Needleless Intravenous Systems

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Purpose

• Provide a historical review of needleless connectors;
• Discuss current guideline recommendations for needleless intravenous systems;
• Prioritize needleless IV systems features that impact potential risk for central line-associated bloodstream infections (CLA-BSIs) and catheter occlusion; and
• Review recent clinical evidence comparing microbial ingress across several different brands of needleless connectors.
The Needlestick Injury (NSI) Problem

• ~385,000 sharps injuries annually among hospital-based healthcare personnel (>1,000 injuries/day)
  – Many more in other healthcare settings (e.g., emergency services, home care, nursing homes)

• Increased risk for bloodborne virus transmission

• Costly to personnel and healthcare system

It takes a team to eliminate sharps injuries...
Devices that Require Manipulation after Use are Associated with an Increased Rate of Injury


It takes a team to eliminate sharps injuries...
Bloodborne Pathogens Standard

29 CFR 1910.1030, Occupational Exposure to Bloodborne Pathogens

Published December 1991

Effective March 1992

Scope

- ALL occupational exposure to blood and other potentially infectious material (OPIM)
Bloodborne Pathogens Standard

Major Provisions by Paragraph
(b) Definitions
(c) Exposure Control Plan (ECP)
(d) Engineering and Work Practice Controls
   - Personal Protective Equipment (PPE)
(e) HIV and HBV Research Labs
(f) Vaccination, Post-Exposure Follow-up
(g) Labeling and Training
(h) Recordkeeping
Needlestick Safety and Prevention Act, P.L. 106-430
The Needlestick Safety and Prevention Act mandated that...

the Occupational Safety and Health Administration (OSHA) clarify and revise

29 CFR 1910.1030, the Bloodborne Pathogens Standard

The ECP must be updated to include:

- changes in technology that reduce/eliminate exposure
- annual documentation of consideration and implementation of safer medical devices
- solicitation of input from non-managerial employees
Solicitation of Non-Managerial Employees
New Provision

- Identification, evaluation, and selection of engineering controls
- Must select employees that are:
  - Responsible for direct patient care
  - Representative sample of those with potential exposure
Engineering and Work Practice Controls: 1910.1030(d)

Employers must select and implement appropriate engineering controls to reduce or eliminate employee exposure.
“Where engineering controls will reduce employee exposure either by removing, eliminating, or isolating the hazard, they must be used.”

CPL 02-02-069
First Strategy:

Eliminate or Reduce Unnecessary Needle Use

*It takes a team to eliminate sharps injuries...*
How Can Needle Use Be Eliminated or Reduced?

- **Use needle-free IV delivery systems**
- Use alternate routes for medication delivery and specimen collection when available and safe for patient care
- Streamline specimen collection systems
- Other ideas?

*It takes a team to eliminate sharps injuries...*
Needle-Free IV Delivery Systems

IV delivery systems use valved ports and connectors, pre-pierced septa using blunt cannulas, or recessed protected needle connectors.
Preventing Sharps Injuries is a National Priority!

• Federal and state laws increase enforcement of sharps injury prevention
  – Needlestick Safety and Prevention Act, 2000
  – OSHA enforcement of needlestick prevention increasing
  – 21 states with laws/regulations
• CDC: targets needlesticks for elimination
• BUT---major focus is on prevention of healthcare worker needlestick injuries NOT reduced risk of central line-associated bloodstream infections (CLA-BSIs) in patients!

It takes a team to eliminate sharps injuries...
## Bloodstream Infection Rates by Type of Intravascular Catheter

<table>
<thead>
<tr>
<th>Type of catheter</th>
<th>Per 100 catheters</th>
<th>Per 1000 catheter days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>95% CI</td>
</tr>
<tr>
<td>Peripheral IV</td>
<td>0.2</td>
<td>0.1 – 0.3</td>
</tr>
<tr>
<td>Arterial</td>
<td>1.5</td>
<td>0.9 – 2.4</td>
</tr>
<tr>
<td>Short-term CVC</td>
<td>3.3</td>
<td>3.3 – 4.0</td>
</tr>
<tr>
<td>Pulmonary artery</td>
<td>1.9</td>
<td>1.1 – 2.5</td>
</tr>
<tr>
<td>Hemodialysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Noncuffed</td>
<td>16.2</td>
<td>13.5 – 18.3</td>
</tr>
<tr>
<td>Cuffed</td>
<td>6.3</td>
<td>4.2 – 9.2</td>
</tr>
<tr>
<td>PICC</td>
<td>1.2</td>
<td>0.5 – 2.2</td>
</tr>
<tr>
<td>Long-term CVC</td>
<td>20.9</td>
<td>18.2 – 21.9</td>
</tr>
<tr>
<td>Implanted port</td>
<td>5.1</td>
<td>4.0 – 6.3</td>
</tr>
</tbody>
</table>

