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

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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”

Moynihan

Br J Surgery 1920; 8 : 27-35

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

<table>
<thead>
<tr>
<th>Hospital</th>
<th>NHSN</th>
<th>ACS NSQIP</th>
<th>Difference</th>
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<tbody>
<tr>
<td>A</td>
<td>3.0</td>
<td>4.6</td>
<td>1.6</td>
</tr>
<tr>
<td>B</td>
<td>4.3</td>
<td>6.0</td>
<td>1.7</td>
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<tr>
<td>C</td>
<td>2.4</td>
<td>5.0</td>
<td>2.6</td>
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<tr>
<td>D</td>
<td>4.8</td>
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<td>4.0</td>
</tr>
<tr>
<td>E</td>
<td>NA</td>
<td>7.1</td>
<td>NA</td>
</tr>
<tr>
<td>F</td>
<td>8.9</td>
<td>10.7</td>
<td>1.8</td>
</tr>
<tr>
<td>G</td>
<td>3.9</td>
<td>12.8</td>
<td>8.9</td>
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<td>2.3</td>
<td>16.2</td>
<td>13.9</td>
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<tr>
<td>I</td>
<td>3.7</td>
<td>12.3</td>
<td>8.6</td>
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<td>J</td>
<td>5.1</td>
<td>11.9</td>
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<td>K</td>
<td>14.5</td>
<td>24.0</td>
<td>9.5</td>
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<td>L</td>
<td>9.6</td>
<td>17.1</td>
<td>7.5</td>
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<td>M</td>
<td>2.0</td>
<td>18.0</td>
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<td>N</td>
<td>4.0</td>
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<td>O</td>
<td>9.0</td>
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<tr>
<td>P</td>
<td>7.8</td>
<td>26.7</td>
<td>18.8</td>
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<tr>
<td>Mean</td>
<td>5.7</td>
<td>13.5</td>
<td>8.3</td>
</tr>
</tbody>
</table>

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

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 önemli risk komplikasyonları.
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

Systematic Reviews and Meta-analyses

Randomized Controlled Double Blind Studies

Cohort Studies

Case Control Studies

Case Series

Case Reports

Ideas, Editorials, Opinions

Animal research

In vitro ('test tube') research

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 Doi, MD, MS, MBA1, Squan S. Desai, MD, PhD, MBA1, Gary B. Schreiber, MD,1 Kellie M. Brown, MD,2 Brian D. Lewis, MD,2 Peter J. Ross, MD,1 Charles E. Edmondson, PhD,1 and Cheung J. Liu, MD,1 Hingham, Wey, and Springfield, IL

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 use. This study aimed to determine the effect SCIP guidelines had on SI in hospital SSI after open vascular procedures. Method: The Nationwide Inpatient Sample (NIS) was retrospecively analyzed using International Classification of Diseases, Ninth Revision, diagnosis codes to capture SSI in hospital patients who underwent either carotid endarterectomy, elective open repair of an abdominal aortic aneurysm (AAA), and/or peripheral bypass. The pre-SCIP era was defined as 2000 to 2005 and post-SCIP era was defined as 2006 to 2010. The year 2006 was excluded because this was the transition year in which the SCIP guidelines were implemented. Analysis of variance and χ² testing were used for statistical analysis. Results: The rate of SSI in the pre-SCIP era was 2.2% compared with 2.7% for carotid endarterectomy (P = .66), for peripheral bypass both in the pre- and post-SCIP era, infection rates were 6.1% (P = .22). For open, elective AAA, the rate of infection in the post-SCIP era increased significantly to 14.5% from 10.9% in the pre-SCIP era (P = .003). Demographics in both groups did not differ significantly between the groups. Conclusion: Implementation of SCIP guidelines has made no significant effect on the incidence of SSI in open vascular procedures: neither an increase in SSI rates in open AAA repairs was observed. Patients entered, managed, and operated on care, rather than current SCIP practices, had further decreased SSI rates in vascular patients undergoing open procedures. (J Vasc Surg 2010;51:341S-4.)
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

