

Making CVAD Patency a
Priority: A Review of Case
Studies, INS Guidance, and
New Research

July 22, 2021

Disclosures

- Lisa Gorski and Bob Buzas have received an honorarium from Nexus Medical
- No other disclosures for either presenter

Agenda

- Case studies in home care
- Review of thrombotic occlusion
- INS Standard 36 Needleless Connectors (NC)
- NC Review: Impact on occlusions

Objectives

At the conclusion of this activity, participants will be able to:

1. Define the pathogenesis, risk factors, and mitigants for preventing intraluminal thrombotic occlusions.
2. Describe how occlusions affect home infusion patients.
3. Recognize the new 2021 Infusion Nurses Society Standards of Practice approach to evidence and needleless connectors.
4. Evaluate a before and after 18-month cohort study of a single home infusion intervention comparing occlusion outcomes of two types of needleless connectors in preventing catheter occlusions.
5. Recognize the importance of occlusion management for patient safety.

Let's Begin with 2 Case Studies

A 55 year-old woman with an infected knee post-knee replacement is referred to home care for 6 weeks of IV antibiotic therapy via a double lumen PICC. Upon admission to home care, the nurse assesses PICC patency, identifying one lumen flushable but unable to obtain a blood return and the second lumen completely occluded – unable to flush or obtain a blood return. The patient states that the second lumen did not work in the hospital either but the nurses just accessed the “working” lumen.

A 70 year-old man, independent with his IVAB infusions after 4 consecutive teaching and observation visits. He uses a positive displacement needleless connector as supplied by the infusion pharmacy. He has been properly instructed to disconnect his flush syringe after the infusion before clamping his PICC. A home visit is made for laboratory work and a routine PICC dressing change. The nurse is unable to get any blood return and the flow is sluggish. The nurse does not have supplies for a peripheral blood draw. A re-review of the patient's flushing technique is that sometimes he clamps his PICC before disconnecting the final locking syringe.

Impact: Patient/Health Care Team

An extra call to the provider's office

Provider reluctance to treat – “just use the lumen that works”
(Case study 1)

Nurse talking points – importance of patency

Order obtained – pharmacy notified

Extra delivery by pharmacy for thrombolytic

Extra visit to instill thrombolytic; wait 30 minutes

Thrombolytic does not work after 30 minutes

Thrombolytic left instilled and another nurse scheduled to re-evaluate patency in the next 4 hours

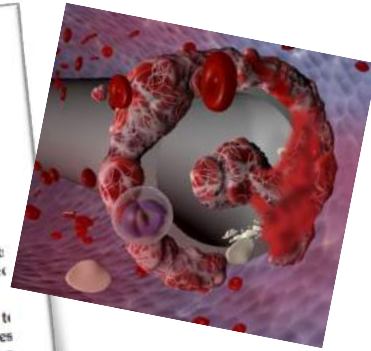
Delay in laboratory studies/need for additional visit

Cost \$\$ drug, extra home visits, additional case coordination time for pharmacy/nurse

Patient/provider & pharmacy frustration – treatment, extra home visits, delay in lab studies/treatment

Follow-up with referral hospital???

Moureau, et al. Central Venous Catheters in Home Infusion



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 patient receiving care. The purpose of this study was to document the natural history of central venous catheters (CVCs) use 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. Even 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 complication 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 day 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

**50,470 Patients; 2.83M Catheter Days
28% CVC intraluminal thrombotic occlusions.¹**

Moureau N. Central Venous Catheters in Home Infusion Care: Outcomes Analysis in 50,470 Patients. *Journal of Vascular Interventional Radiology*. October 2002.

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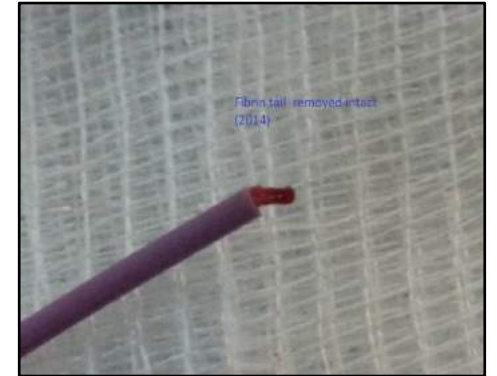


Thrombotic Catheter Occlusion

- Thrombotic catheter occlusion occurs when fibrin or blood within and around the catheter or within the port reservoir of implanted ports slows down or disrupts catheter flow.
- It is important to identify potential thrombotic occlusion because any thrombi in and around the catheter facilitate the adhesion of bacteria which leads to colonization and potentially to a bloodstream infection
- Signs of occlusion include: **Inability to withdraw blood, sluggish flow, inability to flush or infuse, swelling/leaking at the infusion site**

Types of Thrombotic Occlusion

- Fibrin Tail:
 - Layer of fibrin encases the CVAD at the tip (photo).
 - Tail grows as more cells and blood components are deposited.
 - Solutions can be administered and VAD can be flushed but tail acts as a one-way valve as it is pulled over the catheter tip during aspiration, and blood withdrawal is not possible.
- Fibrin sheath:
 - Layer of fibrin forms around the external surface of the catheter which may potentially grow along the entire exterior catheter wall. Persistent withdrawal occlusion may occur as the fibrin sheath grows.
- Intraluminal occlusion:
 - Fibrin accumulates within the internal catheter lumen leading to **sluggish flow or complete inability to infuse**.



Standards and Guidelines: Occlusion

INS Standard 49.1

CVAD patency is routinely assessed, as defined by the ability to flush all catheter lumens without resistance and the ability to yield a blood return.

