




Needleless Devices and Bloodstream Infections

33rd Annual Educational Conference and International Meeting
Tampa, Florida
June 13, 2006

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Disclosure

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Becton Dickinson
Johnson and Johnson
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3M

Purpose

- To provide an overview of the impact of central venous catheter bloodstream infections (CVC-BSIs).
- To discuss recent CVC-BSI prevention interventions.
- To present the continuing worldwide evolution of episodes of increased bloodstream infection rates temporally associated with changing needleless connectors.
- To discuss possible mechanisms for contamination of these devices.

Intravascular Devices Sold Each Year In The Continental United States

- Intravascular catheters:**
 - ~2.0 million peripherally inserted central catheters (PICCs)
 - .2 million subcutaneous ports
 - .1 million cuffed catheters
 - .3 million long-term (surgically-implanted)
 - .3 million hemodialysis
 - 2.6 million Swan-Ganz
 - 1.9 million single- and multi-lumen
 - 5.0 million short-term (percutaneously inserted)
- Central venous catheters:**
 - 5 million arterial catheters
 - 34 million winged needles
 - 118 million peripheral IV catheters

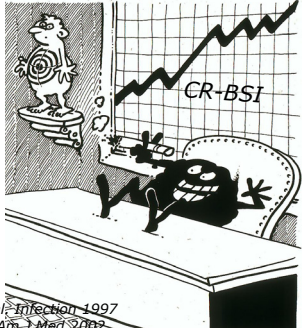
*Manufacturers' estimates and IMS America, LTD

Risk Factors for Nosocomial Bloodstream Infections

<ul style="list-style-type: none"> Host factors Extremes of age Severe illness Malnutrition Infection at another site Underlying disease (burn, immune compromise) Colonization Catheter insertion site Catheter hub Hematogenous seeding 	<ul style="list-style-type: none"> Practice-related factors Multiple lumens Catheter type (CVL, size) Longer duration of catheterization Insertion by cut-down Poor technique related to catheter insertion or manipulation Hemodynamic monitoring Parenteral nutrition, lipid
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Impact of Primary BSI

<u>Crude mortality</u>	10% to 40%
<u>Attributable mortality</u>	2% to 15%
<u>Prolongation of hospitalization</u>	5 to 20 days
<u>Attributable cost</u>	\$34,000 to \$56,000



Wey et al. Arch Intern Med 1988; Voss et al. Infection 1997
Pelz et al. J Int Care Med 2000; Blot et al. Am J Med 2002

The Cost of CVC-BSIs in U.S. ICUs

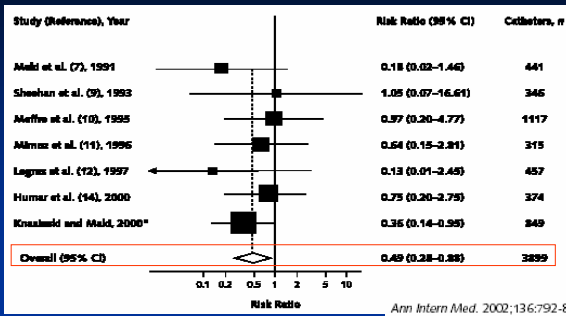
•80,000 CVC-related BSIs occur in U.S. hospital ICUs each year

•Annual cost to the healthcare system **\$296 million-\$2.3 billion** (U.S.)

The Institute for Healthcare Improvement (IHI) CVC-BSI Prevention Bundle-----or what we already knew in infection control but could not get our clinicians to comply with or administrators to mandate!

- Education
- Hand hygiene
- Maximal sterile barrier precautions
- Chlorhexidine skin antiseptics
- Optimal site care
- Catheter removal
- Monitoring of practices
- Leadership

Chlorhexidine Compared with Povidone-Iodine Solution for Vascular Catheter-Site Care: A Meta-Analysis



Prospective, Randomized Trial Of A Chlorhexidine-Impregnated Site Dressing (Biopatch®, J&J) On Central Venous And Arterial Catheters In An ICU

	Control Gauze	Chlorhexidine Patch (Biopatch®)	RR	P-Value
Study population:				
Patients	211	208		
Catheters	544	491		
Catheter-days	3133	2586		
No. pts with CR-BSIs	15	6		
Rate CR-BSIs				
Per 100 CVCs	3.3%	1.2%	0.36	<0.01
Per 1000 CVC-days	5.7%	2.3%	0.41	<0.01
Skin-related BSIs				
per 1000 CVC-days	4.1%	0.8%	0.19	<0.001

Maki DG, Mermel L et al, ICAAC (1999)

