Linking Infection Control & Product Evaluation: A Necessity in the Era of Patient Safety

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Products, Products Everywhere

RG 2

RG 3

RG

RG 5

Why Evaluate Products?

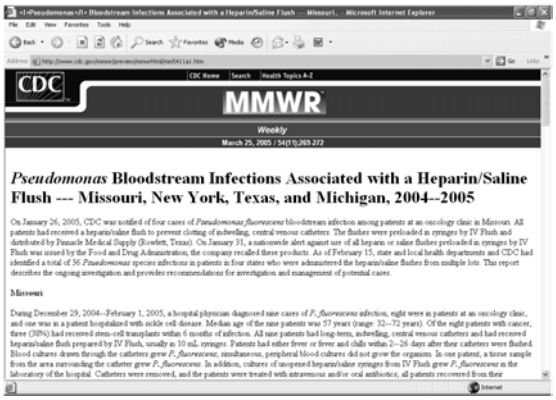
- Emphasis on controlling healthcare costs
- Cost‐efficient medical care by consumers
- Increasing supply costs
- Patient safety
- Managed care and capitation limit reimbursement for billed expenses
- Nosocomial infections
- Liability

RG 6

Medical Device and Infections:
CVC Benchmark Rates for ICU,
NNIS, Jan 2002-Jun 2004

Type of ICU	Central line-associated BSI rate[1]			Percentile				
	No. of units	Central line-days	Pooled mean	10%	25%	50% (median)	75%	90%
Coronary	60	116,546	3.5	1.0	1.5	3.2	7.0	9.0
Cardiothoracic	48	182,407	2.7	0.0	0.9	1.8	2.7	4.9
Medical	94	312,478	5.0	0.5	2.4	3.9	6.4	8.8
Medical-surgical								
Major teaching	100	430,979	4.0	1.7	2.6	3.4	5.1	7.6
All others	109	486,115	3.2	0.8	1.6	3.1	4.3	6.1
Neurosurgical	30	56,645	4.6	0.0	0.9	3.1	5.8	10.6
Pediatric	54	161,314	6.6	0.9	3.0	5.2	8.1	11.2
Surgical	99	358,578	4.6	0.0	2.0	3.4	5.9	8.7
Trauma	22	70,372	7.4	1.9	3.3	5.2	8.2	11.9
Burn	14	43,002	7.0	—	—	—	—	—
Respiratory	6	12,593	4.8	—	—	—	—	—

NNIS System Report. AJIC 2004;32:470-85.



CDC

MMWR

Weekly

March 25, 2005 / 54(11);263-272

***Pseudomonas* Bloodstream Infections Associated with a Heparin/Saline Flush --- Missouri, New York, Texas, and Michigan, 2004--2005**

On January 26, 2005, CDC was notified of four cases of *Pseudomonas fluorescens* bloodstream infection among patients at an oncology clinic in Missouri. All patients had received a heparin/saline flush to prevent clotting of indwelling, central venous catheters. The flushes were preloaded in syringes by IV Flush and distributed by Pinnacle Medical Supply (Rowlett, Texas). On January 31, a nationwide alert against use of all heparin or saline flushes preloaded in syringes by IV Flush was issued by the Food and Drug Administration, the company recalled these products. As of February 15, state and local health departments and CDC had identified a total of 36 *Pseudomonas* species infections in patients in four states who were administered the heparin/saline flushes from multiple lots. This report describes the ongoing investigation and provides recommendations for investigation and management of potential cases.

Missouri

During December 29, 2004--February 1, 2005, a hospital physician diagnosed nine cases of *P. fluorescens* infection; eight were in patients at an oncology clinic, and one was in a patient hospitalized with sickle cell disease. Median age of the nine patients was 57 years (range: 32--72 years). Of the eight patients with cancer, three (38%) had received stem-cell transplants within 6 months of infection. All nine patients had long-term, indwelling, central venous catheters and had received heparin/saline flush prepared by IV Flush, usually in 10 mL syringes. Patients had either fever or fever and chills within 2--26 days after their catheters were flushed. Blood cultures drawn through the catheters grew *P. fluorescens*; simultaneous, peripheral blood cultures did not grow the organism. In one patient, a tissue sample from the area surrounding the catheter grew *P. fluorescens*. In addition, cultures of unopened heparin/saline syringes from IV Flush grew *P. fluorescens* in the laboratory of the hospital. Catheters were removed, and the patients were treated with intravenous and/or oral antibiotics; all patients recovered from their

Guidelines & Medical Devices: Use and Replacement Issues

- *"Observe proper hand-hygiene procedures either by washing hands with conventional antiseptic-containing soap and water or with waterless alcohol-based gels or foams.."*
- *"Disinfect skin with an appropriate antiseptic….2% chlorhexidine…"*
- *"Use either sterile gauze or sterile transparent, semi-permeable dressing…"*
- *"In adults, replace short, peripheral venous catheters at least 72-96 hours to reduce risk of phlebitis…"*
- *"Use aseptic technique including the use of a cap, mask, sterile gown, sterile gloves, and a large sterile sheet, for the insertion of CVC (including PICCs)…"*

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Guidelines & Medical Devices: Use and Replacement Issues (cont'd)

- *"Do not change routinely, on the basis of duration of use, the breathing circuit…that is in use on a patient…"*
- *"Do not routinely change more frequently than every 48 hours an HME that is in use on a patient…"*
- *No recommendation can be made about the frequency of routinely changing in-line suction catheter of a closed-suction system in use on one patient…"*
- *"…develop and implement a comprehensive oral-hygiene program…for patients…at high-risk for…pneumonia…"*
- *"Require patients o shower or bathe with an antiseptic agent on at least the night before the operative day…"*
- *"Use an appropriate antiseptic agent for skin preparation…"*
- *"Perform a preoperative surgical scrub for at least 2 to 5 minutes using an appropriate antiseptic…"*
- *"Wear a surgical mask..", "Wear a cap or hood…", Wear sterile gloves..", "Use surgical gowns and drapes that are effective barriers when wet…"*

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Products & Infection

- It is estimated that greater than >50% of all products reviewed at Products Evaluation Committees have a related infection control issue
- In general, infection control related products deal with
  - creating barriers against, killing, or preventing organisms from entering a body site
  - products used for sterility assurance
  - devices used to administer medications and fluids or to collect or transfer blood or body fluids

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FDA Definition of a Medical Device

- "A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
  - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  - intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

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Is the Medical Device Regulated?

