


**Reducing the Risk of Surgical Site Infections Using Evidence-Based Interventions: Are We Really Improving Outcomes in the Post-SCIP Era?**

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1

**Disclaimer – Caveat**

**“I DON’T HAVE ALL OF THE ANSWERS”**

Surgical Site Infections Often Represent a Complex and Multifactorial Process - the Mechanistic Etiology or the Search for Resolution May be Quite Elusive – Therefore, Risk Reduction is an Evolutionary Process

2

**First a Little History Lesson**



The “Good Old Days” in the Operating Room

3

**Studies in Aseptic Technique**  
 George Emerson Brewer, M.D.  
 JAMA April 24, 1915

- Clean operative wound infection rate

1895	39.0%
(...would bring the profession in disrepute)	
1897	7.0%
1899	3.2%
1912	2.4%
1913	1.6%

4



5

## Goal of the Surgical Care Improvement Project (SCIP)

Reduce preventable surgical morbidity and mortality by 25% by the year 2010

6

### 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
- Did we reduce preventable surgical morbidity and mortality by 25% by the year 2010?

**Is this the Holy Grail?**

7

### Does the Process Improve the Outcome?

**Association of Surgical Care Improvement Project Infection-Related Process Measure Compliance with Risk-Adjusted Outcomes: Implications for Quality Measurement**

Angela M Ingraham, MD, MS, Mark E Cohen, MD, Karl V Bilimoria, MD, MS, Justin B Dimick, MD, MS, Karen E Richards, MD, Mohd Y Razvi, MD, Lee A Finkler, MD, Bruce L Hall, MD, PA, MBA, FACS, Clifford Y Ko, MD, MS, MSFS, FACS

**BACKGROUND:** Facility-level process measure adherence is being publicly reported. However, the association between measure adherence and surgical outcomes is not well established. Our objective was to determine the degree to which Surgical Care Improvement Project (SCIP) process measures are associated with American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) risk-adjusted outcomes.

**STUDY DESIGN:** The cross-sectional study included hospitals participating in the ACS NSQIP and SCIP (n = 206). ACS NSQIP outcomes (36 risk-adjusted metrics) were measured, surgical site infection (SSI), and mortality and adherence to SCIP SS-related process measures (from the Hospital Compare database) were collected from January 1, 2006, through December 31, 2008. Hospital-level correlations and confidences between compliance with a process measure (ie, antibiotic administration within 1 hour before incision [SCIP-1]) appropriate antibiotic prophylaxis (SCIP-2), antibiotic discontinuation within 24 hours after surgery (SCIP-3), and appropriate hair removal (SCIP-4) and risk-adjusted outcomes were calculated. Regression analysis estimated the contribution of process measure adherence to risk-adjusted outcomes.

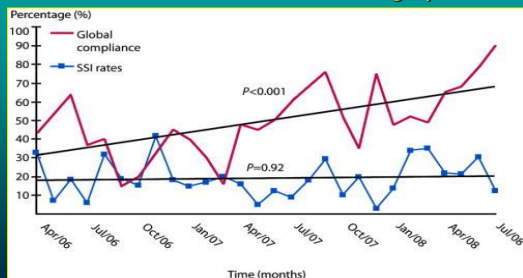
**RESULTS:** Of 211 ACS NSQIP hospitals, 99% had data reported by Hospital Compare. Depending on the measure, hospital-level compliance ranged from 69% to 100%. Of the 15 correlations, 13 demonstrated nonsignificant associations with risk-adjusted outcomes. The exception was the relationship between SCIP-2 and SSI (p = 0.006). SCIP-2 demonstrated an unexpected but nonsignificant relationship with SSI (p = 0.08) and overall mortality (p = 0.08). Although adherence to SCIP-2 was a significant predictor of risk-adjusted SSI (p < 0.0001) and overall mortality (p < 0.0001), inclusion of compliance for SCIP-1 and SCIP-2 caused only slight improvement in model quality.

**CONCLUSIONS:** Better adherence to infection-related process measures over the observed range was not significantly associated with better outcomes with one exception. Different measures of quality might be needed for surgical infection. (J Am Coll Surg 2010;211:705-714. © 2010 by the American College of Surgeons)

Ingraham et al. J Am Coll Surg 2010;211:705-711

8

## 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

9

## Surgical Site Infection Prevention

### Time to Move Beyond the Surgical Care Improvement Program

Mary T. Havon, MD, MPH,<sup>1</sup> Catherine C. Vick, MS,<sup>2</sup> Joshua Richman, MD, PhD,<sup>1</sup> William Holman, MD,<sup>1</sup> Rhannon J. Deterhof, MPH,<sup>3</sup> Laura A. Graham, MPH,<sup>4</sup> William G. Henderson, MPH, PhD,<sup>3</sup> and Kamal M.F. Itani, MD<sup>5</sup>

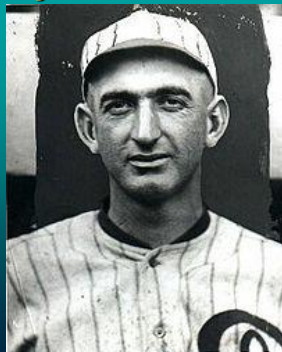
**Results:** There were 60,853 surgeries at 112 VA hospitals analyzed. SCIP adherence ranged from 75% for normothermia to 99% for hair removal and all significantly improved over the study period ( $P < 0.001$ ). Surgical site infection occurred after 6.2% of surgeries (1.6% for orthopedic surgeries to 11.3% for colorectal surgeries). None of the 5 SCIP measures were significantly associated with lower odds of SSI after adjusting for variables known to predict SSI and procedure type. Year was not associated with SSI ( $P = 0.71$ ). Hospital SCIP performance was not correlated with hospital SSI rates ( $r = -0.06$ ,  $P = 0.54$ ).

**Conclusions:** Adherence to SCIP measures improved whereas risk-adjusted SSI rates remained stable. SCIP adherence was neither associated with a lower SSI rate at the patient level, nor associated with hospital SSI rates. Policies regarding continued SCIP measurement and reporting should be reassessed.

(*Ann Surg* 2011;254:494-501)

10

## Say It Ain't So, Joe



11

## 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,<sup>1,2</sup> Maureen Spencer,<sup>3</sup> Brian G. Lauen,<sup>4</sup> Kaitie R. Breen,<sup>5</sup> Peter J. Nease,<sup>6</sup> Cindy R. Hansen,<sup>7</sup> Heidi W. Smith,<sup>8</sup> and Gary R. Sasserock<sup>9</sup>

### Abstract

Background: Surgical site infections (SSIs) are associated with substantial patient morbidity and death. It is estimated that 78,000 to 1 million SSIs occur in the U.S. each year, resulting in 57 million extra hospital days and \$4.6 billion in additional charges. **Results:** The Surgical Care Improvement Project (SCIP) was implemented as a "one-size-fits-all" strategy to reduce postoperative morbidity and mortality. Unfortunately, the evidence suggests that SCIP has not had any 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 patient risk factors such as body mass index and selected surgical practices, including antibiotic application prior to incision. **Conclusions:** Rather than focus on a single risk-reduction strategy, future efforts to improve surgical outcomes should embrace a "SCIP-plus" multi-faceted, tailored, interventional strategy that includes pre-admission antibiotic dosing, use-of-best risk mitigation, innovative antimicrobial technology, active prophylactic surveillance, and pharmacologic-physiologic considerations unique to selected patient populations.

