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Healthcare Epidemiology: The Research Agenda for the Next Decade

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for Intravenous Needleless
Connectors to Prevent
HA-BSI

—By William R. Jarvis, MD

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 risk 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-BSIs risk.¹⁻⁶ 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.

Connector Design Recommendations

Not all NCs have the same design prob-



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lems, and some have design features that are desirable from an infection-control standpoint. Below is a guide to common features in NCs, including a discussion of potential problems and preferable alternatives.

Septum surface. Many current NCs have complex external septum surfaces that include gaps and openings. These gaps and openings create spaces that may not be reached by the clinician's disinfection routine, even if the appropriate routine – a 30-second, vigorous scrub with alcohol or chlorhexidine with alcohol – is performed meticulously. If the septum is not completely disinfected, then connecting a syringe or IV tubing to the NC can result in infusion of potentially contaminating pathogens into the patient's bloodstream.

Preferable: A NC with a smooth external septum surface with few if any gaps that can be more thoroughly disinfected.

Septum seal. Although there are no studies to confirm this, any opening between the septum and fluid pathway is, hypothetically, an area where biofilm can develop and a potential opening for pathogens to invade.

Preferable: A tight seal between the septum and the NC housing to reduce or eliminate space for contamination to occur and biofilm to develop.

Fluid pathway. Some NCs have a fluid pathway that is complex and indirect. If the pathway is indirect, flushing is less likely to remove blood or other nutrient fluids. When blood or other nutrient materials settle on a NC internal surface, they can serve as the nidus for biofilm development.

Preferable: A NC with a direct – that is, straight – fluid pathway that facilitates adequate flushing and reduces the internal surface for biofilm development.

Dead spaces. This issue is related to the directness of the fluid pathway. NCs with indirect or tortuous fluid pathways often have dead spaces that are not always reached by flushing. Contaminating organisms and proteinaceous material (i.e., blood) that enhances biofilm development can “hide” in these dead spaces, increasing HA-BSI risk.

Preferable: NCs with little or no dead space in the fluid pathway minimize the surfaces that infusates can contaminate and where biofilm can develop.

Internal mechanism. Some NC designs involve complicated internal mechanisms that open the fluid pathway when the NC is activated. As with dead spaces, moving

parts in the fluid pathway provide surfaces for infusates to bind to and can serve as a nidus for biofilm development. Also, moving parts themselves often make the fluid pathway more complicated and indirect. Finally, moving parts may fail.

Preferable: NCs with the most direct and least tortuous fluid pathway, with preferably no moving parts, reduce the potential risk of HA-BSI.

Clamping sequence. Both positive and negative pressure luer access mechanical valve NCs require a sequence of clamping steps as part of the disconnection process. The sequence is performed to minimize blood reflux (blood flowing backwards into the distal end of the IV catheter). Different NC types require different sequences, however. With negative pressure NCs, the clinician clamps the IV catheter and then disconnects the NC. In contrast, with positive pressure NCs, one disconnects from the NC and then clamps the IV catheter. This opposite order of clamping and disconnection is seldom understood by clinicians, and thus often the correct clamp-disconnection sequence is not used. This is an even greater potential problem when both positive and negative pressure NCs are being used simultaneously in a facility or healthcare system.

Preferable: Use a needleless connector that does not require a clamping sequence. Or, alternatively, use only one NC type that requires a specific clamp-disconnection sequence (e.g., all negative pressure, all positive pressure or all neutral pressure) throughout the healthcare facility or system – and insure that all HCWs understand and are well trained in this clamp-disconnection sequence.

Visibility. Flushing NCs is critically important because it is the method by which blood or other contaminating infusates (glucose containing solutions, intralipid, etc.) is removed from the NC. Many NCs are opaque; thus, one cannot visualize the internal surface of the NC and determine whether flushing was complete. The ability to visualize the internal surfaces of the NC helps the clinician determine if flushing of the NC is complete. If blood or other contaminants remain in the NC after flushing, they will facilitate the development of biofilm on that surface.

Preferable: A transparent NC is preferable to one that is opaque.

Blood reflux. Theoretically, blood reflux into either the IV catheter or the NC increases both the risk of occlusion and biofilm forma-

tion. Both also increase the risk of HA-BSI. Blood reflux can occur with both positive and negative pressure luer access mechanical valve NCs.

Preferable: A luer access mechanical valve NC with little or no blood reflux.

Flushing solution. Some NC types are designed to be flushed with heparin to reduce the risk of occlusion. In some patient populations, there have been reports of increasing rates of heparin-induced thrombocytopenia or HIT. Thus, a NC that can be flushed with saline rather than heparin containing solutions should decrease the risk of HIT.

Preferable: A NC that can be flushed with saline-only rather than heparin containing solutions avoids the potential risk of heparin-induced side effects.

Many if not most of the aforementioned design features have not been specifically studied for their relative contribution to the risk of HA-BSIs associated with negative or positive pressure luer access mechanical valve NCs. Although their relationship to HA-BSIs is logical, it remains hypothetical. But it is strongly believed that because the origin of HA-BSIs is in biofilm development on the internal and external surfaces of NCs, it makes sense to select a type of NC that minimizes the risk of biofilm formation.

In addition, the association of both positive and negative pressure luer access mechanical valve NCs with increased HA-BSIs risk has been repeatedly reported in the scientific literature.¹⁻⁶ It is my experience in traveling to hospitals worldwide that far more facilities have had HA-BSI problems associated with these NCs than indicated in the literature. The Society for Healthcare Epidemiology of America (SHEA) has recommended against the use of positive pressure mechanical valve NCs without appropriate evaluation.⁷ More recently, the CDC has recommended against use of either negative pressure or positive pressure luer access mechanical valve NCs.⁸

If, despite the SHEA and CDC recommendations, a facility decides to use such NCs, then they should stock just one type of NC, use it institution-wide, and insure that their clinicians understand and are well educated on its proper use. This will help prevent confusion about clamping-disconnection sequences and other recommended NC infection-control practices.

As we attempt to achieve zero tolerance for HA-BSIs, attention to both an insertion bundle and a maintenance bundle (including the type of NC used) is critical. The majority of published data illustrates that if such bundles are fully implemented, very low or zero rates of CVC-

BSI are achievable. Given the extent of the data, such insertion and maintenance bundles should be mandated by the Department of Health and Human Services in all ICUs in the United States today.

What are we waiting for? If prevention is primary, action is essential. If this were done, then the funding currently being used to "study" these bundles further in ICU settings (where most of the interventions have been tried and been successful) could instead be used to expand such prevention programs hospital-wide, where as many as 60 percent of HA-BSIs occur.

At least one hospital has demonstrated success in implementing an insertion and maintenance bundle hospital-wide. Sutter Roseville Medical Center (SRMC) in Roseville, California has completely eliminated HA-BSIs on peripherally inserted central catheters (PICCs) placed in the ICU by the PICC team.⁹ This record of success has persisted for more than four years.¹⁰ This should be a model for all U.S. hospitals. If patient safety is paramount, then implementation of insertion and maintenance bundles proven to prevent HA-BSIs should be a high priority for all hospital administrators. If these hospital administrators do not insure that such bundles are fully implemented, then Federal regulatory agencies should mandate it and insurance companies should refuse to reimburse for these preventable HA-BSIs



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