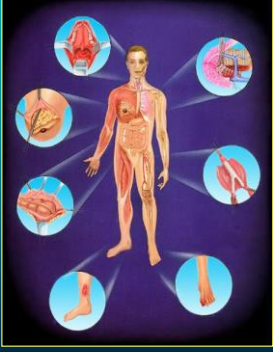



## Moving Beyond SCIP: Development of an Evidence-Based Surgical Bundle to Improve Patient Outcome



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## Froedtert Hospital Infection Control Team 2013 – 2014

**Chairman, Infection Control Committee**  
Mary Beth Graham, MD

**Infection Control Coordinators**  
Pati Wilson, BSN, CIC  
Pat Sadenwasser, BSN, CIC  
Mary Jane Dorava, BSN, CNOR

**Microbiologists**  
Nathan Ledebor, PhD, D-ABMM  
Candy Krepel, MS, SM-ASCP

**Hospital Epidemiologist**  
Charles Edmiston, PhD, CIC

**Administrative Support**  
Donna Weiler, CMSM



### CALIFORNIA

Learn how your hospital is preventing infections: [www.medicare.gov/hospitalcompare](http://www.medicare.gov/hospitalcompare)  
For more information:  
• 2012 HAI Progress Report: [www.cdc.gov/hai/progress-report/](http://www.cdc.gov/hai/progress-report/)  
• Preventing HAIs: [www.cdc.gov/hai](http://www.cdc.gov/hai)  
• NHCES: [www.cdc.gov/nhc](http://www.cdc.gov/nhc)  
• HAI in California: [www.cdph.ca.gov/hai](http://www.cdph.ca.gov/hai)

**HEALTHCARE ASSOCIATED INFECTIONS PROGRESS**

**HEALTHCARE ASSOCIATED INFECTION (HAI) DATA** gives healthcare facilities and public health agencies knowledge to design, implement, and evaluate HAI prevention efforts.

**WHAT IS THE STANDARDIZED INFECTION RATIO?**

The standardized infection ratio (SIR) is a statistic used to track healthcare-associated infection prevention progress over time. The SIR for a facility or state is adjusted to account for factors that might cause infection rates to be higher or lower, such as hospital size, teaching status, the type of patients a hospital serves, and surgery and patient characteristics.

✓ In some cases, states that work to validate, or double check, HAI data may have higher SIRs since they are actively looking for infections.

**WHAT DOES THE STANDARDIZED INFECTION RATIO MEAN?**

**IF THE STATE SIR IS:**

**1** There were more infections reported in the state in 2012 compared to the national baseline data, indicating there has been an increase in infections.

**1** There were about the same number of infections reported in the state in 2012 compared to the national baseline data, indicating no progress has been made.

**1** There were fewer infections reported in the state in 2012 compared to the national baseline data, indicating progress has been made in preventing infections.

**WHAT IS CALIFORNIA DOING TO PREVENT HEALTHCARE ASSOCIATED INFECTIONS?**

California is one of 10 state health departments participating in CDC's Emerging Infections Program, which allows for extra surveillance and research of HAIs. California has a state mandate to publicly report at least one HAI to NCHS.

California has several prevention efforts (known as prevention collaboratives) to reduce specific HAIs, including:

- Central line-associated bloodstream infections
- Catheter-associated urinary tract infections
- Clostridium difficile, steady diarrheal infections
- MRSA infections
- Ventilator-associated pneumonia infections

California implemented prevention efforts in dialysis facilities, and to improve antibiotic stewardship.

\* See [www.medicare.gov/hospitalcompare](http://www.medicare.gov/hospitalcompare) for more information on hospital infection rates, hospital size, and other factors that affect infection rates.

THIS REPORT IS BASED ON 2012 DATA, PUBLISHED MARCH 2014

NUMBER OF CALIFORNIA HOSPITALS THAT REPORTED DATA TO CDC'S NSIS IN 2012 Total hospitals: 41*		STATE SIR	NAT'L SIR
CLABS 302 hospitals	California's 2012 state CLABS SIR is significantly better than the 2012 national SIR.	0.53	0.56
CAUTI 338 hospitals	California's 2012 state CAUTI SIR is significantly better than the 2012 national SIR.	0.85	1.03
SSI, colon surgery 317 hospitals	California's 2012 state colon surgery SSI SIR is significantly better than the 2012 national SIR.	0.70	0.80
SSI, Abdominal hysterectomy 309 hospitals	California's 2012 state Abdominal hysterectomy SSI SIR is similar to the 2012 national SIR.	0.77	0.89

### WISCONSIN

Learn how your hospital is preventing infections: [www.medicare.gov/hospitalcompare](http://www.medicare.gov/hospitalcompare)  
For more information:  
• 2012 HAI Progress Report: [www.cdc.gov/hai/progress-report/](http://www.cdc.gov/hai/progress-report/)  
• Preventing HAIs: [www.cdc.gov/hai](http://www.cdc.gov/hai)  
• NHCES: [www.cdc.gov/nhc](http://www.cdc.gov/nhc)  
• HAI in Wisconsin: [www.dhs.wisconsin.gov/communicable/hai/index.htm](http://www.dhs.wisconsin.gov/communicable/hai/index.htm)

**HEALTHCARE ASSOCIATED INFECTIONS PROGRESS**

**HEALTHCARE ASSOCIATED INFECTION (HAI) DATA** gives healthcare facilities and public health agencies knowledge to design, implement, and evaluate HAI prevention efforts.

**WHAT IS THE STANDARDIZED INFECTION RATIO?**

The standardized infection ratio (SIR) is a statistic used to track healthcare-associated infection prevention progress over time. The SIR for a facility or state is adjusted to account for factors that might cause infection rates to be higher or lower, such as hospital size, teaching status, the type of patients a hospital serves, and surgery and patient characteristics.

✓ In some cases, states that work to validate, or double check, HAI data may have higher SIRs since they are actively looking for infections.

**WHAT DOES THE STANDARDIZED INFECTION RATIO MEAN?**

**IF THE STATE SIR IS:**

**1** There were more infections reported in the state in 2012 compared to the national baseline data, indicating there has been an increase in infections.

**1** There were about the same number of infections reported in the state in 2012 compared to the national baseline data, indicating no progress has been made.

**1** There were fewer infections reported in the state in 2012 compared to the national baseline data, indicating progress has been made in preventing infections.

**WHAT IS WISCONSIN DOING TO PREVENT HEALTHCARE ASSOCIATED INFECTIONS?**

Wisconsin has several prevention efforts (known as prevention collaboratives) to reduce specific HAIs, including:

- Central line-associated bloodstream infections
- Catheter-associated urinary tract infections
- Surgical site infections
- Clostridium difficile, steady diarrheal infections
- Carbapenem-resistant Enterobacteriaceae infections

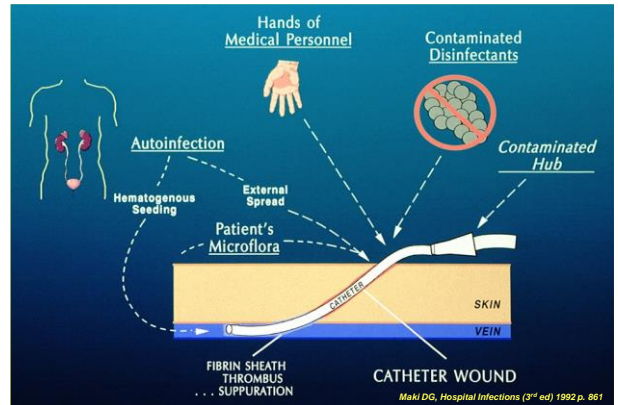
Wisconsin implemented prevention efforts in long-term care facilities and dialysis facilities.

