response through written procedures, including the appropriate agents, dilutions (if any), documentation and reporting requirements, involved personnel, and use of a spill kit according to the affected surface (eg, hard surface, carpet, C-PEC).^{3,6,11} (V)
 - a. Include appropriate steps of spill response: immediately contain, deactivate, and decontaminate the surface, followed by cleaning the spill.
 - b. Spills that exceed the capabilities of the spill kit should be handled by health care workers who are trained in hazardous waste handling, and a cartridge respirator or powered air purifying respirator (PAPR) must be used.
- N. Immediately apply appropriate measures for exposure to hazardous drugs.^{6,11} (V)
1. Immediately following skin exposure, remove contaminated clothing and wash skin with soap and water.
 2. For eye exposure, flush the eye with saline or water for at least 15 minutes and obtain emergency treatment.
 3. For inhalation, move away from the area and obtain emergency treatment if symptoms are severe.
 4. Let the wound of a skin puncture injury (eg, needlestick) bleed freely. Thoroughly cleanse the wound under running water using soap.
 5. Report employee exposure to the organization's occupational health and safety department. Follow organizational policy for reporting patient or visitor exposure.
- O. Dispose of and segregate hazardous waste in accordance with jurisdictional regulations; segregation of types and source of waste, while necessary for safe disposal, may not be performed in some jurisdictions.^{6,24} (V)
1. Place contaminated materials, including empty vials/syringes/containers, administration sets, gloves, and gowns, into sealable, leak-proof bags.^{3,6,24,25} (V)
 - a. Place needles, open ampoules, and other sharps in a puncture-proof hazardous waste container.
 2. Clearly label containers designated for hazardous waste. Use color-coded waste containers to segregate waste. Do not place hazardous waste in medical waste containers because medical waste and hazardous waste are processed and disposed of differently (see Standard 16, *Medical Waste and Sharps Safety*).^{6,24} (V)
 - a. Specify disposal process for unused HD in written procedures to comply with jurisdictional regulations. Bulk HD disposal regulations may differ from trace contaminated waste.
- P. Employ safety precautions when handling patient body fluids and during patient care activities where contact with body fluids (eg, sweat, saliva, emesis, urine, feces, blood) is anticipated or likely for at least 48 hours after receipt of an HD and until the known excretion time is exceeded, as some HDs may be present in body fluids for longer than 48 hours. Consult with pharmacy for

questions regarding metabolism and excretion time for the drug in question.^{6,13,26} (V)

1. If possible, use disposable linens and leakproof pads to contain contaminated body fluids.
2. Place washable linens in a leakproof bag and handle as contaminated.
3. Educate the patient and/or caregiver on safe handling of body fluids.
4. Identify patients with HD-contaminated body fluids through posted signs/warnings or labels.

Q. In the home setting:

1. Provide spill kits whenever HD is administered in the home setting. Cleansing may be performed with dishwashing or laundry detergent using disposable cloths or paper towels followed by cleansing with water using disposable towels.^{3,6,13} (V)
2. Store contaminated clothing or linens in a plastic bag until ready to wash them. Place contaminated linens and clothing in a washable pillowcase and machine wash twice, separate from other items, with regular detergent.^{6,13} (V)
3. Discard disposable diapers in plastic bags and discard used gloves in hazardous waste containers, if available. Place this container in an area away from pregnant individuals, children, and pets.^{13,24} (V)

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16. MEDICAL WASTE AND SHARPS SAFETY

Standard

16.1 Safe handling and disposal of regulated medical waste are based on laws, rules, and regulations established

in each jurisdiction (eg, countries, states, provinces) and defined in organizational policies, procedures, and/or practice guidelines.

16.2 Risk reduction for exposure to potentially infectious materials and for needlestick injuries is included in an organization's quality improvement (QI) program.

16.3 Contaminated sharps are discarded in a closable, nonpermeable, puncture-resistant, tamperproof, biohazard container that is easily accessible and located in the immediate area where sharps are used.

16.4 Safety-engineered devices that isolate or remove the bloodborne pathogens hazard are available in the workplace and used in accordance with manufacturer's directions for use.

Practice Recommendations

- A. Reduce the risk of needlestick injury associated with parenteral medication preparation and administration, vascular access device (VAD) insertion, and blood sampling procedures.
 - 1. Use safety-engineered devices to prevent needlestick injury.¹⁻⁸ (I)
 - 2. Use passive safety-engineered devices whenever possible.^{3,4,7,9,10} (I)
 - 3. Do not recap, break, or bend sharps; discard directly into sharps container.¹¹⁻¹⁴ (I)
 - a. Activate built-in safety controls during use, and discard as a single unit after use.
 - 4. Dispose of sharps in a sharps container large enough to accommodate the disposal of the entire blood collection assembly (ie, holder and needle).^{8,11-13,15} (I)
 - a. Consider additional or enhanced security measures where a higher risk of tampering is possible (eg, pediatric or mental health units, correctional facilities) (see Standard 13, *Drug Diversion in Infusion Therapy*).¹⁵ (V)
- B. Educate clinicians and patients/caregivers in safe practices relative to handling sharps, medical waste disposal, and use of safety-engineered devices; the risk of needlestick injury is reduced when education is combined with the implementation of sharps safety products.
 - 1. Address the importance of reporting needlestick injuries and exposure to bloodborne pathogens; needlestick injuries are prevalent and underreported in several countries.^{2,7,16-21} (I)
 - 2. Involve clinician end users in evaluation of safety-engineered devices (see Standard 12, *Product Management*).^{3,11,12,14} (I)
 - 3. Educate health care workers in proper use and activation of safety-engineered devices in accordance with manufacturer's directions for use.^{3,5,6,22} (IV)
- C. Identify, report, and document exposure to potentially infectious materials or injury from sharps; follow organizational protocol for postexposure follow-up.^{1,8,9,11-14,23-27} (I)

- 1. Monitor and analyze data for trends and implement appropriate QI activities (see Standard 6, *Quality Improvement*).
- D. Consider the use of a checklist as a guideline for handling medical waste.²⁸ (V)
- E. Consider the impact of medical waste on the environment.²⁹⁻³¹ (IV)
- F. Reduce potentially unnecessary sterile packaging; consider Standard-ANTT instead of Surgical-ANTT using the ANTT Risk Assessment framework (see Appendix A, *Aseptic Non Touch Technique Clinical Practice Framework*).³²⁻³⁵ (V)
- G. Instruct patients/caregivers who receive home infusion therapy in proper disposal of medical waste (unused nonhazardous drugs/solutions and infusion-related supplies) in accordance with organizational procedures. (Committee Consensus)
- H. Sort and segregate medical waste. Handle regulated medical waste in accordance with federal, state, and local guidelines and regulations.^{30,31,36,37} (IV)
 - 1. Medical waste segregation and appropriate recycling, together with improved education and waste handling training, may improve medical waste disposal through improved medical waste handlers' knowledge and practice (see Standard 8, *Patient Education*).^{30,31,36} (I)

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Section Three: Infection Prevention and Control

17. HAND HYGIENE

Standard

17.1 Hand hygiene is performed routinely during patient care activities.

Practice Recommendations

- A. Mitigate the transfer of microorganisms by performing hand hygiene, as follows¹⁻⁴: (I)
 1. Before having direct contact with the patient (eg, entering a patient room, before donning gloves)
 2. After having direct contact with the patient (eg, removing wound dressings, after removing gloves)
 3. After body fluid exposure (eg, body excretions, including mucous membranes)
 4. After touching the patient's surroundings (eg, medical devices, equipment, or furniture)
 5. Before, during, as required, and after clinical procedures requiring Aseptic Non Touch Technique (ANTT®) (refer to Standard 19, *Aseptic Non Touch Technique [ANTT®]*), including the following:
 - a. Insertion and removal of indwelling invasive medical devices, including vascular access devices (VADs)
 - b. Ongoing management and manipulation of indwelling medical devices
 - c. Infusion administration
 - d. Immediately following the removal of gloves
 6. Before/after eating and after using a restroom
 7. Before moving from work on a soiled body site to a clean body site on the same patient.
- B. Use an alcohol-based hand rub (ABHR) containing at least 60% ethanol or 70% isopropyl alcohol routinely for hand hygiene, unless the hands are visibly soiled or if the patient is suspected of having/or there is an outbreak of a spore-forming pathogen or norovirus gastroenteritis.^{1,3-7} (I)
 1. Unless hands are visibly soiled, an ABHR is preferred over soap and water in most clinical situations due to evidence of better compliance compared to soap and water. Hand rubs are generally less irritating to hands and are effective in the absence of a sink.^{1,8} (V)
 2. Perform hand hygiene using an ABHR for 15 seconds or according to manufacturer's recommendations.^{3,7} (II)
 3. After handling hazardous drugs, avoid the use of ABHR until after hands have been washed with soap and water to avoid cutaneous absorption of hazardous drugs (refer to Standard 15, *Hazardous Drugs and Waste*).
 4. Consider ethanol-based preparations at a high concentration between 70% and 95% in environments with high viral load.⁵ (IV)
- C. Use either a nonantimicrobial or antimicrobial soap and water for hand hygiene and wash hands for at least 15 seconds.^{1,4,7,9-11} (I)
 1. When the hands are visibly contaminated with blood and/or other body fluids.
 2. After providing care or having contact with patients suspected or confirmed of being infected with norovirus/rotavirus gastroenteritis or a spore-forming pathogen during an outbreak (eg, *Clostridioides difficile*).
- D. Use chlorhexidine gluconate with caution for routine hand hygiene.¹⁰ (II)
- E. Ensure that supplies necessary for adherence to hand hygiene are readily accessible in all areas where patient care is being delivered.^{1,4,8} (IV)
- F. Include fingernail care in organization-specific policies related to hand hygiene.^{3,12-14} (II)
 1. Keep nails clean and nail length short.
 2. Health care workers who provide direct or indirect care in high-risk areas (eg, intensive care unit [ICU], perioperative) should not wear artificial fingernails or extenders; artificial or false nails have been associated with higher levels of infectious agents, especially Gram-negative bacilli and yeast, compared to natural nails.
 3. Nails should not extend past the fingertip.
 4. Prohibitions against fingernail polish (standard or gel shellac) are at the discretion of the infection prevention program, except among scrubbed individuals who interact with Critical Aseptic Fields during surgical procedures; these individuals should not wear fingernail polish or gel shellac.
- G. Remove wrist jewelry for Surgical-ANTT procedures and finger jewelry as per facility-specific policies.^{4,14} (I)

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- H. Educate the patient, caregivers, and family members on when and how to perform hand hygiene and promote asking the clinician to perform hand hygiene before having direct contact with the patient if it was not observed.¹⁵⁻¹⁸ (III)
 1. Consider using a systematic, structured, multistep technique that can be readily taught and replicated.^{1,2,4,7} (I)
- I. Implement organizational strategies to improve hand hygiene compliance and subsequently reduce infection and colonization rates.^{7,17,19-21} (I)
 1. Use a systematic, multimodal approach to deliver and evaluate strategies.^{7,17,19,22} (I)
 2. Use activities that demonstrate improved hand hygiene compliance, such as visualization of bacterial contamination, leader engagement, testing, knowledge, and performance feedback, including sharing progress during regular staff meetings.²³⁻²⁸ (I)
- J. Monitor hand hygiene and provide education and feedback regarding hand hygiene performance.^{24,28-33} (I)
 1. Consider the use of electronic monitoring to improve the objectivity of hand hygiene compliance and associated feedback.^{34,35} (IV)
- K. Involve the clinician with the evaluation of hand hygiene products to assess for product feel, fragrance, and skin irritation. Provide alternatives for clinicians who have sensitivity to a particular product. Other products for skin care, such as gloves, lotions, and moisturizers, should be assessed for compatibility with hand antisepsis products.^{3,6} (IV)

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18. STANDARD PRECAUTIONS

Standard

18.1 Standard precautions are used during all patient care procedures and in all clinical settings that potentially

expose the clinician to blood and body fluids, secretions, excretions (except sweat), nonintact skin, and mucous membranes.

18.2 Personal protective equipment (PPE) is selected and worn based on the nature of the patient interaction and potential for exposure to blood, body fluids, or infectious agents, and based upon transmission-based precautions in effect at the time of the patient encounter for specific communicable diseases and for patients who may be immunocompromised.

18.3 Surfaces that are in close proximity to the patient and frequently touched surfaces in the patient care environment are cleaned and disinfected more frequently than other surfaces using health care grade disinfectant.

18.4 Spills of blood or other potentially infectious materials are promptly cleaned and decontaminated according to facility policy.

18.5 Durable medical equipment (DME) is cleaned and disinfected after each use with appropriate germicides in accordance with manufacturer's directions for use and organizational institutional policies and procedures.

Practice Recommendations

- A. Perform hand hygiene, as it is a major component of Standard Precautions.
 1. Ensure access to hand hygiene facilities and appropriate supplies (alcohol-based hand rub and/or water, soap, and paper towels).
 2. Perform hand hygiene immediately if the hands become contaminated during PPE removal, immediately after removing all PPE, and before leaving the patient's environment (refer to Standard 17, *Hand Hygiene*).
- B. Ensure that sufficient and appropriate PPE is available and readily accessible at the point of care; when wearing any type of PPE, remove at the end of the task before leaving the patient care space.¹⁻⁶ (II)
- C. Wear gloves that fit appropriately and extend to cover the wrist of an isolation gown (if worn) when there is potential contact with blood (eg, during phlebotomy, venipuncture), body fluids, mucous membranes, nonintact skin, or contaminated equipment.¹⁻¹⁰ (II)
 1. Change gloves during patient care when torn, when heavily contaminated, or if moving from a contaminated body site to a clean body site within the same patient.
 - a. Gloves should not be considered as a substitute for hand hygiene. Understand the potential inverse relationship between glove usage and hand hygiene.
 - b. Be aware of the risk of touch contamination when gloves are used.
 2. Gloves are single use; do not reuse or use for more than one patient.
- D. Wear a single-use or disposable gown or apron according to manufacturer's directions for use to protect skin

and clothing during procedures or activities in which contact with blood or body fluids is anticipated. Local and institutional requirements vary and will define the required attire.¹⁻⁶ (II)

1. Do not wear the same gown/apron when caring for more than one patient.
 2. Ensure gown removal is performed in a manner to prevent contamination of the clothing.
- E. Wear eye and face protection, which may include goggles with a face mask, or face shield, to prevent the potential splash or spray of blood, respiratory secretions, or other body fluids to the mouth, nose, and eyes.¹⁻⁶ (II)
1. Ensure reusable eye protection is appropriately decontaminated between uses and if visibly soiled.
- F. Universal PPE may be indicated during times of high transmission of communicable disease; recommendations may vary based upon pathogen and degree of communicability but may include universal respiratory protection (mask or respirator) and universal eye protection.¹¹ (II)
- G. Educate the clinician, patient, family, and caregivers to implement respiratory hygiene/cough etiquette by covering the mouth/nose with a tissue when coughing, promptly disposing of used tissues, and performing hand hygiene.^{1,3,4} (II)
1. Place face mask on the coughing person if tolerated. Source control does not replace the need for caregivers to wear PPE when indicated.
 2. Educate the clinician to stay home when ill.
- H. Clean and disinfect DME (eg, intravenous [IV] poles, flow-control devices, vascular visualization devices) using an appropriate disinfectant (eg, Environmental Protection Agency [EPA]–registered disinfectant) after each use.^{12,13} (II)
1. Develop organizational procedures based upon manufacturers' instructions for cleaning and disinfection.
 2. Maintain separation between clean and soiled equipment to prevent cross-contamination.
- I. Employ practices to reduce the risk for transmission of microorganisms from patient to patient when providing care in all settings.^{14,15} (IV)
1. Clean the inside and the outside of the clinical bag carried between homes or other patient care settings at an interval defined by organization policy.
 2. Perform hand hygiene before opening the clinical bag to retrieve needed supplies and equipment, after removing supplies and before direct patient contact, after contact with the patient's intact skin (eg, taking blood pressure), and after contact with inanimate objects in the patient's vicinity.
- J. Use a multimodal approach to Standard Precautions education and training for all disciplines.¹⁶⁻²⁰ (I)

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19. ASEPTIC NON TOUCH TECHNIQUE (ANTT®)

KEY DEFINITIONS

Aseptic Technique: A set of infection prevention actions aimed at protecting patients from infection during invasive clinical procedures and management of indwelling medical devices; notably, it is a generic term that is variously defined, interpreted, and used interchangeably with other practice terms, such as clean, sterile, and non-touch technique.

Aseptic Non Touch Technique (ANTT®): A specific and comprehensively defined type of aseptic technique with a unique theory-practice framework based on an original concept of Key-Part and Key-Site Protection; achieved by integrating Standard Precautions such as hand hygiene and personal protective equipment with appropriate aseptic field management, non-touch technique, and sterilized supplies. It is designed for all invasive clinical procedures and management of invasive medical devices. In the context of infusion therapy, this includes vascular access device (VAD) insertion and management and infusion administration. ANTT can be successfully implemented as a standalone initiative or as an integral part of a clinical care bundle.

The Standardized Practice Terminology of ANTT®:

- **Key-Site:** Any portal of entry into the patient (eg, VAD site, injection site, open wound) that could transfer harmful microorganisms and cause infection.
- **Key-Part:** The component of equipment within the procedure that, if contaminated, is likely to contaminate the patient (eg, syringe tip, male Luer end, spike of administration set, injection needle).
- **General Aseptic Field:** A decontaminated and disinfected surface (eg, procedure tray, cart, or single-use procedure kit/barrier) used to promote, but not ensure, asepsis. Key-Parts placed onto this surface must be protected by Micro Critical Aseptic Fields (see below) when not in use.
- **Critical Aseptic Field:** A sterile drape/barrier. Used to ensure asepsis; all procedure equipment is placed upon the drape and managed collectively.
- **Micro Critical Aseptic Field:** A small protective sterile surface/housing (eg, sterile caps, covers, the inside of recently opened sterile equipment packaging) that protect Key-Parts individually.

Standard-ANTT: A combination of Standard Precautions and an approach of protecting Key-Parts and Key-Sites individually, using non-touch technique and Micro Critical Aseptic Fields within a General Aseptic Field. Used for clinical procedures where achieving asepsis and protecting Key-Parts and Key-Sites is straightforward and short in duration, such as VAD flushing and locking, administration set preparation and change, intravenous medication administration, and simple wound care. If Key-Parts or Key-Sites require direct touch, sterile gloves must be used.

Surgical-ANTT: A combination of Standard Precautions and an approach of protecting Key-Sites and Key-Parts collectively using a sterile drape(s) and barrier precautions. Used for clinically invasive procedures where achieving asepsis and protecting Key-Parts and Key-Sites is difficult and/or procedures are long in duration, such as surgery and central vascular access device insertion.

Standard

19.1 Aseptic Non Touch Technique (ANTT®) is applied to all infusion-related procedures, including vascular and other infusion access device insertion and management, and administration of infusion medications and solutions, as a critical aspect of infection prevention.

19.2 Clinicians and patients/caregivers who administer infusions and manage vascular access and other infusion devices are educated in ANTT.

Practice Recommendations

- A. Standardize the use of aseptic technique with the international standard approach of ANTT for all invasive clinical procedures.¹⁻³ (V)
- B. Document the clinical competency of ANTT as a core competency for all clinicians. This encompasses all aspects of infusion therapy, including but not limited to, preparation and administration of infusion solutions and medications and insertion and management of vascular access devices

(VADs) and other infusion devices (see Standard 5, *Competency and Competency Assessment*).^{1,2,4-8} (IV)

1. Clinicians are ultimately responsible for ensuring the safe and consistent application of the components of ANTT for all clinical interventions requiring an aseptic technique (refer to Standard 5, *Competency and Competency Assessment*).
 2. Incorporate standardized ANTT practice within the organization, including ANTT education, initial/ongoing competency assessment, and monitoring of practice standards through audit.^{1,3,6,7,9} (IV)
 3. Use multimodal standardized resources for clinician education and training as outlined in the ANTT Clinical Practice Framework.^{7,10,11} (IV)
- C. Employ ANTT through Key-Part and Key-Site Protection, routine integration of Standard Precautions, and appropriate use of aseptic fields and non-touch technique. Hand hygiene is a fundamental component of ANTT (see Standard 17, *Hand Hygiene*; Standard 18, *Standard Precautions*).^{1,3,6,8,12-14} (I)
- D. Select either Standard-ANTT or Surgical-ANTT for the procedure using the defined ANTT risk assessment.

The decision is guided as follows:

1. For a given procedure, the clinician asks if they can protect all Key-Parts individually.^{6,7} (IV)
 - a. If yes, then Standard-ANTT is used. If no, then select Surgical-ANTT.
 - b. The clinician considers a few practice variables, including:
 - i. The number and size of Key-Parts and Key-Sites
 - ii. The invasiveness of the procedure
 - iii. The duration of the procedure
 - iv. The environment within which the procedure will take place
 - v. The level of personal protective equipment (PPE) required.
 2. Use Standard-ANTT for simpler procedures of shorter duration, involving fewer and smaller Key-Parts (easily and readily protected by Micro Critical Aseptic Fields and non-touch technique). Examples include infusion of medications, phlebotomy, and short peripheral intravenous catheter (PIVC) insertion indicated; nonsterile gloves are typically worn. If Key-Parts or Key-Sites require direct touch, wear sterile gloves.^{1,6,7,15,16} (IV)
 3. Use Surgical-ANTT for longer, complex procedures involving multiple or large Key-Parts (eg, central vascular access device [CVAD] insertion, CVAD exchange), while employing barrier precautions and appropriate use of PPE.^{1,6,7,17} (I)
 - a. For Surgical-ANTT, in addition to wearing sterile gloves, use a non-touch technique to protect Key-Parts whenever practical to do so.^{1,3,6,8} (V)
- E. Ensure the aseptic state of Key-Parts and Key-Sites by appropriate device disinfection and skin antisepsis (refer to Standard 31, *Vascular Access Site Preparation and*

Skin Antisepsis; Standard 32, *Vascular Access Device Insertion*; Standard 34, *Needleless Connectors*; Standard 41, *Blood Sampling*).

- F. Use ANTT to apply sterile dressings and appropriate securement devices to maintain asepsis during VAD dwell (refer to Standard 36, *Vascular Access Device Securement*; Standard 39, *Vascular Access Device Post-Insertion Care*).
- G. Ensure effective management of the patient care setting prior to clinical procedures, including purposeful decontamination to help reduce the transmission of pathogenic microorganisms.^{8,12,14,18-21} (I)
 1. Perform appropriate decontamination and disinfection (before, during, and after clinical intervention) of durable medical equipment (DME) used with an ANTT procedure (eg, ultrasound, electronic infusion pump) (see Standard 18, *Standard Precautions*; refer to Section Four, *Infusion Equipment*).⁶ (V)
- H. Adopt a process of continuing practice development; periodically audit clinical practice to evaluate clinician competency in ANTT and compliance with the ANTT Clinical Practice Framework and local clinical procedure guidelines.^{7,22} (IV)
 1. Aseptic Non Touch Technique (ANTT) is a core clinical competency that must be maintained by periodic reeducation and competency reassessment.

See Appendix A, *Aseptic Non Touch Technique (ANTT®) Clinical Practice Framework*.

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20. TRANSMISSION-BASED PRECAUTIONS

Standard

20.1 Transmission-Based Precautions, including Contact Precautions, Droplet Precautions, and Airborne Precautions,

are implemented when strategies, in addition to Standard Precautions, are required to reduce the risk for transmission of infectious agents.

20.2 Contact Precautions are implemented to prevent the transmission of infectious agents, which are spread by direct or indirect contact with the patient or the environment, including when there are excessive bodily discharges, such as wound drainage.

20.3 Droplet Precautions are implemented for patients known or suspected to be infected with pathogens transmitted by respiratory droplets that are generated by a patient who is coughing, sneezing, or talking.

20.4 Airborne Precautions are implemented for patients known or suspected to be infected with pathogens transmitted by the airborne route (eg, tuberculosis, measles, chickenpox, disseminated herpes zoster).

20.5 Transmission-Based Precautions are adapted and applied as appropriate for nonacute care settings where infusion therapy is provided, including long-term care facilities, home care, ambulatory care, and other settings.

20.6 Transmission-Based Precautions are adapted and modified to deal with infectious disease crises, such as pandemics, under the direction of organizations including the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO).

Practice Recommendations

- A. Select and use personal protective equipment (PPE) for Transmission-Based Precautions, in addition to Standard Precautions, based on the nature of the patient interaction and potential for exposure to blood, body fluids, or infectious agents and isolation precaution guidelines in effect at the time of the patient encounter for specific communicable diseases.¹⁻¹⁴ (II)
 1. Ensure users are adequately trained on safe donning and doffing of required PPE.
 2. Understand the impact of isolation precautions on patient experience.
 3. Plan tasks allowing adequate time for safe donning and doffing of required PPE.
- B. Perform hand hygiene before donning PPE, immediately if the hands become contaminated during PPE removal, immediately after removing all PPE, and before leaving the patient's environment (refer to Standard 17, *Hand Hygiene*).
- C. Maintain Transmission-Based Precautions until it is determined that the cause of the symptoms is not due to an infectious agent, or the duration of the recommended isolation precautions has been met.^{4,15,16} (IV)
- D. Observe Contact Precautions, in addition to Standard Precautions, when there is potential for transmission of epidemiologically significant organisms through direct or indirect contact with the patient or the environment by donning gown and gloves before entering the clinical environment when contact may occur.¹⁷⁻²⁷ (I)

1. There is emerging and conflicting evidence regarding the role of contact precautions, as well as universal gloving and gowning for control of endemic, epidemiologically significant organisms.
- E. Observe Droplet Precautions, in addition to Standard Precautions, when there is potential contact with respiratory secretions or sprays of blood or body fluids; wear a face mask and eye protection when there is potential contact with respiratory secretions and sprays of blood or body fluids.^{1,4,5,14} (II)
- F. Observe Airborne Precautions, in addition to Standard Precautions, by wearing a fit-tested, certified, N95-or-higher respirator if an infection spread by airborne route is suspected or confirmed or when microbial agents become airborne transmissible during aerosol-generating procedures (eg, intubation).^{1,4,13,14,28-35} (II)
 1. Perform fit testing prior to initial respirator use and repeat at least annually and as needed if there are significant changes to facial structures.
 2. Instruct clinicians to perform a seal check every time the respirator is worn and adjust as needed.
 3. If reusable elastomeric respirators are selected by the organization, ensure that devices are maintained and cleaned according to established policies and filters are changed as indicated. If exhalation valves are present, additional measures are needed if source control is also indicated. Reusable respirators offer an advantage of protecting against supply chain disruption challenges.³⁰⁻³³ (IV)
 4. Establish and maintain a Respiratory Protection Program.
 5. For patients receiving aerosol-generating procedures in which an airborne transmitted disease is not suspected, staff should minimally wear one of the following: a face shield that fully covers the front and sides of the face, a mask with attached shield, or a mask and goggles.
- G. Employ “enhanced barrier precautions,” a specific strategy required as part of a containment response for United States (US) nursing homes (skilled nursing facilities) when performing high-contact resident care activities that provide opportunities for transfer of multidrug-resistant organisms (MDROs) and epidemiologically significant organisms to staff hands and clothing.^{36,37} (III)
 1. Wear gloves and gown when performing any high-contact care activity in a nursing home, which includes care required for wounds and/or indwelling medical devices (eg, central vascular access device [CVAD], urinary catheter, feeding tube, tracheostomy/ventilator) for those who reside on a unit or wing where a resident known to be infected or colonized with a novel or targeted MDRO resides.
- H. Notify accepting facilities and transporting agencies about suspected infections and the need for Transmission-Based Precautions when patients are transferred.³⁸ (II)
- I. Throughout the continuum of care, when caring for a patient with an MDRO or on Transmission-Based Precautions, limit reusable patient care equipment and dedicate equipment to the patient (leave in the room or in the home until no longer necessary) whenever possible. Clean and disinfect equipment before removing from the patient environment or place in a container (eg, plastic bag) for transport to an appropriate site for cleaning and disinfection per organizational policy.^{3,4,39-41} (II)
 1. When caring for a home care patient with an MDRO or on Transmission-Based Precautions, consider using disposable patient care equipment (eg, stethoscope/blood pressure cuff). Otherwise, dedicate patient care equipment that remains in the patient’s care setting until no longer needed. Decontaminate the equipment (ie, rendering it safe for handling) at the point of use and transport it to another location for cleaning and disinfection before reuse.
- J. Implement strategies during crises, such as pandemics, by reducing health care facility risk (eg, limit visitors, cancel elective procedures), isolate symptomatic patients, and protect clinicians (eg, barriers at triage; limit number of staff caring for patient; ensure availability of PPE where most needed, eg, N95 respirators in the presence of aerosol-generating procedures; and adoption of technology, eg, wireless probes, electrocardiogram [ECG] technology to minimize the need for radiological confirmation of device tip location).⁴² (IV)
 1. Care decisions in a crisis are necessarily constrained by specific conditions under a crisis, such as a pandemic.
 2. Implementation of crisis standards of care are done within the health care organization and in collaboration with health care professionals, policy makers, and the community.
 3. PPE conservation strategies may be necessary and adjusted based on local circumstances. Ensure compliance with current recommendations, which may rapidly evolve during times of crisis.

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Section Four: Infusion Equipment

Section Standards

I. To ensure patient safety, the clinician is competent in the use of infusion or vascular access equipment, including knowledge of appropriate indications, contraindications, and manufacturers' directions for use.

II. The use and maintenance of infusion or vascular access equipment is established in organizational policies, procedures, and/or practice guidelines.

III. Infusion or vascular access equipment is cleaned and disinfected after each patient use with disinfectants that have antimicrobial activity against pathogens likely to contaminate the equipment and in accordance with manufacturers' directions for cleaning and disinfecting.

21. VASCULAR VISUALIZATION

Standard

21.1 Vascular visualization technology is used to increase insertion success of the most appropriate, least invasive vascular access device (VAD), minimizing the need to escalate to an unnecessary, more invasive device and to reduce insertion-related complications.

Practice Recommendations

- A. Assess the patient's medical history (including previous vascular access) to determine the need for vascular visualization technology to assist in locating appropriate peripheral intravenous or arterial insertion sites. Factors likely to increase difficulty of peripheral intravenous and intra-arterial insertion using observation and palpation only (known as landmark techniques) include, but are not limited to, the following^{1,2}: (II)
 1. Patient's age (both neonates and older adults)
 2. History of frequent venipuncture and/or lengthy courses of infusion therapy
 3. Disease processes that result in structural vessel changes (eg, diabetes mellitus, hypertension)
 4. Variations in skin between patient populations, such as darker skin tones and excessive hair on the skin
 5. Skin alterations, such as the presence of scars or tattoos

6. Obesity
7. Fluid volume overload or deficit.
- B. Use ultrasound to assess the size and caliber (diameter and length of intravenous path), as well as other anatomical structures prior to insertion to identify vascular anomalies (eg, occlusion or thrombosis), and location of other structures, such as valves, arteries, and nerves.^{3,4-7} (II)
 1. Select the most appropriate vessel to cannulate based on vessel size, shape, depth, flow, and patency; identification of potential structures to avoid (eg, nerves, arteries) within the vicinity of insertion; respiratory variation; catheter-to-vein ratio; and operator.
 2. Minimize damage to surrounding structures; identify vessels in the short (transverse) axis and proceed with insertion, or, alternatively, if the long (longitudinal) axis for needle insertion is preferred for adult patients, redirect the probe to this plane upon completion of initial assessment.
- C. Consider the use of visible light devices that provide transillumination of the peripheral veins.
 1. Visible light devices aid in locating superficial veins in neonates; however, their usefulness in infants, older children, and adults is limited due to the thickness of subcutaneous tissue and size of the arm circumference.^{3,8} (II)
 2. Use only cold light sources in devices designed for vascular visualization. Thermal burns have been reported due to close contact between skin and the light source when the device emits heat (eg, traditional flashlights).⁸ (V)
- D. Use near infrared (nIR) light technology to aid peripheral intravenous catheter (PIVC) insertion in children and adults with difficult intravenous access (DIVA).
 1. Compared to no technology, nIR provides information about vein selection (ie, bifurcating veins, tortuosity of veins, palpable but nonvisible veins, location of venous valves), particularly in infants and neonates. Small, single-center randomized controlled trials (RCTs) have demonstrated that nIR improves first-time insertion success, and overall PIVC insertion success, and decreases procedural time compared to traditional visual assessment and palpation

- in some populations, such as neonates and infants with difficult intravenous access.^{3,9,10} (II)
2. In adults, small cohort and nonrandomized clinical trials have demonstrated improved first-time insertion success, reduced time to insertion, and fewer extravasation injuries.¹¹⁻¹³ (IV)
- E. Use ultrasound to measure the catheter-to-vessel ratio prior to insertion of an upper extremity VAD; ensure a catheter-to-vessel ratio of less than 45%. The research underpinning this recommendation is specific to peripherally inserted central catheter (PICC) insertion. Consider application of this ratio to midline catheters as well, as they are placed in the same veins (refer to Standard 25, *Vascular Access Device Planning and Site Selection*; Standard 50, *Catheter-Associated Thrombosis*).
- F. Use ultrasound for PIVC and midline catheter insertion.
1. Adults: Increased patient satisfaction, fewer venipuncture attempts, and decreased escalation to central vascular access device (CVAD) insertion have been reported when ultrasound guidance is used for insertion of short/standard length and long PIVC.¹⁴⁻¹⁷ (I)
 2. Pediatric patients: Increased first-time insertion success and overall PIVC insertion success have been demonstrated when ultrasound guidance is used for PIVC insertion compared to palpation and visualization. This effect increases when used in children with difficult intravenous access.^{3,18,19} (I)
 - a. Consider use of short axis (out of plane view) vs long axis (in plane view) for PIVC insertion; this technique has shown improved insertion success in pediatric patients.²⁰ (IV)
 - b. Use dynamic needle tip positioning to complement ultrasound-guided (USG) insertion success compared to static USG technique to improve first-time insertion success, overall PIVC insertion success within 10 minutes, fewer PIVC insertion attempts, and shorter time to cannulation.²¹ (III)
- G. Use real-time ultrasound guidance and a systematic approach to insertion of CVADs in adults and children to improve insertion success rates, reduce number of needle punctures, and decrease insertion complication rates.^{9,22-25} (I)
1. Consider use of long axis in plane approach as an alternative to short axis out of plane approach to internal jugular vein to improve first-time insertion success, overall insertion success, and to reduce posterior wall puncture in neonate, pediatric, and adult patients.^{5-7,26,27} (II)
- H. Use ultrasound guidance for arterial puncture and catheter insertion in adults and children.²⁸⁻³⁴ (I)
1. Ultrasound-guided insertion of the radial artery increases first-attempt success and lowers failure rate compared to palpation, reduces time to insertion, mean number of insertion attempts, and hematoma formation.²⁸⁻³³ (I)
 2. Consider use of real-time ultrasound-guided axillary arterial line insertion. A small RCT demonstrates improved overall insertion success.³⁴ (III)
 3. Use real-time, ultrasound-guided femoral arterial line insertion, as it has been associated with reduced hematoma formation and vascular complications.³⁵ (II)
- I. Use a sterile single-use gel packet and an appropriate sterile barrier over the probe and disinfect before and after each use to reduce the risk for ultrasound probe contamination and subsequent risk for infection; refer to manufacturers' directions for use.³⁶ (V)
1. For preassessment only (intact skin and no needle puncture), use single-use gel; however, a sterile barrier is not required unless institutional guidelines require this.
- J. Establish comprehensive ultrasound guided training programs to support clinicians through the novice-to-expert continuum.³⁷⁻⁴¹ (III)
- K. Assess and document clinician competency in the use of vascular visualization technology for insertion of VADs. This knowledge includes, but is not limited to, assessment of vessels, size, depth, location, potential complications, and adherence to and awareness of Aseptic Non-Touch Technique (ANTT®) (refer to Standard 5, *Competency and Competency Assessment*; Standard 19, *Aseptic Non Touch Technique [ANTT®]*).

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22. CENTRAL VASCULAR ACCESS DEVICE TIP LOCATION

Standard

22.1 Tip location of a central vascular access device (CVAD) is confirmed radiographically or by other imaging technologies prior to initiation of infusion therapy or when clinical signs and symptoms suggest tip malposition.

22.2 The original catheter tip location is documented in the patient's health record and made available to other organizations involved with the patient's care.

22.3 The safest CVAD tip location in adults and children is the superior (upper limb) or inferior (lower limb) cavoatrial junction (CAJ).

Practice Recommendations

A. Approximate the catheter length for insertion by anthropometric measurement, including, but not limited to, external measurement from the planned insertion site to the third intercostal space, use of formulas to calculate length based on body surface area, or measurement from preprocedural chest radiographs.¹⁻³ (IV)

B. Position the tip of a CVAD in the lower third of the superior vena cava (SVC) or upper third of the right atrium (RA) at or near the CAJ for adults and children.

1. For upper body insertion sites, respiratory variation, arm movement, and changes in body position will cause the CVAD tip to move in a caudal or cephaloid direction. Tip location deeper in the right atrium near the tricuspid valve or in the right ventricle is associated with cardiac arrhythmias (refer to Standard 51, *Central Vascular Access Device Malposition*). Tip location proximal to the SVC is associated with increased risk of thrombosis (refer to Standard 51, *Central Vascular Access Device Malposition*; Standard 50, *Catheter-Associated Thrombosis*).
2. For lower body insertion sites, position the CVAD tip in the inferior vena cava (IVC) above the level of the diaphragm.⁴⁻⁶ (IV)
3. For hemodialysis CVADs, position the CVAD tip at the mid-right atrium to avoid vessel and right atrial trauma or complications.⁷ (IV)

C. Avoid suboptimal tip position, except in rare circumstances, including anatomical or pathophysiological changes, where alternative tip positions might be clinically indicated.^{1,8-10} (III)

D. Avoid intracardiac catheter tip location in neonates and infants less than 1 year of age, as this tip location has

been associated with vessel erosion and cardiac tamponade. This complication has been described in the literature in catheters of various size and particularly with the use of small-gauge catheters typically less than 3 French (Fr).⁹⁻¹¹ (IV)

E. Use tip locating methods to identify CVAD tip location during the insertion procedure (ie, "real-time") for neonate, pediatric, and adult patients. Studies have demonstrated greater accuracy, more efficient initiation of infusion therapy, and reduced costs.^{1,12} (IV)

1. Use electrocardiogram (ECG) methods with either a metal guidewire or a column of normal saline inside the catheter lumen and observe the ECG tracing to place the CVAD tip at the CAJ. Follow manufacturers' directions for use with other ECG-based technology using a changing light pattern to detect tip location.^{1,12-30} (I)
 - a. Assess patient for known history of cardiac dysrhythmias and the presence of a P wave on ECG (if available) before planning to use ECG technology for tip confirmation. Contraindications to the use of ECG technology include patients with an abnormal ECG rhythm with an absence or alteration in the P wave (eg, presence of pacemakers, extreme tachycardia). Prospective observational studies have demonstrated safety and efficiency of using ECG to confirm catheter tip position in patients with atrial fibrillation.^{20,29,31,32} (III)
2. Consider the use of ultrasound for CVAD tip location. The clinical applicability of this is currently limited by the small sample sizes used to demonstrate its efficacy as a reliable and safe method to replace chest radiographs in all ages, and its usefulness is limited by the knowledge, skill, and experience of the operator.^{6,33-38} (III)
 - a. The addition of agitated saline to enhance transthoracic echocardiography has been shown to be effective in detecting catheter tip position in the lower third of the SVC, as well as detecting catheter malposition through delayed opacification and reduced echogenicity.^{6,39} (IV)
3. Consider using ultrasound to confirm catheter tip position in neonates and in the emergency department or other critical care environments where immediate confirmation of tip location is time critical.^{6,33,40} (IV)
4. Use fluoroscopy when CVAD placement is difficult or has failed at the bedside.⁴¹ (II)
5. Postprocedure radiograph imaging is not necessary if alternative catheter tip location technology confirms appropriate tip placement.^{1,12-30,42,43} (I)
 - a. Most evidence is specific to peripherally inserted central catheter (PICC), and further research is needed to confirm applicability to other CVADs. Recognize that radiographic or ECG tip location

technology does not differentiate between venous and arterial placement. If arterial placement is suspected, use other methods to confirm or refute arterial placement.

- F. Re-evaluate CVAD tip position if there are signs and symptoms of malposition (refer to Standard 51, *Central Vascular Access Device Malposition*).
- G. Verify the CVAD tip position with ECG, ultrasound, or assessing the postprocedure chest radiograph prior to initiating infusion therapy. (Committee Consensus)
- H. Assess the catheter tip position when a patient is transferred from an external health care facility; if all the following criteria are met, it is appropriate to use the catheter without additional tip confirmation: (Committee Consensus)
 1. Documentation exists confirming catheter tip position at the lower third of SVC, CAJ, or superior RA on insertion
 2. Ability to aspirate blood and flush the catheter without resistance
 3. External catheter length remains the same as documented upon insertion
 4. When any of these criteria are not met, catheter tip placement should be confirmed with a chest radiograph.
- I. Document the time of insertion and CVAD tip location by including a copy of the ECG tracing, chest radiograph note, or other appropriate report in the patient's health record (refer to Standard 10, *Documentation in the Health Record*).

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23. FLOW-CONTROL DEVICES

Standard

23.1 The selection of a flow-control device(s) is based upon factors including the prescribed infusion therapy, rate control requirements, infusion-related risks, patient care setting, and available resources within the organization.

23.2 Administration sets with anti-free-flow mechanisms are used with electronic infusion pumps.

Practice Recommendations

A. Choose a method for flow-control based upon factors such as age, condition, mobility, self-administration ability, preference, and lifestyle of the patient; type of vascular access device (VAD); type of therapy, frequency, dosing, drug stability, and rate of infusion; the potential for side effects or adverse effects of the therapy; health care setting; and reimbursement.¹⁻¹⁰ (III)

1. Use nonelectronic, flow-control devices according to manufacturer's directions for use to infuse low-risk infusions where some variation in flow rate is not critical. These may include gravity infusion sets, mechanical pumps such as elastomeric balloon pumps, spring-based pumps, and negative-pressure pumps.
 - a. Choose gravity infusions as an alternative to electronic infusion pumps as clinically appropriate (eg, intravenous [IV] hydration, some IV antibiotics, medications that are not high-alert, peripheral vesicant infusions) (see Standard 58, *Antineoplastic Therapy*).¹⁰⁻¹³ (V)
 - b. Consider use of a manual flow regulator in lieu of a roller clamp (eg, allows for setting the infusion rate in milliliters per hour) for gravity infusions to allow for easier regulation and more consistent flow; there are also electronic drip monitors that can be used with a gravity

- administration set that provides more accurate rate monitoring.^{1,7,10,14-18} (IV)
- c. Recognize that the use of manual flow regulators may not provide precise control of flow rates with highly viscous infusions (eg, colloids). An electronic infusion pump should be utilized in clinical situations that require precise infusion rates.¹⁹ (V)
2. Consider the use of an elastomeric device as an alternative to electronic infusion pumps for the administration of medication in the home care setting to reduce the constraints associated with infusion by gravity or electronic pumps and limit the number of nurse interventions.^{16,20-22} (I)
 - a. For all infusions, including elastomeric pumps, fully connect the needleless connector to eliminate flow restriction.²³ (V)
 - b. Consider the impact of the environment on drug stability for continuous infusions via elastomeric pumps, which is a potential concern for home infusion, especially in very warm climates (see Standard 66, *Home Infusion Therapy*).¹⁷ (IV)
 3. Use electronic infusion pumps according to manufacturer's directions for use for infusion therapies that require precise flow control for safe infusate administration.^{2,7,8,24,25} (IV)
 - a. Ensure safe and consistent use of electronic infusion pumps by using anti—free-flow protection, air-in-line detection, and pressure and occlusion alarms.^{8,10,26,27} (IV)
 - b. Ensure electronic infusion pump alarm limits are set appropriately for the patient's current condition and that alarms are turned on, functioning properly, and audible to patients and staff.²⁸ (V)
 - c. Use electronic infusion pumps with dose-error reduction systems ([DERS] ie, smart pumps) for IV administration of medication and solutions (eg, continuous, intermittent, secondary infusions, patient-controlled analgesia [PCA], and epidural, spinal, and nerve block infusions) throughout the acute care setting, including ambulatory settings such as perioperative/procedural/radiology care areas, emergency departments, and infusion centers, as they are associated with reduced risk for infusion-related medication errors, including error interceptions (eg, wrong rate) and reduced adverse drug events (see Standard 57, *Infusion Medication and Solution Administration*).^{4,12,29-33} (III)
 - d. Organize an interprofessional team of key stakeholders (eg, pharmacy, clinical nurse specialist) to monitor compliance with use of smart pump dose error-reduction software on a monthly basis and maintain a compliance rate of 95% or greater.^{13,34} (IV)
 - e. Use a smart pump that allows programming of the bolus (or loading dose) and continuous infusion rate with separate limits for each, if available.¹³ (V)
 - f. Follow standards, guidelines, and manufacturer's instructions for safe use of IV smart pumps.^{35,36} (V)
 - i. Use the drug library in accordance with organizational policy, avoiding manual programming and overrides of drug library alerts.^{4,12,29-33,37} (IV)
 - ii. Update drug libraries regularly (to address new drugs, new drug protocols, and drug shortages) to avoid unnecessary alerts, and involve end users in the design of the library.^{12,29,30,33,37-43} (IV)
 - iii. Consider the use of smart pumps with electronic health record (EHR) interoperability to further reduce manual programming errors, decrease infusion pump alarms, improve documentation, and decrease wrong patient infusion administration.^{12,44,45} (IV)
 - g. Use multichannel infusion pumps only for a single patient for the simultaneous delivery of therapies by the same route (eg, IV and epidural infusions are not infused on the same individual pump).¹² (V)
- B. Monitor flow-control devices during the administration of infusion therapy to ensure safe and accurate delivery of the prescribed infusion rate and volume (See Standard 57, *Infusion Medication and Solution Administration* and Table 1: *Medication/Infusion Delivery: Dose Accuracy and Error Prevention*).^{10,35} (V)
 1. Identify medications that should be administered as uninterrupted primary infusions (eg, rapid infusion, critical medications).^{12,46,47} (V)
 2. Ensure accurate dose delivery, compatibility, and reduced risk for infection when administering secondary or piggybacked medications (refer to Standard 40, *Administration Set Management*).
 3. Use only accessory devices (eg, administration sets, syringes, filters) that are designed to work with the flow-control device according to the manufacturers' directions for use (refer to Standard 33, *Filtration*).
 - a. If using syringe pumps for delivery of small-volume infusions, use accessory devices that offer the smallest internal volume (eg, microbore tubing, shorter length) to minimize residual volume.⁴⁸ (V)
 4. Assess manually regulated infusion sets at regular intervals; always verify flow by counting drops and monitoring the infusion volume infused.¹⁸ (V)
 5. Routinely assess the VAD site to detect infiltration or extravasation, as electronic infusion pumps do not detect infiltration or extravasation (see Standard 44, *Infiltration and Extravasation*).^{9,10} (V)

- C. Standardize the types of pumps used in an organization to promote user familiarity with its operation (see Standard 12, *Product Management*).^{10,12,43} (IV)
 1. Use differentiated infusion pumps for epidural infusions, enteral infusions, and irrigations to differentiate from vascular access infusions.^{12,49} (V)
 2. Ensure pumps follow and stay with patients to help minimize the need to re-establish infusions after patient transfers.⁵⁰ (V)
 3. Collaborate with the health care team, including end users, in the evaluation, selection, and launch of flow-control devices (see Standard 12, *Product Management*).^{9,27,31,50} (IV)
- D. Recognize the problem of alarm and alert fatigue with multiple electronic monitoring and therapeutic devices. Implement evidence-based recommendations (eg, alarm parameter settings, pump/infusate height) from professional organizations and device manufacturers utilizing continuous quality improvement (CQI) in collaboration with the health care team to assist in identifying areas of high alerts.^{31-33,43,51,52} (III)
- E. Follow organizational policy regarding use of a flow-control device during care transitions (eg, hospital admission of patient with an insulin pump).^{53,54} (V)
- F. Teach patients and/or caregivers in the home care setting about safe and effective use of flow-control devices and the back-up plan for pump malfunction/failure, identification of potential problems, and available resources (see Standard 8, *Patient Education*).^{10,27,29,37,38} (V)

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24. BLOOD AND FLUID WARMING

Standard

24.1 Blood and fluid warming are performed only with devices specifically designed for that purpose.

24.2 Blood is warmed in a manner to reduce hemolysis.

Practice Recommendations

- A. Ensure competency of clinicians operating blood and fluid warming devices, including the device functionality, the appropriate administration set for the device, the impact of add-on devices, and the proper monitoring of device function and patient tolerance.^{1,2} (IV)
- B. Use blood and fluid warmers when warranted by patient history, clinical condition, and prescribed therapy, including, but not limited to, preventing or treating intraoperative hypothermia, during plasma exchange for therapeutic apheresis, for patients known to have clinically significant cold agglutinins, for neonatal exchange transfusions, during replacement of large blood volumes,

during vaso-occlusive episodes, or when treating trauma, hypothermia, or cold exposure.³⁻²¹ (I)

1. Warm intravenous (IV) fluids reduce postoperative shivering.^{5,9,16,22,23} (I)
 2. Warm IV fluids may enhance a patient's thermal comfort.^{21,24} (III)
- C. Use only a blood or fluid warming device that is indicated for this purpose in accordance with the manufacturers' directions for use; is equipped with warning systems, including audible alarms and visual temperature gauges; and is within the maintenance date.²⁵⁻²⁸ (IV)
1. Ensure that equipment used to warm blood, IV fluids, contrast media, and irrigation solutions (eg, infusion device, warming cabinet) is monitored for proper function, including consistent temperature and alarm function. Remove from service if malfunction is suspected.^{3-5,26,29} (I)
 2. Never use warming methods where temperature and infection risks cannot be controlled (eg, microwave oven, hot water bath).^{3,10,25,26} (IV)
 3. Further research is needed to identify optimal methods of fluid and blood warming in the prehospital setting. Studies indicate that latent heat (eg, products that produce an exothermic effect) and external warming of tubing may be alternatives in resource-limited environments.^{30,31} (IV)
- D. Do not warm solutions and blood above a set temperature recommended by the manufacturer of the warming device or solution.^{12,25,32} (II)
1. Follow organizational policies and manufacturer instructions on warming during administration of specific blood components (eg, platelets, cryoprecipitate). Studies indicate that warming may not reduce platelet function during warming of apheresis platelets and whole blood.^{33,34} (IV)
 2. Monitor the patient's temperature with a device that accurately estimates core temperature to ensure the desired temperature is maintained.^{20,22,23,35} (I)
 3. Recognize factors that impact the ability to accurately infuse blood/fluids at the set temperature, including, but not limited to, characteristics of vascular access device, infusion device, infusion flow rate, length of tubing, presence of add-on devices that may restrict flow rate (eg, needleless connectors), interruptions in administration, initial temperature of blood/fluid, total volume infused, environmental conditions, and other warming methods used (eg, forced air or radiant warming).^{5-8,12,14,15,22,26,27,32,36-42} (I)
 - a. Use caution with add-on devices that may restrict flow during rapid infusion. A case report indicates the potential for rupture of the warming device administration set due to partially closed stopcock during pressure bag delivery (see Standard 34, *Needleless Connectors*).⁴³ (V)
 4. Consider insulating the administration set to reduce heat loss if longer tubing is used and if environmental conditions warrant.^{6,7,14} (IV)

5. Shield the blood component and tubing from phototherapy source (eg, ultraviolet) or heat lamps when administering blood to an infant; inappropriate warming by exposure of blood to heat lamps or phototherapy lights may produce hemolysis.⁴ (V)

- E. Consider warming contrast media to reduce the viscosity. This may help reduce extravasation in the following: higher-viscosity contrast media, flow rates greater than 5 mL/s, and some arterial infusions. When contrast media is warmed, use a temperature log for the warmer and follow the device manufacturer's guidelines for maintenance of the warming device. Consult the manufacturer's package insert for the specific contrast agent regarding whether warming is contraindicated.^{29,44,45} (V)

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Section Five: Vascular Access Device Selection and Insertion

KEY DEFINITIONS

Peripheral intravenous catheters (PIVCs): are inserted into and reside in veins of the periphery that includes all extremities, the external jugular vein, and scalp veins in neonates. PIVCs are inserted into superficial veins located just under the skin in the superficial tissue, as well as deep veins located under the muscle tissue.

INS categorizes 3 types of PIVCs:

Short peripheral intravenous catheter (short PIVC): an over-the-needle catheter with a hollow metal stylet (needle) positioned inside the catheter, generally inserted in superficial veins.

Long peripheral intravenous catheter (long PIVC): inserted in either superficial or deep peripheral veins and offers an option when a short PIVC is not long enough to adequately cannulate the available vein. A long PIVC can be inserted via traditional over-the-needle technique or with more advanced procedures, such as Seldinger and accelerated Seldinger techniques.

Midline peripheral catheter (midline): inserted into a peripheral vein of the upper arm via the basilic, cephalic, or brachial vein with the terminal tip located at the level of the axilla in children and adults; for neonates, in addition to arm veins, midline catheters may be inserted via a scalp vein with the distal tip located in the jugular vein above the clavicle or in the lower extremity with the distal tip located below the inguinal crease.

Section Standards

- I. Insertion and removal of vascular access devices (VADs) are performed by providers/clinicians within the boundaries of their identified scope of practice, licensure, and competency, and in accordance with organizational policies, procedures, and/or practice guidelines.
- II. Indications and protocols for VAD selection and insertion are established in organizational policies, procedures, and/or practice guidelines and according to manufacturers' directions for use.

25. VASCULAR ACCESS DEVICE PLANNING AND SITE SELECTION

Standard

25.1 Infusion therapy and vascular access decisions are collaborative (health care team, the patient/caregiver), with consideration to the patient's diagnosis and clinical presentation, vasculature, device selection, and risk versus benefit of alternative routes of therapy.

25.2 The appropriate vascular access device (VAD), peripheral or central, is selected based on the prescribed therapy

or treatment regimen, anticipated duration of therapy, vascular pathway, patient's age, comorbidities, history of infusion therapy and vascular access, patient preference for VAD type and location, overall vascular health (history of difficult intravenous access, vessel, and skin health at insertion site), and ability and resources available to care for the VAD.

25.3 The least invasive VAD with the smallest outer diameter and fewest number of lumens needed to complete the duration and prescribed therapy is selected.

25.4 Site selection is chosen based on vessel health and preservation strategies (thorough vessel assessment), the planned therapy, patient comfort and preference, and VAD type, beginning at the most distally appropriate site.

Practice Recommendations

I. General Information for Vascular Access Device and Site Selection

- A. Use all available resources, including, but not limited to, evidence-based drug monograph warnings, precautions, and toxicology, and interprofessional collaboration to identify medications that should and should not be given through peripheral veins. Peripheral infusion therapy should be isotonic and of physiological pH. When this is not

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achievable, peripheral intravenous infusion of extremes of pH and osmolarity should be avoided to reduce vascular endothelial damage. In clinical practice, many parameters, including administration site, number of infusion therapies, vein selected, related venous blood flow, infusion volume, infusion time, and planned duration of therapy contribute to vessel damage. There is no well-defined or generally recognized pH or osmolarity limit. Furthermore, some infusates with physiological pH and osmolarity can be cytotoxic, potentiating cell damage or death. Factors to consider include, but are not limited to¹⁻¹¹: (I)

1. The final osmolarity of the infusion, which is influenced by the diluent (refer to Standard 61, *Parenteral Nutrition*; Standard 43, *Phlebitis*)
2. Infusate pH
3. Method of administration (eg, continuous or intermittent infusion or manual injection [ie, IV push]), including infusion durations and frequency of administration.
4. Infusion rate and pressure (eg, power injections)
5. Number of infusion therapies (single vs multiple)
6. Pharmacological effect of the medication on the vein (eg, vasodilation vs vasoconstriction) (see Standard 65, *Vasopressor Administration*)
7. Anticipated duration of therapy (as a guide see below):
 - a. (≤ 4 days): Insert a peripheral intravenous catheter (PIVC) when all the above elements indicate peripherally compatible therapy.
 - b. (5–14 days): Insert a midline catheter in hospitalized adult patients when all the above elements indicate peripherally compatible therapy. A long PIVC may remain appropriate if patient's vasculature, patient's preference, and local health care outcomes support this practice. More high-quality clinical trials are needed to confirm the safety and efficacy of midline catheter use in neonates and infants.
 - c. (>15 days): Consider insertion of a peripherally inserted central catheter (PICC). Midline catheters or PIVCs may remain appropriate when all the above elements indicate peripherally compatible therapy and if patient's vasculature, patient preference, and local health care outcomes support this practice. More high-quality clinical trials are needed to confirm the appropriate use (eg, single vs multiple therapies) and duration of these catheters.
- B. Discuss the preferred site of PIVC insertion with the patient and/or caregiver, including recommendations to use sites of the nondominant side.¹² (IV)
- C. Use vascular visualization technologies to identify and select the most appropriate vein for midline catheter insertion (refer to Standard 21, *Vascular Visualization*).
- D. Avoid the following PIVC insertion sites when possible due to increased risk of nerve damage (refer to Standard 45, *Nerve Injury*):

1. Cephalic vein at the radial wrist with potential injury to the superficial radial nerve
 2. Volar (inner) aspect of the wrist with potential injury to the median nerve
 3. At/above the antecubital fossa with potential injury to the median and anterior interosseous nerve and the lateral and medial antebrachial nerves.
- E. Avoid PIVC insertion in areas of the following:^{7,10,12} (II)
1. Flexion
 2. Pain on palpation
 3. Compromised skin and sites distal to these areas, such as areas with open wounds
 4. Extremities with an infection
 5. Planned procedures
 6. Veins that are compromised (eg, previous cannulation, bruised, reddened/streaked, infiltrated, sclerosed, corded, or engorged).
- F. Do not use visible veins of the chest, breast, abdomen, or other locations on the trunk, as there is no evidence supporting their safe outcomes. These veins are visible due to pathological reasons that might prevent safe infusion. (Committee Consensus)
- G. Do not use veins of the lower extremities (except for neonates and infants), unless needed for an emergent insertion.^{4,12} (V)
- H. Avoid insertion of a PIVC or midline catheter as a central line-associated bloodstream infection (CLABSI) prevention strategy when central venous access is indicated. (Committee Consensus)
- I. Access a patient's implanted vascular access port, unless contraindicated (eg, existing complication with the device), in preference to insertion of an additional VAD when intravenous access is required. (Committee Consensus)

II. Short Peripheral Intravenous Catheters

- A. Select PIVC insertion site based on depth of vein and expected duration of infusion therapy. Remove as soon as PIVC is no longer needed.^{10,12,13} (I)
1. Use a forearm vein, where possible, to prolong the dwell time, reduce pain during dwell, and reduce overall device failure. Choose veins found on the dorsal and ventral surfaces of the upper extremities, including the metacarpal, cephalic, basilic, and median veins.^{4,7,9,10,12} (I)
 2. Consider hand veins for short-term therapy (eg, less than 24 hours).^{4,12} (III)
 3. Avoid the antecubital fossa. PIVC insertion in areas of flexion are associated with higher rates of failure over time.^{4,7,9,10,12} (I)
 4. Consider use of the external or internal jugular vein in patients in acute care settings and in emergency situations when other veins cannot be accessed; collaborate with the provider for an alternative vascular access site as soon as possible.^{14,15} (IV)
- B. Use vascular visualization technology (eg, near infrared, ultrasound) to increase success for patients with difficult

intravenous access (DIVA); (refer to Standard 21, *Vascular Visualization*).

- C. Avoid use of short PIVC for continuous infusion of medication with irritant or vesicant properties.^{1,2,10} (I)
 - 1. For time-critical infusions (eg, vasopressors), consider the type and dose of medication and its mode of action (vasoconstriction vs vasodilation). Where appropriate, begin the infusion through a PIVC. The PIVC should be replaced with a central venous access device (CVAD) as early as possible, balancing the acuity of the patient and the potential harm of peripheral infusion of peripherally incompatible medication (see Standard 65, *Vasopressor Administration*).^{9,10} (I)
- D. Use a restricted dextrose and protein concentration ($\leq 10\%$ and/or 5% , respectively) if it is medically necessary to administer parenteral nutrition (PN) through a peripheral device (refer to Standard 61, *Parenteral Nutrition*).
- E. Do not use a short PIVC when the vein lies deep in subcutaneous tissue or for veins classified as deep veins (lying underneath muscle). This reduces the catheter (length) to vein ratio, which might be a precursor to failure.^{7,16,17} (III)
- F. Select the smallest-gauge PIVC that will accommodate the prescribed therapy and patient need.^{4,7,10,12} (II)
 - 1. Monitor the insertion site for signs and symptoms of complications (eg, pain and redness) and remove when clinically indicated.^{7,10,13,18} (I)
 - 2. Consider a larger-gauge PIVC for adult and pediatric patients when rapid fluid replacement is required (eg, trauma), or a fenestrated catheter for a contrast-based radiographic study, recognizing maximum psi (pounds per square inch) recommended by manufacturer.^{19,20} (IV)
 - 3. Use a 24- to 20-gauge PIVC based on vein size for blood transfusion. A larger-gauge PIVC is appropriate if rapid transfusion is required (refer to Standard 62, *Blood Administration*).
 - 4. Use steel-winged devices for single-dose administration only. Do not leave the device in situ. (Committee Consensus)

III. Long Peripheral Intravenous Catheters

- A. Choose when all aspects of a short PIVC are met, but the vessel is difficult to palpate or visualize with the naked eye. Use ultrasound guidance to improve first-time insertion success (refer to Standard 21, *Vascular Visualization*).
- B. Consider veins found on the dorsal and ventral surfaces of the upper extremities, including the cephalic, basilic, and median veins. Insertion should be in the forearm with the tip below the antecubital fossa (ACF). If this is not possible, commence insertion above the ACF.¹⁶ (III)

IV. Midline Peripheral Catheters

- A. Assess the peripheral compatibility of all infusates (eg, antimicrobials, fluid replacement, and analgesia) and

planned duration of infusion therapy for appropriateness of peripheral vein therapy.^{3-8,21,22} (I)

- 1. Select the least number of lumens that will accommodate the anticipated infusion therapy.
 - a) Single therapy and single lumen midlines have fewer complications than multiple lumen devices.^{6,22-24} (II)
- B. Ensure the midline tip is appropriately positioned distal to the axillary fold to reduce the risk of complications associated with catheter tip crossing a joint.
 - 1. Recent studies have demonstrated similar catheter-related outcomes when the midline catheter tip is positioned in a specific position in the intrathoracic cavity, although some conjecture exists whether this is at the axillary vein, proximal to the subclavian, or at the subclavian vein. Increased observation for signs and symptoms of catheter malfunction is recommended, as the safety and efficacy of midline catheter tip position outside this exact location in the intrathoracic cavity has not been assessed in clinical practice.²⁵⁻²⁸ (III)
- C. Assess the clinical benefit of inserting a midline catheter that inhibits bacterial attachment and biofilm formation.^{29,30} (IV)
- D. Do not use a midline for continuous infusion of vesicant therapy, PN, or other infusates with extremes of pH or osmolarity (refer to Standard 61, *Parenteral Nutrition*; Standard 65, *Vasopressor Administration*).
 - 1. Further clinical trials evaluating the appropriate use of midlines for vasopressors (drug type and duration) are needed (see Standard 65, *Vasopressor Administration*).³¹ (IV)
- E. Increase catheter site surveillance when administering intermittent infusions for any duration of known irritants and vesicants due to increased risk of phlebitis or extravasation (see Standard 39, *Vascular Access Device Post-Insertion Care*; Standard 44, *Infiltration and Extravasation*).^{22-24,32} (II)
- F. Avoid the use of a midline when the patient has a history of thrombosis, hypercoagulability, decreased venous flow to the extremities, or end-stage renal disease requiring vein preservation.^{6,8,22,23} (III)

V. Neonate and Pediatric Patient Considerations for Peripheral Catheters

- A. Use similar criteria as for adults, and based on expected infusion therapy, remove PIVC as soon as no longer needed.
 - 1. In addition to adult PIVC insertion sites, consider veins of the foot if patient activity does not impact the status of the PIVC.
 - 2. For neonates and infants, when no alternative site is available, veins of the scalp may be used as a last resort. Avoid the hands, fingers, and thumbs.^{4,33,34} (III)
 - 3. Long PIVC: Consider veins in the forearm and the saphenous vein in nonambulatory pediatrics.^{4,33,34} (III)

4. Midline catheter: For neonates and pediatric patients, select an upper arm site using the basilic, cephalic, and brachial veins. Additional site selections include veins in the leg (eg, saphenous, popliteal, femoral) with the tip below the inguinal crease and in the scalp with the tip in the neck, above the thorax.^{4,6} (IV)

VI. Special Considerations for Peripheral Access

- A. Lymphedema: Avoid venipuncture of the ipsilateral upper extremities in patients with lymphedema and those at increased risk for lymphedema (eg, axillary surgical dissection or radiation therapy). This recommendation is based on the risk of decreased perfusion, impaired immune function, and increased risk of infection due to compromised axillary drainage.^{7,35-38} (IV)
 1. Consider early referral to an infusion nurse/vascular access specialist.⁷ (IV)
 2. If emergent vascular access is needed, choose the most readily accessible vein for access in either upper extremity, then establish a plan for ongoing vascular access.³⁵⁻³⁸ (IV)
- B. Renal dysfunction, if an arteriovenous fistula (AVF) or arteriovenous graft (AVG) is planned or existing (refer to Standard 27, *Vascular Access and Hemodialysis*).
 1. Use dorsum of the hand for PIVC insertion whenever possible and avoid the cephalic vein, regardless of arm dominance.
 2. Avoid the use of forearm and upper arm veins for peripheral catheter insertion.
 3. Avoid insertion of midline and PICC whenever possible due to an increased risk of thrombosis.
 4. Collaborate between patient and provider (eg, nephrology) to discuss the benefits and risks of using a vein in an affected extremity.
- C. Paralysis or hemiparesis: where possible, avoid venipuncture on the affected extremity (eg, traumatic injury, cerebrovascular accident) due to alteration in normal blood flow and decreased sensation.¹⁰ (II)

VII. CVADs (PICCs, Nontunneled, Tunneled, Cuffed and Non-cuffed Catheters, Implanted Vascular Access Ports)

A. CVAD Selection Considerations

1. Consider the risk versus benefit of direct venous approach compared to subcutaneous skin tunnel approach. A skin tunnel can be either a pseudo tunnel using the length of the needle to access the vein or a surgical tunnel, whereby a tunneling probe is directed through the subcutaneous tissue to the point of vein insertion and the catheter is drawn through this tunnel prior to being advanced into the venous system (refer to Standard 32, *Vascular Access Device Insertion*).

2. Implement an evidence-based list of indications for CVAD insertion to minimize unnecessary use, including, but not limited to^{1,2,4,5,14,22,39-41}: (I)
 - a. Clinical instability of the patient (eg, alteration in vital signs, oxygen saturation)
 - b. Infusion therapy inappropriate for peripheral infusion (eg, vesicant, non-peripherally compatible PN, and/or electrolytes)
 - c. Physical incompatibility and/or complexity of infusion regimen (eg, multiple infusates)
 - d. Insufficient peripheral venous access for planned treatment (eg, periodic chemotherapy)
 - e. Invasive hemodynamic monitoring
 - f. Long-term intermittent infusion therapy (eg, IV therapy for chronic disease, such as cystic fibrosis)
 - g. History of failed or difficult peripheral IV access when use of ultrasound guidance has failed.
3. Consider use in context of history of failed or difficult peripheral IV access when use of ultrasound guidance has failed. Recognize risks associated with CVADs, including venous thrombosis and CLABSI.^{4,5,22,39,42} (I)
 - a. Consider thrombosis and infection risk vs benefit of PICC in patients who have cancer or are critically ill.^{5,22,39} (I)
 - b. Choose a catheter appropriate to the patient's vasculature and therapy requirements (refer to Standard 32, *Vascular Access Device Insertion*).
 - c. Consider antithrombogenic PICC to reduce thrombosis risk, particularly in pediatric patients.⁴² (III)
 - d. Use a CVAD with the least number of required lumens to reduce the risk of thrombosis, infection, and occlusion.^{4,5,42,43} (I)
4. Consider the need for a power-injectable CVAD and know the pressure limits and other limitations (eg, maximum number of power injections) of the device, including all attached or add-on devices (eg, implanted port access needle, extension set, needleless connector) to avoid catheter rupture (refer to Standard 12, *Product Management*).
5. Collaborate with the health care team to choose the most appropriate CVAD.^{4,5,39,44} (II)
 - a. Consider use of anti-infective CVADs in patients with increased risk of infection.
 - b. Avoid PICCs and other intravenous devices that might compromise future fistula sites for patients with chronic kidney disease (CKD), and plan proactively for an arteriovenous fistula (AVF) or an arteriovenous graft (AVG) as a permanent access for dialysis (refer to Standard 27, *Vascular Access and Hemodialysis*).

B. PICCs

1. Select the basilic, brachial, or cephalic vein above the antecubital fossa that is most appropriate for PICC insertion, preferably the basilic vein; ensure a

catheter-to-vessel ratio of less than or equal to 45%.^{43,45,46} (III)

- a. Consider the use of a subcutaneous skin tunnel when the vein of choice is at its largest in the upper third of the upper arm near the axilla. This optimizes the point of needle entry and subsequent catheter exit site in the middle third of the upper arm (refer to Standard 32, *Vascular Access Device Insertion*).
 - b. For neonates and pediatric patients, additional site selection includes the axillary vein, temporal vein, and posterior auricular vein in the head and the femoral, saphenous, and popliteal veins in the lower extremities.⁴ (III)
 - c. Lower extremity PICCs are associated with greater risk of thrombosis; however, other complications are comparable with upper extremity PICCs.⁴⁷ (II)
 - d. Use the best available vein in neonates and infants; however, where possible, avoid^{4,48}: (III)
 - i. Lower limb veins for PICC insertion in patients with abdominal pathology
 - ii. Upper limb veins for neonates, infants, and children with single ventricle physiology.
2. Avoid areas of pain on palpation or areas with wounds and veins that are compromised (eg, previous cannulation, bruised, reddened/streaked, infiltrated, sclerosed, corded, or engorged).^{5,22} (III)

C. Nontunneled Central Venous Catheters

1. Use ultrasound in adult and pediatric patients for vein identification, assessment, and insertion in all sites to decrease risks of cannulation failure, arterial puncture, hematoma, pneumothorax, and hemothorax (refer to Standard 21, *Vascular Visualization*).
2. Use a risk/benefit approach to site selection based on patient physiology, vascular history, infusion needs, and emergent nature of insertion:
 - a. Jugular approach: associated with greater first-time insertion success, fewer needle punctures, and lower mechanical complications on insertion.⁴⁹ (III)
 - b. Consider low internal jugular vein or brachiocephalic to improve first-time insertion success, securement, and patient comfort, and reduce complications such as thrombosis and infection.^{18,50} (IV)
 - c. Femoral approach: associated with higher risk of infection but easily accessed with use of ultrasound in emergent/short-term situations and when all other sites are exhausted.^{50,51} (V)
 - d. Axillo-subclavian approach: associated with lower risks of infection and of symptomatic deep vein thrombosis (DVT) but may be associated with increased mechanical complications on insertion (eg, pneumothorax if inserted

medially). DVT and stenosis risk increases with long-term use of the subclavian site.⁴⁹ (IV)

- e. Use ultrasound-guided lateral axillo-subclavian or internal jugular approach to reduce risk of pinch-off syndrome and to avoid acute angle of catheters inserted into the internal jugular vein (refer to Standard 32, *Vascular Access Device Insertion*).
- f. Avoid placing a CVAD via the subclavian vein for patients with CKD (refer to Standard 32, *Vascular Access Device Insertion*).

D. Tunneled Noncuffed Central Venous Catheters

1. Consider atypical insertion of PICC (tunneled non-cuffed central venous catheter [CVC]) as an alternative to tunneled cuffed central venous catheter or when peripheral veins of the upper and lower limbs are insufficient to accommodate the catheter required for medical treatment.
 - a. Intravenous access is via a large vein of the chest (internal jugular or brachiocephalic); the catheter is predominantly tunneled to exit the anterior chest wall; however, alternative exit sites can be determined based on individual patient preference and/or risk factors.⁵² (IV)
2. Consider tunneling a PICC from superficial femoral vein to mid thigh when upper limb PICC insertion is not possible.⁵³⁻⁵⁶ (IV)
 - a. Advance the catheter tip to inferior vena cava/right atrial (IVC/RA) junction (catheter tip should sit just above diaphragm) (refer to Standard 22, *Central Vascular Access Device Tip Location*).
 - b. Insertion of mid thigh femoral catheter can be safely performed at the bedside.
 - c. Recognize and accept potential risk/benefit of suboptimal catheter tip location in larger adult patient, as current non-cuffed catheters may be of insufficient length to ensure tip advancement above the level of diaphragm. (Committee Consensus)

E. Tunneled Cuffed Central Venous Catheters and Implanted Vascular Access Port

1. Collaborate with the health care team and patient in assessment and site selection for the insertion of tunneled, cuffed catheters and implanted vascular access ports.^{4,39,44} (III)
2. Select internal jugular vein in preference to subclavian and femoral vein.^{49,57,58} (III)
3. Use ultrasound to provide thorough assessment of chest veins (subclavian, internal jugular, and brachiocephalic), improve insertion success, and reduce risk of insertion-related complications (arterial puncture, hematoma, pneumothorax, and hemothorax) (see Standard 21, *Vascular Visualization*).^{59,60} (III)
4. Consider a tunneled, cuffed CVAD for continuous long-term infusion therapy (eg, antineoplastic therapy, PN).^{4,39} (II)

5. Consider use of an implanted vascular access port in patients who require infrequent/intermittent vascular access.^{4,39,44} (III)
 - a. Arm ports are an alternative site; however, compared to chest wall ports, they have an increased risk of post-insertion complication such as thrombosis (see Standard 50, *Catheter-Associated Thrombosis*).⁶¹⁻⁶³ (II)
6. Consider use of nonconventional intravenous access sites (eg, recanalization, intrahepatic, and trans-lumbar) by experienced interventional radiologists for patients in whom traditional venous access sites have been exhausted, such as those patients with end stage renal disease.⁶⁴ (IV)

VIII. Arterial Catheters

- A. Insert an arterial catheter for hemodynamic monitoring, obtaining blood samples, and analyzing blood gas in critically ill patients.⁶⁵ (IV)
- B. Use the smallest gauge catheter possible for radial arterial access to reduce the risk of complications.⁶⁵ (IV)
- C. Use ultrasound for arterial catheter insertion to reduce insertion-related complications (refer to Standard 21, *Vascular Visualization*; Standard 32, *Vascular Access Device Insertion*).
 1. Consider use of smart glasses to improve first-time insertion success in pediatric patients requiring arterial catheter insertion.⁶⁶ (III)
- D. Assess the circulation to the hand prior to puncturing the radial artery; perform a physical examination of hand circulation (assess radial and ulnar pulses with the Allen test, pulse oximetry, or a Doppler flow study). Review the medical history (eg, trauma, previous radial artery cannulation, radial artery harvesting); assess for the use of anticoagulants (refer to Standard 41, *Blood Sampling*).
- E. For adults, the radial artery is the most appropriate access for percutaneous cannulation.⁶⁷ (V/AP)
- F. For pediatric patients, use the radial, posterior tibial, and dorsalis pedis arteries. The brachial artery is not used in pediatric patients due to the absence of collateral blood flow. (AP)

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26. IMPLANTED VASCULAR ACCESS PORTS

Standard

- 26.1 Skin antisepsis is performed prior to each access of an implanted vascular access device port.
- 26.2 Implanted vascular access devices (ports) are accessed only with noncoring needles. Only a power injectable noncoring needle is used with power-injection equipment for radiologic imaging in accordance with manufacturers' directions for use.

26.3 A sterile dressing is maintained over the access site if the port remains accessed.

Practice Recommendations

- A. Assess patient needs and preferences related to pain management during port access (refer to Standard 30, *Pain Management for Venipuncture and Vascular Access Procedures*).
- B. Access a patient's implanted vascular access port, unless contraindicated (eg, existing complication with the device), in preference to insertion of an additional vascular access device (VAD) when intravenous access is required. (Committee Consensus)
- C. Adhere to Aseptic Non-Touch Technique (ANTT®) during port access (refer to Standard 19, *Aseptic Non Touch Technique [ANTT®]*).
 1. Assess port site in preparation for port access: observe/palpate for swelling, pain, erythema, and drainage; presence of venous collaterals on the chest wall that may signal occlusion; erosion of the portal body through the skin; or signs of catheter-associated deep vein thrombosis (CA-DVT). If present, do not access port and collaborate with the health care team for further evaluation (see Standard 47, *Vascular Access Device-Related Infection*; Standard 50, *Catheter-Associated Thrombosis*).¹⁻⁵ (V)
 2. Perform skin antisepsis and allow to fully dry prior to port access (refer to Standard 31, *Vascular Access Site Preparation and Skin Antisepsis*).
 3. Adhere to either Standard-ANTT or Surgical-ANTT during port access.
 - a. Don sterile gloves to palpate or locate port site after skin antisepsis and prior to insertion of noncoring needle (see Standard 19, *Aseptic Non Touch Technique [ANTT®]*).^{3,4,6-8} (V)
- D. Access the port with the smallest-gauge noncoring needle to accommodate the prescribed therapy; use of a safety engineered noncoring needle is recommended and required in some jurisdictions (see Standard 16, *Medical Waste and Sharps Safety*).⁷ (V)
 1. Reduce the risk of needle dislodgement after access; use appropriate length that allows the external components (eg, wings/disc) to sit level with the skin and securely within the port hub (needle touches bottom of port upon insertion).^{2,7,9} (V)
 2. Orient the bevel of the noncoring needle in the opposite direction from the outflow channel where the catheter is attached to the port body. In vitro testing demonstrates that a greater amount of protein is removed when flushing with this bevel orientation.^{7,10-12} (IV)
 3. Replace the noncoring needle according to manufacturer's directions for use or in accordance with organizational procedures; there is insufficient evidence to recommend the frequency of replacement

- of the noncoring needle when the port is used for a continuous infusion.³ (V)
4. Consider use of a needle insertion assistive device, which may improve first-attempt success with insertion of the noncoring needle into the port.^{9,13} (V)
 5. Use the manufacturer-recommended catheter when accessing an implanted port with a funnel design for apheresis (refer to Standard 29, *Vascular Access and Therapeutic Apheresis*).
- E. Flush and lock the port to assess function and maintain patency.
1. Ensure presence of a blood return upon insertion of a noncoring needle and prior to each infusion to ensure patency (refer to Standard 38, *Flushing and Locking*).
 2. There is insufficient evidence to recommend the optimal frequency, solution, or volume to maintain the patency of implanted vascular access ports not accessed for infusion (refer to Standard 38, *Flushing and Locking*).
 - a. Use at least 10 mL of 0.9% sodium chloride (adult).
 - b. Use of 0.9% sodium chloride alone may be as effective as heparin in maintaining patency.
 - c. Extending maintenance flushing to every 3 months with 10 mL of 0.9% sodium chloride and 3 or 5 mL of heparin (100 units/mL) was found to be safe and effective in maintaining patency.
 - d. Flush accessed but non-infusing implanted vascular access ports daily.
- F. Use a transparent semipermeable membrane (TSM) dressing that covers the noncoring needle and access site when the port is accessed.^{6,8} (V)
1. Change the TSM dressing at least every 7 days; if gauze is used over the noncoring needle and access site, change the dressing every 2 days (refer to Standard 39, *Vascular Access Device Post-Insertion Care*).
 - a. If gauze is used under the TSM dressing to solely support the wings of a noncoring needle, does not obscure the access site, and its integrity is not compromised (eg, not visibly soiled and remains free of moisture, drainage, or blood), change the TSM dressing at least every 7 days. (Committee Consensus)
 2. Consider chlorhexidine-containing dressings in adults and patients over 2 months of age. Guidelines for oncology patients suggest use of a chlorhexidine-containing dressing around the needle insertion site based on duration of infusions exceeding 4 to 6 hours (see Standard 47, *Vascular Access Device-Related Infection*).^{6,7} (V)
 3. Secure the noncoring needle to reduce the risk for needle dislodgement and subsequent risk for infiltration/extravasation (eg, sterile tape strips), assuring protection of skin integrity around the insertion site.^{7,8} (V)
- G. Confirm that a port and the noncoring needle are indicated for power injection before using it for this purpose.^{2,14} (V)
1. Ports are assigned a unique device identifier, an alphanumeric code, specific to that product. When used in the patient's health record in a retrievable manner, this code is used to obtain all information about that device (eg, product and manufacturer name, lot and serial number, date manufactured).¹⁵⁻¹⁷ (IV)
 2. Other identification methods include review of operative procedure documentation, presence of identification (eg, cards) provided by the manufacturer, radiographic scout scan, and palpation of the port; however, do not use palpation of the port as the only identification method, as not all power-injection-capable ports have unique characteristics identifiable by palpation. (Committee Consensus)
 3. During and after power injection, be aware of the potential for catheter rupture, which can lead to extravasation, catheter fragment embolism, and the need for port removal and replacement. Suspect catheter rupture if the patient shows signs of localized swelling or erythema or reports pain (refer to Standard 48, *Catheter Damage [Embolism, Repair, Exchange]*).
- H. Consider an annual chest radiograph-imaging assessment of port position and integrity (see Standard 48, *Catheter Damage [Embolism, Repair, Exchange]*).^{18,19} (IV)
- I. Provide patient/caregiver education:
1. Prior to port implantation surgery, provide information about: procedure, type of port, routine care (flushing frequency, ANTT during access, use for power injection, if indicated), and identification of potential complications and interventions.^{15,16,20-22} (IV)
 2. Provide written information about ports before insertion to decrease anxiety and improve knowledge.^{3,16,17,20,22,23} (IV)
 3. Home infusion: educate patient/caregiver to check dressing daily, manage activities of daily living (bathing, clothing, seatbelts) to prevent needle dislodgement, report signs or symptoms of complications (pain, burning, stinging, or soreness) and follow-up actions (see Standard 8, *Patient Education*).^{3,17,22,24} (V)
 4. Post-treatment device: provide information and education on port removal versus maintenance and the potential for complications related to prolonged dwell time (eg, infection, thrombosis, tip migration).^{1,6,23,25-31} (III)

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27. VASCULAR ACCESS AND HEMODIALYSIS

Standard

- 27.1 Selection of the most appropriate vascular access device (VAD) for hemodialysis occurs in collaboration with the patient/caregiver and the health care and nephrology teams based on the projected treatment plan.
- 27.2 Hemodynamic monitoring, venipuncture, or blood pressure measurement are not performed on the extremity with an arteriovenous fistula (AVF) or arteriovenous graft (AVG).
- 27.3 Only nephrology/dialysis clinicians access hemodialysis VAD lumens unless there is a life-threatening condition

and/or when there is validation of clinician training and competency.

Practice Recommendations

- A. Use principles of vessel health and preservation for both peripheral and central vasculature for patients on hemodialysis or likely to require future hemodialysis.^{1,2} (IV)
 1. Begin planning for hemodialysis vascular access with the patient and family beginning at chronic kidney disease (CKD) stage 4 (glomerular filtration rate [GFR] <30 mL/min/1.73m²).^{1,3,4} (IV)
 - a. Preserve vessels in patients with acute kidney injury; in the 2-year period prior to hemodialysis, acute kidney injury was associated with significantly lower odds of transitioning to hemodialysis with an AVF/AVG.
 2. Determine the access method in preparation for hemodialysis; the order for access preference is AVF, AVG, and long-term central venous access device (CVAD) (tunneled, cuffed hemodialysis catheter); nontunneled hemodialysis CVADs may be placed for short-term immediate hemodialysis needs in the hospitalized patient.^{1,5-8} (IV)
 3. Limit use of temporary, non-cuffed, nontunneled hemodialysis CVADs to a maximum of 2 weeks due to increased risk for infection and consider their use only in patients with need for emergent access.^{1,9} (IV)
 - a. Recognize that some temporary dialysis catheters have a center third lumen appropriate for infusions. This lumen has a 1% recirculation rate during dialysis or continuous renal replacement therapy (CRRT). Collaborate with the interprofessional team to determine optimal timing of infusions, as well as any filter changes that may be necessary on the dialysis equipment. Organizational policies and procedures should outline which clinicians are responsible for care of the infusion lumen with regard to flushing, tubing, and needleless connector changes.⁹ (V)
 - b. Avoid placement of a CVAD via the subclavian vein and avoid peripherally inserted central catheters (PICCs) and midlines whenever possible due to an increased risk for thrombosis, central vein stenosis, and occlusion; the order of preference for CVAD placement is internal jugular, external jugular, femoral, subclavian, and lumbar vein.¹⁰ (IV)
 - i. PICC placement before or after hemodialysis initiation is associated with failure to transition to a working fistula; consult with the nephrology team, when available, before PICC placement.
 4. AVF or AVGs should be created as distally as possible in patients with heart failure, as fistula/graft formation affects cardiac function and can worsen heart failure.¹¹ (V)
- a. Evaluate life expectancy, surgical risk, patient preferences, and quality of life for older patients requiring hemodialysis when considering an AVF or AVG vs a hemodialysis catheter.^{1,2,7,12,13} (IV)
5. For both phlebotomy and peripheral intravenous catheter (PIVC) placement, use the dorsum of the hand whenever possible, regardless of arm dominance, in patients with an actual or planned dialysis fistula or graft. Avoid use of forearm and upper arm veins, including the antecubital fossa, for phlebotomy or peripheral catheter placement in patients with an actual or planned dialysis fistula or graft.¹⁴ (V)
- B. Provide access, dressing changes, and site care for hemodialysis access devices, including AVFs and AVGs (when dressings are present), in accordance with Aseptic Non Touch Technique (ANTT®)¹⁵⁻¹⁹ (refer to Standard 19, *Aseptic Non Touch Technique [ANTT®]*). (I)
 1. Use a rope ladder or buttonhole technique for needle insertion into the AVF/AVG; while the buttonhole technique is less painful for patients, the risk for infection may be higher as compared to rope ladder technique.
 2. Consider use of point-of-care ultrasound to assess AVF vessel maturation and vessel abnormalities and to assist with difficult AVF access.
 3. Use an alcohol-based chlorhexidine solution as a first-line antiseptic solution for VAD exit site care; if sensitive to chlorhexidine, use povidone iodine preferably with alcohol.
 4. Consider the use of a chlorhexidine-containing dressing as a strategy to reduce infection risk.
 5. In addition to site cleansing, apply topical antiseptic or antimicrobial barrier at the CVAD exit site during the site care and catheter dressing change if not using a chlorhexidine-containing dressing; alternatives include triple antibiotic ointment (bacitracin/neomycin/polymyxin B).
 - a. Recognize that ingredients in antibiotic and povidone-iodine ointments may interact with the chemical composition of certain catheters; check with the catheter manufacturer to ensure that the selected ointment will not interact with the catheter material.
 - b. Avoid use of mupirocin ointment at the catheter insertion site due to the risks of facilitating mupirocin resistance and the potential damage it can cause to polyurethane catheters.
- C. Provide hub care in accordance with ANTT (refer to Standard 19, *Aseptic Non Touch Technique [ANTT®]*).
 1. Wear appropriate personal protective equipment (PPE) with additional thought to wearing a mask (both clinician and patient) to reduce the risk of droplet transmission of oropharyngeal flora.¹⁴ (V)
 2. Disinfect hemodialysis catheter lumens before and after every access. If a dead-end cap is used, disinfect the connection between the cap and the lumen

before removing the dead-end cap. Disinfect the threads and sides of the lumen using friction to remove any residue. If a closed system, high-flow needleless-style connector is used, follow the manufacturer's directions for cleaning and changing of caps (see Standard 34, *Needleless Connectors*).^{1,20,21} (II)

3. For patients receiving hemodialysis through a CVAD, consider the use of an antimicrobial barrier cap as a strategy to reduce bloodstream infections (Refer to Standard 47, *Vascular Access Device-Related Infection*).

