Clearing the Confusion about Needleless Connectors

Bacterial Risk due to Connector Design
The Consequences of what Practice Cannot Correct and the Implications for Device Selection

This Program is Supported by CareFusion the Makers of MaxPlus®

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Mr. Lange's Disclosure Statement:
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Learning Objectives

1. Describe the potential role of needleless connectors in contamination within the patient care setting.
2. Review current guidelines and practice recommendations concerning the use and types of needleless connectors.
3. Examine the important design features of needleless access connectors that address clinical practice concerns and reduce contamination of the devices.
4. Review the current evidence involving practice decisions and outcomes impacted by needleless connectors.
5. Identify key considerations that clinicians should know when selecting products that align with their infection prevention strategies.

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Importance of Disinfection

Removal of Bacteria from Needleless Connectors

**Skin organisms**
- Endogenous
- Extrinsic
- HCW hands
- Contaminated disinfectant

**Contaminated catheter hub**
- Endogenous
- Extrinsic
- HCW hands
- Contaminated disinfectant

**Contaminated infusate**
- Extrinsic
- Fluid medication
- Intravenous manufacturer

**Hematogenous**
- Seeding from distant infection


**Sources of Intraluminal Contamination**
- Poor hand hygiene
- Contamination of injections ports coupled with poor disinfection/design
  - Inadequate disinfection of needleless access port
  - Needleless connector design
  - Use of open port systems
- Contaminated syringes/solutions – unsafe injection practices
- Contamination of male luer on tubing set
- Thrombotic occlusions and resulting manipulation
- Inadequate flushing of cap and catheter
- Frequency of cap/tubing change
- Multilumen catheters
Intraluminal Contamination

- Approximately 30-60% of ICU central line-associated bloodstream infections appear to be derived from intraluminal contamination – hub colonization.\(^1\)\(^3\)
- This occurs through repeated access and manipulation of the system and/or breaks in technique during which bacteria gain access to the internal lumens of the catheter.
- Mahieu and colleagues studied CLABSI risk factors in neonatal intensive care unit patients and found that hub colonization demonstrated the highest risk for infection (OR=44.4, CI=4.8 to 42.6), much higher than exit site colonization (OR=5.13) and other factors.\(^4\)


Preventing Intraluminal Contamination

May occur through touch contamination (port) from healthcare care worker (HCW) hands or when the access port lies against the skin or contacts a contaminated environmental surface. If the catheter lumen is not protected with a closed system such as a needleless connector with a sealed surface that can be disinfected prior to access, contamination can enter the line.

Critical Surface Contamination is PREVENTABLE

- Disinfection of needleless connector
  - Scrub the NC using friction
  - Use alcohol or alcohol/chlorhexidine as the disinfectant
- Contamination of access port after scrubbing
  - Ensure hands are sanitized before beginning the process
  - Safe injection practices
History of Needleless Connector Design

Needles to Current

Generations of Connector Design

- The split-septum interlink is the oldest and most studied connector, providing the gold standard in clinical outcomes in studies up until about 2007. The 2011 CDC guidelines state that this split septum design may be preferred over some mechanical valves. The split-septum device is not neutral.
- There is a clinically relevant similarity between the old-time needle access and/or split septum design and some existing technology that has proven effective reducing use of needles without creating reflux or contamination.

Did solving one problem create another?
What did FDA Substantial Equivalence indicate for needleless connectors in 1992?

- Initially the FDA used only the feature of needle-free access for substantial equivalence.
- This led to complicated designs which only eliminated needles.
- For substantial equivalence to a needle-access device in 1992, a connector should have had:
  - a simple design
  - an open fluid path
  - a solid sealed access surface
  - a clear housing

What should “Substantial Equivalence?” have included?

- To be substantially equivalent to a needle-access device, a connector should have:
  - a simple design
  - open fluid path
  - solid sealed access surface
  - a clear housing

- Using only the feature of needle-free access for substantial equivalence led to complicated designs which only eliminated needles.