- Certain medical devices require review by the Food and Drug Administration (FDA)
- In general, a device to be used on a person in a healthcare setting must have an initial manufacturer filing and a 510(k) pre- market notification
- The vendor should provide clear documentation that this has been obtained

http://www.fda.gov/cdrh/devadvice/

RG 13

What is Product Evaluation?

- "the process of appraisal that considers the value and significance of quality, cost, safety, and practitioner choice for product selection"
  - Murray M, Stockard R, Blaylock B, et al. Product evaluation and process improvement. *J Nurs Care Quality* 1994;9:16-20.

RG 14

What Criteria is PE based on?

- *Quality* refers to the extent which the product performs its defined function
- *Efficacy* refers to how effectively the product meets its specified function
- *Safety* refers to a level of risk avoidance
- *Cost* is not price
- *Serviceability* refers to the ease of use and maintenance, user acceptability, durability

RG 15

Systematic product review and value analysis: Basic Questions

- Will the product improve the satisfaction of the patient or the product user?
- Will the treatment outcome of the patient be changed by using the product?
- Will the product alter practice or have an impact on clinical decisions related to patient care?

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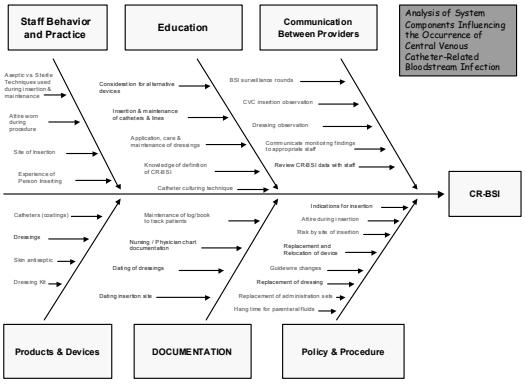
More on Value Analysis…

- Good value analysis requires accurate estimates of total costs, including not only purchase price, but cost of labor, utilities, maintenance, etc.
- If a product is more expensive than one currently used, value analysis assists in determining the incremental cost of the product vs. the expected benefit to the patient
- *Focuses on procedures rather than products*

RG 17



Product Standardization

- Eliminates duplication
- Reduces inventory
- Sets and encourages a procedure standard
- Reduces educational needs for the staff
- Results in enhanced patient safety (if decision process is ideal)

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Product Evaluation Committee

- Multidisciplinary
- Reports to administration
- Establishes subcommittees
- Monthly meetings to ensure timeliness
- Establish timelines

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Multidisciplinary

- Administration
- Purchasing/Materials Management
- Finance
- Nursing
- Education
- Infection Control
- Operating room
- Emergency Room
- Pediatrics
- Central services
- Respiratory Therapy
- Biomedical
- Physicians
- *End users, End users*

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Handout:

A Recommended Step-by-Step Protocol for Evaluating Infection Control-Related Products

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Steps in Product Evaluation

- *Step 1: Products are requested to be reviewed by the PEC*
- *Step 2: Role of Materials Management & Infection Control*
- *Step 3: Materials Management presents findings to PEC; PEC members review clinical details of product*
- *Step 4: Determine outcomes of initial screening*
- *Step 5: Trial of product is conducted*
- *Step 6: Results of Evaluation are reported to the PEC*
- *Step 7: PEC approves product for use*

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Key Contribution by IC: Regulatory Review

- OSHA
- AORN
- EPA
- FDA
- HICPAC (CDC)
- APIC
- JCAHO
- AAMI
- AIA
- INS
- AHCSP
- State & local govt.

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Key Contribution by IC:
Review of Supportive Science

- Published data
- Best practice
- Policy & procedure
- Experiences
- Practices of colleagues
- Outcome data

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Issues and Insights to Consider in Products and Services

RG 26

The Practice Arena of Interventional Epidemiologists

RG 27

Handwashing Products or System?

Medicated lotion soap

Education

Monitoring

HICPAC Guidelines

Hand lotion

Alcohol-based hand sanitizer

Photographs courtesy of Steris, Inc.

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HICPAC Recommendations: Performance Indicators

- *"Periodically monitor and record adherence as the number of hand-hygiene episodes performed by personnel/number of hand-hygiene opportunities, by ward or service. Provide feedback to personnel regarding their performance."*
- *"Monitor the volume of alcohol-based hand rub (or detergent used for handwashing or hand antisepsis) used per 1,000 patient-days."*

Guideline for Hand Hygiene in Health-Care Settings. HICPAC, MMWR, October, 2004.

RG 29

Value-Added Programs

- Provide an additional resource which benefits institution, e.g. regulatory compliance
- Steris *Partners in Your Care* program
  - Empowers patient not employee
  - Aim is to change behavior in employee
  - Study indicates increase in handwashing of 34% [1]
  - Facility provides handwashing soap and alcohol based sanitizer usage data and patient days; Univ. of Pennsylvania calculates usage.

[1] McGuckin M, et al. Patient education model for increasing handwashing compliance. AJIC 1999;27:309-14.

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Don't be shy!

Your healthcare workers are interested in your care and will expect you to ask them about hand hygiene!

