

Let Evidence Lead the Way to Practice Change: A Review of Needleless Connectors and Displacement

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Speaker

Dr. Nancy Moureau is an internationally recognized speaker and expert in the field of peripherally inserted central catheters and vascular access practice. A nurse for more than 40 years, Nancy works as the CEO of PICC Excellence, creating online education to help provide best practice training to clinicians who insert and manage vascular access devices. PICC Excellence supports the only PICC Certification process, Certified PICC Ultrasound Inserter, where those who meet and maintain qualifications gain the credentials CPUI.

Nancy works as an active clinician visiting home infusion patients for medication delivery with Infinity Infusion Nursing, and contracted PICC/midline insertions with PICC Access, LLC.

Nancy was a Recipient of the Herbst Award for excellence, constantly works performing research and literature analysis. Maintains adjunct associate professor status with Griffith University and is a member of the AVATAR group Alliance for Vascular Access Teaching and Research. Having received her PhD based on published research Dr. Moureau shares her knowledge through speaking, publication and development of educational programs. She is happy to be a resource and can be reached at

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Disclosures

Nancy Moureau has the following financial relationships to disclose:

Owner and CEO of PICC Excellence, Inc

***Speakers Bureau** for education and research 3M, Access Vascular, Accuvein, Advanced Medical Solutions, BBraun, Cathaid, Chiesi, CIVCO, Cleansite, Dale Medical, IV National, Linear, Nexus Medical, Parker Laboratories, and Teleflex*

All conflicts of interest have been resolved.

Contact hours are awarded after attending the educational activity and completion of the educational activity evaluation

Consider Implicit Bias



Please take a moment to reflect upon how our attitudes or internalized stereotypes may impact patients requiring peripheral or central intravenous catheters

“Implicit bias” means the attitudes or internalized stereotypes that affect nurses’ perceptions, actions, and decisions in an unconscious manner, that exist and often contribute to unequal treatment of people based on race, ethnicity, gender identity, sexual orientation, age, disability, and other characteristics that contribute to health disparities. (CA Bill 241)

Learning Objectives

Evaluate

Evaluate the evidence associated with the science and function of needleless connectors

Describe

Describe the impact of pressure on fluid movement and normal patient activities

Explain

Explain and discuss loss of patency and how control of blood reflux can reduce complications

Blood Reflux, What's That???



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Have you ever walked into a room to troubleshoot an IV and there was blood in the catheter?

Bedside Nurse is certain she flushed.

So, how does the blood get back in the catheter?

Bi-Directional Pressure Sensitive Anti-Reflux Needleless Connectors

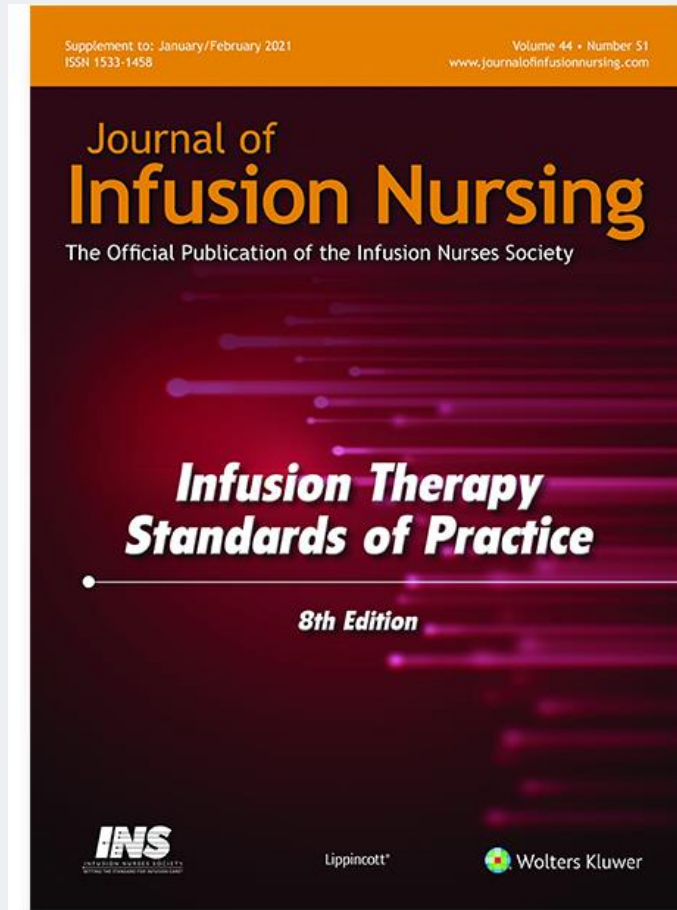


No bi-directional flow control
– Pressure changes and **Blood Flows Back**



Bi-directional flow control
-Pressure changes and **NO** back flow

What Do the Standards Say?



Gorski, et al. Infusion Therapy Standards of Practice 2021 Edition

Journal of Infusion Nursing

Needleless Connectors (Section 36)

Many additional factors, such as body movement, respirations, syringe plunger rebound, and coughing, cause changes within a catheter lumen that can allow blood to move into the lumen.

Thrombotic Catheter Occlusions

- *Moureau, et al. Thrombotic Catheter Occlusions*
- *Journal of Vascular Access Devices, 1999*
- Intraluminal thrombi develop from blood build-up within the lumen of a Catheter
- According to the literature thrombosis and infection are the two most common and serious occurring complications associated with VADs

Multidisciplinary management of

Thrombotic Catheter Occlusions

in Vascular Access devices

- Nancy L. Moureau, BSN, CRNI
- Barbara Thompson McKinnon, PharmD, BCNSP
- Claudia M. Douglas, RN, MA, CNN, CNS.C

Successful management of vascular access devices (VADs) can be challenging in any setting. When complications such as thrombotic occlusion occur, the clinician requires a comprehensive knowledge of the management options to overcome the problem.

association with VADs are intraluminal thrombus, mural thrombus, fibrin tail or flap, and fibrin sheath or sleeve.

As more cells and other blood products are added, a full venous thrombus may form.

Thrombosis Clinical Management

Thrombosis is the development of a blood clot within a vessel, a catheter, or both. Immediately after a VAD is inserted into a vessel, a coagulation cascade begins. Platelets and white blood cells attach to the catheter surface. As the platelets begin to aggregate, fibrin strands form to cover the foreign object. Thrombus formation may occur within 24 hours of the insertion of a device,¹ and the presence of a fibrin sleeve around central venous catheters is common in catheters that have been in place for greater than one week.² The types of thrombotic occlusions noted in

Intraluminal Thrombus

Intraluminal thrombi develop from blood build-up within the lumen of a catheter as the result of insufficient flushing, inadequate flow through the lumen of the catheter, or frequent withdrawals of blood via the catheter. Intraluminal thromboses frequently occur as partial occlusions, not completely blocking the catheter, but appearing as a crescent moon shape. As a result, flow may be compromised, with sluggishness apparent upon flushing or infusing solutions.

Mural Thrombus

The tip of the catheter may cause a vessel wall injury, initiating another coagulation cascade. A mural thrombus is formed when the fibrin from the vessel wall injury attaches to the fibrin building on the catheter surface.

Fibrin Tail or Flap

The adherence of fibrin, blood cells and platelets to the end of a catheter is called a fibrin tail or flap. As the tail, attached to the catheter, sticks out into the blood stream, more cells and other blood products become deposited onto the tail. As a result, fibrin tails can become quite long. The inability to aspirate blood from a functional catheter is frequently caused from a fibrin flap or tail. A persistent withdrawal occlusion is the presence of a fibrin flap that acts as a one way valve, allowing the catheter to flush easily, but not allowing blood to be aspirated.

Fibrin Sheath/Sleeve

A fibrin sheath or sleeve is formed extraluminal, from adherence of fibrin to the external surfaces of the catheter. Fibrin sleeves may act as a sock, covering

Benchmarking Incidence of Loss of Patency

- Moureau, et al. Central Venous Catheters in Home Infusion
- *Journal of Vascular Interventional Radiology*, 2002
- Strategic HealthCare Programs National Database
- Retrospective observational study [of home care patients with a CVC catheter from April 1999 to September 2000] utilizing a large healthcare database
- 50,470 patients representing 2.83 million catheter days; patients who underwent home infusion care and had undergone placement of a Central Venous Catheter (CVC).
- Thrombotic dysfunction was defined as thrombus accumulation within a catheter resulting in partial or complete blockage.
- Thrombotic occlusion was the principal cause of catheter dysfunction, occurring in 28% of patients in this group.
 - BSI was reported in 541 patients, generally more than 30 days after catheter insertion.
 - Catheter thrombosis outcomes resulted in therapy interruption (43%), catheter replacement (29%), premature CVC removal (14%), unscheduled emergency room visits (9%), and/or hospitalizations (6%).

Clinical Studies

Central Venous Catheters in Home Infusion Care: Outcomes Analysis in 50,470 Patients

Nancy Moureau, BSN, CRNI,¹ Susan Poole, MS, CRNI, CNSN,¹ Margie A. Murdock, RN, MSN,¹ Sarah M. Gray, PhD, and Charles P. Semba, MD¹

PURPOSE: Outpatient home infusion therapy is increasing; however, little data exists on the outcomes of patients receiving care. The purpose of this study was to document the natural history of central venous catheters (CVCs) used in home infusion care to determine the rate and type of catheter complications.

MATERIALS AND METHODS: Data from the Strategic HealthCare Programs National Database from April 1999 to September 2000 were analyzed. Primary study objectives were to identify (i) types of CVCs and principal diagnoses, (ii) type and rate of catheter complications, and (iii) outcomes in managing thrombotic catheter complications. Event rates were calculated per 1,000 catheter days; 50,470 patients representing 2.83 million catheter days met study criteria.

RESULTS: The rates of complications (per 1,000 catheter days) for the most common events were: catheter dysfunction (0.83 total; 0.6 nonthrombotic, 0.23 thrombotic), catheter site infections (0.26), and bloodstream infections (BSIs; 0.19). A total of 4,138 complication events were identified (event rate per 1,000 days: 1.5). The total rates of complications with each catheter type were: midline catheters (4.5), PICCs (2.0), nontunneled central catheters (1.1), tunneled catheters (1.0), and chest ports (0.52). Catheter dysfunction with loss of patency was the most common group of complications. Thrombotic occlusion was the principal cause of catheter dysfunction, occurring in 28% of patients in this group, typically within 7 days of catheter insertion. BSI was reported in 541 patients, generally more than 30 days after catheter insertion. Catheter thrombosis outcomes resulted in therapy interruption (43%), catheter replacement (29%), premature CVC removal (14%), unscheduled emergency room visits (9%), and/or hospitalizations (6%).

CONCLUSION: Catheter dysfunction is the most frequent complication of all CVCs in our population, almost twice that of infections. Outpatient home infusion catheter dysfunction results in delays to therapy, unscheduled hospitalizations, and need for device replacement.

Index terms: to come

J Vasc Interv Radiol 2002; 13:000-000

Abbreviations: BSI = bloodstream infection, CVC = central venous catheter, PICC = peripherally inserted central catheter

GREATER than 5 million central venous catheters (CVCs) are inserted each year in the United States (1-4).

From PICC Excellence (N.M., Orange Park, Florida; OptimaCare (S.P., Bensenville, Illinois; Genesis (M.A.M., S.M.G., C.P.S.), South San Francisco, and Division of Cardiovascular and Interventional Radiology (C.P.S.), Stanford University, Stanford, California. From the 2002 SCVIR Annual Meeting. Received January 10, 2002; revision requested February 27; final revision received May 28; accepted May 29. Address correspondence to N.M., PICC Excellence, 1833 Castille Dr., Orange Park, FL 32067; E-mail: nancy@piccexcellence.com

¹ These authors have identified the existence of a potential conflict of interest.