<table>
<thead>
<tr>
<th>Organisms</th>
<th>n</th>
<th>Serum</th>
<th>Tissues</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>70</td>
<td>68.6%</td>
<td>27.1%</td>
</tr>
<tr>
<td><em>Staphylococcus epidermidis</em></td>
<td>110</td>
<td>34.5%</td>
<td>10.9%</td>
</tr>
<tr>
<td><em>E. coli</em></td>
<td>85</td>
<td>75.3%</td>
<td>56.4%</td>
</tr>
<tr>
<td><em>Klebsiella pneumoniae</em></td>
<td>55</td>
<td>80%</td>
<td>65.4%</td>
</tr>
</tbody>
</table>


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

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)
Microbial Ecology of Skin Surface

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

Surgical Microbiology Research Laboratory 2008 – Medical College of Wisconsin
Preoperative bathing or showering with skin antiseptics to prevent surgical site infection (Review)

Wilmot J, Osborne S

THE COCHRANE COLLABORATION®

Draft Guideline for the Prevention of Surgical Site Infection

Sandra I. Berrios-Torres, MD, Craig A. Umscheid, MD, MSCE, Dana W. Bradley, DO, MPH3, Brian Lees, MA, MSc4, Erin C. Stone, MS5, Rachel B. Kels, MD, MSCE, FASCT3, Caroline Kerlee, MD, MPH6, Sherry Morgan, RN, MS, PhD2, Joseph S. Sobekno, MD7, John E. Mazzoli, MD, PhD3, E. Pelchen-Delinger, MD4, Kamar Han, MD, Erin F. Briner, MD4, John Sargent, MD2, I. Javed Parvid, MD2, Joan Blanchard, MS, BSN, RN, CNOR, CCRN7, George AKH, PhD, CIC, CNOR7, I. A. J. W. Vuykman, MD2, Rodney Dymond, PhD2, William P. Schepeter, MD and the Healthcare Infection Control Practices Advisory Committee2

1Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention, Atlanta, GA. 2Center for Evidence-based Practice, University of Pennsylvania Health System, Philadelphia, PA. 3University of Oklahoma Health Sciences Center, College of Public Health, Oklahoma City, OK. 4School of Medicine, University of Cincinnati, Cincinnati, OH. 5Washington University School of Medicine, Saint Louis, MO. 6University of Nebraska Medical Center, Omaha, NE. 7Temple University.

Professional Organizations’ Current and Draft Recommendations

<table>
<thead>
<tr>
<th>Source</th>
<th>Previous Recommendations</th>
<th>Draft Recommendation</th>
<th>New Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>AORN</td>
<td>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(67)</td>
<td>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(45)</td>
<td></td>
</tr>
<tr>
<td>Hospital Infection Control Practice Advisory Committee for Disease Control and Prevention</td>
<td>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. 12(87)</td>
<td>Cleanse at least 1X with Soap or Antiseptic. *Advise patients to shower or bathe (full body) with either soap or an antiseptic agent on at least the night before the operative day. 13(88)</td>
<td></td>
</tr>
<tr>
<td>Institute for Healthcare Improvement – Project JOINS</td>
<td>Cleanse 3X with CHG. *Instruct patients to bathe or shower with chlorhexidine gluconate (CHG) soap for at least three days before surgery. 14(89)</td>
<td>Cleanse 1X with Soap or Antiseptic. *Advise patients to shower or bathe (full body) with either soap or an antiseptic agent on at least the night before the operative day. 15(90)</td>
<td></td>
</tr>
</tbody>
</table>

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$^a$

<table>
<thead>
<tr>
<th>Subgroups (mean C, µg/ml)</th>
<th>Groups</th>
<th>Pilot$^b$ (4%)</th>
<th>1 (4% Aqueous)</th>
<th>2 (2% Cloths)</th>
<th>$\frac{C_{CHG}}{MIC_{90}}$</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Group A (20)</td>
<td>evening (1X)</td>
<td>3.7±2.5</td>
<td>24.4±5.9</td>
<td>436.1±91.2</td>
<td>0.9</td>
</tr>
<tr>
<td></td>
<td>Group B (20)</td>
<td>morning (1X)</td>
<td>7.8±5.6</td>
<td>79.2±26.5</td>
<td>991.3±58.2</td>
<td>1.9</td>
</tr>
<tr>
<td></td>
<td>Group C (20)</td>
<td>both (2X)</td>
<td>9.9±7.1</td>
<td>126.4±19.4</td>
<td>1745.5±204.3</td>
<td>2.5</td>
</tr>
</tbody>
</table>

