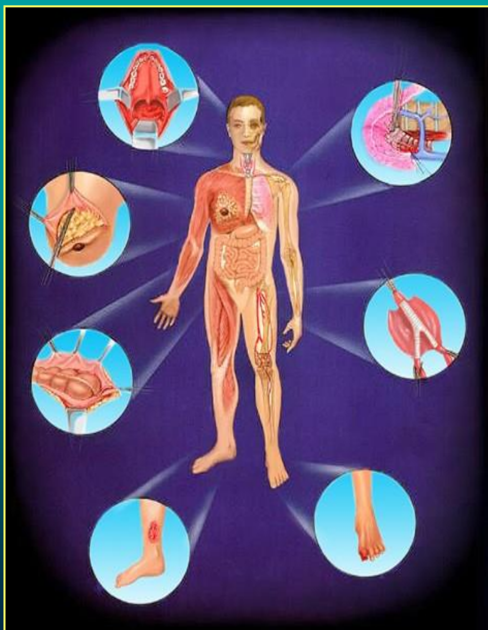


Reducing the Risk of Surgical Site Infections: Improving Patients Outcomes through an Evidence-Based Pathway

Charles E. Edmiston Jr., PhD., CIC
Emeritus Professor of Surgery & Hospital Epidemiologist - Department of Surgery
Medical College of Wisconsin
Milwaukee, Wisconsin USA
edmiston@mcw.edu

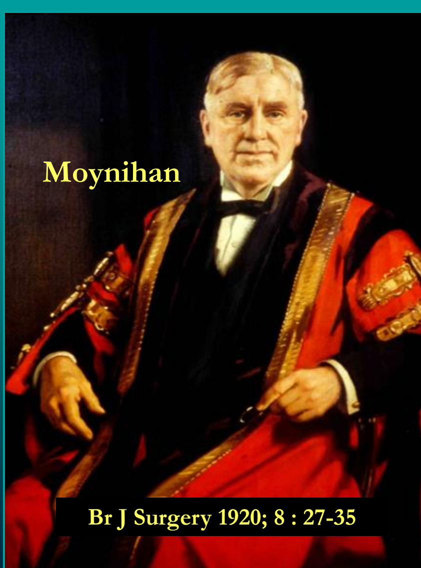
MEDICAL COLLEGE OF WISCONSIN

Items For Discussion Today

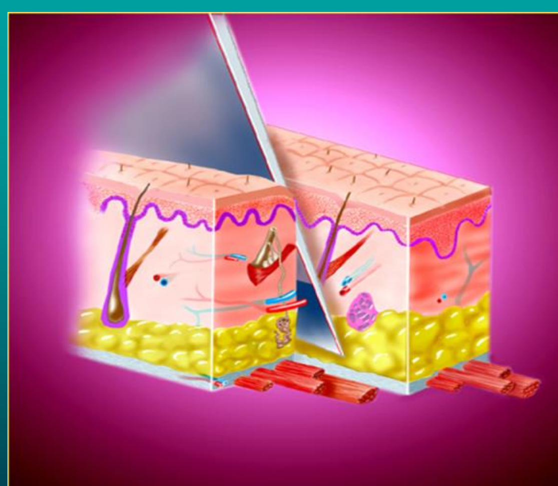
- Complexity of Surgical Site Infections
- Impact of Current Process (SCIP) Interventions
- Reducing Risk through an Evidence-Based Perspective
- Role of the Meta-Analysis in Validating Antimicrobial Closure
- Choosing the Right Evidence-Based Interventions Across the Spectrum of Surgery

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

"Every operation is an experiment in bacteriology"



"It's all about the surgical wound"



"….all surgical wounds are contaminated to some degree at closure – the primary determinant of whether the contamination is established as a clinical infection is host (wound) defense"

Belda et al., JAMA 2005;294:2035-2042

A Question of Definitions

Table 3. Observed Colon SSI Rates for the NHSN vs the ACS NSQIP per Hospital

Hospital	SSI Rate, %		
	NHSN	ACS NSQIP	Difference
A	3.0	4.6	1.6
B	4.3	6.0	1.7
C	2.4	5.0	2.6
D	4.8	8.8	4.0
E	NA	7.1	NA
F	8.9	10.7	1.8
G	3.9	12.8	8.9
H	2.3	16.2	13.9
I	3.7	12.3	8.6
J	5.1	11.9	6.8
K	14.5	24.0	9.5
L	9.6	17.1	7.5
M	2.0	18.0	16.0
N	4.0	18.2	14.2
O	9.0	17.1	8.1
P	7.8	26.7	18.8
Mean	5.7	13.5	8.3

Ju MH et al. JAMA Surgery (online) November 26, 2014

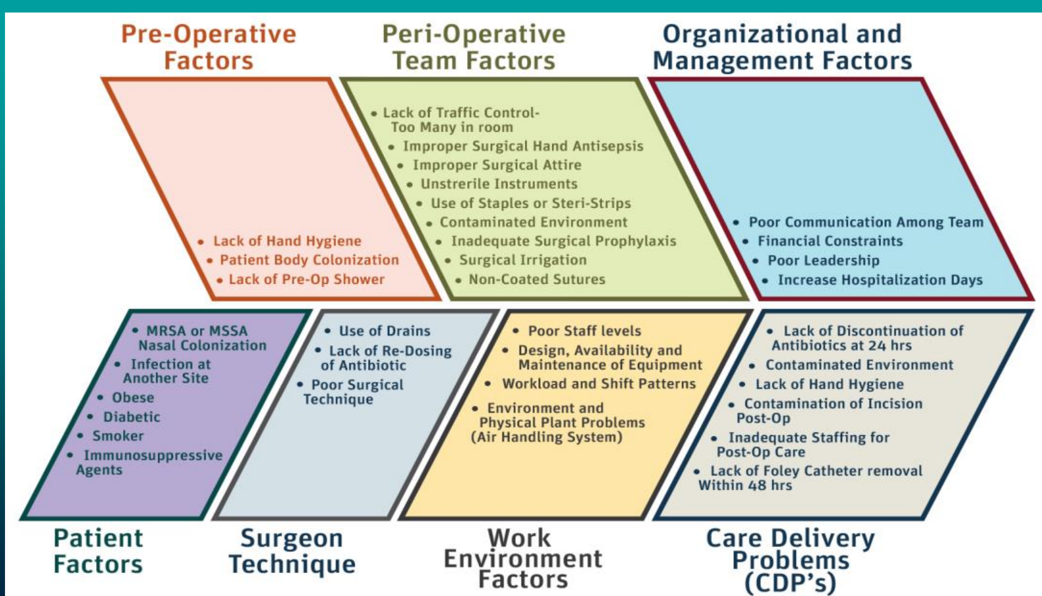
❖ The Complexity of Risk

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

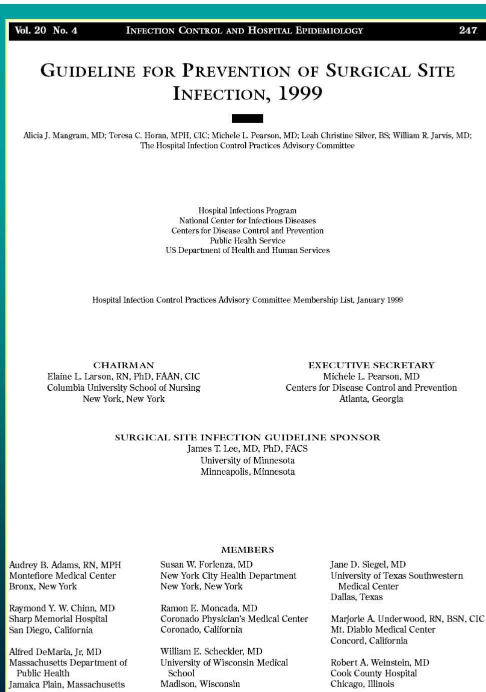
High Risk Patient:

- 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

Risk is a Myriad of Events - SSI Fishbone Diagram



Evidence-Based Hierarchy



Vol. 20 No. 4 INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY 247

GUIDELINE FOR PREVENTION OF SURGICAL SITE INFECTION, 1999

Alicia J. Mangram, MD; Teresa C. Horan, MPH, CIC; Michele L. Pearson, MD; Leah Christine Silver, BS; William R. Jarvis, MD; The Hospital Infection Control Practices Advisory Committee

Hospital Infections Program
National Center for Infectious Diseases
Centers for Disease Control and Prevention
Public Health Service
US Department of Health and Human Services

Hospital Infection Control Practices Advisory Committee Membership List, January 1999

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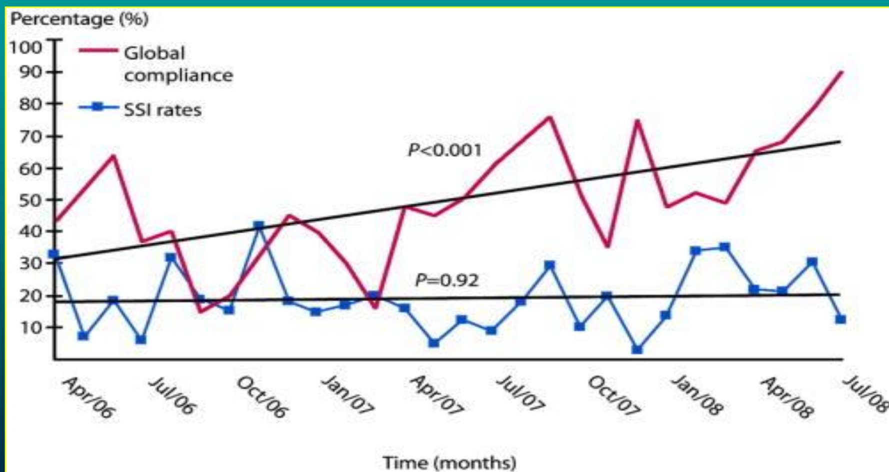
Chicago, Illinois

Mitigating Risk - Surgical Care Improvement Project (SCIP) – An Evidence-Based "Bundle" Approach

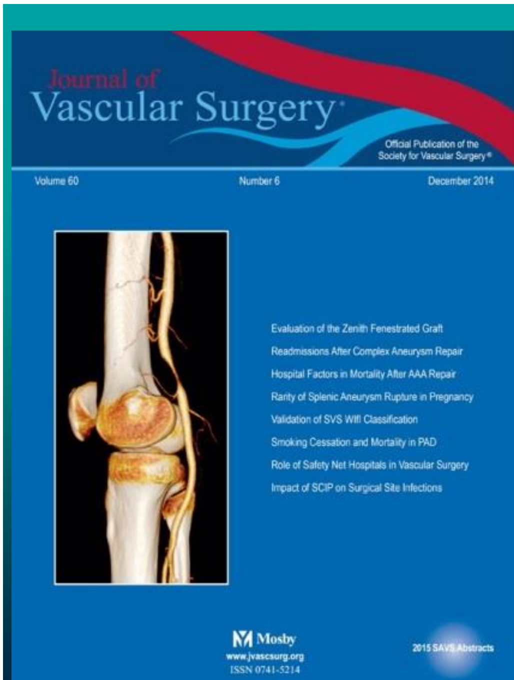
- Timely and appropriate antimicrobial prophylaxis
- Glycemic control in cardiac and vascular surgery
- Appropriate hair removal
- Normothermia in general surgical patients

Is this the Holy Grail?