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The demand for CVCs is increasing as medical therapies become more complex and provide a broader range of functions, including delivery of intravenous fluids, parenteral nutrition, antibiotics, chemotherapy, and blood products, and blood sampling for laboratory monitoring. Outpatient infusion services have risen dramatically as providers have come under increasing pressure to reduce hospital costs and the population of the United States has grown older (5). CVC use already has become integral to therapy outside the traditional hospital setting. Herbst and colleagues (6) reported that CVCs are used in 93% of patients receiving home infusion therapy, com-

pared to 13% of hospitalized patients (6).

As interventional radiologists are becoming key providers in managing CVCs, understanding long-term outcomes is necessary to identify problems, improve clinical practice algorithms, and create economic models that will reduce health care costs. Extensive data exists for the frequency and types of catheter complications that arise in the inpatient hospital-based setting (7-9); however, there is sparse data on catheter-related complications in the rapidly growing outpatient home infusion environment (10-12). The purpose of this study was to document the complications associ-

Occlusion is the most common complication of Central Catheters

- Hadaway. Reopen the Pipeline
- *Nursing Journal*, 2005
- Problems within the catheter lumen. Occlusion of the catheter lumen is the most common noninfectious complication of CVCs.
- Affecting about one-third of all CVCs, occlusions may originate from biofilm (a slimy material containing microorganisms that coats the catheter), a thrombus, or drug precipitate.
- Organisms are introduced to its surface during venipuncture and into its lumen during infusions and manipulation of the catheter hub during tubing or cap changes, medication administration, and flushing.
- Thrombus in the catheter lumen. Just as protein and fibrin from the blood collect on the catheter's outer surface, they can build up inside the catheter from blood aspirated to assess catheter patency or from blood reflux into the lumen.
- Several factors can cause unintentional reflux into the I.V. catheter lumen:
 - When you release pressure on the plunger rod, the plunger rebounds and draws blood back into several centimeters of the catheter lumen
 - Coughing, sneezing, vomiting, lifting heavy objects, or heart failure can increase intrathoracic pressure, forcing blood into the catheter lumen

Reopen the pipeline

Learn why a vein or catheter may become occluded, how to head off trouble, and what to do if your patient has problems.

BY LYNN C. HADAWAY, RN, C, CRNI, MEd

WALTER ZINKOFF, 77, has bacterial endocarditis and receives vancomycin through a peripherally inserted central catheter (PICC). Attempting to flush the catheter before infusing his next dose, you encounter a lot of resistance and can't aspirate blood. Mr. Zinkoff tells you that his last dose took 2 hours to infuse—twice as long as normal.

You should get a free-flowing blood return whenever you use a syringe to gently aspirate from any intravenous (I.V.) catheter, so you're facing a problem. To protect Mr. Zinkoff from serious complications, investigate whether a thrombus or something else is occluding his PICC or the vein where it resides before you try to inject or infuse anything through it.

The vein and the catheter are two distinct flow systems, each vulnerable to occlusion during I.V. therapy. The causes of vein and catheter problems vary, as do prevention and management techniques. In this article, I'll discuss problems that can affect catheters in both peripheral and central veins, explain what you can do to protect your patient from injury, and offer suggestions that may help you save a line.

Problems with peripheral catheters

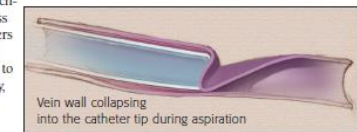
Because their tips remain in peripheral veins, both short peripheral and longer midline catheters are considered peripheral catheters.

A **short peripheral catheter**, less than 3 inches (7.5 cm) long, is typically placed in a small, superficial vein of the hand or arm. If the I.V. bag runs dry and blood backs up, a thrombus can occlude the catheter. If the dressing doesn't adequately stabilize the catheter, movement can cause the external portion to kink or the internal portion to damage the vein wall and trigger thrombosis. (You'll learn more about how

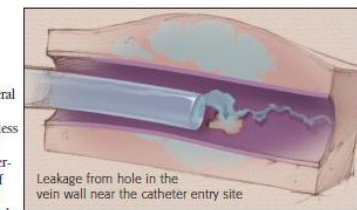
thrombosis develops later.) Phlebitis or infiltration also can slow or stop the flow of fluid.

Routinely assess your patient's hand and arm where the I.V. device was placed. Look for reddened, blanched, tight, translucent, or cool skin; swelling; pain; numbness; streak formation; a palpable venous cord; purulent drainage; and circulatory impairment. If you detect any of these problems, immediately remove the peripheral catheter.

Although blood return is a key assessment finding in I.V. therapy, inability to get a blood return isn't a sure sign of occlusion in a peripheral catheter. Aspirating from a catheter resting in a small-diameter vein could collapse the vein wall into the catheter tip to block the backflow of blood. Assess your patient for other signs and symptoms of complications and try other ways to get a blood return. For example, hold the I.V. bag lower



than the catheter or gently pinch the administration set near the catheter. If you still don't get blood return, replace the catheter.



Even when you get a brisk blood return from a peripheral catheter, you can't rule out complications if other problem signs are present. For example, swelling around the insertion

site may indicate a hole in the vein wall near the catheter tip in addition to the one where the catheter entered the vein. (See *Assessing for problems and responding* for details.)

Catheter Occlusions are Costly

- Ernst, et al. LOS, Costs, Readmissions Alteplase or Replacement of CVCs
- *Journal of Hospital Medicine*, 2014
- Premier Research Services; Charlotte, NC
- Retrospective observational study [of hospitalized patients treated for a catheter occlusion from January 2006 to December 2011] utilizing a large hospital database
- 34,579 patients treated for a CVC occlusion by replacement (N=1028) or by alteplase (2mg) administration (N=33,551)
- 30 and 90-day readmission rates were 23.7% and 33.9% for alteplase group
- Mean length of stay pre-occlusion in the alteplase group (7.3 days) and post occlusion (8.8 days)
- The alteplase group had lower daily post occlusion costs than patients who received catheter replacements

Comparison of Hospital Length of Stay, Costs, and Readmissions of Alteplase Versus Catheter Replacement Among Patients With Occluded Central Venous Catheters

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BACKGROUND: Central venous catheter (CVC) occlusion is common, affecting 30% of all CVCs.

OBJECTIVE: To compare length of stay (LOS), costs, and readmissions associated with the use of alteplase to clear catheter blockage to outcomes associated with catheter replacement.

DESIGN: Retrospective observational study utilizing a large hospital database.

PARTICIPANTS: Hospitalized patients treated for catheter occlusion from January 2006 to December 2011.

MAIN MEASURES: Univariate analyses of patient characteristics and treatment patterns and multivariable regression analyses of postocclusion hospital costs, LOS, and 30- and 90-day readmissions were conducted.

KEY RESULTS: We included 34,579 patients treated for a CVC occlusion by replacement (N = 1028) or by alteplase (2 mg) administration (N = 33,551). Patients receiving alteplase were somewhat younger than those having catheter replacement (60 ± 19 vs 62 ± 20 years old, P = 0.0002). After adjust-

ing for patient and hospital factors via regression modeling, average daily postocclusion costs were \$317 lower for alteplase recipients than for catheter replacement patients (95% confidence interval [CI]: 238.22–392.24; P < 0.0001). Adjusted total postocclusion costs were \$1419 lower for alteplase recipients versus patients receiving catheter replacement (95% CI: 307.27–2458.12; P = 0.0121). Postocclusion operating room/surgery, radiology, and supply costs were significantly lower for alteplase recipients (P < 0.001). Average adjusted postocclusion LOS was similar for both groups (P > 0.05). Odds of readmission were not significantly different at 30 or 90 days.

CONCLUSIONS: Among patients treated for an occluded CVC, alteplase-treated patients had lower daily and total postocclusion costs than patients receiving catheter replacement. Cost differences were mainly driven by lower operating room/surgery, radiology, and supplier costs. *Journal of Hospital Medicine* 2014;9:490–496. © 2014 The Authors. *Journal of Hospital Medicine* published by Wiley Periodicals, Inc. on behalf of Society of Hospital Medicine.

Long-term central venous catheters (CVCs) facilitate care for patients with chronic illness by providing easy venous access for laboratory tests, administration of medication, and parenteral nutrition. However, several complications resulting from the use of CVCs, including sepsis, extravasation of infusions, and venous thrombosis, can increase associated morbidity and mortality. These complications can also interrupt and delay treatment for the underlying

disease and thereby affect outcomes. One of the most common CVC complications is catheter occlusion.¹

Catheter occlusion occurs in 14% to 36% of patients within 1 to 2 years of catheter placement.^{2–8} A catheter occlusion can be partial or complete, and can occur secondary to a variety of mechanical problems, including an uncommon, but potentially life-threatening, pinch-off syndrome. Medication or parenteral nutrition can also cause occlusion, which can be acute or gradual, with increasingly sluggish flow through the catheter. Inappropriate concentrations or incompatible mixtures can cause medications to precipitate within the catheter lumen.

Occlusions are either thrombotic or nonthrombotic. One autopsy study of patients with a long-term CVC found that a fibrin sheath encased the catheter tip in every case.⁹ An occluded catheter may compromise patient care,^{10,11} it may cause cancellation or delay of procedures, it potentially interrupts administration of critical therapies including vesicants, it may result in risk of infection, and it potentially leads to catheter replacement. This can further complicate care, leading to increased length of stay (LOS) and hospital costs.

To better understand resource utilization, LOS, and cost implications of alteplase compared with catheter

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Additional Supporting Information may be found in the online version of this article.

Received: November 21, 2013; Revised: March 5, 2014; Accepted: March 10, 2014

Published 2014. The Authors. *Journal of Hospital Medicine* published by Wiley Periodicals, Inc. on behalf of Society of Hospital Medicine. DOI 10.1002/jhm.2288

Published online in Wiley Online Library (Wileyonlinelibrary.com).

Understanding the Science

- Hawthorn, et al. Maintaining Vascular Patency
- *The Journal of Vascular Access*, 2019
- School of Nursing, Queensland University of Technology, Australia
- Up to 85% of hospital in-patients will require some sort of VAD during their admission, which may be inserted into the central or peripheral vasculature.
- VADs fail due to thrombosis and occlusion and is therefore imperative to maximize VAD patency



Causes of Loss of Patency



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What Does the Evidence Show?

Top 5 NC studies

- All needleless connectors are NOT the same
- Many clinicians do NOT know the difference
- Clamping sequences are not understood
- Clamping sequences are performed inconsistently or not at all

1. ELLI et.al., 2016
2. HULL et.al., 2018
3. GIBSON et.al., 2020
4. GORZEK et.al., 2021
5. SANSALONE et.al., 2021





Common Categories of Needleless Connectors

Negative displacement

Positive displacement

Neutral displacement

Anti-Reflux no-displacement



Needleless Connector Definitions

Needleless Connector (NC) is a device that allows intermittent access to a vascular access device with an administration set or syringe, without the use of needles while maintaining a closed system; types are categorized by description (ie, simple or complex) and function or open for flow upon set or syringe disconnection (ie, negative, positive, neutral, or anti-reflux) .

Simple NC. Allows a straight fluid pathway through the center lumen without any internal mechanism to control flow; example is a pre-pierced septum accessed with either a blunt cannula or male luer device; eg, split septum.

Negative Displacement NC. Allows blood reflux into vascular access device (VAD) lumen upon disconnection due to movement of valve mechanism or removal of syringe/set.

Positive Displacement NC. Allows a small amount of fluid to be held in the device; upon set or syringe disconnection, this fluid is pushed through the catheter lumen to clear any blood that refluxed into the lumen.

Neutral NC. Contains an internal mechanism intended to prevent blood reflux into the catheter lumen upon connection or disconnection.

Anti-Reflux NC. Contains a pressure-sensitive internal mechanism designed to prevent movement of fluid or blood into the catheter lumen when the flow of infusion solution has stopped. **Complex NC.** Has a variety of moving internal components that allow fluid flow in both directions; eg, mechanical valves.

What Do the Standards Say?

