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Feature Article

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CLE³AR Study

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

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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 declotting 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]

Tissue plasminogen activator (tPA) is used to restore catheter patency.[12] However, studies have shown that tPA has the unintended consequence of dislodging bacteria, which can be introduced through intraluminal contamination by healthcare staff, contaminated entry ports, or contaminated infusate.[4,13–15] Once bacteria are disseminated within the bloodstream, the patient may develop sepsis.[4,13]

Decisions about when to administer tPA and selecting the most appropriate needleless connector can be challenging for many reasons. First, there is no universally accepted occlusion management protocol, and often, there

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Disclosures: Lee Steere is a consultant with BBraun, Nexus Medical, and Eloquest Healthcare; he serves on the speakers bureau for Nexus Medical and Eloquest Healthcare.

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Table 1. Causes of Mechanical and Physiological Pressure Changes Within a Patient's Vasculature[6,11]

Patient Activity
• Movement
• Crying
• Coughing
• Sneezing
• Vomiting
• Lifting heavy objects
Catheter Access Management
• Intravenous (IV) bags (connecting, disconnecting)
• IV pumps
• Clamping/unclamping protocols
• Syringe connection/disconnection
• Syringe plunger rebound
Ventilator-Related Issues
• Immobility

is a lot of variation within the same institution. This variability can lead to wasteful, inefficient processes that negatively impact clinical outcomes. Second, there are several types of commercially available needleless connectors with various design features. Currently, no needleless connector is recognized as superior over another. The 2021 Infusion Nurses Society Standards only recommends using the device that produces the least amount of blood reflux.[16,20]

Intravenous catheter occlusions and their complications can be prevented, in part, by selecting a needleless connector that is designed to produce the lowest amount of blood reflux and biofilm formation within the catheter. Antireflux needleless connectors have been shown to do this most effectively.[11,16–20] In addition, their bidirectional fluid control design helps minimize end-user error because they do not require a specific clamping sequence to flush the catheter.[11,16,18]

Faced with the ongoing concerns over occlusion-related complications, Hartford Hospital launched a Lean Six Sigma (LSS) quality program to identify and address sources of waste, process variability, and defects that negatively impacted patient safety and outcomes. Using the Lean thinking principles (efficiency, effectiveness, and economics), the Hartford team was able to significantly reduce overall tPA and needleless connector consumption within the first 26 months of launching the program. In addition, Hartford Hospital recognized a cost savings of $107 315.[20] The Vascular Access Specialist Team has continued to use the interventions that were developed, and the aim of this article is to describe the clinical and financial impact that the CLE^{3}AR study measures have had in the 5 years since the program was initiated. The study name has a duality: it refers to Central Line patency ("CLEAR") as well as the "3 E's" of LSS methodology (efficiency, effectiveness, and economics) and the use of antireflux technology.

METHODS

Setting and Subjects

The setting was the acute inpatient care units of Hartford Hospital, an 867-bed regional referral center and the largest hospital in the Hartford Health System.

LSS Implementation

Between October 2014 and December 2016, clinicians at Hartford Hospital who were trained in LSS evaluated the hospital's occlusion management processes and historical medical supply consumption data.

The LSS team's findings were used to identify interventions aimed at reducing (1) pharmacy and medical supply consumption (ie, tPA, heparin, and needleless connectors), (2) variability in catheter maintenance practices, and (3) risk of occlusion-related complications. All interventions were implemented within the hospital's 5 Intensive Care Units (ICU's). Details of the value-added actions and improvements identified at each phase of the DMAIC (define, measure, analyze, improve, and control) process have been described elsewhere and are summarized in Figure 1.[20]

Interventions

Controls were established that required all catheter occlusions be evaluated and managed by the vascular access specialist team. Team members also developed a catheter patency assessment algorithm designed to inform decisions about tPA use (Figure 2). Furthermore, tPA assessment, ordering, and instillation were restricted to registered nurses on the IV management team. Finally, negative displacement needleless connectors (Clave; ICU Medical, Inc, San Clemente, California) were replaced with antireflux needleless connectors (TKO-6P; Nexus Medical, Lenexa, Kansas) to reduce the risk of blood reflux and other complications associated with intraluminal thrombotic catheter occlusion.

Outcomes and Measurements

Central line days, monthly pharmacy and medical supply consumption, and associated direct costs were measured at baseline and every year between 2014 and 2020. The cost of a 1 mg aliquoted dose of tPA was calculated at US $65 per dose. Prefilled heparin flushing syringe cost was calculated at US$0.55 per 10 mL syringe. The cost of negative displacement needleless connectors was calculated at US$0.94 per unit and antireflux needleless connector cost was calculated at US$1.69 per unit.