An Increase in Compliance With the Surgical Care Improvement Project Measures Does Not Prevent Surgical Site Infection in Colorectal Surgery



Pastor et al. Diseases of the Colon & Rectum 2010; 53:24-30



The effect of Surgical Care Improvement Project measures on national trends on surgical site infections in open vascular procedures

Anahita Dua, MD, MS, MBA,[a] Sapan S. Desai, MD, PhD, MBA,[b] Gary R. Seabrook, MD,[a] Kellie R. Brown, MD,[a] Brian D. Lewis, MD,[a] Peter J. Rossi, MD,[a] Charles E. Edmiston, PhD,[a] and Cheong J. Lee, MD,[a] *Milwaukee, Wisc; and Springfield, Ill*

Objective: The Surgical Care Improvement Project (SCIP) is a national initiative to reduce surgical complications, including postoperative surgical site infection (SSI), through protocol-driven antibiotic usage. This study aimed to determine the effect SCIP guidelines have had on in-hospital SSIs after open vascular procedures.
Methods: The Nationwide Inpatient Sample (NIS) was retrospectively analyzed using International Classification of Diseases, Ninth Revision, diagnosis codes to capture SSIs in hospital patients who underwent elective carotid endarterectomy, elective open repair of an abdominal aortic aneurysm (AAA), and peripheral bypass. The pre-SCIP era was defined as 2000 to 2005 and post-SCIP was defined as 2007 to 2010. The year 2006 was excluded because this was the transition year in which the SCIP guidelines were implemented. Analysis of variance and χ^2 testing were used for statistical analysis.
Results: The rate of SSI in the pre-SCIP era was 2.2% compared with 2.3% for carotid endarterectomy ($P = .06$). For peripheral bypass, both in the pre- and post-SCIP era, infection rates were 0.1% ($P = .22$). For open, elective AAA, the rate of infection in the post-SCIP era increased significantly to 1.4% from 1.0% in the pre-SCIP era ($P < .001$). Demographics and in-hospital mortality did not differ significantly between the groups.
Conclusions: Implementation of SCIP guidelines has made no significant effect on the incidence of in-hospital SSIs in open vascular operations; rather, an increase in SSI rates in open AAA repairs was observed. Patient-centered, bundled approaches to care, rather than current SCIP practices, may further decrease SSI rates in vascular patients undergoing open procedures. (J Vasc Surg 2014;60:1635-9.)

Embracing the Surgical Care Bundle – Selective Elements

❖ Antimicrobial Prophylaxis – Weight-Based Dosing

Does BMI Increase Risk?

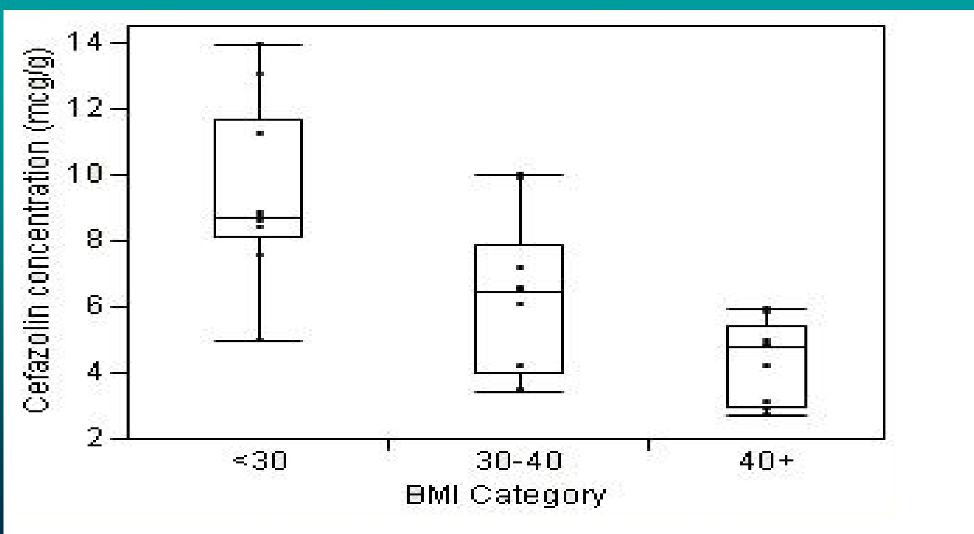
Perioperative Antimicrobial Prophylaxis in Higher BMI (>40) Patients: Do We Achieve Therapeutic Levels?

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
Staphylococcus aureus	70	68.6%	27.1%
Staphylococcus epidermidis	110	34.5%	10.9%
E. coli	85	75.3%	56.4%
Klebsiella pneumoniae	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

❖ 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 DELLINGER, KEITH M. OLSEN, TRISH M. PERL, PAUL G. AUWAERTER, MAUREEN K. BOLON, DOUGLAS N. FISH, LENA M. NAPOLITANO, ROBERT G. SAWYER, DOUGLAS SLAIN, JAMES P. STEINBERG, AND ROBERT A. WEINSTEIN

Am J Health-Syst Pharm. 2013; 70:195-283

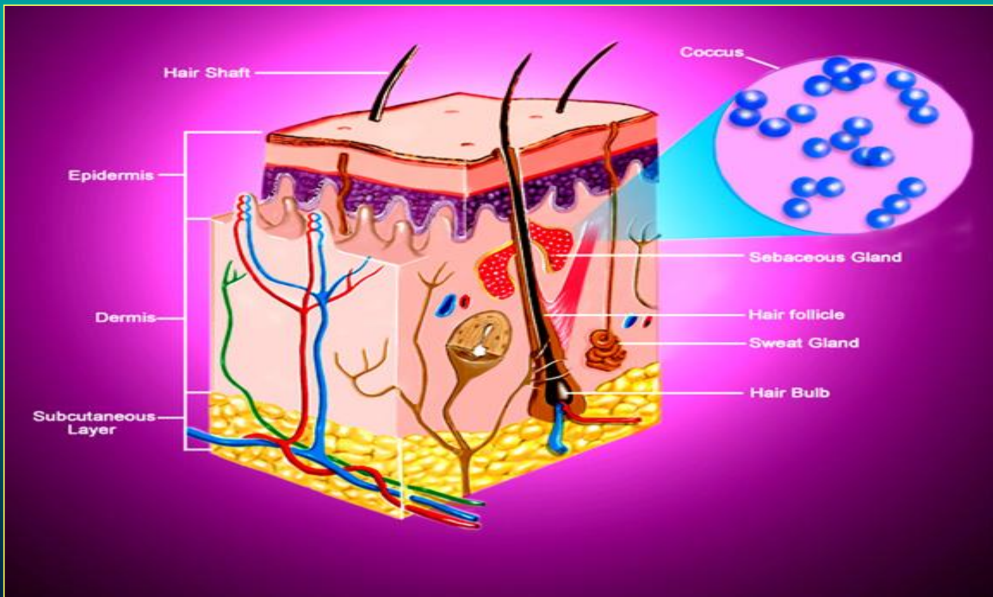
These guidelines were developed jointly by the American Society of Health-System Pharmacists (ASHP), the Infectious Diseases Society of America (IDSA), the Surgical Infection Society (SIS), and the Society for Healthcare Epidemiology of America (SHEA). This work represents an update to the previously published ASHP Therapeutic Guidelines on Antimicrobial Prophylaxis in Surgery,[1] as well as guidelines from IDSA and SIS.[2,3] 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 issues.

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

❖ Preadmission Showering/Cleansing



Microbial Ecology of Skin Surface

- Scalp 6.0 Log_{10} cfu/cm^2
- Axilla 5.5 Log_{10} cfu/cm^2
- Abdomen 4.3 Log_{10} cfu/cm^2
- Forearm 4.0 Log_{10} cfu/cm^2
- Hands 4.0-6.6 Log_{10} cfu/cm^2
- Perineum 7.0-11.0 Log_{10} cfu/cm^2

Surgical Microbiology Research Laboratory 2008 – Medical College of Wisconsin

Preoperative bathing or showering with skin antiseptics to prevent surgical site infection (Review)

Webster J, Osborne S

THE COCHRANE COLLABORATION®

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2015, Issue 2

http://www.thecochranelibrary.com

Draft Guideline for the Prevention of Surgical Site Infection

Sandra I. Berríos-Torres, MD[1], Craig A. Umscheid, MD, MSCE[2], Dale W. Bratzler, DO, MPH[3], Brian Leas, MA, MS[2], Erin C. Stone, MS[1], Rachel R. Kelz, MD, MSCE, FACS[2], Caroline Reinke, MD, MPH[2], Sherry Morgan, RN, MLS, PhD[2], Joseph S. Solomkin, MD[4], John E. Mazuski, MD, PhD[5], E. Patchen Dellinger, MD[6] Kamal Itani, MD[7], Elie F. Berbari, MD[8], John Segreti, MD[9], Javad Parvizi, MD[10], Joan Blanchard, MSS,BSN,RN,CNOR,CIC[11], George Allen, PhD, CIC, CNOR[12], J. A. J. W. Kluytmans, MD[13], Rodney Donlan, PhD[1], William P. Schecter, MD[4] and the Healthcare Infection Control Practices Advisory Committee[15]

[1]Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention, Atlanta, GA; [2]Center for Evidence-based Practice, University of Pennsylvania Health System, Philadelphia, PA; [3]University of Oklahoma Health Sciences Center, College of Public Health, Oklahoma City, OK; [4]University of Cincinnati, University of Cincinnati College of Medicine, Cincinnati, OH; [5]Washington University, Washington University School of Medicine, Saint Louis, MO; [6]University of Washington Medical Center, Seattle, WA; [7]Veterans Affairs Boston Healthcare System, Boston, MA; [8]Mayo Clinic College of Medicine, Rochester, MN; [9]Rush University Medical Center, Chicago, IL; [10], Rothman Institute, Philadelphia, PA; [11] Littleton Adventist Hospital, Quality Department, Denver, CO; [12] Downstate Medical Center, Brooklyn, NY; [13] Laboratory for Microbiology and Infection Control Amphia Hospital, Breda, the Netherlands; [14]University of California, San Francisco, San Francisco General Hospital San Francisco, CA