Impact of Primary BSI

**Crude mortality**
10% to 40%

**Attributable mortality**
2% to 15%

**Prolongation of hospitalization**
5 to 20 days

**Attributable cost**
$34,000 to $56,000

Factors That Influence Central Line Associated Bloodstream Infection Rates

• Types of patients with catheters (medical, surgical, neonatal, pediatric, etc.)
• Type, number, location of insertion, site of insertion, and duration of catheters (impregnated or not, number of lumens), etc.
• Types of connectors (needleless—split septum vs. mechanical valve, stopcocks, etc.)
• What is infused through the catheter
• Who inserts/manipulates the catheter (IV team or not)
• Method of documenting BSI (central line cultures—number of lumens and number of catheters cultured, only peripheral culture, etc.)
• Interpretation and application of the CDC Definitions and protocols
• Infection control practices, etc.
Extraluminal biofilm is the major source of CRBSI within the first week of catheterization in short-term catheters.
Extraluminal biofilm is the major source of tunnel infections in long-term catheters.

Intraluminal biofilm is the major source of CRBSI after 1 week in both short- and long-term catheters.

So, Needleless connectors were designed and initially introduced to reduce the risk of healthcare worker needlestick injury, not to protect patients.
First Introduced Needleless Connector (1990s)


• Risk factors for bloodstream infection: needleless connector, receipt of parenteral nutrition/lipid emulsion, frequency of end-cap change.
Although Devices are Easy to Use, There are Many Opportunities for User Error!

**The Clinician May Not:**

- Disinfect the surface
- Flush completely, correctly or per protocol
- Clamp the extension set correctly
- Replace the device per protocol

The frequency of user error is unknown.
CVC-BSI Outbreaks Associated with Mechanical Valve Needleless Connectors
Increased BSI Rate Temporally Associated With Switching From A Split Septum to Mechanical Valve Needleless Device in a Long-Term Acute Care Hospital

- **Study location**: 40 bed long-term acute care hospital.
- **Split septum (SS) period**: January 2002-December 2003 (Interlink).
- **Mechanical valve (MV) period**: January 2004-October 2005 (SmartSite).

<table>
<thead>
<tr>
<th></th>
<th>SS Period</th>
<th>MV Period</th>
<th>RR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BSI Rate*</td>
<td>1.79</td>
<td>5.41</td>
<td>3.02</td>
<td>2.62-3.39</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>GNB-BSIs</td>
<td>8%</td>
<td>39.5%</td>
<td>4.93</td>
<td>1.27-19.19</td>
<td>.0006</td>
</tr>
</tbody>
</table>

*BSI rate per 1,000 catheter days; BSI rate has decreased since returning to a split septum needleless device. Salgado C et al. ICHE 2007;28:684-8.
Increase in BSIs Temporally Associated with Switching From A Split Septum to a Positive Displacement Needleless Valve Device

- **Study location**: Academic medical center
- **Split septum (SS) period**: January 2003-February 2005 (Interlink/Q-Syte)
- **Positive displacement needleless valve (PDV) period**: March-August 2005 (SmartSite Plus)

<table>
<thead>
<tr>
<th>Unit</th>
<th>BSI</th>
<th>Rate*</th>
<th>P-value</th>
<th>Post-PDV SS Period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SS Period</td>
<td>PDV Period</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Critical Care/Transplant</td>
<td>3.87</td>
<td>10.43</td>
<td>&lt;.0001</td>
<td>7.62</td>
</tr>
<tr>
<td>9 other inpatient</td>
<td>3.47</td>
<td>7.51</td>
<td>&lt;.0001</td>
<td>2.36</td>
</tr>
<tr>
<td>Cooperative care (OPD TX)</td>
<td>5.80</td>
<td>15.18</td>
<td>.0005</td>
<td>4.30</td>
</tr>
</tbody>
</table>

*BSI Rate per 1,000 CVC-days

Rupp M et al. CID 2007;44:1408-14
Increased CVC-BSIs Temporally Associated with a Change From a Mechanical Valve to a Positive Pressure Mechanical Valve

• Johns Hopkins Hospital (JHH) used a mechanical valve without positive pressure (CLAVE, ICU Medical) for 10 years institution-wide.

• To reduce the use of heparin flushes in CVCs, JHH changed to the use of a positive pressure mechanical valve, SmartSite (Alaris). This new device was implemented in all units from April to December 2004.

• Active catheter-related bloodstream infection (CR-BSI) surveillance was conducted in all ICUs.

• An aggressive, multi-faceted program to lower CR-BSI was conducted in all ICUs.

• No changes in IV policies. Both mechanical valves and IV administration sets were changed every 96 hours. 70% alcohol was used for device disinfection. With their initial mechanical valve, the line was clamped before syringe disconnection. Whereas, the positive pressure mechanical valve was clamped after the syringe was disconnected.