\* See [www.medicare.gov/hospitalcompare](http://www.medicare.gov/hospitalcompare) for more information on hospital infection rates, hospital size, and other factors that affect infection rates.

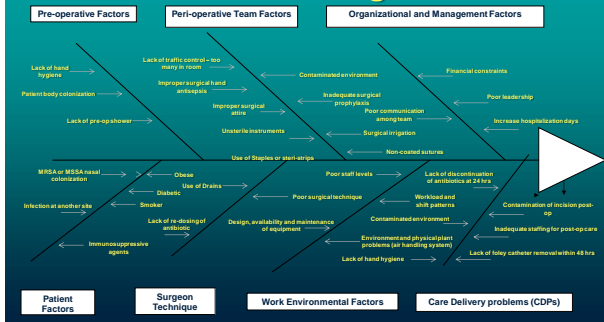
THIS REPORT IS BASED ON 2012 DATA, PUBLISHED MARCH 2014

NUMBER OF WISCONSIN HOSPITALS THAT REPORTED DATA TO CDC'S NSIS IN 2012 Total hospitals: 44*		STATE SIR	NAT'L SIR
CLABS 78 hospitals	Wisconsin's 2012 state CLABS SIR is significantly better than the 2012 national SIR.	0.45	0.56
CAUTI 89 hospitals	Wisconsin's 2012 state CAUTI SIR is significantly better than the 2012 national SIR.	0.79	1.03
SSI, colon surgery 77 hospitals	Wisconsin's 2012 state colon surgery SSI SIR is similar to the 2012 national SIR.	0.83	0.80
SSI, Abdominal hysterectomy 71 hospitals	Wisconsin's 2012 state Abdominal hysterectomy SSI SIR is similar to the 2012 national SIR.	0.97	0.89

**“Risk Reduction Requires an Understanding of the Mechanistic Factors which Potentiate the Risk of Infection in the Surgical Patient Population”**



**Risk is a Myriad Event - SSI Fishbone Diagram**



**A More Than a Typical Scenario – What is the True Risk of Infection?**

**High Risk Patient:**

- Immunosuppressive meds - RA
- Diabetes
- Advanced age
- Prior surgery to same joint
- Psoriasis
- Malnourished
- morbid obesity
- sAlb < 35
- low sTransferrin
- Remote sites of infection
- Smokers
- ASA ≥ 3



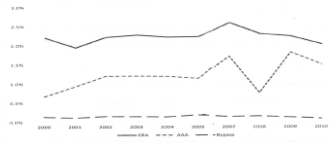


## National Inpatient Sample – AHRQ 2000 – 2010 study period (1 year hiatus period – 2006)

Table 2. Breakdown of surgical site infections by year between 2000-2005 and 2007-2010 for patients who underwent vascular endovascular, elective repair of an aortic abdominal aortic aneurysm, and peripheral bypass. Posttest values between 2000-2005 and 2007-2010 were compared using Chi-squared with Yates correction with 5% significance (P).

	2000	2001	2002	2003	2004	2005	2007	2008	2009	2010
SSI	496	584	457	611	568	500	854	738	700	551
CAA	16,250	15,700	16,550	16,050	16,554	15,183	15,888	14,189	13,534	12,311
%	2.3%	3.7%	2.7%	3.7%	3.4%	3.3%	5.3%	5.2%	5.1%	4.5%
AAA	121	127	90	177	100	111	20	20	82	17
Total	6,572	6,369	4,558	6,859	6,154	5,570	8,516	8,937	8,300	5,783
%	0.7%	0.6%	0.5%	0.8%	0.7%	0.6%	1.2%	1.2%	1.0%	0.6%
LOS	42	43	44	44	44	40	30	30	24	19
Repeat	16,517	16,190	16,470	16,400	16,450	15,166	16,510	14,941	14,300	13,485
%	0.3%	0.3%	0.3%	0.3%	0.3%	0.2%	0.3%	0.3%	0.3%	0.3%

- 437,420 vascular procedures
- Infection rate - 1.5%
- No significant difference pre and post-SCIP



Dua, Desai, Edmiston and Lee. Submitted 2014 JAMA

## Pre / Post-SCIP ERA

Table 3. Demographics and outcomes for patients who underwent CEA, elective AAA repair, or bypass separated by the development of an SSI in the ER from 2000-2005.

	CEA - SSI	CEA - No SSI	AAA - SSI	AAA - No SSI	Bypass - SSI	Bypass - No SSI
N	212	172,028	511	30,205	2,049	126,483
Age	71 yf 10	71 yf 9	72 yf 8	72 yf 8	67 yf 10	68 yf 12
Female	61%	62%	20%	23%	56%	61%
Caucasian	80%	80%	80%	81%	73%	74%
COVD	21%	20%	41%	37%	28%	25%
IMA	21%	15%	1%	1%	17%	24%
LOS	17	7	7	7	17	6
Industrial Mortality	51%	5%	33%	6%	7%	3%
Total Charges	\$84,870	\$15,139	\$102,976	\$41,093	\$69,877	\$30,253

- No significant difference in morbidity or mortality
- No significant difference in LOS
- Patient care costs for managing infected cases have increased ~ 60%

Table 4. Demographics and outcomes for patients who underwent CEA, elective AAA repair, or bypass separated by the development of an SSI in the ER from 2007-2010.

	CEA - SSI	CEA - No SSI	AAA - SSI	AAA - No SSI	Bypass - SSI	Bypass - No SSI
N	614	51,302	518	5,123	1,241	10,812
Age	70 yf 10	71 yf 10	71 yf 9	71 yf 9	66 yf 14	67 yf 13
Female	33%	42%	20%	27%	42%	37%
Caucasian	79%	80%	88%	88%	75%	74%
COVD	21%	22%	46%	25%	28%	27%
IMA	24%	16%	1%	1%	17%	24%
LOS	15	3	19	7	15	5
Industrial Mortality	7%	0%	13%	4%	9%	2%
Total Charges	\$140,876	\$23,246	\$155,147	\$65,862	\$112,726	\$49,490

Dua, Desai, Edmiston and Lee. Submitted 2014 JAMA



RESEARCH REPORT  
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### Reducing the Risk of Surgical Site Infections: Did We Really Think SCIP Was Going to Lead Us to the Promised Land?

