Turning Technology-related Evidence into Optimal Protocols for Line Maintenance

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Speaker Disclosure

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- Genentech
- BD

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Sometimes we just need to
change our perspective...

Objectives

1. The evolution of Needle free connectors

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

3. Considerations for determining protocols

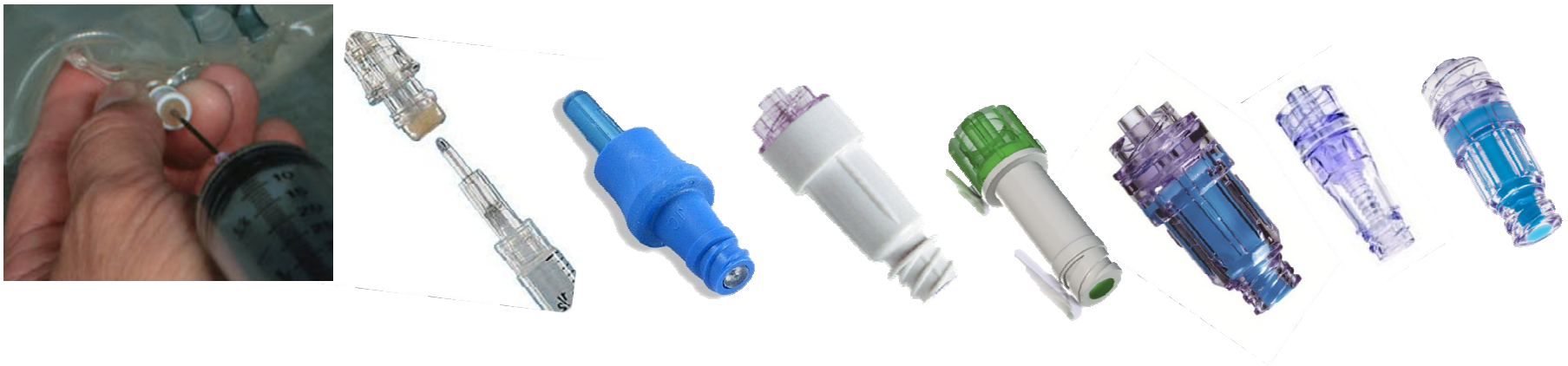
Evolution

"unfolding, change, progression, metamorphosis." Dictionary.com

The Evolution of Light

- All provide a source of light
- Designs evolved to improve:
  - Safety
  - Effectiveness
  - Efficiencies
- All have varying degree of risk associated with use

Needleless Connector Evolution



- 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

1980's	1991	2000	2001	2005	2008
Bloodborne pathogen exposure risks gain greater attention[1]	Occupational Safety & Health Administration (OSHA) recommends healthcare facilities use "engineering controls" to help protect Health Care Workers from these pathogens[2]	Needlestick Safety and Prevention Act (Pub. L 106-430) signed into law[3]	Engineered controls, including Needleless Connector (NC) systems mandatory under Needlestick Safety and Prevention Act[4]	**FDA recognizes microbial risk** with NC's Testing should demonstrate disinfection procedures used are effective for removing microorganisms from the device	**FDA revises Guidance Testing** should demonstrate disinfection procedures are effective
Healthcare Worker Protection				Patient Protection	

Health Care Worker Protection

- Risk of infection from contaminated sharp?[5]
  - **Hepatitis B – 1 in 5** (if you're not vaccinated)
  - **Hepatitis C – 1 in 50**
  - **HIV – 1 in 300**
- **$51 to $3,766USD -** average cost per exposure to the healthcare institution[6]
- **$71- $4,838USD -** 2004 study of 4 facilities showed a range of cost of exposure management[7]
- **$1 MillionUSD or more -** costs related to lost work time/disability payments due to serious infection[8]
- Intangible Costs of Exposure
  - Emotional Distress
  - Physical Distress
  - Family Impact
  - Co-Worker Impact

Early Evolution

Now we understand the **Critical Features**:

ACCESS SURFACE is *solid and sealed*

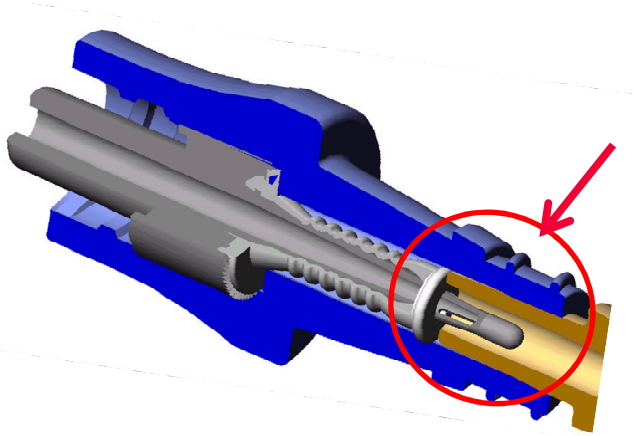
- Could be effectively disinfected
- No crevices, slits, holes or gaps that can trap or allow contaminants to penetrate the connector

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.

Luer Activated Design Introduced

- 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*



Internal cannula creates complex mechanism

External cannula requires extra part or needle

Total Confusion!

External vs internal cannula?

reflux

"Slit" septum vs. Split septum

Mechanical valve

Changes in technique

Negative

Interstitial space

Catheter Infections

Catheter Occlusions

Flush-ability

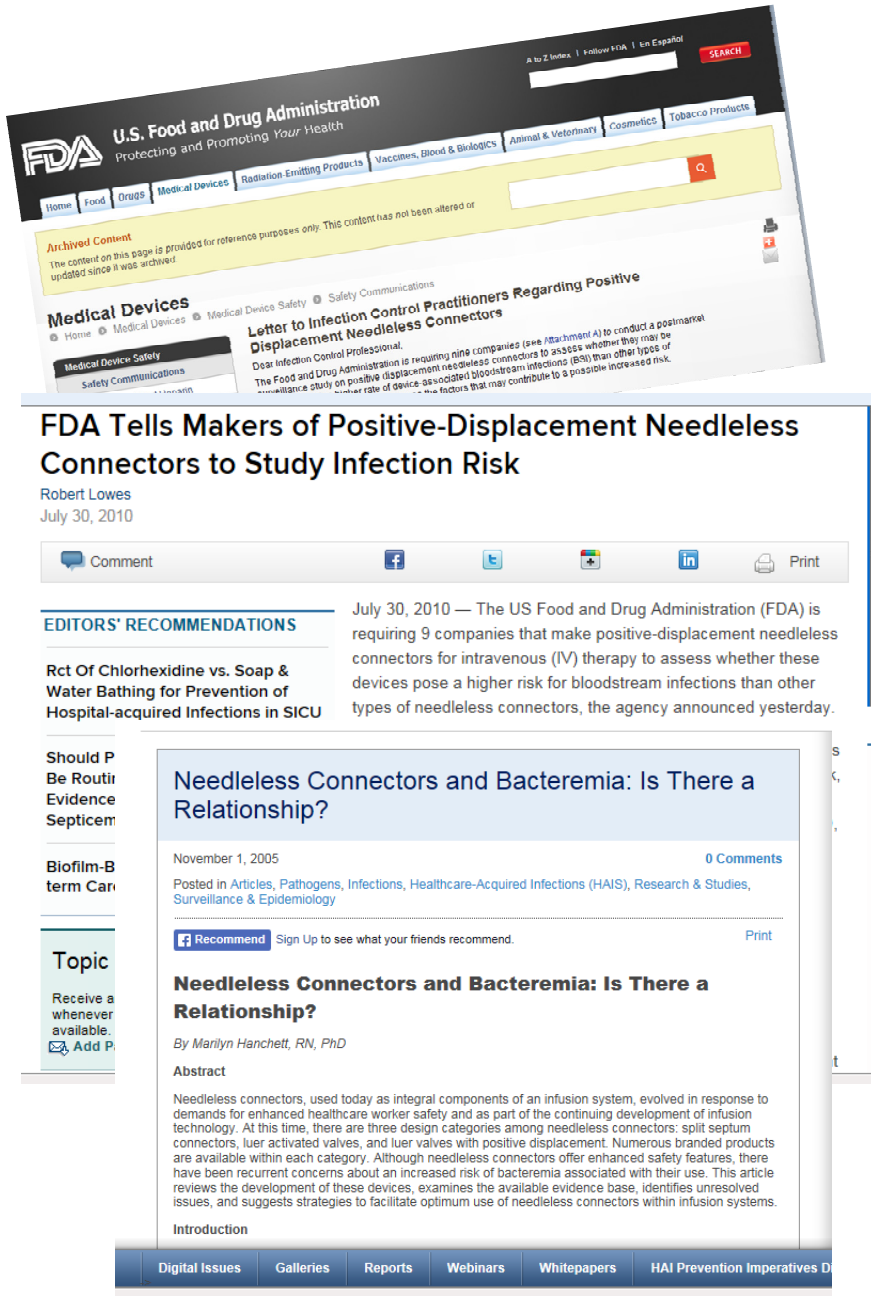
Neutral

positive

Residual volumes

disinfection

Swab-ability



Contamination Risk related to Needleless Connector **Design** is *NOT* a new concept

- *Rupp (2007):* "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."[9]
- *Field (2007):* "difficulty in sterilizing the gap between the valve and the hub"[10]
- *Maragakis (2006):* "intricate access surfaces that are more difficult to disinfect"[11]
- *Salgado (2007):* "mechanical valve could be more difficult to disinfect because of the complicated nature of the multi-part device"[12]