## Comparison of BSI Rates During Mechanical Valve (MV) and Positive Pressure Mechanical Valve (PPMV) Periods, JHH

<table>
<thead>
<tr>
<th>Location</th>
<th>BSI Rate MV Period</th>
<th>Rate* PPMV Period</th>
<th>IRR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All ICUs</td>
<td>1.50</td>
<td>2.40</td>
<td>1.6</td>
<td>1.04-2.48</td>
<td>.05</td>
</tr>
<tr>
<td>Children’s Center</td>
<td>1.55</td>
<td>2.79</td>
<td>1.79</td>
<td>1.1-2.9</td>
<td>.01</td>
</tr>
<tr>
<td>--PICU</td>
<td>5.4</td>
<td>17.3</td>
<td>3.22</td>
<td>1.1-9.6</td>
<td>.02</td>
</tr>
<tr>
<td>--NICU</td>
<td>0.51</td>
<td>1.34</td>
<td>2.63</td>
<td>0.52-12.2</td>
<td>.17</td>
</tr>
<tr>
<td>--Ped Onc</td>
<td>2.61</td>
<td>4.71</td>
<td>1.81</td>
<td>0.64-4.9</td>
<td>.21</td>
</tr>
</tbody>
</table>

*Rate per 1,000 catheter-days; PPMV=Positive Pressure MV

Nosocomial Catheter-Related BSI Rates, Pediatric Intensive Care Unit, Johns Hopkins Medical Center, 2003 – 2004

**Q4 only thru PPMV removal date**

RR=3.22, p=0.02

Quarter/Year

*Q4 only thru PPMV removal date*
Health Care–Associated Bloodstream Infections Associated with Negative- or Positive-Pressure or Displacement Mechanical Valve Needleless Connectors

William R. Jarvis, Cathryn Murphy, Kerri K. Hall, Pamela J. Fogle, Tobi B. Karchner, Glenda Harrington, Cassandra Salgado, Eve T. Giannetti, Carol Cameron, and Robert J. Sherertz

In Australia, we conducted point-prevalence surveillance using clinical criteria for disease control and prevention definitions for both ICUs. The HV-BSI rates and prevention practices were compared during the pre-MV period, MV period, and post-MV period.

Results. The HV-BSI rate increased in all ICUs, seven years when SS-NCs were replaced by MV-NCs. In the 16 ICUs, the HV-BSI rate increased significantly when SS-NCs or needles were replaced by MV-NCs (6.15 vs 9.39 BSIs per 1000 central venous catheter [CVC] days; relative risk, 1.54; 95% confidence interval, 1.37–1.74; P < .001). The 14 ICUs that switched back to SS-NCs had significant reductions in their HV-BSI rates (9.49 vs 5.77 BSIs per 1000 CVC days; relative risk, 1.65; 95% confidence interval, 1.38–1.96; P < .001). HVBSI infection prevention strategies were similar in the pre-MV and MV periods.

Conclusions. We found strong evidence that MV-NCs were associated with increased HV-BSI rates, despite similar HV surveillance definitions and prevention strategies. Hospital personnel should monitor their HV-BSI rates and, if they are elevated, examine the role of newer technologies, such as MV-NCs.
### Table 1. Participant Bloodstream Infection Prevention Strategies

<table>
<thead>
<tr>
<th></th>
<th>Antibiotic/antiseptic impregnated catheters</th>
<th>Catheter securement device</th>
<th>Vancomycin prophylaxis</th>
<th>Use of stopcocks in IV line</th>
<th>Blood draws through NC</th>
<th>NC disinfectant</th>
<th>SS period: use of maximum barrier precautions</th>
<th>SS period skin antiseptic for CVC placement</th>
<th>MV period: use of maximum barrier precautions</th>
<th>MV period: skin antiseptic for CVC placement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Yes*</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>ETOH</td>
<td>Yes</td>
<td>ETOH/PI</td>
<td>Yes</td>
</tr>
<tr>
<td>B</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>ETOH</td>
<td>No</td>
<td>ETOH/PI</td>
<td>Yes</td>
</tr>
<tr>
<td>C</td>
<td>No</td>
<td>No/Yes*</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>ETOH</td>
<td>Yes</td>
<td>CHG/ETOH</td>
<td>Yes</td>
</tr>
<tr>
<td>D</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>ETOH</td>
<td>Yes</td>
<td>CHG/ETOH</td>
<td>Yes</td>
</tr>
<tr>
<td>E</td>
<td>No</td>
<td>SS period, no; MV period, yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>ETOH</td>
<td>Yes*</td>
<td>CHG/ETOH</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**NOTE.** CHG, chlorhexidine gluconate; ETOH, alcohol; IV, intravenous; MV, mechanical valve; NC, needleless connector; PI, povidone iodine; SS, split septum.