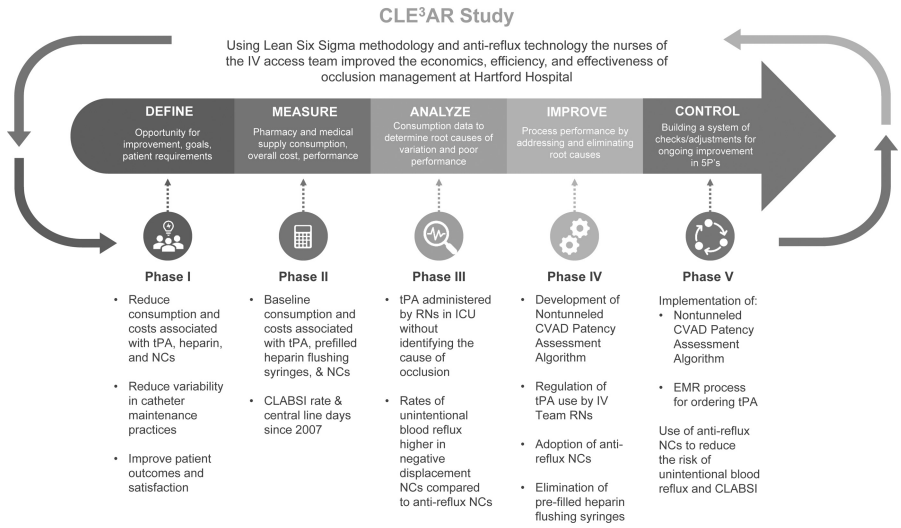

FIGURE 1. Value-added actions and improvements to occlusion management practices identified through the LSS DMAIC (define, measure, analyze, improve, and control) process. Hartford Hospital is currently in the Control/Sustained Improvement phase (V) of the process. 5Ps, processes, protocols, practices, products, and patient outcomes; CVAD, central venous access device; EMR, electronic medical record; NC, needleless connector; RN, registered nurse.

Data Analysis

Data are expressed as mean values.

RESULTS

Central Line Days

Central line days represent the number of days a central line is in place for each patient in the hospital unit; the count is performed daily and each patient with a central line is counted as a central line day. A total of 159 934 central line days were reported between 2014 and 2020 (Figure 3A). The central line days reported between 2014 and 2016 represent data collected from the hospital's 5 ICUs alone. Beginning in 2017, the reporting was changed to include central line days collected from the hospital's medical-surgical units as well. A 50.3% increase in central line days was observed between 2017 and 2020.

Pharmacy and Medical Supply Consumption

At baseline, an average of 1428 patients received tPA in 2014 (Figure 3B). This number decreased by 55.3% within the first year after implementing the LSS interventions. Consumption of tPA continued to decline over the next 5 years, with an average of 410 patients receiving tPA in 2020, representing a 35.7% decline from 2015.

Prefilled heparin flush syringes were permanently eliminated from the flushing protocol after antireflux needleless connectors were introduced in 2015.

Annual needleless connector usage dropped by 40.2%, from 110 593 units in 2014 to 66 100 units in 2015. This reduction was primarily because of the switch from negative displacement needleless connectors to antireflux needleless connectors, which have a bidirectional flow control diaphragm that automatically prevents unintentional blood reflux (Figure 3C).[16,18] The 41% reduction in needleless connector consumption has remained relatively constant since 2016. On average, 65 400 units are consumed annually.

Cost Savings

Annual occlusion costs dropped from $92 820 in 2014 to $41 496 in 2015 (55.3%) and from $41 496 in 2015 to $26 650 in 2020 (35.8%); costs beyond 2016 represent costs associated with tPA usage alone (Figure 4). The 5-year cost savings for these interventions are estimated to be $356 005.

DISCUSSION

It is estimated that central venous catheters are inserted in 3 of 4 acute care inpatients.[21] The number of critically ill patients continues to rise as older adults with comorbidities and patients with acute organ dysfunction are hospitalized.[22] One study evaluating critical care admissions in the United States found that between 1996 and 2010, there was a rise in admissions primarily due to sepsis, as well as musculoskeletal diseases and injuries among the elderly.[22] Our data showing an increase in central line days most likely reflect this national trend, as well the growing number of critically ill patients being hospitalized because of the COVID-19 pandemic.