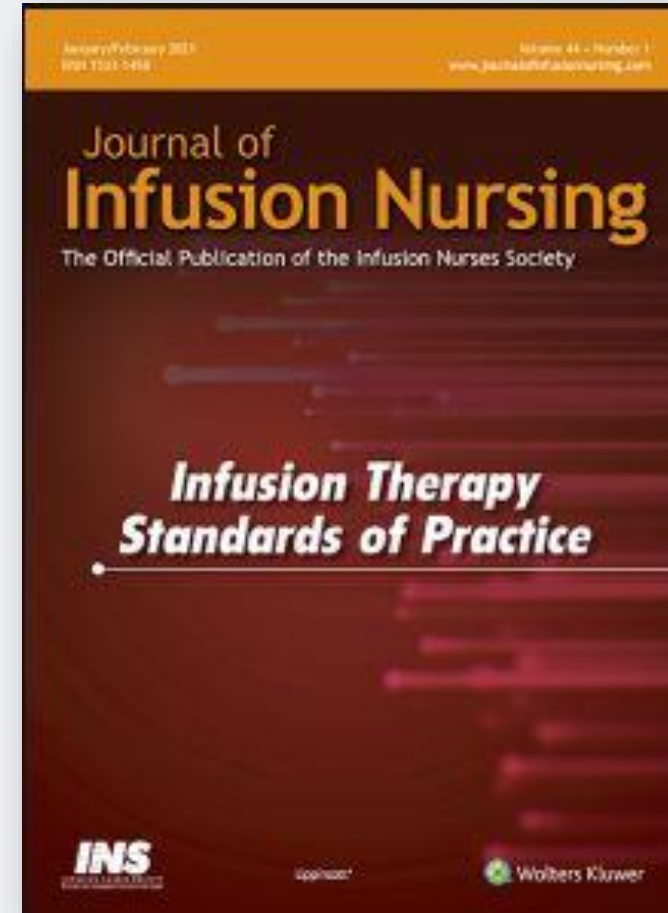
INS Standard 36

Fluid reflux is documented by in vitro studies in all types of needleless connectors, with quantities ranging from 0.02 to 50.37 μL .

Due to the internal mechanism, positive displacement devices have the greatest volume of reflux at connection, while the greatest amount of reflux occurs at disconnection for all other types of needleless connectors. (V)

Negative displacement devices produce the greatest volume of reflux, and

Anti-reflux devices containing a bidirectional, pressure-sensitive valve have the least amount of reflux.



What Does the Evidence Show?

JVA
ISSN 1129-7298

J Vasc Access 2016; 00 (00): 000-000
DOI: 10.5301/jva.5000583

ORIGINAL RESEARCH ARTICLE

In vitro evaluation of fluid reflux after flushing different types of needleless connectors

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ABSTRACT

Purpose: To evaluate fluid reflux, when disconnecting syringe, for different needleless connectors.

Materials: Nine connectors were tested; 540 measurements were carried out.

Results: The connectors tested showed very different performances, about reflux, on disconnection of the syringe used for flushing.

The calculated reflux volumes are: Max Zero® - BD: 6.90 (± 2.47) mm³; MicroClave Clear® - mm³; Bionecteur® - Vygon: 1.24 (± 0.73) mm³; Neutron® - ICU Medical: 0.12 (± 0.15) mm³; 33.51 (± 11.50) mm³; Safe Plus® - Cremascoli: 23.54 (± 3.56) mm³; NeutraClear® - Cair: 9.33 (± 3.33) mm³; - Cair: 0.33 (± 0.31) mm³; Dasa® BTC: 2.38 (± 1.67) mm³.

Differences between investigated devices were statistically significant ($p < 0.001$).

Discussion: It is difficult to establish the best quality-price ratio for needleless connectors. It is important to consider several variable factors: continuous or discontinuous infusion, catheter type, usage of catheter used. It would therefore be useful to have an indication of the intraluminal pressure changes by blood reflux in relation to a specific device.

Conclusions: Needleless connector is one of the main factors involved in keeping catheter patency. It is important to perform the best choice among the connectors available.

An empirical reflux measurement, relative to the needleless connector and the catheter in use, can be obtained using an 18G cannula.

Keywords: Blood, Catheter, Connector, Needleless, Occlusion, Reflux

Conclusions: Needleless connectors are one of the main factors involved in keeping catheter patency. It is important to make the best choice among the connectors available.

Elli S, Abbruzzese C, Cannizzo L, Lucchini A. In vitro evaluation of fluid reflux after flushing different types of needleless connectors. *The Journal of Vascular Access*. 2016 Sep;17(5):429-34. DOI: 10.5301/jva.5000583

What Does the Evidence Show?

JVA
ISSN 1129-7298

J Vasc Access 2017; 00 (00): 000-000
DOI: 10.5301/jva.5000781

ORIGINAL RESEARCH ARTICLE



Quantitative assessment of reflux in commercially available needle-free IV connectors

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ABSTRACT

Introduction: Blood reflux is caused by changes in pressure during disconnection of a syringe or intravenous tubing from a catheter. Reflux occurring with each brand of NFC, may result in fluid movement through catheter occlusions and increase the potential for catheter occlusions and increase the potential for catheter occlusions.

Methods: In this study, 14 NFC brands representing a range of connector designs were evaluated. Theoretical estimates of fluid movement occurring during connection were compared to 1) theoretically estimate amount of blood reflux volume based on component measurements, and 2) experimentally measured amount of negative, neutral and anti-reflux NFC and fluid movement.

Results: The results demonstrated fluid movement/reflux volumes of 9.75 μL to 56.54 μL for negative displacement, 3.60 μL to 10.80 μL for neutral displacement, and 0.02 μL to 1.73 μL for pressure-activated anti-reflux NFC. Separate experiment was performed measuring connection reflux of 18.23 μL to 38.83 μL for positive displacement NFC connectors.

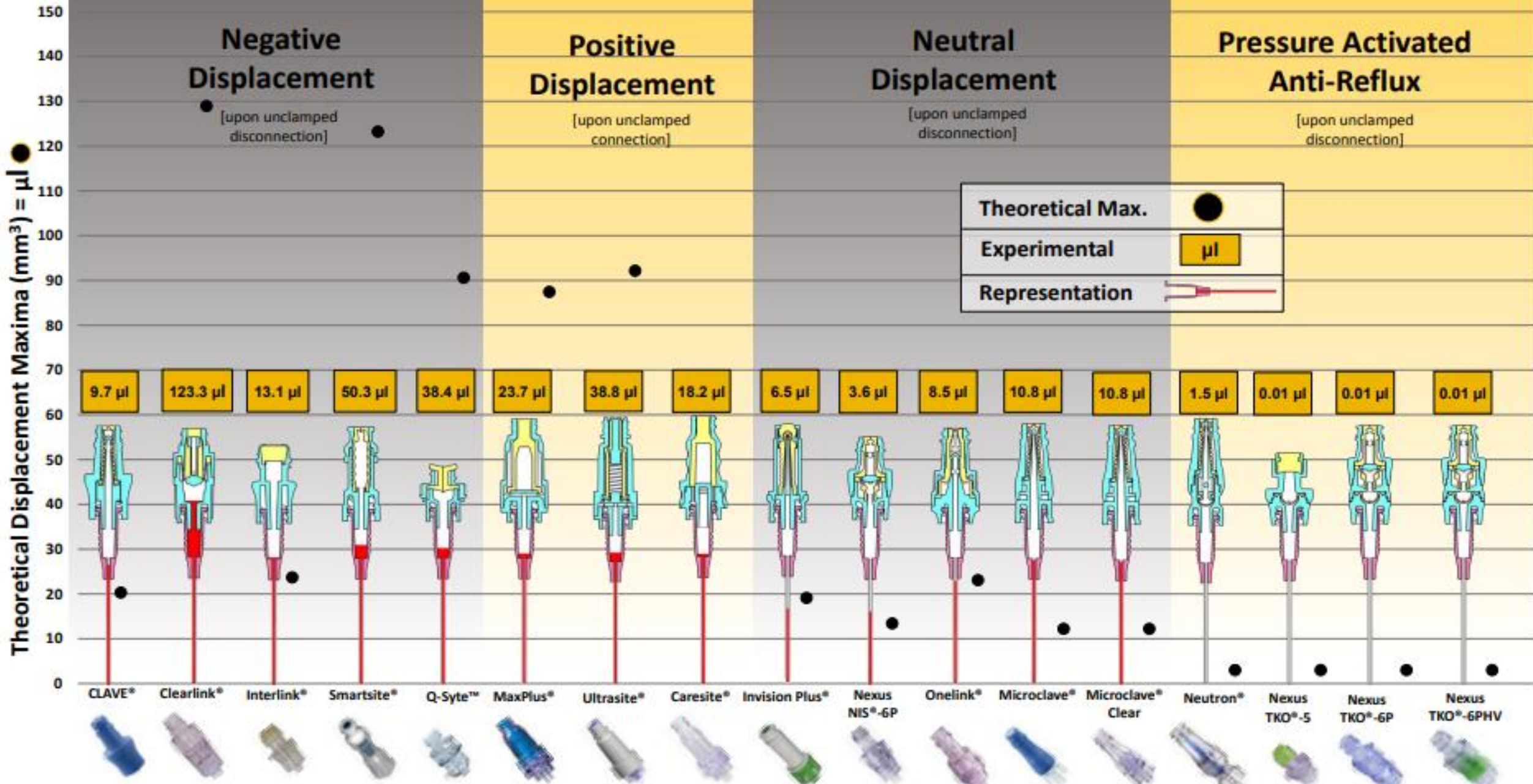
Conclusions: This study revealed significant differences in reflux volumes for fluid displacement based on NFC design. While more research is needed on effects of blood reflux in catheters and NFCs, results highlight the need to consider NFCs based on performance of individual connector designs, rather than manufacturer designation of positive, negative and neutral marketing categories for NFCs without anti-reflux mechanisms.

Conclusions: This study revealed significant differences in reflux volumes for fluid displacement based on NFC design. While more research is needed on effects of blood reflux in catheters and NFCs, results highlight the need to consider NFCs based on performance of individual connector designs, rather than manufacturer designation of positive, negative and neutral marketing categories for NFCs without anti-reflux mechanisms.

Hull GJ, Moureau NL, Sengupta S. Quantitative assessment of reflux in commercially available needle-free IV connectors. *The Journal of Vascular Access*. 2018 Jan;19(1):12-22. DOI: 10.5301/jva.5000781

Results

Hull GJ, Moureau NL, Sengupta S. Quantitative assessment of reflux in commercially available needle-free IV connectors. *The Journal of Vascular Access*. 2018 Jan;19(1):12-22. DOI: 10.5301/jva.5000781



What Does the Evidence Show?

ORIGINAL ARTICLE

Do Needleless Connector Manufacturer Claims on Bidirectional Flow and Reflux Equate to In Vitro Quantification of Fluid Movement?

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University of Michigan, Ann Arbor, Michigan

Highlights

- NC labeling does not appear to correspond with manufacturer claims.
- Two of 13 NCs passed the test for bidirectional flow control.
- All NCs reflux either on connection or disconnection.
- Neutral displacement does not appear to be present in the NCs tested in this observational study.
- Accurate bidirectional flow control, reflux cycle, and volume of reflux beyond the manufacturer's performance claims will assist in the proper use of NCs.

Abstract

Background: Manufacturers designed needleless connectors to bloodborne pathogens. All NCs displace fluid, and most of the observed bidirectional fluid movement and reflux may device describes NC. Reflux may lead to a significant patient occlusion and infection.

Methods: The in vitro observational study 1 (OS1) systematically prevented retrograde fluid from flowing into the infusion system. The observational study 2 (OS2) measured the amount of displacement on connection and disconnection of a Luer locking device.

Results: OS1: Eleven NCs failed bidirectional flow control. OS2: 13 NCs had varying amounts of fluid displacement or reflux. The measured volume of reflux for NCs during connection was 0.17 μ L to 114.65 μ L. The measured volume of reflux for NCs during disconnection was 0.17 μ L to 114.65 μ L. The measured volume of reflux for NCs during connection was 11.73 μ L to 34.43 μ L.

Conclusion: NC labeling does not appear to correspond with manufacturer claims. Neutral displacement does not appear to be present in the NCs used in this observational study. To properly instruct health care professionals about using the various NCs available, it is imperative to know the accurate bidirectional control, reflux cycle, and volume of reflux beyond the manufacturer's performance claims. Precise information may assist the clinician in reducing intraluminal blood exposure of vascular access devices.