* On wards but not in the intensive care unit for peripheral catheters, but not central venous catheters.

* Some antiseptic-impregnated catheters used on the basis of patient risk.

* Yes, except uses drape covering half the body.
Table 2. Participants Split Septum (SS) and Mechanical Valve (MV) Needleless Connectors and Use Periods.

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Country</th>
<th>SS/needle used</th>
<th>Duration SS use, months</th>
<th>MV used</th>
<th>Duration of MV use, months</th>
<th>Post-MV device used</th>
<th>Duration post-MV period, months</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>United States</td>
<td>Interlink</td>
<td>18</td>
<td>UltraSite</td>
<td>39</td>
<td>Q-Syte</td>
<td>8</td>
</tr>
<tr>
<td>B</td>
<td>United States</td>
<td>Interlink</td>
<td>24</td>
<td>Clearlink</td>
<td>21</td>
<td>Interlink</td>
<td>5</td>
</tr>
<tr>
<td>C</td>
<td>United States</td>
<td>Interlink</td>
<td>18</td>
<td>Clearlink</td>
<td>11</td>
<td>Interlink</td>
<td>18</td>
</tr>
<tr>
<td>D</td>
<td>Australia</td>
<td>Interlink</td>
<td>12</td>
<td>SmartSite</td>
<td>12</td>
<td>Not available</td>
<td>Not available</td>
</tr>
<tr>
<td>E</td>
<td>Australia</td>
<td>Needles</td>
<td>6</td>
<td>SmartSite</td>
<td>11</td>
<td>Not available</td>
<td>Not available</td>
</tr>
</tbody>
</table>
## Results

### Table 3. Participating Hospital Bloodstream Infection (BSI) Rates during Split Septum (SS) and Mechanical Valve (MV) Needleless Device Use Period.

<table>
<thead>
<tr>
<th>Hospital, unit/ward</th>
<th>SS BSI rate[^a]</th>
<th>MV BSI rate</th>
<th>Relative risk (95%CI)</th>
<th>P</th>
<th>Post-MV-BSI rate</th>
<th>Relative risk (95%CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>A: Adult ICUs (n = 4)</td>
<td>8.47</td>
<td>9.84</td>
<td>1.16 (0.94–1.44)</td>
<td>.16</td>
<td>6.10</td>
<td>1.61 (1.18–2.22)</td>
<td>.003</td>
</tr>
<tr>
<td>B: Adult ICUs (n = 6)</td>
<td>3.09</td>
<td>8.82</td>
<td>2.85 (2.15–3.65)</td>
<td>&lt;.001</td>
<td>5.29</td>
<td>1.87 (1.12–2.48)</td>
<td>.008</td>
</tr>
<tr>
<td>C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adult wards</td>
<td>2.46</td>
<td>3.41</td>
<td>1.36 (0.98–1.93)</td>
<td>.05</td>
<td>2.29</td>
<td>1.49 (1.04–2.11)</td>
<td>.02</td>
</tr>
<tr>
<td>Adult ICUs (n = 4)</td>
<td>3.15</td>
<td>3.47</td>
<td>1.10 (0.67–1.46)</td>
<td>.67</td>
<td>2.89</td>
<td>1.20 (0.74–1.95)</td>
<td>.43</td>
</tr>
<tr>
<td>D</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adult ICU</td>
<td>0</td>
<td>4.30</td>
<td>NC (0.03–999)</td>
<td>.60</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adult oncology ward</td>
<td>2.70</td>
<td>6.20</td>
<td>2.30 (2.09–2.71)</td>
<td>.04</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E: Adult ICU</td>
<td>6.80</td>
<td>11.8</td>
<td>1.79 (1.24–2.56)</td>
<td>&lt;.001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A–E: Adult ICUs (n = 16)</td>
<td>6.15</td>
<td>9.49</td>
<td>1.54 (1.37–1.74)</td>
<td>&lt;.001</td>
<td>5.77[^b]</td>
<td>1.85 (1.38–1.96)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

**NOTE.** CI, confidence interval; ICU, intensive care unit; NC, not calculated.

[^a]: Rates are based on health care-associated BSIs per 1000 central venous catheter-days for all except hospital C, which used 1000 patient-days for the adult ward health care-associated BSI rate that includes the entire hospital.

[^b]: Includes 3 hospitals with 14 adult ICUs. Post-MV rate includes the health care-associated BSI rate only in facilities changing from MV needleless connectors to SS needleless connectors.

Highly significant increase when 16 ICUs introduced MVs.