D. Lock hemodialysis CVADs with heparin solution or low-concentration citrate (<5%); consider locking CVAD with tissue plasminogen activator (tPA) prophylactically once per week to reduce the risk of CVAD occlusion; other antimicrobial solutions may be used in accordance with organizational policies, procedures, or practice guidelines (see Standard 38, *Flushing and Locking*). When locking with heparin, dose to the fill volume stamped on the lumen. Typical concentration is 1000 u/mL in adults. Consider using lower-concentration heparin to decrease systemic exposure and risk for heparin-induced thrombocytopenia (HIT).^{1,16,22,23} (IV)

1. Choose a locking solution based upon nephrology team preferences due to inadequate evidence to demonstrate a difference between solutions.

E. Conduct ongoing surveillance for bloodstream infections and other dialysis adverse events and share outcomes with the health care team (refer to Standard 6, *Quality Improvement*).

F. Promote patient engagement through activities, including shared decision-making and empowerment, such as monitoring clinician infection prevention practices (eg, hand hygiene before each hemodialysis access procedure); provide patient education as an integral part of patient engagement. Address the following patient education topics^{1,7,21,24-28}: (IV)

- a. Hemodialysis vascular access when the patient is at CKD stage 4
- b. Vein preservation
- c. Infection prevention
- d. Protection and care of AVF, AVG, or CVAD
- e. Assessment and management when away from the dialysis unit
- f. Signs/symptoms of VAD dysfunction, infection, or other complications and how to report.

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28. UMBILICAL CATHETERS

Standard

28.1 Assess daily the continued clinical need for the umbilical catheter. Promptly remove the catheter when it is no longer needed.

Practice Recommendations

- A. Establish organizational guidelines to guide appropriate use of umbilical arterial catheters (UACs) and umbilical venous catheters (UVCs), including gestational age and birth weight, severity of illness, and intended therapy to minimize unnecessary use and potential complications.¹⁻⁷ (II)
 1. Use UACs for obtaining frequent blood samples and continuous blood pressure monitoring.
 2. Use UVCs for the infusion of medications and solutions, parenteral nutrition (PN), and blood products.
 3. Maintain patency and reduce risk of thrombosis by continuous infusion of heparin 0.25 to 1.00 unit/mL (total dose of heparin: 25–200 units/kg/d).
 4. Insert smallest gauge catheter to reduce risk of complications.
- B. Perform skin antisepsis prior to insertion.⁸⁻¹¹ (II)
 1. Use povidone-iodine, alcohol-based chlorhexidine solution, or aqueous chlorhexidine solution.
 2. Use both aqueous and alcohol-based chlorhexidine with caution in preterm neonates, low birthweight

neonates, and within the first 14 days of life due to risks of chemical burns to the skin. Systemic absorption is possible due to skin immaturity; however, systemic effects are not documented. Use chlorhexidine antiseptic agents with caution in infants under 2 months of age. Studies have not established one antiseptic solution as superior for safety or efficacy in neonates.

3. Avoid the use of tincture of iodine in premature neonates (<32 weeks) due to the potential deleterious effect on the neonatal thyroid gland (refer to Standard 31, *Vascular Access Site Preparation and Skin Antisepsis*).
 4. Remove antiseptics after the procedure is complete using sterile water or saline (refer to Standard 31, *Vascular Access Site Preparation and Skin Antisepsis*).
- C. Place the catheter tip for:
 1. UACs in the thoracic portion of the descending aorta below the aortic arch (ie, between the thoracic vertebrae 6 and 9 for high position) or below the renal arteries and above the aortic bifurcation into the common iliac arteries (ie, between lumbar vertebrae 3 and 4 for low position).¹² (V, A/P)
 - a. The high position is associated with decreased risk of complications.^{12,13} (IV, A/P)
 2. UVCs in the inferior vena cava (IVC) at, or superior to, the diaphragm below the junction with the right atrium.^{2,14} (IV)
 - a. Emergently placed UVCs with the tip sited in a noncentral position should be replaced with more definitive intravenous access as soon as practicable, due to higher risk of infection and complications.^{1,2,15,16} (IV)
 - D. Estimate the length of catheter to be inserted by anatomical measurements and equations based on body weight, or with other research-based protocols to achieve successful tip placement. However, these methods are relatively unreliable and catheter tip position should be confirmed with imaging prior to use.^{2,14,17-23} (I)
 - E. Use radiography, echocardiography, or ultrasonography to confirm catheter tip position before use.^{2,21,22} (I)
 1. For UVC, obtain anteroposterior (AP) radiographic view of the chest and abdomen for tip location at or slightly cephalad to the diaphragm. Use of the cardiac silhouette is reported to be more accurate than positioning based on vertebral bodies. When an AP view is insufficient to identify the catheter pathway and tip location, a lateral or cross-table view may be needed, or alternative form of imaging, such as ultrasound.^{21,24-26} (II)
 2. For UAC, obtain AP radiographic view of the chest and abdomen to verify tip location. Various formulas exist to guide approximate catheter length; however, observational studies have demonstrated low level of accuracy.²² (V)

3. Consider real-time ultrasound-guided (USG) UVC insertion to reduce mispositioned catheter tips at insertion.^{2,15,26-30} (I)
 4. Ultrasound imaging using parasternal long- and short-axis views for UVC tip location compares favorably to radiography. Injection of normal saline through the catheter may assist in visualizing the exact tip location.^{21,24,25,31,32} (IV)
 5. Neonatal echocardiography may be superior to chest and abdominal radiography in extremely low-birthweight neonates or for identifying malpositioned catheters.³³⁻³⁵ (IV)
 6. Consider regular surveillance of catheter tip position, as malposition is common, particularly in patients of low-birthweight and diagnosis of necrotizing enterocolitis.^{2,12,29,33,36,37} (II)
- F. Use sterile tape to secure the UVC or UAC based on promotion of security, skin integrity, decreasing complications such as infection, and ease of utilization and management. There is currently a lack of evidence demonstrating the superiority of one method over others. These catheters are at risk for significant complications resulting from migration and dislodgement, such as extravasation, thrombosis, and necrotizing enterocolitis. Powered randomized controlled trials (RCTs) are needed to establish the superiority of one securement method over another.^{2,13,38} (II)
1. Organizational protocols should be developed also recognizing that neonates are at high risk for catheter-associated skin injuries (refer to Standard 52, *Catheter-Associated Skin Injury*).
- G. Do not use topical antibiotic ointment or creams on umbilical sites due to the risk of fungal infections and antimicrobial resistance.³⁹ (IV)
- H. Monitor for signs and symptoms of potential complications, including, but not limited to, bleeding from the umbilical stump, extravasation, hemorrhage, air embolism, infection, thrombosis, pleural effusion, pericardial effusion, cardiac tamponade, cardiac arrhythmias, liver damage, and peripheral vascular constriction. Anticipate the use of point-of-care ultrasound, as available, or echocardiogram for diagnostic purposes.^{1,3,12,32,39} (III)
- I. Consider implementing a bundle of care to reduce risk of umbilical catheter-associated bloodstream infection.⁴⁰ (IV)
- J. Remove umbilical catheters promptly when no longer needed or in the event of a complication.
1. Consider limiting UVC dwell time to 7 to 10 days; risks of infectious and thrombotic complications are increased with longer dwell times.¹⁻³ (III)
 2. Consider UVC removal at 4 days, followed by insertion of a peripherally inserted central catheter (PICC) for continued infusion as one infection-preventive strategy, particularly for patients at greater risk of infection.^{2,3,6,28,39,41} (III)
 3. Consider limiting UAC dwell time to no more than 5 days.³ (IV)

4. A small cohort study demonstrated peripheral arterial lines might be as effective with fewer complications than UAC. A larger, randomized controlled trial is needed to confirm this.⁴² (V)
5. Remove umbilical catheters slowly over several minutes after placing an umbilical tie around the stump. For removal of UACs, the final 5 cm of catheter length should be slowly withdrawn at 1 cm/minute to allow vessel constriction. (V, A/P)

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29. VASCULAR ACCESS AND THERAPEUTIC APHERESIS

Standard

29.1 The most appropriate vascular access device (VAD) for therapeutic apheresis is selected in collaboration with the patient/caregiver and the interprofessional team based on the projected treatment plan.

Practice Recommendations

A. Choose the most appropriate VAD for therapeutic apheresis based on the type of apheresis procedure (centrifugation-based or filter-based systems); adequacy of superficial and deep peripheral veins; patient acuity; anticipated duration and frequency; inpatient vs outpatient; patient preference; underlying disease state(s);

and availability of staff and resources to obtain vascular access.¹⁻³ (IV)

- B. Consider either peripheral or central VADs for therapeutic apheresis; peripheral venous access is the primary access method in European countries, while central vascular access devices (CVADs) are used primarily in North America, South America, and Central America, and increasingly in Asia.^{2,4,5} (V)

1. Consider an ultrasound-guided peripheral intravenous catheter (PIVC) for apheresis in selected patients, as peripheral insertion is associated with fewer risks of complications compared to CVADs for apheresis and may decrease the need for CVADs.^{4,6-9} (IV)
2. Insert 2 PIVCs for peripheral apheresis: 1 for access or withdrawal of blood for apheresis and 1 for return of the patient's cells and replacement fluid. Single-needle procedures have been used for patients with limited access but may significantly increase procedure time.¹⁰ (IV)
3. Use a large-gauge PIVC or dialysis cannula (eg, 16- to 20-gauge) in the antecubital vein or other large veins, such as the basilic or cephalic veins, in the forearm for access and in smaller veins for the return.^{2,5,11} (III)
4. In one study, direct venipuncture of the femoral vein was used in a patient with unsuitable upper extremity vessels.¹² (V)
5. Peripheral vein access is not recommended in young children due to small veins but may be possible with older children and adolescents.¹ (IV)
6. There have been case reports of small-gauge CVADs being used successfully in neonates.¹³ (V)

- C. Consider the benefits of dialysis-capable CVADs that provide reliable blood flow, ability to withstand high negative pressures during blood draws, and a catheter size of at least 11.5 French (Fr) for adults.^{2,3,14} (IV)

1. Appropriate catheter sizes for use of a nontunneled or tunneled cuffed CVAD in pediatric patients range from 6.0 to 7.0 Fr for patients weighing less than 10 kg, 6.0 to 8.0 Fr for patients weighing between 10 and 30 kg, 8.0 to 10.0 Fr for patients weighing between 30 and 50 kg, and 11.5 Fr or larger for children weighing more than 50 kg. Consider vessel size as well when selecting catheter size.^{3,14} (IV)
2. Peripherally inserted central catheters (PICCs) are not appropriate for apheresis due to small catheter gauge and higher failure rates.² (IV)
3. Midline catheters may provide sufficient flow rates. New catheters are required for each procedure. Follow manufacturer's directions for use.¹⁵ (IV)
4. General recommendations for locking CVADs used for apheresis include high-concentration heparin and sodium citrate (see Standard 38, *Flushing and Locking*).^{2,16,17} (IV)
 - a. Heparin-induced thrombocytopenia (HIT) was identified as a particular risk in patients with

multiple myeloma who required stem cell harvesting for autologous hematopoietic stem cell transplantation. An unusually high frequency of HIT was identified (4%).¹⁸ (IV)

- D. Consider specially designed apheresis implanted vascular access ports for patients requiring long-term treatment; specialized port design allows for high flow.^{2,3,19,20} (V)
1. Infection, thrombotic occlusion, migration, and fibrin sheath and sludge formation are complications associated with implanted vascular access ports.^{19,21,22} (IV)
 2. Determine port access device requirements based on port type and assess proper positioning prior to beginning apheresis procedures.^{23,24} (V)
- E. Avoid arteriovenous fistulas (AVFs) and arteriovenous grafts (AVGs) for long-term apheresis; the failure rate associated with AVFs is high.^{2,25} (V)

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30. PAIN MANAGEMENT FOR VENIPUNCTURE AND VASCULAR ACCESS PROCEDURES

Standard

- 30.1 All patients undergoing painful procedures have the right to safe and effective pain management.
- 30.2 Appropriate strategies are implemented to reduce pain associated with needle-related procedures (eg, vascular access device [VAD] insertion, venipuncture, implanted vascular access port access, implanted intrathecal drug delivery access) based upon assessment of age, developmental level, patient condition, and engagement of patients and families to determine preferences.

Practice Recommendations

- A. Educate patients and caregivers about realistic expectations about the potential for pain or discomfort involved with procedures and engage them in decision-making to reduce pain.¹ (IV)
- B. Employ interventions to increase first-time success with VAD insertion (see Standard 21, *Vascular Visualization*; Standard 25, *Vascular Access Device Planning and Site Selection*; Standard 32, *Vascular Access Device Insertion*).²⁻⁵ (IV)
- C. Identify barriers that influence clinician's use of pain management strategies. These might include underestimation of procedural pain, focusing on the technical task, time constraints, lack of orders/protocols, workload, and cost.^{2,6,7} (II)
 1. Preterm infants have sensitive developing nervous systems; long-term changes in response to the pain and stress involved with preterm hospitalizations have been identified (eg, reduced white matter microstructure and subcortical gray matter, dorsal horn central desensitization).⁸⁻¹⁰ (IV)
 2. Repeated needle-related procedures, particularly in early to middle childhood, increase the risk for development of long-term consequences such as procedural anxiety and hospital avoidance.^{11,12} (III)
 3. Adolescents experience similar values of pain and distress associated with peripheral intravenous catheter (PIVC) insertion yet receive less in terms of pain relief interventions.¹³ (IV)
- D. Use age and developmentally appropriate pain assessment tools.
 1. Infants: crying, facial expression, and body posture/limb movements are indicative of pain; a variety of pain evaluation tools are available, including the Neonatal Infant Pain Scale (NIPS); Premature Infant Pain Profile (PIPP); Neonatal Pain Agitation and Sedation Scale (NPASS); Face, Legs, Activity, Cry, Consolability (FLACC); Modified Behavioral Pain Scale (MBPS); and the Newborn Comfort Behavior Scale (NCBS).¹⁴ (IV)
 2. Toddlers: behaviors such as facial expression, bodily movement, and crying; FLACC may be used.¹⁵ (IV)
 3. Preschoolers and school-aged children can self-report pain; FACES® pain rating scale; FLACC may be used in conjunction with self-report for preschoolers; numerical pain scale for older children.¹⁵ (IV)
 4. Children with intellectual disabilities may be unable/less able to communicate pain verbally and experience more pain and anxiety during needle-related procedures compared to children without disability; FLACC may be used.¹⁶ (IV)
 5. Adults: patient self-report is the most valid and reliable indicator of pain; asking about pain in different ways may be necessary; for adults with mild-to-moderate cognitive impairment, tools such as Pain in Advanced Dementia (PAINAD) and Doloplus 2 are recommended.¹⁷ (II)

E. Provide appropriate pain management strategies with every painful procedure for neonates/infants.

1. Involve parents when present in the neonatal intensive care unit (NICU) and when the infant is exposed to a painful procedure. Educate parents about infant pain and their role in pain management; consider timing of procedures/visitation policies to allow for parental involvement.¹⁸⁻²¹ (IV)
2. Use nonpharmacologic interventions (sucrose/glucose, non-nutritive sucking (pacifier), breastfeeding, olfactory/auditory stimulation, skin-to-skin care ["Kangaroo Care"], therapeutic massage, swaddling, facilitated tucking [FT], acupressure, white noise/music/lullabies), as they are safe, effective, and easily applied. FT, oral sucrose, and kangaroo care decreased behavioral and physiologic pain response alone and in combination with other behavioral and environmental interventions in preterm infants.^{8,10,14,22-35} (I)
3. Avoid lidocaine/prilocaine cream, as it is inferior to sucrose or breastfeeding in controlling pain, and there are safety concerns, including methemoglobinemia and increased skin blanching.^{36,37} (I)
4. Consider culturally based strategies (eg, acupuncture, foot massage/reflexology, aromatherapy). Positive results are reported from various countries; however, it is recognized that such interventions are difficult to standardize and to measure impact.³⁸ (IV)
5. Consider massage therapy; it may be effective for neonates during procedural pain based upon a literature review. However, there is substantial variation in body part(s) massaged, duration, and intensity of massage; the risk for inappropriate pressure is a risk for potential trauma.³⁹ (I)

F. Provide nonpharmacologic pain management strategies to children, with attention to growth and developmental level:

1. Encourage parents to take an active role in managing a child's procedural pain to reduce child's fear, anxiety, and distress; the presence of parents was beneficial for the child's pain response, especially when the parents successfully implement the interventions that they were instructed to do (eg, distraction).⁴⁰⁻⁴² (I)
 - a. Instruct parents to avoid restraining or "holding down" a child during the procedure, which may be inadvertently forceful or punitive and increase fear; rather emphasize "hugging" and use of distraction techniques.⁴³ (V)
2. Use distraction techniques feasible for implementation in the health care setting and desirable to the child:
 - a. The use of any type of distraction technique is associated with reduced anxiety and perception of procedural pain in school-aged children and children with cancer. Reported distraction

techniques include television, DVDs, videos, computers/tablets, smartphones, video games, virtual reality (VR), humanoid robots, therapeutic clowning, breathing exercises, hypnosis, and toys. Despite low quality of evidence among systematic reviews, the efficacy of such interventions is supported.^{42,44-49} (I)

- i. Distraction was not effective for children who have received solid organ transplants and required venipuncture; frequent exposure to painful procedures may have impacted the ability to detect a reduction in pain using distraction.⁵⁰ (III)
 - b. "Peekaboo," blowing bubbles, and reading books are effective with toddlers.¹⁵ (II)
 - c. VR was effective in several populations (children ages 4-18; children with kidney disease undergoing venipuncture, intrathecal pump refills; pediatric oncology patients). VR is well-tolerated and well-liked by patients; however, the risk for cybersickness is a consideration.⁵¹⁻⁶² (I)
 - d. Music intervention provided an analgesic effect in both infants and children; classical, kids', and pop music have the greatest impact on alleviating pain delivered via headset, earphones, or speakers.³⁴ (I)
 - e. Use of a vibrating cold device can provide distraction, reduce anxiety, and decrease self-reported, parent-reported, and observer-reported pain through blocking of pain impulses consistent with gate control theory of pain management.⁶³⁻⁶⁷ (I)
 - f. Massage therapy may alleviate distress associated with burns and cancer.⁶⁸ (I)
 - g. Acupressure was significantly associated with reduced pain with venipuncture in a single randomized controlled trial (RCT); specific clinician training in acupressure is required.⁶⁹ (III)
- G. Consider application of ice for several minutes prior to venipuncture, as this was cost-effective, simple, and efficacious in reducing pain in children.^{70,71} (III)
- H. Provide an appropriate pharmacologic pain management strategy for children.
1. All anesthetics were effective in pain prevention in a large RCT. Anesthetics included 10% lidocaine spray allowed to act for 5 minutes; lidocaine HCL 2% gel onset of action at 5 minutes and lasts 20-30 minutes; lidocaine/prilocaine for 60 minutes; ethyl chloride 5-second spray; and lidocaine cream for 30 minutes. Application time and costs are considerations when selecting the anesthetic.⁷² (III)
 2. Topical lidocaine/prilocaine for PIVC insertion was more effective than subcutaneous needleless lidocaine; however, needleless lidocaine should be considered when a delay in treatment is contraindicated.^{73,74} (III)

3. Vapocoolant spray is associated with a significant reduction in pain compared to placebo.^{75,76} (I)
- I. Provide appropriate pain management interventions to adults with consideration for patient preferences.
 1. Recognize that some patients may have a significant fear of needles (ie, needle phobia) and that pain management strategies may reduce fear.⁷⁷ (IV)
 2. Nonpharmacologic interventions:
 - a. Use of heat packs reduced pain and anxiety before PIVC insertion.⁷⁸ (III)
 - b. Cold therapy before port needle removal was associated with reduction in pain and anxiety; aromatherapy was associated with decreased pain during port needle access.^{79,80} (III)
 - c. Behavioral interventions such as distraction, relaxation, breathing exercises, hand massage.^{2,81} (IV)
 - d. Valsalva maneuver to alleviate the severity of pain in noncardiac patients; also avoid in patients with retinopathy and intraocular lens implantation due to rise in intraocular pressure.^{82,83} (I)
 - e. Cold and vibration.⁸⁴ (III)
 3. Pharmacologic interventions:
 - a. Injectable (eg, intradermal lidocaine) or topical (eg, lidocaine/prilocaine) anesthetic prior to PIVC insertion.⁸⁵⁻⁸⁸ (I)
 - i. Intradermal lidocaine (2% lidocaine most effective); bacteriostatic saline (containing benzyl alcohol) has analgesic properties but is not as effective as lidocaine.⁸⁵ (I)
 - ii. Lidocaine buffered with saline resulted in pain relief during peripherally inserted central catheter (PICC) insertion and was comparable to lidocaine buffered with bicarbonate.⁸⁹ (V)
 - iii. Topical diclofenac and topical ketamine were efficacious in pain reduction with PIVC insertion.⁹⁰⁻⁹² (III)
 - b. Vapocoolant to reduce pain during PIVC insertion and blood collection; recognize that it is associated with mild discomfort during application.^{75,76,93} (I)
 - c. Application of room-temperature lidocaine (1-2 mL) to the skin prior to a 1% lidocaine subcutaneous injection for bedside procedures insertion resulted in a small absolute reduction in pain scores, particularly for PICC insertion.⁹⁴ (III)

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31. VASCULAR ACCESS SITE PREPARATION AND SKIN ANTISEPSIS

Standard

- 31.1 Skin antisepsis is performed prior to vascular access device (VAD) insertion.
- 31.2 The intended VAD insertion site is visibly clean prior to application of an antiseptic solution; if visibly soiled, the intended site is cleansed with soap and water prior to application of antiseptic solution(s).

Practice Recommendations

- A. Remove excess hair at the insertion site if needed to facilitate application of VAD dressings. Use single-patient-use scissors or disposable-head surgical clippers; do not shave, as this may increase the risk for infection.^{1,2} (I)
- B. Evaluate patient history of any allergy or sensitivity to skin antiseptics (see Standard 52, *Catheter-Associated Skin Injury*).^{3,4} (I)
- C. Perform skin antisepsis using alcoholic chlorhexidine gluconate (CHG) as the preferred antiseptic solution.⁴⁻¹⁴, (I)
 1. Use an alcoholic CHG solution containing at least 2% chlorhexidine gluconate.^{10,15} (I)

2. Use an iodophor (eg, povidone-iodine) or 70% alcohol if there is a contraindication to chlorhexidine solution.^{4,7,11,12} (I)
3. Consider use of aqueous chlorhexidine if there is a contraindication to alcohol-based chlorhexidine (see Standard 52, *Catheter-Associated Skin Injury*).¹⁴ (I)
4. For preterm neonates, low-birthweight infants, and within the first 14 days of life¹⁶⁻¹⁹: (III)
 - a. Use povidone-iodine, alcohol-based or aqueous chlorhexidine solution.
 - b. Use both aqueous and alcohol-based chlorhexidine with caution, weighing the benefits versus the risks of chemical burns to the skin. Systemic absorption has been reported due to skin immaturity; however, systemic effects are not documented. Studies have not established one antiseptic solution as superior for safety or efficacy in neonates (see Standard 52, *Catheter-Associated Skin Injury*).^{16,20} (III)
 - c. Avoid the use of tincture of iodine due to the potential deleterious effect on the neonatal thyroid gland.^{17,20,21} (I)
 - d. Remove povidone-iodine after the procedure is complete using sterile water or saline; while there is no evidence of sustained toxicity resulting from CHG remaining on the skin, an aqueous formulation may require removal due to its soapy consistency, which may affect dressing adherence.^{16,20} (IV)
- D. Use a single-use applicator containing an antiseptic solution.^{4,8,21} (V)
 1. Follow manufacturers' directions for use to determine appropriate product application and dry times; always allow product to naturally dry completely without wiping, fanning, or blowing on skin.^{8,9} (V)
 2. Adhere to Aseptic Non Touch Technique (ANTT®) while performing skin antisepsis. (see Standard 19, *Aseptic Non Touch Technique [ANTT®]*).^{8,9} (V)

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32. VASCULAR ACCESS DEVICE INSERTION

Standard

- 32.1 A new, sterile vascular access device (VAD) is used for each catheterization attempt, including needle for venipuncture/arterial puncture and introducer.
- 32.2 The VAD is not altered outside the manufacturers' directions for use.
- 32.3 Appropriate tip location for central venous access devices (CVADs) is verified prior to use.
- 32.4 The patient and caregiver are educated about the rationale for VAD insertion and expectations during the procedure.

Practice Recommendations

I. Peripheral Intravenous Catheters (PIVCs): Short PIVCs, Long PIVCs, and Midline Catheters

- A. Consider implementation of a local PIVC insertion bundle to improve insertion success and reduce complications. Although no specific bundle has been defined, evidence supports application of local bundle to improve outcomes.¹⁻³ (I)
- B. Consider early referral to an infusion/vascular access specialist if patient assessment yields no visible or palpable veins.⁴⁻¹⁰ (IV)
 1. Use population-specific difficult intravenous access (DIVA) assessment tools to guide early referral to an infusion/vascular access specialist. Further research is needed in various clinical settings to ensure generalizability of these tools.^{5,7,8,10} (I)
- C. Use pain relieving measures to reduce insertion-related pain (refer to Standard 30, *Pain Management for Venipuncture and Vascular Access Procedures*).
- D. Use visualization technology to improve peripheral vein assessment, identification, and selection, particularly for patients with DIVA (refer to Standard 21, *Vascular Visualization*).
 1. Consider use of dynamic needle tip positioning to increase first-attempt and overall success rates of ultrasound-guided peripheral venous catheterization in pediatric patients.¹¹ (III)
- E. Choose a long PIVC as follows:
 1. When all aspects of a short PIVC are met, but the vessel is difficult to palpate or visualize with the naked eye, ultrasound guidance is recommended.¹²⁻¹⁵ (II)
 2. Evaluate depth of vessel when choosing a long PIVC to ensure sufficient catheter lies within vein. A small observational study in an adult emergency department demonstrated significant reduction in PIVC failure when two-thirds of the PIVC length was within the vein.^{12,13} (III)
 3. Long PIVCs should be used in well-monitored clinical environments, as few adequately powered

randomized controlled trials have investigated the safety and generalizability in all clinical settings.¹² (II)

- F. Use appropriate aids such as a single patient tourniquet, warming, or blood pressure cuff to promote vascular distention when inserting a PIVC.¹⁶ (IV)
- G. Adhere to principles of Aseptic Non Touch Technique (ANTT®) for PIVC insertion (refer to Standard 19, *Aseptic Non Touch Technique [ANTT®]*).
 - 1. Use Standard-ANTT for simple PIVC insertion.
 - a. Use single-patient-use tourniquets.^{17,18} (III)
 - b. Don a new pair of disposable, nonsterile gloves for PIVC insertion; do not touch/palpate the insertion site after skin antisepsis.
 - c. Use sterile gloves if re-palpation of the vein is necessary after skin antisepsis. Contamination of nonsterile gloves is well documented.³ (II)
 - 2. Consider Surgical-ANTT for more complex insertion techniques (eg, accelerated/Seldinger).
- H. Restrict PIVC insertion attempts to no more than 2 attempts per clinician. Multiple unsuccessful attempts cause pain to the patient, delay treatment, limit future vascular access, increase cost, and increase the risk for complications.^{1,4,5,19} (IV)
 - 1. After 2 unsuccessful attempts, escalate to a clinician with a higher skill level and technological support and/or consider alternative routes of medication administration. (Committee Consensus)
- I. Choose a midline catheter of appropriate length to achieve appropriate tip location relative to site of insertion.
 - 1. Adult: tip location should be at level of axilla.^{20,21} (IV)
 - 2. Neonates and pediatric patients: select an upper arm site using the basilic, cephalic, and brachial veins. Additional site selections include veins in the leg (eg, saphenous, popliteal, femoral) with the tip below the inguinal crease and in the scalp with the tip in the neck above the thorax (refer to Standard 25, *Vascular Access Device Planning and Site Selection*).^{22,23} (II)
 - 3. Measure baseline circumference of the extremity with a midline catheter upon insertion, noting location for future measurements to ensure consistent measurement. Assess circumference when edema or signs and symptoms of deep vein thrombosis (DVT) present, noting the location and characteristics of edema (refer to Standard 50, *Catheter-Associated Thrombosis*).
- J. Immediately remove the PIVC in the following situations:
 - 1. Suspected nerve damage: patient reports severe pain on insertion (ie, electrical shock-like pain) or paresthesia (eg, numbness or tingling) related to the insertion; promptly notify the provider (refer to Standard 45, *Nerve Injury*).
 - 2. Inadvertent arterial puncture: remove the catheter and apply pressure to the peripheral site until hemostasis is achieved. Assess circulatory status and, if impaired, notify the provider promptly.²⁴ (V)

II. CVADs

- A. Implement the central line bundle when placing CVADs (hand hygiene, skin antisepsis with alcohol-based chlorhexidine, maximal sterile barrier precautions, upper body insertion, if able) (refer to Standard 47, *Infection*).
 - 1. Use a standardized checklist to ensure adherence to mandatory insertion practices. The checklist should be completed by an educated health care clinician assisting with the CVAD procedure.^{25,26} (III)
 - 2. Use a standardized supply cart or kit that contains all necessary components for the insertion of a CVAD.²⁶⁻²⁸ (IV)
- B. Use ultrasound when inserting CVADs to improve vessel assessment, insertion success, and reduce insertion-related complications (refer to Standard 21, *Vascular Visualization*).
 - 1. For tunneled, cuffed CVADs and implanted vascular access port insertion: use an ultrasound-guided modified Seldinger technique (MST) with micro-puncture kit for large bore catheters rather than venous cutdown or landmark percutaneous technique to improve insertion success and reduce postinsertion complication rates in both adult and pediatric patients.²⁹⁻³² (I)
 - 2. Consider level of skill of clinician/proceduralist and insertion technique to improve internal jugular catheterization success. Varying degrees of success have been reported when using syringe-free, long-axis in-plane, and dynamic short axis insertion. Studies consistently reported improved outcomes when the needle tip is constantly visualized (see Standard 21, *Vascular Visualization*).³³⁻³⁶ (I)
- C. Consider right-sided peripherally inserted central catheter (PICC) insertion, unless contraindicated during patient assessment to reduce risk of catheter-related complications, such as tip malposition.³⁷ (III)
 - 1. Ensure a catheter to vein ratio of less than 45% (refer to Standard 25, *Vascular Access Device Planning and Site Selection*).
 - 2. Consider the use of a subcutaneous skin tunnel when the vein of choice is at its largest in the upper third of the upper arm near the axilla. This optimizes point of needle entry and subsequent catheter exit site in the middle third of the upper arm.³⁸⁻⁴² (II)
 - 3. Measure baseline circumference of the extremity with a PICC upon insertion, noting location for future measurements to ensure consistent measurement. Assess circumference when edema or signs and symptoms of DVT present, noting the location and characteristics of edema (refer to Standard 50, *Catheter-Associated Thrombosis*).
- D. Implement appropriate actions to manage insertion-related complications:
 - 1. Inadvertent arterial puncture: remove and apply direct digital pressure until hemostasis is achieved.

- a. Inadvertent arterial puncture during insertion of a large-bore CVAD or dilator may be a life-threatening complication. Leave the device in situ and immediately consult with a surgeon or interventional radiologist. Treatment options include open operative approach and repair and, more commonly, endovascular management (refer to Standard 51, *Central Vascular Access Device Malposition*).
2. Cardiac arrhythmias: typically resolve with reposition of guidewire or catheter. If arrhythmias persist, notify the provider.^{32,43,44} (V)
3. Pneumothorax: notify provider.^{32,43,44} (IV)
4. Potential related symptoms of nerve damage include diaphragmatic paralysis, hoarseness, impaired muscle strength, and dysfunction of sympathetic nervous system (refer to Standard 45, *Nerve Injury*).
5. Air embolism (refer to Standard 49, *Air Embolism*).
6. Catheter malposition (refer to Standard 51, *Central Vascular Access Device Malposition*).
- E. Advance catheter tip to cavoatrial junction (CAJ), lower one-third of the superior vena cava (SVC), or superior aspect of right atrium (refer to Standard 22, *Central Vascular Access Device Tip Location*).
 1. For lower body insertion sites, advance the CVAD tip to the inferior vena cava (IVC) above the level of the diaphragm.
 2. Prior to using the CVAD for infusion, the inserter should verify tip position using a recognized tip locating technique, eg, fluoroscopy, electrocardiography, etc. (refer to Standard 22, *Central Vascular Access Device Tip Location*).
- F. Evaluate and assess complex CVAD insertion (site and catheter), eg, CVAD insertion in the presence of a cardiovascular implantable electronic device.
 1. Preference is for the contralateral side.⁴⁵ (V)
 2. Determine the integrity of a pre-existing cardiovascular implantable electronic device and leads before and after CVAD insertion. There are currently no practice guidelines developed related to pacemakers and CVADs.⁴⁵ (V)
 3. Consider options that preserve vessel health in the patient with chronic kidney disease (CKD) who requires insertion of a CVAD and a cardiovascular implantable electronic device. Nontunneled catheters should be avoided, with rapid progression to fistula/graft creation recommended (refer to Standard 27, *Vascular Access and Hemodialysis*).

III. Arterial Catheters

- A. Use ultrasound to assess arterial access and insertion site (refer to Standard 21, *Vascular Visualization*).
- B. Use dynamic needle tip positioning to increase first-time arterial catheter insertion success.^{46,47-49} (I)
- C. Wear a cap, mask, sterile gloves, and eyewear, and use a small fenestrated sterile drape when inserting a

peripheral arterial catheter (refer to *Standard 19, Aseptic Non Touch Technique [ANTT®]*).

- D. Use Surgical-ANTT, including maximal sterile barrier precautions when inserting a pulmonary artery catheter and arterial catheters via the axillary or femoral artery (refer to *Standard 19, Aseptic Non Touch Technique [ANTT®]*).

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Section Six: Vascular Access Device Management

Section Standards

I. To ensure patient safety, the clinician is competent in vascular access device (VAD) management, including knowledge of relevant anatomy, physiology, and VAD management techniques aimed at maintaining vascular access and reducing the risk of complications.

II. Indications and protocols for VAD management are established in organizational policies, procedures, and/or practice guidelines and according to manufacturers' directions for use.

33. FILTRATION

Standard

33.1 Parenteral nutrition (PN) solutions are filtered using a 1.2-micron filter.

33.2 Blood and blood components are filtered using a filter appropriate for the prescribed component.

33.3 Intraspinal infusion solutions are filtered using a surfactant-free, particulate-retentive, and air-eliminating filter.

33.4 Medications in glass ampoules are withdrawn using a filter needle or filter straw (eg, 5 micron); medications are never administered through a filter needle.

Practice Recommendations

A. Use a filter only when the benefits outweigh the risks and according to the medication or solution and manufacturer's instructions (indications, contraindications, and filter type).¹⁻³ (III)

1. While as yet poorly understood, filter risks include sorption of active or solution-stabilizing inactive ingredients onto the filter; leaching or extraction of filter components into the infusate; shedding of filter particles; elevated line pressure, which can mask infiltration or extravasation; shearing of liposomal globules; and increased risk of hypersensitivity reactions.³⁻⁸ (III)

2. Choose a filter that is compatible with the medication or solution (pore size, filter composition,

electrical charge, and filter manufacturer), especially for small doses or medications with a narrow therapeutic index. Infusate filter compatibility data is an area of needed research. In the absence of compatibility information, consult with a pharmacist to determine an appropriate filter.^{1,2,9,10} (IV)

3. For protein-based medications, including biologic therapies, follow the manufacturer's directions for filtration (eg, should, should not, or may be filtered) to prevent immune system reactions or dose trapping.^{2,9-11} (IV)

B. Use air-eliminating filters, unless otherwise contraindicated, for all infusions in patients with a medical diagnosis involving right-to-left cardiac or pulmonary shunting to reduce the amount of air and particulate matter that reaches the arterial circulation, also known as *paradoxical embolization*. The presence of microbubbles in the arterial system can also impede endothelial lining-mediated arterial contractility potentially through damage to endothelial lining or decreased perceived shear stress.^{12,13} (III)

1. A relative contraindication to filtration would be a small dose or narrow therapeutic index medication without filter infusate compatibility information.^{2,10} (IV)

C. Consider filtration of solutions and medications in high-risk patients to reduce microemboli-mediated inflammation and microcirculation impairment resulting from administration of microbubbles of air (<1000 microns) or particles entrained in infusion solutions and medications. The patient populations most likely to benefit from particle and microbubble reduction have yet to be determined but might include neonates, critically ill patients, or those with tissue injury.^{14,15} (II)

1. Avoid routine, indiscriminate filtration in neonates. Use filtration when indicated by the infusate or by patient-specific risk factors (eg, right-to-left shunting).¹⁶⁻¹⁸ (I)

2. Consider the routine use of in-line filters outside a definitive indication in pediatric critical care patients for a potential protective effect against lung, renal, or hematologic dysfunction and systemic inflammatory response syndrome (SIRS).^{19,20} (III)

3. Avoid routine, indiscriminate use of filtration in adult critical care patients.^{21,22} (III)

4. Recognize that many factors, including the identity of the medications or solutions, compounding and preparation environment, supplies, and techniques, as well as infusion rates and VAD components, can influence the particle and microbubble sizes and quantities in infusions.^{10,23} (IV)
5. Understand that not all particles and bubbles are dangerous. Infused microbubbles can be absorbed by the blood, or coagulation on the bubble's surface can cause platelets and fibrin to encapsulate the bubble. In the absence of right-to-left shunting or venous-arterial shunting, encapsulated bubbles or particles larger than pulmonary capillaries (ie, >5-6 microns in diameter) tend to deposit in the lungs, where particles smaller than 13 microns can be phagocytized. After passage through the lungs, smaller emboli can deposit in other capillaries that range from 4-9 microns in diameter, but predominantly particles 1 micron in diameter are taken in by the liver, and particles between 3 and 6 microns-wide lodge in the spleen or hepatic lymph nodes. Frequent, repeated exposure to exogenous microbubbles, such as those introduced via hemodialysis, can result in pulmonary fibrosis (in patients without right-to-left shunting).^{12,15,24} (II)
6. Recognize that filters are effective in removing about 84%-98% of particles larger than their pore size, but that in some instances, as a result of infusate-filter interactions, infusate precipitation, or filter shedding, the particulate count downstream of the filter can actually be higher than prefiltration particle counts.^{1,4,10,25} (III)
- D. Do not infuse incompatible medications or solutions together with or without the use of a filter. The mixing of physically incompatible solutions or medications that occurs downstream from the filter, even after entering the bloodstream, can result in deadly intravascular precipitation. Upstream precipitation from the drug-drug incompatibility can also clog the filter, leading to interruptions in life-sustaining continuous infusions.²⁵⁻²⁷ (IV)
- E. Avoid routine use of in-line filters as a thrombophlebitis prevention measure since the patient population most likely to benefit from this intervention has yet to be determined.^{15,28,29} (I)
- F. In patients with a history of allergy to a particular filter, select an appropriate alternative filter for all subsequent infusions.⁷ (V)
- G. Prime and position filters adhering to manufacturers' directions for use.
 1. Locate the in-line filter on the administration set as close to the VAD hub as possible. Shedding from add-on components (eg, extension sets, stopcocks) below or after the filter can result in additional particulate matter infusing into the patient.^{25,30} (V)
 2. Secure all air-eliminating filters at the level of the VAD insertion site to prevent negative flow rates or an inadvertent bolus of the infusion. When the air-eliminating filter is located below the insertion site, a back-siphoning of blood into the tubing by force of gravity occurs, along with an inadvertent pause in drug administration. When the filter is positioned above the level of the insertion site, the reservoir of fluid in the air-venting chamber drains by force of gravity into the patient. An inadvertent pause or bolus of a rate-sensitive continuous infusion could be life threatening. To prevent inadvertent rate changes during repositioning, place a clamp between the air-venting filter and the VAD insertion site. Close the downstream clamp temporarily whenever the position of the filter relative to the insertion site is adjusted.³¹ (IV)
- H. Change add-on filters to coincide with administration set changes without exceeding the filter's approved length of use. Use a primary administration set with an integrated in-line filter whenever possible to reduce tubing manipulation and risks of contamination, misuse, and accidental disconnection/misconnection (refer to Standard 40, *Administration Set Management*).
- I. Use a 1.2-micron filter for administration of all parenteral nutrition (PN) solutions with or without lipid injectable emulsions (ILEs) and for ILE infused separately from PN. PN and ILE infused without a filter can cause death by pulmonary embolism (refer to Standard 61, *Parenteral Nutrition*).
 1. Change the filter every 24 hours for PN with or without ILE and every 12 hours for separately infused ILE (refer to Standard 61, *Parenteral Nutrition*).
- J. Filter blood and blood components using a filter designed to remove blood clots and harmful particles; standard blood administration sets include a 170- to 260- μ m filter. Sets for other components (eg, platelets) may have similar filter pore size but also have a smaller total priming volume (refer to Standard 62, *Blood Administration*).

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34. NEEDLELESS CONNECTORS

Standard

34.1 A luer-locking needleless connector is used to connect syringes and/or administration sets to a vascular access device (VAD) hub or other injection site to eliminate use of needles and reduce needlestick injuries.

Practice Recommendations

- A. Use a needleless connector attached directly and securely to the VAD hub, the female hub of an attached extension set, or an injection site on an administration set to facilitate intermittent infusion of solutions and medications. The primary purpose of needleless connectors is to eliminate the use of needles when connecting administration sets and/or syringes to the VAD or injection sites and reduce subsequent needlestick injuries and exposure to bloodborne pathogens.¹⁻⁵ (I)
 1. Avoid using a needleless connector for red blood cell (RBC) transfusion and when rapid flow rates of continuous infusion of crystalloid solutions are required. In vitro testing with all types of needleless connectors demonstrates the greatest reduction in flow rates through large-bore catheters. Negative clinical outcomes (eg, hypothermia or rapid blood loss) might result when therapies with rapid flow rates (eg, above 1000 mL/hour) are required and impeded.^{6,7} (V)
- B. Needleless connectors are designed to allow bidirectional fluid flow within the device through a variety of

mechanisms (eg, mechanical valve, internal blunt cannula, pressure sensitive antireflux valve) and are categorized by how they function, although there are no established criteria for which devices fall into each group. All needleless connectors allow some fluid movement and blood reflux upon connection, disconnection, or both.⁸⁻¹² (IV)

1. Know the internal mechanism for fluid displacement of the needleless connector in use (eg, negative or positive displacement or antireflux). Follow manufacturers' directions for use for flushing, clamping, and disconnection when provided. The category names of needleless connectors are derived from clinical application of their functionality; however, there are no established criteria from device regulatory agencies that determine which device is assigned to each category.² (V)
2. In the absence of manufacturer directions, consider the reported reflux volume for each type as recorded in the published studies and use the following sequence⁸⁻¹²: (IV)
 - a. Negative displacement – flush, clamp, disconnect;
 - b. Positive displacement – flush, disconnect, clamp;
 - c. Antireflux – no specific sequence recommended but clamping advised, as some displacement is unavoidable.
 - d. The term neutral may be used to describe needleless connector function; no specific sequence recommended but clamping advised, as some displacement unavoidable.
3. Fluid reflux is documented by in vitro studies in all types of needleless connectors, with quantities ranging from 0.02 to 50.37 μ L. Observational studies demonstrated benefits of antireflux valves in minimizing amount of reflux. Overall, different needleless connectors demonstrated variable risks and performance. Recommendation currently is to use best flushing and clamping sequence to minimize reflux and potential associated occlusive or infection risks.^{2,9-16} (III)
- C. The type of needleless connector that produces the least amount of thrombotic VAD lumen occlusion remains controversial and requires further study. The quantity and frequency of thrombolytic drugs used for catheter clearance have been used as surrogates for monitoring VAD lumen occlusion and correlated to the type of needleless connector in use.^{1,17,18} (IV)
- D. Evaluate published outcomes of infection risks associated with each type of needleless connector when making product purchase decisions, focusing on risks, benefits, and educational requirements. Clinical studies comparing different types of needleless connectors demonstrate that all types allow microbial ingress, if not properly and effectively disinfected, and one type is not superior to another if the disinfection step is not performed prior to access. A recent in vitro study identified connector design features associated with the least bacterial transfer and

biofilm formation were connectors with a split septum, minimal seal length, internal cannula, low internal surface area and volume, minimal displacement, and simple hydrodynamics of the flow path.¹⁹⁻²⁶ (II)

- E. Disinfect the connection surface and sides of the needleless connector attached to any VAD to reduce introduction of intraluminal microbes. Use active or passive disinfection. Follow manufacturers' directions for use of both the needleless connector and disinfectant agent and/or product. Primary factors influencing this practice include the disinfection agent, the time required (ie, application and drying), and the method of application.
 1. Perform active disinfection by a vigorous mechanical scrub using a flat swab pad containing 70% isopropyl alcohol or alcohol-based chlorhexidine suitable for use with medical devices.
 - a. Laboratory simulation demonstrated greatest bacterial elimination rates associated with scrubbing in a straight line (compared with rotational scrubbing), using a force equal to that when applying arterial compression, and when the connector is scrubbed twice with a new swab each time.²⁷ (V)
 - b. Recent studies show varied effectiveness of scrub time between 5 and 15 seconds with 70% isopropyl alcohol and alcohol-based chlorhexidine gluconate. One study showed comparable decontamination, and another demonstrated superior decontamination with longer decontamination time.^{28,29} (III)
 - c. Similarly, varied effectiveness has been reported with different solutions. Some studies showed comparable effectiveness in decontamination between 70% isopropyl alcohol or alcohol-based chlorhexidine and others demonstrated superior decontamination with alcohol-based chlorhexidine. International guidelines recommend either solution as part of good Aseptic Non Touch Technique (ANTT®) practice.³⁰⁻³² (II)
 2. Adequate needleless connector drying time after disinfection is essential to reduce microbial load and potential for entry into the bloodstream, thus reducing bloodstream infections. Observational research demonstrated drying time with 70% isopropyl alcohol is 5 seconds; alcohol-based chlorhexidine requires 20 seconds. Povidone-iodine requires longer than 6 minutes to be thoroughly dry, making it less favorable to clinical practice. Drying times in clinical practice depend on the humidity and climate in the care setting.³³ (IV)
 3. Consider passive disinfection by applying a cap or covering containing a disinfectant agent (eg, 70% isopropyl alcohol, iodinated alcohol, chlorhexidine gluconate) over the needleless connector. A systematic review (of randomized and nonrandomized studies) has demonstrated high level of decontamination

- compliance and reductions in central line-associated bloodstream infection (CLABSI) rates and related health care costs associated with avoided harm. When using caps, follow manufacturers' directions for use regarding time for effectiveness after attaching and the maximum length of effectiveness. Once removed, discard used disinfection caps and do not reattach to the needleless connector. Use multidisciplinary implementation strategies, including staff education and leadership support, and provide consistent feedback to staff regarding outcomes, as this has been shown to decrease catheter-associated bloodstream infection (CABSI) rates.³⁴⁻³⁷ (II)
4. Studies comparing active and passive methods of disinfection show both processes to be effective.
 - a. Active disinfection with alcohol-based chlorhexidine gluconate swab pads or passive disinfection with caps containing 70% isopropyl alcohol were associated with lower rates of CABSI, while swab pads containing 70% isopropyl alcohol were the least effective, according to a meta-analysis of quasi-experimental studies.³⁰ (II)
 - b. Recent research has demonstrated that passive decontamination with 70% isopropyl alcohol-impregnated caps was associated with reduced phlebitis and infection. This may be associated with the improved consistency with decontamination practice and/or prolonged exposure to disinfectant agent.³⁸⁻⁴⁵ (II)
 - c. Compared to active disinfection, passive disinfection has been associated with increased clinician compliance largely due to the continuous dwell nature of the device.^{46,47} (IV)
 - i. However, other studies show no difference between passive decontamination with caps and active decontamination with swabs. More high-quality trial research is required.^{48,49} (III)
 5. Disinfect the needleless connector before re-entry on contamination or suspicion of contamination of a Key-Part (eg, tip of syringe, needleless connector access) to provide protection for the intraluminal fluid pathway. Studies focus on disinfection practices before the initial entry into the needleless connector; however, studies do not address the need for disinfection before each sequential re-entry to administer one or more intermittent medications (eg, saline flush before and after each medication administration) (refer to Standard 19, *Aseptic Non Touch Technique [ANTT®]*). (Committee Consensus)
 6. Adhere to Standard-ANTT when accessing and changing a needleless connector.^{1,3,4,50,51} (I)
 - a. Attach only a sterile syringe tip or sterile male luer end of the intravenous (IV) administration set to the needleless connector.
 - b. Ensure that disinfecting supplies are readily available at the bedside to facilitate staff compliance with needleless connector disinfection (see Standard 19, *Aseptic Non Touch Technique [ANTT®]*).
 7. Consider the use of an antimicrobial needleless connector when there is an increased risk of infection. Use of needleless connectors with an antimicrobial coating (eg, silver, chlorhexidine/silver) does not negate decontamination, as technology alone does not replace disinfection practices. Silver-coated needleless connectors have been shown to decrease rates of CABSI, although significant amounts of biofilm and microorganisms were recovered from coated and noncoated connectors.^{52,53} (V)
 8. Monitor clinician compliance to ensure that the chosen method for disinfection is applied consistently for needleless connectors on all peripheral VADs and central vascular access devices (CVADs), as this is a critical element for reduction of intraluminal contamination and subsequent bloodstream infection (BSI).^{34,35} (V)
 - F. Use manifolds with a bonded needleless connector or close by adding a needleless connector rather than a solid cap. The method of closure has greater influence on contamination than the type of fluid displacement inside the needleless connector. Replace the stopcock with a needleless connector as soon as clinically indicated (see Standard 35, *Other Add-On Devices*).^{54,55} (I)
 - G. Change the needleless connector in the following circumstances: if the needleless connector is removed for any reason; prior to drawing a sample for blood culture from a CVAD; as per local policies, procedures, and/or practice guidelines; and per manufacturers' directions for use or when clinically indicated (eg, any loss of product integrity such as contamination, dysfunction, or any residual blood or debris within the needleless connector), whichever occurs sooner (see Standard 47, *Vascular Access Device-Related Infection*).² (V)
 1. When used within a continuous infusion system, change the needleless connector when the primary administration set is changed (eg, up to every 7 days) (refer to Standard 40, *Administration Set Management*).
 2. One clinical study reported that changing the needleless connector every 24 hours with blood or lipid infusion increased CLABSI rates in pediatric stem cell transplant patients.^{3,56} (IV)
 3. A recent in vitro study identified connector design features associated with the least bacterial transfer and biofilm formation, indicating that different designs may drive frequency of device changes.²⁶ (IV)
 4. Variation in research and context reiterates the need for sound product knowledge and regular device assessment to ascertain optimal function and integrity. (Committee Consensus)

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Note: All electronic references in this section were accessed between December 8, 2022, and August 7, 2023.

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35. OTHER ADD-ON DEVICES

Standard

35.1 Add-on devices are used only when clinically indicated for a specific purpose and in accordance with manufacturers' directions for use.

35.2 Add-on devices are of luer-lock or integrated design and are compatible with the administration system to ensure a secure connection, reduce manipulation, and minimize the risk of leaks, disconnections, misconnections, or premature loss of vascular access. A catheter with an integrated extension set is not considered an add-on device.

Practice Recommendations

- A. Use add-on devices of luer-lock or integrated design (eg, single lumen and multilumen extension sets, manifold sets, extension loops, cannula caps, needleless connectors, in-line filters, stopcocks [3-way tap], closed system transfer devices [CSTD], and safety release valves/connectors) to add length, enable filtration capabilities, for safe handling, or to enhance function of the infusion system (eg, adding an extension to decrease movement/manipulation at the peripheral intravenous catheter [PIVC] hub)(see Standard 33, *Filtration*; Standard 34, *Needleless Connectors*.^{1,2} (IV)
- B. Limit the use of add-on devices whenever possible to decrease excessive manipulations, accidental disconnections or misconnections, and risk of contamination and subsequent infection. Add-on devices may cause challenges with drug delivery and increase costs.³ (IV)
 1. Use a stopcock or manifold with an integrated needleless connector rather than a solid cap, or replace the solid cap with a needleless connector to maintain a closed system, reduce risk for infection, and ensure adequate priming and flushing prior to and after use.⁴⁻⁶ (I)

2. Avoid routine use of in-line filters as a thrombophlebitis prevention measure since the patient population most likely to benefit from this intervention has yet to be determined; infusate contaminants are potential etiologic factors for phlebitis; however, results of clinical studies regarding the clinical benefit of filtration are uncertain/controversial, with further studies needed to identify beneficial effects, potential disadvantages, and cost-effectiveness (see Standard 33, *Filtration*).⁷⁻¹⁰ (IV)
 3. Check instructions for use (IFU) for pump manufacturer concerning the use of in-line devices with extra-long tubing. All add-on devices would potentially contribute to alterations in flow rate; as a result, accuracy of medication delivery may be compromised (refer to Table 1, Medication/Infusion Delivery: Dose Accuracy and Error Prevention, in Standard 57, *Infusion Medication and Solution Administration*).
 4. Before accessing the add-on device, disinfect the hub with active or passive disinfection (refer to Standard 34, *Needleless Connectors*).
 5. Consider use of emerging devices such as CSTDs and safety release valves/connectors on a case-by-case basis, as research is limited and caveats within recommendations reflect this.^{11,12} (V)
- C. Change an add-on device with new vascular access device (VAD) insertion, with each administration set if integrated (eg, filter portion of administration set), on removal from the VAD for any reason, as per local policies, procedures, and/or practice guidelines; as per manufacturers' directions for use; or when clinically indicated (eg, any loss of product integrity such as contamination or dysfunction), whichever occurs sooner (see Standard 47, *Vascular Access Device-Related Infection*).¹ (V)
- D. Disinfect catheter hub prior to replacement of an add-on device and/or if evidence of blood, residue, or suspected contamination. Check manufacturer IFU about the compatibility of disinfectant agent with add-on device material to minimize material degradation and compromise. (Committee Consensus)

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KEY DEFINITIONS

Adhesive securement device (ASD): an adhesive-backed device that adheres to the skin with a mechanism to hold the vascular access device (VAD) in place; a separate dressing is placed over the ASD. Both the dressing and ASD must be removed and replaced at specific intervals during the VAD dwell time.

Integrated securement device (ISD): a device that combines a dressing with securement functions; includes transparent, semipermeable window, and a bordered fabric collar with built-in securement technology.

Subcutaneous anchor securement system (SASS): a securement device that anchors the VAD in place via flexible feet/posts that are placed just beneath the skin; these act to stabilize the catheter right at the point of insertion. A separate dressing is placed over the SASS. The SASS does not need to be changed at regular intervals when the dressing is changed; it can remain in place if there are no associated complications.

Tissue adhesive (TA): a medical-grade cyanoacrylate glue that can seal the insertion site and temporarily bond the catheter to the skin at the point of insertion and under the catheter hub. Depending on the chemical makeup, TA may be reapplied at each dressing change. Various formulations of TA for wound closure are commercially available, including first generation *N*-Butyl-2-cyanoacrylate (quick drying, rigid/brittle), second generation 2-octyl-cyanoacrylate (longer dry time, more flexible) and *N*-Butyl-2octyl cyanoacrylate formation (increased tensile strength and flexibility) with an additional indication for vascular access securement. Each TA formulation has varied properties and the clinical decision to use should be based on research outcomes relative to the chosen product.

Standard

36.1 VADs are secured to prevent complications associated with VAD dislodgement and VAD motion at the insertion site.

36.2 Methods used to secure the VAD do not interfere with the ability to routinely assess and monitor the access site or impede vascular circulation or delivery of the prescribed therapy.

Practice Recommendations

A. Use a securement method, such as adhesive securement device (ASD), integrated securement device (ISD), subcutaneous anchor securement system (SASS), or tissue adhesive (TA), in addition to the primary dressing, to stabilize and secure VADs. Inadequate securement can cause dislodgement and complications requiring premature removal.

1. Additional securement as an adjunct to the primary dressing reduces motion at the insertion site and associated complications. Adequate securement can reduce pain, fear, and anxiety and reduces health care costs associated with VAD replacement.¹⁻¹¹ (I)

B. Choose the most appropriate method for VAD securement based on factors including VAD type, patient age, skin turgor and integrity, anticipated duration of therapy, previous adhesive skin injury, and any type of drainage from the insertion site.¹²⁻¹⁴ (III)

C. Avoid the use of sutures, as they are not an effective alternative to a securement method; sutures are associated with needlestick injury, support the growth of biofilm, and increase the risk of catheter-associated bloodstream infection (CABSI).^{15,16} (III)

D. Evaluate the effectiveness of a combination of securement measures to reduce complication and failure.

More randomized controlled trials (RCTs) with appropriate sample sizes are needed to confirm this bundled approach.¹⁷⁻²⁰ (III)

1. Do not use rolls of nonsterile tape; rolls of nonsterile tape can become contaminated with pathogenic bacteria.²¹⁻²⁴ (II)

E. Evaluate the use of securement options, such as TA, in addition to a primary dressing or an ISD for enhanced catheter stabilization for peripheral intravenous catheters (PIVCs), particularly in high-risk patients such as those with difficult intravenous access (DIVA) and prolonged catheter dwell.^{3,8,25-27} (II)

1. There is some evidence that additional securement, either an ISD or TA, for PIVCs reduces complication rates. These small studies are inconclusive, and more large efficacy trials are needed.^{2,3,6,8,21,28,29} (II)

2. Two small studies (one in adults and one in pediatric patients) did not show a reduction in complications or failure of short PIVCs when an ASD was used as an adjunct to the primary dressing.^{5,6} (III)

3. Various formulations of cyanoacrylate TA for securement have been studied in vitro, in vivo, in pilot PIVC and arterial RCTs, and in 2 large superiority PIVC RCTs. Conflicting results have been reported. One large RCT in an adult emergency department, along with a small pediatric pilot RCT and observational studies, demonstrated reduced failure and increased dwell time when TA is applied in addition to a transparent dressing with or without a border. However, a large superiority PIVC securement RCT in adult inpatients demonstrated no reduction in PIVC failure, concluding that larger RCTs are needed to confirm the safety and cost effectiveness of innovative

- dressing and securement methods, and clinicians should use inpatient populations most likely to benefit (DIVA and dwell time greater than 48 hours), as well as consider the TA formulation used in these trials when applying the results to their clinical practice.^{3,8,25,30} (III)
- F. Use a securement method in addition to the primary dressing or an ISD to secure midline catheters.^{31,32} (III) (Committee Consensus)
 - G. Use an ASD, ISD, SASS, or TA for peripherally inserted central catheters (PICCs) as an alternative to sutures; they are safer than sutures and reduce risk of complications, including infection and dislodgement.^{4,32-43} (I)
 1. Small pilot and observational studies report improved outcomes when securement methods, including SASS, ISD, and TA, are used compared to ASDs. More powered clinical trials are needed to confirm the safety and efficacy of various securement methods in all patient populations.^{4,32-43} (II)
 - H. Evaluate the potential for clinical and fiscal efficacy of SASS for PICCs and CVADs, including both tunneled cuffed and tunneled noncuffed catheters in adult and pediatric patients.⁴⁴⁻⁴⁷ (III)
 1. Studies comparing the use of ASD and SASS as effective and acceptable securement for PICCs; tunneled cuffed and tunneled noncuffed CVADs are limited to one pilot RCT and several small descriptive studies. Single-center observational studies demonstrate SASS to be more effective than traditional sutures and ASD in preventing catheter failure, especially dislodgement in patients with altered skin integrity. Patient and clinician satisfaction with SASS has been favorable; however, more powered clinical trials are needed to confirm clinical safety and efficacy.⁴⁴⁻⁴⁷ (III)
 2. The National Institute for Clinical Excellence (NICE) in the United Kingdom advocates improved patient safety and cost benefit of SASS, particularly for use greater than 15 days.⁴⁸ (IV)
 - I. Use TA as an adjunct to the primary method of dressing and securement, as it immediately seals the insertion site, prolonging the interval between VAD insertion and the first dressing change.^{3,32,49} (III)
 1. In vivo, in vitro, and some small clinical trials demonstrate TA at the catheter insertion site might provide a barrier to microorganism growth on the catheter tip. Confirmatory clinical trials are inconclusive. A pediatric pilot RCT reported a reduction in catheter tip colonization; however, one large, adult RCT reported no reduction in microorganisms cultured on catheter tips, suggesting more larger clinical RCTs are required to confirm these results.^{3,49-51} (IV)
 2. Consider cautious use of novel catheter securement, such as TA, in the neonatal population. Few robust, prospective clinical trials have adequately studied the safety and efficacy of this novel securement in early premature neonates and low to extremely low birthweight neonates.^{52,53} (V)
 - J. For nontunneled CVADs inserted into veins of the neck and groin, the most effective method of dressing and securement remains challenging and unclear. Pilot trials undertaken in adult and pediatric patients in critical care units demonstrate that alternatives such as ISDs and TA used in conjunction with sutures might reduce failure and increase dwell time compared to ASDs and traditional sutures alone; however, further trials are necessary.^{7,33,54} (III)
 1. More large clinical trials are needed to examine additional innovative securement technologies to improve peripheral arterial catheter securement.
 - K. Consider innovative securement strategies such as TA or keyhole dressing (foam-bordered dressing with clear membrane window) in addition to the primary dressing for peripheral arterial catheters to reduce failure. Both have demonstrated reduced failure compared to keyhole dressing alone or primary dressing alone.⁵⁵⁻⁵⁷ (III)
 1. Do not use rolled bandages, with or without elastic properties, as a primary method of VAD securement, as they do not adequately secure the VAD.
 1. A single tubular sleeve that can be easily removed to inspect the insertion site is preferred to a rolled bandage if additional site protection is required (see Standard 37, *Site Protection and Joint Stabilization*).²¹ (IV)
 2. The presence of skin disorders that contradict the use of medical adhesives (ie, pediatric epidermolysis bullosa, toxic epidermal necrolysis, and burns) may necessitate the use of tubular gauze mesh rather than conventional securement. Single-center observational studies demonstrate SASS might be effective and safe in this patient population; however, these studies are small, and close observation of this vulnerable patient group is recommended (see Standard 52, *Catheter-Associated Skin Injury*).^{37,47,48,58} (III)
 - L. Assess the integrity of VAD securement with each dressing change and change the securement device according to the manufacturers' directions for use. Remove ASDs with each dressing change to allow for appropriate skin antisepsis and apply a new ASD. TA should be reapplied at each dressing change. A securement device designed to remain in place for the life of the VAD (eg, SASS) does not need to be removed and replaced regularly with each dressing change; however, it should be assessed during catheter care and management to ensure its integrity.^{39,46,59-61} (I)
 - M. Be aware of the risk of catheter-associated skin injury.
 1. Assess skin when the securement device is changed; anticipate potential risk for skin injury due to age, joint movement, and presence of edema.^{39,46,60,61} (III)
 2. Apply barrier solutions to skin prior to dressing and securement to reduce the risk of catheter-associated

skin injury (refer to Standard 52, *Catheter-Associated Skin Injury*).

- O. Never readvance a dislodged VAD into the vein. Secure the VAD at the current location, assess the position of the new tip location, the infusion therapy (peripheral or central), and other influencing factors such as remaining duration of therapy. Reinsertion at a new site or exchange might be the most appropriate intervention if the catheter is no longer in an appropriate position for infusion of the required therapy (refer to Standard 51, *Central Vascular Access Device Malposition*).

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37. SITE PROTECTION AND JOINT STABILIZATION

KEY DEFINITIONS

Site protection. Strategies used in addition to vascular access device (VAD) insertion site securement (may also be called secondary securement), including:

- Interventions/products used to reduce the risk of VAD dislodgement due to the pulling/tugging of the administration set
- Interventions/products (eg, VAD covers, mitts, vests) to protect/disguise the VAD from patient manipulation, such as with pediatric patients, those with cognitive impairment/confusion, and/or other risk factors for VAD misuse
- Strategies to prevent exposure of the VAD site to water or other contaminants.

Joint stabilization. Use of a device to support and stabilize a joint (eg, arm board, splint) when veins or arteries used for VAD insertion are located in an area of flexion.

Physical restraint. A manually applied method that immobilizes or reduces the ability of a patient to move arms, legs, or body.

Standard

37.1 Site protection methods are used to protect VADs or VAD sites from patient manipulation, inadvertent dislodgement, and exposure to contaminants.

37.2 Physical restraints are avoided, except in cases where behavior that hinders medical treatment, such as repeated removal of a VAD; the least restrictive form of restraint should be used.

37.3 Joint stabilization devices, such as arm boards or splints, are used when appropriate to facilitate infusion delivery, maintain device functionality, minimize infusion therapy complications, and are not considered restraints.

Practice Recommendations

- A. Recognize that inadvertent VAD dislodgement is a clinically important problem for patients with VADs due to movement and subsequent risk for pulling at the VAD site.¹⁻⁵ (II)
 1. Pediatric patients and those with cognitive issues (eg, delirium, dementia) are at increased risk.
- B. Consider the use of appropriate site protection products/interventions for patients at increased risk for accidental VAD dislodgement, tampering, or removal; such interventions are in addition to VAD site securement interventions (see Standard 36, *Vascular Access Device Securement*).⁶⁻¹² (III)
 1. Small studies have shown efficacy for devices that separate if there is excessive force or devices that reduce tension at the administration set/VAD junction (eg, central line vest).
 2. Mittens (“mitts”) may be used as a site protection intervention as an alternative to physical restraints; mitts are not considered a physical restraint if they are applied without any other restraint and when a patient can easily remove the mitt.
 3. A single tubular sleeve that can be easily removed may provide additional site protection in addition to a VAD securement strategy (refer to Standard 36, *Vascular Access Device Securement*).
- C. Use a site protection product/barrier to protect the VAD site/dressing and infusion connections from water (eg, during bathing/showering).¹³ (V)
- D. Avoid routine use of physical restraints as a site protection intervention.^{1,8,14-19} (IV)
 1. The use of physical restraints (eg, wrist restraints) impacts patient dignity and may increase or aggravate anxiety and agitation. There is a lack of data substantiating the efficacy of restraints in preventing device removal. Restraint use is a common practice, particularly in intensive care units, as an intervention to maintain integrity/prevent the loss of a device (eg, VAD or other invasive devices).
 2. The use of temporary physical restraints may be considered in situations such as central vascular access device (CVAD) insertion to ensure maintenance of patient positioning and adherence to Aseptic Non Touch Technique (ANTT®).
 3. Reduce the need for physical restraints in children during painful procedures (eg, venipuncture) by use of age-appropriate pain management strategies (eg, distraction, analgesia), including hugging rather than “holding down” (refer to Standard 30, *Pain Management for Venipuncture and Vascular Access Procedures*).
- E. Improve clinician knowledge about alternatives to physical restraint use; there is a need for nurse-directed education, as nurses are most likely to consider use of restraints, and for high-quality practice guidelines. A decision-making tool for physical restraint use resulted in a reduction in the use of restraints.^{8,14,15,17,20} (IV)
- F. Recognize and assess for complications related to physical restraint use, including skin trauma, pressure ulcers, muscle atrophy, limb/nerve injury, contractures; the use

- of physical restraints may increase anxiety, agitation, and delirium.^{17,21} (V)
- G. Consider application of a joint stabilization device (eg, armboard, “splint”) when the VAD is inserted in an area of flexion to reduce the risk of complications (eg, phlebitis, infiltration).^{22,23} (III)
1. Apply any joint stabilization device in a manner to reduce risk of pressure and skin breakdown, padding the joint stabilization device as needed and supporting the area of flexion (eg, hand, arm, elbow, foot) to maintain a functional position.^{24,25} (V)
 2. There are limited data supporting the use of a splint in neonatal patients to improve duration of catheter dwell time. Use of an arm board for pediatric patients with a peripheral arterial catheter was associated with increased risk of catheter failure in a single study, as an unexpected finding; further investigation is required.^{26,27} (III)
 3. Do not use wooden tongue depressors as joint stabilization devices in preterm infants or immunocompromised individuals due to the risk of fungal infection.²⁸ (V)
- H. Use the selected site protection, joint stabilization, or physical restraint device in a manner that allows for visual inspection and assessment of the VAD site and that does not interfere with the infusion and vascular pathway. Ensure that it does not exert pressure that will cause circulatory constriction, pressure injuries, or nerve damage, and is in accordance with manufacturers’ directions for use (eg, indications, device cleaning).^{9,17,21,24} (IV)
1. Remove device at established intervals to allow assessment of the circulatory status of the extremity and provide an opportunity for supervised range-of-motion activities.
 2. Regularly assess the need for the device and discontinue it as soon as the patient’s condition allows.
- I. Educate the patient/caregiver on the need for and appropriate use and care of any site/joint/physical immobilization devices (refer to Standard 8, *Patient Education*).

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38. FLUSHING AND LOCKING

Standard

38.1 Vascular access devices (VADs) should be assessed for patency (ie, flushed and aspirated for a blood return) prior to each infusion to assess catheter function and prevent complications.

38.2 VADs are flushed after each medication administration with sufficient volume and appropriate rate to complete the medication administration and to reduce the risk of contact between incompatible medications.

38.3 Each VAD lumen is locked after completion of the final flush and infusion ceased to decrease the risk of intraluminal occlusion and/or to reduce catheter-associated bloodstream infection (CABSI) risk, depending on the solution used.

38.4 Standardized protocols for flushing and locking solutions are established within each organization.

Practice Recommendations

- A. Use single-dose systems (eg, single-dose vials and syringes or prefilled labeled syringes) for all VAD flushing and locking.^{1,2} (V)
 1. A syringe or needle should be considered contaminated once it has been used to enter or connect to a patient's intravenous (IV) solution container or administration set.¹ (V)
 2. Use commercially manufactured prefilled flush syringes (when available) to reduce the risk of catheter-associated bloodstream infection (CABSI) and device failure, save time for syringe preparation, and aid optimal flushing technique and objectives.³⁻⁸ (II)
 3. Do not use IV solution containers (eg, bags or bottles) as a source for obtaining flush solutions (see Standard 56, *Compounding and Preparation of Parenteral Solutions and Medications*).^{2,9} (IV)
 4. Use new, unopened, single-use, commercially available prefilled syringes for flushing before and after

medications. Using the same prefilled syringe to flush a VAD before and after the medications can potentially contaminate the prefilled syringe tip and thereby transfer the contamination to the VAD.^{2,9,10} (IV)

5. If a patient reports disturbance in taste and odor/smell, inform them that prefilled flush syringes are occasionally associated with this and that it has been found to be more prominent when flushing central venous access devices (CVADs) than with peripheral intravenous catheters (PIVCs). The cause is thought to be substances leaching from the plastic syringe due to sterilization methods. These sensations may be significant enough to impact appetite and may increase nausea, especially if administered rapidly. This sensation can be minimized with a slower injection rate. Reassure patient that sensation will subside when injection/flush has ceased.¹¹ (III)

- B. Disinfect connection surfaces (ie, needleless connectors, injection ports) before flushing and locking procedures (refer to Standard 34, *Needleless Connectors*).

- C. Flush all VADs with preservative-free 0.9% sodium chloride.¹² (V)

1. Use a minimum volume equal to twice the internal volume of the catheter system (eg, catheter plus add-on devices). Larger volumes (eg, 5 mL for PIVC, 10 mL for CVADs) may remove more fibrin deposits, drug precipitate, and other debris from the lumen. Factors to consider when choosing the flush volume include the type and size of catheter, age and weight of the patient, and type of infusion therapy being given. Blood sampling or infusion of blood components, parenteral nutrition (PN), contrast media, and other viscous solutions may require larger flush volumes.¹³⁻¹⁶ (V)
2. If bacteriostatic 0.9% sodium chloride is used, limit flush volume to no more than 30 mL in a 24-hour period to reduce the possible toxic effects of the preservative, benzyl alcohol.¹² (V)
3. Use only preservative-free solutions for flushing all VADs in neonates and infants to prevent toxicity.¹² (V)
4. Use 5% dextrose in water followed by preservative-free 0.9% sodium chloride when the medication is incompatible with sodium chloride. Do not allow dextrose to reside in the catheter lumen, as it provides nutrients for biofilm growth.^{2,9} (IV)
5. Never use sterile water for flushing VADs.¹⁷ (V)

- D. Assess VAD function using a 10-mL syringe or a syringe specifically designed to generate lower injection pressure (ie, 10-mL diameter syringe barrel), taking note of any resistance.^{13,15,16} (V)

1. Use a single-use prefilled 0.9% sodium chloride syringe to slowly aspirate the VAD for free-flowing blood return that is the color and consistency of whole blood, an important component of assessing catheter function during the initial flush and prior to administration of medications and solutions (see Standard 46, *Vascular Access Device Occlusion*;

Standard 51, *Central Vascular Access Device Malposition*).^{9,10} (IV)

- a. When blood return is sluggish/absent or assessment of blood return is contraindicated due to the patient's condition (eg, hemodynamic instability dependent on vasopressor delivery), VAD patency should be evaluated through alternative signs, including ongoing clinical response to an infusing medication, lack of resistance to flushing, site evaluation, and patient symptom report. This assessment can assist in determining patency.
 - i. For a peripheral VAD (eg, short/long PIVC, midline) that no longer has a positive blood return, increase the frequency of assessment of the insertion site and the venous pathway of the VAD to minimize the risk and severity of complications, such as infiltration, extravasation, and occlusion. If using the PIVC for vesicant administration, plan to transition the infusion to a new VAD when clinically possible. Peripheral administration of certain antineoplastic vesicants is contraindicated in the absence of blood return (refer to Standard 58, *Antineoplastic Therapy*).
 - ii. In situations with increased line/luminal volume and high-risk medications (eg, vasopressors, inotropes), aspirating for blood return might be contraindicated in patients where interruptions of the infusion or inadvertent bolus could cause a clinically relevant decline in the patient's condition. In these patients, blood return could be evaluated when the infusion is paused for other reasons (eg, bag change, blood draw, tubing change). Increase the frequency of assessment of the insertion site and clinical response to the medications. Promptly evaluate and treat CVAD occlusion (refer to Standard 44, *Infiltration and Extravasation*; Standard 46, *Vascular Access Device Occlusion*; Standard 65, *Vasopressor Administration*). (Committee Consensus)
2. Do not forcibly flush any VAD with any syringe size. If resistance is met and/or no blood return noted, take further steps (eg, checking for closed clamps or kinked sets, removing dressing, conducting a thorough patient and site assessment) to locate an external cause of the obstruction. Internal causes may require diagnostic tests, including, but not limited to, a chest radiograph to confirm tip location and mechanical causes (eg, pinch-off syndrome), color duplex ultrasound, or fluoroscopy to identify thrombotic causes (see Standard 50, *Catheter-Associated Thrombosis*; Standard 51, *Central Vascular Access Device Malposition*).^{13,14,18} (V)
3. After confirming catheter patency, use an appropriately sized syringe for medication dose. Do not transfer the medication to a larger syringe (see Standard 56, *Compounding and Preparation of Parenteral Solutions and Medications*).² (V)
4. Do not use prefilled flush syringes for dilution of medications. Differences in gradation markings, an unchangeable label on prefilled syringes, partial loss of the drug dose, and possible contamination increase the risk of serious medication errors with syringe-to-syringe drug transfer (see Standard 56, *Compounding and Preparation of Parenteral Solutions and Medications*).² (V)
- E. Flush the VAD lumen with preservative-free 0.9% sodium chloride following the administration of an IV push medication at the same rate of injection as the medication. Use an amount of flush solution to adequately clear the medication from the lumen of the administration set and VAD.^{2,9,13,15,16} (V)
- F. Use positive-pressure techniques to minimize blood reflux into the VAD lumen.^{13,15,16,18,19} (I)
 1. Prevent syringe-induced blood reflux by leaving a small amount (eg, 0.5 mL to 1.0 mL) of flush solution in a traditional syringe (ie, one without a positive pressure plunger) to avoid compression of the plunger rod gasket and prevent this type of reflux.^{13,15,16,18,19} (V)
 2. Prevent connection/disconnection reflux by using the appropriate sequence for flushing, clamping, and disconnecting determined by the type of needleless connector being used (refer to Standard 34, *Needleless Connectors*).
 3. Use a gentle pulsatile flushing technique to deliver flush into the catheter.
 - a. In vitro studies have shown that intermittent, pulsatile (eg, 10 short boluses of 1-mL solution interrupted by brief pauses) may be more effective at removing solid deposits (eg, fibrin, drug precipitate, intraluminal bacteria) compared to continuous low-flow techniques.^{20,21} (IV)
 - b. The Centers for Disease Control and Prevention (CDC) recommends flushing CVADs vigorously using pulsating technique.²² (V)
 - c. Other computational, in vitro, and animal studies have demonstrated that the vessel endothelium is vulnerable to damage with repeated, high-pressure injection, and blood components are vulnerable to clotting through stasis at the catheter tip.^{18,23-25} (IV)
 - d. A further laboratory study and small clinical trial demonstrated no significant differences in device clearance or occlusion rates between continuous or pulsatile flush techniques, suggesting that either method is acceptable.^{26,27} (III)
 - e. Larger clinical trials are needed to provide more clarity on the most appropriate flush technique

contextualized to the population and situation. Consequently, the current recommendation is to use a gentle, pulsatile flush technique to balance the need to maintain catheter patency, reduce the risk of mixing incompatible medications/fluids, and optimize vessel health and preservation. (Committee Consensus)

4. Consider flushing all lumens of a multilumen catheter after obtaining blood samples to reduce the possibility of changing intraluminal pressure causing blood reflux into the other lumens. (Committee Consensus)
5. Follow manufacturers' directions for use regarding clamping the VAD when not in use. Clamping can prevent contamination and exsanguination in the event of inadvertent disconnection of any set or add-on device, per manufacturer instructions for use (IFU) (refer to Standard 34, *Needleless Connectors*).
- G. Lock short and long PIVCs and midline catheters immediately following each use.
 1. In adults, use preservative-free 0.9% sodium chloride for locking.^{28,29} (II)
 2. In neonates and pediatric patients, use preservative-free 0.9% sodium chloride or heparin 0.5 to 10 units/mL. Outcome data in these patient populations are inconclusive.¹⁹ (II)
 - a. In one prospective trial, intermittent flushing with 0.9% sodium chloride was associated with a lower rate of complication and similar duration of patency when compared to continuous infusion in PIVCs placed in newborns.³⁰ (IV)
 3. For PIVCs and midline catheters not being used for intermittent infusion or medication administration, remove as soon as no longer required; but if they must be maintained, assess, flush, and relock at least once every 24 hours using a volume reflective of the device and any add-on devices, as per minimum flush calculation stated prior and with a 10-mL syringe or syringe with same barrel size as a 10-mL syringe (see Standard 42, *Vascular Access Device Removal*).^{14,31} (III)
- H. Lock CVADs with either preservative-free 0.9% sodium chloride or heparin according to the provider order for the VAD and needleless connector.^{13,15,18,32,33} (I)
 1. In adults, randomized controlled trials (RCTs) and systematic reviews have shown equivalent outcomes with heparin and sodium chloride lock solutions for multilumen, nontunneled CVADs, peripherally inserted central catheters (PICCs), and implanted vascular access ports while accessed and when the access needle is removed.^{15,16,18,32,34} (I)
 2. Use heparin or preservative-free 0.9% sodium chloride for locking CVADs in children. There is insufficient evidence regarding the best antithrombotic lock solution in CVADs in children.³⁵ (II)
 3. The volume of the lock solution should equal the internal volume of the VAD and add-on devices plus 20% (10% in infants/neonates). Flow characteristics during injection will cause overspill into the bloodstream. Lock solution density is less than whole blood, allowing leakage of lock solution and ingress of blood into the catheter lumen when the CVAD tip location is higher than the insertion site. Careful monitoring of patient and device response is required.¹³ (V)
4. There is insufficient evidence to recommend the optimal frequency, solution, volume, or technique to maintain the patency of implanted vascular access ports not accessed for infusion.³⁶ (II)
 - a. Use at least 10 mL of 0.9% sodium chloride (adult).
 - b. Use of 0.9% sodium chloride alone may be as effective as heparin in maintaining patency (see Standard 26, *Implanted Vascular Access Ports*).³⁷ (III)
 - c. Extending maintenance flushing to every 3 months with 10 mL of 0.9% sodium chloride and 3 or 5 mL of heparin (100 units/mL) was found to be safe and effective in maintaining patency.³⁸ (II)
 - d. Flush implanted vascular access ports daily when accessed but are without regular medication or a continuous infusion in progress (see Standard 26, *Implanted Vascular Access Ports*).^{36,39-41} (V)
 - e. In vitro studies demonstrated that flushing with 10-20 mL of 0.9% sodium chloride solution and sequencing parenteral nutrition administration post-intravenous lipid emulsion (ILE) may reduce ILE build up and prolong device dwell time (see Standard 61, *Parenteral Nutrition*).⁴² (V)
- I. Because of potential conflicts with religious beliefs, inform patients when using heparin derived from animal products (eg, porcine, bovine) and obtain assent. Use preservative-free 0.9% sodium chloride instead of heparin when possible in this patient population.⁴³ (V)
- J. When locking hemodialysis CVADs with citrate or heparin lock solution, low-concentration citrate (<5%) is recommended to reduce the risk of central line-associated blood stream infections (CLABSI) and CVAD dysfunction. Tissue plasminogen activator (tPA) may be used prophylactically once per week to reduce CVAD occlusion. The choice of locking solution is based upon clinician discretion due to inadequate evidence to demonstrate a difference between solutions (refer to Standard 27, *Vascular Access and Hemodialysis*).
- K. General recommendations for maintaining patency in CVADs used for apheresis include high-concentration heparin and sodium citrate.
 1. Use heparin and citrate cautiously in some patient populations and monitor patient tolerance closely, as heparin-induced thrombocytopenia (HIT) was identified as a risk in patients with multiple myeloma who required stem cell harvesting for auto transplantation. An unusually high frequency of HIT was

identified (4%) (refer to Standard 29, *Vascular Access and Therapeutic Apheresis*).

- L. Use solution containing heparin (eg, 1 unit/mL of heparin) or preservative-free 0.9% sodium chloride as a continuous infusion to maintain patency of arterial catheters used for hemodynamic monitoring. The decision to use preservative-free 0.9% sodium chloride instead of heparin infusion should be based on the clinical risk of catheter occlusion, the anticipated length of time the arterial catheter will be required, and patient factors such as heparin sensitivities.⁴⁴ (III)
- M. Apply the following recommendations for neonates and pediatric patients:
 - 1. Use a continuous infusion of heparin 0.5 units/kg for all CVADs in neonates. There is insufficient evidence to support use of intermittent heparin vs 0.9% sodium chloride in long-term CVADs in infants and children.^{19,45} (II)
 - 2. Maintain patency and reduce risk of thrombosis by continuous infusion of heparin 0.25 to 1 unit/mL (total dose of heparin: 25-200 units/kg/d) for umbilical arterial catheters in neonates (refer to Standard 28, *Umbilical Catheters*).
- N. Change to an alternative locking solution when the heparin lock solution is thought to be the cause of adverse drug reactions from heparin; when heparin-induced thrombocytopenia and thrombosis (HITT) develops; and when there are spurious laboratory studies drawn from the CVAD that has been locked with heparin. High concentrations of heparin used in hemodialysis catheters could lead to systemic anticoagulation. HIT has been reported with the use of heparin lock solutions, although the prevalence is unknown.^{13,15} (IV)
- O. Use antimicrobial locking solutions for therapeutic and prophylactic purposes in patients with long-term CVADs in the following circumstances: patients with a history of multiple CABSIs, high-risk patient populations, and in facilities with unacceptably high rates of CLABSI, despite implementation of other methods of infection prevention (see Standard 61, *Parenteral Nutrition*).^{15,39,46-53} (II)
 - 1. There is insufficient evidence to indicate the optimal locking solution for long-term CVADs. Factors associated with increased risk of complication (eg, occlusion, infection, altered catheter integrity) in outpatients with CVADs include devices with more than 1 lumen, female gender, and administration of PN.^{15,51} (III)
 - a. Antibiotic lock solutions contain supratherapeutic concentrations of antibiotics and may be combined with heparin; however, heparin may stimulate *Staphylococcus aureus* biofilm formation. Anticipate the chosen antibiotic to be based on the specific infecting organism or on prevalent organisms within the organization when prophylaxis is the indication. For therapeutic use, start the antibiotic lock

solutions within 48 to 72 hours of diagnosis; however, the optimal duration of use is not established.^{15,39,46-48,52} (II)

- b. Antiseptic locking solutions include solutions used alone or in numerous combinations, including, but not limited to, ethanol, sodium bicarbonate, taurolidine, citrate, concentrated sodium chloride, and ethylenediaminetetraacetic acid (EDTA).^{15,49-51,53-56} (II)
- 2. Consult with pharmacy to assure that combination lock solutions are physically compatible, chemically stable, and produce the desired antimicrobial effect. (Committee Consensus)
- 3. Consider and evaluate compatibility of the catheter material with the lock solution.
 - a. While ethanol lock solution has been proven to be effective in eliminating bacterial growth within biofilm, it has also been associated with negative outcomes: altered catheter integrity, systemic symptoms, and plasma precipitation with potential for catheter occlusion. The impact on catheter integrity is related to the concentration of ethanol lock solution used and the duration of exposure to the catheter inner lumen.¹⁵ (II)
- 4. Monitor patients treated with sodium citrate (an anticoagulant with antimicrobial effects) for systemic anticoagulation, hypocalcemia that could produce cardiac arrest, and protein precipitate formation with concentrations greater than 12%.^{15,46,49-51} (III)
 - a. Monitor trisodium citrate for protein precipitation, which could cause lumen occlusion.¹⁵ (V)
- 5. The length of time that antimicrobial lock solutions should reside inside the CVAD lumen is inconclusive; up to 12 hours per day may be required, thus limiting use in patients receiving continuous or frequent intermittent infusions.^{15,57} (IV)
- 6. Aspirate all antimicrobial locking solutions from the CVAD lumen at the end of the locking period. Do not flush the lock solution into the patient's bloodstream, as this could increase development of antibiotic resistance and other adverse effects. Gentamicin-resistant bacteria from gentamicin lock solution have been reported to increase CABSIs rates.^{15,49} (V)

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39. VASCULAR ACCESS DEVICE POST-INSERTION CARE

Standard

- 39.1 The entire infusion system, from the vascular access device (VAD) insertion site to the solution container, is routinely assessed for system integrity, infusion accuracy, identification of complications, and expiration dates of the infusate, dressing, and administration set.
- 39.2 The necessity of the VAD is routinely assessed and is removed upon unresolved complication and when no longer necessary for treatment.
- 39.3 Site care, including skin antisepsis and dressing changes, is performed at established intervals and immediately if the dressing integrity becomes compromised.
- 39.4 A sterile dressing, combined or integrated with a securement device appropriate for patient's condition and patient preference, is maintained on all peripheral and central VADs to protect the site, provide a microbial barrier, and promote skin health and VAD securement.
- 39.5 Aseptic Non Touch Technique (ANTT®) is adhered to when providing site care and dressing changes on VADs.