PARTNERS IN YOUR CARE℠ PROGRAM

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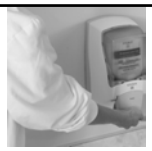
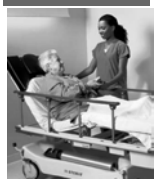
Penn STERIS



Facts About Hand Hygiene…

- Hand Hygiene is the single most important procedure that is performed in the hospital for preventing the spread of infection to you, the patient.
- Germs that cause infections can be spread in a number of ways. The most common is through hands. Hand hygiene removes germs from the hands and helps protect YOU from infections.

"Did you wash / sanitize your hands?"



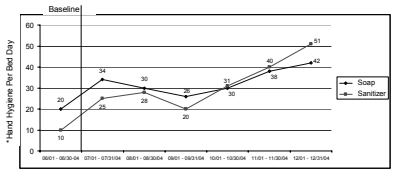
PARTNERS IN YOUR CARE℠ PROGRAM

Hospital Name

Penn STERIS

SAMPLE

Medical Center
June 1 – December 31, 2004
Location: 4 South



*The number of times hand hygiene occurred in a 24 hour period when there was a patient in the bed.

Dr. McGuckin Summary/Comments:

Current Month's Percent Increase from Baseline: 72%

Benchmark Compliance – Hand hygiene per bed day rate for similar hospitals:

Soap: 48 Sanitizer: 63

Chlorhexidine Skin Antisepsis

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Results of Trial of Three Antiseptics

Source of Septicemia	10% Povidone-iodine (*n* = 227)	70% Alcohol (*n* = 227)	2% CHG (*n* = 214)
Catheter-related	6	3	1
Contaminated:			
Infusate	0	3	0
Hub	1	0	0
All sources (%)	7 (3.1)	6 (2.6)	1 (0.5)*

668 patients with either central venous or arterial catheters.

***Compared with the other two groups combined: OR=0.16, 95% CI 0.30-1.17, p=.04**

Maki et al. Prospective randomized trial of povidone-iodine, alcohol, and chlorhexidine for the prevention of infection associated with central venous and arterial catheters. Lancet 1991:338:339-343.

RG 34

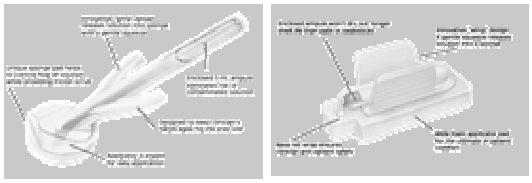
Meta-Analysis on CHG vs. PI

- Reviewed eight randomized, controlled trials involving a total of 4,143 catheters (peripheral venous, peripheral arterial, pulmonary arterial, PICC, introducer sheaths, hemodialysis).
- The summary risk ratio for CRBSI for all catheters was 0.49 indicating *"a significantly reduced risk in patients using chlorhexidine gluconate."*

Chaiyakunapruk N, et al. Chlorhexidine compared with povidone-iodine solution for vascular catheter-site care: A meta-analysis. Ann Intern Med 2002;136:792-801.

RG 35

CHG Standardization



BUMC converted 7 povidone-iodine products (solution, swabs, wipes, etc.) to 2 70% alcohol-2% chlorhexidine products.

RG 36

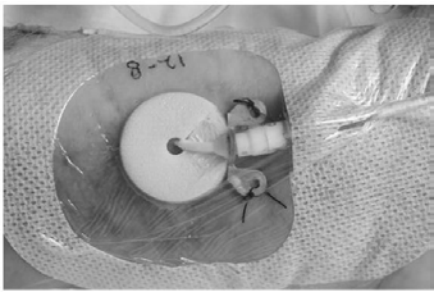
Blood Culture Skin Prep

- CHG has been equated with PI with low rates of blood culture contamination
- Study whereby BCs were drawn by MDs and phlebotomists
  - CHG rate: 0.5%
  - PI rate: 1.4%

Trautner BW, et al. Skin antisepsis kits containing alcohol and chlorhexidine gluconate or tincture of iodine are associated with low rates of blood culture contamination. ICHE 2002;23:397-401.

RG 37

Chlorhexidine-impregnated Patch



Photograph courtesy of Johnson & Johnson

RG 38

Is a CHG Patch Effective?

- Bacterial inhibition [1]
  - Study to assess the activity of CHG foam against primary organisms, including antibiotic-resistant, causing intravascular-related infections
  - Zones of inhibition were observed for all test organisms including MRSA, VRE, Candida, and P. aeruginosa.
- Preventing Bacteremia [2]
  - Controlled, randomized, multi-center trial
  - 24 CRBSIs in 736 pts in control group
  - 8 CRBSIs in 665 pts Biopatch group
  - Conclusion: significant reduction using CHG-impregnated patch (RR 0.38)

Bhende S, et al. In vitro assessment of chlorhexidine gluconate-impregnated polyurethane foam antimicrobial dressing using zone of inhibition assays. ICHE 2004;25:664-67.

Maki DG, et al. The efficacy of a chlorhexidine-impregnated sponge (Biopatch) for the prevention of of intravascular catheter-related infection – a prospective, randomized, controlled, multicenter study. 40th ICAAC Conference, Sep 2004, Toronto, Canada.

RG 39

Is a CHG Patch Cost Beneficial?