Highly significant reduction when 14 ICUs MVs were discontinued and SS reintroduced.
Safeguarding public health
MEDICAL DEVICE ALERT

Issued: 18 March 2008 at 12:00 (Ref: MDA/2008/016; http://www.mhra.gov.uk)
Medicines and Healthcare products Regulatory Agency

- **Immediate action:** Information request
- **Device:** Needle-free intravascular connectors. All brands.
- **Problem:** There is a risk of infection if the top/septum of the connector remains recessed within its housing. Swabbing of the connector in this condition may lead to inadequate decontamination.
- **Action by:** All medical and nursing staff, particularly infection control nurses and IV specialist nurses.
- **Action:** • Prior to accessing the device and following use of the device, ensure that the top/septum of the connector is in its closed/home position. This position may vary between brands.
  • Follow the manufacturer's instructions for use with regard to any warnings and recommendations relating to a recessed connector.
  • For application of clamps to IV line/catheters fitted with these connectors, follow the manufacturer’s instructions for use.
  • After following the above, if the top/septum remains recessed, replace the connector and report the incident to the MHRA.

Distributed to: NHS trusts in England, Commission for Social Care Inspection (CSCI), Healthcare Commission (CHAI), Primary care trusts in England, Health Protection Agency (HPA): – Chief Executives, Headquarters, Chief Executives, Directors
How May the Mechanical Valves Lead to BSIs?

- **Location**: Wake Forest University School of Medicine.
- **Study Design**: Quantitative cultures of blood from ICU patients drawn through MV ND from December 12, 2004 to January 21, 2005 (initial syringe pull back of morning blood draw).
- **Results**:
  - 226 “discards” obtained from 83 patients.
  - 39/226 (17%; range 8% to 50%, by unit) culture positive.
  - Colony forming units (CFU/ml): median=0.3, range 0.1->100.
  - Pathogens: 25 CNS, 5 yeast, 2 S. *aureus*, 2 each Serratia or Enterococcus spp., 1 each S. *maltophilia* or Acinetobacter spp.; 31% would be considered pathogens in a blood culture.
  - 31% of nurses did not disinfect the MV before accessing system.

Karchmer TB et al. SHEA 2005, Abstract #307
Characteristics of Needleless Connectors

- Fluid displacement upon connect/disconnect:
  - Negative, Positive, or less negative (Neutral)
- Internal mechanisms:
  - Simple or Complex?
  - Multiple moving parts?
- Access to fluid path:
  - Blunt cannula access
  - Luer activated access
- Internal design:
  - Straight path
  - Flow around path
- Priming Volume:
  - The amount of fluid required to remove all air
- Dead Space:
  - Spaces inside the housing where fluid can leak or be flushed into, although the original design did not intend for fluid to move into these spaces.
Characteristics of Needleless Connectors

- **Access type**: split septum or luer activated access.

- **Visibility**: Clear or opaque. INS Standard 35: Injection and Access Caps states: “If the integrity of the injection or access cap is compromised or if residual blood remains within the cap, it should be replaced immediately and consideration should be given to changing the catheter and administration set.”

- **Connector external surface**: Needleless connectors can have a relatively flat surface, an area of indentation in the center of the surface, and angled post in the center, or some other form of irregular surface. There is also a category of mechanical valves that requires closure with a new sterile end cap. The more intricate designs could present difficulty in reaching all surfaces to clean adequately before each use.

Characteristics of Needleless Connectors

• Fluid displacement upon connect/disconnect:
  – Negative, Positive, or Neutral

• Internal mechanisms:
  – **Simple**: One design requires the use of a blunt plastic cannula attached to the administration set or syringe and inserted through the pre-pierced septum of the needleless connector. A second design eliminates the blunt plastic cannula and allows the male luer end of an administration set or syringe to be inserted into the pre-pierced septum. Neither of these designs has any internal moving pieces,

  – **Complex**: contain some type of internal mechanism, and this group is commonly called a *mechanical valve*. *Valve* is defined as a mechanical device that controls the flow of fluid within a system.

Characteristics of Needleless Connectors

- **Internal mechanisms:**
  - Mechanical valves;
  - Split septum with internal blunt cannulas;
  - Split septum with no internal mechanisms; or
  - Pressure-sensitive valves (only in the United States).

- **Internal springs:** present or absent.

- **Microbial barrier:** intraluminal and extraluminal microbial protection with silver or CHG-silver (impregnated or coated-sprayed painted or dipped).

- **Actuations:** The projected number of activations or actuations that can occur before the device fails.

_Hadaway L et al. J Infusion Nursing 2010; 33:1-10._
Characteristics of Needleless Connectors – Access Type

- **Split Septum (BCAD)**
- **Luer Activated**

Characteristics of Needleless Connectors - Visibility

INS Standard 35: “If the integrity of the injection or access cap is compromised or if residual blood remains within the cap, it should be replaced immediately and consideration should be given to changing the catheter and administration set.”

Characteristics of Needleless Connectors – External Surface

- Needleless connectors can have a relatively flat surface, an area of indentation in the center of the surface, and angled post in the center, or some other form of irregular surface. There is a category of connectors that requires closure with a new sterile end cap. The more intricate design could present difficulty reaching all surfaces to clean adequately before each use.