CDC-HICPAC – March 2014

Professional Organizations' Current and Draft Recommendations

Source	Previous Recommendations	Draft Recommendation	New Recommendations
AORN	**Cleanse 2X with CHG** "Patients undergoing open Class I surgical procedures below the chin should have two preoperative showers with chlorhexidine gluconate (CHG) before surgery, when appropriate."[4(p73)]		**Cleanse 1X with Soap or Antiseptic** "The patient should be instructed to bathe or shower before surgery with either soap or a skin antiseptic on at least the night before or the day of surgery."[11(p45)]
Hospital Infection Control Practice Advisory Committee-Centers for Disease Control and Prevention	**Cleanse at least 1X with an Antiseptic** "Require patients to shower or bathe with an antiseptic agent on at least the night before the operative day."[2(p267)]	**Cleanse at least 1X with Soap or Antiseptic** "Advise patients to shower or bathe (full body) with either soap (antimicrobial or non-antimicrobial) or an antiseptic agent on at least the night before the operative day."[12(p49)]	
Institute for Healthcare Improvement – Project JOINTS	**Cleanse 3X with CHG** "Instruct patients to bathe or shower with chlorhexidine gluconate (CHG) soap for at least three days before surgery."[5(p6)]		

Edmiston, Assadian, Spencer, Olmsted, Barnes, Leaper et al. AORN Journal 2015;101:239-238

Critiquing the Evidence for Both Cochrane and CDC Draft Recommendations – 7 Studies Cited

- The seven studies as a collective group expressing a high-level of surgical heterogeneity (Class 1, 2 and 3).
- In 4 of the studies, the patients showered once, in 2 studies patients showered or bathed twice and in one study, the patients showered a total of 3 times.
- Inadequate postoperative SSI surveillance was noted in 5 of the 7 cited studies.
- No written showering instructions or inadequate instructions were noted in 5 of the 7 studies.
- There was no evidence in any of the seven studies that an effort was made to measure patient compliance.
- Only two studies used a standardized method for assessing postoperative wound infection.
- Selective elements of operational bias were noted in 4 of the 7 studies.
- Finally one study was conducted over an extended 6 year period (1978-1984) which may have impacted upon the continuity of patient selection and enrollment.

What is the Evidence-Based Argument?

Mean Chlorhexidine Gluconate (CHG) Skin Surface Concentrations (μg/ml±SD) Compared to MIC_{90} (5 μg/ml) for Staphylococcal Surgical Isolates Including MRSA[a]

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

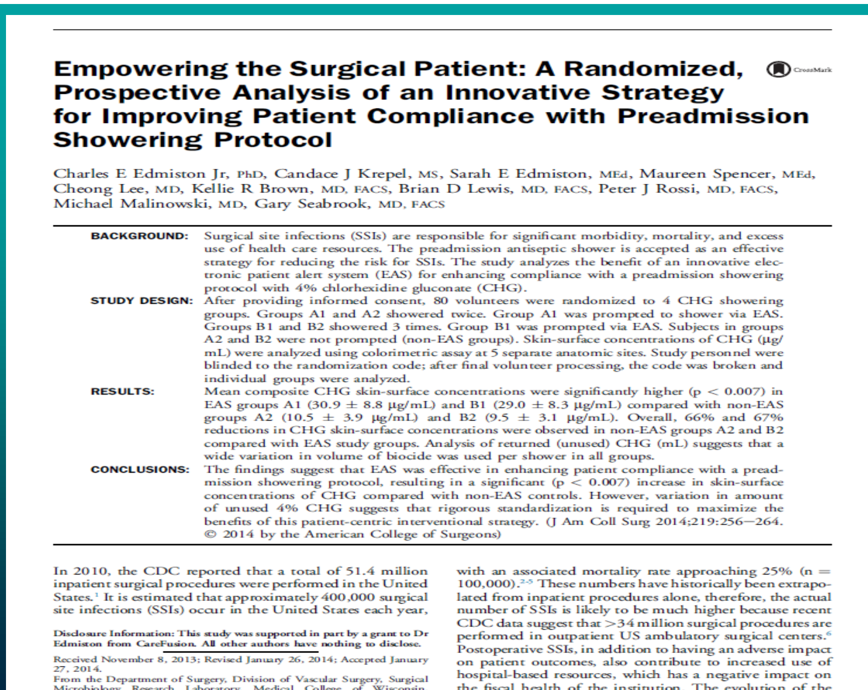
[a] N = 90
[b] Pilot group N = 30

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

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)

Could an electronic alert system (SMS-texting) improve patient compliance?



Empowering the Surgical Patient: A Randomized, Prospective Analysis of an Innovative Strategy for Improving Patient Compliance with Preadmission Showering Protocol

Charles E Edmiston Jr, PhD, Candace J Krepel, MS, Sarah E Edmiston, MEd, Maureen Spencer, MEd, Cheong Lee, MD, Kellie R Brown, MD, FACS, Brian D Lewis, MD, FACS, Peter J Rossi, MD, FACS, Michael Malinowski, MD, Gary Seabrook, MD, FACS

BACKGROUND: Surgical site infections (SSIs) are responsible for significant morbidity, mortality, and excess use of health care resources. The preadmission antiseptic shower is accepted as an effective strategy for reducing the risk for SSIs. The study analyzes the benefit of an innovative electronic patient alert system (EAS) for enhancing compliance with a preadmission showering protocol with 4% chlorhexidine gluconate (CHG).

STUDY DESIGN: After providing informed consent, 80 volunteers were randomized to 4 CHG showering groups. Groups A1 and A2 showered twice. Group A1 was prompted to shower via EAS. Groups B1 and B2 showered 3 times. Group B1 was prompted via EAS. Subjects in groups A2 and B2 were not prompted (non-EAS groups). Skin-surface concentrations of CHG (µg/mL) were analyzed using colorimetric assay at 5 separate anatomic sites. Study personnel were blinded to the randomization code; after final volunteer processing, the code was broken and individual groups were analyzed.

RESULTS: Mean composite CHG skin-surface concentrations were significantly higher ($p < 0.007$) in EAS groups A1 (30.9 ± 8.8 µg/mL) and B1 (29.0 ± 8.3 µg/mL) compared with non-EAS groups A2 (10.5 ± 3.9 µg/mL) and B2 (9.5 ± 3.1 µg/mL). Overall, 66% and 67% reductions in CHG skin-surface concentrations were observed in non-EAS groups A2 and B2 compared with EAS study groups. Analysis of returned (unused) CHG (mL) suggests that a wide variation in volume of biocide was used per shower in all groups.

CONCLUSIONS: The findings suggest that EAS was effective in enhancing patient compliance with a preadmission showering protocol, resulting in a significant ($p < 0.007$) increase in skin-surface concentrations of CHG compared with non-EAS controls. However, variation in amount of unused 4% CHG suggests that rigorous standardization is required to maximize the benefits of this patient-centric interventional strategy. (J Am Coll Surg 2014;219:256–264.

In 2010, the CDC reported that a total of 51.4 million inpatient surgical procedures were performed in the United States.[1] It is estimated that approximately 400,000 surgical site infections (SSIs) occur in the United States each year, with an associated mortality rate approaching 25% (n = 100,000).[2-5] These numbers have historically been extrapolated from inpatient procedures alone, therefore, the actual number of SSIs is likely to be much higher because recent CDC data suggest that >34 million surgical procedures are performed in outpatient US ambulatory surgical centers.[6] Postoperative SSIs, in addition to having an adverse impact on patient outcomes, also contribute to increased use of hospital-based resources, which has a negative impact on the fiscal health of the institution. The evolution of the

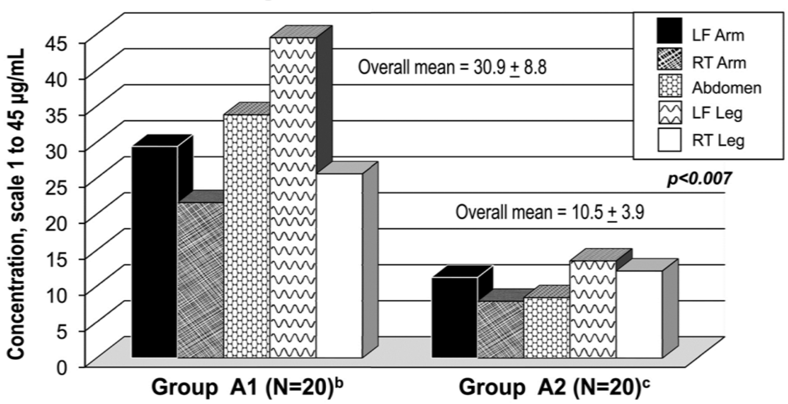
Disclosure Information: This study was supported in part by a grant to Dr Edmiston from CareFusion. All other authors have nothing to disclose.

Received November 8, 2013; Revised January 26, 2014; Accepted January 27, 2014.

From the Department of Surgery, Division of Vascular Surgery, Surgical Microbiology Research Laboratory, Medical College of Wisconsin,

Edmiston et al. J Am Coll Surg 2014;219:256-264

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



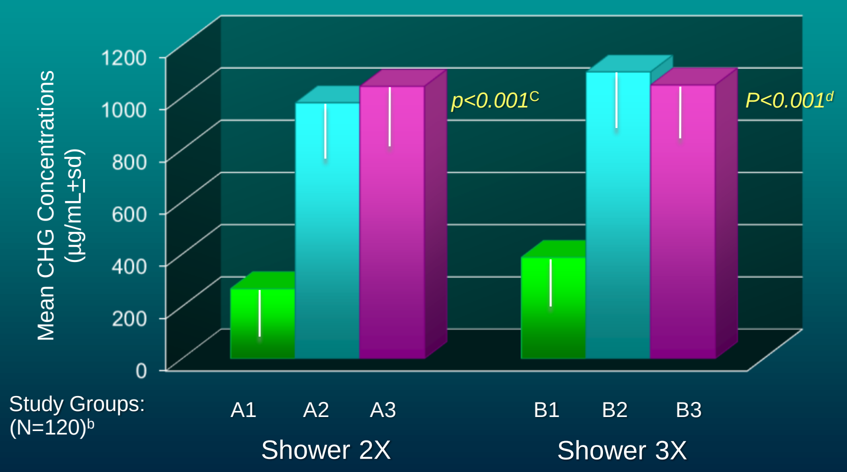
[a]MIC[90] for skin staphylococcal flora (including MRSA = 5 µg/mL)
[b]Subjects prompted using text, email or voicemail
[c]Subjects were not prompted

Edmiston et al. J Am Coll Surg 2014;219:256-264

❖ Looking at the Preadmission Shower from a Pharmacokinetic Perspective

Dose
Duration
Timing

Comparison of Mean Chlorhexidine Gluconate Skin-Surface Concentrations (µg/mL) of 4% Chlorhexidine Gluconate for Combined Anatomic Sites in Groups A (N=60) and B (N=60)[a]



Edmiston et al. JAMA-Surgery August 29, 2015

To Maximize Skin Surface Concentrations of CHG – A Standardize Process Should Include:

- An SMS, text or voicemail reminder to shower
- A standardized regimen – instructions
- TWO SHOWERS (CLEANSINGS) – NIGHT BEFORE/MORNING OF SURGERY
- A 1-minute pause before rinsing (4% CHG)
- A total volume of 4-ozs. for each shower

Remember the devil is always in the details

Edmiston and Spencer AORN 2014;100:590-602

OPINION

To Bathe or Not to Bathe With Chlorhexidine Gluconate: Is It Time to Take a Stand for Preadmission Bathing and Cleansing?