- Analysis comparing the costs with benefits of using a CHG impregnated sponge on CVCs to determine effectiveness of reducing BSI, costs, mortality
- Decision model assuming sponge cost of $7.50, BSI cost of $8,000 – $25,000, sponge effectiveness of 60%, and mortality of 1 – 5%
- Results:
  - Avoided costs per pt.: $237.76 - $964.86
  - Avoided costs, nationally: $275m – $1.97b
  - Decreases in mortality: 329-3,906 patients per year

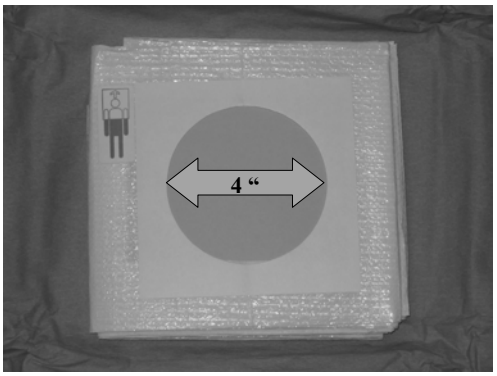
Crawford AG, et al. Cost-benefit analysis of chlorhexidine gluconate dressing in the prevention of catheter-related bloodstream infections. ICHE 2004;25:668-74.

RG 40

Large Sterile Drape

Drape size approx. 5’ (60”) long x 4’ (48”) wide

RG 41



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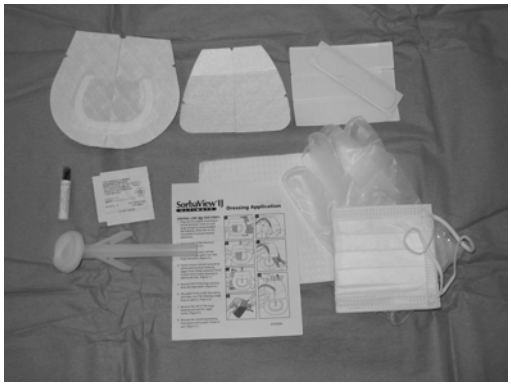
RG 45



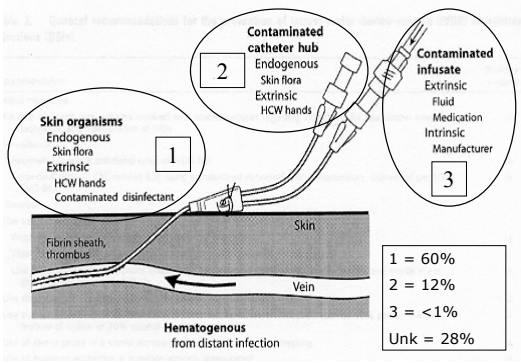
RG 46

Sterile Barriers: Economic Incentives

- Cost-effectiveness analysis using a decision model
- Calculated total direct medical costs and incidences of CR-BSI
- Results:
  - Lowered costs from $621 to $369 per catheter
  - Lowered CRBSI from 5.3% to 2.8%
  - Lowered death from 0.8% to 0.4%

Hu KK, et al. Use of maximal sterile barriers during central venous catheter insertion: clinical and economic outcomes. Clin Infect Dis 2004;39:1441-5.

RG 47



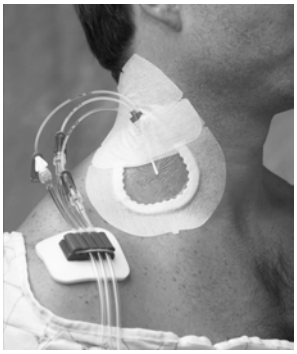
Safdar N, Maki DG. The pathogenesis of catheter-related bloodstream infection with noncuffed short-term central venous catheters. Int Care Med 2004;30:62-7.

Does the Dressing Matter?

	# Pts.	# LD	# Observ. Days	# Dressings Peeled	% peeled	# CRBSI
Prod. A	120	1227	345	180	52.2	6
Prod. B	117	1220	338	44	13.0	2

Study conducted at Brookdale University Medical Center; Population included adult patients with a central venous catheter; Product A & B are both transparent dressings; Similar percent by site in both groups (femoral, subclavian, jugular); Observations of site conducted on days 1,3,5 after application; dressing policy – replace as needed; unpublished data.

RG 49



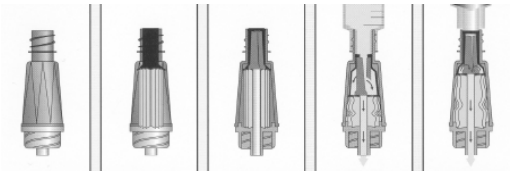
Dressings that better conform to a patient's anatomy; photo courtesy of Tri-State Hospital Supply, Inc.

RG 50

Needleless IV Connectors

RG 51

Positive Displacement Valves



Figures courtesy of Baxter Healthcare, Inc.

RG 52

Needleless IV Connectors: In Vitro Studies Indicating No Increased Contamination

- Arduino MJ, et al. Microbiologic evaluation of needleless and needle-access devices. AJIC 1997; 25:377-80.
- Brown JD, et al. The potential for catheter microbial contamination from a needleless connector. J Hosp Infect 1997;36:181-9.
- Yebenes JC, e al. Resistance to the migration of microorganisms of a needle-free disinfectable connector. AJIC 2003;31:462-4.
- Seymour VM, et al. A prospective clinical study to investigate the microbial contamination of a needleless connector. J Hosp Infect 2000;45:165-8.
- Trautman M, et al. Experimental study on the safety of a new connecting device. AJIC 2004;32:296-300.

RG 53

Needleless IV Connectors: In Vivo Studies Indicating No Increased Contamination or Infection

- Mendelson MH, et al. Study of a needless intermittent intravenous-access system for peripheral infusions: analysis of staff, patient, and institutional outcomes. ICHE 1998;19:401-6.
- Casey AL, et al. A randomized, prospective trail to assess the potential infection risk with the PosiFlow needleless connector. J Hosp Infect 2003;54:288-93.
- Bouza E, et al. A needleless closed system device (CLAVE) protects from intravascular catheter tip and hub colonization: a prospective randomized study. J Hosp Infect 2003;54:279-87.
- Yebenes JC, et al. Prevention of catheter-related bloodstream infection in critically ill patients using a disinfectable, needle-free connector: A randomized controlled trial. AJIC 2004;32:291-5.
- Trautman M, et al. Experimental study on the safety of a new connecting device. AJIC 2004;32:296-300.