Disinfection of Needleless Catheter Connectors

- **Study design**: In vitro study.
  - 3 luer-activated valved connectors (Clearlink [Baxter Healthcare], PosiFlow [Becton-Dickinson], and Micro CLAVE [ICU Medical]) were studied.
  - One device as control, the rest inoculated by immersing the membranous surface in a suspension of *E. faecalis* containing >10^8 colony forming units (CFUs) per ml. Septum allowed to dry for 24 hours (final inoculum 10^5 CFU/ml).
  - Accessed by sterile syringe containing 3ml of sterile tryptocase soy broth and flushed with broth.
  - **Vigorous 3-5 second swabbing**.

<table>
<thead>
<tr>
<th>Variable</th>
<th>No Disinfection</th>
<th>Disinfection With 70% Alcohol</th>
<th>Disinfection With Antiseptic-Barrier Cap</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of connectors showing microbial transmission across the membrane/total no. of connectors studied (%)</td>
<td>15/15 (100)</td>
<td>20/30 (67)</td>
<td>1/60 (1.6)³</td>
</tr>
<tr>
<td>Approximate no. of colony-forming units traversing the membrane</td>
<td>4,500-28,000</td>
<td>442-25,000</td>
<td>0-350</td>
</tr>
</tbody>
</table>

³ P < .001.
Disinfection of Mechanical Valves

• **Study design**: 300 MVs (4 types from 3 manufacturers) were tested. Each septum inoculated with $10^5$ CFUs/ml of *S. epidermidis*, *S. aureus*, *P. aeruginosa*, and/or *C. albicans*. Membranous septum disinfected for 15 seconds with friction, using 70% alcohol or 3.15% chlorhexidine/70% alcohol (Chlorascrub™). 0.9% non-bacteriostatic saline flush solutions were collected downstream and quantitatively cultured.

• **Results**: Disinfection of the membranous septum for 15 seconds with friction, using either 70% alcohol alone or 3.15% chlorhexidine/70% alcohol (Chlorascrub™) was equally effective in preventing the transfer from the membranous septum downstream in the process of accessing the ports.

Key Intraluminal Care and Maintenance Strategy: Septum Disinfection

Before Swabbing

After Swabbing

Gaps

After Connection


Biofilm & Bacteria on External Surface of Needleless Connector

Ryder et al. Microscopic Evaluation of Microbial Colonization on Needleless Connectors. 2009. APIC Poster Presentation
Biofilms on indwelling medical devices

Figure 1. Scanning electron micrograph of a Staphylococcus biofilm on the inner surface of a needleless connector. Photograph by Janice Carr, Centers for Disease Control and Prevention, Atlanta, GA USA

www.cdc.gov/ncidod/EiD/vol7no2/donlan.htm
## Features that INCREASE Risk

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficulty cleaning access surface</td>
<td>HCW’s may not adequately clean the intricate surface details, leading to fluid path contamination.</td>
</tr>
<tr>
<td>Gap around plunger harbors bacteria</td>
<td>Gap cannot be accessed for disinfection and can lead to fluid path contamination especially with repeated access such as SAS or SASH method.</td>
</tr>
<tr>
<td>Opaque housing hides incomplete flushing of media based fluids</td>
<td>During the course of normal manipulation of the catheter small amounts of media like fluid contaminate the valve. If these organisms proliferate, then they can be infused with subsequent manipulations.</td>
</tr>
<tr>
<td>Internal mechanisms obscure fluid path</td>
<td>Impossible to visually confirm complete flushing.</td>
</tr>
</tbody>
</table>
The Latest Recommendations on the Use of Needleless Connectors
Strategies to Prevent Central Line-Associated Bloodstream Infections (CLA-BSIs) in Acute Care Hospitals.

Needleless Intravenous Access Devices

• “Do not routinely use positive-pressure needleless connectors with mechanical valves before a thorough assessment of risk, benefits, and education regarding proper use (B-II)

  – Routine use of the currently marketed devices that are associated with an increased risk of CLA-BSI is not recommended”


1National Institutes of Health, Bethesda, Maryland
2Infusion Nurses Society, Norwood, Massachusetts
3Vermont Hospital, Greenfield, Vermont
4University of Washington, Seattle, Washington
5Providence Franciscan Healthcare, Seattle, Washington
6University of Massachusetts Medical School, Worcester, Massachusetts
7State University of New York at Albany, Albany, New York
8Wake Forest University School of Medicine, Winston-Salem, North Carolina
9Rhode Island Hospital, Providence, Rhode Island
10Beth Israel Deaconess Medical Center, Boston, Massachusetts
11University of Alabama at Birmingham, Birmingham, Alabama
12University of Kansas Medical Center, Kansas City, Kansas
13University of Vermont Medical Center, Burlington, Vermont
14Atlanta VA Medical Center and University of Michigan, Ann Arbor, Michigan

Category II Recommendations: Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale.