$^a$ N = 90  
$^b$ Pilot group N = 30

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### 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, FACS, Candace J Korbel, MS, Sarah E Edmiston, MBI, Maureen Spencer, MBI, Cheeung Lue, MD, Kellee R Brown, MD, FACS, Brian D Lewis, MD, FACS, Peter J Ross, MD, FACS, Michael Malinowski, MD, Gary Seabrook, MD, FACS

BACKGROUND:
Surgical-site infections (SSIs) are responsible for significant morbidity, mortality, and excess cost of health care resources. The preadmission antibiotic shower is accepted as an effective strategy for reducing the risk for SSIs. The study analyzes the benefits 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 colormetric assay in 5 separate anatomic sites. Study personnel were blinded to the intervention arm; after final volunteer processing, the code was broken and individual groups were analyzed.

RESULTS:
Mean preoperative CHG skin-surface concentrations were significantly higher (p < 0.007) in EAS groups A1 (30.9 ± 8.8 µg/mL) and B1 (29.0 ± 8.8 µg/mL) compared with non-EAS groups A2 (18.5 ± 3.5 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供需 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 intervention strategy. (J Am Coll Surg 2014;219:256-264. © 2014 by the American College of Surgeons)

In 2010, the CDC reported that a total of 5.14 million inpatient surgical procedures were performed in the United States. It is estimated that approximately 400,000 surgical-site infections (SSIs) occur in the United States each year.

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

- LF Arm
- RT Arm
- Abdomen
- LF Leg
- RT Leg

Overall mean = 30.9 ± 8.8

Overall mean = 10.5 ± 3.9

+MIC<sup>a</sup> for skin staphylococcal flora (including MRSA = 5 µg/mL).
+Subjects prompted using text, email or voicemail
+Subjects were not prompted

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)\(^a\)

<table>
<thead>
<tr>
<th>Study Groups: (N=120)(^b)</th>
<th>A1</th>
<th>A2</th>
<th>A3</th>
<th>B1</th>
<th>B2</th>
<th>B3</th>
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<tbody>
<tr>
<td>Shower 2X</td>
<td></td>
<td></td>
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<tr>
<td>Mean CHG Concentrations</td>
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<tr>
<td>(µg/mL±sd)</td>
<td></td>
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</tbody>
</table>

\(p<0.001\)\(^c\)  
\(P<0.001\)\(^d\)

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

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

Charles E. Edmiston Jr, PhD, MS, BS, CIC, RnD, Fshea; Juan Assadian, MD, DTMH; Maureen Spencer, MEd, BSN, CIC; Russell N. Oltstead, 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 indigenous microbial burdens on the skin of patients undergoing elective surgery, with the case of reducing the risk of surgical site infections (SSI). According to a recent study by Buziou et al., 97% 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. The Association for Professionals in Infection Control and Epidemiology (APIC)/SHEA, the Association for Healthcare Epidemiology of America (AHEA), and the National Association for Healthcare and Care Facilities (NAHF) all recommend bathing and/or cleansing with an antiseptic agent before surgery as a component of a broader strategy to reduce SSI. The 2008 Society for Healthcare Epidemiology of America (SHEA) Selective Decontamination of Skin (SDS) strategies to prevent SSI in acute care hospitals declined to recommend a specific application policy regarding selection of an antiseptic agent for preoperative bathing but acknowledged that the intrinsically antagonistic nature of chlorhexidine gluconate (CHG) are dependent on achieving adequate skin surface concentrations.