Chetan E. Edmiston, Jr,<sup>1,2</sup> Muzum Sapani,<sup>3</sup> Brian D. Lewis,<sup>4</sup> Rakhi R. Bhatia,<sup>5</sup> Peter J. Rhee,<sup>6</sup> Cindy H. Heinen,<sup>7</sup> Heidi W. Smith,<sup>8</sup> and Gary H. Sessler<sup>9</sup>

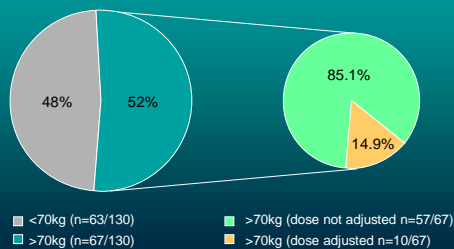
#### Abstract

Background: Surgical site infections (SSIs) are associated with increased patient morbidity and death. It is estimated that 761,000 to 1,000,000 SSIs occur in the U.S. each year, incurring 17 million extra hospital days and costing more than \$2.6 billion in excess hospital charges. Methods: The Surgical Care Improvement Project (SCIP) was introduced as a “best-practice” strategy to reduce postoperative infection morbidity 20% by 2003. Unfortunately, the evidence suggests that SCIP by itself has had little effect on reducing the overall risk of SSIs. Although the SCIP initiative ultimately is a great product effort for the reducing postoperative infection morbidity and death, it still is considered critical for future efforts to reduce surgical site infections, including implementation of the following strategies: (1) patient selection, (2) antibiotic prophylaxis, (3) hair removal, (4) skin antisepsis, (5) glucose control, (6) normothermia, (7) normoventilation, (8) normohemodynamics, (9) normoglycemia, (10) normocalcemia, (11) normoalbumin, (12) normohemoglobin, (13) normohematocrit, (14) normohemoglobin, (15) normohemoglobin, (16) normohemoglobin, (17) normohemoglobin, (18) normohemoglobin, (19) normohemoglobin, (20) normohemoglobin, (21) normohemoglobin, (22) normohemoglobin, (23) normohemoglobin, (24) normohemoglobin, (25) normohemoglobin, (26) normohemoglobin, (27) normohemoglobin, (28) normohemoglobin, (29) normohemoglobin, (30) normohemoglobin, (31) normohemoglobin, (32) normohemoglobin, (33) normohemoglobin, (34) 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❖ Embracing the Surgical Care Bundle – Selected Elements

❖ Antimicrobial Prophylaxis – Weight-Based Dosing

**Does BMI Increase Risk?**  
Somewhere in Wisconsin - Patient's Weight vs. Dose (N= 520 - pre-SCIP)



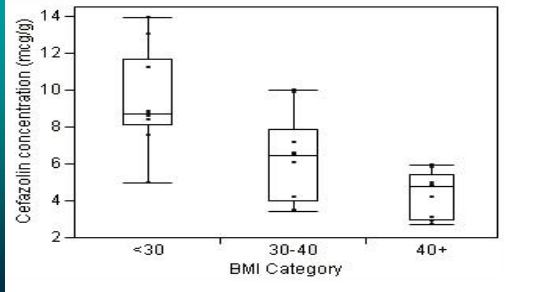
**Does BMI Increase Risk?**  
Perioperative Antimicrobial Prophylaxis in Higher BMI (>40) Patients: Do We Achieve Therapeutic Levels?

Percent Therapeutic Activity of Serum / Tissue Concentrations Compared to Surgical Isolate (2002-2004) Susceptibility to Cefazolin Following 2-gm Perioperative Dose

Organisms	n	Serum	Tissues
<i>Staphylococcus aureus</i>	70	68.6%	27.1%
<i>Staphylococcus epidermidis</i>	110	34.5%	10.9%
<i>E. coli</i>	85	75.3%	56.4%
<i>Klebsiella pneumoniae</i>	55	80%	65.4%

Edmiston et al, Surgery 2004;136:738-747

## Effect of Maternal Obesity on Tissue Concentration Of Prophylactic Cefazolin During Cesarean Delivery



Pevzner L, Edmiston CE, et al. *Obstet & Gynecol* 2011;117:877-882

### ❖ Element 1

All surgical patients will receive a minimum dose of 2 gram unless their BMI is >30 – Then the correct dose is 3 grams (1A pharmacologically – weight adjusted)

#### ASHP REPORT

### Clinical practice guidelines for antimicrobial prophylaxis in surgery

DALE W. BRATZLER, E. PATCHEN ZELLINGER, KEITH M. OLSEN, TRISH M. PERL, PAUL G. AUNAUERTER, MAUREEN K. BOGON, DOUGLAS N. FUSIL, LENA M. NAPSZLETANS, ROBERT G. SAWYER, DOUGLAS SLAIN, JAMES P. STEINBERG, AND ROBERT A. WEINSTEIN

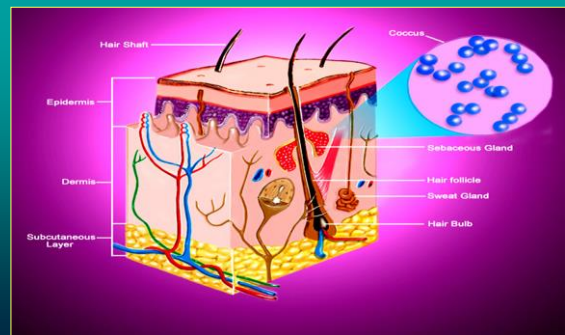
These guidelines were developed jointly by the American Society of Health-System Pharmacists (ASHP), the Infectious Diseases Society of America (IDSA), the Surgical Infection Society (SIS), and the Society for Healthcare Epidemiology of America (SHEA). This work represents an update to the previously published ASHP Therapeutic Guidelines on Antimicrobial Prophylaxis in Surgery, as well as guidelines from IDSA and SIS.<sup>1,2</sup> The guidelines are intended to provide practitioners with a standardized approach to the rational, safe, and effective use of antimicrobial agents for the prevention of surgical site infections (SSIs) based on currently available clinical evidence and emerging trends.

Prophylaxis refers to the prevention of an infection and can be characterized as primary prophylaxis, secondary prophylaxis, or eradication. Primary prophylaxis refers to the prevention of an initial infection; secondary prophylaxis refers to the prevention of recurrence or reactivation of a preexisting infection; eradication refers to the elimination of a colonized organism to prevent the development of an infection. These guidelines focus on primary perioperative prophylaxis.

Guidelines development and use. Members of ASHP, IDSA, SIS, and SHEA were appointed to serve on an expert panel established to ensure the validity, reliability, and utility

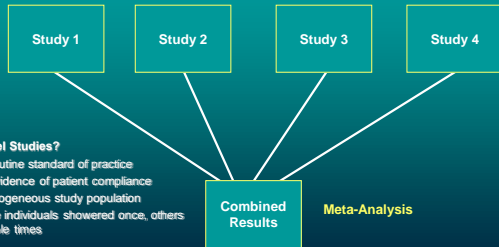
of the revised guidelines. The work of the panel was facilitated by faculty of the University of Pittsburgh School of Pharmacy and University of Pittsburgh Medical Center Drug Use and Disease State Management Program who served as contract researchers and writers for the project. Panel members and contractors were required to disclose any possible conflicts of interest before their appointment and throughout the guideline development process. Drafted documents for each surgical procedural section were reviewed by the expert panel and, once revised, were available for public comment on the ASHP website. After additional revisions were made to address reviewer comments, the final document was

### Risk Reduction Begins on the Front End





## Revisiting the Preadmission (Preoperative) Shower



### 7 Sentinel Studies?

- No routine standard of practice
- No evidence of patient compliance
- Heterogeneous study population
- Some individuals showered once, others multiple times

Webster J, Osborne S. The Cochrane Collaboration. The Cochrane Library, 2009;4:1-34.

