Needlefree Connectors and Risk of Infection

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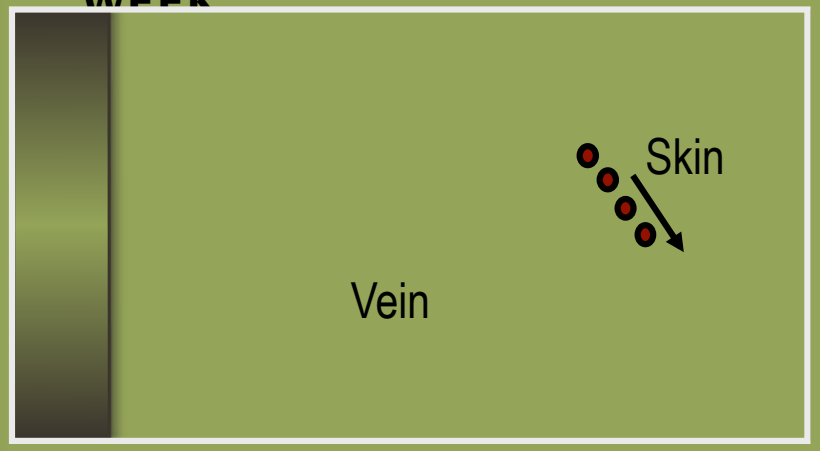
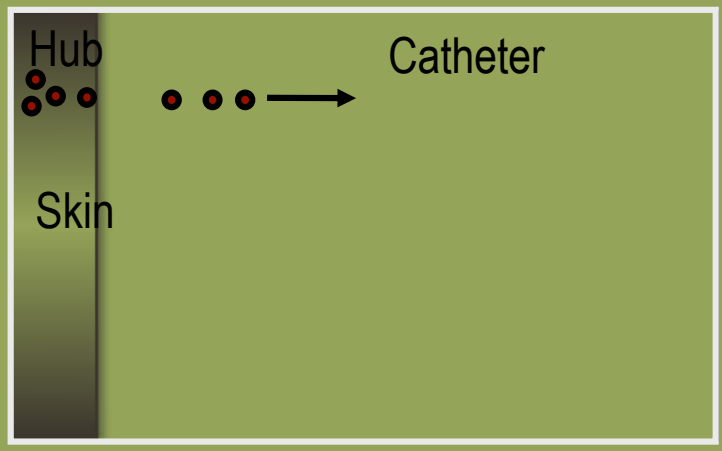
Microbial Source of CR-BSI

» **EXTRALUMINAL -FIRST WEEK**



INTRALUMINAL- After first week



» 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

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

Contaminated Catheter Hub

2

Endogenous

Skin flora

Extrinsic

HCW hands

Skin Organisms

Endogenous

Skin flora

Extrinsic

HCW hands

Contaminated disinfectant

1

Fibrin Sheath, Thrombus

Skin

Vein

1 = 60%

2 = 12%

3 = <1%

Unk = 28%

1992: First “needleless” connector 2015

The original features of the first needleless connector include (1) a solid, sealed access surface, (2) a simple, fluid filled internal design and (3) a visible fluid path.

Easy to Use But With Inherent Risks Due to Design?

- Clinicians may not be able to:
  - Disinfect the surface
  - Ensure the line is flushed correctly or per protocol.
- Confusion may cause clinicians to not:
  - Clamp the extension set correctly

The frequency of user error is unknown.

Design risks are known.

Outbreaks Associated With Needleless Connectors

Author	Reference	SS	MV	Location	CLA-BSI	Rate*	P-value
		Device	Device		SS	MV	
Salgado	ICHE 2007;28:684	NPSS	NPMV	LTAC	1.8	5.4	<0.001
Rupp	CID 20007;44:1408	NPSS	PPMV	ICU	3.9	10.43	<0.001
				Inpatient	3.5	7.5	<0.001
				Outpatient	5.8	15.2	0.005
Maragakis	ICHE 2006;27:67	NPMV	PPMV	ICU	1.5	2.4	0.05
				Children	1.6	2.8	0.01
				PICU	5.4	17.3	0.02
Jarvis	CID 2009;49:1821	NPSS	NP/ PPMV	ICUs	6.2	9.5	<0.001