Practice Recommendations

- A. Implement a post-insertion care bundle in conjunction with a culture of safety and quality during care and management to reduce the risk of catheter-related infection (refer to Standard 47, *Vascular Access Device-Related Infection*).
- B. Assess and discuss daily with the patient's health care team the continuing need for the VAD (refer to Standard 42, *Vascular Access Device Removal*).
- C. Assess the entire infusion system through visual inspection, from the solution container, progressing down the administration set to the patient and VAD insertion site with each infusion intervention.¹⁻⁷ (IV)
 1. Assess VAD patency (refer to Standard 38, *Flushing and Locking*).
 2. Assess the VAD site and surrounding area by palpation and inspection, including catheter pathway, for integrity of skin, dressing, and securement device. Identify signs of complications (eg, evidence of malposition, redness, tenderness, swelling, infiltration, induration, body temperature elevation, and drainage) by visual inspection and palpation through the dressing and through patient reports about any discomfort (eg, pain, paresthesia, numbness, or tingling) (refer to Section Seven: Vascular Access Device Complications).
 - a. Remove nontransparent dressing to visually inspect site if patient has local tenderness or other signs of possible local infection; otherwise, use palpation for assessment.
 - b. Measure the external vascular access device (VAD) length at each dressing change and when catheter malposition is suspected and compare to the external length documented at time of insertion (refer to Standard 10, *Documentation in the Health Record*; Standard 51, *Central Vascular Access Device Malposition*).
 - c. Measure circumference of the extremity and compare to baseline measurement when clinically indicated to assess the presence of edema and possible catheter-associated deep vein thrombosis (CA-DVT) for midline catheters and peripherally inserted central catheters (PICCs) (refer to Standard 10, *Documentation in the Health Record*; Standard 50, *Catheter-Associated Thrombosis*).
- D. Assess VAD site, entire infusion system, and patient for signs of complications at a frequency dependent on patient factors, such as age, condition, and cognition; type/frequency of infusate; and health care setting.^{2,3,8-11} (V)
 1. In inpatient and nursing facilities, assess central vascular access devices (CVADs) with each infusion and at least daily.
 2. In inpatient and nursing facilities, assess peripheral intravenous catheters (PIVCs) at least every 4 hours; every 1 to 2 hours for patients who are critically ill/sedated or have cognitive deficits; hourly for neonatal/pediatric patients; and more often for patients receiving infusions of vesicant medications (refer to Standard 43 *Phlebitis*; Standard 44, *Infiltration and Extravasation*).
3. In outpatient or home care settings, assess VAD at every visit, and teach the patient or caregiver to check the VAD site with each infusion or at least once per day or, for continuous PIVC infusions, every 4 hours during waking hours for signs of complications and to report signs/symptoms or altered dressing integrity immediately to their home care or other health care provider (refer to Standard 66, *Home Infusion Therapy*).
- E. Assess the integrity of securement devices designed to remain in place for the life of the VAD (eg, subcutaneous anchor securement systems [SASS]) with each dressing change (refer to Standard 36, *Vascular Access Device Securement*).
- F. Change transparent semipermeable membrane (TSM) dressings at least every 7 days (except neonatal patients) or immediately if dressing integrity is disrupted (eg, lifted/detached on any border edge or within transparent portion of dressing; visibly soiled; presence of moisture, drainage, or blood) or evidence of compromised skin integrity under the dressing, and following manufacturer's instruction for use.^{2,5,8,9,12-14} (III)
 1. In neonatal patients, perform dressing change as needed per patient or clinical indications (eg, soiled, damp, or loose, regardless of gestational age and not according to a specific time interval) due to risk of catheter dislodgement, patient discomfort, or skin injury (see Standard 52, *Catheter-Associated Skin Injury*).^{4,13,15-17} (V)
 2. Change sterile gauze dressings every 2 days or earlier if dressing integrity is disrupted (eg, if damp, loose, or visibly soiled); note that a gauze dressing underneath a TSM dressing is considered a gauze dressing, unless the site is not obscured (eg, to support wings of an implanted VAD noncoring needle).^{7,9,14} (III)
- G. Perform dressing changes on VADs using either Standard-ANTT or Surgical-ANTT (based on ANTT risk assessment of ability to prevent touching Key-Sites and Key-Parts) (see Standard 19, *Aseptic Non Touch Technique [ANTT®]*).^{7,8} (V)
- H. Use a dressing change kit to standardize the procedure and improve efficiency.^{1,18} (V)
- I. Prepare skin for optimal skin health and dressing adherence.
 1. Remove dressing and adhesive-based securement device, maintaining skin integrity and preventing VAD dislodgement (eg, avoiding rapid and/or vertical pulling or insufficient support of skin when removing the dressing). Use sterile gloves if there is a need to touch the insertion site, as this is a Key-Site in accordance with ANTT.^{3,19,20} (IV)

2. Remove excess hair at the insertion site if needed to facilitate application of VAD dressings; use single-patient-use scissors or disposable-head surgical clippers; do not shave, as this may increase the risk for infection (refer to Standard 31, *Vascular Access Site Preparation and Skin Antisepsis*).
3. Perform skin antisepsis at VAD site, ensuring all solutions are allowed to dry per manufacturer's instructions (refer to Standard 31, *Vascular Access Site Preparation and Skin Antisepsis*).
4. Assess and protect skin integrity at VAD site with each dressing change (see Standard 52, *Catheter-Associated Skin Injury*).³ (V)
5. Do not apply antimicrobial ointment to VAD insertion sites as part of routine catheter site care, with the exception of hemodialysis catheters (see Standard 27, *Vascular Access and Hemodialysis*).¹⁴ (I)
6. Adding tissue adhesive to the insertion site at the time of insertion may be associated with decreased dressing changes and increased survivability for peripheral as well as central lines secondary to the hemostatic effect of the product (see Standard 36, *Vascular Access Device Securement*).²¹⁻²⁵ (II)
7. Consider the beneficial use of gum mastic liquid adhesive on adult patients when enhanced adhesive dressing adherence is needed (eg, diaphoresis); consider use of skin barrier film prior to application. Use correct technique in dressing removal to prevent catheter-associated skin injury due to increased bonding of adhesives to skin (see Standard 52, *Catheter-Associated Skin Injury*).^{24,26-28} (III)
8. Select the type of sterile dressing (TSM or gauze) considering factors such as the type of VAD, risk of bleeding or infection, skin condition, known allergies or sensitivities, patient size, patient preference, cost, sterility, wear time, and ease of use of dressing, with the goal of selecting and applying a dressing that will have minimal dressing disruptions, as multiple dressing changes increase the risk of infection.^{24,29-48} (I)
 - a. Limited evidence suggests that a TSM dressing is associated with longer dwell times and fewer catheter failures due to dislodgement or accidental removal.^{32,49} (I)
 - b. Use sterile gauze or sterile absorbent dressing for drainage from the catheter exit site (unless hemostatic agent used to absorb serosanguinous drainage) or if patient is diaphoretic.^{9,37,50-52} (IV)
 - i. Consider frequency of dressing change and risk for infection when selecting a dressing to achieve hemostasis. Follow manufacturer's instructions for use with hemostatic agents.⁵ (V)
 - c. Use chlorhexidine gluconate (CHG)-containing dressings unless contraindicated (eg, sensitivity or allergy to CHG) to prevent central line-associated bloodstream infections (CLABSI) in patients greater than 2 months of age with short-term CVADS (refer to population specific recommendations in Standard 47, *Vascular Access Device-Related Infection*).
- d. Consider an alternative dressing if catheter-associated skin injury is present and not resolved with use of a transparent or gauze dressing (refer to Standard 52, *Catheter-Associated Skin Injury*).
- e. For tunneled, cuffed CVADS, a dressing may no longer be required when the subcutaneous tunnel is healed. Time to heal is patient specific, although one study cited 3 weeks.^{9,48,53} (V)
- J. Use a securement method to stabilize and secure VADs, considering a bundled approach (refer to Standard 36, *Vascular Access Device Securement*).
- K. Consider the need for an additional site protection strategy to reduce the risk of VAD dislodgement or joint stabilization when the VAD is in an area of flexion (refer to Standard 37, *Site Protection and Joint Stabilization*).
- L. Label the dressing with the date performed or date to be changed, avoiding placement of the label over the insertion/exit site.^{1,54} (V)
- M. Use chlorhexidine bathing to minimize the risk of CLABSIs in hospitalized patients. Consult manufacturer's instructions regarding potential risk of dressing integrity with VAD dressing exposure to bathing products (refer to Standard 47, *Vascular Access Device-Related Infection*).
- N. Do not use rolled bandages, with or without elastic properties, as a primary method of VAD securement or site protection, as they do not adequately secure the VAD (refer to Standard 36, *Vascular Access Device Securement*).
 1. Use a single tubular sleeve that can be easily removed to inspect the insertion site rather than a rolled bandage (refer to Standard 36, *Vascular Access Device Securement*).
 2. The presence of skin disorders that contradict the use of medical adhesives (eg, pediatric epidermolysis bullosa, toxic epidermal necrolysis, and burns) may necessitate the use of tubular gauze mesh rather than adhesive securement devices (ASDs). Single-center observational studies demonstrate that the use of SASSs might be effective and safe in this patient population; however, these studies are small, and close observation of this vulnerable patient group is recommended (refer to Standard 36, *Vascular Access Device Securement*; Standard 52, *Catheter-Associated Skin Injury*).
 3. If using medical tape for additional securement of add-on devices or portions of catheter beyond the dressing, select the type of tape based on the intended use and patient's skin condition; use a roll of sterile tape dedicated to a single-patient use.⁵⁴⁻⁵⁷ (IV)
- O. Keep sharp objects away from the VAD; never use scissors, hemostats, or pins on or near the catheter.¹ (V)

- P. Protect VAD when patient is showering or bathing by covering the entire catheter dressing site with a clear plastic wrap or device designed for this purpose. Cover the connections and protect hub connections from water contamination (see Standard 37, *Site Protection and Joint Stabilization*).¹ (V)
- Q. Avoid taking blood pressure measurements or placement of a tourniquet over the site/upper extremity with a PICC or on an extremity with a peripheral VAD, including midline peripheral catheters, during periods of infusion.¹ (V)

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KEY DEFINITIONS

Sorption. A complex process including both adsorption and absorption that varies greatly with components within the infusion container, the administration set, type of infusate, the flow rate of infusates, and the contact duration and conditions during storage, preparation, and administration.

- **Absorption.** Drug penetration inside of the infusion system.
- **Adsorption.** Interaction of the drug with the surface of the infusion container and/or administration set; results in patient receiving a smaller amount of the drug.

Leaching: Process of a solute becoming detached or extracted from its carrier substance.

Shedding: Particle release (solids) from an infusate container, administration set, or filter.

Intermittent administration set: A primary or secondary administration set that has been disconnected from the initial access point (eg, needleless connector, vascular access device [VAD] hub) and left disconnected due to completion or a pause in an infusion. It must be disconnected aseptically, with the distal tip protected by a new sterile end cap.

Continuous administration set: A primary or secondary administration set that remains connected to the vascular access device (VAD) for the duration of an infusion or until the scheduled administration set change occurs. This set may be disconnected from the VAD for a brief period (eg, blood sampling, transition to a new VAD lumen) and reconnected to the VAD with adherence to ANTT and needleless connector cleansing.

Continuous infusion: A controlled method of intravenous administration given over at least several hours or longer without interruption.

Intermittent infusion: A small volume given by manual push or short infusion (eg, 30 or 60 minutes); an infusion technique that would easily allow for patency assessment before, during, and after the medication infuses.

Standard

40.1 Administration set use and replacement is performed with adherence to Aseptic Non Touch Technique (ANTT®) at a frequency based upon factors such as patient condition, solution administered (type, rate, and frequency), immediately upon suspected contamination, and when the integrity of the product or system has been compromised.

40.2 Administration sets are designed with anti-free-flow mechanisms to protect against inadvertent bolus and are of a luer-lock design to ensure a secure connection, reduce manipulation, and minimize the risk of leaks, disconnections, or misconnections.

40.3 Administration sets are single-patient use only.

NOTE: This Standard addresses administration set selection, preparation, and replacement. Also see Table 1: Medication/Infusion Delivery: Dose Accuracy and Error Prevention in Standard, 57, *Infusion Medication and Solution Administration*.

Practice Recommendations

I. General

- Standardize flow-control devices, related administration sets, and drug concentrations, when possible, to reduce potential for errors.¹ (V)
- Educate clinicians on factors that impact accurate dose delivery to reduce errors in administration: proper use of flow-control devices and their respective administration sets, flow rate variability, residual or dead space volume, compliance and function of administration

sets, and proper use of add-on devices (see Table 1: Medication/Infusion Delivery: Dose Accuracy and Error Prevention in Standard 57, *Infusion Medication and Solution Administration*; Standard 35, *Other Add-On Devices*).¹⁻⁸ (IV)

- Use administration sets with integrated add-on devices (eg, filters) to minimize the number of connections, thus reducing the risk of contamination, misuse, and accidental disconnection (see Standard 35, *Other Add-On Devices*).^{9,10} (IV)
- Use an administration set without any injection ports with external epidural/intrathecal infusions to reduce the risk of inadvertent epidural/intrathecal access (refer to Standard 53, *Epidural and Intrathecal Access Devices*).
- Use administration sets with composite material recommended for drugs at risk of tubing sorption, which may affect accuracy of drug delivery and desired therapeutic effect (eg, nitroglycerin, diazepam, insulin, propofol, therapeutic proteins, granulocyte colony stimulating factor, certain antibiotics, amiodarone). Monitor clinical response to medication.^{5,11-18} (IV)
 - Sorption may be reduced with concomitant fluid delivery and/or flush after medication delivery.
 - Further study is needed to quantify sorption risk for specific medications and to develop administration sets that limit the risk of dose reduction.
- Consider the risks of leaching or shedding products from the infusate container or administration set into the infusate solution before or during administration. Factors that may increase the risk of leaching or shedding include type of infusate; compressive and shear

forces exerted on the administration set with clamping and with infusion device functions; contact duration; storage condition (eg, temperature); agitation during transport (eg, pneumatic tube system). These contaminants can be administered to the patient as subvisible particles within the infusate, with the potential to produce an inflammatory response. Further study is needed to reduce the risk of administration of leachable components.¹⁹⁻²⁵ (IV)

1. Avoid the use of polyvinyl chloride (PVC) (containing di(2-ethylhexyl)phthalate [DEHP]) infusion bags for therapeutic protein dilution and administration due to risk of DEHP droplet formation that may bind to proteins within the bag or administration set.²² (IV)
 2. Filters prevent a large percentage of subvisible particles from reaching the patient; however, filters can also cause sorption of medication and shedding of particles (See Standard 33, *Filtration*).^{17,21} (IV)
- G. Label all the administration sets (see Table 1: Medication/Infusion Delivery: Dose Accuracy and Error Prevention in Standard, 57, *Infusion Medication and Solution Administration*).^{1,8,26} (V)
1. Indicate the date of placement on the administration set according to organizational policies, procedures, and/or practice guidelines.
 2. When there are different access sites (ie, peripheral, central, epidural, intraosseous [IO], subcutaneous) or multiple fluid containers connected to a vascular access device (VAD), label the tubing with the route and/or medication/solution near the connection to the solution container and near the patient's access site.
- H. Organize the infusion administration system to minimize errors related to multiple infusions and variations in infusion delivery methods. Trace all catheters/administration sets/add-on devices between the patient and solution container to the VAD before connecting or reconnecting any infusion/device, at each care transition to a new setting or service, and as part of the handoff process.^{1,8,26} (V)

II. Primary and Secondary Continuous Infusions

- A. Replace primary and secondary continuous administration sets used to administer solutions other than lipid, parenteral nutrition, blood, or blood products at least every 7 days (unless otherwise stated in manufacturers' directions for use) or when clinically indicated (eg, any loss of product integrity such as contamination or dysfunction), whichever occurs sooner.²⁷⁻²⁹ (III)
1. Additional high-quality study is needed to provide clear evidence to inform optimal replacement of administration sets, including the impact of flexural and compressive stress on administration sets with extended use.^{25,27,30} (IV)
 2. A single-center study found no bacterial growth in intravenous (IV) solution from prespiked bags that

were prepared in advance of surgical procedures. With appropriate monitoring and application of ANTT, priming IV solutions and administration sets within 4 hours of a procedure was not associated with bacterial growth.³¹ (IV)

- B. Plan to change the primary administration set to coincide with the VAD change (eg, transition from a peripheral intravenous catheter [PIVC] to a newly inserted central vascular access device [CVAD]) and/or initiation of a new solution container, with consideration of the impact on the patient's clinical condition.²⁹ (IV)
- C. Secondary administration set (see Table 1: Medication/Infusion Delivery: Dose Accuracy and Error Prevention in Standard, 57, *Infusion Medication and Solution Administration*).
1. Use a primary continuous administration set that contains a back-check valve or use a dedicated pump set with integrated mechanisms to prevent retrograde flow of the secondary medication into the primary solution container.^{10,32} (IV)
 2. Develop a standardized method and ensure staff competency in administration for intermittent medication delivery. Significant variation exists in practice, resulting in increased potential for dosing errors.^{1,33} (IV)
 3. Avoid disconnecting primary and secondary continuous administration sets whenever possible.
 - a. If disconnection of a continuous or an intermittent infusion administration occurs, aseptically attach a new, sterile, compatible covering device to protect male luer ends on administration sets, ensuring correct connection of catheters/administration sets/add-on devices. Do not attach the exposed male luer end of the administration set to a port on the same administration set (ie, looping). Replace an administration set that is suspected of contamination.^{8,34} (V)
 - b. If the secondary administration set is disconnected from the primary set, the secondary administration set is now considered a primary intermittent administration set and is changed every 24 hours. (Committee Consensus)

III. Primary Intermittent Infusions

- A. Change intermittent primary and secondary administration sets every 24 hours.
1. There is an absence of studies addressing administration set changes for intermittent infusions. When an intermittent infusion is repeatedly disconnected and reconnected for infusion delivery/administration, there is increased risk of contamination at the spike end, catheter hub, needleless connector, and the male luer end of

the administration set, potentially increasing risk for catheter-associated bloodstream infections (CABSI). (Committee Consensus)

IV. Parenteral Nutrition (PN) (refer also to Standard 61, Parenteral Nutrition).

- A. Replace solution containers and administration sets used for PN (total nutrient admixture [TNA] and amino acid/dextrose formulations) and lipids every 24 hours; replace administration sets used for lipid injectable emulsion (ILE) with each new infusion. Hang time for PN should not exceed 24 hours.
- B. Limit separate ILE infusion to a 12-hour maximum time; if volume limitations require separate ILE administration for a period longer than 12 hours, the American Society for Parenteral and Enteral Nutrition (ASPEN) recommends strong consideration for a new ILE container and administration set for the second 12-hour portion. The hang time of a TNA can be extended to 24 hours because bacterial growth in these solutions is inhibited due to reduced pH and to increased total osmolality compared to infusing ILE separately. Use administration sets free of DEHP to administer lipid-based infusates, such as ILE or TNA. DEHP is lipophilic and leaches into the lipid solution with commonly used PVC administration sets and containers. DEHP is considered a toxin, and studies have demonstrated increased DEHP levels in lipid solutions, which is a risk especially with neonatal, pediatric, and long-term home care patients.

V. Propofol Infusions

- A. Replace administration sets (and any add-on devices such as stopcocks) used to administer propofol infusions at least every 6 to 12 hours, per the manufacturers' directions for use.^{9,35} (V)

VI. Blood and Blood Components

- A. Change the transfusion administration set in conjunction with manufacturers' directions for use.³⁶ (V)
 1. Clinical studies establishing the maximum time for administration set use are lacking; in accordance with the Association for the Advancement of Blood and Biotherapies (AABB), if the first unit requires 4 hours or more for transfusion, the administration set and filter are not reused. National guidelines from other countries recommend changing the administration set every 12 hours.
 2. Note that most standard filters have a 4-unit maximum capacity; follow manufacturers' directions for use (refer to Standard 62, *Blood Administration*).
 3. Consider whether add-on devices (eg, stopcock, needleless connectors) would limit the blood

infusion rate in patients requiring rapid blood resuscitation.³⁷ (VI)

VII. Hemodynamic and Arterial Pressure Monitoring

- A. Replace the disposable or reusable transducer and other components of the system, including the administration set, continuous flush device, and flush solution used for invasive hemodynamic pressure monitoring after 96 hours, immediately upon suspected contamination, or when the integrity of the product or system has been compromised.²⁴ (II)
 1. In a noninferiority trial, 7-day peripheral arterial line set replacement was found to be noninferior when compared to 4-day replacement regarding infection.²⁸ (III)
 2. Current recommendations for hemodynamic administration sets are generally based on guidelines for venous access. Further research is needed to guide optimal frequency for hemodynamic administration set change.^{38,39} (III)

VIII. Quality Improvement

- A. Monitor and review quality data (ie, accurate dose delivery, impact of practice change regarding administration set replacement frequency) through an interprofessional review process. Adjust clinical practices to ensure optimization of patient outcomes (see Standard 6, *Quality Improvement*).^{1,7,8,26} (V)

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41. BLOOD SAMPLING

Standard

41.1 Patient identification and proper labeling of all blood sample containers are performed at the time of sample collection and in the presence of the patient.

41.2 Blood conservation techniques are employed to reduce the risk of iatrogenic anemia.

41.3 Monitor use of blood sampling through collaboration from all departments (managers, clinicians, and providers) to reduce overuse of blood sampling and reduce preanalytical errors.

41.4 Adherence to Aseptic Non Touch Technique (ANTT®) is maintained when obtaining blood samples (skin cleansing for direct venipuncture, needleless connector cleansing, and when accessing a vascular access device) to prevent contamination.

Practice Recommendations

I. General

A. Educate the patient about the purpose and process for blood sampling.

1. Advise the patient to avoid any exercise for 24 hours before blood sampling. Exercise and changes from supine to upright positions can alter plasma volume because of gravity, venous hydrostatic changes, and distribution of body fluids. Changes may include alterations in hemoglobin, hematocrit, and other cell counts.^{1,2} (V)
2. If fasting is required, inform the patient of the fasting time period prior to specimen collection. Assess adherence prior to obtaining the sample.¹ (V)

B. Reduce the risk of iatrogenic anemia by collaborating with laboratory management, managers from other patient care areas, and providers to limit blood tests to only those that are necessary for diagnosis and treatment decisions. Health care–acquired anemia impacts patients of all ages and may increase the need for blood transfusion and its inherent risks.³⁻⁶ (IV)

1. Use strategies to reduce blood loss, including drawing specimens based on clinical need of individual patient (ie, targeted testing), establishing minimal volume required, using small volume collection tubes if validated for a specific test, point-of-care testing methods when appropriate, closed-loop systems for venous and arterial sampling that returns blood to the patient, use of the push-pull (mixing method), and delay in umbilical cord clamping in stable term and preterm infants.⁷⁻³³ (I)

C. Provide educational programs to preserve the patient's own blood supply through effective treatment of anemia and to improve blood sample ordering and collection practices.³⁴⁻³⁶ (II)

1. Goals include reduction of needed transfusions, the frequency of daily blood tests, the number of

rejected samples, contamination of blood cultures, and hemolysis rates (see Standard 62, *Blood Administration*).

2. Systematic reviews have identified specific educational and competency processes that produce improvement in outcomes of blood sampling, including standardization of blood sampling protocols (see Standard 5, *Competency and Competency Assessment*).

D. Employ a standardized procedure to prevent errors (hemolysis, clotted samples) in the preanalytical phase. These errors delay treatment decisions due to spurious laboratory values, enhance the potential for patient harm, and increase costs of care. Preventative measures may include strategies listed below.^{3-6,22,35,37-49} (II)

1. Develop standardized processes for direct venipuncture and blood sampling from peripheral and central vascular access devices (CVADs), including use of flush, amount of discard, site selection, and amount of hold time for infusion, if drawn from a VAD.
 - a. Consider the use of the common femoral vein under ultrasound guidance for neonatal and infant patient population for large-volume phlebotomy.⁵⁰ (V)
2. Confirm patient identification. Electronic patient identification systems (eg, barcoding) for labeling have been shown to reduce errors when compared to manual methods.
3. Use the correct supplies in the correct sequence (eg, color of the collection tube closure, order of draw) according to manufacturers' directions for use.
4. Complete the specimen preparation (eg, proper fill volume, gentle inversion) per manufacturers' instructions.
5. Label each specimen in the presence of the patient.
6. Document pertinent specimen information (eg, source, sequence) per facility policy.
7. Send samples for processing promptly after collection. If delivery of the specimen is delayed, properly store the specimen until it can be transported for processing.
8. Prior to transport, ensure the specimen is prepared and secured per manufacturers' instructions.

E. Monitor and reduce blood specimen rejection through mitigation of risks. Compromised technique during collection or whole specimen destruction during transport is the most common cause of blood sample rejection by the laboratory and causes erroneous values for many tests (eg, electrolytes, glucose, cardiac biomarkers, coagulation times). Consider potential for risk factors listed below.^{3,48,51-54} (I)

1. Drawn in the emergency department (ED) compared to non-ED areas.^{26,55} (IV)
2. Drawn by nurses and medical staff compared to phlebotomists.^{3,56,57} (IV)

3. Drawn from peripheral intravenous catheters (PIVCs) when compared to a direct venipuncture by straight needles or steel-winged needles.^{56,58} (IV)
 - a. A small tube device advanced through an existing short PIVC is associated with decreased blood specimen rejection rates in studies of volunteers and patients. Follow manufacturers' recommendations related to wait times and waste volumes.⁵⁸⁻⁶⁰ (V)
 4. Drawn from veins of the hand and forearm compared to the antecubital fossa.²⁹ (V)
 5. Pneumatic systems not designed or maintained for blood transportation or improperly secured samples when compared to hand transport.^{61,62} (IV)
 6. Filling less than half of evacuated tubes compared to those filled more than halfway.^{3,5,22,44,63} (IV)
 7. From venipunctures with greater than 1 minute of tourniquet time.^{3,46} (V)
 8. There is a need for further research in the impact of specific specimen equipment, collection technique, and patient characteristics on blood specimen rejection.^{3,22,23,52,63,64} (I)
- F. Therapeutic drug level: draw the blood sample from a dedicated or separate lumen or VAD not used for administration of the drug being monitored, if possible. Therapeutic drug monitoring is most common for anticoagulants, antibiotics, insulin, and immunosuppressants, with dosage adjustment based on test results. Concerns and variables include, but are not limited to, medication/drug, flush volumes, device design, device material (eg, silicone, polyurethane, and polyurethane with silver), waste/discard vs push-pull technique in obtaining samples.^{29,38,65,66} (IV)
1. Evaluate elevated test results based on clinical exam prior to dose adjustment; retesting via direct venipuncture may be necessary. Provide drug name, dose, time of last infusion, and specimen collection time to the laboratory.
- G. Blood Cultures:
1. Use precautions for obtaining blood cultures to avoid false-negative and false-positive results and to reduce incorrect classification as a catheter-associated bloodstream infection (CABSI), unnecessary antibiotic delivery, potential increased length of stay, and related costs.⁶⁷⁻⁷¹ (IV)
 - a. Consider standardized methods (eg, a dedicated phlebotomy team, a standardized sterile collection kit) to reduce blood culture contamination rates.^{57,70,72,73} (III)
 - b. Obtain blood for culturing prior to administering antibiotics and prior to drawing other specimens, when possible.^{67,68} (IV)
 - c. Drawing the blood culture specimen:
 - i. Peripheral venipuncture:
 - a) Avoid drawing blood cultures from a PIVC on insertion due to increased risk of contamination. Do not draw blood cultures from a PIVC or peripheral arterial line during the dwell of the catheter.^{35,70,74-76} (IV)
 - 1) Ensure proper ANTT is used throughout the procedure if drawing a blood culture from a newly inserted PIVC.⁷⁴ (V)
 - b) Monitor contamination rates to inform process improvements.⁷⁴⁻⁷⁶ (V)
 - c) Consider the costs and benefits in implementing a consistent process to divert and discard the initial blood sample when drawing blood cultures. Studies have demonstrated reduction in blood culture contamination with use of a diversion device.^{60,75-78} (IV)
- ii. CVAD:
- a) Use a CVAD for drawing blood cultures only when the catheter is suspected of being the source of infection. Use of a clinical decision tool, such as a blood culture decision algorithm, has been associated with reduced CVAD blood culture draws.^{29,67,68} (IV)
 - b) Draw a set of blood cultures from a peripheral vein simultaneously with the CVAD sample to confirm a catheter-related bloodstream infection (CR-BSI) diagnosis.^{48,70,75} (V)
 - c) Recognize that the presence of antimicrobial locking solution in the CVAD may interfere with culture results. (Committee Consensus)
 - d) Replace the needleless connector before obtaining the blood culture sample.⁴⁸ (V)
 - e) If using a blood culture bottle designed for direct filling from the CVAD, maintain the bottle upright and follow manufacturers' directions for use to avoid reflux of the broth medium into the CVAD and vein.^{40,48} (V)
 - f) Use the initial blood volume aspirated from the CVAD for the blood culture without a discard volume.^{48,75} (V)
- d. For multilumen CVADs, studies recommend obtaining separate samples from each lumen for blood cultures. One small comparative study on adults found that pooled blood cultures had the same sensitivity as individually cultured lumens.^{79,80} (V)
- e. Obtain 2 sets of blood cultures to increase the sensitivity for detecting organism growth.⁷² (III)
 - f. Draw a quantity of blood that is sufficient for isolating organisms per manufacturers' and age-related guidelines for aerobic and anaerobic containers. Disinfect and inoculate the blood

culture containers per manufacturers' instructions.⁸¹ (IV)

- g. Recognize that differential time to positivity (DTP) may be used to diagnose CR-BSI; however, continuous monitoring blood culture systems and shorter incubation times have reduced the use of DTP.⁶⁷ (IV)
- h. Transport blood culture bottles to the laboratory within 2 hours; do not refrigerate, as this may kill some organisms.^{38,48,67,82} (IV)

II. Considerations in Blood Sampling Based on Device

A. Carefully analyze risks vs benefits before deciding to use a direct venipuncture versus a VAD for obtaining blood samples.^{28,35,48,56,83} (II)

- 1. Risks of direct venipuncture include contamination; pain; damage to skin, vessel, and nearby nerves; and hematoma in patients receiving anticoagulants or with bleeding disorders, as well as psychological stress, anxiety, and dissatisfaction with care. Benefits may include reduced hemolysis rate and improved accuracy of resulted value.
- 2. Risks associated with sampling from a PIVC include hemolysis of the sample, contamination of the sample from infusing solutions and medications, local complications from excessive catheter movement (eg, phlebitis, infiltration), and dislodgement from the insertion site.
 - a. A systematic review found that hemolysis rates were higher with sampling via a PIVC versus direct venipuncture but could be reduced with the use of a standard protocol.³⁵ (II)
 - b. A prospective cohort study found that technique (eg, increased tourniquet time, repeated attempts) and patient age were risk factors for hemolysis but found that PIVC drawn versus direct venipuncture was not a factor.⁴⁹ (IV)
- 3. Risks associated with sampling from a CVAD include increased hub manipulation and the potential for intraluminal contamination, alterations in VAD patency, and erroneous laboratory values associated with adsorption of medications infused through the VAD or inadequate flushing. Benefits include reduction in risks of peripheral venipuncture, as listed above.

B. Blood sampling via direct venipuncture:

- 1. Prevent venous stasis and other causes of inaccurate laboratory data by avoiding repetitive fist clenching or hand pumping, limiting tourniquet time to less than 1 minute, and removing tourniquet as soon as blood begins to flow into evacuated tube. Use of infrared visualization devices will identify the vein and may eliminate the need for a tourniquet (see Standard 21, *Vascular Visualization*). (A/P)
- 2. Perform venipuncture for phlebotomy on the opposite extremity of an infusion. If phlebotomy must be

performed on the extremity with infusing solutions, a vein below or distal to the site of infusion should be used.^{29,56,65} (IV)

- 3. Restrict venipuncture for blood sampling to the dorsum of the hand whenever possible, regardless of hand dominance, in patients with an actual or planned dialysis fistula or graft (see Standard 27, *Vascular Access and Hemodialysis*).⁸⁴ (V)
 - 4. Consider restricting venipuncture for blood sampling to the contralateral upper extremities in patients with lymphedema and those at risk for lymphedema (axillary surgical lymph node dissection, radiation therapy).⁸⁵⁻⁹⁰ (IV)
 - a. Avoidance of the ipsilateral arm has been based on the risk of infection from punctures due to compromised axillary drainage. Evidence for avoiding all venipuncture on the at-risk upper extremity comes from conflicting studies; however, there remain recommendations to avoid all venipuncture procedures on at-risk extremities.
 - 5. When feasible, avoid venipunctures on an extremity with alteration in normal venous blood flow (eg, paralysis or hemiparesis from a cerebrovascular accident) and/or decreased sensation that could prevent perception of pain, such as needle-to-nerve contact (see Standard 45, *Nerve Injury*).²⁹ (V)
 - 6. Use caution in venipuncture of the median cubital, cephalic, or basilic veins of the antecubital fossa using a straight needle or steel-winged needle. Nerve damage at/above the antecubital fossa may occur due to injury to the median and anterior interosseous nerve and the lateral and medial antebrachial nerves (refer to Standard 45, *Nerve Injury*).
 - 7. Perform venipuncture in neonates by a skilled phlebotomist instead of heel lance methods due to the increased pain from the heel lance. Automatic lanc-ing devices are preferred over manual devices to control the depth of puncture and to reduce the risk of bone or cartilage infection.^{91,92} (V)
- C. Blood sampling via direct arterial puncture:
- 1. Assess the circulation to the hand prior to puncturing the radial artery; perform a physical examination of hand circulation, such as assessing radial and ulnar pulses with an Allen test, pulse oximetry, or Doppler flow study. Review medical history (eg, trauma, previous radial artery cannulation, radial artery harvesting); assess presence of anticoagulants.^{47,93-95} (IV)
 - 2. Use a 20-gauge or smaller needle to reduce pain associated with radial artery puncture and to reduce arterial damage; however, smaller needles could cause hemolysis. Choose a needle with sufficient length to access the artery.⁴⁷ (V)
 - 3. Use ultrasound guidance to improve insertion success (refer to Standard 21, *Vascular Visualization*).
- D. Blood sampling via indwelling PIVC:

1. Pause infusing solutions for 1 to 2 minutes and waste 1 to 2 mL of blood prior to obtaining sample.^{56,65} (IV)
 2. Sampling of blood from indwelling short PIVCs produced results for complete blood count, blood chemistry, and coagulation studies that are not different from a direct venipuncture.^{56,58,65,92,96} (IV)
 3. Midline catheters may be labeled for obtaining blood samples; however, limited evidence is available regarding the techniques or outcomes of this procedure. A prospective observational study noted a low hemolysis rate of 0.69% in 1021 blood samples drawn from midline catheters. Further high-quality research is needed to establish a standard procedure for blood sampling via the midline catheter.^{97,98} (IV)
- E. Blood sampling via CVADs:
1. Accuracy of coagulation values from a blood sample obtained from a heparinized CVAD is inconclusive due to many confounding variables. These include specific procedures used (eg, waste/discard, push-pull), adherence of heparin to the catheter material and/or intraluminal biofilm, and discard volumes that could be detrimental to the patient.⁶⁶ (V)
 2. Evaluate the use of the push-pull vs discard vs closed-loop methods for obtaining a sample from CVADs.
 - a. The push-pull method produces clinically useful laboratory values in adults and pediatric patients, while reducing the amount of wasted blood and reducing hub manipulation. Studies include complete blood count, electrolytes, renal and liver function tests, glucose, coagulation studies, blood gases, C-reactive protein, and therapeutic drug monitoring for gentamicin.^{28,56,83,99} (IV)
 - b. For the discard method, volume for discard depends upon the internal volume of the CVAD, intraluminal lock solution, saline flush prior to drawing the discard volume, and the specific laboratory tests needed. Coagulation studies require the largest discard volume to produce accurate results. Do not reinfuse the discard sample from a disconnected syringe due to risk of contamination and blood clot formation.^{66,100,101} (II)
 - c. Use of a closed-loop blood collection system for arterial and venous catheters in adults and pediatric patients allows return of blood withdrawn for the purpose of clearing the catheter lumen.¹⁰⁰ (II)
 3. Consider avoiding routine blood sampling in CVADs where parenteral nutrition (PN) is infused, as manipulation may increase the risk factor for CABS (refer to Standard 61, *Parenteral Nutrition*).
- F. Blood sampling via intraosseous access devices:
1. Consider reserving the initial intraosseous (IO) aspirate for laboratory analysis when there are no other options. Use caution in interpretation of laboratory

results of IO aspirate, as IO blood samples have been found to have inconsistent correlation with venous and arterial samples in the critically ill (refer to Standard 54, *Intraosseous Access Devices*).

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Note: All electronic references in this section were accessed between March 28, 2023, and August 4, 2023.

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42. VASCULAR ACCESS DEVICE REMOVAL

KEY DEFINITIONS

Removal when clinically indicated

- Effective removal when clinically indicated is predicated on the following:
 - Accurate and consistent vascular access device (VAD) assessment based on patient and infusate risk
 - Adherence to Aseptic Non Touch Technique (ANTT®) principles (refer to Standard 19, *Aseptic Non Touch Technique*, ANTT®)
 - Early recognition and management of complications.
- Remove the VAD when:
 - It is no longer clinically needed; evaluation of this should occur at least daily and with each VAD assessment (inpatient), or with each outpatient event
 - There has been a suspected contamination of a Key-Site or Key-Part
 - It has evidence of:
 - a complication that cannot be readily resolved (eg, lack of blood return due to mechanical obstruction that cannot be consistently and readily restored) or
 - a complication that might indicate the need for VAD removal (eg, edema, erythema, leakage, skin color and temperature changes, patient report of pain or discomfort with and without flushing or infusion, palpable cord)
 - It is no longer functioning in an optimal fashion or contains substances that may impact patient safety (eg, precipitate, blood products that cannot be cleared by flush).

Standard

42.1 The clinical need for each vascular access device (VAD) is assessed daily for acute inpatient settings and during regular assessment visits in other settings,

such as the home, outpatient facility, or skilled nursing facility.

42.2 VADs are removed when clinically indicated (eg, unresolved complication, discontinuation of infusion therapy, or when no longer necessary for the plan of care).

Practice Recommendations

I. Short and Long Peripheral Intravenous Catheters (PIVCs) and Midline Catheters

- A. Remove if no longer included in the plan of care or if not used for 24 hours or more.¹⁻⁴ (III)
- B. Remove PIVCs and midline catheters in pediatric and adult patients when clinically indicated, based on findings from site assessment and/or clinical signs and symptoms of systemic complications and not solely on dwell time (refer to Standard 43, *Phlebitis*; Standard 44, *Infiltration and Extravasation*; Standard 45, *Nerve Injury*; Standard 47, *Vascular Access Device-Related Infection*).
- C. Label catheters inserted under suboptimal aseptic conditions in any health care setting (eg, “emergent”). If peripheral access is still indicated, remove and insert a new catheter as soon as possible, within 24 to 48 hours.^{2,5} (IV)
- D. Assess the removed catheter to ensure it is fully intact. If a retained fragment is suspected, notify the provider immediately. Fracture of a catheter and potential embolization can occur from excessive force during infusion therapy, the force of inadvertent removal, or from adherence to internal structures.⁶ (V)
- E. Notify the health care team of signs and symptoms of suspected catheter-associated infection, including purulence, and discuss the need for obtaining blood cultures or a culture of drainage at the insertion site before removing a PIVC (see Standard 47, *Vascular Access Device-Related Infection*).^{7,8} (IV)
- F. If extravasation with a vesicant occurs, detach all administration sets and aspirate from the catheter hub prior to peripheral catheter removal (refer to Standard 44, *Infiltration and Extravasation*).

II. Nontunneled Central Vascular Access Devices (CVADs), Including Peripherally Inserted Central Catheters (PICCs) and Tunneled Noncuffed CVADs

- A. Assess and discuss daily with the health care team the continued need for the CVAD and remove when no longer needed for the planned treatment. Criteria for justification of continued use of a CVAD include, but are not limited to, the following⁹⁻¹²: (IV)
 1. Clinical instability of the patient (eg, alteration in vital signs, oxygen saturation)
 2. Prescribed continuous infusion therapy that is not peripherally compatible
 3. Hemodynamic monitoring
 4. Physical incompatibility and/or complexity of infusion regimen (multiple infusates)
 5. Documented history of difficult peripheral venous access (see Standard 25, *Vascular Access Device Planning and Site Selection*).
- B. Employ strategies to facilitate timely CVAD removal, including, but not limited to, the following^{11,13-15}: (II)
 1. Daily patient rounds by the health care team

2. Use of a standardized tool, including factors to be considered for making the decision to remove the CVAD
 3. Regular assessment by designated infusion/vascular access specialists or qualified nurse/clinician
 4. Removal within 24-48 hours if the catheter is inserted under suboptimal aseptic conditions
 5. Consider using an electronic communication tool to facilitate shared decision-making between the patient’s health care team and the infusion team/vascular access specialist team (VAST) regarding CVAD removal. The infusion team/VAST would provide consultation regarding clinical practice guidelines for appropriate removal, thus decreasing complications and costs and avoiding premature and unnecessary CVAD removals.
- C. Assess and report signs and symptoms of CVAD complications and changes in catheter function. Consider the need for alternative vascular access if removal is necessary (refer to Section 7, *Vascular Access Device Complications*).
 - D. Collaborate with the health care team, including infusion/vascular access specialists when applicable, to plan removal and insertion of a new VAD to meet vascular access needs in the presence of unresolved complication(s) and/or a continued need for infusion therapy (refer to Standard 4, *Infusion and Vascular Services*).
 1. Removal of a CVAD may be the goal with changes in the patient’s infusion needs and/or transfer to another level of care. Continuing needs for vascular access are based on assessment of the condition of the patient’s peripheral veins, risk of complications, and characteristics of the remaining infusion therapy. Further research is needed on clinical indications for CVAD removal (see Standard 25, *Vascular Access Device Planning and Site Selection*).^{9,10,14,16-20} (IV)
 2. Determine the removal or salvage of a CVAD due to suspected or confirmed catheter-associated bloodstream infection (CABSI) on blood culture results, specific cultured organism(s), patient’s current condition, available vascular access sites, effectiveness of antimicrobial or ethanol lock therapy, and provider direction (see Standard 47, *Vascular Access Device-Related Infection*).^{12,13,15,19,21-29} (II)
 3. Do not remove a CVAD solely due to catheter-associated deep vein thrombosis (CA-DVT) when the catheter is correctly positioned at the lower third of the superior vena cava (SVC) at or near the cavoatrial junction (CAJ), is functioning properly with a blood return, has no evidence of any infection, and patient comfort can be maintained. The decision to remove the CVAD should consider the severity of deep vein thrombosis (DVT)-related symptoms, presence of contraindications for systemic anticoagulation, and the continued need for infusion therapy requiring a CVAD (eg, vesicants, irritants) (see Standard 50, *Catheter-Associated Thrombosis*).^{9,21} (IV)

- a. In a small retrospective study, in patients with upper extremity superficial or deep vein thrombosis, there were no symptomatic pulmonary emboli upon PICC removal.³⁰ (IV)
4. Remove a CVAD with a primary or secondary catheter tip malposition that cannot be repositioned to the lower third of the SVC at or near the CAJ (see Standard 51, *Central Vascular Access Device Malposition*).³¹ (IV)
5. Consult with the health care team regarding diagnostic imaging studies and the appropriate medical management prior to removal of a CVAD in the event of infiltration or extravasation (refer to Standard 44, *Infiltration and Extravasation*).
- E. Implement precautions to prevent air embolism during removal of CVADs, including, but not limited to, the following (see Standard 49, *Air Embolism*)^{6,32-35}: (IV)
 1. Place the patient in a supine flat or Trendelenburg position (unless contraindicated; Trendelenburg position is contraindicated in premature infants) when removing the CVAD, so that the insertion site is below the level of the heart.
 - a. While there are no published cases of air embolism associated with PICC removal, there may be risk due to an intact skin-to-vein tract and fibrin sheath. Position patient so that the exit site is at or below the level of the heart during PICC removal and place an air-occlusive dressing (eg, petroleum gauze, covered with gauze and transparent semipermeable membrane) over the insertion site. (A/P; Committee Consensus)
 - b. Documentation of air embolism from removal of a CVAD inserted via the femoral vein has not been published, although there is evidence of air entering the femoral catheter during insertion and during other procedures. Because the exit site will be at or below the level of the heart, the risk of air embolism on removal would be minimal, unless the patient is in Trendelenburg position.
 2. Instruct the patient to perform a Valsalva maneuver at the appropriate point during catheter withdrawal.
 - a. The Valsalva maneuver may increase intra-abdominal and intrathoracic pressures and, thus, be contraindicated in patients with cardiac dysfunction, glaucoma, and retinopathy. If the Valsalva maneuver is contraindicated, use a Trendelenburg or left lateral decubitus position, have the patient hold their breath, or time removal to exhalation.
 3. Apply digital pressure with a sterile dry gauze pad at and just above the insertion site until hemostasis is achieved by using manual compression.
 4. Apply an air-occlusive dressing (eg, petroleum gauze, covered with gauze and transparent semipermeable membrane) to the access site for at least 24 hours for the purpose of occluding the skin-to-vein tract and decreasing the risk of retrograde air emboli.
 5. Encourage the patient to remain in a flat or reclining position, if able, for 30 minutes after removal.
- F. Never forcibly remove a CVAD if resistance is encountered. Contact the provider and collaborate with the interprofessional team to discuss appropriate interventions for successful removal. Over-the-wire technique may be useful in removing retained catheters. Maximal sterile barriers should be employed for this procedure.³⁶ (V)
- G. Assess the removed catheter to ensure it is fully intact after planned or inadvertent CVAD removal. If a retained fragment is suspected, notify the provider immediately. Fracture of a catheter and potential embolization can occur from excessive force during infusion therapy, the force of inadvertent removal, or from adherence to internal structures.^{32,33,36-39} (IV)
 1. Catheter pieces retained in the vein should be removed with endovascular techniques to reduce the risk of infection, thrombosis, and migration of the catheter piece.

III. Surgically Placed CVADs: Tunneled, Cuffed Catheters and Implanted Vascular Access Ports

- A. Assess the clinical need for a tunneled cuffed catheter or implanted vascular access port on a regular basis.⁴⁰ (V)
- B. Arrange for removal with the provider (which may include consultation to interventional radiology or surgery, depending on the type of VAD) when infusion therapy is completed, in the presence of an unresolved complication, or when it is no longer needed for the plan of care. Before removal, consider the possibility for infusion therapy to resume in the future (eg, patients with sickle cell anemia, cystic fibrosis, or cancer diagnoses).^{12,40,41} (II)
- C. Consult with the health care team regarding the decision to remove or salvage a CVAD due to suspected or confirmed CABS (see Standard 47, *Vascular Access Device-Related Infection*).^{22-24,42} (IV)
- D. Immediately report cuff, port body exposure, or catheter fracture to the health care team, and anticipate appropriate interventions (eg, repair, resuture of incision), including CVAD removal.³⁸ (V)
- E. Ensure complete removal of the CVAD, including subcutaneous cuff, to prevent subcutaneous abscess and delayed healing. Fluoroscopy and ultrasound guidance may be necessary to verify CVAD or cuff location and facilitate surgical removal.^{37,38} (V)

IV. Arterial Catheters

- A. Remove the catheter on evidence of signs/symptoms of infection, unresolved catheter dysfunction, complication (ie, occlusion, hematoma, altered circulatory status), or when it is no longer needed for the plan of care. Recognize the risk of an arterial catheter as a potential source for CABS.⁴³ (V)
- B. Apply digital pressure at and just above the insertion site using a sterile gauze pad until hemostasis is achieved by using manual compression. A sterile dressing should be applied to the access site.⁴⁴ (V)

- C. Assess and document the circulatory status distal to the area of cannulation after removal of the arterial catheter and notify the provider if circulatory and/or sensory abnormalities are noted.⁴⁴ (V)

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Section Seven: Vascular Access Device Complications

Section Standards

- I. To ensure patient safety, the clinician is competent in the recognition of and appropriate intervention for signs and symptoms of vascular access device (VAD)-related complications during insertion, management, and removal.
- II. Prevention, assessment, and management of complications are established in organizational policies, procedures, and/or practice guidelines.

43. PHLEBITIS

Standard

43.1 The clinician assesses the vascular access site for signs and symptoms of phlebitis; determines the need for and type of intervention; educates the patient and/or caregiver about phlebitis, the intervention, and any follow-up; and assesses patient response to treatment.

43.2 The clinician collaborates with the interprofessional team about the need for continued or alternative vascular access when the VAD is removed due to phlebitis.

Practice Recommendations

A. Recognize causal factors for phlebitis:

1. Chemical phlebitis associated with endothelial inflammation/injury: infusion of irritating infusates (eg, amiodarone, nicardipine, norepinephrine, levetiracetam, dextrose [$>10\%$]; cancer chemotherapy agents; antibiotics, including flucloxacillin, vancomycin; dobutamine; potassium chloride; iron sucrose; infusates with extremes of pH or osmolality); inadequate hemodilution; excessive infusion rate for a short peripheral intravenous catheter (PIVC); increased number of infusion medications; particulate matter in the infusate; and skin antiseptic solution that is not fully dried and pulled into the vein during catheter insertion (see Standard 25, *Vascular Access Device Planning and Site Selection*; Standard 61, *Parenteral Nutrition*).¹⁻¹⁷ (II)

2. Mechanical phlebitis may be related to effects on the endothelial cells, eg, high catheter-to-vein ratio, catheter insertion in an area of flexion, angle of catheter insertion and tip position, polytetrafluoroethylene (Teflon™) catheters; rapid infusion rate, inadequate securement, insertion trauma, or catheter material and stiffness. Improvements in catheter materials may reduce VAD-related complications, including phlebitis.^{1,9,10,13,18-22} (II)

3. Infectious phlebitis (septic or suppurative thrombophlebitis): bacterial contamination via extraluminal contamination (inadequate skin antisepsis, contamination of the catheter during insertion); intraluminal contamination through the hub; intraluminal contamination due to contaminated fluids/medications; and hematogenous seeding from an infection elsewhere in the body (eg, emergent VAD insertions, poor aseptic technique, and contaminated dressings).^{1,13,23} (IV)

4. Postinfusion phlebitis occurs 48-96 hours after catheter removal due to any of the factors above; the only risk factor cited in a large study was PIVC insertion in the emergency department.²⁴⁻²⁶ (IV)

- B. Recognize patient-related risk factors, including, but not limited to, current infection, immunodeficiency, reduced mobility, family history of deep vein thrombosis, and comorbidities; insertion in the patient's dominant side; insertion in a lower extremity, except for infants; female gender; and age (≥ 60 years). Based upon a systematic review, the overall rate of phlebitis may be lower in pediatric patients than in adults.^{4,6,7,27-29} (II)

C. Reduce risk for phlebitis:

1. Consider use of a peripherally inserted central catheter (PICC) or other central vascular access device (CVAD) for infusates identified as causing phlebitis based upon length of infusion time and anticipated duration of therapy (refer to Standard 25, *Vascular Access Device Planning and Site Selection*).
2. Use skilled clinicians to insert PIVCs. PIVC insertion in adults by infusion/vascular access specialist teams produced greater first-attempt insertion success and lower rates of complications (refer to Standard 4, *Infusion and Vascular Access Services*).

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3. Allow skin to thoroughly dry after application of antiseptic solution (refer to Standard 19, *Aseptic Non Touch Technique [ANTT®]*; Standard 31, *Vascular Access Site Preparation and Skin Antisepsis*).
 4. Choose the smallest catheter for intended therapy. Consider larger veins, secure catheter with securement technology, avoid areas of flexion and lower limb insertion except in neonates and nonmobilizing infants, and stabilize joint as needed (see Standard 25, *Vascular Access Device Planning and Site Selection*; Standard 36, *Vascular Access Device Securement*; Standard 37, *Site Protection and Joint Stabilization*).^{4,10,11,18-20,27,30-33} (III)
 5. Evaluate/mitigate drug-related factors, including dilution. One study reported that standardized drug administration measures supervised by a pharmacist, including attention to drug composition, choice of administration rate/route, and any contraindications to compounding were associated with a reduction in phlebitis in an intensive care unit (ICU) setting.^{10,11,14} (IV)
 - a. Administer continuous vancomycin infusions via a CVAD. In a small study, thrombophlebitis occurred in all patients receiving the infusion via a midline catheter, regardless of dilution, as assessed via daily ultrasound.³⁴ (IV)
 - b. Avoid routine use of in-line filters as a thrombophlebitis prevention measure since the patient population most likely to benefit from this intervention has yet to be determined. Infusate contaminants are potential etiologic factors for phlebitis; however, results of clinical studies regarding the clinical benefit of filtration are uncertain/controversial, with further studies needed to identify beneficial effects, potential disadvantages, and cost-effectiveness (see Standard 33, *Filtration*).^{1,3} (IV)
 6. Consider a PIVC insertion and maintenance bundle to reduce PIVC complications, including phlebitis (see Standard 32, *Vascular Access Device Insertion*).^{33,35-39} (II)
 7. Replace a catheter inserted emergently under sub-optimal aseptic technique when the patient is stabilized and within 48 hours. Move a catheter inserted in a lower extremity to an upper extremity in adults; move to a new proximal site or opposite side for pediatric patients, if possible (refer to Standard 42, *Vascular Access Device Removal*).
- D. Regularly assess the vascular access sites of PIVCs, midline catheters, and PICCs, based on patient population, type of therapy, and risk factors for signs and symptoms of phlebitis (swelling, erythema, leakage, palpable venous cord, purulent discharge, warmth, and pain/tenderness). Instruct the patient to report pain or tenderness at the vascular access site (refer to Standard 39, *Vascular Access Device Post-Insertion Care*).
1. Remove and reinsert PIVCs based upon clinical indication; there is no clear difference in the rate of thrombophlebitis between clinically indicated or routine replacement of PIVC, based upon a systemic literature review and meta-analysis (see Standard 42, *Vascular Access Device Removal*).^{40,41} (I)
 2. Evaluate pain as a potential early indicator of phlebitis.^{10,42} (III)
 3. Based upon a meta-analysis, the incidence of phlebitis was not significantly different between midline catheters and PICCs.⁴³ (I)
 4. Use a standardized phlebitis scale or definition consistently within an organization; however, recognize the limitations of existing tools.
 - a. The type, number, or severity of signs and symptoms, and definitions that indicate phlebitis differ among published studies; studies have shown low interrater reliability for signs, symptoms, and scales commonly used in phlebitis assessment. Further study is recommended for valid and reliable assessment tools.^{42,44-47} (III)
 5. Monitor the PIVC site for postinfusion phlebitis for 48 hours or upon discharge; provide the patient/caregiver written instructions about signs and symptoms of phlebitis and whom to contact if this occurs. Reported postinfusion phlebitis rates vary widely, ranging from 1% to 23%.^{25,26} (IV)
 6. Recognize the potential future role of technology in identifying phlebitis, such as ultrasound and infrared thermography. Infrared thermography may be a promising and helpful technique in objective identification of early development of phlebitis, based upon findings, including an increased difference in temperature.^{17,18,48,49} (V)
- E. Intervene and manage vascular access in the presence of phlebitis:
1. Remove PIVC upon signs/symptoms of phlebitis (see Standard 42, *Vascular Access Device Removal*).^{33,47} (V)
 2. Consider management of transient mechanical phlebitis after midline catheter/PICC insertion: ensure catheter securement, apply heat, elevate limb, and monitor for 24 hours postinsertion. If signs and symptoms persist, remove catheter. (Committee Consensus)
 3. Provide interventions for comfort/decrease of symptoms of phlebitis.
 - a. Application of warm or cold compresses; elevate limb; provide analgesics as needed; and consider other pharmacologic interventions such as anti-inflammatory agents.^{50,51} (V)
 - b. A variety of topical interventions have been reported in the prevention and treatment of phlebitis (eg, nonsteroidal anti-inflammatory drugs, glycerine, aloe vera, chamomile) without clear evidence for efficacy.⁵²⁻⁵⁵ (I)

4. Re-evaluate the need for ongoing vascular access when chemical phlebitis is suspected; evaluate need for alternative vascular access, different medication, slower infusion rate, infusate dilution.¹⁴ (V)
5. Infectious phlebitis: if suspected or purulence present, remove catheter; obtain a culture of the purulent exudate and catheter tip, document findings of site assessment, and monitor for signs of systemic infection; surgical intervention may be required. Antibiotic and anticoagulation therapy were associated with resolution of septic thrombophlebitis in 57% of pediatric patients, as reported in a small retrospective study (see Standard 42, *Vascular Access Device Removal*; Standard 47, *Vascular Access Device-Related Infection*).²³ (V)
 - a. In United States (US) hospitals performing CLABSI surveillance following National Healthcare Safety Network (NHSN) protocols, matching cultures from purulent drainage at a noncentral line site are relevant in determining CLABSI attribution for public reporting metrics.⁵⁶ (V)

Note: The INS Phlebitis Scale and Visual Infusion Phlebitis Scale are located in Appendix C.

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44. INFILTRATION AND EXTRAVASATION

Standard

44.1 The risk of infiltration and extravasation is reduced through careful selection of the most appropriate vascular

access device (VAD) and insertion site and through validation of VAD position and patency prior to and during infusion therapy.

44.2 Peripheral and central vascular access device (CVAD) sites are regularly assessed for signs and/or symptoms of infiltration and extravasation before and during each infusion.

44.3 Appropriate intervention(s) are implemented immediately upon recognition of infiltration/extravasation, as determined by the characteristics of the solution or medication escaping from the vein.

Practice Recommendations

A. Select the most appropriate VAD and insertion site to reduce the risk for infiltration/extravasation. Escalate VAD insertion to a vascular expert or infusion/vascular access specialty team as early as possible in patients with difficult venous access risk factors present (see Standard 25, *Vascular Access Device Planning and Site Selection*).¹⁻¹⁷ (I)

1. Studies indicate the need to address significant learning needs within nursing regarding risk factors, optimal VAD selection, recognition, and treatment strategies for infiltration and extravasation across health care settings and populations.^{1,5,9,11,13,15,18-21} (I)
2. In a controlled before-and-after study in a neonatal unit, implementation of clinical practice guidelines for peripheral intravenous catheter (PIVC) insertion and management was associated with a significant reduction in extravasation events.¹¹ (IV)

B. Recognize the differences between vesicant, nonvesicant, and irritant solutions and medications. Each organization should reach a consensus on what medication is considered to be a vesicant and irritant based on their internal formularies and the populations they serve.^{1,2,4,7,13,22-27} (I)

1. Identify the vesicant nature of certain antineoplastic and nonantineoplastic medications prior to administration; be prepared to use the recommended pharmacologic and nonpharmacologic treatments in the event of extravasation or to escalate to a clinician capable of managing these injuries.^{1,5,9,11,12,15,20,22-24,26-29} (II)
 - a. There is a paucity of data on extravasation incidence and treatment recommendations (often based on animal and case studies). This is an area in need of further study, with the recommendation to form an extravasation registry to improve dissemination of outcomes.^{20,23,27,29-33} (II)

C. Evaluate risk factors associated with infiltration/extravasation to determine the frequency of monitoring and to evaluate alternative vascular access options for patients at increased risk (eg, use of a CVAD) (see Standard 25, *Vascular Access Device Planning and Site Selection*; Standard 39, *Vascular Access Device Post-Insertion Care*).^{1,5,9,11,13,15,17,20} (I)

1. Identify patient-specific factors associated with an increased risk of infiltration and extravasation, as identified in multiple studies^{1,4,5,7,9,12,17,21,24,28,32,34-39}: (II)
 - a. Female gender
 - b. Current infection
 - c. Patients with altered sensation near the VAD (eg, neuropathy, application of preinsertion pain relief product) and/or who have difficulty communicating the onset of pain, tightness, or other discomfort
 - d. Patients with altered mental status or cognition (eg, encephalopathy, confusion, sedating medications)
 - e. Diseases that produce changes in vasculature or impaired circulation (eg, cancer, diabetes mellitus, lymphedema, systemic lupus, Raynaud's disease, peripheral neuropathy, peripheral vascular disease)
 - f. Difficulty with peripheral venous access related to history of multiple venipunctures and obesity
 - g. Age-related changes to vasculature, skin, and subcutaneous tissue.
 - i. Neonates and young children are at increased risk for infiltration and extravasation due to factors such as inability to communicate discomfort/nonverbal, fragile vasculature and skin, limited resources to repair cellular damage, and a lack of safe and effective VAD securement and dressing options.^{5,13,14,17,20,21,27,33,40,41} (I)
 - ii. Anatomical changes in the elderly patient, including loss of thickness of the dermal skin layer, thickening of the tunica intima/media, and loss of connective tissue contribute to vein fragility and present challenges in vascular access (refer to Standard 2, *Special Patient Populations*).
2. Assess the risk of mechanical causes of infiltration/extravasation and take preventative action as needed. Risk factors include the following:
 - a. Reduction or loss of patency of the VAD and/or vessel due to abnormalities such as fibrin sleeve, venous thrombosis, pinch-off syndrome, and catheter fracture.^{1,9,11,42} (II)
 - b. Patient movement and positioning that impact VAD performance, such as normal body movements, unpredictable patient activity (eg, infants/children, confused patient); events that can increase tension on or malposition of the VAD (eg, patient repositioning, patient transport); and procedures that require specific positions (eg, "tucked arm" during a procedure).^{17,43,44} (IV)
 - c. Events that increase the risk of vessel trauma, including:

- i. Rapid infusions, use of a bolus feature on a pump.^{3,4,9,32,45} (II)
 - ii. Insertion of the VAD in an area of flexion.⁵ (IV)
 - a) Infiltration and extravasation rates were found to be significantly higher in PIVCs inserted in the emergency department as opposed to other units, likely due to high volume infusions, frequent insertion at the antecubital fossa, large bore catheters, and blood sampling.³ (I)
 - iii. Multiple insertion attempts, especially in the same anatomic location.^{1,4,17,25,38,41,46,47} (IV)
 - iv. Catheter malposition during the lifespan of the VAD.
- d. Reduce the risk of VAD malposition during insertion and postinsertion care.
- i. Ensure adequate length of the intraosseous (IO) needle for the patient per manufacturers' recommendations (see Standard 54, *Intraosseous Access Devices*).^{34,44} (V)
 - ii. Ensure an adequate vein purchase or length of the catheter that resides within the vessel (see Standard 21, *Vascular Visualization*).^{6,41,48} (IV)
 - iii. Extravascular CVAD tip malposition, dislodgement, or fracture can occur in many anatomical locations and at any point during dwell time (refer to Standard 51, *Central Vascular Access Device Malposition*).
 - a) Measure vessel depth in tissue using ultrasound prior to CVAD insertion to ensure all lumen exit sites are within the patient's vasculature. Partial dislodgement can result in more proximal lumen exit sites infusing into the subcutaneous tissue.^{49,50} (V)
 - b) Monitor daily catheter position and compare it to insertion measurements in an inpatient setting and on a regular basis in an outpatient setting. Ensure all catheter lumens aspirate for blood return, and flush prior to use. Do not assume appropriate intravascular tip position of all lumens when blood aspirate is possible from one lumen but not all.^{49,50} (V)
 - c) In addition to mechanical risk factors listed above, the CVAD may gradually become malpositioned due to growth of the infant or child with a long-term CVAD.⁵¹ (IV)
 - d) Monitor for sudden changes in clinical condition in patients of all ages that may indicate extravascular administration of medication involving a centrally administered vesicant (eg, new onset hypoxia, respiratory distress, hypotension, abdominal distension and/or pain, edema, airway impingement).^{11,24,27,51-55} (IV)
- 1) Evaluate clinical criteria (eg, radiologic imaging, laboratory values, aspiration of fluid) to determine presence of infiltration/extravasation versus other clinical complications in the setting of new pleural effusion, abscess, or lesion in an area related to the CVAD. Administration of a vesicant (eg, hypertonic parenteral nutrition in fragile vessels) and/or the mechanical forces of the catheter may cause vessel erosion, allowing the vesicant to invade surrounding structures (liver, mediastinum, abdomen, thoracic cavity).^{50,52,53} (V)
 - 2) The neonate is at high risk for extravasation with CVAD insertion (eg, umbilical, peripherally inserted central catheter (PICC), femoral catheter), resulting in morbidity and mortality, including ascites, abdominal compartment syndrome, hepatic laceration/necrosis/abscess, pleural and pericardial effusion, and hemi-diaphragmatic paralysis.^{51,52,54,56-64} (V)
- e) Anticipate use of radiographic tests to validate the CVAD tip location (refer to Standard 51, *Central Vascular Access Device Malposition*).
- 1) Timing of CVAD removal depends on the plan of care, which is based on identified extravascular location of the catheter tip.
 - 2) Assess the location of a subcutaneous tunnel or port pocket and its proximity to the wound to determine if the long-term CVAD should be removed for healing to occur. Consider consultation with a wound care specialist. (Committee Consensus)
3. Assess for additional PIVC-related factors that may increase the risk of infiltration/extravasation (see Standard 39, *Vascular Access Device Post-Insertion Care*; Standard 37, *Site Protection and Joint Stabilization*).^{2,3,8,9,12,16,21,24,25,28,31,32,37,38,41,65,66}: (II)
 - a. PIVC sites in the hand, wrist, foot, ankle, antecubital fossa, and areas with minimal subcutaneous tissue coverage
 - i. If it is deemed necessary to insert the PIVC in an area of flexion, more frequent monitoring is required, joint stabilization may be needed, and consideration should be given to early removal and reinsertion in a location with reduced risk of complication.

- b. Use of steel “butterfly” needle
 - c. Inadequate catheter securement
 - d. Short PIVC dwell time longer than 24 hours
 - e. Increased manipulation of the PIVC at the catheter hub
 - f. Inability to establish patency through positive blood return or site assessment during flushing (eg, diffuse edema)
 - g. Delivery of a vesicant in an insertion site below a recent (eg, less than 24 hours) venipuncture
 - h. Depth of PIVC (eg, delayed visual signs and symptoms of PIVC failure when tip of the PIVC lies in a deep vein), particularly in nonverbal population
 - i. PIVC administration of contrast media.
4. Evaluate the pharmacologic or physiochemical properties associated with infiltration/extravasation and severity of tissue damage. These include length of infusion of vesicant via a PIVC, drug concentration, and volume escaping into the tissue; ability of surrounding tissues to absorb the drug; hyperosmolality and nonphysiological pH; the medication’s ability to bind DNA, kill replicating cells, and/or cause vascular constriction; and excipients, such as alcohol or polyethylene glycol, used in the formulation of some medications.^{1,5,7-9,12,16,22-24,27,36,64,67} (II)
- D. Limit the extent of infiltration/extravasation injury through preventative measures and early recognition of signs and symptoms of infiltration/extravasation with regular visual inspection and palpation of limbs bilaterally.
- 1. Assess the VAD insertion site at a frequency based upon the specific patient population and characteristics of the infusion therapy (see Standard 39, *Vascular Access Device Post-Insertion Care*).^{1,8,9,11,12,28,34,36,64,68,69} (II)
 - a. An area for further research is establishment of monitoring standards for VADs utilized in the intraoperative and intraprocedural areas with inherent barriers to visualization, including sterile drapes, tucked limbs, competing priorities, and rapid infusions.^{41,43,70-72} (IV)
 - 2. Promptly recognize and report acute abnormalities in pain, sensation, or circulation. Compartment syndrome and arterial and nerve damage may be caused by infiltration or extravasation of a sufficient infusate volume to cause tissue ischemia/injury. Significant long-term complications may include complex regional pain syndrome, neurovascular compromise, or limb amputation.^{12,28,31,32,34,70-74} (II)
 - a. Recognize high risk with VAD insertion in small vessels, areas of flexion, and/or areas with tight subfascial compartments (eg, hand, wrist, forearm).
 - b. If suspected, elevate the affected extremity to level of the heart to optimize perfusion.
 - c. Notify the surgeon/plastic surgeon immediately if circulatory or neurological compromise is suspected.
3. Observe the VAD site and areas proximal and distal to the insertion site for abnormalities.^{1,4,23,27,34,75} (IV)
- a. Fluid leakage from the puncture site, subcutaneous tunnel, or port pocket, which may be visible or subcutaneous.
 - b. Skin injury, including vesicle formation, may appear within hours (eg, contrast media) or may be delayed for days (eg, antineoplastic agents); progression to ulceration may vary from a few days to 1 to 2 weeks, depending on the vesicant administered.
 - c. Discoloration or hyperpigmentation.
4. Rule out other conditions that may have similar symptoms (eg, phlebitis, flare reactions, rash).^{4,76} (V)
- a. A notable case report illustrates a subdural infiltration from a scalp PIVC in a neonate used to deliver fluid and blood products. The changes in neurovascular status were thought to be due to an intracranial hemorrhage but were found to be due to a significant intracranial infiltration.⁷⁷ (V)
5. Consider the use of infiltration/extravasation detection technology to aid in early recognition. Further research is needed to determine optimal use. Options that are under investigation include thermosensitive crystal film, near infrared camera, radiofrequency, gamma scintillation, color flow doppler, impulse oscillometry, and point-of-care ultrasound.^{10,12,45,78-83} (IV)
- a. Use careful assessment in conjunction with detection technology, as the device may fail to detect abnormalities or fail to adequately warn clinicians, especially in settings where the VAD is not readily accessible.^{10,79} (IV)
 - b. Do not rely on the alarm from an electronic infusion pump to identify infiltration and extravasation; alarms are not designed to detect the presence or absence of complications. Electronic infusion pumps do not cause infiltration/extravasation; however, they may mask or exacerbate the problem until the infusion is stopped.^{10,43} (V)
6. Assess the extremity and areas proximal and distal to the insertion site and compare to the contralateral limb.^{4,8,11,27,49} (IV)
- a. Palpate the insertion site to assess for swelling and pain.
 - i. Swelling/edema may appear as a raised area under the skin near the peripheral VAD site or as an enlarged and tense extremity due to fluid accumulating in compartments of the extremity. Edema from a CVAD may appear as a raised area on the neck, chest, or groin.

- b. Compare the circumference of both extremities if unilateral edema is noted. Compare to baseline measurement at insertion, if available.
 - c. Changes in color may include redness and/or blanching; however, infiltration/extravasation into deep tissue may not produce visible color changes.
 7. Elicit the patient's report of pain; observe the nonverbal patient for other cues indicating pain.
 - a. Pain may be the initial symptom and may be sudden and severe when associated with a rapid injection of solution or medications; may be out of proportion to the injury; or may appear with passive stretching of the muscles in the extremity. Pain intensity may increase over time, which may indicate compartment syndrome.^{4,5,9,26,27,32} (IV)
 8. Insert a VAD designed for contrast administration in an optimal location to ensure adequate monitoring during contrast administration. Assess for proper function prior to, during, and postcontrast media infusion. Adjust delivery of contrast to conform to the chosen VAD.^{12,32,37,84} (II)
 - a. Extravasation can occur with manual and with automated delivery of contrast. Automated power or pressure injectors produce a jet of fluid exiting the catheter tip. Distal tip malposition has been documented following power injection in PICCs. It has also been postulated that this jet could induce vessel perforation and extravasation.^{12,32,73,74} (II)
 - b. Fluid warming may be associated with lower rates of extravasation. Fluid with high viscosity, such as contrast media, requires less force to administer when it is warmed to 37°C (see Standard 23, *Flow-Control Devices*; Standard 24, *Blood and Fluid Warming*).^{12,32,37,74,85} (II)
 - c. Consider use of extravasation detection accessories, such as equivalent dose rate monitoring, to provide early detection, automated interruption of power injection, and guidance for contrast extravasation management.^{12,86,87} (IV)
- E. Immediately stop the infusion upon identification of an infiltration/extravasation injury, and initiate appropriate intervention(s).^{1,4,9,11,12,23,24,26,84} (II)
 1. Do not flush the VAD, as this will inject additional medication into the tissue. Disconnect the administration set from the catheter hub and aspirate from the catheter or implanted port access needle with a small syringe, even though a very small amount of fluid may be retrieved. The role of aspiration is not clear with extravasation of contrast media.^{1,4,9,11,12,23,24,26,27,29,31,32,36} (II)
 2. Remove the peripheral catheter or implanted vascular access port access needle.^{1,4,26,29,88} (IV)
 3. Avoid application of pressure to the area.^{4,24,26} (IV)
 4. Elevate the extremity to encourage lymphatic reabsorption of the solution/medication, unless compartment syndrome is suspected.^{2,9,12,23,26,30,32,36} (II)
5. Avoid use of the affected extremity for subsequent VAD insertion until resolved.⁸⁹ (V)
6. Assess the insertion site and surrounding tissue.
 - a. Assess the area distal (located below) to the VAD site for capillary refill, sensation, and motor function.^{23,26,32,34} (II)
 - b. Using a skin marker, outline the area suspected of infiltration/extravasation to assess progression.^{9,12} (IV)
 - c. Photograph the area to identify progression or exacerbation of the tissue injury in accordance with organizational policy.^{1,9,15} (IV)
7. Estimate the volume of solution that has escaped into the tissue based on the original amount of solution in the container, the amount remaining when stopped, and rate and duration of injection or infusion.^{24,36,74} (V)
 - a. Estimated extravasated volumes of contrast media of less than 50 mL are more likely to resolve with conservative treatment, while volumes of greater than 50 mL are at higher risk to cause tissue damage, requiring treatment. However, the patient's symptoms should dictate treatment options over the estimated extravasated volume. Radiologic imaging to evaluate a contrast extravasation is rarely indicated.^{12,32,37,74} (IV)
8. Notify the provider about the event and activate the established treatment protocol or the prescribed treatment.^{1,4,9,12,24,26,28,32,36} (II)
 - a. The need for surgical consultation is based on organizational policy, clinical signs and symptoms and their progression, volume of injury, and/or the tissue-destroying nature of a vesicant medication.
 - i. Consider options for treatment that include subcutaneous irrigation with or without hyaluronidase, open incision and irrigation, small incisions followed by massage to force drainage, and debridement; skin graft/flap as indicated. There is a paucity of evidence to support one surgical intervention over another, so consideration should be given to the risks and benefits of conservative versus invasive treatment.^{2,27,28,32,90} (IV)
- F. Initiate treatment promptly as appropriate for the type and volume of solution/medication in the tissue surrounding the VAD, with the goal of limiting the damage from medication/solution exposure. Provide convenient access to the list of vesicants and irritants, infiltration/extravasation management protocols, electronic order forms, supplies, and other materials needed to manage the event.^{2,11,23,26,31,36} (IV)
 1. Avoid wet compresses, as they may cause maceration.^{24,26} (V)

2. There is a lack of high-quality evidence to recommend use of heat or cold application in the treatment of extravasation injury.^{23,27,32} (V)
 - a. Cold application is used to decrease absorption, to keep the infusate localized, and to decrease inflammation, while heat is used to encourage vasodilation and to improve blood flow to disperse the medication through the tissue.^{1,4,26} (IV)
 - i. Use of cold and heat applications are recommended in contrast extravasation, with a general preference for cold due to the potential to reduce inflammation.^{12,32} (V)
 - ii. A scoping review on treatment of extravasation in infants and children found that cold and heat application is rarely used in this population.⁹¹ (II)
 - b. Apply dry, cold compresses for DNA-binding agents and valproate because the goal is to cause vasoconstriction to localize the medication in the tissue and reduce inflammation.^{1,4,9,24,36} (II)
 - c. Do not use cold compresses with extravasation in the presence of agents that may cause vasoconstriction or in the presence of vaso-occlusive events (eg, sickle cell anemia).^{23,26} (IV)
 - d. If dexrazoxane is indicated, remove the cold compress 15 minutes before the infusion of dexrazoxane begins.^{1,9,24,29} (II)
 - e. Apply dry, warm compresses for non-DNA binding agents to encourage vasodilation.^{1,4,36} (IV)
3. Administer the appropriate antidote for the solutions or medication in the tissue.
 - a. Daily IV infusion of dexrazoxane over 3 days is the recommended antidote for anthracycline extravasation (also used with liposomal and pegylated anthracycline).^{1,9} (II)
 - i. Begin the infusion within 6 hours of the extravasation and infuse into the opposite extremity.^{1,9,24} (II)
 - ii. Topical dimethyl sulfoxide (DMSO) should not be applied to patients receiving dexrazoxane, as it may diminish dexrazoxane efficacy.^{9,24} (II)
 - b. Inject other antidote or dispersal enzyme into the subcutaneous tissue surrounding the extravasated site per facility protocol and the specific manufacturer's directions for dose and administration.
 - i. Hyaluronidase is not considered to be an antidote to a specific vesicant; it is an enzyme that increases absorption and dispersion of the medication or solution in the tissue. Its use is reported with cytotoxic and noncytotoxic agents, including both acidic and alkalotic drugs (eg, amiodarone, phenytoin), vinca alkaloids, as well as hyperosmolar solutions (eg, parenteral nutrition [PN] and calcium salts). Recombinant hyaluronidase is not derived from animals and may have a lower risk of allergic response. Subcutaneous injection within 1 hour of the extravasation event produces the best response. Use of dry heat in conjunction with hyaluronidase works synergistically to increase blood flow and disperse the extravasated drug. Hyaluronidase is not considered first-line treatment for contrast extravasation.^{1,9,11,12,23,24,26,32,38,92} (II)
 - a) Consider subcutaneous saline irrigation or saline irrigation with prior hyaluronidase administration for vesicant removal/dispersion in neonates. Further study is needed in the use of this practice, as resolution with conservative treatment is common.^{10,64,91} (IV)
 - ii. Sodium thiosulfate is recommended for mechlorethamine extravasation and has been suggested for bendamustine, calcium, and large extravasations of cisplatin.^{1,8,9,92} (IV)
 - iii. Phentolamine is preferred for vasopressor extravasation. Normal perfusion of the area may be seen within 10 minutes of administration. Repeated injection may be necessary if hypoperfusion is still present or if vasoconstriction is extending to a greater area.^{23,26,36} (IV)
 - iv. Terbutaline injection has been used for vasopressor extravasation when phentolamine is not immediately available.^{8,23} (V)
 - v. Topical nitroglycerin 2% may be applied as a 1-inch strip to the site of vasopressor extravasation in the absence of phentolamine; repeat every 8 hours as clinically indicated.^{8,23,93} (V)
 - vi. Consider use of oral, topical, or intraleisional steroid on a case-by-case basis. Single-center studies and case reports have reported reduced inflammation and swelling; however, evidence of benefit is inconsistent and may not be recommended.^{8,9,12,24} (V)
4. Consider use of irrigation or washout to assist in removal of specific infusates from surrounding tissue (eg, acidic, alkalotic, contrast, specific cytotoxic agents, PN).^{9,12,27,30,36,42,94} (IV)
 - a. Other treatments that have been reported in the treatment of severe tissue injury due to extravasation include negative pressure wound therapy, needle aspiration, emergency evacuation with low-pressure suction, ethacridine lactate dressing with phototherapy, acellular fish skin graft dressing, and dehydrated human amniotic membrane allograft.^{2,28,39,76,94-97} (IV)

- b. Avoid injection of an acidic or alkaline medication to neutralize the pH of an extravasated acidic or alkaline vesicant, as the resulting chemical reaction could cause gas formation and exacerbate the tissue injury.^{8,98} (V)
 - c. While skin discoloration from iron infiltration may be permanent, laser treatment has been reported to be successful in reducing staining.⁹⁹ (V)
- G. Use a standardized age/population-specific tool or definition to consistently evaluate infiltration/extravasation events from all types of VADs that is valid, reliable, and clinically feasible. The chosen scale should also be accompanied by appropriate interventions to manage each level of the scale of injuries. Several scales have been published; however, further research is needed to establish validity and interrater reliability for specific populations.^{4,11,12,20,21,23,25,26,30,33,64,100} (II)
 1. An infant infiltration scale was recently revised and found to be valid and reliable for this population in an observational, prospective study.¹⁰⁰ (IV)
- H. Use a standardized format to document initial and ongoing assessment and monitoring of the infiltration/extravasation site and all factors involved with the event.^{9,10,23,26,29,32,36,40} (II)
 1. Accuracy of PIVC complication rates (eg, phlebitis, extravasation, occlusion) is reduced by clinical knowledge deficits in symptom recognition, gaps in documentation, and a lack of consistent PIVC outcome definitions used in the literature.^{1,3,5,13,18,20,101} (I)
- I. Continue to monitor the site as needed based on severity of the event and the venue of care, as signs and symptoms of infiltration and extravasation may be delayed in presentation. Assess changes in the area by measurement and/or photography; observe skin integrity, level of pain, sensation, and motor function of the extremity.^{8,9,15,20,36,40,76} (II)
 1. Inflammation post-contrast media extravasation generally peaks at 24-48 hours from the event.³² (V)
 2. Consider conducting follow-up phone calls or a follow-up visit to evaluate progression of an extravasation in the outpatient setting.^{12,15,26,32} (IV)
- J. Educate the patient and caregivers regarding extravasation risk to improve prompt recognition of symptoms (see Standard 8, *Patient Education*).^{1,4,8,9,11,12,24,25,32,75} (II)
 1. Preinfusion: the risks of receiving an infusion prior to administration, emphasizing the signs and symptoms to immediately report.
 2. Postinfusion: the possible progression of the signs and symptoms of infiltration/extravasation; the need to protect the site from sunlight; the frequency of follow-up visits to the provider as needed.
- K. Review infiltration/extravasation incidents causing harm or injury, using adverse event reports and health record reviews for quality improvement opportunities (see Standard 6, *Quality Improvement*; Standard 11, *Adverse and Serious Adverse Events*).^{1,9,15,28,41,90} (V)

1. Consider performing an investigation of each significant extravasation event (eg, root cause analysis) to identify and implement needed quality improvement strategies.

Note: The INS Infiltration Scale and Extravasation Staging tool are located in Appendix C.

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45. NERVE INJURY

Standard

- 45.1 A vascular access device (VAD) or phlebotomy needle is immediately removed upon patient report of paresthesia-type pain during venipuncture and during VAD dwell time.
- 45.2 During the insertion or dwell of central vascular access devices (CVADs), the possibility of nerve injury is considered and evaluated whenever the patient complains of respiratory difficulty or unusual presentations of pain or discomfort.

Practice Recommendations

- A. Recognize the risk for nerve injury during phlebotomy and during VAD insertion/dwell time. There are some sites associated with a greater risk for injury; use caution with these sites, while also recognizing that anatomical variations in veins, arteries, and nerves are common.¹⁻³ (V)

 1. Peripheral venous sites associated with increased risk of nerve damage:
 - a. Cephalic vein at the radial wrist, with potential injury to the superficial radial nerve
 - b. Volar (inner) aspect of the wrist, with potential injury to the median nerve
 - c. At/above the antecubital fossa, with potential injury to the median and anterior interosseous nerve and the lateral and medial antebrachial nerves.^{1,2,4-23} (V, A/P)
 2. Peripheral arterial sites associated with risk for nerve damage:
 - a. Brachial artery, with potential injury to the median nerve
 - b. Radial artery, with potential injury to the median and radial nerve.^{24,25} (V, A/P)
 3. Nerve injuries associated with central vascular access devices are rare, but axillary/subclavian and internal jugular insertions with injury to the phrenic nerve or nerves of the brachial plexus and Horner's syndrome have been reported.^{15,22,26-33} (V, A/P)

- B. Reduce the risk for nerve injury:
 1. Avoid multiple attempts at venipuncture (see Standard 32, *Vascular Access Device Insertion*).
 - a. Repeated peripheral and central venous access device venipuncture attempts, subcutaneous probing techniques, and multiple passes of the

needle are associated with an increased risk for nerve injury.^{9,13,16,18,22,29,33} (IV)

2. Use ultrasound guidance to improve first-time insertion success and to identify veins, arteries, and associated structures, including nerves, to reduce the risk of nerve injury when placing short or long peripheral catheters in patients with difficult intravenous access and when placing peripheral arterial catheters, CVADs, and midline catheters (see Standard 21, *Vascular Visualization*).^{14,17,18,24,25,29,32,34-39} (I)
 3. Assess vein depth and avoid a steep angle when inserting a phlebotomy needle or when inserting a peripheral intravenous catheter (PIVC) without ultrasound to reduce the risk for damage or penetration through the posterior vein wall. For shallow veins and veins of older adults, consider a 5° to 15° angle; a steeper angle may be required when accessing deep veins.^{5,21,40} (V, A/P)
 4. Choose the median cubital vein or the cephalic vein for phlebotomy, as these veins are closer to the surface and in an area where nerve damage and brachial artery puncture are less likely.^{5,6,8,14,19,21} (V, A/P)
 - a. The medial and lateral portions of the antecubital fossa (eg, basilic and median basilic veins) are avoided due to proximity to the median nerve, as well as the brachial artery; injury to the median nerve can result in loss of extension, flexion, and sensation in the hand/forearm.
 5. Avoid the cephalic vein in the first quarter of the forearm (ie, above the wrist).^{4,10,12} (V, A/P)
 6. Minimize the risk of needle movement during phlebotomy procedures while attaching and removing the blood collection tube(s).^{5,21,41} (V)
 7. Stop the VAD insertion procedure immediately and carefully remove the VAD or phlebotomy needle if the patient reports symptoms of a direct puncture nerve injury, including paresthesia, such as radiating electrical pain, tingling, burning, prickly feeling, or numbness. Stop the procedure upon the patient's request and/or when the patient's actions indicate severe pain.^{6,7,16,22} (V)
 - a. Inform the provider of the patient's report of symptoms, as early recognition and early intervention for nerve injury produce a better prognosis. Consultation with an appropriate specialist (eg, hand specialist, neurologist) may be required; the majority of venipuncture-related nerve injuries resolve within 6 months.^{16,17,20,22} (IV)
 8. Reduce the risk for nerve compression and compartment syndrome:
 - a. Limit the amount of solution that enters the tissue through early recognition of signs/symptoms of infiltration/extravasation (refer to Standard 44, *Infiltration and Extravasation*).
 - b. Control bleeding at attempted and successful sites to reduce the risk of hematoma that can lead to nerve injury due to compression. Identify if the patient is on anticoagulant therapy, as this increases the risk for hematoma.^{13,29,33,42} (V)
 - c. Remove a VAD immediately when the patient reports any pain, neuropathy, or weakness in the extremity of the VAD during the dwell time. Nerve injury following peripherally inserted central catheter (PICC) insertion has been reported. Nerve compression injuries can originate from infiltrated intravenous (IV) solutions, hematoma, and edema associated with the inflammatory process of phlebitis and thrombophlebitis.^{7,43-45} (IV)
 - d. Identify and immediately report signs and symptoms of nerve compression, including pain, pallor, paresthesia, paralysis, and pulselessness. Pain progresses from paresthesia to paralysis. Pallor and loss of peripheral pulse indicate an advanced stage of compartment syndrome. Surgical fasciotomy to reduce pressure within the affected compartments is required within a few hours to prevent loss of the extremity. Notably, there are numerous compartments in the hand, as compared to the wrist or forearm.^{42,46,47} (V, A/P)
 - e. Consider risk factors associated with compartment syndrome from IV infiltration. While rare, risk factors identified in a literature review included contrast media, pressurized infusion delivery, and patients with barriers to effective communication (younger than 3 years old, impaired sensation, altered mentation).⁴⁵ (IV)
9. Recognize that complex regional pain syndrome (CRPS) is a chronic, debilitating condition characterized by ongoing neuropathic pain over a regional area; the pain is not proportional to the original injury and progresses to include sensory, motor, and autonomic changes. Venipuncture-induced CRPS is rare and often difficult to recognize as the cause of the pain, as this syndrome frequently spreads to nontraumatized extremities. Lifelong management may be required, including multiple pain medications, steroids, nerve blocks, physical therapy, and surgical procedures (eg, sympathectomy).^{48,49} (V)
- C. Observe for respiratory difficulties or dyspnea.^{31,32} (V)
 1. Subclavian and jugular insertion sites can produce damage to the phrenic nerve, which is seen on a chest radiograph as an elevated right hemidiaphragm. Right shoulder and neck pain, distended neck veins, and hiccups may also be present. Phrenic nerve injury can come from direct trauma associated with multiple needle insertions, compression due to the presence of the catheter itself, intraventricular tip locations, hematoma, and infiltration/extravasation of infusing solutions. CVAD removal is indicated.

- D. Observe for changes in the eye, such as pupil constriction and upper eyelid drooping in the presence of any CVAD.^{28,29} (IV)
1. PICCs and catheters inserted in the internal jugular vein have been reported to produce vision-related changes, suggestive of inflammation of cervical sympathetic nerves, known as Horner's Syndrome. Risk reduction strategies include ultrasound-guided insertion; avoiding excessive head rotation during skin puncture, repeated insertion attempts, and a steep angle between needle and skin during insertion; and attention to compression to avoid hematoma if carotid artery inadvertent injury.

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46. VASCULAR ACCESS DEVICE OCCLUSION

Standard

46.1 Vascular access device (VAD) patency is routinely assessed and defined by the ability to flush all catheter lumens without resistance after establishing blood return from each lumen.

46.2 Catheter salvage is preferred over catheter removal with the choice of clearing agents based on a thorough assessment of potential causes of occlusion.

46.3 When catheter patency cannot be confirmed and there is continued need for the device, alternative actions are implemented, such as evaluation by an infusion/vascular access specialist team (VAST), radiographic studies to identify catheter tip location or to evaluate catheter flow, and/or pharmacy consult to determine cause of occlusion.