INS Practice Recommendation:

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). (V)

Association for Vascular Access (AVA)

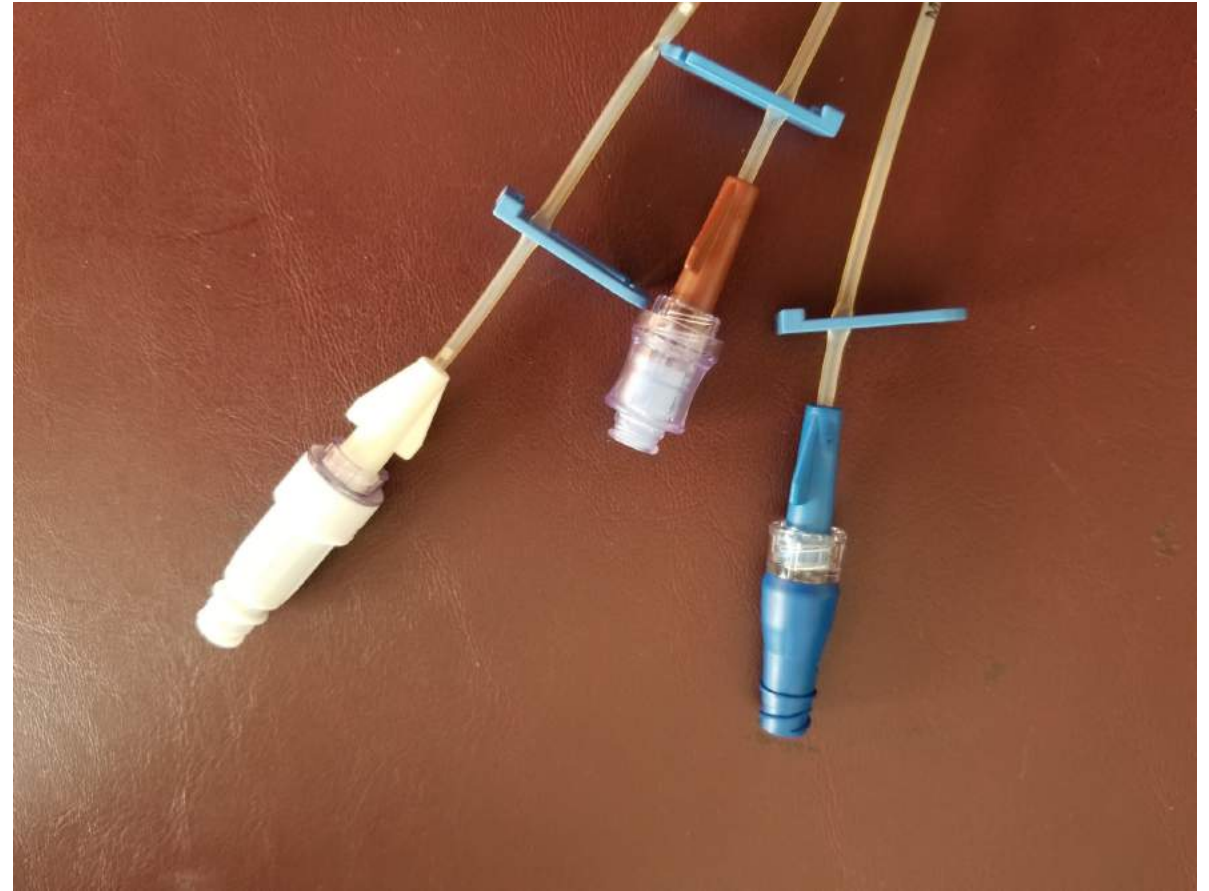
Ensure patency by flushing all lumens ...if lack of blood return or sluggish flow is encountered, take measures to restore patency.

-I SAVE That Line! Campaign

Standard 36: Needleless Connectors

- Standard Statement:
- A luer-locking needleless connector is used to connect syringes and/or administration sets to a VAD hub or other injection site to eliminate use of needles and reduce needlestick injury.

Standard 36. Needleless Connectors: p. S104



Some Key Points about NCs

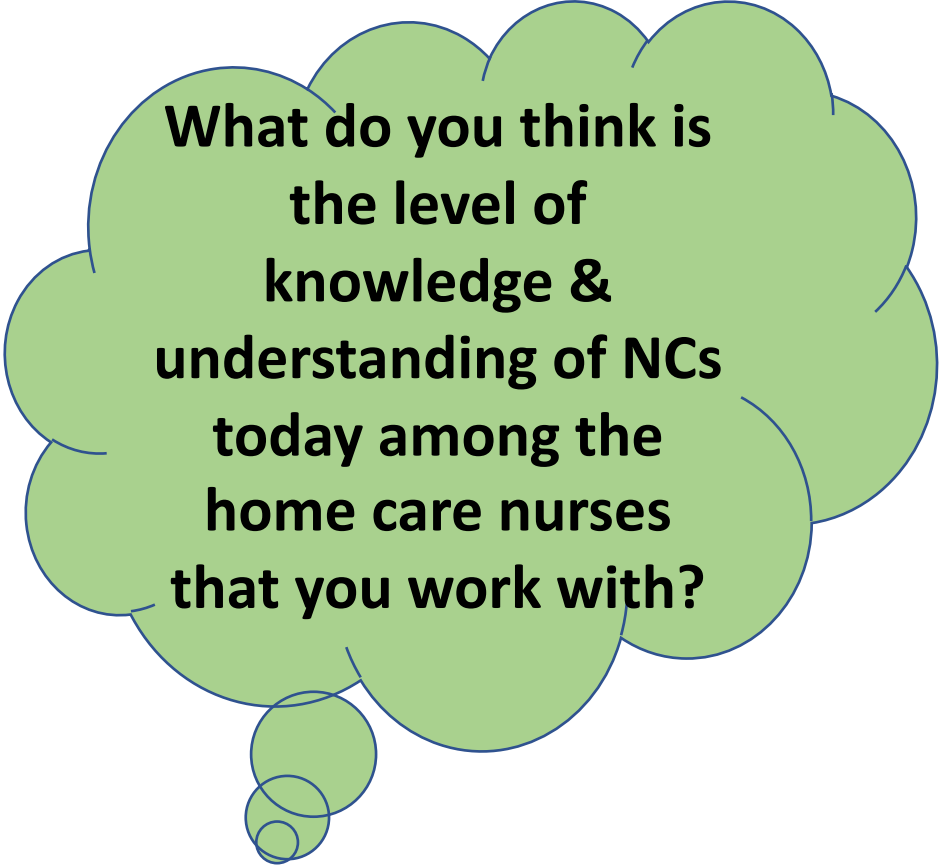
- NCs used to facilitate intermittent infusions
 - When used as an additional add-on device between VAD and administration set for continuous infusions, unknown clinical outcomes/? necessity
- **Practice Recommendation A3:** Avoid using when infusing RBCs and with rapid flow rates of crystalloid infusions – based upon in vitro testing, flow rate was significantly impeded (V) (Lin & Keijzers, 2013; Lehn et al, 2015)
- Disinfection of the NC before attaching a syringe or administration set is critical due to risk for intraluminal introduction of microbes that may result in a CABSI