Keywords: needleless connectors, reflux, positive, negative, neutral displacement, displacement, antireflux

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Gibson SM, Primeaux J. Do Needleless Connector Manufacturer Claims on Bidirectional Flow and Reflux Equate to In Vitro Quantification of Fluid Movement? *Journal of the Association for Vascular Access*. 2020 Dec 1;25(4):28-36. <https://doi.org/10.2309/JAVA-D-20-00031>

What Does the Evidence Show?

The Art and Science of Infusion Nursing

Assessment of Reflux From Needleless Connectors: Blinded Comparison of Category Designation to Benchtop Function Using a Venous Simulator

Sarah Gorzek, BS • John F. LaDisa, Jr, PhD

ABSTRACT

Needleless connectors (NCs) for vascular access have limited needlestick injuries, but complications including occlusion, thrombosis, and infections have increased despite reduced needlestick injuries. These complications relate to the ability of an NC design to limit volume fluctuations, prevent air embolism, and prevent bacterial contamination. Different NC designs requiring specific use instructions may vary in function relative to manufacturer-designated categories, and comparisons of different NCs have resulted in confusion, ultimately leading to suboptimal vascular access. The authors therefore quantified the function of NCs using a venous simulator. Thirteen blinded NC design categories (antireflux, neutral, and antireflux) were tested to quantify flow characteristics at a representative intravenous pressure (3 NCs per design); displacement trends leading to tight error bars. Blinded results were compared with their category designation after unblinding. Results were consistent with their respective category designations. Conversely, all NCs categorized as neutral actually functioned with negative displacement (ie, reflux upon disconnection; 4/5 NCs) or positive displacement (1/5 NCs). Only NCs classified as antireflux functioned as neutral, which was confirmed in a blinded bidirectional flow test. These results suggest that the neutral NC-marketed category may be confusing to users unless the particular NC design has an integrated antireflux component.

Key words: catheter occlusion, catheter-related bloodstream infections, catheter-related thrombosis, microbial contamination, needleless connector, reflux, vascular access

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Gorzek S, LaDisa JF. Assessment of Reflux From Needleless Connectors: Blinded Comparison of Category Designation to Benchtop Function Using a Venous Simulator. *Journal of Infusion Nursing*. 2021 Nov 1;44(6):323-30. DOI: 10.1097/NAN.0000000000000447

What Does the Evidence Show?

Original research article

JVA | The Journal of
Vascular Access

Needle-free connectors to prevent central venous catheter occlusion at a tertiary cardiac center: A prospective before and after intervention study

The Journal of Vascular Access
1-8
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DOI: 10.1177/11297298211039653
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SAGE

Andrea Sansalone¹, Raffaello Vicari¹, Fabio Orlando¹,
Alessandro Dell'Avo¹, Silvia Giuffrida¹, Paula Deelen²,
Stefano Bernasconi^{1,2} and Michele Villa² 

Abstract

Objectives: To evaluate the effectiveness of needle-free connectors to prevent central venous catheter occlusion.

Background: Loss of patency is a common complication associated with central venous catheters, which is often painful, and can result in a delay in infusion therapy. Pressure-activated anti-reflux connectors are available on most modern devices; however, no studies have compared this technology to three-way stopcocks in terms of the incidence of CVC occlusion.

Methods: This study is a prospective before and after intervention study. The first phase was conducted with the three-way stopcock as the standard device (phase 1). After implementation of needle-free connectors (phase 2), the study was conducted in three phases (phase 2, phase 3, and phase 4) from September 2019 to January 2020 (phase 3).

Results: Of 199 CVCs analyzed, 41.2% (40/97) occluded in at least one lumen in the first phase, and 13.7% (14/102) occluded after introducing the technological device, absolute risk reduction 27.5% (95% confidence interval 15.6%–39.4%). The lumens supported by needle-free connectors showed a higher probability of maintaining patency compared with three-way stopcocks. No differences were observed in the rate of infection.

Conclusions: Pressure-activated anti-reflux needle-free connectors are effective and safe devices suitable for the management of vascular access in cardiac patient care. Staff training, even on apparently simple devices, is essential to avoid the risk of infection.

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Sansalone A, Vicari R, Orlando F, Dell'Avo A, Giuffrida S, Deelen P, Bernasconi S, Villa M. Needle-free connectors to prevent central venous catheter occlusion at a tertiary cardiac center: A prospective before and after intervention study. *The Journal of Vascular Access*. 2021 Aug DOI: [10.1177/11297298211039653](https://doi.org/10.1177/11297298211039653) U.S. National Library of Medicine, pubmed.ncbi.nlm.nih.gov/34396802/

What Does the Evidence Show?

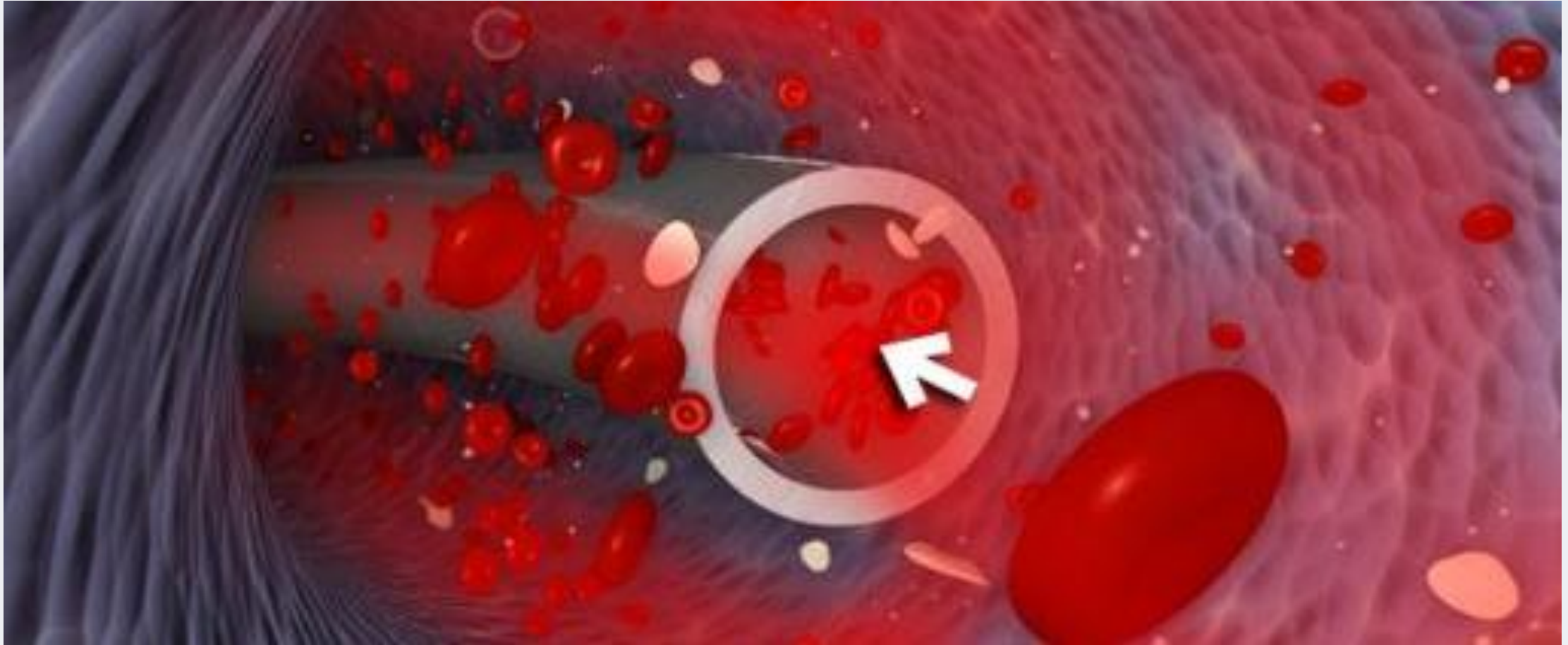
Needleless Connector Understanding Evidence:

- A survey conducted 2011 – 554 respondents
 - 114 (21.9%) did not know type used with their central catheter
 - 132 (25.4%) **did not know whether their type was positive, neutral or negative**
 - 244 (47.2%) **did not understand the correct way to flush and clamp** a catheter with their needleless connector attached



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There is No Getting Away from Blood



Used with permission PICC Excellence, Inc.

What is Displacement or Reflux?

Mechanical Pressure Changes

Displacement or Reflux is the movement of fluid often caused by changes in pressure from muscular activity, coughing, connection or disconnection of syringes or other gravity induced changes in medication administration

Within a catheter and needleless connector, reflux of fluid is represented as blood movement into and out of the terminal end of the catheter positioned in the bloodstream

What Does the Evidence Show?

ALL Needleless connectors ALLOW fluid displacement

- Reflux of fluid
- Reflux of blood
- Fluid displacement with any pressure change
- Check the scores

Gibson SM, Primeaux J. Do Needleless Connector Manufacturer Claims on Bidirectional Flow and Reflux Equate to In Vitro Quantification of Fluid Movement? *Journal of the Association for Vascular Access*. 2020 Dec 1;25(4):28-36. <https://doi.org/10.2309/JAVA-D-20-00031>

NEEDLELESS CONNECTOR RESULTS: RANKED BY REFLUX AMOUNT

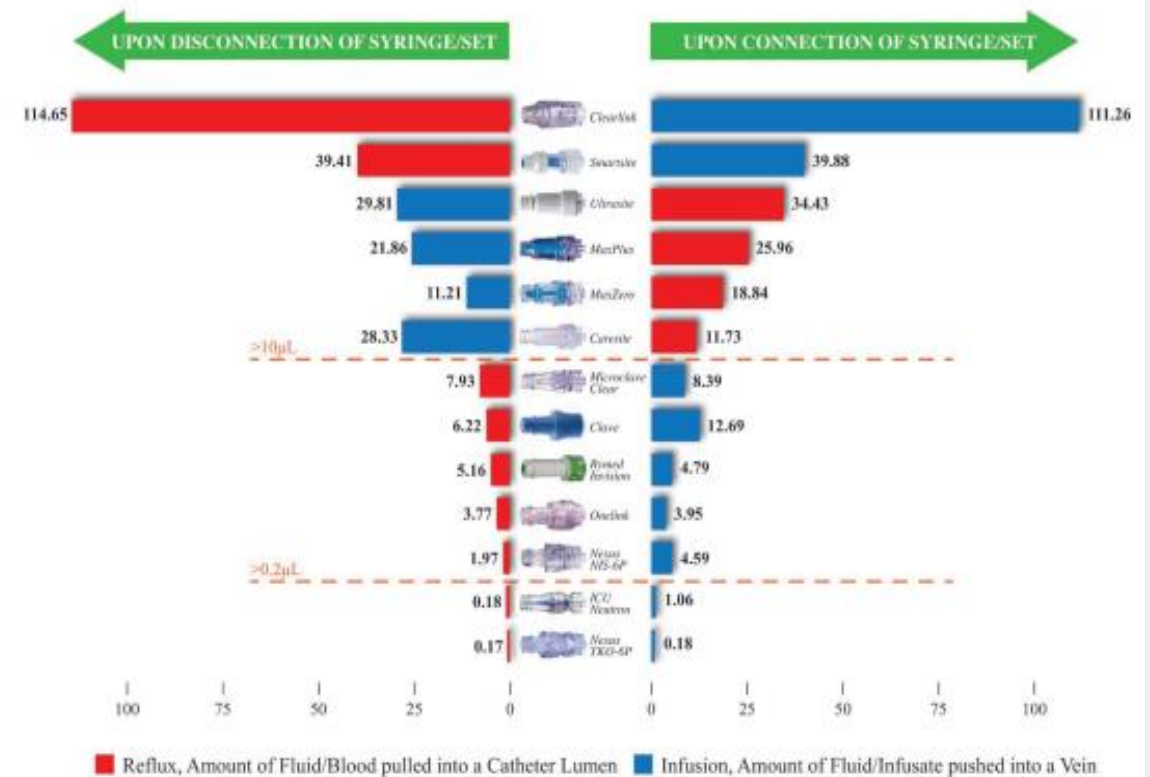


Figure 3. Results of observational study 2. This chart shows when reflux occurs (i.e., connection or disconnection) and how much blood reflux would occur in a closed intravenous (IV) system upon unclamped connection and disconnection of a male Luer lock syringe or IV administration set.