### Minimizing Risk Reduction—The SCIP Mandate


Theoretically, one might expect compliance with an evidence-based strategy to reduce the risk of postoperative surgical site infection (SSI) to have negative surgical technique, timely and appropriate antimicrobial prophylaxis, and preoperative skin antisepsis. However, recognition of the influence of certain patient characteristics has required additional consideration. It is estimated that 78,000 to 1 million SSIs occur each year, resulting in an additional 57 million hospital days of a cost exceeding \$4.6 billion.<sup>1,2,3,4</sup>

The Surgical Care Improvement Project (SCIP), developed by the Centers for Medicare and Medicaid Services and implemented in 2003, 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 2009.<sup>5</sup> The specific infection prevention measures are improvements in antimicrobial prophylaxis that involve timing, choice of agent, and administration method. It is appropriate that several other risk factors (including normothermia and glucose control in diabetic patients), which has been translated in most initiatives to include the development of risk-stratified control protocols.

Implementation of the SCIP mandate required a multi-disciplinary approach to achieve 95% compliance with each core process measure. Failure to achieve individual best-practice goal results in a positive reduction in CMS reimbursement (2%) which corresponds to a "pay-for-performance" credit and risk approach to improving patient outcomes. The original SCIP implementation process measure has been expanded to include patients other than those having selected surgery.

Edmiston et al. *Surgical Infection* 2011;12:169-177

12



**Hierarchy of Research Designs & Levels of Scientific Evidence**

Based on ability to control for bias and to demonstrate cause and effect in humans

- Clinical Practice Guidelines
- Meta-Analysis Systematic Reviews
- Randomized Controlled Trial
- Cohort Studies
- Case Control Studies
- Case Report or Case Series
- Narrative Reviews, Expert Opinions, Editorials
- Animal and Laboratory Studies

Secondary, pre-appraised, or filtered Studies

Primary Studies

Observational Studies

No design

Not involved in Humans

**“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*

13

**“Healthcare institutions, professionals, and perhaps surgeons in particular tend to believe that their care and outcomes are better than they actually are.”**

*Olle Ljungqvist, MD, PhD; Michael Scott, MD; Kenneth C. Fearon, MD, PhD 'Enhanced Recovery After Surgery. JAMA Surg. 2017;152(3):292-298*

14

**A Recent Experience Documenting That Our Efforts at Risk-Reduction Are Far From Perfect**

*The Challenges of Implementing Evidence-Based Strategies to Reduce Surgical Site Infections in Patients Undergoing Colon Surgeries*

15

**Institutional Evidence-Based (Standard of Care)**

Studied Components from Guidelines	Abbreviation	Where published*
Administering a weight-dependent dose of preoperative intravenous (IV) antimicrobial agents	IV Antibiotics	WHO, ACS, CDC
Using triclosan-coated sutures at the deep layer, organ layer and superficial layer	Triclosan Sutures	WHO, ACS, CDC
Controlling a patient's blood glucose at or below 200 mg/dl perioperatively	Blood glucose	WHO, ACS, CDC
Maintaining the patient's body temperature above 36.5 degrees Celsius once under care	Body temp	ACS, CDC
Putting a patient on oxygenation from preoperative period until at least 2 hours after waking in the post-operative period (delivered at a minimal with nasal cannula at 3 L)	Oxygenation	WHO, ACS, CDC
Prepping skin with 2% CHG/70% isopropyl alcohol (ChlorPrep); or 4% aqueous CHG-gentamicin; or Aqueous iodophor (betadine); or Alcohol/Iodophor + (Durasprep) or PCMX	Skin prep	WHO, ACS, CDC
Ordering mechanical bowel prep and antibiotics before surgery	MSP + oral ABs	WHO, ACS

**Documented Compliance to Evidence-Based Mitigation Strategies**

Total number of observed cases	Component Met						
	Skin Prep	IV Antibiotics	Triclosan Sutures	Blood glucose	Body temp	Order pre-op MSP + oral ABs	Oxygenation
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Site 1	319 (99.6)	319 (99.6)	176 (55.2)	263 (82.4)	40 (12.5)	122 (38.2)	3 (0.9)
Site 2	277 (99.6)	277 (100)	277 (100)	249 (89.7)	171 (61.7)	18 (6.5)	62 (22.4)
Site 3	262 (99.6)	261 (99.6)	212 (80.9)	48 (18.3)	30 (11.5)	18 (6.9)	16 (6.1)
Aggregate Sum	858 (99.8)	856 (99.8)	665 (77.5)	555 (64.7)	151 (17.6)	158 (18.4)	81 (9.4)

\*WHO: World Health Organization (WHO); ACS: American College of Surgeons (ACS); CDC: Centers for Disease Control and Prevention (CDC)

16

Perceived Reason for Non-Compliant Behavior – Lack of Documentation or Lack of Data

**Observation 1**

**Observation 2**

**Observation 3**

**Observation 4**

**Observation 5**

**Observation 6**

**Observation 7**

**Observation 8**

**Observation 9**

**Observation 10**

**Observation 11**

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**Observation 99**

**Observation 100**

“The finding of a recent internal review conducted of twenty-nine hospital site visits by the American College of Surgeons (ACS) found that most sites prioritized the need for more data over more improvement efforts, even when extensive data collection was already in place.”

Ko CY et al, JAMA Surgery 2022 Sept 7, doi: 10.1001/jamasurg.2022.3122

The Baseline Risk For All Patients Occurs At The Moment Of Incision




“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 related to host (wound) defense”

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

Lets Take a Deep Dive:  
Do We Really Need a Surgical Care Bundle to Reduce the Risk of Infection?







### IBM MarketScan Analysis of 498,681 Orthopedic Patients 2009 – 2015 Observational Cohort

- 335,134 – TKR
- 14,488 – rTKR (revision)
- 163,547 – THR
- 11,791 – rTHR (revision)
- TKR – 2.2% Infection rate
- rTKR – 15.6% " "
- THR – 2.1% " "
- rTHR – 8.6% " "

We found 34 comorbid risk factors  
Baseline Cost - superficial/deep/  
device-related: \$10k to >100K  
". prevention is always better than  
the cost of resolving the problem.."

American Journal of Infection Control 47 (2018) 1225–1232

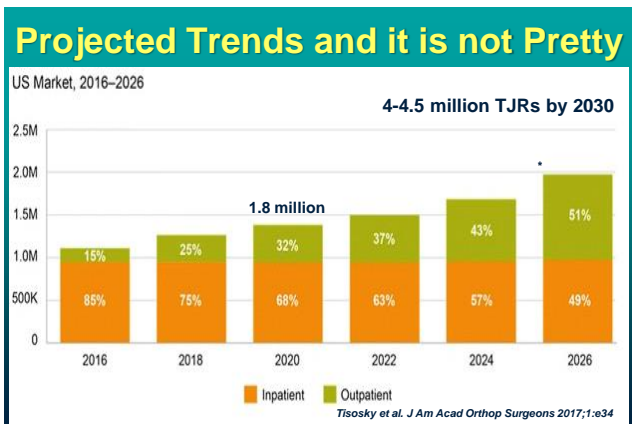
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## A More Than a Typical Scenario – What is the True Risk of Infection?

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 = 4

26



27

### 4-4.5 Million Total Joint Implantations per Year by 2030 – Assuming a 2.18% Infection Rate Translates into ~80,000-90,000 PJI

★ Baseline - Conservative estimate ~\$100,000 = 8-9 Billion US healthcare system

- Overall lifetime cost for a single case of a septic THA (age 65) using a one-way sensitivity analysis of \$390,806 per patient.
- PJI is associated with a mortality rate of between 2 – 7%.
- Experts report that the five-year survival rate of patients with PJI is worse than with most cancers.