Incorrect use
&
management
of NCs can
increase the
risk of
infection and
the risk of
occlusion

Standard 36. Needleless Connectors: p. S104

It is also important that the clinicians know and understand proper use based upon an understanding of NC function – these are complex devices!

- 2011 survey
 - 21.9% did not know what type of NC connector was used with CVADs
 - 25.4% did not know what type of NC was used with PIVCs
 - 47.2% did not understand the correct way to flush & clamp a catheter with the NC used within the organization (Hadaway, 2011)



What do you think is the level of knowledge & understanding of NCs today among the home care nurses that you work with?

A Closer Look at Reflux and NCs

- Reflux of blood within the catheter lumen *may* lead to catheter occlusion - time to coagulate/volume of blood unknown
 - Amount of reflux can be affected by bodily movement, respirations, syringe plunger rebound
 - Smaller catheter lumens & greater surface area (e.g., PICC, midlines) -- greater distance of reflux into lumen
 - Can lead to sluggish flow, loss of patency

- **The type of NC that produces the least amount of thrombotic VAD lumen occlusion requires further study!**
- **The quantity/frequency of thrombolytic drug use is often used as a surrogate for monitoring occlusion and correlating to type of NC used**

Standard 36. Needleless Connectors: p. S104

4 categories of needleless connectors as defined in the INS 2021

Glossary (p. S209)

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

FLUSH, CLAMP, DISCONNECT

Neutral. Contains an internal mechanism designed to reduce blood reflux into the VAD lumen upon connection or disconnection however **the sequence of flushing, clamping, and disconnecting the syringe may improve patency.**

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.**

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; **FLUSH, DISCONNECT, CLAMP.**

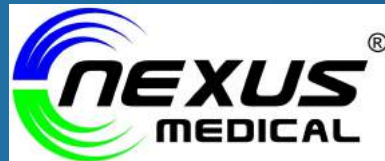
PRACTICE RECOMMENDATION

Standardize type of needleless connector within the organization to reduce the risk for confusion about these steps (V)

REDUCE
CONFUSION!!



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

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Purpose: To estimate the amount of blood reflux caused by suction pressure during periods of compression from syringe connection & disconnection (in vitro study)

Method: An invitro venous model designed to replicate conditions which cause blood reflux into the IV catheter; 14 different NC brands tested

Findings:

- All NCs have some fluid movement/reflux either on connection/disconnection or both
- Greatest amount of reflux: negative displacement NCs
- Least amount of reflux: antireflux NCs
- Greatest amount of reflux at connection: positive displacement NCs
- Greatest amount of reflux at disconnection: all other types of NCs

In Vitro Study of NCs

- Study of NC manufacturer claims on bidirectional flow and reflux
- 13 different NCs (10 of each) tested using an arm venipuncture training model, manometer
- Findings:
 - **NC labels do not necessarily correspond with manufacturer claims**
 - All NCs labeled neutral did reflux; no bi-directional flow control
 - Neutral is not an accurate label
 - Considerable intraluminal blood exposure with connection of positive NCs
 - Suggest appropriate labeling: reflux on connection (positive displacement), reflux on disconnection (negative displacement)
 - NCs labeled antireflux had the least amount of fluid displacement
- Study limitations: In vitro studies do not account for patient variables; catheter composition may impact ability to repel binding protein from blood

Gibson, SM, Primeaux, J (2020) Do needleless connector manufacturer claims on bidirectional flow and reflux equate to in vitro quantification of fluid movement? *Journal of the Association of Vascular Access* 25 (4), 28-36.

INS Standard – Minimize reflux

Use positive-pressure techniques to minimize blood reflux into the VAD lumen. (I)

1. Prevent syringe-induced blood reflux by leaving a small amount (eg, 0.5–1.0 mL) of flush solution in a traditional syringe (ie, not a prefilled syringe) to avoid compression of the plunger rod gasket or by using a prefilled syringe designed to prevent this type of reflux. (IV)
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 36, Needleless Connectors).
3. Use a pulsatile flushing technique. In vitro studies have shown that 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. Clinical studies are needed to provide more clarity on the true effect of this technique

Home care clinicians must understand NCs and how they work

NCs impact blood reflux within the catheter lumen and risk for intraluminal occlusion

Catheter occlusion impacts patients and home care providers

Occlusions cause delays in care, cost \$\$ drug, extra home visits, additional case coordination time for pharmacy/nurse

We need accurate information about how a NC can impact reflux

We need more research and clinical evaluation studies

Buzas, et al. Reduce Intraluminal CVAD Occlusions and Use of Alteplase

Poster at the National Home Infusion Association Conference, 2021

Keeping You Connected: Anti-Reflux Connectors Reduce Catheter Occlusions and Use of Alteplase

NHIA 2021 Annual Conference



Bob Buzas, RPh, Director of Pharmacy Operations
Allegheny Health Network Home Infusion, Pittsburgh, PA

Background

Central Venous Access Devices (CVADs) are routine in the treatment of critical care patients both in the hospital and when they return home. As the patient population ages and the prevalence of chronic diseases (eg, diabetes, heart issues, cancer) increases, the need for home infusion therapy is expected to rise accordingly. That trend is already underway: US home infusion and specialty providers served more than 3 million patients in 2019, a 300% increase over patients served in 2006.¹ Increasing technological advancements to ensure catheter patency are critical if home infusion is to be successful and patient outcomes are to improve.