Practice Recommendations

- A. Reduce the risk for VAD occlusion.
 1. Use recommended flushing and locking procedures (refer to Standard 38, *Flushing and Locking*).
 2. Prevent catheter dislodgement (partial or complete) through appropriate catheter securement (refer to Standard 36, *Vascular Access Device Securement*; Standard 51, *Central Vascular Access Device Malposition*).
 3. Avoid incompatible mixing of intravenous (IV) solutions and/or medications.
 - a. Check for incompatibility when 2 or more drugs/solutions are infused together (eg, combined in same container, administered as an intermittent solution for a short-term infusion or a manual injection, or administered concomitantly through the same VAD). Consult with a pharmacist or use an evidence-based compatibility reference when unsure of compatibility; if no compatibility information is found, consider the mixture as incompatible.¹⁻⁵ (IV)
 - b. Identify medications/solutions at high risk for precipitation. These may include alkaline drugs such as phenytoin, diazepam, ganciclovir, acyclovir, ampicillin, imipenem, and heparin; acidic drugs such as vancomycin and parenteral nutrition (PN) solutions; ceftriaxone and calcium gluconate; and mineral precipitate in PN solutions with increased levels of calcium and phosphate.¹⁻⁵ (IV)
 - c. Perform a gentle, pulsatile flush between infusions with 10 mL of preservative-free 0.9% sodium chloride (less in pediatric/neonatal, fluid restricted patients) or use separate catheter lumens, if available (refer to Standard 38, *Flushing and Locking*).
 4. Identify risk of lipid residue occlusion when administering lipid-containing infusions. Employ preventative strategies (eg, increased flushing) if lipid residue buildup is suspected.¹⁻⁵ (IV)
- B. Assess for signs and symptoms of possible VAD occlusion:
 1. Inability to withdraw blood or sluggish blood return.^{1,2,5} (IV)
 2. Sluggish flow; resistance or inability to flush lumen; inability to infuse fluid.^{1,2,5} (IV)
 3. Frequent occlusion alarms on electronic infusion pump.^{1,2} (V)
 4. Swelling/leaking at infusion site.^{1,2,4} (V)
 5. No reflow or insufficient blood flow in hemodialysis central vascular access devices (CVADs).³ (V)

- C. Assess VAD patency by aspirating for a blood return and flushing each lumen with 0.9% preservative-free sodium chloride prior to administering any solution (see Standard 38, *Flushing and Locking*).^{1-3,6} (IV)
 1. If no blood return on aspiration, conduct a thorough VAD site and clinical assessment and consider the safety and merit of alternating gentle aspiration with gentle instillation of small amounts of saline.^{1-4,7} (V)
 2. Use a small-barrel syringe to aspirate blood if no blood return obtained and able to flush catheter. A small-barrel syringe exerts less negative pressure when withdrawing blood and may result in more success.² (V)
 3. When blood return remains sluggish/absent, or assessment of blood return is contraindicated due to the patient's condition (eg, hemodynamic instability dependent on vasopressor delivery), VAD patency should be evaluated through alternative signs, including ongoing clinical response to an infusing medication, lack of resistance to flushing, site evaluation, and patient symptom report. This assessment can assist in determining patency (see Standard 44, *Infiltration and Extravasation*, Standard 65, *Vasopressor Administration*). (Committee Consensus)
 - a. Increase the frequency of site assessment for potential complications (eg, infiltration, extravasation).
 - b. If using the peripheral intravenous catheter (PIVC) for vesicant administration, plan to transition the infusion to a more appropriate VAD or CVAD when clinically possible.
 - c. Promptly evaluate and treat CVAD occlusion. If unable to restore patency, consult with provider to evaluate the need for VAD removal/replacement.
- D. Assess the infusions, injections, flushing procedures, and other events with the VAD that led to the occlusion to determine the possible cause.
 1. Rule out/resolve external mechanical causes, assessing the entire infusion system from the administration set to the VAD insertion site under the dressing.^{1,2,5,6} (IV)
 - a. Assess securement device or tight suture for constriction of catheter, kinked/clamped catheter or administration set, obstructed/malfunctioning filter or needleless connector, change in external catheter length, or malposition of an implanted port access needle (refer to Standard 36, *Vascular Access Device Securement*; Standard 39, *Vascular Access Device Post-Insertion Care*).
 - b. Remove add-on devices; assess catheter patency by attaching syringe at the hub and attach new add-on device. External kinks may be resolved by repositioning the catheter and reapplying a sterile dressing. Replace an implanted port access needle that is malpositioned or occluded.^{1-6,8} (IV)
 - c. Attempt short-term resolution of withdrawal occlusion (inability to obtain blood return) by changing the patient's position (eg, raise arm, cough, or breathe deeply) to alter catheter position. Further investigation should be initiated for recurrent/persistent withdrawal occlusion.^{1,2,4,5,7,9} (IV)
 - d. Assess for catheter damage (eg, catheter bulging, leaking, or swelling along CVAD pathway) and repair or replace VAD (refer to Standard 48, *Catheter Damage [Embolism, Repair, Exchange]*).
2. For CVADs, assess for internal mechanical causes, such as pinch-off syndrome, secondary CVAD malposition, catheter-associated deep vein thrombosis (CA-DVT), implanted vascular access port failure, and kinks related to the tissue and vasculature (eg, head and neck movement causing kinking of catheters inserted in internal or external jugular vein) (refer to Standard 48, *Catheter Damage [Embolism, Repair, Exchange]*; Standard 50, *Catheter-Associated Thrombosis*; Standard 51, *Central Vascular Access Device Malposition*).
 - a. Assess external catheter length, arm or shoulder discomfort, arrhythmias, and need to roll shoulder or raise the ipsilateral arm to allow flow or obtain blood return. If pinch-off syndrome is suspected, gently flush the CVAD with 10 mL of 0.9% preservative-free sodium chloride (less for pediatric or neonatal patient), while asking the patient to raise the ipsilateral arm and roll the shoulder backward. If the flow is dependent upon arm position, pinch-off syndrome should be investigated through informed radiographic studies.¹⁰ (V)
 - b. Collaborate with the provider to manage suspected CVAD malposition, pinch-off syndrome, or CVAD damage.² (V)
3. Suspect thrombotic occlusions based on visible blood in catheter or add-on devices, inability to aspirate blood, or sluggish flow. A thrombotic occlusion may be intraluminal due to fibrin or clot formation or extraluminal, related to a fibrin tail, fibrin sheath or sleeve, or mural thrombus.¹⁻⁴ (V)
4. Suspect chemical occlusion based on the type(s) of medications or solutions administered, duration of contact of drugs, and observation of the catheter or administration set for any visible precipitate, history of infusion rate, dilution properties and sequences, light exposure, and flushing frequency.^{1-4,6} (IV)
 - a. Suspect calcium phosphate precipitation if calcium or phosphate concentrations in PN solutions are elevated, in fluid restricted PN, or if the PN recipe's calculated calcium phosphate solubility is low (ie, when the solubility product is less than 75 mmol²/L²).¹¹ (II)
 - b. Suspect lipid residue if infusing total nutrient admixture (TNA) with lipid concentration greater than 10%.¹¹ (II)
 - c. Suspect chemical occlusion if thrombolytic agent is unsuccessful.² (V)

5. Consider a contrast study for persistent or recurring unresolved CVAD occlusion.^{2,5} (IV)
- E. Review the patient's medication record and collaborate with the pharmacist for the appropriate intervention/catheter clearance agent.⁴ (V)
- F. In multilumen CVADs, treat all catheter lumens with partial, withdrawal, or complete occlusion. Do not leave an occluded lumen untreated because another lumen is functional; prolonged fibrin formation is a risk factor for catheter-associated bloodstream infection (CABSI).^{3,4} (V)
 1. Avoid applying excessive force when instilling a catheter clearance agent to reduce risk of catheter damage.² (V)
 2. Promptly resolve a suspected thrombotic occlusion or occlusion of unknown cause to increase the efficacy of thrombolysis use in CVADs and avoid or at least delay the need for catheter replacement.^{2,3,9,12} (IV)
 - a. Assess risks/benefits of thrombolysis. Determine if CVAD removal or replacement is warranted (eg, contraindications for thrombolytic agent, patients with CVAD-associated sepsis due to candidemia or *Staphylococcus aureus*).^{1,2} (V)
 - b. For CVADs, instill tissue plasminogen activator ([tPA] alteplase) in the catheter lumen in accordance with manufacturer directions for use and repeat one further time if first attempt is unsuccessful.^{1,2,7,13,14} (IV)
 - i. tPA for catheter occlusion may be administered in all health care settings, including community and long-term care settings.^{1,2,4,15} (IV)
 - ii. Stop all infusions prior to and during thrombolytic agent dwell time, if possible (particularly if treating a suspected fibrin tail/sheath), to optimize thrombolysis and to facilitate contact between the thrombolytic and thrombus/fibrin on the intraluminal and extraluminal surfaces of the catheter.^{1,2} (V)
 - iii. Lower doses of tPA (eg, 1 mg/mL) in lumens requiring less than or equal to 1-mL volume and cryopreserved aliquots have been demonstrated to be effective; however, randomized controlled trials (RCTs) are required to determine the efficacy of alternate dosing.^{7,15-19} (III)
 - iv. For neonatal and pediatric patients weighing 30 kg or less, use a volume equal to 110% of the catheter priming volume.^{1,2,20} (IV)
 - v. Alternative thrombolytic agents such as urokinase, reteplase, tenecteplase, and alteplase have been shown to be effective in smaller studies; further safety data are recommended to compare the efficacy, safety, and cost of different thrombolytic agents.^{1,2,8,15,19,21-29} (III)
 - vi. Consider alternative methods to deal with persistent/recurring CVAD occlusions not resolved by instillation of a thrombolytic agent:
 - a) Push method over 30 minutes.^{2,8,9} (IV)
 - b) Low-dose infusion (relative to patient weight) over 30 minutes to 3 to 4 hours.^{8,27} (IV)
 - c) Dual syringes and implanted port access needles method.^{2,29} (IV)
 - vii. Let thrombolytic agent reside in the CVAD lumen for duration recommended in manufacturers' directions for use or as per organizational policies, procedures, and/or practice guidelines.^{1-4,6,7} (IV)
 - viii. Two retrospective studies have reported use of tPA in management of thrombotic occlusions in midline peripheral catheters. Use of tPA off-label to restore function to midline catheters should be used with caution and only after careful assessment of continued need for vascular access, and to rule out catheter malfunction. Consider use due to (a) thrombus in the vessel (eg, leaking at catheter insertion site), (b) infiltration/extravasation (assess for swelling, discoloration, subcutaneous fluid visualized on ultrasound, complaints of pain or assessment of pain validated for the patient), and/or (c) catheter malposition that can be resolved with catheter/patient reposition (eg, that has migrated catheter into the vein valve or lodged against the vein wall). Once satisfied that catheter malfunction is due to occlusion within or at the tip of the catheter, consider administration of tPA in accordance with provider order, if supported and appropriate to do so (see Standard 44, *Infiltration and Extravasation*).^{30,31} (V)
 3. Consider resolving a suspected CVAD chemical occlusion (eg, medication precipitate or lipid residue), using a catheter-clearance agent based on the catheter lumen priming volume and allowing it to dwell for 20 to 60 minutes.¹⁻⁴ (V)
 - a. L-cysteine 50 mg/mL or 0.1 N hydrochloric acid (HCl) have been used with acidic drug precipitates (pH 1-5).^{1,2,4,7,11} (II)
 - b. Sodium bicarbonate 8.4% or sodium hydroxide 0.1 mmol/L have been used with alkaline drug precipitates (pH 9-12).⁴ (V)
 - c. Sodium hydroxide 0.1 mmol/L (first attempt) or L-cysteine hydrochloride 50 mg/mL have been reported for PN and calcium phosphate.^{1,2,4,7,11} (II)
 - d. Sodium hydroxide (0.1 mmol/L) and 70% ethanol (with a systematic review finding the sodium hydroxide to be more effective and trial research and observational studies yielding mixed responses) have been used to treat lipid residue.^{2,4,7,11,12,32-34} (II)
 - e. Repeat instillation of catheter-clearance agent one further time, if necessary.^{1,2} (V)
 4. After appropriate dwell time of catheter clearance agent, aspirate and discard degradation products prior to flushing the lumen to assess catheter patency.^{1,2} (V)
 - a. There is limited research on use of more than 2 doses of thrombolytic therapy. Additional assessment is recommended (see below) before

considering additional doses of thrombolysis. (Committee Consensus)

G. If catheter patency is not restored:

1. Consider alternative actions, such as radiography, to rule out catheter tip malposition and/or a referral to interventional radiology for contrast study or removal of fibrin using procedures such as an internal snare, ablation of implanted CVAD, catheter exchange with fibrin sheath disruption, or angioplasty of central veins.^{1,2,11,35} (IV)
 2. Collaborate with the health care team and infusion/VAST services (if available) regarding further investigation to rule out catheter-associated thrombosis, as venous thrombosis is a predictor for ineffective thrombolytic instillation procedures.^{1,2,5,14} (IV)
 3. Catheter removal may be necessary, with an alternative plan for vascular access as indicated. (Committee Consensus)
- H. Monitor the patient who has received a thrombolytic agent for signs of catheter-related infection or catheter-related thrombosis. Recognize that bacteria may adhere to thrombi in and around the CVAD, leading to potential infection.^{1,2,5,14} (IV)
- I. Monitor outcomes, including known/suspected causes of occlusions, treatment success or failure, and other measures required. Identify barriers to implementing VAD occlusion prevention and interventions, and implement appropriate strategies, including policies and procedures and clinician education and training (refer to Standard 6, *Quality Improvement*).
- J. Improvements in catheter materials may reduce complications such as occlusion and thrombosis. Consider use of devices made of novel or alternative material as a preventative method if catheter occlusion/thrombosis incidence is high in the patient population. Definitive trial evidence is required to support routine and/or wider use (see Standard 50, *Catheter-Associated Thrombosis*).³⁶ (V)

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47. VASCULAR ACCESS DEVICE-RELATED INFECTION

KEY DEFINITIONS

Catheter-Associated Bloodstream Infection (CABSI): Given variability in international definitions, outcome reporting, and application of the terms catheter-related bloodstream infection (CR-BSI) and central line-associated bloodstream infection (CLABSI), the INS Standards of Practice Committee is using the terminology catheter-associated bloodstream infection (CABSI) to refer to bloodstream infections (BSIs) originating from either peripheral intravenous catheters (PIVCs) and/or central vascular access devices (CVADs). Both are equally injurious and can occur from 4 possible sources:

1. During catheter insertion through transfer of microbes down the catheter tract.
2. Via the catheter hub/lumen during routine administration and manipulation at the hub/lumen.
3. Due to endogenous microorganisms within the bloodstream.
4. From contaminated infusates.

When CABSI is used within a standard, refer to the respective references in that standard to understand the terminology and definitions used in the cited studies.

Catheter-Related Bloodstream Infection (CR-BSI): The recognized diagnostic criterion that more accurately confirms the catheter as the source of the infection. It is diagnosed if the same organism is isolated from a blood culture and the tip culture and the quantity of organisms isolated from the tip is greater than 15 colony forming units (CFUs). Alternatively, differential time to positivity (DTP) requires the same organism to be isolated from a peripheral vein and a catheter lumen blood culture, with growth detected 2 hours sooner (ie, 2 hours less incubation) in the sample drawn from the catheter.

Central Line-Associated Bloodstream Infection (CLABSI): This is most commonly reported as a surveillance term; however, it is not an established diagnostic criterion. CLABSI is a primary BSI in a patient who had a central line the day of or day before infection and had more than 2 days of central access. CLABSI surveillance definition may overestimate the true incidence of CR-BSI.

Standard

47.1 Infection prevention measures are implemented with the goal of preventing infusion- and vascular access device- (VAD) related infections.

47.2 The patient with a VAD is assessed for signs and/or symptoms of infection and is educated about infection, risks, interventions, and any required follow-up.

Practice Recommendations

- A. Implement a care bundle in conjunction with a culture of safety and quality to reduce the risk of infection associated with VADs during insertion and during daily care and management.¹⁻¹³ (IV)
 - 1. Ensure that clinicians who insert VADs have sufficient training and documented competency (see Standard 5, *Competency and Competency Assessment*).
 - 2. Optimize VAD lumen utilization to avoid increased risk for infection. Consider working with the interdisciplinary team for scheduled dosing, as needed, to provide safe care with the minimum number of lumens needed.
 - 3. Ensure key aspects of insertion and postinsertion care are documented and readily retrievable to assist infection prevention efforts (see Standard 10, *Documentation in the Health Record*).
 - 4. Consider implementation of an infusion/vascular access specialist team (VAST) for reducing catheter-associated bloodstream infection (CABSI) when basic prevention measures have failed to control CABSI incidence (refer to Standard 4, *Infusion and Vascular Access Services*).
- B. Consider collaborative rounds and audits as a strategy to enhance compliance with infection prevention efforts (refer to Standard 6, *Quality Improvement*).
- C. Evaluate site selection for VAD placement as a strategy to reduce infection risks (refer to Standard 25, *Vascular Access Device Planning and Site Selection*).
- D. Assess the VAD insertion and/or exit site for signs and symptoms of a VAD-related infection.^{1,14-17} (IV)
 - 1. This includes, but is not limited to, erythema, edema, pain, tenderness or drainage, fluid in the subcutaneous pocket, and/or tunnel of a totally implanted intravascular device or tunneled catheter, induration at the exit site or over the pocket, drainage, or skin breakdown at the VAD insertion site, and/or body temperature elevation.
 - 2. When signs and symptoms of a VAD-related infection are present, immediately notify the provider and implement appropriate interventions.
 - 3. Not all microorganisms produce local site symptoms; absence of exit site complications does not rule out the possibility of infection.
- E. Perform skin antisepsis at the VAD site prior to placement and as part of routine site care (refer to Standard 31, *Vascular Access Site Preparation and Skin Antisepsis*).
- Standard 39, *Vascular Access Device Post-Insertion Care*).
- F. Remove catheters that are inserted under emergent conditions and without full compliance with Aseptic Non Touch Technique (ANTT®) as soon as clinically practicable (refer to Standard 42, *Vascular Access Device Removal*).
- G. Ensure needleless connectors are appropriately disinfected prior to use (refer to Standard 34, *Needleless Connectors*).
- H. Consider use of an antimicrobial catheter to reduce the risk of CABSI.^{1,5,18-22} (III)
- I. Use chlorhexidine gluconate (CHG)-containing dressings to prevent CLABSI in patients greater than 2 months of age with short-term CVADs, unless contraindicated (eg, sensitivity or allergy to CHG), including patients with oncohematological disease (see Standard 39, *Vascular Access Device Post-Insertion Care*).^{1,20,23-31} (I)
 - 1. Weigh risks and benefits of the use of chlorhexidine-containing dressings in patients with complicated skin disorders (eg, Stevens-Johnson syndrome, graft-vs-host disease, burns, and anasarca) and highly exudative sites; immunocompromised patients, infants/young children, and as indicated by product directions for use (refer to Standard 52, *Catheter-Associated Skin Injury*).
 - 2. Guidelines for oncology patients suggest use of a chlorhexidine-containing dressing around the needle insertion site based on duration of infusions exceeding 4 to 6 hours.³² (V)
 - 3. Catheter-related infection reduction has also been observed in both inpatient and outpatient hemodialysis patients with the addition of a CHG-containing dressing.^{24,33} (III)
 - 4. One retrospective cohort study demonstrated a decrease in CLABSI with the use of silver-plated dressings for intensive care unit (ICU) patients.³³ (IV)
- J. For patients receiving outpatient dialysis through a central venous catheter, consider the use of an antimicrobial barrier cap as a strategy to reduce bloodstream infection.³⁴⁻³⁶ (II)
- K. Consider the use of daily chlorhexidine bathing in patients with a CVAD in situ, including infants, as a strategy to reduce CABSI. Use with caution, particularly in low-birthweight and premature infants to reduce the risk of skin injury.^{1,20,27,37-43} (I)
 - 1. Consult manufacturer instructions regarding application of a chlorhexidine-impregnated cloth over the transparent semipermeable membrane (TSM) and along the first 6 inches of the administration set daily. (Committee Consensus)
 - 2. Consider the additional impact of nasal decolonization combined with CHG bathing.^{37,44} (IV)
- L. Remove a PIVC if the patient develops symptoms of complication and failure, such as infection (eg,

- erythema extending at least 1 cm from the insertion site, induration, exudate, fever with no other obvious source of infection), or the patient reports any pain or tenderness associated with the catheter (see Standard 42, *Vascular Access Device Removal*).^{1,14,15,45,46} (II)
- M. Do not remove a functioning CVAD solely on suspicion of infection when there is no other confirmatory evidence of catheter-related infection other than an elevation in core body temperature.^{1,14,15} (II)
 - N. Assess the risk and benefit of CVAD removal or catheter salvage based on the type of CVAD (long-term vs short-term), infecting organism, and ability to insert replacement CVAD if necessary. Consider a consultation to an infectious disease medical service.^{14,47-51} (II)
 - O. Remove the CVAD if there is clinical deterioration or persisting or relapsing bacteremia. The timing of insertion of a new CVAD at a new site should be a collaborative decision based on the specific risks, benefits, and need for central vascular access for each patient.^{1,14,45,47} (II)
 - P. Evaluate the use of a prophylactic, antimicrobial catheter lock solution for high-risk patients and in a patient with a long-term CVAD who has a history of multiple CABSIs despite optimal maximal adherence to ANTT (refer to Standard 38, *Flushing and Locking*).
 - Q. Do not use a guidewire exchange to replace a nontunneled central venous catheter suspected of infection.⁵² (V)
 - R. Assess risk versus benefit of a catheter exchange procedure when other vascular access sites are limited and/or bleeding disorders are present. Consider using an antimicrobial-impregnated catheter for catheter exchange.^{14,15} (IV)
 - S. Collect and culture a specimen of purulent exudate from a peripheral or CVAD exit site to determine the presence of fungi or gram-negative or gram-positive bacteria, and initiate empirical antimicrobial therapy as ordered by the provider.^{1,10,11} (IV)
 - T. Do not routinely culture the VAD tip upon removal unless the patient has a suspected CABSIs. Catheter colonization may be detected, resulting in inappropriate use of anti-infective medications and increasing the risk of emergence of antimicrobial resistance. Recognize that the catheter tip culture will identify microorganisms on the extraluminal surface and not microorganisms located on the intraluminal surface.^{1,14,15} (IV)
 - U. Culture the tip of short-term CVADs, PIVCs, and arterial catheters suspected of being the source of a CABSIs using a semiquantitative (roll-plate) method or quantitative (sonication) method upon removal. Culture the introducer/sheath tip from a pulmonary artery catheter when a CABSIs is suspected.^{1,14,15} (IV)
 - V. Culture the reservoir contents of a port body of an implanted vascular access port and the catheter tip when it is removed for suspected CABSIs.^{1,14,15} (IV)
 - W. Consider contamination of the infusate (eg, parenteral solution, intravenous (IV) medications, or blood products) as a source of infection. This is a rare event, but an infusate can become contaminated during the manufacturing process (intrinsic contamination) or during its preparation or administration (eg, parenteral nutrition) in the patient care setting (extrinsic contamination).⁵² (IV)
 - X. Consider the impact of specimen collection technique and blood culture contamination rates when assessing CABSIs (see Standard 41, *Blood Sampling*).^{53,54} (IV)
 - Y. Obtain paired blood samples for culture when CABSIs is suspected to definitively diagnose CR-BSI. These should be drawn from the catheter and a peripheral vein before initiating antimicrobial therapy. CR-BSI is the likely diagnosis when clinical signs of sepsis are present in the absence of another obvious source with one of the following findings (see Standard 41, *Blood Sampling*).^{1,14,15,53,55} (IV)
 1. Positive semiquantitative (>15 colony forming units [CFUs]) or quantitative ($\geq 10^3$ CFUs) culture from a catheter segment with the same organisms isolated peripherally
 2. Simultaneous quantitative blood cultures with a ratio of $\geq 3:1$ (CVAD vs peripheral)
 3. Time to culture positivity difference of more than 2 hours between CVAD cultures and peripheral cultures.
 - a. Early PICC insertion in *Staphylococcus aureus* BSI appears safe in one retrospective audit. Further prospective studies are needed to validate these findings; however, early establishment of safe, reliable vascular access in patients with *Staphylococcus aureus* bacteremia should be considered.⁵⁶ (V)

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48. CATHETER DAMAGE (EMBOLISM, REPAIR, EXCHANGE)

Standard

- 48.1 Preventative strategies are implemented to maintain catheter integrity and reduce the risk for catheter damage.
- 48.2 Assessment of the patient's risk-to-benefit ratio and vascular access need is performed prior to undertaking catheter repair or exchange.

Practice Recommendations

I. General

- A. Prevent catheter damage.¹⁻⁸ (IV)
 1. Use a 10-mL diameter barrel syringe to assess vascular access device (VAD) function; do not forcibly push against resistance (see Standard 38, *Flushing and Locking*).
 2. Limit contrast power injections to VAD and add-on devices with labeled indication for power injection.
 3. Do not withdraw the catheter or guidewire from the needle during insertion, as the needle bevel can damage the wire, and always maintain control of the guidewire to prevent inadvertent wire embolus.
 4. Avoid stretch force, frequent bending, or friction against the catheter (eg, rotate location of integrated clamp[s] on central vascular access devices [CVADs], if required).
 5. Consider ultrasound-guided internal jugular approach or, if necessary, subclavian approach for

implanted vascular access port placement to reduce the risk of pinch-off syndrome and avoid acute angle of catheters inserted into the internal jugular vein (see Standard 32, *Vascular Access Device Insertion*).

6. Consider an annual chest radiograph assessment of long-term CVADs, including implanted vascular access port position and integrity.
 - a. Recognize that younger age, femoral placement, and longer dwell times may be associated with catheter fracture.
7. Avoid inadvertent catheter damage during insertion/removal, such as accidental puncture with needle/scalpel, overly tight sutures, placement of CVAD in the subclavian vein in a position prone to pinch-off syndrome, incorrect attachment of catheter to a port body, and pulling against resistance when removing CVAD.
8. Protect and secure catheter.
 - a. Educate the health care provider and patient/caregiver on how to prevent catheter damage/embolism (eg, avoid flushing against resistance, use of sharp objects, pulling on the catheter; apply gauze to protect the catheter if a clamp is used, and rotate clamp area to avoid continuous pressure on a particular segment if a clamping sleeve is unavailable).
 - b. Cover catheter with clothing and avoid friction of heavy items (eg, backpacks, straps, stiff collars, and jewelry) over external CVADs.
 - c. Use clamps only at clamping sleeve, if present.
 - d. Attach luer-lock connectors carefully to the catheter hub (see Standard 37, *Site Protection and Joint Stabilization*).^{7,9-11} (IV)
- B. Suspect catheter damage/embolism if assessment reveals signs and symptoms such as visible catheter or fractured hub, leaking at the site, catheter dysfunction (eg, inability to aspirate blood, frequent infusion pump alarms), localized pain and/or swelling along CVAD pathway during infusion, paresthesia in the arm, radiographic findings, respiratory distress, or arrhythmias (although patient may be asymptomatic). As many as 20% of catheter fragments are missed on radiographic studies.^{5,8,9} (IV)
 1. Evaluate catheter integrity for the presence of signs and symptoms of catheter damage. Catheter separation may occur at the lumen–hub junction or other external connections, as well as at the internal junction of the septum and outflow tubing in implanted ports with resultant infiltration, bleeding, or exsanguination. Verify all connections are secure, and ensure all connections are visible during hemodialysis to enable assessment of connections.⁵ (V)
 2. Assess the patient for signs or symptoms of catheter damage and catheter, air, or thrombotic embolism when VAD removal is difficult or in the presence of catheter dysfunction (see Standard 42, *Vascular Access Device Removal*).² (V)
3. Recognize early signs and symptoms of pinch-off syndrome in patients with catheters inserted via the subclavian vein, such as resistance with flushing, infusion or blood return relieved by specific postural change (eg, rolling shoulder, raising arm, neck movement), frequent occlusion alarms, infraclavicular pain, pain during flushing or infusion, possible swelling at the insertion site, and a change in the clinical picture with arm or shoulder movement.^{2,3,5,9} (V)
 - a. Confirm the presence of pinch-off syndrome through radiographic examination, indicating on radiology requisition to “rule out pinch-off syndrome” to ensure proper arm positioning during radiographic examination.^{2,3,9,11,12} (V)
- C. Manage catheter damage (eg, ballooning, fracturing, rupturing, and cracking of the hub) in a timely manner to reduce the risk of catheter fracture and embolization, air emboli, bleeding, catheter-lumen occlusion, catheter-associated bloodstream infection (CABSI), and treatment interruption or failure, as well as to prolong catheter longevity.^{7,10,12-14} (IV)
 1. Stop any infusions. Clamp or seal a damaged catheter (eg, close an existing clamp, add a clamp, cover the damaged area with adhesive dressing material, or fold the external segment and secure) between the catheter exit site and the damaged area to prevent air embolism or bleeding from the device immediately upon discovery of catheter damage. Label the damaged catheter, “Do Not Use,” while waiting for the repair or exchange procedure to be performed.^{15,16} (IV)
 2. Determine appropriate intervention, considering patient and health care team preference for the following options:
 - a. Catheter repair may promote catheter longevity and limit loss of vascular access sites and reduce risk of infection compared to catheter exchanges.^{13,15} (V)
 - b. Catheter exchange:
 - i. Associated with reduced risk for technical complications of new catheter insertion (eg, pneumothorax, hemothorax, arterial puncture) but may be associated with higher thrombosis rates.^{10,17,18} (IV)
 - ii. Should not be performed in the setting of suspected infection in patients with conditions where removal is warranted (eg, sepsis, hemodynamic instability, persistent bacteremia beyond 72 hours of appropriate antibiotics).¹⁹ (V)
 - iii. Peripherally inserted central catheter (PICC) exchanges have been associated with a 2-fold increased risk of thromboses compared to those without exchanges.¹⁸ (IV)

- c. Catheter removal and replacement.^{5,10,11,14,15,18,20,21} (IV)
3. Assess risks versus benefits of the procedure.
 - a. Consider factors such as the patient's age, venous integrity, and condition (eg, compromised immune systems, burns, transplants, confirmed or suspected infection); length of time remaining and characteristics (eg, osmolality) of infusion therapy; availability of alternative vascular access options; and catheter status and history (eg, femoral catheterization, patency, external length, catheter material), possible exposure of catheter to microorganisms due to the catheter damage, resulting changes in appropriate tip position with repair, damage located near exit site (eg, within 3.0 cm of exit site or <2.5 to 5.0 cm of undamaged length proximal to bifurcation of catheter), persistent leakage postrepair attempts, and previous catheter repairs or exchanges.^{7,10,13-15,18,21} (IV)
 - b. Consider exceptions to catheter repair/exchange, such as sepsis, endocarditis, and suppurative thrombophlebitis.¹⁸ (IV)
4. Confirm tip location radiographically or by other imaging technology prior to initiating or resuming prescribed therapies after catheter repair (if CVAD was withdrawn as a result of damage or repair) and after catheter exchange (see Standard 22, *Central Vascular Access Device Tip Location*).⁹ (V)
5. If unable to repair/exchange catheter, collaborate with health care team for replacement or removal, as required.⁹ (V)
6. Monitor for signs of postprocedural complications (eg, catheter-related infection, leakage, migration of metallic stent, occlusion, or thrombosis).^{10,13,15,18} (IV)

II. Catheter and Guidewire Embolism

- A. Suspect catheter/guidewire embolism when patient exhibits symptoms such as palpitations, arrhythmias, dyspnea, cough, or thoracic pain that are not associated with the patient's primary disease or comorbidities. In some cases, there are no signs or symptoms, but damage often occurs over time with lengthy usage.^{2,8} (V)
- B. Examine guidewire, catheter tip, and length after removal, comparing the removed length to the inserted length for damage and possible fragmentation. If damage is seen or suspected, a chest radiograph or further evaluation is required.⁹ (V)
- C. Promptly manage catheter or guidewire embolism.^{3,9,11,13,18} (V)
 1. Place patient on left side in Trendelenburg position, unless contraindicated (eg, increased intracranial pressure, eye surgery, or severe cardiac or respiratory disease); minimize movement of patient and

involved limb; reassure patient; call immediately for emergency medical assistance.

2. Pressing the limb over the target vein may decrease the chance of migration of the fracture; consider immediate application of a tourniquet above site when catheter or guidewire embolization is observed.
3. Notify health care team; percutaneous interventional/surgical procedures are likely required for fragment/catheter removal to prevent further complications.

III. Catheter Repair

- A. Repair catheter with catheter-specific repair kit, according to the manufacturer's directions for use. If no device-specific repair kit is available, consider alternative strategies, such as catheter exchange or removal and replacement.¹³⁻¹⁵ (IV)
- B. Maintain Surgical-ANTT for catheter repair procedures (refer to Standard 19, *Aseptic Non Touch Technique [ANTT®]*).
- C. Do not use the catheter for the time indicated on the repair instructions to allow adhesive to bond catheter segments; inspect the catheter for patency and leakage before catheter use.¹³⁻¹⁵ (IV)
- D. Assess the catheter regularly after repair to confirm the integrity of the repair and identify potential problems. The repaired catheter may not have the same strength as the original catheter.¹³ (V)
- E. Consider a catheter exchange or replacement after performing a risk-benefit analysis if the catheter repair fails.¹⁰ (IV)

IV. Catheter Exchange

- A. Avoid routine exchanges for CVADs that are functioning and without evidence of local or systemic complications.¹⁸ (IV)
- B. Consider CVAD exchange, including tunneled, cuffed catheters and implanted vascular access ports if there is no evidence of infection.²² (IV)
 1. Consider CVAD exchange in the setting of an actual or suspected infection (excluding septic shock or metastatic infection) when there is limited vascular access. Consider use of an antimicrobial impregnated, coated, or bonded catheter and prophylactic antimicrobials. Limited evidence suggests hemodialysis catheter revision with a new tunnel, new exit site, and the same venotomy site may result in a lower infection rate compared to catheter exchanges (see Standard 47, *Vascular Access Device-Related Infection*).²² (IV)
- C. Maintain Surgical-ANTT and use techniques to reduce the risk of air embolism during the catheter exchange (see Standard 19, *Aseptic Non Touch Technique [ANTT®]*; Standard 49, *Air Embolism*).²³ (IV)
- D. Monitor postprocedure for complications such as bleeding or hematoma, infection, or recurrence of malfunction due to intact fibrin sheath.¹² (V)

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Note: All electronic references in this section were accessed between September 30, 2022, and August 19, 2023.

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49. AIR EMBOLISM

Standard

- 49.1 All infusion connections are of a luer-lock design to ensure a secure connection (eg, intravenous [IV] administration sets, syringes, needleless connectors, extension sets, and any add-on devices).
- 49.2 Air is always purged/removed from administration devices (eg, IV administration sets, syringes, needleless connectors, extension sets, and add-on devices) prior to connection or initiating an infusion.
- 49.3 Clinicians, patients, and/or caregivers initiating and managing infusion therapy are instructed in air embolism recognition, prevention, and implementation of critical actions in the event an air embolism is suspected.

Practice Recommendations

- A. Instruct the patient and/or caregivers not to disconnect or reconnect any IV administration sets or connectors from the catheter hub unless they have been instructed in IV administration and evaluated as competent in the procedure.¹⁻³ (IV)
- B. Never use sharp objects (eg, scissors, hemostats, or razors) near the catheter.⁴ (V)
- C. For all vascular access devices (VADs), use the following techniques to prevent air embolism:
 1. Prime and purge air from all administration sets and add-on devices.^{1-3,5,6} (IV)
 2. Use patient positioning and air-occlusive techniques during insertion, use, replacement, and following VAD removal.⁷⁻¹⁶ (IV)
 3. Use luer-lock connections and equipment with safety features designed to detect or prevent air

- embolism, such as administration sets with air-eliminating filters and electronic infusion pumps with air sensor technology.^{2,5,6} (IV)
4. Do not leave unprimed administration sets attached to solution containers.^{1,2,6} (V)
 5. Ensure the VAD is clamped before changing administration sets or needleless connectors.^{3,5,6} (IV, A/P)
- D. Implement special precautions to prevent air embolism during placement of central vascular access devices (CVADs) and other procedures involving entry into the vascular system, such as catheter exchange and extracorporeal membrane oxygenation.^{5,10,11,15,17-25} (IV, A/P)
1. Air embolic events have occurred related to contrast administration, endoscopy, guidewire-assisted procedures, sheath exchange, arterial catheterization, neurosurgery in an upright position, cardiopulmonary bypass, during extracorporeal membrane oxygenation, and unsecured connections.^{1,3,5,11,17,26,27} (IV)
- E. Implement precautions to prevent air embolism during removal of CVADs, including, but not limited to, the following:
1. Place the patient in a supine position or Trendelenburg, if tolerated, during CVAD removal (contraindicated in premature neonates), so that the CVAD insertion site is at or below the level of the heart. While there are no published cases of air embolism associated with peripherally inserted central catheter (PICC) removal, there may be risk due to an intact skin-to-vein tract and fibrin sheath (see Standard 42, *Vascular Access Device Removal*).^{24,28-37} (IV, A/P)
 2. Instruct the patient to perform a Valsalva maneuver during catheter withdrawal, unless contraindicated. The Valsalva maneuver may be contraindicated in patients including, but not limited to, those with supra-ventricular tachycardia (SVT), acute myocardial infarction, hemodynamic instability, aortic stenosis, carotid artery stenosis, glaucoma, or retinopathy because it increases intra-abdominal and intrathoracic pressure, which reduces cardiac output and affects blood pressure.^{29,30,33-35,38,39} (IV)
 - a. When the Valsalva maneuver is contraindicated, place the patient in Trendelenburg. If unable to tolerate Trendelenburg position, or for femoral lines, use the supine position. Time removal to exhalation (end expiration of the respiratory cycle) if the patient is on mechanical ventilation or unable to cooperate with instructions.^{29,30,33,34} (IV, A/P)
 3. Apply digital pressure until hemostasis is achieved (by using manual compression with a sterile, dry gauze pad).^{2,5,10,11,15,17-21} (IV)
 4. Apply petroleum ointment and an air-occlusive dressing (eg, petroleum, covered with gauze and transparent semipermeable membrane) to the access site for at least 24 hours for the purpose of occluding the skin-to-vein tract and decreasing the risk of retrograde air emboli.^{2,29,33,34} (V)
5. Encourage the patient to remain in a flat or reclining position for 30 minutes after removal, if able. While documentation of air embolism during removal of a PICC has not been reported, the exit site could be at the same level as the patient's heart, increasing the risk of air entering through an intact skin-to-vein tract and fibrin sheath (see Standard 42, *Vascular Access Device Removal*).^{2,29,33,34,36} (V, A/P)
- F. Suspect an air embolism with the sudden onset of dyspnea, gasping, continued coughing, breathlessness, chest pain, hypotension, tachyarrhythmias, wheezing, tachypnea, altered mental status, headache, seizures, altered speech, changes in facial appearance, numbness, or paralysis, as clinical events from air emboli produce cardiopulmonary and neurological signs and symptoms.^{2,5,10,11,15,17-21,25,28-36,40} (IV)
1. Implement immediate actions to prevent more air from entering the bloodstream. Close, fold, clamp, or cover the existing catheter or cover the puncture site with an air-occlusive dressing or pad if the catheter has been removed.^{2,5,10,11,17-21,28-35} (IV)
 2. Position patient immediately on the left side in the Trendelenburg position or in the left lateral decubitus position if not contraindicated by other conditions, such as increased intracranial pressure, eye surgery, or severe cardiac or respiratory diseases. The goal is to trap the air in the lower portion of the right ventricle.^{2,5,10,11,17-21,28-35,37} (IV, A/P)
 3. For arterial air embolism, the recommendations are to position the patient in the supine position. The left lateral recumbent position is insufficient to prevent arterial air emboli from entering the systemic circulation. Head down positioning may exacerbate cerebral edema in patients who sustain cerebral air embolisms.⁶ (V)
- G. Implement additional actions once air embolism is suspected.
1. Initiate resuscitation team if in acute care setting or call emergency medical services if in patient's home or alternative care setting.^{2,6,10,11,17-20,28-35,41} (IV)
 - a. Notify provider.
 - b. Ensure adequate vascular access.
 - c. Provide 100% oxygen, if available, and further support actions as needed.
 2. Alternative treatments, if available, that have shown effectiveness:
 - a. Hyperbaric oxygen^{29,30,41} (V)
 - b. Manual removal of air through a catheter^{5,28,33,41,42} (V)
 - c. Forced expulsion of air through smaller segments of the pulmonary arteries via chest compression.^{21,31,33,37,43} (V)

H. Anticipate diagnostic tests such as transesophageal echocardiography, precordial doppler ultrasonography, computed tomography, magnetic resonance imaging, electrocardiogram, or ultrasound.^{2,5,10,11,17,20,21,28-31,33-35} (V)

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50. CATHETER-ASSOCIATED THROMBOSIS

KEY DEFINITIONS

Catheter-associated thrombosis is a global term (synonymous with catheter-related thrombosis [CRT]) that encompasses the spectrum of peripheral and central catheter-associated thrombosis. Recent research is heterogenous in the use of definitions and of methodologies to report catheter-associated thrombotic outcomes. The global term catheter-associated thrombosis (CAT) and definitions below will be used within the standard, with specific use of different terms when used by a particular study.

- **Catheter-associated thrombosis (CAT):** initiated as an inflammatory response to vessel wall injury and appears as an anechoic or hypoechoic image on ultrasonic evaluation, partially or fully occluding the vessel lumen. It is generally subdivided into deep versus superficial vein thrombosis (DVT, SVT) and symptomatic versus the larger percentage that are asymptomatic. Rates of CAT are generally low (but vary widely), and CAT rarely results in more serious complications, but may impact the function of the vascular access device (VAD), delay required treatment, require anticoagulant therapy, cause VAD failure/premature removal, increase costs, and may result in postthrombotic syndrome.
 - **Deep vein thrombosis (DVT):** thrombosis involving the deep veins of the arm (brachial, axillary), subclavian, or internal jugular veins, or the leg (iliac, femoral, popliteal) detected by compression and flow ultrasonography, venography, or computed tomography (CT) scan.
 - **Upper extremity DVT (UE-DVT):** often associated with VADs inserted in smaller upper arm veins with lower blood flow velocity.
 - **Superficial vein thrombosis (SVT):** thrombosis involving the superficial veins of the upper extremity (eg, basilic, and cephalic) or lower extremity (eg, saphenous veins).
 - **Venous thromboembolism (VTE):** a clinical episode of VTE includes deep vein thrombosis and pulmonary embolism (may include SVT in some studies).
- **Fibroblastic sleeve:** a sleeve of connective tissue that develops as an apparent adaptive process to a foreign body and may eventually surround a VAD. The sleeve does not originate from the vein wall; contains fibroblasts, smooth muscle cells, and collagen; is typically asymptomatic; but may potentiate catheter dysfunction if it obstructs the distal tip of the catheter.
- **Post-thrombotic syndrome (PTS):** a complication occurring after a venous thrombosis (typically a DVT) in either a lower or upper extremity characterized by pain, tenderness, swelling, and skin changes. Endothelial injury secondary to VAD insertion is a potential source.

Standard

50.1 The clinician identifies risk factors, implements preventative strategies, assesses the patient for signs/symptoms of suspected catheter-associated thrombosis (CAT), and assesses patient response to treatment, including optimal vascular access device (VAD) removal.

Practice Recommendations

- A. Identify risk factors for CAT in patients who require a VAD to assist in VAD planning and to inform the need for increased monitoring and for potential prophylaxis.
 1. Malignancy (type of cancer, tumor size, and characteristics), diabetes mellitus, obesity, chemotherapy

administration, thrombophilia (eg, Factor V Leiden, protein C deficiency, protein S deficiency), critical illness, and personal and family history of thrombosis.¹⁻¹³ (I)

- a. Routine investigation of thrombophilia is not recommended in pediatric patients with catheter-associated DVT (CA-DVT).^{4,5} (I)
2. Other risk factors include SARS-CoV 2 virus infection (COVID-19), patient age (but varies widely per study and population risks), pregnancy, elevated triglycerides, elevated low-density protein, ethnicity (higher risk reported in Black or African Americans), reduced functional capacity (as measured by Eastern Oncology Cooperative Group [ECOG] scoring), readmission to the hospital shortly after central vascular access

- device (CVAD) insertion, inadequate hydration and nutrition, non-O blood types, and blood transfusions.^{2,7-9,14-18} (I)
3. VAD-related risk factors include distal tip malposition, higher catheter-to-vessel ratio (venous, arterial), reduced blood velocity in the area of the VAD, VAD- and infusate-related endothelial injury, multiple insertion attempts, longer VAD dwell time, increased arm circumference, increased vein depth, and presence of concurrent VAD.^{2,3,6,16,19-27} (I)
 - a. In a prospective cohort study regarding peripherally inserted central catheter (PICC)-related thrombosis, it was noted that localized factors (in the area of the VAD) may contribute more to CAT risk than systemic factors within the first 2 weeks of VAD insertion.²⁸ (IV)
 - b. Repetitive PICC insertions in the same arm were associated with an increased risk and speed of progression of symptomatic thrombosis in pediatric patients.²⁹ (IV)
 4. CAT risk factors vary based on patient characteristics and VAD selection. Various methods have been studied to identify validated risk reduction measurement tools for CAT in specific populations (primarily with PICC insertion), but further research is needed in this area.^{9,20,30,31} (IV)
 - a. The Caprini Risk Assessment Model may have predictive value for PICC-related thrombosis, especially in high-risk patients. The Caprini score, however, was found to have moderate sensitivity and low specificity, possibly leading to overdiagnosis.³²⁻³⁴ (IV)
 - b. Machine learning predictive techniques using genotypes may assist in identifying patients at high risk for PICC-related thrombosis.⁹ (IV)
- B. Evaluate the risk of CAT during the process of VAD selection with careful consideration of patient vasculature, urgency and type of treatment required, and patient preference and functional needs (including laterality) (see Standard 25, *Vascular Access Device Planning and Site Selection*).^{10,17,22,23,29,35-37} (I)
1. Consider risk reduction recommendations for general patient populations.
 - a. Use the smallest diameter, least number of lumens possible to deliver the required infusion therapy.^{12,17,20,22,23,29,37-40} (I)
 - b. Consider the risks of non-PICC central vascular access devices (CVADs).
 - i. Nontunneled CVADs inserted via the subclavian site are associated with lower thrombotic risk compared to jugular or femoral in adult patients in intensive care units (ICUs) but should be avoided in patients with chronic kidney disease (CKD) due to increased risk of stenosis. The femoral insertion site is reported to have higher thrombotic risk.^{24,41-43} (III)
 - c. Employ risk reduction interventions when selecting where to insert a PICC. PICCs have been associated with higher rates of DVT than other CVADs due to reduced blood velocity in upper extremity vessels. Increased thrombotic risk has been noted with PICC insertion in critically ill patients.^{3,16,22,23,35,41} (I)
 - i. In a meta-analysis of PICC-related outcomes, optimal insertion techniques and use of single-lumen, smaller diameter PICCs reduced PICC-related DVT risk to a rate comparable to other CVADs.²³ (I)
 - ii. Use a bundled approach for PICC insertion, including systematic ultrasound evaluation and identification of optimal area for placement, insertion methods that reduce vascular trauma, optimal tip placement verification, optimal catheter-to-vein ratio, and use of smallest diameter/fewest number of lumens.^{23,35,44,45} (II)
 - iii. Consider tunneling PICCs. A single-center, randomized, controlled, nonblinded, prospective trial demonstrated tunneled PICCs had a lower incidence of venous thrombosis and lower costs of catheter maintenance compared to nontunneled PICCs (See Standard 32, *Vascular Access Device Insertion*).⁴⁶ (III)
 - iv. Further high-quality studies are needed to determine the optimal PICC characteristics and insertion technique for CAT risk reduction.^{23,45} (I)
 2. Consider CAT risk reduction recommendations for cancer-related treatment.
 - a. Consider insertion of an implanted vascular access port rather than a PICC for treatment of cancer due to a reported lower thrombotic risk.^{10,47-50} (II)
 - b. Balance known risks of location of insertion of implanted vascular access ports (chest versus the arm), with patient preference and treatment needs (eg, breast cancer).⁵¹⁻⁵³ (II)
 - i. Total complications associated with arm ports (including thrombosis) were not significantly different between arm- and chest-placed implanted ports in patients with cancer, based upon a meta-analysis.⁵² (II)
 - ii. In a retrospective study, insertion of an implanted port in the arm was associated with a significant increase in symptomatic radiologically confirmed UE-DVT when compared to ports inserted in the chest in patients with breast cancer.⁵¹ (V)
 - iii. In a prospective study with adult cancer outpatients who were candidates for home parenteral nutrition and had a CVAD inserted, the rates of catheter-related

- symptomatic thrombosis were low and similar for PICCs, tunneled-cuffed CVADs, and ports.⁵⁴ (IV)
3. Consider the potential benefits of thromboresistant or antithrombotic CVAD and midline catheter use. Confirmatory clinical evaluation of various catheter surface and composition modifications are needed, including hydrogel, drug coating, and hydrophilic, hydrophobic, and biologic characteristics.⁵⁵⁻⁵⁷ (II)
 - a. This is an evolving area of research with the potential for reduction in thrombotic risk. Further high-quality evidence with sufficient sample sizes is needed to optimize catheter characteristics to reduce thrombotic risk.^{20,56,58-62} (II)
 4. Consider CAT risk reduction recommendations for pediatric patients.
 - a. Use implanted ports as the preferred VAD (compared to tunneled and nontunneled CVADs) to reduce VTE risk in children with cancer diagnosis.⁵ (I)
 - b. In a multicenter, prospective, observational cohort study with pediatric patients with a newly inserted PICC, implanted venous port, or tunneled cuffed CVAD, PICCs were associated with a significantly higher risk of catheter-related VTE than tunneled lines.¹⁷ (IV)
 5. Consider the risk for CAT with midline catheters. The utilization of midline catheters has increased rapidly, with an urgent need for high quality research to guide optimal use.^{59,63,64} (II)
 - a. In a systematic review and meta-analysis, including 40 871 adult patients, the prevalence of VTE (defined as DVT or PE) with midline catheters was significantly higher than with PICCs ($P < .00001$). Further research is needed to establish the thrombotic risk of midline catheters versus PICCs in the pediatric population.⁶⁴ (II)
 6. Reduce thrombotic risk with arterial catheter insertion and management through use of ultrasound for accurate insertion, optimization of the catheter entry angle and length within the artery, catheter securement and stabilization, and frequent monitoring of circulatory status.^{65,66} (V)
- C. Implement preventative interventions for CAT during VAD insertion (see Standard 32, *Vascular Access Device Insertion*).
1. Ensure that the selected VAD is inserted by staff with specific training, using vascular visualization (see Standard 21, *Vascular Visualization*).^{6,22,35,39,67} (II)
 2. Position the tip of a CVAD in the lower third of the superior vena cava (SVC) or upper third of the right atrium (RA) at or near the cavoatrial junction (CAJ) for adults and children. For lower body insertion sites, position the CVAD tip in the inferior vena cava (IVC) above the level of the diaphragm (refer to Standard 22, *Central Vascular Access Device Tip Location*).
- a. The use of electrocardiography to confirm appropriate PICC tip positioning has been associated with reduced thrombotic risk.^{22,39} (III)
 - b. Ensure proper tip placement after umbilical venous catheter (UVC) insertion before use to prevent thrombotic complications such as UVC-related portal vein thrombosis (see Standard 28, *Umbilical Catheters*).⁶⁸ (IV)
3. Measure the catheter-to-vessel ratio prior to insertion; ensure no more than 45% ratio (see Standard 32, *Vascular Access Device Insertion*).^{2,22,28,35,45,69} (II)
 4. Evaluate the need and appropriateness of PICC exchange. PICC exchange was independently associated with a twofold greater risk of thrombosis in a retrospective study. However, this risk may have been influenced by the fact that patients who experienced exchanges were more likely to have had multilumen PICCs (see Standard 48, *Catheter Damage [Embolism, Repair, Exchange]*).³⁸ (IV)
 5. Consider upper extremity exercise to reduce venous stasis; handgrip exercise using an elastic ball 3 or 6 times per day for 3 weeks was associated with a lower incidence of ultrasound-confirmed CA-DVT in patients with cancer who had a PICC. Further research is needed to identify postinsertion nursing interventions that reduce thrombotic risk.^{15,70,71} (III)
 6. Recommendations for prophylactic anticoagulation for CA-DVT prevention have not been established for all patient populations but should be guided by individual patient risk.^{23,72} (I)
 - a. VTE prophylaxis is recommended during cancer treatment requiring CVAD insertion and has not been associated with a risk of major bleeding.^{10,72,73} (I)
 - b. The role of pharmacologic VTE prophylaxis is unclear in pediatric patients but has been associated with decreased CAT risk without increased bleeding risk in specific pediatric populations.^{17,74-76} (II)
- D. Monitor for signs, symptoms, and potential consequences of CAT; recognize that CA-DVT often does not produce overt signs and symptoms. Clinical signs and symptoms are related to obstruction of venous blood flow and may include, but are not limited to, pain/edema/erythema in the extremity, shoulder, neck, or chest, and engorged peripheral veins of the extremity.^{2,34} (IV)
1. Measure baseline circumference of the extremity with a PICC or a midline catheter upon insertion, noting location for future measurements to ensure consistent measurement. Assess circumference when edema or signs and symptoms of DVT present, noting the location and characteristics of edema. A 3-cm increase in mid-arm circumference in adults with PICCs was associated with CA-DVT (see Standard 10, *Documentation in the Health Record*).^{2,34,77} (IV)
 2. Reports of CAT-related pulmonary emboli are rare but may occur with CVADs and midline catheters.^{3,59,78} (II)

3. Recognize post-thrombotic syndrome as a potential long-term consequence of CA-DVT characterized by chronic pain, swelling, and skin changes.^{6,79,80} (II)
- E. Diagnose and confirm CA-DVT using color-flow Doppler ultrasound by the presence of at least 2 of the following: an echogenic mass in the venous structure assessed; noncompressibility of the vein, abnormal color Doppler vein pattern, and/or vein filling defect. Venography with contrast injection may also be used to assess more proximal veins (eg, brachiocephalic) that are obscured by the clavicle or ribs.^{2,3,9,17,50} (II)
 1. Do not remove a CVAD in the presence of CA-DVT when the catheter is correctly positioned, functional, and necessary for infusion therapy. The decision to remove a CVAD should be made based on the individual patient's characteristics, symptoms, and imaging.^{10,19,81} (I)
 2. Treat CA-DVT with anticoagulant medication for at least 3 months after diagnosis. For CVADs with a longer dwell time, continue the treatment for as long as the CVAD is in situ; unfractionated heparin infusion or catheter-directed thrombolysis may be of benefit to patients with severe symptoms.^{2,10,16} (IV)
- F. Remove the VAD when no longer clinically needed to reduce the risk of thrombotic complications (refer to Standard 42, *Vascular Access Device Removal*).
 1. Carefully consider the need to retain or remove an implanted port at the conclusion of chemotherapy, evaluating the patient risks and need for further therapy.⁵¹ (V)

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Note: All electronic references in this section were accessed between December 31, 2022, and August 5, 2023.

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51. CENTRAL VASCULAR ACCESS DEVICE MALPOSITION

Standard

51.1 The clinician assesses for central vascular access device (CVAD) malposition and uses appropriate resources and interventions when malposition is suspected or confirmed.

Practice Recommendations

- A. Correlate normal vascular anatomy and the acceptable CVAD tip location to aberrant locations in the thorax, abdomen, and neck on insertion (ie, primary malposition) and during dwell (ie, secondary malposition).
 1. Primary intravascular malposition of CVADs occurs during or immediately after the insertion procedure

and includes locations in the aorta, lower portion of the right atrium and right ventricle, ipsilateral and contralateral brachiocephalic (innominate) and subclavian veins, ipsilateral and contralateral internal jugular veins, azygous vein, internal mammary, and many other smaller tributary veins. Femoral insertion sites may produce malposition of the catheter in the lumbar, ilio-lumbar, and common iliac veins. Causes of malposition include the following¹⁻¹³: (IV)

- a. Inadequate catheter length and insertion depth
- b. Patient position changes (eg, from supine to upright)
- c. Respiratory movement of the diaphragm and use of mechanical ventilation
- d. Upper extremity and shoulder movement
- e. Body habitus (eg, obesity, breast size)
- f. Congenital venous abnormalities, including persistent left superior vena cava (PLSVC) and variations of the inferior vena cava (IVC), azygous vein, and pulmonary veins. Many of these anatomical variations are undiagnosed until CVAD insertion is required.
- g. Trauma
- h. Acquired venous changes, including thrombosis, stenosis, and malignant or benign lesions prohibiting advancement to appropriate tip position.
2. Secondary intravascular malposition of CVADs, also known as tip migration, occurs any time during the dwell and is related to sporadic changes in intrathoracic pressure (eg, coughing, vomiting); original tip located high in the superior vena cava (SVC); deep vein thrombosis (DVT); congestive heart failure; neck or arm movement; positive pressure ventilation; exercise; and dislodgement (partial or complete).^{14,15} (V)
3. Primary and secondary extravascular CVAD malposition includes location in the following^{2,9,11,12}: (IV)
 - a. Mediastinum producing infiltration/extravasation
 - b. Thoracic duct producing chylothorax
 - c. Pleura producing hemothorax or pleural effusion
 - d. Pericardium producing pericardial effusion and cardiac tamponade, especially in infants
 - e. Peritoneum producing intra-abdominal bleeding and abdominal compartment syndrome
 - f. Trachea and other structures due to fistula formation
 - g. Epidural space in neonates.
- B. Recognize and control the risk of malposition during insertion, if possible.^{2,16-18} (IV)
 1. Insertions on a patient's left side are more prone to malposition due to a longer left brachiocephalic (innominate) vein and a more diagonal pathway to the heart. Left-sided insertions are more prone to abut the contralateral side of the SVC, leading to vessel erosion.
 2. Bevel orientation during guidewire insertion may reduce malposition. For internal jugular sites, medial bevel orientation, and for subclavian sites, caudal bevel orientation, facilitate guidewire advancement and subsequent tip location.
 3. Tip location in the lower right atrium is associated with infective endocarditis due to abrasion of the tricuspid valve or cardiac wall from the catheter tip and subsequent organism introduction into the bloodstream causing infection.
- C. Use tip location technology to enhance awareness of primary CVAD malposition during the insertion procedure (see Standard 22, *Central Vascular Access Device Tip Location*).^{3,19,20} (III)
- D. Use real-time ultrasound during the insertion procedure to reduce the risk of inadvertent arterial insertion. Ultrasound is also useful to rule out cephalad tip orientation in the jugular vein prior to removal of the sterile field (see Standard 21, *Vascular Visualization*).²¹⁻²⁷ (IV)
- E. Assume inadvertent arterial CVAD insertion as a possibility if the patient presents with a stroke or other neurological injury, hematoma, or hemothorax at insertion or during the dwell time.^{2,8,16} (IV)
 1. Confirm arterial or venous placement by assessing waveforms using a pressure transducer, blood gas values from a sample taken from the CVAD, or computed tomography angiogram (CTA). Pulsatile flow and color of the blood are not always reliable indicators for arterial placement due to low blood pressure or the length of the catheter.
 2. For inadvertent arterial placement in axillo-subclavian or jugular insertion sites, consult with the provider, radiology, and/or vascular surgery teams to develop a plan for removal. Withdrawal of large catheters from an accessed artery (eg, carotid) with site compression increases the risk of brain ischemia from lack of blood flow, hematoma, or emboli. Endovascular techniques or open surgical repair may be needed.
 3. Consult with interventional radiology and/or surgeon to develop a plan for urgent removal. Delay can increase the risk of thrombosis.
- F. Monitor the growth of infants and children with CVADs, as growth can produce suboptimal intravascular tip location when a CVAD is indwelling over extended periods of time. Correlate growth to tip location, and plan for CVAD changes as needed.^{11,28} (IV)
- G. Use only a CVAD labeled for power injection of contrast agents. Power injection is reported to produce mediastinal extravasation if the tip is malpositioned and may be the cause of malposition due to force of injection. Assess for clinical signs and symptoms and patency of the CVAD by manual flush, aspirate for a blood return, and confirm the correct tip location before and after power injection. Uncertainty about tip position or catheter patency should be assessed with a scout scan or topogram before power injection.^{1,29} (IV)

- H. Identify CVAD dislodgement, another cause of secondary malposition, by monitoring and measuring the external CVAD length with dressing changes and compare to the documented external length at insertion.³⁰ (V)
 1. Dislodgement alters tip location and is associated with arm movement, body habitus, patient manipulation (eg, Twiddler's syndrome), inadequate catheter securement and/or incorrect dressing, and securement device removal.
 2. Never advance any external portion of the CVAD that has been in contact with skin into the insertion site. No antiseptic agent or technique applied to skin or the external catheter will render skin or the catheter to be sterile, and no studies have established an acceptable length of time after insertion for such catheter manipulation.
 3. Management may require an exchange over a guidewire or removal and insertion at a new site.
- I. Assess the patient and the CVAD for signs and symptoms of catheter dysfunction and associated complications before each CVAD infusion, as these factors will be the first indication of malposition^{4,31-34}. (IV)
 1. Absence of blood return from any catheter lumen
 2. Changes in blood color and pulsatility of the blood return from any catheter lumen
 3. Difficulty or inability to flush the CVAD
 4. Arterial vs venous waveform from an attached pressure transducer
 5. Atrial and/or ventricular dysrhythmias
 6. Changes in blood pressure and/or heart rate
 7. Shoulder, chest, or back pain during insertion or dwell time
 8. Edema in the neck or shoulder
 9. Changes in respiration
 10. Complaints of hearing gurgling or flow stream sounds on the ipsilateral side
 11. Paresthesia and neurological effects due to retrograde infusion into the intracranial venous sinuses.
- J. Withhold infusion through a malpositioned catheter until appropriate tip position has been established. Assess the prescribed infusion therapy and, if possible, insert a short peripheral intravenous catheter (PIVC) to continue therapy. If the infusion therapy is not possible through a peripheral vein, assess the potential risk for discontinuing therapy and consult with the provider regarding changing the infusion therapy until the appropriate CVAD tip location can be reestablished.³¹ (V)
- K. Obtain diagnostic tests, including chest radiograph with or without contrast injection, fluoroscopy, echocardiogram, computed tomography (CT) scan, and/or magnetic resonance imaging (MRI) to diagnose CVAD malposition based on clinical signs and symptoms and problems with catheter function.^{2,3,8,21,35} (IV)
 1. Provide the radiology department with clinical information to enhance their ability to identify the problem.
2. Chest radiographs at specific intervals may not identify tip migration because of the sporadic and unpredictable nature of malposition. Each acute care facility should assess the need for chest radiograph when patients with a CVAD are admitted.
3. Collaborate with the radiology department to have chest radiographs or other diagnostic radiographic procedures include catheter tip location. Establish and follow organizational policy for reporting and management of malpositioned catheters found during these procedures.
- L. Manage malposition depending upon the location of the CVAD, the continued need for infusion therapy, and the patient's acuity. Consult with the provider and/or radiology department as needed.^{4,34,36} (V)
 1. Noninvasive or minimally invasive techniques are preferred as the initial step to reposition a CVAD. Bedside ultrasound may be useful in identifying catheter malposition in the internal jugular vein.^{14,28,37-40} (IV)
 2. Intracardiac location in the lower two thirds of the right atrium or right ventricle should have the CVAD retracted based on electrocardiogram results or measurement of the specific distance on the chest radiograph.^{17,39} (V)
 3. CVADs angling cephalad into the internal jugular vein, the contralateral subclavian or brachiocephalic (innominate) vein, or other tributary veins may be repositioned by a high-flow flush technique involving elevating the patient's head to a 60° to 90° angle (ie, high Fowler's position) and flushing the catheter. Instructing the patient to cough while flushing may also change intrathoracic pressures, allowing catheter movement. Repeat radiograph should be performed to determine tip location.^{37,38,41} (V)
 4. Invasive techniques include catheter exchange over a guidewire and other radiological techniques under fluoroscopy.^{14,38} (V)
 5. For a PICC inadvertently placed in an artery, remove the catheter and apply and maintain direct manual pressure on the arterial puncture site until hemostasis is achieved. Inform primary clinicians of arterial placement for continuing close observation.³¹ (V)
 6. For PICC malposition in neonates, attempt noninvasive repositioning by elevating the head of the bed for internal jugular placement, lying on the opposite side with head elevated for brachiocephalic placement, or gentle flushing or fluid infusion. Secondary intravascular malposition may be corrected by abduction, adduction, flexion, or extension of the extremity.^{40,42} (IV)
 7. Repositioning of long-term CVADs may require using a diagnostic catheter inserted via the femoral vein under fluoroscopy and manipulating the tip using a snaring technique.³⁸ (V)

8. Fluid aspiration from the CVAD before removal may be indicated if cardiac tamponade is suspected. Consult with the provider and/or radiology department.^{7,31} (V)
9. Removal when an infiltration/extravasation has occurred will require a treatment plan for the specific medication involved (see Standard 44, *Infiltration and Extravasation*).^{4,14,37-39} (IV)

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52. CATHETER-ASSOCIATED SKIN INJURY

KEY DEFINITIONS

- **Catheter-associated skin injury (CASI):** an abnormality including, but not limited to, erythema, vesicle, bulla, erosion or tear, at a peripheral or central vascular access device (VAD) site that is noted in the area of the device dressing and/or securement device and that is observable for 30 minutes or more after dressing/securement removal. CASI is associated with increased patient discomfort (eg, pain, pruritis), increased cost, delays in treatment, and a potential for VAD removal and replacement. Skin conditions from other sources (eg, eczema, autoimmune disorders, medication adverse events) are not included.
 - **Medical adhesive-related skin injury (MARS):** erythema or cutaneous abnormality (including occurrence of, but not limited to, vesicle, bulla, erosion, skin tear or vesicle) that continues to be observable 30 minutes or more post adhesive removal. This definition will be used in the standard only if it was specifically mentioned in the reference.
- **Conditions related to adhesive and catheter-associated skin injury include the following:**
 - **Erythema:** Red discoloration to skin; may be painful, pruritic; may be difficult to detect with darker pigmented skin
 - **Allergic contact dermatitis (ACD):** Cell-mediated immune response in the area of the catheter; corresponds to the area of exposure; possible appearance: erythema, vesicles, pruritic dermatitis; typically, longer length of symptoms (eg, up to a week)
 - **Irritant contact dermatitis (ICD):** Nonimmunological skin injury; corresponds to area of exposure; possible appearance: erythema, edema, vesicles; typically, short in duration when exposure is eliminated
 - **Tension injury or blister:** Separation of epidermis from dermis, caused by tension, shear; can be potentiated by severe edema
 - **Skin stripping:** Removal of one or more layers of the stratum corneum, often due to removal of adhesive, excess friction with site cleansing
 - **Maceration:** Skin injury caused by prolonged exposure to moisture; area may appear pale, white, grey, wrinkled; increases permeability and susceptibility to injury
 - **Skin tear:** Separation of epidermis from dermis due to shear/friction forces; may be partial or full thickness
 - **Pressure injury:** Injury to superficial and potentially deeper structures due to prolonged pressure
 - **Folliculitis:** Small, inflamed, elevated skin pustules at hair follicles; often due to trapped microbes, damage from shaving.

Note: Within this standard, the acronym CASI will refer to the global term catheter-associated skin injury, inclusive of all vascular access device-related skin injury. The acronym CASI is also used in Appendix B. In those documents, CASI refers to the 2017 central vascular access device (CVAD)-associated skin impairment algorithm. This algorithm is included to provide guidance on assessment and treatment of CVAD-related skin impairment.

Standard

52.1 Preventative strategies are implemented to eliminate or minimize the risk of catheter-associated skin injury (CASI).

52.2 Vascular access device (VAD) site, dressing, and securement status are routinely assessed for signs and symptoms of skin injury.

52.3 Appropriate interventions are implemented to manage and prevent further risk of CASI.

Practice Recommendations

- A. Use prevention strategies that incorporate individual patient risk factors to prevent skin injury related to VAD placement and management.¹⁻⁵ (II)
- 1. Assess risk of skin injury based on patient characteristics, required VAD, and infusates.^{1,2,5-13} (II)
 - a. Consider patient population risks for CASI. Risks cited most frequently are shown in Table 1 below.
 - 2. Incorporate skin injury risk assessment into VAD device and site selection (see Standard 25, *Vascular Access Device Planning and Site Selection*; Standard 32, *Vascular Access Device Insertion*).^{3,7,9,10,27,29,30} (IV)
 - a. Reduce vascular trauma associated with VAD insertion using vascular visualization; bruising and hematoma formation may promote skin injury.^{9,10} (IV)
 - b. Administration of chemotherapy in an implanted port may have reduced risk of skin injury with chemotherapy that has a high risk of skin toxicity.²⁷ (V)
 - 3. Assess the patient’s history of CASI and related allergies prior to VAD placement to mitigate risk of skin injury.^{1,3-5,9,14,31} (III)
 - 4. Ensure that preventative strategies are incorporated as appropriate, based on identified patient risk factors:
 - a. Avoid insertion into areas of pre-existing injury.^{2,10,32} (II)
 - b. Reduce site infection and folliculitis by clipping or trimming hair at the insertion site vs shaving.⁵ (IV)
 - c. Choose VAD-related products (eg, antiseptic, skin barrier, dressing, securement) based on a thorough risk assessment, and individualize strategies to the patient’s clinical needs. Utilize them per manufacturer guidelines and patient population guidelines. The preferred skin antiseptic agent is alcohol-based chlorhexidine solution. Use chlorhexidine gluconate (CHG)-containing dressing unless contraindicated (eg, sensitivity or allergy to CHG) to prevent central line-associated bloodstream infections (CLABSIs) in patients greater than 2 months of age with short-term central vascular access devices (CVADs), including patients with onco-hematological disease (refer to Standard 31, *Vascular Access Site Preparation and Skin Antisepsis*; Standard 47, *Vascular Access Device-Related Infection*).^{1,2,5,18,33,34} (II)
 - i. Ensure the integrity of products prior to use; maintain single-patient use.^{5,14} (IV)
 - ii. Select antiseptic products that will provide effective antimicrobial action between applications and that minimize skin irritation and damage.
 - a) Carefully review product information, especially for patients at high risk for infection, as some antiseptic products are provided in nonsterile form and may contain contaminants.³⁵ (V)
 - b) Use lower concentrations of antiseptic or aqueous solutions, if needed, to reduce

TABLE 1	
Population Risks for CASI	
Population	CASI Risk Factors Include (But Are Not Limited To)
General	Extremes of age, decreased mobility, history of CASI, dwell time of VAD, obesity, low BMI, altered cognitive status, malnutrition, dehydration, comorbidities (eg, diabetes, infection, renal insufficiency, venous insufficiency, immune deficiency), smoking, history of chronic dermatological conditions (including allergies), ethnicity (eg, darker pigment), medications (eg, chemotherapy, long-term steroid use, anticoagulants), use of phototherapy. ^{1,2,4-6,9,10,13-17} (II) • Dry skin has been found to be an independent risk factor for MARSIs, with one study noting that patients with dry skin had over 5-fold greater risk of MARSIs.^{2,13,14,18,19} (IV)
Neonates	Immature stratum corneum (not fully mature until at least 34 weeks’ gestation), immature immunity, cardiovascular compromise. ^{5,20-22} (IV)
Pediatrics	Particularly critically ill, have high reported rates of contact dermatitis and skin injury due to impaired dressing integrity. ^{8,12,23} (III) • In an observational study in the pediatric intensive care unit, MARSIs occurred in 58.3 per 100 cases.¹² (IV)
Older	Loss of dermal matrix and subcutaneous tissue, epidermal thinning, reduced cohesion between dermis and epidermis, suboptimal hydration, and reduced vasculature and tensile strength of skin. ^{5,14,18,24} (IV)
Critically Ill	Altered immunity, malnutrition, hemodynamic instability (reduced tissue perfusion), longer length of stay, low Braden scale. ^{2,10,14,18,25} (IV) • Edema was found to be predictive of MARSIs risk.¹⁰ (IV)
Oncology	Hormone use, chemotherapy-induced skin toxicity, female gender. ^{6,10,16,17,26-28} (IV)

BMI, body mass index; CASI, CVAD-associated skin impairment; MARSIs, medical adhesive-related skin injury; VAD, vascular access device.

skin irritation. Sterile saline may be used in the presence of severe skin conditions (refer to Standard 31, *Vascular Access Site Preparation and Skin Antisepsis*).

- c) Allow the product to fully dry to reduce risk of maceration and skin irritation.
 - 1) Allergy to chlorhexidine (CHG) is uncommon but has been reported. Note that a history of skin irritation may be listed in the patient history as an allergy, limiting antiseptic options. Consider performing patch tests to determine true allergy status.^{5,7,9,31,34} (IV)
 - 2) In the neonatal population, risk of skin injury from chlorhexidine use has been well documented; however, chlorhexidine is reportedly used in many neonatal intensive care units (NICUs), often with weight and age criteria to determine respective safety. Tincture of iodine is avoided due to risk of absorption/thyroid toxicity. There is insufficient evidence to identify optimal skin antisepsis in neonates, especially in low- and extremely low-birthweight infants (LBW, ELBW). Recommendations to reduce skin injury are to use the lowest effective concentration (<1% CHG), and avoid alcohol in high-risk infants, with aqueous CHG preferred (see Standard 31, *Vascular Access Site Preparation and Skin Antisepsis*).^{3,5,20-22,36,37} (III)
 - (a) Sodium hypochlorite has been used with minimal skin irritation in neonates.^{20,38} (IV)
- iii. Aseptically, apply an alcohol-free skin barrier product that is compatible with the antiseptic solution, enhancing protection for the skin around the VAD insertion site. The barrier provides a physical barrier to protect the epidermis from irritants. A variety of products are available with variable effectiveness. Follow manufacturers' instructions for application. Allow to fully dry.^{2,4,5,19,30-32,39-41} (II)
- iv. Select the most appropriate dressing based on the intended purpose, the impact on the ability to assess the insertion site, area of application, patient status (eg, including positioning), and clinical setting. VAD dressings are generally composed of a polyurethane film with an acrylate adhesive backing that is pressure sensitive. Consider breathability, stretch, conformity, character of adhesive, and compatibility with other products in use.^{1,4,5} (III)
 - a) Use proper application technique: apply firm, gentle pressure; eliminate tension/stretch on the dressing. Limit or avoid use of substances that increase the adhesion of dressings/tape (eg, tackifier, bonding agents). Avoid use of circumferential coverage, as it may contribute to pressure injury.^{2,4,5} (II)
 - b) Weigh risks and benefits of allowing longer intervals between CVAD dressing changes due to increased risk of infection in some populations.^{42,43} (IV)
 - c) If a nontransparent dressing (eg, gauze) is required, apply the dressing per manufacturer's instructions and consider expert consult (eg, wound care, infusion/vascular access specialist team (VAST), infectious diseases) on frequency of site assessment/dressing change (refer to Standard 39, *Vascular Access Device Post-Insertion Care*). (Committee Consensus)
- d. Monitor patients for symptoms of contact dermatitis and adjust product choice based on the individual patient tolerance. The incidence of contact dermatitis from use of CHG skin antisepsis and CHG-containing dressings is reportedly low but requires further high-quality research to evaluate the impact of single and multiple product regimens.^{44,45} (IV)
 - i. Weigh risks and benefits of the use of chlorhexidine-impregnated dressings in patients with complicated skin disorders (eg, Stevens-Johnson syndrome, graft-vs-host disease, burns, and anasarca) and highly exudative sites; immunocompromised patients, infants/young children, and as indicated by product directions for use.^{32,42,46,47} (III)
 - ii. Consider dressing options for challenging clinical situations with increased frequency of assessment: a dressing alternative that does not contain a patient-specific allergen, gauze only (eg, severe exfoliative dermatitis), silicone-based, silver ion alginate antibacterial (reduced risk of folliculitis), hydrocolloid (increased absorption), absorbent clear acrylic, hemostatic (bleeding at site).^{1,14,26,28} (IV)
- e. Change the VAD dressing promptly if soiled, not intact, or upon initial signs/symptoms of skin impairment. Follow manufacturers' instructions for use.

- i. Consider use of hemostatic agent/dressing for patients at risk of bleeding post-VAD insertion; increase frequency of monitoring (refer to Standard 39, *Vascular Access Device Post-Insertion Care*).
- f. Select the method of VAD dressing and securement to reduce frequency of dressing changes that may increase risk of skin injury, that incorporates patient characteristics, area of application, length of dwell, and delivered therapy.^{4,5,33,39} (III)
 - i. Consider use of gum mastic liquid adhesive that is compatible with antiseptic and dressing products when enhanced dressing adherence is needed.^{23,39,48} (IV)
 - ii. Cyanoacrylate tissue adhesive has been associated with improved hemostasis to reduce localized bleeding at the insertion site and a reduction in the need for early dressing changes (see Standard 36, *Vascular Access Device Securement*).^{46,49} (II)
 - iii. Consider use of skin barrier film prior to application of liquid adhesive and ensure correct technique in dressing removal to prevent catheter-associated skin injury due to increased bonding of adhesive to skin (see Standard 36, *Vascular Access Device Securement*).^{4,5,14} (III)
 - iv. Consider options for securement based on patient risks, with potential for reduction in CASI: subcutaneous anchor securement system (SASS), integrated securement dressing, silicone splinting for infants, central line vest (see Standard 37, *Site Protection and Joint Stabilization*).⁵⁰⁻⁵² (III)
 - v. Evaluate the risks of skin stripping when evaluating use of medical adhesive tape as additional securement and when anchoring tubing. There are multiple products available with rubber-backed tape associated with increased risk of skin stripping.¹⁸ (IV)
 - a) Further research is needed to identify optimal properties that facilitate high adhesion yet safe removal of medical tapes. Recent research shows promise in development of temperature-sensitive and photo-thermal release prototypes.^{53,54} (IV)
- g. Use appropriate removal technique for dressing, securement, and tape removal: keep the product horizontal to the skin, as a vertical pull increases peel force. Support the skin at the peel line during removal.^{3-6,55} (IV)
 - i. Use medical adhesive remover per manufacturer instructions and adhering to Aseptic Non Touch Technique (ANTT®). Use additional precautions with dressing and securement removal for patients at high risk for skin injury. Sterile saline may be used to aid removal in high-risk patients.^{1,3-5,15,18,39,48} (III)
- h. Skin health is supported by proper hydration and nutrition.^{5,7,31} (IV)
 - i. Educate staff and patients on VAD site care, as well as early recognition and prompt management of CASI. Educate clinicians/parents/caregivers on antiseptic solutions and atraumatic dressing application and removal.^{1,2,4,5,7,21,31,33} (II)
 - j. Consider multi-disciplinary collaboration for high-risk patients, including dermatology and wound care consultations as needed.^{1,5,7,9,26,28,48} (IV)
 - k. Remove the VAD as soon as clinically indicated to prevent skin injury (see Standard 42, *Vascular Access Device Removal*).^{15,56} (V)
- B. Assess the status of the VAD site (including integrity of the skin, dressing and securement, evidence of patient discomfort) to promptly recognize the development of skin injury.^{2,5,6,10,12,18,27,31,57} (II)
 1. Assess the skin in the area of the VAD for texture, color, uniformity of appearance, and integrity using adequate lighting. Document skin condition and noted abnormalities (eg, vesicles, exudate, erythema, warmth, edema, pressure-related injury).^{1,4-6,31,58} (II)
 - a. If skin injury is noted, assess the severity to determine the impact on the VAD, the treatment regimen, and management.⁵ (IV)
 - i. For premature infants with signs of a chemical burn or irritation, take immediate action, removing the potential source of irritation. Treat, and if necessary, promptly consult with other specialists, including dermatology and surgery specialists.²⁰ (V)
 - b. Assess for pain related to skin injury and treat, if needed, with analgesic, anti-inflammatory, and/or cool compress.^{6,7,31,32} (II)
 - c. Assess for VAD-related pruritis. Treatment with antihistamines or steroids may be indicated. Pruritis is common in some populations (eg, end-stage renal failure), which may mask CASI or other serious conditions.^{31,56} (IV)
 - d. Rule out the presence of infiltration, extravasation, thrombophlebitis, and skin conditions related to other body regions (eg, eczema, impetigo, cellulitis, erysipelas, or drug eruptions) and treat accordingly. Consider wound care and/or dermatology consultation as needed (see Standard 43, *Phlebitis*; Standard 44, *Infiltration and Extravasation*).³¹ (IV)
 - e. Assess for signs of localized or systemic infection, including fungal infection (eg, Candida; whitish or raised red areas unresponsive to other treatment).

Adhesives and resultant skin injury may promote bacterial overgrowth.^{4,5,7,28,30,41,48} (III)

- f. Rule out dressing, antiseptic, and securement-related factors if an abnormality is noted (eg, failure to allow product to fully dry, frequent dressing changes, improper removal technique).^{5,14,31} (IV)
 - g. Monitor and intervene early if allergy or sensitivity to a product is suspected. Identify alternative products for cleansing and VAD dressing and securement use.^{4,9,34} (IV)
2. Further validation of CASI resources is needed to establish a thorough CASI-related skin assessment resource.^{6,31} (II)
- C. Employ strategies to promote skin regeneration and protection in the presence of skin injury (see Appendix B for CASI algorithm; Standard 36, *Vascular Access Device Securement*; Standard 37, *Site Protection and Joint Stabilization*; Standard 51, *Central Vascular Access Device Malposition*).
1. There is wide variation in practice in the management of CASI. Further research is needed. Recommended interventions are listed.^{1,5,7,9,14,18,29-31,57} (III)
 - a. Avoid subsequent exposure to products suspected of causing CASI.
 - b. Consider changing to a different antiseptic product and/or a reduced concentration.
 - c. Consider dressing alternatives, balancing adhesion/securement with prevention of further skin damage at removal.
 - i. Consider risks of insufficient adhesion for securement in loss of device.
 - d. Consider securement alternatives that reduce the use of adhesives.
 - i. Address catheter securement and site protection if using a dressing system with no securement properties; more frequent monitoring may be required.
 - e. Perform patch testing if new allergy is suspected. Refer for allergy testing, if indicated.
 - f. Use medical adhesive remover if not already in use.
 2. For skin tears, if skin flap is present, realign skin flap edges prior to dressing application.^{31,55} (IV)
 - a. Avoid use of transparent, semipermeable membrane (TSM) dressings, adhesive strips, and hydrocolloid dressings for the skin tear management due to risk of epidermal stripping if not removed properly.
 - b. If skin damage/drainage is not in the immediate VAD insertion area, isolate the wound and exudate from the exit site, apply absorbent dressing over the injury, and apply the transparent dressing over the insertion site. A recent published protocol indicates that

silicone mesh and TSM dressing may be used, ensuring the dressing is applied over a healthy skin border.⁵⁵

3. If no improvement with inflammation and pruritis at the site, consider short-term use of topical low-to-moderate potency corticosteroid (do not apply directly on VAD insertion site; agent is non-sterile) and consider obtaining culture of insertion site.³¹ (IV)
 4. If no improvement in skin within 3 to 7 days or skin condition deteriorates with above measures, seek expert consultation (eg, wound care, dermatology).^{5,31,32} (IV)
 5. Consider VAD removal, if required, and reassess plan for vascular access needs.³² (V)
 6. Ensure that the patient/caregiver understands strategies in place to mitigate further skin injury and products that should be avoided to prevent future recurrence.^{4,31} (IV)
- D. Employ quality improvement measures to monitor and address incidence of CASI. Monitor current evidence to explore options.^{5,48} (IV)

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Section Eight: Other Infusion Devices

Section Standards

- I. The clinician is competent in the management of epidural/intrathecal, intraosseous (IO), and subcutaneous devices, including knowledge of anatomy, physiology, infusion administration, and management techniques aimed at maintaining access and reducing risk of complications.
- II. Insertion, care and management, and complication management for epidural/intrathecal, IO, and subcutaneous access are established in organizational policies, procedures, and/or practice guidelines.

53. EPIDURAL AND INTRATHECAL ACCESS DEVICES

Standard

53.1 Epidural and intrathecal (neuraxial) access devices and administration sets are identified and labeled as a specialized infusion administration system and differentiated from other infusion administration and access systems.

53.2 Medications administered via a neuraxial route are free of preservatives.

53.3 Infusion solutions administered via a neuraxial route are filtered using a 0.2-micron, surfactant-free, particulate-retentive, and air-eliminating filter.

53.4 Neuraxial (NRFit) connectors are used to prevent inadvertent neuraxial administration of non-neuraxial medications, solutions, or enteral feedings.

53.5 Neuraxial access device placement, removal, care and management, and medication administration are performed either by or upon the order of the provider in accordance with regulations established by regulatory and accrediting bodies and in accordance with organizational policies and procedures.