What Do the Standards Say?



INS Standard 36

Know the internal mechanism for fluid displacement of the needleless connector in use (eg, negative or positive displacement, neutral, or anti-reflux).

Follow manufacturers' directions for use for flushing, clamping, and disconnection.

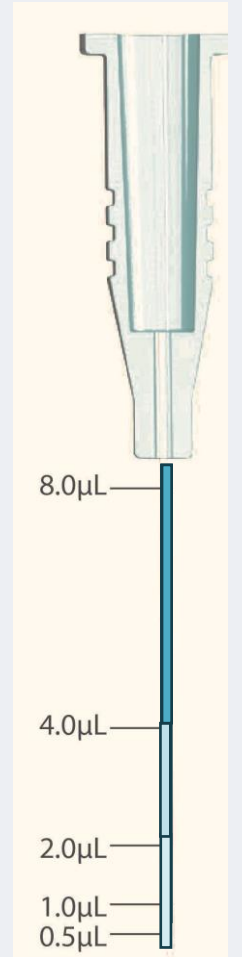
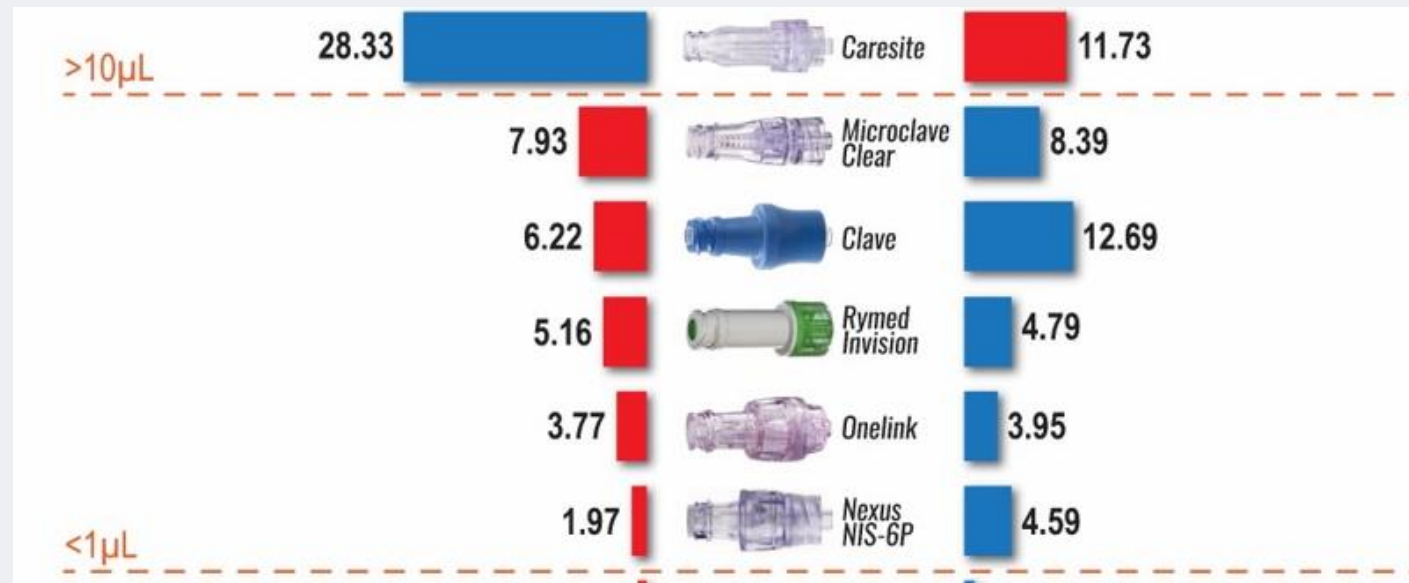
Category names of needleless connectors are derived from clinical application of their functionality; however, there are no established criteria from device regulatory agencies that determine which device is assigned to each category.

1. In the absence of manufacturer directions, consider the reported reflux volume for each type and use the following sequence:
 - a. Negative displacement–flush, clamp, disconnect
 - b. Positive displacement–flush, disconnect, clamp
 - c. Neutral and anti-reflux–no specific clamping sequence required.
2. Standardize the type of needleless connector within the organization to reduce the risk for confusion about these steps and improve clinical outcomes.

What Does the Evidence Show?

The term NEUTRAL

- Is misleading
- Is not correct

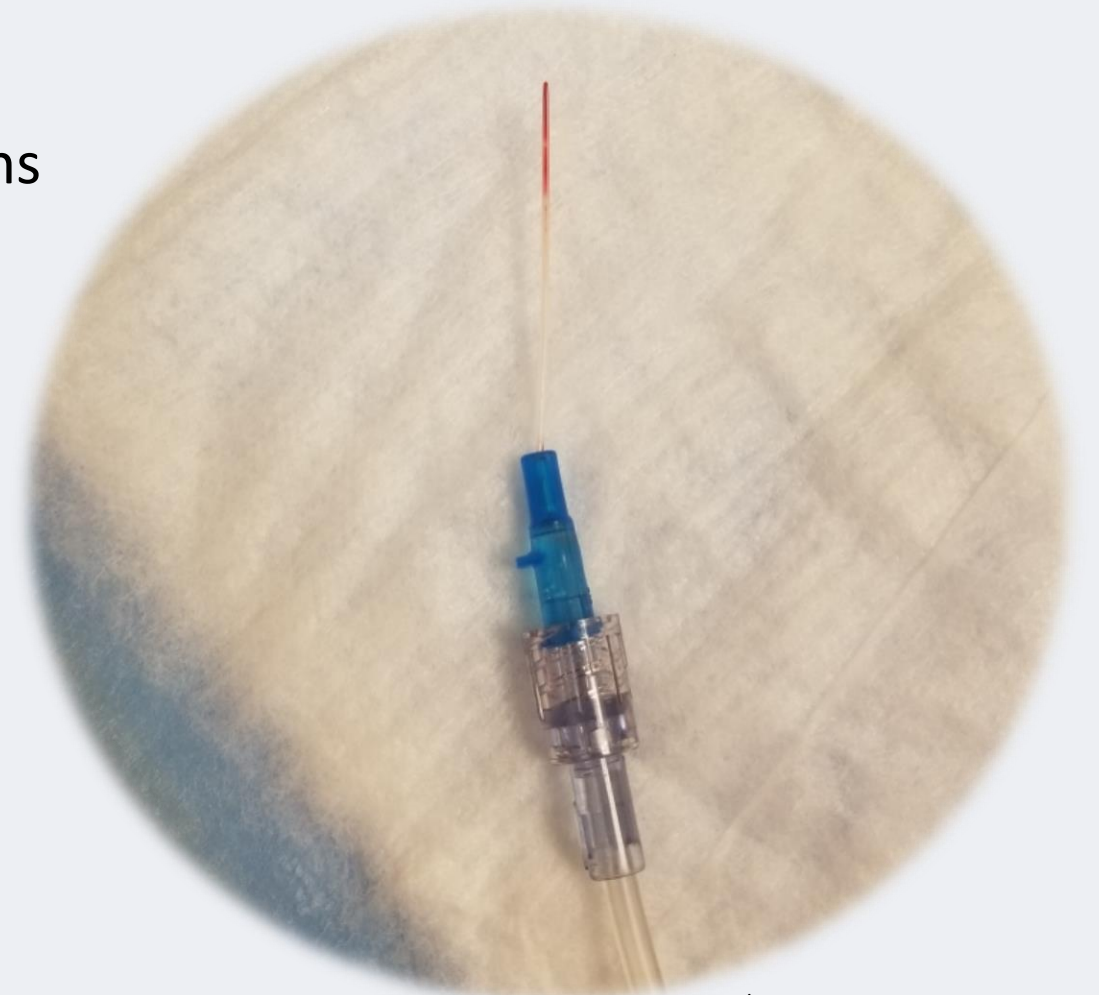


Gibson SM, Primeaux J. Do Needleless Connector Manufacturer Claims on Bidirectional Flow and Reflux Equate to In Vitro Quantification of Fluid Movement? *Journal of the Association for Vascular Access*. 2020 Dec 1;25(4):28-36. <https://doi.org/10.2309/JAVA-D-20-00031>

Consequences of Reflux from Needleless Connectors

PIVCs and CVADs

- Reduced function and delayed infusions
- No blood return
- No labs from catheter
- Greater risk venous thrombosis
- Greater risk of infection
- Risk of pulmonary emboli



Anti-Reflux - Bi-Directional Flow Control Demo



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The Design and Science of Anti-Reflux NC

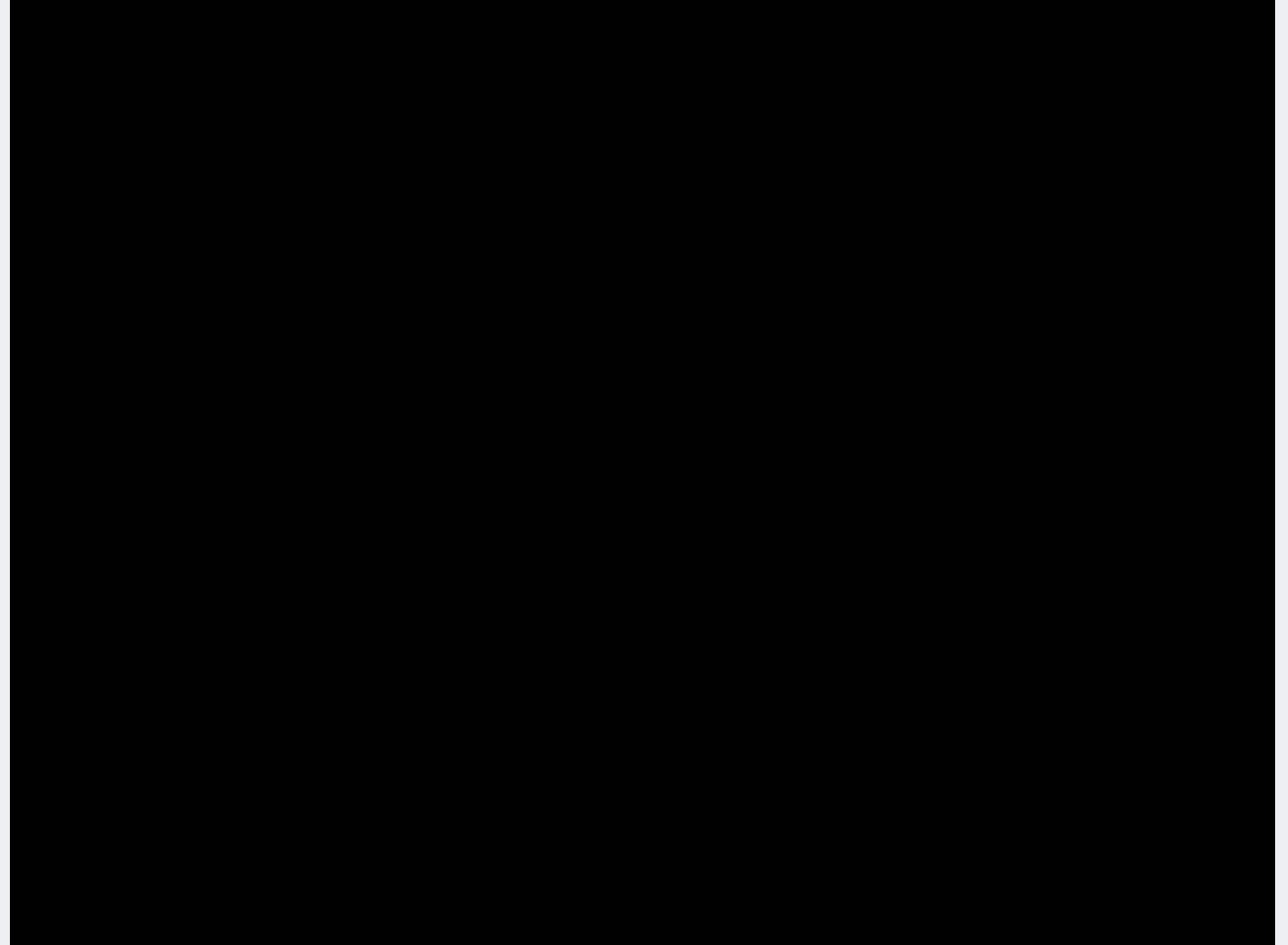


The Anti-Reflux Diaphragm

What is the Impact of Reflux or Catheter Clotting on the Vein

Thinking about
peripheral catheters and
flushing

What is the effect of
pushing just a bit harder
when a PIVC is difficult to
flush or blocked?



