Turning Technology-Related Evidence into Optimal Protocols for Line Maintenance

Michele Biscossi, MS, ACNP-BC, RN, CNL, VA-BC

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Michele Biscossi is a paid consultant for BD.
Objectives

1. Discuss the impact of needleless connector design on documented risk of contamination, complications and cost.

2. Describe optimal design features identified in both in-vitro and in-vivo studies.

3. Discuss integration of recently reported, evidence-based data into design-specific needleless connector protocols.
Sometimes we just need to change our perspective...
• All provide an access point
• Designs evolved to improve:
  • Safety
  • Effectiveness
  • Efficiencies
• All have varying degrees of risk and benefits associated with protocols for use in various clinical settings
## Evolution of Needleless Technology

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| Healthcare Worker Protection | Patient Protection |

- Healthcare Worker Protection
- Patient Protection
Risk of infection from contaminated sharp?¹
  - Hepatitis B – 1 in 5  (if you’re not vaccinated)
  - Hepatitis C – 1 in 50
  - HIV – 1 in 300

$51 to $3,766- average cost per exposure to the healthcare institution²

$71- $4,838- 2004 study of 4 facilities showed a range of cost of exposure management³

$1 Million or more- costs related to lost work time/disability payments due to serious infection⁴

Intangible Costs of Exposure
  - Emotional Distress
  - Physical Distress
  - Family Impact
  - Co-Worker Impact

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3. infection Control, May 2004
5. American Hospital Association “Pugliese & Salahuddin” 1999

NOTES: CI = 95% confidence interval. The Standardized Infection Ratio compares the observed number of HAI cases during a reporting period with the 2006-08 baseline number of HAI cases.

SOURCE: National Healthcare Safety Network (NHSN), CDC/NCEZID.
Now we understand the **Critical Features**:

**ACCESS SURFACE is solid and sealed**
- Could be effectively disinfected
- No crevices, slits, holes or gaps that can trap or allow contaminants to penetrate the connector

**INTERNAL DESIGN is simple**
- No internal cannulas or complex mechanisms
- **No** empty space within the fluid path **OR** the housing
  - This empty space is at risk for contamination, yet cannot be disinfected or flushed.
These critical features were not recognized and luer designs eliminated them, replacing with:

- **Access surface with splits, slits, gaps, crevices and holes** – non-solid surfaces through which contamination can penetrate
  - *Internal cannula, springs and sleeves created extra space outside the fluid path*
  - *Internal mechanism was concealed*
Total Confusion!

External vs internal cannula?

Mechanical valve

Changes in technique

"Slit" septum vs. Split septum

Interstitial space

Catheter Infections

Flush-ability

Neutral

Positive

Negative

Catheter Occlusions

Residual volumes

Swab-ability

reflux

FDA Tells Makers of Positive-Displacement Needleless Connectors to Study Infection Risk

Robert Lowes
July 30, 2010

Needleless Connectors and Bacteremia: Is There a Relationship?

November 1, 2005

Abstract

Needleless connectors, used today as integral components of an infusion system, evolved in response to demands for enhanced healthcare worker safety and as part of the continuing development of infusion technology. At this time, there are three design categories among needleless connectors: split septum connectors, luer activated valves, and luer valves with positive displacement. Numerous branded products are available in each category. Although needleless connectors offer enhanced safety features, there have been recent concerns about an increased risk of bacteremia associated with their use. This article reviews the development of these devices, examines the available evidence base, identifies unresolved issues, and suggests strategies to facilitate optimum use of needleless connectors within infusion systems.
"The internal mechanism of the valve contains moving parts which introduces irregularities in the fluid flow and may promote stagnation and create potential reservoirs for microbial growth."²

"difficulty in sterilizing the gap between the valve and the hub"³

"intricate access surfaces that are more difficult to disinfect"⁴

"mechanical valve could be more difficult to disinfect because of the complicated nature of the multi-part device"⁵

There is More than Meets the Eye

It’s what’s under the surface that can do the most damage
Needleless Intravascular Catheter Systems

Recommendations

1. Change the needleless components at least as frequently as the administration set. There is no benefit to changing these more frequently than every 72 hours. [39, 187–193]. Category II

2. Change needleless connectors no more frequently than every 72 hours or according to manufacturers’ recommendations. Category II

Which recommendation do you follow?

Refer to device manufacturers’ recommendations for use
F. Perform a vigorous mechanical scrub for manual disinfection of the needleless connector prior to each VAD access and allow it to dry.