Abbreviations: SS=split septum; MV=mechanical valve; Rate per 1,000 catheter days; NPSS=negative pressure split septum; NPMV=negative pressure mechanical valves; LTAC=long term acute care; ICU=intensive care unit; PPMV=positive pressure mechanical valve; PICU=pediatric ICU

Needleleless Device Features that INCREASE Infection Risk

Difficulty cleaning access surface	HCW's may not adequately clean the intricate surface details, leading to fluid path contamination.
Gap around plunger harbors bacteria	Gap cannot be accessed for disinfection and can lead to fluid path contamination especially with repeated access such as SAS or SASH method.
Opaque housing hides incomplete flushing of media based fluids	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.
Internal mechanisms obscure fluid path	Impossible to visually confirm complete flushing.

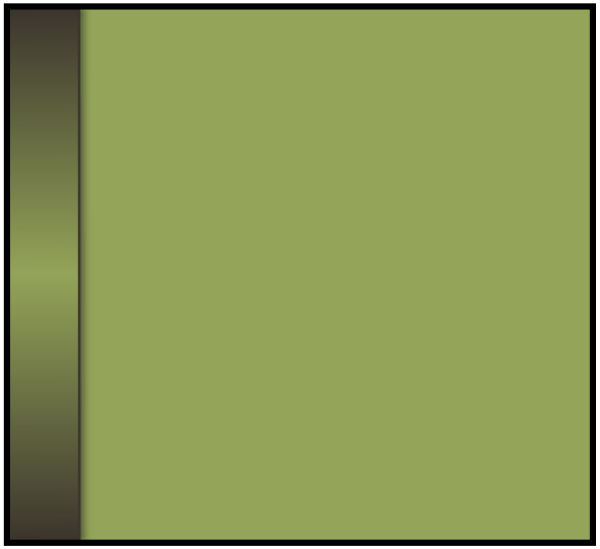
Reference: William Jarvis, MD – Presented at CHICA (Community and Hospital Infection Control Association) February 24, 2009 , APIC and AVA 2006, SHEA 2005, 2006.

Biofilms on Indwelling Medical Devices

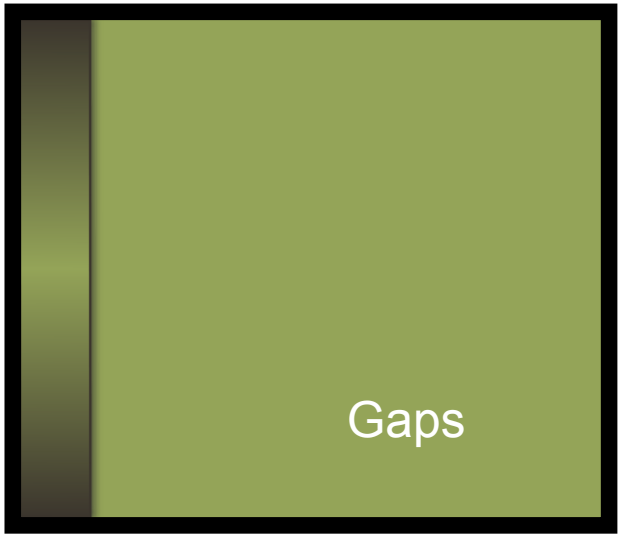
» **Figure 1.** Scanning electron micrograph of a Staphylococcus biofilm on the inner surface of a needleless connector. Photograph by Janice Carr, Centers for Disease Control and Prevention, Atlanta, GA USA