Impact on CVADs

More interventions and time

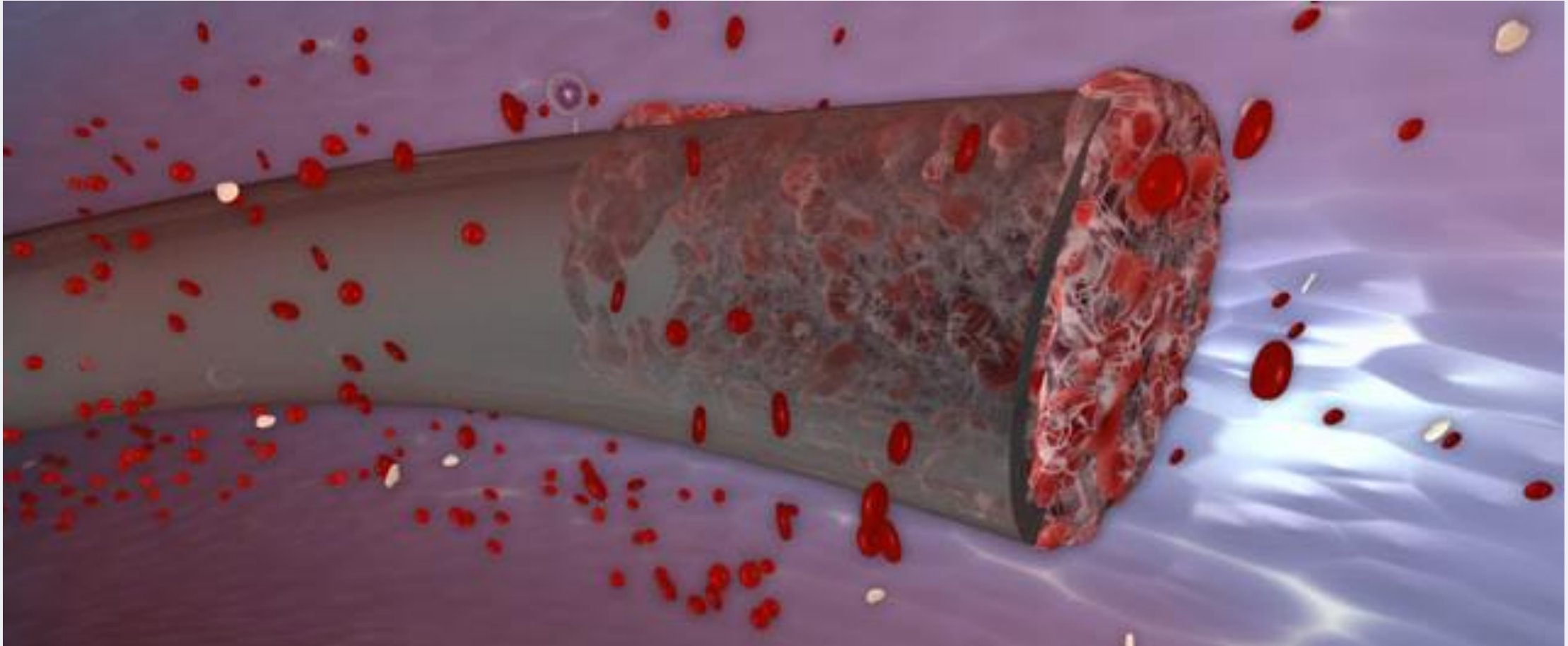
More delays in treatment

More risk with each thrombolytic usage (Thakara

More cost with nursing time and thrombolytics

CLABSI risk increases

Everyone Loses with Occlusion



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How will Anti-Reflux Needleless Connectors Improve your Care Setting?

Inpatient

- Thrombolytic use reduced – evidence says yes – (Steere, 2022 & 2018; Hitchcock, 2016)
- Reduced number of needleless connector changes – evidence says yes (Steere, 2018,2019,2022; Buzas 2022)

Home infusion

- Heparin not needed – evidence says yes (Buzas, 2022)

Reduced cost for all – evidence says yes (Steere, 2018,2019,2022; Buzas, 2022)

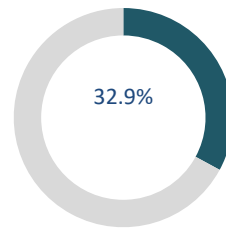
1. Steere L. CLE3AR Study. 2022 Mar;36(2):92-98.
2. Steere L. Lean Six Sigma for Intravenous Therapy Optimization. 2018;23(1):42-50.<https://doi.org/10.1016/j.java.2018.01.002>
3. Steere, Lee, et al. Reaching One Peripheral Intravenous Catheter the PIV5Rights™ Bundle. 2019;24(3):31–43. doi:10.2309/j.java.2019.003.004.
4. Buzas B, Smith J, Gilbert GE, Moureau N. Home infusion pharmacy quality improvement for central venous access devices using anti-reflux needleless connectors. 2022 Jul 1;79(13):1079-85.
5. Hitchcock, Jan. “Preventing Intraluminal Occlusion in Peripherally Inserted Central Catheters.” British Journal of Nursing, doi:10.12968/bjon.2016.25.19.s12.
6. Sansalone A;Vicari R;Orlando F;Dell'Avo A;Giuffrida S;Deelen P;Bernasconi S;Villa M; Needle-Free Connectors to Prevent Central Venous Catheter Occlusion at a Tertiary Cardiac Center: A Prospective before and after Intervention Study. The Journal of Vascular Access, U.S. National Library of Medicine, pubmed.ncbi.nlm.nih.gov/34396802/.

PIV Complication Rates

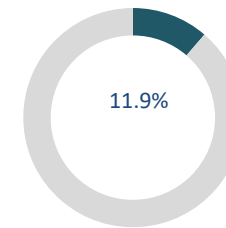
Complication SnapShot



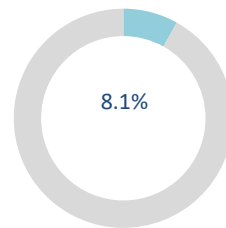
124 of 234 PIVs had a complication



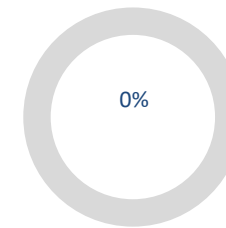
Occlusions
77/234



Phlebitis
28/234



Infiltrates
19/234



Dislodgement
0/234

PIV Complication Cost Analysis

Per Dr Randall Jones 'Cost for Poor-Quality Infusion Therapy' the cost is \$475,882 per 10,000 peripheral IVs placed

Number of Beds	Current Cost per Bed	Current Total Cost	Future Cost per Bed	Future Total Cost	Total Savings
2877	\$1755	\$5,049,135	\$630	\$1,812,510	\$3,236,625
Number of PIVs*	Current Cost per Bed	Estimated Future Cost		Total Savings	
504,050	\$23,986,832	\$11,993,416		\$11,993,416	

* Estimated PIV count comes from manufacturer formula = # of beds * 365 * .8

Estimated Annual Savings Potential: \$15,230,041

1. Jones RK. Short peripheral catheter quality and economics: the intravenous quotient. Journal Of Infusion Nursing. 2018 Nov 1;41(6):365-71.
2. Data collected from unpublished acute care annual usage study of current state

Central Catheter Occlusion and Cost

Declots per Month = 57

Annual tPA Costs (\$140 per)	\$95,760
------------------------------	----------

Annual Supply Costs (\$3.91 per)	\$2,674
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Annual Labor Costs (\$32/hr)	\$18,166
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Total:	\$116,600/mo
---------------	---------------------

1. Steere L. CLE3AR Study. 2022 Mar;36(2):92-98.
2. Steere L. Lean Six Sigma for Intravenous Therapy Optimization. 2018;23(1):42-50.<https://doi.org/10.1016/j.java.2018.01.002>
3. Data from acute care observational study and current state Alteplase usage

Evidence of Performance

Choosing the Best Design for Intravenous Needleless Connectors to Prevent Healthcare-Associated Bloodstream Infections

By William R. Jarvis, MD

Healthcare-associated catheter-related bloodstream infections (HA-BSIs) remain a major cause of morbidity and mortality in the U.S. While the Centers for Disease Control and Prevention (CDC) recently reported a drop of 18 percent in the incidence of HA-BSIs, overall progress in reducing these infections has been a fraction of what is possible, and necessary.

The CDC had previously estimated that more than 80,000 HA-BSIs occur annually in intensive care unit (ICU) patients alone. Thus, an 18 percent drop in these infections means that tens of thousands of patients are still endangered by HA-BSIs each year. Many infection control experts believe that HA-BSIs can be markedly reduced, if not completely eliminated. Recognition of the preventability of HA-BSIs is one reason why the Centers for Medicare and Medicaid Services (CMS) and many health insurance carriers have eliminated enhanced reimbursement for these complications.

The design of intravenous (IV) needleless connectors (NCs) plays a substantial role in HA-BSI risk. These devices are used to connect catheters, administration sets, and/or syringes to deliver IV therapy. In the past two decades, connectors have evolved in a direction that has inadvertently increased the risk for HA-BSIs.

With some notable exceptions, the devices have become more complex in design. These complexities have made NCs harder to: disinfect, flush completely, and use correctly. This

situation is compounded by the wide variety of NCs in the marketplace. Clinicians often are faced with several types of NCs in use at their hospital or healthcare system. Because each NC can require different routines for proper use (i.e., disconnection, clamping, disinfection and flushing sequence) such variety can be confusing to clinicians and endanger patients' lives. The confusion can lead to medical errors, and ultimately HA-BSIs.

This article provides a short history of IV needleless connectors; to show how the current situation developed, and then describes the crucial features of NCs that reduce the risk of HA-BSIs.

A Brief History of the Modern Connector

When healthcare workers (HCWs) use needles in conjunction with IV therapy, they incur accidental needlestick injuries and potential infection with bloodborne pathogens, e.g., hepatitis B or C viruses or Human Immunodeficiency Virus (HIV). In 1992, the Occupational Safety and Health Administration (OSHA) recommended that healthcare facilities use "engineering controls" to help protect HCWs from these pathogens. The use of such controls, including NC systems when applicable, became mandatory under the Needlestick Safety and Prevention Act in 2001.

The NCs that we see today evolved from industry's efforts to make devices that comply with OSHA regulations. They were primarily designed for HCW safety. Ironically, some

NCs have had an unintended consequence of increasing patients' HA-BSI risk. In particular, two of the most widespread designs, so-called "positive" and "negative" pressure luer-access mechanical valve NCs, have been associated in a number of studies with increased HA-BSI risk.¹⁻⁴ In general, the infection-related problems associated with these luer-access mechanical valve NCs are related to their complicated design. They have complex internal surfaces—including in some instances, moving parts—that are difficult to disinfect and flush properly. The internal surfaces then can become contaminated and serve as a nidus for biofilm development and subsequent HA-BSI. Most NCs also require a specific routine clamping sequence for disconnection, either clamp and then disconnect or disconnect and then clamp. If the clamping-disconnection sequence is not executed correctly, the risk of inadequate disinfection and contamination increases HA-BSI risk.