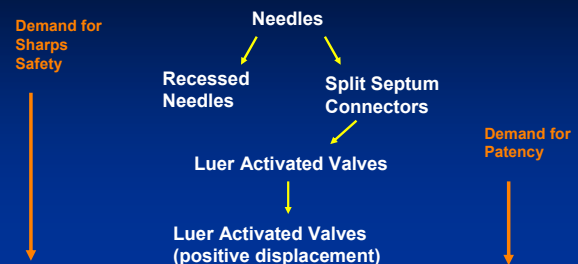
Trial Of Vancomycin-Heparin Lock Solutions (VHLS) With PICCs In An NICU

OUTCOME - PRIMARY BSI

	Controls [N=43]	VHLS [n=42]	RR (95% CI)	P-value
• Definite CR-BSI	8 (19%)	0	(NC)	0.003
• Probable CR-BSI	5 (11%)	2 (5%)	0.4 (0.1-2.0)	0.43
• Any CR-BSI	13 (30%)	2 (5%)	0.2 (0-0.6)	0.002
• BSI w/o a source	5 (12%)	5 (12%)	1.0 (0.3-3.3)	0.97
• All BSIs	18 (42%)	7 (17%)	0.4 (0.2-0.9)	0.01

Garland and Maki J Pedis 2005

Evolution of Needleless Connectors



Increased BSIs Temporally Associated With the Introduction of A Mechanical Valve (MV) Needleless Device (ND)

- **Hospital:** University of Virginia (hospital-wide)
- **Problem:** Increased BSI rate after introduction of a MV ND in May 2002
 - By June 2002, nosocomial BSI rate increased 61%;
 - January-May 2002 vs. May-December 2002: BSI rate: 2.2 vs. 3.5 per 1000 pt-days (RR=1.6, p<.0001)
 - 2.9-fold increase in CR-BSI with common skin organisms.
 - 1.8-fold increase in CR-BSI with non-skin organisms.

Hall K et al, SHEA Annual Meeting 2004

Disclosure/Disclaimer

- Preceding emergence of this problem, I was consulting for Becton Dickinson (BD) on patient safety, including CVC-BSI prevention programs.
- After the SHEA UVA presentation, they and I were hearing of other hospitals with similar experiences.
- BD asked me if I would be willing to co-ordinate/moderate ≥ 1 focus group sessions with those experiencing increases in BSIs associated with NDs, to attempt to gain further understanding of the epidemiology of this problem.
- I agreed, if:
 - I (and the hospital participants) had control over the content of the meetings,
 - BD personnel could not dictate/control the meetings content or outcome, and
 - We would focus on the science and go where ever it took us (including implicating BD's products).
- No manufacturer screened this presentation and none of the data for this presentation was reviewed, screened, or altered, etc. by anyone from BD (or any other manufacturer).

First Peer Discussion

- June 8, 2004, APIC meeting in Phoenix, AZ.
 - Infection control personnel from seven hospitals attended.
 - All presented evidence of a temporal association between an increased BSI rates and changing from a split septum to a Mechanical Valve (MV) needleless connector.
 - Multiple interventions (i.e., education, chlorhexidine skin antiseptics, maximum barrier precautions) did not reduce BSI rates to pre-MV levels.

Second Peer Discussion

- October 30, 2004, meeting at APIC headquarters in Washington, D.C.
- Original 7 participants plus 7 new sites.
- Home health company and 6 additional hospitals reported increased BSI rates with the introduction of, or change in, MV.
- Additional BSI/infectious disease/infection control experts invited to evaluate the reports.

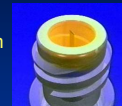
Split Septum Devices

(AKA split systems or blunt cannula devices)

- First truly needleless systems
 - Widespread use in 1990s
 - Multi-piece systems requiring blunt cannulas
 - Marketing did not address occlusion
 - Negative pressure occurs at disconnect
- Interlink (Baxter/BD)**
Safeline (B Braun)
Lifeshield (Abbott)
Q-Syte (BD)

Split Septum Needleless Devices

Split septum surface



Blunt cannula insertion

Reasons for Transition From Split-Septum to Mechanical Valves (MVs)

- To reduce use of needles (potentially reduce needlestick injuries).
- IV system change, such as the intravenous pump, may lead to needless device change.
- Concern that split-septum was being “phased out” by manufacturers.
- Enhance visibility of the hub area in some MVs.
- Desire for neutral or positive pressure or positive displacement device.
- Reduce intravascular device occlusion and use of thrombolytics.

Luer Activated Valves

- Compatible with any standard luer (not blunt cannulas)
- Less reflux than split septum system
- “Neutral” displacement?