Central venous catheters are typically used for patients who require long-term treatment and/or laboratory monitoring; however, they can negatively impact patient health and safety.[1,3] Ongoing concerns over occlusion-related complications prompted Hartford Hospital to examine process inefficiencies, waste, and variations in occlusion maintenance practices within the 78-bed, ICU units. The vascular access team, in conjunction with the hospital's nursing leadership, pharmacy, and supply chain team, applied LSS

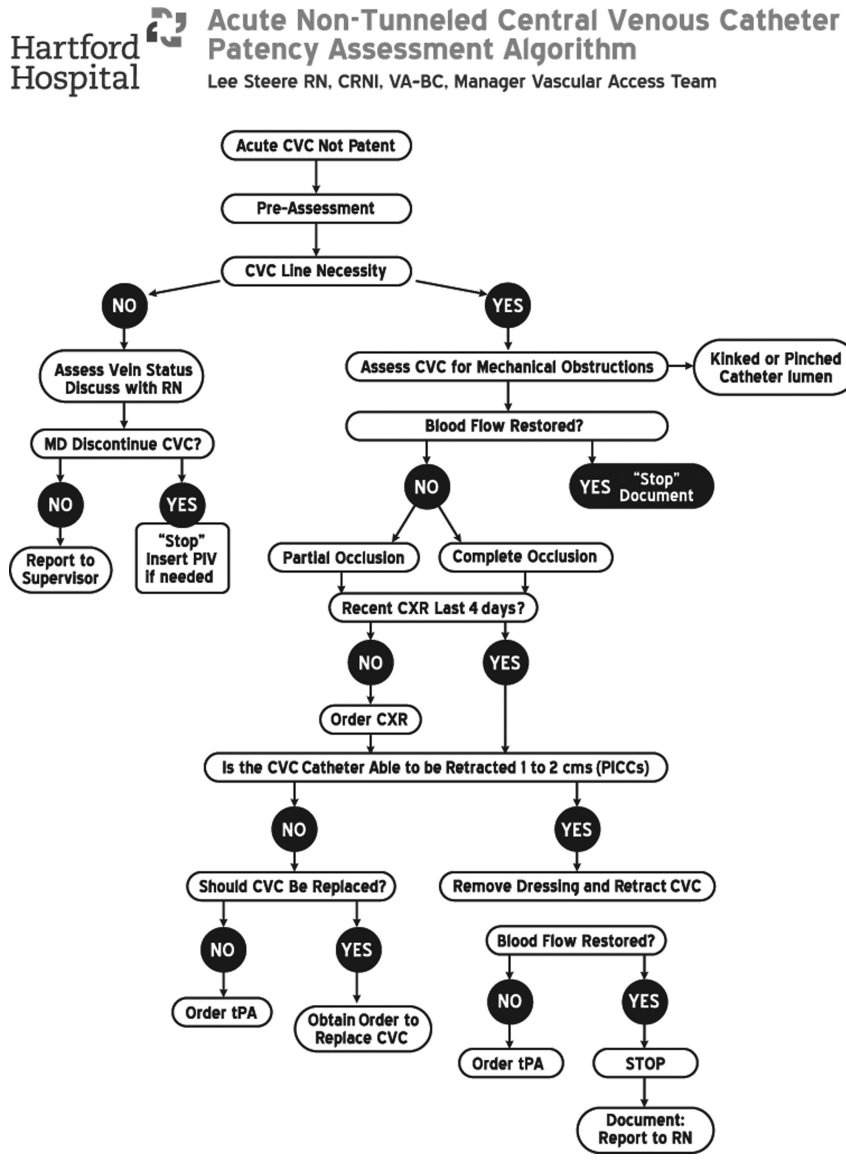

FIGURE 2. Hartford Hospital acute nontunneled central venous catheter patency assessment algorithm. All catheter occlusions must be evaluated by a vascular access nurse specialist using this algorithm. Only IV team RNs have access to the tPA ordering screen in the electronic medical record. CVC, central venous catheter; CXR, chest x-ray; MD, physician; PICC, peripherally inserted central catheter; PIV, peripheral IV line; RN, registered nurse.

principles to identify and address costly deficiencies in patient care. Substantial gains were reported in the first year after the implementation of quality control interventions. The results reported here, which were sustained over the 5-year postintervention, indicate that the 2 interventions led to continuing improvements in pharmacy and medical supply consumption, as well as cost savings.