Figure A. Early formation of intraluminal thrombotic occlusion.

Intraluminal thrombotic occlusions are common with CVADs, with an incidence of 28% in home infusion patients.² Occlusions often begin with blood reflux into the lumen of the catheter (Figure A). This initial step allows the blood to deposit a conditioning layer of plasma proteins inside the catheter. Once the conditioning layer is in place, subsequent reflux episodes trigger a cascade of events attracting more blood proteins to continue to layer into the site, leading to a thrombus.³ It is not currently known how long it takes for blood to coagulate inside a catheter, or how much is required to cause an occlusion, but studies are ongoing.

Reflux often results from mechanical and physiological pressure changes within the patient's vasculature caused by patient activity/movement (eg, coughing, sneezing, yawning) and catheter access management such as that which occurs when changing IV bags, clamping/unclamping, syringe connection/disconnection, or syringe plunger rebound.⁴

The recently released INS Standards⁵ recommend that infusion staff know which needlessly connector (NC) is in use because the directions for use vary and can influence reflux. While reflux has been documented with all types of NCs, the Standards note that anti-reflux devices employing a bidirectional, pressure-sensitive valve (Figure B) have the least amount of reflux.

When CVADs are blocked, alteplase is administered to clear the line. Thrombolytic use in peripherally inserted central catheter (PICC) patients is associated with a 3-fold higher risk of infection (3.59 adjusted odds ratio).⁶ Since unintentional blood reflux within the catheter is the primary cause of these occlusions, and anti-reflux needlessly connectors with bidirectional flow control (ANCs) demonstrate the least amount of blood reflux,⁴ this study sought to determine if implementation of ANCs could reduce occlusions and associated cost.^{3,7}

Purpose

The purpose of this study was to measure the impact of anti-reflux needlessly connector usage in preventing intraluminal thrombotic occlusions among CVADs, and whether ANC implementation would reduce occlusions, represented in alteplase usage, in this home infusion patient population.

Methods

This quality improvement initiative sought to quantify thrombolytic use and analyze the economic impact of the change in clinical practice from neutral to anti-reflux needlessly connectors. This uncontrolled before/after 16-month cohort study of a single home infusion intervention compared occlusion outcomes of two types of needlessly connectors, neutral needlessly connector with no bidirectional flow control (NNC) (MicroClave, ICU Medical) and anti-reflux needlessly connector with bidirectional flow control (ANC) (TKO-6PHV, Nexus Medical), with CVAD occlusions requiring alteplase (CathFlo, Genentech) (\$144/2mg dose) from May 2019 through December 2020. A transitional period of February–March 2020 included product changeover and staff education. Outcome parameters were nurse reported occlusion of venous central catheters that required alteplase (2mg), patient encounters, time to occlusion from hospital discharge, and unscheduled emergency room visits. Outcome parameters included patient census (PC), patient therapy days, alteplase usage (CPU), patient encounters to de clot catheters (PDE), time from discharge to occlusion in home, and ER visits (ERV).

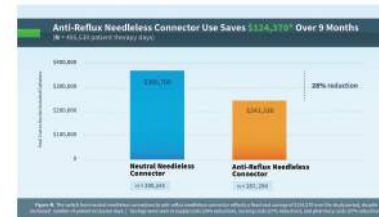
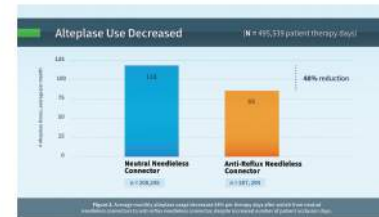
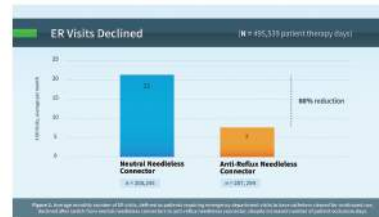
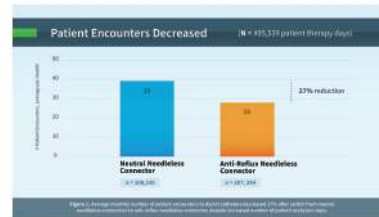


Figure B. The anti-reflux needlessly connector used in the study contains a bidirectional, pressure-sensitive valve which is designed to prevent blood reflux. Images show the valve during infusion, while closed, and during aspiration.

Results

The hypothesis was accepted with a total of 405,539 patient therapy days studied; 42% were NNC group (208,245) and 58% ANC (287,294) resulting in average occlusion days for NNC 26,031 (837 PC, 39 PDE, 118 CPU, 21 ERV), and for ANC 35,912 days resulting in a higher patient census (947 PC, 28 PDE, 85 CPU, 7 ERV). The reduction in patient encounters required to de clot catheters reflected a 27% drop in nursing time (Figure 1). There was a 66% reduction in ER visits (Figure 2). Rates of alteplase usage with NNC and ANC were 4.6% vs 2.9% with median 112 (95% CI:89-160), vs 82 (95% CI:68-109) (p<.001). Of patients requiring alteplase, 10% were recently discharged from the hospital suggesting that signs of occlusion likely occurred during their inpatient stay. Anti-reflux intervention reduced alteplase use by 48%/therapy days (Figure 3), and by 36%/census. The ANC needlessly connector intervention reflected a fixed cost savings of \$124,370 (Figure 4).