“Substantial Equivalence”

When the FDA granted “substantial equivalence” of needleless connectors to needle access ports, additional features should have been considered:

“We recommend that you provide results from a simulated use test that compares microbial ingress in your device with a similar legally marketed device. Testing should simulate the use of the device in a clinical setting, i.e., the number of microbial challenges in the study should approximate the number of user interactions with the access site that would be expected clinically. The testing should demonstrate that disinfection procedures you use are effective for removing microorganisms from the device.”

(2005 Microbial Ingress Testing Requirement)
2005 FDA recommendations for microbial ingress testing of needleless connectors*:

- Repeat insertions with the same luer
- Static insertion for more than an hour
- Connector inoculations should approximate the number of daily interactions with site
- More than 5 connector inoculations per day
- 10-20 microliters of inoculant
- *Staphylococcus aureus and Staphylococcus epidermidis as inoculants
- Allow inoculant to dry for at least one minute
- Use 70% IPA to disinfect

*Additional recommendations were issued in 2008 by the FDA

Where we are now
Guidelines, Recommendations and Best Practices

Where Do the Guidelines Point Us? Does the evidence support?..
SHEA Compendium

- Stresses the importance of thorough assessment of risks and benefits of devices.
- Also notes the importance of education regarding devices
- Avoid using devices associated with an increased risk of infection

APIC Elimination Guide

- APIC’s CR-BSI Elimination Guide devotes discussion to the conundrum that exists with devices
  - Stresses the importance of disinfection, misuse of the devices, product assessment and evaluation
  - Encourages diligent assessment of the literature to guide decision-making

Studies Cited in the Guideline

Common Theme?

Device deficits are design related
CDC 2011 Guidelines

- 6. When needleless systems are used, a split septum valve may be preferred over some mechanical valves due to increased risk of infection with the mechanical valves [197–200]. Category II

All access devices are not created equal
- Knowing attributes and limitations of the products is critical in making decisions for protocols
- Care practices within the given organization must also be considered
- Same studies cited as in SHEA/IDSA with one exception...

A new observational study of pediatric ICU patients cited by the 2011 CDC Guidelines


Review of Evidence

"For access to the CVLs, we converted our needleless connector system from a luer lock-activated valve system to a device that has a flat access surface and contains a positive displacement valve (MaxPlus needleless connector..."

The 5 Key Design Features of a Needleless Connector

It's about the design

Five Key Design Features

5 key features in choosing a needleless connector:
1. Easy to disinfect
2. Simple design
3. Visible fluid path
4. Open fluid path
5. Anti-reflux

1. Easy to Disinfect

- Disinfection through “scrub the hub” action
- Quickly and easily
- Without crevices or open areas

ULTRASITE® by B. Braun
CLAVE® by Hospira/ICU Medical
MaxPlus® by CareFusion
2. Simple Design

Simple Design
- Minimal Mechanical and Moving Parts
- Minimal internal parts
- No slits, crevices or gaps
- No interstitial or “dead” space
  - Reduces accumulation of blood or fluid that can foster bacterial growth

3. Open Fluid Path

Flow-around designs offer the HCW visual cues that reinforce proper priming, disinfection and flushing of the line that the connector is protecting.

Flow-through designs may have interstitial space that serve as a reservoir for moisture and bacteria to accumulate.

Clinical practice of flushing and maintaining line patency can be enhanced by a flow-around fluid path that the clinician can ensure is visually clear.

4. Visible Fluid Path

Visible Fluid Path
- Clear housing provides complete visualization of the fluid path
  - Reduces the risk of incomplete flushing
  - Helps to confirm that the catheter is clear
  - Reinforces best practice

“The nurse should change the needleless connector in the following circumstances: …if there is blood or debris within the needleless connector…”

- 2011 INS Standards of Practice
5. Practice Neutral

The concern over clamping practice should be eliminated by connector design. The connector should not REQUIRE clamping in order to prevent reflux of blood. No action on the nurses part is needed.