Parisi TJ, et al. Clin Orthop Relat Res. 2017;475:1891  
Edmiston et al. AJIC 2019;37:1225  
Kurtz et al. J Arthroplasty 2012;27:61-64

28





**Consensus Statement**

### Consensus Bundle on Prevention of Surgical Site Infections After Major Gynecologic Surgery

Joseph E. Pellegrini, MD, FCCO, FRCO, FRCO, FRCO, David E. Soper, MD, William C. Bowdoin, MD, Deborah A. Cox, MD, MCh, Barbara S. Levy, MD, and Lauren A. Leman, MD

Surgical infections are the most common complication of surgery in the United States. Of targets for women of reproductive age, hysterectomy is one of the most frequently performed, second only to cesarean birth. Therefore, prevention of surgical site infections in women undergoing gynecologic surgery is an ideal target for a patient safety bundle. The primary purpose of this safety bundle is to provide information that can be implemented into any surgical environment in an effort to reduce the incidence of surgical site infections. This bundle was developed by a multidisciplinary team convened by the Council on Patient Safety to Improve Obstetrics Care. The bundle is organized into four domains: **Readiness (Every Case) – Establish standardized preoperative care protocols**, **Recognition and Prevention (Every Patient) – Preoperative assessment of patient risk factors**, **Response (Every Case) – Evidence-based mitigation of risk factors**, and **Reporting and Systems Learning (Every Facility) – Monitor outcomes and process metrics (standardize)**.

**Key Steps to Improving Surgical Outcomes in Gynecologic Surgery**

- Readiness (Every Case) – Establish standardized preoperative care protocols
- Recognition and Prevention (Every Patient) – Preoperative assessment of patient risk factors
- Response (Every Case) – Evidence-based mitigation of risk factors
- Reporting and Systems Learning (Every Facility) – Monitor outcomes and process metrics (standardize)

*Pellegrini et al. Obstet Gynecol 2017; 129:50*

33

### 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

Julian Tanser, PhD,<sup>1</sup> Wendy Palfrey, MD,<sup>2</sup> Olaya Samad, MD,<sup>3</sup> David Lopez, MD,<sup>4</sup> Martin Korman, MPH,<sup>5</sup> and Charles Edmonson, PhD,<sup>6</sup> Nottingham, Leicester, Huddersfield, and London, UK, and Edinburgh, UK

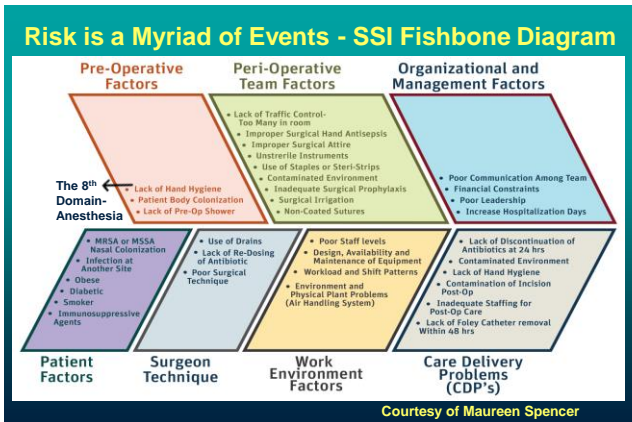
**Background:** Care bundles are a strategy that aim to reduce the risk of surgical site infections (SSI), but individual studies of care bundles report conflicting outcomes. This study assesses the effectiveness of care bundles to reduce SSI among patients undergoing colorectal surgery.

**Methods:** We performed a systematic review and meta-analysis of randomized controlled trials, quasi-experimental studies, and cohort studies of care bundles in colorectal SSI. The search strategy included Medline and Clinical Study Register searches from 2012 until June 2015, identifying reference lists of relevant studies and contacting study authors to obtain missing data. The *Diagnosis and Effect* checklist was used to assess the quality of included studies. Reported care bundle implementation rates (CIR) were analyzed using Cochran Heterogeneity Manager. The 1<sup>st</sup> instance and forest plots were performed to identify publication bias. Secondary analyses were carried out to examine the influence of individual data sets on pooled SSI.

**Results:** Sixteen studies were included in the analysis, with 43 providing sufficient data for a meta-analysis. Most study bundles included one intervention such as antibiotic administration, appropriate hair removal, glycemic control, and normothermia. The CIR was in the target group was 7.5% (95% CI 6.6-8.4) compared with 25.1% (19.5-30.6) 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 *OR* of 0.57 (95% CI 0.47-0.72, *P* = 0.0005). **Conclusion:** The systematic review and meta-analysis demonstrates that use of an evidence-based surgical care bundle in patients undergoing colorectal surgery significantly reduced the risk of SSI (Surgery 2015;25:66-72).

**Tanner J et al. Surgery 2015;158:66-77**

34



35

### Are SSI Prevention Guidelines Helpful – A Mechanistic Basis?

**Are SSI Prevention Guidelines Helpful – A Mechanistic Basis?**

36



# Standardization of the Preadmission Shower/Cleansing Strategy



- Scalp 6.0 Log<sub>10</sub> cfu/cm<sup>2</sup>
- Axilla 5.5 Log<sub>10</sub> cfu/cm<sup>2</sup>
- Abdomen 4.3 Log<sub>10</sub> cfu/cm<sup>2</sup>
- Forearm 4.0 Log<sub>10</sub> cfu/cm<sup>2</sup>
- Hands 4.0-6.6 Log<sub>10</sub> cfu/cm<sup>2</sup>
- Perineum 7.0-11.0 Log<sub>10</sub> cfu/cm<sup>2</sup>

Surgical Microbiology Research Laboratory – Medical College of Wisconsin

# Maximizing Skin Surface Concentrations of CHG: Embracing a Standardize Process Utilizing a Pharmacokinetic Perspective (Dose, Timing, Duration)

## 4% Aqueous CHG

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

CHG conc ≥1000 µg/ml



Edmiston et al. JAMA Surg 2015;150:1027

www.dhs.wiscconsin.gov/publications/1p01p00749.pdf

Remember the devil is always in the details

# Evidence-Based Bundled Quality Improvement Intervention for Reducing Surgical Site Infection in Lower Extremity Vascular Bypass Procedures

Kashner T, Hahnke M, et al. Infect Dis Clin Pract 2015;23(1):1-8

**OBJECTIVE:** Surgical site infections (SSIs) pose a significant burden to patients and healthcare systems. Lower extremity vascular bypass (LEVB) has shown a higher rate of SSI for lower extremities than other vascular procedures. Bacterial interventions have successfully reduced SSI in other surgical procedures.

**STUDY DESIGN:** We evaluated our institution-specific SSI data for vascular SSI from January 2010 through October 2013. We implemented an evidence-based bundle consisting of 10 interventions including preoperative chlorhexidine (CHG) showers, preoperative skin preparation, and postoperative wound care. We compared the incidence of SSI before and after implementation of the bundle. Risk-adjusted SSI rates were estimated from March 2010 through August 2013. We assessed the pre-post reduction of SSI risk differences in reducing SSI.

**RESULTS:** In the pre-intervention period, 43 of 261 (16%) patients had SSI. The risk ratios associated with SSI in lower vs. higher weight (BMI) were not readily available. In an attempt to find the relationship of our intervention, differences in preoperative chlorhexidine (CHG) showers, preoperative skin preparation, and postoperative wound care were 70% (12 of 17), 48% (12 of 25), and 100% (14 of 14), respectively. Compliance with all available bundle components was 70% (24 of 34). **SSIs were significantly reduced.**

**CONCLUSIONS:** In the post-intervention period, 17% (10 of 58) patients had SSI. The risk ratios associated with SSI in lower vs. higher weight (BMI) were not readily available. The mean number of SSI per patient was significantly lower after implementation of the bundle (0.12 vs. 0.16) and 42% (p = 0.003) SSI risk reduction from the preoperative and postoperative chlorhexidine showers, respectively.

