Disinfecting Needleless Access Valves

Improve Practice and Decrease CRBSIs: Three Hospitals’ Experience With a New Technology

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November marks the 10th anniversary of the Needlestick Safety and Prevention Act, which requires healthcare providers to use needle-free or needle-protected devices where available to reduce the risk of accidental needlesticks. While movement to these products was already underway, the legislative mandate heightened needle safety awareness and fostered the development of new safety-focused needle technology for the U.S. market.

Key among these developments was the introduction of needleless luer-activated valves (LAVs). Today there are more than 15 brands of LAVs on the market, which are accessed via the luer tip of a syringe or the distal male luer connector of an IV set. The valves can utilize either positive, negative or neutral displacement technology—as well as split-septum design. While this technology ensures healthcare worker safety by preventing needlesticks, the past decade has demonstrated that certain aspects of the design could actually put patients at risk of catheter-related bloodstream infections (CRBSIs).

Numerous published reports and studies have concluded that the inherent design and utilization of LAVs in healthcare delivery may be associated with increased rates of patient CRBSIs. In addition, this past July the Food and Drug Administration (FDA) began requiring nine LAV manufacturers to conduct a post-market surveillance studies on positive displacement needleless valves to assess whether they may be associated with a higher rate of device-associated bloodstream infections than other types of needleless connectors, and to assess the factors that may contribute to a possible increased risk. Specifically, the FDA is asking manufacturers to address the question: “Are there patient demographics, comorbidities/severity of illness, or device cleaning practices for which placement of your positive displacement connector for central line access increases patients risk of bloodstream infections compared with other needleless connectors?”

This initial FDA action will aid the market to better understand what role a specific LAV design may play in the increased incidence of BSIs. However, it is clear that all LAVs, regardless of design, are continually exposed to bacteria. If they are not disinfected consistently and reliably prior to each access, LAVs can provide a direct path to a patient’s bloodstream for any bacteria residing on the port. Therefore, if used improperly, LAVs carry an increased risk of BSIs.

BSIs and Health Policy Today

Bloodstream infections are considered preventable events, and as such, in October 2008, the Centers for Medicare and Medicaid Services (CMS) ceased reimbursing providers for the care and treatment of a BSI acquired while a patient was under their care. Numerous private insurers have adopted similar reimbursement policies.

These actions, along with increased tracking and reporting requirements, have heightened the focus on reducing the risk of BSIs and other avoidable complications. Numerous published research studies have focused on the reduction of CRBSIs through best practice process bundling and new product innovation for central line maintenance. A landmark study conducted by Peter Pronovost, MD, PhD, FCCM, medical director at the Center for Innovation in Quality Patient Care at Johns Hopkins Medical Center in Baltimore, showed that the incidence of CRBSIs could be cut by two-thirds if hospital personnel followed a five-step insertion checklist.

Despite the increased awareness, hospital-acquired BSIs remain a major issue for the healthcare system today. The Centers for Disease Control and Prevention (CDC) estimates there are a minimum of 250,000 incidents of catheter-related bloodstream infections (CRBSIs) annually in the United States. The implications and costs of a bloodstream infection are considerable:

- The average cost to treat a BSI ranges from $36,441 to $91,733
- BSIs have been reported to increase hospital stays, on average, 20 days
- Patients who acquire a BSI are at risk for increased mortality, an estimated 19 percent of patients die from their infections

In addition, a survey conducted by the Association for Professionals in Infection Control and Epidemiology (APIC) indicated that the majority of respondents agreed with the statement: “Despite the evidence demonstrating that many, if not most, CRBSIs can be prevented through consistent application of best practices and the financial penalty imposed by CMS and many private insurers, CRBSIs are still a persistent problem for many healthcare institutions.”