Findings in reports published in the past 10 years have identified SSI to be the most common health care-associated infection (HAI) and the most expensive in terms of resource utilization. This provides a strong business case for health care institutions to invest in targeted, evidence-based, intervention strategies that reduce the risk of postoperative complications. In addition, because the microbial flora of the skin, especially methicillin-resistant Staphylococcus aureus (MRSA), provides a reservoir for pathogens that cause SSI, focused intervention aimed at mitigating the reservoir in preoperative patients represents a logical and effective risk reduction strategy.

The Yin and Yang of Preadmission Bathing: A Rational Consideration of Benefits

Despite the widespread practice of preoperative bathing with CHG, data from non-controlled trials with CHG and AORN recommendations. The current proposed AORN guidelines for preoperative patient skin antisepsis and the CDC draft guidelines both have expanded their recommendations for preoperative skin antisepsis from using CHG products to also using other cleansing products (e.g., antimicrobial or nonantimicrobial soaps, or compelled skin antiseptics). These expanded recommendations mirror 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

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

<table>
<thead>
<tr>
<th>Sutures</th>
<th>Presence of Biofilm (%)</th>
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</thead>
<tbody>
<tr>
<td>Non-Infected Cases</td>
<td>Infected Cases</td>
</tr>
<tr>
<td>Skin Sutures</td>
<td>Superficial SSI</td>
</tr>
<tr>
<td>Nylon a</td>
<td>50</td>
</tr>
<tr>
<td>Braided b</td>
<td>70</td>
</tr>
<tr>
<td>Monofilament c</td>
<td>60</td>
</tr>
</tbody>
</table>

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 Edmundson, 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

![Graph showing microbial recovery](image)

**Exposure Time 2 Minutes**

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

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

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

![Evidence-Base Pyramid](image)
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 Edmiston, Jr, Ph.D.; Frederic C. Daoud, MD, and David Leaper, MD, FACS, Manchester, 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 adjuvant strategy for SSIs risk reduction, but data collected by independent literature reviews and meta-analyses suggested that no clinical benefit is associated with this technology. However, that study was hampered by sparse selection of available randomized controlled trials (RCTs) and lack of 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, and Cochrane Databases (Cochrane Database of Systematic Reviews, Health Economic Evaluations Database, Database of Health Technology Assessments), and www.clinicallink.org to identify RCTs of triclosan-coated sutures compared with conventional sutures and assessing the clinical effectiveness of triclosan-coated sutures to decrease the risk for SSIs. A fixed- and random-effects model was developed, and pooled estimates were reported as risk ratios (RR) with a corresponding 95% confidence interval (CI). Publication bias was not ascertained by applying a funnel plot of individual studies and using the Egger regression tests.

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 = 0.73; 95% CI: 0.59-0.93; P = .005; random-effect RR = 0.70; 95% CI: 0.53-0.92; P = .021). No publication bias was detected (P = .16). Conclusion: Decreasing the risk for SSIs with a multifaceted “smart bundle” approach, and this meta-analysis of current, pooled, pre-revision, randomized controlled trials suggests a clinical effectiveness of a triclosan-coated suture (triclosan) in the prevention of SSIs, supporting Centers for Disease Control and Prevention guidelines. (Surgery 2015;158:89-100)

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

Meta-Analysis

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

Z. X. Wang1,2, C. P. Jiang1,2, Y. Cao1,2 and Y. T. Ding1,2

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Background: Surgical-site infections (SSIs) increase morbidity and mortality in surgical patients and represent an economic burden to healthcare systems. Experimental studies have shown that triclosan-coated sutures (TCS) are beneficial in the prevention of SSIs, although the results from individual randomized controlled trials (RCTs) are inconsistent. A meta-analysis of available RCTs was performed to evaluate the efficacy of TCS in the prevention of SSIs.

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 suture materials on SSIs was conducted until June 2013. The primary outcome was the incidence of SSI. Pooled relative risk (RR) with 95% confidence interval (CI) were estimated with Fixed Effects model.

Results: Seventeen RCTs involving 1,753 patients were included. No heterogeneity of statistical significance across studies was observed. TCS showed a significant advantage in reducing the rate of SSI by 9.6% per one (relative risk [RR] = 0.90, 95% CI: 0.87-0.94, P = 0.001). Subgroup analyses revealed consistent results in favor 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.