Discussion

Patients with intraluminal CVAD occlusions experience delays in treatment, increased ER visits, decreased patient satisfaction, and higher overall pharmacy costs from supplies and alteplase used to de clot catheters. While certain catheters, like small diameter PICCs, are more prone to occlusion, the blood reflux resulting from mechanical and physiologic pressure changes contribute to the overall incidence of occlusion in all CVADs. Implementation of anti-reflux connectors reduced occlusion incidence by almost half and resulted in significant cost savings. Since 10% of patient occlusions were within 7 days of home infusion admission, future research may indicate ANC placement at the time of hospital insertion to improve patient outcomes.

Previous authors have noted that reducing the incidence of thrombotic occlusion has impact well beyond the cost of the thrombolytic alone.⁸ Assessment of the device and installation of the thrombolytic may require one to two extra nursing visits lasting 30-120 minutes for a single dose, and even more time if a second dose is required. Compromised catheter patency increases patient risk, discomfort, and inconvenience, not to mention cost, particularly if emergency department visits are necessary. Reducing these complications led to a better overall patient experience under our service.

Conclusion

There is statistical evidence that integration of anti-reflux needlessly connectors on CVADs to reduce occlusions substantially reduced the need for alteplase in this home infusion study population. This quality improvement measure reduced cost associated with occlusion complications including those that required nursing and emergency room visits, while positively affecting patient satisfaction.

Disclosure: Nothing to disclose.

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For more information, contact Bob Buzas, RPh, at bebuzas@gmail.com

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What convinced us ?




Allegheny
Health Network

Fit

- AHN's MISSION is to create a "Remarkable Patient Experience"
- What is the patient experience when a catheter is occluded? Is it Preventable?

Data

- Drug Expenditure List, Top 20  Alteplase
- Why are we spending so much money on something that really is not treating the disease? It's treating a failure of something.
- Costs are both direct (cash flow, inventory management, supplies) and indirect (time to coordinate); Reimbursement varies

Validation

- Reviewed the Evidence; Intraluminal Thrombotic Occlusions are Preventable
- Contacted Author - 5-year sustained improvements (↓occlusions/heparin)
- Documented our Progress



Steere L. Lean Six Sigma JAVA 2018



Buzas, et al. Anti-Reflux NCs reduce Catheter Occlusions and Use of Alteplase

16-month study period cohort study

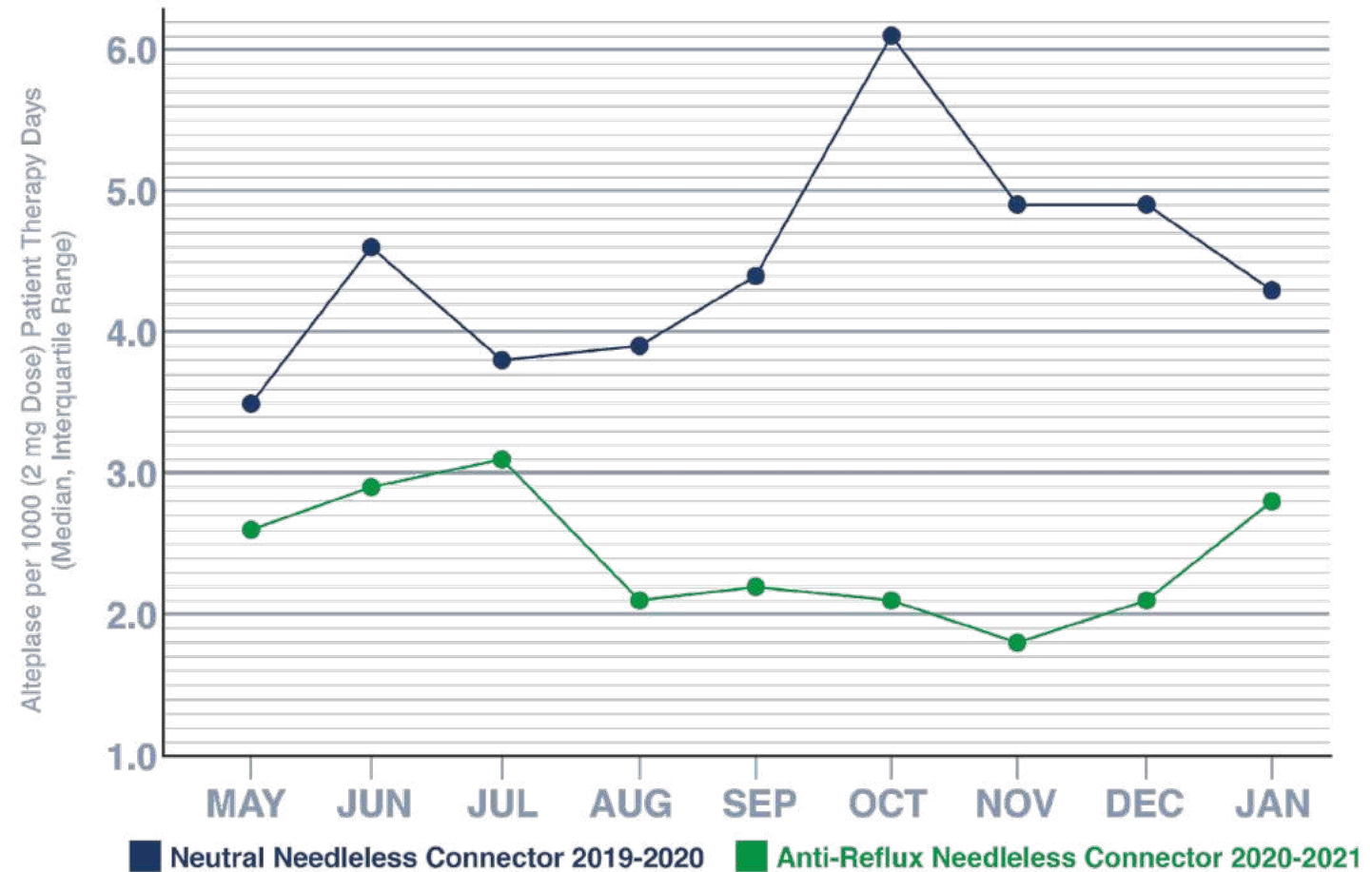
- Allegheny Home Infusion (Sharpsburg, PA & Meadville, PA)