According to the survey, institutions should take the following steps in order to reduce the improper procedures that cause CRBSIs:

- The need for additional education and resources to prepare for the successful prevention of CRBSIs
- Additional focus by hospital administration on the issue
- Stronger monitoring of compliance with best practices for the prevention of BSIs and holding clinical staff accountable to these practices

The Disinfection Challenge

Because their surfaces are not covered, LAVs are exposed to bacteria through both touch and airborne contamination that occurs in normal everyday use. As such, clinicians are required to swab to disinfect the valve prior to use. Historically, most facilities find this practice to be inconsistent, at best. While significant attention has been placed on the improved maintenance of lines in the delivery of care, the disinfection of ports prior to use has, until recently, totally relied on internal education programs, such as “scrub the hub” campaigns. These campaigns attempt to raise awareness and focus nursing attention on proper disinfection of LAVs prior to use. Unfortunately, they offer no new tools to assist clini-
nurses in improving their practices. The current requirement of a 15-second scrub followed by a 30- to 60-second dry time is effective when followed, but is often unrealistic in a time-compressed environment.

Improving compliance and gaining consistent and reliable disinfection of LAVs continues to elude the great majority of healthcare facilities. Relying on clinicians to comply with prescribed practices alone will not win the battle—think about handwashing. However, today’s practices can be enhanced—or even made easier—with the help of additional technology. Process improvement can be achieved through the combination of improved technology and clinical education.

**LAV Disinfection Technology Advances**

A new technology, disinfecting port protectors, has recently been developed to aid healthcare providers in the overall improvement of port disinfection practice with the goal of reducing the rate of CRBSIs. In June 2009, Ivera Medical, a San Diego-based medical device company, introduced the Curos® Port Protector which is the first protector to disinfect and protect LAVs against exposure to touch and airborne contamination. The patented Curos Port Protector is a small, easy-to-use disinfection cap designed to securely twist onto all currently available LAVs.

The device is designed to:

- Disinfect and protect luer-activated ports, eliminating the need to swab LAVs. For the first time, this technology provides facilities with consistent and reliable disinfection of their LAVs no matter who performs the procedure.
- Act as a visible and auditable tool by which the facility can monitor and measure compliance with disinfection protocol. The high visibility green color demonstrates compliance at a glance and provides an additional safety layer by negating any confusion with other ongoing therapies.
- Minimize cost by reducing unnecessary packaging waste (Curos has only a small foil seal to discard prior to use).

Numerous healthcare providers in the U.S. have evaluated Curos and adopted the device into their disinfection protocols. Three such hospitals in the Southern California area have documented their practice, experience, and results with the use of this product.

**Sharp Chula Vista Medical Center, Chula Vista, Calif.**

Sharp Chula Vista Medical Center, a member of the Sharp HealthCare System, is a 343-bed acute-care facility located in Chula Vista, Calif. The hospital prides itself on its attention to patient care and overall patient safety and is consistently evaluating and implementing new technology and procedures to improve patient care and ensure patient safety.

In July 2009, the hospital evaluated Curos Port Protectors as an addition to its central line bundle protocol for line maintenance. The hospital uses both MicroClave® and SmartSite® LAVs. The initial trial was conducted in the 35-bed MICU/SICU. Prior to the trial, the vascular access team was auditing LAVs and dressing changes every day. The MICU educator modified the team’s standard Central Line Audit Tool to include an area to track the use of Curos Port Protectors on all lines.

For the 30-day trial, Curos was used for the disinfection and protection of all LAVs on all central lines and PICC lines in the unit. During the evaluation period, the hospital experienced a significant decrease in BSI rates in these units; it later elected to continue use of Curos in the MICU/SICU as well as expand its use throughout the hospital on all LAVs, central, and PICC lines. Use of the product continues to produce extremely positive results with the MICU/SICU reporting zero BSIs for the first two quarters of 2010.

“The use of Curos has made a significant impact on our ability to reduce bloodstream infections,” says Mary Ann David, RN, clinical lead nurse of the MICU/SICU. “This product does represent a practice change for clinicians,” she adds, “and changes to practice have to be reinforced to be successful.”