Practice Recommendations

- A. Recognize indications for epidural/intrathecal medication infusions for patients across practice settings from acute care to outpatient and home care:
 1. Management of short-term acute pain associated with surgical procedures, trauma pain, and during

labor in hospitalized patients; a temporary catheter is placed for analgesic/anesthetic medication administration (see Standard 60, *Patient-Controlled Analgesia*).¹⁻³ (V)

2. Management of chronic cancer and non—cancer-related pain refractory to medical management and/or intolerable side effects associated with systemically administered analgesics. Infusions may include opioids alone, opioids in combination with ziconotide (first choice), local anesthetics, and opioids in combination with local anesthetics and clonidine. Access options for chronic pain include long-term tunneled catheters, implanted ports with epidural/intrathecal catheters, and implanted intrathecal drug delivery (ITDD) systems consisting of an intrathecal catheter attached to an implanted infusion pump.³⁻¹² (IV)

- a. Patient selection criteria include history of adherence to a treatment plan and ongoing appointments for pump maintenance, general medical/psychosocial status/social support and disease prognosis.^{13,14} (V)

- b. The clinical site for trialing and dosing for patients with chronic pain generally requires hospital admission, which allows for flexibility in trialing different intrathecal medications and regimens. Low-dose opioid trialing may be considered in the outpatient setting with a shorter observation period before releasing the patient; however, an overnight hospital admission is recommended with high starting doses. Trialing may include a single bolus or catheter-based bolus or infusion via the epidural or intrathecal route. Medications are carefully titrated during medication initiation when converting from one route to another (eg, intravenous [IV] to epidural to intrathecal), one medication to another, and when adding adjuvant medications. Dosing and opioid conversion guidelines should be used, and dosing should start low when converting from one medication to another; opioid dosing for intrathecal drug infusion is about 1/10 the dosing for an epidural drug infusion.^{3,12,14,15} (V)

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- c. ITDD therapy was similarly efficacious with no significant difference in side effects when placed in younger patients (<65 years old) as compared to those 65 years and older in a small retrospective study representing approximately 11 years on ITDD. The researchers suggest that, in carefully selected patients, intrathecal opioids are helpful in avoiding unwanted side effects from oral pain management.¹⁶ (V)
3. Spasticity treated with intrathecal baclofen.^{7-9,17,18} (IV)
4. Treatment of primary central nervous system cancers and leptomeningeal metastases.^{3,19,20} (IV)
- B. Assess the patient's current coagulation status; anticoagulants must be withheld before epidural/intrathecal insertion and before removal due to risk for hematoma and paralysis.^{1,2,14,21-23} (IV)
 1. Obtain dosage, route, date, and time of last anticoagulant administration.
 2. Review coagulation panel results.
 3. Consult guidance from American Society of Regional Anesthesia and Pain Medicine and the Polyanalgesic Consensus Conference guidelines for time frames to withhold each type of anticoagulant.
 4. Review platelet count; spinal epidural hematoma in thrombocytopenic patients with a platelet count of 75 000/microliter or above is rare. There is no current consensus about the minimum threshold platelet count; patients should be monitored carefully for any signs of bleeding (eg, petechiae, bruising) for the first 24 hours.
- C. Implement specific practices to prevent medication errors; errors from inadvertent administration of IV medications administered via the intrathecal route (eg, vinca alkaloids, potassium chloride, antibiotics) and anesthetic solutions (eg, fentanyl and bupivacaine, ropivacaine) inadvertently administered by the IV route have resulted in profound toxicity and death.^{19,20,24-28} (IV)
 1. Use neuraxial ([NRFit] International Organization for Standardization [ISO]–approved connector) to prevent misconnections among IV, enteral, and neuraxial infusions. Neuraxial medications are prepared in NRFit syringes and/or administered via NRFit administration sets; standard luer needleless connectors/infusion administration sets will not fit into NRFit connectors.
 2. Ensure clinicians involved in neuraxial procedures are educated about NRFit connectors and the importance/rationale for this change. Evaluate and update procedures, related order sets, and pharmacy preparation and dispensing processes to include NRFit connectors.
 3. Trace all catheters/administration sets/add-on devices between the patient and the container before connecting or reconnecting any infusion/device, at each care transition to a new setting or service, and as part of the handoff process (refer to Standard 40, *Administration Set Management*).
4. Recognize that antineoplastic medications administered via an intrathecal route are administered by physicians and advanced practice providers in conjunction with local and national regulations and organizational policy.
5. Use different delivery devices and systems for medications to be administered via an epidural/intrathecal versus other parenteral routes. IV vinca alkaloid administration should be prepared in a small-volume infusion bag (ie, minibag) and administered as an infusion, not in a syringe; this is also advised for other antineoplastics such as anthracyclines.
6. Prepare and store intrathecal medications separately. These should be clearly labeled "For Intrathecal Use" (refer to Standard 56, *Compounding and Preparation of Parenteral Solutions and Medications*).
7. Limit access to epidural analgesia; require the clinician who will administer the neuraxial medication to bring the medication to the patient's bedside immediately before use.
8. Perform an independent double check with another qualified nurse, pharmacist, or physician prior to administration (including when syringe/medication container, rate, and/or concentration is changed), including verification of the safety of intraventricular/intrathecal route and its mixture with preservative-free 0.9% sodium chloride or Elliotts B solution (used for methotrexate sodium and cytarabine).
9. Use a time-out procedure prior to medication administration.
- D. Maintain Surgical-Aseptic Non Touch Technique (ANTT®) during catheter insertion, implanted neuraxial port access, and access and filling of implantable intrathecal drug delivery systems. Wear a mask during all neuraxial medication injections to reduce the risk of droplet transmission of oropharyngeal flora (see Standard 19, *Aseptic Non Touch Technique [ANTT®]*).^{1-3,29} (IV)
- E. Confirm position of external epidural/intrathecal access devices before any infusion or medication administration.
 1. Aspirate epidural access devices prior to medication administration to ascertain the absence of spinal fluid and blood; if greater than 0.5 mL of serous fluid is aspirated, notify the provider, and do not administer the medication, as this finding is indicative of catheter migration into the intrathecal space.
 2. Aspirate intrathecal and ventricular access devices prior to medication administration to ascertain the presence of spinal fluid and the absence of blood.^{2,3} (A/P)
- F. Use an electronic infusion pump with anti-free-flow protection to administer continuous infusions. Patient-controlled analgesia may be used with epidural infusions; ITDD systems provide precise medication dosage at constant or variable rates with refilling of the pump reservoir based upon the individual patient requirements

(eg, every 1-6 months) (see Standard 23, *Flow-Control Devices*).^{2,3,13} (V)

1. Use an administration set without any injection ports with external epidural/intrathecal infusions to reduce the risk of inadvertent epidural/intrathecal access.^{2,3} (V)
- G. Provide pain management when accessing an implanted intrathecal drug delivery system, as this is a needle-related procedure (see Standard 30, *Pain Management for Venipuncture and Vascular Access Procedures*).³⁰ (V)
- H. Ensure safe management of patients with an implanted intrathecal drug delivery (ITDD) system.
 1. Ensure that clinicians who perform the access procedure, medication filling, and pump programming are educated and competent. Skills required include infusion pump interrogation and programming, pump refill with attention to ANTT, ability to recognize a “pocket fill” (accidental injection into surrounding tissue), and identification of residual volume discrepancies and actions to take.
 - a. Inadequate training is reported; pump refill errors and nerve damage, whether from intraoperative injury, infection, or intrathecal granuloma formation, were causes of patient injury in an analysis of malpractice claims. Inadvertent pocket fills and programming errors were often performed by clinicians who lacked adequate education and training. Guidelines recommend a minimum of 20 supervised pump refills for competency assessment prior to refills being performed independently.^{7,13,14,31-34} (IV)
 - b. In a hospital at-home pilot program, successful pump refills by a nurse/physician team were effective and safe, with high reported patient satisfaction. The program included a post-refill ultrasound to ensure that there was no subcutaneous drug injection.³⁵ (V)
 2. Observe patients for 30-60 minutes after a pump refill; an appropriate method to confirm a pocket fill is to re-access the pump reservoir to check for a volume discrepancy.^{31,33} (V)
 3. Evaluate for potential catheter dysfunction when there is an inadequate response to therapy despite adjustments in pump rate.^{7,13} (IV)
 4. Consider ultrasound guidance with pump refills if port is difficult to locate/palpate, and consider ultrasound to identify pocket fills; notably, ultrasound is less effective than use of palpation to identify the septum with a raised septum ITDD.^{6,36,37} (V)
 5. Monitor patient in controlled setting. Transfer to emergency department (ED) in the event of a pocket fill. Signs/symptoms include site swelling, patient report of burning/stinging during procedure, and technical difficulty during the fill procedure.³³ (V)
 6. Evaluate patients admitted to the ED or hospital who have an ITDD. Obtain information about level of catheter tip; medications/concentrations via continuous, patient-administered dosage; if applicable, pump reservoir volume and date and refill alarm date; signs/symptoms of under/overdose of infusion.^{13,18}
- I. Apply and maintain a sterile dressing that is clean, dry, and intact over the insertion site, and secure the access site.
 1. Use a securement product or tape a tension loop of tubing to the patient’s body to reduce the risk of accidental dislodgement; external catheter (eg, epidural) dislodgment is a recognized risk. There are limited data about the optimal securement technique (see Standard 36, *Vascular Access Device Securement*).^{2-4,38,39} (V)
 2. Perform site care and dressing changes over a tunneled and accessed implanted neuraxial device in accordance with organizational policy; there are no evidence-based recommendations for routine site care and dressing changes. (Committee Consensus)
 3. Avoid use of alcohol with device access and when site care is performed; use aqueous chlorhexidine solution or povidone iodine solution; however, allow any skin antiseptic agent to fully dry, as all antiseptic agents have the potential to be neurotoxic.^{2,3} (V)
 4. Use a transparent semipermeable dressing to allow for site visualization; consider the use of chlorhexidine-impregnated dressings for patients with an epidural access device. A significant reduction in epidural skin colonization and catheter tip colonization has been demonstrated with their use.^{3,40} (I)
- J. Assess and monitor patients frequently for 24 hours after initiating or restarting a neuraxial infusion (eg, every 1 to 2 hours until stable, then every 4 hours). Include the following assessment parameters^{1,2,13,41,42}: (IV)
 1. Pain rating using a validated pain scale based on the patient’s age and condition, both at rest and with activity.
 2. Blood pressure, pulse, respiratory rate, temperature.
 3. Level of sedation if opioid is being administered.
 4. Number of bolus doses, if used (eg, patient-controlled epidural analgesia).
 5. Fetal status and response to epidural infusion for the patient in labor.
 6. Presence of any side/adverse effects, such as pruritus, nausea, urinary retention, orthostatic hypotension, motor block, ringing in the ears.
 7. Changes in sensory or motor function such as new onset of pain, unexplained back pain, leg pain, bowel or bladder dysfunction, and motor block.
 8. Catheter exit site for any signs/symptoms of infection such as erythema, swelling, or local pain; catheters should be removed when such signs are present. Other signs/symptoms of infection may include back pain, tenderness, erythema, swelling, drainage,

- fever, malaise, neck stiffness, progressive numbness, or motor block.
9. Signs of catheter tip migration, such as a change in external catheter length, decrease in pain control, or increased side effects.
10. Dressing for intactness and absence of moisture/leakage.
11. Catheter and administration set connections.
12. Electronic infusion pump for history of analgesic use and correct administration parameters.
13. ITDD pump-related complications, which may be evident as loss of pain control, oversedation with opioid infusions, or increased/decreased spasticity with baclofen infusions.
14. Oxygen saturation levels via pulse oximeter and end-tidal carbon dioxide levels (capnography) in accordance with organizational policy. Use of capnography is more sensitive in identifying respiratory depression than oxygen saturation monitoring.
- K. Address the following patient education topics^{2,3,13,33}: (V)
 1. Principles of neuraxial access device placement and what to expect during the insertion procedure.
 2. The importance of reporting alcohol use and all medications used, including prescription, over-the-counter, and complementary medications.
 3. Signs and symptoms to report, including changes in pain perception, new or worsening side effects, and fever and to seek immediate medical care in the event of such signs/symptoms.
 4. Clinical signs of overdose, including dizziness, sedation, euphoria, anxiety, seizures, and respiratory depression or underdose, such as increased pain or spasticity.
 5. Patients with ITDD systems: no bending/twisting at the waist for 6 weeks and overall caution with active repetitive bending or twisting of spine, as these may increase the risk for catheter damage or dislodgement. Increased pain and withdrawal symptoms may be indicative of problems.

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Note: All electronic references in this section were accessed between January 13, 2023, and June 19, 2023.

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54. INTRAOSSEOUS ACCESS DEVICES

Standard

54.1 The clinician evaluates the patient and anticipates appropriate use of the intraosseous (IO) route in the event of difficult vascular access for emergent, urgent, and medically necessary situations.

Practice Recommendations

- A. Use the IO route in the event of a cardiac arrest if intravenous (IV) access is not available or cannot be obtained promptly.¹⁻⁵ (IV)
 1. Pediatric advanced life support guidelines recommend the use of the IO route as an initial vascular access route in case of cardiac arrest or if intravenous access cannot be obtained within 30 seconds.^{6,7} (V)
 2. Neonatal guidelines recommend umbilical access for resuscitation, but IO may be considered if intravenous (IV) access is not feasible. Venous access is recommended for blood and fluid expansion in the neonate (see Standard 28, *Umbilical Catheters*).⁸⁻¹¹ (IV)
 - a. There is a paucity of evidence to guide IO utilization in neonate resuscitation, resulting in low utilization. Further research is needed to improve vascular access options when umbilical access is delayed or not feasible. A recent animal study noted similar survival outcomes in epinephrine delivery IO versus IV.^{9,11-14} (IV)
 3. IO access has a reported high rate of first-time insertion success with low complications and reduced vascular access insertion attempts.^{1,5,10,15-20} (II)
 4. Escalate to a venous access option if the patient status does not improve with IO use; prompt escalation facilitates rapid delivery of resuscitation medications and solutions (see Standard 25, *Vascular Access Device Planning and Site Selection*).²¹⁻²³ (IV)
 5. The clinical impact on patient outcomes of IO delivery of medications and fluid resuscitation versus IV (eg, peripheral or central) delivery requires further investigation.^{2,3,21,24-31} (II)
 - a. Multiple factors impact patient outcomes (eg, return of spontaneous circulation, survival to discharge, length of stay), leading to indeterminate recommendations and a need for further investigation to determine optimal IO use:

- i. Lack of quality research (eg, heterogenous and retrospective methodology) regarding the impact of IO versus venous delivery.^{24,25,32} (II)
 - a) High-quality research is needed to illustrate pharmacokinetic properties from various IO sites to measure the impact of “time to intervention” and to prospectively measure outcomes in the critically ill patient.^{5,23,24,29,31-33} (II)
 - ii. Preferential use of IO in high-acuity patients with higher risk of negative outcomes.^{15,33-36} (IV)
 - iii. Reported underutilization of the IO route due to lack of training and available equipment to insert.^{11,20,37-39} (IV)
 - iv. Transition to the IO once attempts at IV access are unsuccessful, causing potential deterioration in patient condition during that delay.^{22,27,28,32,40-43} (III)
 - v. Lack of documentation of IO site or IV attempts in many clinical settings.^{3,34} (IV)
 - vi. Factors that may reduce flow rates with IO use: viscosity of infusate, add-on devices, anatomic resistance in the medullary space, needle malposition, distal IO sites (proximal tibia, distal tibia).^{5,32,44,45} (IV)
 - vii. Factors that influence bone perfusion and absorption: hypoperfusion states, hypovolemia, impact of catecholamines on red marrow, and lipid binding in medullary space.^{5,27,32,45} (IV)
- B. Consider the IO route for emergent and nonemergent use in patients with limited or no vascular access or when the patient may be at risk of increased morbidity or mortality if access is not obtained.
1. Clinical situations where the IO route has been utilized successfully include hemorrhagic and septic shock, life-threatening seizures/status epilepticus, extensive burns, traumatic injuries, transfusion, severe dehydration, administration of anesthesia, rapid sequence intubation, hypertonic saline administration in acute intracranial hypertension, palliative/end-of-life care, and radiologic imaging with radiologic confirmation of placement prior to contrast administration. Consult manufacturer instructions for use to verify appropriateness of IO use in a specific clinical situation.^{11,13,19,20,34,46-57} (III)
 - a. Use caution with IO delivery of injectable lipid emulsion, based on a case report of delayed improvement in patient outcome.⁵⁸ (V)
 - b. In a prospective interventional randomized clinical trial, resuscitation of pediatric patients with septic shock with IO insertion was associated with a significantly shorter time to vascular access, shorter length of stay, and reduced mortality when compared to resuscitation with peripheral IV access.⁵⁴ (III)
 - c. Recent studies have reported low incidence of complications with IO administration of blood products. Research indicates successful delivery of whole blood, freeze-dried plasma, warm fresh whole blood (WFWB) in trauma settings, with secondary IO insertion potentially required in polytrauma situations. Further research is needed.^{17,18,55,59,60} (II)
- C. Restrict IO access in the following sites/situations:
1. Absolute contraindications (related to anatomic issues): compartment syndrome in target extremity, previously used IO site or recent failed IO attempt, fractures at or above the site, previous orthopedic surgery/hardware, presence of infection or severe burns near the insertion site, local vascular compromise, and history of sternotomy.^{1,19,61,62} (IV)
 2. Avoid use of IO access in the presence of bone diseases, such as osteogenesis imperfecta and osteoporosis.¹ (IV)
- D. Improve appropriate use of the IO route through education and competency programs; underuse of the IO route in multiple settings is reported.
1. Include the following in competency programs: initial and ongoing validation of safe insertion knowledge and skills through demonstration; demonstration of appropriate device management; ability to recognize complications related to IO access and IO removal (see Standard 5, *Competency and Competency Assessment*).^{1,4,20,34,37,38,63,64} (IV)
 2. Conduct training for IO insertion under simulated challenging clinical situations (eg, biohazardous exposure, nighttime), using appropriate personal protective equipment (PPE) and supplies.
 - a. Research conducted during the COVID-19 pandemic to compare IO and peripheral intravenous catheter (PIVC) access with full PPE in place indicates that PPE impacts dexterity and time to procedure completion, with reduced time to successful IO insertion compared to PIVC insertion.⁶⁵⁻⁶⁸ (I)
 - b. Use of the tactical headlamp was found to be superior to use of night vision goggles during nighttime IO insertion.⁶⁹ (III)
- E. Use an appropriate IO device for the patient’s age and condition. Performance (success rates, time of placement, ease of use, user preference) of different IO devices is dependent on training and user preference. There is no clear evidence of superiority of one device over another. In a 3-arm randomized clinical simulation study in neonates, IO needles were found to have higher rates of successful insertion when compared to an IO drill.⁷⁰ (III)
- F. Consider the use of a safety-engineered IO device (see Standard 16, *Medical Waste and Sharps Safety*).^{1,18,40} (IV)
- G. Select an appropriate IO insertion site and needle size based on the clinical situation and in accordance with

manufacturers' directions for use. Current needle size recommendations are based on weight and age.

1. Adjust needle length for the thickness of skin over the IO insertion site in the child and adult (eg, with higher body mass index [BMI]).⁷¹⁻⁷⁵ (IV)
 - a. Pretibial subcutaneous skin thickness correlates most strongly with BMI.⁷⁴ (IV)
2. Consider sites most commonly reported in the literature for use in both adults and children, including the proximal and distal tibia, the proximal humerus, distal femur, and the sternum in adults.^{1,5,7,19,53,61,76} (IV)
 - a. Sites less commonly reported in the literature include the medial surface of the ankle, radius, ulna, iliac crest, and clavicle. Alternative sites may be required due to traumatic injury, amputations.^{1,60} (IV)
 - i. The sternal insertion site is U.S. Food and Drug Administration (FDA)-approved for ages 12 years and older due to risk to retro-sternal structures in pediatric patients. The sternal IO insertion site has been used successfully during chest compressions and offers the following advantages in chosen clinical situations: increased flow rates with gravity flow possible, lower density bone and minimal overlying skin for easier insertion, readily visible location, direct access to central circulation, presence of red marrow to improve absorption.^{17,34,55,61} (II)
 - ii. In a radioanatomical study, the optimal adult proximal tibial IO insertion site was found to be 0.5 cm below the tibial tuberosity at the mid-line of the medial surface, with the standard needle length noted to be 17 mm.⁷¹ (IV)
 - iii. A cadaveric study of neonates suggests that the proximal humerus and distal femur can be considered IO insertion options.⁷⁷ (IV)
3. Ensure that proper landmarks are identified prior to insertion to avoid complications related to improper placement. Ultrasound visualization improves landmark identification.⁷³ (IV)
4. Ultrasound has been found to be reliable in identifying proximal humerus landmarks in patients of various BMIs.^{39,72,73} (IV)
5. Obesity is identified as a common factor for insertion failure due to difficulty identifying landmarks.^{5,72} (IV)
- H. Consider the use of subcutaneous lidocaine as a local anesthetic prior to insertion at the intended site. For infusion-related pain, consider IO administration of 2% preservative-free and epinephrine-free lidocaine given slowly prior to infusion initiation.^{1,7,19} (IV)
- I. Adhere to Aseptic Non Touch Technique (ANTT®) during IO placement and infusion. Consider the complexity of placement of the IO access device, including consideration of use of sterile gloves when placing IO devices (refer to Standard 19, *Aseptic Non Touch Technique [ANTT]®*).
 1. Perform skin antisepsis using an appropriate solution (eg, alcohol-based chlorhexidine, povidone-iodine, 70% alcohol) based on organizational policies and procedures. There is no evidence addressing the optimal antiseptic solution for IO insertion.^{1,78-80} (IV)
- J. Confirm correct placement of the IO device by assessing the following: correct needle position, sensation of loss of resistance upon bone penetration, and absence of any signs of infiltration upon flushing with 5- to 10-mL (adult) or 2- to 5-mL (pediatric) preservative-free 0.9% sodium chloride. The ability to aspirate blood or bone marrow also assists in confirmation but may be difficult in certain patients (eg, severe dehydration) and, therefore, is not an indication of improper placement if other indications of placement confirmation are present.^{1,19} (IV)
 1. Consider the use of color Doppler ultrasound to confirm initial and ongoing placement.¹⁹ (V)
- K. Consider reserving the initial IO aspirate for laboratory analysis when there are no other options. Use caution in interpretation of laboratory results of IO aspirate, as IO blood samples have been found to have inconsistent correlation with venous and arterial samples in the critically ill.^{1,54,81} (II)
 1. IO aspirate point of care testing has been found to be accurate for glucose, calcium, sodium, pH, and bicarbonate. Potassium levels drawn from the IO may overestimate serum levels but may be helpful to rule out hyperkalemia.⁸² (IV)
 2. IO blood sampling may be accurate for blood typing. IO aspirate should not be used for rotational thromboelastometry (ROTEM) in trauma care due to increased coagulation.^{83,84} (IV)
 3. The majority of blood sampling research has been conducted on healthy subjects. Further research is needed to establish reference values for IO laboratory values and to improve the validity of laboratory analysis from IO aspirate in critically ill patients.⁸¹ (II)
- L. Apply a sterile dressing over the IO access site and secure the device.
 1. Ensure that securement is intact prior to transport to prevent dislodgement.^{1,19,85} (III)
- M. Use an external pressure device (300 mm Hg) or infusion pump for consistent solution/medication delivery. IO infusion may be successfully administered via gravity; however, significant variability in flow rates based on the device and site of insertion have been demonstrated.^{1,17,19,44,55,85} (II)
- N. Monitor for complications associated with IO access. While the rate of immediate complications is very low, data regarding long-term complications is lacking. Potential IO-related complications include infiltration and extravasation (into surrounding tissue and intra-articular), compartment syndrome, iatrogenic

bony fracture, site infection, osteomyelitis, fat and air embolism, and traumatic bullae.^{1,19,79,80,85-92} (IV)

1. Reduce risk for infiltration/extravasation by avoiding multiple attempts at IO access at the same site; ensuring proper needle placement (straight path, perpendicular); properly securing IO device; monitoring flow and loss of flow, immobilizing the involved extremity if required, validating IO placement and patency with transport or repositioning of the patient and before infusing highly irritating solutions/known vesicants and large-volume infusions; ongoing assessment of the IO site and extremity, including palpation and calf circumference for tibial placement; and limiting infusion time to less than 24 hours (see Standard 44, *Infiltration and Extravasation*).^{1,19,28,43,62,75,79,80,86,92} (IV)

- a. Infants and young children may be at greater risk for extravasation and subsequent compartment syndrome due to small bone size and inappropriate needle length.^{9,40,75,93} (IV)
 - i. In a postmortem study of infants after IO insertion, a 53% failure rate (nonmedullary placement) was noted in infants 6 months and younger.³⁷ (IV)

2. Observe and promptly treat patients for IO-related complications. Infectious complications are more likely to occur with prolonged infusion or if bacteremia was present during the time of insertion. Risk of IO-related fat emboli may be increased with rapidly repeated infusions or high flow rates.^{1,79,87-91} (IV)

3. IO-related complications may be delayed in presentation. Accurate documentation of IO insertion (location, failed attempts), duration, and removal is critical to assure proper identification of IO-related complications, such as infection, fracture, or nerve injury.^{19,62,94} (V)

- O. Promptly remove the IO device within 24 hours, when therapy is complete, or if signs of dysfunction occur. Dwell time for specific devices may be extended (not to exceed 48 hours total) in instances where alternative vascular access is not successfully established. Follow manufacturers' directions for use and removal of IO device to reduce risk of complications.^{1,4,19,85} (IV)

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55. SUBCUTANEOUS INFUSION AND ACCESS DEVICES

Standard

55.1 The subcutaneous route is considered as an alternative to intravenous (IV) access as part of a vessel health and preservation strategy.

55.2 The patient is assessed for appropriateness of the subcutaneous route in relation to the prescribed medication or solution, the patient's clinical condition, and the presence of adequate subcutaneous tissue.

Practice Recommendations

- A. Consider subcutaneous administration of isotonic solutions (hypodermoclysis) for treatment of mild-to-moderate dehydration in both older adults and children as an alternative to the IV route when the oral route is not feasible; outcomes are favorable relative to effectiveness, safety, acceptability, and efficiency.¹⁻⁶ (I)
 1. Advantages include ease of access, simplicity of procedure, cost-effectiveness, and patient satisfaction. Home-based hypodermoclysis may be administered by caregivers with minimal burden, equipment, and technical support.^{1,7} (I)
 2. Contraindications to hypodermoclysis include severe dehydration or malnutrition, severe electrolyte disturbances, decreased tissue perfusion, compromised skin integrity/evidence of skin infection, bleeding/coagulation disorders, and generalized edema.¹ (IV)
 3. Local site reactions include transient swelling, erythema, and pain with needle access; the risk for local reactions is reduced with attention to infusion rate and proper needle placement.^{1,3} (I)
 4. Reported infusion rates vary widely among studies^{1,3}: (I)

- a. Older adults: 5 to 167 mL/hour or boluses of 500 mL over 2 to 6 hours
 - b. Pediatric patients: 15.4 mL/kg/hour
 - c. Palliative care patients: 42 to 72 mL/hour.
- B. Consider the subcutaneous infusion of medications:
 1. Ideal medications for subcutaneous administration are hydrosoluble, of neutral pH, have low viscosity, and have low molecular weight. Based upon outcomes evaluating effectiveness, safety, acceptability, and efficiency, evidence was strong for subcutaneous administration of the following 10 medications, including opioids (hydromorphone, morphine, ketamine), antimicrobials (ceftriaxone, ertapenem), hydrocortisone, trastuzumab, immunoglobulin, treprostinil, and deferoxamine.^{3,8} (I)
 2. Antibiotics with longer half-lives that are well-absorbed and well-tolerated are appropriate for subcutaneous infusion, including ceftriaxone and ertapenem. Adverse events associated with antibiotics included local pain, hematoma, induration, and erythema.⁹ (IV)
 3. Subcutaneous or IV administration of diuretics in the management of heart failure was associated with symptom relief and low risk of adverse effects based upon a systematic review. A new subcutaneous formulation of furosemide was made available for home treatment in 2022 (see Standard 66, *Home Infusion Therapy*).^{10,11} (I)
 4. Avoid infusion rates greater than 5 mL/hour unless recommended by manufacturer (eg, subcutaneous immunoglobulin).^{3,12,13} (I)
- C. Consider the use of hyaluronidase in both adults and pediatric patients for initiation and maintenance of subcutaneous hydration and for some medications to facilitate dispersion and absorption of the infusate. Consult drug information references to determine stability and compatibility with hyaluronidase.^{1,3,6,14,15} (V)
- D. Recognize that continuous subcutaneous insulin infusion is a common therapy for patients with diabetes mellitus and requires safe management across care settings.^{16,17} (IV)
 1. Establish policies and procedures to assess patient appropriateness for self-management of insulin therapy during hospitalization and to guide patients and nursing staff in the management of continuous subcutaneous insulin infusion. Patients who are familiar with treating their own glucose levels can often adjust insulin doses more knowledgeably than inpatient staff who do not personally know the patient or their management style.
 2. Supervise patients to ensure their ability to adjust insulin doses in a hospitalized setting, where factors such as infection, certain medications, immobility, changes in diet, and other factors can impact insulin sensitivity and the response to insulin.
- E. Select an appropriate subcutaneous site.^{1,3,6,13} (I)

1. Consider patient's comfort, mobility, and site preference. Select areas with intact skin and adequate subcutaneous tissue (eg, 1.0-2.5 cm), abdomen (at least 4 fingers-width away from the umbilicus), upper chest, upper extremities, flank, hips, thighs, and/or as recommended by the drug manufacturer.
 2. Avoid sites near bony prominences, joints, previous surgical incisions, radiotherapy, damaged skin, intercostal space in patients with cachexia (due to high risk of pneumothorax), mastectomy, tumors, ascites, lymphedema, inner thigh if urinary catheter present, or thigh if peripheral vascular insufficiency exists.
- F. Adhere to Aseptic Non Touch Technique (ANTT®) during subcutaneous access device insertion and infusion; perform skin antisepsis prior to inserting the subcutaneous access device (refer to Standard 19, *Aseptic Non Touch Technique [ANTT®]*; Standard 31, *Vascular Access Site Preparation and Skin Antisepsis*).
- G. Use a small-gauge (eg, 24- to 27-gauge) and short-length nonmetal cannula with luer-lock design for infusions. A metal-winged needle is not recommended for infusions; however, use a subcutaneous needle labeled for high flow rates when indicated by the drug manufacturer.^{1,3,6,8} (I)
1. May use 2 or more sites, as required for high-volume hydration solutions (eg, up to 1 L/d per site).
- H. Remove and insert new device at a new site if blood return is present during device placement.^{6,13} (V)
1. Due to a lack of data and the low likelihood of injecting subcutaneous immunoglobulin (SCIg) into a small blood vessel, assessment of blood return prior to SCIg varies by manufacturer.⁸ (V)
- I. Apply a transparent semipermeable membrane (TSM) dressing over the site to allow for continuous observation and assessment. Change the TSM dressing with each subcutaneous site rotation or immediately if the integrity of the dressing is compromised.^{3,6,13} (I)
- J. Assess the subcutaneous access site and rotate the site as follows:
1. As clinically indicated, based on access site assessment findings (eg, erythema, swelling, leaking, local bleeding, bruising, burning, abscess, or pain).^{6,12,13} (V)
 2. For hydration solutions, reported dwell times range from 24 to 48 hours or after 1.5 to 2.0 liters of solution have infused.^{6,12} (IV)
 3. For continuous medication infusion, every 2 to 7 days; for intermittent infusions (eg, SCIg), the site is changed with each infusion. Site reactions from SCIg (eg, swelling and site erythema, pain, and pruritus) are common and tend to decrease over time, with persistent reactions possibly requiring a slower infusion rate or decreased volume per site, longer needle, or site change.^{3,6,8,12,13} (I)
- K. Regulate the flow rate of the infusion. The following devices have been reported for use with:
1. Hypodermoclysis: gravity infusion set, electronic infusion pump; gravity infusion may reduce risk for local edema, as the infusion will naturally slow down with increased pressure in the subcutaneous tissue.^{1,3,7,14} (I)
 2. Medications: mechanical infusion device; electronic infusion pump; newer "on body" delivery systems consist of a type of infusion pump that is adhered to the skin and delivers the subcutaneous dose.^{3,8,9} (I)
- L. Monitor patient and access site regularly (refer to Standard 39, *Vascular Access Device Post-Insertion Care*).
- M. Address the following patient education topics:
1. Signs/symptoms of access site complications and how/where to report.
 2. Activity limitations/protecting the subcutaneous access site (refer to Standard 8, *Patient Education*).

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Section Nine: Infusion Therapies

Section Standards

- I. Current references and resources on infusion medications and solutions are readily available to the clinician at the point of care.
- II. At least 2 patient identifiers, including patient's full name (or distinct methods of identification for infants), are used to ensure accurate patient identification when administering medications.
- III. Aseptic Non Touch Technique (ANTT®) is applied to all infusion-related procedures as a critical aspect of infection prevention.

56. COMPOUNDING AND PREPARATION OF PARENTERAL SOLUTIONS AND MEDICATIONS

Standard

56.1 Parenteral solutions and medications are compounded in accordance with laws, rules, and regulations established by regulatory and accrediting bodies in each jurisdiction (eg, countries, states, provinces).

56.2 Parenteral solutions and medications are compounded and/or prepared following processes to create a sterile product.

Practice Recommendations

- A. Administer, whenever possible, medications that have been compounded (prepared, mixed, packaged, and labeled) in a pharmacy that complies with compounding standards and regulations.¹⁻⁶ (I)
 1. Do not compound, reconstitute, or otherwise manipulate hazardous medications outside the environmentally controlled hazardous drug preparation area (refer to Standard 15, *Hazardous Drugs and Waste*).
 2. Use infusions supplied by the manufacturer or pharmacy in a ready-to-administer form to minimize the need for manipulation outside the pharmacy sterile compounding area. Infusions prepared or manipulated outside the pharmacy are more likely to contain microbial contamination.

3. Perform complex compounding preferentially in the pharmacy environment.
 - a. Whenever possible, medications that require special attention during the compounding or preparation process should be supplied to the nurse in a ready-to-administer form. Such medications may include those requiring filtration during preparation, susceptible to microbial growth (eg, lipids or dextrose), involving a complex calculation, requiring dilution, or those with long dissolution times, multistep procedures, or specialized reconstitution instructions.
 - b. Limit preparation to the pharmacy, whenever possible, when it is necessary to combine more than 1 medication in a single syringe for intravenous (IV) administration or more than 3 sterile products into a final product for administration.
- B. Avoid unnecessary manipulation to decrease the risk of dosing errors and contamination.^{4,6,7} (IV)
 1. Do not withdraw IV push medications from commercially available, cartridge-type syringes into another syringe for administration.
 2. After measuring the dose in an appropriately sized syringe, do not transfer the medication to another (eg, larger) syringe prior to administration.
 3. Avoid unnecessary dilution. Only dilute IV push medications when recommended by the manufacturer or in accordance with organizational policies, procedures, or practice guidelines.
 4. Use single-use, commercially prepared, prefilled syringes of appropriate solution to flush and lock vascular access devices (VADs) (refer to Standard 38, *Flushing and Locking*).
 5. Dedicate multidose vials (eg, multidose vial if used for IV flush) to a single patient.
- C. Prepare medications and assemble needed supplies in a clean area using a General Aseptic Field/Micro Critical Aseptic Field in accordance with Aseptic Non Touch Technique (ANTT®) (see Standard 19, *Aseptic Non Touch Technique [ANTT®]*).¹⁻¹³ (III)
 1. Compound outside of the pharmacy only when performing in immediate-use situations with appropriate precautions to limit patient risk.

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2. Use a syringe small enough to accurately measure the dose. For improved accuracy, select a syringe close in volume to the desired dose, such that at least 20% of the syringe capacity is occupied by the dose. For hazardous drugs, to decrease the likelihood that the plunger separates from the syringe barrel, use a syringe sized such that no more than 75% of the capacity is occupied by the dose.
3. Remove contaminants physically and chemically by wiping the Key-Site (eg, vial stopper, bag septum, or ampoule neck) with 70% isopropyl alcohol prior to vial/bag access or breaking of an ampoule. Allow the disinfectant to dry prior to entry of the vial/bag or breaking of the ampoule.
4. Use a second clinician to check that the volumes and identities of all compounding ingredients are correct (including any diluents) prior to combining the ingredients.
 - a. Whenever possible, the second clinician should be a pharmacist who remotely verifies the compounding process through video or still images.
5. Use vials (a closed system) instead of ampoules (an open system) to decrease microbial contamination risk.
 - a. Use a filter every time medication is withdrawn from an ampoule.
 - i. Use a 5-micron or smaller filter straw or blunt fill filter needle to withdraw medication from an ampoule and immediately discard any left-over medication along with the broken ampoule and the filter straw or filter needle. The use of a blunt fill needle or filter straw decreases the likelihood that the medication is inadvertently administered through the used filter. If a needle is required for administration, after discarding the filter needle or filter straw, place a new needle on the syringe prior to administration. Do not infuse or inject medication through a filter needle that was used to draw up medication.¹⁴ (II)
6. Only use supplies intended for compounding.
 - a. Do not use IV solutions in containers intended for infusion, including minibags, as common-source containers to dilute or reconstitute medications.
 - b. Do not use prefilled flush syringes for dilution of medications. Differences in gradation markings, an unchangeable label on prefilled syringes, partial loss of the drug dose, and possible contamination increase the risk of serious medication errors with syringe-to-syringe drug transfer.
7. Label any prepared medications (that are not immediately administered) at the location of preparation without any break in the procedure. Protect Key-Parts (eg, injection needle) from contact with nonsterile surfaces, biological fluids, or particulate matter (including aerosolized particles). If administration of the immediate-use sterile product has not begun within 4 hours of preparation, discard the product (refer to Standard 57, *Infusion Medication and Solution Administration*).
8. Never reuse compounding supplies either for the same patient or different patients.
 - a. Use medications packaged as single-dose or single-use for only 1 patient.
 - b. Use a new needle and syringe for every entry into a vial or bag and for every injection. Never use the same needle or syringe to administer medication to more than 1 patient.
9. Use a multidose vial for up to a maximum of 28 days after opening or first puncture unless there is a different beyond-use date (BUD) specified by the manufacturer. After the first use, label the multidose vial with the BUD. The BUD should never exceed the manufacturer's expiration date.
 - a. Whenever possible, use multidose vials for only 1 patient. Multidose vials used for more than 1 patient should never enter the immediate patient care area. If a multidose vial has entered the immediate patient care area, it must become dedicated to that patient only and discarded after use.
- D. Provide education and ongoing (at least annual) competency assessment. Nurse medication administration skills were found to need improvement, particularly in the areas of medication preparation and administration.^{3,7,15} (II)

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57. INFUSION MEDICATION AND SOLUTION ADMINISTRATION

Standard

57.1 Medications and infusion solutions are identified, compared against the medication order and infusion control device (if applicable), and verified by reviewing the label for the name (brand and generic), dosage and concentration, total volume, beyond-use/expiration date, route of administration, frequency, rate of administration, and any other special instructions.

57.2 The prescribed medication/solution, including indications, dosing/diluent, acceptable infusion routes/rates, compatibility data, and adverse/side effects is reviewed for appropriateness prior to administration.

57.3 Concerns about the appropriateness of orders are addressed with the pharmacist, provider, supervisor, and/or risk management, or as defined in organizational policy.

57.4 The infusion system is inspected for clarity of the solution and integrity of the system (ie, leakage, secure connections), accurate flow rate, and for expiration date and beyond-use date (BUD) of the infusate and administration set prior to infusion.

Practice Recommendations

- A. Perform a medication reconciliation at each care transition and when a new medication is ordered (eg, admission, transfers to different levels of care, discharge to new health care setting). Include verification of discontinued medications to reduce the risk of medication errors, including omissions, duplications, dosing errors, and drug interactions.¹⁻⁶ (I)
- B. Recognize physiologic characteristics and effects on drug dosage and volume limitations, pharmacologic actions, interactions, side effects/toxicities, monitoring parameters, and response to infusion therapy when administering solutions and medications to special patient populations (refer to Standard 2, *Special Patient Populations*).
- C. Use a structured clinical reasoning guide or set of cues (eg, the “rights” of medication administration, WARRIORS acronym below) to support safe medication administration.
 1. Perform a cognitive review of all components of the medication assessment, including and beyond the medication rights (eg, appropriateness of drug, dose, route, compatibility of multiple drugs, monitoring test results, flow-control device settings, correct infusion is activated).^{7,8} (V)
 2. Teach patients/caregivers who administer medications to consistently confirm the medication cues.^{9,10} (V)
 3. The WARRIORS clinical guide for medication administration⁸: (V)
 - a. Why: what is the reason this patient is receiving this medication?
 - b. Allergies: Does the patient have allergies? If so, will I give or hold this medication?
 - c. Right laboratory values and vital signs: What are the laboratory values or vital signs that are trending out of range for the patient or will be impacted if this medication is administered or withheld?
 - d. Range: What is the correct range? Is this dose incorrect or correct?
 - e. Implications or interactions: What are the implications and interactions of this medication for this patient?
 - f. Only: Am I the only nurse giving this medication?
 - g. Return: When should I return for reassessment?
 - h. Safety: What should the patient be taught for safe use now or at discharge?
- D. Avoid interruptions during all phases of medication administration, and educate staff, patients, and families, as there is a significant association between medication errors and interruptions.¹¹ (V)
 1. Set up multiple infusions one at a time. Set up each infusion as completely as possible before beginning preparation of the next infusion (ie, label set and pump, spike and hang solution container, connect set to pump, and program pump).^{4,12-14} (V)

- E. Implement safeguards to reduce the risk of medication errors with high-alert medications, as follows:
 1. Standardize storage, preparation, and administration (eg, standard order sets, standardized drug concentrations, and dosing units); improve access to drug information; limit access (eg, stored securely, limited quantities); use supplementary labels and automated alerts.¹⁵⁻¹⁷ (V)
 2. Consider using centralized pharmaceutical reconstitution/admixture service to minimize errors and optimize delivery of medication.^{2,13,18,19} (I)
 3. Perform an independent double-check by 2 clinicians for the organization's selected high-alert medications that pose the greatest risk of harm (eg, opioids, insulin, heparin, chemotherapy).
 - a. Develop a standard process and educate staff in how to perform the double-check. Consider the use of a checklist.^{17,20,21} (II)
- F. Organize the infusion administration system to minimize errors related to multiple infusions and variations in infusion delivery methods (refer to *Table 1: Medication/Infusion Delivery: Dose Accuracy and Error Prevention*).
- G. Use approved, standardized nomenclature for communication of medication information. Use a list of error-prone drug names, abbreviations, symbols, and dose designations (eg, sound-alike, look-alike drugs) to implement safeguards to reduce the risk for medication errors, such as using both generic and brand names; including reason for medication on label; and changing the appearance of look-alike names by using approved, bolded, tall man (mixed-case) lettering.^{4,9,14,17,22,23} (V)
- H. Use technology when available to verify medications prior to administration as one of multiple infusion safety strategies. Analyze effectiveness and limitations related to technology through organizational quality improvement (QI) processes.^{12,23-31} (II)
 1. Use barcode scanning (preferred) or similar technology immediately prior to the administration of medication (unless its use would result in a clinically significant delay and potential patient harm, such as in cardiac arrest). Barcode scanning is associated with decreased risk of medication errors and is increasingly common among acute care organizations, and there is emerging research supporting its use in long-term care settings. Studies have reported that errors still occur, as staff may create "work-arounds" that bypass safety mechanisms with barcode technology.^{17,32} (I)
 2. Use electronic infusion pumps that include dose error reduction systems ([DERS], ie, smart pumps) with current and relevant drug libraries, as these are associated with reduced risk for infusion-related medication errors, including error interceptions (eg, wrong rate) and reduced adverse drug events.^{12,17,24-30,33} (II)
 - a. Provide regular education and training, including usability issues and avoidance of work-arounds, and assessment of use for both routine users and new staff members; failure to comply with appropriate use, overriding of alerts, and use of the wrong drug library contribute to the risks associated with smart pumps and high-risk medications.^{12,17,24-30,33} (II)
- I. Assess vascular access device (VAD) function and patency prior to administration of parenteral solutions and medications and during continuous infusions, as clinically indicated.
 1. Assess patency during a continuous infusion when the following are present: sluggish infusion (eg, gravity infusion), frequent infusion pump alarms, leakage of fluid from the insertion site, pain during infusion, and/or signs/symptoms of infiltration/extravasation (see Standard 38, *Flushing and Locking*).¹⁰ (V)
 2. Assess patency during a continuous infusion by attaching a syringe to the lowest injection port on the administration set; do not disconnect administration set from the VAD hub. (Committee Consensus)
 - a. When blood return is sluggish/absent or assessment of blood return is contraindicated due to the patient's condition (eg, hemodynamic instability dependent on vasopressor delivery), VAD patency should be evaluated through alternative signs, including ongoing clinical response to an infusing medication, lack of resistance to flushing, site evaluation, and patient symptom report. This assessment can assist in determining patency.
 - b. For a peripheral VAD (eg, short/long peripheral intravenous catheter [PIVC], midline) that no longer has a positive blood return, increase the frequency of assessment of the insertion site and the venous pathway of the VAD to minimize the risk and severity of complications, such as infiltration, extravasation, and occlusion. If using the PIVC for vesicant administration, plan to transition the infusion to a new VAD when clinically possible. Peripheral administration of certain antineoplastic vesicants is contraindicated in the absence of blood return (refer to Standard 58, *Antineoplastic Therapy*).
 - c. In situations with increased line/luminal volume and high-risk medications (eg, vasopressors, inotropics), aspirating for blood return might be contraindicated in patients where interruptions of the infusion or inadvertent bolus could cause a clinically relevant decline in the patient's

TABLE 1

Medication/Infusion Delivery: Dose Accuracy and Error Prevention

Clinical situation	Factors to consider	Practice recommendations
Intermittent secondary medication administration small-volume medications (50—100 mL)	• Potential for incompatibility of primary solution to subsequent intermittent medications. • Increased risk of contamination if intermittent set is disconnected from primary set, then reconnected later. • Risk of secondary medication infused at incorrect rate that primary solution is set for. • Incomplete delivery of dose if administered on a primary line. It is estimated that up to 33% dosage loss occurred when intermittent medications were delivered (via gravity and flow-controlled devices) without adequate flush after delivery, reducing therapeutic effect of medication, increasing time to minimum inhibitory concentration for antibiotics.³⁹	• Ensure a consistent process is used for delivery of all intermittent medications to promote accurate dose delivery and reduce infection risk.^{40,41} (IV) • Use a primary continuous administration set with a back-check valve to prevent retrograde flow of the medication into the primary solution container, and connect to a port above the electronic infusion pump.^{14,42} (V) • Consider the compatibilities of all infusions, volume of each intermittent medication, any overfill, the priming volume of the administration set, any shared volume, and the infusion pump function/variability.^{40,41,43,44} (IV) • Deliver small-volume intermittent medications on secondary tubing with a carrier fluid on the primary administration set; follow administration with a flush of adequate volume to ensure full dose delivery and prevent incompatibilities. Monitor fluid intake.^{39,40,45-49} (IV) • Consider adopting a uniform administration process, where all intermittent medications are given via secondary tubing, with primary fluid as carrier, and administration is followed with flush to assure full dose delivery to standardize the process. (Committee Consensus) • Manage the height of each infusate per flow-control device and administration set manufacturer indications to ensure accurate dose delivery. Recent studies have found head height differential to be a persistent knowledge gap for clinicians, challenging to adhere to in many clinical settings, and a significant source of medication errors. Further education and technological advancement are needed to promote patient safety.^{41,50-52} (IV) • Ensure that antimicrobial medications are infused with minimal loss of drug as a component of antimicrobial stewardship.⁵³ (IV) • Avoid disconnecting intermittent sets from primary administration set, when possible, by establishing compatibility of medications. • If the intermittent medications that are to be connected to a primary set are compatible, use 1 secondary administration set and back prime from the primary infusion container. • If intermittent medications given as secondary infusions are incompatible with each other, use a different secondary set with each medication and ensure an adequate flush of the primary set between medication administrations (see Standard 40, <i>Administration Set Management</i>). (Committee Consensus) • Avoid administration of continuous infusions (eg, rate-sensitive, narrow therapeutic window) as a secondary medication to avoid delay in delivery or inadvertent bolus.⁴¹ (V) • Administer IV push medications through an injection port closest to the patient, at the rate recommended by the drug manufacturer and/or per organizational policy/practice guidelines. Complete the administration by flushing the line at the same rate to ensure that the entire dose has reached the bloodstream (see Standard 38, <i>Flushing and Locking</i>).⁵⁴ (V)
IV push medications	• Risk of inadvertent bolus or delayed delivery of IV push medications.	

(continues)

TABLE 1

Medication/Infusion Delivery: Dose Accuracy and Error Prevention (continued)

Clinical situation	Factors to consider	Practice recommendations
More than 1 infusion required for a patient and/or multiple routes in use (eg, peripheral, central, epidural, hemodynamic monitoring)	• Risk of dose error if pump is programmed for the wrong medication or concentration. • Risk of incompatibility, dose error if a medication is connected to a medication that is incompatible or should not be delivered at a faster than intended rate. • Risk of tension on lines, VAD malposition during repositioning/mobility. • Risk of misconnection/disconnection. • Risk of dose error if discontinued medication is left connected to a chain of administration sets.	• Limit use of add-on devices to only those clinically indicated to reduce risk for contamination and dosing errors (refer to Standard 35, <i>Other Add-On Devices</i>). • Trace all catheters/administration sets/add-on devices between the patient's VAD and the solution container before connecting or reconnecting an infusion/device and with transitions in caregivers. Label each tubing with the route and medication/solution near the connection to the solution container and near the patient's access site.^{4,14,16,41,47,55} (V) • Align the solution container/bag with the corresponding infusion device(s)/channels.^{41,47,55} (V) • Do not force connections; validate that the administration set is configured to be connected to a device/VAD prior to connection.⁵⁵ (V) • When preparing multiple infusions for administration, set up each infusion as completely as possible before beginning preparation of the next infusion (ie, label set and pump, spike and hang container, connect and program pump).⁵ (V) • Promptly disconnect the administration set when discontinuing a medication. Patient harm has resulted from incorrectly infusing a discontinued medication when left connected to the patient.^{56,57} (V)
Patient movement or mobility with 1 or more attachments (eg, ECG cable, administration sets)	• Risk of disconnection, misconnection to administration sets. • Risk of tension on administration sets and VAD insertion site. • Risk of patient injury/dose error if tubing is not connected properly.	• Train unlicensed staff not to disconnect or reconnect IV administration sets. In some instances (ie, home care), caregivers may be trained to aseptically disconnect and connect administration sets.^{55,58} (V) • Use a process and/or device (ie, secondary securement) to stabilize administration sets and other lines during patient repositioning and mobilization (see Standard 37, <i>Site Protection and Joint Stabilization</i>).^{59,60} (IV) • High-risk medications should be administered on a primary administration set, not as a secondary, to prevent inaccurate dose delivery.⁴¹ (V)
High-risk medication administration using large volume flow infusion pump (eg, medications that have a high risk of causing significant patient harm when the infusion is not delivered as indicated, such as vasopressors, anti-arrhythmic)	• Delays/inadvertent bolus if given as secondary.	• Consider changing tubing with a change in concentration of a solution or medication.⁴¹ (V)
Change in concentration of an infusion	• Potential of dosing error (ie, reduction or escalation) with change in rate if primary administration set retains previous concentration.	
Antineoplastic medication that requires rate changes during administration	• Potential for dosing error if primary administration set is not properly primed.	• For medications that require rate increases, prime the tubing with the antineoplastic medication. Utilize engineering controls (priming the line under a biosafety cabinet with a CSTD on the end of the tubing) to prevent HD exposure (see Standard 58, <i>Antineoplastic Therapy</i>).
Hemodynamic readings performed with continuous and/or intermittent medications given in same lumen	• Risk of interruption and/or bolus of medication.	• Avoid connection of a continuous IV medication to a lumen where central venous pressure monitoring and/or cardiac output measurements will be obtained.⁴¹ (V)

(continues)

TABLE 1 Medication/Infusion Delivery: Dose Accuracy and Error Prevention (continued)			
Clinical situation	Factors to consider	Practice recommendations	
Multiple medications infused in a single VAD or single lumen of a multi-lumen VAD “shared volume”	• Risk of bolus or delay in delivery due to increased dead or shared volume. • Risk of incompatibility.	• Limit “shared infusion volume/space” by administering primary continuous infusions as close to the patient VAD site as possible to reduce dose variability.^{41,47,61} (V) • Use parallel extension set (multiple lumen extension set with minimal inner luminal volume) rather than multiple stopcocks or manifold. • Connect IV infusions as close as possible to the hub of the VAD. Do not sequentially connect more than 1 primary continuous administration set to the Y-sites of other sets connected to the same lumen (ie, daisy chain), to prevent dose inaccuracy.^{62,63} (V) • Consider tubing compliance, presence of filters, compatibility, and variability of flowrates when multiple medications are delivered in the same VAD/lumen and adjust delivery as indicated.^{41,63} (V) • Avoid sudden rate change to 1 medication where other infusates are being concurrently administered, as this may cause an inadvertent bolus of medication(s).^{41,61,63} (V)	
Syringe pump exchange of high-risk medications (eg, medications that have a high risk of causing significant patient harm when the infusion is not delivered as indicated, such as vasopressors, anti-arrhythmics)	• Risk of inadvertent bolus or delay in dose during syringe initiation, administration set, or syringe exchange when administering medications with narrow therapeutic window (ie, vasopressors), with elevated risk of error in infusions delivered at low rates (eg, 5 mL/hour or less)	• Optimize syringe delivery of high-risk medications through standardized concentrations and flow rates of high-risk medications, identification of optimal syringe sizes for required flow rates, and length and type of administration set size. Follow manufacturers’ instructions. • Establish a protocol for syringe and administration set exchange of high-risk medications that accounts for patient variations and eliminates interruption or inadvertent bolus delivery. • Ensure proper height of syringe pump during delivery of high-risk medications to avoid delivery errors; follow manufacturers’ recommendations based on pump function.⁶⁴⁻⁶⁸ (IV)	
Pumps outside of room during critical shortage of supplies (eg, COVID-19 pandemic)	• Increased infection risk with potential for tubing misconnections. • Increased risk of inaccurate dose delivery with increased length of tubing/varying tubing compliance. • Potential for decreased surveillance of patient. • Potential for decreased attention to pump alarms.	• Carefully consider the risks and benefits of adding extension tubing to enable moving pumps outside of the patient room. • Monitor the processes to ensure that pump alarms are being addressed. • Monitor therapeutic effect of medications being administered to ensure that the clinical outcomes are being achieved. • Assess VAD sites as indicated by patient risk. • Respond to pump alarms promptly with assessment of full system to determine source.^{56,69,70} (V)	
Increased risk of patient harm from strangulation or entanglement with administration set	• Patient risk factors (ie, extremes of age, risk of self-harm, fall risk) that may contribute to injury from presence of tubing.	• Consider risks/benefits of continuous versus intermittent medication delivery. • Provide increased supervision or video surveillance as indicated. • Avoid use of additional extension sets. • Consider use of a device (eg, medical tubing stabilizer, administration set safety release connector) to reduce risk. • Evaluate impact of nearby structures (eg, side rails) and reposition device/tubing as indicated. • Use accessories (eg, sleeve) over insertion site/tubing to provide secondary securement, central line vest (see Standard 37, <i>Site Protection and Joint Stabilization</i>).^{71,72} (V)	
Abbreviations: CSTD, closed system transfer device; ECG, electrocardiogram; HD, hazardous drug; IV, intravenous; VAD, vascular access device.			

condition. In these patients, blood return could be evaluated when the infusion is paused for other reasons (eg, bag change, blood draw, tubing change). Increase the frequency of assessment of the insertion site and clinical response to the medications (refer to Standard 65, *Vasopressor Administration*). (Committee Consensus)

- J. Administer the first dose of medications with an appreciable risk of a severe allergic/anaphylactic reaction or other unknown response (eg, antimicrobials, immunoglobulins [Igs]) in nonacute care settings (eg, home, skilled nursing facility) only if conditions for safe administration are evaluated and verified^{10,14,22,37}: (V)
 1. Patient has no history of allergy to medications in the same class.
 2. Patient is alert, cooperative, and able to respond appropriately.
 3. There is reasonable geographic access to emergency services, should a severe reaction occur.
 4. The first dose is administered under clinician supervision with ability to respond to a life-threatening immediate hypersensitivity or anaphylactic reaction. The patient is observed for at least 30 minutes after infusion of the first dose is completed.
 - a. Recognize that the first exposure may not result in or cause a reaction and that the risk exists with subsequent exposures. Educate the patient/caregiver in signs and symptoms of reactions and actions to take.
 5. Medications are available in the home and there are orders for their use (eg, epinephrine) and clinicians have completed a basic life-support provider course and are competent in managing an anaphylactic reaction (see Standard 59, *Biologic Therapy*; Standard 66, *Home Infusion Therapy*).^{10,14} (V)
- K. Administer solutions and medications prepared and dispensed from the pharmacy or as commercially prepared solutions and medications whenever possible; do not add medications to infusing solution containers (refer to Standard 56, *Compounding and Preparation of Parenteral Solutions and Medications*).
- L. Prepare solutions and medications for administration as close as possible to the time of administration (eg, spiking infusion container, priming administration set).⁵ (V)
- M. Replace IV solution containers in accordance with organizational policy, procedures, and/or practice guidelines.
 1. There is insufficient evidence to recommend the frequency of routine replacement of IV solution containers, with the exceptions of parenteral nutrition (PN) solutions, which are replaced every 24 hours. One study found no relationship between length of time used and likelihood of colonization and suggests that routine replacement at regular

time intervals may not be necessary. Further research is needed (see Standard 61, *Parenteral Nutrition*).³⁸ (IV)

- N. Provide patient/caregiver education, including, but not limited to, infusion administration method and signs and symptoms to report, including those that may occur after the patient leaves the health care setting (refer to Standard 8, *Patient Education*).
- O. Evaluate and monitor response to and effectiveness of prescribed therapy, documenting patient response, adverse events, and interventions; communicating the results of laboratory tests; and achieving effective delivery of the prescribed therapy.¹⁴ (V)
- P. Report adverse events/medication discrepancies associated with medications and biologic agents to the appropriate department within the organization and authoritative reporting organizations. Medication errors should be regularly monitored and results communicated to staff as a means of prevention (refer to Standard 11, *Adverse and Serious Adverse Events*).
- Q. Discontinue infusion medications/solutions as follows:
 1. Upon provider order.
 2. In the event of a severe reaction (eg, anaphylactic reaction, speed shock, circulatory overload); notify code or rapid response team, as available, and provider immediately.¹⁴ (V)

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Note: All electronic references in this section were accessed between March 21, 2023, and August 18, 2023.

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58. ANTINEOPLASTIC THERAPY

Standard

58.1 Antineoplastic medications are administered only upon orders written or directly entered via computerized prescriber order entry (CPOE) by a physician or other

provider in accordance with laws, rules, and regulations established by regulatory and accrediting bodies in each jurisdiction (eg, countries, states, provinces). Verbal orders are acceptable only if antineoplastic medications are to be placed on hold or discontinued.

58.2 Antineoplastic medications are prepared and administered with attention to ensuring the safety of patients and health care workers and providing environmental protection.

58.3 Clinicians who prepare and administer antineoplastic medications are educated about potential hazards and special handling to reduce the risk of occupational exposure and risk for significant adverse health effects.

Practice Recommendations

- A. Use personal protective equipment (PPE) and engineering controls when working with hazardous antineoplastic medications in all health care settings, including the home setting, as there is no known level of exposure that is considered to be safe.¹⁻³ (III)
 1. Provide access to PPE, safety data sheets, spill kits, containment bags, and designated waste disposal containers in all areas where hazardous drugs are prepared and administered. Provide PPE at the point of use to promote compliance.^{1,4} (V)
 2. Use PPE that has been tested for use with hazardous drugs.^{1-3,5} (IV)
 - a. Wear gloves that meet American Society for Testing and Materials Standard D6978 (ASTM) (in the United States).
 - b. Wear double gloving for all hazardous drug (HD) handling.
 - c. Use single-use gowns meant for single use; must be disposable (nonsterile settings) and shown to resist permeability to hazardous drugs, with long sleeves, elastic or knit cuffs, closed in the back, and without seams or closures that could allow HDs to pass through.
 - d. Use respirators (National Institute for Occupational Safety and Health [NIOSH]-approved filtering facepiece or powered air-purifying respirator) when inhalation exposure is possible.
 - e. Apply eye and face protection when HD splashing is possible (refer to Standard 15, *Hazardous Drugs and Waste*).
 3. Use closed-system drug transfer devices for antineoplastic hazardous drugs when the dosage form allows.^{1,5} (IV)
 4. For antineoplastic medications that require rate increases, prime the tubing with the antineoplastic medication. Utilize engineering controls (priming the line under a biosafety cabinet with a closed system transfer device [CSTD] on the end of the tubing) to prevent HD exposure.² (V)
5. Employ safe precautions during transportation of hazardous drugs (refer to Standard 15, *Hazardous Drugs and Waste*).
6. Discard hazardous drugs and contaminated disposable equipment in approved containers.⁵ (V)
7. Employ safety precautions when handling patient body fluids and during patient care activities where contact with body fluids (eg, sweat, saliva, emesis, urine, feces, blood) is anticipated or likely for at least 48 hours after receipt of an HD and until the known excretion time is exceeded, as some HDs may be present in body fluids for longer than 48 hours. Consult with pharmacy for questions regarding metabolism and excretion time for the drug in question (refer to Standard 15, *Hazardous Drugs and Waste*).
- B. Ensure that only qualified clinicians administer antineoplastic therapy based on completion of a specialized education and competency program (see Standard 5, *Competency and Competency Assessment*).^{2,6} (V)
- C. Ensure that informed consent was obtained prior to initiation of antineoplastic therapy, which should include a description of risks, benefits, and treatment alternatives; an opportunity to ask questions; and the right to accept or refuse treatment. A variety of approaches may be used to obtain informed consent (see Standard 9, *Informed Consent*).^{2,6,7} (V)
- D. Assess patient's level of understanding of treatment and provide patient/caregiver education related to antineoplastic therapy, including mechanism of action, potential side effects, signs and symptoms to report/whom to call, physical and psychological effects, and schedule of administration/treatment plan.^{2,6,8} (IV)
 1. Educate the patient/caregivers in the home about safe disposal of all items in contact with antineoplastic medications, management of body waste and laundry, and skin and eye care if exposed (see Standard 8, *Patient Education*).^{2,3} (V)
- E. Assess patient prior to each treatment cycle, including the following^{2,6,9}: (V)
 1. Accurately measured weight and height (at least weekly when present in health care setting)
 2. A review of current laboratory data, diagnostic tests pertinent to the specific agent, and current medications (including over-the-counter, supplements, complementary and alternative therapies)
 3. The patient's medical history, comorbidities, substance use, immunizations, pretreatment vital signs
 4. Risk factors for acute infusion-related reactions, expected side effects of therapy, presence of new signs or symptoms of toxicity, and allergies (medication, food, environmental)
 5. Psychosocial assessment, including patient and caregiver comprehension of the disease and planned cancer treatment, therapy goals, and planned frequency of future visits.

- F. Implement safeguards to reduce the risk of medication errors with antineoplastic medications. Antineoplastics are high-alert medications.
 1. Review laboratory values prior to each treatment, which will be specific to the individual patient and treatment plan. Laboratory tests may be ordered to calculate doses, assess for toxicity from prior treatments, and ensure that the agent will be adequately metabolized and excreted. Examples of laboratory tests include complete blood count (CBC), serum creatinine and creatinine clearance, total bilirubin and liver function tests, electrolytes, hepatitis B antibodies, thyroid function tests, and serum cortisol tests.^{2,9} (V)
 2. Use independent dual verification, standardized orders, standardized dosage calculation, established dosage limits, CPOE, barcode technology, and electronic infusion pumps with dose-error reduction systems ([DERS]; ie, smart pumps) (see Standard 23, *Flow-Control Devices*; Standard 57, *Infusion Medication and Solution Administration*).^{10,11} (IV)
 3. Consult with the pharmacist to review drug interactions with any changes in the patient's medication list.⁶ (V)
 4. Obtain orders for emergency treatment before drug administration.⁹ (V)
 5. Verify accuracy of the treatment plan against published standards before administration (dose, route, schedule, rate).¹⁰ (IV)
 6. Compare the medication and label with the treatment plan.
 7. Verify the patient (2 identifiers minimum), medication, and pump programming (as applicable). Involve the patient and family members in medication identification; patients often observe and report errors and adverse events. Strategies to involve patients in the process of medication verification should be considered a risk-reduction strategy.^{2,9,10} (IV)
 8. Monitor cumulative chemotherapy dose, as appropriate, to ensure that the medication is discontinued if the maximum lifetime dose is reached.^{6,10} (V)
 9. Administer vinca alkaloids only by infusion (eg, prepared in bags and not dispensed in a syringe, to avoid inadvertent intrathecal administration) (see Standard 53, *Epidural and Intrathecal Access Devices*).⁶ (V)
 10. Assess appearance and physical integrity of drug prior to administration.⁷ (V)
- G. Administer antineoplastic vesicant medications safely via a short peripheral intravenous catheter (PIVC).^{2,10,12-14} (IV)
 1. Limit to intravenous (IV) push or infusions lasting less than or equal to 30 minutes and remain with the patient during the entire infusion.
 2. Do not use an infusion pump for peripheral vesicant administration.
 3. Do not use scalp veins in the neonate and pediatric patient.
4. Assess patient-related risk factors for extravasation: small/fragile veins, lymphedema, obesity, impaired level of consciousness, previous multiple venipunctures (see Standard 44, *Infiltration and Extravasation*).
5. Choose a vein that is large, smooth, and palpable, or if vascular visualization technology is necessary, choose a vein with a straight venous pathway (refer to Standard 25, *Vascular Access Device Planning and Site Selection*). Use the smallest size of adequate cannula in the largest vein available.
6. Avoid the following sites: dorsal surface of the hand, wrist; antecubital fossa; near a joint; lower extremities; areas distal to a recent venipuncture, including laboratory draws; and in the limb where there is impaired sensation, circulation, or lymphatic drainage, and/or history of lymph node dissection.
7. Do not use an established IV site that is greater than 24 hours old. If a new IV site is initiated, use the smallest-gauge catheter possible. If the insertion attempt is unsuccessful, additional attempts should be proximal to the previous attempt or on the opposite arm.
8. Verify the functional integrity of the vascular access device prior to administration.
9. Inform patients of the risks of and signs/symptoms of extravasation. Instruct patient in the importance of immediately reporting any pain, burning, sensation changes, or feeling of fluid on skin during the infusion.
10. Confirm and document a blood return prior to vesicant administration. Do not administer antineoplastic vesicants in the absence of a blood return or if other signs and symptoms of infiltration are present (see Standard 44, *Infiltration and Extravasation*).
11. Provide dilution by administering through a free-flowing infusion of a compatible solution.
12. Assess and verify blood return every 2 to 5 mL for IV push, every 5 minutes during an infusion, and upon completion. Remain with the patient during the entire short-term infusion.
13. Discontinue infusion at first sign of extravasation (refer to Standard 44, *Infiltration and Extravasation*).
- H. Do not use long peripheral IVs or midline catheters for continuous infusions of antineoplastic vesicants.² (V)
- I. Do not aspirate air with a syringe from intravenous tubing with a solution containing hazardous drugs (see Standard 15, *Hazardous Drugs and Waste*).¹⁵ (V)
- J. Administer vesicant medications safely via a central vascular access device (CVAD).² (V)
 1. Confirm tip placement for newly placed central catheters and with suspicion for catheter malposition (refer to Standard 51, *Central Venous Access Device Malposition*).
 2. Confirm and document a blood return prior to vesicant administration. Do not administer in the absence of a blood return (see Standard 44, *Infiltration and Extravasation*).

3. Do not administer if signs of inflammation, swelling, or venous thrombosis are present (refer to Standard 50, *Catheter-Associated Thrombosis*).
4. Ensure proper placement and adequately secure and stabilize the noncoring needle within implanted vascular access ports.
5. Provide dilution by administering through a free-flowing infusion of a compatible solution.
6. Assess and verify blood return every 2 to 5 mL for IV push; for infusions, assess and verify blood return before infusion, during the infusion in accordance with organizational policy, and after the infusion.
7. Discontinue infusion at first sign of extravasation (refer to Standard 44, *Infiltration and Extravasation*).
- K. Safely dispose of hazardous waste and materials contaminated with hazardous drugs (refer to Standard 15, *Hazardous Drugs and Waste*).
- L. Contain, manage, and treat hazardous drug spills as soon as possible to reduce the risk of environmental contamination and exposure to health care workers (see Standard 15, *Hazardous Drugs and Waste*).² (V)
- M. Monitor for and educate patients about adverse reactions, which can include hypersensitivity, anaphylaxis, and cytokine release syndrome (CRS).² (V)
 1. Distinguishing between the types of reactions is challenging, as symptoms from each may overlap.
 2. Common signs and symptoms of acute infusion reactions include fever, shaking, chills, flushing, itching, dyspnea, back or abdominal pain, nausea, vomiting, diarrhea, skin reactions, and fluctuations in heart rate and blood pressure.
 3. Common signs and symptoms of hypersensitivity and/or anaphylaxis include flushing, pruritus, hives, angioedema, shortness of breath, wheezing, nausea, vomiting, diarrhea, hypotension, oxygen desaturation, and cardiovascular collapse.
 4. Common signs and symptoms of cytokine release syndrome include fever, oxygen desaturation, hypotension, tachycardia, chills, nausea, anorexia, myalgia, headache, and rigors.
 5. Instruct patient to report signs and symptoms immediately.

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59. BIOLOGIC THERAPY

Standard

59.1 Biologic therapies, such as colony-stimulating factors, gene therapy, monoclonal antibodies, fusion proteins, interleukin inhibitors, and immunoglobulins (Igs), are administered in a setting in which the clinician monitors the patient closely and is prepared to recognize and manage severe adverse reactions.

59.2 Patients are assessed for contraindications and risk factors before initiation of a biologic therapy and for adverse reactions prior to each subsequent administration.

Practice Recommendations

- A. Implement safeguards to reduce the risk of adverse reactions and errors with biologic therapies.¹ (V)

1. Standardize prescribing, storage, dispensing, and medication administration (refer to Standard 57, *Infusion Medication and Solution Administration*).
2. Determine the most appropriate care setting for biologic therapy administration.^{2,3} (V)
 - a. Care settings include hospital inpatient, hospital outpatient, provider office, free-standing infusion suite, long-term care, and the patient's home (refer to Standard 66, *Home Infusion Therapy*).
 - b. Administer biologic therapy in the setting that best ensures safety and the ability to respond to adverse reactions.
 - i. The risk for potential adverse reactions and the ability to manage/reduce risk are identified before administering biologic therapy in a home setting. First doses administered in the home are provided by educated clinicians and when there is availability of medications to treat an adverse reaction and rapid access to emergency medical services (refer to Standard 57, *Infusion Medication and Solution Administration*; Standard 66, *Home Infusion Therapy*).
3. Ensure clinician access to drug information.^{1,3} (V)
4. Confirm indication for use when administering biosimilars.⁴ (V)
 - a. Recognize that biosimilars are biologic products that are highly similar to, with no clinically meaningful differences in, safety, purity, or an existing US Food and Drug Administration (FDA)-approved reference product. Biosimilars are not exact duplicates but must be chemically, functionally, and clinically similar to the reference product. Biosimilars are not the same as generic medications.
5. Collaborate with the health care team regarding serious risks associated with some biologic therapy; risk evaluation and mitigation strategies (REMS) may be required.⁵ (V)
6. Identify agents at high risk for hypersensitivity reactions. Anticipate potential orders for premedications, such as acetaminophen, diphenhydramine, and corticosteroids. Ensure availability of medications for treatment of adverse reactions and anaphylaxis; consider patient safety as a primary factor when selecting the treatment setting.^{3,6-8} (II)
- B. Store, prepare, and administer biologic therapy according to the manufacturers' directions for use and dispose of biologic waste in accordance with regulations established by regulatory bodies in each jurisdiction (refer to Standard 16, *Medical Waste and Sharps Safety*).
 1. Adhere to Aseptic Non Touch Technique (ANTT®) during reconstitution/preparation of biologic therapy in a clean environment (refer to Standard 19, *Aseptic Non Touch Technique [ANTT®]*; Standard 56, *Compounding and Preparation of Parenteral Solutions and Medications*).
2. Utilize personal protective equipment if biologic therapy is considered hazardous (refer to Standard 15, *Hazardous Drugs and Waste*).⁹
3. Select the most appropriate flow-control device for the biologic infusion therapy, including the following: need for rate control, dosing considerations, volume, duration; age, acuity, and mobility of the patient; health care setting; and the potential for side effects or adverse effects of the therapy (refer to Standard 23, *Flow-Control Devices*).
4. Filter infusion, if required, in accordance with manufacturer's instructions (refer to Standard 33, *Filtration*).
5. Avoid switching Ig brands, as this puts the patient at greater risk for adverse reactions.² (V)
- C. Assess patients before initiation of therapy and with subsequent administrations.^{2,3,8,10-12} (V)
 1. Identify risk factors, including, but not limited to, the following: comorbidities; infections; allergy profile (food, medications, environment); history of any previous treatment with a reaction to biologic therapy; tuberculosis testing; history of malignancies; weight changes; and hepatitis B and C screenings.¹³ (V)
 2. Evaluate vaccination status and requirements relative to the biologic agent in accordance with the manufacturer's directions for use; follow recommended intervals for vaccination administration.
 3. Identify any significant changes in health status prior to each administration, such as disease progression, changes in weight, presence of any acute illness, infection, or presence of diarrhea.
 4. Check vital signs prior to administration and as indicated during and after the dose.
 5. Review laboratory data specific to the biologic therapy prior to initiation and during subsequent administrations, as indicated.
 6. Monitor for adverse reactions, including hypersensitivity and anaphylaxis (refer to Standard 58, *Antineoplastic Therapy*).
- D. Consider the option for self-administered subcutaneous immunoglobulin (SCIg) infused at various intervals, usually weekly or biweekly, using a subcutaneous pump and needle set, or daily as a subcutaneous push infusion; self-administered hyaluronidase-facilitated SCIg is infused at 3- or 4-week intervals using a subcutaneous infusion pump.^{11,12,14-16} (II)
 1. Ensure that the first SCIg dose is administered in a setting where there is availability of medications to treat an adverse reaction and rapid access to emergency medical services.
 2. Limit infusion volume of standard SCIg to no more than a 30-mL volume per site.
 - a. For hyaluronidase-facilitated SCIg, follow manufacturers' recommendations for site

volume limits (see Standard 55, *Subcutaneous Infusion and Access Devices*).

3. Keep needle insertion sites at least 2 inches (5 cm) apart if using multiple sites simultaneously.
4. Identify the best method for flow control. This is generally via a syringe pump; however, a manual push can be utilized for some patients. Consider product, patient preference, and interprofessional team recommendation.
5. Educate the patient/caregiver about infection prevention, drug preparation, equipment needed, common side effects, subcutaneous administration, the importance of site rotation, adherence to therapy, local site reactions, and what to monitor or report during and after the injection. Educate specifically on preparation, pump setup, administration, infusion techniques, and supply disposal (see Standard 66, *Home Infusion Therapy*).
6. Minimize risk for local site reactions: utilize a dry insertion technique to minimize dermatitis; start with a low volume and gradual escalation; use appropriate size needle based on patient's subcutaneous tissue and mobility; apply ice packs after administration to relieve symptoms.
- E. Administer subcutaneous biologics in accordance with manufacturers' directions for use (refer to Standard 55, *Subcutaneous Infusion and Access Devices*).
- F. Consider the option for nurse-administered home administration of intravenous immunoglobulin (IVIg) in long-term, stable patients who require extended therapy for primary immune deficiency diseases.¹⁷ (IV)
 1. Data suggest that treatment outcomes were enhanced by home administration, as reflected by improved adherence to therapy, decreased rates of infection, and decreased cost per infusion (see Standard 66, *Home Infusion Therapy*).^{14,18} (II)
- G. Teach the patient and caregiver about all aspects of the biologic agent, including physical and psychological effects, adverse effects, timing of vaccines, potential toxicities, and delayed reactions. Address how to manage adverse effects and when to escalate concerns or notify the health care team for further assessment (see Standard 8, *Patient Education*).^{2,3,8,12,15} (V)

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60. PATIENT-CONTROLLED ANALGESIA

Standard

60.1 The clinician is knowledgeable of the appropriate drugs used with patient-controlled analgesia (PCA), including pharmacokinetics and equianalgesic dosing, contraindications, side effects and their management, appropriate administration modalities, and anticipated outcomes.

60.2 The decision to initiate PCA occurs in collaboration with the patient and the health care team based on assessment of PCA risk factors and the patient's level of understanding and ability to use PCA.

60.3 Pain management is comprehensive and individualized and involves the patient and caregiver in developing a treatment plan and setting realistic and measurable goals.

Practice Recommendations

A. Assess the patient for the appropriateness of PCA therapy and the patient's comprehension of and ability to participate in the intended therapy.¹⁻⁴ (II)

1. The goal of PCA utilization is adequate pain management, while minimizing analgesia-related side effects. Opioids are most commonly used for PCA delivery, but various medications and combinations are reported. Medications used include morphine, fentanyl, hydromorphone, oxycodone, sufentanil, remifentanil, dexmedetomidine, dezocine, ketamine, and tramadol/lornoxicam.⁵⁻¹² (I)

a. Drug stability should be established for PCA delivery.¹³⁻¹⁵ (IV)

b. Based on a systematic review of meperidine use in postoperative and labor patients, meperidine is not recommended for use due to higher risk of side effects and lower analgesic efficacy.¹⁶ (I)

2. Reported benefits of PCA therapy include increased patient and caregiver/parent satisfaction and autonomy, reduced delay to pain treatment, reduction in breakthrough pain, increased mobility, improved quality of life, better utilization of nursing resources, and improved outcomes when compared to intravenous (IV) push narcotics in adults with pain related to cancer and surgical procedures and in pediatric patients.^{8,17-20} (II)

a. Intravenous and subcutaneous PCA has been found to be safe and effective when used for pain management outside of the acute care setting in children and adults (eg, palliative care, cancer-related pain, vaso-occlusive episodes), and when patient safety measures are appropriately addressed.^{4,13,17,21} (IV)

i. Further study is needed to optimize the pharmacokinetics and pharmacodynamics of PCA therapy for infants and pediatric patients.^{17,21,22} (III)

b. Epidural pain management remains the gold standard in the postoperative period for many abdominal, thoracic, and orthopedic surgical procedures due to reported lower pain scores, increased mobility, and improved long-term outcomes. However, epidural catheter placement may be contraindicated (eg, anticoagulation, infection, patient refusal, patient anatomic

variants) and carries risks (eg, hypotension, neurovascular trauma, infection).

i. Multiple research studies have investigated the efficacy of epidural versus IV PCA routes in various clinical settings. The IV PCA route has been found to be effective as an alternative to the epidural route when required by patient characteristics.^{7,11,23-29} (III)

ii. In the labor and delivery setting, the epidural route is associated with successful pain management during active labor and post-delivery, using combinations of continuous, intermittent bolus, and patient-controlled epidural analgesia (PCEA). Alternatives to epidural use have been studied due to epidural-related complications, such as maternal hypotension and fever.^{5,30-32} (I)

a) Remifentanil PCA has been successfully used in the labor and delivery setting as an alternative to the epidural route. It is a potent, short-acting opioid with increased risk of hypoxemia, bradycardia, and hypotension, requiring close monitoring of patient tolerance to ensure optimal maternal and neonatal outcomes.^{5,32,33} (I)

3. Risks associated with opioid pain management include hyperalgesia (hypersensitivity to pain), hypotension, bradycardia, respiratory depression, nausea and vomiting, pruritis, potentiation of cancer growth, pressure ulcer development, urinary retention, tolerance to opioids, addiction, constipation, ileus, and iatrogenic withdrawal syndrome (IWS) in infants and children (syndrome of tolerance and dependence). The extensive risks and related complications have the potential to increase length of stay, morbidity, and mortality.^{9,17,22,25,28,34-44} (I)

a. Because of the risks and complexity involved in PCA analgesia, multiple studies have investigated alternative pain management regimens to either reduce PCA-related opioid consumption or eliminate PCA use. This research has investigated several avenues to optimize pain management, minimize side effects, and improve functional capacity.

i. Alternative modes of PCA delivery: oral-administered patient-controlled analgesia, time-scheduled decremental continuous infusion, variable-rate feedback infusion plus demand dosing, and dosing that adjusts to increasing or decreasing patient demand and vital signs.^{20,33,44,45} (III)

ii. Multimodal pain management strategies for high-risk patients (eg, total joint replacement, lumbar fusion, open and laparoscopic abdominal and thoracic surgical procedures):

- enhanced recovery after surgery (ERAS) strategies, wound or intra-articular infiltration of local anesthetic, concomitant epidural or intrathecal dosing, intercostal block, and nonopioid analgesics.^{10,24,35,36,39,46-48} (III)
- iii. PCA medication combinations that have synergistic effect with opioids and/or reduce opioid-related side effects: dexmedetomidine, ropivacaine, ketamine, and low or ultra-low dose naloxone (may enhance antinociceptive effect of opioids and may reduce postoperative nausea and vomiting).^{6,10,12,23,34,38,49} (III)
- B. Assess the patient and caregiver for appropriateness of using authorized agent-controlled analgesia (AACA) if the patient is unable to actively participate in PCA or patient/nurse-controlled analgesia (PNCA) for infants, children, and critically ill adults. Further research is needed to determine the optimal use of AACA for specific populations.^{1,6-8} (IV)
 1. Develop predefined protocols or algorithms for AACA or PCA by proxy with clear assessment parameters for dose delivery and adjustment. In the absence of a defined structure, PCA by proxy has been associated with negative patient outcomes.
 2. Provide caregiver education and evaluate competency prior to AACA, including patient assessment, what to report to the provider, operating instructions for electronic infusion pump, appropriate actions to take if therapy is not meeting patient needs, and contact information for support services.
 3. Provide oversight of outpatient-based AACA through a health care entity (eg, community-based nurses) to assure compliance, availability of supplies, and expertise to manage complications and device concerns.^{2-4,17,21,22} (III)
- C. Use standardized medication concentrations and standardized or preprinted provider order sets for PCA and AACA that allow for individualization of dose.^{1,22,42,50-54} (III)
 1. Use dosing that is based on comprehensive patient assessment and not based solely on pain assessment score (numeric or behavioral).^{6,17,18,22,36,39,41,51,55} (III)
- D. Identify patient risk factors for opioid-induced respiratory depression (OIRD) that include, but are not limited to, prematurity, older age, male gender, morbid obesity, known/suspected sleep disorder breathing problems, pre-existing pulmonary and/or cardiac disease, renal insufficiency, impaired liver function, and continuous basal infusions.^{1,42,51,53,56,57} (I)
 1. A combination of factors precipitates OIRD in all ages: decreased respiratory drive, decreased level of consciousness, and upper airway obstruction. OIRD has been associated with increased length of stay, increased readmissions, and increased mortality.^{42,53} (IV)
 2. In the presence of risk factors, use continuous monitoring of capnography, pulse oximetry, and/or other clinically effective methods.^{5,32,51,53,55,58} (I)
 - a. Continuous capnography monitoring provides an earlier warning of respiratory depression as compared to continuous oximetry and is associated with significant reduction in the incidence of OIRD, duration in opioid treatment, and opioid-related serious adverse events.^{1,42,57} (IV)
 - b. Assess the efficacy of the chosen capnography device (ie, oral, nasal) and adjust, if needed, to improve accuracy.⁵⁹ (IV)
 - c. Carefully evaluate patient safety in the setting of concomitant use of sedating medications with opioid delivery.^{38,56,57} (IV)
- E. Perform an independent double-check by 2 clinicians prior to initiation of the PCA and when the syringe, solution container, drug, or rate is changed. Provision of PCA therapy is a complex process, vulnerable to many points of error. The administration phase has the highest reported error rates. Globally, these errors have been associated with negative outcomes, such as increased pain through delays or interrupted treatment, cardiopulmonary compromise, and mortality.
 1. Give special attention to drug, concentration, dose, and rate of infusion according to the provider order and as programmed into the electronic infusion pump in order to reduce the risk of adverse outcomes and medication errors.
 2. Validate that the administration set is correctly connected for immediate delivery of analgesic and is configured to prevent retrograde flow of medication (see Standard 23, *Flow-Control Devices*; Standard 57, *Infusion Medication and Solution Administration*).^{8,18,54,60} (IV)
- F. Provide patient and caregiver education appropriate to duration of therapy and care setting, treatment options, the purpose of PCA therapy, frequency of monitoring, expected outcomes, precautions, potential side effects, symptoms to report, and how dose will be adjusted.^{17,31,39,50-52,54} (III)
- G. Evaluate the effectiveness of PCA/AACA/PNCA and potential adverse events, using valid and reliable monitoring and assessment methods and documentation tools.
 1. Monitor parameters, including pain score, breakthrough pain, ability to perform functional milestones, respiratory depression, nausea and vomiting, urinary retention, and parental and patient satisfaction with analgesia.^{6-9,18,20,23,30,36,39,41,44,48} (I)
 2. Conduct regular assessment and reassessment of patient self-report of pain or objective measure of pain using a valid, reliable, developmentally appropriate pain assessment tool individualized to the patient. Assess and reassess pain at rest and with movement.^{1-4,6,9,11,17,20,22-24,36,40,44,48,51,52} (I)

- a. An area in need of further research is the development of pain assessment tools validated for palliative care and end-of-life. Pain scales in use are generally designed for acute pain and not reflective of quality of life/end-of-life patient needs.⁴ (IV)
 3. Use a validated sedation scale and direct assessment of quality and adequacy of cardiopulmonary status.^{6,17,20,22,44} (I)
 4. Individualize alarm settings for each patient to assure alarms are valid and to reduce alarm fatigue.^{1,57} (IV)
 5. Recognize the risk of supplementary oxygen delivery in masking-reduced respiratory drive.^{42,53,57} (IV)
 6. Assess for risk factors and treat opioid-related nausea and vomiting.⁴³ (IV)
 7. Regularly evaluate PCA device function, number of injections and attempts, and the potential for patient/caregiver manipulation.^{18,54} (IV)
 8. Regularly assess the vascular access device (VAD) site, including patency, to assure correct analgesia delivery (refer to Standard 46, *Vascular Access Device Occlusion*; Standard 57, *Infusion Medication and Solution Administration*).
 9. Evaluate the need to change treatment methods as necessary. Adjust the pain management plan based on pain relief and presence of adverse effect.^{4,33,37,50-52} (IV)
 - H. Ensure clinicians receive education that addresses pain assessment, pharmacokinetics and pharmacodynamics of opioids and adjuvant medications, risk of concomitant use of sedating medications, operation of electronic infusion pump, and the need to individualize pain management based on individual needs of the patient.^{1,15,18,38,50-52,54,57,60} (IV)
 - I. Assure adequacy of the pain management plan and patient stability during handoffs to different clinicians and/or settings.^{1,53} (V)
 - J. Participate in selection and evaluation of PCA electronic infusion pump and monitoring equipment and in quality processes to promote patient safety, which includes review of administration of opioid reversal and opioid-related resuscitation, technology/decision support, evaluation of workflows, barcoding technology, root cause analysis, Healthcare Failure Mode and Effect Analysis (HFMEA), long-term outcomes from pain management strategies, and prescription drug monitoring programs to evaluate opioid utilization.^{10-18,22,46,50-52,54,60} (IV)
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- 61.2 PN is administered using filtration and an electronic infusion pump with anti-free-flow control and appropriate alarms.
- 61.3 Medications are not added or co-infused with the PN solution before or during infusion without consultation with a pharmacist regarding compatibility and stability.

Practice Recommendations

- A. Plan for safe and appropriate PN.
 1. Use the enteral route in preference to the parenteral route for nutrition support whenever feasible.¹⁻³ (IV)
 2. Recognize that PN is a complex and high-alert medication; reported incidents and errors that may lead to patient harm include microbial contamination, inappropriate prescriptions, and compounding and dispensing errors (see Standard 11, *Adverse and Serious Adverse Events*).⁴⁻⁹ (IV)
 3. Ensure an interdisciplinary approach to promote safe use and encourage error reporting and error analysis to improve safety; nutritional support teams are associated with a reduction in catheter-related infection, inappropriate PN use, and reduced mortality.^{5,7,10-12} (I)
 4. Use standardized order forms or templates and computerized order entry (COE) throughout the continuum of care whenever feasible, as they have been found to prevent errors related to PN prescriptions.^{1,7,11,12} (V)
 5. Develop written protocols for PN component substitution or conservation methods in the event of drug/component shortage.^{1,11,12} (V)
 6. Coordinate care using a patient-centered, interprofessional team approach for patients who will transition between health care settings (eg, acute care, skilled nursing facility, home, long-term acute care hospital).
 - a. Address the following factors in the transition process: PN orders/formula, clinical status, appropriateness for patient setting, patient/caregiver education, available patient support, insurance coverage, appropriate vascular access device (VAD), and monitoring plan (eg, laboratory studies) (see Standard 66, *Home Infusion Therapy*).^{1,12-14} (IV)
- B. Administer PN safely.
 1. Plan for an appropriate VAD based upon expected duration of therapy, nutritional requirements, and the patient's vascular condition and preferences (see Standard 25, *Vascular Access Device Planning and Site Selection*).
 - a. Consider a VAD with a minimal number of lumens.^{3,11,15,16} (V)
 - b. Consider peripherally inserted central catheters (PICCs) and tunneled, cuffed central vascular access devices (CVADs) for infants and

61. PARENTERAL NUTRITION

Standard

61.1 The decision to implement parenteral nutrition (PN) occurs in collaboration with the patient/caregiver and the health care team based on the projected treatment plan.

- children who require prolonged PN during hospitalization.^{15,17} (IV)
- c. Consider tunneled, cuffed CVADs or PICCs for home parenteral nutrition (HPN) in both adults and children; implanted vascular access ports with the noncoring needle changed at least every 7 days may also be an option.^{14-16,18-22} (V)
2. Administer peripheral PN (PPN) solutions/emulsions with a final concentration of 10% dextrose or lower through a PIVC as a bridge to central PN, when oral intake or enteral nutrition is suboptimal, or when the patient's clinical condition does not justify CVAD placement. Consider dextrose and other additives that affect osmolality. The American Society for Enteral and Parenteral Nutrition (ASPEN) recommends not exceeding an osmolality of 900 mOsm/L; studies show endothelial damage begins to occur at 600 mOsm/L. The osmolality limit for PPN is an area of needed research.^{1,3,11,23} (IV)
 - a. Recognize the increased risk for phlebitis with PPN; weigh the risks vs benefits for PPN administration and limit duration of therapy to no more than 14 days. ASPEN recommendations do not address PPN administration via midline catheters.^{1,3} (IV)
 - b. Do not use midline catheters for continuous vesicant therapy, PN, or solutions with extremes of pH or osmolality; the use of midline catheters for PPN is not established; the location of midline catheters in a deeper vein may mask early signs of phlebitis, extravasation, and thrombosis (refer to Standard 25, *Vascular Access Device Planning and Site Selection*).
 3. Filter PN solutions and place the filter on the administration set as close to the patient as possible. Prime the filter in accordance with manufacturer's directions.^{24,25} (IV)
 - a. Use a 1.2-micron filter for all PN solutions, including dextrose-amino acid admixtures, lipid injectable emulsions (ILE), and PN solutions containing ILEs (also known as total nutrient admixture [TNA]).
 4. Replace solution containers and administration sets used for PN (TNA and amino acid/dextrose formulations) and lipids every 24 hours; replace administration sets used for ILE with each new infusion. Hang time for PN should not exceed 24 hours.^{1,11,14} (IV)
 - a. In a laboratory study, TNA and ILE support *Candida albicans* growth after minimal initial contamination with microorganisms migrating from the fluid bag to the CVAD. Attention to Aseptic Non Touch Technique (ANTT®) during management of the administration set is imperative, and administration sets should be replaced daily (see Standard 40, *Administration Set Management*).²⁶ (IV)
 - b. Limit separate ILE infusion to a 12-hour maximum time; if volume limitations require separate ILE administration for a period longer than 12 hours, ASPEN recommends strong consideration for a new ILE container and administration set for the second 12-hour portion. The hang time of a TNA can be extended to 24 hours because bacterial growth in these solutions is inhibited due to reduced pH and to increased total osmolality compared to infusing ILE separately.^{1,9} (V)
 - c. Change the filter to coincide with initiation of a new PN mixture and administration set; change filters used for separately infused ILEs every 12 hours. Prime filters immediately before use.^{24,25} (IV)
5. Use PN containers and administration sets free of Di[2-ethylhexyl]phthalate (DEHP) to administer lipid-based solutions, such as ILE or TNA. DEHP is a lipophilic toxin that can leach from commonly used polyvinyl chloride administration sets and containers into lipid-based solutions (see Standard 40, *Administration Set Management*).^{1,8} (IV)
 6. Protect PN admixtures from light for premature infants; degradation of PN components occurs with light exposure, resulting in oxidation; preterm infants are more susceptible than children and adults and face potential complications as a result of oxidative stress (eg, bronchopulmonary dysplasia, retinopathy, necrotizing enterocolitis).^{1,27-30} (IV)
 - a. ASPEN recommends complete PN light protection for preterm infants beginning during compounding and continuing until the entire PN/ILE infusion is complete (eg, during transport/delivery and administration). ASPEN acknowledges that full implementation may not be currently feasible, given product availability, but organizations should define what steps can be achieved and implement attainable strategies.
 - b. While partial light protection does not offer clinical benefits, recommendations from ASPEN for non-preterm infants state to refrigerate and protect the PN solution from light exposure until just before infusion. There is a need for further studies about light protection for children and adults receiving long-term PN.
 7. Use electronic infusion pumps with anti-free-flow protection and alarms for occlusion; consider the use of electronic infusion pumps with dose error reduction software (DERS) (ie, smart pumps), as they are associated with reduced risk for infusion-related medication errors, including error interceptions (eg, wrong rate), and reduced adverse drug events (refer to Standard 23, *Flow-Control Devices*).
 8. Reduce the risk of catheter-associated bloodstream infection (CABSI) when administering PN.