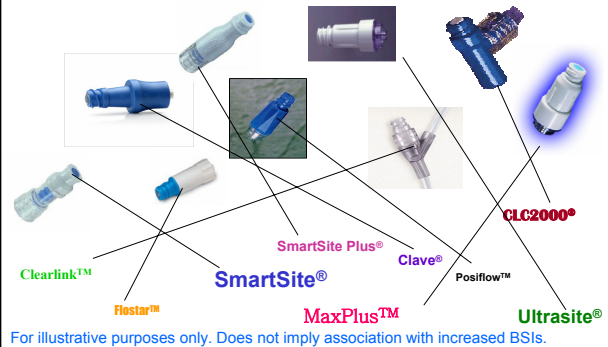
CLAVE (ICU Medical)
Safesite (B Braun)
SmartSite (Alaris)
Clearlink (Baxter)
FloStar (Intravascular)
InVision Plus (Rymed)

Luer Activated Valves with Positive Displacement

- Designed to reduce risk of occlusion & prevent needlestick injury
- Positive pressure at disconnect

CLC2000 (ICU Medical)
Posi-Flow (BD)
UltraSite (B Braun)
SmartSite Plus (Alaris)
MaxPlus (Medegen)

Mechanical Valves



Other Potential Advantages of Mechanical Valve (MV) Needleless Devices

MV intravenous ports have been reported to reduce:

1. Colonization of the catheter tip (Bouza E. et al. JHI 2003;54:279-287)
2. Passage of microorganisms into the catheter lumen (Yebeles JC et al. AJIC 2003;31:462-464)
3. Catheter-related BSI rates (Yebeles JC et al. AJIC 2004;32:291-295).

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.

Increased CVC-BSIs Temporarily 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.

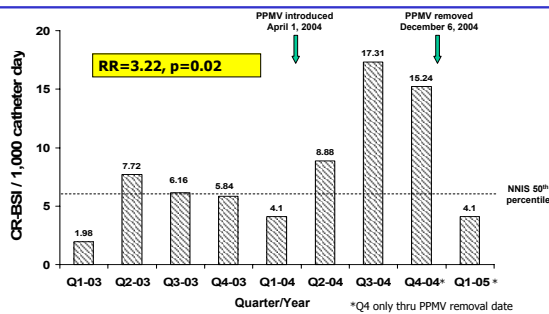
Maragakis LL et al. ICHE 2006;27:67-70

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

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

*Rate per 1,000 catheter-days; PPMV=Positive Pressure MV Maragakis L et al ICHE 2006;27:67-70.

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



Participants' Hospital, Needleless Devices (ND), and ND Use or Comparison Periods

Hospital	ND Period 1	ND Period 1	ND Period 2	ND Period 2
Hospital A	Interlink	1-3/03	SmartSite	4-6/03
Hospital B	Interlink	1-5/02	Ultrasite	6/02-4/03
Hospital C	Clave	1-3/04	SmartSite Plus	7-9/04
Hospital D	Interlink	10-12/03	Clave	2-4/04
Hospital E	Interlink	7/00-6/03	Clearlink/Posi-flow	7/03-6/04

Bloodstream Infection Rates# Temporarily Associated With Change In Needleless Devices

Hospital	Location	ND Period 1	BSI Rate	ND Period 2	BSI Rate
Hospital A-1*	HW-Peds	1-3/03	1.8	4-6/03	3.9
Hospital B*	HW	1-5/02	2.3	6/02-4/03	3.5
Hospital C^	PICU	1-3/04	5.4	7-9/04	17.3
Hospital D*	HW	10-12/03	1.5	2-4/04	5.1
Hospital E*	ICU	7/00-6/03	5.7	7/03-6/04	8.5

BSIs per 1,000 CVC- or patient-days; HW=Hospital-wide; BSI=Bloodstream infection; * change from split septum to mechanical valve; ^ change from neutral to positive pressure mechanical valve

Participating Hospital Characteristics

Hospital	ND Period 1	ND Period 1	ND Period 2	ND Period 2
Hospital A-2	Smartsite/ Ultrasite	3/03-1/05	Interlink	1-5/05

ND=Needless Device

CVC-BSI Rates, PICU and NICU, Hospital A-2, March 2002-May 2005

	PICU	NICU	Total
MV Period	11.5	10.3	10.7
SS Period	4.6	7.9	6.8

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.
- **Mechanical valve (MV) period:** January 2004-October 2005.

	SS Period	MV Period	RR	95% CI	P-value
BSI Rate*	1.79	5.41	3.02	2.62-3.39	<.0001
GNB-BSIs	8%	39.5%	4.93	1.27-19.19	.0006

*BSI rate per 1,000 catheter days; BSI rate has decreased since returning to a split septum needleless device.