1. Acceptable disinfecting agents include 70% isopropyl alcohol, iodophors (ie, povidone-iodine), or > 0.5% chlorhexidine in alcohol solution. 7,16 (II)

2. **Length of contact time for scrubbing and drying depends on the design of the needleless connector** and the properties of the disinfecting agent.

For 70% isopropyl alcohol, **reported scrub times range from 5 to 60 seconds** with biocide activity occurring when the solution is wet and immediately after drying. 3,17,18 (II)

3. Use vigorous mechanical scrubbing methods even when disinfecting needleless connectors with antimicrobial properties (eg, silver coatings). 19-24 (IV)
Change the needleless connector no more frequently than 96-hour intervals. Changing on a more frequent time interval adds no benefit and has been shown to increase the risk of CLABSI.

1. When used within a continuous infusion system, the needleless connector is changed when the primary administration set is changed (eg, 96 hours).

3. Additionally, the needleless connector should be changed in the following circumstances: if the needleless connector is removed for any reason; if there is residual blood or debris within the needleless connector; prior to drawing a sample for blood culture from the VAD; upon contamination; per organizational policies, procedures, and/or practice guidelines; or **per the manufacturer’s directions for use** (see Standard 49, Infection ). 7,34,35 (IV)
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**Healthcare Worker Protection** | **Patient Protection**
Manufacturers' Evidence

Under the Microscope
Strength of Evidence

- Randomized Controlled Double Blind Studies
- Systematic Reviews and Meta-analyses
- Cohort Studies
- Case Control Studies
- Case Series
- Case Reports
- Ideas, Editorials, Opinions
- Animal research
- In vitro ("test tube") research

Started Here

Finished Here
Study Purpose:
Identify any differences between the rates of microbial ingress into different devices following contamination.

- Tested 5 second and 15 second disinfection protocols.
- 7-day clinical simulation = repeated microbial contamination of access surface and disinfection followed by saline flushes.
- Plus blood aspiration through the devices, mimicking blood discard and sampling, commonly carried out in clinical practice.
Interesting Conclusions

• The MaxPlus was associated with ingress of significantly fewer microorganisms compared with the other devices tested.

• Significantly fewer CFU were recovered from needleless IV access devices with relatively large priming volumes, such as MaxPlus, than those with small priming volumes.

• The MaxPlus was associated with significantly fewer contaminated administration set male luers than the other devices tested, which supports the conjecture that the injection site design may protect the male luer sterility.
**Two Critical Features**

**ACCESS SURFACE** is **solid and sealed**
- Can be effectively disinfected
- No crevices, slits, holes or gaps that can allow contaminants to penetrate the connector

**INTERNAL DESIGN** is **simple**
- No internal cannula or complex mechanism creating empty space in the connector outside the fluid pathway, where contamination can become trapped and cannot be flushed or disinfected.

This In-vitro study demonstrated the importance of these features for effective decontamination, 5 and 15 seconds were equally effective in reducing contamination on the MaxPlus.

This study also reported 5 and 15 second disinfection times were ineffective in reducing contamination of some other designs.
Sources searched for studies:

- MEDLINE
- ClinicalTrials.gov
- Embase
- Cochrane Database
- Studies using the positive-displacement study NC compared with negative- or neutral-displacement NCs were analyzed.
Seven studies met the inclusion criteria:

- 4 were conducted in intensive care units
  - One Pediatric Cardiac ICU
  - One Neonatal ICU
  - Two Medical ICU
- 1 in a home health setting
- 2 in long-term acute care settings.
A Needleless Connector with improved engineering design that facilitates effective IV line care is associated with lower risk of bacterial contamination.

Many NCs have become complex in design. The complexities might have made some NCs harder to disinfect, flush completely, or use correctly, all of which could contribute to the risk of complications.
In order to satisfy an FDA post-market surveillance request, CareFusion undertook the largest analysis known to-date for needleless connectors.

Used 2013 Center for Medicare and Medicaid Services Hospital Compare data

- 3,074 hospitals
- Nearly 11,000 recorded events
- Nearly 10 million catheter days
- Merged with Manufacturer’s client database
The advantages of using publicly reported outcome data such as used in this study include:

1) There is no sampling bias, because all eligible hospitals are included

2) There is no potential conflict of interest compared to data collected by manufacturers themselves

3) It is most current with minimal time lag

4) The comparison is concurrent, which eliminates potential bias inherent to pre-post period study designs.
CareFusion submitted data from the Meta-Analysis article (Jarvis et al) and the CMS Data Analysis to the FDA in response to a request for Post Market Surveillance.