Key Intraluminal Care and Maintenance Strategy: Septum Disinfection

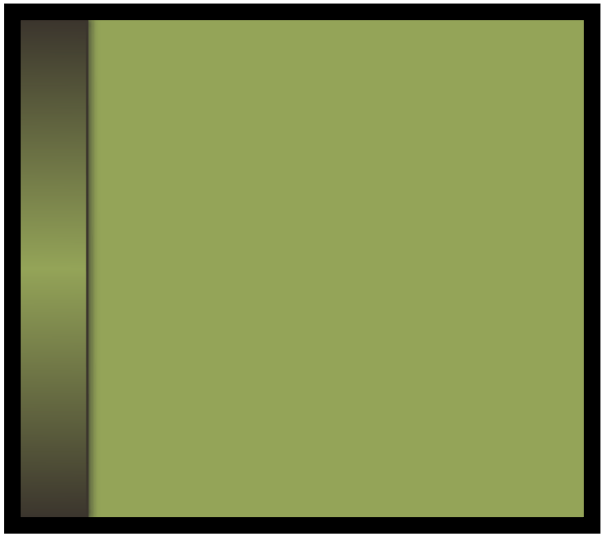
Before Swabbing



After Swabbing



After Connection

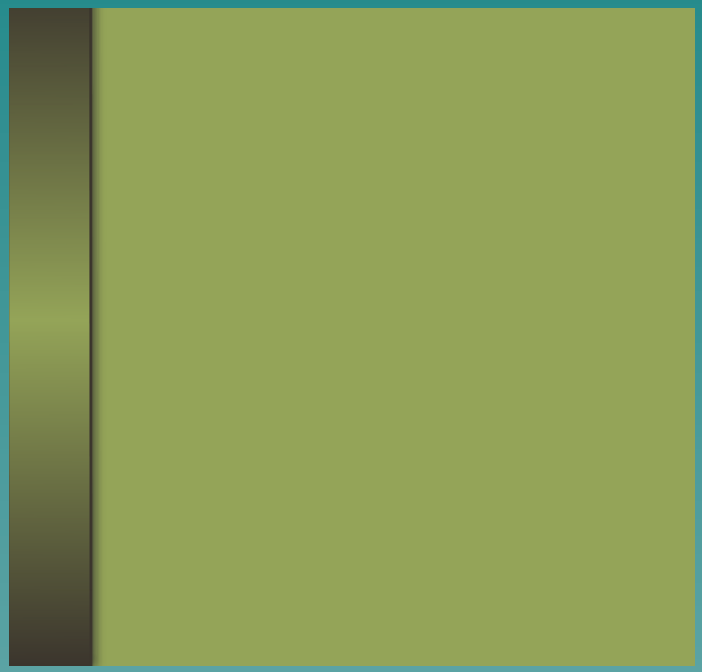


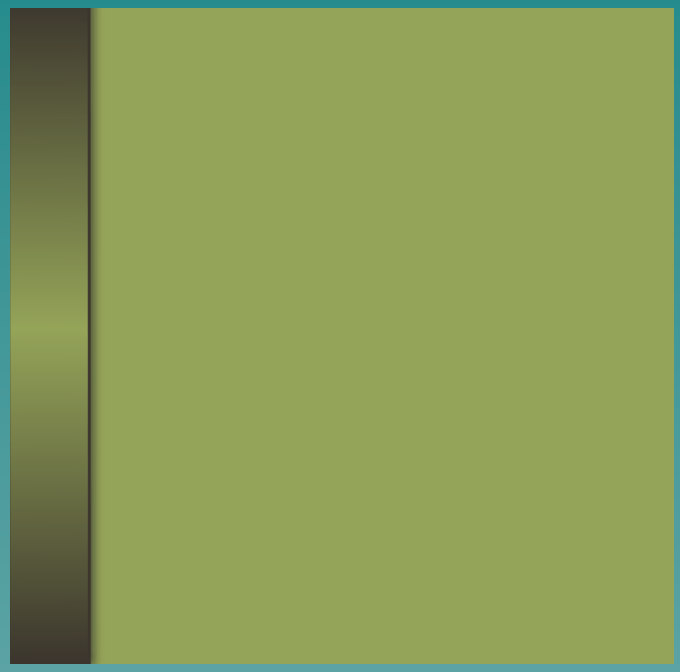
1. Seymour VM. Et al., J Hosp Infec. 2000;45:165-168; 2. Menyhay SZ et al., ICHE 2006;27: 23-27; 3. Ryder, MA. Catheter-Related Infections: It's All About Biofilm. Topics in Advanced Practice Nursing eJournal. 2005;5(3) ©2005 Medscape

Posted 08/18/2005 . http://www.medscape.com/viewarticle/508109.