CrossMark

CHARLES E. EDMISTON JR, *PhD, MS, BS, CIC, FIDSA, FSHEA;*
OJAN ASSADIAN, *MD, DTM&H;* **MAUREEN SPENCER**, *MEd, BSN, CIC;*
RUSSELL N. OLMSTED, *MPH, BS, CIC;* **SUE BARNES**, *BSN, RN, CIC;*
DAVID LEAPER, *MD, ChM, FRCS, FACS, FLS*

Many health care facilities have incorporated an antiseptic skin cleansing protocol, often referred to as preoperative bathing and cleansing, to reduce the endogenous microbial burden on the skin of patients undergoing elective surgery, with the aim of reducing the risk of surgical site infections (SSIs). According to a recent study by Injean et al,[1] 91% of all facilities that perform coronary artery bypass surgery in California have a standardized preoperative bathing and cleansing protocol for patients. Historically, this practice has been endorsed by national and international organizations, such as the Hospital Infection Control Practice Advisory Committee and the Centers for Disease Control and Prevention,[2] the Association for Professionals in Infection Control and Epidemiology (APIC),[3] AORN,[4] the Institute for Healthcare Improvement (IHI),[5] and the National Institute for Health and Care Excellence (NICE),[6] which recommend bathing and/or cleansing with an antiseptic agent before surgery as a component of a broader strategy to reduce SSIs. The 2008 Society for Healthcare Epidemiology of America (SHEA)/Infectious Diseases Society of America (IDSA)/Surgical Infection Society (SIS) strategies to prevent SSIs in acute care hospitals declined to recommend a specific application policy regarding selection of an antiseptic agent for preoperative bathing but acknowledged that the (maximal) antiseptic benefits of chlorhexidine gluconate (CHG) are dependent on achieving adequate skin surface concentrations.[7]

Findings in reports published in the past 10 years have identified SSIs to be the most common health care–associated infection (HAI) and the most expensive in terms of resource utilization.[8,9] This provides a strong business case for health care institutions to invest in targeted, evidence-based, interventional strategies that reduce the risk of postoperative complications. In addition, because the microbial flora of the skin, especially staphylococci, provides a prominent reservoir of pathogens that cause SSIs,[7,10] focused interventions aimed at mitigating this reservoir in preoperative patients represent a logical and effective risk reduction strategy.

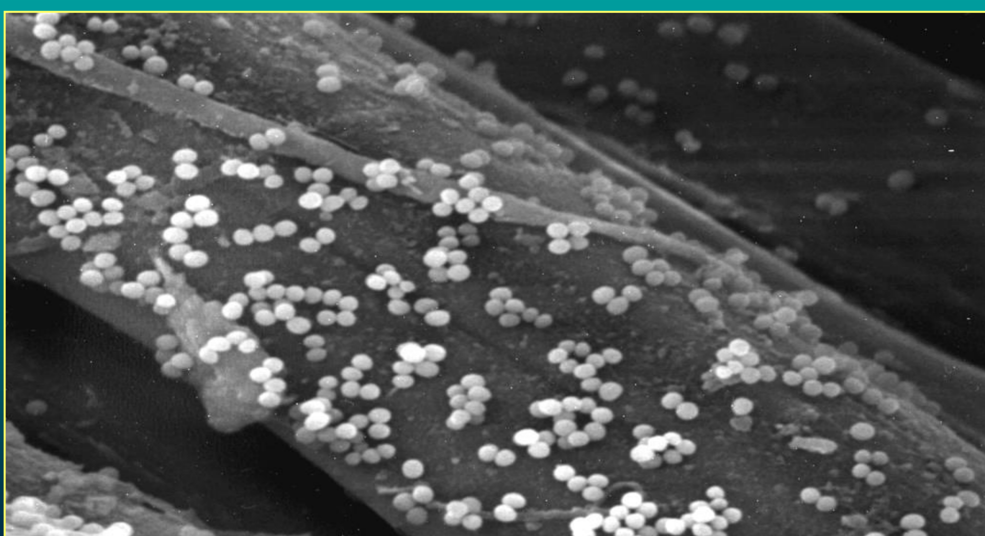
THE YIN AND YANG OF PREADMISSION BATHING: A RATIONAL CONSIDERATION OF BENEFIT

Despite the prevalent clinical practice of preoperative bathing with CHG, clinicians are now confronted with a possible shift in both CDC and AORN recommendations. The current proposed draft recommendations for preoperative showering or cleansing are summarized in Table 1. The 2015 AORN "Guideline for preoperative patient skin antisepsis"[11] and the CDC draft guideline[12] both have expanded their recommendations for perioperative skin antisepsis from using CHG products to also using other cleansing products (eg, antimicrobial or nonantimicrobial soap, other unspecified skin antiseptics). These expanded recommendations marginalize the practice of

AORNJ 2015;101;229

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

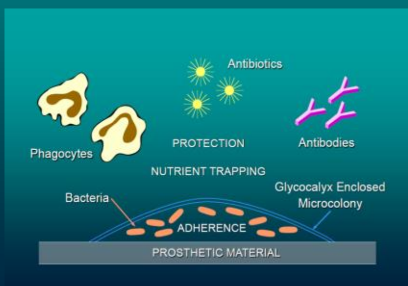
Adherence of Methicillin-Resistant *Staphylococcus aureus* (MRSA) to Braided Suture



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

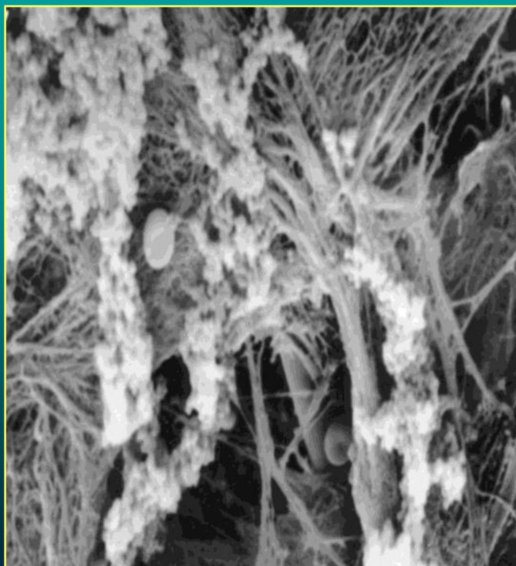
Presence of Biofilm on Selected Sutures from Non-infected and Infected Cases

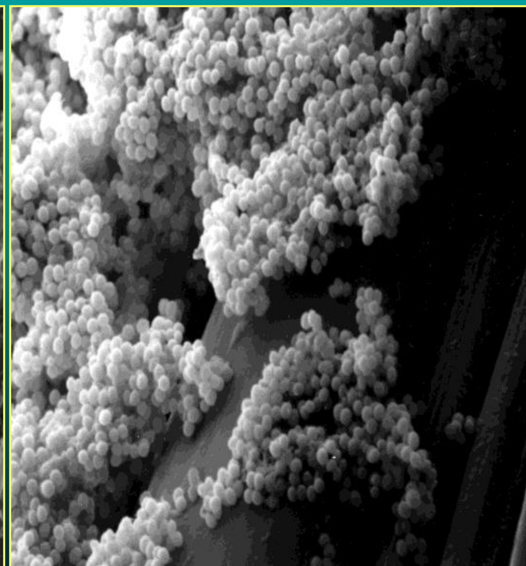
[a]non-infected nylon suture segments were randomly selected for microscopy, culture positive
[b]infected braided suture segments were randomly selected for microscopy
[c]infected monofilament suture segments were randomly selected for microscopy

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

Are Sutures Really a Nidus for Infection?

Staphylococcus epidermidis **Incisional Wound Infection**





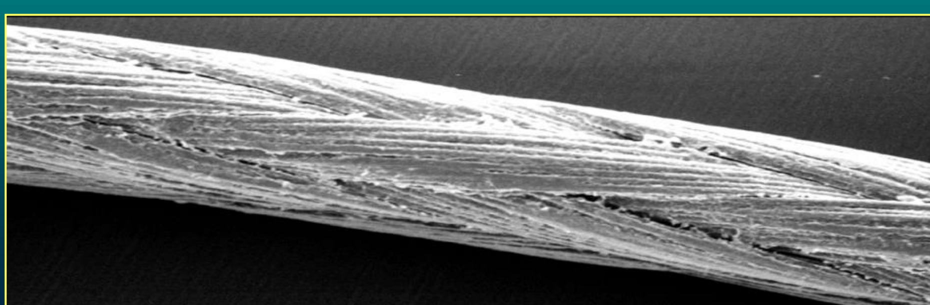
Surgical Microbiology Research Laboratory, Milwaukee - 2005

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

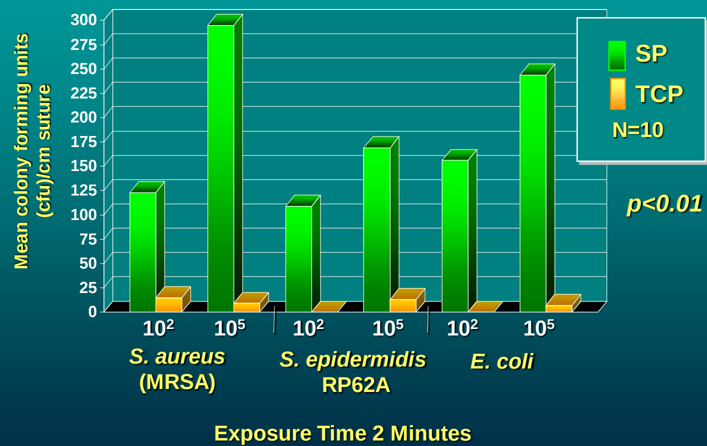
Bacterial Adherence to Surgical Sutures: Can Antibacterial-Coated Sutures Reduce the Risk of Microbial Contamination?