Guidelines and Standards of Practice

CDC 2011 Guidelines[13]

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

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Guidelines and Standards of Practice

2016 Infusion Therapy Standards of Practice, Infusion Nurses Society[14]

27. Needleless Connectors (NC)

D. The nurse should be aware of and implement manufacturers' directions for use, implement appropriate infection prevention practices, and **review the research and published literature related to this issue to promote and provide quality patient outcomes**. (II)

F. The nurse should be knowledgeable about the manufacturer's directions for use and other device performance criteria to assist in the development of policies and procedures for needleless connector change frequency. The optimal time frame for changing the needleless connector has not been determined.

- The optimal technique or disinfection time frame has not been identified. (III)

Refer to device manufacturers' recommendations for use

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Evolution of Needleless Technology

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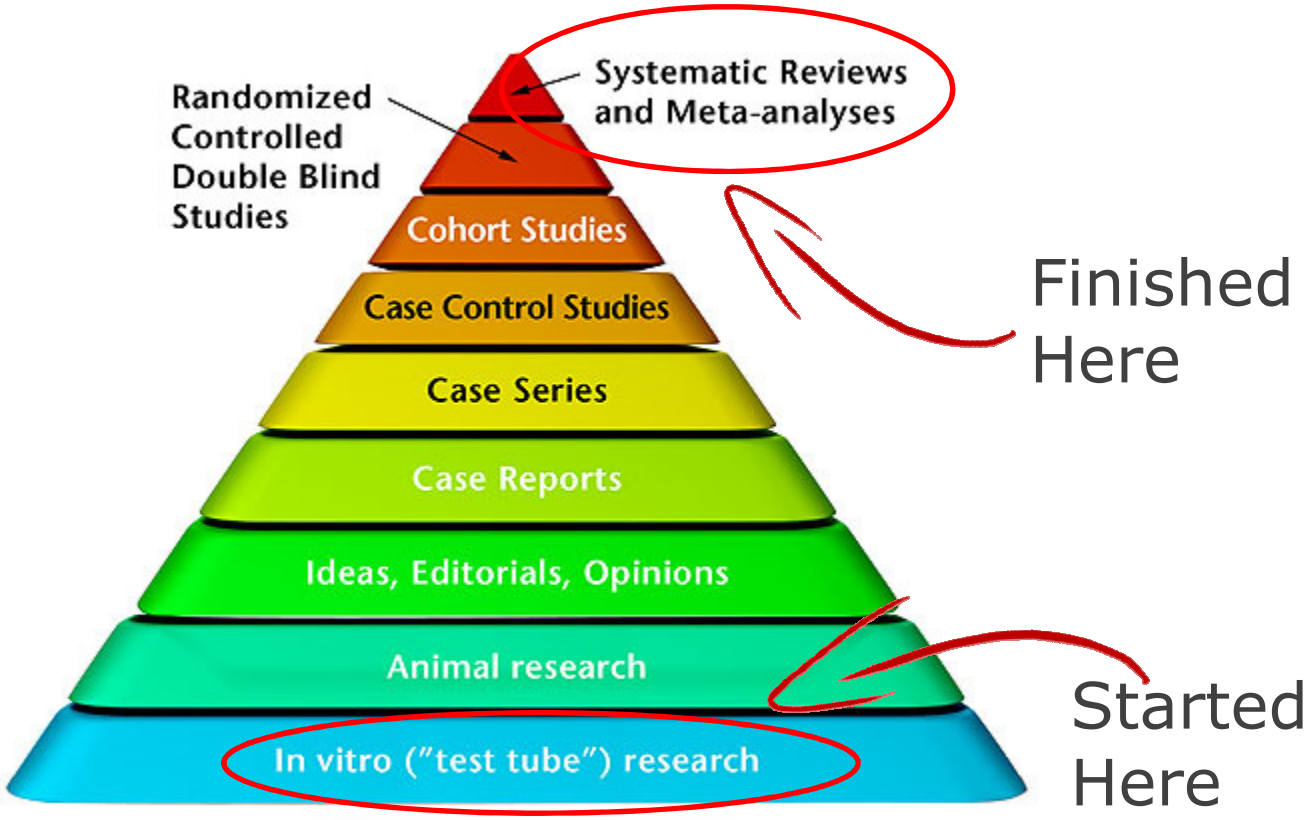
Healthcare Worker Protection				Patient Protection	