## Mean Chlorhexidine Gluconate (CHG) Skin Surface Concentrations ( $\mu\text{g/ml} \pm \text{SD}$ ) Compared to $\text{MIC}_{90}$ (5 $\mu\text{g/ml}$ ) for Staphylococcal Surgical Isolates Including MRSA<sup>a</sup>

Groups	Subgroups (mean C, $\mu\text{g/ml}$ )			[C <sub>CHG</sub> /MIC <sub>90</sub> ]	p-value
	Pilot <sup>b</sup> (4%)	1 (4% Aqueous)	2 (2% Cloths)		
Group A (20) evening (1X)	3.7 $\pm$ 2.5	24.4 $\pm$ 5.9	436.1 $\pm$ 91.2	0.9 4.8 87.2	<0.001
Group B (20) morning (1X)	7.8 $\pm$ 5.6	79.2 $\pm$ 26.5	991.3 $\pm$ 58.2	1.9 15.8 198.2	<0.0001
Group C (20) both (2X)	9.9 $\pm$ 7.1	126.4 $\pm$ 19.4	1745.5 $\pm$ 204.3	2.5 25.3 349.1	<0.0001

<sup>a</sup> N = 90

<sup>b</sup> Pilot group N = 30

Edmiston et al. J Am Coll Surg 2008;207:233-239  
Edmiston et al. AORNJ 2010;92:509-518

## ❖ What is the Evidence-Based Argument?

## Presurgical Skin Preparations as a Pathway to Improving Surgical Outcomes

- Reducing the risk of SSI in orthopaedic surgery
  - Standardized precleansing initiative in total joint patients (night before/morning of surgery)
  - SSI rate prior to intervention – 3.2% (N=727)
  - SSI rate post intervention – 1.6% (N=824) 50% reduction  $p < 0.01$   
*Eiselt – Orthopaedic Nursing 2009;28:141-145*
- Bundling risk reduction strategies – Quality initiative
  - MRSA prescreening in orthopaedic, obstetric, bariatric patients – decolonization
  - Presurgical antisepsis prior to surgery
  - Preintervention SSI rate 1.6% (N=17/1,095) vs postintervention SSI rate 0.57% (N=7/1,225) >60% reduction
  - MRSA SSI rate 0.73% vs 0.16% >75% reduction  $p < 0.01$   
*Lipke VL, Hyatt AS. AORNJ 2010;82:288-296*

### Institutional Prescreening for Detection and CHG Eradication of *Staphylococcus aureus* in Patients Undergoing Elective Orthopaedic Surgery

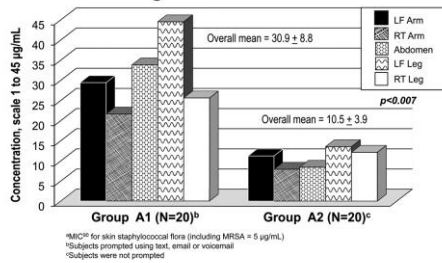
	Study Period 6/2006-9/2007	Control Period 10/2005-6/2006	p value
N	7019	5293	
MRSA Infection	4 (0.06%)	10 (0.18%)	0.0315
MSSA Infection	9 (0.13%)	14 (0.26%)	0.0937
Total SSIs	13 (0.18%)	24 (0.46%)	0.0093

Kim DH, Spencer M, Davidson SM, et al. *J Bone Joint Surg Am* 2010;92:1820-1826

### Measuring Patient Compliance

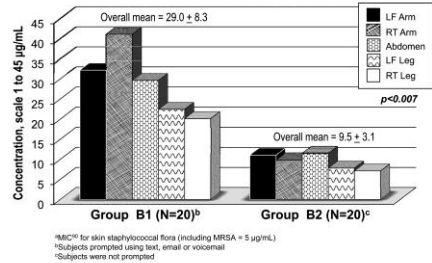
- All patients undergoing elective surgical procedures take 2 CHG preadmission showers/cleansing
- 100 random orthopaedic and general surgical patients queried as to whether or not they complied with preoperative instructions (2012)
- 71 indicated that they had taken two showers/cleansing
- 19 indicated that they took one shower (morning prior to admission 15/19)
- 10 indicated they did not use CHG at all
- Reasons for non-compliance
  - Didn't realize it was that important (institutional failure - communication)
  - Forgot (patient failure - low priority/apathy)
  - Thought one shower would be sufficient (patient - institutional failure)

**Figure 1 Mean Skin Surface Concentration (µg/mL) of 4% Chlorhexidine Gluconate (CHG) Following Two Pre-Admission Showers<sup>a</sup>**



Edmiston et al. *J Am Coll Surg* 2014: On Line

**Figure 2 Mean Skin Surface Concentration (µg/mL) of 4% Chlorhexidine Gluconate (CHG) Following Three Pre-Admission Showers<sup>a</sup>**



Edmiston et al. *J Am Coll Surg* 2014: In Press



#### Standardization of the CHG Preadmission Shower Regimen

The following components should be included in preadmission CHG shower regimens, as part of a comprehensive surgical site infection prevention program.

1. Incorporate methods for reminding patients of the need to complete the shower regimens, using electronic alert systems (i.e., text messaging, emails, voice mails).
2. Emphasize the overall benefits of the preadmission antiseptic shower.
3. Provide both oral and written instructions to patients.
4. Define a precise amount of CHG (mL) used for each shower. Double application is warranted.
- ★ 5. Instruct patients to take a 60-second pause (time-out) prior to rinsing.
6. Tell patient to avoid application of lotions, creams, emollients or perfumes following CHG application. These products may mask or have an adverse pharmacologic effect on antimicrobial activity of the CHG, and may also heighten skin sensitivity.
7. Direct patients to wear loose-fitting garments following CHG application.
8. Advise patients to rinse the CHG product immediately if significant burning or itching occurs, and to report occurrence to their healthcare provider.
9. Instruct patients to keep CHG from the eyes or ears, and if exposed, rinse immediately.
10. Provide the CHG product to patients.
11. Include a telephone contact for patients to call with questions or concerns.

Edmiston et al. J Am Coll Surg 2014. In Press

#### ❖ Element 2

All patients undergoing an elective surgical procedure will take a minimum of 2 CHG antiseptic shower/cleansings using a standardized regimen – The CHG must be provided to the patient by the hospital and the protocol must be enhanced to assure patient compliance (Remember the devil is in the details)

N ENGL J MED 362:1 NEJM.ORG JANUARY 7, 2010

#### ORIGINAL ARTICLE

### Chlorhexidine-Alcohol versus Povidone-Iodine for Surgical-Site Antisepsis

Rabih O. Darouiche, M.D., Matthew J. Wall, Jr., M.D., Kamal M.F. Itani, M.D., Mary F. Otterson, M.D., Alexandra L. Webb, M.D., Matthew M. Carrick, M.D., Harold J. Miller, M.D., Samir S. Awad, M.D., Cynthia T. Crosby, B.S., Michael C. Mosier, Ph.D., Atef AlSharif, M.D., and David H. Berger, M.D.