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

❖ The Meta-Analysis – Tip of the Evidence-Base Pyramid

A quantitative analysis to understand the net benefit of a clinical intervention

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,[a] **Frederic C. Daoud, MD,**[b] *and* **David Leaper, MD, FACS,**[c] *Milwaukee, WI, 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, but a recently published systematic literature review and meta-analysis suggested that no clinical benefit is 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 13 randomized, international RCTs, totaling 3,568 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 Evaluations Database/Database of Health Technology Assessments), and www.clinicaltrials.gov to identify RCTs of triclosan-coated sutures compared with conventional sutures and assessing the clinical effectiveness of antimicrobial sutures to decrease the risk for SSIs. A fixed- and random-effects model was developed, and pooled estimates reported as risk ratio (RR) with a corresponding 95% confidence interval (CI). Publication bias was assessed by analyzing a funnel plot of individual studies and testing the Egger regression intercept.*
Results. *The meta-analysis (13 RCTs, 3,568 patients) found that use of triclosan antimicrobial-coated sutures was associated with a decrease in SSIs in selected patient populations (fixed effect: RR = 0.734; 95% CI: 0.590–0.913; P = .005; random-effect: RR = 0.693; 95% CI: 0.533–0.920; P = .011). No publication bias was detected (Egger intercept test: P = .145).*
Conclusion. *Decreasing the risk for SSIs requires a multifaceted "care bundle" approach, and this meta-analysis of current, pooled, peer-reviewed, randomized controlled trials suggests a clinical effectiveness of antimicrobial-coated sutures (triclosan) in the prevention of SSIs, representing Center for Evidence-Based Medicine level 1a evidence. (Surgery 2013;154:89-100.)*

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

Meta-analysis

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

Z. X. Wang[1,2], C. P. Jiang[1,2], Y. Cao[1,2] and Y. T. Ding[1,2]

[1]Department of Hepatobiliary Surgery, Affiliated Drum Tower Hospital, School of Medicine, Nanjing University, and [2]Jiangsu Province's Key Medical Centre for Liver Surgery, Nanjing, Jiangsu Province, China
Correspondence to: Professor Y. T. Ding, 321 Zhong Shan Road, Nanjing, Jiangsu Province, China 210008 (e-mail: dingyitao@yahoo.com.cn)

Background: Surgical-site infections (SSIs) increase 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 inconclusive. A meta-analysis of available RCTs was performed to evaluate the efficacy of TCS in the prevention of SSI.
Methods: A systematic search of PubMed, Embase, MEDLINE, Web of Science®, the Cochrane Central Register of Controlled Trials and internet-based trial registries for RCTs comparing the effect of TCS and conventional uncoated sutures on SSIs was conducted until June 2012. The primary outcome investigated was the incidence of SSI. Pooled relative risks with 95 per cent confidence interval (c.i.) were estimated with RevMan 5.1.6.
Results: Seventeen RCTs involving 3720 participants were included. No heterogeneity of statistical significance across studies was observed. TCS showed a significant advantage in reducing the rate of SSI by 30 per cent (relative risk 0·70, 95 per cent c.i. 0·57 to 0·85; $P < 0·001$). 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

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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,[1] Charles E. Edmiston, Jr,[2] and David Leaper[3]

Abstract

Background: A systematic literature review (SLR) and meta-analysis of surgical site infections (SSIs) after surgical incision closure with triclosan-coated sutures (TS) compared with non-antibacterial coated 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.
Conclusions: 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.

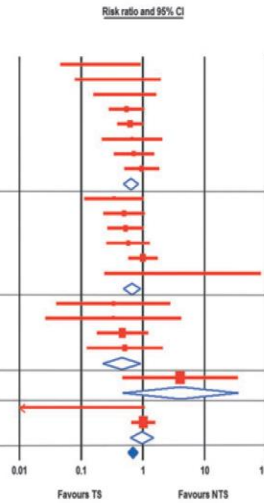
Daoud, Edmiston, Leaper - Surgical Infections 2014: On Line

Meta-Analysis of Risk Reduction by Wound Classification

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

Group by CDC class	Study name	Risk ratio	Lower limit	Upper limit	p-Value	TS	NTS	Relative weight
I	Rozelle I	0.207	0.047	0.915	0.038	2 / 46	8 / 38	3.38
I	Zhang I	0.392	0.080	1.928	0.249	2 / 51	5 / 50	2.95
I	Galal I	0.509	0.157	1.643	0.258	4 / 117	8 / 119	5.45
I	Justinger I	0.545	0.285	1.042	0.066	14 / 286	22 / 245	17.84
I	Thimour-Bergström I	0.625	0.388	1.006	0.053	23 / 184	38 / 190	33.00
I	Isik I	0.667	0.218	2.036	0.477	4 / 170	12 / 340	6.01
I	Williams I	0.714	0.339	1.506	0.377	10 / 75	14 / 75	13.47
I	Seim I	0.959	0.502	1.831	0.899	16 / 160	17 / 163	17.90
I		0.632	0.481	0.831	0.001	75 / 1089	124 / 1220	
II	Rasic II	0.341	0.114	1.017	0.054	4 / 91	12 / 93	8.48
II	Nakamura II	0.495	0.228	1.076	0.076	9 / 205	18 / 203	16.84
II	Justinger II	0.524	0.268	1.026	0.059	14 / 162	16 / 97	22.49
II	Galal II	0.579	0.259	1.295	0.184	8 / 71	14 / 72	15.68
II	Baracs II	1.004	0.588	1.716	0.988	23 / 188	24 / 197	35.33
II	Ford II	4.400	0.239	81.159	0.319	3 / 34	0 / 21	1.19
II		0.656	0.477	0.902	0.010	61 / 751	84 / 683	
III	Mingmalairak III	0.333	0.040	2.769	0.309	1 / 12	3 / 12	11.19
III	Nakamura III	0.333	0.027	4.186	0.395	0 / 1	1 / 1	7.84
III	Galal III	0.468	0.181	1.208	0.116	5 / 35	11 / 36	55.68
III	Justinger III	0.507	0.124	2.072	0.344	3 / 37	4 / 25	25.29
III		0.447	0.220	0.908	0.026	9 / 85	19 / 74	
IV	Mingmalairak IV	4.000	0.468	34.157	0.205	4 / 38	1 / 38	100.00
IV		4.000	0.468	34.157	0.205	4 / 38	1 / 38	
missing	Zhuang missing	0.064	0.004	1.067	0.056	0 / 150	15 / 300	2.43
missing	Turtiainen missing	1.018	0.654	1.586	0.935	31 / 139	30 / 137	97.57
missing		0.952	0.615	1.475	0.827	31 / 289	45 / 437	
Overall		0.680	0.567	0.814	0.000	180 / 2252	273 / 2452	

(Statistics for each study: Risk ratio, Lower limit, Upper limit, p-Value; Infections / Total: TS, NTS)



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

ORIGINAL ARTICLE

Triclosan-Coated Sutures Reduce the Risk of Surgical Site Infections: A Systematic Review and Meta-analysis

Anucha Apisarnthanarak, MD;[1] Nalini Singh, MD, MPH;[2] Aila Nica Bandong, MS;[3] Gilbert Madriaga, PTRP[4]

OBJECTIVE. To analyze available evidence on the effectiveness of triclosan-coated sutures (TCSs) in reducing the risk of surgical site infection (SSI).

DESIGN. Systematic review and meta-analysis.

METHODS. A systematic search of both randomized (RCTs) and nonrandomized (non-RCT) studies was performed on PubMed Medline, OVID, EMBASE, and SCOPUS, without restrictions in language and publication type. Random-effects models were utilized and pooled estimates were reported as the relative risk (RR) ratio with 95% confidence interval (CI). Tests for heterogeneity as well as meta-regression, subgroup, and sensitivity analyses were performed.

RESULTS. A total of 29 studies (22 RCTs, 7 non-RCTs) were included in the meta-analysis. The overall RR of acquiring an SSI was 0.65 (95% CI: 0.55–0.77; $I^2 = 42.4\%$, $P = .01$) in favor of TCS use. The pooled RR was particularly lower for the abdominal surgery group (RR: 0.56; 95% CI: 0.41–0.77) and was robust to sensitivity analysis. Meta-regression analysis revealed that study design, in part, may explain heterogeneity ($P = .03$). The pooled RR subgroup meta-analyses for randomized controlled trials (RCTs) and non-RCTs were 0.74 (95% CI: 0.61–0.89) and 0.53 (95% CI: 0.42–0.66), respectively, both of which favored the use of TCSs.

CONCLUSION. The random-effects meta-analysis based on RCTs suggests that TCSs reduced the risk of SSI by 26% among patients undergoing surgery. This effect was particularly evident among those who underwent abdominal surgery.

Infect Control Hosp Epidemiol 2015;36(2):1–11

What Do the Various Meta-Analyses Tell Us About Risk Reduction?

- *Wang et al, BJS 2013;100-465: 17 RCT (3720 patients) – 30% decrease in risk of SSI (p<0.001)*
- *Edmiston et, Surgery 2013;154:89-100: 13 RCT (3568 patients) – 27% to 33% decrease in risk of SSI (p<0.005)*
- *Sajid et al, Gastroenterol Report 2013:42-50: 7 RCT (1631 patients) – Odds of SSI 56% less in triclosan suture group compared to controls (p<0.04)*
- *Daoud et al, Surg Infect 2014;15:165-181: 15 RCT (4800 patients) – 20% to 50% decreased risk of SSI (p<0.001)*
- *Apisarnthanarak et al. Infect Cont Hosp Epidemiol 2015;36:1-11: 29 studies (11,900 patients) – 26% reduction in SSI (p<0.01)*

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY AUGUST 2014, VOL. 35, NO. 8

ORIGINAL ARTICLE

An Economic Model: Value of Antimicrobial-Coated Sutures to Society, Hospitals, and Third-Party Payers in Preventing Abdominal Surgical Site Infections

Ashima Singh, MS;[1] Sarah M. Bartsch, MPH;[2] Robert R. Muder, MD;[3] Bruce Y. Lee, MD, MBA[2]

BACKGROUND. While the persistence of high surgical site infection (SSI) rates has prompted the advent of more expensive sutures that are coated with antimicrobial agents to prevent SSIs, the economic value of such sutures has yet to be determined.

METHODS. Using TreeAge Pro, we developed a decision analytic model to determine the cost-effectiveness of using antimicrobial sutures in abdominal incisions from the hospital, third-party payer, and societal perspectives. Sensitivity analyses systematically varied the risk of developing an SSI (range, 5%–20%), the cost of triclosan-coated sutures (range, $5–$25/inch), and triclosan-coated suture efficacy in preventing infection (range, 5%–50%) to highlight the range of costs associated with using such sutures.