# Does Preadmission Cutaneous Chlorhexidine Preparation Reduce Surgical Site Infections After Total Hip Arthroplasty?

Marwan H, Kapadia SB, Jahn J, Jaeger M, Shafiq F, Murray RA, Mirza J, Nave SB

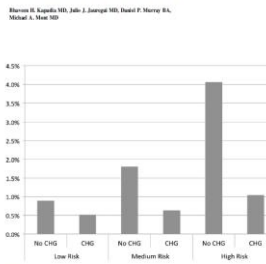


Fig. 1. Bar graph representing the incidence of infection stratified by risk classification. CHG = chlorhexidine gluconate.

# Antimicrobial Prophylaxis - Does BMI Increase Risk?

## Perioperative Antimicrobial Prophylaxis in Higher BMI (≥30) Patients: Do We Achieve Therapeutic Levels?

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

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

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

### Clinical practice guidelines for antimicrobial prophylaxis in surgery

DALE W. BRATZLER, E. PATCHEN DELLINGER, KEITH M. OLSEN, TRISH M. PELL, PAUL G. AUWAERTER, MAUREEN K. BOJON, DOUGLAS N. FISH, LENA M. NAPOLITANO, ROBERT G. SAVYER, DOUGLAS SLAIN, JAMES S. STEINBERG, AND ROBERT A. WEINSTEIN

Ann Intern Med. 2013; 158:955-983

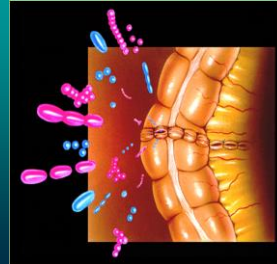
These guidelines were developed jointly by the American Society of Health-System Pharmacists (ASHP), the Infectious Diseases Society of America (IDSA), the Surgical Infection Society (SIS), and the Society for Healthcare Epidemiology of America (SHEA). This work represents an update to the previously published ASHP Therapeutic Guidelines on Antimicrobial Prophylaxis in Surgery,<sup>1</sup> as well as guidelines from IDSA and SIS.<sup>2,3</sup> The guidelines are intended to provide practitioners with a standardized approach to the rational, safe, and effective use of antimicrobial agents for the prevention of surgical site infections (SSIs) based on currently available clinical evidence and emerging 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 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

## The Mechanistic Benefit of Oral Antibiotics and Mechanical Bowel Prep



Edmiston CE et al. World Journal of Surgery 1990;14: 176-183

### The Efficacy of Oral Antimicrobials in Reducing Aerobic and Anaerobic Colonic Mucosal Flora

Anastasia L. Groner, MD, Charles E. Edmiston, Jr, PhD, Charles J. Krepel

October 1, 2004, 37(10):1047-1052, doi:10.1097/PSA.0b013e318041104d

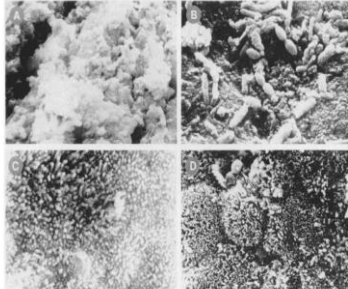


Table 1.—Quantitative Recovery of Aerobic and Anaerobic Mucosa-Associated Bacteria From Canine Colonic Segments\*

Group	Microbial Recovery		
	Proximal	Midcolon	Distal
<b>Aerobes</b>			
A	8.6 ± 0.5	8.3 ± 0.6	8.7 ± 0.5
B	7.4 ± 1.6	6.7 ± 2.0	7.2 ± 1.7
C	5.8 ± 0.6	5.4 ± 0.8	5.7 ± 1.0
D	2.4 ± 0.7	3.1 ± 0.2	2.5 ± 1.2
<b>Anaerobes</b>			
A	9.5 ± 0.4	9.7 ± 0.4	9.8 ± 0.9
B	9.0 ± 0.9	8.6 ± 2.1	8.6 ± 1.6
C	8.2 ± 0.9	7.4 ± 0.7	7.4 ± 1.0
D	2.6 ± 1.0	3.0 ± 1.4	2.6 ± 1.1

\*Expressed as log<sub>10</sub> colony-forming units per milligram (wet weight) of tissue, mean ± SD. Group A (n = 6) received no bowel preparation; group B (n = 7), oral-liquid diet; group C (n = 8), mechanical preparation; and group D (n = 7), oral antimicrobial prophylaxis.

Groner, Edmiston, Krepel et al. Arch Surg. 1989;124:281

ORIGINAL ARTICLES

#### The Role of Bowel Preparation in Colorectal Surgery

Results of the 2012–2015 ACS-NSQIP Data

Aaron L. Ehrlich, MD,<sup>1</sup> Michael D. Cohen, MD,<sup>2</sup> Christopher J. Mendicino, MD, PhD, MPH,<sup>1</sup> David Rock, MD,<sup>1</sup> Brian Kwon, MD,<sup>1</sup> Michael D. Sogge, MD,<sup>1</sup> Charles Wilkins, MD,<sup>1</sup> and David Margolin, MD<sup>1</sup>

**OBJECTIVE:** To evaluate the impact of oral antimicrobial prophylaxis on the risk of surgical site infection (SSI) in colorectal surgery. **DESIGN:** Retrospective cohort study. **SETTING:** National Surgical Quality Improvement Program (NSQIP) database. **PATIENTS:** 10,000 patients who underwent colorectal resection between 2012 and 2015. **MEASUREMENTS AND MAIN RESULTS:** The use of oral antimicrobial prophylaxis was associated with a lower risk of SSI (OR 0.75, 95% CI 0.60–0.95). The use of oral antimicrobial prophylaxis was also associated with a lower risk of wound-healing problems (OR 0.75, 95% CI 0.60–0.95). The use of oral antimicrobial prophylaxis was not associated with a lower risk of mortality (OR 1.00, 95% CI 0.80–1.25). **CONCLUSIONS:** The use of oral antimicrobial prophylaxis is associated with a lower risk of SSI and wound-healing problems in colorectal surgery. **KEY WORDS:** colorectal surgery, oral antimicrobial prophylaxis, SSI, wound-healing problems.

**INTRODUCTION:** The use of oral antimicrobial prophylaxis in colorectal surgery has been a topic of debate for many years. Some studies have shown that oral antimicrobial prophylaxis is associated with a lower risk of surgical site infection (SSI) and wound-healing problems, while other studies have shown no benefit. The purpose of this study was to evaluate the impact of oral antimicrobial prophylaxis on the risk of SSI and wound-healing problems in colorectal surgery using data from the National Surgical Quality Improvement Program (NSQIP) database.

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META-ANALYSIS

#### The Role of Oral Antibiotic Preparation in Elective Colorectal Surgery

A Meta-analysis

Kevin Z. Butler, MD,<sup>1</sup> Hannah Stewart-Emmott, MD,<sup>1</sup> Adam G. Salzman, MD, PhD,<sup>1</sup> and Diego A. Laine, MD, PhD, FRCR, FRCR<sup>1</sup>

**OBJECTIVE:** To evaluate the impact of oral antibiotic prophylaxis on the risk of surgical site infection (SSI) in elective colorectal surgery. **DESIGN:** Systematic review and meta-analysis. **SETTING:** Literature search of PubMed, Embase, and Cochrane. **PATIENTS:** 10,000 patients who underwent elective colorectal resection. **MEASUREMENTS AND MAIN RESULTS:** The use of oral antibiotic prophylaxis was associated with a lower risk of SSI (OR 0.75, 95% CI 0.60–0.95). The use of oral antibiotic prophylaxis was also associated with a lower risk of wound-healing problems (OR 0.75, 95% CI 0.60–0.95). The use of oral antibiotic prophylaxis was not associated with a lower risk of mortality (OR 1.00, 95% CI 0.80–1.25). **CONCLUSIONS:** The use of oral antibiotic prophylaxis is associated with a lower risk of SSI and wound-healing problems in elective colorectal surgery. **KEY WORDS:** colorectal surgery, oral antibiotic prophylaxis, SSI, wound-healing problems.