#### DESIGN: A PROSPECTIVE, RANDOMIZED, MULTICENTER CLINICAL TRIAL OF 2% CHLORHEXIDINE GLUCONATE / 70% ISOPROPYL ALCOHOL (Alc-CHG) VS POVIDONE-IODINE (PI) FOR PREVENTION OF SSI

Multi Center: Michael E. DeBakey Veterans Affairs Medical Center, Ben Taub General Hospital, Houston, Veterans Affairs Medical Center, Boston, Medical College of Wisconsin, Milwaukee, Veterans Affairs Medical Center, Atlanta, Baylor College of Medicine, Houston

- Patients > 18 years, undergoing clean-contaminated procedures (gastrointestinal, thoracic, urologic and gynecologic)
- N = 849 surgical patients: 409 Alc-CHG vs 440 PI
- 1:1 randomization
- Patients monitored for 30 days post-op
- Overall rate of SSI was significantly reduced in Alc-CHG vs PI groups: 9.5% vs 16.1%,  $p=0.004$
- Significant difference for both superficial incisional site rate: 4.2% A-CHG vs 8.6% PI ( $p=0.008$ ) and deep incisional: 1% A-CHG vs 3% PI ( $p=0.05$ )
- No significant adverse events noted during the study in either group
- Alc-CHG superior to PI in reducing the risk of SSI in clean-contaminated procedures

New England Journal of Medicine 2010;362:18-26

## Why Should We Consider Chlorhexidine Gluconate (CHG)?

- Persistent antimicrobial activity for up to 6 hours <sup>1, 5, 6</sup>
- Documented residual activity and repeat applications will maximize antimicrobial effect <sup>2, 5, 6</sup>
- Rapid bactericidal action <sup>3, 5, 6</sup>
- Has good to excellent activity against gram-positive and gram-negative bacteria <sup>4, 5, 6</sup>
- CHG activity is not adversely impacted by either blood or tissue proteins <sup>5, 6</sup>

1. Larson E. *Am J Infect Control*. 1988;16(6):253-65; 2. Paulson D. *Am J Infect Control*. 1993;21:205-9; 3. Denton GW. Chlorhexidine. In Seymour S. Block (Ed.) *Disinfection, sterilization, and preservation*. 4th Ed. Lea & Febiger, Williams & Wilkins, Media PA, 1991:279; 4. Mangram AJ, et al. *Guideline for prevention of surgical site infection, 1999*. Centers for Disease Control and Prevention, Hospital Infection Control Practices Advisory Committee, Atlanta GA.; 5. Edmiston CE et al. *Am J Infection Control* 2007;35:89.; Edmiston CE et al. *Am J Infection Control* 2013;41:S49-S55.

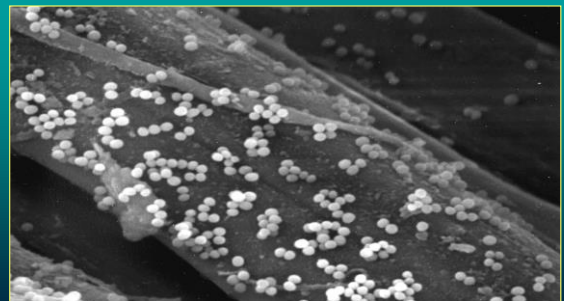
## ❖ Element 3

### Alcohol/chlorhexidine gluconate represents the state-of-the-art skin antiseptic agent (1A)

**Note:** Froedtert services using Alcohol/CHG for skin antiseptics: general, vascular, CT, orthopaedic, urology, neurosurgery, OB/GYN, hepatobiliary, solid organ transplant

## ❖ Is There an Evidence-Based Rationale for Antimicrobial Wound Closure Technology as a Risk-Reduction Strategy?

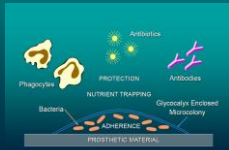
### Adherence of Methicillin-Resistant *Staphylococcus aureus* (MRSA) to Braided Suture



Edmiston et al. *Surgical Microbiology Research Laboratory, Milwaukee* – APIC 2004

## Extrinsic Risk Factor: Bacterial Colonization of Implantable Devices

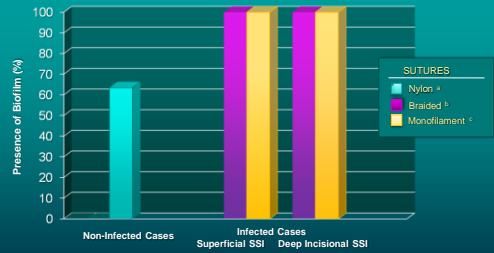
- Sutures are foreign bodies – As such can be colonized by Gram +/- bacteria
- Implants provide nidus for bacterial adherence
- Bacterial colonization can lead to biofilm formation
- Biofilm formation enhances antimicrobial recalcitrance



As little as 100 staphylococci can initiate a device-related infection

Ward KH et al. *J Med Microbiol.* 1992;36: 406-413.  
 Kathju S et al *Surg Infect.* 2009;10:457-461  
 Mangram AJ et al. *Infect Control Hosp Epidemiol.* 1999;27:97-134  
 Edmiston CE, *Problems in General Surgery* 1993;10: 444  
 Edmiston CE, *J Clinical Microbiology* 2013;51:417

## Presence of Biofilm on Selected Sutures from Non-infected and Infected Cases



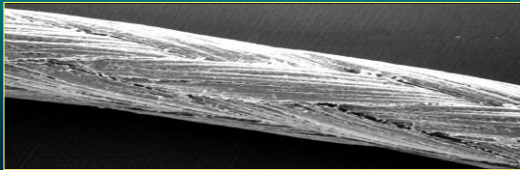
\*non-infected nylon suture segments were randomly selected for microscopy, culture positive  
 †infected braided suture segments were randomly selected for microscopy  
 ‡infected monofilament suture segments were randomly selected for microscopy

Edmiston CE et al., *J Clin Microbiol* 2013;51:417

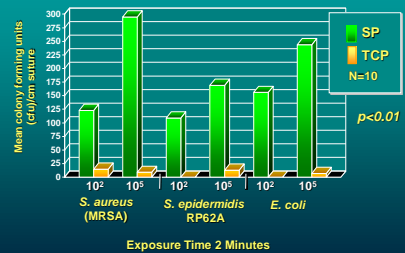
## Utilizing Innovative Impregnated Technology to Reduce the Risk of Surgical Site Infections

### Bacterial Adherence to Surgical Sutures: Can Antibacterial-Coated Sutures Reduce the Risk of Microbial Contamination?