Vascular access specialist teams possess advanced skills and expertise regarding insertion and management of vascular access devices. Hartford Hospital's results are similar to other studies that support the use of vascular access nurse specialists rather than bedside nurse as part of a larger approach for reducing catheter failures and occlusion-related complications.[23] Because of the sustained improvements in IV care, the vascular access team has taken on more responsibilities within the hospital. These include peripheral line placements in all inpatient units, central line care and maintenance outside of the ICUs, and monoclonal antibody infusions for COVID-19-positive patients. In addition, the team is responsible for IV care and maintenance within the outpatient parenteral antibiotic unit.

This increase in responsibilities enabled the vascular access team to expand personnel at a time when many hospitals are finding ways to cut the vascular access team. In 2015, the vascular access team consisted of 7 people. Today, there are 23 IV personnel. It is important to note that during this

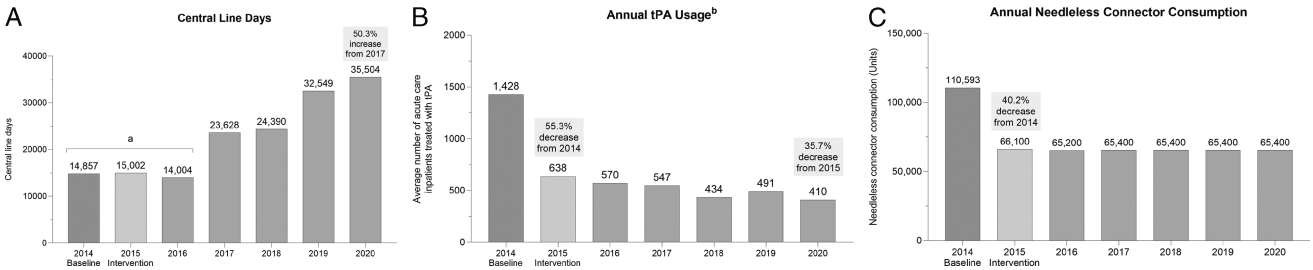

FIGURE 3. Clinical impact of Lean occlusion management initiatives at Hartford Hospital, 2014 to 2020. Interventions were aimed at reducing medical and pharmacy supply consumption in the hospital's ICUs. (A) Central line days. (B) Annual tPA usage in acute care inpatients. Consumption of tPA decreased dramatically in 2015 because of protocol interventions and the adoption of antireflux needleless connectors. Use of tPA continued to decline despite the rise in central line days. (C) Annual needleless connector consumption. Negative displacement needleless connectors were in use during 2014. Antireflux needleless connectors were introduced in 2015. Needleless connector consumption was significantly reduced after the adoption of antireflux needleless connectors. Antireflux needleless connectors can be used for 7 days versus twice per week with negative displacement needleless connectors. This resulted in less consumption. [a] Between 2014 and 2016, central line days were reported only for Hartford Hospital's 5 ICUs. After 2017, the central line days reported included data collected from the 5 ICUs and the medical-surgical units. [b] 1 mg dose.

expansion, no full-time equivalents were added to the overall nursing budget, but rather staff RN hours were reallocated to vascular access specialist hours to reflect hospital needs. Furthermore, over the 5-year study period, less than 1% overtime was utilized, most of which was due to staff working extra shifts or covering callouts. This team's focus on efficiency and lean care has helped avoid at least $400 000 in overexpenditures in areas that do not add value to the patient or treatment. These cost savings offset the costs associated with additional full-time equivalents.

Pharmacy and medical supply reductions not only represent cost savings for the organization but also point to wider improvements in patient healthcare outcomes. Use of tPA is associated with increased risk of CLABSI in patients with intraluminal thrombotic catheter occlusion. Preintervention analysis revealed that all catheter occlusions were treated with tPA, regardless of cause. Controls that required that (1) all catheter occlusions be evaluated by the vascular access specialist team, (2) the need for tPA instillation be determined by using a catheter patency access algorithm, and (3) tPA ordering and access be restricted to vascular access specialists contributed to significant and sustained reductions in tPA consumption over 5 years. Despite a nearly 3-fold increase in central line days, fewer patients were administered tPA—representing a nearly 71% reduction in tPA use since 2014. By extension, these data suggest that these 2 interventions also increased patient safety.