RESULTS. Triclosan-coated sutures saved $4,109–$13,975 (hospital perspective), $4,133–$14,297 (third-party payer perspective), and $40,127–$53,244 (societal perspective) per SSI prevented, when a surgery had a 15% SSI risk, depending on their efficacy. If the SSI risk was no more than 5% and the efficacy in preventing SSIs was no more than 10%, triclosan-coated sutures resulted in extra expenditure for hospitals and third-party payers (resulting in extra costs of $1,626 and $1,071 per SSI prevented for hospitals and third-party payers, respectively; SSI risk, 5%; efficacy, 10%).

CONCLUSIONS. Our results suggest that switching to triclosan-coated sutures from the uncoated sutures can both prevent SSIs and save substantial costs for hospitals, third-party payers, and society, as long as efficacy in preventing SSIs is at least 10% and SSI risk is at least 10%.

Infect Control Hosp Epidemiol 2014;35(8):1013-1020

❖ We Cannot Forget the Environment of Care as an Etiologic Pathway to SSIs

Pathogens Survival on Surfaces

Organism	Survival period
Clostridium difficile	35- >200 days.[2,7,8]
Methicillin resistant *Staphylococcus aureus* (MRSA)	14- >300 days.[1,5,10, 12]
Vancomycin-resistant enterococcus (VRE)	58- >200 days.[2,3,4]
Escherichia coli	>150- 480 days.[7,9]
Acinetobacter	150- >300 days.[7,11]
Klebsiella	>10- 900 days.[6,7]
Salmonella typhimurium	10 days- 4.2 years.[7]
Mycobacterium tuberculosis	120 days.[7]
Candida albicans	120 days.[7]
Most viruses from the respiratory tract (eg: corona, coxsackie, influenza, SARS, rhino virus)	Few days.[7]
Viruses from the gastrointestinal tract (eg: astrovirus, HAV, polio- or rota virus)	60- 90 days.[7]
Blood-borne viruses (eg: HBV or HIV)	>7 days.[5]

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12. Edmiston et al. 2004 Surgery 138:572.

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Surface Contamination in Operating Rooms: A Risk for Transmission of Pathogens?

Saber Yezli,[1] Frédéric Barbut,[2] and Jonathan A. Otter[1,3]

Abstract

Background: The role of surface contamination in the transmission of nosocomial pathogens is recognized increasingly. For more than 100 years, the inanimate environment in operating rooms (e.g., walls, tables, floors, and equipment surfaces) has been considered a potential source of pathogens that may cause surgical site infections (SSIs). However, the role of contaminated surfaces in pathogen acquisition in this setting generally is considered negligible, as most SSIs are believed to originate from patients' or healthcare workers' flora.
Methods: A search of relevant medical literature was performed using PubMed to identify studies that investigated surface contamination of operating rooms and its possible role in infection transmission.
Results: Despite a limited number of studies evaluating the role of surface contamination in operating rooms, there is accumulating evidence that the inanimate environment of the operating room can become contaminated with pathogens despite standard environmental cleaning. These pathogens can then be transmitted to the hands of personnel and then to patients and may result in SSIs and infection outbreaks.
Conclusion: Contaminated surfaces can be responsible for the transmission of pathogens in the operating room setting. Further studies are necessary to quantify the role of contaminated surfaces in the transmission of pathogens and to inform the most effective environmental interventions. Given the serious consequences of SSIs, special attention should be given to the proper cleaning and disinfection of the inanimate environment in operating rooms in addition to the other established infection control measures to reduce the burden of SSIs.

Modern operating rooms (ORs) have strict measures to reduce contamination, including sterilization of instruments, environmental cleaning and disinfection, and advanced air handling and ventilation. Notwithstanding these measures, infections affect 2%–5% of all surgical patients, and surgical site infections (SSIs) represent a substantial factor in perioperative morbidity, poor surgical outcomes, and total healthcare expenditure [1,2]. In the U.S. alone, it has been estimated that more than one-half million SSIs occur annually, with a direct cost of as much as $10 billion [3].

The role of surface contamination in the transmission of nosocomial pathogens is being recognized increasingly [4]. Contaminated surfaces act as reservoirs on which microorganisms can survive for several months, increasing the risk of cross-contamination through direct or indirect contact with patients. Pathogens responsible for SSIs, including multidrug-resistant (MDR) strains, can originate from endogenous and exogenous sources. Some SSIs originating from an exogenous source could be acquired indirectly after transmission of pathogens from contaminated surfaces to the hands of healthcare workers. Transmission is exacerbated in settings with a high number of interactions among healthcare workers' hands, patients, and the environment. Failures in cleaning and disinfection or poor compliance with proper infection control practices, in particular hand hygiene and gloving, also contribute to transmission [5–7]. Recent literature shows that both the cleaning and the disinfection of the OR environment as well as the frequency of hand hygiene among anesthesiologists while providing care in ORs is less than optimal [7–10]. Thus, there is a potential for transmission from the environment in ORs where there are multiple and frequent contacts among patients, the hands of healthcare personnel, and the environment, combined with skin breaches during surgery. Given this dynamic interchange among patients, surfaces, and the hands of healthcare personnel, it is difficult to determine accurately the source of a SSI. Although for

[1]Bioquell (UK) Ltd., Andover, Hampshire, United Kingdom.
[2]Assistance Publique- Hôpitaux de Paris, Hôpital Saint-Antoine, Paris, France.
[3]Centre for Clinical Infection and Diagnostics Research (CIDR), Department of Infectious Diseases, King's College London & Guy's and St. Thomas' NHS Foundation Trust, London, United Kingdom.

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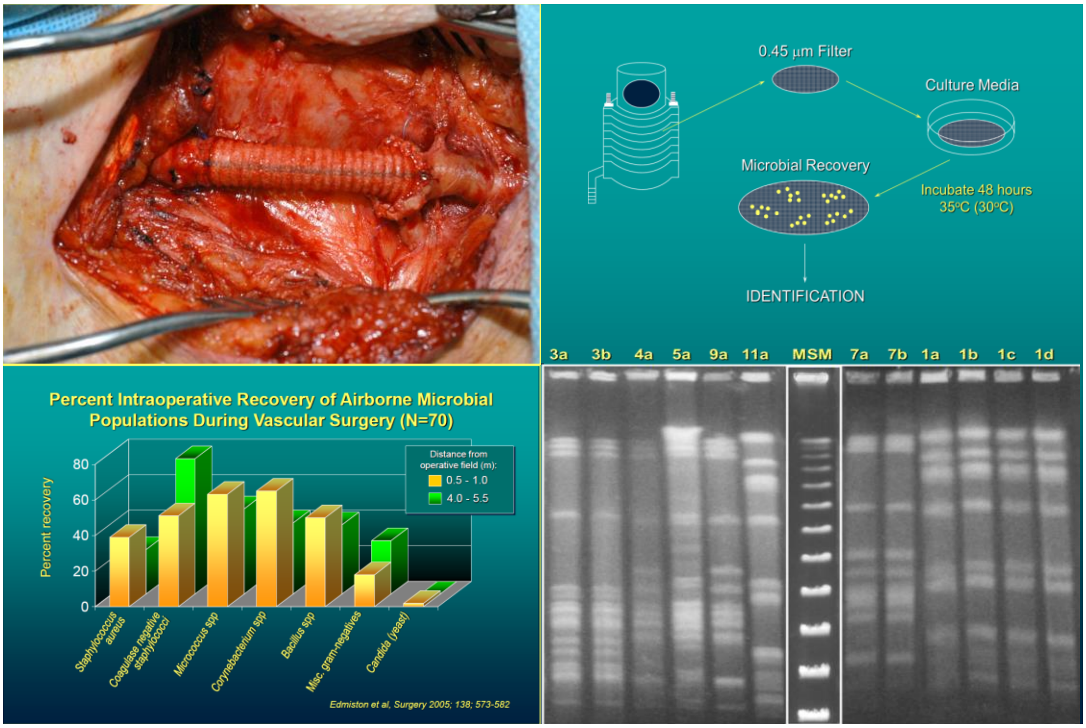
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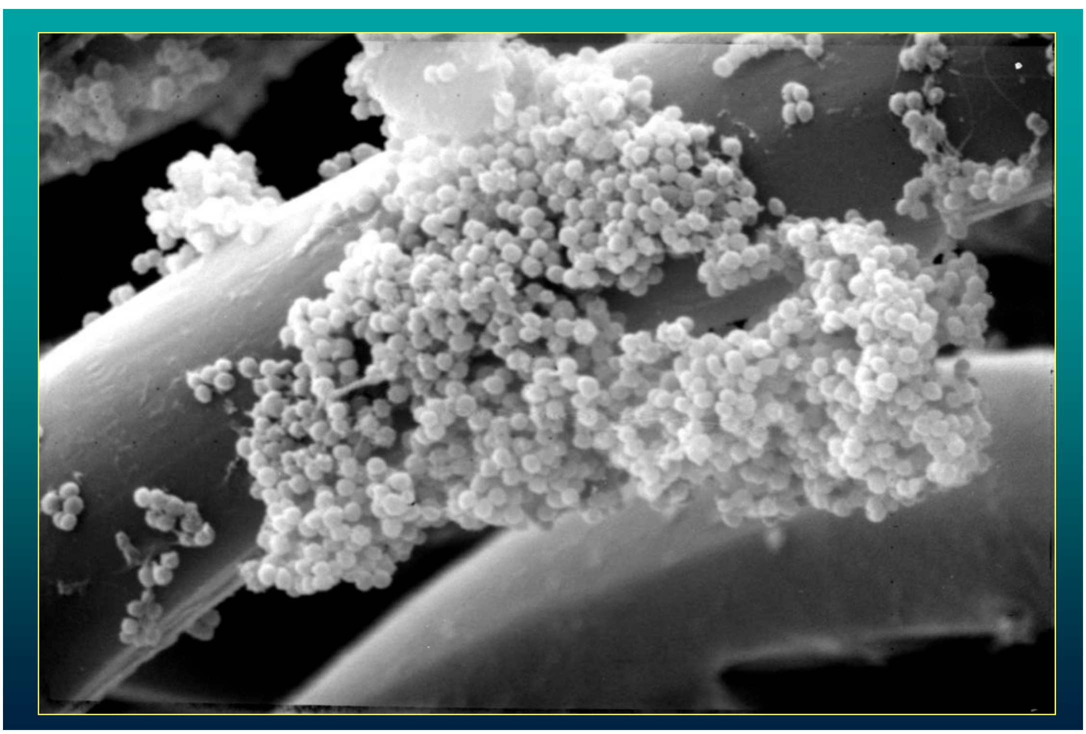
Culture Media
Microbial Recovery
Incubate 48 hours
35°C (30°C)
IDENTIFICATION
Percent Intraoperative Recovery of Airborne Microbial Populations During Vascular Surgery (N=70)
Percent recovery
80
60
40
20
0
Distance from operative field (m):
0.5 - 1.0
4.0 - 5.5
Staphylococcus aureus
Coagulase negative staphylococci
Micrococcus spp
Corynebacterium spp
Bacillus spp
Misc. gram-negatives
Candida (yeast)
Edmiston et al, Surgery 2005; 138; 573-582
3a 3b 4a 5a 9a 11a MSM 7a 7b 1a 1b 1c 1d



What Constitutes the Ideal Surgical Care Bundle?