Potential Risk Factors for Bloodstream Infections Associated with Mechanical Valves

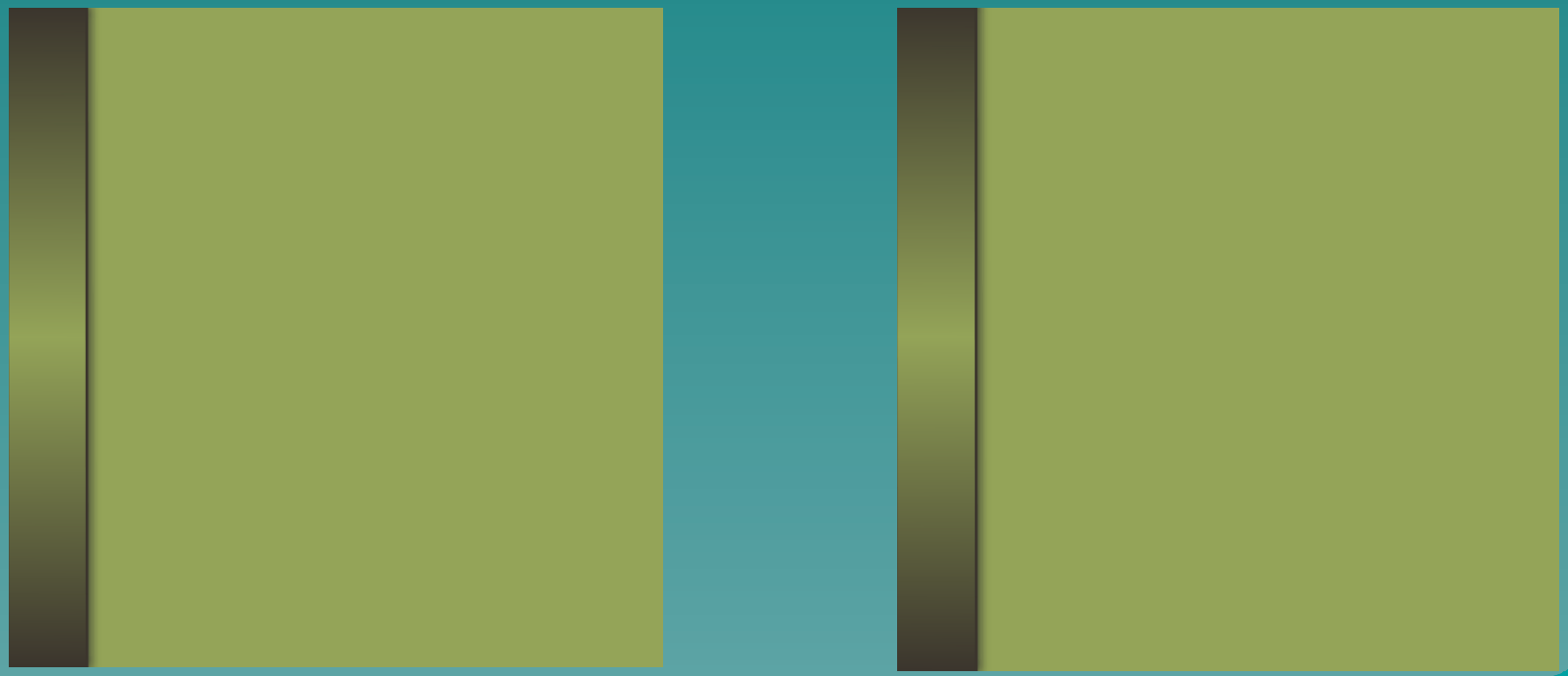
- "Difficulty cleaning access surface"