**INTRODUCTION:** The use of oral antibiotic prophylaxis in elective colorectal surgery has been a topic of debate for many years. Some studies have shown that oral antibiotic prophylaxis is associated with a lower risk of surgical site infection (SSI) and wound-healing problems, while other studies have shown no benefit. The purpose of this meta-analysis was to evaluate the impact of oral antibiotic prophylaxis on the risk of SSI and wound-healing problems in elective colorectal surgery.

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**Clostridium difficile disease: Diagnosis, pathogenesis, and treatment update**

Lena M. Napolitano, MD, FICS, FCCP, MCCM<sup>1</sup> and Charles E. Edmiston, Jr, PhD, GC, FBA, FBA, FAPC<sup>2</sup>, Ann Arbor, MI, and Milwaukee, WI

*Clostridium difficile* infections are the leading cause of health care-associated infectious diarrhea, posing a significant risk for both medical and surgical patients. Because of the significant morbidity and mortality associated with *C. difficile* infections, knowledge of the epidemiology of *C. difficile* in combination with a high index of suspicion and susceptible patient populations (including surgical, post-operative, and inflammatory bowel disease patients) is warranted. *C. difficile* infections present with a wide spectrum of disease, ranging from mild diarrhea to fulminant colitis or small bowel resection and recurrent *C. difficile* infections. Early implementation of medical and operative treatment strategies for *C. difficile* infections is imperative for optimal patient outcomes. National and international guidelines recommend early operative consultation and total abdominal colectomy with end ileostomy and preservation of rectum. Inserting leg flasks and colonic lavage followed by intravenous metronidazole and intracolonic vancomycin administered via the opened lumen of the ileostomy should be considered as an alternative to total colectomy in selected patients. New and emerging strategies for *C. difficile* infection treatment include monoclonal antibodies, vaccines, probiotics, bacteriophages, and new antibiotics. A successful *C. difficile* prevention and eradication program requires a multidisciplinary approach that includes early disease recognition, implementation of guidelines for minimizing antibiotic use, environmental control, infection hand hygiene, infection-based treatment and management strategies, and a focused antibiotic stewardship program. Surgeons are an important part of the clinical team in the management of *C. difficile* infection prevention and treatment. (Surgery 2017;162:325-348.)

From the Department of Surgery, University of Michigan Health System, Ann Arbor, Michigan; and the Department of Surgery, Medical College of Wisconsin, Milwaukee, Wisconsin

**Napolitano & Edmiston Surgery 2017;162:325-348**

49

**Can a Suture Really be a Nidus for Infection?**

50

**Do Evidence-Based Studies Validate the Use of an Antimicrobial (Triclosan) Wound Closure Technology?**

51

**THE VIRULENCE OF STAPHYLOCOCCUS PYOGENES FOR MAN. A STUDY OF THE PROBLEMS OF WOUND INFECTION**

D. ELEK and F. E. COHEN  
From the Department of Bacteriology, St. George's Hospital Medical School (University of London), London, S.W.1

Received for publication 9 August, 1957

LITTLE direct evidence is available about the virulence of strains of *Staph. pyogenes* to man. Gaert (1951) infected himself with a strain obtained from a fatal case of osteomyelitis by rubbing a whole slope culture into the skin of the left forearm. Small pustules appeared around the hair follicles within a few hours, which enlarged and eventually coalesced into a large carbuncle, which took three weeks to heal with much scar formation. Similar experiments were carried out subsequently by Blum (1955) and by Bockhart (1957). In this early work the dosage was not stated with accuracy as the aim was to prove that staphylococci were the true cause of carbuncles and wound infections, rather than an attempt to compare the virulence of different strains. It is noteworthy that both Gaert and Bockhart failed to produce lesions in some of their experiments, and similar failures by other early workers were referred to by Neisser (1925). No quantitative information is available at present on the susceptibility of different individuals and the relative virulence to man of different strains.

The virulence of a microbe always relates to a given animal species. The mere fact that lesions may be set up in one experimental animal gives little if any indication of virulence for another species. In staphylococcal infection, the traditional approach of using convenient laboratory animals may be completely fallacious, as was shown by the divergent results obtained by Freytag, Jones and Frazier (1955), when they compared the virulence of a number of strains using different methods and animals. In spite of the vast volume of work done on the source of *Staph. pyogenes* there is no clear evidence that the same factors play a part in man, rabbit or guinea-pig. Indeed there is reasonable doubt about the role of alpha toxin in man, though this factor undoubtedly plays an important part in the evolution of lesions in rabbits.

As yet we have virtually no information about the minimal infective dose of any pathogen to man: only circumstantial evidence and analogies are available. The advent of penicillin and other antibiotics however, has enabled direct inoculation in volunteers relatively safe. The extensive literature on the virulence of staphylococci at present relates either to the production of coagulase and diffusible toxins demonstrable *in vitro* or *in vivo*, or to experimental lesions in animals, usually rabbits. These methods relate to the production of group of staphylococci commonly associated with human disease, but they throw no light on possible differences in virulence between strains isolated from different sources. The wide distribution of coagulase positive staphylococci on the human body and its environment suggests that in the evolution of lesions other factors must be

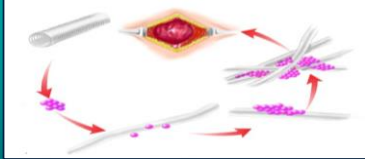
**Elek SD, Cohen PE. Br J Exp Pathol. 1957;38: 573-586**

52

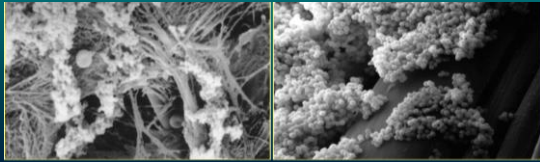
“The presence of a foreign body reaction in the form of sutures resulted in a dramatic reduction in the minimum inoculum required to produce pus (infection).”



### Microscopic Perspective of a Deep Incisional Biofilm-Mediated Surgical Site Infection

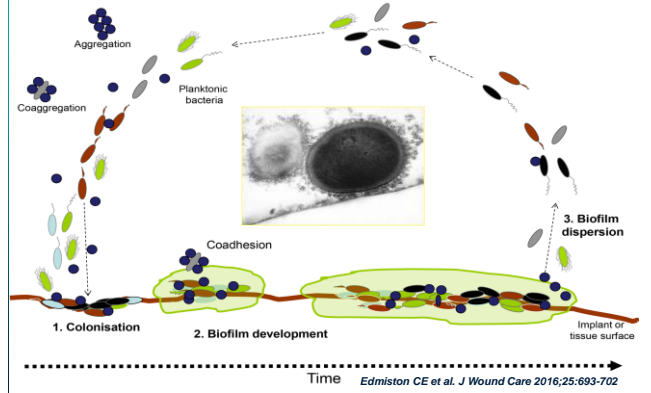


Seabrook & Edmiston, *Critical Care Infectious Diseases* 2001; 875-888



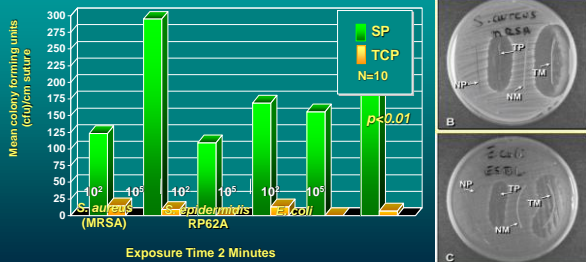
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Fig. 1. Edmiston et al.