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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,7 and David Leaper7

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-antibiotic 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 was estimated to be a relative risk of 0.67 (95% CI: 0.54-0.84; P = .0001) with an overall lower frequency of SSI in the TS arm than in the NTS arm. Results were robust to sensitivity analysis.

Conclusions: Two additional peer-reviewed double-blind RCTs of this update confirmed the predominant effect seen 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.
Meta-Analysis of Risk Reduction by Wound Classification

![Meta-Analysis Table](image)

**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

Amucha Apsaraantharanar, MD,1 Nalini Singh, MD, MPH,2 Aila Nica Bandong, MS,3 Gilbert Madriaga, PTRF4

**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; I² = 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 = .01). 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 al, 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 ($p<0.01$)
We Cannot Forget the Environment of Care as an Etiologic Pathway to SSIs

Pathogens Survival on Surfaces

<table>
<thead>
<tr>
<th>Organism</th>
<th>Survival period</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Clostridium difficile</em></td>
<td>35- &gt;200 days.</td>
</tr>
<tr>
<td>Methicillin resistant <em>Staphylococcus aureus</em> (MRSA)</td>
<td>14- &gt;300 days.</td>
</tr>
<tr>
<td>Vancomycin-resistant enterococcus (VRE)</td>
<td>58- &gt;200 days.</td>
</tr>
<tr>
<td><em>Escherichia coli</em></td>
<td>&gt;150- 480 days.</td>
</tr>
<tr>
<td><em>Acinetobacter</em></td>
<td>150- &gt;300 days.</td>
</tr>
<tr>
<td><em>Klebsiella</em></td>
<td>&gt;10- 900 days.</td>
</tr>
<tr>
<td><em>Salmonella typhimurium</em></td>
<td>10 days- 4.2 years.</td>
</tr>
<tr>
<td><em>Mycobacterium tuberculosis</em></td>
<td>120 days.</td>
</tr>
<tr>
<td><em>Candida albicans</em></td>
<td>120 days.</td>
</tr>
<tr>
<td>Most viruses from the respiratory tract (eg: corona, coxsackie, influenza, SARS, rhino virus)</td>
<td>Few days.</td>
</tr>
<tr>
<td>Viruses from the gastrointestinal tract (eg: astrovirus, HAV, polio- or rota virus)</td>
<td>60- 90 days.</td>
</tr>
<tr>
<td>Blood-borne viruses (eg: HBV or HIV)</td>
<td>&gt;7 days.</td>
</tr>
</tbody>
</table>

2. BIOQUELL trials, unpublished data.
Surface Contamination in Operating Rooms: A Risk for Transmission of Pathogens?

Saber Hess**, Holistic Bazaz**, and Jonathan A. Orsi**

Abstract

Background: The role of surface contamination in the transmission of nosocomial pathogens is recognized increasingly. For more than 100 years, the immune environment in operating rooms (e.g., walls, tables, linens, and instruments) has been known to harbor microorganisms that can cause surgical site infections (SSIs). However, the role of contaminated surfaces in pathogen acquisition in this setting generally is unexamined 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 in 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 immediate 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: The role of contaminated surfaces in the operating environment must be sufficiently considered 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 immediate environment in operating rooms; in addition to other established infection control measures to reduce the burden of SSIs.

**Department of Orthopedic Surgery, University of California, San Francisco, California, USA


What Constitutes the Ideal Surgical Care Bundle?
Developing an argument for bundled interventions to reduce surgical site infection in colorectal surgery

Seth A. Waits, MD,* Danielle Fritz, MD,* Mouwumi Banerjee, MD,* Wenyong Zhang, MA,* James Kubus, MS,* Michael J. Englesbe, MD,* Darrell A. Campbell, Jr, MD,* and Samantha Hendren, MD, MPH,* 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 on 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, and 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], 7.9–9.5%), 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 is required to confirm this finding. (Surgery 2014;155:602–9.)