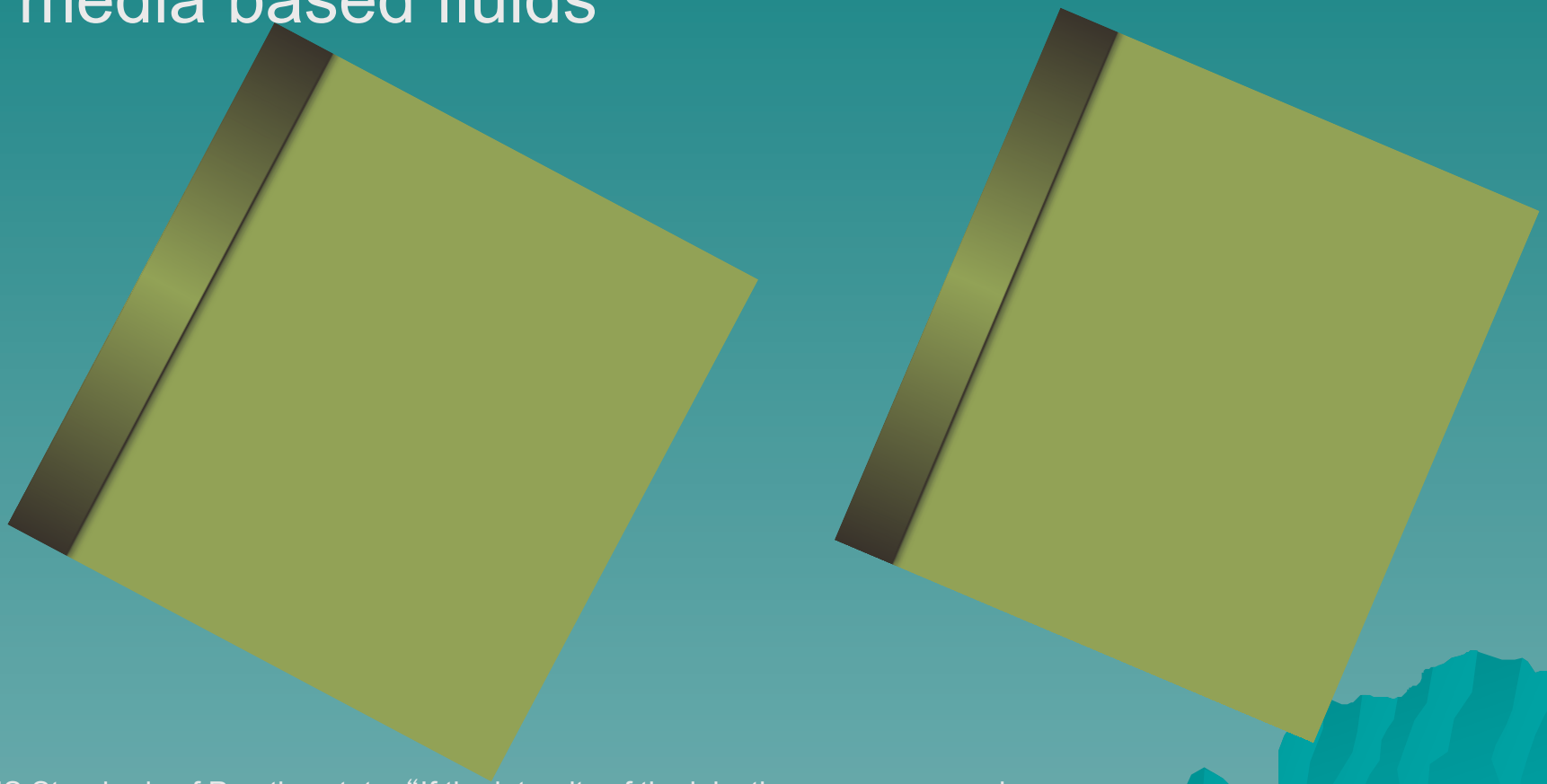
Potential Risk Factors for Bloodstream Infections Associated with Mechanical Valves

- "Gap around plunger harbors bacteria"



Potential Risk Factors for Bloodstream Infections Associated with Mechanical Valves

- "Opaque housing hides incomplete flushing of media based fluids"



2006 INS Standards of Practice state: "If the integrity of the injection or access cap is compromised or if residual blood remains within the cap, it should be replaced immediately…" (S36)

Potential Risk Factors for Bloodstream Infections Associated with Mechanical Valves

- "Internal mechanisms obscure fluid path"