Charles E Edmiston, PhD, Gary R Seabrook, MD, FACS, Michael P Goheen, MS, Candace J Krepel, MS, Christopher P Johnson, MD, FACS, Brian D Lewis, MD, FACS, Kellie R Brown, MD, FACS, Jonathan B Towne, MD, FACS  
*J Am Coll Surg* 2006;203:481-489



## Mean Microbial Recovery from Standard Polyglactin Sutures Compared to Triclosan (Antimicrobial)-Coated Polyglactin Closure Devices



Edmiston et al., *J Am Coll Surg* 2006;203:481-489

# Is there an evidence-based argument for embracing an antimicrobial (triclosan)-coated suture technology to reduce the risk for surgical-site infections?: A meta-analysis

Charles E. Edmiston, Jr PhD<sup>1</sup>, Frederic C. Daoud, MD<sup>2</sup>, and David Leaper, MD, FACS<sup>3</sup>, <sup>1</sup>Missouri, <sup>2</sup>WI, <sup>3</sup>Paris, France, and London, UK

**Background:** It has been estimated that 750,000 to 1 million surgical-site infections (SSIs) occur in the United States each year, causing substantial morbidity and mortality. Triclosan-coated sutures were developed as an adjunctive strategy for SSI risk reduction. There is widely published literature literature review and meta-analysis suggesting that triclosan-coated sutures are associated with this technology. However, that study was hampered by poor selection of available randomized controlled trials (RCTs) and low patient numbers. The current systematic review involves 17 randomized, controlled RCTs, totaling 1,560 surgical patients.

**Methods:** A systematic literature search was performed on PubMed, Embase/Medline, Cochrane Database Group (Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Health Economic Evaluation Database/Database of Health Technology Assessment), and cross-checked, plus to identify RCTs of triclosan-coated sutures compared with conventional sutures and assessing the clinical effectiveness of antimicrobial sutures to decrease the risk for SSI. A fixed and random-effects model was developed, and pooled estimates reported as risk ratios (RR) with a corresponding 95% confidence interval (CI). Publication bias was assessed by measuring a funnel plot of individual studies and using the Egger regression intercept.

**Results:** The meta-analysis (17 RCTs, 1,560 patients) found that use of triclosan antimicrobial-coated sutures was associated with a decrease in SSI in a selected patient population (fixed effect: RR = 0.234, 95% CI: 0.570-0.913; P = .005; random effect: RR = 0.493, 95% CI: 0.353-0.690; P = .001). No publication bias was detected (Egger intercept: P = .415).

**Conclusion:** Decreasing the risk for SSI requires a multi-modal "one health" approach, and this meta-analysis of current, published, randomized-controlled trials suggests a clinical effectiveness of antimicrobial-coated sutures (triclosan) in the prevention of SSI, representing Center for Evidence-Based Medicine that is evidence. (Surg 2013;154:89-100)

Edmiston et al., Surgery 2013;154:89-100

# Systematic review and meta-analysis of triclosan-coated sutures for the prevention of surgical-site infection

Z. X. Wang<sup>1,2</sup>, C. P. Jung<sup>1,2</sup>, Y. Cao<sup>1,2</sup> and Y. T. Ding<sup>1,2</sup>

<sup>1</sup>Department of Plastic Surgery, Affiliated Duxi Tower Hospital, School of Medicine, Nanjing University, and Jiangsu Province Key Medical Center of Plastic Surgery, Nanjing Jiangsu Province, China

**Background:** Surgical-site infection (SSI) increases morbidity and mortality in surgical patients and represent an economic burden to healthcare systems. Experiments have shown that triclosan-coated sutures (TCS) are beneficial in the prevention of SSI, although the results from individual randomized controlled trials (RCTs) are inconsistent. Hence, a meta-analysis of available RCTs was performed to evaluate the effect of TCS in the prevention of SSI.

**Methods:** A systematic search of PubMed, Embase, MEDLINE, Web of Science<sup>®</sup>, the Cochrane Central Register of Controlled Trials and Internet-based trial registers for RCTs comparing the effect of TCS and conventional sutures on SSI was conducted until June 2012. The primary outcome investigated was the incidence of SSI. Pooled relative risk with 95 per cent confidence interval (CI) were estimated with RevMan 5.1.6.

**Results:** Seventeen RCTs involving 1720 participants were included. No heterogeneity of statistical significance across studies was observed. TCS showed a significant advantage in reducing the rate of SSI by 49 per cent relative risk (RR), 95 per cent CI: 0.517-0.645, P < 0.001. Subgroup analyses revealed consistent results in favour of TCS in adult patients, abdominal procedures, and clean or clean-contaminated surgical wounds.

**Conclusion:** TCS demonstrated a significant beneficial effect in the prevention of SSI after surgery.

Wang et al., British J Surg 2013;100:465-473

# Is there an evidence-based argument for embracing an antimicrobial (triclosan)-coated suture technology to reduce the risk for surgical-site infections?: A meta-analysis

Charles E. Edmiston, Jr PhD<sup>1</sup>, Frederic C. Daoud, MD<sup>2</sup>, and David Leaper, MD, FACS<sup>3</sup>, <sup>1</sup>Missouri, <sup>2</sup>WI, <sup>3</sup>Paris, France, and London, UK

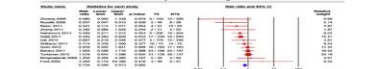


Fig. 6. Forest plot showing effect of triclosan-coated sutures and risk for bacterial contamination of skin, haemostatic coagulation, wound healing, and other clinical outcomes (RR = 0.493, 95% CI: 0.353-0.690).

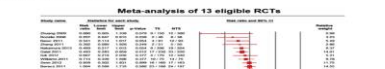


Fig. 6. Forest plot showing effect of triclosan-coated sutures and risk for bacterial contamination of skin, haemostatic coagulation, wound healing, and other clinical outcomes (RR = 0.493, 95% CI: 0.353-0.690).

SURGICAL INFECTIONS  
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# Meta-Analysis of Prevention of Surgical Site Infections following Incision Closure with Triclosan-Coated Sutures: Robustness to New Evidence

Frederic C. Daoud<sup>1</sup>, Charles E. Edmiston, Jr<sup>2</sup>, and David Leaper<sup>3</sup>

## Abstract

**Background:** A systematic literature review (SLR) and meta-analysis of surgical site infections (SSIs) after surgical incision closure with triclosan-coated sutures (TCS) compared with non-antibacterial control sutures (NTS) previously published by the authors suggested that fewer SSIs occurred in the TS study arm. However, the results were vulnerable to the removal of one key randomized control trial (RCT) because of insufficient data. Furthermore, recently published RCTs highlighted the need for an update of the SLR to challenge the robustness of results.

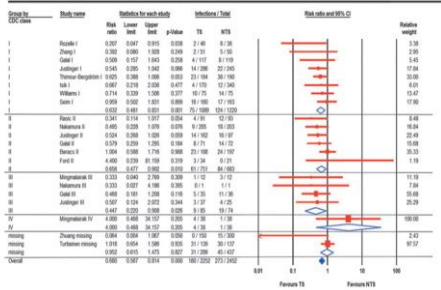
**Methods:** The protocol for the new SLR included more stringent tests of robustness than initially used and the meta-analysis was updated with the results of two new RCTs as well as the count of patients and SSIs by U.S. Centers for Disease Control and Prevention (CDC) incision class.