- a. Consider peripheral venipuncture for blood sampling instead of via the CVAD used for PN (see Standard 41, *Blood Sampling*).¹ (V)
 - i. Adhere to ANTT if blood sampling via the CVAD is necessary; blood sampling via the CVAD is a quality-of-life issue for patients receiving long-term PN.¹⁵ (IV)
 - b. Consider dedicating a single lumen to PN administration when a multilumen CVAD is in place.^{3,14,15} (IV)
 - i. Based upon a systematic review, data are insufficient to ascertain whether dedicating a lumen to PN results in a lower risk of infection; this remains an area of needed research.³¹ (I)
 - c. Avoid attaching administration sets before the time of infusion; the risks of spiking containers and priming administration sets in advance has not been studied.^{1,11} (V)
 - d. Consider antimicrobial lock therapy for patients receiving cyclic HPN as an infection-prevention strategy (see Standard 38, *Flushing and Locking*).
 - i. Taurolidine was effective in prevention of catheter-related bloodstream infections (CR-BSIs) for patients on HPN and, while considered generally safe, rare allergic reactions and VAD-related problems, including pain, have been reported.^{14,32-38} (I)
 - ii. Other antimicrobials, including 4% tetrasodium, ethylenediaminetetraacetic acid (EDTA) and 70% ethanol (limited to patients with silicone CVADs) are also associated with reduced incidence of CR-BSI.³⁷⁻⁴² (I)
 - e. Consider CVAD repair for damaged subcutaneously tunneled, cuffed CVADs to extend CVAD survival and to reduce risk for future compromised vascular access. Retrospective studies have reported extension of CVAD survival without increased risk for central line-associated bloodstream infection (CLABSI) (see Standard 48, *Catheter Damage [Embolism, Repair, Exchange]*).^{35,43-45} (IV)
- C. Monitor the patient and provide patient education.
1. Monitor patient receiving PN for the following: body weight; fluid and electrolyte balance; metabolic tolerance, especially glucose control; VAD-related complications, including CABSIs; organ function; nutrition therapy-related complications; functional performance; and psychological responses.^{11,14,16,46-48} (IV)
 2. Monitor blood glucose; when changing to a cyclic infusion, monitor on and off PN during initial cycling in the acute care or home setting; once stable, less frequent monitoring may be acceptable. Insulin may be used to control blood glucose levels and administered via the subcutaneous or intravenous (IV) route (may be added to PN solution).^{1,47} (V)
 3. Teach patients or family members of patients who receive home PN about importance of ANTT during all PN procedures, access device care, weight and hydration monitoring, blood/urine glucose monitoring, electronic infusion pump use and troubleshooting, and signs and symptoms to report; and assist patients on how to fit PN into their lifestyles (see Standard 8, *Patient Education*; Standard 19, *Aseptic Non Touch Technique [ANTT®]*; Standard 66, *Home Infusion Therapy*).^{1,14,16,49,50} (IV)
 4. Assess and address patient and family management and coping with HPN (refer to Standard 66, *Home Infusion Management*).

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62. BLOOD ADMINISTRATION

Standard

62.1 Administration of blood and blood components, including the use of infusion devices and ancillary equipment, and the identification, evaluation, and reporting of adverse events related to transfusion are established in organizational policies, procedures, and/or practice guidelines.

62.2 Verification of the correct patient and blood product is performed in the presence of the patient prior to transfusion.

62.3 Blood and blood components are transfused through a transfusion administration set that has a filter designed to retain potentially harmful particles.

Practice Recommendations

A. Recognize the risks versus the benefits of transfusion prior to administering human blood and blood components (whole blood, red blood cells [RBCs], plasma and plasma components, platelets, granulocytes, cryoprecipitate).

1. Patient blood management (PBM) is an evidence-based, multidisciplinary approach aimed at optimizing the care of patients who might require a blood transfusion. PBM programs provide guidance and decision-making for the appropriate use of transfusions, eliminate unnecessary transfusions, and increase patient safety. Strategies include evidence-based indications for transfusion, maintaining hemoglobin (Hgb) concentration, optimizing coagulation/hemostasis, close post-operative monitoring to minimize oxygen consumption, and management/prevention of anemia (eg, reducing blood loss associated with blood sampling) (see Standard 41, *Blood Sampling*).¹⁻⁹ (II)
 - a. Transfusion of red blood cells at a lower Hgb level (eg, 7.0-8.0 g/dL) compared to higher Hgb

level is considered safe in both adults and stable, nonbleeding, critically ill children.^{6,10} (I)

- b. Key elements for PBM specific to the neonatal population include management of anemia, blood conservation strategies, optimization of coagulation and hemostasis, as well as surgical and anesthetic techniques and patient and family-centered decision-making.^{4,11} (IV)

B. Provide patient/caregiver education and ensure that informed consent is obtained.^{2,12-17} (IV)

1. Include a description of risks, benefits, and treatment alternatives, while providing the opportunity to ask questions and ensuring understanding of the right to accept or refuse the transfusion.
2. Allow the opportunity for patients to discuss their religious/cultural beliefs regarding blood transfusion.
3. Include the following in the educational process:
 - a. Elements of the transfusion procedure (eg, compatibility testing, vascular access)
 - b. Signs/symptoms associated with complications of transfusion therapy (eg, vague uneasy feeling, pain, breathing difficulties, hypotension, chills/flushing/fever, nausea, dizziness, rash/urticaria, hives, pruritus, localized angioedema, dark/red urine).

C. Perform a baseline physical assessment prior to obtaining blood for transfusion, including vital signs, respiratory assessment, skin (eg, evidence of rash), identification of conditions that may increase the risk of transfusion-related adverse reactions (eg, current fever, heart failure, renal disease, and risk of fluid volume excess), the presence of an appropriate and patent vascular access device (VAD), and current laboratory values.^{8,12,14,17} (V)

1. Identify and report any symptoms to the health care team that may later be mistaken for a transfusion reaction; recognize that fever may be a cause for delay in transfusion, as it could mask a symptom of an acute transfusion reaction.
 - a. Based upon a multicenter retrospective review, transfusions associated with febrile reactions had higher pretransfusion temperatures and pulse rates; transfusions associated with transfusion-associated circulatory overload (TACO) had higher pretransfusion respiratory rates.¹⁸ (V)
2. Administer premedications, if ordered. Oral medications should be administered 30 minutes before start of transfusion; intravenous (IV) medications can be given immediately before starting the transfusion.
 - a. Routine premedication with acetaminophen and antihistamines did not prevent nonhemolytic transfusion reactions. The impact of premedication for patients with a history of transfusion reactions is unknown; further research is needed.¹⁹ (I)

- D. Choose an appropriate VAD based on patient condition and transfusion needs.
 1. Peripheral intravenous catheters (PIVCs):
 - a. Adults: A 20- to 22-gauge is acceptable for routine transfusions; a 16- to 18-gauge may be used for rapid transfusions; red blood cells can be safely administered via smaller-gauge catheters/needles (eg, 24/25); however, the flow rate should be slower, as the pressure with rapid transfusion through a small catheter may cause hemolysis.^{8,12,15,17,20} (V)
 - b. Infants/children: Options include the umbilical vein (neonates) or a vein large enough to accommodate a 23- to 25-gauge needle or a 22- to 24-gauge catheter (see Standard 28, *Umbilical Catheters*).^{12,17} (V)
 2. Central vascular access devices (CVADs) are acceptable for blood administration.^{12,14,15,17,20} (V)
 3. Blood components may be administered by the intraosseous route (refer to Standard 54, *Intraosseous Access Devices*).
- E. Perform patient and blood product identification and inspect blood component for abnormalities at the time the blood component is released from the transfusion service and in the presence of the patient before preparing the transfusion.^{4,11-14,17,21} (IV)
 1. Verify the following: provider order for transfusion; patient's core independent identifiers, ABO group and Rh type, donation identification number, cross-match test interpretation, if performed, expiration date/time, and date/time of issue, special transfusion requirements (eg, irradiated, cytomegalovirus [CMV]-negative, leukocyte reduced, hepatitis E negative, washed cells, platelet in additive solutions, hemoglobin S negative).
 2. Verify volume requirements for certain populations (eg, neonatal, pediatric, older adult).
 3. Use an independent double-check by 2 adults in the presence of the patient (eg, hospital/outpatient setting: 2 persons trained in the identification of the recipient and blood components; in home setting: nurse and responsible adult).
 - a. Use of electronic patient identification technologies for blood draw and sample labeling, blood collection procedures, and blood administration were associated with a lower incidence of wrong component transfusions and near misses compared to a manual system.²² (V)
 4. Inspect each blood component prior to transfusion and do not use if container is not intact or if the appearance is not normal (eg, abnormal color, presence of clots, leakage, excessive air/bubbles, unusual odor), and return it to the transfusion service.
- F. Administer blood or blood components.^{8,12,14,15,17} (IV)
 1. Never add or infuse any other solutions or medications through the same administration set with blood or blood components (do not piggyback blood administration sets into other infusion administration sets).
 2. The administration set used to administer the blood or blood component is primed only with 0.9% sodium chloride or the blood component itself.
- G. Filter all blood components and follow the manufacturers' directions for filter use.^{8,12,14,15,17} (IV)
 1. Use a filter designed to remove blood clots and harmful particles; standard blood administration sets include a 170- to 260-micron filter.
 2. Do not use microaggregate filters routinely; these may be used for reinfusion of blood shed during high-blood-loss surgical procedures.
 3. Leukocyte reduction filtration is preferred "prestorage" or shortly after blood collection. Bedside leukocyte reduction is a less efficient method and has been associated with dramatic hypotension in some patients. Use of leukocyte-reduced blood products (RBCs and platelets) decreases the risk of febrile transfusion reactions, risk of human leukocyte antigen (HLA) alloimmunization, allergic reactions, and transmission of CMV.
 4. Never use leukocyte filtration when transfusing granulocyte or hematopoietic progenitor cells.
- H. Change the transfusion administration set in conjunction with manufacturers' directions for use.^{8,12,17} (IV)
 1. Clinical studies establishing the maximum time for set use are lacking. In accordance with the Association for the Advancement of Blood & Biotherapies (AABB), if the first unit requires 4 hours for transfusion, the administration set and filter are not reused. National guidelines from some countries recommend changing the administration set every 12 hours.
 2. Note that most standard filters have a 4-unit maximum capacity; follow manufacturers' directions for use.
- I. Administer and complete each unit of blood or blood component within 4 hours.^{8,12,14,15,17} (IV)
 1. Ask the transfusion service to divide a unit of RBCs or whole blood into smaller aliquots when it is anticipated that the unit cannot be transfused within 4 hours (eg, pediatric patients or adult patients at risk for fluid overload).
 2. Usual duration of transfusion: red blood cells over 1-2 hours based upon hemodynamic stability; platelets over 1 to 2 hours; granulocytes over 2 hours; plasma as quickly as tolerated by the patient or over 15 to 60 minutes; cryoprecipitate as rapidly as tolerated.
 3. Only electronic infusion pumps that have a labeled indication for blood transfusion should be used. Electronic infusion pumps can be used to deliver blood or blood components without significant risk of hemolysis of RBCs or platelet damage. Syringe

infusion pumps can be used for small-volume transfusions in neonatal and pediatric patients. Follow the manufacturers' directions for use (see Standard 23, *Flow-Control Devices*).

4. Manual pressure cuffs can be used to increase RBC flow rate when rapid transfusion is required. Externally applied compression devices should be equipped with a pressure gauge, totally encase the blood bag, and apply uniform pressure against all parts of the blood container. Pressure should not exceed 300 mm Hg. A standard sphygmomanometer is never used for this purpose. For rapid infusion, a large-gauge catheter may be more effective than a pressure device.
- J. Use blood and fluid warmers when warranted by patient history, clinical condition, and prescribed therapy, including, but not limited to, preventing or treating intraoperative hypothermia, during plasma exchange for therapeutic apheresis, for patients known to have clinically significant cold agglutinins, for neonate exchange transfusions, during replacement of large blood volumes, vaso-occlusive episodes, or when treating trauma, hypothermia, or cold exposure (refer to Standard 24, *Blood and Fluid Warming*).
- K. Initiate transfusion and monitor for immediate adverse transfusion reactions.^{8,12,14,17,23,24} (IV)
 1. Check the patient's vital signs within 30 minutes prior to transfusion, 15 minutes after the blood enters the vein upon transfusion initiation, upon completion of the transfusion, and 1 hour post-transfusion. Visually check the patient for any adverse reactions at least every 30 minutes throughout the transfusion; check vital signs immediately upon identification of any change in the patient's condition.
 2. Initiate nonemergent transfusions slowly and remain near the patient; major reactions usually appear before the first 50 mL have been transfused. Increase the transfusion rate after 15 minutes when there are no signs of a reaction and to ensure the completion of the unit within 4 hours.
 - a. Recognize that the first 10-15 minutes of any transfusion are the most critical.
 3. Stop the transfusion immediately if signs and symptoms of an acute transfusion reaction are present (eg, fever, chills, tachycardia, chest/flank/back pain, hypotension, bronchospasm, dyspnea); perform a clerical check of the blood component (ABO confirmation), notify the provider and transfusion service, and administer emergency medications as prescribed.
 - a. Do not administer emergency medications through the blood administration set; prime a new administration set with 0.9% sodium chloride for infusion through the VAD.
- L. Monitor patients for signs/symptoms of other acute transfusion reactions^{12,15,17,23,25-27}: (IV)
 1. Pruritis, urticaria, flushing, or wheezing associated with mild allergic reactions
 2. Respiratory failure, hypoxemia, hypotension, and/or pulmonary edema associated with transfusion-related acute lung injury (TRALI)
 3. Dyspnea, jugular venous distention, cough, increased blood pressure, cough associated with TACO. TACO is the leading cause of transfusion-related morbidity and mortality; patient risk factors include older adults and history of cardiac disease, acute/chronic renal failure. Signs/symptoms of circulatory overload (eg, respiratory distress, tachycardia, increased blood pressure) occur 6-12 hours after the transfusion.
- M. Recognize age-related complications.
 1. Adverse events of red blood cell transfusions are more frequent in older patients, and TACO is the most frequent complication in transfused older adults.²⁸ (IV)
 2. Immature organ function in neonates is associated with increased risk for metabolic complications and for infectious and immunologic complications (see Standard 2, *Special Patient Populations*).^{11,21} (IV)
- N. Ensure safe transfusion practice if transfusing in an out-of-hospital setting (eg, dialysis, skilled nursing facilities, home, outpatient surgery).^{12,17,29} (IV)
 1. Develop well-planned programs that incorporate all relevant aspects for hospital transfusion, including educated clinicians trained in the management of transfusion, transfusion reaction, anaphylaxis, and emergency support.
 - a. The most common adverse reactions occurring in out-of-hospital settings were febrile non-hemolytic reactions (28.6%), allergy (26.9%), and TACO (6.3%). The researchers emphasize the need for patient/caregiver education and the importance of having plans of action in place for adverse reactions.²⁹ (V)
 - b. Provision of written instructions regarding signs/symptoms of transfusion reactions and contact information is essential due to lack of prolonged assessment by a clinician postinfusion.^{12,13} (V)
 2. Employ the following when transfusing in a home setting: documentation showing no identified adverse events during previous transfusions; immediate access to the provider by phone during the transfusion; presence of another competent adult in the home who is available to assist with patient identification and summon for medical assistance if needed; a telephone to contact emergency personnel; ability to transport blood product in appropriate containers; and the ability to appropriately dispose of medical waste.¹⁷ (V)

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63. MODERATE SEDATION/ANALGESIA USING INTRAVENOUS INFUSION

Standard

63.1 Intravenous infusion of moderate sedation/analgesia is provided in accordance with laws, rules, and regulations established by regulatory and accrediting bodies in each jurisdiction and in accordance with organizational policy.

63.2 Target sedation level and optimal sedation and/or analgesic agents are selected based on a thorough assessment of the specific characteristics of the patient (eg, age, pain, anxiety, sedation history, medical condition) and the procedure (eg, potential for pain, positioning, duration).

63.3 An emergency cart and reversal agents are immediately accessible, and clinicians with expertise in patient age and size-appropriate airway management, emergency intubation, advanced cardiopulmonary life support, and management of potential complications are immediately available.

Practice Recommendations

- A. Implement a comprehensive educational and competency program for clinicians providing moderate sedation, including age-specific interventions, levels of sedation, medications (onset, peak, duration, synergistic action), effective use of monitoring equipment, airway management, positioning requirements, and postrecovery care.¹⁻⁵ (IV)
- B. Identify a list of medications that may be administered in specific clinical settings based on patient needs and existing clinician competencies and monitoring capabilities.
 1. Select sedation/analgesic medications with the lowest effective dose and widest therapeutic index for patient and procedural characteristics, using a multimodal approach as indicated.

- a. Medications that may be administered for moderate sedation include sedative/hypnotics (eg, midazolam, diazepam, dexmedetomidine), narcotics (eg, fentanyl), anesthetic agents (eg, propofol, ketamine), neuroleptic tranquilizers (droperidol), and combination agents (eg, ketamine/fentanyl, ketamine/propofol).^{1,6-14} (IV)
 - i. In a prospective, observational evaluation of a pediatric population receiving sedation for painful procedures, preprocedural opioids administered close to sedation were significantly associated with increased risk of oxygen desaturation and vomiting.¹⁵ (IV)
 - b. Slower titration and use of target-controlled infusions are recommended in elderly and obese populations due to variability in pharmacokinetics.^{8,16} (IV)
 - c. Select initial dosing as fixed dosing or dosing based on actual, adjusted, or ideal body weight depending on the medication and the patient's weight, body mass index (BMI), and sedation goals. Then titrate dose to achieve sedation goal.^{11,16} (V)
2. Ensure that the administration of moderate sedation medications (eg, anesthetic agents) is within the scope of practice for the clinician performing this role.
 - a. Registered nurse-administered moderate sedation is appropriate when performed under the supervision of a physician.^{1,8,11} (IV)
 - i. In a retrospective study, patients diagnosed with obstructive sleep apnea (OSA) received nurse-administered moderate sedation under the guidance of an algorithm and use of continuous positive airway pressure (CPAP) during the procedure with no adverse events noted.¹⁷ (IV)
 - b. Propofol may safely be administered for moderate sedation by nonanesthesia clinicians with proper training, competency, and when propofol in the moderate sedation setting falls within the jurisdiction of their governing body, generally in patients with American Society of Anesthesiology (ASA) Physical Status Classification System scoring of I to III.^{6,8,18-20} (III)
 - C. Ensure that informed consent was obtained according to organizational policy and procedure (see Standard 9, *Informed Consent*).^{6,7,9,11} (IV)
 - D. Establish the discharge plan prior to the procedure, including the need to have a family member/caregiver/friend drive the patient home and observe the patient after the procedure.^{1,7,11} (IV)
 - E. Perform a comprehensive preprocedural assessment to include medical history/current condition, airway assessment, body mass index (BMI), current prescribed and over-the-counter medications that may impact tolerance of moderate sedation medications (such as sedatives, long-acting opioids, cannabis), allergies, previous sedation experience, opioid history, current pain assessment, risk of respiratory depression, drug/alcohol/tobacco use, and fasting status/risk of vomiting and aspiration.^{1,6-8,11-13,21-26} (IV)
 1. Consider preprocedural assessment of sleep apnea risk with a validated tool, such as the STOP BANG tool.^{1,7,16,27,28} (IV)
 - F. Consult with an anesthesia provider for issues identified during the assessment that may increase risk of adverse events, such as complex procedure (eg, duration, positioning, painful), anatomic airway abnormalities, ASA score greater than III/IV, infants, children with special needs, significant opioid use, history of intolerance to moderate sedation, airway issues, allergies, sleep apnea, morbid obesity, gastric outlet obstruction, and gastroparesis.^{7,8,11,21,29,30} (IV)
 - G. Establish a process for the procedural timeout to assess and address potential patient and procedure-related risks. Moderate sedation may convert to deep sedation and loss of consciousness due to multiple factors, such as the types of agents used, the patient's physical status, and drug sensitivities.
 1. Ensure that all required equipment is appropriate for the procedure/environment (eg, magnetic resonance imaging [MRI] suite, operating room) and the patient age and body habitus (eg, size of blood pressure cuff, monitoring devices).
 2. Initiate and maintain vascular access throughout the procedure and recovery for administration of medications and for potential need for emergency resuscitative medications and/or reversal agents.^{1,7-9,11,13,16,19,21} (III)
 - H. Monitor the patient continuously throughout the procedure, including blood pressure, respiratory rate, ventilatory status, oxygen saturation, cardiac rate and rhythm, and level of consciousness.^{1,7,8,11,13,21} (IV)
 1. Assign a dedicated, trained assistant for sedation monitoring during procedure.^{1,6-8,11,13,21} (IV)
 2. Supplementary oxygen is often utilized in procedural sedation but may result in a delay in recognition of respiratory depression.^{7,25,31,32} (IV)
 - a. In a prospective, observation evaluation of the effects of sedation on arterial blood gas results during cardiac catheterization, significant hypercarbia and respiratory acidosis was noted in patients receiving supplemental oxygen, indicating that oximetry alone may lead to delay in recognition of respiratory acidosis.³³ (IV)
 3. Select a validated method to monitor the patient's level of sedation periodically through the procedure (eg, Richmond Agitation and Sedation Scale, American Society of Anesthesia Society Depth of Sedation Levels).
 - a. No single scale has been shown to be superior due to diversity of settings/sedation used.^{7,9,13,19} (III)

- b. Document assessment parameters at regular intervals (eg, every 5 minutes) throughout the procedure, as indicated by type of medication, patient status, and type of procedure.^{7,21,23,24} (IV)
- c. Use of advanced monitoring techniques such as acoustic respiratory monitoring, transtracheal auscultation, respiratory volume monitoring, and processed electroencephalography (eg, bispectral indexing [BIS]) may be useful in early detection of level of sedation, hypoxia, and respiratory depression.^{9,21,25,34-37} (IV)
 - i. Further evaluation is needed to establish the role of BIS monitoring in moderate sedation. This monitoring tool is frequently used in general anesthesia to assess depth of sedation; however, use of BIS is challenging in moderate sedation due to more frequent artifact, lack of consistent signal with some medications, other factors influencing the signal (eg, critically ill patient), and lack of evidence to support, especially in the pediatric population.^{8,9,11,38,39} (III)
- d. Consider the use of capnography to measure adequacy of ventilation, unless contraindicated by patient, procedure, or equipment characteristics.^{1,7,24,40-46} (II)
 - i. Use capnography in the following clinical settings: ASA score of III or greater, BMI greater than 30, elderly patients, patients with significant cardiopulmonary risk, high risk gastrointestinal procedures (eg, percutaneous endoscopic gastronomy [PEG] insertion), patient at high risk for respiratory compromise, sedation target is deep sedation.^{11,47-49} (II)
 - a) In a secondary analysis from a prospective observation study, an increased risk of apnea was associated with a change of greater than 10% from the baseline capnography reading in bolus doses of midazolam and fentanyl.⁵⁰ (IV)
 - ii. Recent research continues to indicate concerns with a mandate for universal use of capnography use in procedural sedation, indicating that further research is needed. These concerns include the following:
 - a) A lack of high-quality evidence associated with early recognition of adverse events and cost-effectiveness in healthy adults undergoing procedural sedation.^{8,9,21,31,47,49,51-55} (II)
 - b) Continued underutilization and lack of availability of capnography in rural and low-to-moderate income countries.^{52,54,56,57} (II)
- e. Provide postprocedure recovery monitoring and care appropriate to the patient and procedure characteristics.
 1. Design discharge criteria and facility guidelines for postrecovery monitoring and discharge, using a validated scoring tool (eg, Modified Aldrete, Post-Anesthesia Discharge Scoring System/PADSS).
 2. Monitor the patient until they are at or near baseline status, as assessed preprocedure, with no risk of hypoxia or cardiorespiratory compromise.^{1,6,7,9,21} (IV)
 - a. One prospective cohort study of pediatric patients undergoing sedation for fracture reduction noted a greater than 50% higher frequency of hypoxia during the recovery period than during the procedure.⁵⁸ (IV)
- f. Address the following patient/caregiver education topics prior to, and reinforce teaching after, the procedure.^{6,11,59} (III)
 1. Sedation/analgesia infusion and procedure and what to expect during the procedure
 2. Postprocedural restrictions
 3. Signs and symptoms to report that may indicate an adverse reaction to medications, the vascular access device, or procedure
 - a. A prospective cohort study of children who had received ketamine procedural sedation in the emergency department for fracture reduction noted that high presedation anxiety and ethnicity were associated with significant negative behaviors within 1 to 2 weeks after discharge.⁶⁰ (IV)
 4. Emergency instructions and 24-hour contact phone number.
- g. Monitor moderate sedation patient outcomes (eg, reversal requirement, transfer to higher level of care, airway intervention) and implement process improvement and improve standardization of moderate sedation care as indicated by quality data.^{1,7,9-11,23,29,54,61,62} (IV)

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64. THERAPEUTIC PHLEBOTOMY

Standard

- 64.1 Selection of the most appropriate type of vascular access device (VAD) for therapeutic phlebotomy occurs in collaboration with the patient/caregiver and the health care team based on the projected treatment plan.
- 64.2 Interventions to reduce the risk for side effects and/or adverse reactions associated with therapeutic phlebotomy are implemented.
- 64.3 All medical waste, including the blood from the therapeutic phlebotomy, is disposed of in accordance with organizational policies, procedures, and/or practice guidelines.

Practice Recommendations

- A. Establish parameters for therapeutic phlebotomy: laboratory values to be assessed specific to the patient's diagnosis, including, but not limited to, hemoglobin, hematocrit and/or ferritin levels; parameters for laboratory values guiding the indication and continuation of phlebotomy, frequency of phlebotomy, type of VAD, and volume of blood to be withdrawn.¹⁻¹⁵ (V)
 1. Erythrocytapheresis (an apheresis procedure where red cells are extracted, with the remaining blood returned to the patient) may be an alternative to therapeutic phlebotomy when rapid attainment of treatment goals becomes necessary to reduce blood viscosity and risk of thrombosis or when therapeutic phlebotomy fails to accomplish treatment goals. However, apheresis has higher rates of adverse reactions and is more costly.¹⁶ (V)

- B. Prevent, manage, and recognize common side effects (eg, hypovolemia, nausea/vomiting) by using a reclining chair or exam table/bed for the procedure; monitor vital signs before and after the procedure; encourage oral hydration before and after the procedure; ask about fear of needles or blood; and administer parenteral solution replacement if prescribed, indicating the type of solution, amount, and rate of infusion. Oral hydration is preferred over parenteral.^{1,10,14,17-19} (IV)
- C. Assess for history of self-harm prior to initiating phlebotomy. Therapeutic phlebotomy can become a substitute for usual self-harm practices. Be aware that cessation of therapeutic phlebotomy in these patients may result in an increase in self-harm behaviors.²⁰ (V)
- D. Select the most appropriate VAD based on patient condition, anticipated duration of treatment, and other infusion therapies:
 1. Short peripheral intravenous catheter (PIVC) using a 16- to 18-gauge device and inserted before phlebotomy and removed upon completion.⁴ (V)
 2. Central vascular access device (CVAD) (including implanted vascular access port), if already placed and therapeutic phlebotomy will not compromise other infusion therapies.²¹ (V)
- E. Blood collection receptacles may include collection bags used for volunteer blood donation or bags specifically designed for therapeutic phlebotomy; syringes may also be used based on the VAD. Do not use vacuum bottles to facilitate blood flow due to risk of air embolism. (Committee Consensus)
- F. Instruct the patient to remain in a reclining position for several minutes after the procedure, then to rise slowly.²² (V)
- G. Address the following topics in patient education: cost; potential impacts to quality of life; potential side effects, such as a hematoma, dizziness, syncope, headache, nausea/vomiting, and fatigue; and consequences of missing treatments, as well as activity restrictions before and after the procedure.²³ (V)
- H. Therapeutic phlebotomy may be used alone or in combination with other therapies to achieve treatment goals.^{5,7,24,25} (IV)
- I. It may be safe to use blood collected from therapeutic phlebotomy for blood transfusion.^{26,27} (IV)

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65. VASOPRESSOR ADMINISTRATION

KEY DEFINITION

Vasopressor Therapy: includes medications that promote vasoconstriction with potential for positive inotropic activity. Examples include, but are not limited to, norepinephrine, epinephrine, dopamine, dobutamine, vasopressin, terlipressin, phenylephrine, angiotensin II.

Standard

65.1 The most appropriate vascular access device (VAD) is selected when initiating vasopressor administration to ensure prompt and effective medication delivery, accommodate patient-specific characteristics, minimize the potential for infusion-related complications, and support vascular health and preservation.

65.2 Patency of the selected VAD is validated prior to initiation and during the vasopressor infusion.

65.3 VAD planning and assessment occurs on a regular basis as the condition of the patient requiring vasopressor therapy evolves.

Practice Recommendations

- A. Initiate the required vasopressor infusion in a VAD that is patent (eg, positive blood return) with site assessed to be within normal limits to assure prompt, safe and effective delivery of time-sensitive treatment. This is accomplished with consideration of the risks and benefits of peripheral administration of a vesicant, patient-specific risks with central vascular access device (CVAD) insertion, trajectory of patient condition, and potential delays in medication delivery (eg, including low resource settings).¹⁻⁸ (IV)
 1. An evolving area of research is the role of supportive therapy to reduce vasopressor requirements and associated mortality; this will impact VAD selection due to potential for additional vesicant administration. Examples include early use of a second vasopressor (eg, vasopressin), methylene blue to reduce

excess nitric oxide production, and amiodarone to control shock-related tachycardia.⁹⁻¹⁴ (IV)

- B. Balance fluid resuscitation and vasopressor administration based on the individual patient clinical needs to improve tissue perfusion.^{15,16} (II)
 1. Assess the patient's responsiveness to fluid resuscitation and medication delivery using the most accurate blood pressure measurement and monitoring clinical signs, including dynamic measures to optimize/improve tissue perfusion (eg, passive leg raise test, mottling score, peripheral or central arterial monitoring) as appropriate to the patient's clinical condition.^{1,6,8,13,15,17-22} (II)
 - a. There is insufficient evidence to inform the optimal timing and titration of vasopressor administration in the hypoperfused adult or pediatric patient (eg, hypotension, mottled, increased capillary refill, elevated lactic acid) due to the wide spectrum of pathophysiology. Early vasopressor delivery has been associated with more rapid achievement of clinical targets (eg, mean arterial pressure of 65 mm Hg), reduction of fluid volume required, and reduction of end organ damage. However, vasopressor delivery may lead to tissue ischemia, increased afterload, and a reduction in needed fluid delivery. Multiple studies illustrate significant heterogeneity in management of hypotension in hypoperfused states. There is a need for high-quality, controlled trials in various clinical settings.^{5,16,17,21,23-32} (IV)
- C. Use a CVAD as the preferred route for continuous vasopressor infusions to reduce the risk of complications (eg, extravasation, phlebitis/thrombophlebitis) when CVAD insertion will not delay life-saving treatment or when a properly functioning CVAD is already present.^{6,21,33,34} (IV)
 1. Insert a CVAD to reduce the risk of VAD-related complications when rapid escalation of vasopressor infusions and/or infusion of more than 1 vasopressor is required.^{35,36} (IV)
 - a. In a retrospective, cohort study, the time to central line insertion and time to vasopressor initiation were found to be reduced in those who received a peripherally inserted central catheter (PICC) placed by a dedicated team versus non-tunneled CVAD at intensive care unit (ICU) admission.³⁷ (IV)
- D. Evaluate potential complications associated with each VAD option (eg, venous depletion, extravasation, bloodstream infection, and thrombotic risks).³⁸⁻⁴⁰ (IV)
 1. Do not insert a peripheral intravenous catheter (PIVC) or midline catheter as a central line-associated bloodstream infection (CLABSI) prevention strategy (refer to Standard 25, *Vascular Access Device Planning and Site Selection*; Standard 44, *Infiltration and Extravasation*; Standard 47, *Vascular Access*

Device-Related Infection; Standard 50, Catheter-Associated Thrombosis). (Committee Consensus)

2. Initiate vasopressor administration via a short PIVC for short-duration vasopressor infusion (24 hours or less in the adult) if CVAD insertion is not immediately available (eg, limited resources for insertion, patient characteristics) or if the vasopressor requirement is likely of short duration (eg, hypotension related to epidural anesthesia, high probability of successfully weaning off within 24 hours).^{2,4-6,8,29,36,41-53} (II)
 - a. Numerous studies have reported low prevalence of adverse events in adults and children associated with peripheral administration of vasopressors, with reduction in CVAD utilization and limited long-term sequelae.^{7,42,47-55} (II)
 - i. The risk of extravasation appears to increase with duration of the infusion.^{2,36,42,47} (IV)
 - a) In 3 systematic reviews of peripheral administration of vasopressors in adults and children, the mean duration of peripheral infusion ranged from 12 to 25 hours.⁴⁹⁻⁵¹ (II)
 - b) There is insufficient evidence to draw conclusions on the safety of peripheral vasopressor infusions longer than 24 hours.⁵⁰ (III)
 - ii. Optimal duration for peripheral vasopressor administration is unknown for the pediatric population. Research has indicated durations of 9.5 to 21 hours, with the majority progressing to a central line as soon as clinically possible.^{47,56} (IV)
 - a) In a retrospective cohort study in the pediatric population, the PIVC option was found to be an adequate option for pediatric patients with lower illness severity and older age (mean age 10.3 years). PIVC locations were listed as hand, arm, lower extremity.⁴² (IV)
 3. Consider an intraosseous VAD for vasopressor administration, placed by a trained and competent clinician, if unable to establish a short PIVC or a CVAD in all ages (see Standard 54, *Intraosseous Access Devices*).^{2,34,57-59} (IV)
 4. Do not use the midline peripheral catheter or long peripheral intravenous (IV) catheter placed in deep peripheral vessels for continuous vesicant therapy, as there is insufficient evidence to support this practice and there is an increased risk of extensive tissue damage due to the depth of the catheter (refer to Standard 25, *Vascular Access Device Planning and Site Selection*).
 - a. Further high-quality, prospective research is needed to establish the safety of the use of the midline PIVC for vasopressor administration.⁶⁰⁻⁶² (IV)
 - i. In a secondary analysis of a randomized controlled trial comparing 2 midline catheters, administration of norepinephrine was associated with an increased risk of midline catheter failure.⁶² (IV)
 - b. Initial and ongoing assessment of VAD patency is required for continuous administration of vesicants. Midline catheter failure due to thrombotic and occlusive events (eg, nonpatent, occlusion, leaking) are among the most frequently reported outcomes, with causative factors yet unclear.⁶¹⁻⁶⁵ (II)
 5. There is an urgent need for high-quality, prospective research trials due to limitations in current research regarding peripherally administered vasopressors: variation in definitions of PIVC complications, a preponderance of retrospective methodology, well-documented inconsistency in documentation of PIVC status, high heterogeneity in population base, risk of bias, and inconsistent reporting of study characteristic (eg, location of PIVC, concentration and dose of vasopressor).^{6,33,49-51,66-68} (II)
- E. Monitor the patient and VAD for expected and unexpected outcomes related to vasopressor administration, according to patient and infusate risk (refer to Standard 39, *Vascular Access Device Post-Insertion Care*).
1. Validate VAD patency regularly during the infusion of a vasopressor by obtaining positive blood return.
 - a. In situations with increased line/luminal volume and vasopressor administration, aspirating for blood return might be contraindicated in patients where interruption of the infusion or inadvertent bolus would cause a clinically relevant decline in the patient's condition. In these patients, blood return could be evaluated when the infusion is stopped or paused for other reasons (eg, bag/tubing change). Increase the frequency of assessment of the insertion site and clinical response to the medication. (Committee Consensus)
 2. Plan to transition the vasopressor to an alternate VAD when blood return is not obtainable (eg, inability to obtain blood return from a central or peripheral VAD that previously had positive blood return, PIVC site that is difficult to assess due to dressings, patient position, or generalized edema). During this transition, other methods of patency assessment may be used when blood return cannot be obtained (eg, assessment of the insertion site and surrounding area, expected clinical effect of the medication).
 - a. Further high-quality research is needed to validate a definition of PIVC occlusion and to establish effective PIVC occlusion prevention and treatment strategies as an important precursor to long-term peripheral administration of

vasopressor therapy (see Standard 46, *Vascular Access Device Occlusion*). (Committee Consensus)

- F. Consider the following criteria for initiation and assessment of peripheral vasopressor administration. There is insufficient evidence to construct a bundle of interventions regarding peripheral administration of vasopressors; however, consistent utilization of a pre-established safety protocol has been associated with improved outcomes.^{47-51,54,55,66,67} (II)
1. Restrict use of the PIVC to clinical situations in which there is an anticipated short duration of vasopressor use (eg, lower severity of illness, epidural-related hypotension).^{36,42,54,69} (III)
 2. Limit to 1 vasopressor infusion per PIVC site.⁴³ (IV)
 3. Limit concentration and/or dose of the vasopressor to the lowest possible. Severity of tissue damage from extravasation is associated with higher concentration of the medication.^{8,47,48,52,54,55,69} (IV)
 4. Place the PIVC in a vessel of sufficient diameter to promote adequate hemodilution (eg, >4 mm, at least 2/3 of catheter within the vessel); preferably placed by infusion/vascular access specialists with use of visualization technology.^{49,70} (IV)
 5. Avoid areas of flexion for PIVC insertion. In emergent treatment, the antecubital (AC) fossa is often utilized due to ease of insertion. If the AC is used for peripheral vasopressor administration emergently, it should be monitored closely and transitioned to a site with a lower risk of complication as soon as clinically possible (see Standard 25, *Vascular Access Device Planning and Site Selection*).⁶⁹ (V)
 - a. Several publications indicate that peripheral vasopressor administration should be accomplished in a site in or proximal to the AC or in the external jugular. The more proximal insertion site recommendation is based on the potential for improved hemodilution with a PIVC placement in a larger diameter vessel and the increased risk of extravasation distally in the severely hypoperfused patient.^{6,35,36,43,54,69,70} (IV)
 - i. This recommendation, however, does not address the risk of delay in the recognition of an extravasation and the potential for more extensive tissue damage in PIVCs placed in deeper vessels.⁶¹ (V)
- G. Assure staff competency in recognition and treatment of VAD-related complications, such as phlebitis and extravasation.^{47,49,66,70,71} (IV)
1. Monitor the VAD status closely (eg, every hour) for potential adverse events, with close monitoring required during transport of the patient.^{2,47,49,55,66,70,71} (IV)
 - a. In a cross-sectional observation study in adults, patients with a vasopressor or inotropic infusion had 9-times higher odds of adverse events during transport between departments within a facility.⁷² (IV)
- H. Assess the complete medication regimen to assure safe delivery of all required treatment (eg, incompatibilities, timing, shared volume in administration sets) (see Standard 57, *Infusion Medication and Solution Administration, Table 1: Medication/Infusion Delivery: Dose Accuracy and Error Prevention*).^{70,73} (IV)
1. Use electronic infusion pumps that include dose error reduction systems ([DERS], ie, smart pumps) with current and relevant drug libraries, as these are associated with reduced risk for infusion-related medication errors, including error interceptions (eg, wrong rate) and reduced adverse drug events (refer to Standard 23, *Flow-Control Devices*; Standard 57, *Infusion Medication and Solution Administration*).
 - a. In a small observational study, implementation of a protocol for a peripherally administered norepinephrine infusion for management of septic shock in a low resource setting (eg, unavailability of DERS infusion system, of CVAD placement, or of ICU placement) was associated with improved mortality rates and no localized adverse events.⁴¹ (IV)
 - I. Develop an extravasation policy and protocol that guides prompt notification of the provider and evidence-based treatment (see Standard 44, *Infiltration and Extravasation*).^{49,54,71,74} (IV)
 - J. Monitor outcomes related to vasopressor administrations to inform quality improvement (refer to Standard 6, *Quality Improvement*).
 1. A new area of research is the creation of prediction models to better inform the optimal VAD for the hypotensive patient. Further study is needed to inform device selection in a rapidly evolving patient situation.^{75,76} (IV)

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66. HOME INFUSION THERAPY

Standard

66.1 Home infusion therapy is provided with attention to appropriate patient selection and in collaboration with the patient/caregiver and the interprofessional team.

66.2 The risks of infusion-related complications, appropriateness of the infusion access device/infusion delivery method, patient and clinician safety are evaluated and considered by the home care organization and provider prior to accepting a patient for home infusion administration.

66.3 Home care organizations provide a comprehensive program that includes clinician education and competency assessment, evidence-based policies and procedures, and attention to quality improvement, including infection surveillance and reporting.

Practice Recommendations

A. Confirm that home infusion therapy is appropriate for the patient as part of a comprehensive planning/transition process and based upon multiple factors, including the following¹⁻¹³: (IV)

1. Home care organization ability to provide home infusions (eg, specialized clinician education and competency assessment, evidence-based policies/procedures, quality improvement program, infection surveillance).
2. Infusion therapy that is appropriate for home care. General categories of home infusion therapy include antimicrobials, hydration solutions, parenteral nutrition (PN), antineoplastics, analgesics, biologics, and inotropes; when considering medications/solutions outside of these categories, rationale and safety issues for home infusion should be carefully investigated by the health care team.
3. Patient stability relative to clinical condition and need for home infusion therapy (eg, no adverse reactions to prescribed infusion, metabolic stability for home parenteral nutrition [HPN], hemodynamically stable for inotropic infusions).
4. The risk for potential adverse reactions and the ability to manage/reduce risk are identified before considering home infusion therapy and when initiating

infusion therapy at home without a prior hospitalization or outpatient administration (eg, first dose) (see Standard 57, *Infusion Medication and Solution Administration*).

5. Patient/caregiver preference for home infusion; motivation, ability, and willingness to participate in care; provision of patient education about home infusion therapy and home care expectations.
 6. Availability of services in the patient's geographic area (eg, 24-hour pharmacy/nursing support, drug/supply delivery, telehealth/telemonitoring, laboratory services).
 7. Consideration for telehealth for reinforcing patient education and monitoring patients in distant/isolated areas.
 8. Reimbursement for infusion medications/solutions and services at home or for other options (eg, outpatient); the patient is informed of any financial responsibility and availability of financial assistance programs.
 9. Appropriate vascular access device (VAD) for the prescribed home infusion therapy (refer to Standard 25, *Vascular Access Device Planning and Site Selection*).
 10. Appropriate infusion administration method; factors include drug/solution stability, frequency/duration of infusions. Patient preference should be considered whenever possible to improve success and satisfaction with home infusion; methods include intravenous (IV) push, elastomeric pumps, gravity infusions, and electronic infusion pumps (see Standard 23, *Flow-Control Devices*).¹⁴ (V)
- B. Evaluate patient/caregiver and clinician home environmental safety and risk factors; develop alternative infusion plans with the patient and health care team if home care is not a safe option.
1. Identify that the home is reasonably safe and clean for medication/supply storage and infusion administration with running water, electricity, refrigeration, and telephone access.^{2,9,15} (V)
 2. Assist patients/caregivers to mitigate potential home hazards by establishing a clean, uncluttered area for supply storage/infusion administration, and educate about how to protect the VAD and manage household tasks.^{2,3,15} (V)
 3. Consider drug stability, which is a potential concern with continuous infusions, especially in very warm climates. Suggestions include discussion about home conditions before accepting patients for continuous home infusion and patient education that includes spending time in the most temperate area of home/air conditioning if possible; also ensuring that deliveries of drugs/supplies are promptly brought into the home.¹⁵⁻¹⁸ (IV)
 4. Evaluate potential/actual clinician safety issues, such as abusive patient/caregiver behaviors, illegal

- drug use, presence of weapons, or aggressive pets; mitigate any risks, if possible, or develop alternative plan of care (eg, outpatient services).^{1,15} (V)
5. Ensure presence of emergency medications and supportive care measures in the event of adverse reactions, as appropriate, based upon the type of home infusion therapy (eg, antineoplastics, biologics, inotropics) (see Standard 58, *Antineoplastic Therapy*; Standard 59, *Biologic Therapy*).¹⁹⁻²¹ (V)
 6. Ensure availability and clinician competency in use of supplies needed for safe handling when administering hazardous drugs (eg, personal protective equipment [PPE], protective devices, disposal containers, spill kits) (see Standard 15, *Hazardous Drugs and Waste*).^{21,22} (IV)
- C. Provide home-based outpatient antimicrobial therapy (OPAT) based upon above criteria; OPAT is a well-accepted and common home infusion therapy for both adults and pediatric patients.²³⁻³² (IV)
1. Favorable outcomes, including treatment success, are reported when there is attention to careful patient selection (eg, clinically stable, presence of caregiver support, no cognitive impairment).
 2. An infectious disease (ID) expert review prior to the initiation of OPAT is recommended. ID follow-up during OPAT is recommended, especially for immunosuppressed patients, as readmission for worsening or complication of infection is a common cause for hospital readmission. OPAT-related adverse drug events were highest in the first 2 weeks of home OPAT.^{33,34} (IV)
- D. Consider home-based OPAT for persons who inject drugs (PWID) on a case-by-case basis when defined patient selection criteria are in place.^{31,35-39} (IV)
1. Home-based OPAT can be safe and effective for PWID when there is care coordination between infectious disease and addiction specialists and case management; when patients are engaged in treatment and used no illicit substances during hospitalization; have a safe home and family/caregiver support; are counseled about risks with an indwelling VAD (eg, peripherally inserted central catheter [PICC]); have safe housing; agree to the plan for home care and close follow-up by home care agencies/video visits.
 2. Misuse of VADs is low, despite perceptions; however, some programs use a tamper-evident procedure/product at the catheter hub. A characteristic associated with adverse outcomes included lack of family involvement in discharge planning.
- E. Consider HPN for patients transitioning from an inpatient setting who are clinically stable, with attention to safe transition planning, patient/caregiver education, and attention to an appropriate VAD and administration schedule (refer to Standard 61 *Parenteral Nutrition*).
1. PN is initiated in the home only when benefits outweigh the risks and when there are organizational policies in place, including clear admission/eligibility criteria; a comprehensive patient assessment, including medical, clinical, and psychosocial parameters; strict protocols for initiation and monitoring PN.¹³ (V)
- F. Evaluate the safety profile and potential risks of biologic and antineoplastic infusion therapies when considering either the initiation of infusions in the home or when transitioning patients from acute care or outpatient administration (see Standard 58, *Antineoplastic Therapy*; Standard 59, *Biologic Therapy*).
1. Home-based immunoglobulin (Ig) therapy may be appropriate for carefully selected patients. Ig-naïve patients and/or those with a prior history of adverse drug reactions should receive Ig therapy in a setting that ensures safety and the ability to respond to severe, adverse reactions (eg, acute care, outpatient) to ensure their safety because adverse drug reactions (ADRs) can occur more frequently in these patients.⁴⁰ (IV)
 - a. Overall safe administration of home intravenous immunoglobulin (IVIg) infusions was reported in a large retrospective study; an increased risk for adverse events was associated with first course of treatment, younger age, female gender, and higher doses. In another report, patients were successfully transitioned from outpatient therapy during the pandemic to decrease exposure to COVID-19, with no impact on patient satisfaction, adherence, or efficacy.^{41,42} (V)
 2. Successful home administration of biologic infusions, including natalizumab, infliximab, blinatumomab, and ocrelizumab are reported. Characteristics of programs included specific infusion protocols, clinically competent clinicians, attention to patient safety, consideration of patient preferences, attention to careful evaluation of potential adverse events. Any home administration of a biologic is carefully evaluated based upon the adverse event profile.⁴³⁻⁴⁸ (IV)
 3. Home infusion for cancer treatment should be done with caution and consideration of the risk of harm for nurses, patients, and other household members. First doses should be completed without incident prior to converting to home infusion. Home care nurses should be competent in administration of chemotherapy/immune therapy. Infusion of investigational antineoplastic drugs is not recommended for home administration.²¹ (V)
 - a. In a single study, 140 children received cytosine arabinoside (ARA-C) by parents trained in administration, with no medication errors and reported benefits of reduced cost, decreased time spent in the hospital, less disruption to routines, less travel time, and less stress to the child. Another study reported home administration of a variety of

- antineoplastic agents, hydration fluids, and antimicrobials (136 pediatric patients receiving 1701 home visits) as part of a hospital-at-home program, with no reports of adverse events.^{49,50} (V)
- G. Evaluate risks versus benefits when considering home cardiac infusion therapies for patients with heart failure.
 1. Inotropic infusions (most commonly dobutamine or milrinone) include a palliative approach for patients with end-stage heart failure (HF) or a bridge to transplant in both adult and pediatric patients and may be administered as continuous or intermittent infusions.^{19,20,51,52} (I)
 2. Evidence suggests that inotropic infusions for patients with advanced HF are associated with an improvement in functional class and do not increase the risk of death.⁵² (I)
 3. Other cited benefits include improved quality of life and reduced complications, while risks include central vascular access device (CVAD)-related complications, burden of infusion-related care, and need for caregiver support. There is a need for well-designed studies to address implications relative to survival, harm, and benefits.^{19,20,51-53} (IV)
 4. Discharge planning should address the following elements relative to the plan for home care: frequency of vital signs monitoring and acceptable parameters; maximum time off in the event of a CVAD malfunction; evaluation for need of devices, including a back-up infusion pump, weight scale, and defibrillator.^{19,20} (IV)
 5. Subcutaneous or IV administration of diuretics in the management of HF was associated with symptom relief and low risk of adverse effects based upon a systematic review. Cited benefits included reduction in edema/weight and high patient satisfaction, while challenges included difficult venous access in a primarily older patient population. A new subcutaneous formulation of furosemide was made available for home treatment in 2022 (see Standard 55, *Subcutaneous Infusion and Access Devices*).⁵⁴⁻⁵⁷ (IV)
 - H. Provide effective patient/caregiver education.
 1. Identify the required level of procedural education based upon the type of infusion therapy; for example, biologic and antineoplastic drugs are more commonly administered by the home care nurse, while patients/caregivers will most often learn to self-infuse therapies, such as OPAT, PN, and cardiac infusion therapies. Safe home management of the VAD is always addressed.^{1,2} (V)
 2. Select teaching methods based upon an assessment of age, culture, developmental and cognitive level, health literacy, preferred language, and learning style. Identify factors impacting readiness to learn, such as weakness, fatigue, anxiety, functional/cognitive limitations (see Standard 8, *Patient Education*).^{1,2} (IV)
 3. Address basic infusion administration with attention to preventing complications, including all necessary tasks: flushing/locking all lumens, needleless connector disinfection, priming infusion system of air, clamping sequence, frequency of administration set change, VAD care and protection (eg, bathing, risk for inadvertent VAD dislodgement), infusion pump management, supply management, troubleshooting, and when/how to notify home care organization.^{1,2,58} (V)
 - a. Emphasize and observe adherence to basic infection prevention strategies, including hand hygiene and Aseptic Non Touch Technique (ANTT®); address self-monitoring of site; provide a list of complications, symptoms, and actions to take; use interactive/videotaped educational material.⁵⁹ (V)
 - b. Evaluate learning outcomes with methods that directly measure knowledge, such as demonstration/return demonstration for psychomotor skills, verbal feedback for cognitive knowledge (teach-back) (refer to Standard 8, *Patient Education*).
 - c. Consider telehealth visits; areas of focus during telemedicine visits may include CVAD methods materials, clinical concerns, and equipment management (see Standard 19, *Aseptic Non Touch Technique [ANTT®]*).^{6,8} (IV)
 4. Re-evaluate and periodically review infusion-related skills, including adherence to ANTT; identify need for re-education.¹ (V)
 - a. In a qualitative study involving interviews and observations of patients receiving OPAT, hazards to learning included misleading information from the hospital, rushed instructions, different instructions by different nurses, confusing/inaccurate written instructions, unfamiliar terminology. Six goals were identified: understanding and developing skills, receiving supplies, infusion medication administration and VAD maintenance, preventing VAD harm during activities of daily living, managing when hazards lead to failures, and monitoring.⁵⁸ (V)
 5. Provide easy access to technical support when medical devices are used in the home. In a retrospective study, safety risks relative to home infusion pumps were identified, resulting in device malfunction and medication underdosing; delays in recognizing and reporting problems were identified. Greater monitoring and oversight of medical devices used in the home are recommended, with easy access to technical support.⁶⁰ (V)
 - I. Evaluate and monitor response to and effectiveness of the home infusion therapy, including patient response, side effects/adverse drug events, laboratory study results as appropriate, and VAD-related complications (refer to Standard 39, *Vascular Access Device*)

Post-Insertion Care; Section Seven: Vascular Access Device Complications).

1. In a systematic review of observational studies of hospital-at-home and OPAT episodes, more than 88% of the studies reported a cure or treatment success rate of greater than 80%; adverse events with drugs ranged from 0% to 30.2%; VAD-related adverse events ranged from 0% to 29%; readmission rates varied from 1% to 26%, and mortality rates from 0% to 27.5%. Methodologies used to measure these parameters were inconsistent, and some demographic groups had only a small number of studies.²⁸ (IV)
2. In a systematic review of studies (varied designs) comparing home infusion to inpatient/outpatient settings, patients receiving home infusion were no more likely to experience ADRs or side effects.⁶¹ (IV)
3. Risk factors associated with VAD-related complications included younger patients, female gender, more than 1 CVAD lumen, and patients receiving PN. The most common CVAD-related complications were catheter occlusion and mechanical complication (accidental breakage, inadvertent outward migration). Adverse VAD-related events, including extravasation, blockage, and displacement were significantly more common with midline catheters in a retrospective study including over 500 OPAT episodes.⁶²⁻⁶⁴ (IV)
- J. Assess and address patient and family management and coping with home infusion therapy.
 1. Ensure clear delineation of roles. Role ambiguity is common (eg, which health care provider to contact if problems, different information provided by different providers); there should be clear delineation of the roles of the patient, caregiver, and health care team.⁵ (V)
 2. Consider and address patient quality-of-life (QOL) issues relative to the infusion therapy.
 - a. Factors known to negatively impact the QOL of patients receiving HPN include sleep disturbance, frequent urination, fear of therapy-related complications, inability to eat, and increased occurrence of depression. Consider supportive interventions; the Oley Foundation is a national support group that provides education, advocacy, and networking for patients requiring both enteral and HPN.⁶⁵ (V)
 - b. Reduction in frequency of HPN infusions (eg, 5-6 infusions per week versus 7) was associated with improved QOL; when clinically appropriate and without sacrificing nutritional status, reducing infusion frequency should be considered (see Standard 61, *Parenteral Nutrition*).⁶⁶ (IV)
 3. Assess for caregiver stress and need for support in providing care, and identify appropriate services or resources. Caregiver stress may be apparent,

especially with more complex therapies such as PN, antineoplastic, and inotropic infusions, as caregivers are also coping with the diagnosis, treatment, and implications of treatment (eg, side effects, inability to eat) and dealing with their own social restrictions, depression, difficulty watching a loved one suffer.^{49,50,67-71} (IV)

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Note: All electronic references in this section were accessed between September 13, 2022, and August 16, 2023.

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Appendix A

Aseptic Non Touch Technique (ANTT®) Clinical Practice Framework

INS recognizes the historical and contemporary problems with aseptic technique and the consequential risks to patient safety. It is widely noted that variable and ambiguous terminology for this critical clinical practice has inhibited effective education, standardized practice, and ultimately patient safety.¹⁻⁴

In consideration of these problems and challenges, this edition of the *Infusion Therapy Standards of Practice* (the *Standards*) has introduced a new dedicated standard for aseptic technique. It features the original and explicitly defined ANTT Clinical Practice Framework that is used widely as a de facto international standard. All reference to aseptic technique throughout the *Standards* is therefore articulated using unique practice terms and principles of ANTT as outlined below.

WHY HAS INS ADOPTED ANTT AS A SPECIFIC STANDARD FOR ASEPTIC TECHNIQUE?

Although recognizing problems with practice, stakeholder organizations over recent years have typically only “prescribed aseptic technique” with virtually no meaningful description. Such “prescription without description” of aseptic technique, and the lack of consistent education and competency assessment, does not provide the level of clinical oversight and attention to quality improvement that this critical clinical competency demands.

INS provides global leadership for infusion practice and ultimately patient advocacy by developing and disseminating standards of practice. Establishing standards of aseptic technique is a global concern, and standardizing practice internationally with ANTT as a universal approach will help improve patient safety. The best example of a standardized approach to an important clinical competency is basic life support. Internationally, the health care community shares common clinical guidelines, recommendations, and practice terminology for resuscitation, thus supporting consistent practice across the globe.⁵

INS seeks to promote research inquiry for practice advancement, and aseptic technique is integral to a wide

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range of research in infusion practices. It is clear from an increasing number of international publications that the common and standardized language in the ANTT Clinical Practice Framework is being used to support more meaningful and generalizable research.⁶⁻⁹

Some clinicians may find ANTT terminology a change. Therefore, it is useful to remember it reflects a rationalization of the inaccurate, interchangeable, and variable practice terms that exist, and a step forward to a more universal approach for the ultimate benefit of consistent patient care.

THE ANTT FRAMEWORK EXPLAINED

Originated by Rowley¹⁰ and defined by the National Institute for Health and Care Excellence (NICE),¹¹ ANTT is a specific type of aseptic technique with a unique theory and Clinical Practice Framework. The Framework is designed for use with all invasive clinical procedures and management of indwelling medical devices in all patients. As well as robustly defining the different elements of aseptic practice, it better explains the necessary integration of these elements for different clinical situations. To this end, maintaining asepsis during infusion therapy is a diverse and challenging practice, and applying ANTT principles supports clinical decision-making.

The Aim Is Always Asepsis

ANTT is fundamentally based on the practice aim of asepsis for all invasive clinical procedures. This is because:

- The practice aim of **clean** technique is not appropriate for invasive procedures, as it is a visual standard of hygiene applied to invisible microorganisms.
- The practice aim of **sterile** technique, free of ALL microorganisms, is not achievable in typical health care settings due to the ever presence of microorganisms in the air environment.
- The practice aim of **asepsis** or **aseptic** technique, the absence of pathogenic organisms, in sufficient quantity to cause infection, is achievable. ANTT includes the words ‘non-touch’ to be descriptive, as non-touch technique is a critical component of this practice.

How Asepsis Is Achieved

To achieve asepsis in practice and support education and research, ANTT uses a novel approach termed **Key-Part and Key-Site Protection**.^{3,11} This model educates the clinician to always identify and protect the most important parts of the equipment and the vulnerable sites on the patient during any clinical procedure.

- **Key-Parts**

Key-Parts are the parts of equipment that if touched or contaminated are most likely to contaminate and potentially infect the patient. Examples include the syringe tip, male luer end/spike of administration set, needleless connector, injection needle, or the open lumen of a central vascular access device (CVAD).

- **Key-Sites**

Key-Sites are any portal of entry for microorganisms into the patient. Examples include any vascular access device (VAD) site, injection site, or open wound.

The Key-Part and Key-Site Rule

Safe practice is assured when clinicians always adhere to this rule: *Key-Parts must only come into contact with other aseptic Key-Parts and Key-Sites.*

ANTT Needs to Be Efficient as Well as Safe

The ANTT Clinical Practice Framework establishes two ANTT approaches to efficiently accommodate simple and complex procedures:

- **Standard-ANTT**

Key-Parts are protected individually. It is used for procedures where it is simple to achieve and maintain asepsis. Such procedures, for example intravenous (IV) medication administration, will typically have few small Key-Parts, be minimally invasive, have a short duration of less than 20 minutes, and require low levels of personal protective equipment (PPE). Two types of aseptic fields are used in Standard-ANTT to protect Key-Parts independently.

- **General Aseptic Field:** A decontaminated and disinfected surface or single-use procedure kit/barrier. Used to provide a controlled work space, promoting, but not ensuring asepsis.
- **Micro Critical Aseptic Field:** A small protective sterile surface/housing (eg, sterile caps, covers, or the inside of recently opened sterile equipment packaging). Used to protect Key-Parts individually and placed/transported within a General Aseptic Field.

- **Surgical-ANTT**

Key-Parts are protected together. It is used for procedures that are technically complex to achieve and maintain asepsis. Such procedures, for example peripherally inserted central catheter (PICC) insertion, will typically involve many and/or large Key-Parts, a relatively large open Key-Site, have a long duration of more than 20 minutes, be significantly invasive, and require high levels of PPE.

One type of aseptic field is used in Surgical-ANTT to protect Key-Parts together as a group.

- **Critical Aseptic Field:** A large sterile drape/barrier. Used to ensure asepsis; all procedure equipment is placed upon the drape and protects multiple and often large Key-Parts collectively.

ANTT RISK ASSESSMENT

Infusion therapy is a diverse specialty ranging from relatively simple to very complex clinical procedures. Often, the most suitable type of ANTT for any particular procedure is defined in organizational policy. In other situations, the ANTT Risk Assessment should be used to determine the type of ANTT approach to use. The decision is guided by asking the question:

Is it technically easy to protect and maintain the asepsis of the Key-Parts and Key-Sites during this procedure?

If yes, then Standard-ANTT is used. If no, then Surgical-ANTT would be selected. To help make this clinical judgment the clinician will consider a number of practice variables, including:

- The number and size of Key-Parts and Key-Sites.
- The invasiveness of the procedure.
- The duration of the procedure.
- The environment within which the procedure will take place.
- The level of PPE required.

APPLYING ANTT TO PRACTICE

Example 1: IV Drug Preparation and Administration

By applying the ANTT Risk Assessment above, the clinician would likely determine the use of Standard-ANTT due to asepsis being relatively easy to establish and maintain. This is due to the following factors:

- Few and small Key-Parts are used.
- The Key-Parts are relatively easy to protect individually with a combination of Micro Critical Aseptic Fields (eg, sterile caps and the inside of recently opened sterile packaging) and use of a non-touch technique within a General Aseptic Field (eg, a procedure tray).
- The procedure is short in duration (typically <20 minutes) and minimally invasive.

Preparation

The clinician performs hand hygiene and selects the appropriate PPE. The procedure tray is disinfected, providing a clean work space, or a barrier is used (General Aseptic Field). While the work space dries, all required equipment is gathered and placed around the procedure tray. Immediately prior to equipment assembly, hand hygiene is repeated and nonsterile gloves donned according to organizational policy. Once opened and assembled, immediately protect individu-

al Key-Parts with Micro Critical Aseptic Fields and place onto the work space. Waste and sharps are safely disposed, PPE removed, and hand hygiene performed.

Administration

With clean hands and fresh nonsterile gloves (as required), the clinician will disinfect the injection port/needleless connector and allow to dry fully. Syringes are removed from the procedure tray/barrier (General Aseptic Field). The protective syringe cap is removed or the syringe is removed from its packaging (both Micro Critical Aseptic Fields) and connected immediately and directly to the injection port/needleless connector (ie, aseptic Key-Part to aseptic Key-Part).

Example 2: PICC Placement

By applying the ANTT Risk Assessment, the provider would determine the use of Surgical-ANTT due to sepsis being more difficult to achieve and maintain. This is due to the following factors:

- Many, and some large, Key-Parts and one small but invasive Key-Site are used.
- The Key-Parts are not easily managed and all Key-Parts need to be protected.
- The procedure is typically 30 to 60 minutes or more in duration, relatively invasive, and is associated with a risk for infection.

Preparation

The clinician performs hand hygiene and selects appropriate PPE. The procedural area is disinfected providing a clean work space. While the work space dries, all required equipment is gathered. Immediately prior to opening sterile drapes/procedure pack, hand hygiene is repeated, creating a Critical Aseptic Field. The equipment and sterile supplies are placed onto the Critical Aseptic Field using a non-touch technique.

Procedure

After a surgical hand scrub is performed, the clinician dons a sterile gown and sterile gloves. Using a non-touch technique, equipment is assembled and local anesthesia is prepared. Although wearing sterile gloves, Key-Parts, such as syringe tips and the PICC, are not touched where practical not to do so. At all times, all equipment must stay on and within the Critical Aseptic Field(s).

ANTT QUALITY IMPROVEMENT

Like any critical clinical competency that is integral to patient safety, ANTT must be supported as part of a

comprehensive quality improvement program. Namely, effective clinician education, training, competency assessment, and the ongoing monitoring of standards of practice through periodic audit.

ANTT is overseen and disseminated internationally by the Association for Safe Aseptic Practice (ASAP), providing free support, advice, and resources to help with ANTT implementation and maintenance at ANTT.org. Although ANTT® is trademarked and is copyrighted material, this is to protect the integrity of ANTT and not inhibit its free utilization for educational noncommercial activities.

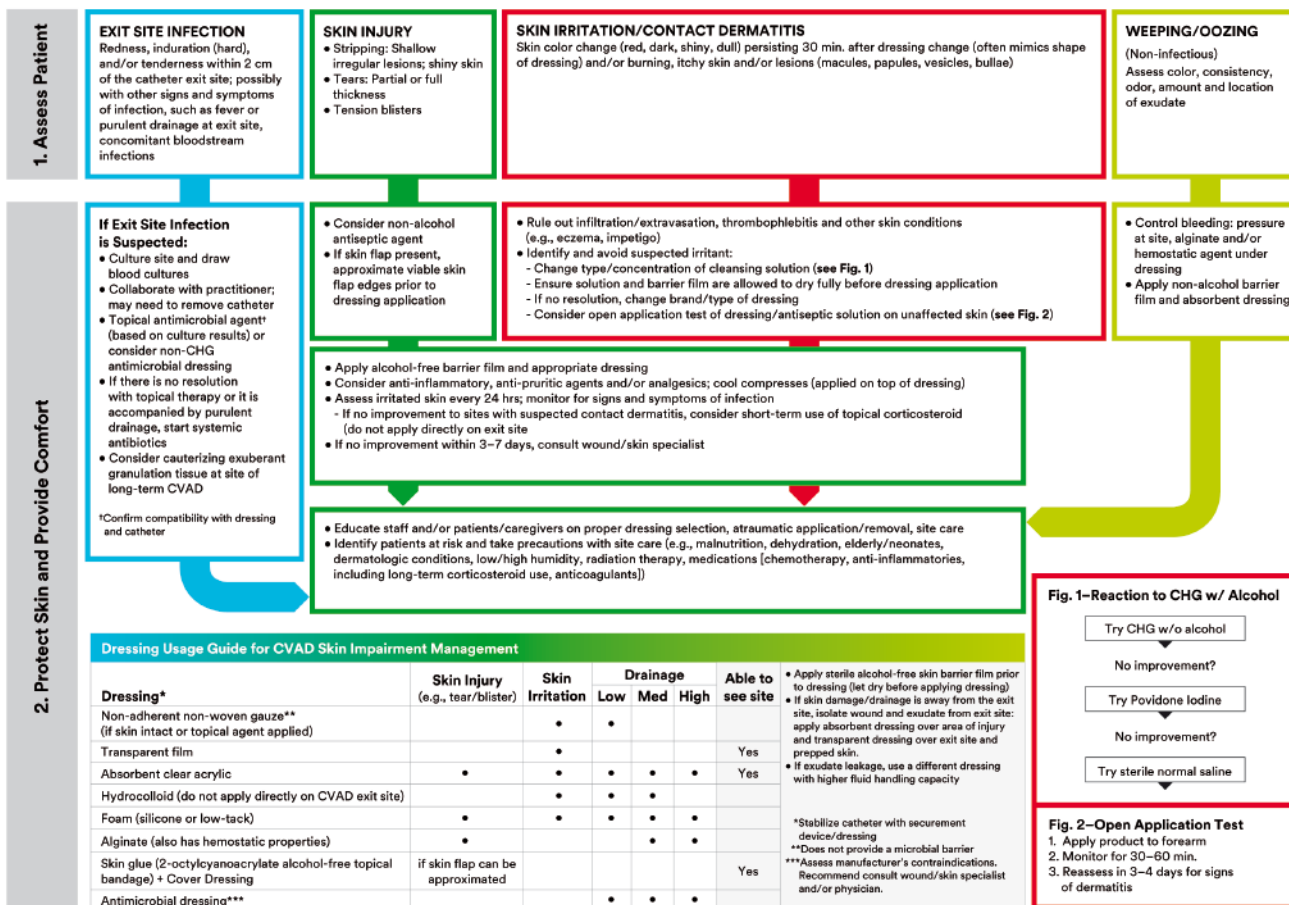
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CATHETER-ASSOCIATED SKIN INJURY

CVAD– Associated Skin Impairment (CASI) Algorithm

(Broadhurst, Moureau, Ullman. *J Wound Ostomy Continence Nurs.* 2017;44(3):11-10)



Appendix B. Abbreviations: CASI, CVAD-associated skin impairment; CHG, chlorhexidine gluconate; CVAD, central vascular access device; w, with; w/o, without. Reprinted with permission from Broadhurst D, Moureau N, Ullman AJ; The World Congress of Vascular Access (WoCoVA) Skin Impairment Management Advisory Panel. Management of central venous access device-associated skin impairment: an evidence-based algorithm. *J Wound Ostomy Continence Nurs.* 2017;44(3):211-220. doi:10.1097/WON.0000000000000322

Assessment Scales - Infiltration Scale, Phlebitis Scale, Visual Infusion Phlebitis Scale, and Extravasation Staging

Use a standardized tool/scale to accurately perform and document vascular access device (VAD) assessment for infiltration, extravasation, and phlebitis. Consistent use of one assessment and documentation method within an organization is essential. The population for which the tool/scale is appropriate should be identified as adult or pediatric.

The INS Infiltration Scale (Table 1) was last published in *The Infusion Nursing Standards of Practice* in 2006 and is republished here for archival purposes. Further study is recommended for validation of this specific tool.

The tool, Extravasation Staging (Table 2), was designed by Ong and Van Gerpen,² who utilized published literature to identify extravasation staging, assessment of symptoms, and treatment options.

The two phlebitis scales, the INS Phlebitis Scale (Table 3) and the Visual Infusion Phlebitis (VIP) Scale (Table 4), and a set of signs/symptoms have been evaluated for validity and interrater reliability in different populations with insufficient definitions and mixed results. There is often a lack of direction for interventions with a specific clinical finding. Further study is recommended for valid and reliable assessment tools.

TABLE 1

INS Infiltration Scale

Grade	Clinical Criteria
0	No symptoms
1	Skin blanched Edema < 1 inch in any direction Cool to touch With or without pain
2	Skin blanched Edema 1–6 inches in any direction Cool to touch With or without pain
3	Skin blanched, translucent Gross edema > 6 inches in any direction Cool to touch Mild–moderate pain Possible numbness
4	Skin blanched, translucent Skin tight, leaking Skin discolored, bruised, swollen Gross edema > 6 inches in any direction Deep pitting tissue edema Circulatory impairment Moderate–severe pain Infiltration of any amount of blood product, irritant, or vesicant

TABLE 2**Extravasation Staging**

Stage	Assessment	Treatment Options
1	• Painful infusion site • No erythema • Localized swelling (1%-10% of extremity above or below site)	• Remove cannula • Elevate extremity • Warm/cold compresses
2	• Painful infusion site • Slight swelling at site (up to 25% of extremity above or below site) • Slight erythema (localized to the central area of extravasation) • Good pulse below site • Brisk (1-2 seconds) capillary refill below site	• Remove cannula • Elevate extremity • Warm/cold compresses • Consider antidote
3	• Painful infusion site • Moderate swelling at site (25%-50% of extremity above or below site) • Marked erythema (extends beyond central area of extravasation) • Blanching (for vasopressor extravasation only) • Good pulse below site • Brisk (1-2 seconds) capillary refill below site • Skin cool to touch	• Leave cannula in place; using a 1 mL syringe, aspirate as much fluid as possible • Remove cannula unless it is needed for antidote administration • Elevate extremity • Warm/cold compresses • Consider antidote
4	• Painful infusion site • Severe swelling at site (more than 50% of extremity above or below site) • Very marked erythema (extends beyond borders of swelling) • Blanching (non-vasopressor extravasation) • Decreased or absent pulse • Prolonged capillary refill > 4 seconds • Skin cool to touch • Skin breakdown including blistering or necrosis	• Leave cannula in place; using a 1 mL syringe, aspirate as much fluid as possible • Remove cannula unless it is needed for antidote administration • Elevate extremity • Warm/cold compresses • Consider antidote • If swelling of the site is tense and skin is blanched, obtain surgical consult

Ong J, Van Gerpen R. Reprinted with permission. Recommendations for management of noncytotoxic vesicant extravasations. *J Infus Nurs.* 2020;43(6):319-343. doi:10.1097/NAN.0000000000000392

TABLE 3**INS Phlebitis Scale**

Grade	Clinical Criteria
0	No symptoms
1	Erythema at access site with or without pain
2	Pain at access site with erythema and/or edema
3	Pain at access site with erythema Streak formation Palpable venous cord
4	Pain at access site with erythema Streak formation Palpable venous cord >1 inch in length Purulent drainage

TABLE 4**Visual Phlebitis Scale**

Score	Observation
0	IV site appears healthy
1	One of the following is evident: Slight pain near IV site OR Slight redness near IV site
2	Two of the following are evident: • Pain at IV site • Erythema • Swelling
3	All of the following signs are evident: • Pain along path of cannula • Induration
4	All of the following signs are evident and extensive: • Pain along path of cannula • Erythema • Induration • Palpable venous cord
5	All of the following signs are evident and extensive: • Pain along path of cannula • Erythema • Induration • Palpable venous cord • Pyrexia

Abbreviation: IV, intravenous.

Data from Jackson A. Infection control—a battle in vein: infusion phlebitis. *Nurs Times.* 1998;94(4):68-71. Reprinted with permission.

A

Accreditation. A quality assurance process under which health care services and operations are evaluated and verified by an external body to determine if recognized standards are met.

Active disinfection. Use of a disinfectant to physically scrub the injection site/port before each access; often referred to as “scrub the hub.”

Add-on device. Additional components, such as an in-line filter, stopcock (3-way tap), Y-site, extension set, manifold set, needleless connector, and/or dead end cap that is added to the administration set or vascular access device.

Adhesive securement device (ASD). An adhesive-backed device that adheres to the skin with a mechanism to hold the vascular access device (VAD) in place; a separate dressing is placed over the ASD. Both the dressing and ASD must be removed and replaced at specific intervals during the VAD dwell time.

Adjuvant medication. Additional medications given to facilitate or enhance a primary drug or medical treatment.

Administration set. A tubing set composed of plastic components that is used to deliver infusions and typically includes a spike, a drip chamber, injection ports, and a male luer end. Variations may include a Y-set, integrated filter, and microbore tubing.

- **Primary administration set.** The tubing set connecting the infusate container directly to the vascular access device (VAD) or to a lower access point (eg, Y-site) of another primary set; may be used for gravity delivery or designed to be used with a flow-control device; may be continuous or intermittent.
- **Secondary administration set (eg, piggyback).** Additional, shorter tubing set that is connected to an access point on the primary set; may be used to administer infusates concurrently or intermittently with the primary infusate; may be used for gravity delivery or designed to be used with a flow-control device; commonly used for intermittent infusions, but may be used for secondary continuous infusions.
- **Intermittent administration set.** A primary or secondary administration set that has been disconnected from the initial access point (eg, needleless connector, VAD hub) and left disconnected due to completion or a pause in an infusion. It must be disconnected aseptically, with the distal tip protected by a new sterile end cap.
- **Continuous administration set.** A primary or secondary administration set that remains connected to the vascular access device (VAD) for the duration of an infusion or until the scheduled administration set change occurs. This set may be disconnected and reconnected to a VAD

for a brief period (eg, blood sampling, transition to a new VAD lumen) with adherence to Aseptic Non Touch Technique (ANTT®) and needleless connector cleansing.

- **Continuous infusion.** A controlled method of intravenous administration given over at least several hours or longer without interruption.
- **Intermittent infusion.** A small volume given by manual push or short infusion (eg, 30 or 60 minutes); an infusion technique that would easily allow for patency assessment before, during, and after the medication infuses.

Admixture. A combination of 2 or more medications.

Advanced practice registered nurse (APRN). US state boards of nursing recognize 4 types of APRNs, including certified registered nurse anesthetist, certified nurse midwife, certified nurse practitioner, and clinical nurse specialist, with practice occurring in all health care settings with patients of all ages.

Adverse event. Any unintended or untoward event that occurs with a patient receiving medical treatment that is related to a medication, product, equipment, procedure, etc.

Air embolism. The presence of air in the vascular system that obstructs blood flow primarily to the lungs or brain.

Airborne precautions. A type of isolation precaution to reduce the risk of infection from airborne transmission of airborne droplet nuclei that may remain suspended in the air.

Alarm/alert fatigue. Exposure to frequent alarms (alerts) from multiple sources can result in sensory overload and desensitization. Desensitization can lead to delayed response times, which could potentiate missed critical early warning signs.

Allen test. A test performed on the radial and ulnar artery of the hand prior to arterial puncture to ascertain adequate arterial perfusion.

Alternative site. A health care setting outside of the acute care hospital that includes, but is not limited to, the home, long-term care/assisted living facility, outpatient center/clinic, and physician office.

Alternative to discipline program (for drug diversion). Generally administered by third party through contractual agreements with a state board of nursing; the nurse refrains from practice for a designated time while undergoing treatment, establishing sobriety and a program of recovery.

Ambulatory infusion pump. A portable electronic infusion pump designed to be worn on the body to promote patient mobility and independence. See *Electronic Infusion Pump*.

Amino acids. Organic components of protein.

Ampoule. Hermetically sealed glass medication container that must be broken at the neck to access the medication.

Anaphylaxis. A severe, potentially life-threatening allergic reaction with immunologic and nonimmunologic causes.

Ante area. A buffer zone of laminar or displacement airflow near a clean work area, such as a pharmaceutical compounding space.

Antimicrobial stewardship. The effort to improve antibiotic prescribing by clinicians and use by patients so that antibiotics are only prescribed and used when needed; to minimize misdiagnoses or delayed diagnoses leading to underuse of antibiotics; and to ensure that the right drug, dose, and duration are selected when an antibiotic is needed. Goals include improving safe and appropriate use of antimicrobials, reducing patient harm, and reducing antimicrobial resistance.

Anti-free-flow protection. Administration set technology that prevents free flow of intravenous solutions into the patient when the administration set is removed from the flow-control device.

Anti-infective vascular access device. A vascular access device whereby an antiseptic or antimicrobial agent is coated, impregnated, or incorporated; or the base catheter material has been engineered to inhibit bacterial attachment and biofilm formation.

Antimicrobial locking solutions. Solutions of supratherapeutic concentrations of antibiotic, or a variety of antiseptic agents, to lock the central vascular access device lumen for a prescribed period to prevent or treat catheter-associated bloodstream infection.

Antineoplastic therapy. Includes chemotherapy (chemical agents used to treat cancer), targeted therapy (agents that selectively target molecular pathways to block the growth and spread of cancer), and immunotherapy (a broad category of agents that harness the body's immune system to eradicate cancer cells).

Antiseptic. A substance used to reduce the risk of infection by killing or inhibiting the growth of microorganisms.

Apheresis. Process of separating blood into 4 components: plasma, platelets, red blood cells, and white blood cells, removing 1 of the components, and then reinfusing the remaining components.

Arterial pressure monitoring. Use of an indwelling arterial catheter connected to an electronic monitor that displays continuous information about arterial pressure.

Arteriovenous fistula (AVF). Surgical anastomosis between an artery and vein to provide vascular access for long-term dialysis.

Arteriovenous graft (AVG). Surgical structure created between an artery and a vein to provide vascular access for long-term dialysis, usually of a manufactured synthetic material.

Asepsis. The absence of pathogenic organisms in sufficient quantity to cause infection, achievable through aseptic technique.

Aseptic technique. A set of infection prevention actions with the aim of protection of patients from infection during invasive clinical procedures and management of indwelling medical devices; notably, it is a generic term that is variously defined, interpreted, and used interchangeably with other practice terms, such as clean, sterile, and nontouch technique.

Assent. Agreement by an individual not competent to give legally valid informed consent (eg, a child or cognitively impaired person).

Authorized agent-controlled analgesia. A competent person authorized and educated by the prescriber to activate the analgesic dose when a patient is not able to do so.

Automated dispensing cabinet (ADC). A computerized medicine cabinet for hospitals and health care settings. ADCs allow medications to be stored and dispensed near the point of care while controlling and tracking drug distribution.

B

Backcheck valve. A feature incorporated within an intravenous administration set that functions to prevent retrograde solution flow.

Bacteria. Microorganisms that may be nonpathogenic (normal flora) or pathogenic (disease-causing).

Barcode scan. Barcode medication administration (BCMA); the barcode is scanned on the patient's wristband and on the medication to be administered as a safeguard to reduce the risk of medication errors.

Beyond-use date (BUD). The date added to a product label during the compounding process after which a product may not be used because the manufacturer's original container has been opened, exposed to ambient atmospheric conditions, and may not have the integrity of the original packaging.

Biofilm. A community of microorganisms that form on and coat the surfaces of an implanted or indwelling device.

Biologic therapy. Biologics are large, complex molecules made from living sources such as bacteria, yeast, and animal cells. Examples of biologic therapies include immunoglobulins, monoclonal antibodies, interferons, interleukins, and vaccines.

Biological safety cabinet (BSC). A ventilated cabinet used for preparation of hazardous drugs for the purpose of controlling airflow to protect personnel and the product being prepared; environmental protection is provided by exhaust air passing through a high-efficiency particulate air (HEPA)/ultra-low particulate air (ULPA) filter.

Biosimilars. A biologic product that is highly similar to, and has no clinically meaningful differences in safety, purity, and potency from, an existing FDA-approved reference product. Biosimilars are produced from living systems that may cause minor structural and chemical

differences; however, none of these changes result in any differences in efficacy. Biosimilars are not exact duplicates but must be chemically, functionally, and clinically similar to the reference product. Biosimilars are not the same as generic medications.

Blood return. A component of vascular access device patency assessment; blood that is the color and consistency of whole blood flows readily into the syringe upon aspiration.

Blood/fluid warmer. An electronic device with adequate temperature controls that raises refrigerated blood or parenteral solutions to a desired temperature during administration.

Body surface area. Surface area of the body expressed in square meters. Used in calculating pediatric dosages, managing burn patients, and determining radiation and other classes of drug dosages.

Bolus. Concentrated medication and/or solution given over a short period of time.

C

Caregiver. Refers to person(s) who assist with a patient's care needs, eg, family members, friends, neighbors, church members; includes paid caregivers.

Catheter. A hollow, flexible tube made of a biocompatible material such as thermoplastic polyurethane or silicone elastomer, or newer materials, which may reduce the risk of complications such as occlusion and thrombosis; inserted into the body and used for injecting or evacuating fluids.

Catheter-associated bloodstream infection (CABSI). Given variability in international definitions, outcome reporting, and application of the terms catheter-related bloodstream infection (CR-BSI) and central line-associated bloodstream infection (CLABSI), the INS Standards of Practice Committee is using the terminology "Catheter-Associated Bloodstream Infection" (CABSI) to refer to bloodstream infections originating from either peripheral intravenous catheters and/or central vascular access devices. See *Catheter-Related Bloodstream Infection (CR-BSI)* and *Central Line-Associated Bloodstream Infection (CLABSI)*.

Catheter-associated skin injury (CASI). An abnormality including, but not limited to, erythema, vesicle, bulla, erosion, or tear at a peripheral or central vascular access device (VAD) site that is noted in the area of the device dressing and/or securement device and that is observable for 30 minutes or more after dressing/securement removal. CASI is associated with increased patient discomfort (eg, pain, pruritis), increased cost, delays in treatment, and a potential for VAD removal and replacement. Skin conditions from other sources (eg, eczema, autoimmune disorders, medication adverse events) are not included.

Catheter-associated thrombosis (CAT). Initiated as an inflammatory response to vessel wall injury and appears as an anechoic or hypoechoic image on ultrasonic evaluation, partially or fully occluding the vessel lumen. It is generally subdivided into deep versus superficial vein thrombosis (DVT, SVT) and symptomatic versus the larger percentage that are asymptomatic. Rates of CAT are generally low (but vary widely), and CAT rarely results in more serious complications but may impact the function of the vascular access device (VAD), delay required treatment, require anticoagulant therapy, cause VAD failure/premature removal, increase costs, and may result in postthrombotic syndrome.

- **Deep vein thrombosis (DVT).** Thrombosis involving the deep veins of the arm (brachial, axillary), subclavian, or internal jugular veins, or the leg (iliac, femoral, popliteal) detected by compression and flow ultrasonography, venography, or computed tomography (CT) scan.
- **Upper extremity DVT (UE-DVT).** Often associated with VADs inserted in smaller upper arm veins with lower blood flow velocity.
- **Superficial vein thrombosis (SVT).** Thrombosis involving the superficial veins of the upper extremity (eg, basilic, cephalic) or lower extremity (eg, saphenous veins).
- **Venous thromboembolism (VTE).** A clinical episode of VTE includes deep vein thrombosis and pulmonary embolism (may include superficial in some studies).

Catheter clearance. The process to re-establish catheter lumen patency using medications or chemicals instilled into the lumen for a specified time.

Catheter dislodgement. Catheter movement into or out of the insertion site indicating tip movement to a suboptimal position; may be partial (catheter tip still remains within the venous system but is in a suboptimal location) or total (catheter tip is removed completely from the venous system).

Catheter exchange. Replacement of existing central vascular access device (CVAD) with a new CVAD using the same catheter tract.

Catheter-related bloodstream infection (CR-BSI). The recognized diagnostic criterion that more accurately confirms the catheter as the source of the infection. It is diagnosed if the same organism is isolated from a blood culture and the tip culture and the quantity of organisms isolated from the tip is greater than 15 colony forming units (CFUs). Alternatively, differential time to positivity (DTP) requires the same organism to be isolated from a peripheral vein and a catheter lumen blood culture, with growth detected 2 hours sooner (ie, 2 hours less incubation) in the sample drawn from the catheter.

Central line-associated bloodstream infection (CLABSI). This is most commonly reported as a surveillance term; however, it is not an established diagnostic criterion. CLABSI is a primary BSI in a patient who had a central

line the day of or day before infection and had more than 2 days of central access. CLABSI surveillance definition may overestimate the true incidence of CR-BSI.

Central vascular access device (CVAD). A catheter that is inserted via a peripheral vein of the upper or lower limbs or large vein of the chest or groin with the tip advanced to a central position, either the superior vena cava (upper body insertion) or inferior vena cava (lower body insertion).

Central vascular access device (CVAD) malposition. CVAD tip located in an aberrant position that differs from the original position on insertion within the vena cava or cavoatrial junction.

- **Extravascular malposition.** CVAD tip located outside the vein in subcutaneous tissue or nearby anatomical structures, such as mediastinum, pleura, pericardium, or peritoneum.
- **Intravascular malposition.** CVAD tip located in a suboptimal or aberrant position inside a vein; occurs as primary or secondary malposition.
- **Primary malposition.** CVAD tip positioned in a suboptimal or unacceptable location during the insertion procedure.
- **Secondary malposition.** CVAD tip found to be in a suboptimal or unacceptable location at any time during the catheter dwell time; commonly referred to as tip migration.