Needleless Connector Issues

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.

2. Change caps no more frequently than every 72 hours for the purpose of reduced infection rates or according to manufacturers' recommendations.

3. Ensure that all components of the system are compatible to minimize leaks and breaks in the system.

4. When needleless systems are used, the split septum valve is preferred over the mechanical valve due to increased risk of infection.
• There continue to be new needleless connectors introduced into the marketplace.

• There are few studies comparing different needleless connectors.

• There are no randomized controlled trials of needleless connectors.

• Small before/after studies are being conducted assessing selected needleless connectors.

• Newest generation positive pressure needleless connectors may be different than the initial generation of such devices.
Meta-analysis

• To assess the Relative Risk of Central Line-associated Bloodstream Infection (CLA-BSI): Comparison of MaxPlus Positive Displacement Connector with Other Negative or Neutral Displacement Connectors.
## Description of Studies Included in Meta-analysis

<table>
<thead>
<tr>
<th>General Information</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study lead author/principal investigator/immunologist</td>
<td>Koebel, Taft, Cain, Stoud, Steinerger, Chemaly, Lange</td>
</tr>
<tr>
<td>Where was the study published/presented (journal, conference name)</td>
<td>Pediatrics, INCA, NPA, IUMAI, SMI, SI</td>
</tr>
<tr>
<td>Study participation institute name</td>
<td>Boston Children's Hospital, Rogue Valley, Community Health Home Care, Mercy Health Pediatric Center, Hospital, PA site, acute-care sites, CA</td>
</tr>
<tr>
<td>Hospital (geographic region)</td>
<td>Northeast, West, Midwest, Midwest, West, Northeast, West</td>
</tr>
<tr>
<td>Hospital (ICU bed size)</td>
<td>24, 26, n/a, 25, 51, unknown, n/a</td>
</tr>
<tr>
<td>Study design</td>
<td>Retrospective, Retrospective,Prospective, Prospective, Retrospective, Retrospective, Retrospective, Retrospective</td>
</tr>
<tr>
<td>Study population (MICU, SICU, ICU, ward, etc)</td>
<td>Pediatric ICU, NICU level 3, Home health, ICU, Adult long-term acute care, MICU, Adult long-term acute care</td>
</tr>
<tr>
<td>Outcome measure (CLA-BSI, BSI)</td>
<td>CLA-BSI, CLA-BSI, CLA-BSI, CLA-BSI, CLA-BSI, CLA-BSI, CLA-BSI, CLA-BSI</td>
</tr>
</tbody>
</table>
### Pre- and Post-Period Meta-analysis Information

#### Pre-Period Information (Control Period)

<table>
<thead>
<tr>
<th>Device name</th>
<th>Clearlink</th>
<th>Clave</th>
<th>Clave</th>
<th>Clave</th>
<th>Microlive</th>
<th>Max-Plus</th>
<th>Z-Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device mechanism (positive, negative, neutral, etc)</td>
<td>negative</td>
<td>negative</td>
<td>negative</td>
<td>negative</td>
<td>neutral</td>
<td>positive</td>
<td>negative</td>
</tr>
<tr>
<td>Device design (mechanic, split-septum, other)</td>
<td>mechanical</td>
<td>mechanical</td>
<td>mechanical</td>
<td>mechanical</td>
<td>mechanical</td>
<td>mechanical</td>
<td></td>
</tr>
<tr>
<td>Data collection start date (mm/yy)</td>
<td>Jan-05</td>
<td>Jan-04</td>
<td>Apr-06</td>
<td>Not specified</td>
<td>Jan-07</td>
<td>Feb-09</td>
<td>Jan-09</td>
</tr>
<tr>
<td>Data collection end date (mm/yy)</td>
<td>Mar-06</td>
<td>Oct-06</td>
<td>May-09</td>
<td>Dec-08</td>
<td>Dec-07</td>
<td>Aug-09</td>
<td>Oct-09</td>
</tr>
</tbody>
</table>

#### Post-Period Information (Test Period)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Device mechanism (positive, negative, neutral, etc)</td>
<td>Flolink</td>
<td>MaxPlus</td>
<td>Clear</td>
<td>Clear</td>
<td>Clear</td>
<td>Invision Plus</td>
</tr>
<tr>
<td>Device design (mechanic, split-septum, other)</td>
<td>mechanical</td>
<td>mechanical</td>
<td>mechanical</td>
<td>mechanical</td>
<td>mechanical</td>
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</tr>
<tr>
<td>Data collection start date (mm/yy)</td>
<td>Apr-06</td>
<td>Nov-06</td>
<td>Jun-09</td>
<td>Jan-09</td>
<td>Apr-08</td>
<td>Feb-10</td>
</tr>
<tr>
<td>Data collection end date (mm/yy)</td>
<td>Dec-06</td>
<td>Dec-08</td>
<td>Mar-10</td>
<td>Aug-10</td>
<td>Apr-09</td>
<td>Aug-10</td>
</tr>
</tbody>
</table>
### Summary of Studies Included in Meta-analysis