Manufacturers' Evidence

Strength of Evidence



2014 Meta-Analysis

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

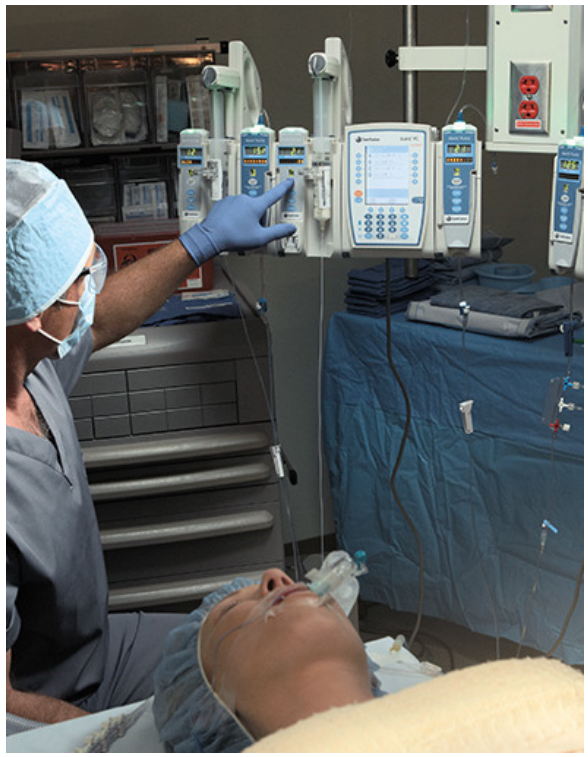
Sources searched for studies:

- MEDLINE
- ClinicalTrials.gov
- Embase
- Cochrane Database
- Studies using the positive-displacement study NC compared with negative- or neutral-displacement NCs were analyzed.

Studies included in Meta-Analysis[18]

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.



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'Preferred Design' [19] and throughout Extended Usage

- **OPPORTUNITIES TO IMPROVE DISINFECTION AND PATIENT CARE**

Needleless Connectors
and the Improvement of Patient and Healthcare Professional Safety

By William R. Jarvis, MD

INTRODUCTION

When it comes to improving patient and healthcare safety, many factors are considered: time to treatment, antimicrobials and increased reporting standards to name a few. However, a small device – the needleless connector for intravenous systems – can have a big impact, particularly on protecting healthcare workers from needlestick injuries and in reducing bacterial contamination. There are numerous options for these devices, and there may be confusion on current guidelines, as well as protocols for appropriate disinfection and use. With all the variables and increasing time constraints, how can healthcare professionals – such as critical care nurses and infection preventionists – improve patient care and safety, as well as protect themselves? By understanding the differences between the device options, healthcare professionals can more easily tailor their patient care, improve adherence to clinical best practice and ensure their safety.