495,539 patient therapy days

- Single home infusion intervention compared occlusion outcomes of two types of needleless connectors
 - A neutral needleless connector (NNC) with no bidirectional flow control
 - An anti-reflux needleless connector (ANC) with bidirectional flow control

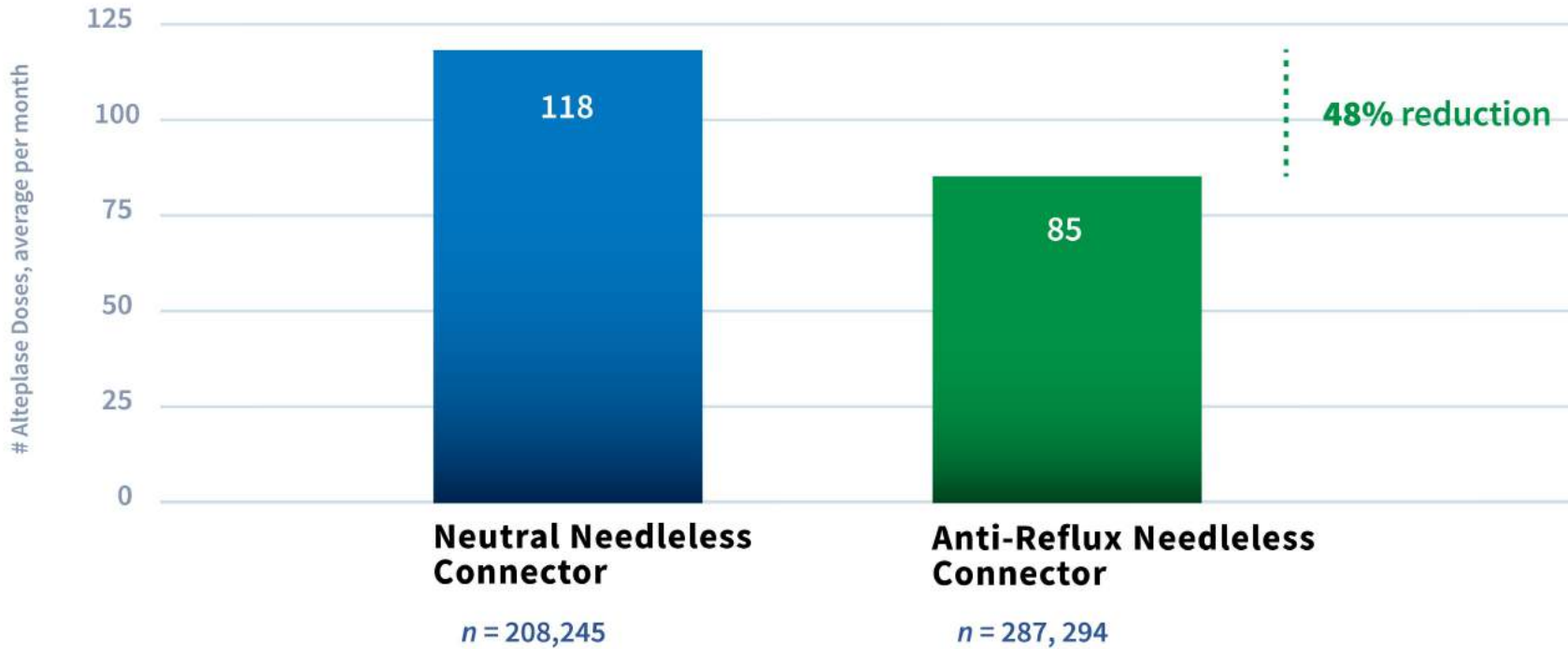
Alteplase usage with NNC & ANC were 4.6% vs 2.9%; median 112 (95% CI:89-169) vs 82 (95% CI:68-109) ($p<.001$).

Chart Comparison between Neutral and Anti-Reflux Connectors for Alteplase per 1000 Patient Therapy Days