**Results:** The updated SLR included 15 RCTs with 4,800 patients. No publication bias was suggested in the analysis. The predominant effect estimated a relative risk of 0.67 (95% CI: [0.54, 0.84], p = 0.00053) with an overall lower frequency of SSI in the TS arm than in the NTS arm. Results were robust to sensitivity analysis. **Conclusion:** The two additional peer-reviewed double-blind RCTs of this update confirmed the predominant effect found in the authors' previous meta-analysis and established the robustness of conclusions that were previously lacking. This SLR and meta-analysis showed that the use of triclosan antimicrobial sutures reduced the incidence of SSI after clean, clean-contaminated, and contaminated surgery. The Centre for Evidence-based Medicine (CEBM) evidence concentration Ia of this SLR was reinforced.

Daoud, Edmiston, Leaper - Surgical Infections 2014; On Line

# Meta-Analysis of Risk Reduction by Wound Classification

## Random-effects pooled RR of SSIs - 15 RCTs - RR by CDC class



RR: Risk Ratio, SSI: Surgical Site Infections, TS: Triclosan Sutures, NTS: Non-Triclosan Sutures, RCT: Randomized Controlled Trial

Daoud, Edmiston, Leaper - Surgical Infections 2014; On Line

❖ **Element 4**

Three prospectively planned meta-analyses of randomized clinical trials (RCT) were performed on the use of suture containing triclosan to lower surgical site infection rates – The results of these analyses were deemed 1a clinical evidence

**Building the Next Evidence-Based Initiative**

“It is not the air, it is something in the air”  
*Lister 1861*

**Epidemiology of Total Joint Infections**

“The personnel who enter the OR carry the bacteria”

*Ritter MS., Clin Orthop Relat Res. 1999;369:103-109.*

- Presence of OR personnel - increases shedding by a factor of 40X
- 20% to 30% of all OR personnel – *Staphylococcus aureus* carriers
- “High shedders” (>10,000 bacteria/min):
  - 13% males
  - 5% postmenopausal females
  - 1% premenopausal females



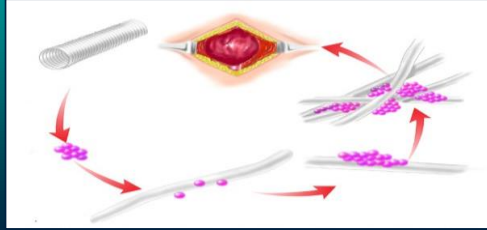


## Anastomotic femoral pseudoaneurysm: An investigation of occult infection as an etiologic factor

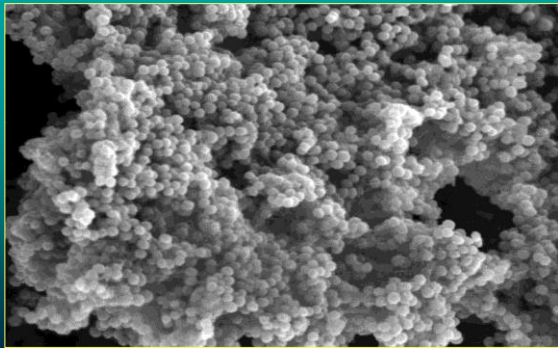
Gary R. Seabrook, MD, David D. Schmitt, MD, Dennis F. Bandyk, MD, Charles E. Edmiston, PhD, Candace J. Krepel, BS, M(ASCP), and Jonathan B. Towne, MD, *Milwaukee, Wis.*



1990;11:622-634

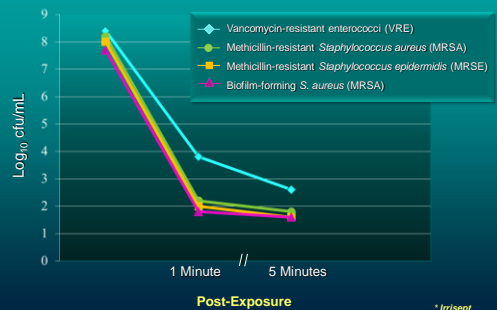


Seabrook & Edmiston, *Critical Care Infectious Diseases* 2001; 875-888



Staphylococcal Biofilm - Surgical Microbiology Research Laboratory 2006 - Medical College of Wisconsin

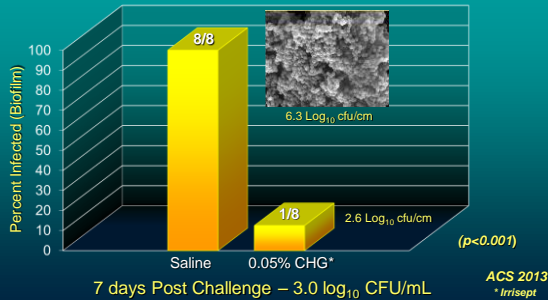
## Impact of 0.05% CHG\* Time-Kill Log Reduction – Selective Gram-Positive MDR Surgical Pathogens



\* IriSept



### Impact of Intraoperative Saline and 0.05% CHG Irrigation on Resolution of MRSA Contaminated Polypropylene Mesh – Sprague-Dawley Animal Model



### Chlorhexidine Gluconate (CHG)

- CHG is a broad-spectrum biocide effective against Gram-positive bacteria, Gram-negative bacteria and fungi.<sup>1, 6</sup>
- CHG inactivates microorganisms with a broader spectrum than other antimicrobials (e.g. antibiotics) - has a quicker kill rate than other antimicrobials (e.g. povidone-iodine, PI).<sup>2, 6</sup>
- It has both bacteriostatic and bactericidal mechanisms of action - kills by destabilizing the cell membrane within 20-30 second of application.<sup>3, 4</sup>
- Unlike PI, CHG is not affected by the presence of body fluids such as blood.<sup>5</sup>

1. Edmiston et al. *Am J Infect Control* 2013;41:49
2. McDonnell et al. *Clin Microbiol Rev* 1999;12:147
3. Mangram et al. *Am J Infect Control* 1999;27:97
4. Genuit et al. *Surg Infect* 2001;2:5
5. Lim et al. *Anaesthesia Intensive Care* 2008;36:4
6. Barnes et al. *Am J Infect Control* 2014;42:525

#### ❖Element 5

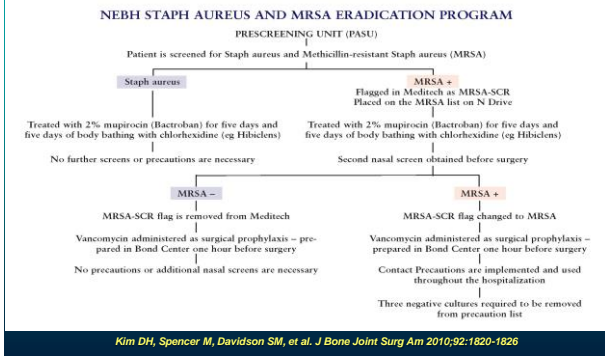
Laboratory, animal and clinical experiences indicates that 0.05% CHG is effective and safe for intraoperative irrigation - The evidence-based picture is still evolving

### MRSA Surveillance and Decolonization How Common is the Practice?

Surgical Service	Preop MRSA Surveillance (%)	Nasal Mupirocin Decolonization (%)	Preop CHG Bathing(%)
N = 342			
Ortho	100 (29.4)	68 (19.9)	109 (31.9)
CT	85 (24.8)	92 (26.9)	91 (26.6)
Implant	62 (18.1)	33 (9.7)	46 (13.5)
Neuro	25 (7.3)	17 (5.0)	33 (9.7)
Other Misc	38 (11.1)	26 (7.6)	47 (13.7)