Salgado C et al. SHEA 2006, Abstract #7

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
- **Positive displacement needleless valve (PDV) period:** March-August 2005

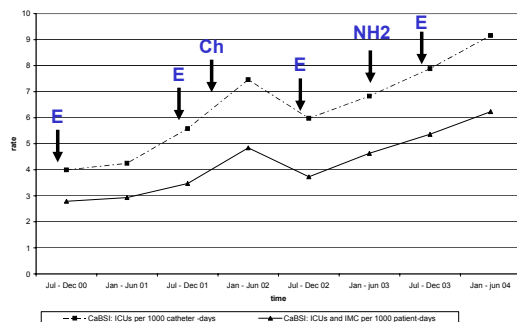
Unit	BSI		P-value	Post-PDV SS Period
	SS Period	Rate* PDV Period		
Critical Care/ Transplant	3.87	10.43	<.0001	7.62
9 other inpatient	3.47	7.51	<.0001	2.36
Cooperative care (OPD TX)	5.80	15.18	.0005	4.30

*BSI Rate per 1,000 CVC-days Ruop M et al. SHEA 2006. Abstract #227

Potential Risk Factors for Bloodstream Infections Associated With Mechanical Valves

Factor	Potential Impact
Difficulty cleaning access surface	HCWs may not adequately clean the intricate surface details before access, leading to fluid path contamination.
Gap around plunger harbors bacteria	Gap cannot be accessed for disinfection and can lead to fluid path contamination (esp. with repeated entry-SAS or SASH flushing).
Opaque housing hides incomplete flushing of media-based fluids	During course of normal manipulation of catheter, small amounts of bacteria and media-like fluids 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.

Catheter associated BSI from Jul 2000 - June 2004



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

Disinfection of Needleless Catheter Connectors

- **Study design:** In vitro study.
 - 3 leur-activated valved connectors (Clearlink [Baxter Healthcare], PosiFlow [Becton-Dickinson], and Micro CLAVE [ICU Medical]) were studied.
 - 36 connectors from each tested concurrently.
 - 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.

Menyhay and Maki ICHE 2006;27:23-27

Results of Simulation Study

Variable	No Disinfection	Disinfection With 70% Alcohol	Disinfection with Antiseptic-Barrier Cap (CHG)
# connectors showing microbial transmission across the membrane/total # connectors studied	15/15 (100%)	20/30 (67%)	1/60 (1.6%)*
Approx. # CFU traversing membrane	4,500-28,000	442-25,000	0-350
* P<.001			

Menyhay and Maki ICHE 2006;27:23-27

Additional Potential Considerations When Selecting a Mechanical Valve Needleless Connector

- Design of the cap surface (ease of disinfection).
- Size of the blunt cannula/valve penetration surface.
- Ease of connection.
- Pressure needed to make the connection.
- Fluid path in the device (direct/indirect).
- Degree of backflow after the positive pressure during disconnect.
- Pressure needed to inject.
- Flow rates.

Issues & Obstacles in the MV/LAD Market

- Clinicians do not fully understand the products
- Sales staff do not fully understand the products
- There is minimal research and maximum hearsay
- Frequency of catheter occlusion often is not monitored/tracked
- Competition for market share is fierce
- Procedures for MV/LAD use vary among/within institutions

Consistent use of aseptic technique when using LADS is unknown but could be a serious problem.

Countries With Hospitals Experiencing an Increase in Bloodstream Infections Temporally Associated with Introduction of Mechanical Valve Needleless Devices

- United States
- Australia
- New Zealand
- Japan
- England

Take Home Message

- All facilities introducing mechanical valve NDs are not experiencing an increase in bloodstream infections (BSIs).
- All facilities using CVCs should be conducting BSI surveillance and evaluating secular trends in their BSI rates.
- Whenever changes are made to the IV system, an evaluation of the impact of that change on the BSI rate should be performed.
- If an increase in BSIs occurs, evaluate the ND as one potential factor.
- Many factors influence BSI rates, including the population served; infusion of blood, TPN or lipid; presence/absence of an IV team; the number of people accessing the device; the method of device disinfection; blood draws through the device; adequacy of flushing, etc., etc.

Minimum Data YOU Should Collect If Considering a Change In Intravenous Device

- CVC-BSI rate (for comparisons before and after the change)
- Needlestick injury rate for healthcare workers secondary to IV manipulation or connector access.
- Catheter occlusion and thrombolytic use (if selecting a positive pressure device).

Summary

1. Needleless intravascular devices (split-septum) were introduced to reduce HCW needlestick injuries.
2. Initially, split-septum needleless devices were associated with BSI outbreaks, temporally associated with breaks in aseptic technique.
3. Mechanic valves (leur-lock) needleless devices were introduced to reduce needlestick injuries and to reduce catheter occlusion.
4. Look-alike devices and differences in infection control practices with each device complicate their use.
5. Increased BSIs associated with mechanical valves may be caused by inadequate infection control practices, device design, or both.

Thank You