RG 54

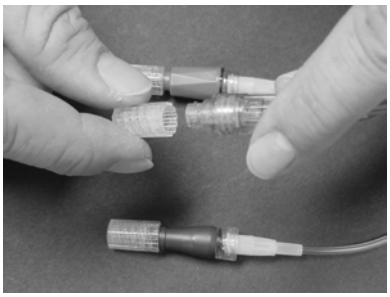
Reports of Possible Contamination or Infection with Use of Needleless Injection Caps

- Danzig LE, et al. Bloodstream infections associated with a needleless intravenous infusion system in patients receiving home infusion therapy. JANA 1995;273:1862-4.
- Cookson ST, et al. Increased bloodstream infection rates in surgical patients associated with variation from recommended use and care following implementation of a needleless device. ICHE 1998;19:23-7.
- McDonald LC, et al. Line-associated bloodstream infections in pediatric intensive-care unit patients associated with needleless device and intermittent intravenous therapy. ICHE 1998;19:772-7.
- Do AN, et al. Bloodstream infection associated with needleless device use and the importance of infection-control practices in the home health care setting. J Infect Dis 1999;179:442-8.

➢ *Most reports indicate a lack of compliance with proper disinfection of connector ports in central venous catheter lines in use for >7 days*

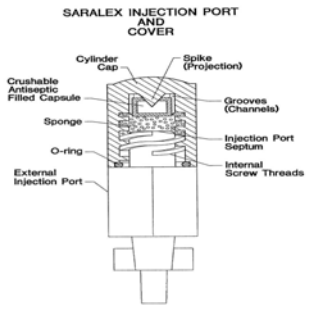
RG 55

Antiseptic-Barrier Cap



Photograph courtesy of Mehyhay Medical, Inc.

RG 56



RG 57

Is it Effective?

	No disinfection (positive controls)	Conventional disinfection with 70% alcohol	Antiseptic-barrier cap
No. needleless hubs studied	15	30	60
No. showing microbial transmission across the membrane	15 (100%)	20 (67%)	1 (1.6%)
No. CFU traversing the membrane, range	4,500-28,000	445-25,000	0-350
p = <0.01			

Menyhay SZ, Maki DG. Abstract. Disinfection of needleless vascular catheter hubs and access ports with alcohol may not prevent microbial entry. APIC Conference, Phoenix, AZ, June 2004.

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Incremental Cost of New Interventions

Item	Description	Incremental cost per item	# items used in 10 days	Total Cost
Maximal sterile barrier kit	Sterile gown, gloves, mask, large drape, dressing components	$7.00	2	$14.00
Dressing kit	Transparent dressing, 2% CHG antiseptic, tincture of benzoin, tape	$2.00	1	$2.00
Skin antiseptic	70% alcohol-2% CHG in 3ml applicator	$0.70	2	$1.40
Antiseptic patch	Chlorhexidine-impregnated patch	$5.00	2	$10.00
Antimicrobial catheter	Silver-platinum catheter	$10.00	2	$10.00
Total incremental cost per patient: →				**$47.40**

Avoided Costs in CRBSI Prevention

A	B	C	D	E	F	G	H
Infection rate	# Expected infections/yr.	Total attributable infection cost	# Infections avoided	Infection cost avoided	Incremental Intervention cost	Total avoided costs (E-F)	# Times infection costs greater than intervention costs (C/F)
10%	84	$3,801,336	XX	XX	XX	XX	XX
9%	76	$3,439,304	8	$362,032	$39,816	$322,216	86.4
8%	67	$3,032,018	17	$769,318	$39,816	$729,502	76.2
7%	59	$2,669,986	25	$1,131,350	$39,816	$1,091,534	67.1
6%	50	$2,262,700	34	$1,538,636	$39,816	$1,498,820	56.8
5%	42	$1,900,668	42	$1,900,668	$39,816	$1,860,852	47.7
4%	34	$1,538,636	50	$2,262,700	$39,816	$2,222,884	38.6
3%	25	$1,131,350	59	$2,669,986	$39,816	$2,630,170	28.4
2%	17	$769,318	67	$3,032,018	$39,816	$2,992,202	19.3
1%	8	$362,032	76	$3,439,304	$39,816	$3,399,488	9.1
# pts.= 840							
Mean attributable cost per CRBSI (CDC) = $45,254							
Total annual Intervention cost = $39,816							

RG 60

Safety Sharps Selection Criteria

- Should minimize or eliminate the risk of a needlestick or other sharps injury to the user during and after use, and during and after disposal
- Should have a reliable safety mechanism that clearly indicates when the mechanism is activated and remains closed even if exposed to reasonable force
- The safety mechanism should be integral to the device.
- Activation preference in order: automatic, one-handed, two-handed
- Preferred that safety mechanism activates before removal from patient

RG 61

Safety Sharps

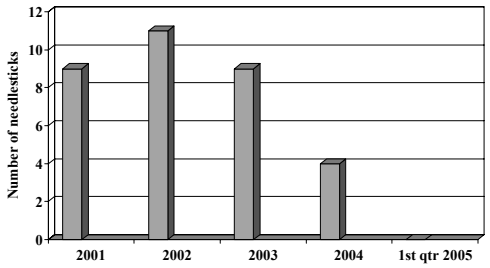
- *….and….*
  - On the current trends and assessment of needlesticks in your institution
  - Example: does the lack of *ease of use* contribute to an increase in needlesticks in that device category?