Based on this data, the FDA provided input to CareFusion. CareFusion added the following statement to the MaxPlus DFU:

2013 CMS Hospital Compare data from 3,074 hospitals, accounting for nearly 11,000 CLABSIs associated with nearly 10 million catheter days show that hospitals using CareFusion MaxPlus needleless connector had lower unadjusted CLABSI rates, as well as lower standardized infection ratios, compared to hospitals not using MaxPlus needleless connector.

MaxPlus is a registered trademark of CareFusion Corporation or one of its subsidiaries. All other trademarks are the property of their respective owners.
MaxPlus® needleless connector

Manufactured for
CareFusion
Switzerland 317 Sàrl
CH-1180 Rolle

Distributed by
CareFusion
San Diego, CA USA
1.800.854.7128

STERILE

INDICATIONS FOR USE:
The MaxPlus is a sterile, single patient use, positive displacement connector for needleless access to the IV line and/or IV catheter during IV therapy. The MaxPlus connector can be used for direct injection, intermittent infusion, continuous infusion or aspiration.

Description:
The MaxPlus needleless connector is a closed luer activated device. The accessing ISO male luer from standard administration sets, extension sets, and syringes activate the flow of fluid through the device. The MaxPlus features Tru-Swab® technology which provides a flat, smooth surface for optimum disinfection during pre-access swabbing. The positive displacement feature of the MaxPlus product produces a positive bolus of fluid to clear the catheter upon disconnection of the male luer.

2013 CMS Hospital Compare data from 3,074 hospitals, accounting for nearly 11,000 CLABSI is associated with nearly 10 million catheter days show that hospitals using CareFusion MaxPlus needleless connector had lower unadjusted CLABSI rates, as well as lower standardized infection ratios, compared to hospitals not using MaxPlus needleless connector.
This is the future for medical devices.
Lessons Learned
There’s more than meets the eye ...

What should we be evaluating with needleless connectors?

What should we be looking at?

Access Surface

Internal Design
OPPORTUNITIES TO IMPROVE DISINFECTION & PATIENT CARE

Features to improve disinfecting & flushing techniques:

- Solid access surface
- Sealed between access surface and housing
- Completely fluid filled design with a one piece internal mechanism (no internal cannula or complicated design)

GUILDLINES

The Food and Drug Administration (FDA) has regulatory authority over the marketing of needleless connectors. The requirements for marketing have changed over time. In 2001, the FDA recognized that there is a minimal risk with needleless connections. The guidelines released that year said, “The testing should demonstrate that the device does not cause any infection.” However, in 2008, the guidelines changed and became less clear, stating, “The testing should demonstrate that the device does not cause any serious infection.” Unfortunately, the requirements were not clarified, leaving the field to develop on its own. The result was several different needleless connectors, each with different performance characteristics. It is important that the healthcare professional develop and adhere to the manufacturer’s recommended disinfection protocols for their needleless connectors and use a sterile cannula on the male luer connector of the needleless connector attached to the intravenous catheter to help reduce the risk of contamination. The difference in performance of each connector indicates that the specific connector should be used in its application to help reduce the risk of contamination. Each connector should be used in its application to help reduce the risk of contamination.
Great Two Bedroom Home

- Quiet neighborhood
- Attached garage
- Close to Shopping
- Beautiful view of the river

- Canoe Optional!!!!!!
Needleless Connectors

Preventing complications and contamination, and reducing costs

A thorough evaluation requires a look at the Whole Picture
Design Determines Protocol

Interstitial Space
Design determines protocol

Slits, Crevices, and Spaces
Design determines protocol

- Simple, fluid filled designs eliminate area outside the fluid path that can trap contamination, which can then be transferred to the luer and subsequently the fluid path.

- The steps to contamination in Complex Designs:
  1. Internal space outside fluid path traps contamination
  2. Contamination is passed to the male luer during access
  3. Repeated access passes contamination to the fluid path
Design determines protocol

- Multiple actuations
  - How many times can the device be accessed?

- Disinfection
  - Cleaning the injection surface to remove contamination and prevent contaminants from being pushed into internal space

- Fluid filled or internal space
  - Are there areas that are not part of the fluid path within the device that can trap contamination?

Split Top and interstitial space leads to contamination
The FDA recommends that manufacturer’s conduct microbial ingress testing of needleless connector devices. The testing is intended to simulate repeated access.