Certification/board certification. A voluntarily earned credential that demonstrates the holder's specialized knowledge, skills, and experience within a given specialty; awarded by a third-party, nongovernmental entity or association, such as the Infusion Nurses Certification Corporation (INCC), after the individual has met predetermined and standardized criteria.

Chelator-based lock solution. Solutions such as citrate and ethylenediaminetetraacetic (EDTA) that bind with metallic cations (eg, calcium, magnesium, iron) to produce an antithrombotic effect and/or disrupt biofilm formation.

Chemical incompatibility. Change in the molecular structure or pharmacological properties of a substance that may or may not be visually observed when a solution or medication contacts an incompatible solution or medication within the vascular access device lumen, administration set, or solution container.

Cleaning. The removal of visible soil (eg, organic and inorganic material) from objects and surfaces. Thorough cleaning is essential before performing disinfection and sterilization procedures because inorganic and organic materials that remain on the surfaces interfere with the effectiveness of these processes.

Clinical bag. The container carried by home care clinicians when traveling from home to home; contains equipment (eg, blood pressure cuff, stethoscope, pulse oximeter) and necessary supplies (eg, dressings).

Clinician. Refers to the nurse, physician, or other appropriately trained and educated health care individual involved with infusion administration or vascular access device insertion, care, and management.

Close call. An event or situation that could have resulted in an accident, injury, or illness, but did not, either by chance or through timely intervention. Such events have also been referred to as a *near miss* or *good catch*.

Closed system transfer. The movement of sterile products from one container to another, in which the containers, closure system, and transfer devices remain intact through the entire transfer process, compromised only by the penetration of a sterile, pyrogen-free needle or cannula through a designated closure or port to effect transfer, withdrawal, or delivery.

Closed system transfer device. A transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drugs or vapor concentrations outside the system; used in compounding and administering sterile doses of chemotherapy and other hazardous drugs.

Color coding. System that identifies products and medications by use of a color system.

Compartment. Muscles, nerves, and blood vessels are in compartments, which are inflexible spaces bound by skin, fascia, and bone.

Compartment syndrome. Excessive fluid within a compartment that leads to increased pressure on capillaries, nerves, and muscles. The increased hydrostatic pressure leads to vascular spasm, pain, and muscle necrosis inside the compartment, which can result in functional loss. Signs and symptoms include pain, pallor, paresthesia, pulselessness, and paralysis.

Compatibility. Capable of being mixed and administered without undergoing undesirable chemical and/or physical changes or loss of therapeutic action.

Competency. A required level of effective performance in the work environment defined by adherence to professional standards, including knowledge, skills, abilities, and judgment based on established science.

Competency assessment. A dynamic process used to verify an individual's performance; designed to empower the individual and support positive behavior in patient care activities.

Compounding. The act of preparing, mixing, assembling, packaging, and labeling a drug, drug delivery device, or device according to a prescription for an individual patient or based on a professional agreement between the practitioner, patient, and pharmacist.

Computerized prescriber order entry (CPOE). A system in which clinicians directly enter medication, test, or procedure orders into an electronic system; medication orders are transmitted directly to the pharmacy.

Contact Precautions. Strategies implemented to prevent the transmission of infectious agents, such as wound drainage, which are spread by direct or indirect contact between the patient and environment.

Containment primary engineering control (C-PEC). A ventilated device designed to minimize microbial contamination and worker and environmental exposure by controlling emissions of airborne contaminants by using enclosure, airflow, air pressure, and high-efficiency particulate air (HEPA) filtration. Two main types of C-PECs are biological safety cabinets and compounding aseptic containment isolators.

Contamination. Introduction or transfer of pathogens or infectious material from one source to another.

Contrast media. Intravenous administration of iodinated or gadolinium-based pharmaceutical agents to improve imaging of internal structures. They have a wide range of osmolarity and viscosity compared to normal serum values and may be associated with tissue injury if extravasation occurs.

Controlled substance: Drugs and other substances are divided into 5 schedules under the Controlled Substances Act (CSA) based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and the likelihood of causing dependence when abused. (www.deadiversion.usdoj.gov)

Crisis standards of care. Guidelines designed to help organizations and health care professionals deliver the best possible care in circumstances in which resources are severely limited and health care standards are compromised.

Cross contamination. The indirect movement of pathogens or other harmful substances from one patient to another patient.

Cultural competency. Care delivery that is respectful of and responsive to the beliefs, culture, practices, and linguistic needs of patients and their families served by the health care organization.

D

Dead end cap. Nonvented sterile cap used to cover the vascular access device (VAD) hub.

Dead space. The internal space outside the intended fluid pathway into which fluid can move, as applied to needleless connectors.

Decontamination. The removal of pathogenic microorganisms from objects so they are safe to handle, use, or discard.

Delegation. The process for a clinician (eg, registered nurse) to direct another person (eg, unlicensed assistive personnel) to perform a task or activity not commonly performed by that person; however, that person has the knowledge and skill to perform the task. The delegating

clinician retains accountability for the outcome of the delegated task.

Di(2-ethylhexyl)phthalate (DEHP). A plasticizer that is added to polyvinyl chloride to make solution containers and administration set tubing soft and pliable. It is a known toxin that can seep from the plastic into the bloodstream. Risk of exposure is greatest in infants.

Difficult intravenous access (DIVA). Refers to multiple unsuccessful attempts to insert a catheter. This can be acute due to sudden illness or chronic, resulting from complex medical intervention. Characteristics of DIVA include, but are not limited to, patient characteristics (overweight/underweight), extremes of age (history of prematurity and older adult), gender (female), and vein characteristics (limited visibility and palpability).

Dilution. To add a diluent (eg, 0.9% sodium chloride, sterile water) to a solution of medication in order to make it less concentrated, to provide additional solution for ease of administration and titration, or to decrease the risk of tissue damage by bringing the final osmolarity closer to an isotonic solution.

Disclosure. The process of revealing all the facts necessary to ensure that the patient/caregiver or a surrogate understands what occurred when a patient experiences a significant complication from a medical error or mistake; information that is necessary for the patient's well-being or relevant to future treatment.

Disinfectant. Agent that eliminates most microorganisms except bacterial spores.

Disinfection. A process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects.

Disinfection Cap. Disinfectant-impregnated protective cap containing an antiseptic solution placed on top of the connection surface of a needleless connector/male luer end of administration set to disinfect the surface and provide protection between intermittent use. There are also disinfection caps that attach directly to the catheter hub.

Distal. Farthest from the center or midline of the body or trunk or from the point of attachment; opposite of proximal.

Doppler flow study. A form of ultrasound technology that produces audible sounds to determine characteristics of circulating blood.

Dose error reduction systems (DERS). Electronic infusion pumps manufactured with drug libraries containing drug name and soft and hard infusion limits; designed to prevent errors in solution and medication delivery, often called smart pumps.

Droplet Precautions. A type of isolation precaution to reduce the risk of infection from pathogens spread through close respiratory or mucous membrane contact with respiratory secretions.

Drug diversion. Removal of Drug Enforcement Administration (DEA)–scheduled medication from and within the lawful process of a hospital or health care system to an unlawful channel of distribution or use.

E

Elastomeric pump. A portable, single-use device with an elastomeric reservoir (ie, balloon). Used to deliver a variety of infusion therapies.

Electronic infusion pump. Device that is powered by electricity or battery to regulate infusion rate.

Electronic infusion rate monitor/drop counter. Used as an adjunct to gravity infusions by providing an electronically monitored infusion; placed around the administration set drip chamber; does not “pump” the fluid, rather monitors the drip rate.

Electronic medical record (EMR)/electronic health record (EHR). EMR is the same collection of documents as in the health record but manages the documents using electronic clinical information systems (specialized software) that protect and secure patient data. The EMR can track patient data, schedule visits and reminders, and is a source for quality monitoring and improvement. The EMR is used in a single clinic, hospital, or practice. The EHR often offers more functionality than an EMR and is used across many clinics, hospitals, or practices.

Elliotts B[®] Solution. A sterile, nonpyrogenic, isotonic solution containing no bacteriostatic preservatives. Elliotts B[®] Solution is a diluent for intrathecal administration of methotrexate sodium and cytarabine.

Embolus. Mass of undissolved matter present in blood or lymphatic vessel; an embolus may be solid, liquid, or gaseous.

End-tidal capnography. The measurement of the partial pressure of carbon dioxide during expiration (end-tidal carbon dioxide); used with general anesthesia, moderate/deep procedural sedation, and mechanical ventilation; a more sensitive indicator of respiratory depression than oxygen saturation monitoring with patient-controlled analgesia.

EnFit[®] connector. Designed to reduce the risk of inadvertent misconnections by ensuring that feeding tube connectors are incompatible with the connectors for unrelated delivery systems, such as intravenous catheters, tracheostomy tubes, and other catheters.

Engineering controls. Devices that isolate or remove the bloodborne pathogens hazard from the workplace, such as sharps disposal containers, self-sheathing needles, needleless systems, and sharps with engineered protections.

Enhanced barrier precautions. A recommendation from the Centers for Disease Control and Prevention (CDC) for long-term care facilities. Enhanced barrier precautions should be used in a location (eg, wing, floor, unit) when

a resident of that location is colonized or infected with a novel or targeted multidrug resistant organism (MDRO). The use of personal protective equipment is expanded for high-risk residents in these locations (eg, those with wounds, vascular access devices), including the use of gowns and gloves during high-contact care activities that provide opportunities for transfer of MDROs to staff hands and clothing (eg, during dressing, bathing/showowering, transferring, device care, or use: central line, urinary catheter, feeding tube, tracheostomy/ventilator, any skin opening requiring a dressing).

Enrolled nurse (EN). A designation used in Australia; an enrolled nurse works under the direct supervision of a registered nurse.

Epidural space. Space surrounding the spinal cord and its meninges; contains fatty tissue, veins, spinal arteries, and nerves; considered a potential space that is not created until medication or air is injected.

Erythema. Redness of skin in a specific area or more generalized.

Evidence-based practice. Application of the best available synthesis of research results in conjunction with clinical expertise and with attention to and inclusion of patient preferences.

Expiration date. The date and time, when applicable, beyond which a product should not be used; the product should be discarded beyond this date and time.

Extravasation. Inadvertent infiltration of vesicant solution or medication into surrounding tissue; rated by a standard tool or definition.

Extrinsic contamination. Contamination that occurs after the manufacturing process of a product.

F

Fat emulsion. See *Lipid Injectable Emulsion (ILE)*.

Fibroblastic sleeve. A sleeve of connective tissue that develops as an apparent adaptive process to a foreign body and may eventually surround a vascular access device (VAD). The sleeve does not originate from the vein wall; contains fibroblasts, smooth muscle cells, and collagen; is typically asymptomatic; but may potentiate catheter dysfunction if it obstructs the distal tip of the catheter.

Filter. A special porous device used to prevent the passage of air, particulate matter, and microorganisms; product design determines size of substances retained.

Flow-control device. Device used to regulate infusion flow rate; includes categories of manual devices (eg, slide, roller clamp, screw), non-electronic flow-control devices, and electronic infusion pumps. See *Non-Electronic Flow-Control Device* and *Electronic Infusion Pump*.

Flushing. The act of moving fluids, medications, blood, and blood products out of the vascular access device into the bloodstream; used to assess and maintain patency

and prevent precipitation due to solution/medication incompatibility.

G

Gamma scintillation sensors. Can be used for extravasation sensing: when the injected medium is radioactive, the flow of the medium can be detected via gamma scintillation sensors.

Guidewire. A long, flexible, metal structure, composed of tightly wound coiled wire in a variety of designs. Only guidewires specifically designed for vascular access (eg, atraumatic tip at one end) should be used for this purpose. Only the atraumatic (floppy, nonstiff) end of the guidewire should be advanced into the vein.

H

Hazardous drug. Drug exhibiting 1 or more of the following 6 characteristics in humans or animals: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity, and structure and toxicity profiles of new drugs that mimic existing drugs, determined hazardous by the above criteria.

Hazardous drug spill. Any fluid containing hazardous drugs escaping from its container in a quantity more than a few drops.

Hazardous waste. In the context of this document, hazardous waste is differentiated from medical waste and refers to that generated from administration of hazardous drugs (eg, intravenous containers, equipment, and supplies used to administer hazardous drugs).

Health literacy. The degree to which individuals have the capacity to obtain, process, and understand basic health care information and services needed to make appropriate decisions.

Health record/medical record/patient record. A patient-specific chronological and legal collection of health care documents that describe services/care provided, facilitate communication among health care team members, and support payment practices. Documents include, but are not limited to, assessments, observations, problem lists, intervention/procedure descriptions, instructions, orders, progress notes, medications administered, summaries, laboratory and radiologic reports, exams, and/or pictures. This collection may be in paper form, digitized, or stored as an electronic medical record or electronic health record.

Healthcare failure mode and effect analysis (HFMEA). A systematic, proactive method used to evaluate a process or device for the purposes of identifying where and how a process might fail; results are used to identify and prioritize the most needed process changes.

Hemodynamic pressure monitoring. A general term that describes the functional status of the cardiovascular

system as it responds to acute stress, such as myocardial infarction and cardiogenic or septic shock. A pulmonary artery catheter is used to directly measure intracardiac pressure changes, cardiac output, blood pressure, and heart rate.

Hemolysis. Destruction of the membrane of the red blood cells resulting in the liberation of hemoglobin, which diffuses into the surrounding fluid.

Hemostasis. An arrest of bleeding or of circulation.

Heparin-induced thrombocytopenia (HIT). An acute, transient prothrombotic disorder caused by heparin-dependent, platelet-activating antibodies; a hypercoagulable state with a strong association to venous and arterial thrombosis.

High-alert medication. Medications that possess a heightened risk of causing significant patient harm when used in error.

Hypertonic. Solution of higher osmotic concentration than that of a reference solution or of an isotonic solution; having a concentration greater than the normal tonicity of plasma.

Hypodermoclysis. The subcutaneous administration of isotonic hydration solutions; used to treat mild-to-moderate dehydration.

Hypotonic. Solution of lower osmotic concentration than that of a reference solution or of an isotonic solution; having a concentration less than the normal tonicity of plasma.

I

Immunocompromised. Having an immune system with reduced capability to react to pathogens or tissue damage.

Impaired practice. Functioning poorly or with diminished competence, as evident in changes in work habits, job performance, appearance or other behaviors in any setting.

Implanted pump. A catheter inserted into a vessel, body cavity, or organ attached to a subcutaneous reservoir that contains a pumping mechanism for continuous medication administration.

Implanted vascular access port. A catheter inserted into a vein, attached to a reservoir located under the skin.

Incompatible. Incapable of being mixed or used simultaneously without undergoing chemical or physical changes or producing undesirable effects.

Independent double check. A process whereby 2 people working separately and apart from each other verify each component of a work process (eg, the prescribed dose, calculated rate of infusion) for select high-risk tasks, vulnerable patients, or high-alert medications.

Infection. The presence and growth of a pathogenic microorganism(s) having a local or systemic effect.

Infiltration. Inadvertent administration of a nonvesicant solution or medication into surrounding tissue; rated by a standard tool or definition.

Informed consent. A person's voluntary agreement to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure, based upon adequate knowledge and understanding of relevant information.

Infusate. Parenteral solution administered into the vascular or nonvascular systems; infusion.

Infusion team/vascular access specialty team (VAST). A group of clinicians centrally structured within the facility charged with the goal of accurate, efficient, and consistent delivery of infusion and vascular access services. Staff mix varies; however, this team should be led by a registered nurse specializing in this practice. Scope of service, team name, and roles of team members vary greatly.

Instill/instillation. Administration of a solution or medication into a vascular access device (VAD) intended to fill the VAD rather than systemic infusion; examples include locking solutions to maintain catheter patency, thrombolytic medications, and medications/solutions used to dissolve precipitate.

Integrated securement device (ISD). A device that combines a dressing with securement functions; includes transparent, semipermeable window and a bordered fabric collar with built-in securement technology.

Interprofessional/interprofessional collaboration. A cooperative approach to patient care acknowledging and respecting the unique knowledge, skills, and abilities of each professional health team member.

Intraosseous (IO). The spongy, cancellous bone of the epiphysis and the medullary cavity of the diaphysis, which are connected; the vessels of the IO space connect to the central circulation by a series of longitudinal canals that contain an artery and a vein. The Volkmann's canals connect the IO vasculature with the major arteries and veins of the central circulation.

Intrathecal. The subarachnoid space between the arachnoid and pia mater; contains cerebrospinal fluid.

Intrinsic contamination. Contamination that occurs during the manufacturing process of a product.

Irritant. An agent capable of producing discomfort (eg, burning, stinging) or pain as a result of irritation in the internal lumen of the vein with or without immediate external signs of vein inflammation.

Isotonic. Having the same osmotic concentration as the solution with which it is compared (eg, plasma).

J

Joint stabilization. Use of a device to support and stabilize a joint (eg, arm board, splint) when veins or arteries used for vascular access device (VAD) insertion are located in an area of flexion.

Just Culture. A model of shared accountability in health care based on the premise that organizations are accountable for the systems they design and for how they respond to staff behaviors fairly and justly; a just culture understands that individuals should not be held responsible for system failure.

L

Laminar flow hood. A contained workstation with filtered air flow; assists in preventing bacterial contamination and collection of hazardous chemical fumes in the work area.

Leaching. Process of a solute becoming detached or extracted from its carrier substance.

Lean Six Sigma. Refers to the 8 types of waste that organizations strive to eliminate as "DOWNTIME" ("defects, overproduction, waiting, nonutilized talent, transportation, inventory, motion, and extra processing"). Resources that do not create value are wasteful and should be eliminated.

Lipid injectable emulsion (ILE). Combination of liquid, lipid, and an emulsifying system formulated for intravenous use.

Locking. The instillation of a solution into a vascular access device (VAD) used to maintain patency in between VAD use and/or reduce risk of catheter-associated bloodstream infection.

Long peripheral intravenous catheter (long PIVC). Inserted in either superficial or deep peripheral veins and offer an option when a short PIVC is not long enough to adequately cannulate the available vein. A long PIVC can be inserted via traditional over-the-needle technique or with more advanced procedures, such as Seldinger and accelerated Seldinger techniques. See *Peripheral Intravenous Catheter (PIVC)*.

Long-term. Referring to vascular access devices placed for anticipated need of greater than 1 month.

Luer. A standardized system of small-scale fluid fittings used for making leak-free connections between a male-taper fitting and its mating female fitting on all global intravenous (IV) medical devices and laboratory devices; includes, but is not limited to, syringe tips, IV administration sets, extension sets, manifolds, and stopcocks.

Lumen. The interior space of a tubular structure, such as a blood vessel or catheter.

M

Manifold. An accessory to an intravenous administration set that provides multiple stopcocks and regulates the directional flow of fluids for simultaneous/alternate infusion therapy.

Maximal sterile barrier protection. Equipment and clothing used to avoid exposure to pathogens, including sterile coverings for the clinicians and patient: mask,

gown, protective eyewear, cap, gloves, large or full body drapes, and towels.

Medical adhesive-related skin injury (MARS). Erythema or cutaneous abnormality (including occurrence of, but not limited to, vesicle, bulla, erosion, skin tear) that continues to be observable 30 minutes or more post adhesive removal. This definition is only used if it was specifically mentioned in the reference.

Medical waste (regulated). Includes contaminated sharps; liquid or semiliquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious material in a liquid or semiliquid state if compressed; items that are caked with dried blood or other potentially infectious materials and capable of releasing these materials during handling; and microbiological wastes containing blood or other potentially infectious materials.

Medication reconciliation. The process of collecting and documenting complete and accurate medication information for each patient, including all medications—prescribed, over-the-counter, and herbals/nutritional supplements—that the patient is currently taking.

Microaggregate blood filter. Filter that removes microaggregates (includes platelets, leukocytes, and fibrin that are present in stored blood) and reduces the occurrence of nonhemolytic febrile reactions.

Microorganism. Extremely small living body not perceptible to the naked eye.

Midline peripheral catheter (midline). Inserted into a peripheral vein of the upper arm via the basilic, cephalic, or brachial vein with the terminal tip located at the level of the axilla in children and adults; for neonates, in addition to arm veins, midline catheters may be inserted via a scalp vein with the distal tip located in the jugular vein above the clavicle or in the lower extremity with the distal tip located below the inguinal crease. See *Peripheral Intravenous Catheter (PIVC)*.

Milliosmoles (mOsm). One thousandth of an osmole; osmotic pressure equal to 1 thousandth of the molecular weight of a substance divided by the number of ions that the substance forms in a liter of solution.

Minimum inhibitory concentration (MIC). The lowest concentration of a drug that will inhibit bacterial growth.

Moderate/conscious sedation. Drug-induced depression of consciousness in which a patient is able to persistently respond to verbal commands or light tactile stimulation; interventions are not needed to maintain a patent airway, and the cardiorespiratory functions are sufficient and usually preserved.

Mottling score. Mottling score is estimated from 0–5 according to mottling over the knee and described as clinical evaluation of tissue perfusion.

Multidrug-resistant organism (MDRO). A microorganism, predominantly bacteria, resistant to 1 or more classes of

antimicrobial agents. MDROs include, but are not limited to, methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), and certain gram-negative bacilli that have important infection control implications.

N

Narcotic count. Process for periodically validating inventory of narcotics; may be blinded if those performing the count are unable to see the system automatic count totals but enter the number of actual products into the system for comparison and potential discrepancy recognition.

Near infrared (nIR) light technology. A device using near infrared light, a range of 700 to 1000 nanometers on the electromagnetic spectrum; works by either transilluminating the extremity and projecting the vessel image to a screen or by capturing an image of the superficial veins and reflecting it to the skin surface.

Needleless connector. A device that allows the connection of the male luer tip of a syringe or administration set directly to the hub of a vascular access device (VAD) or other injection sites on the infusion system without the use of needles; bidirectional fluid flow occurs within the device. Includes a variety of mechanisms (eg, mechanical valve, internal blunt cannula, pressure sensitive valve) categorized by how they function, although there are no established criteria for which devices fall into each group. All needleless connectors allow some fluid movement and blood reflux upon connection, disconnection, or both.

- **Anti-reflux.** Contains a 3-position pressure-activated silicone valve that opens and closes based on infusion pressure; a specific clamping sequence is not required.
- **Negative displacement.** Allows blood reflux into the VAD lumen upon disconnection due to movement of valve mechanism or withdrawal of the luer tip of a syringe or administration set. Use of the specific sequence of flush and clamp prior to disconnecting the syringe will minimize fluid movement.
- **Neutral.** Contains an internal mechanism designed to reduce blood reflux into the VAD lumen upon connection or disconnection. The sequence of flush then clamp prior to disconnecting the syringe may improve patency.
- **Positive displacement.** Allows blood reflux on connection and disconnection; a small amount of fluid is held inside the device that displaces intraluminal blood upon disconnection of the set or syringe. Use of the specific sequence of flush, disconnect, syringe, and then clamp the catheter will minimize this.

Needleless system. A device that does not use needles for (1) the collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (2) the administration of medication or solutions; or (3) any other procedure involving the potential for

occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

Neonate. Birth to 28 days of life; pertaining to the first 4 weeks of life.

Neuraxial anesthesia. Administration of medications into the intrathecal or epidural space to produce anesthesia or analgesia.

Noncritical equipment. Items that can come in contact with intact skin but not mucous membranes.

Nonelectronic flow-control device. Refers to both gravity infusions and use of mechanical pumps such as elastomeric/spring-based pumps. Gravity infusions control fluid flow rate by manual adjustment of components such as a roller clamp or flow regulator and require reliance on counting drops. It is affected by factors such as dislodgement of the components or distance between the solution container and the device and, therefore, is the least accurate.

Nonpermeable. Prevents passage of fluid or gases.

Nontunneled central vascular access device (CVAD). A type of CVAD for short-term use that is inserted percutaneously, usually via the axillary-subclavian, internal jugular, or femoral vein.

Nonvesicant. Solutions and medications that do not produce tissue damage when inadvertently delivered into subcutaneous tissue; a large volume of a nonvesicant can produce tissue damage through compartment syndrome but would not cause tissue destruction that leads to blistering and necrotic ulcer.

NRFit® connectors. Designed to reduce the risk of inadvertent misconnections by ensuring that neuraxial (ie, intraspinal) connections are incompatible with the connectors for unrelated delivery systems such as intravenous (IV) catheters, tracheostomy tubes, and catheters. NRFit connectors are 20% smaller in diameter, preventing medical devices meant for neuraxial administration from connecting to devices used for IV, enteral, and other therapies.

Nurse-controlled analgesia. Used for infants and children if they are too young, physically unable, or cognitively impaired and unable to use patient-controlled analgesia.

Nurse practice act. A law enacted by a jurisdiction (eg, state, province, country) that establishes the board of nursing and defines the qualifications of and scope of practice for registered nurses and licensed practical or vocational nurses.

O

Occlusion. Obstruction of a vascular access device lumen, preventing or limiting the ability to flush and/or administer solutions through a lumen or withdraw blood.

- **Complete occlusion.** Inability to administer solutions or withdraw blood from the central vascular access device (CVAD) lumen.

- **Partial occlusion.** Decreased ability to administer solutions and/or withdraw blood from the CVAD lumen.

- **Withdrawal occlusion.** Ability to infuse solutions with decreased ability or inability to obtain blood return.

Off-label use (extra-label use). The use of a marketed drug or device in a manner that is not included in the written directions for use and other written material that accompany the product as approved by the US Food and Drug Administration.

Older adult. Greater than 65 years of age, as defined by the American Geriatric Society.

Opioid-induced respiratory depression (OIRD). A combination of opioid-induced central respiratory depression (ie, decreased respiratory drive), sedation, and upper airway obstruction due to decreased supraglottic airway tone.

Osmolality. The characteristic of a solution determined by the ionic concentration of the dissolved substances per unit of solvent; measured in milliosmoles per liter.

Osmolarity. The number of osmotically active particles in a solution.

P

Palpable cord. A vein that is rigid and hard to the touch.

Palpation. Examination by application of the hands or fingers to the surface of the body to detect evidence of disease or abnormalities in the various organs; also used to assess location and quality of superficial peripheral veins.

Parenteral. Administered by any route other than the alimentary canal, such as the intravenous, subcutaneous, intramuscular, or mucosal route.

Parenteral nutrition (PN). The intravenous provision of nutritional needs for a patient who is unable to take appropriate amounts of food enterally; typical components include carbohydrates, proteins, and/or fats, as well as additives such as electrolytes, vitamins, and trace elements.

Paresthesia. Pain associated with nerve injury, including tingling, prickling, or shock-like sensations.

Particulate matter. Mobile undissolved particles, excluding gas bubbles unintentionally present in solutions. Sources include the environment (eg, dust, fibers), packaging material (eg, rubber, silicone), product-package interactions (eg, rubber, plastic), processes for manufacturing and dilution (eg, metal, glass), and the drug formulations and components (eg, drug precipitate, protein aggregation, undissolved material).

Passive disinfection. Use of a disinfectant-impregnated protective cap or covering to provide a constant physical barrier against contamination of the needleless connector septum between accesses; may also be used with the male luer end of the administration set when the set is disconnected between intermittent uses.

Passive leg raise test. The passive leg raising (PLR) test increases cardiac preload and allows the assessment of preload responsiveness of both ventricles.

Passive safety-engineered device. A device (eg, needle, catheter) that does not require additional steps to initiate the safety mechanism since it activates automatically during device use.

Pathogen. A microorganism or substance capable of producing disease.

Patient care setting. Where patient care is provided; may include hospital, outpatient or physician office setting, skilled nursing facility, assisted living facility, and the home.

Patient-controlled analgesia (PCA). A drug delivery system that dispenses a preset dose of a narcotic analgesia upon activation by the patient; most often used with intravenous infusion but may also be used with subcutaneous and epidural infusions.

Pediatric. Newborn to 21 years of age. (Note: the American Academy of Pediatrics states that pediatrics is actually the fetal period to 21 years of age; upper age limit may vary across countries); neonate refers to the first 28 days of life. See *Neonate*.

Percutaneous. Technique performed through the skin.

Peripheral. Pertaining to or situated at or near the periphery; situated away from a center or central structure.

Peripheral intravenous catheter (PIVC). A catheter that is inserted into and resides in veins of the periphery that includes all extremities, the external jugular vein, and scalp veins in neonates. PIVCs are inserted into superficial veins located just under the skin in the superficial tissue, as well as deep veins located under the muscle tissue. See *Short Peripheral Intravenous Catheter (Short PIVC)*, *Long Peripheral Intravenous Catheter (Long PIVC)*, and *Midline Catheter*.

Peripherally inserted central catheter (PICC). A catheter inserted through veins of the upper extremities in adults and children; for infants, may be inserted through veins of the scalp or lower extremity. The catheter tip is advanced to the superior vena cava, preferably at the cavoatrial junction (upper limb insertion), or inferior vena cava, above the diaphragm (lower limb insertion).

Personal protective equipment (PPE). The equipment worn to minimize exposure to a variety of hazards, including bloodborne pathogens; examples of PPE include items such as gloves, eye protection, gown, and face mask.

pH. The degree of acidity or alkalinity of a substance.

Phlebitis. Inflammation of a vein; may be accompanied by pain/tenderness, erythema, edema, purulence, and/or palpable venous cord; rated by a standard scale or definition.

Phlebotomy. Withdrawal of blood from a vein by direct venipuncture or via a vascular access device.

Physical Restraint. Physical, mechanical, or manual device that immobilizes or decreases the ability of the patient to move arms, legs, body, or head freely.

Pinch-off syndrome. A relatively rare but significant and often unrecognized complication; occurs when the central vascular access device enters the costoclavicular space medial to the subclavian vein and is positioned outside the lumen of the subclavian vein in the narrow area bounded by the clavicle, first rib, and costoclavicular ligament. Catheter compression causes intermittent or permanent catheter occlusion and, because of the “scissoring” effect of catheter compression between the bones, can result in catheter tearing, transection, and catheter embolism.

Policy. Written, nonnegotiable statement(s) that establish rules guiding the organization in the delivery of patient care.

Postthrombotic syndrome (PTS). A complication occurring after a venous thrombosis (typically a deep vein thrombosis [DVT]) in either lower or upper extremity characterized by pain, tenderness, swelling, and skin changes. Endothelial injury secondary to vascular access device (VAD) insertion is a potential source.

Pounds per square inch (psi). A measurement of pressure; 1 psi equals 50 mm Hg or 68 cm H₂O.

Power injectable. A device (eg, vascular access device, extension set) capable of withstanding injection pressure used for radiology procedures; an upper limit is usually 300 to 325 psi.

Practice guidelines. Provide direction in clinical care decisions based on the current state of knowledge about a disease state or therapy.

Preanalytic phase. The period of time before a body fluid specimen reaches the laboratory; includes obtaining, labeling, and transporting the specimen to the laboratory.

Precipitation. The act or process of a substance or drug in solution to settle in solid particles; most commonly caused by a change in pH.

Preservative-free. Contains no added substance capable of inhibiting bacterial growth. Free of any additive intended to extend the content, stability, or sterility of active ingredients, such as antioxidants, emulsifiers, or bacteriocides.

Priming volume. Amount of fluid required to fill the fluid pathway of the vascular access device, any add-on devices, and administration set.

Procedure. Written statement of a series of steps required to complete an action.

Product integrity. The condition of an intact, uncompromised product suitable for intended use.

Provider. A practitioner permitted by law and by the organization to provide care and services within the scope

of the practitioner license and consistent with individually assigned clinical responsibilities. These titles may include, but are not exclusive to, physician, nurse practitioner, clinical nurse specialist, and physician assistant.

Proximal. Closest to the center or midline of the body or trunk, nearer to the point of attachment; the opposite of distal.

Psychomotor. Characterizing behaviors that place primary emphasis on the various degrees of physical skills and dexterity as they relate to the preceding thought process.

Pulsatile flushing technique. Repetitive injection of short (eg, 1 mL) pushes followed by a brief pause for the purpose of creating turbulence within the vascular access device (VAD) lumen.

Purulent. Containing or producing pus.

Q

Quality improvement (QI). An ongoing, systematic approach that uses problem solving to improve quality outcomes or health care processes. This usually involves a cycle of planning, implementation, audit, and evaluation.

R

Radiofrequency sensing. Can be used for extravasation sensing; technologies base their operating principle on changes in electrical permittivity when the extravasation event occurs.

Radiopaque. Impenetrable to x-rays or other forms of radiation; detectable by radiographic examination.

Ready-to-administer. An injectable product containing the active drug in solution at the required concentration and volume, presented in the final container (syringe, infusion bag, or elastomeric device), and ready to be administered to the patient.

Reconstitute. The act of adding diluent to a powder to create a solution.

Refractory. When multiple evidence-based therapies have been used appropriately but have failed to reach treatment goals.

Restraint, physical. A manually applied method that immobilizes or reduces the ability of a patient to move arms, legs, or body.

Risk evaluation and mitigation strategies (REMS). A US Food and Drug Administration program for monitoring medications with a high potential for serious adverse effects. REMS applies only to specific prescription drugs but can apply to brand name or generic drugs. REMS focus on preventing, monitoring, and/or managing a specific serious risk by informing, educating, and/or reinforcing actions to reduce the frequency and/or severity of the event.

Risk management. Process that centers on identification, analysis, treatment, and evaluation of real and potential hazards.

Root cause analysis (RCA). The process for identifying basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event; focuses primarily on systems and processes, not individual performance; identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future or determines, after analysis, that no such improvement opportunities exist.

S

Safety-engineered device. Also known as Sharps with Engineered Sharps Injury Protections. A needle-free sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other solutions, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident. Used to prevent percutaneous injuries and blood exposure before, during, or after use.

Scope of practice. The roles, responsibilities, and functions that a qualified health professional is deemed competent to perform and allowed to undertake, in keeping with the terms of their professional license.

Sentinel event. See *Serious Adverse Event*.

Sepsis. The systemic response caused by the presence of infectious microorganisms or their toxins in the bloodstream.

Serious adverse event. Any unexpected, undesirable event, often resulting in death or serious physical injury that may or may not prolong hospitalization or require intervention to prevent permanent damage. When this is associated with the use of a medical product/medication in a patient, it should be reported to the US Food and Drug Administration.

Sharps. Objects in the health care setting that can be reasonably anticipated to penetrate the skin and to result in an exposure incident; including, but not limited to, needle devices, scalpels, lancets, broken glass, or broken capillary tubes.

Shedding. Particle release (solids) from an infusate container, administration set, or filter.

Short peripheral intravenous catheter (short PIVC). An over-the-needle catheter with a hollow metal stylet (needle) positioned inside the catheter; generally inserted in superficial veins. See *Peripheral Intravenous Catheter (PIVC)*.

Short-term. When used in reference to a vascular access device, a time frame of less than 1 month.

Simulation. A technique that produces a scenario, environment, or experiment meant to allow a learner to experience a clinical event as close to real as possible for purposes of learning or to acquire or refine a skill.

Site protection. Strategies used in addition to vascular access device (VAD) insertion site securement (may also be called secondary securement), including:

- Interventions/products used to reduce the risk of VAD dislodgement due to the pulling/tugging of the administration set
- Interventions/products (eg, VAD covers, mitts, vests) to protect/disguise the VAD from patient manipulation, such as with pediatric patients, those with cognitive impairment/confusion, and/or other risk factors for VAD misuse
- Strategies to prevent exposure of the VAD site to water or other contaminants.

Smart pump. Electronic infusion pump with imbedded computer software aimed at reducing drug dosing errors through the presence and use of a drug library.

Sorption. A complex process including both adsorption and absorption that varies greatly with components within the infusion container, the administration set, type of infusate, the flow rate of infusates, and the contact duration and conditions during storage, preparation, and administration.

- **Absorption.** Drug penetration inside of the infusion system.
- **Adsorption.** Interaction of the drug with the surface of the infusion container and/or administration set; results in patient receiving a smaller amount of the drug.

Standard. Authoritative statement enunciated and promulgated by the profession by which the quality of practice, service, or education can be judged.

Standard Precautions. The minimum infection prevention practices that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting where health care is delivered. These practices are designed to both protect health care providers from infection and prevent the spread of infection from patient to patient; includes hand hygiene; environmental cleaning and disinfection; injection and medication safety; use of appropriate personal protective equipment; minimizing potential exposures (eg, respiratory hygiene and cough etiquette); reprocessing of reusable medical equipment between each patient and when soiled.

Standard-ANTT. A combination of Standard Precautions and an approach of protecting Key-Parts and Key-Sites individually, using non-touch technique and Micro Critical Aseptic Fields within a General Aseptic Field. Used for clinical procedures where achieving asepsis and protecting Key-Parts and Key-Sites is straightforward and short in duration, such as vascular access device flushing and locking, administration set preparation and changes, intravenous medication administration, and simple wound care. In the event of Key-Parts or Key-Sites requiring direct touch, then sterile gloves must be used.

Sterile. Free from living organisms; this is not achievable in a general health care setting, due to the ever presence of microorganisms in the air environment.

Stylet. A sharp rigid metal hollow-bore object within a peripheral catheter designed to facilitate venipuncture and catheter insertion.

Stylet wire. A long stiffening wire within the catheter lumen that provides assistance advancing a vascular access device along the vein; may be multiple pieces welded together and is not intended for advancement into the vein alone, as it does not have an atraumatic tip.

Subcutaneous. Refers to the tissue located beneath the dermal layer of the skin.

Subcutaneous anchor securement system (SASS). A securement device that anchors the vascular access device in place via flexible feet/posts that are placed just beneath the skin; these act to stabilize the catheter right at the point of insertion. A separate dressing is placed over the SASS. The SASS does not need to be changed at regular intervals when the dressing is changed; it can remain in place if there are no associated complications.

Subcutaneous infusion. Administration of a medication into the subcutaneous layer of the skin (below the epidermis and dermal layers).

Substance use disorder. Can be diagnosed by criteria that specify a pattern of pathological behavior on a continuum: impaired control, social impairment, risky use, and pharmacological criteria.

Surgical-ANTT. A combination of Standard Precautions and an approach of protecting Key-Sites and Key-Parts collectively, using a sterile drape(s) and barrier precautions. Used for clinically invasive procedures where achieving asepsis and protecting Key-Parts and Key-Sites are difficult and/or procedures are long in duration, such as surgery or central vascular access device insertion.

Surrogate. Also referred to as legally authorized representative; someone who acts on behalf of the patient when the patient cannot participate in the decision-making process. Surrogates may be designated by the patient and know the patient's preferences or may be court appointed with or without this knowledge; without such knowledge, a surrogate is required to make decisions that are in the patient's best interest.

Surveillance. Active, systematic, ongoing observation of the occurrence and distribution of disease within a population and of the events or conditions that increase or decrease the risk of such disease occurrence.

T

Tackifier. A liquid adhesive used to increase the tack or the stickiness of a product.

Therapeutic phlebotomy. Removal of blood from the circulatory system via venipuncture or vascular access device to reduce a fraction of the patient's whole blood volume.

Thrombolytic agent. A pharmacological agent capable of lysing blood clots.

Thrombophlebitis. Inflammation of the vein in conjunction with formation of a blood clot (thrombus).

Thrombosis. The formation, development, or existence of a blood clot within the vascular system.

Tissue adhesive (TA). A medical-grade cyanoacrylate glue that can seal the insertion site and temporarily bond the catheter to the skin at the point of insertion and under the catheter hub. Depending on the chemical makeup, TA may be reapplied at each dressing change. Various formulations of TA for wound closure are commercially available, including first generation *N*-Butyl-2-cyanoacrylate (quick drying, rigid/brittle), second generation 2-octyl-cyanoacrylate (longer dry time, more flexible) and *N*-Butyl-2octyl cyanoacrylate formation (increased tensile strength and flexibility) with an additional indication for vascular access securement. Each TA formulation has varied properties, and the clinical decision to use should be based on research outcomes relative to the chosen product.

Transducer. A device that converts one form of energy to another.

Transfusion reaction. Complication of blood transfusion where there is an immune response against the transfused blood cells or other components of the transfusion.

Transient mechanical phlebitis. Phlebitis associated with the insertion of a midline or a peripherally inserted central catheter (PICC); may be due to rapid catheter insertion. Symptoms occur soon after insertion and often resolve. Catheter removal is indicated if symptoms do not resolve 24 hours postinsertion.

Transillumination. Shining a light at a specific body part (ie, extremity) to identify structures beneath the skin.

Transmission-Based Precautions. The use of Airborne, Droplet, and/or Contact Precautions, which are implemented in addition to Standard Precautions when strategies beyond Standard Precautions are required to reduce the risk for transmission of infectious agents.

Transparent semipermeable membrane (TSM). A sterile air-permeable dressing that allows visual inspection of the skin surface beneath it; water resistant.

Tunneled, cuffed catheter. A central vascular access device with a segment of the catheter lying in a subcutaneous tunnel with the presence of a cuff into which the subcutaneous tissue grows to offer security for the catheter;

indicates that the skin exit site and vein entry site are separated by the subcutaneous tunnel.

Tunneled, noncuffed central venous catheter. A non-cuffed catheter that is inserted into a large vein of the neck or groin. The catheter is traditionally tunneled through the subcutaneous tissue to an exit point on the anterior chest wall or mid-thigh. In comparison to a tunneled cuffed catheter, this catheter is reliant on external securement for anchorage.

U

Ultrasound. A device using sound waves at frequencies greater than the limit of human hearing; sound waves directed into human tissue to identify and display physical structures on a screen.

Umbilical catheter. A catheter that is inserted into the umbilical artery or vein at the umbilicus.

Unlicensed assistive personnel (UAP). A category of health care individuals who work as assistants to and under the direction of licensed health care professionals, including both nursing and medical assistants.

V

Vascular access device (VAD). Catheter, tube, or device inserted into the vascular system, including veins, arteries, and bone marrow.

Vascular access specialty team (VAST). See Infusion Team/Vascular Access Specialty Team (VAST).

Vascular visualization technology. Device that employs the use of sound or light waves to allow for the location and identification of blood vessels and guide device insertion.

Vasopressor therapy. Medications that promote vasoconstriction with potential for positive inotropic activity. Examples include, but are not limited to, norepinephrine, epinephrine, dopamine, dobutamine, vasopressin, terlipressin, phenylephrine, angiotensin II.

Vesicant. An agent capable of causing tissue damage when it escapes from the intended vascular pathway into surrounding tissue.

Visible light devices. A device using light from 400 to 700 nanometers, or the middle of the electromagnetic spectrum, to transilluminate an extremity to locate superficial veins.

The *Infusion Therapy Standards of Practice* (the *Standards*) is a significant work impacting clinical practice across the globe, with the goal of safe, high-quality patient care. The influence of the *Standards* on infusion practice is unparalleled. The *Standards* have been published in several languages over the years, are widely cited in clinical articles and books, and are used to develop and support clinical procedures in many published manuals. With the 2024 edition, the process evolved from an every 5-year to an every 3-year cycle. Due to the growing research base, a more frequent update was clearly needed.

In this edition, three new standards, Vasopressor Administration, Drug Diversion in Infusion Therapy, and Home Infusion Therapy, were added. With a trend toward an increase in peripheral vesicant infusions and the recognized risk for extravasation, it became important to include recommendations for vascular access for vasopressor administration. Similarly, it seemed prudent to address drug diversion in infusion therapy and to provide practice recommendations to optimize patient safety during procurement, dispensing, handling, and administration of controlled substances. Home infusion therapy continues to grow, with more studies to guide practice. With home infusion therapy, patients or their caregivers must be educated to safely live with a vascular access device and, in many cases, learn how to self-administer their infusions and minimize or completely avoid hospitalization. The new standard provides guidance for safe transitioning of patients to home infusion, to safe practices for a variety of home infusion therapies, patient education, and ongoing monitoring.

As I reflect on my involvement with the Infusion Nurses Society (INS), and as I finish my work with the Standards of Practice Committee, I am honored to write this *Afterword* after a 20-year journey participating in the development of the *Standards* and to share a bit of my personal journey. I began as a committee member for the 2006 *Standards*, as the chair for the 2011, 2016, and 2021 editions, and finally, as the co-chair for the 2024 edition.

I am fortunate to have an amazing career as a nurse working in post-surgical care, a critical care nurse and educator, and for the majority of my years, as a home care clinical nurse specialist (CNS), primarily focusing on home infusion therapy. As I transitioned from critical care to home care, literally “trying” out home care while I still worked in the hospital, I ultimately fell in love with home care. It was during that time of transition in the mid-to-late 1980s that great growth in home health care occurred due to a number of factors, including changes in United States (US) hospital reimbursement regulations. It was also the time of the acquired immunodeficiency syndrome (AIDS) epidemic, and complex home infusions were not uncommon in my practice. Based upon my acute care background and desire to provide care for those home care patients

requiring a variety of infusions, I was given a position to develop a home infusion therapy program and have never looked back!

So, here began my history with INS and the *Standards*. As a CNS working with our small home infusion pharmacy, I reviewed the literature, spending time in the hospital library (no online searches then!), and looked for resources to help me. The *Standards* became an essential reference. Notably, in 1984, INS (then the National Intravenous Therapy Association [NITA]) published *Home IV Therapy Standards*, a one-page document. As I wrote policies and procedures and developed competency assessment tools for my home care organization, the *Standards* was my essential tool and reference. I published my first book in 1994 (*High Tech Home Care*), using the *Standards* as an important reference.

As a CNS focused on best practice, I wanted to become more involved beyond my local work; specifically, I wanted to be part of the *Standards* work! Expressing this desire to Mary Alexander, INS’ CEO at the time, she invited me to become a member of the 2006 Standards development committee and, ultimately, to chair the committee starting in 2011.

After publication of the 2006 *Standards*, I was provided the opportunity to develop a column for the *Journal of Infusion Nursing*, entitled “Speaking of Standards,” providing a focused discussion of some of the standards that generated the most questions. As this feature ended after 2 years, the work of the next committee began. With the 2006 edition, our committee reviewed the literature and added references to support the practice criteria. However, it did not qualify as an “evidence-based” document. As I transitioned to the chairperson for the 2011 *Standards*, my personal goal with our committee was to develop the *Standards* as an evidence-based document. Mary Hagle, a nurse researcher, was a central figure in helping our committee develop the content found in the “Strength of the Body of Evidence” and to be our leader in evaluating research identified in our literature reviews. From that point forward, instead of just listing our references, we have appraised the types and quality of the cited literature and rated the body of evidence for each practice criterion. As the work continued through development of the 2016 *Standards*, the level of global interest in the work afforded me and others increased opportunities to present our work beyond the United States. My opportunity to share the *Standards*, have dialogues with many clinicians, and understand local practices and resources was invaluable. Traveling to China and countries in Latin America, the Middle East, Africa, and Europe was a highlight of my career.

So, as I began the planning process with Mary Alexander for the 2021 *Standards*, it was clearly important to grow our committee to include more members beyond nurses from the United States. Members representing Canada, the United Kingdom, and Australia joined us. We continued in

2024 with global membership and added new non-nurse members from disciplines representing infection prevention and pharmacy.

When I served as INS president from 2007 to 2008, my presidential theme was “Advancing the Science of Infusion Therapy.” I am honored that I have played a role in continuing this theme beyond my time as president, with the help of the committee members and the work of the incredible researchers who ask the important questions and do the research. I congratulate Barb Nickel,

who could not be a better choice in continuing the leadership of the *Standards*. I offer my sincere thanks to Mary Alexander for giving me the opportunity to chair the *Standards*, to all the committee members over the years for the dedication of their time and expertise, to all of the peer reviewers, the INS membership, and all clinicians who have used this work to enhance their practice and deliver safe infusion care.

Lisa A. Gorski, MS, RN, HHCNS-BC, CRNI®, FAAN



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Intravenous therapy device labeling in Intensive Care Units: an integrative review

Rotulagem de dispositivos de terapia intravenosa em Unidades de Terapia Intensiva: revisão integrativa
Etiquetado de dispositivos de terapia intravenosa en Unidades de Cuidados Intensivos: revisión integradora

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ABSTRACT

Objectives: to synthesize the evidence on intravenous device labeling used to identify medications administered to patients in Intensive Care Units, with a view to preventing medication errors. **Methods:** an integrative review, in the LILACS, IBECs, Embase, MEDLINE, Scopus, Web of Science and CINAHL databases, from November to December 2021, using descriptors and selection criteria. Data were collected in 11 articles and subsequently classified, summarized and aggregated. **Results:** pre-designed labels, with pre-defined colors and information, help to prevent medication identification errors. There is still a lack of standardization in the practice of labeling syringes, intravenous lines, infusion pumps and saline solution bags. There are errors related to the lack of labeling devices or to their performance with incomplete information. **Conclusions:** device labeling is a barrier to defending the medication system safety and should be standardized.

Descriptors: Infusions, Intravenous; Drug Labeling; Critical Care; Patient Safety; Nursing.

RESUMO

Objetivos: sintetizar as evidências sobre a rotulagem de dispositivos intravenosos utilizada para a identificação de medicamentos administrados nos pacientes em Unidades de Terapia Intensiva, com vistas à prevenção dos erros de medicação. **Métodos:** revisão integrativa, nas bases de dados LILACS, IBECs, Embase, MEDLINE, Scopus, Web of Science e CINAHL, no período de novembro-dezembro de 2021, com uso de descritores e emprego de critérios de seleção. Os dados foram coletados em 11 artigos e, posteriormente, classificados, sumarizados e agregados. **Resultados:** rótulos pré-desenhados, com cores e informações pré-definidas contribuem para prevenir os erros de identificação dos medicamentos. Persiste a falta de padronização da prática de rotulagem em seringas, linhas intravenosas, bomba infusoras e bolsas de soro. Há erros relacionados à ausência de rotulagem dos dispositivos ou à sua realização com informações incompletas. **Conclusões:** a rotulagem dos dispositivos é uma barreira para a defesa da segurança do sistema de medicação, devendo ser padronizada.

Descritores: Infusões Intravenosas; Rotulagem de Medicamentos; Cuidados Críticos; Segurança do Paciente; Enfermagem.

RESUMEN

Objetivos: sintetizar las evidencias sobre el etiquetado de dispositivos intravenosos utilizados para identificar medicamentos administrados a pacientes en Unidades de Cuidados Intensivos, con el objetivo de prevenir errores de medicación. **Métodos:** revisión integradora, en las bases de datos LILACS, IBECs, Embase, MEDLINE, Scopus, Web of Science y CINAHL, de noviembre a diciembre de 2021, utilizando descriptores y criterios de selección. Los datos fueron recolectados en 11 artículos y posteriormente clasificados, resumidos y agregados. **Resultados:** etiquetas prediseñadas, con colores e información predefinidos, ayudan a prevenir errores de identificación de medicamentos. Todavía hay una falta de estandarización en la práctica de etiquetado de jeringas, líneas intravenosas, bombas de infusión y bolsas de suero. Hay errores relacionados con la falta de etiquetado de los dispositivos o con su realización con información incompleta. **Conclusiones:** el etiquetado de los dispositivos es una barrera para defender la seguridad del sistema de medicamentos y debe ser estandarizado.

Descriptores: Infusiones Intravenosas; Etiquetado de Medicamentos; Cuidados Críticos; Seguridad del Paciente; Enfermería.

INTRODUCTION

Among healthcare-associated incidents, those involving medication therapy are common in institutions, likely to occur at all stages of the medication system, from prescribing, dispensing, preparing and administering the medication to monitoring, with possibilities of serious harm and even death of patients⁽¹⁻²⁾.

These medication incidents that cause harm to patients are called adverse medication events, which have medication errors as one of their causes⁽¹⁾. Medication errors are any preventable events that can cause or induce medication misuse and even harm while the medication is under the control of the patient, health care provider, or consumer⁽³⁾.

In 2017, the World Health Organization reinforced its concern about medication incidents with the launch of the 3rd Global Patient Safety Challenge – Medication Without Harm, whose goal is to reduce serious and preventable medication-related harm by 50% by the year from 2022⁽¹⁾.

Medication errors are considered a public health concern, being present in various care scenarios⁽⁴⁻⁶⁾. In the context of Intensive Care Units (ICUs), in particular, such a problem may be even greater, since they are units that receive patients with acute and severe clinical situations⁽⁷⁾. They are patients who depend on multiple medications administered concomitantly aiming at maintaining the hemodynamic balance of their clinical status, especially through intravenous (IV) medication administration. Therefore, due to the critical nature of their diseases and the great need for medication interventions, the occurrence of medication errors in this group can have very serious consequences⁽⁷⁾.

In the specificity of errors involving IV medications administered to ICU patients, we highlight, in this research, those related to identification, which involve the identification of syringes, infusion pumps, saline solution bags, IV routes and lines. The absence, incompleteness and/or misidentification of these devices can cause changes in the infused dosage, change in medication administration, change in IV bolus solution, among other possibilities, with potential risks to patient safety.

An example of these errors is seen in the cases of failures in the identification of routes and IV lines. Multiple IV medications given to critically ill patients lead to more IV bags, infusion pumps and IV lines. This situation causes visual disarray and intertwining of IV lines, making it difficult to quickly and correctly identify what is being infused, especially in situations of complications. Thus, the chances of errors in the handling of IV lines increase, an aspect that has been pointed out by the literature⁽⁸⁻⁹⁾.

A study conducted with 40 nurses in a simulated ICU setting aimed to identify the risks associated with multiple IV infusions and the ability to administer them safely. Among the findings, 7.7% of errors were identified in the screening of IV lines during the identification of infusions⁽⁸⁾.

Research reviewed the reporting reports of medication errors in Pennsylvania from 2004 to 2013. In this analysis, 907 errors related to IV-line handling were identified. The most common mistakes were the inclusion of setting infusion rates, changes when handling disordered IV lines, and IV lines not connected to patients. Potentially dangerous medications were involved in 71% of errors associated with IV lines, and heparin was the most

commonly found medication, an error that can lead patients to death⁽⁹⁾.

Given this scenario, identification errors can be minimized with the adoption of barriers that contribute to the medication and route identification, such as label/labeling use. The term label is defined as the display of written, printed, or graphic material in a container. Labeling is defined as all labels and other printed, written or graphic materials on any article or any container⁽¹⁰⁾.

The term medication labeling is linked to using written, printed or graphic materials in a medication container or packaging, and may include effects, duration, dose, routes, warnings, among other relevant information⁽¹¹⁾. Thus, it is understood in this research that medication labeling refers to label content and type of material used in devices used to administer a particular medication, such as syringes, saline solution bags, bottles, infusion pumps and IV lines.

Device labeling emerged in the area of anesthesia, created by the International Society of Anesthesia and, currently, different shapes and colors associated with the medication class are used, in addition to visibly adequate texts and sources⁽¹²⁾.

The International Organization for Standardization (ISO) 26825 publication was considered a milestone regarding labeling practices, as it established guidelines for standardizing this care. However, the publication of this standard is aimed at the anesthetic area and the syringe device. Although its use can be extended to other areas, such as intensive care, and to other devices, this is not a practice validated by the regulatory agencies themselves. Thus, labeling practices vary throughout the world and are commonly established by the hospital and/or professional institution itself, which impacts the way medications are identified in their devices⁽¹³⁻¹⁴⁾.

In Brazil, the recommendations regarding labeling refer to medication bottles⁽¹⁵⁾, however, in the case of lines IV, the researchers' practical experience shows that these are still frequently identified with handwritten, non-standardized adhesive tapes, with differences according to institutional policies.

Based on the above, it is assumed that labeling has the potential to promote numerous benefits for the team and patients, such as: rapid and correct identification of IV infusion; reduced connection errors between syringes and IV lines; and signaling of an exclusive route for medications considered to be of high risk, in order to avoid handling or performing inappropriate flushing. Given the need to understand how labeling has been used in ICU settings, with a view to thinking about strategies for the prevention of medication errors that can cause irreversible damage to patients, this review is justified.

OBJECTIVES

To synthesize the evidence on intravenous device labeling used to identify medications administered to patients in Intensive Care Units, with a view to preventing medication errors.

METHODS

Study design

This is an integrative literature review, a research method that comprises the search, critical assessment and synthesis of relevant research on a given topic⁽¹⁶⁾. The methodological approach adopted

for developing this review was composed of six phases⁽¹⁶⁾, namely: theme identification and hypothesis or research question selection; establishment of inclusion and exclusion criteria for studies; definition of the information that would be extracted from the included studies/study categorization; assessment of studies included in the integrative review; interpretation of results; and review report. The PRISMA tool was used to support the presentation of this review.

Methodological procedures

After identifying the focus theme of this review, in the first phase of the method, the review question, the descriptors and the bases that served as a source of search for scientific articles were defined. The guiding question was structured through the mnemonic strategy PCC (Problem, Concept and Context), proposed by Joanna Briggs Institute⁽¹⁷⁾, in which: P (medication errors); C (medication labeling); C (critical care), which gave rise to the following question: what is the evidence on labeling IV therapy devices for medication identification and prevention of medication errors in the ICU? This question guided the choice of descriptors and keywords referred to in each language (Portuguese, English and Spanish), which were defined as shown in Chart 1.

The chosen databases were Latin American and Caribbean Literature (LILACS), National Library of Medicine (MEDLINE via PubMed), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Spanish Bibliographic Index of Health Sciences (IBECS), SciVerse Scopus (Scopus), Embase and Web of Science. The data search was carried out from November 1 to December 31, 2021, through online and direct access to each database via the CAPES portal.

Search strategies in databases that had vocabulary control, such as LILACS, MEDLINE, CINAHL and Embase, composed a cross of indexed and standardized descriptors in each base, plus additional keywords customized for the target language. In the IBECS, Scopus and Web of Science databases, due to the fact that the descriptors applied in the other databases are not standardized for these, it was decided to carry out the crossings using only keywords already standardized in their indexes, which were chosen according to the PCC strategy adopted.

In compliance with the PRISMA tool recommendation, Chart 2 details the strategy of crossing the terms used in one of the databases (MEDLINE), as an example of the methodological procedures adopted to capture the articles in the research.

The second phase was to outline the criteria for selecting the research corpus and its application in the research process. Thus, the following inclusion criteria were adopted: scientific articles, results of primary studies; published in English, Portuguese, or Spanish; period from 2008 to 2021, time frame established by the start of publication of guidelines on labeling of devices IV; full text available in selected databases; refer to labeling IV devices in ICU settings. Articles that did not establish links with patient safety were excluded.

In the selection process, after crossing the descriptors and keywords in each chosen base, initial filters of full text, article design and language were applied. Then, with the help of Mendeley, duplicate references were excluded. After this step, the articles found were first submitted to an exploratory reading of title and/or abstract. Those that did not comply with the theme were pre-selected for the reading phase in full. In the full text assessment,

articles were assessed regarding their eligibility considering the answer to the research question. This phase of article selection was carried out by two researchers, with disagreements about the final inclusion of the article being decided jointly.

Chart 1 - Descriptors adopted to carry out search strategies

Descriptors			
Type	Problem	Concept	Context
DeCS	"Segurança do Paciente" OR "Prevenção de Acidentes" OR "Erros Médicos" OR "Erros de Medicação"	"Rotulagem de Medicamentos"	"Cuidados Críticos" OR "Enfermagem de Cuidados Críticos"
MeSH	"Patient Safety" OR "Accident Prevention" OR "Medical Errors" OR "Medication Errors"	"Drug Labeling"	"Critical Care" OR "Critical Care Nursing"
CINAHL Subject Headings	"Patient Safety" OR "Adverse Drug Event" OR "Medication Errors" OR "Health Care Errors" OR "Treatment Errors"	"Drug Labeling" OR "Product Labeling"	"Critical Care" OR "Critical Care Nursing" OR "Intensive Care Units"
Emtree	'Patient safety'/ de OR 'Accident Prevention'/de OR 'Medical Error'/de OR 'Medication Error'/ de OR 'Potentially Inappropriate Medication'/de	'Drug Labeling'/ de	'Intensive Care'/de OR 'Intensive Care Nursing'/de

Chart 2 - Example of search strategy applied in the MEDLINE database

("Patient Safety"[MeSH Terms] OR "Accident Prevention"[MeSH Terms] OR "Medical Errors"[MeSH Terms] OR "Medication Errors"[MeSH Terms] OR safety[Title/Abstract] OR error[Title/Abstract] OR errors[Title/Abstract] OR "adverse event"[Title/Abstract] OR "adverse events"[Title/Abstract]) AND ("Drug Labeling"[MeSH Terms] OR (label[Title/Abstract] OR labels[Title/Abstract] OR labeling[Title/Abstract] OR labelling[Title/Abstract] OR sticker[Title/Abstract] OR stickers[Title/Abstract] OR adhesive[Title/Abstract] OR adhesives[Title/Abstract]) AND (drugs[Title/Abstract] OR drug[Title/Abstract] OR medication[Title/Abstract] OR medications[Title/Abstract] OR medicines[Title/Abstract] OR medicine[Title/Abstract])) AND ("Critical Care"[MeSH Terms] OR "Critical Care Nursing"[MeSH Terms] OR "intensive care"[Title/Abstract] OR "intensive unit"[Title/Abstract] OR "critical care"[Title/Abstract] OR "critical unit"[Title/Abstract])

Dara collection, organization and analysis

Data collection in the articles corresponded to the third step of the method, which was based on an instrument previously prepared by the authors that contained the information defined for data extraction, such as identification of author and article, objective, methodological characteristics and results, in addition to a section for assessment regarding clarity and scope in relation to the study theme. These data, after collected, were summarized in a table that gathers the main information related to the research question. The selected studies received the letter "S", for Study, followed by the Arabic number.

In the fourth phase, the critical analysis of included studies took place, taking into account the problem and the research

question outlined. Thus, the previously organized data were categorized into evidence synthesis units, in which the data were aggregated and the desired synthesis of knowledge was obtained. Such synthesis units make it possible to apprehend evidence of IV device labeling practice by professionals in intensive care, their links with patient safety, the types/characteristics of labels and their effects on the prevention of medication errors.

After presenting the results regarding this synthesis, they were interpreted in the fifth phase, considering the existing literature on the subject and the concepts that support patient safety, which resulted in the final product of this integrative review, the sixth phase of the method.

RESULTS

This study consisted of a sample of 11 articles. Figure 1 shows the article selection flowchart produced by the authors. Regarding the origin of scientific productions, 27% of studies (three articles) were developed in Canada and 27% in Brazil. The other countries had one article each: Germany (9%), Australia (9%), United Kingdom (9%), United States (9%) and Malaysia (9%). Regarding the year of publication, three articles (27%) were published in 2016, followed by 2019, 2012 and 2008, with two articles published in each of these years (18%). Finally, there was only one article (9%) for each of the following years: 2018 and 2014.

The selected articles were organized in Chart 3, which presents the synthesis of the relevant findings for the study.

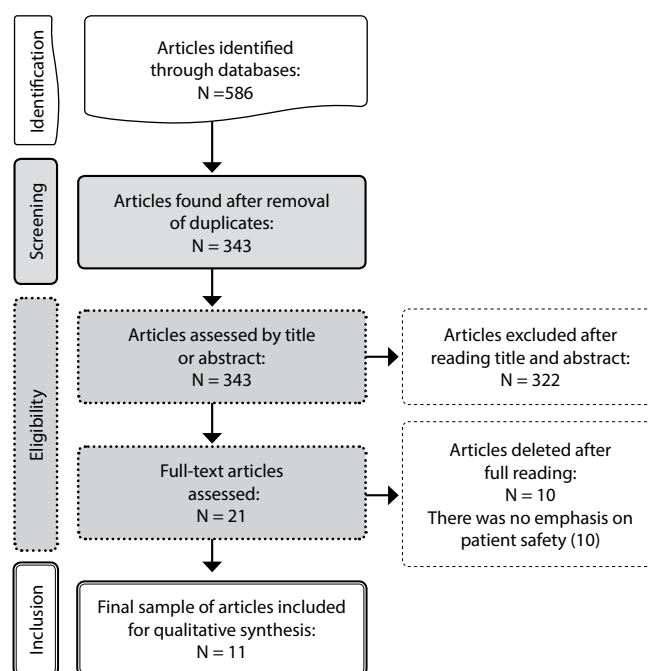


Figure 1 - Article selection flowchart

Chart 3 - Synthesis of selected articles on intravenous device labeling

	Title/country/year	Objective	Design	Conclusion
S1 ⁽¹³⁾	<i>Avaliação da rotulagem com código de cores para identificação de medicamentos intravenosos</i> Brazil/2019	Analyze the opinion of nursing professionals about the design, practicality of use and usefulness of color-coded labeling in a pediatric ICU.	Cross-sectional, quantitative Total number of participants: 42	The labeling technology was considered appropriate for the design and practicality for all devices, as well as useful in preventing medication errors, reducing the average time developing labeling tasks.
S2 ⁽¹⁸⁾	Untangling Infusion Confusion: a comparative evaluation of interventions in a simulated intensive care setting Canada/2019	Assess the impact of interventions performed by participants in four different conditions in a simulated ICU scenario: current practice; using IV-line labels and infusion organizers; with infusion pump; and with an infusion route lighting system.	Experimental, quantitative Each participant should perform two tasks in each condition: correctly identify and disconnect an infusion. Total number of participants: 40	Using IV-line labels and infusion organizers may increase accuracy and efficacy in the correct identification of IV medication infusion.
S3 ⁽¹²⁾	Standardized drug labelling in intensive care: results of an international survey among ESICM members USA/2009	Compare a color-coded label for high-risk medications with the current labeling practice in a simulated ICU scenario.	Quasi-experimental, quantitative Total number of participants: 61	Using color code improved identifying bags and IV lines, facilitated the identification of errors and decreased the average time in tasks. The task of color-coding the syringe did not show a significant difference when compared to the control scenario, as participants reported difficulty in handling syringe labels.
S4 ⁽¹⁹⁾	Standardized medication labelling in intensive care: results of an international survey among ESICM members Germany/2012	Investigate whether standardized medication syringe labeling is used in ICUs, whether these standards are similar in other countries, and whether intensivists expect standardized medication syringe labeling to be provided by the pharmaceutical industry.	Survey type, multinational, quantitative Total number of participants: 482	The adoption of standardized syringe labeling in terms of color, design and structure is still lacking among many ICUs, leading to variability in labeling policies between sectors within the same hospital and between hospitals in the same region. This failure can induce professionals to misidentify medications.

To be continued

Chart 3

	Title/country/year	Objective	Design	Conclusion
S5 ⁽¹⁴⁾	Multiple Intravenous Infusions Phase 2a: Ontario Survey Canada/2014	Investigate practices or policies that can help identify and prevent risks in patient safety.	Prospective, quantitative study Total number of participants: 64	Inconsistencies between policies and practices were found in some units. It was concluded that these non-conformities in label use can lead to erroneous handling of continuous infusions, erroneous disconnection of infusion, difficulty in administering medications through IV lines in the scenario of clinical emergencies.
S6 ⁽²⁰⁾	Variability of intravenous medication preparation in Australian and New Zealand Intensive Care Units Australia/2016	Examine variability in the preparation of continuous infusion medications.	Survey-type study, quantitative Participants: 40	There was little variability in device labeling among the investigated ICUs. Labeling, whether for syringes or medication bags, is color-coded and the medication name is handwritten.
S7 ⁽²¹⁾	Variability in the concentrations of intravenous medication infusions prepared in a critical care unit The United Kingdom/2008	Check if there is a relationship between syringe label quality and medication preparation.	Audit study N=149 syringes The discarded syringe labels received a score on a scale of 11 points for quality, as well as the analysis of the concentration of residual solutions present in the syringes.	Better labeled syringes were more likely to contain the medication at the correct concentration.
S8 ⁽²²⁾	Errors associated with IV infusions in critical care Canada/2012	Determine the most frequent type of error with IV medications.	Observational, prospective, quantitative study N=1,882 infusions	Incomplete labeling of IV lines was the most common error and posed a risk to patient safety.
S9 ⁽²³⁾	An investigation of errors: the preparation and administration of parenteral medications in an intensive care unit of a tertiary teaching hospital in Malaysia Malaysia/2015	Investigate type, incidence and factors related to errors with IV medications.	Prospective observational study N= 122 IV medications prepared by 39 nurses	Not labeling the syringe is supposed to be an indicator for medication preparation failure, with more chances of dose errors.
S10 ⁽²⁴⁾	<i>Erros no preparo de medicação intravenosa em uma unidade de terapia intensiva neonatal</i> Brazil/2018	Analyze the occurrence of errors in IV medication preparation in the neonatal ICU.	Observational, quantitative study N= 70 medication doses	Labeling has not been commonly used in care practice.
S11 ⁽²⁵⁾	<i>Utilização de barreiras de segurança no preparo de drogas vasoativas e sedativos/analgésicos em terapia intensiva pediátrica</i> Brazil/2018	Analyze safety barrier use in vasoactive medication and sedative/analgesic preparation in a pediatric ICU.	Observational, quantitative study N=17 professionals in 204 observations on medication preparation	Labeling practice has been carried out incompletely.

The synthesis constructed after the aggregation of the selected research results indicated that the evidence on IV device labeling was organized into three units.

Label types and effects on prevention of medication errors in intensive care

The data from this synthesis unit provide indications of the potential benefits of the characteristics of labels for IV lines, syringes, infusion pumps and IV bags in preventing medication errors. Among the impacts of using labeling evidenced in the studies, in S1⁽¹³⁾ and S2⁽¹⁸⁾, using color coding for IV lines

helped to distinguish which medications were infused, increasing effectiveness in correctly identifying medication infusion and providing greater ease in handling multiple infusion pumps and lines. Using color code also improved the identification of bags, reducing the average time developing labeling tasks, facilitating the identification of errors and reducing the average time of tasks in general (S1⁽¹³⁾, S3⁽¹²⁾).

Moreover, in S2⁽¹⁸⁾, participants who used electronic medication identification through the medication library of infusion pumps required more time to handle IV lines when compared to participants who handled pumps in common use, in association with using labels on IV lines.

Regarding the characteristics of label types, it is noteworthy that, in S1⁽¹³⁾ and S3⁽¹²⁾, the labels were differentiated by color codes according to the pharmacological class, according to the ISO 26825 standard, being used for IV-line syringes, infusion pumps and saline solution bags. In S1⁽¹³⁾, writing the medication name was differentiated using CAPITAL LETTER when names were similar. Specific labels for potentially dangerous medications have also been standardized with white background and red letters. In both S1⁽¹³⁾ and S3⁽¹²⁾, the label was printed with the medication name, and the other information was filled in manually.

In S2⁽¹⁸⁾, the IV-line label did not use colors for pharmacological classes, but used a white background in its manufacture. The label was adhesive and printed with the medication name, with visualization on both sides of the device, and fixation occurred 8 cm below the continuous infusion pumps and at the end of each IV line.

In S7⁽²¹⁾, discarded medication labels were analyzed (midazolam, insulin, magnesium, norepinephrine), measuring the concentration of residual solutions present in the syringes. The syringe label should contain the medication name, dose, concentration, diluent, patient name and location, initials of the person who prepared it, initials, day and time. Of 149 syringes, 61 were correctly labeled; 51% of labels did not have the medication concentration; and 47.6% had no information about the diluent. From the analysis of the 149 discarded syringes, the authors found that the best labeled syringes were more likely to contain the medication at the correct concentration. Magnesium syringes were the least likely to be labeled correctly, and insulin syringes were the most correctly labeled.

In S9⁽²³⁾, the results were similar to those of S7⁽²¹⁾: in 15% of the doses observed, the syringes were not labeled correctly. The syringe label should contain the medication name and dose information. Poorly labeled syringes had more errors per dose (1.9 times more) when compared to well-labeled syringes (1.1 times). The authors attributed these rates to the absence of a specific label for the syringe, since, in the scenario studied, there were only pre-printed labels for bags.

Medication identification errors in labeling intravenous devices by professionals in the Intensive Care Unit

It was found that, in ICU settings, professionals make medication errors related to their labeling practice, when they do not label a device or when they label it incompletely, without identifying the medication route, concentration, dilution, name. These situations were considered in the studies as medication errors.

In S10⁽²⁴⁾, of 70 doses observed that were prepared by nursing professionals, 65.7% did not receive any label on the devices in which they were inserted. Among those containing the label, only 11.4% were complete. This absence of information filled out by professionals on labels was a practice commonly observed in other studies, such as S5⁽¹⁴⁾, S8⁽²²⁾ and S11⁽²⁵⁾.

In S11⁽²⁵⁾, for instance, of the 204 medications administered by saline solution bags, 12.2% were not labeled by professionals. Identification with patients' full name was present in only 3.4% of labels; 99.4% of devices were labeled without a route description; the label was fixed on only 17.3% of medications and, even so, there was no compliance regarding the fixation place.

These results were in line with those obtained in S5⁽¹⁴⁾ and S8⁽²²⁾. In S8⁽²²⁾, 5,641 errors were identified. Incomplete labeling of IV lines comprised 31.5% of all errors, and incorrect labeling, 26.8%, representing a risk to patient safety. Discrepancies in labeling IV lines were more common during day shifts. Finally, in S5⁽¹⁴⁾, 95% of participants reported not performing IV-line labeling. There were disagreements about how these labels should be filled and exchanged. Some participants reported that some labels were too small for use.

Variability in labeling practice for the identification of devices in the Intensive Care Unit

Overall, there was great variability in studies regarding the label structure, which could be printed labels (S2⁽¹⁸⁾ and S5⁽¹⁴⁾), with information related to the previously printed medication; preprinted (S1⁽¹³⁾, S3⁽¹²⁾, S5⁽¹⁴⁾ and S11⁽²⁵⁾), previously printed content, with space to fill in other information manually; and completion only handwritten (S5⁽¹⁴⁾ and S6⁽²⁰⁾).

As for the label content for IV devices, the information that appeared most frequently was the medication name in seven studies and the dose in three studies. Labels that contained more information were the syringes and saline solution bags, mainly the medication name, dose, concentration, diluent, patient name and location, initials of the person who prepared it, initials, day and time. IV line and infusion pump labels presented less information, with emphasis on the medication name and route (central or peripheral), in the case of the lines. Infusion pump labels were found only in two articles, containing the medication name, infusion dose/volume and color related to the medication's therapeutic class according to ISO 26825⁽¹³⁻¹⁴⁾.

Regarding the evidence about lack of standardization, in S5⁽¹⁴⁾, 29.6% of participants mentioned that there is no standard practice where they work in relation to IV-line labeling. This result was repeated in S4⁽¹⁹⁾ in relation to syringes, when only 39% reported that standardized medication labeling on the syringe was used in the ICU where they work and 30% of participants reported using ISO 26825 (in its original form). In S6⁽²⁰⁾, there was a lower degree of variability in labeling practice among the ICUs of the institutions studied in Australia and New Zealand, particularly for syringes and saline solution bags, which should be made with color code and with the medication name handwritten.

DISCUSSION

The results found on labeling IV therapy devices in the ICU indicated: absence of a uniform pattern of structuring the labels in terms of content; color and design applied to different infusion devices; positive effects of labeling on patient safety and on better performance of activities by nursing professionals, especially studies that used pre-designed labels, with pre-defined colors and information or with spaces to be filled in handwritten form; and low compliance with IV device labeling (saline solution bags, syringes and IV lines) or their performance with incomplete information by nursing professionals, aspects that are configured in medication identification errors.

Regarding this last result related to non-labeling or incomplete labeling of IV devices, it is pointed out that, in critical patient

care environments, using potentially dangerous medications is frequent, which are recognized for their high chances of causing harm to patients when there is an error in their use.

On this, a systematic review developed to determine the prevalence of errors and the main damage caused by using potentially dangerous medications found an overall prevalence of 16.3%, of which 0.01 led to patient death. The highest prevalence of damage occurred after using medications such as potassium chloride, insulin and epoprostenol⁽²⁶⁾. Already analysis of incident reports involving medications identified that the potentially dangerous were involved in 281 of 624 events, i.e., responsible for 45% of security failures⁽²⁷⁾.

Errors related to the handling of IV lines of potentially dangerous medications, for instance, are considered a problem of great relevance. This relevance is seen in the list of the top ten health technology-related hazards drawn up by the Emergency Care Research Institute (ECRI) for 2015. Among them, errors with IV lines were cited, which lead to incorrect medication and solution administration, mainly due to the tangle of lines that exist when multiple IV infusions are administered to a single patient. Among the risks involved in handling IV lines, the infusion line being connected to the wrong device, delivering inappropriate fluid to patients, and doses being titrated wrongly or through an inappropriate route stood out⁽²⁸⁾.

One of the situations mentioned in this list is the notification of an incident, in which there was IV medication administered in an epidural catheter. Thus, difficulties in discerning one IV line from another and the tangle of lines can compromise correct tracking from line to IV pouch and vice versa. Therefore, to prevent these errors, it is recommended to label each infusion with the medication name being infused⁽²⁸⁾.

This context indicates that nursing care for critically ill patients with multiple IV infusions is complex, with a substantial risk of errors in the identification of IV medications, which directly interfere with patients' recovery, ranging from minor clinical repercussions to cases of death. Therefore, the importance of complying with using labels in care practice is reiterated, promoting a safer medication system.

As for the label characteristics and their effects on the prevention of medication errors, the results obtained can be compared with those of studies developed in other settings where intensive care is also provided, such as the operating room and emergency room. These results reiterate that characteristics, such as pre-design of labels and color, are important for the correct identification of medications, increasing practicality, reducing the average time spent on labeling tasks, in addition to identifying errors more quickly.

Research developed in a simulated scenario sought to quantify the impact of medication label design on safety. To this end, 96 anesthetists were randomly divided into two groups, with the objective of identifying the hetastarch bottle in the anesthesia cart of a simulated operating room, to fulfill a medical prescription for hemodynamic instability correction. The anesthesia cart contained three 500 ml bottles of hetastarch and one 500 ml bottle of lidocaine. In the intervention situation, the medication bottle should be identified using the redesigned label; in the control situation, using the normal label. The percentage of participants

who correctly selected the hetastarch bag after adopting the new medication label was significantly higher than with the current model (63% versus 40%). The authors concluded that using a new label helped participants select the correct medication and avoid harm to patients⁽²⁹⁾.

Also in the operating room, it is verified that the studies bring data mainly on syringe labeling. One of them compared medication errors before and after the implementation of a secure medication bundle and a barcode-based computerized medication system. Among the measures adopted in the bundle were syringe labeling and color use. A barcode system was also used that generated a label for each syringe. Errors with syringe change were significantly reduced after implementing the bundle. After using a barcode, there was no difference in error index. Evidence from this study suggested that identifying the syringe with a label is associated with a reduction in medication errors from needle exchanges⁽³⁰⁾.

A study in a pediatric resuscitation scenario in an emergency compared syringes previously prepared with medications and labeled with color codes with the syringes used in conventional medication administration. The group with the conventional syringe had an average time of 47 seconds to administer the medication. Of the 118 doses administered, 17% had critical dosing errors. The group with the pre-filled and color-labeled syringe took an average of 19 seconds, and of the 123 doses administered, there were no medication errors. It was concluded that labeled prefilled syringes shortened the time to administer the medication, as well as reduced critical dosing errors in pediatric cardiac arrest⁽³¹⁾.

The international studies that composed the analyzed corpus indicated that there is still variability in labeling practice regarding the label structure and content. Particularly, the Brazilian National Health Regulatory Agency (*Agência Nacional de Vigilância Sanitária*) recommends identifying medication containers with patient name, date of birth, medication, time and route of administration, dose and flow rate in the case of infusions. Route identification aims at correct connection during IV medication administration. As for continuous IV infusions, no particular label is indicated, only to conference drip speed and programming⁽³²⁾.

There are also recommendations regarding label use on potentially dangerous medications in the storage stage, as mentioned: "the use of colored labels in the storage process with the writing of high-risk medication". However, recommendations on labels in the administration phase are absent. Furthermore, according to the protocol for safe medication administration, medications with similar spellings and names must have part of the name written in bold and capital letter⁽³²⁾.

It is also noteworthy that the Institute for Safe Practices in Medication Use - Brazil (*Instituto para Práticas Seguras no Uso de Medicamentos - Brasil*) presented a set of recommendations for the prevention of errors involving potentially dangerous medications. Among these, we emphasize: ensure the correct label of the syringe with patient name, solution, concentration and route of administration; identify pouches of vinca alkaloid solutions labeled "Intravenously only - fatal if administered otherwise"; use labels that emphasize the difference in spelling with capital letter and in bold⁽³³⁾.

Considering the results, it is considered that standardized labeling of devices should be encouraged and rethought, so

that it occurs in the daily work of nursing in a safe way, since these professionals are responsible for medication preparation in the ICU. This strategy can contribute to: modifying problems related to low compliance with labeling in intensive care settings, which leads to lack of information or transcription errors; avoid errors related to handling IV lines, changing syringes or IV bags; and provide greater safety of medication administration in emergency situations.

The evidence presented in this research on labeling IV devices reiterated the importance of this practice for patient safety, i.e., when performed properly, it contributes to reducing medication errors and increasing professional safety in providing nursing care. Thus, this practice can be considered an important barrier to defending the medication system safety.

From the conceptual perspective of safety, the weaknesses of the health system (failures) can be compared to the holes in a Swiss cheese, in which, for an incident to happen, the alignment between the holes in the cheese must occur. In view of this, we seek to propose barriers that prevent this alignment of the holes and that the damage affects patients⁽¹⁵⁾.

Therefore, based on the understanding that labeling improves the identification of information about the medication and visually indicates the pharmacological class to which it belongs, it can be configured as the last barrier before administering a medication. It alone does not guarantee that a medication is prepared correctly, as if a medication has been prepared incorrectly and labelled correctly, the label will not fit what will actually be administered. But if a medication has been prepared correctly and mislabeled, unlabeled or with incorrect information, it may be administered to another patient as well as there may be under-dosage or overdose.

An example of these situations is seen in the research that, from the errors identified in the handling of IV lines of potentially dangerous medications, presented three real cases: a) a patient was using fentanyl and was requested for a bolus of physiological saline solution, however, the saline and fentanyl lines were mixed up and a bolus of fentanyl was given instead of saline; b) tracing the IV lines of heparin and nitroglycerin caused nitroglycerin to be administered at 30 ml/h, when, in fact, it should be set at 1.5 ml/h. Heparin was infused at 1.5 ml/h instead of 30 ml/h as a consequence of the error; and c) phenylephrine bag was on the line in which IV fluid was programmed at 150 ml/h, leading patients to death⁽⁹⁾.

Study limitations

The limitation of this study was related to the lack of detail in some studies of information on the characteristics of the labels used in the studies, which limited the in-depth analysis of the findings in the synthesis of knowledge presented in this review.

Contributions to nursing and health

Medication errors are currently the most common causes of morbidity and mortality in patients in the context of patient safety. In turn, the costs related to these errors represent an important burden on the health system and an important source of waste^(1,34). This reinforces the need for preventive measures that envision effective impacts on patient safety at all stages of the medication system and that maximize the offer to patients of care permeated by safe actions.

The synthesis of knowledge obtained in this study about labeling IV therapy devices in ICU settings contributes to the development of actions aimed at creating barriers to prevent medication errors related to the identification of devices for medication administration, as well as to reduce the costs associated with them, thus bringing potential benefits to patient safety.

CONCLUSIONS

The results indicated that pre-designed labels, with colors and predefined information for bags of saline solution, IV lines, infusion pumps and syringes, contribute to prevent errors in medication identification. Moreover, they showed that well-labeled syringes had lower chances of medication dosing errors. Despite these effects on patient safety, there is still a lack of standardization of labeling practice to identify medications in syringes, infusion pumps, IV lines and IV bags in institutions, both in terms of content, structure and color. Additionally, it was found that there is a low compliance with labeling IV devices or its performance with incomplete information in practice by nursing professionals, which configured an error in the identification of medications.

Based on these results, further studies are recommended to develop proposals for labels to identify medication delivery devices and to test their applicability in practice, in order to adopt a standard of information visualization. Standardization of labels across institutions can lead to faster and more effective patient interventions in administering, monitoring, and removing IV infusions in critically ill patients. In addition to this, it can contribute to the nursing team's work in the correct identification of these infusions and, thus, minimize medication errors, such as connections and disconnections of infusions, flushing in wrong routes, among others. In this way, both patients benefit, when receiving medication therapy without interruptions and errors, and professionals, when they feel safer in the handling of such devices.

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Peripheral insertion of reverse-tapered and non-tapered central catheters (PICC) in patients receiving tumor chemotherapy

ABSTRACT

Objective: The objective of the study is to investigate the effect of the reverse-tapered peripherally inserted central catheters (PICC) and the nontapered PICC in tumor chemotherapy.

Materials and Methods: Retrospective January to May 2019, 110 subjects were collected in the study, including a group of 49 patients with the reverse-tapered PICC catheters. In the other group, 61 patients were implanted with the nontapered PICC catheters. The incidence of PICC catheter-related symptomatic thrombosis, the difficulty degree of catheterization, and the rate of bleeding at the puncture point 24 h after catheterization were compared between two groups.

Results: The comparison of the difficulty of catheterization and the permeability rate at puncture point 24 h after catheterization between the two groups showed statistically significant differences (all $P < 0.05$). There was no significant difference in the incidence of symptomatic thrombosis associated with PICC catheters between the two groups ($P > 0.05$).

Conclusion: The reverse-tapered PICC and the nontapered PICC catheters have similar safety performance in tumor chemotherapy; different design types of PICC were selected according to the treatment needs of patients.

KEY WORDS: Chemotherapy, the nontapered peripherally inserted central catheters, the reverse tapered peripherally inserted central catheters

INTRODUCTION

Peripherally inserted central catheters (PICCs) provide an effective intravenous vessel for patients prolonged intravenous therapy. There are two style features PICC to need clinical setting: the reverse tapered and the nontapered. 5F Dual-Lumen Power PICC SOLO Catheter features a reverse-taper catheter design, approximately 7 cm distal of catheter hub increase in outer diameter, from 5F to 7F. "Reverse tapered." The main purpose of this design is strain relief (prevention of kinking) at the insertion site. In addition, the thicker portion of the PICC could potentially reduce bleeding after catheter placement. 4F Single-Lumen the Groshong PICC Catheter features a nontapered catheter design. Alternative PICC designs have a uniform diameter from the tip toward the hub. PICC-related venous thrombus (PICC-related VT), the difficulty degree of catheterization, and the rate of bleeding at the puncture point were focus on. One of the most common complications of PICC insertion is venous thrombosis,^[1] PICC diameter

has been found to be a predictive factor for thrombosis in several studies.^[2] Reverse tapered can result in increased thrombosis rate according predictive, especially at the insertion site, because the largest outer diameter ends are inserted into the smallest diameter veins. However, some studies have found that the occurrence of PICC-related thrombosis has no correlation with the diameter of the catheter.^[3,4] Dose reverse-tapered PICC inserted increase thrombosis the difficulty degree of catheterization, and the rate of bleeding at the puncture point 24 h after catheterization was also closely concerned. Therefore, the purpose of this study was to provide support for the selection of appropriate infusion tools for tumor chemotherapy patients in terms of the incidence of thrombus, the difficulty of catheterization and the bleeding

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situation at the puncture point after catheterization of 5FR reverse-tapered PICC and 4FR the nontapered PICC.

MATERIALS AND METHODS

Patients and setting

From January 2019 to May 2019, a total of 110 patients receiving intravenous chemotherapy in the department of oncology chemotherapy were selected. According to the chemotherapy regimen, the patients were divided two groups. One group included 49 patients with mFOLFOX6 or FOLFIRI, reverse-tapered 5FR PowerPICC, dual-channel administration, one channel was used to continuous infusion of fluorouracil 46 h, and another to inject antiacid, rehydration, and other drugs. The other group received 4FR nontapered single-channel PICC, 61 patients received receiving intravenous chemotherapy through 4FR nontapered single-channel PICC. This study was approved by The Ethics Committee of Shandong Provincial Hospital affiliated with Shandong First Medical University. Inclusion and Exclusion Criteria.

Inclusion criteria

patients ≥ 18 years old receiving an intravenous chemotherapy regimen following doctor's instructions; normal platelet count and clotting function; signed informed consent.

Exclusion criteria

previous upper extremity or central venous thrombosis; patients undergoing oncology treatment in another hospital.

Devices

Catheters were 5Fr double-lumen reverse-tapered PICCs (Bard Access Systems, Salt Lake City, Utah) and 4Fr single-lumen non-tapered PICCs (Groshong catheter, Bard Access Systems). The diameter of reverse-tapered PICC increases from 5Fr to 7Fr over 7 cm from the hub. The nontapered PICC diameter remains 4Fr over the entire length of the catheter.