RG 62

Product B as manufactured by Tyco Kendall

RG 63

Needlesticks during use of insulin syringes, BUMC



Note: Product A used Jan 2001-Sep 2004; Product B used Oct 2004- March 2005; only 2 needlesticks since conversion to new insulin syringe

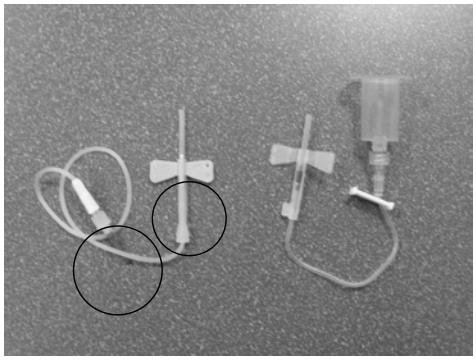
RG 64

Evaluation Results (Final Criteria), Needles & Syringes

I would recommend that this product be purchased by the facility

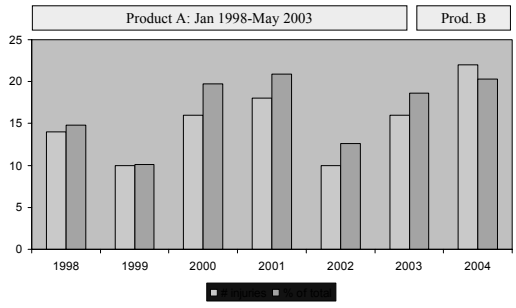
	Toatl respon	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree
11chc	29	0	0	2	8	19
10chc	25	0	0	1	7	17
CCU	9	0	0	0	3	6
9chc	15	0	0	0	4	11
6A	15	0	0	1	1	13
SICU	15	0	0	1	6	8
MICU	21	0	1	2	3	15
NSICU	8	0	0	0	4	4
5chc	13	0	0	1	6	6
Peds	25	0	0	2	13	10
L&D	14	0	1	1	5	7
MBU	5	0	0	0	2	3
NICU	22	0	1	2	10	9
OR	28	0	0	2	15	11
ED	33	0	0	1	14	18
Total #	277	0	3	16	101	157
Percent		0.0	1.1	5.8	36.5	56.7

RG 65



RG 66

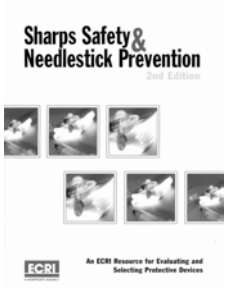
Butterfly-related Sharps Injuries, BUMC



RG 67

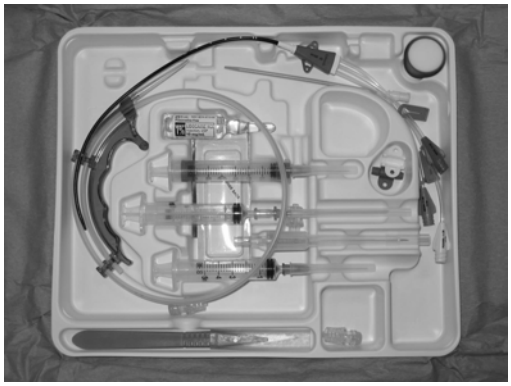
Sharps Evaluation Process

- Provides comparative products
- Objective ratings based on set criteria
- Provides guide for establishing and evaluating a sharps injury program



RG 68

RG 69



RG 70

Device Category	Device Used	ECRI Rating
Arterial blood gas syringes	Anaerobic Pulsator (Portex)	Not rated
Blood collection needle sets (Butterflys)	Saf-T Wing, (Portex)	Acceptable
Blood collection needles and tube holders	Safety Blood Collection Device (Tyco Kendall)	Not rated
Disposable syringes and injection needles	Monoject Magellan Safety Needle (Tyco Kendall)	Acceptable
Disposable PPD-Tuberculin Syringes	Monoject Tuberculin or PPD Syringes (Tyco Kendall)	Acceptable
Flush Syringes	Monoject Prefill IV Flush Syringes (Tyco Kendall)	*IV flush devices not evaluated*
Hemodialysis needle sets	MasterGuard Hemodialysis Fistula Needle Set (MediSystems)	Preferred
Huber needles	Safe Step, (MDC)	Not rated
Introducer needles	Insyte Autoguard (BD)	Not rated
Lancets (fingerstick, adults)	Unistik 2 (Owen-Mumford)	Not rated
Lancets (heelstick, neonates)	Microtainer Quickheel Premie Lancet (BD)	Acceptable
Needleless IV Systems	PosiFlow IV Access System (BD); Clearlink IV Access System (Baxter)	Acceptable
Peripheral Intravenous catheters	Insyte Autoguard (BD)	Acceptable
Scalpels	Futura Safety Scalpel (Portex)	Preferred
Suture needles	BP Series Ball Point Suture Needle (US Surgical)	Not rated
Vial Access devices	Tyco Kendall Monoject Bluntip Safety IV Access System	*Vial access systems not evaluated*

Outsourcing Sharps Collection

Photograph courtesy of Biosystems

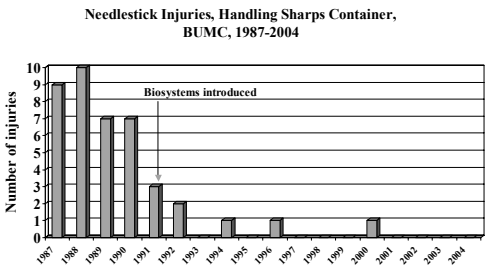
RG 72

Benefits of Outsourcing Sharps Collection

- Uniform system throughout facility
- Reduces labor
- Environmentally friendly
- Sanitized containers
- Increases storage space by reducing container storage
- Bar code tracking
- Reduces needlesticks in employees
- Reduces liability