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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?

Charles E. Edmiston, Jr.,[1,2] Maureen Spencer,[3] Brian D. Lewis,[2] Kellie R. Brown,[2] Peter J. Rossi,[2] Cindy R. Henen,[4] Heidi W. Smith,[4] and Gary R. Seabrook[2]

Abstract

Background: Surgical site infections (SSIs) are associated with substantial patient morbidity and death. It is estimated that 750,000–1 million SSIs occur in the U.S. each year, utilizing 3.7 million extra hospital days and costing more than $1.6 billion in excess hospital charges.
Method: Review of pertinent English-language literature.
Results: The Surgical Care Improvement Project (SCIP) was embraced as a "one-size-fits-all" strategy to reduce postoperative infectious morbidity 25% by 2010. Unfortunately, the evidence suggests that SCIP by itself has had little efficacy in reducing the overall risk of SSI. Whereas the SCIP initiative represents a first national effort to focus on reducing postoperative infectious morbidity and deaths, it fails to consider salient risk factors such as body mass index and selected surgical practices, including tourniquet application prior to incision.
Conclusion: Rather than focus on a single risk-reduction strategy, future efforts to improve surgical outcomes should embrace a "SCIP-plus" multi-faceted, tiered interventional strategy that includes pre-admission antiseptic showering, state-of-the-art skin antisepsis, innovative antimicrobial technology, active staphylococcal surveillance, and pharmacologic-physiologic considerations unique to selective patient populations.

Nationalizing Risk Reduction—The SCIP Mandate

TRADITIONALLY, THE THREE CORNERSTONES viewed as essential for reducing the risk of postoperative surgical site infection (SSI) were exquisite surgical technique, timely and appropriate antimicrobial prophylaxis, and peri-operative skin antisepsis. However, recognition of the influence of certain patient co-morbidities has required additional considerations. It is estimated that 750,000–1 million SSIs occur yearly, resulting in an additional 2.5 million hospital days at a cost exceeding $1 billion [1,2].

The Surgical Care Improvement Project (SCIP), developed by the Centers for Medicare and Medicaid Services and implemented in 2006, was designed as an evidence-based initiative to be applied broadly across selected surgical services, with a stated goal of reducing morbidity and mortality rates 25% by the year 2010 [3]. The specific infection prevention measures are improvements in antimicrobial prophylaxis that involve timing, choice of agent, and discontinuation within 24 h; appropriate hair removal (clipping rather than shaving); normalizing core body temperature within a defined time in colorectal procedures; and glycemic control in cardiac patients, which has been translated in most institutions to include the development of tight glycemic control protocols.

Implementation of the SCIP initiative required a multidisciplinary approach to achieve 95% compliance with each core process measure. Failure to achieve a national benchmark goal results in a punitive reduction in CMS reimbursement (2%), which corresponds to a "pay-for-performance" carrot-and-stick approach to improving patient outcomes. The original SCIP normothermia process measure has been expanded to include patients other than those having colorectal surgery,

[1]Surgical Microbiology Research Laboratory, Medical College of Wisconsin, Milwaukee, Wisconsin.
[2]Division of Vascular Surgery, Medical College of Wisconsin, Milwaukee, Wisconsin.
[3]Universal Health Services, King of Prussia, Pennsylvania.
[4]Department of Pharmacy, Froedtert Hospital, Milwaukee, Wisconsin.
Presented in part at a scientific symposium of the Thirtieth Annual Meeting of the Surgical Infection Society, Las Vegas, Nevada, April 17–20, 2010.

1

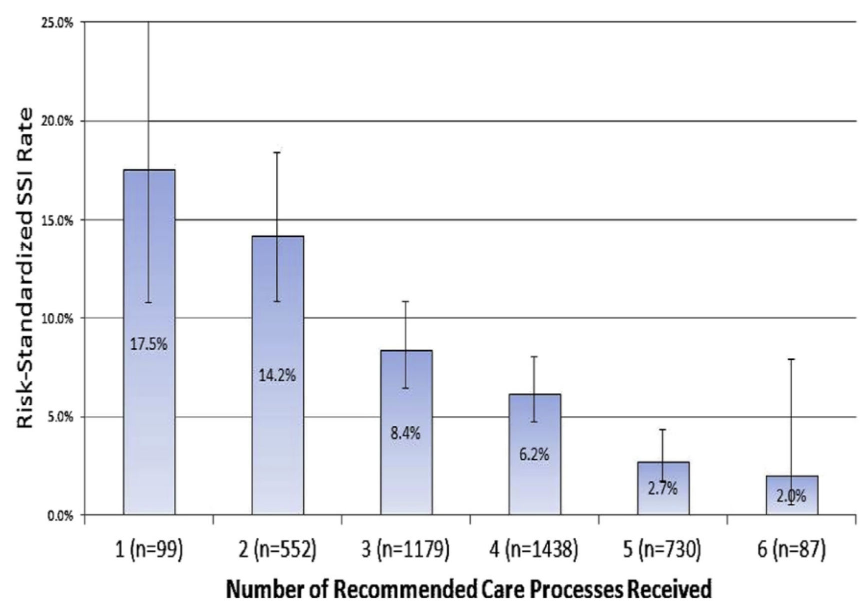
Developing an argument for bundled interventions to reduce surgical site infection in colorectal surgery

Seth A. Waits, MD,[a] Danielle Fritze, MD,[a] Mousumi Banerjee, PhD,[a,b] Wenying Zhang, MA,[a] James Kubus, MS,[a] Michael J. Englesbe, MD,[a] Darrell A. Campbell, Jr, MD,[a] and Samantha Hendren, MD, MPH,[a] *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], 7.9–0.5%), whereas patients who received only 1 bundle measure had SSI rates of 17.5% (95% CI, 27.1–10.8%).*
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[a] and Biostatistics,[b] University of Michigan, Ann Arbor, MI

Waits et al, Surgery 2014;155:602



Waits et al, Surgery 2014;155:602

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Published online August 27, 2014.

Original Investigation

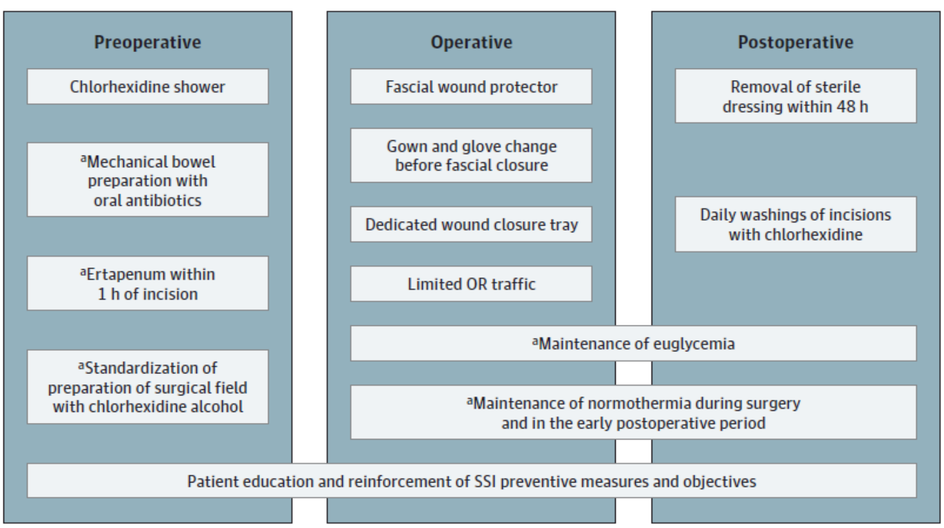
The Preventive Surgical Site Infection Bundle in Colorectal Surgery
An Effective Approach to Surgical Site Infection Reduction and Health Care Cost Savings

Jeffrey E. Keenan, MD; Paul J. Speicher, MD; Julie K. M. Thacker, MD; Monica Walter, DNP;
Maragatha Kuchibhatla, PhD; Christopher R. Mantyh, MD

RESULTS Of 559 patients in the study, 346 (61.9%) and 213 (38.1%) underwent their operation before and after implementation of the bundle, respectively. Groups were matched on their propensity to be treated with the bundle to account for significant differences in the preimplementation and postimplementation characteristics. Comparison of the matched groups revealed that implementation of the bundle was associated with reduced superficial SSIs (19.3% vs 5.7%, $P < .001$) and postoperative sepsis (8.5% vs 2.4%, $P = .009$). No significant difference was observed in deep SSIs, organ-space SSIs, wound disruption, length of stay, 30-day readmission, or variable direct costs between the matched groups. However, in a subgroup analysis of the postbundle period, superficial SSI occurrence was associated with a 35.5% increase in variable direct costs ($13 253 vs $9779, $P = .001$) and a 71.7% increase in length of stay (7.9 vs 4.6 days, $P < .001$).

CONCLUSIONS AND RELEVANCE The preventive SSI bundle was associated with a substantial reduction in SSIs after colorectal surgery. The increased costs associated with SSIs support that the bundle represents an effective approach to reduce health care costs.

Figure 1. The Preventive Surgical Site Infection (SSI) Bundle in Colorectal Surgery



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PLOS | ONE

Implementation of a Bundle of Care to Reduce Surgical Site Infections in Patients Undergoing Vascular Surgery

Jasper van der Slegt[1]*, Lijckle van der Laan[1], Eelco J. Veen[1], Yvonne Hendriks[2], Jannie Romme[2], Jan Kluytmans[2,3]

1 Department of Surgery, Amphia Hospital, Breda, The Netherlands, 2 Laboratory for Microbiology and Infection Control, Amphia Hospital, Breda, The Netherlands, 3 Department of Medical Microbiology and Infection Control, VU University Medical Center, Amsterdam, The Netherlands

Abstract

Background: Surgical site infections (SSI's) are associated with severe morbidity, mortality and increased health care costs in vascular surgery.

Objective: To implement a bundle of care in vascular surgery and measure the effects on the overall and deep-SSI's rates.

Design: Prospective, quasi-experimental, cohort study.