David says the keys to the successfully changing practice, in the MICU/SICU at Sharp, have included:

- Assigning specific audit and reinforcement responsibilities to a key clinical staff member – in the case of Sharp it was the resource nurse.
- Ensuring regular audits of lines are conducted to confirm compliance with protocol and use of Curos. The vibrant green color of the product allows for easy visibility.
- Explaining the benefits of the use of the product to the staff – understanding why the hospital has elected to implement Curos so that peers will reinforce its use with each other. Once benefits are explained the staff will use Curos because they want to insure patient health and safety.

Since Sharp Chula Vista Medical Center began using Curos, experience has shown that when compliance rates with maintenance bundles, which include the use of Curos, are above 95 percent, the facility-wide BSI rates were significantly reduced. Conversely, when clinician practice had become lax and Curos compliance fell below 90 percent, the hospital reported increased BSI rates. The facility continues to increase its overall compliance through daily audits of lines and reinforcement of Curos compliance.

“Curos provides us with the ability to have consistent and reliable disinfection of valves no matter who performs the function,” David says. “It also gives us the ability to actively manage the process in order to improve overall practice and compliance. This activity pays off for the hospital, clinicians, and the patients through lower BSI rates and improved patient care.”

**Rady Children’s Hospital, San Diego, Calif.**

Rady Children’s Hospital is a 272-bed children’s hospital located in San Diego. Focusing on achieving a reduction in BSI rates in the facility’s 41-bed NICU, the hospital began an evaluation of Curos Port Protectors in October 2009. The hospital currently uses the MicroClave and SmartSite LAVs. Before the six-month evaluation period began, the NICU staff attended in-service training as well as mandatory staff meetings. Initially, the hospital used Curos only on central and PICC and did not include peripheral lines. Staff also continued their normal practice of swabbing the LAVs on all lines and using the caps as an added protective measure. After five months, in an effort to standardize procedures, the protocol was changed and Curos was used on all ports, central lines, and peripheral lines.

The transport team makes daily rounds on central lines, ensuring that dressings are intact; Curos became another item on their audit list as...
they measured compliance rates. The Curos evaluation was eventually expanded to all inpatient units. In an effort to ensure standardization of this new practice, Rady Children’s developed auditing tools to ensure daily use of Curos on all lines. This daily auditing process, along with the ease of use and visibility of Curos, has helped the facility achieve a 98 percent to 100 percent compliance rate in the NICU, driving positive outcomes for the hospital’s overall BSI rate.

“Staff familiarity with this new product is key,” says Cindy Salgado, RN, CIC, infection control coordinator. “Focusing our educational efforts on helping staff understand the product’s potential benefit to our line care is critical for success — auditing and taking steps when compliance falls makes a real difference.” As with most patient care quality initiatives, Salgado says that front-line engagement is imperative to change.

“The placement of Curos in strategic locations on the unit is also extremely important for ease of access and use,” adds Salgado. “Stocking the product near the patient so the nurse can access it easily at the bedside helps staff comply.”

Salgado notes that the keys to success at her institution were:

- Audit daily compliance. The responsibility for auditing was given to the transport team, clinical educators, or designated clinical staff.
- Clearly delineate to clinical staff the overall benefits of using Curos to keep LAVs from becoming contaminated with pathogens in the first place—including pathogens found on the patients’ own skin.
- Present the science behind the components of the maintenance bundle. In the case of the Curos caps, the staff needs to understand how keeping the LAV clean can play such a large role in reducing bloodstream infections and improving overall patient care.
- Forge partnerships with champion physicians, engaged clinical educators, and clinical leadership to support a BSI initiative.
- Place Curos in a convenient location in each unit so clinicians can easily access them.

“As most ICPs know, there are multiple variables to grapple with when attempting to reduce BSI rates,” Salgado says. “However, our experience so far with using the Curos caps has been promising. We reached 183 days without a BSI in our NICU, which is a historical first in our hospital.”

As a Children’s Hospital when they expanded the use of the Curos caps outside the NICU, there was considerable debate as to whether young patients would play with the product and if it could present a choking hazard. The luer-lock design of Curos helped to alleviate some of the concern about this issue and, ultimately, in order to achieve reduced BSIs, the facility chose to adopt Curos to be used with existing practices for similar small devices, restricting use in patients where it was felt to be contraindicated.