HISTORY

At the front line of patient interaction, hospital-based healthcare professionals have a great responsibility to provide quality patient care. But when it comes to protecting themselves, these professionals were at one time at a great risk for needlestick injury. A study by Jagger, et al., revealed that devices that required manipulation after use, such as intravenous (IV) tubing needles and disposable syringes, were associated with an increased rate of injury to the healthcare professional. At a rate of approximately 385,000 per year, sharps injuries posed a great issue to healthcare professionals, including an increased risk for bloodborne pathogen transmission.

To help protect the healthcare professional, the Needlestick Safety and Prevention Act mandated that the Occupational Safety and Health Administration (OSHA) clarify and revise the Bloodborne Pathogens Standard. The subsequent new provisions put forth in the Exposure Control Plan stated that, "Where engineering controls will reduce employee exposure either by removing, eliminating or isolating the hazard, they must be used."

A first-line strategy for compliance was to eliminate or reduce the unnecessary use of needles, primarily using a needle-free IV delivery system. While needleless connectors were initially developed to help improve healthcare professional safety, in recent years the use of needleless connectors may have contributed to improved patient care as well.

GUIDELINES

The Food and Drug Administration (FDA) has regulatory authority over the marketing of needleless connectors. The requirements for marketing have changed over time. In 2005, the FDA recognized that there is a microbial risk with needleless connectors. The guidance released that year said, "The testing should demonstrate that disinfection procedures you use are effective for removing microorganisms from the device." However, in 2008, this guidance changed and became less clear, stating: "The testing should demonstrate that disinfection procedures you use are effective." Unfortunately, that allowed some laboratory studies to demonstrate the transfer of microorganisms, rather than validating the removal of them. This still leaves a concern of organism transfer, which would have been otherwise avoided if the organism were removed in the first place. FDA requirements should mimic the clinical situation and be straightforward and consistent for manufacturers.

It is imperative that the healthcare professional develop and adhere to manufacturer recommended disinfection protocols for their needleless connectors and use a sterile end cap on the male luer of the IV tubing during intermittent infusions to help reduce the risk of contamination. This disinfection process should specify the specific disinfecting agent, the method for disinfection (e.g., scrub the access surface) and the duration such disinfection should occur, such requirements may be needleless connector specific.

CHARACTERISTICS OF NEEDLELESS CONNECTORS

When identifying a disinfection protocol, it is important to consider the features of

At a rate of approximately 385,000 per year, sharps injuries posed a great issue to healthcare professionals, including an increased risk for bloodborne pathogen transmission.

'Preferred Design' [19] and throughout Extended Usage

- Flat, smooth, easy to disinfect external surface - *More complex design = more nooks & crannies to hide in. Flat surfaces are easier to disinfect by design*
- No opening or gap around the septum seal - *Nowhere to hide. Gaps are hypothetically an area where pathogens can invade*
- Clear housing - *User can see the effectiveness of their technique*
- Least complex internal mechanisms - *complex moving parts in the fluid pathway provide surfaces for infusates to bind to and serve as a nidus for biofilm development.*
- Straight fluid path - *If the pathway is indirect, flushing is less likely to remove blood or other nutrient fluids. When these settle on a NC internal surface, they can serve as the nidus for biofilm development.*
- Minimal dead space - *Contaminating organisms and material (i.e., blood) that enhances biofilm development can "hide" in these dead spaces.*
- No blood reflux-*Theoretically, blood reflux into either the IV catheter or the NC increases both the risk of occlusion and biofilm formation. Both also increase the risk of HA-BSI.*
- Flush with saline - *or HIT. Thus, a NC that can be flushed with saline rather than heparin containing solutions should decrease the risk of HIT/ thrombocytopenia*

Design determines protocol:
Change Out Practice

- 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.[16]

Guidance for Industry and FDA Staff

Intravascular Administration Sets Premarket Notification Submissions [510(k)]

Document issued on: July 11, 2008

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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 saline 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 using the same luer and prolonged access	• Inoculate, allow to dry 30 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	• Repeat rounds 1 through 5 once every 24 hours over eight (8) days. • Final eluate filtration is repeated at end of each day for each test device

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Design determines 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.

Look at the whole picture!

- Change out protocol
- Disinfection practice
- Flushing
- Blood draws

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Ultimately Protocols affect work flow and cost of use

Connector Change Intervals

- Should the NC be considered part of the line …?
- Or 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**

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Questions?