Methods: A prospective surveillance for SSI's after vascular surgery was performed in the Amphia hospital in Breda, from 2009 through 2011. A bundle developed by the Dutch hospital patient safety program (DHPSP) was introduced in 2009. The elements of the bundle were (1) perioperative normothermia, (2) hair removal before surgery, (3) the use of perioperative antibiotic prophylaxis and (4) discipline in the operating room. Bundle compliance was measured every 3 months in a random sample of surgical procedures and this was used for feedback.

Results: Bundle compliance improved significantly from an average of 10% in 2009 to 60% in 2011. In total, 720 vascular procedures were performed during the study period and 75 (10.4%) SSI were observed. Deep SSI occurred in 25 (3.5%) patients. Patients with SSI's (28,5±29.3 vs 10.8±11.3, p<0.001) and deep-SSI's (48.3±39.4 vs 11.4±11.8, p<0.001) had a significantly longer length of hospital stay after surgery than patients without an infection. A significantly higher mortality was observed in patients who developed a deep SSI (Adjusted OR: 2.96, 95% confidence interval 1.32–6.63). Multivariate analysis showed a significant and independent decrease of the SSI-rate over time that paralleled the introduction of the bundle. The SSI-rate was 51% lower in 2011 compared to 2009.

Conclusion: The implementation of the bundle was associated with improved compliance over time and a 51% reduction of the SSI-rate in vascular procedures. The bundle did not require expensive or potentially harmful interventions and is therefore an important tool to improve patient safety and reduce SSI's in patients undergoing vascular surgery.

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* E-mail: jvanderslegt@gmail.com

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Do surgical care bundles reduce the risk of surgical site infections in patients undergoing colorectal surgery? A systematic review and cohort meta-analysis of 8,515 patients

Judith Tanner, PhD,[a] **Wendy Padley, MSc,**[b] **Ojan Assadian, MD,**[c] **David Leaper, MD,**[c] **Martin Kiernan, MPH,**[d] *and* **Charles Edmiston, PhD,**[e] *Nottingham, Leicester, Huddersfield, and London, UK, and Milwaukee, WI*

Background. *Care bundles are a strategy that can be used to reduce the risk of surgical site infection (SSI), but individual studies of care bundles report conflicting outcomes. This study assesses the effectiveness of care bundles to reduce SSI among patients undergoing colorectal surgery.*
Methods. *We performed a systematic review and meta-analysis of randomized controlled trials, quasi-experimental studies, and cohort studies of care bundles to reduce SSI. The search strategy included database and clinical trials register searches from 2012 until June 2014, searching reference lists of retrieved studies and contacting study authors to obtain missing data. The Downs and Black checklist was used to assess the quality of all studies. Raw data were used to calculate pooled relative risk (RR) estimates using Cochrane Review Manager. The* I^2 *statistic and funnel plots were performed to identify publication bias. Sensitivity analysis was carried out to examine the influence of individual data sets on pooled RRs.*
Results. *Sixteen studies were included in the analysis, with 13 providing sufficient data for a meta-analysis. Most study bundles included core interventions such as antibiotic administration, appropriate hair removal, glycemic control, and normothermia. The SSI rate in the bundle group was 7.0% (328/4,649) compared with 15.1% (585/3,866) in a standard care group. The pooled effect of 13 studies with a total sample of 8,515 patients shows that surgical care bundles have a clinically important impact on reducing the risk of SSI compared to standard care with a CI of 0.55 (0.39–0.77; P = .0005).*
Conclusion. *The systematic review and meta-analysis documents that use of an evidence-based, surgical care bundle in patients undergoing colorectal surgery significantly reduced the risk of SSI. (Surgery 2015;158:66-77.)*

From the School of Health Sciences,[a] *University of Nottingham, Nottingham; Faculty of Health and Life Sciences,*[b] *De Montfort University, Leicester; Institute of Skin Integrity and Infection Prevention,*[c] *University of Huddersfield, Huddersfield; Richard Wells Research Centre,*[d] *University of West London, London, UK; and Department of Surgery,*[e] *Medical College of Wisconsin, Milwaukee, WI*

Surgery 2015;158:66-77

Study or Subgroup	Care Bundle Events	Care Bundle Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI
Anthony 2010	45	100	24	97	8.7%	1.82 [1.21, 2.74]
Berenguer 2010	7	84	15	113	6.2%	0.63 [0.27, 1.47]
Bull 2011	22	175	27	180	8.1%	0.84 [0.50, 1.41]
Cima 2012	8	198	52	531	6.9%	0.41 [0.20, 0.85]
Crolla 2012	61	377	86	394	9.3%	0.74 [0.55, 1.00]
Hedrick 2007	21	132	45	175	8.4%	0.62 [0.39, 0.99]
Keenan 2014	18	212	55	212	8.2%	0.33 [0.20, 0.54]
Liau 2010	11	2408	33	1040	7.2%	0.14 [0.07, 0.28]
Lutfiyya 2012	13	195	91	430	7.9%	0.32 [0.18, 0.55]
Pastor 2010	49	253	45	238	9.0%	1.02 [0.71, 1.47]
Tillman 2013	12	104	19	79	7.3%	0.48 [0.25, 0.93]
Waits 2013	2	87	17	99	3.6%	0.13 [0.03, 0.56]
Wick 2012	59	324	76	278	9.3%	0.67 [0.49, 0.90]
Total (95% CI)		**4649**		**3866**	**100.0%**	**0.55 [0.39, 0.77]**
Total events	328		585			

Heterogeneity: $Tau^2 = 0.30$; $Chi^2 = 73.22$, df = 12 ($P < 0.00001$); $I^2 = 84\%$

Test for overall effect: Z = 3.47 (P = 0.0005)

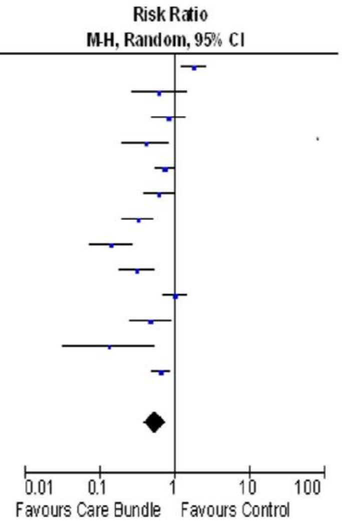

Fig 2. Forest plot. Surgical care bundles to reduce the risk of surgical site infections.

Surgery 2015;158:66-77

Table II. Bundle interventions

SSI bundle interventions	Anthony 2011	Berenguer 2010	Bull 2011	Cima 2013	Crolla 2012	Hawn 2011	Hedrick 2007	Keenan 2014	Larochelle 2011	Liau 2010	Lutfiyya 2012	Pastor 2010	Tillman 2013	Waits 2014	Wick 2008	Wick 2012
Appropriate antibiotic selection/dose		✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
Prophylactic antibiotics within 60 min before surgery	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	
Prophylactic antibiotics discontinued within 24 h		✓		✓		✓	✓		✓		✓	✓	✓		✓	
Antibiotic re-dose within 3–4 h after incision				✓							✓	✓			✓	
Glycemic control			✓				✓	✓		✓	✓	✓		✓	✓	
Normothermia pre-operatively	✓		✓		✓						✓					✓
Normothermia intra-operatively	✓		✓		✓		✓	✓		✓	✓		✓		✓	
Normothermia post-operatively		✓	✓		✓	✓		✓	✓	✓		✓		✓	✓	
Appropriate hair removal		✓			✓	✓	✓			✓	✓	✓	✓		✓	
Supplemental oxygen	✓		✓								✓					
Systolic pressure ≥90 mmHg			✓													
Reduction in intravenous fluids during operation	✓															
Wound edge protector	✓							✓								
CHG cloths on admission				✓												
Preoperative CHG wipes or shower				✓				✓			✓					✓
CHG in alcohol skin preparation				✓				✓			✓					✓
Double gloving											✓					
Glove and/or gown change				✓				✓								
Theatre discipline/restricted traffic					✓			✓								
Smoking cessation											✓					
Patient SSI education				✓				✓			✓					
Tray for closure of fascia and skin				✓				✓								✓
Omission of mechanical bowel preparation	✓															*
Mechanical bowel preparation plus oral antibiotics								✓			✓					✓*
Oral antibiotics given with mechanical bowel prep if used														✓		

(*continued*)

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ORIGINAL ARTICLE

Surgical site infection: poor compliance with guidelines and care bundles

David J Leaper[1], Judith Tanner[2], Martin Kiernan[3], Ojan Assadian[4] & Charles E Edmiston Jr[5]

1 School of Applied Sciences, University of Huddersfield, Huddersfield, UK
2 Clinical Nursing Research, DeMontfort University, Leicester, UK
3 Prevention and Control of Infection, Southport and Ormskirk Hospitals NHS Trust, Southport, UK
4 Department of Hospital Hygiene, Medical University of Vienna, Vienna, Austria
5 Department of Surgery, Medical College of Wisconsin, Milwaukee, WI USA

Key words
Care bundles; Compliance; Guidelines; Surgical site infection

Correspondence to
DJ Leaper
Professor of Clinical Sciences
University of Huddersfield
Huddersfield
West Yorkshire
UK
E-mail: profdavidleaper@doctors.org.uk

Leaper DJ, Tanner J, Kiernan M, Assadian O, Edmiston CE Jr. Surgical site infection: poor compliance with guidelines and care bundles. Int Wound J 2014; doi: 10.1111/iwj.12243

Abstract

Surgical site infections (SSIs) are probably the most preventable of the health care-associated infections. Despite the widespread international introduction of level I evidence-based guidelines for the prevention of SSIs, such as that of the National Institute for Clinical Excellence (NICE) in the UK and the surgical care improvement project (SCIP) of the USA, SSI rates have not measurably fallen. The care bundle approach is an accepted method of packaging best, evidence-based measures into routine care for all patients and, common to many guidelines for the prevention of SSI, includes methods for preoperative removal of hair (where appropriate), rational antibiotic prophylaxis, avoidance of perioperative hypothermia, management of perioperative blood glucose and effective skin preparation. Reasons for poor compliance with care bundles are not clear and have not matched the wide uptake and perceived benefit of the WHO 'Safe Surgery Saves Lives' checklist. Recommendations include the need for further research and continuous updating of guidelines; comprehensive surveillance, using validated definitions that facilitate benchmarking of anonymised surgeon-specific SSI rates; assurance that incorporation of checklists and care bundles has taken place; the development of effective communication strategies for all health care providers and those who commission services and comprehensive information for patients.

Leaper et al. Int Wound J. 2014 Feb 25. doi: 10.1111/iwj.12243

"The practice of evidence-based medicine means integrating individual clinical expertise with the best external evidence from systematic reviews."

Sackett et al. Evidence-based medicine: what it is and what it isn't. BMJ 1996;312:71-72

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