**Miller Children’s Hospital, Long Beach, Calif.**

Miller Children’s Hospital Long Beach is a 324-bed facility located in Long Beach, Calif., and is part of the MemorialCare Health System. The hospital participates in the California Perinatal Quality Care Collaborative (CPQCC) in partnership with California Children’s Services (CCS). The collaborative’s aim is to reduce the occurrence of CRBSIs to almost zero systemwide. When Ching Tay, MSN, RN, clinical nurse specialist, learned about Curos and the results at Rady Children’s, she implemented a 30-day evaluation of the product in the hospital’s 93-bed NICU.

The unit, which uses the MicroClave valve, elected to utilize Curos on all central, PICC, and peripheral LAVs. Initial in-services of the NICU staff were conducted on all shifts and the unit conducted periodic audits. After the initial evaluation period, BSIs in the NICU remained unchanged. Upon review, it was determined that compliance over this period was less than 50 percent. Realizing that compliance was not where it should be, the unit elected to extend the evaluation for another 30 days.

To increase compliance the two staff developers in the unit reinforced the potential benefits of the product and took an additional step of following up with non-compliant staff during auditing. They also stocked Curos in convenient locations to aid ease of use. During the second 30-day period, compliance significantly increased and the unit achieved a milestone of zero BSIs. As a result, the NICU continues to utilize Curos on all of their lines and has not had a bloodstream infection for more than 90 days.

“We really like the green color of Curos,” says Ching. “It is easy to see and helps us manage compliance — something we were unable to do prior to the use of this product.” The NICU can experience large swings in patient census and acuity, making it more of a challenge to reinforce the initial staff education and build compliance with the new practice.

“Another very positive step we made,” says Ching, “was to inform the children’s parents about the use of Curos, and encourage them to look at their child’s lines when visiting.” If there was not a green cap in place, the parents were encouraged to report it to a nurse. “Parents really like the idea of Curos. They check for Curos on their child’s IV lines.”

The hospital also made sure that Curos was placed in easy to access areas — in supply areas in the patient rooms and/or on the medication cart located just outside the rooms—so nurses could have easy access at the point of care. “During our initial 30-day evaluation, we kept the Curos only in our Pyxis® equipment and it was not that convenient for the nurses,” Ching says. “When we extended the evaluation, we moved them to the patient care areas and it helped make a difference in our overall utilization and compliance.”

According to Ching, the success at Miller Children’s Hospital Long Beach was attributable to:

- Assigning audit responsibility to a member of the NICU PICC team and reinforcing Curos utilization when LAVs were discovered unprotected. They have made the use of Curos a part of their standard catheter maintenance bundle and have modified their Central Line Access Audit Tool to include Curos compliance.
- Working with the staff developers on the unit to educate and inform both the unit’s permanent staff as well as the nurses floating onto the unit as to the benefit and value that using Curos can provide.
- Alerting parents to the use of Curos and encouraging them to check for use on their child’s IV lines, and aid in ensuring compliance.
- Placing Curos in very convenient locations close to the patient and/or work station to provide ease of access to the product for the nurses at the site of use.

“The reason we put Curos on all our lines was to gain compliance and standardization of disinfection practice. Curos protects the port from exposure to bacteria and helps ensure consistent and reliable disinfection of the ports,” concludes Ching. “Everyone is very excited about the results that Curos has helped us to achieve.” As a result of the reduced BSIs in the NICU, the hospital is now moving forward to implement Curos throughout its 324-bed facility.

For a list of references, please visit www.infectioncontroltoday.com.

Jack Saladow has more than 36 years of experience in healthcare sales, marketing and strategic planning, with a specialty in the delivery of intravenous medications to patients. As president of Jack Saladow and Associates, he provides sales, marketing, strategic planning and technology assessment consulting services to healthcare companies throughout North America, Europe and Israel.