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

Studies of Needleless Connector (NC) Disinfection

Author	Reference	Organism/ Dose	NC studied	Disinfectant used	
Menyhay	ICHE 2006;27:23	E. faecalis 10^8cfu/ml	1 NPMV 1 PPMV 1 NMV	3-5 sec scrub 70% alcohol CHG-cap	67+ 1.6%+
Kaler	JAVA 2007;12:140	S. aureus, S. epidermidis, P. aeruginosa, C. albicans/ 10^5 cfu/ml	1 NPSS 1 NPMV 2 PPMV	15 sec scrub 70% alcohol 3% CHG w/ 70% alcohol	All sterile
Rupp	ICHE 2012;33:661	S. epidermidis 10^3, 10^5, 10^8 cfu/ml	1 SS	70% IPA 0, 5, 10, 15, & 30 sec swab	5 sec: 10^3 and 10^5 16 sterile

Characteristics of Needleless Connectors That You Should Evaluate

- **Access to fluid path:**
- Needle or blunt cannula?
- Luer-activated access
- How well does seal prevent bacterial contamination?

Access Surface
-and-
Internal Design

- **Internal Design: Simple or Complex?**
- An unintended design consequence of a complex internal mechanism is that it causes space inside connector but outside the fluid path
  - fluid and contamination can leak into this space
  - This contamination can contaminate the luer and enter the fluid path

Ways To Reduce/Eliminate the Infection Risks Associated With Needleless Connectors (NC)

- Maintain a closed system with a NC.
- Flush the NC every 8 hours (and after each use).
- Select the NC with the design features associated with lowest risk.
- Insure adequate disinfection with each manipulation of the NC.

Needleless Connector (NC) Studies That Are Needed

- Comparative studies of different NC--good or bad experience.
- NC-specific disinfection recommendations.

2014 ID Week Poster Presentation

- Used 2013 Center for Medicare and Medicaid Services (CMS) Hospital Compare data.
- 3,074 hospitals
- Nearly 11,000 CLA-BSIs
- Nearly 10 million catheter days
- Merged with Manufacturer's client database

2014 ID Week Poster Presentation

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.

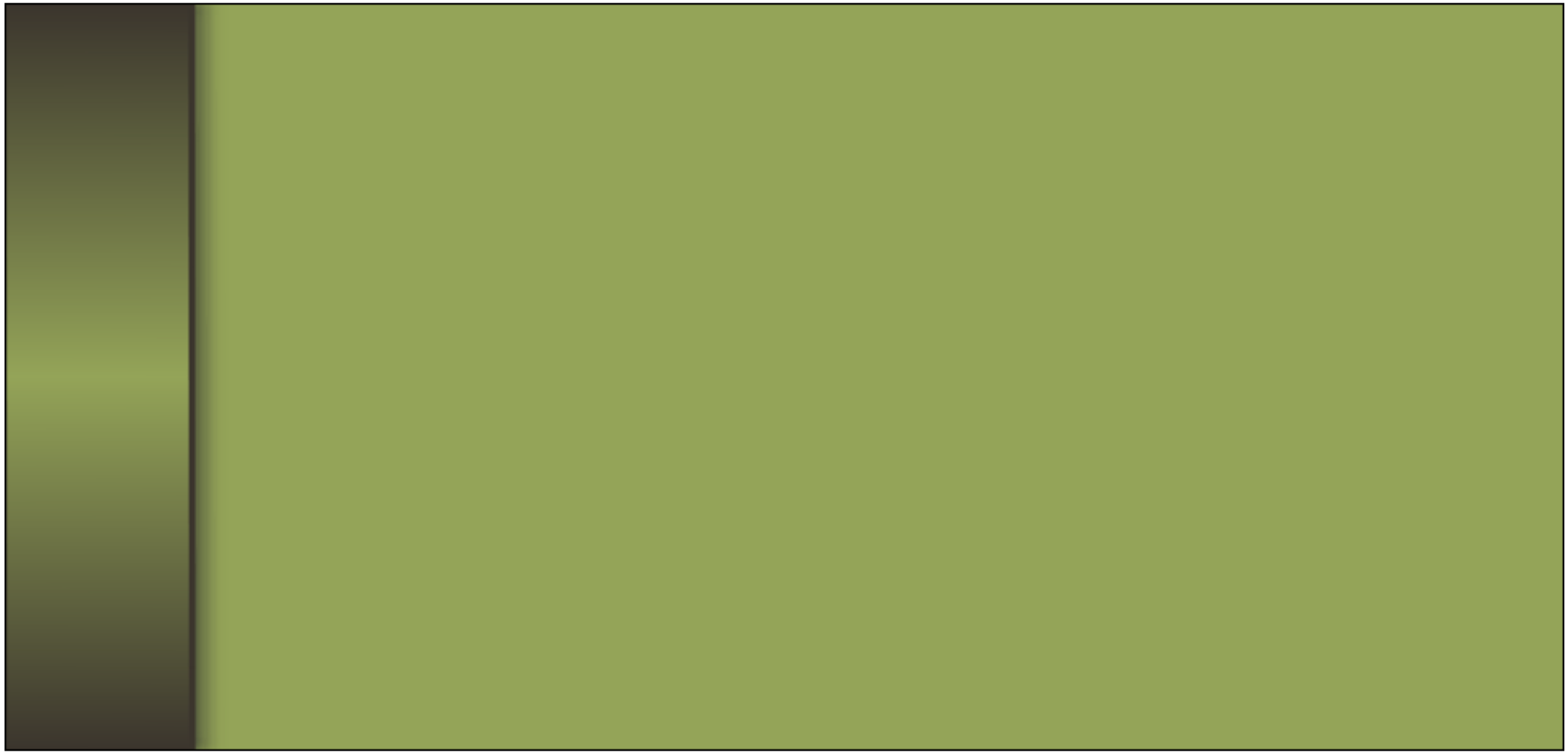
3) It is most current with minimal time lag.