Alteplase Use Decreased

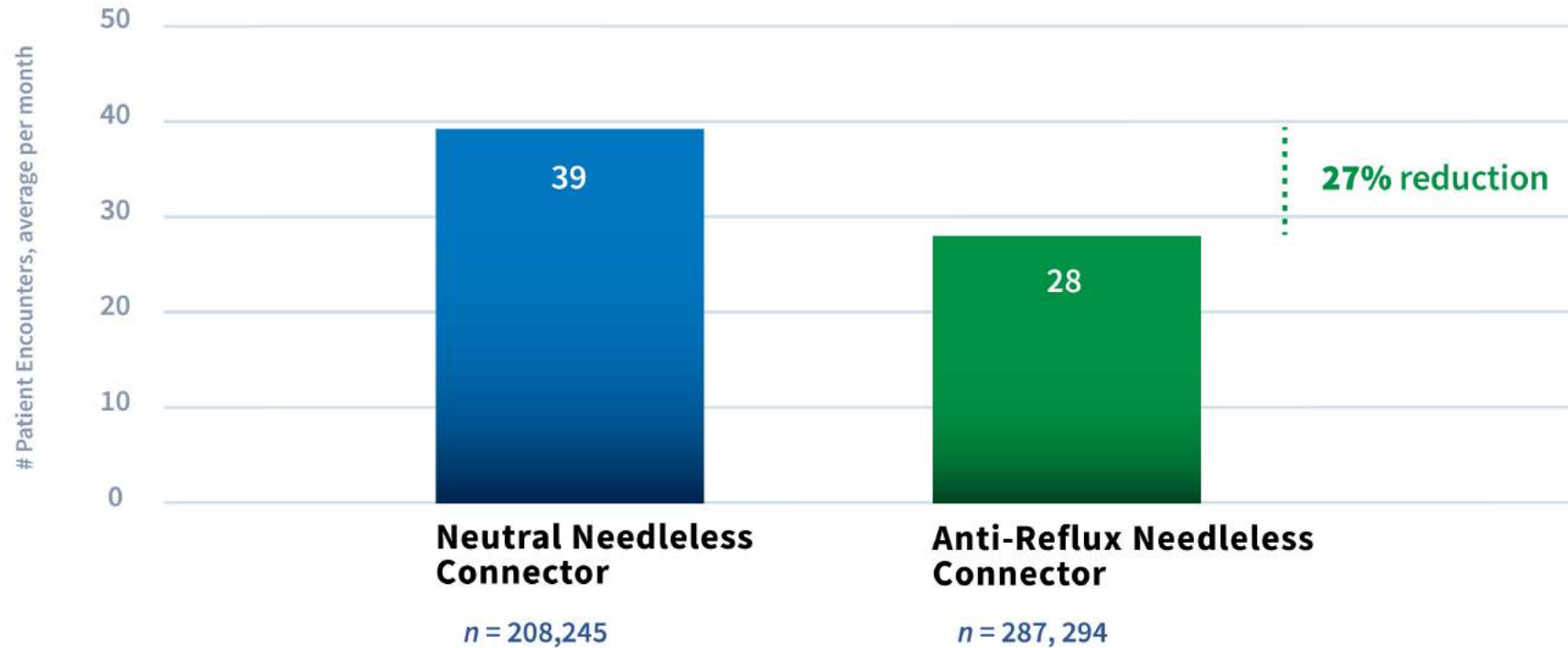
(n = 495,539 patient therapy days)



Average monthly alteplase usage decreased 48% per therapy days after switch from neutral needleless connectors to anti-reflux needleless connector, despite increased number of patient therapy days.

Patient Encounters Decreased

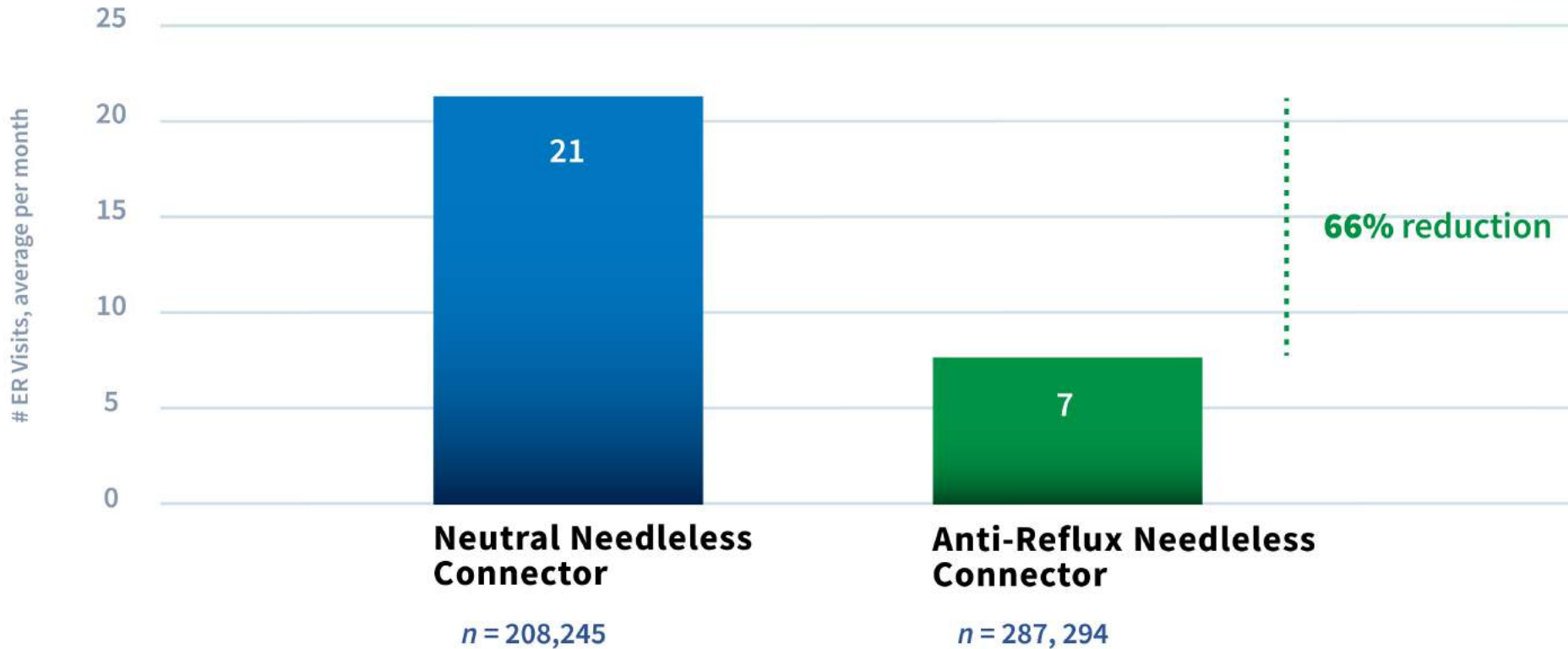
(*n* = 495,539 patient therapy days)



Average monthly number of patient encounters to declot catheters decreased 27% after switch from neutral needleless connectors to anti-reflux needleless connector, despite increased number of patient therapy days.