The general design principle that "simple is better" applies to NCs. Simpler NCs are less likely to be associated with increased HA-BSI risk because there are fewer opportunities for HCWs to incorrectly use them and there are fewer parts or other design elements to function incorrectly or fail. In addition, the external and internal surfaces of simpler NCs are easier to completely and adequately disinfect and flush.

Each year in the United States, >150 million intravenous (IV) catheters are used. IV catheters are the major risk factor for health care-associated catheter-related bloodstream infections (HA-BSIs). HA-BSIs result in substantial morbidity and mortality and cost \$34,000–

Health Care–Associated Bloodstream Infections Associated with Negative- or Positive-Pressure or Displacement Mechanical Valve Needleless Connectors

William R. Jarvis,¹ Cathryn Murphy,² Kei K. Hall,³ Pamela J. Fogle,⁴ Tohi B. Karchner,⁵ Glensy Harrington,⁶ Cassandra Salgado,⁷ Eve T. Giannetta,⁸ Carol Cameron,⁹ and Robert J. Sherez¹⁰

¹Jason and Jarvis Associates, Hilton Head Island, and ²Medical University of South Carolina, Charleston, South Carolina; ³University of Virginia Medical Center, Charlottesville; ⁴Wake Forest University School of Medicine, Winston-Salem, North Carolina; and ⁵Bond University and Infection Control Plus, Gold Coast, and ⁶Mater Health Service, Brisbane, Queensland, and ⁷The Alfred, Bayville Health, Melbourne, Victoria, Australia

Background. Health care-associated, central venous catheter-related bloodstream infections (HA-BSIs) are a major cause of morbidity and mortality. Needleless connectors (NCs) are an important component of the intravenous system. NCs initially were introduced to reduce health care worker needlestick injuries, yet some of these NCs may increase HA-BSI risk.

Methods. We compared HA-BSI rates on wards or intensive care units (ICUs) at 5 hospitals that had converted from split septum (SS) connectors or needles to mechanical valve needleless connectors (MV-NCs). The hospitals (16 ICUs, 1 entire hospital, and 1 oncology unit; 3 hospitals were located in the United States, and 2 were located in Australia) had conducted HA-BSI surveillance using Centers for Disease Control and Prevention definitions during use of both NCs. HA-BSI rates and prevention practices were compared during the pre-MV period, MV period, and post-MV period.

Results. The HA-BSI rate increased in all ICUs and wards when SS-NCs were replaced by MV-NCs. In the 16 ICUs, the HA-BSI rate increased significantly when SS-NCs or needles were replaced by MV-NCs (6.15 vs 9.49 BSIs per 1000 central venous catheter [CVC]-days; relative risk, 1.54; 95% confidence interval, 1.37–1.74; $P < .001$). The 14 ICUs that switched back to SS-NCs had significant reductions in their BSI rates (9.49 vs 5.77 BSIs per 1000 CVC-days; relative risk, 1.65; 95% confidence interval, 1.38–1.96; $P < .001$). BSI infection prevention strategies were similar in the pre-MV and MV periods.

Conclusions. We found strong evidence that MV-NCs were associated with increased HA-BSI rates, despite similar BSI surveillance, definitions, and prevention strategies. Hospital personnel should monitor their HA-BSI rates and, if they are elevated, examine the role of newer technologies, such as MV-NCs.

Each year in the United States, >150 million intravenous (IV) catheters are used. IV catheters are the major risk factor for health care-associated catheter-related bloodstream infections (HA-BSIs). HA-BSIs result in substantial morbidity and mortality and cost \$34,000–

\$56,000 per episode [1–3]. The Centers for Disease Control and Prevention (CDC) estimates that, in US intensive care unit (ICU) patients, >80,000 HA-BSIs occur, costing up to \$29 billion annually [1, 4, 5]. In October 2008, the Center for Medicare and Medicaid Services (CMS) and major US health insurance carriers discontinued increased payment for HA-BSIs, so HA-BSI prevention is even more critical for facility financial viability.

Needles used with IV catheters are a source of health care worker (HCW) needlestick injuries (NSIs). In 1992, the US Occupational Safety and Health Administration recommended that health care facilities use safer IV devices to protect HCWs. The first generation of these devices introduced were needle devices with

MAJOR ARTICLE



Lisa M. Jasinsky, BSN, RN
Julie Wurster, MSN, RN

Occlusion Reduction and Heparin Elimination Trial Using an Antireflux Device on Peripheral and Central Venous Catheters

ABSTRACT

Catheter occlusion and thrombosis are common problems associated with central venous catheters, peripherally inserted central catheters, and peripheral intravenous catheters. A prospective study was performed at a community hospital to determine whether an antireflux valve device would reduce the frequency of complications in these catheters and safely allow the elimination of heparin flushes for central venous catheters and peripherally inserted central catheters. The study compared complications with current intravenous practice to complication rates for the antireflux valve device. The study used evidence obtained during this trial to institute the best clinical practice.

Central venous catheters (CVCs), peripherally inserted central catheters (PICCs), and peripheral intravenous (IV) catheters are widely used in the hospital setting and are essential for the delivery of IV fluids and

medications and for hemodynamic monitoring. Common problems associated with these catheters include occlusion, thrombosis, refluxed blood, phlebitis, and infiltration. Nurses and healthcare workers are challenged daily to maintain the patency of peripheral and central catheters. They often attempt to salvage the current IV or discontinue it and then start a new one, which takes valuable nursing time and increases supply costs.

Wide variations in clinical practice exist on the maintenance of IVs.¹ Multiple studies since 1989 support the use of saline flushes instead of heparin flushes for maintenance of peripheral IV catheters.^{2,3} Traditionally, CVCs and PICCs have been maintained with standard protocols using an anticoagulant (heparin) that prevents clot formation and improves patency of the catheter. Positive-pressure IV devices were introduced more recently for use on central catheters and PICCs. Positive-pressure valves have resulted in decreased occlusions and led to an elimination of heparin in flushing procedures due to the design of the valve.⁴

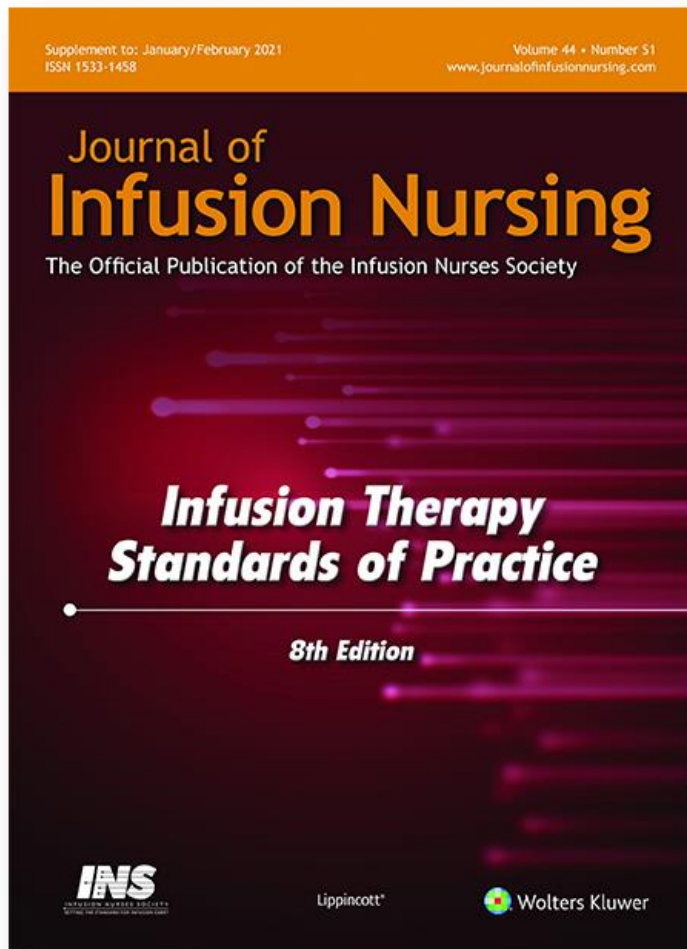
Recent observational reports describe an increase in bloodstream infections associated with the advent of these positive-pressure valves. One report notes an increase in catheter-related bloodstream infections after switching to a luer-activated mechanical valve (MV) with positive-pressure device from a standard luer-access MV.⁵ In addition, Rupp et al⁶ describe an association between primary bloodstream infections and the type of needleless connector valve used. That facility changed from a split-septum device to a positive-displacement MV and noted an increase in infections per 1000 catheter days when the positive-pressure valve was used (10.64 infections compared with baseline of 2.79 infections).

Doctors Hospital, a 200-bed community hospital in Columbus, Ohio, and a part of the OhioHealth system, used a luer-activated MV (CLAVE Needle Free Connector; CLAVE[®], ICU Medical Inc, San Clemente, California) but had problems with catheter occlusions, refluxed blood, and loss of catheters. In addition, heparin flushes were still required for CVC and PICC

Author Affiliations: Assistant Nurse Manager, Radiology (Ms Jasinsky), and Clinical Resource Specialist (Ms Wurster), Doctors Hospital, OhioHealth, Columbus, Ohio. Lisa M. Jasinsky is an Assistant Nurse Manager in Radiology responsible for placing peripherally inserted central catheters for OhioHealth in Columbus, Ohio. In this role, she coordinates intravenous education and policy and procedures for peripherally inserted central catheters. She is involved with the IV Value Analysis Committee for continued improvement in intravenous therapy. She received her ADN from the Kettering College of Medical Arts and her BSN from Mount Carmel College of Nursing. Julie Wurster is a Clinical Resource Specialist for OhioHealth in Columbus, Ohio. In this role, she coordinates valve analysis processes and reviews new medical technologies with emphasis on evidence-based literature, patient safety, and cost risks/benefits. She received her BSN from the University of Kansas and her MSN from the University of Missouri. **Corresponding Author:** Lisa M. Jasinsky, BSN, RN, Doctors Hospital, OhioHealth, 5100 W Broad St, Columbus, OH 43228



What Do the Standards Say?



- Gorski, et al. Infusion Therapy Standards of Practice 2021 Edition
- *Journal of Infusion Nursing*
- Needleless Connectors (Section 36; S104)
 - The quantity and frequency of thrombolytic drugs used for catheter clearance have been used for monitoring VAD lumen occlusion (incidence) and correlated to the type of needleless connector in use.

What Does the Evidence Show?

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Feature Article

OPEN

CLE³AR Study

5-Year Impact of LEAN Central Venous Catheter Occlusion Management & Quality Interventions

Lee Steere, RN, CRNI, WA-BC

Problem/Purpose: Intraluminal thrombotic catheter occlusions are associated with a greater risk of delayed treatment, morbidity, and mortality and higher healthcare costs.

Methods: The Vascular Access Specialist Team at Hartford Hospital used Lean Six Sigma methodology to identify and address waste, variability, and defects associated with occlusion management.

Interventions: Beginning in 2015, all central venous catheter occlusions in acute inpatient care were assessed by a vascular access nurse specialist. First, the decisions to treat with tissue plasminogen activator were determined using a catheter patency algorithm. Second, negative displacement needleless connectors were replaced by antireflux needleless connectors to reduce unintentional blood reflux and other complications associated with intraluminal thrombotic catheter occlusion.