4) The comparison is concurrent, which eliminates potential bias inherent to pre-post period study designs.

Hospital-Compare Analysis

- 2013 Hospital Compare data was downloaded from the CMS website.
- CareFusion clients were linked to CMS data.
- CareFusion clients were grouped by intensity and consistency of use.
- Only hospitals reporting >1 Central Line day were used in the analysis.
- Raw standardized infection ratios (SIR) were computed.
- The SIR was further adjusted using hospital intern-to-resident ratio, bed size, rural/urban status and geographic location using a random effects Poisson regression approach.

Hospital Compare Results



* Hospitals with > 1 CLD

Source: Tabak et al Poster 897 IDWEEK 2014

2014 ID Week Poster Presentation

- The NHSN location adjusted relative risk for CLA-BSI of the Study NC hospitals was 0.91 (95% CI: 0.83, 0.98; P=0.02).
- Adjusting for hospital bed size, teaching, urban status, and geographic regions, the multivariable relative risk for CLA-BSI of the Study NC hospitals was 0.94 (95% CI: 0.86, 1.02; P=0.11)
- Study NC hospitals significantly more likely to be:
  - Major teaching (larger IRB) (P<0.0001)
  - Urban (P<0.0001)
  - With larger number of beds (P<0.0001)

2013 CMS Data

Comparator data:

Number of Hospitals = 2,316

Central venous line days= 6,963,405

Number of CLA-BSI's = 7,847

CLA-BSI rate = 1.13 per 1,000 CL days

Positive Pressure Mechanical Valve data:

Number of Hospitals = 758 (25%)

Central venous line days = 2,923,859 (30%)

Number of CLA-BSI's = 3,017 (28%)

CLA-BSI rate = 1.03 per 1,000 CL days

FDA Post Market Surveillance

This is the future for medical devices.

Remember the Two 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

- Entire interior of connector is active space where 100% of fluid can be exchanged.
- 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

Conclusions

- Over 20 years of central line-associated bloodstream infection (CLA-BSI) outbreaks associated with NCs illustrate their potential impact on patients.
- Several generations of NCs with different designs have been introduced.
- Studies are conclusive associating different NC designs with increased CLA-BSI risk.
- NCs are an integral part of CLA-BSI prevention, insertion and maintenance bundles.
- Special attention to NC design, flushing and disinfection will reduce intralumenal contamination/ colonization and their risk of infection.