Determining Factors in Device-Related Infections

Applied to Needleless Connectors

Factors

Frequency of Replacement

Product Users

Product Developers and Manufacturers

Product Investigators and Regulators

Surface Disinfection

Device Design

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CLASSIFICATION OF NEEDLELESS CONNECTOR DEVICE DESIGN

NEEDLES/ LATEX INJECTION PORTS

PROTECTED NEEDLE SYSTEMS

CLICK LOCK ®

KLEEN-NEEDLE ®

SPLIT SEPTUM/ EXTERNAL CANNULA

OPEN FLOW PATH

INTERLINK ®

LIFE SHIELD ®

SAFELINE ®

LUER-ACTIVATED DEVICES

CAPPED LUER-ACTIVATED DEVICES

OPEN FLOW PATH

SAFE SITE ®

LIFE SHIELD ®

SWABBABLE LUER-ACTIVATED DEVICES

SPLIT SEPTUM

OPEN FLOW PATH

INTERNAL CANNULA

Q-SYTE ™

SECURISEND ®

Neutral Displacement

CLAVE ®

MICROCLAVE ®

INVISION PLUS™

FLOSTAR ®

BIONECTOR ®

MECHANICAL VALVE

MECHANICAL VALVE

CLC 2000 ®

POSIFLOW ®

ULTRASITE ®

FLOLINK®

MAX PLUS ®

Positive Displacement

Marcia Ryder PhD MS RN, 2007
This document is color-coded to correspond with the IVAAP Research Algorithm.

Subcategories are listed in rank order according to level of evidence.

Citations within each category are listed by date of publication and are not ranked.

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### Key Publications on Needleless Connectors

**2000-2007**

**Classified by Level of Evidence**

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### Publications of Experimental Research

**Randomized Controlled Clinical Trials**

Prospective design that compares the results of one or more specific variables to a control. Subjects are randomly assigned. Establishes causality.

**Non-Randomized Controlled Clinical Trials**

Groups assigned by non-random methods or may include all relevant cases. Includes control or comparison group. Also known as quasi-experimental research.

**Non-Clinical Experimental Research**

Controlled experiments conducted using in vitro, ex vivo or animal models. May utilize any experimental design.

**In Vitro Studies**


Schilling S, Doellman D, Hutchinson N, Jacobs BR. The impact of needleless connector device design on central venous catheter occlusion in children: a prospective controlled trial. J Parenter

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### Publications of Observational Research

**Observational Research**

Study subjects are observed for the incidence of outcomes over time. Also called descriptive research.

**Meta-Analysis**


**Cohort Study**


**Observational**

Menyhay SZ, Maki D. Disinfection of needleless catheter connectors and access ports with alcohol may not prevent microbial entry: the promise of a non-antiseptic barrier cap. Infect Control & Hosp Epidemiol 2006;19:750-753.

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### Other Publications, All Non-Experimental

**Review of Published Literature**

Structured review of published studies, with or without statistical interpretation of findings.

**General Articles and Reports**


ECRI. Increased infection rates with positive-fluid-displacement luer-activated devices. Health


Cheeseman D. Intravenous care: benefits of closed system connectors. Br J Nurs
<table>
<thead>
<tr>
<th>NON-RANDOM TRIALS</th>
<th>IN VITRO STUDIES</th>
<th>COHORT</th>
</tr>
</thead>
</table>

Note: Abstracts that have been published as full text articles appear in the appropriate categories above and are not listed in this section.
valve ports may be associated with a high rate of catheter-related bloodstream infection. Abstract presented at SHEA Annual Scientific Meeting, April 2005.


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Lower Level of Prediction with Lower Ranked Subcategories

The IVAAP Needleless Connector Evidence List was originally developed by Hanchett and Ryder in 2006. The content of this tool is subject to change based on emerging scientific research and other new publications. Last updated Aug, 2007. © 2007 IVAAP

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Research Terminology

**In Vivo**: Experiments conducted on or in a living being. Includes animal models and tests using human subjects.

**In Vitro**: Experiments conducted in a controlled environment rather than in or on a living being. Terminology comes from the Latin root “in glass” since many early biological experiments were done using a glass test tube or plate.

**Ex Vivo**: Experiments done on living tissues or specimens obtained from test subjects e.g. catheters, but conducted outside the living being. Study of cultured cell tissue is a common example, e.g., stem cell research. Similar to but not synonymous with “in vitro” research.
Determining Factors in Device-Related Infections

Applicable to Analysis of Any Medical Product

Institute for Vascular Access Advanced Practice

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**Needleless Access Device Risk Assessment**

This tool is designed to facilitate comparative product analysis according to specific risk criteria.