Peripherally inserted central catheters insertion procedure

Both catheters were placed by the same PICC specialist nurse. Both catheters were carried out by ultrasonic-guided upper arm puncture combined with the modified Seldinger technique. The right basilic vein was the first choice and the inner diameter of the catheterized vessel was measured. The length of the indwelling tube in body was accurately measured before placement. The catheter sheath was carefully pulled out and torn when the remaining 7 cm of the catheter was inserted. Then the catheter 5Fr double-lumen reverse-tapered PICCs, was slowly and uniformly inserted to the preset length. 4Fr single-lumen nontapered PICCs was slowly and uniformly inserted to the preset length after the catheter sheath was cautious pulled out and torn. The internal jugular vein was carefully examined by ultrasound (US) for catheter displacement. Chest X-ray was performed to determine the location of the catheter tip and observe whether the catheter was retracted or knotted. The 2016 Infusion Nursing Society

standard of practice for intravenous treatment states that the PICC tip should be located at the cavoatrial junction between the superior vena cava and the right atrium.^[5] After the location of the PICC catheter tip was determined, 8 layers of 2 cm $\times$ 2 cm sterile gauze were used to compress the puncture site, and transparent dressing was used to fix the puncture and catheterization records were made.

Measures

Symptomatic thrombosis was defined as the presence of clinical symptoms (pain, arm swelling) and confirmation of venous thrombosis by US examination. The measurement time was from successful catheterization to catheter removal at the end of the chemotherapy regimen; the clinician makes the diagnosis.

The difficulty degree of catheterization: after successful PICC puncture, the one-time arrival rate of catheter tip and the presence of kink in the catheter: such as reversion and knotting. The measurement time was throughout PICC insertion procedure and after X-ray taking. It was measured by the same PICC specialist nurse.

Leakage of blood at the puncture point after catheterization: the incidence of bleeding 24 h after successful catheterization. Leakage at the puncture point was soaked through the pressed gauze, and there was visible bleeding. It was measured by nurse.

Peripherally inserted central catheters catheter maintenance and follow-up

If the patient has bleeding at the puncture site within 24 h after catheterization, change the dressing in time. Before and after intermittent infusion, and after each infusion, normal saline pulsed flushing tube and positive pressure sealing tube were used. The nurse in charge observed whether there was oozing blood at the puncture point within 24 h of catheter placement and observed whether there was swelling and/or pain in the limb during the hospital stay. During the interval of treatment, patients were observed daily for swelling and/or pain in the extremeside of the catheter. If there were such symptoms, vascular US was performed in time to check for thrombosis. If there was thrombosis, medication was given according to the doctor's advice, and a PICC nurse was assigned to follow-up patients once a week.

The deadline is November 2019, all 110 patients have completed chemotherapy and the catheter has been pulled out. The longest retention time is 256 days, while the shortest is 92 days.

RESULTS

Patient characteristics

A total of 110 subjects were included in this study, 49 of whom were implanted reverse tapered with PICC (5FR). The disease

types included: 26 cases of gastric cancer (53.06%), 21 cases of colorectal cancer (42.86%), and 1 case of bile duct cancer and 1 case of esophageal cancer (2.04%). Nontapered PICC (4FR) was implanted in 61 patients with the following diseases: 35 cases of breast cancer (57.38%), 8 cases of stomach cancer (13.11%), 5 cases of lung cancer (8.20%), 5 cases of colorectal cancer (8.20%), 2 cases of lymphoma (3.27%), 1 case of endometrial cancer, 1 case of abdominal cancer, 1 case of liver cancer, 1 case of cervical cancer, 1 case of prostate cancer, and 1 case of mandibular cancer (1.64%). Among the 49 patients with reverse-tapered PICC (5FR) implantation, 41/49 (83.67%) were male, 8/49 (16.33%) were female, 44/49 (89.80%) were placed in the right upper limb, 5/49 (10.02%) were placed in the left upper limb, and 47/49 (95.92%) were placed in the vein. Humeral vein was inserted 2/49 (4.08%); among the 61 patients with nontapered PICC (4FR) implantation, 13/61 (21.31%) were male, 48/61 (78.69%) were female, 36/61 (59.02%) were placed in the right upper limb, 25/61 (40.98%) were placed in the left upper limb, and 52/61 (85.25%) were placed in the bilateral vein. The brachial vein was inserted 9/61 (14.75%) [Table 1].

Comparison of the incidence of symptomatic thrombus

The incidence of PICC catheter-related symptomatic thrombosis was 3.64% (4 of 110 patients). The symptomatic thrombosis rate was 3.28% (2 of 61 patients) in the nontapered PICC group and 4.08% 2 of 49 patients in the reverse-tapered PICC group ($P > 0.05$) [Table 2].

The one-time arrival rate of catheter tip

One-time access rate of catheter tip in reverse-tapered PICC was 81.6% (40/49), of which 4 cases of PICC, catheter placement failed after tearing and withdrawing the sheath at the remaining 7 cm of catheter placement, and re-selecting other vessels or the other side of the upper limb was successful. After the successful placement of reverse-tapered PICC in 3 cases, the internal jugular vein was examined by the US and the catheter was found to be displaced, and the catheter was successfully readjusted. Among them, 1 case with reverse-tapered PICC was found to have a knot

in the subclavian vein after chest X-ray radiography and positioning. The catheter was re-adjusted and re-radiography was performed, and the catheter direction in the body was correct. In the last case of reverse-tapered PICC, the catheter was found to fold back at the tip of the catheter after chest X-ray radiography and positioning, and the positioning was normal again after the adjustment. The disposable access rate of the nontapered PICC catheter tip was 95.08% (58/61). After successful placement of PICC catheter in 2 cases, the internal jugular vein was examined by US and catheter displacement was found, and catheter readjustment was successful. One of them underwent chest X-ray radiography and found that the catheter was running from the subclavian vein to the contralateral subclavian vein. The catheter was readjusted and the catheter tip was in normal position again.

The difference in one-time arrival rate of catheter tip was statistically significant ($P < 0.05$) [Table 2].

The rate of bleeding at the puncture point 24 h after catheterization

Comparison of the rate of bleeding at the puncture point 24 h after catheterization the rate of bleeding at the puncture point 24 h after catheterization was 8.20% (5 of 61 patients) in the nontapered PICC group and 0% 0 of 49 patients in the reverse-tapered PICC group ($P < 0.05$) [Table 2].

DISCUSSION

The one-time arrival rate of the reverse-tapered PICC tip is lower than that of the nontapered PICC. In this study, the difficulty of catheterization reduced the one-time catheter arrival rate. There are not many such studies. The reason for the failure of PICC catheter placement in the reverse-tapered design is that the inverted conical design increases the difficulty of placement, especially when the tumor patient is too thin, and the less subcutaneous fat will affect the support of blood vessels, resulting in increased subcutaneous bending of the catheter, leading to the difficulty of placement.^[6] Initial catheter malposition is one of the most common complications of PICC, internal jugular vein ectopic is the most common, with an incidence of 4.42%,^[7] which was close to the results of this study, the total rate ectopic to the internal jugular vein was 4.5% (5/110). the reverse-tapered PICC is more likely to be ectopic to the internal jugular vein. The nontapered PICC catheter is made of silica gel, with good biocompatibility and flexibility. According to the floating principle of the catheter, it is not easy to cause difficulty in placement and

Table 1: Patient characteristics

	Reverse-tapered PICC (n=49)	Nontapered PICC (n=61)	P
Average age (years) (SD)	57.21 (12.05)	54.08 (11.57)	0.17
Male/female (%)	81.63/18.37	21.31/78.69	
Basilic vein (%)	95.92	85.25	0.064
Brachial vein (%)	4.08	14.75	
Right arm placement (%)	89.80	59.02	
Left arm placement (%)	10.20	40.98	

SD=Standard deviation, PICC=Peripherally inserted central catheters

Table 2: Measure

	Reverse-tapered PICC (n=49), n (%) (95%CI)	Nontapered PICC (n=61), n (%) (95%CI)	P
The incidence of symptomatic thrombus	2/49 (4.08) (-0.01-0.09)	2/61 (3.28) (-0.01-0.08)	0.823
The one-time arrival rate of catheter tip	40/49 (81.6) (0.71-0.93)	58/61 (95.08) (0.897-1.01)	0.025
The rate of bleeding at the puncture point 24 h after catheterization	0/49 (0.0) (0-0)	5/61 (8.20) (0.01-0.15)	0.040

PICC=Peripherally inserted central catheters, CI=Confidence interval

Table 3: Vessel diameter of peripherally inserted central catheters inserted

	≤0.29, n (%)	0.3-0.39, n (%)	0.4-0.49, n (%)	0.5-0.59, n (%)	≥0.60, n (%)
Reverse tapered PICC (n=49)	0	3 (6.12)	16 (32.65)	20 (40.82)	10 (20.41)
Nontapered PICC (n=61)	5 (8.20)	19 (31.15)	30 (49.18)	5 (8.20)	2 (3.27)

PICC=Peripherally inserted central catheters

knot of the catheter. The reverse-tapered PICC is made of pressures-resistant polyurethane, which is hard. During placement, the operator failed to send the catheter in the natural direction of the catheter and repeated turning of the catheter easily made the tip of the catheter point to the direction of the internal jugular vein, resulting in ectopic internal jugular vein.^[8] Some scholars pointed out that after the occurrence of ectopic catheter, the catheter should be softened in human body for 25–30 min before adjustment, so as to improve the success rate of catheterization.^[9]

The bleeding rate at the puncture site 24 h after catheterization of the reverse-tapered PICC was lower than that of the nontapered PICC. The bleeding rate at the puncture site 24 h after the placement of the reverse-tapered PICC catheter was 0, which was lower than that of the nontapered catheter. The reason is related to the catheter design. The inverted cone design PICC catheter has the largest diameter at the puncture site, which can effectively fill the puncture site and reduce the occurrence of blood oozing at the puncture site. This is consistent with the research of Deng *et al.*^[10]

There were two different types of PICC catheters in this study: reverse tapered and nontapered. There was no significant change in the incidence of PICC catheter-related symptomatic thrombosis during tumor chemotherapy compared with nontapered PICC design. Venous thrombosis is a common complication of PICC catheterization, which can cause significant discomfort in patients, require anticoagulation therapy and prolong the length of hospital stay. It may lead to thrombotic sequelae, pulmonary embolism, and an increased incidence of catheter-related infections. It has been reported that the incidence of symptomatic thrombosis is 3%–20%,^[2,5] the incidence of asymptomatic thrombosis was 61.9%.^[11] The results of this study showed that the incidence of symptomatic thrombosis in PICC was 3.64% (4/110), a low incidence, which was close to the results of Prandoni *et al.*^[12] (3.8% thrombosis incidence), but asymptomatic thrombosis was not included in all the studies. The study of Mitrović *et al.*^[13] showed that symptomatic thrombosis occurred in 4.7% of PICC catheter-related thrombosis, which was also similar to the results of this study. Studies have found that tumor is a risk factor for PICC-related thrombosis,^[14] and the occurrence of PICC-related thrombosis is not only related to the hypercoagulability of tumor patients but also can be directly affected by many chemotherapy drugs can directly damage vascular endothelial cells, and the nausea, vomiting, fatigue, and discomfort brought by chemotherapy can increase patients' bed time. Therefore, tumor is a risk factor for PICC-associated thrombosis.

Studies have shown^[15] that 5F and 6F PICC catheters have a higher risk of thrombosis than 4F catheters, and the occurrence time is earlier. Evans *et al.*^[16,17] showed that small-diameter PICC can reduce the risk of PICC-related thrombosis. According to the design characteristics of the catheter, reverse tapered can result in increased thrombosis rate, especially at the insertion site, because the largest outer diameter ends are inserted into the smallest diameter veins. Why did the predicted results not appear in this study? Among the risk factors of PICC-related thrombosis – catheter-related factors, the smaller the ratio of the diameter of a PICC catheter to the inserted vein, the lower the risk of PICC-related thrombosis. Therefore, it is highly recommended to choose a catheter with the ratio of catheter vein ≤45%. In this study, the vessel diameter was carefully evaluated before catheterization to maximize the vessel diameter/vessel outer diameter ≤45% [Table 3]. The diameter of 5FR catheter is large, but the inserted vein diameter is also large, and the proportion of catheter vein is small, thus reducing the impact on blood flow. The inverted tapered design of the 5FR catheter enables the maximum diameter of the catheter to be reached at the “0” scale at the end of the catheter. In clinical catheterization, the puncture point is 2–3 cm away from the “0” scale, thus increasing the ratio of catheter/vessel outer diameter at the puncture point, thus reducing the incidence of thrombosis. Therefore, it is very important to carefully evaluate the vessel diameter before PICC catheterization and to select a catheter with a vein ratio of <45% under the premise of meeting the treatment regimen.

CONCLUSION

The reverse-tapered PICC and the nontapered PICC have the same safety in tumor chemotherapy. Nursing staff should choose different design types of PICC according to the treatment needs of patients. Nontapered PICC can meet the requirements of various drug infusion in tumor chemotherapy patients. If you need to meet the dual channel for patients with drugs and high-pressure injection of contrast agent, you need to choose taper design PICC catheter, so it is very important for clinical nursing staff before transfusion carefully assess the clinical situation and requirements according to the patient needs to choose the appropriate transfusion tool.

Limitation

Because the sample size is less, this study for single-center studies, multicenter, large sample research is needed. Although there are limitations, our research can be helpful to clinical practice.

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Conflicts of interest

There are no conflicts of interest.

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BMJ Open Peripherally Inserted Central catheter iNnovation to reduce Infections and Clots (the PICNIC trial): a randomised controlled trial protocol

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ABSTRACT

Introduction Peripherally inserted central catheters (PICCs) are vital for the delivery of medical therapies, but up to 30% of PICCs are associated with complications such as deep vein thrombosis or infection. The integration of antimicrobial and hydrophobic catheter materials, and pressure-activated valves, into polyurethane PICCs are innovations designed to prevent infective and/or thrombotic complications.

Methods and analysis A multicentre, parallel group, superiority randomised controlled trial with two experimental arms ((1) hydrophobic PICC (with pressure-activated valve); (2) chlorhexidine gluconate-impregnated PICC (with external clamp)) and one control group ((3) conventional polyurethane PICC (with external clamp)). Recruitment of 1098 adult and paediatric patients will take place over 2 years at three tertiary-referral hospitals in Queensland, Australia. Patients are eligible for inclusion if their PICC is to be inserted for medical treatment, with a vascular size sufficient to support a 4-Fr PICC or larger, and with informed consent. The primary outcome is *PICC failure*, a composite of thrombotic (venous thrombosis, breakage and occlusion) and infective complications (PICC-associated bloodstream infection and local infection). Secondary outcomes include: all-cause PICC complication; thrombotic complications; infective complications; adverse events (local or systemic reaction); PICC dwell time; patient/parent satisfaction; and healthcare costs. Differences between both intervention groups and the control group will be compared using Cox proportional hazards regression. Effect estimates will be presented as HRs with corresponding 95% CI.

Ethics and dissemination Ethical approval from Queensland Health (HREC/QCHQ/48682) and Griffith University (Ref. No. 2019/094). Results will be published.

Trial registration number ACTRN12619000022167.

INTRODUCTION

Peripherally inserted central catheters (PICCs) are inserted via deep peripheral

Strengths and limitations of this study

- This is an adequately powered, multicentre, randomised controlled trial in adults and children to provide much-needed evidence for the clinical effectiveness and cost-effectiveness of new peripherally inserted central catheters (PICCs) that feature updated designs and materials.
- Allocation will not be concealed to clinical staff, since they must insert, access and monitor PICCs; however, blinded infectious disease physicians and interventional radiologists will assign infectious and thrombotic outcomes according to standardised definitions, and data analysis will be performed by a blinded statistician.
- The trial is from a single region that may limit the generalisability of the findings, and data for children will be limited due to the unavailability of smaller sizes of some PICCs.

veins, predominantly of the upper arm, into the central vasculature.¹ PICCs are vital for many acute and chronic diagnoses requiring prolonged and/or frequent therapy, vesicant medications, irritant pH and osmolality infusions, for patients with limited veins in both outpatient and inpatient settings.² The last 40 years have seen rapid acceleration in PICC use, due to their relative safety, ease of use and cost-effectiveness compared with more invasive centrally inserted devices. However, it is now established that PICC-related complications are universally common, with up to 30% of PICCs failing prior to completion of treatment due to thrombotic (eg, deep vein thrombosis (DVT)) and infective complications (eg, catheter-associated bloodstream

infection (CABSI) including those caused by *Staphylococcus aureus*).^{3–5} Innovations that prevent these complications are necessary to reduce healthcare-associated harm for vulnerable patients.

PICC materials

Integrating antithrombotic and anti-infective technologies into the PICC materials are potential innovations to prevent complications. Several PICC materials have been developed since their inception in the 1970s⁶; however, the majority of PICCs currently in use are made of relatively stiff, third-generation uncoated polyurethane that softens with body temperature and withstands pressures of >300 pounds per square inch.⁶

Material technologies introduce antithrombotic and anti-infective properties in PICCs, with two major products entering the market over the last 5–10 years. The BioFlo PICC from AngioDynamics Inc (Queensbury, New York, USA) has hydrophobic (water repelling) properties, which has been achieved by the addition of ‘Endexo’ (a surface-modifying macromolecule based on the incorporation of fluorine atoms) during the moulding manufacture process. The fluorinated PICC material inhibits platelet adhesion, suppresses protein procoagulant conformation and potentially reduces thrombus formation in medical devices (based on platelet counts in manufacturer completed in vitro studies only).^{6 7} Our pilot randomised controlled trial (RCT) in a paediatric population (n=150) demonstrated the feasibility and potential for the hydrophobic BioFlo PICC to reduce PICC thrombotic and infective complications, but the study was not powered for clinical effectiveness (PICC failure: standard polyurethane 22% (16/72)) vs BioFlo 11% (8/72): risk ratio (RR) 0.50; 95% CI 0.23 to 1.09; p=0.07).⁸

Anti-infective properties impregnated into PICCs include antibiotics (eg, minocycline-rifampicin) and antiseptics (eg, chlorhexidine gluconate (CHG)). These technologies have been well studied in other central venous catheter types, with a Cochrane review⁹ concluding there was high-quality evidence that antimicrobial (non-PICC) central venous catheters significantly reduced CABSI risk (RR 0.62; 95% CI 0.52 to 0.74, n=10 405, 42 RCTs). Building on this indication, Teleflex Inc (Wayne, Pennsylvania, USA) developed the CHG-impregnated Arrowgard Blue Advance PICC. CHG is widely used in healthcare, due to its broad spectrum of germicidal activity against most CABSI-causing pathogens, especially *S. aureus*.¹⁰ Some manufacturer-funded, laboratory studies also suggest CHG coating has a role in the prevention of thrombosis development, with in vivo ovine models demonstrating a significant reduction in fibrin sheath development after 30 days in situ, in comparison with uncoated catheters (median 0.05 g (CHG) vs 0.7 g (uncoated)).¹¹ However, the effectiveness of CHG-coated PICCs to prevent thrombotic and infective complications has not been formally tested in clinical trials in humans.

PICC designs

PICC design evolution has primarily focused on the integration of internal valves, replacing external clamps, with the aim of preventing thrombotic occlusion by reducing blood reflux.⁶ External clamps prevent gravity and pressure-related backflow of blood into and out of the PICC when not in use. Modern pressure-activated valves, such as those incorporated in the BioFlo PICC from AngioDynamics Inc (Queensbury, New York, USA), negate the need for external, clinician-initiated clamping during periods of disuse. The valves are incorporated at either the distal or proximal portion of the PICC and open with injection and aspiration pressure but remain closed during minor pressure fluctuations.¹² Despite the integration of valves into many PICCs, data regarding their performance in preventing complications in clinical trials are minimal. Only one RCT (n=180) of the pressure activated valve versus older PICC valve technologies has been published, and this RCT was stopped early due to safety concerns with an older valve (Becton Dickinson – Bard, Murray Hill, New Jersey, USA).¹²

The ideal PICC would be: (A) soft and flexible to reduce procedural risks (including ease of insertion, patient discomfort and vessel irritation); (B) structurally strong to withstand pressure during rapid injection; (C) prevent microbial colonisation and adherence of blood components to reduce CABSI and DVT; and (D) cost-effective. Little research has been undertaken examining the safety and effectiveness of either hydrophobic or CHG PICCs, with or without valves, to meet these criteria, prevent thrombotic and infection complications and promote PICC function. The aim of this study is to compare two novel technologies (hydrophobic and CHG PICCs) with standard care (conventional polyurethane PICCs), to identify clinically effective and cost-effective methods to reduce the incidence of PICC failure, due to thrombotic and infectious complications.

METHODS AND ANALYSIS

This multicentre, parallel group, open, superiority, randomised controlled trial will compare the clinical effectiveness and cost-effectiveness in adult and paediatric patients of the:

1. Hydrophobic PICC: with pressure activated valves; BioFlo.
2. CHG-impregnated PICC: with external clamps; Arrowgard Blue Advance.
3. Conventional polyurethane PICCs: pressure injectable polyurethane with external clamps.

Embedded in the RCT are additional microbiological and thrombogenic subgroup studies to determine the effect of these interventions on bacterial colonisation, PICC-associated infection and CHG resistance, as well as assessing haematological, coagulation profiles and platelet activation.

Hypotheses

Primary

1. Patients with either (1) hydrophobic or (2) CHG PICCs will have significantly fewer device failures (composite outcome of thrombosis, infection, occlusion and breakage) compared with patients receiving (3) usual care (conventional polyurethane PICCs).

Secondary

1. Patients with the (1) hydrophobic and (2) CHG PICCs will have significantly longer complication-free device life compared with patients receiving (3) usual care (conventional polyurethane PICCs).
2. Patients with the (1) hydrophobic PICCs will have significantly lower rates of thrombotic complications (composite of thrombosis, occlusion and breakage), compared with patients receiving (3) usual care (conventional polyurethane PICCs).
3. Patients with (2) CHG PICCs will have significantly lower rates of PICC associated infections, than patients receiving (3) usual care (conventional polyurethane PICCs).
4. There will be significant cost savings to the Australian health system when using (1) hydrophobic or (2) CHG PICC, compared with patients receiving (3) usual care (conventional polyurethane PICCs).

Study setting and sample

Adult and paediatric patients are being recruited at three tertiary referral hospitals in South East Queensland, Australia (Royal Brisbane and Women's Hospital (RBWH); Princess Alexandra Hospital (PAH); and Queensland Children's Hospital (QCH)), aiming for recruitment over 2 years. Sites have phased recruitment commencement (QCH 8 November 2019; PAH 20 January 2020 and RBWH 1 June 2020), with delayed commencement at RBWH due to COVID-19. Patients requiring a PICC are being recruited via departments of medical imaging and vascular access services from cancer care, medical,

surgical and intensive care areas. Patients who meet all inclusion and no exclusion criteria (see table 1) are eligible to participate in the study once.

Outcome measures and definitions

Primary outcome

The primary outcome is *PICC failure*, a composite of thrombotic (venous thrombosis, breakage and occlusion) and infective complications (PICC-associated bloodstream infection and local infection) (all defined further) severe enough to cause cessation of PICC function prior to therapy completion.^{5 13}

- *Venous thrombosis*: ultrasound/venographic/image confirmed thrombosis occurring within the same vessel as the PICC within 1 week of PICC removal, in a symptomatic patient (pain and swelling),¹⁴ confirmed by blinded radiologist.
- *Breakage*: split in PICC material with leakage or radiographic evidence of extravasation/infiltration into tissue, in a PICC flushed to clear thrombosis and/or occlusion.¹⁵
- *Occlusion: complete*: ≥1 lumens cannot be flushed or aspirated, or resolved post-thrombolytic dwell¹⁶ and *partial*: decreased ability of ≥1 lumens to either infuse blood or fluid and/or withdraw blood or fluid from ≥1 lumens despite the use of thrombolytic.¹⁷
- *PICC-associated bloodstream infection (BSI)*: a laboratory confirmed BSI where an eligible BSI organism is identified with PICC in place for >2 consecutive calendar days on the day of the BSI (day of PICC placement being day 1) and the PICC in place on the date of the event or the day before (see CDC Device-associated Module BSI for full criteria),¹⁸ confirmed by a blinded infectious disease specialist.
- *Local infection*: clinical signs of local venous infection at the PICC insertion site (eg, purulent drainage), confirmed with a positive (>15cfu) swab or catheter tip but with negative or no blood culture (see CDC VASC definition for full criteria)¹⁸ confirmed by a blinded infectious disease specialist.

Secondary outcomes

- *All-cause PICC complication*: a composite of the thrombotic and infective complications previously, but evident at any stage during PICC dwell, and may or may not require PICC removal.
- *Thrombotic complication*: a composite of venous thrombosis, occlusion and breakage at any stage during PICC dwell.
- *Infective complication*: a composite of PICC-associated BSI and local infection at any stage during PICC dwell.
- *Individual complications*: individual thrombotic (venous thrombosis, breakage and occlusion) and infective (PICC-associated BSI and local infection) complications evident at any stage during PICC dwell and may or may not require PICC removal.
- *Adverse events*: any local or systemic allergic reaction (eg, pruritus), pain and mortality.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
► PICC to be inserted for medical treatment. ► Informed consent. ► Vascular size sufficient to support 4-Fr PICC or larger.	► Previous enrolment in the current study. ► Current catheter-related bloodstream infection. ► Thrombosis in vein where PICC is to be inserted. ► Non-English speaking without an interpreter. ► Known sensitivity to study products (including CHG). ► <i>Added since trial commencement</i>: admitted for COVID-19, or to a designated COVID-19 unit/facility.

CHG, chlorhexidine gluconate; Fr, French; PICC, peripherally inserted central catheter.

- ▶ *PICC dwell time*: hours from PICC insertion until removal.
- ▶ *Patient/parent and staff satisfaction*: collected at PICC insertion (staff) and study end (staff and patient/parents), using 0–10 numeric rating scales of increasing satisfaction.¹³
- ▶ *Healthcare costs*: estimate of direct product costs, healthcare resource utilisation (including additional equipment and staff time) and failure-associated resource usage (described further).¹⁹

Sample size and study power

Our baseline PICC failure rate associated with the conventional PICCs is 15%.^{20–22} We expect PICC failure of 7.5% with hydrophobic and CHG PICCs based on pilot trials⁸ and systematic reviews.^{9,23} That is, we expect hydrophobic and CHG PICCs to have a 50% relative risk reduction in PICC failure rates compared with conventional PICCs. Using a two-sided alpha significance level of 0.035 (chosen to facilitate comparison of the two intervention arms against a single control arm), 366 PICCs in each group achieves 85% power to detect a relative 50% difference in failure rates between intervention ((1) and (2)) hydrophobic and CHG PICCs and control ((3) conventional PICCs) groups. Consequently, we are required to enrol 1098 participants.

Recruitment, randomisation, allocation concealment and blinding

Hospital-based research nurses (ReNs) are screening patients, gaining informed consent from patients/parents, randomising, educating clinical staff, patients and families, monitoring protocol compliance and collecting weekly data on patients 'on trial' plus final outcome data for completed patients. Patients are randomised via a central web-based service (Griffith University) immediately prior to each PICC insertion to ensure allocation concealment until study entry. Randomisation is at a 1:1:1 ratio between groups, with randomly varied block sizes (up to 20) and stratification by: (1) hospital and (2) hypercoagulable state (adults: high risk of thrombosis as per Michigan Risk Score²⁴; paediatrics: previous thrombosis or active cancer).

PICC inserters have been provided training by the product manufacturers regarding the insertion of intervention PICCs, with additional resources available to support practice. The inserters are provided with the randomised PICC in prepacks, immediately prior to insertion, to ensure study fidelity. It is not possible to blind clinical staff, since they must insert, access and monitor PICCs, and they are visibly different. However, the outcome of PICC failure is objective, easily assessed and routinely assigned by clinical staff who are not investigators. Infectious disease physicians and radiologists are masked when determining infection and thrombosis outcomes, standardised definitions are used for these outcomes and the biostatistician will be masked to allocation when provided the dataset.

Insertion and care of PICC

Other than PICC type, all other PICC insertion, care and management have been standardised in accordance with Queensland Health clinical practice guidelines (at all study sites).²⁵ This includes skin preparation with 2% CHG in 70% alcohol prior to insertion, sterile insertion, ultrasound guidance for insertion, securement with sutureless securement devices and polyurethane dressings and removal as soon as clinically appropriate. Maintenance and removal will be by usual hospital staff, with existing guidelines in place. As a pragmatic trial, variations in such care are being noted but not considered as protocol violations. A protocol violation is the insertion of a non-randomised PICC.

Data collection

Data are being directly collected into a secure online database (Research Electronic Data CAPture, Vanderbilt).²⁶ The ReNs are following participants weekly for a maximum of 8 weeks (captures 90% of dwell data; will be censored at that point) or until PICC failure/removal if earlier. Discharged patients are having follow-up data collected by phone, a method that we have previously demonstrated reliability.²⁷ The study manager are undertaking quality checks and monitoring 100% source data verification for: all data for the first patient per site, all consent forms, all primary endpoints and a random 5% of other data for all patients.

At enrolment, ReNs are collecting consent forms and data on patient, provider and device factors that potentiate PICC-associated complications and failure.² These include: patient (eg, critical illness factors, coagulopathy, diagnostic group, neutropaenia, previous history of CABS or venous thrombosis); device (PICC lumens, PICC size and vessel size); and provider (eg, inserter discipline, care during insertion and care during access) factors.

Immediately or within 24 hours of recruitment, PICC inserters are asked to rate the ease of PICC insertion (0=very difficult, 10=very easy).

Weekly, the ReNs are visiting or contacting participants to assess for primary and secondary outcomes, current use, and any clinical, PICC or treatment factors that have changed since recruitment.

Within 24 hours of PICC removal or at 8 weeks, the ReNs are collecting data on reason for removal including presence and type of failure if present, PICC dwell and infusates. Also within 24 hours, ReNs are asking the patient/parent about satisfaction with the PICCs (0=completely dissatisfied, 10=completely satisfied).

Within 1 week of PICC removal or at 8 weeks (maximum data collection), ReNs are collecting microbiological and clinical data for infectious, thrombotic and microbiological outcomes.

Microbiological substudy

To determine the effect of (1) hydrophobic and (2) CHG PICCs on bacterial colonisation, PICC-associated infection

and CHG resistance, compared with (3) conventional PICCs, catheter tips are being sent for further microbiological analysis in a selection of participants following PICC removal. This includes all PICC tips removed due to suspected infection, plus a control group of PICC tips from participants with no symptoms of infection (matched according to randomisation arm at a ratio of 2:1 cases to controls). All PICC tips are being cultured using the roll-plating method on blood agar, with quantification of cfus, species identification using Vitek-MS (BioMerieux) and susceptibility testing for a standard panel of antibiotics by Vitek 2 automated broth microdilution. In addition, CHG tolerance is being tested by determining minimum inhibitory concentrations against organisms isolated from PICC tips using broth microdilution (with an MIC ≥ 4 mg/L defining reduced susceptibility to CHG).²⁸ Genes known to be associated with CHG tolerance (eg, *qacA/B* and *smr*) are being confirmed by PCR. In patients with suspected CASBI and the same species grown in PICC tip cultures, organisms isolated from both blood and tip cultures are having DNA extracted and whole genome sequencing performed on the Illumina MiniSeq platform. Raw reads are being trimmed, checked for quality metrics, assembled and analysed using a custom pipeline to confirm species identification, define *in silico* multilocus sequence type and detect the presence of any antibiotic resistance genes. Other genes known to be associated with CHG tolerance and biofilm formation are being sought by BLAST against the assembled genomes. To confirm whether PICC tip and blood culture isolates are clonal, core genome differences between blood and PICC tip isolates are being determined by comparing single nucleotide polymorphisms.

Thrombogenic substudy

A subgroup of participants (n=120) are having blood collected on PICC insertion and, if possible, at the time of removal to assess haematological, coagulation profile and platelet activation. Blood samples are being collected via the PICC (from discard and whole blood aspirate) by ReN in sodium citrate and EDTA vacutainers (platelet/full blood count), and the samples will be analysed for full blood examination (including white blood cell differentiation), clotting times (prothrombin time and activated partial thromboplastin time), platelet activation studies (flow cytometry) and D-dimer. These analyses will link the theoretical proposed mechanism of action to the clinically reported outcomes, strengthening study outcomes. Scanning electron microscopy will semiquantitatively assess blood component adherence to internal and external surfaces of removed PICCs.

Data analysis

Analysis will be 'intention to treat' with patient the unit of analysis. Baseline characteristics for each of the PICC groups will be descriptively presented using frequencies and percentages for categorical variables and means and SDs (or median and IQR if appropriate) for continuous variables. Primary analyses will compare between-group device failure rates using Cox proportional hazards regression, with treatment group

included as the main effect. Effect estimates will be presented for hydrophobic PICCs versus conventional polyurethane PICCs and for CHG-impregnated PICCs versus conventional polyurethane PICCs as HRs with corresponding 95% CIs. Time-to-event data will be displayed graphically using Kaplan-Meier curves, and the differences between each of the hydrophobic and CHG PICC treatment groups and the conventional polyurethane PICC group will be compared using the log-rank test. The cause of any missing data will be assessed, and sensitivity analyses to investigate the potential impact of missingness will be undertaken using multiple imputation techniques if appropriate. A per-protocol analysis will assess the effect of protocol violations (ie, insertion of an unallocated PICC). P values ≤ 0.05 will be considered statistically significant, except for the primary outcome (≤ 0.031), which has been chosen due to the two intervention arms being tested against a single control and to account for the two interim analyses of each intervention arm against control.

Estimating cost parameters

We hypothesise significantly reduced costs over control from a direct hospital perspective for the episode of care (2020 standardised \$). We will quantify additional costs, cost offsets and net monetary benefit, considering PICC failure, reinsertions and treatment costs of complications per group. A micro-costing or bottom-up approach will be used with detailed resource use for PICC insertion/removal recorded for 75 procedures selected at random (25/group). Staff wage costs for application, troubleshooting, replacement, consultation and equipment used will be recorded. Regression analysis of the total cost per patient as the dependent variable will be conducted using a generalised linear model with trial group allocation (either intervention or usual care) as the predictive variable and controlling possible confounders. A gamma family, log-link model has been assumed given the typically skewed nature of health cost data but will be further tested for appropriate model specification. To explore potential differences in health-related quality of life and patient experience, participants are being asked to complete both the EuroQol Five Dimension (EQ-5D) multiattribute utility instrument at insertion and removal (including EQ-5D-Youth for 8–17 year-olds)^{29 30} and the Australian Hospital Patient Experience Question Set, developed by the Australian Commission on Safety and Quality in Health Care,³¹ at removal.

Patient and public involvement

Feedback regarding the acceptability of the intervention products was sought from patients and their families during the pilot studies, which informed the development of this study. The overall results of the study will be communicated to the study participants by sending a plain language summary, and the associated peer-reviewed articles, to the provided email address.

ETHICS AND DISSEMINATION

This trial is registered with the Australian New Zealand Clinical Trials Registry. The trial has approval from the

Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC) (HREC/QCHQ/48682) and Griffith University HREC (Ref. No. 2019/094) and is being managed in accordance with the Australian Government National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research³² and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

A Data Safety Monitoring Committee will review unblinded data and serious adverse events at n=400 and n=800 to advise on any recruitment and safety issues they identify and to investigate whether one or more of the intervention arms should be stopped early for efficacy. The intervention arm will stop recruiting if the arm is significantly different to the control arm at $p < 0.002$.³³

Serious adverse events are being monitored and reported to the HRECs, as are protocol modifications. If important protocol amendments are made (eg, changes to eligibility criteria), AJU will update all investigators, HRECs, patient information and consent forms and the trial registry. Clinical trial insurance is held by the university. Written informed consent is being obtained from participants or representatives prior to participation (see online supplemental file 1 for example of the patient consent form). Consent can be withdrawn. Identifying details are being kept confidential via study IDs.

The trial and substudies were written by the investigators and will be published in peer-reviewed journals using appropriate reporting formats (ie, EQUATOR) with authorship consistent with the International Committee of Medical Journal Editors Guidelines. Data will be held at Griffith University.

Trial status

The trial began on the 8 September 2019. At the time of manuscript submission, 174 patients had been recruited, with a 2-year recruitment period per study site planned.

Data statement

The data generated and/or analysed during the trial are not yet publicly available as the trial is ongoing. When the trial is complete, data sets will be available from the chief investigator (AJU) on reasonable request and after agreement by ethics.

DISCUSSION

PICCs are a common medical device and an important component of modern healthcare, but the current failure rate of up to 30% is unacceptable and leads patients to experience multiple adverse events. As demonstrated in other vascular access types, innovations in PICC materials and design are an opportunity to reduce this preventable harm to patients and improve efficiencies in healthcare. These technologies are novel and potentially life-saving; however, this independent, sufficiently powered RCT is necessary to ascertain efficacy. Adoption of new

technologies without evidence, including economic, may increase expenditure without increased value or cause unintended adverse events.

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Contributors AJU, TK, NMM, AB and PNAH conceived the study; AJU and JB designed the economic evaluation; AJU, DA, TK, RW, NMM, RSW, VC, CMR and PNAH designed the protocol; AJU, TK, RW, NMM, AB, BP, NR, PL-A, AC, JB, RW, VC, AC, PM, CMR and PNAH secured funding; all authors prepared and approved the final version of the manuscript.

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Competing interests Griffith University (AJU's former employer) has received unrestricted research and educational grants to support her research (unrelated from the current project) from 3M, Becton Dickinson and Cardinal Health. Griffith University (DA's employer) has received consultancy payments for educational lectures based on her research and clinical expertise from 3M and Johnsons and Johnsons. Griffith University (TK's employer) has received unrestricted research and educational grants from 3M, Becton Dickinson and Medical Specialties Australasia. Griffith University (RW's employer) has received unrestricted research and educational grants to support her research (unrelated to current project) from Becton Dickinson. Griffith University (NMM's former employer) has received unrestricted research and educational grants to support her research (unrelated from the current project) from 3M, Becton Dickinson and Cardinal Health. Griffith University (AB's employer) has received consultancy payments from Becton Dickinson (unrelated to the current project). Griffith University (JB's employer) has received unrestricted research and educational grants to support her research (unrelated to current project) from Becton Dickinson, and Navi Technologies. PM is a member of Myeloma Advisory Boards for Celgene, Janssen, Amgen, Takeda and Amyloidosis Advisory Boards for Pfizer and Caelum. No personal fees have been received for these services. PM's has received a research grant from Janssen for a clinical trial. PM has accommodation and registration provided by Amgen for attendance at the International Myeloma Workshop in 2019. Griffith University (CMR's former employer) has received unrestricted research and educational grants to support her research (unrelated to the current project) from 3M, Becton Dickinson and Cardinal Health. Other authors have no conflicts of interests to disclose.

Patient and public involvement statement Feedback regarding the acceptability of the intervention products was sought from patients and their families during the pilot studies, which informed the development of this study. The overall results of the study will be communicated to the study participants by sending a plain language summary, and the associated peer-reviewed articles, to the provided email address.

Patient consent for publication Not required.

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RESEARCH

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Clinical experience with power-injectable PICCs in intensive care patients

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See related Letter by Zampieri,

<http://ccforum.com/content/16/2/425>

Abstract

Introduction: In the ICU, peripherally inserted central catheters (PICCs) may be an alternative option to standard central venous catheters, particularly in patients with coagulation disorders or at high risk for infection. Some limits of PICCs (such as low flow rates) may be overcome with the use of power-injectable catheters.

Methods: We retrospectively reviewed all of the power-injectable PICCs inserted in adult and pediatric patients in the ICU during a 12-month period, focusing on the rate of complications at insertion and during maintenance.

Results: We collected 89 power-injectable PICCs (in adults and in children), both multiple and single lumen. All insertions were successful. There were no major complications at insertion and no episodes of catheter-related bloodstream infection. Non-infective complications during management were not clinically significant. There was one episode of symptomatic thrombosis during the stay in the ICU and one episode after transfer of a patient to a non-intensive ward.

Conclusion: Power-injectable PICCs have many advantages in the ICU: they can be used as multipurpose central lines for any type of infusion including high-flow infusion, for hemodynamic monitoring, and for high-pressure injection of contrast media during radiological procedures. Their insertion is successful in 100% of cases and is not associated with significant risks, even in patients with coagulation disorders. Their maintenance is associated with an extremely low rate of infective and non-infective complications.

Introduction

The use of peripherally inserted central catheters (PICCs) has many theoretical advantages in the ICU setting because these devices are associated with low-risk insertion, even in patients with altered coagulation and/or difficult neck anatomy [1]. PICC insertion can be carried out with no risk of pleura-pulmonary damage and with no clinically significant risk of local hemorrhage or hematoma, if compared with standard central venous catheters (CVCs) [2]. Furthermore, PICC insertion in the upper mid-arm is characterized by an easy dressing of the exit site, this benefit being particularly evident in

patients with tracheostomy [3]. Although the issue is somehow controversial [4,5], PICCs are also usually considered a device at low risk for catheter-related bloodstream infection (CRBSI), which may be an additional advantage in acutely ill patients [2]. PICCs can also be used for central venous pressure monitoring [6], specifically when using polyurethane, open-ended catheters > 4 Fr, as long as they have no evidence of malfunction.

Although the potential benefit of PICCs in the acutely ill patient was proposed almost 10 years ago [7], some technical limitations have slowed their introduction into clinical practice in the ICU. The ICU patient usually requires high flow rates of intravenous infusion as well as simultaneous administration of potentially incompatible drugs, which should ideally be delivered through

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multiple-lumen catheters. Since standard PICCs are catheters with small caliber (typically, 4 to 5 Fr) and relevant length (30 to 40 cm on average), they are associated with a high resistance to flow. A single-lumen 4 Fr PICC may achieve a flow rate of 2 to 3 ml/minute (by gravity infusion) and 10 to 11 ml/minute (with pump); the flow rates of a single-lumen 5 Fr PICC are only slightly higher (3 to 4 ml/minute by gravity and 11 to 13 ml/minute with pump). Double-lumen PICCs have worse performance in terms of flow, because increasing the number of lumens reduces the lumen size and further decreases the flow rate.

The situation changed following the recent development of PICCs made of ultra-resistant polyurethane, which were originally introduced for use with the high-pressure pumps (so-called power injectors) commonly utilized for high-velocity infusion of contrast media during computed tomography scan and other radiological procedures. The rationale for these so-called power-injectable PICCs was the concern of potential mechanical damage to standard polyurethane and silicon PICCs when used during high-pressure injection. Power injectors may develop pressures as high as 300 psi (silicone catheters tolerate no more than 50 to 60 psi, and most polyurethane catheters approximately 100 psi). Several reports of mechanical damage to PICCs and other devices have been described in the literature, leading to an official warning from the US Food and Drug Administration [8] - which recommended that power injection should be done exclusively through venous access devices specifically registered for this use.

Such power-injectable PICCs - developed and marketed by several companies - have been shown to have the additional advantage of delivering infusions at a very high rate (3 to 5 ml/second = 180 to 300 ml/minute), if coupled with an appropriate infusion pump. Multiple-lumen PICCs were also developed shortly thereafter, and their use in the ICU started to spread. At present, several brands of power-injectable PICCs are available - single lumen (3, 4 or 5 Fr), double lumen (4 or 5 Fr) and triple lumen (6 Fr). They all share several features that make them particularly attractive for the ICU setting: low risk of mechanical and hemorrhagic complications at insertion, low risk of CRBSI, high flow (up to 300 ml/minute), easy monitoring of central venous pressure, low risk of lumen obstruction, and safe use for radio-diagnostic procedures. Most power-injectable PICCs also have a reverse-taper design at the proximal end; that is, the diameter of the catheter that enters the exit site is slightly thicker than the diameter of the rest of the catheter. This technical feature is potentially associated with reduced bleeding at the exit site soon after insertion, with increased stability of the PICC (reduced

risk of dislodgement) and with protection against exit site contamination.

In the present paper, we report our preliminary experience with the use of power-injectable PICCs in adult and pediatric ICU patients.

Materials and methods

We reviewed retrospectively all power-injectable PICCs inserted in acutely ill patients admitted to the shock/trauma ICU and the pediatric ICU of our institution (a 1,100-bed university hospital), during 12 months.

According to our hospital policies, indications for PICC insertion were (a) need for a central line for parenteral nutrition, and/or infusion of drugs that require a central line (pH < 5 or > 9, osmolarity > 500 mOsm/l, drugs associated with endothelial damage), and/or (b) central venous pressure monitoring, and/or (c) need for frequent blood sampling. Need for a central line with more than three lumens was considered a clear indication for a standard multiple-lumen CVC. Also, all PICCs were inserted as an elective procedure; all central lines inserted in emergency were standard CVCs. Overt sepsis was also considered a contraindication to PICC insertion. Other standard contraindications to PICC insertion, according to our hospital policies, were small deep veins of the arm (brachial/basilic vein < 4 mm), local contraindications due to specific arm conditions (skin infection, burns, orthopedic devices blocking the arm, previous axillary node resection due to breast cancer surgery, and so forth) as well as actual or impending chronic renal failure requiring an arteriovenous fistula. Severe arm edema and/or obesity are not considered contraindications to PICC insertion, although in these situations the brachial and basilic vein might be too deep (> 3 cm) so the cephalic vein is preferentially cannulated.

We considered both multiple-lumen and single-lumen catheters, of different sizes (from 4 to 6 Fr) and different brands, as long as they were power injectable and were inserted during the ICU stay (Figures 1 and 2). All PICCs were inserted according to the specific protocol defined by our hospital PICC team [9]. All of the catheters were inserted by ultrasound-guided puncture of the deep veins in the upper mid-arm (Figure 3), as recommended by current guidelines [3,10], using the micro-introducer technique. A standard 5 to 10 MHz linear ultrasound probe (adult patients) or a small 10 to 14 MHz hockey-stick ultrasound probe (children) was used. Veins with diameter = or > 4 mm were considered suitable for 4 Fr catheters, veins = or > 5 mm suitable for 5 Fr catheters and veins = or > 6 mm suitable for 6 Fr catheters. Maximal barrier precautions were consistently used during the procedure (cap, mask, sterile gown,



Figure 1 Triple-lumen power-injectable peripherally inserted central catheter inserted in an adult patient in the ICU.



Figure 2 Double-lumen power-injectable peripherally inserted central catheter inserted in a pediatric patient in the ICU.



Figure 3 Ultrasound scan at the mid-arm. Left to right: basilic vein, brachial nerve, and brachial artery between two small brachial veins.

sterile gloves, vast sterile field). The correct position of the tip of the catheter (that is, in proximity of the junction between the superior vena cava and the right atrium) was verified during the procedure using the intracavitary electrocardiography (EKG) method [11]; a post-procedural chest X-ray for checking the tip position was required only when the EKG method was not applicable (atrial fibrillation and/or no evident P-wave at the basal EKG). All PICCs were secured to the skin using sutureless devices, as currently recommended [12-14]. All procedures were performed by nurses or physicians specifically trained for PICC insertion. Maintenance of the line and dressing policies were carried out according to the intervention bundle for preventing line infections developed by the GAVeCeLT - Gruppo Accessi Venosi Centrali a Lungo Termine - and adopted by our hospital PICC team (preferential use of 2% chlorhexidine for antisepsis of the exit site, preferential use of transparent dressing, and so forth) [15]. Occlusion of the line was prevented by a specified policy of periodic flushing and locking with saline.

Acutely ill pediatric patients were also included in the study. Since 3 Fr power-injectable PICCs were not yet available in Italy at that time, power-injectable PICCs

could be inserted in children only when an arm vein > 4 mm was available. In many acutely ill children, power-injectable PICCs had been inserted as direct central lines, by ultrasound-guided puncture of the internal jugular vein or of the brachio-cephalic vein, or as access to the inferior vena cava, by ultrasound-guided puncture of the femoral vein: all of these off-label uses of power-injectable PICCs were excluded from this analysis (only PICCs inserted into the upper mid-arm were considered).

According to our hospital policies, diagnosis of CRBSI was established by the differential time to positivity method (blood culture from the catheter becoming positive at least 120 minutes before the peripheral blood culture) or by direct culture of the tip of the catheter, should the catheter be removed or replaced over guide-wire (culture of the same microorganism from the blood and from the tip of the catheter).

Diagnosis of catheter-related thrombosis was established by ultrasound examination (compression ultrasonography and duplex Doppler), performed only when clinically indicated by signs and symptoms suggesting venous occlusion (edema of the arm, PICC malfunction, unexplained local pain, and so forth). Catheter-related

peripheral venous thrombosis was defined as the presence of occlusive thrombosis of the deep veins of the arm containing the PICC, extending or not to the axillary vein. Catheter-related central venous thrombosis was defined as the presence of any extent of thrombosis in the subclavian, internal jugular or brachio-cephalic vein or in the superior vena cava on the side of PICC insertion.

We collected all relevant data and information, including patient's age and disease, indication for PICC insertion, duration of the dwell time for the device, incidence of complications at insertion or during maintenance, and cause of removal. All data were included in a software-operated database and analyzed by standard descriptive statistics. Values are reported as the mean $\pm$ standard deviation.

According to the policy of our hospital, retrospective studies do not require approval from the Ethics Committee and do not require informed consent from the patient. Informed consent was obtained, however, from the patients represented in Figures 1 and 2 for publications of their images.

Results

During the study period, 89 open-ended, power-injectable polyurethane PICCs were inserted in our ICUs. Sixty-five catheters were inserted in adult patients (50 triple-lumen 6 Fr, six double-lumen 5 Fr and nine single-lumen 4 Fr) and 24 catheters in pediatric patients (15 double-lumen 5 Fr, two double-lumen 4 Fr and seven single-lumen 4 Fr).

All PICCs were successfully inserted without major complications. Minor complications at insertion were local hematoma (three cases, 3.4%), repeated punctures of the vein (five cases, 5.6%), difficulty in progression of the catheter (four cases, 4.5%), and one malposition (one patient with no evident P-wave on basal EKG, where the intracavitary EKG method could not be used). This latter case required repositioning of the PICC by exchange over guidewire. A few adult patients had severe obesity (body mass index > 35 , seven patients); in these patients PICCs were inserted without difficulty, mostly via the cephalic vein since brachial and basilica veins were too deep.

The average dwell time of the device in the ICU was 25 ± 12 days (median value 22 days): most catheters stayed in place for > 2 weeks and were removed when the patient was transferred to a non-intensive ward. No PICC was removed because of complications while in the ICU. One patient died while the PICC was still indwelling. In a few cases of adult patients, the PICC was left in place even after discharge from the ICU.

Most PICCs were used easily for high-flow intravenous infusions ($> 1,000$ ml/hour, by infusion pump), as

well as for measurement of the central venous pressure. In almost one-half of patients, PICCs were also used for injection of contrast medium during computed tomography scans. There were no relevant episodes of occlusion or of persistent difficulty in blood withdrawal; eight cases of partial obstruction were resolved by simple saline infusion under pressure. There was not a single case of CRBSI. Symptomatic catheter-related central venous thrombosis occurred only in one adult in the ICU (a patient with a hematological neoplastic disease, admitted to the ICU for respiratory failure); a second case occurred in a patient after his transfer to a non-intensive ward. Both episodes occurred within 10 days after PICC insertion. There were no dislodgements or accidental removals of the device while the patients were in the ICU; one case of accidental removal occurred after transfer of the patient to a non-intensive ward.

Discussion

The first clinical experience with PICCs in the ICU was reported in 1996 [16]. At that time PICC insertion was usually performed at the antecubital fossa, without ultrasound guidance, but the results of this experience were particularly promising - especially in terms of minimal incidence of CRBSI (91 PICCs, 0.6 episodes per 1,000 catheter-days). The potential advantages of PICCs in the ICU have been described by other authors [7]; however, reports dealing specifically with the use of power-injectable PICCs [17,18], and particularly of power-injectable PICCs in the ICU [19], are scarce. To our knowledge, the present paper is the first clinical study reporting a detailed analysis of the complications associated with the use of power-injectable PICCs in adult and pediatric patients in the ICU.

Our rate of complications at insertion has been extremely low, especially considering the anatomical difficulties expected in acutely ill patients. Complications at insertion are known to be minimal when using both ultrasound guidance and the micro-introducer technique [2,10,20,21].

With regards to the incidence of CRBSI, evidence is accumulating that PICCs are associated with a lower rate of infection if compared with CVCs, probably because of an exit site that is less prone to contamination (upper mid-arm skin is characterized by a lower bacterial colonization if compared with skin at the neck or in the infra-clavicular area) [2,3]. This lower infection rate has also been shown in ICU patients. In a 2008 multicenter study including eight Spanish ICUs, the CRBSI rate of PICCs was significantly lower than that of CVCs (1.08 episodes vs. 3.83 episodes for 1,000 catheter-days), although ultrasound guided insertion was not used [22]. In a recent study carried out regarding 37 PICCs in a burn unit [23] the incidence of PICC-related

bloodstream infection was 0 episodes, as compared with 6.6 episodes of CVC-related bloodstream infection for 1000 catheter-days. In another study in a surgical ICU [24], PICCs presented 2.2 episodes of CRBSI per 1,000 catheter-days versus 6 episodes in CVCs. Even in a recent clinical study [19], which reported a high incidence of PICC-related thrombosis (see below), there was not one episode of CRBSI in a cohort of 50 PICCs consecutively inserted into ICU patients. According to another recent paper in ICU patients [25], the occurrence of CRBSI appears to happen later in PICCs compared with CVCs (23 days vs. 13 days). As reported in similar papers on ICU patients [19,23], in our experience the rate of CRBSI was zero - although it must be stressed that our investigation was a noncontrolled retrospective study and did not aim to compare CVCs with PICCs in terms of infection rate.

Mechanical complications were also uncommon in our series. Dislodgement has been described as a problem only in studies not using ultrasound-guided insertion in the upper mid-arm and/or not using sutureless devices for PICC securement [16]. Also, mechanical damage such as ruptures usually occurs with silicon PICCs rather than with polyurethane PICCs [21]. The ultrasensitive polyurethane of power-injectable PICCs appears to protect from mechanical damage, dislodgement and occlusion. In a recent clinical study [18], a decreased risk of occlusion and rupture was reported with power-injectable PICCs if compared with silicon and standard polyurethane PICCs.

A high incidence of clinically symptomatic PICC-related thrombosis has been recently reported by two papers, one dealing with non-power-injectable PICCs in the ICU [26] and the other with triple-lumen 6 Fr power-injectable PICCs in the ICU [19]. These findings are in contrast with the low incidence of symptomatic thrombosis reported by our present study and by a recent study of a series of 473 power-injectable PICCs [17]. This apparent contradiction may be explained by the observation that PICC-related venous thrombosis is known to be secondary to many different factors [2], including the use of ultrasound guidance during insertion, the choice of vein (the diameter of the vein should be at least three times the diameter of the PICC), the proper position of the tip, as well as the material of the catheter and the use of sutureless devices for securement. The low rate of symptomatic PICC-related thrombosis in our study may thus be explained by the consistent use of ultrasound guidance, by the careful choice of a vein of an appropriate diameter, by the intra-procedural verification of the position of the tip by the intracavitary EKG method, as well as by the use of a sutureless securement device in 100% of cases. On the contrary, in the papers quoted above, the same catheter

size - either 5 Fr [26] or 6 Fr [19] - was adopted in every patient.

Conclusions

This preliminary retrospective report shows that power-injectable PICCs can be successfully utilized in most ICU patients, even in those requiring high volumes of fluids, multiple intravenous lines and/or monitoring of the central venous pressure, as well as in children. Contraindications to PICC insertion are few, such as the need for an emergency central line, need for a central line with more than three lumens, and lack of availability of a vein > 4 mm in the upper mid-arm. CRBSI and catheter-related venous thrombosis appear to be uncommon. Most early and late complications can be successfully minimized by the adoption of an insertion protocol [27] including key recommendations such as ultrasound guidance, by the choice of a vein with appropriate caliber, by careful positioning the tip by the EKG method, and by the consistent use of sutureless securement devices.

Considering the results of this preliminary retrospective analysis, further prospective, controlled, randomized trials comparing the clinical outcome of CVCs with PICCs in intensive care patients are warranted.

Key messages

- Power-injectable PICCs are a promising alternative option to standard CVCs in ICU patients.
- Power-injectable PICCs may have a role in many ICU patients, with few contraindications (emergency, need for more than three lumens, small deep veins of the arm, or local contraindications to brachial/basilic venipuncture).
- If inserted with a proper protocol (including ultrasound guidance, proper choice of vein, EKG guidance, aseptic technique, securement with sutureless device, and so forth), the insertion of PICCs is not associated with any relevant risk, even in patients with severe cardiorespiratory problems.
- If inserted with a proper protocol (see above), the risk of catheter-related infection is similar to or even lower than that with CVCs.
- If inserted with a proper protocol (see above), the risk of catheter-related thrombosis is similar to that with CVCs.

Abbreviations

CRBSI: catheter-related bloodstream infection; CVC: central venous catheter; EKG: electrocardiography; PICC: peripherally inserted central catheter.

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Authors' contributions

The study was conceived, designed and coordinated by MPi and GS. The clinical data were collected by AB, MPo, DC and MPi. MPi, DGB, MGA and GS analyzed the data and prepared the manuscript. All authors have read and approved the manuscript for publication.

Competing interests

The authors declare that they have no competing interests.

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A comparison of silicone and polyurethane PICC lines and postinsertion complication rates: a systematic review

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ABSTRACT

Purpose: To determine postinsertion complication rate for peripherally inserted central catheters (PICCs), in particular the difference between silicone and polyurethane lines in general population groups as well as oncology and non-oncology patient groups.

Methods: A systematic review of prospective and retrospective studies in the English language between January 2000 and October 2013 focusing on postinsertion complication rates for PICCs in the adult population. Joanna Briggs Institute tools were used to extract data from the final 19 articles with information collated relating to catheter type, patient type, overall complication rate, rates of infection, occlusion, dislodgment, phlebitis, thrombus and rupture.

Results: Overall, the PICCs complication rates ranged from 8 to 50%. Although both lines saw similar overall rates upon closer observation, the strengths and weaknesses of both lines are shown.

Polyurethane PICC lines were found to provide lower rates of infection, dislodgment, thrombus and rupture complications.

Mixed results were found with catheter line occlusions, overall averages showing polyurethane lines slightly higher rates than silicone. Oncology patients however saw opposite results.

Phlebitis rates saw the largest division among the postinsertion complication rates, with 6.7% more phlebitis in the general patient group and 14.5% in the oncology group more for those with polyurethane PICC lines compared with the silicone.

Conclusions: Both silicone and polyurethane PICC lines exhibit nearly identical overall average postinsertion complication rates; however, it is the type of complications experienced that differ. Overall, oncology patients can expect to experience higher levels of postinsertion complications.

Keywords: Complications, Medical imaging nursing, Peripherally inserted central catheter, Vascular access

What is already known about the topic?

- Peripherally inserted central catheters (PICCs) are an established form of intravenous (IV) access for patients undergoing medium to long-term therapy and their popularity is spreading.
- There are a number of different PICC lines on the market.
- PICC lines constructed of either silicone or polyurethane are well established in the industry; however, opinions still vary regarding their corresponding complication rates and best line to insert for positive patient outcomes.

What this paper adds

- A systematic review comparing postinsertion complication rates in silicone and polyurethane PICC lines.
- A systemic review of tier one-quantitative studies comparing postinsertion complication rates in PICC lines with different patients types: oncology and non-oncology.

Introduction

A PICC line is a central venous access device (CVAD) that provides a safe long-term access via a long catheter inserted in the patient's upper arm (1). The catheter is generally inserted at the bedside or in the radiology suite by an interventional radiologist, doctor or more recently by specialty nurse-lead insertion teams (2). Given that around 80% of patients in a hospital setting require some form of intravenous (IV) access (3) and the many advantages of PICC lines for medium to short-term IV access, PICC lines are becoming increasingly commonplace (3).

PICC lines have come a long way in design and popularity since their first insertion by a German physician back in 1929 (4).

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The device, once seen as a last resort, has become widely used since the 1960s due to the introduction of silicone PICC line technology vastly increasing its practicality (4). Although PICC lines are widely considered a safe and reliable form of IV access, they do still carry risks of various common postinsertion complications as outlined in Table I, perhaps most notably infection, both at the insertion site and in the bloodstream, blockage of the PICC, phlebitis, thrombus, rupture of the PICC line and dislodgment (5). These complications may lead to the need for the premature removal of the current PICC line and reinsertion of another PICC exposing the individual to further risks of complications. Obviously, this is less than ideal for a number of reasons including but not limited to monetary, resources and patient comfort (6).

As PICC's popularity has grown, an array of different lines have become available on the market, including those now manufactured using a tougher polyurethane material and those utilising inbuilt valve technology. A recent trend in America has seen the use of polyurethane PICC lines dominating the market with around 70% of all PICC lines manufactured from polyurethane material (7). It is anticipated that this percentage will increase to 95% by 2017 edging silicone catheters nearly completely out of the market (7). This could easily be linked to some of the characteristics of PICC lines manufactured from polyurethane such as their strengthened wall allowing power injections (8) as well as tolerating signifi-

cantly higher flow rates with lower risks of rupture (9). However, as Table II shows, there is little clear evidence regarding postinsertion complication rates.

Most facilities provide some form of PICC maintenance policy to guide postinsertion care in an attempt to limit the complications experienced by individuals requiring this therapy, and although the use of these lines have increased in popularity in health systems around the globe (1), comparatively few studies have been conducted into the complication rates and virtually no data exist comparing the complication rates between different PICC line types. It is for this reason this study aims to explore existing research in order to ascertain if there are any increased risks for postinsertion complication rates between PICC lines manufactured of either polyurethane or silicone. The study will also explore if certain patient groups experience fewer complications based on which PICC line they have inserted. The research questions to be addressed in this study are:

1. Is there a difference in postinsertion complication rates between polyurethane and silicon PICCs?
2. Do particular patient groups experience different rates of complications with a certain type of PICC line?

By answering these research questions, information will be available to guide inserting teams as to the most appropriate

TABLE I - PICC complication types

Complication type	Causes	Symptoms	Action
Infection: either at the insertion site or a blood stream infection (BSI).	Infection can occur due to improper aseptic techniques and hand hygiene.	Insertion site infection is characterised by erythema, purulent discharge and tenderness at the site, whereas BSI includes fever, chills, weakness and malaise (5).	Entry site infection can often be treated with antibiotics; however, catheter-related bacteraemia or sepsis will usually necessitate the removal of the PICC (12).
Occlusion	Intraluminal blockage is commonly the result of a reflux of blood entering the line and forming a thrombus inside the lumen. Extraluminal occlusion originates outside of the catheter such as development of a fibrin sheath, kinking or twisting of the catheter (3).	PICC line blocked, unable to be aspirated or flushed (3).	Intraluminal thrombus may be reversed by procedures used to dissolve the occlusion and vary depending on the origin of the occlusion (3).
Thrombus	Development of a deep vein thrombosis in the upper extremity.	Swollen and painful upper extremity (2).	Patient would need to be reviewed by a doctor, appropriate treatment given and the PICC line removed (13).
Dislodgement	Migration of the catheter usually resulting accidentally during PICC maintenance or confused patient.	PICC line no longer in same position. Most PICC lines have markers on the catheter, so this may be easily identifiable at external fixation.	Tip position would need to be reconfirmed by imaging and may necessitate removal (5).
Phlebitis	Inflammation of the vein in which the PICC line sits that may be categorised as mechanical, chemical or infective (5).	May present as redness, swelling and tenderness of the arm along the vein the catheter sits in (5).	Mechanical phlebitis may be treated by warm compresses, arm elevation and analgesia, but if the symptoms persist past 1 week, then the PICC should be removed (5).

TABLE II - Physical properties of polyurethane and silicone (PU polyurethane) (8)

Physical properties	PU	Silicone
Softness (prevent from intimal damage of vessel)	Not good	Excellent
Durability and easy bending	Moderate	Excellent
Maintenance of straight forward configuration	Excellent	Poor
Lubricability (easy and smooth withdrawal of stylete)	Not good	Not good
Wettability and water absorption	Not good	Poor
Tensile elongation at break	Moderate	Good

PICC line that will provide the patient with the best possible outcome.

Materials and Methods

Study identification and selection

Using a combination of predetermined search terms, a range of databases was searched for literature published between 1 January, 2000 and 31 October, 2013. The databases were all searched using the same search terms and parameters. The databases utilised were Cinhal, Pubmed, Health collection, Medline and Academic search complete. The search terms PICC 'and' was used in conjunction with complications, silicone and polyurethane were entered into the various databases. Only studies in English were sought.

Inclusion criteria

The inclusion of studies ranging from 2003 to 2013 was used to maintain contemporary relevance and ensure that the studies reflected current PICC line technologies. Studies were only included if they were primary studies derived directly from retrospective or prospective studies. All studies focused solely on PICC lines in an adult population and contained evidence pertaining to post-PICC line insertion complication rates. They all followed the progress of the PICC line from its insertion to either a set timeframe from insertion or until removal of the line as a result of complication or therapy completion.

Quality assessment

All of the studies attained from the databases from the above search terms were filtered by publication date, English language and so as to focus on an adult population. This was not possible with the complete database academic search, so at that stage, all abstracts were reviewed by one of the researchers and articles that focused on paediatric and neonatal PICC lines were manually excluded. With the

papers remaining, further manual elimination followed via the examination of article abstracts. Papers were excluded if they did not focus on PICC lines but incorporated them with other CVAD devices or did not involve a prospective or retrospective study of postinsertion complications. Duplicates were also removed. From this point, the remaining articles were subjected to the Joanna Briggs institute audit tool for the validity of cohort studies. This tool has been developed specifically to enable data extraction from articles to support evidence-based practice (The Joanna Briggs institute, 2011). The tool took a detailed look at each of the articles comparing them with a checklist for validity of cohort studies, which allowed for the accurate comparison of the strength of each study. This led to the exclusion of one of the articles, as it did not accurately or consistently document or follow the lines throughout their Tab. III pertains to the remaining articles.

Results

Included articles came from all over the world.

Twelve of the studies were prospective studies, seven retrospective and one that saw a combination of both study types and one undefined study type. Of the PICC types inserted, six were polyurethane, seven silicone, five studies did not specify and three studies compared more than one PICC type. Ten of the studies looked primarily at an oncology patient base, two were surgical/medical patients and nine were samples from all of patients, all receiving PICC insertions over a specified period of time in the department. With 11 studies, the PICC lines were inserted primarily by either doctors or interventional radiologists, eight were inserted by nurse-lead teams and two were left unspecified. The sample size varied in the studies from 5 with less than less than 50 participants, six with 50-100 participants, three with 100-150 participants and eight studies had more than 200 participants. Four of the studies did not utilize ultrasound for insertion, whereas six stated they did; two used both ultrasound and nonultrasound techniques and the remaining nine studies did not specify.

With all of the data extracted from the articles and entered into an excel spreadsheet, a data table (see Tab. III) was constructed.

Total complication rates, as the name suggests, generally encompass a total of all of the complications reported. In some studies, this is inclusive of complications that do not have any long-term effects or result in removal of the line. The overall complication rates for PICC lines the percentage ranged from as little as 8% (10) through to a height of 50% (11). This overall complication rate averaged out at 28.4% across all of the studies with the two different PICC types almost identical at 29.53% for polyurethane and 29.46% for silicone lines. Figure 1 presents a comparison of average complications rates presented in the research reports sources for this study. Using Chi-square, this offers no statistical significance.

When delving further into the data regarding particular types of complications, the two PICC lines start to show their strengths and weaknesses. When comparing the averages of both PICC types for infection, the polyurethane line experienced 8% and the silicone 11.2%. Overall, 11.2% was

TABLE III - Articles for inclusion

Study	Focus group	Type of study	PICC used in the study	Who inserted the PICC	Size of Study group	Country of studies origin	Outcomes	Insertion technique ultrasound or venography
Bard PowerPICC solo2 vs. Cook turbo-ject: A Tale of Two PICCs (12).	All from a single surgical ward with patients known to have uncorrected coagulopathy or being treated for venous thrombus excluded.	Combination of prospective data collection and retrospective chart audit.	Bard Power PICC Solo2 (Power injectable polyurethane) and Cook Turbo-ject (traditional polyurethane).	Interventional radiologist at Royal University Hospital Medical Imaging department.	53; 25 Bard Power PICC solo2 and 28 Cook Turbo-ject.	Canada	Total complication rates for Bard 48% (16.7/1000 catheter days) with 3 suspected infection, 5 occlusions, no thrombus compared to Cook at 25% (15.2/1000 catheter days). 3 suspected infection, 3 occlusion and one thrombus.	Ultrasound or venography at discretion of radiologist
The use of the peripherally inserted central catheter (PICC) in the hospital environment (13).	Conveniences sample all adults with PICC insertion from 2000 to 2007 at Moinhos de Vento Hospital.	Historical cohort approach with retrospective data collection.	Unspecified	Unspecified	229	Brazil	25.8% reported some form of post insertion complication. 20.3% suspected infection, 15.3% obstruction, 28.8% migration and 6.8% listed as other complications.	Not stated
Peripherally inserted central catheters (PICCs) in the management of oncohaematological patients submitted to autologous stem cell transplantation (14).	Patients undergoing autologous peripheral blood stem cell transplantation.	Patients were enrolled in the study but data collection method unspecified.	Bard 4Fr single lumen Groshong silicone PICC.	Physicians and nurses of the haematology unit University Cattolica. All lines were inserted bedside.	60	Italy	Complications recorded; accidental removal 5%, suspected venous thrombus 5% and Catheter related blood stream infection (CRBSI) 3.3%.	Ultrasound guidance
High rate of complications associated with Peripherally inserted central venous catheters in patients with solid tumours (15).	Patients with solid tumours.	Retrospective medical records review.	Not Specified.	Interventional radiologist insertion at Flinders Medical Centre.	27	Australia	40.7% rate of complication requiring premature PICC removal. 11% experienced systemic septic complications, 17.6% CRBSI, 4% thrombosis, 4% blockage and 7% leakage issues.	Not stated
Efficacy and complications in peripherally inserted central catheter insertion: a study using 4-Fr nonvalved catheters and a single infusate (16).	Inpatients undergoing long term intravenous antibiotics (IVAB).	Not fully specified.	Vaxcel 4-Fr non-valved catheter heparin locked (traditional polyurethane).	Interventional radiologist insertions at Queen Mary hospital.	44	China	Overall complication rate of 18.4%. Thrombosis 5.26%, Kinking of line 5.26%, insertion site infection 2.63%, Hub breakage 2.63% insertion site pain 2.63%.	Ultrasound guidance

To be continued

TABLE III - Continued

Study	Focus group	Type of study	PICC used in the study	Who inserted the PICC	Size of Study group	Country of studies origin	Outcomes	Insertion technique ultrasound or venography
Comparison of three peripherally inserted central catheters: pilot study (2).	Cancer services department.	Pilot study	Polyurethane PICC with antimicrobial coating (traditional polyurethane), valved silicone PICC and Power injectable PICC. All lines were 5 Fr dual lumen.	Nurse-led team insertion at Whittington Hospital.	300	United Kingdom	Complication rates for polyurethane antimicrobial coated PICC; 20% occlusion, 70% mechanical phlebitis 10% infective phlebitis, 1% migration and 10% sepsis. Complication rates for valved silicone PICC; 30% occlusion, 20% rupture, 3% infective phlebitis, 3% migration and 10% sepsis. Complication rates for Power injectable PICC; 2% occlusion, 10% mechanical phlebitis, 1% migration and 1% sepsis.	Ultrasound guidance
Two-year trends of peripherally inserted central catheter line complications at a tertiary- care hospital: role of nursing experience (17).	Patients receiving PICC between May 1996 and May 1998 at St Boniface General hospital.	Retrospective chart review, coupled with a prospective survey.	Not specified.	Nurse-led PICC insertion team at St Boniface General hospital. PICCs inserted at the bedside.	202	America	Overall complication rate 20.4%. Accidental removal 3.5%, occlusion 8.7%, phlebitis 5.2%, breakage 3.3% and infection 1.6%.	Not stated
Determination of complication rate of PICC lines in Oncological patients (18).	All PICC lines inserted for a period of one year in the radiology department of the Aga Khan university hospital.	Perspective cohort study	4 Fr single lumen non-valved polyurethane PICC. (Unclear if traditional or power injectable).	Inserted in the radiology department by interventional radiologist.	146	Pakistan	Overall complication rate of 32.8%. Of these 25% were infection, 4.1% blockage, 2% accidental removal and .7% for both leakage and thrombosis.	Not stated
Peripherally inserted central venous catheters for autologous blood progenitor cell transplantation in patients with hematological malignancies (19).	Patients with hematological malignancies.	Prospective study	5 Fr Olimpicc and LIFEATH PICC (traditional Polyurethane).	Physicians inserted.	70 37 olympicc and 28 LIFEATH.	Germany	Complication rates for the Olimpicc PICC; overall complication rate 32.4%. Complications were 5.4% Phlebitis, 2.6% catheter occlusion, 18.9% leaking of the catheter, 5.4% catheter colonisation. Complication rates for the LIFEATH PICC; overall complication rate 28.5%. Complications were 10.7% Phlebitis, 10.7% catheter colonisation, and 7.1% catheter related bacteraemia.	Not stated

To be continued

TABLE III - Continued

Study	Focus group	Type of study	PICC used in the study	Who inserted the PICC	Size of Study group	Country of studies origin	Outcomes	Insertion technique ultrasound or venography
Peripherally inserted central catheter complications highlight the need for ongoing support: results of a chart audit (20).	Patients receiving PICC insertion in the medical imaging department of Townsville hospital over a 13-month period. Outpatients were excluded.	Retrospective chart audit.	Not specified.	Nurse lead team at Townsville hospital.	575	Australia	Over 10% of patients needed their PICC line replaced to complete their therapy. The main complications leading to the removal were; suspected infection at 44% occluded lines 23% and accidental removal at 15%.	Ultrasound guidance
Regular article: a nurse led peripherally inserted central catheter line insertion service is effective with radiological support (21).	Patients undergoing chemotherapy at Bradford Royal Infirmary.	Prospective study.	Both 4 and 5 Fr Groshong PICC were used number of lumens not specified.	Nurse-led insertion team on the ward and radiologist insertions.	144	United Kingdom	Complication rates were as follows; catheter related sepsis rate 4.9%, subclavian vein thrombosis 4.9%, occlusion. 7%, leaking 2.1% line displacements 13.9%.	Non ultrasound placement by nursing staff and ultrasound guidance by radiologists.
Performance comparison of peripherally inserted central venous catheters in gastrointestinal surgery: a randomized controlled trial (22).	26 consecutive patients.	Prospective study.	Groshong silicone PICC and an open-ended PI polyurethane PICC line. Both were 4 Fr single lumen.	Doctors under radiological guidance.	25	Japan	Groshong complications were one line phlebitis and one CRBSI. PI catheter saw two lines with occlusion and one case of phlebitis.	Nonultrasound guidance
Prospective, randomized, comparative evaluation of proximal valve polyurethane and distal valve silicone peripherally inserted central catheters (4).	Various patients receiving PICC line insertions. Of the recruited patients some were excluded from the data due to; death (unrelated), transfer from the facility, self-requested PICC removal with discharge against advice.	Prospective randomised trial.	Proximally valved polyurethane PICC Vaxcel with PASV (traditional polyurethane) technology and distally valved silicone PICC Groshong.	All PICCs inserted by interventional radiologist.	459 in total. 228 received the polyurethane PICC line and 231 the silicone PICC. Final number of insertions after exclusions 392.	Singapore	Silicone PICC complication rates; total 26.8%, Phlebitis 11.6%, infection 2%, occlusion 9.6% leakage 1% and dislodgement 2.5%. Polyurethane PICC complication rates; total 47.9%, phlebitis 23.2%, infection 6.2% occlusion 11.9% leakage 3.6% and dislodgement 3.1%.	Ultrasound guidance

To be continued

TABLE III - Continued

Study	Focus group	Type of study	PICC used in the study	Who inserted the PICC	Size of Study group	Country of studies origin	Outcomes	Insertion technique ultrasound or venography
Vascular access via peripherally inserted central venous catheters (PICCs): experience in 40 patients with acute myeloid leukemia at a single institute (23).	Patients with acute myeloid leukaemia, Hahassah university hospital.	Retrospective study.	Single lumen 5 Fr Cook PICC silicone lines.	All PICC lines inserted by interventional radiologists.	52 PICC lines in total of 40 patients.	Israel	Complications; total 71%, blood stream infection 33% dislodgement 2% catheter tear 3.8%, obstructing clot 25% insertion site phlebitis 23%.	Nonultrasound guidance
Efficacy of multifaceted interventions in reducing complications of peripherally inserted central catheter in adult oncology patients (24).	Two focus groups. Pre-interventional group all medical oncology patients in the department with PICC inserted 1/8/2004-31/11/2006. The second group were the post intervention group including all PICC lines in the department between 1/1/2007-31/10/2008.	Prospective study.	4 Fr silicone Groshong single lumen PICC.	All PICC lines inserted by nurse lead insertion team.	Preintervention group 69. Postintervention group 165.	China	Preintervention complications rates; total complications 30.43%. Infective complication 13.04%, phlebitis 7.25%, occlusion 4.35%, thrombosis 2.9% and dislodgement 2.9%. Post intervention complications rates; total complications 11.52%. Infective complications 4.24%, phlebitis 3.03%, occlusion 1.21% thrombosis 0.61% dislodgment 1.81% and catheter leakage 0.61%.	Not stated
Retrospective study of the total insertion period of peripherally inserted central catheter: Discussion of anti-thrombogenic surface and other biomaterial requirements (8).	All patients were admitted to Taipei medical university hospital over a two-year period with 6 omitted and defined as failures as the PICC was removed within 3 days of insertion.	Retrospective study of patient's records.	4 Fr single lumen silicone PICC.	Unspecified.	120	Taiwan	Reason for PICC removal in under one month insitu; persistent oozing/ bleeding >3days 25.8%, infection related or phlebitis 6%, occlusion 4.1%, leaking 2.5% and accidental removal 2.5%.	Nonultrasound guidance

To be continued

TABLE III - Continued

Study	Focus group	Type of study	PICC used in the study	Who inserted the PICC	Size of Study group	Country of studies origin	Outcomes	Insertion technique ultrasound or venography
Complication rates among cancer patients with peripherally inserted central catheters (25).	All PICC lines inserted at Memorial Sloan-Kettering Cancer Centre between 21/11/1998-21/11/1999.	Prospective study.	Groshong silicone PICC, 4 Fr single lumen and 5 Fr dual lumen.	Nursing and physician.	351	America	Total complication rate 32.8%. Consisting of: infection related 7.4%, phlebitis 6.6% vein thrombosis 3.4%, occlusion 4% leaking 6% and accidental removal 5.4%.	Both ultrasound and nonultrasound insertions.
Patient-reported usefulness of peripherally inserted central venous catheters in terminally ill cancer patients (26).	Patients in a palliative care unit during a one-year period at Shirone Ohdori hospital from February 2007 to January 2008.	Prospective study.	Single lumen 60 cm catheter no further specification.	Inserted by physician at the bedside.	38	Japan	26% experienced complications. 18% catheter coagulation (8% of these were irreversible) and mild upper extremity oedema in 8%. 18% were removed due to dislodgement.	Not stated
Reducing the risk of peripherally inserted central catheter line complications in the oncology setting (27).	All medical oncology patients undergoing PIC insertion 1/1/2003-31/12/2003.	Retrospective review.	Dual lumen Groshong silicone PICC.	Interventional radiologists.	88	Australia	Overall complication rate of 15.9%. Infective complication 5.7%, thrombosis 4.5%.	Ultrasound guidance
The efficacy of upper arm placement of peripherally inserted central catheters using bedside ultrasound and microintroducer technique (28).	Adult population undergoing PICC placement in the facility.	Prospective study.	6 Fr dual or triple lumen polyurethane power injectable PICC line.	Nursing staff.	500	America	Overall complication rate 3.2%. Infection 0.9%, occlusion 0.9%, rupture 0.5%.	Ultrasound guidance
Triple-lumen peripherally inserted central catheter in patients in the critical care unit: prospective evaluation (11).	ICU setting.	Prospective randomized study converted to a single arm trial.	6 Fr power injectable and traditional polyurethane PICC.	Nursing team.	50	America	Overall complication rate of 50%. Suspected infection 16%, occlusion 14%, dislodgement 6% and thrombus 20%.	Ultrasound guidance

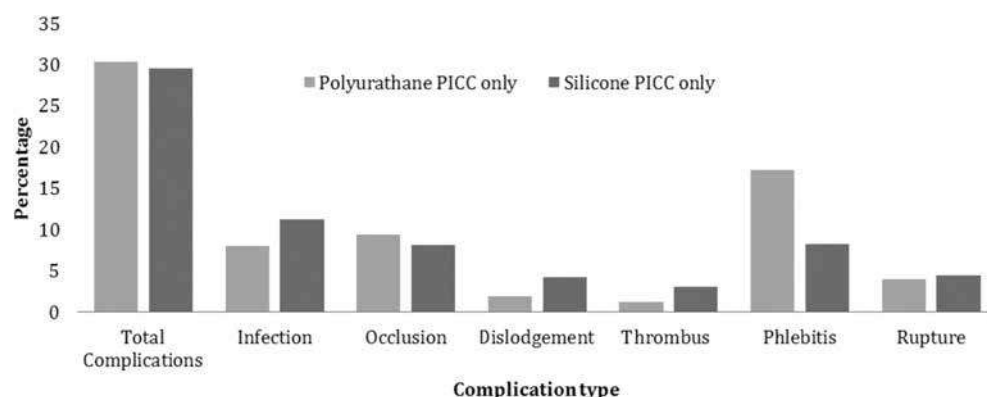


Fig. 1 - A comparison of average complications rates.

the average for infection rates. This was true in the oncology patients as well with 10.2% for polyurethane compared with 12.6% for silicone.

The incidences of phlebitis rates are the most dramatic of the comparisons. Overall, 12.2% of PICC lines experienced this complication, but the differences between the two lines are the largest of all of the complications. Polyurethane PICC lines experiences phlebitis rates of 15%, while their silicone counterparts just 8.3%. In one study, the group with an antimicrobial-coated polyurethane PICC line saw 70% phlebitis rate, whereas those in the same study receiving a standard polyurethane line 10% and no phlebitis rates from the silicone lines (2). This was also reflected in oncology patients with the higher rate of 23% experiencing phlebitis with polyurethane PICC compared with 8.5% for silicone lines.

When further dividing the results into those specifically with oncology patient groups or medical/surgical patients, further trend starts to appear. Cancer patients experienced higher rates of all complication types collected, that is, overall complication rates, suspected or confirmed infection, occlusion, dislodgement thrombus, phlebitis and rupture/leakage of the line. Across these studies, the overall complication rate for oncology patients with PICC lines was 33.2%, as medical/surgical patients held a much lower average of 22.3%.

When isolated, all of the studies that included only oncology patients, the average infection rate was 12.5% with those receiving a polyurethane PICC line experiencing an average of 10.2%. In one study that compared three different PICC types, this polyurethane group did not experience any infection at all (2). The average infection rate for cancer patients with a silicone PICC line was marginally higher than 12.6%.

The differences between ultrasound and nonultrasound-guided insertion overall complication rates for all PICC lines was found to be 27% for ultrasound and 34.9% for nonultrasound-guided insertions. The ultrasound-inserted studies showed lower infection rates at 9.1 than 12% for the nonultrasound-guided study groups. In addition, the ultrasound-inserted studies had a much lower rate of dislodgement at only 2.5% than nonultrasound studies, which recorded 6.1% dislodgement. However, nonultrasound insertion groups showed lower occlusion rates at 7.6% than 10.3%, and lower rates of phlebitis at 14.9% than 18.4% for the ultrasound insertion group. There were marginal differences in thrombus formation with 3.23% for the nonultrasound insertion groups

and 4.25% for ultrasound insertion. Finally, levels of rupture were 2.8% for nonultrasound and 4.55% for ultrasound-inserted PICC studies.

Discussion

The research questions for this study focused on whether particular patient groups are better suited to a certain type of PICC line and whether post insertion complications are influenced by the type of PICC line used. The results indicate that the overall the complication rates for both types of PICC lines were nearly identical, but closer interpretation showed the strengths of each of the lines. Perhaps the complication, which stood out the most in these data, was phlebitis. This was true for both the overall studies and the oncology-specific studies. The stiffness of the polyurethane that allows for the pressure injection does create mechanical phlebitis at much higher rates than the silicone. This compatibility with pressure injection can be invaluable for patients requiring a number of computed tomography (CT) scans, such as oncology staging scans and delivery of IV fluids at a faster rate and also where peripheral IV access is difficult. This form of phlebitis is a complication that is possible to resolve in a majority of cases in a very cheap and efficient manner without the need for removal.

Surprisingly, the levels of rupture of the PICC line are almost identical. Although the polyurethane line is a stronger line, its rupture rate is nearly level with that of the softer silicone line; however, the silicone lines are incompatible with any form of power injection. The softness of the silicone may also contribute to higher dislodgement rates, as the stiffness of the polyurethane line may result in the line remaining in place.

The overall averages saw the higher rates of occlusion in the larger internal polyurethane catheter, although this was only marginal and the opposite was seen among oncology patients. In the oncology patient group, the thicker wall and therefore smaller inner lumen of the silicone PICC line occluded more instances in 2.5%. It is unclear why these differences are seen, but a larger study at the one facility comparing these factors when all the same postinsertion care is undertaken would determine whether this is an area for further investigation.

The polyurethane PICCs did display a lower infection rate in both the general and oncology patients, with silicone PICC

lines seeing a 2-3% higher infection rate than their polyurethane counterparts.

There was an insufficient amount of data to compare complication rates for polyurethane and silicone PICC lines in medical/surgical patients, as there was only the one study that specified silicone PICC line use in surgical patients. This study by Miyagaki et al was also a small sample size of just 25. This lack of depth into this patient group also meant that comparison to the oncology patients was not viable. Limited studies were available related to the inclusion of a PICC line with a proximally located valve making further research into this area another to be explored.

Throughout the data extraction, it became apparent that there are substantial differences in complication rates postinsertion regardless of the PICC or patient type. This may be due to a lack of universal standardised postinsertion PICC care. Most of the studies did not specify postcare information such as who in that facility was qualified to access the PICC line as well as other postinsertion care. This difference noted does make generalisations difficult to establish if the number of studies is low. Some of the studies showed limited sample sizes. This may have led to a less accurate portrayal of overall complication rates in those particular studies.

Oncology patients were shown to exhibit a higher than average complications across all of the data collected except dislodgment. This shows that this patient group is particularly vulnerable, which could be attributed to a number of physiological reasons such as immunosuppression and altered haemostatic issues as the result of their conditions and/or treatments. Although this group had the largest amount of data available, limited studies focused on nononcology patients making further in-depth comparisons unavailable. As a result, limited data were available to address research question two, which focused on patient group suitability for particular PICC lines, opening the way for further research in this area. In addition, the reviewed studies paid limited attention to the presence or location of valves on the PICC line. Further research into the different PICC types, including the inclusion and location of valves in both oncology and nononcology patients, are needed with a particular focus on nononcology patient groups needed.

Limitations of the review included:

- There were some substantial differences in complication rates between studies regardless of PICC and patient type. This may be due to the different methods of PICC care utilised between different facilities and countries.
- The majority of the studies focused on oncology patient groups. Further research into different patient groups receiving particular PICC lines is required.
- Some of the studies included were built on small sample sizes.
- There was a lack of studies of substantial size regarding medical/surgical patients receiving silicone PICC lines, so the ability to compare the two different PICC types within this patient group was diminished.
- The presence and location (distal or proximal) of valves was not recorded and entered into consideration.
- Few articles are related to the traditional polyurethane PICC line.

Conclusions

Regardless of the material used in the manufacturing of PICC lines, they all remain a safe long-term alternative to more invasive forms of vascular access. Although complication rates vary greatly between the studies, overall complication rates between the two main PICC materials, polyurethane and silicone, are barely separable at 30.4 and 29.5%, respectively. It is only when delving further that each line seems to offer its own characteristics. Silicone PICC lines experience higher rates of infection, dislodgement, thrombus and rupture, whereas the polyurethane PICC lines received greater rates of phlebitis and occlusion complications.

The comparisons between oncology and the general medical/surgical patient groups highlighted the susceptibility of oncology patients with a rise in overall complications of 10%, with this trend applying across all of the complications. Unfortunately, with a lack of nononcology patient group studies or studies directly comparing the two patient groups, the extension of comparing the PICC types to conclude whether either type of line is better suited for oncology or nononcology is unavailable.

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