“Positive fluid displacement within the lumen of the catheter should be maintained to prevent reflux of blood upon luer disconnection. This is accomplished with either a flushing technique or a needleless connector designed to overcome blood reflux.”

- 2011 INS Standards of Practice

Aligning Products with Infection Prevention Strategies

Trust the Evidence

- “Perform a thorough assessment of risks, benefits, and education.” SHEA/IDSA
- Consider the hospital’s policies regarding disinfecting the connector, misuse of the connector, and product assessment and evaluation. APIC
- “Implement evidence-based practices to prevent central line-associated bloodstream infections.” NPSG.07.04.01
- “…using study designs… that optimize external validity remain necessary… implement these evidence-based practices so they become part of routine clinical care.” CDC
Objective Review of Connector Design


Implementing a Better Bundle to Achieve and Sustain a Zero Central Line-Associated Bloodstream Infection Rate

Product Checklist

- Does the product have the desired attributes?
- Have we included the right personnel to help make product decisions?
- Does the product align with the needs of the patients in our facility?
- Does practice within the facility align with uses of the product as outlined by the manufacturer?
- Are we gathering data to demonstrate patient outcomes that may be influenced by this device?
- Do we have a plan in place to ensure that supply of the produce is uninterrupted?
### The Question vs. The MaxPlus Answer

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<thead>
<tr>
<th>The Question</th>
<th>The MaxPlus Answer</th>
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<tbody>
<tr>
<td>Is the connector indicated for a 7-day change out?</td>
<td>Yes, per 3-day microbial loop, 10 to 14 days</td>
</tr>
<tr>
<td>Does the sealed surface support CDC and INS disinfection recommendations?</td>
<td>Yes, The MaxPlus® is the only connector designed with a patented flat, sealed access surface with no slits or gaps making disinfection and antiseptic for removal unnecessary. The sealed surface can be inoculated with disinfectants, immersed in disinfectant and all leaves was removed from the MaxPlus with a sterile brush (100% RISIUS)</td>
</tr>
<tr>
<td>Is a disinfecting cap required or recommended to prevent contamination when in use?</td>
<td>No, due to the sealed surface that provides ample contact and allows for removal of bacteria with 3 seconds of motion and no wiping with an alcohol wipe, there is no need to use disinfecting cap to prevent entry of bacteria when not in use or with other surface designs.</td>
</tr>
<tr>
<td>Is “ASPIRATION” specified in the 510(k) indications for use of the needleless access device or does the connector need to be removed for blood draw?</td>
<td>Yes, MaxPlus® is indicated for ASPIRATION (510k K072532) and therefore reduces risk of potential contamination that may occur when opening the line.</td>
</tr>
<tr>
<td>If the connector is clear, does it flush clear visually when flushed before the catheter is clear of blood?</td>
<td>No, as the design of the connector maintains the clarity of the catheter; there is no back pressure when the catheter is clear of blood.</td>
</tr>
<tr>
<td>Is there a flushing and/or clamping sequence required or recommended upon disconnection from the connector to reduce risk of occlusions?</td>
<td>MaxPlus® does not require clamping or positive pressure flush technique to prevent reflux of blood following final flush. Because the connector design promotes proper flushing, the heparin lock solution is not required.</td>
</tr>
<tr>
<td>Does the design of the connector maintain the sterility of a male luer, or is there any dry or empty space in the connector area that may harbor bacteria?</td>
<td>Yes, the MaxPlus® will maintain a sterile luer, there are no dry or empty spaces where bacteria may harbor. The company has also been FDA approved FDA 510K, cleared 510K072532 to insure that the MaxPlus® meets the Microbiological Recommendations outlined by the FDA in their 2005 guidelines.</td>
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### Design not category affects practice

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<td>It may be Simpler than it Seems</td>
<td>Does the connector meet ALL expectations set by the FDA and CDC for actual use in the hospital setting?</td>
</tr>
<tr>
<td>Does the connector meet ALL the features that thought leaders have called out as necessary for clinicians to achieve the best clinical outcomes on Peripheral lines and Central lines?</td>
<td>You decide...</td>
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Thank you