Manufacturer’s support dwell time recommendations with simulated clinical use testing which must demonstrate effective disinfection over multiple days of testing with multiple inoculations and multiple accesses.
### TESTING PROCEDURE

| Round 1 Blood Aspiration | Inoculate, allow to dry 30 minutes
|                         | Disinfect 3 seconds, allow to dry 30 seconds
|                         | Activation: flush each device with a new 10 mL saline flush syringe
|                         | Aspiration: Draw 5 mL of 10% (v/v) bovine blood through each device using the empty syringe by drawing the plunger back. Push the aspirated blood to waste. Repeat
|                         | Disinfect
|                         | Activation: flush each device with a new 10 mL saline syringe to waste

| Round 2, 3, 4 Simulated IV Therapy | Inoculate, allow to dry 30 minutes
|                                  | Disinfect 3 seconds, allow to dry 30 seconds
|                                  | Activation: flush each device with a new 10 mL saline flush syringe

| Round 5 Simulated Intermittent Therapy | Inoculate, allow to dry 3 minutes
|                                   | Disinfect 3 seconds, allow to dry 30 seconds
|                                   | Prolonged activation: connect a sterile 10 mL saline syringe to each device and flush approximately 8 mL from flush syringe and leave syringe attached to test device for one hour, then flush remaining 2 mL saline
|                                   | With same syringe, repeatedly access test device without fully disconnecting luer 12 times

| Eight Day Simulated Use | Repeal rounds 1 through 5 once every 24 hours over eight (8) days
|                         | Final eluate flirtation is repeated at end of each day for each test device
Long Term Use: Extended Microbial Challenge Test

Test completed at independent third party laboratory, LGGS. Simulated clinical use included blood draw, 25 accesses per day over 8 days, 5 inoculations per day with a 3 second disinfection protocol.
The ability to use a connector for an extended period to maintain a closed line varies depending on internal design and access surface design. The time is determined by microbial ingress testing following FDA Guidelines.

**Simple designs with solid sealed access surface**
- Solid sealed access surface can be easily and quickly disinfected, allowing little or no bacteria to enter the connector
- Evidence supports 7 day change out

**Complex designs with splits, slits, crevices and internal cannula or other mechanisms**
- Evidence demonstrates ineffective disinfection and areas inside connector that can trap contamination
- Evidence does not support 7 day change out
3-5 Second Disinfection

- Connector design has a solid, sealed access surface which can be effectively disinfected.
- Connector design is simple and all internal space is actively part of the fluid path.
- Manufacturer’s testing demonstrates 3-5 second disinfection is effective and is not diminished over several days of use.
- What does peer reviewed published data demonstrate?

Is disinfection effective?

- Connector design has a split, slit or crevice in the access surface which does not support effective disinfection.
- Connector design permits contamination to fall into interior space created by complex design and the spaces cannot be flushed or disinfected.
- What does manufacturer’s data demonstrate?
- What does peer reviewed published data demonstrate?
**Design determines protocol**

### Disinfecting Caps

**No cap needed if:**
- Connector design has a solid, sealed access surface which can be effectively disinfected.
- Connector design is simple and all internal space is actively part of the fluid path.
- Testing demonstrates effective disinfection in 3 to 5 seconds over extended 7-8 day testing.

**Cap is needed if:**
- Connector design has a split, slit or crevice in access surface which does not support effective disinfection.
- Connector design permits contamination to fall into interior space created by complex design and the spaces cannot be flushed or disinfected.
- Testing demonstrates ineffective disinfection, effectiveness diminishes over several day testing.
Is the connector INDICATED for aspiration of blood?

How is this determined?

- Review the Indications for use (IFU) of specific needleless connector on FDA website

Using a connector that is indicated for aspiration protects the catheter hub, reducing change outs and blood exposure
Design determines protocol

Disinfection Practice

- Unresolved issue for developing one guideline
- Individual design of each connector dictates different practices
- Time required? Can the connector be disinfected?
- Method required? An alcohol swab or cap?
- Solution required? Alcohol alone or CHG?

Why does design matter?

- Quality of the surface seal
- Complex internal mechanism eliminates a solid sealed access surface
Unresolved practice issues are caused by different connector designs

- One practice cannot be applied to all connector designs

Some practices are “Design Specific”

- It depends on the connector being used
- Design specific practice should be established by the Manufacturer in the devices’ Instructions for Use
Connector Change Intervals

- Should the Needleless Connector be considered part of the line ...?
- Or the part of the administrations set?

Important Practice Questions:

- Is the connector indicated for blood aspiration?
- Can bacteria be effectively removed via friction and scrubbing with a solution?
- Does the manufacture recommend covering the connector when showering, or changing when contaminated? How does that affect your practice? How does that affect healthcare $$’s
1. What is the impact of needleless connector design on performance outcomes in your clinical practice?
2. What steps have you taken to mitigate performance risks associated with needleless connectors?
3. How will you integrate a device risk reduction strategy into your catheter care protocols?
4. What is the best pathway to integrate technology solutions into your best clinical practices?
Questions