From the Departments of Surgery* and Biostatistics,* University of Michigan, Ann Arbor, MI

Waits et al, Surgery 2014;155:602

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Risk-Standardized SSI Rate

<table>
<thead>
<tr>
<th>Number of Recommended Care Processes Received</th>
<th>1 (n=99)</th>
<th>2 (n=552)</th>
<th>3 (n=1179)</th>
<th>4 (n=1438)</th>
<th>5 (n=730)</th>
<th>6 (n=87)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk-Standardized SSI Rate</td>
<td>17.5%</td>
<td>14.2%</td>
<td>8.4%</td>
<td>6.2%</td>
<td>2.7%</td>
<td>2.8%</td>
</tr>
</tbody>
</table>
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 $9,779, \( P = .001 \)) 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

<table>
<thead>
<tr>
<th>Preoperative</th>
<th>Operative</th>
<th>Postoperative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorhexidine shower</td>
<td>Fascial wound protector</td>
<td>Removal of sterile dressing within 48 h</td>
</tr>
<tr>
<td>*Mechanical bowel preparation with oral antibiotics</td>
<td>Gown and glove change before fascial closure</td>
<td>Daily washings of incisions with chlorhexidine</td>
</tr>
<tr>
<td>*Ertapenem within 1 h of incision</td>
<td>Dedicated wound closure tray</td>
<td>*Maintenance of euglycemia</td>
</tr>
<tr>
<td>*Standardization of preparation of surgical field with chlorhexidine alcohol</td>
<td>Limited OR traffic</td>
<td>*Maintenance of normothermia during surgery and in the early postoperative period</td>
</tr>
</tbody>
</table>

Patient education and reinforcement of SSI preventive measures and objectives
Implementation of a Bundle of Care to Reduce Surgical Site Infections in Patients Undergoing Vascular Surgery

Jasper van der Sloot1, Lijckie van der Laan1, Ecko J. Veen1, Yvonne Hendriks2, Janneke Romme2, Jan Klaymans1,2

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

Abstract

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

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

Design: Prospective, quasi-experimental, cohort study.

Methods: A prospective surveillance for 501 vascular surgery patients was performed in the Amphia hospital in Breda, from 2009 until 2011. A bundle was developed as the Dutch hospital action plans program (DHAP) was introduced in 2006. The elements of the bundle were: (1) preoperative intravenous antibiotics, (2) hair removal before surgery, (3) the use of perioperative antibiotic prophylaxis and its discontinuation 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 from an average of 10% in 2009 to 60% in 2011. In total, 705 vascular procedures were performed during the study period and 75 (5.3%) SSIs were observed. Deep SSI occurred in 25 (3.5%) patients. Patients with 501 (2.35, 95% CI: 1.30 to 3.93) in 2010 (p = 0.0036) and deep SSI (3.1, 95% CI: 1.14 to 8.11, p = 0.0012) had a significantly shorter length of hospital stay after surgery than patients without an infection. A significantly higher mortality rate was observed in patients with a SSI compared to patients without an infection. The Chi square analysis showed a significant and independent decrease of the SSI rate over time that paralleled the introduction of the bundle. The SSI rate was 5% 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 surgery. The bundle did not require expensive or potentially harmful interventions and is therefore an important tool to improve patient safety and reduce SSI in patients undergoing vascular surgery.


doi: 10.1371/journal.pone.0071566

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

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Nottingham, Leuven, 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 2018, 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. Flow data were used to calculate funnel plots with the trim-and-fill method. Heterogeneity was assessed using Cochrane Review Manager. The V-statistic and funnel plots were performed to identify publication bias. Sensitivity analysis was carried out to determine the influence of individual data sets on the pooled SSI.

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, aggressive hair removal, glycerin ointment, and normothermia. The SSI rate in the bundle group was 7.0% (95% CI: 6.6% to 7.4%) compared to 12.3% (95% CI: 11.6% to 13.0%) in the control 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 = 0.0005).

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).
Fig 2. Forest plot. Surgical care bundles to reduce the risk of surgical site infections.
The practice of evidence-based medicine means integrating individual clinical expertise with the best external evidence from systematic reviews.

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