<table>
<thead>
<tr>
<th>Study</th>
<th>Number of CVL days</th>
<th>Number of Cla-BSI events</th>
<th>CLA-BSI rate (per 1,000 CVL days)</th>
<th>Number of CVL days</th>
<th>Number of Cla-BSI events</th>
<th>CLA-BSI rate (per 1,000 CVL days)</th>
<th>Relative Risk of MaxPlus</th>
<th>Point Estimate</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costello, 2000</td>
<td>5,234</td>
<td>30</td>
<td>5.73</td>
<td>3,675</td>
<td>11</td>
<td>2.99</td>
<td>0.52</td>
<td>(0.26, 1.04)</td>
<td></td>
</tr>
<tr>
<td>Taft, 2009</td>
<td>4,123</td>
<td>17</td>
<td>4.12</td>
<td>2,838</td>
<td>4</td>
<td>1.41</td>
<td>0.34</td>
<td>(0.12, 1.02)</td>
<td></td>
</tr>
<tr>
<td>Cain, 2010</td>
<td>61,816</td>
<td>11</td>
<td>0.18</td>
<td>50,148</td>
<td>2</td>
<td>0.04</td>
<td>0.22</td>
<td>(0.05, 1.01)</td>
<td></td>
</tr>
<tr>
<td>Gould, 2010</td>
<td>5,391</td>
<td>22</td>
<td>4.08</td>
<td>6,011</td>
<td>0</td>
<td>0</td>
<td>0.00</td>
<td>(0.00, 0.34)</td>
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</tr>
<tr>
<td>Steininger, 2010</td>
<td>8,947</td>
<td>20</td>
<td>2.24</td>
<td>6,930</td>
<td>8</td>
<td>1.15</td>
<td>0.52</td>
<td>(0.23, 1.17)</td>
<td></td>
</tr>
<tr>
<td>Cheynecky, 2011</td>
<td>2,605</td>
<td>4</td>
<td>1.54</td>
<td>2,766</td>
<td>12</td>
<td>4.34</td>
<td>2.83</td>
<td>(0.91, 8.76)</td>
<td></td>
</tr>
<tr>
<td>Lange, 2012</td>
<td>23,139</td>
<td>66</td>
<td>2.85</td>
<td>23,015</td>
<td>11</td>
<td>0.48</td>
<td>0.17</td>
<td>(0.09, 0.32)</td>
<td></td>
</tr>
</tbody>
</table>
Results

• In the pre-MaxPlus period:
  – Central venous line (CVL)-days ranged from 4,123 to 8,947
  – CLA-BSI rate ranged from 0.18 to 5.73 CLA-BSIs per 1,000 CVL-days.

• In the post-MaxPlus period:
  – CVL-days ranged from 2,838 to 6,930
  – CLA-BSI rate ranged from 0 to 2.99 CLA-BSIs per 1,000 CVL-days
Results:
MaxPlus/Clear vs. Negative and Neutral Valves

Constant effects test: $Q_w = 5.90$, $P=0.2066$
Results

- Pooled fixed effect showed 59% CLA-BSI risk reduction associated with MaxPlus connectors (RR: 0.41; 95% CI: 0.26-0.65).
- Pooled random effect method showed 62% CLA-BSI risk reduction associated with MaxPlus (RR: 0.38; 95% CI: 0.21-0.68).
- The random effect Poisson model showed 69% CLA-BSI risk reduction associated with MaxPlus (RR: 0.31, 95% CI: 0.19-0.47)
### Conclusion

- MaxPlus is associated with reduced CLA-BSI risk compared to devices with negative or neutral displacement connectors in the studies we reviewed.

- MaxPlus does not contribute to higher rates of CLA-BSI in comparison to Negative/Neutral Needleless connectors.
Conclusions

• Needleless connectors initially were introduced to protect healthcare workers from needlestick injuries.
• Central line-associated bloodstream infection (CLA-BSI) outbreaks associated with needleless connectors illustrated their potential impact on patients.
• Several generations of needleless connectors with different designs (split septum, negative, positive and then neutral mechanical valves) have been introduced.
• New needleless connectors continue to be introduced.
• Further studies are needed to evaluate the association of different needleless connectors and CLA-BSI risk.
• Needleless connectors are an integral part of CLA-BSI prevention insertion and maintenance bundles.
• Needleless connectors with the best designs improve patient outcomes.