54

### 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

55

FIGURE 2  
CONTINUOUS SUTURING TECHNIQUES  
Two strands knotted at each end and knotted in the middle.

FIGURE 3  
INTERRUPTED SUTURING TECHNIQUES  
Simple interrupted

56

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

Charles E. Edmiston, Jr, PhD<sup>1</sup>, Frederic C. Daoud, MD<sup>2</sup>, and David Leaper, MD, FRCGS<sup>3</sup>, *Miltona, RI, 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 identified as an effective 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 includes 13 randomized, international RCTs, totaling 13,564 surgical patients.

**Methods:** A systematic literature search was performed on PubMed, Embase/Medline, Cochrane Database of Systemic Reviews, Cochrane Database of Systemic Reviews, Health Economic Evidence Database (Database of Health Technology Assessment), and extra clinical trials, to identify RCTs of triclosan-coated sutures compared with conventional sutures and assessing the clinical effectiveness of antimicrobial sutures to decrease the risk for SSI. A final and meaningful study was developed, and pooled estimates reported as risk ratio (RR) with a corresponding 95% confidence interval (CI). Publication bias was assessed by analyzing a forest plot of individual studies and using the Egger regression strategy.

**Results:** The meta-analysis (13 RCTs, 13,564 patients) found that use of triclosan antimicrobial-coated sutures was associated with a decrease in SSI in selected patient populations (fixed effect: RR = 0.734; 95% CI, 0.596-0.912; P = .005; random effect: RR = 0.675; 95% CI, 0.553-0.820; P = .011). No publication bias was detected (Egger intercept P = .145).

**Conclusions:** Decreasing the risk for SSI requires a multifaceted "one health" approach, and this meta-analysis of current, pooled, randomized, international controlled trials suggests a clinical effectiveness of antimicrobial-coated sutures (triclosan) in the prevention of SSI, representing a benefit for Evidence-Based Medicine level. *Infect Control Hosp Epidemiol* 2013;134:89-100

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

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<sup>2</sup>Department of Pediatric Surgery, Affiliated Drum Tower Hospital, Nanjing, Jiangsu Province, China 210008

<sup>3</sup>Department of Pediatric Surgery, Affiliated Drum Tower Hospital, Nanjing, Jiangsu Province, China 210008

**Background:** Surgical-site infections (SSIs) increase morbidity and mortality in surgical patients and represent an economic burden to healthcare systems. Experimental data shows that triclosan-coated sutures (TCS) are beneficial in the prevention of SSI, 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 SSI.

**Methods:** A systematic search of PubMed, Embase, MEDLINE, Web of Science<sup>®</sup>, the Cochrane Central Register of Controlled Trials and internet-based trial registries for RCTs comparing the effect of TCS and conventional sutured sutures on SSI was conducted until June 2012. The primary outcome investigated was the incidence of SSI. Pooled relative risks with 95 per cent confidence interval (CI) were estimated with the Meta-5.1A.

**Results:** Seventeen RCTs involving 1720 participants were included. No heterogeneity of statistical significance across studies was observed. TCS showed a significant advantage in reducing the rate of SSI by 10 per cent (relative risk 0.76, 95 per cent CI, 0.67 to 0.85; P < 0.001). Subgroup analyses revealed consistent results in favor of TCS in adult patients, abdominal procedures, and clean or clean-contaminated surgical wounds.

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

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

## What Do the Various Meta-Analyses Tell Us About Triclosan Suture as a Risk Reduction Strategy?

- 2013 - 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)
- 2013 - Wang et al, *BJS* 2013;100:465: 17 RCT (3720 patients) – 30% decrease in risk of SSI (p<0.001)
- 2013 - Edmiston et al, *Surgery* 2013;154:89-100: 13 RCT (3568 patients) – 27% to 33% decrease in risk of SSI (p<0.005)
- 2014 - Daoud et al, *Surg Infect* 2014;15:165-181: 15 RCT (4800 patients) – 20% to 50% decreased risk of SSI (p<0.001)
- 2015 - Apisarnthanarak et al, *Infect Cont Hosp Epidemiol* 2015;36:1-11: 29 studies (6,930 patients) – 26% reduction in SSI (p<0.01)
- 2016 - Guo et al, *Surg Research* 2016; doi:10.1016/j.srs.2015.10.015 – 13 RCT (5256 patients) (risk ratio [RR] 0.76, 95% confidence interval [CI] 0.65e0.88, p < 0.001)
- 2017 - Wu et al, *Eur J Clin Microbiol Infect Dis* 2017;36:19-32: 13 RCT (5,346 patients) (risk ratio [RR] 0.72, 95% confidence interval [CI] 0.59-0.88, p<0.001)
- 2017 - De Jonge et al, *BJS* 2017;104:e118-e133; 21 RCT (6,462 patients) (risk ratio [RR] 28% reduction, 95% confidence ratio [CI] 0.60-0.88, p<0.001)
- 2019 - Ahmed I et al, *BMJ* 2019;9:029727; doi:10.1136/bmj-open-2019-029727: 25 RCT (11,957 patients) – Test of overall effect: Z = 5.2 (p<0.0001)

57

58

## How Does One Evaluate An Antimicrobial Risk - Reduction Technology – The Triclosan Suture Story?

Safety (>1 Billion strands)

- No MAUDE (FDA) reports (20 years) documenting significant evidence linking triclosan to adverse impact in surgical wounds; No evidence of pediatric toxicity, *Renko et al, Lancet Infectious Disease* 2016;17:50-57; No evidence of chronic toxicity, carcinogenicity, reproductive toxicity, immunotoxicity, cytotoxicity or intracutaneous reactivity *Roidnickis et al, Crit. Rev. Toxicol.* 2010;40:422. doi: 10.3109/10408441003667514.

Microbicidal Activity (Spectrum)

- Gram-positive and Gram-negative antimicrobial activity - No published studies have demonstrated that use of triclosan coated sutures are associated with the emergence of resistant surgical pathogens.

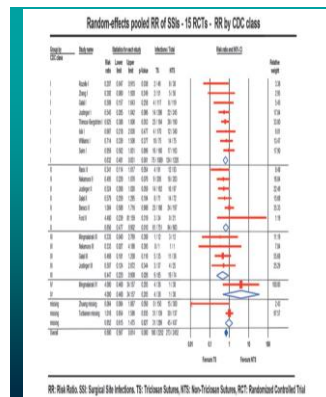
Evidence-based Clinical Effectiveness (Meta-Analysis)

- Currently 31 RCT/Meta-Analysis in the peer-literature document clinical efficacy of triclosan (antimicrobial) suture technology.

Cost-Effectiveness

- Two recent studies, [Singh et al, *Infect Control Hosp Epidemiol* 2014;35:1013; Leaper and Edmiston, *British Journal Surgery* 2017;104:e134-e144] document that use of triclosan-coated sutures provides significant fiscal benefit to hospital, third party-payer and patient.

59



Daoud, Edmiston, Leaper - *Surgical Infections* 2014;15:165-181

Multiple Clinical Studies Have Documented That Triclosan-Coated Sutures Provide A Significant SSI Risk Reduction For:

- Clean – Class I
- Clean-Contaminated – Class II
- And Contaminated Surgical Procedures – Class III

What about Class IV – Dirty surgical wounds?