RG 73

Reducing Sharps Injuries During Disposal Container Collection

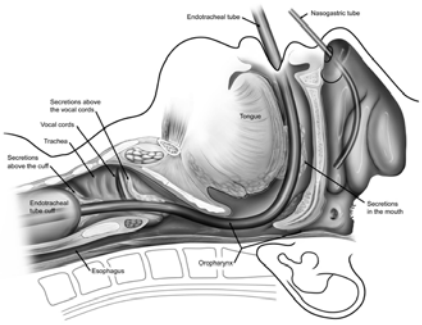


RG 74

Preventing VAP: A New Strategy

- Do all of these strategies address a root cause?
  - Replacing vent circuits on a routine basis
  - Use of HME filters
  - Use of closed suction
  - Raising the head of the bed
  - Stress ulcer prophylaxis
  - Selective digestive decontamination
  - Weaning

RG 75



RG 76

1. Oral Cavity vs. Gastric Colonization

- Prospective study of 86 mechanically vented ICU patients to assess relationship between oropharyngeal colonization and subsequent occurrence of pneumonia
- Patients oral and gastric specimens were collected on admission and twice weekly
- When pneumonia suspected, bronchoscopic specimens were taken with protected specimen brush
  - In 31 cases of pneumonia identified, DNA genomic analysis demonstrated that oropharyngeal colonization was the predominant factor in the development of pneumonia compared with gastric colonization

Garrouste-Orgeas M, et al. Oropharyngeal or gastric colonization and nosocomial pneumonia in adult intensive care unit patients. A prospective study based on genomic DNA analysis. *Am J Respir Crit Care Med* 1997;156:164

RG 77

Acquired bacterial colonization: Location of the microorganisms in the 44 carrier patients

Colonizing microorganisms	Patients with OC	Patients with GC	Patients with BC	Colonized patients
A. baumanii	7	0	1	8
K. Pneumoniae	12	0	3	15
Enterobacteriaceae	9	5	8	22
Psuedomonadaceae	8	2	1	11
S. aureus	17	0	3	20
Enterococcus sp.	2	1	1	4
Total	**22**	**5**	**17**	

Garrouste-Orgear M, et al. Am J Resp Crit Care Med 1997.

Oropharyngeal rather than gastric colonization: further support

- Kerver AJ, et al. Colonization and infection in surgical intensive care patients – a prospective study. Intensive Care med 1987;13:347-51.
- Bonten MJM, et al. Risk factors for pneumonia, and colonization of respiratory tract and stomach in mechanically ventilated ICU patients. Am J Resp Crit Care Med 1996;154:1339-46.
- Ewig S, et al. Bacterial colonization patterns in mechanically ventilated patients with traumatic head injury. Am J Resp Crit Care Med 1999;158:188-98.

RG 79

2. Decontamination of the Oropharynx

- Prospective, randomized, double blind study of ICU patients to determine VAP while manipulating oropharyngeal colonization and without influencing gastric or intestinal colonization
- 87 given topical antibiotics (study group), 139 given placebo (control group)
- Results:
  - VAP in study group: 10%
  - VAP in control group: 27%

Bergmans D, et al. Prevention of ventilator-associated pneumonia by oral decontamination. Am J Resp Crit Care Med 2001;164:382-88.

RG 80

Additional Studies and Reviews using Antibiotic Pastes or Solutions

- Rodriguez-Roldan JM, et al. Prevention of nosocomial lung infection in ventilated patients: use of an antimicrobial nonabsorbable paste. Crit Care Med 1990;18:1239-42.
- Pugin J, et al. Oropharyngeal decontamination decreases incidence of ventilator-associated pneumonia: a randomized, placebo-controlled, double-blind clinical trial. J Am Med Assoc 1991;265:2704-10.
- Bonten MJ, et al. Role of colonization of the upper intestinal tract in the pathogenesis of ventilator-associated pneumonia. Clin Infect Dis 1997;24:309-19.

RG 81

3. Oral Decolonization: Use of Chlorhexidine

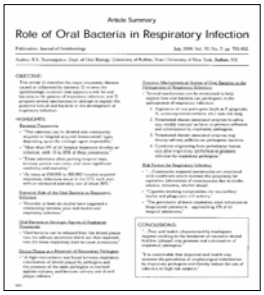
- Prospective, randomized, double-blind, placebo-controlled trial testing the effectiveness of oral decontamination on nosocomial infection
- 353 pts undergoing coronary bypass surgery
- Used chlorhexidine gluconate (0.12%) as oral rinse to prevent nosocomial infections
- Randomized to receive CHG or placebo
- Results:
  - Overall reduction in nosocomial infections of 65% when using CHG
  - Respiratory infections were reduced 69% in CHG group

DeRiso AJ II, Ladowski JS, Dillon TA, Justice JW, Peterson AC. Chlorhexidine gluconate 0.12% oral rinse reduces the incidence of total nosocomial respiratory infection and non-prophylactic systemic antibiotic use in patients undergoing heart surgery. *Chest* 1996;109:1556-61.

RG 82

4. Link Between Oral Pathogens & Respiratory Infection

- A review article
- 6 articles cited as support for a relationship between poor oral health and respiratory infection
- Bacteria from colonized dental plaque may be aspirated into the lower airway


Article Summary

Role of Oral Bacteria in Respiratory Infection

Scannapieco, FA. Role of oral bacteria in respiratory infection. J Periodontol 1999;70:794-802

RG 83

5. Dental Plaque as a Bacterial Source of VAP

- Study on dental plaque colonization and ICU nosocomial infs.
- 57 patients studied
- Results:
  - Dental plaque occurred in 40% of pts.
  - Colonization of dental plaque was highly predictive of nosocomial infection
  - Salivary, dental, and tracheal aspirates cultures were closely linked

Fourrier E, et al. Colonization of dental plaque: a source of nosocomial infections in intensive care patients. Crit Care Med 1998;26:301-8.