Jarvis WR, et al. *Am J Infect Control* 2012;40:194-200

**Institutional Prescreening for Detection and Eradication of Methicillin Resistant Staphylococcus aureus in Patients Undergoing Elective Orthopaedic Surgery**



❖ **Element 6:**  
**Preoperative surveillance for MRSA and MSSA is an effective SSI risk-reduction strategy for selective surgical procedures**

**Thoughtful Approach to Adjunctive Risk Reduction: 6 Point Interventional Process (SCIP + nBest Practice)**

- MSSA & MRSA (selective) active surveillance - EB
- CHG shower or cleansing - EB
- CHG/Alc - Perioperative - EB
- Augment (weight-based) antibiotic dosing - 2 to 3 grams - EB
- CHG intraoperative irrigation (0.05%) - TBD
- Antimicrobial wound closure technology - EB

*Improving Patient Outcome Requires Commitment & Innovation*

**Less We Forget Element # 7- A Safer Operating Room**

- Traffic control, number staff in room
- Air handling systems, filtration, grills
- Room turnover and terminal cleaning
- Instrument cleaning/sterilization process (SPD)
- Storage of supplies, clean supply bins, carts, tables, stationary equipment

## 2014 CDC HICPAC SSI GUIDELINES "you have got to be kidding"

Criteria	Core Measures Questions 1-10	Arthroplasty Questions 11-20
Category 1A	7	2
Category 1B	3	1
Category 1C	0	0
Category II	4	0
No Recommendation/	15	11
Unresolved Issue		

Does Not Address: Active Staphylococcal Surveillance, Decolonization, Surgical Care Bundles  
Potential Impact: Reallocation of Resources

## Developing an argument for bundled interventions to reduce surgical site infection in colorectal surgery

Seth A. Wain, MD,\* Danielle Fréze, MD,\* Monami Banerjee, PhD,<sup>2</sup> Wenying Zhang, MA,\* James Kuhse, MS,<sup>2</sup> Michael J. Englesbe, MD,<sup>2</sup> Doreen A. Campbell, Jr, MD,\* and Samantha Hendren, MD, MPH,<sup>2</sup> Ann Arbor, MI

**Background.** Surgical site infection (SSI) remains a costly and morbid complication after colectomy. The primary objective of this study was to investigate whether a group of perioperative care measures previously shown to be associated with reduced SSI would have an additive effect in SSI reduction. If so, this would support the use of an "SSI prevention bundle" as a quality improvement intervention.

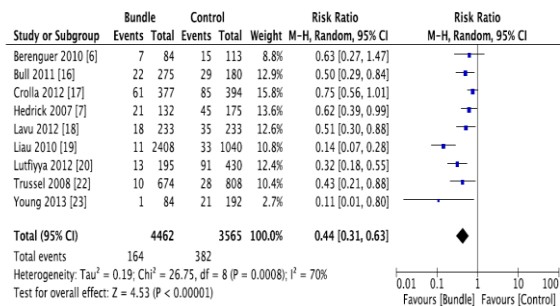
**Methods.** Data from 24 hospitals participating in the Michigan Surgical Quality Collaborative were included in the study. The main outcome measure was SSI. Hierarchical logistic regression was used to account for clustering of patients within hospitals.

**Results.** In total, 4,085 operations fulfilled inclusion criteria for the study (Current Procedural Terminology codes 44140, 44160, 44204, and 44205). A "bundle score" was assigned to each operation, based on the number of perioperative care measures followed (appropriate Surgical Care Improvement Project-2 antibiotics, postoperative normothermia, oral antibiotics with bowel preparation, perioperative glycemic control, minimally invasive surgery, and short operative duration). There was a strong stepwise inverse association between bundle score and incidence of SSI. Patients who received all 6 bundle elements had risk-adjusted SSI rates of 2.0% (95% confidence interval [CI], 1.9–2.1%), whereas patients who received only 1 bundle measure had SSI rates of 17.3% (95% CI, 16.1–18.5%).

**Conclusion.** This multi-institutional study shows that patients who received all 6 perioperative care measures attained a very low, risk-adjusted SSI rate of 2.0%. These results suggest the promise of an SSI reduction intervention for quality improvement; however, prospective research are required to confirm this finding. (Surgery 2014;155:602-6.)

From the Departments of Surgery\* and Biostatistics,<sup>2</sup> University of Michigan, Ann Arbor, MI

Waits et al, Surgery 2014;155:602



Tanner, Padley, Assadian, Kiernan, Leaper and Edmiston – In Press 2014. J Hosp Infect



Although uncommon, infections sometimes happen after surgery, in the area of the body where the procedure took place. These are called surgical site infections, or SSIs.

You and your healthcare team can do many things before, during and after your surgery to make sure you have the best outcome possible. Ask your surgeon to check the items that are important for your type of procedure.



What I can do to prevent...



## Surgical Site Infections

...by working together with my healthcare team.





Versos Pub #

**Top 10 things my healthcare team can do to help prevent a surgical site infection.**


- Screen for staph bacteria.
- Provide chlorhexidine (CHG) soap or cloths to clean skin at home before surgery. 
- Use clippers, not razors, if hair needs removing.
- Give antibiotics at the right time before surgery and again during surgery depending on the procedure length.
- Adjust antibiotic amount according to weight, if necessary.
- Use an alcohol-based CHG skin prep in the operating room.
- Keep blood sugar levels below 200 mg/dl during and after surgery.
- Keep patient's body temperature and oxygen at recommended levels. 
- Provide an oral CHG wash just before the procedure.
- Give clear instructions for home care and make sure patients understand them.

**Top 10 things I can do to help prevent a surgical site infection.**

- Use medicine for my nose if I test positive for staph bacteria.
- Take at least two showers with chlorhexidine (CHG) soap or use the CHG cloths at least twice, following all instructions.
- Do not shave around the surgical area for at least 2 days before surgery. 
- Lose weight before surgery if I am overweight.
- Stop smoking before surgery and during my recovery.
- Ask my doctor about keeping my diabetes in control before, during and after surgery.
- Tell my doctor all the medicines (including vitamins) I take and how much caffeine and alcohol I use. 
- Tell my doctor or nurse when I am in pain and take medicine as directed.
- Wash hands before changing dressings or touching the wound, keep my home clean, wear clean clothes, and keep pets from touching the wound.
- Call my doctor if I have a fever, increased pain, drainage, redness or swelling around the incision.

**More Information**

- American College of Surgeons <http://www.facs.org/education/for-surgeons.html>
- Association for Professionals in Infection Control and Epidemiology <http://www.apic.org/for-patients>
- Centers for Disease Control and Prevention <http://www.cdc.gov/ssi/prevention.html>
- Institute for Healthcare Improvement <http://www.ihc.org/ihcweb/Initiatives/Completed/ProjectCONTIP/www.ihc.org>



**❖Caueat: Surgical Site Infections Often Represent a Complex and Multifactorial Process - the Mechanistic Etiology or the Search for Resolution May be Quite Elusive**