60

**Infection Prevention in Practice**

**Evaluation of the effect of triclosan coated sutures in the prevention of surgical site infections in a Spanish hospital setting: A prospective, observational study**

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<sup>1</sup>Servicio de Cirugía General y Digestiva, Complejo Hospitalario Universitario de Santiago, Santiago de Compostela, Spain  
<sup>2</sup>Servicio de Farmacología, Complejo Hospitalario Universitario de Santiago, Santiago de Compostela, Spain  
<sup>3</sup>Servicio de Neumología, Complejo Hospitalario Universitario de Santiago, Santiago de Compostela, Spain  
<sup>4</sup>Servicio de Neurología, Complejo Hospitalario Universitario de Santiago, Santiago de Compostela, Spain  
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<sup>6</sup>Servicio de Otorrinolaringología, Complejo Hospitalario Universitario de Santiago, Santiago de Compostela, Spain  
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<sup>8</sup>Servicio de Ginecología, Complejo Hospitalario Universitario de Santiago, Santiago de Compostela, Spain  
<sup>9</sup>Servicio de Urología, Complejo Hospitalario Universitario de Santiago, Santiago de Compostela, Spain  
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**ARTICLE INFO**

**Keywords:** Surgical site infections (SSI), triclosan, antimicrobial suture, SSI, prevention, observational study.

**Background:** Surgical site infections (SSI) are one of the most frequent hospital-acquired types of infection acquired in the hospital and are associated with substantial clinical and economic burden.

**Objective:** To evaluate the incidence of SSI and related antibiotic use before and after the implementation of triclosan-coated sutures.

**Methods:** A prospective, observational study was conducted in the Intensive Care Unit (ICU) and the Surgical Ward of the Complejo Hospitalario Universitario de Santiago, Spain. Data were collected on patients undergoing elective surgery in the following specialties: general surgery, orthopedics, urology, gynecology, and traumatology. The primary outcome of the study was the incidence of SSI. Secondary outcomes were length of hospital stay and antibiotic consumption.

**Results:** A total of 5081 patients were included in the study, of whom 2490 were treated with non-antimicrobial sutures and 2591 with triclosan-coated sutures. The incidence of SSI was significantly lower in the triclosan-coated suture group (1.8%) compared to the non-antimicrobial suture group (3.6%) (p < 0.003). The length of hospital stay was also significantly lower in the triclosan-coated suture group (10.2 days) compared to the non-antimicrobial suture group (11.5 days) (p < 0.003). Antibiotic consumption was significantly lower in the triclosan-coated suture group (1.2 DDD) compared to the non-antimicrobial suture group (1.8 DDD) (p < 0.003).

**Conclusion:** The use of triclosan-coated sutures significantly reduces the incidence of SSI, length of hospital stay, and antibiotic consumption in patients undergoing elective surgery in the ICU and the Surgical Ward of the Complejo Hospitalario Universitario de Santiago, Spain.

**Bustamante-Montalvo M. et al. Infect Prev Pract 2022 Mar;4:100192.**

61

**Prospective, Observational Study of the Efficacy of Triclosan Coated/Impregnated Sutures Across the Surgical Spectrum**

- 5081 patients included in the study: 2591 patients treated with non-antimicrobial sutures while 2490 treated with triclosan antimicrobial sutures
- Use of antimicrobial sutures resulted in a 36% reduction in SSI compared to non antimicrobial closure technology ( $p < 0.003$ )
- A significant risk reduction was observed across the surgical spectrum including class IV (dirty) wounds ( $p = 0.019$ )

**20 Year Evidence-Based Journey**

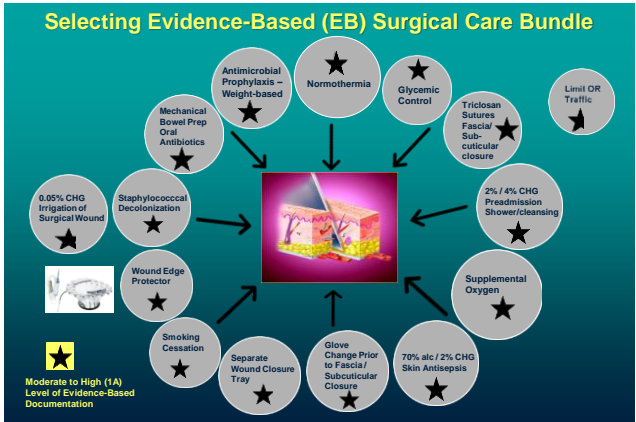
The collage includes several items:
 

- Scientific papers with titles like 'Surgical Site Infections' and 'Antimicrobial Sutures'.
- Book covers, including one from 2018.
- A central diagram of a surgical wound being closed with sutures.
- Other diagrams and images related to surgical care and infection prevention.

62

**In 2022 – How Many Evidence-Based Interventions are Validated to Reduce the Risk of Surgical Site Infections Across the Surgical Spectrum?**

63



64

**CLINICAL**

## Implementation of a Wisconsin Division of Public Health Surgical Site Infection Prevention Champion Initiative

Gwen Borlaug, MPH, CIC, FAPIC, Charles E. Edmiston, Jr, PhD, CIC, FIDSA, FSHEA, FAPIC

**ABSTRACT**  
 Approximately 900 surgical site infections (SSIs) were reported to the Wisconsin Division of Public Health annually from 2013 to 2015, representing the most prevalent reported health care-associated infection in the state. Personnel at the Wisconsin Division of Public Health launched an SSI prevention initiative in May 2015 using a surgical care champion to provide surgical team peer-to-peer guidance through voluntary, nonregulatory, fee-exempt onsite visits that included presentations regarding the evidence-based surgical care bundle, tours of the OR and central processing areas, and one-on-one discussions with surgeons. The surgical care champion visited 10 facilities from August to December 2015, and at those facilities, SSIs decreased from 83 in 2015 to 47 in 2016 and the overall SSI standardized infection ratio decreased by 45% from 1.61 to 0.88 (P = .002), suggesting a statewide SSI prevention champion model can help lead to improved patient outcomes.

**Key words:** surgical champion, surgical care bundle, SSI prevention, peer collaboration, evidence-based practice.

*Borlaug and Edmiston – AORNJ 2018;107:570-578.*

65

## Building an Effective Surgical Care Bundle\*

Baseline Evidence-Based Interventions – Designated High-1A\*\*

- Normothermia – 1A
- Perioperative antimicrobial prophylaxis – Weight-based – 1A
- Antimicrobial (triclosan) coated sutures (fascia / subcuticular closure) – 1A
- Preadmission CHG shower/cleansing – Standardized regimen – 1A
- Perioperative antisepsis – 2% CHG/ 70% alcohol – 1A
- Glycemic control – 1A
- Separate wound closure tray – Moderate
- Glove change prior to fascia/subcuticular closure – Moderate
- Smoking cessation - High

Inclusive Evidence-Based Intervention for Consideration in 2019\*\*

- Supplemental oxygen – Colorectal – 1A
- Oral antibiotics / Mechanical bowel prep – Colorectal – 1A
- Wound edge protector – Colorectal – 1A
- Staphylococcal decolonization – Orthopedic / CT - 1A
- Irrigation with 0.05% CHG - Moderate
- OR traffic control – Device-related procedures – Low

\*Evidence-Based Medicine is a Moving Target      \*\* Published level of evidence

66

## A New Era In Improving Patient Outcomes

**Enhanced Recovery After Surgery A Review**

Requires multidisciplinary team working together around the patient

- Multimodal strategy to resolve issues that delay recovery and cause complications
- A scientific, evidence-based approach to care protocols
- Studies document reduction in length of stay (LOS), decreased mortality, fewer postop complications and cost-effective
- Focus on nutritional aspects of care – includes the role of specific amino acids and perioperative nutrition
- May include 24 or more core elements that have scientific documentation for improving clinical outcome
- Requires an interactive management with continuous audits – Surgical leadership (support) is crucial and must exist within a collaborative framework