RG 84

Additional Evidence Linking Colonized Dental Plaque and Respiratory Infection

- Scannapieco FA, et al. Colonization of dental plaque by respiratory pathogens in medical intensive care patients. Crit Care Med 1992;20:740-45.
- Fitch JA, et al. Oral care in the adult intensive care unit. Am J Crit Care 1999;8:314-18.
- Sumi Y, et al. Colonization of denture plaque by respiratory pathogens in dependant elderly. Gerontolog 2002;9:25-9.
- Russel SL, et al. Respiratory pathogen colonization of the dental plaque of institutionalized elders. Spec Care Dentist 1999;19:128-34.

RG 85

Reduction of Microbial Colonization in the Oropharynx and Dental Plaque Reduces Ventilator-Associated Pneumonia.

R. Garcia, L. Jendresen, L. Coldren. Brookdale University Medical Center (BUMC), Brooklyn, NY.

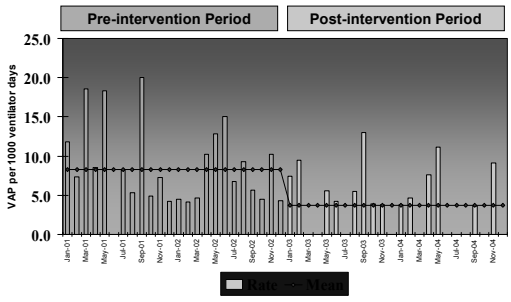
Abstract

Background

86

RG 87

VAP Rates, MICU, BUMC, 2001-2004

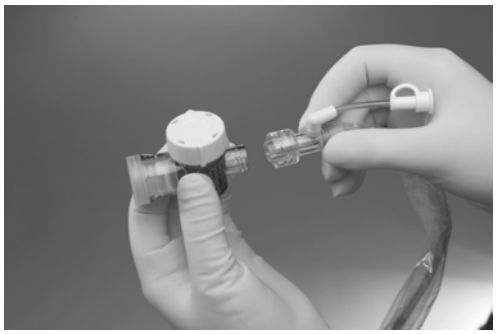


RG 88

Closed Suction Devices

Photograph courtesy of C.R. Bard

RG 89



Photograph courtesy of C.R. Bard

RG 90

Closed Suction Catheter Replacement

- Manufacturers: replace at 24 hours
- HICPAC:
  - *No recommendation can be made about the frequency of routinely changing the in-line suction catheter of a closed-suction system in use on one patient.* (Unresolved issue)
- Kollef MH, Prentice D, Shapiro SD, Fraser VJ, Silver P, Trovillion E, et al. Mechanical ventilation with or without daily changes of in-line suction catheters. Am J Resp Crit Care Med, 1997;156:466-72

RG 91

Closed Suction Cost Analysis

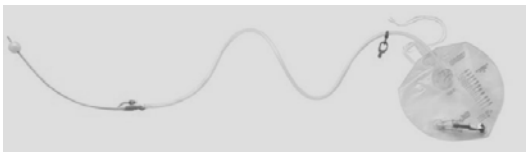
Product (Endotracheal tube model)	1-day cost	3-day cost	5-day cost	7-day cost
Current	$6.95	$20.85	$34.75	$48.65
Proposed	$7.50	$19.50	$31.50	$43.50
Savings with proposed device		$1.35	$3.25	$5.15

If you use 6,000 units per year with 3-day replacement policy:

Current = $125,100; Proposed = $117,000; **SAVINGS PER YEAR = $8,000**

RG 92

Urinary Catheters



RG 93

Cost of a Catheter-associated UTI

- What are the direct costs of a nosocomial catheter-associated UTI (CAUTI)?
  - Prospective study of 1,497 patients
  - Daily cultures reviewed by author (MD)
  - In 123 CAUTIs, $20,662 in extra lab costs, $35,872 in extra medication costs = avg. of $589 (1998 dollars)
  - *However, urine in collection bags has the largest reservoir of multi-antibiotic resistant pathogens*

Tambyah PA, et al. The direct costs of nosocomial catheter-associated urinary tract infection in the era of managed care. ICHE 2002;23:27-31.

RG 94

Do Silver Urinary Catheters Reduce UTIs & are they Cost Effective?

- Prospective study in 10 patient care units
- 2 24 month periods; >48,500 catheter days
- Use of silver catheters decreased rate from 6.13 to 2.62/1000 catheter days.
- Cost Analysis (low range):
  - 110 UTIs x $666 (cost of UTI)
  - + 110 UTIs x 0.02 (percent bacteremia) x $2041 (cost of bacteremia)
  - – $64,281 (additional cost of silver catheters)
  - = $13,469

Rupp ME. Effect of silver-coated urinary catheters: efficacy, cost-effectiveness, and antimicrobial resistance. AJIC 2004;32:445-50.

RG 95

Brushless Surgical Scrubs

RG 96

Are Brushless Surgical Scrubs the Way to Go?

- Replacement of impregnated surgical scrub brushes with antimicrobial solutions
- *The question is not if the new product is effective, but are we replacing a bad habit?*
- Surgeons in general are meticulous about surgical scrub because it is ingrained in them
- If we change to a similar practice as routine handwash, will we have compliance rates as we do now with routine handwash?
- In the end, does a facility replace or supplement?

RG 97

Summary

- Every procedure in healthcare involves the use of a product
- If Infection Control is not involved in the decision making process, the decision must be questioned
- A step-by-step process for product evaluation ultimately yields the greatest benefit to the institution
- Always question, never accept that it works for your institution
- *Make it fun!!!*

RG 98

Thank You for Your Support!

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RG 99

The Next Few Teleclasses

May 18	***Antibiotic Prescribing Practices*** … with Dr. Dick Zoutman
May 25	***Infection Control in the Cruise Ship Industry*** … with Dr. Robert Wheeler
June 1	***Infection Control in Healthcare Construction*** ... with Dr. Andrew Steifel
June 8	***Zoonosis from Companion Animals & Pets*** … with Dr. Corrie Brown

For the full teleclass schedule – www.webbertraining.com