<table>
<thead>
<tr>
<th>© Ryder &amp; Hanchett 2006</th>
<th>Manufacturer</th>
<th>Manufacturer</th>
<th>Manufacturer</th>
<th>Manufacturer</th>
<th>Manufacturer</th>
</tr>
</thead>
</table>

### 1. Product Materials

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>External Housing</td>
<td>Polycarbonate, Valox</td>
</tr>
<tr>
<td>Access Mechanism</td>
<td>Silicone, Polyester</td>
</tr>
<tr>
<td>Fluid Pathway</td>
<td>Polyethylene, Stainless Steel</td>
</tr>
<tr>
<td>Chemical Incompatibilities</td>
<td>Alcohol, Lipids, Antineoplastics</td>
</tr>
<tr>
<td>Latex free</td>
<td>Contains no latex</td>
</tr>
</tbody>
</table>

### 2. Design Features

#### 2A. Basic Device Design

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Split septum design (non-valve)</td>
<td>External or Internal septum activation</td>
</tr>
<tr>
<td>Mechanical, moveable valve</td>
<td>Yes or No</td>
</tr>
<tr>
<td>Luer Lok™ compatible</td>
<td>Yes or No</td>
</tr>
<tr>
<td>Suitable for venous and arterial catheters</td>
<td>Yes or No</td>
</tr>
<tr>
<td>Hemolysis with blood aspiration</td>
<td>Yes or No (or specify amount)</td>
</tr>
</tbody>
</table>

#### 2B. Surface Topography

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swabable or Nonswabable</td>
<td>Swabable</td>
</tr>
<tr>
<td>Configuration of surface</td>
<td>Flat, Irregular, Raised, Concave</td>
</tr>
</tbody>
</table>

### 2C. Functional Activations

200 over 72 hours

### 3. Flow Path Analysis

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infusion fluid path (surface area)</td>
<td>Straight or irregular</td>
</tr>
<tr>
<td>Residual volume (dead space)</td>
<td>0.25 ml</td>
</tr>
<tr>
<td>Maximum flow rate</td>
<td>200 ml/minute</td>
</tr>
<tr>
<td>Visualization of flow path</td>
<td>Complete, partial, or none</td>
</tr>
</tbody>
</table>

### 4. Displacement Volume

<table>
<thead>
<tr>
<th>Type</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>0.03 ml flush</td>
</tr>
<tr>
<td>Negative</td>
<td>0.09 ml reflux</td>
</tr>
<tr>
<td>Neutral (Passive)</td>
<td>0.000 ml</td>
</tr>
</tbody>
</table>

**Points to Remember**

Use tool with review of current scientific literature and product information.
#412
04 / 07

Bacterial transfer through needlefree connectors: Comparison of nine different devices

Marcia Ryder1, Steve Fisher2, Gordon Hamilton3, Martin Hamilton3 and Garth James2

1Research & Consulting: Medical Biofilm Infections and Related Access. 2Center for Biofilm Engineering. 3Big Sky Statistical Analysts LLC

A national Science Foundation Engineering Research Center in the MSU College of Engineering

In 1991, the U.S. Occupational Safety and Health Administration encouraged healthcare facilities to "look for engineering controls that make the environment healthier and safer for workers" due to increased reports of injuries among healthcare workers. In April 1992, the FDA issued a needlestick safety alert with stringent encouragement for the replacement of needlestick hazards with needlefree systems to reduce needlestick injuries. Since then, numerous reports of increased bloodstream infection rates involving Staphylococcus epidermidis and other pathogens have been linked to needlefree connector devices. This has led to increased awareness of the need for needlefree connectors that are effective in reducing the risk of needlestick injury while not increasing infection rates.

CONCLUSIONS

The observed transfer of bacteria from the surface of needlefree connectors to injected fluids underscores the importance of adequate surface disinfection prior to connection. Furthermore, the observed differences between connector products suggest that device design has an important influence on bacterial transfer.

Funding for this study was provided by ICU Medical, Inc.

INTRODUCTION

Numerous risk factors for catheter-related bloodstream infections associated with needlefree connectors have been proposed. The primary factors are attributed to device design, aseptic device management and frequency of exchange of the connector. Device design, product materials, engineering components and features of the connector vary widely, and may have an impact on the risk of infection. The variability of these designs makes classification and comparisons quite difficult.

The major design components include the access seal or septum configuration (flat, recessed, irregular), mechanism of access to the flow path (external orifices, minimal orifices, internal), residual volume of liquid left in the connector after flushing, surface disinfection prior to connection, and the observed decreases in the number of bacteria retained on swabbing surfaces or seals which become part of the fluid path.

The results and conclusions from these experiments are color-coded in Figure 1 and demonstrate the variability and significant differences among nine needlefree connector devices.