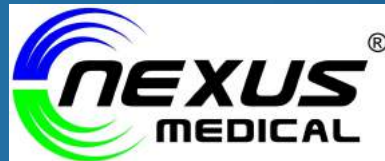
ER Visits Declined

(n = 495,539 patient therapy days)



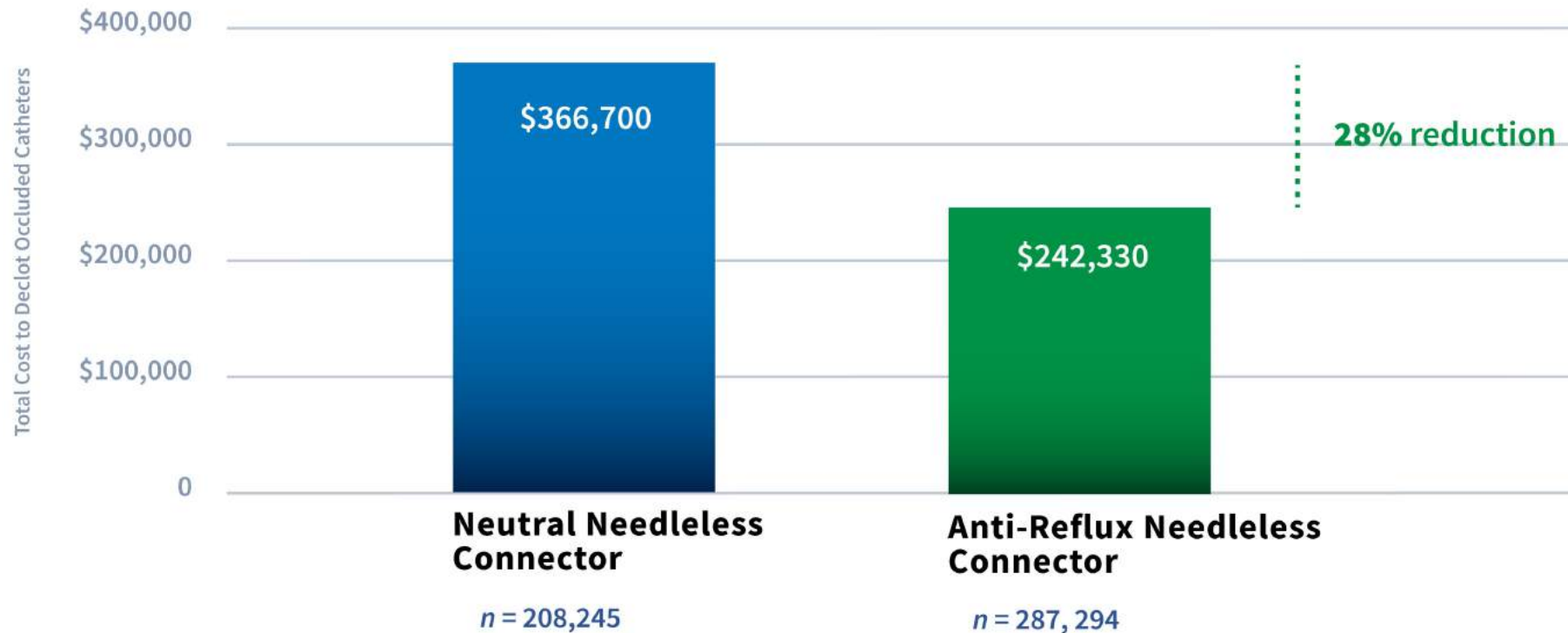
Average monthly number of ER visits, defined as patients requiring emergency department visits to have catheters cleared for continued use, declined after switch from neutral needleless connectors to anti-reflux needleless connector, despite increased number of patient therapy days.

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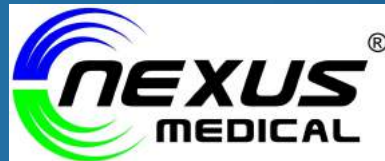
Anti-Reflux Needleless Connector Use Saves **\$124,370*** Over 9 Months

(*n* = 495,539 patient therapy days)



The switch from neutral needleless connectors to anti-reflux needleless connector reflects a fixed cost savings of \$124,370 over the study period, despite increased number of patient therapy days. | *Savings were seen in supply costs (28% reduction), nursing costs (27% reduction), and pharmacy costs (27% reduction).

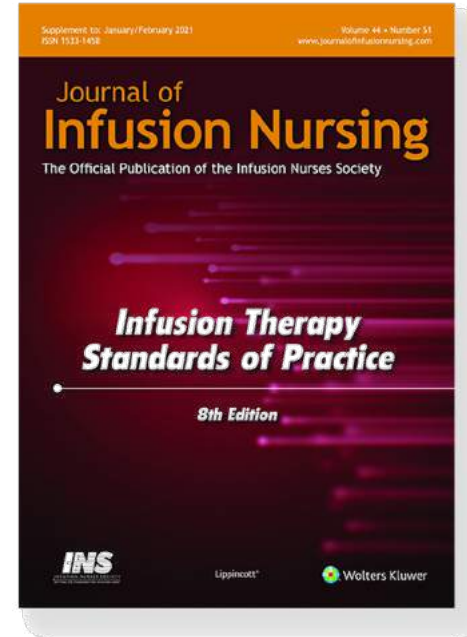
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In Process



Heparin Usage and Cost Reduction
(2x Saline)



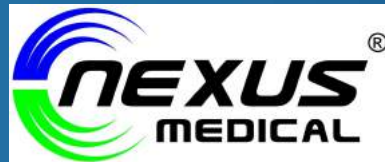
Evaluating lower doses of tPA (eg, 1 mg/mL) in lumens requiring less than or equal to 1-mL volume;
Reviewing dispensing regimen (used vs dispensed)

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Thank you.

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