67

## Colorectal Surgery Enhanced Recovery Protocol

**Pre-operative**

- Patient education
- Smoking cessation
- Prehabilitation
- Nutrition assessment
- WOCN visit
- Diabetes Optimization
- Universal HBLC
- Preop Optimization Clinic
- Standardized Labs
- MBSA Screening
- Immunonutrition
- Impact Brix 3-5 days
- Skin decontamination
- CHG Shower
- Mechanical Bowel Prep
- SUPREP split dose
- Oral Antibiotics
- Neomycin 1g
- Metronidazole 500mg
- Carbohydrate Loading
- Ensure Pre-Surgery
- NPO
- Continue clears

**Day of Surgery**

- Bowel Preparation
- Clears until 3-4 hours preop
- Carbohydrate Loading
- Ectours Pre-Surgery
- Hair Management
- Skin decontamination
- CHG Wipes
- Glucose Management
- Acucheck in preop
- Patient Warming
- Hair Paws
- Heat Prevention
- Alvimopan 12mg
- DVT Prophylaxis
- Heparin 5000u
- Pain Management
- Gabapentin 600mg
- Celecoxib 400mg
- Acetaminophen 975mg

**Intra-operative**

- Limit DR traffic
- Patient Warming
- Hair Paws
- Skin Prep
- Chlorazep by RN
- Antibiotics
- Ceftriaxone 2g
- Metronidazole 500mg
- Pain
- TAP Liposomal bupivacaine
- Ketorolac 30 mg
- Metamsin 2 mcg/kg/min
- IV Fluids
- Avoid overload
- Avoid SNS
- Glucose management
- Hourly I/DNI
- Supplemental O<sub>2</sub> 80%
- PONV prevention
- Dexamethasone 8mg
- Ondansetron 4 mg
- Avoid NEST / drains
- Minimally Invasive Surgery
- Wound protector
- Claving protocol
- Rebound team
- Redrape patient
- Closing Instruments
- Triclosan sutures
- Irrigation
- Prevena dressing

**Post-operative**

- Patient Warming
- Acucheck in PACU
- PONV
- Ondansetron 4mg q6 x 48
- Ileus
- Alvimopan 12 mg QID
- Clearing Gum QID and PRN
- DVT Prophylaxis
- Heparin 5000u q8
- Pain
- Acetaminophen 650mg q6
- Metorobin q6 x 6
- Gabapentin 600 q12
- Ketamine drip x 24-48h
- Tramadol 50mg q6
- Norco/Oxycodone PRN
- Rehabilitation
- Up to chair POD#0
- Ambulate QID
- WOCN
- Immunonutrition
- Nutrition
- Clear POD#0
- Low Residue POD#1
- Haplock POD#1
- POD#1 for colectomy
- POD#2 for proctectomy
- Supplemental O<sub>2</sub> until POD#1
- Post discharge phone call
- Follow up 1 week

Marc Singer, MD, FACS, FASCRS - Loyola University Medical Center, Chicago, IL

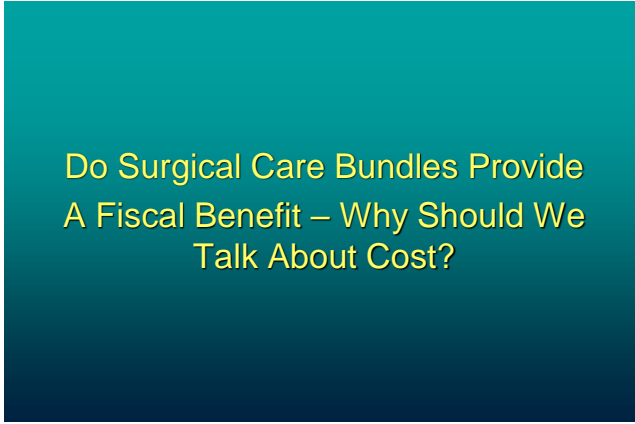
68



**Incisional Wound Closure Bundle**

- Gown/Gloves change prior to wound closure <sup>1,2,3</sup>
- Dedicated wound closure tray <sup>1,2,3</sup>
- Irrigation with 0.05% CHG <sup>2,3</sup>
- Use of antimicrobial sutures for wound closure <sup>1,2,3</sup>
- Remove surgical drape after applying dressing <sup>2,3</sup>
- Application of skin adhesive (2-octyl cyanoacrylate) following subcuticular wound closure <sup>2,3</sup>
- Comprehensive postoperative patient instructions <sup>2,3</sup>

1: SSI Guidelines; 2: Expert opinion; 3: Peer Literature  
*Edmiston CE, AORNJ 2018;107:552-565*



**Is There A Fiscal Benefit For Implementing a Surgical Care Bundle – The Actual Cost of Using Antimicrobial Wound Closure – A Generic 7 Item Colorectal – OB/GYN Scenario**

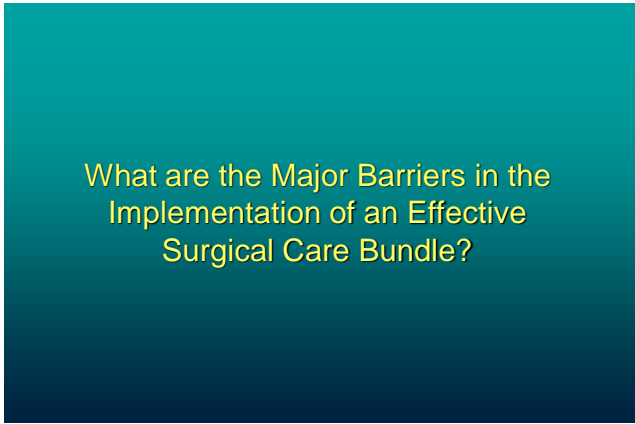
(Estimated Cost of Surgical Care Bundle = \$50-\$75 ~ \$60USD)

**Low Estimated Cost Benefit of Surgical Care Bundle**  
 \$36,429 / \$60 USD = can fund 607 additional surgeries

**High Estimated Cost Benefit of Surgical Care Bundle**  
 \$144,809 / \$60 USD = can fund 2,413 additional surgeries

A case in point: Are antimicrobial suture an expensive commodity?  
 3 to 5 strands ~\$<0.30 per strand = \$0.90 to \$1.50 additional cost per case  
 (1.5% ~ 4.0% of total bundle cost)

★ Cost Data from Leaper, Spencer and Edmiston – DCR 2020;63:1628-1638





## The Complexity of Risk – Major Barriers to Improving Surgical Patient Outcome



- Poor compliance – Complacency (laxity) and lack of documentation
- Lack of shared goals and priorities
- Poor communication
- Less than robust institutional commitment – Failure to standardized evidence-based initiative across the institution

“Remember when they say it is never about the money – It is always about the money”

73

ORIGINAL ARTICLE

### Surgical site infection: poor compliance with guidelines and care bundles

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**Key words:**  
 Care bundles, Compliance, Guidelines, Surgical site infection

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Leaper DJ, Tanner J, Kiernan M, Assadian O, Edmiston CE Jr. Surgical site infections: 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 anonymized organ-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

74

## In Conclusion – What Have We Learned From Our Efforts to Improve Surgical Patient Outcomes Using Evidence-Based Practice?

- The efficacy of an evidence-based strategy to improve surgical outcomes requires institutional compliance (quality) and clear documentation of effort - The institution must have sufficient “skin in the game”
- All co-morbid risk must be considered when developing an effective mitigation strategy.
- The cost of mitigation is always minuscule compared to the human and fiscal cost of a surgical site infection – Will ERAS be the next frontier for change?

SSI Prevention Is Not a Solo Recital  
 But Rather a Symphony and We Are  
 All Part of the Orchestra

75



Thank You

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76