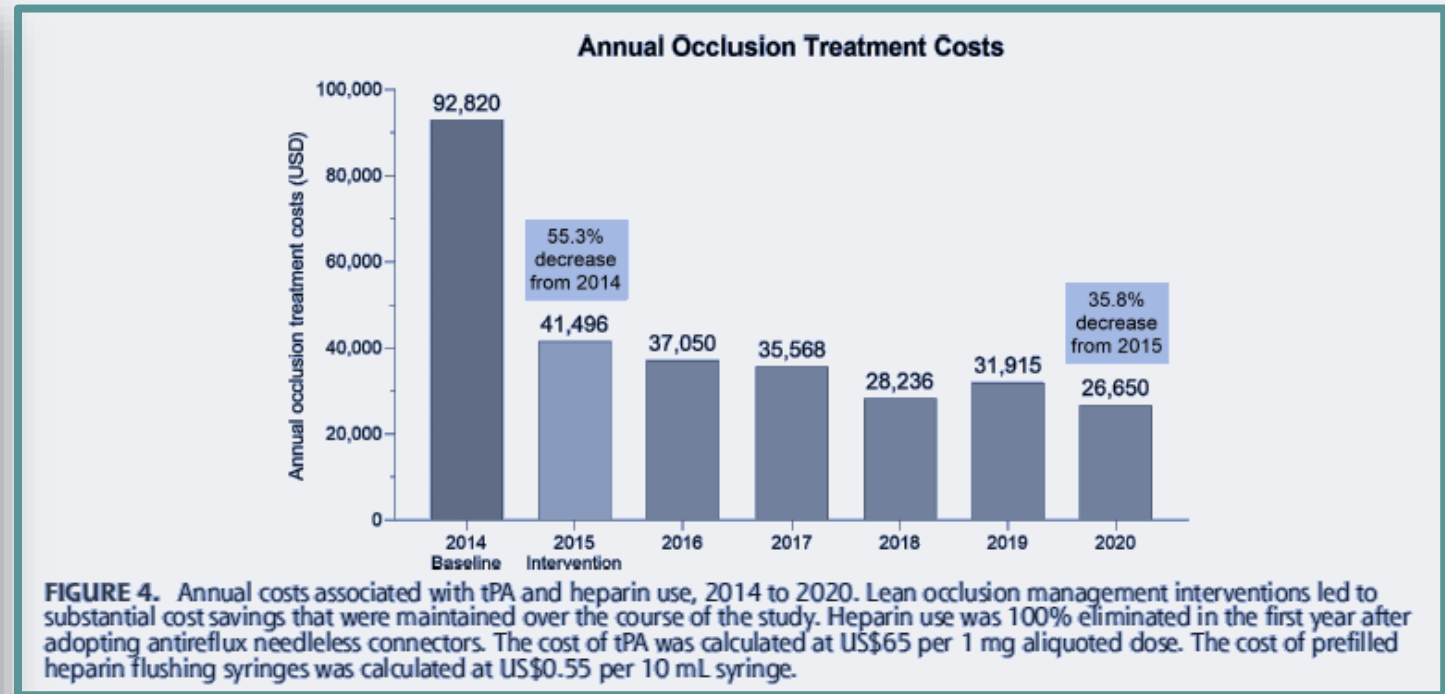
Results: A total of 159 934 central line days were reported between 2014 and 2020. The hospital achieved a 71.3% reduction in annual tissue plasminogen activator used for occlusions over the study period. There was a sustained decrease in annual average needleless connector consumption of 41% after switching to antireflux needleless connectors in 2015. The 5-year cost savings for these 2 interventions were estimated to be \$356 005.

Conclusions: Lean occlusion management interventions were associated with reduced pharmacy use, medical supply waste, and spending, which have been sustained for over a 5-year period.

KEY WORDS: central venous catheter, cost savings, Lean Six Sigma, tPA reduction

Intraluminal thrombotic catheter occlusion is a leading cause of intravenous (IV) catheter failure and central line-associated bloodstream infection (CLABSI).¹⁻⁴ Occlusions are associated with catheter failure, costly declogging treatment, potential catheter replacement, and extended hospital stays, all of which can result in increased healthcare costs and poor patient outcomes.⁵⁻⁷

Thrombotic complications arise when blood comes into contact with the polyurethane surfaces of the IV catheter.^{8,9} Within seconds, plasma proteins form a thin conditioning layer on the luminal surfaces of the catheter.¹⁰ As blood refluxes into the lumen of the catheter, because of mechanical or physiological pressure changes within the patient's vasculature (Table 1),^{6,11} additional proteins and cells adhere to the conditioning layer.⁵ Gradually, platelets and plasma proteins form a mesh, and with repeated blood exposure, the conditioning layer begins to accumulate and occlude the IV catheter.⁶



Intraluminal thrombotic catheter occlusions are a major, yet mostly preventable, complication associated with the use of IV catheters. Using needleless connectors designed to produce the least amount of unintentional blood reflux is an effective way to reduce occlusion risk.

What Does the Evidence Show?

ACCEPTED MANUSCRIPT

Home infusion pharmacy quality improvement for central venous access devices using anti-reflux needleless connectors to reduce occlusions, emergency room visits, and alteplase costs

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American Journal of Health-System Pharmacy, zxac083,

<https://doi.org/10.1093/ajhp/zxac083>

Published: 22 March 2022 Article history

PDF Split View Cite

Abstract

Disclaimer

In an effort to expedite the publication of manuscripts during the COVID-19 pandemic, AJHP is posting these manuscripts as accepted manuscripts. Accepted manuscripts have not yet undergone peer review but are posted online before technical editing. Accepted manuscripts are not the final version of the article. The final article (formatted per AJHP style and layout) will be published at a later time.

Purpose

The study's purpose was to measure the impact of anti-reflux needleless connector usage in prevention of intraluminal thrombotic occlusions among central venous catheters, as represented by alteplase usage, in a home infusion patient population.

Methods

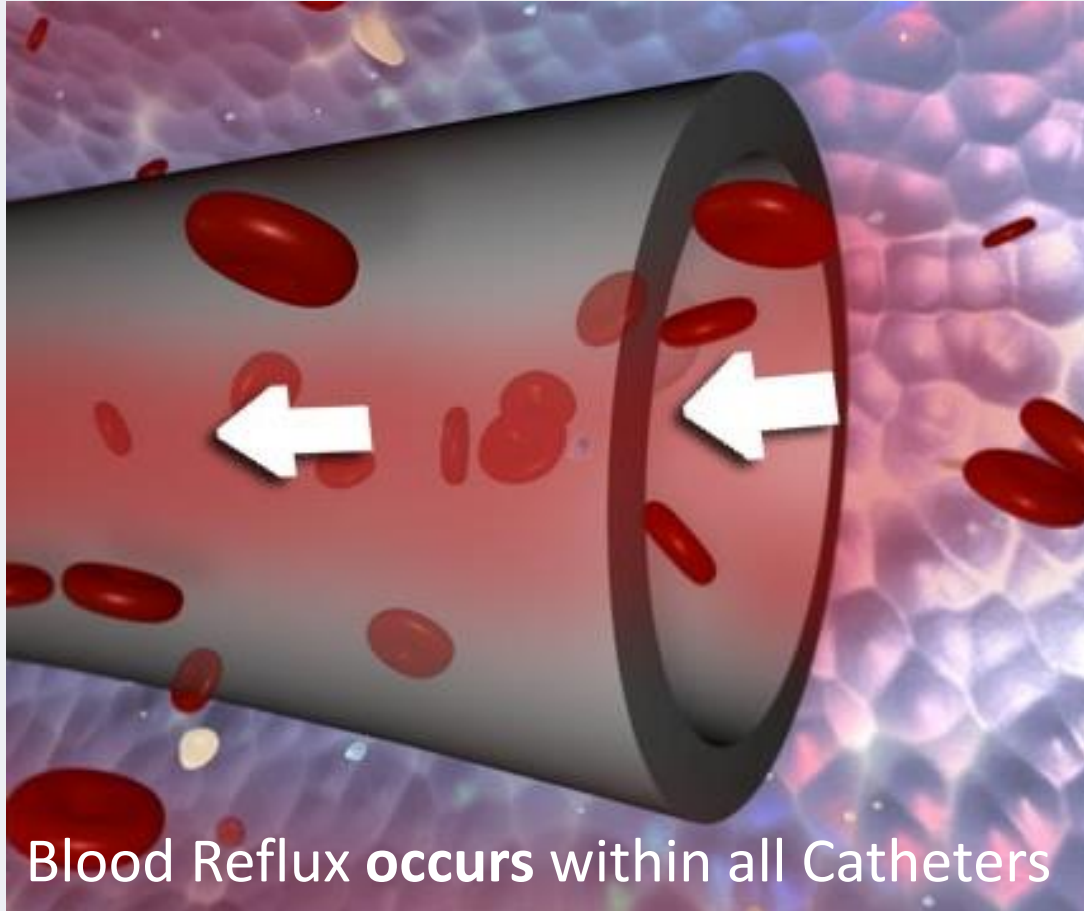
An 18-month before-and-after cohort study of a single home infusion intervention was conducted to compare occlusion outcomes with use of two types of needleless connectors—neutral and anti-reflux—in preventing catheter occlusions, which have been reported to occur in 28% of home infusion patients, resulting in treatment delays, increased nursing encounters and emergency room visits, and higher overall pharmacy costs for supplies and alteplase.

Statistical evidence demonstrated that use of anti-reflux needleless with central venous access devices reduced the need for alteplase in study population. Since 10% of patient occlusions were within 7 days after home infusion admission, future research may indicate that placement of anti-reflux needleless connectors at the time of in-hospital insertion can improve patient outcomes. This quality improvement measure reduced central catheter occlusions, alteplase costs, and the number of required nursing and emergency room visits.

...ied: 42.5% in the neutral (days) and 57.5% in the anti-therapy days). The rate of needleless connectors was 4.4% alteplase use of 112 (95% CI, $P < 0.001$). Implementation of alteplase usage by 48%.

...i-reflux needleless connectors need for alteplase in the study population. Since 10% of patient occlusions were within 7 days after home infusion admission, future research may indicate that placement of anti-reflux needleless connectors at the time of in-hospital insertion can improve patient outcomes. This quality improvement measure reduced central catheter occlusions, alteplase costs, and the number of required nursing and emergency room visits.

Our Goals



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- Better function without problems or added cost
- Longer catheter dwell time with fewer restarts
- Blood return reducing liability with infusions
- Reduced complications
- Completion of therapy with VAD
- Happy patients

Conclusion



- Reduce risk and complications by controlling blood reflux
- Know your connectors and standardize
- Provide education on flushing and clamping sequence – or use Anti-Reflux connectors
- Avoid occlusions and dec clotting by understanding valve function
- Choose products wisely

Making Catheter Complications History

What is your choice AND Why??

Know the evidence

Know the outcomes

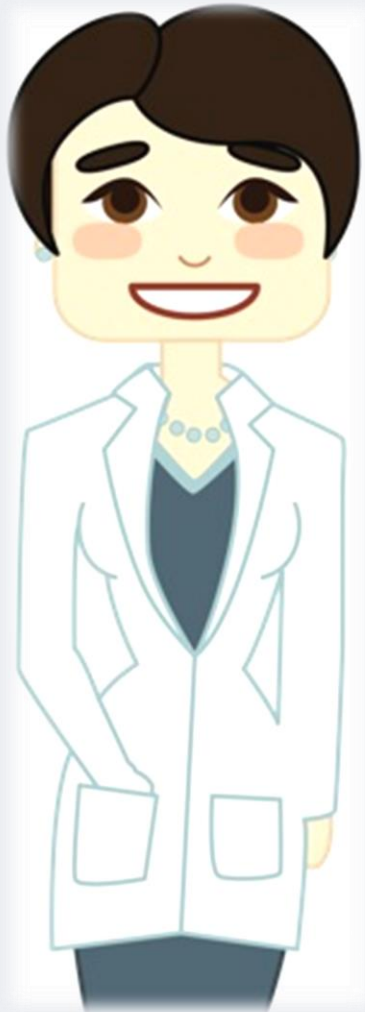
Know how to make a positive
practice change



California Board of Nursing: Implicit Bias

In accordance with Assembly Bill 241, 16 CCR 1451.2, as a Continuing Education Provider (CEP) for the California Board of Registered Nursing, all continuing educational sessions shall address at least one or in combination of the following:

- Examples of how implicit bias affects perceptions and treatment decisions of registered nurses leading to health disparities in health outcomes
- Strategies to address how unintended biases in decision making may contribute to health care disparities by shaping behavior and producing differences in medical treatment along lines of race, ethnicity, gender identity, sexual orientation, age, socioeconomic status, or other characteristics.



Thank you

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Special thanks to
Nexus Medical for
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