Educating staff about how to use evidence-based strategies for troubleshooting an occluded line and guidelines for appropriate use of tPA was also essential to the success of these interventions. Because of the low number of

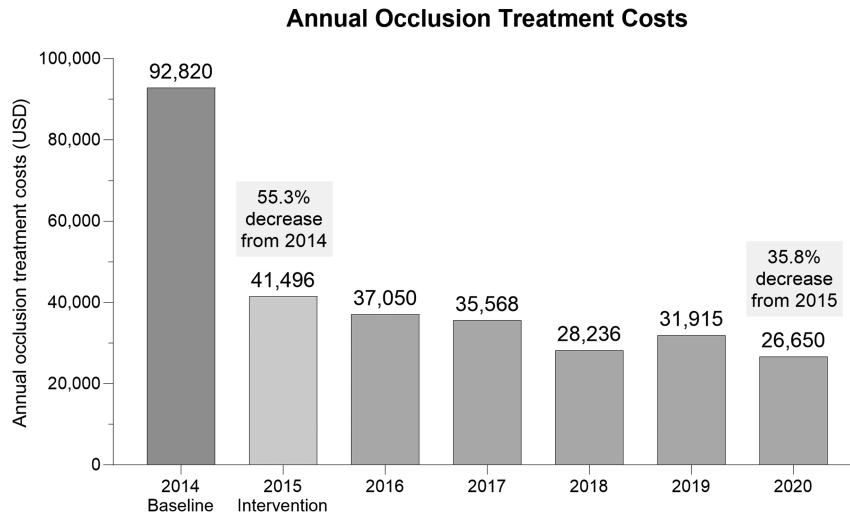

FIGURE 4. Annual costs associated with tPA and heparin use, 2014 to 2020. Lean occlusion management interventions led to substantial cost savings that were maintained over the course of the study. Heparin use was 100% eliminated in the first year after adopting antireflux needleless connectors. The cost of tPA was calculated at US$65 per 1 mg aliquoted dose. The cost of prefilled heparin flushing syringes was calculated at US$0.55 per 10 mL syringe.

clinical nurse specialists (CNSs) on staff in the acute inpatient care units, this was carried out almost exclusively by the vascular access team. However, we envision that this role could be carried out by CNS leadership in hospitals with a larger CNS presence.

Intraluminal thrombotic catheter occlusions are a major, yet mostly preventable, complication associated with the use of IV catheters.[24] Using needleless connectors that are designed to produce the least amount of unintentional blood reflux is an effective way to reduce occlusion risk.[11,16,20,25] After reviewing the efficacy of commercially available needleless connectors, we decided to adopt the Nexus TKO-6P antireflux needleless connector because it has been shown to produce the least amount of blood reflux and because it has been validated for 7-day use. In contrast, negative displacement needleless connectors produce the greatest amount of blood reflux and need to be changed twice a week. Within the first year postintervention, we reported a sustained decrease in needleless connector consumption. The adoption of an antireflux needleless connector eliminated the need for heparin flushing and contributed to a sustained decrease in the number of catheter occlusions requiring tPA recanalization over the 5-year period.

LIMITATIONS

This LSS occlusion management initiative was completed within the acute inpatient care units at Hartford Hospital. Two interventions were implemented in 2015, making it difficult to clearly determine the direct impact of each intervention. Analysis of retrospective data from 2007 to 2013 combined with CLABSI results collected during the first 26 months of the study showed a 77% reduction in CLABSIs over 9 years. However, changes in CLABSI metrics and Center for Medicare and Medicaid Service reporting were made in 2016 that do not permit direct comparison with previous data. Therefore, it is unknown whether the reduction in CLABSI was sustained over the 5-year postintervention period.

CONCLUSIONS

Implementation of Lean occlusion management interventions within Hartford Hospital's acute inpatient care units was associated with less pharmacy and medical supply waste and consumption over a 5-year period. Consumption of tPA was curbed, in part, by a new algorithm that helped vascular access nurse specialists more accurately identify which patients required tPA to restore line patency. The adoption of an antireflux needleless connector also played an important role in the team's success. Switching from negative displacement needleless connectors to antireflux needleless connectors eliminated the need for heparin and resulted in fewer line occlusions and CLABSIs. In addition, needleless connector consumption dropped dramatically because antireflux needleless connectors automatically prevented unintentional blood reflux and did not need to be changed as frequently.

Results from this 5-year study demonstrate that prevention of catheter occlusion with antireflux technology combined with effective management and treatment of catheter occlusion improved patient safety and outcomes. Applying LSS principles resulted in sustained improvements in occlusion management and cost savings for Hartford Hospital.

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